I2.SYMPOSIUM

2601

i2.Carotid Artery Disease

Saturday, March 28, 2009, 10:00 a.m.-Noon
Orange County Convention Center, Room W414C

11:30 a.m.

2601-10 The SAPPHIRE Worldwide Registry: 30-Day Outcomes of 4,005 Patients Undergoing Carotid Artery Stenting With Distal Embolic Protection

Christopher Metzger, Maurice Solis, Majdi Ashchi, Rasesh Shah, Ravish Sachar, William Bachinsky, Farrell Mendelsohn, Robert Hibbard, Greg Schultz, Holston Valley Medical Center, Kingsport, TN

Background: Periprocedural outcomes after carotid artery stenting (CAS) continue to improve over time as reported with current CAS registries. A decrease in periprocedural events could be attributed to increased operator experience, improvements in procedural technique and better patient selection. The primary objective of this study is to evaluate 30-day outcomes after CAS performed at multiple centers by physicians with varied experience and utilizing a formal training program.
Methods: SAPPHIRE Worldwide is a multicenter, prospective, post-approval, observational study. CAS was performed using the Cordis PRECISE® Stent and ANGIOGUARD™ Emboli Capture Guidewire. The primary endpoint is 30-day major adverse events (MAE), including death, stroke, and myocardial infarction.
Results: Enrollment began October 2006, and presently 4,005 patients have been enrolled and completed 30-day follow up. Among these patients, the mean age was 72.1 years, 26.5% of patients were ≥80 years of age, and 27.9% are symptomatic. Preliminary 30-day MAE rate for the overall population was 3.3% (table). MAE was significantly lower in asymptomatic patients vs. symptomatic patients. Periprocedural stroke or death rate was below recommended AHA guidelines.
Conclusions: Results from SAPPHIRE Worldwide along with other contemporary CAS registries will continue to provide evidence in support of optimal patient selection, lesion criteria, and operator experience in performing CAS in patients at high-surgical risk.

Efficacy Measures	Symptomatic (N1 = 1117)	Asymptomatic (N2 = 2887)	Total (N = 4005)	Fisher P-value
MAE	5.4% (60/1117)	2.5% (71/2887)	3.3% (131/4004)	< 0.0001
Any Death or Stroke	5.1% (57/1117)	2.2% (63/2887)	3.0% (120/4004)	< 0.0001
Any Death	1.7% (19/1117)	0.5% (15/2887)	0.8% (34/4004)	0.0007
MI	0.7% (8/1117)	0.5% (13/2887)	0.5% (21/4004)	0.3296
Any Stroke	4.1% (46/1117)	1.8% (52/2887)	2.4% (98/4004)	< 0.0001

I2.SYMPOSIUM

2602

i2.Congenital I: ASD / PFO Closure

Saturday, March 28, 2009, 10:00 a.m.-Noon
Orange County Convention Center, Room W414A-B

11:00 a.m.

2602-7 PFO Morphology in Young and Older Patients With Cryptogenic Stroke on Transesophageal Echocardiography

Sachin S. Goel, E Murat Tuzcu, Eduardo I. de Oliveira, Mehdi H. Shishehbor, Leonardo L. Rodriguez, Richard Krasuski, Samir R. Kapadia, Cleveland Clinic, Cleveland, OH

Background: Recently patent foramen ovale (PFO) was shown to be associated with cryptogenic stroke (CS) in older patients (≥55 years).
Methods: We blindly compared pre-closure TEEs of 33 young patients with 25 older patients who had PFO closure for CS. We also compared these with TEEs of consecutive asymptomatic 18 young and 40 older controls with incidentally detected PFO. We analyzed data for PFO size (maximum separation of septum primum and secundum), tunnel length (maximum overlap of the two septa), atrial septal aneurysm (ASA) (>11 mm mobility), shunt severity (mild: 3-9, moderate: 10-30, severe >30 microbubbles), prominent Eustachian valve and Chiari network.
Results: There were no differences in PFO morphology between young and older patients with CS. However, young CS group had larger PFOs (3.6 ± 1.5 mm vs. 2.5 ± 1.1, p=0.007), greater proportion of large PFOs (≥ 4 mm) (41% vs. 11%, p=0.03) and higher frequency of ASA (36% vs. 11%, p =0.05) compared to the young asymptomatic controls. Similarly, the older CS group had larger PFOs (4.3 ± 1.8 vs. 3.1 ± 1.6, p=0.007), greater proportion of large PFOs (52% vs. 20%, p=0.007), long tunnels (≥1 cm) (84% vs. 58%, p=0.03), higher frequency of ASA (56% vs. 25%, p=0.01) and severe shunting (24% vs. 5%, p=0.02) compared to older asymptomatic controls.
Conclusion: Young and older patients with cryptogenic stroke have similar PFO morphology on TEE. Compared to asymptomatic controls, both young and older patients with cryptogenic stroke have larger PFO and ASA more frequently.

Morphological characteristics	Young (age <55) patients with cryptogenic stroke (n=33)	Older (age ≥55) patients with cryptogenic stroke (n=25)	P value
PFO Size (mm)	3.6 ± 1.5	4.3 ± 1.8	0.14
Large PFO (size ≥4mm) (%)	41	52	0.39
Presence of atrial septal aneurysm (ASA) (%)	36	56	0.14
Tunnel Length (mm)	14 ± 7	14 ± 4	0.82
Long Tunnel (≥ 1cm) (%)	73	84	0.31
Degree of shunting (%) mild moderate severe	 58 18 9	 44 24 24	 0.31 0.59 0.12
Prominent Eustachian valve (%)	24	16	0.44
Prominent Chiari network (%)	3	0	0.38

11:15 a.m.

2602-8 Association of Patent Foramen Ovale With Obstructive Sleep Apnea

Brian K. Whisenant, Benjamin D. Horne, Sherman G. Sorenson, Jeffrey L. Anderson, Heidi T. May, Tami L. Bair, Joseph B. Muhlestein, Intermountain Medical Center, Murray, UT

Background: Preliminary investigations have identified an increased prevalence of patent foramen ovale (PFO) among patients with sleep apnea when compared with controls. Sleep apnea induced pulmonary hypertension has been hypothesized to open PFOs. Hypoxic or peptide signals traversing the PFO may inhibit the central respiratory center. PFOs may also exacerbate sleep hypoxia as apnea induced thoracic pressure changes induce right to left shunting. Transcatheter PFO closure has been reported to diminish sleep hypoxia. We sought to compare the incidence of sleep apnea diagnosis in a population of patients with and without PFO.
Methods: Patients from the Intermountain Heart Collaborative Study (IHCS) with a PFO (n=245) confirmed by a history of transcatheter PFO closure were compared with IHCS patients (n=11,302) undergoing cardiac catheterization who were found to be free from coronary artery disease, unstable angina, or myocardial infarction. The PFO and control patients were queried for ICD-9 diagnoses (327.2, 780.51, 780.53, 780.57) that indicate the presence of clinically-diagnosed sleep apnea.
Results: Significant demographic differences were detected among the PFO and control populations. PFO patients were younger (51 years vs. 61 years, p<0.001), more likely to be women (61% vs. 43%, p<0.001), less likely to have hypertension (HTN) (10% vs. 51%, p<0.001), or to use tobacco (4% vs. 16%, p<0.001). Sleep apnea occurred among PFO patients more than among controls (30% vs. 21%, p=0.009). After adjusting for age, sex, HTN, smoking history, chronic obstructive pulmonary disease, and body mass index, PFO remained significantly associated with sleep apnea (odds ratio= 1.59, 95% confidence interval=1.19, 2.12; p=0.002).
Conclusions: PFO was associated with sleep apnea among non-coronary cardiac patients. Further investigation is warranted to determine if a causative relationship exists between PFO and sleep apnea and if PFO closure benefits sleep disordered breathing or sleep hypoxia.

I2.SYMPOSIUM

2627

i2.Interventional Pharmacology

Saturday, March 28, 2009, 10:00 a.m.-Noon
Orange County Convention Center, Room W415D

11:30 a.m.

2627-10 Platelet Response to Clopidogrel Assessed With Point-of-Care Analysis and Drug-Eluting Stent Thrombosis

Dirk Sibbing, Siegmund Braun, Tanja Morath, Julinda Mehilli, Wolfgang Vogt, Albert Schomig, Adnan Kastrati, Nicolas von Beckerath, Deutsches Herzzentrum Munchen, Munich, Germany

Background: Prospective studies implementing different methods of platelet function testing have reported that an attenuated response to clopidogrel is associated with an increased risk of ischemic events following percutaneous coronary intervention (PCI) including stent thrombosis (ST). Light transmission aggregometry (LTA) has been the most widely used technique in this setting. However, LTA is time- and labor-intensive and a point-of-care assay with similar predictive power would be of great value. The aim of this prospective trial was to assess whether platelet response to clopidogrel measured with multiple electrode platelet aggregometry (MEA), a newly developed point-of-care assay, correlates with the risk of drug-eluting stent thrombosis.
Methods: Between February 2007 and April 2008, a total of 1608 consecutive patients with coronary artery disease and planned drug-eluting stent implantation were enrolled. Before PCI all patients received 600 mg clopidogrel. Blood was obtained directly before PCI. Adenosine diphosphate (ADP)-induced platelet aggregation was assessed in whole blood with MEA on a Multiplate analyzer (Dynabyte, Munich, Germany). The primary

endpoint was definite ST at 30 days.
Results: The upper quintile of patients according to MEA measurements (n=323) were defined as clopidogrel low-responders. Compared with normal-responders (n=1285), low-responders had a significantly higher risk of definite ST within 30 days [2.2% vs. 0.2%; odds ratio (OR) 9.4; 95% confidence interval (CI) 3.1-28.4; P<0.0001]. The composite of death or ST was higher in low- vs. normal-responders [3.1% vs. 0.6%; OR 5.1; 95% CI 2.2-11.6; P<0.001]. In a multivariate Cox proportional hazards model, low-response to clopidogrel assessed with MEA was found to be an independent predictor for the occurrence of ST [Hazard Ratio 10.95; 95% CI 2.31-51.99; P=0.003]. At the ACC meeting 2009, 6 month follow-up data will be presented as well.
Conclusions: Low-response to clopidogrel assessed with MEA is significantly associated with an increased risk of ST. Further studies are warranted to evaluate the ability of MEA to guide antiplatelet therapy in patients undergoing PCI.

I2.ORAL CONTRIBUTIONS

2901

DES Outcomes

Saturday, March 28, 2009, 10:00 a.m.-Noon
Orange County Convention Center, Room W414D

10:00 a.m.

2901-5 Four-Year Clinical Outcomes After Drug-Eluting and Bare-Metal Stents in Patients With Diabetes Mellitus: Pooled Analysis From 10 Randomized Clinical Trials

Adriano Caixeta, Roxana Mehran, Eugenia Nikolsky, Alexandra Lansky, George Dangas, Jeffrey W. Moses, Ajay Kirtane, Martin Fahy, Gregg Stone, Martin Leon, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Drug-eluting stents (DES) reduce the need for repeat revascularization, but their long-term safety has recently been called into question, particularly in pts with diabetes mellitus (DM). We sought to compare the clinical outcome of patients with DM treated with DES vs. BMS.
Methods: Patient-level data were pooled from 10 prospective, double-blind, randomized trials of DES (TAXUS I, II, IV, V and VI; SIRIUS, C-SIRIUS, E-SIRIUS, RAVEL, and ENDEAVOR II) vs. BMS. Safety and efficacy outcomes through 4-year follow-up were assessed in 1,493 patients with DM.
Results: Baseline angiographic and demographic characteristics were similar between the 2 groups. Four-year outcomes are shown in Table.

Variable Description	DES	BMS	Hazard Ratio [95% C.I.]	P-value
Death	10.5%	8.7%	1.22 [0.86,1.75]	0.2649
Cardiac Death	5.9%	4.1%	1.40 [0.85,2.31]	0.1781
MI*	7.0%	8.1%	0.80 [0.55,1.19]	0.2720
TLR**	12.0%	26.1%	0.40 [0.31,0.52]	<.0001
Any ST†	4.9%	3.5%	1.24 [0.73,2.11]	0.4223
Definite/Probable ST	1.7%	1.8%	0.80 [0.35,1.79]	0.5804
Death/MI	15.9%	14.5%	1.01 [0.77,1.34]	0.9158
Death/MI/TLR	25.2%	36.1%	0.59 [0.49,0.72]	<.0001

MI*: myocardial infarction, TLR**: target lesion revascularization, ST†: stent thrombosis by Academic Research Consortium definition
Conclusions: In patients with diabetes mellitus, treatment with DES was associated with similar rates of death, MI, composite of death/MI, and stent thrombosis compared with BMS. DES was also associated with significant and durable reduction in TLR at 4-year follow-up.

10:12 a.m.

2901-6 Cardiovascular Outcomes in Patients With Drug Eluting Coronary Stents Undergoing Noncardiac Surgery

Nicholas Cruden, Scott Harding, Andrew D. Flapan, Cat Graham, Sarah Wild, Rachel Slack, Jill Pell, David E. Newby, University of Edinburgh, Edinburgh, United Kingdom

Background: Noncardiac surgery within 6 weeks of bare metal coronary stent (BMS) implantation is associated with an increased risk of stent thrombosis. It is unclear whether this risk extends beyond 6 weeks for drug eluting stents (DES).
Methods: We examined perioperative cardiovascular outcomes in patients treated with DES or BMS in Scotland between 01/04/03 and 31/03/07 who subsequently underwent noncardiac surgery.
Results: 570 patients receiving a DES and 1383 receiving only BMS underwent noncardiac surgery. There were no differences in perioperative mortality (0.7% vs 0.6%; p=0.8), or rates of myocardial infarction (AMI) (1.2 vs 0.7%; p=0.3) or any ischaemic cardiac (IHD) event (13% versus 14%; p=0.8) between the DES and BMS groups. Compared to surgery performed after 42 days, perioperative mortality, AMI and IHD events were all significantly greater when noncardiac surgery was performed within 42 days of stent implantation (Table 1). There were no temporal differences in cardiovascular outcomes between the DES and BMS groups. Following multivariate regression, previous coronary bypass grafting (OR 1.55 [1.07-2.26] and increasing age (OR 1.02[1.01-1.03]/yr) were associated with adverse cardiac outcomes.
Conclusion:Patients undergoing noncardiac surgery within 6 weeks of coronary stent implantation are at increased risk of death, myocardial infarction and ischaemia. Cardiac event rates were similar for DES and BMS, irrespective of the timing of surgery relative to stent implantation.

Table 1. Perioperative Cardiovascular Outcomes According to Duration of Noncardiac Surgery from Stent Implantation

		<42 days	42 days – 1 year	>1 year	P
		n= 40	n=477	n=866	
BMS	Death	2 (5%)	5 (1%)	1 (0.1%)	<0.0001
	AMI	3 (8%)	3 (0.6%)	4 (0.5%)	<0.0001
	Any IHD event	17 (43%)	60 (13%)	100 (12%)	<0.001
		n= 19	n=255	n=282	
DES	Death	1 (5%)	2 (0.8%)	1 (0.4%)	<0.05
	AMI	2 (10%)	2 (0.8%)	3 (1%)	<0.005
	Any IHD event	7 (37%)	40 (16%)	34 (12%)	<0.01

Data presented as n (%). BMS, bare metal coronary stent; DES, drug eluting coronary stent; AMI, acute myocardial infarction; IHD, ischaemic heart disease.

10:24 a.m.

2901-7 Perioperative Cardiac Risk of Noncardiac Surgery After Drug Eluting Stent Implantation

Yohei Ohno, Akio Kawamura, Takahide Arai, Ayaka Endo, Toshimi Kageyama, Takaharu Katayama, Kimi Koide, Yusuke Jo, Kentaro Hayashida, Shinsuke Yuasa, Yuichiro Maekawa, Satoshi Ogawa, Keio University School of Medicine, Division of Cardiology, Tokyo, Japan

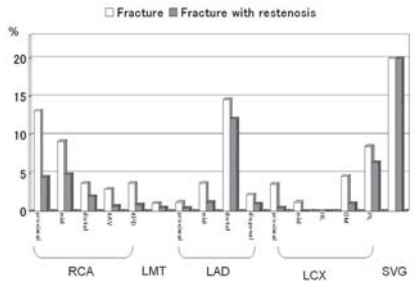
Background: Perioperative coronary stent thrombosis is a life-threatening complication that can occur in patients receiving drug-eluting stents (DES). Noncardiac surgery (NCS) appears to increase the risk of stent thrombosis, especially when it is performed early after stenting, and particularly if dual antiplatelet therapy is discontinued. The guideline recommends 12 months of dual antiplatelet therapy, however little is known about cardiac risk of patients with DES who are undergoing NCS. This study was aimed to investigate the incidence and outcome of NCS after DES implantation.
Methods: This single-center, retrospective study examined the incidence and outcome of NCS performed within 3 years after DES placement and examined whether this risk changed based on the timing of surgery, timing of antiplatelet agent discontinuation, and patient characteristics. Outcome measures included postoperative myocardial infarction (MI), stent thrombosis, major bleeding, and all-cause mortality during the hospitalization for NCS.
Results: From June 2004 to October 2007, 519 patients received Sirolimus-eluting stent (SES) and we identified 76 (14.6%) patients who underwent NCS a median of 401 days (IQR 229-866) after SES implantation. NCS included 10 endoscopic procedures (13%), 29 minor surgery (38%), and 37 major surgery (49%).Thirteen patients (17%) underwent surgery within 180 days of stenting, 4 of whom (5%) underwent surgery within 90 days. In 42 patients (55%), all antiplatelet agents were discontinued a median of 5 days before surgery. Intravenous antiplatelet agent or anticoagulant was not used for substitution. In 34 patients (45%), single or dual antiplatelet therapy was continued. No patients died nor suffered MI/stent thrombosis. One patient developed major bleeding which required transfusion (1.3%). The majority (79%) of patients were consulted to cardiologists before NCS.
Conclusions: A considerable number of patients face the need of NCS after DES implantation. Although NCS is performed safely after discontinuation of single or dual antiplatelet agents, more cardiologists should be involved in the perioperative care of these patients.

10:36 a.m.

2901-8 Unique Distributions of Stent Fracture and Stent Fracture With Restenosis After Sirolimus-Eluting Stent Implanattion

Kazushige Kadota, Kazuaki Mitsudo, Katsumi Inoue, Tsuyoshi Goto, Satoki Fujii, Hiroyuki Yamamoto, Harumi Kato, Yasushi Fuku, Shingo Hosogi, Hiroyuki Tanaka, Seiji Habara, Daiji Hasegawa, Masao Imai, Suguru Ootsuru, Masakazu Miyamoto, Kurashiki Central Hospital, Kurashiki, Japan

Background: Stent fracture (SF) after drug-eluting stent implantation has been reported to occur more frequently at RCA than other native coronary arteries. However, further information on common sites of SF and SF-related restenosis remain unclear. Thus, we evaluated the sites of SF and SF with restenosis according to the coronary branches after Sirolimus-eluting stent (SES).
Methods: Between November 2002 and December 2006, a total of 2417 consecutive patients with 3888 lesions underwent SES implantation. Of these, 2291 patients with 3621 lesions were treated with SES exclusively and successfully. A total of 1979 patients with 3090 lesions who were followed by angiography constituted the study population. Angiographic SF was defined as apparent complete separation of stent segments at any view of angiogram.
Results: SF was observed at 163 lesions and SF with restenosis at 59. Prevalence of stent fracture of RCA, LMT, LAD, LCX and SVG were 8.0 % (97/1207), 2.8 % (4/142), 3.3 % (34/1032), 3.3 % (23/688) and 25 % (5/20) respectively. Prevalence of SF with restenosis of RCA, left main trunk LMT, LAD, LCX and SVG were 3.0 % (36/1207), 0.7 % (1/142), 1.3 % (13/1032), 0.6 % (4/688) and 25 % (5/20) respectively. Prevalence of SF and SF with restenosis at various branches of native coronary artery and SVG was shown in Figure. **Conclusions:**Unique distributions of SF and SF with restenosis after SES implantation were observed. These findings could be useful to prevent SF with or without restenosis.



10:48 a.m.

2901-9 **Randomised Trial of 3 Rapamycin-Eluting Stents With Different Coating Strategies for the Reduction of Coronary Restenosis - Two-year Follow-Up Results**

Robert A. Byrne, Julinda Mehilli, Anna Wieczorek, Raisuke Iijima, Stefanie Schulz, Olga Bruskina, Jürgen Pache, Rainer Wessely, Adnan Kastrati, Albert Schömig, Deutsches Herzzentrum, Munich, Germany, 1. Medizinische Klinik rechts der Isar, Munich, Germany

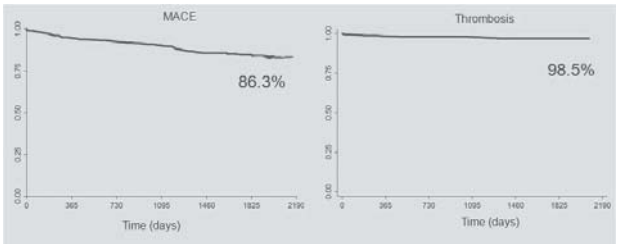
Background: Drug-eluting stent platforms devoid of durable polymer may potentially be associated with enhanced long-term safety and efficacy outcomes. The ISAR-TEST-3 study was a randomized trial comparing 3 rapamycin-eluting stents with different coating strategies incorporating angiographic follow up at 6-8 months and clinical follow up to one year. The purpose of the current study was to examine 2-year outcomes of these patients.
Methods: Patients with *de novo* coronary lesions in native vessels were randomly assigned to receive one of 3 types of rapamycin-eluting stents: biodegradable polymer (BP), permanent polymer (PP; Cypher) and polymer-free (PF) stents. Additional follow-up coronary angiography was scheduled at 2 years. We assessed late lumen loss (LLL), target lesion revascularization (TLR), death or myocardial infarction and definite stent thrombosis.
Results: A total of 605 patients were enrolled: 202 patients received BP stents, 202 were treated with PP stents and 201 received PF stents. As previously reported LLL at 6-8 months differed across the groups: 0.17±0.45 mm with BP, 0.23±0.46 mm with PP stent and 0.47±0.56 with PF stent (p<0.001). Repeat angiography at 2 years was available for 574 patients (94.9%). LLL was significantly different across the treatment groups: 0.21±0.48 mm in the BP stent group, 0.34±0.53 mm in the PP group and 0.48±0.58 mm in the PF stent group (p<0.001). TLR was required in 17 (8.4%), 21 (10.4%) and 28 (13.9%) cases in BP, PP and PF groups respectively (p=0.20). There were no differences in safety outcomes which occurred infrequently after 1 year: death or myocardial infarction occurred in 14 cases (6.9%) with BP stent, 14 cases (6.4%) in PP stent and 13 cases (7.0%) with PF stent (p=0.97); definite stent thrombosis occurred in 0 cases with the BP stent, 1 case with the PP stent and 2 cases with the PF stent (p=0.36).
Conclusions: At 2 years, inhibition of neo-intimal formation (late loss) may be more durable with a biodegradable polymer stent. At this time point, there was no signal of a differential safety profile between the 3 stent platforms, though investigation with larger patient numbers should be the subject of future studies.

11:00 a.m.

2901-10 **Defining the Incidence of Late Major Cardiac Adverse Events (MACE) in a Non-Selected, Complex, Real-World Population: Very Long-Term Outcomes (≥ 4 years) of Patients in the DESIRE-Late Registry**

Jose de Ribamar Costa Jr, Amanda Sousa, Adriana C. Moreira, Ricardo A. Costa, Galo Maldonado, Manuel N. Cano, Mariana Carballo, Cantídio Campos, Maria Helena Bib, Abrão Cury, Otávio Berwanger, J. Eduardo Sousa, Instituto de Ensino e Pesquisa do Hospital do Coração, São Paulo, Brazil

Background: Despite the efficacy of DES in reducing repeat TLR, concerns regarding the occurrence of stent thrombosis (ST), mainly after the 1st year of the procedure, have partially obscured the benefits of this novel technology. We sought to access the incidence of late MACE and ST in non-selected, complex pts followed for a minimum 4-year period.
Methods: Since the first DES was marked approved in our country (May 2002) all pts treated solely with these devices were included in this prospective, non-randomized, single center registry. In order to access the very long-term clinical impact of DES, we included in the present analysis pts treated until October 2004 (minimum 4-year period from the index procedure). Virtually all subsets of patients and lesions were included. Pts were followed at 1, 6 and 12 months and then yearly up to 6 years.
Results: 976 consecutive pts were enrolled. Most were men (77%) with mean age of 64±12 years-old. 28% had DM. SVG were treated in 7% of the cases and STEMI was the initial clinical presentation in 12%. Stent/patient rate was 1.4. Pts were kept in dual anti-platelet therapy for 3 and 6 months after Cypher and Taxus, respectively. FU was obtained in 98% of the cohort (median 5.2 years). Survival-free of MACE and definite/probable ST are displayed on the chart. Five of the 14 ST occurred after the 4th year of FU.
Conclusions: The deployment of DES in complex, real-world pts resulted in a low rate of very long-term MACE (<15%)and ST (<2%). However, ST still occurs very long after the index procedure.



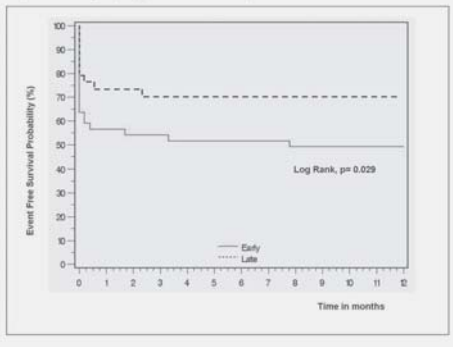
11:12 a.m.

2901-11 **Clinical Outcome and Prognosis of Patients who Present With Early Versus Late Stent Thrombosis**

Gilles Lemesle, Laurent Bonello, Axel De Labriolle, Sara D. Collins, Asmir I. Syed, Gabriel Maluenda, Itsik Ben-Dor, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Late stent thrombosis (ST) is a major complication of drug eluting stents. The prognosis of late ST is still poorly described. This study aimed to compare the outcome of patients presenting with early versus late definite ST after percutaneous coronary intervention (PCI).
Methods: Between 2003 and 2007, 91 patients presenting with definite ST were included. We compared patients with an early ST (n=51) to patients with a late ST (n=40) as defined by the ARC definition.
Results: Baseline characteristics were similar between the 2 groups. The indication of the initial PCI was more often an acute MI in the early ST group than in the late ST group (43% vs 18%, p=0.007). The ST presented as STEMI with high and equal frequency in both groups (73% vs 77%, p=0.6), but the rate of cardiogenic shock was higher in the early ST group (39% vs 20%, p=0.04). There was no difference in the ST treatment between the groups except for intra-aortic balloon pump use. The angiographic success rate was similar between the groups (83% vs 87%, p=0.5). The incidence of the composite endpoint death-MI-recurrent ST at 1 year was 53% in the early ST group vs 30% in the late ST group (p=0.03).
Conclusion: Patients with early definite ST have worse prognosis when compared to patients with late definite ST. This could be attributed to the occurrence of a subsequent MI within 30 days from the first one in 45% of the patients with early ST, leading to a higher rate of cardiogenic shock. Special efforts should be taken to minimize the occurrence of early ST.

Figure: Event free survival curves for the composite endpoint Death-MI-Recurrent ST at 1 year in both groups (Kaplan Meier curves).



11:24 a.m.

2901-12 **Revascularization With Cardiac Surgery Versus Paclitaxel-Eluting Stents in Patients With Diabetes and Metabolic Syndrome: 1-Year Results From the SYNTAX Study**

Adrian P. Banning, Stephen Westaby, Friedrich W. Mohr, A. Pieter Kappetein, Marie-Claude Morice, Katrin Leadley, Keith D. Dawkins, Patrick W. Serruys, John Radcliffe Hospital, Oxford, United Kingdom, Boston Scientific Corporation, Natick, MA

Background: Optimal revascularization strategy in diabetic patients with multivessel coronary disease is under debate. TAXUS paclitaxel-eluting stents yield comparable outcomes in diabetic and nondiabetic patients with 1- and 2-vessel disease. SYNTAX is a contemporary worldwide randomized comparison of surgery (CABG) versus TAXUS Express.
Methods: SYNTAX enrolled only patients with left main and/or 3-vessel disease--the most complex patient group ever studied in a coronary artery revascularization trial. Of 1800 randomized patients, 452 had medically treated diabetes and 656 had metabolic syndrome.
Results: There were no significant differences in composite safety in any cohort but revascularization was increased in TAXUS-treated patients compared to surgery. MACCE

in nondiabetic patients was 11.8% in the CABG arm and 15.1% in the TAXUS arm (*P*=0.08). In diabetic and metabolic syndrome patients, the MACCE difference increased with SYNTAX score; MACCE was not different between arms in the lowest SYNTAX score tercile but was higher in TAXUS in the intermediate and high terciles.

Conclusion: Cardiovascular complications are the leading cause of death in diabetes. However, optimal revascularization strategy in patients with diabetes is unclear. This analysis provides a treatment algorithm for physicians to determine the patient risk profile based on co-morbidity, diabetes severity, and lesion characteristics, and choose the most safe and effective revascularization option for each patient.

	CABG	TAXUS	P Value
Nondiabetic Patients (N=1348)†			
Death/CVA/ MI	6.8% (44/645)	6.8% (45/664)	0.97
Revascularization	5.7% (37/645)	11.1% (74/664)	<0.001
Medically Treated Diabetes‡ (N=452)			
Death/CVA/ MI	10.3% (21/204)	10.1% (23/227)	0.96
Revascularization	6.4% (13/204)	20.3% (46/227)	<0.001
Metabolic Syndrome (N=656)			
Death/CVA/ MI	8.8% (27/307)	7.8% (26/333)	0.65
Revascularization	6.5% (20/307)	14.7% (49/333)	<0.001
HbA1c≥7.0% (N=246)			
Death/CVA/ MI	7.6% (9/119)	10.2% (12/118)	0.48
Revascularization	7.6% (9/119)	19.5% (23/118)	0.007

Composite safety = death, CVA (cerebrovascular accident), myocardial infarction (MI).
MACCE = death, CVA, MI, and revascularization (any vessel)
†Includes 59 patients treated with diet control for hyperglycemia.
‡Treatment with oral hypoglycemic agents or insulin at enrollment; randomization was stratified by presence or absence of medically treated diabetes.

I2.SYMPOSIUM

2604

i2.09 Complex Lesions I: Bifurcations/LM

Saturday, March 28, 2009, 1:00 p.m.-3:00 p.m.
Orange County Convention Center, Room W415D

1:40 p.m.

2604-7 Angiographic Restenosis at 9 Months in the DIVERGE Trial, a Multi-Center Investigation of a Dedicated Drug-Eluting Bifurcation Lesion Stent

Alexandra J. Lansky, Stefan Verheye, Christophe Dubois, Josef Dens, John Ormiston, Stephen Worthley, Ecaterina Cristea, Ovidiu Dressler, Martin Fahy, Iulian Benetato Giuran, Roxana Mehran, The Cardiovascula Research Foundation, New York, NY

Background: The AXXESS™ stent is a self-expandable bifurcation drug eluting stent (DES). In this multicenter study, 9 month angiographic outcomes were assessed after complex bifurcation treatment of 150 pts.

Methods: The DIVERGE study enrolled 302 pts with bifurcation lesions treated with AXXESS DES and Cypher stents in the distal parent vessel (PV) and side branch (SB) as needed for optimal outcomes. Follow up angiography was performed in a pre-specified subgroup of 150 pts. Restenosis was measured in the PV and SB and results were compiled to reflect total bifurcation lesion outcomes per patient. Outcomes by SB treatment mode (PTCA or stent) were also evaluated. There was 100% source document monitoring independent core laboratory and independent clinical events committee.

Results: Angiographic follow up was completed in 140 patients (93.3%) at 9 months. Overall bifurcation restenosis was 6.4%, of which 3.6% was in PV and 4.3% in SB. Within the stented segments, restenosis most frequently occurred within the first 5mm distal to the carina. Overall results by vessel segment are presented in Table 1. At 9 months, MACE in this subgroup was 9.4% and TLR was 5.4%.

Conclusion: In the DIVERGE Trial, an optimal stenting strategy combining the AXXESS and Cypher stents demonstrated markedly low MACE, TLR and restenosis rates in both PV and SB.

Table 1: Bifurcation Restenosis Segmental Analysis in 140 Patients

Location	Restenosis Rate
All Bifurcation (per patient)*	6.4% (9/140)
PV	3.6% (5/140)
Proximal Edge	2.1% (3/140)
Axxess Stent	0.7% (1/140)
Distal Stent	2.3% (3/128)
Ostial-5mm location	1.4% (2/128)
Distal Edge	0% (0/140)
SB	4.3% (6/140)
In-stent	4.8% (5/105)
PTCA	2.9% (1/35)
Ostial-5mm location	3.6% (5)
Distal Edge	0

*Two patients had RS in both PV and SB

2:35 p.m.

2604-12 Syntax Score in Patients With Left Main Disease: Prediction of Long-Term Clinical Outcome Following Percutaneous Coronary Intervention

Chrysafios Girasis, Yoshinobu Onuma, Neville Kukreja, Ron van Domburg, Patrick W. Serruys, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands, Cardialysis BV, Rotterdam, The Netherlands

Background: The Syntax score was developed as an angiographic scoring system to grade the complexity of coronary artery disease and to risk-stratify patients before treatment. To appreciate its long-term prognostic value, we applied it retrospectively to the Left Main (LM) population of the Thoraxcenter.

Methods: Between January 1, 2000 and December 31, 2005, 207 consecutive patients underwent PCI for unprotected LM disease; 77 (37.2%) of them due to stable angina, 79 and 51 for unstable angina and myocardial infarction (MI) respectively. Cineangiograms of patients were reviewed and lesion-specific data were entered into a custom-made software application to compute the individual scores. Annual follow-up on the occurrence of death and clinical events were collected for 3 years. The primary end-point was all-cause mortality. Secondary endpoints included MI, target vessel revascularization (TVR) and composite major adverse events (MACE: all-cause death, MI or TVR).

Results: Syntax score, calculated for 196 out of 207 patients, varied considerably (minimum 10, maximum 118.5) displaying a median value of 32.5 (21.25-49.75). Values for Syntax score tertiles were ≤25, 26-43 and ≥44 respectively. Intertertile differences in 3-year clinical event rates were considerable (table).

Conclusion: Syntax score varied considerably within this Left Main cohort. However, when stratified into tertiles, it succeeds in predicting long-term clinical events.

3-year clinical event rates _ Syntax score					
	SS ≤ 25	SS=26-43	SS≥44	P value 1st vs. 2nd tertile	P value 1st vs. 3rd tertile
All-cause mortality	11.0%	28.8%	50.0%	0.015	<0.001
MI	0.0%	6.4%	14.4%	0.039	0.002
TVR	20.0%	13.0%	21.1%	0.41	0.80
Death+MI	11.0%	33.7%	51.4%	0.003	<0.001
MACE	29.9%	44.6%	59.3%	0.066	<0.001
Log rank test, pairwise comparisons over strata, p<0.05 significant					

I2.ORAL CONTRIBUTIONS

2902

Aortic and Pulmonic Valve Disease

Saturday, March 28, 2009, 1:00 p.m.-3:00 p.m.
Orange County Convention Center, Room W414D

1:00 p.m.

2902-5 Clinical Outcomes After Transcatheter Aortic Valve Replacement: An Interim Report From the Pooled REVIVE II and REVIVAL II Clinical Studies

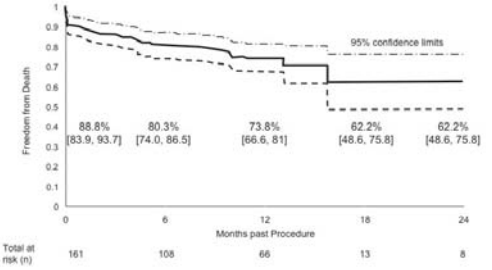
Susheel Kodali, William O'Neill, Helene Eltchaninoff, Murat Tuzcu, Thierry Lefevre, Craig Smith, Lars Svensson, Mathew Williams, John Webb, Jeffrey Moses, Martin B. Leon, Columbia University, New York, NY

Background: There is limited long-term clinical follow-up after transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis (AS) who are at high surgical risk or are non-operable.

Methods: All patients undergoing transfemoral TAVR using the Edwards Sapien valve in the REVIVE II (EU) or REVIVAL II (US IDE) non-randomized feasibility studies were followed at 1,3,6,12,18,and 24 months. Patients were symptomatic with severe AS (valve area < 0.7 cm^2) and were either non-operative or high-risk for conventional AVR.

Results: TAVR was attempted in 161 patients with successful valve deployed in 142 (88.2%). Thirty day MACCE was 18.6%; 18 (11.2%) deaths, 5 (3.1%) MIs and 7 (4.3%) CVAs. Other major complications included vascular events (15.5%) and permanent pacemakers (4.9%). One-year survival was 73.8% (figure). Additional MACCE endpoints between one and twelve months included 3 CVAs and 1 MI. Multivariate analysis indicated that significant predictors of one-year mortality were prior CABG, baseline NYHA class and procedural vascular complications.

Conclusions: TAVR was successfully performed (~90%) in a high risk patient population during these early clinical trials. Long-term survival is influenced by both patient co-morbidities and procedural complications. Ongoing randomized trials will establish the role of TAVR in this high risk patient population.



1:12 p.m.

2902-6 Effectiveness of Percutaneous Aortic Valve Replacement to Improve Left Ventricular Hemodynamics and Reduce Hypertrophy: Serial Echocardiographic Data From the Italian CoreValve Registry

Marco De Carlo, Angelo Ramondo, Federica Ettori, Gian Paolo Ussia, Cristina Giannini, Massimo Napodano, Claudia Fiorina, Giuseppe Tarantini, Ermanna Chiari, Anna S. Petronio, Corrado Tamburino, University of Pisa, Pisa, Italy, University of Padova, Padova, Italy

Background: Percutaneous aortic valve replacement (PAVR) represents a major breakthrough in the treatment of patients with severe aortic valve stenosis. Our aim is to evaluate the effects of the implantation of the CoreValve prosthesis (CoreValve Inc., Irvine, CA) by means of serial echocardiographic examinations.
Methods: In September 2007 we started the implantation of the 3rd generation CoreValve prosthesis at 4 sites in Italy. Inclusion criteria were: 1) symptomatic, severe aortic valve stenosis (area index <0.6cm^2/m^2); 2) aortic valve annulus between 20 and 27 mm; 3) aortic sino-tubular junction <44 mm; 4) at least one of the following: (a) age >74 years; (b) logistic EuroSCORE >14%; (c) age >64 years plus severe prespecified comorbidities. The procedure was performed under general or local anesthesia, with fully percutaneous approach, and without hemodynamic support. Changes in echographic parameters from baseline to 1- and 3-month follow-up was performed with repeated measures ANOVA.
Results: 138 patients were treated, 82 with the small device (26mm), and 56 with the large one (29mm). Twelve in-hospital deaths (9.1%) occurred. Baseline, 1-month, and 3-month echocardiographic data are reported in the Table. A highly significant improvement in all parameters was observed.
Conclusion: serial echocardiographic examination showed evident hemodynamic improvement at 1- and 3-month after CoreValve implantation, entailing improvement in LV ejection fraction and reduction in LV hypertrophy.

	Before PAVR (n=138)	1-month (n=107)	3-month (n=72)	P
NYHA class (mean)	2.7±0.7	1.4±0.6	1.3±0.5	<0.001
LV Ejection fraction, %	51±12	54±11	55±11	<0.001
Peak gradient, mmHg	84±27	18±8	18±7	<0.001
Mean gradient, mmHg	54±19	10±4	10±4	<0.001
LV mass index, g/m2	149±45	123±37	129±41	<0.001
Pulmonary artery pressure, mmHg	43±14	38±10	38±11	<0.001

1:24 p.m.

2902-7 Use of Transesophageal Echocardiography to Assist Positioning of a Balloon Expandable Transcatheter Heart Valve

Stamatios Lerakis, Vasilis Babaliaros, Zahid Junagadhwalla, Vinod Thourani, Robert Guyton, Thomas Vassiliades, Jacob Green, Kush Agrawal, Roy Abrahamian, Collins Kwarteng, William Whitley, Stephen Clements, Randolph Martin, Peter Block, Emory University, ATLANTA, GA

Background: The ideal positioning of a Transcatheter Heart Valve (THV) before deployment is primarily done by fluoroscopic guidance. The use of transesophageal echocardiography (TEE) to aid the optimal placement of THV has not been fully studied because of the inability to differentiate the THV from the balloon it is mounted upon.
Methods: Patients (pts, n=26) underwent balloon expandable trans-femoral THV for aortic stenosis. Both 2 and 3-Dimensional TEE were utilized to determine the optimal location for deployment in the 120-130 degrees long axis view. The ideal position of THV by TEE was confirmed by two separate operators and fluoroscopy prior to implantation.
Results: In 26/26 pts, the proximal end of the THV could be visualized and in 20/26 pts, the distal end was visualized (FIGURE 1). When the larger THV (26mm) was implanted, the proximal and distal ends could be visualized (n=14/14 pts). With the smaller THV (23mm), the distal end was only seen in 6/12 pts. 3-D TEE was able to better visualize the distal end of the 23 mm THV (3/12 vs 6/12 pts). Using TEE guidance confirmed by fluoroscopy, THV deployment resulted in no occurrence of coronary artery occlusion, valve embolization, or significant paravalvular leak.
Conclusion: TEE guidance can assist in the placement of THV, though the distal end of the smaller THV is more difficult to visualize. 3D and 2D TEE are complementary techniques for THV visualization. More experience with TEE and THV implantation is needed.

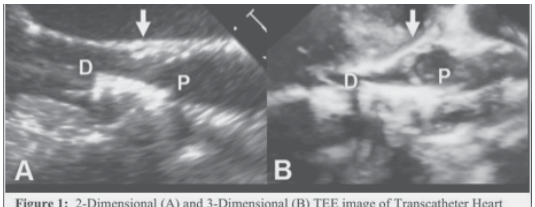


Figure 1: 2-Dimensional (A) and 3-Dimensional (B) TEE image of Transcatheter Heart Valve (THV) placement at the level of native aortic valve (arrow) prior to deployment (P= proximal or aortic end of THV, D = distal or left ventricular end of THV).

1:36 p.m.

2902-8 Increase in Diastolic and Systolic Coronary Flow After Percutaneous Aortic Valve Replacement in Patients With Severe Aortic Stenosis

Itsik Ben-Dor, Augusto Pichard, Ron Waksman, Satler Lowell, Petros Okubagzi, Zuyue Wang, Steven.A Goldstein, Washington Hospital Center, Washington DC, DC

Background: In patients with severe aortic stenosis and normal coronary angiogram the coronary flow is reduce. Doppler evaluation of proximal coronary flow is feasible using transesophageal echocardiography (TEE).
We aimed to assess the change in coronary flow in patients with severe aortic stenosis undergoing percutaneous aortic valve replacement (PAVR).
Methods: The left main coronary artery was visualized clearly using TEE in 9 patients undergoing PAVR using EDWARDS SAPIEN transcathether heart valve. Peak systolic and diastolic velocity of the coronary flow and the time-velocity integral were obtained before and after PAVR using pulsed wave Doppler **Results:** The mean age was 86.8±6.0 years. Mean aortic gradients decreased from 53.4±20.7 mmHg before and 1.7±1.9 mmHg after valve implantation. The aortic valve area increased from 0.5±0.2 cm^2 to 2.0±0.6cm^2. Cardiac output decreased from 3.3±1.5 to 3.2±1.1 l/min.
The coronary flow parameter pre and post PHV are presented in Table 1.
Conclusions: After PAVR there is a significant increase in coronary flow as measured by peak systolic velocity, diastolic velocity and velocity time integral using pulse wave Doppler by TEE. This may improve anginal symptoms in this subset of patients.

Table 1

	Pre PAVR	Post PAVR	P
Peak systolic velocity cm/s	21.5±7.5	38.6± 18.6	0.03
Peak diastolic velocity cm/s	51.1±18.6	76.1±38.2	0.03
Total velocity time integral cm	22.0±7.9	28.1±12.9	0.03
Systolic velocity time integral cm	3.1± 5.4	6.5±8.2	0.09
Diastolic velocity time integral cm	18.9±7.2	21.8±9.1	0.3

1:48 p.m.

2902-9 True Percutaneous Implantation of the Edwards Aortic Valve Prosthesis Using a Suture-Mediated Closure Device. Results of a Multicenter Study

Thierry Lefevre, John Webb, Alaide Chieffo, David Wood, Iassen Michev, Francesco Maesano, Mauro Romano, Antonio Colombo, Marie-Claude Morice, Institut Hospitalier Jacques Cartier, Massy, France

Objectives -To evaluate the feasibility, safety and efficacy of suture-mediated closure devices (Prostar XL) for access site management after percutaneous aortic valve implantation (PAVI) with the Edwards valve.
Background: - PAVI has recently emerged as a new therapeutic option in high-risk patients (Pts) with severe aortic stenosis. With the retrograde approach, femoral artery access is commonly demanding surgical closure and general anaesthesia. A truly percutaneous intervention may reduce procedural complexity and decrease complications.
Methods - After direct puncture of the common femoral artery, 1 or 2 Prostar XL were deployed. A 12 or 14F was inserted for predilatation of the aortic valve. A 22 or 24 French sheath was then inserted and the aortic valve deployed. At the end of the procedure, the preloaded sutures were tied and an angiogram was performed from the controlateral approach.
Results - A total of 87 Pts were included in 3 centers, age 80.3±7.0 years, logistic euroscore 24.4+13.8%. The right femoral approach was used in 59.8% of cases using a 24 Fr sheath in 60.9% and two closure devices in 82.7%. Minimal femoral size was 7.75±0.86 mm, calcification score (0 to 3) 0.94±0.74 and tortuosity score (0 to 3) 0.96±0.82.. Complete closure success was obtained in 91.8% of cases (87.2% for the first 47 cases and 95.0% for the last 40 cases, p=NS). Femoral surgical repair of the femoral access was necessary in 9.2% and of controlateral access in 1.1%. Femoral stenosis or occlusion at the closure site was observed in 5.7% and successfully treated with stents in 4/5 cases and with surgery in one. Other access site complication not related to closure were iliac or femoral dissection treated by stent in 5.1% of case and iliac rupture treated by covered stents in 6.3%. Before hospital discharge significant hematoma were observed in 10.8% of cases, pseudoaneurysm in 1.1% and local infection 2.3%. There was 3 deaths at discharge (3.4%). No deaths were related to the use of closure devices.
Conclusions - Access site management still remains an issue when using 22 or 24 French sheaths for PAVI. However, percutaneous approach using suture-mediated closure devices is a promising technique.

2:00 p.m.

2902-10 The Clinical Outcome of Patients With Severe Aortic Stenosis Who Were Not Eligible to Participate in a Clinical Trial Evaluation Percutaneous Aortic Valve Replacement

Itsik Ben-Dor, Augusto Pichard, Lowell Satler, Petros Okubagzi, Rebecca Torguson, Sara Collins, Asmir Syed, William O. Suddath, Kenneth Kent, Ron Waksman, Washington Hospital Center, Washington DC, DC

Background: Percutaneous aortic valve replacement (PAVR) is currently under evaluation in clinical trials for pts with severe aortic stenosis (AS), who are high-risk surgical candidates. However, many pts are not eligible to participate in these trials. We aimed to study the demographics and the outcome of the pts who could not enter a trial.
Methods: The study cohort consisted of 195 pts with severe AS referred to participate in

a clinical trial of PAVR. All pts were evaluated based on the protocol-specific inclusion / exclusion criteria and the group deferred from a study was followed clinically.
Results: Of the 195 pts, 143 (73.3%) were not eligible. The major reasons for non-eligibility were significant PVD in 25.9%, STS <10% in 20.3%, and aortic valve area (AVA) >0.8 cm^2 in 13.2%. This cohort was divided into 3 groups: 1) medically treated 31.4%; 2) balloon aortic valvuloplasty (BAV) 47.5%; and 3) surgery 21.0%. The pts' mean age was similar among the groups. The STS and Euro scores were lower in the surgical group. The mean AVA was higher and the mean gradients were lower in the medically treated group. The EF was lower in the BAV group. Death was lower in surgical treated group. (Table)
Conclusion: The most common reason for exclusion in a PAVR clinical trial was concomitant peripheral artery disease. The mortality rate for the excluded group treated with the current alternative modalities is high. Efforts should be directed to minimize the profile of the PAVR delivery systems to increase the eligibility of pts with PVD.

TABLE

	Medically treated N=45	Balloon valvuloplasty N= 68	Surgical aortic valve replacement N=30	P
Age years	81.7±8.7	81.0±9.6	80.7±9.0	0.69
Thoracic Surgeons score (%)	10.7±5.1	10.6±4.5	5.9±2.7	0.001
Logistic Euro score (%)	30.8±21.3	35.9±12.8	18.7±8.6	0.001
Ejection fraction (%)	52.2±16.6	46.0±18.1	60.0±13.9	0.02
Aortic valve area(cm2)	0.81±0.24	0.65±0.09	0.73±0.21	0.01
Mean gradient (mmHg)	40.5±14.6	45.0±10.2	43.1±21.4	0.33
Mean duration follow up (days)	269.4±179.8	307.5±194.0	216.7±135.1	0.009
Mean time from screening to mortality (days)	87.0±91.1	80.5±75.3	25.6±22.3	0.04
Mortality (%)	33.3	38.2	10	0.001

2:12 p.m.

2902-11 Percutaneous Pulmonary Valve Replacement in Thirty Patients

K. AL SENAIDI, D. TAYLOR, J. RUTLEDGE, F. DICKE, G. MACK, JY COE, University of Alberta, Edmonton, AB, Canada

Background: Percutaneous pulmonary valve replacement (PPVR) is gaining popularity in patients with failed pulmonary homografts (PH) or prosthetic valves (PV). The Melody valve is a stent mounted bovine jugular vein valve.
Method: We reviewed our experince with PPVR at the University of Alberta.The patients pre and post PPVR data presented as median (range) and analyzed by paired t-test. p <0.05 is considered significant.
Result: PPVR was successful in 32 of 33 procedures (30 patients, 22 male). The median age was 17 (8-39) years & median weight 60 (17-97) kg. Femoral vein was used in 31 and jugular in 2. There were 11 homografts &19 prosthetic valves in patients with tetralogy of Fallot (n= 16), pulmonary atresia-VSD (n=9), transposition of the great arteries-Rastelli, (n=2), AS-Ross (n=2), truncus arteriosus (n=1). Pulmonary stenosis was present in all and significant regurgitation in 25. Median duration from surgery to PPVR was 8 (3-12) years. Exertional dyspnea was present in 16, and 13 had exercise intolerance. The Median procedural time was 100 (50-180) minutes. All patients had a statistically significant decrease in right ventricular systolic and end diastolic pressure and Right ventricular to pulmonary artery gradient after PPVR. All Melody valves were competent post PPVR. All except 3 patients were discharged home the next day. Replacement failed in one, significant bleeding in another, and surgical valve replacement in two patients with significant post PPVR gradient. On follow up at median of 10 (1-23) months (n=24), PV regurgitation mild in 2 with no mortality. Second valve (n: 2) There was no statistically significant change in tricuspid regurgitation gradient and right ventricular to pulmonary artery gradient by echocardiography immediately post PPVR and on last follow-up.
Conclusion:
PPVR is not only an effective alternative to surgical replacement of pulmonary valve, but significantly shortened the hospital stay, rarely required blood transfusion, and accomplished without thoracotomy. The short term result is remarkable. Long term outcome remains to be evaluated.

2:24 p.m.

2902-12 The Safety and Efficacy of Cutting Balloon Versus High Pressure Balloon Therapy for the Treatment of Resistant Pulmonary Artery Stenosis: A Multi-Center Randomized Trial

Lisa Bergersen, Kimberlee Gauvreau, Jonathan Rome, Jackie Kreutzer, David Nykanen, Evan Zahn, Larry Latson, Jonathan Rhodes, Alan Nugent, Henri Justino, Phillip Moore, James Lock, Kathy Jenkins, Childrens Hospital Boston, Boston, MA

Background: We sought to determine the safety and efficacy of Cutting Balloon (CB) versus conventional high pressure balloon (HPB) therapy for the treatment of pulmonary artery stenosis.
Methods: A prospective, randomized, multi-center, IDE trial compared CB to HPB therapy. Patient eligibility was determined at the pre-catheterization assessment; for each patient, only native pulmonary vessels with favorable anatomy for balloon delivery, and without an associated stent, or recent surgical intervention were evaluated. In these vessels a balloon was inflated to 8 ATM, low pressure balloon dilation (LPB); if the waist in the balloon was not eliminated the vessel was randomized to CB vs HPB. The primary study outcome was percent change in minimum lumen diameter. A core laboratory performed all vessel measurements and angiographic assessment of vessel damage. A Data and Safety Monitoring Board reviewed all adverse events. Three changes were made to the study design during the enrollment period: 1) cross-over treatment permitted, 2) 1 cm peripheral CB replaced by 2 cm length peripheral CB, and 3) randomization changed from 1:1 to 2:1 (CB:HPB). Multiple vessels within a patient could be randomized, and analytical methods accounted for this clustering.
Results: 73 patients from 8 pediatric hospitals in the United States were enrolled between 2004 and 2008. In these patients, 71 vessels responded to LPB dilation. 172 vessels met eligibility criteria; 106 were randomized to CB and 66 to HPB. In vessels randomized to HPB, the balloon waist was eliminated in 29% vs 97% CB, p<0.001. Vessels randomized to CB had a greater percent increase in lumen diameter (86% vs 53% HPB, p=0.003). After cross-over was introduced, 25 of 47 vessels treated with HPB underwent CB therapy and experienced an additional 39% increase in lumen diameter, final 105%. Neither treatment arm experienced a serious adverse event attributed to CB or HPB therapy. There was no difference in total events due to balloon angioplasty in a study vessel: 18 (17%) randomized to CB versus 9 (14%) HPB, p = 0.7.
Conclusions: CB therapy for pulmonary artery stenosis not responsive to LPB is more effective than HPB therapy and has an equivalent safety profile.

I2.POSTER CONTRIBUTIONS

2501

PCI - DES I

Sunday, March 29, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2501-501 Fractional Flow Reserve versus Angiography in Multivessel Evaluation

Pim A.L. Tonino, Bernard De Bruyne, Nico H.J. Pijls, Uwe Siebert, Fumiaki Ikeno, Marcel van 't Veer, Volker Klauss, Ganesh Manoharan, Thomas Engstrom, Keith G. Oldroyd, Peter N. Verlee, Philip A. MacCarthy, William F. Fearon, for the FAME Study Investigators, Catharina Hospital, Eindhoven, The Netherlands, Stanford University Medical Center, Stanford, CA

Background In patients with multivessel coronary artery disease (CAD) undergoing percutaneous coronary intervention (PCI) it is unclear whether routine measurement of fractional flow reserve (FFR) in addition to angiography improves outcomes.
Methods At 20 U.S. and European medical centers, 1005 patients with multivessel CAD were randomized to PCI with drug-eluting stents (DES) guided by angiography alone or guided by FFR measurements. Prior to randomization, lesions requiring PCI were identified based on their angiographic appearance. Patients randomized to angiography-guided PCI underwent stenting of all indicated lesions, while those randomized to FFR-guided PCI underwent stenting of indicated lesions only if the FFR was ≤ 0.80. The primary endpoint was the rate of death, nonfatal myocardial infarction or repeat revascularization at 1 year.
Results Baseline characteristics were similar. The 1-year event rate was 18.4% in the angiography-guided group and 13.2% in the FFR-guided group (P=0.02). The rate of death or myocardial infarction was 11.1% and 7.3%, respectively (P=0.04). In the angiography-guided group 78% of patients were free from angina, as compared to 81% in the FFR-guided group (P=0.20).
Conclusions Routine measurement of FFR in patients with multivessel CAD undergoing PCI with DES significantly reduces the rate of death, nonfatal myocardial infarction or repeat revascularization at 1 year. (ClinicalTrials.gov Identifier: NCT00267774)

	Angiography-group N= 496	FFR-group N= 509	P Value
Age - yr	64.2±10.2	64.6±10.3	0.47
Previous PCI	129(26)	146(29)	0.34
Diabetes	125(25)	123(24)	0.65
Indicated lesions per patient - no.	2.7±0.9	2.8±1.0	0.34
Drug eluting stents used per patient- no.	2.7±1.2	1.9±1.3	<0.001
Procedure time - min.	70±44	71±43	0.51
Contrast agent used - ml.	302±127	272±133	<0.001
Lesions with FFR ≤ 0.80 - no. (%)	n/a	874(63%)	
Lesions with FFR > 0.80 - no. (%)	n/a	513(37%)	
Death, myocardial infarction, CABG or repeat PCI	91(18.4)	67(13.2)	0.02
Death	15(3.0)	9(1.8)	0.19
Myocardial infarction	43(8.7)	29(5.7)	0.07
Death or myocardial infarction	55(11.1)	37(7.3)	0.04
CABG or repeat PCI	47(9.5)	33(6.5)	0.08
Patients free from angina - no. (%)	374(78)	399(81)	0.20
Patients without event and free from angina	326(68)	360(73)	0.07
Materials - USD	6007±2819	5332±3261	<0.001
Hospital stay at baseline admission - days	3.7±3.5	3.4±3.3	0.05

9:30 a.m.

2501-502 Long Term Outcome of Paclitaxel- and Sirolimus-Eluting Stents Versus Bare Metal Stents. From Western Denmark Heart Registry

Per Thayssen, Anne Kaltoft, Hans Henrik Tilsted, Lisette Okkels Jensen, Michael Maeng, Jens Flensted Lassen, Knud Noerregaard Hansen, Klaus Rasmussen, Morten Madsen, Soeren Paaske Johnsen, Lars Pedersen, Henrik Toft Soerensen, Leif Thuesen, Odense University Hospital, Odense, Denmark

Background: The long term effectiveness and safety of drug-eluting stent (DES) outside clinical trials is controversial. Therefore, we examined stent thrombosis, myocardial infarction (MI), mortality and target vessel revascularisation (TLR) in patients treated with percutaneous coronary intervention (PCI) and paclitaxel- (PES) or sirolimus-eluting (SES) or bare metal (BMS) stent implantations in Western Denmark.
Methods: From January 2002 to June 2005 all consecutive patients, who had SES, PES or BMS implantation where identified in the population based Western Denmark Heart Registry. All patients received were followed for 36 months. We used Cox regression analysis to estimate relative risk controlled for potential confounding.
Results: A total of 12,374 patients were treated: 1,304 with PES, 2,212 with SES and 8,858 with BMS. Very late definite stent thrombosis (between 12 and 36 months after implantation) was seen more often in DES treated compared to BMS treated patients [adjusted RR=2.89 (95% CI: 1.48-6.78)]. Compared to BMS treated patients an elevated risk of very late definite stent thrombosis was seen in PES treated patients [adjusted RR 4.23 (95%CI: 1.97-9.09)].The risk was not significantly increased in SES treated patients [adjusted RR 1.81 (95%CI: 0.78-4.20)]. The risk of MI was slightly increased in DES treated patients [adjusted RR 1.27 (95%CI: 1.07-1.51)]. Compared to BMS treatment an elevated risk of MI was seen in PES treated patients [adjusted RR 1.38 (95%CI: 1.09-1.74)] and SES treated patients [adjusted RR 1.23 (95%CI: 1.00-1.51)]. Mortality did not differ between DES and BMS treated patients [adjusted RR=0.94 (95% CI: 0.82-1.08)]. TLR was reduced significantly in DES treated patients [adjusted RR=0.71 (95% CI: 0.63-0.81)]. Compared to BMS treated patients SES reduced TLR significantly [adjusted RR=0.61 (95% CI: 0.52-0.72)], whereas this association became weaker after 3 years in PES treated patients [adjusted RR=0.86 (95% CI: 0.73-1.03)].
Conclusion: After 3 years an increased risk of definite stent thrombosis and MI were seen in PES treated patients compared with BMS treated patients. A sustained better outcome was seen after SES treatment.

9:30 a.m.

2501-503 Does African-American Race Influence Development of Stent Thrombosis in the Drug-Eluting Stent Era?

Sara D. Collins, Michael A. Gaglia, Jr., Asmir Syed, Itsik Ben-Dor, Yanlin Li, Gilles Lemesle, Gabriel Manuela, Mickey Scheinowitz, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, Joseph Lindsay, Kenneth Kent, Lowell Satler, William O. Suddath, Augusto Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: It has been suggested that African American (AA) race predicts stent thrombosis after drug-eluting stent (DES) implantation. Whether socioeconomic status or comorbid conditions confound the contribution of AA race to the development of stent thrombosis is unclear.
Methods: 104 patients with definite DES thrombosis (ST) were compared to 5862 patients with DES implantation who did not develop stent thrombosis (NoST). Multivariable Cox regression analysis was performed adjusting for comorbities, including median household income, to assess the impact of AA race on development of stent thrombosis.
Results: On univariate analysis, patients with stent thrombosis were more likely to be AA (41.3% ST vs. 22.1% NoST, p<0.001), and have a history of diabetes (50.5% ST vs. 34.5% NoST, p<0.001). Clopidogrel compliance at the time of the ST event was similar in the AA versus Non-AA population (AA 66.7%, Non-AA 63.4%, p=0.936). After multivariate analysis, including adjustment for median income (Table 1), AA race emerged as the strongest predictor of cumulative definite stent thrombosis at 3 years.
Conclusion: African American race is an independent predictor of cumulative stent thrombosis. As clopidogrel compliance was similar, and household income did not predict ST, further investigation into potential mechanisms of this influence must be pursued.

	Hazard Ratio	95% Confidence Interval	p value
African American race	2.3	1.5-3.5	<0.001
Previous PCI	1.8	1.2-2.7	0.006
History of diabetes	1.8	1.2-2.7	0.007
Median household income (zip code)	1.0	1.0-1.0	0.582
History of CRI	0.8	0.4-1.5	0.557

Table 1: Multivariate Cox proportional hazard model of definite DES thrombosis at 3 years follow-up

9:30 a.m.

2501-504 Delayed Arterial Healing Is Associated With Late Stent Thrombosis in Off-Label Use of Drug-Eluting Stents: A Pathologic Study

Gaku Nakazawa, Andrew Farb, Marc Vorpahl, Aloke V. Finn, Frank D. Kolodgie, Renu Virmani, CVPath Institute, Inc., Gaithersburg, MD

Background: Currently > 60% drug-eluting stents (DES) are implanted beyond the labeled indications for use ("off-label"). Observational studies show that off-label use is associated with an increased risk of stent thrombosis, but the mechanism of DES thrombosis when used off-label is poorly understood.
Methods: A total of 158 lesions (implant duration >30 days) from 108 patients in the CVPath DES autopsy registry were divided into on- and off-label use. On-label was defined as de novo native coronary lesion of length <30mm in patients with symptomatic ischemic disease. Pathologic comparisons between on- versus off-label were performed for DES implanted 12 months separately.
Results: DES were placed off-label in 84 of 158 lesions (53%). The indications for off-label use were acute MI (45%), long lesion stenting (44%), bifurcations (23%), bypass grafts (11%), and left main lesions (4%). The rate of late stent thrombosis (>30 days) was significantly higher (p<0.0001) in off-label (43%) as compared to on-label use (4%). Morphometric analysis showed higher prevalence of uncovered struts and greater fibrin score in off-label as compared to on-label not only within 12 months but also beyond 12 months (Table).
Conclusions: A higher rate of late stent thrombosis was observed in off-label as compared to on-label use at autopsy. Delayed arterial healing in off-label use remained discernable beyond 12 months.

Morphometric and pathologic analysis (>30days)

	< 12 months			> 12 months		
	On-label (n=47)	Off-label (n=48)	p value	On-label (n=27)	Off-label (n=36)	p value
Duration, day; Median (IQR)	120 (57, 240)	126 (60, 213)	0.75	558 (465, 990)	645 (450, 848)	0.94
Stent length, mm	17.7±7.0	27.0±11.6	<0.0001	18.9±5.7	29.8±16.2	0.004
Stent area, mm2	6.9±3.7	7.2±2.3	0.72	7.2±2.3	7.0±2.0	0.67
Max Neointimal thickness, mm	0.22±0.21	0.20±0.17	0.52	0.27±0.22	0.28±0.18	0.88
Inflammation score	1.1±1.1	1.1±0.9	0.87	1.2±1.2	1.7±1.5	0.19
Fibrin score	1.4±1.3	2.1±1.1	0.01	0.8±0.9	1.3±1.1	0.11
%Uncovered struts	31±32	46±34	0.03	13±17	25±23	0.03
Thrombosis (%)	2 (4)	21 (44)	<0.0001	1 (4)	15 (42)	0.0009

9:30 a.m.

2501-505 The Homozygous LDL Receptor Deficient Swine Predicts Efficacy Following DES Implantation: A Prospective Endovascular Imaging Feasibility Study.

Armando Tellez, Christian G. Krueger, Michael S. Aboodi, Yanping Cheng, Shigenobu Inami, Genghua Yi, Jennifer McGregor, Tom Crenshaw, Jess D. Reed, Greg L. Kaluza, Juan F. Granada, Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, New York, NY, Department of Animal Sciences, University of Wisconsin, Madison, WI

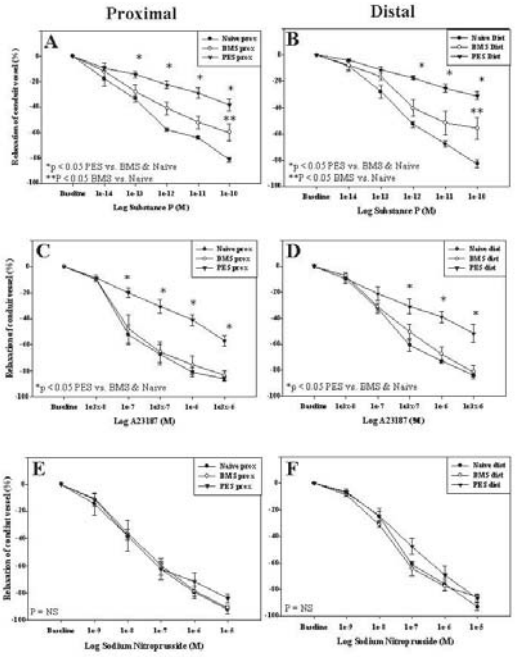
Background: To date, most of coronary DES technology is tested using the normal juvenile swine model. Although reliable in demonstrating the safety profile of these devices, this model has not been particularly useful in demonstrating device efficacy. In this study, we aimed to compare the vascular response occurring following DES implantation in the homozygous LDL receptor deficient swine (FHS) compared to weight-matched domestic swine controls (DS).
Methods: A total of 25 coronary (11 Taxus stents, 14 BMS stents) and 22 peripheral stents (11 Paclitaxel eluting stents and 11 BMS stents) were implanted in 12 swine (6 DS versus 6 FHS) using a 10% overstretch ratio. All animals were fed with regular cholesterol diet to the completion of the study. At 28 days follow up, OCT analysis was performed in the coronaries and IVUS analysis in the peripheral arteries. Stents were harvested and sent for histological evaluation.
Results: At sacrifice the mean LDL cholesterol levels were 415±45 mg/dl in the FHS group and 100±14 mg/dl in the DS group (P=<0.001). In the DS group, the neointimal area measured with OCT in the coronary arteries was similar between the two stent types (BMS=21.9%±10% versus DES=16.9%±8%; P=0.1). On the contrary, in the FHS group, there was more than 50% reduction in neointimal area compared to the DS controls (BMS=25.4%±12% versus DES=11%±3%; P=<0.001). In addition, OCT analysis of both DES groups demonstrated complete strut coverage in the DS group compared to 86% coverage in the FHS group (P=<0.001). In the peripheral arteries, IVUS analysis showed similar neointimal areas in both stent types in the DS group (BMS=6.3%±9.2% versus DES=4.8%±6%; P=0.9) compared to a more than 50% reduction in the FHS group (BMS=6.5%±2.6% versus DES=2.9%±1.5%; P=0.015).
Conclusions: The FHS seems to provide a more favorable vascular environment for the testing of DES technologies compared to the DS. In this particular model, the hyper-proliferative effect commonly seen in the juvenile DS appears not to be present, allowing the evaluation of efficacy outcomes following DES implantation. Histological correlates among groups will be presented at the meeting.

9:30 a.m.

2501-506 Vasomotor Dysfunction in Pig Coronary Arteries with Paclitaxel-Eluting Stents is Associated with Increased Inflammation and Oxidative Stress

Lakshmana K. Pendyala, Jinsheng Li, Toshiro Shinke, Sarah Geva, Xinhua Yin, Joseph P. Chen, Spencer King, III, Keith Robinson, Nicolos Chronos, Dongming Hou, Saint Joseph's Translational Research Institute, Atlanta, GA

Background: Underlying mechanisms of vasomotor dysfunction after paclitaxel-eluting stent (PES) implantation remain unknown. We evaluated coronary arterial vasomotor function, local inflammatory reaction, and superoxide anion ($O_2^{\cdot-}$) production after PES implantation.
Methods: Nine pigs received overlapping PES and bare metal stents (BMS), and 3 sham animals were naïve. At one month, inflammatory response at the overlapped region was assessed by histopathology and scanning electron microscopy (SEM). Endothelial vasomotor function and $O_2^{\cdot-}$ at non-stented coronary reference segments (NSRS) were measured by angiography and organ chamber tensiometry, and lucigenin luminometry.
Results: PES showed reduced late lumen loss, but inflammation and luminal inflammatory cell adherence were higher than for BMS ($p < 0.001$ respectively) at overlapped segments. Endothelium-dependent relaxation (EDdR) to substance P and A23187 was significantly impaired in PES at NSRS ($p < 0.05$ vs. BMS and naïve, respectively). Local $O_2^{\cdot-}$ production at both proximal and distal NSRS was elevated for PES compared to BMS and naive arteries (proximal: PES 36 ± 3 vs. BMS 15 ± 2 and naïve 12 ± 1, $p < 0.001$ Distal: PES 77 ± 4 vs. BMS 23 ± 5 and naïve 19 ± 1 RLU/s/mg tissue, $p < 0.001$, respectively).
Conclusions: Abnormal endothelium-dependent relaxation was demonstrated after overlapping PES implantation. Profound localized inflammatory reaction, as well as enhanced local oxidative stress, may contribute to vasomotor dysfunction.



9:30 a.m.

2501-507 Stent Related Death Rates are higher in Drug Eluting Stents than Bare Metal Stents at Autopsy

Marc Vorpahl, Gaku Nakazawa, Andrew Farb, Aloke Finn, Elena Ladich, Renu Virmani, CV Path Institute, Gaithersburg, MD

Background: Recent clinical studies have shown a higher rate of complications including in-stent restenosis, myocardial infarction, and death in bare metal stents (BMS) versus drug eluting stent (DES). No pathologic study of cause of death from a large number of patients implanted with DES and BMS have been reported.
Methods: CVPath registry of coronary arteries with DES and BMS implantation involving 270 autopsy cases >30 days were reviewed to determine the incidence of stent related death. Stent related death was classified as either stent-thrombosis or in stent restenosis (>75%) or chronic total occlusion (CTO) in the absence of other coronary disease in non-stent related regions with or without myocardial infarction.
Results: A total of 106 cases of DES (21 female vs. 85 male, 148 lesions) and 164 cases of BMS (48 female vs. 116 male, 254 lesions) were included in the analysis. No differences in age (60±12 vs. 63±13 years; n.s.), stents per patient (1.9±1.2 vs. 1.9±1.5, n.s.), vessels diseased (2.2±0.8 vs. 2.4±9; n.s.) and lesion distribution (LAD: 41.1% vs. 42.1%, LCx: 23.4% vs. 18.9%, RCA: 29.1% vs. 39%; n.s.) were present between DES and BMS. Significant differences were observed in the neointima formation (37±16% vs. 60±24 %; p<0.0001), number of stents per lesion (1.4±0.7 vs. 1.3±0.6; p=0.04), stent length per lesion (24±12 vs. 18±9 mm; p<0.0001) and the time of duration of implantation (370±351 vs. 742±932; p<0.0001). The duration to death was significantly less in females than males in both DES (248±196, 397±373; p=0.04) and BMS (422±543, 852±1011; p= 0.001). The cause of stent related death in DES was 32.1% versus BMS 14.6% (p=0.0007). The main cause of death in DES and BMS was thrombosis (28.3% vs. 4.9% p<0.0001) and restenosis/CTO (3.8% vs. 9.8%, p= 0.05).
Conclusions: DES result in a significant reduction in neointima formation (37±16% vs. 60±24 % BMS; p<0.05). Whereas overall stent related death is lower in BMS than DES (14.6% vs. 32.1% p=0.0007) with females dying earlier after coronary stenting then males. DES stenting results in a reduction of death by in-stent restenosis/CTO (3.8% vs 9.8% BMS; p=0.05) but a significant increase in death by late stent thrombosis (28.3% vs. 4.9% BMS; p<0.0001).

9:30 a.m.

2501-508 Thrombosis in Real Practice With Second Generation Drug-Eluting Stents. Results from the ESTROFA-2 Spanish Registry.

Jose M. de la Torre Hernandez, Federico Gimeno, Jose A. Diarte, Ramon Lopez-Palop, Armando Perez de Prado, Fernando Rivero, Juan Sanchis, Mariano Larman, Javier Martin-Moreiras, Jose M. Hernandez, Josepa Mauri, Juan A. Bullones, Jose R. Rumoroso, Jose A. Baz, Javier Botas, Jose Diaz-Fernandez, Jose Moreu, Francisco Bosa, Rafael Melgares, Felipe Hernandez, Bruno Garcia del Blanco, Jose M. Vazquez, Jaime Elizaga, Iñigo Lozano, Angel Sanchez-Recalde, Grupo ESTROFA, Coordination in Santander, Spain

Background: First generation drug-eluting stents are associated to a variable incidence of late thrombosis (0.4-0.6% /yr up to 4 years), specially in off-label indications. There is no data regarding incidence and predictors for thrombosis with the second drug-eluting stent generation, zotarolimus-eluting stent (ZES) ENDEAVOR® and everolimus-eluting stents (EES) XIENCE V® and PROMUS®, in real practice with frequent off-label indications.
Methods: We have designed a large-scale, nonindustry-linked multicentered prospective registry in order to evaluate thrombosis (ARC definitions) of second generation DES in clinical practice. Complete clinical-procedural data of all patients treated with these stents is reported and a systematic follow up is done every year (up to 3 yrs) in a web-based registry supported by the Spanish Working Group on Interventional Cardiology.
Results: Up to now 3709 pts have been included in 34 centers, 2104 treated with ZES and 1605 with EES, 61% in off-label indications.Nowadays median follow up is 395 days (212-605) for pts with ZES and 245 days (128-365) for pts with EES. The cumulative incidence of definite + probable stent thrombosis for ZES was 1% at 30 days, 1.5% at 12 months and 1.8% at 18 months and for EES was 0.6% at 30 days and 1.4% at one year. In STEMI cases (n=752, 74% with ZES) incidence was 0.8% at 30 days, 1.2% at 1 yr and 1.7% at 18 months. Early discontinuation of antiplatelet dual therapy was observed in 8% of cases with thrombosis (all due to bleeding). Univariant predictors for thrombosis were: age, diabetes, renal failure, high blood pressure, ejection fraction, stent length and stent diameter. Multivariant analysis yielded as independent predictors for thrombosis: ejection fraction (HR 0.96; 95% CI 0.94-0.99: p=0.03), high blood pressure (HR 7; 95% CI 1.6-28:p=0.008) and stent diameter (HR 0.35; 95%CI 0.16-0.87:p=0.02).
Conclusions: In a real practice setting with frequent off-label indications the incidence of stent thrombosis at 1 year with second generation drug-eluting stents, ZES and EES, was similarly low. However, a longer follow up is needed to determine the incidence of thrombosis over following years.

9:30 a.m.

2501-509 Efficacy and safety of drug eluting stents versus bare metal stents in ST-elevation myocardial infarction: a meta-analysis of randomized clinical trials

Henri Roukoz, Basel Al Aloul, Shashank Vats, Anthony A. Bavry, University of Minnesota, Minneapolis, MN, University of Florida, Gainesville, FL

Background: Some registry reports have suggested decreased mortality with drug eluting stents, while others have documented increased adverse events in patients with ST-elevation myocardial infarction (MI). We sought to evaluate the safety and efficacy of drug-eluting stents (DES) compared with bare metal stents (BMS) in this patient population.
Methods: We performed a comprehensive meta-analysis of randomized clinical trails comparing DES versus BMS in ST-elevation MI.
Results: We identified 14 trials with a total of 7,439 patients (76.6% males, 14.9% diabetics). The trials' follow-up ranged from 8 to 36 months, with a weighted mean duration of follow-up of 13.2 months. The incidence of all cause mortality for DES vs. BMS was 3.9 % vs. 4.4 %, RR=0.91 (0.72-1.15), p=0.43, cardiovascular mortality was 2.8% vs. 3.3 %, RR=0.93 (0.69-1.27), p=0.67, MI was 3.4% vs. 3.9 %, RR=0.81 (0.63-1.04), p=0.09, and target vessel revascularization was 5.5 % vs. 11.9 %, RR=0.44 (0.35-0.54), p<0.001. The incidence of definite stent thrombosis (ST) was 2.1% vs. 2.4 %, RR=0.79 (0.57-1.10), p=0.17, and definite or probable ST was 2.8% vs. 3.1 %, RR=0.88 (0.65-1.19), p=0.39.
Conclusion: With the available data, there appears to be similar all-cause and cardiovascular mortality, recurrent MI, and stent thrombosis between DES and BMS in patients with ST-elevation MI. Target vessel revascularization is significantly reduced with DES.

9:30 a.m.

2501-510 Vasomotion and endothelial function 2-year after implantation of an Everolimus-eluting bioabsorbable stent

Yoshinobu Onuma, John A. Ormiston, Evelyn Regar, Dariusz Dudek, Leif Thussen, Nieves Gonzalo, Hector Garcia-Garcia, Mark Webster, Susan Veldhof, Patrick W. Serruys, Thorax center, Erasmus MC, Rotterdam, The Netherlands

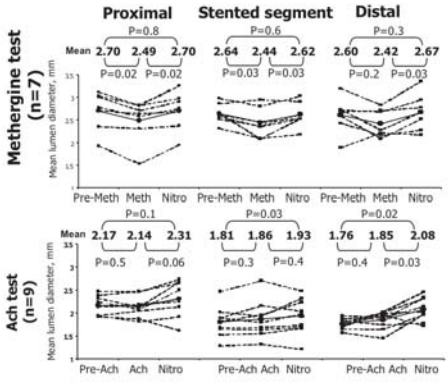
Background: The BVS stent is a fully absorbable drug-eluting stent with a backbone of poly-L-lactic acid and a coating of poly-DL-lactic acid that controls the release of everolimus. In first-in-man study (ABSORB), the BVS demonstrated an acceptable in-

stent loss with alteration or disappearance of stent struts at 6 month. It is unclear whether vasomotor function is restored after absorption of the polymeric strut.

Methods: In the ABSORB study, 30 patients underwent implantation of a BVS stent (Abbott Vascular, Santa Clara, CA). In 16 patients who underwent follow-up angiography at 2 years, vasomotion was assessed with quantitative coronary angiography before and after intracoronary infusion of acetylcholine (Ach) in 9 patients, or before and after intravenous administration of Methylergonovine Maleate (Meth) in 7 patients.

Results: There is methergine-induced non-endothelium dependent vasoconstriction in the proximal (pre 2.7±0.43 vs. post 2.49±0.46 mm, p=0.02) and stented segments (2.64±0.22 vs. 2.44±0.33mm, p=0.03) (figure). Non-significant Ach-induced endothelium dependent vasodilation was observed in the stented segments (pre 1.81±0.33 vs. post 1.86±0.40 mm, p=0.3) as well as in the distal segment (1.76±0.11vs. 1.85±0.19mm).

Conclusion: Two years after implantation of the BVS, vasomotion tests suggest a restoration of vasoconstrictive ability in the proximal and the stented segments and a potential for normalization of endothelial function in the stented and distal segments.



9:30 a.m.

2501-511 **Stent Strut Distribution at Implantation and 9-Month Follow-up in TAXUS and Bare Metal Stents and Its Effect on Neointimal Hyperplasia. An Intravascular Ultrasound Integrated Analysis of the Randomized TAXUS IV, V and VI Trials**

Maksymilian P. Opolski, Radoslaw Pracon, Gary S. Mintz, Neil J. Weissman, Lazar Mandinov, Jerzy Pregowski, Mariusz Kruk, Adam Witkowski, Hong Wang, Stephen G. Ellis, Eberhard Grube, Keith D. Dawkins, Gregg W. Stone, Cardiovascular Research Institute/Medstar Research Institute, Washington Hospital Center, Washington, DC, Cardiovascular Research Foundation, New York, NY

Background: Stent strut fracture (1) affects neointimal hyperplasia (NIH) after drug-eluting stent implantation and (2) is identified by an increase in interstrut angle from implantation to follow-up.

Methods: In 445 patients with serial (post-implantation and follow-up) volumetric intravascular ultrasound (IVUS) from TAXUS IV, V and VI, the # of stent struts was counted and the largest interstrut angle was measured at 1mm intervals along the stent. IVUS binary restenosis was defined as NIH >50%.

Results: After stent implantation, both the interstrut angles and the # of visible stent struts were comparable between TAXUS and bare metal stents (BMS, Table). During follow-up, the maximal interstrut angle for BMS (n=117 paired cases) increased from 71.8±0.8º to 84.5±20.8º (p<0.0001), while in TAXUS stents (n=125 paired cases) the maximal interstrut angle increased from 73.7±17.9º to 95.1±23.6º (p<0.0001) leading to a larger maximal interstrut angle and fewer visible stent struts as compared with BMS. Receiver-operating characteristic (ROC) analysis showed that a maximal interstrut angle of 81° at 9-month follow-up best distinguished 9-month IVUS restenosis from no restenosis in TAXUS stents (c=0.75). These relationships were not seen for BMS.

Conclusions: Serial IVUS analysis (1) showed that stent strut fracture was more common in TAXUS compared to BMS as evidenced by a greater increase in the maximal interstrut angle in TAXUS stents and (2) identified the threshold that lead to IVUS restenosis.

	TAXUS	BMS	P-Value
Post-Implantation	N=141	N=126	
Min No of Struts per Stent	7 ± 1	7 ± 1	0.41
Max Interstrut Angle per Stent	73.5 ± 17.5	71.3 ± 19.1	0.32
Mean Interstrut Angle	43.2 ± 6.8	41.7 ± 7.4	0.10
At 9-Month Follow-up	N=225	N=220	
Min No of Struts per Stent	6 ± 1	6.5 ± 1	0.0032
Max Interstrut Angle per Stent	91.4 ± 23.9	84.3 ± 22.9	0.0015
Mean Interstrut Angle	51.4 ± 9.7	47.4 ± 9.0	<0.0001

9:30 a.m.

2501-512 **Safety and Efficacy of Biodegradable-Polymer Coated Sirolimus-Eluting Stents in "Real-World" Practice: 18-month Clinical and 9-month Angiographic Outcomes**

Yaling Han, Quanmin Jing, Bo Xu, Lixia Yang, Huiliang Liu, Xiaoming Shang, Tieming Jiang, Zhanquan Li, Hua Zhang, Hui Li, Jian Qiu, Xingfeng Liu, Yi Li, Xuezhi Chen, Runlin Gao, Shenyang Northern Hospital, Shenyang, People's Republic of China

Background: It has been hypothesized that persistent presence of polymer may compromise the safety of drug-eluting stents, and that therefore biodegradable polymer coatings might reduce late adverse events. The aim of the present study was to evaluate the safety and efficacy of a biodegradable-polymer coated sirolimus-eluting stent (EXCEL) with 6-month dual antiplatelet therapy in daily practice.

Methods: Between June and November 2006, 2077 patients, exclusively treated with EXCEL stents at 59 centers from 4 countries, were enrolled in this prospective, multicenter registry. Recommended antiplatelet regimen included clopidogrel and aspirin for 6 months followed by chronic aspirin therapy.

Results: The average duration of clopidogrel treatment was 199.8±52.7 days and 80.5% of discharged patients discontinued clopidogrel at 6 months. The cumulative rates of major adverse cardiac events (MACE) were 0.9% at 30 days, 2.7% at 1 year and 3.1% at 18-month. Overall rate of stent thrombosis was 0.87% at 18-month and the rates of acute, subacute and late stent thrombosis were 0.1%, 0.38% and 0.39%, respectively. Angiographic follow-up, performed in 974 (31.6%) lesions from 653 patients (31.7%), revealed a mean in-stent late lumen loss of 0.21±0.39mm. Binary restenosis rates were 3.8% in-stent and 6.7% in-segment.

Conclusions: This multicenter registry documents satisfactory safety and efficacy profiles, as evidenced by low rates of MACE and stent thrombosis up to 18 months, for the EXCEL biodegradable-polymer based SES when used with 6 months of dual antiplatelet therapy in a "real-world" setting.

9:30 a.m.

2501-513 **Relative Dose and Vascular Response After Drug-Eluting Stent Implantation: A Dosimetric 3D-Intravascular Ultrasound Study**

Katsuhisa Waseda, Takao Hasegawa, Daisaku Nakatani, Bon-Kwon Koo, Hiromasa Otake, Takao Shimohama, Hyeonsoo Chang, Junya Ako, Paul G. Yock, Peter J. Fitzgerald, Yasuhiro Honda, Stanford University, Stanford, CA

Background: In DES implantation, a fixed loading dose per metal surface area may result in a considerable variability in actual delivered dose, due to difference in spacing of the struts once expanded. The aim of this study was to evaluate the effect of different local dose concentration, as measured by 3D-IVUS dosimetry, on neointimal suppression among DESs.

Method: Follow-up 3D-IVUS was analyzed in 613 coronary lesions treated with sirolimus- (SES, n=148), paclitaxel- (PES, n=162), zotarolimus- (ZES, n=187) and everolimus-eluting stent (EES, n=116). In each lesion, local drug concentration was calculated as known loading dose divided by measured stented segment surface area at follow-up. Lesions were divided into tertiles according to calculated local dose: high, medium, and low dose groups.

Results: The calculated local dose ranged from 0.74 to 1.76μg/mm² for SES, 0.41 to 1.18μg/mm² for PES, 0.71 to 1.57μg/mm² for ZES and 0.45 to 0.84μg/mm² for EES. Although SES, PES and EES showed no significant difference of neointimal growth and neointimal thickness among 3 dosimetry groups, ZES showed significantly less neointimal hyperplasia and neointimal thickness in high dose group.

Conclusion: Detailed 3D-IVUS dosimetry suggested a significant lesion-to-lesion variability in local dose concentration after DES implantation. However, within each stent type, current DES appears to yield equally effective neointimal suppression, regardless of the varying delivered dose intensity, except for ZES.

		High dose	Medium Dose	Low Dose	p
SES	Neointimal volume Index (mm3/mm)	0.1±0.2	0.1±0.2	0.2±0.2	NS
	%NVI* (%)	2.5±4.7	2.2±3.2	2.3±2.9	NS
	Intimal thickness (mm)	0.02±0.04	0.02±0.02	0.02±0.02	NS
PES	Neointimal volume Index (mm3/mm)	0.6±0.5	0.8±0.8	0.9±07	NS
	%NVI* (%)	11.9±9.4	11.2±10.4	9.5±8.3	NS
	Intimal thickness (mm)	0.08±0.07	0.09±0.09	0.09±0.08	NS
ZES	Neointimal volume Index (mm3/mm)	0.8±0.6	1.3±0.7	1.5±1.0	<0.01
	%NVI* (%)	16.6±12.0	18.3±10.8	16.5±10.2	NS
	Intimal thickness (mm)	0.11±0.08	0.15±0.11	0.15±0.10	<0.05
EES	Neointimal volume Index (mm3/mm)	0.3±0.2	0.3±0.3	0.2±0.2	NS
	%NVI* (%)	5.7±5.1	4.9±5.3	2.9±3.0	<0.05
	Intimal thickness (mm)	0.04±0.03	0.04±0.04	0.02±0.02	NS
* %NVI=neointimal volume / stent volume					

9:30 a.m.

2501-514 **Randomized Comparison of Everolimus-eluting and Paclitaxel-eluting Stents: Pooled analysis of Two-Year Clinical Follow-up from the SPIRIT II and III Trials**

Yoshinobu Onuma, Patrick W. Serruys, Neville Kukureja, Gregg W. Stone, SPIRIT II and III investigators, Thorax center, Erasmus MC, Rotterdam, The Netherlands

Background: In the multicenter randomized trials of SPIRIT II (SII) and III (SIII), the XIENCE V everolimus-eluting stent (EES) demonstrated superiority to the TAXUS paclitaxel-eluting stent (PES) for angiographic late loss and non-inferiority for Target Vessel Failure (TVF) at 1 year. In SII, a late catch-up of in-stent neointimal hyperplasia was observed between 1 and 2 years in EES but not in PES. In SIII, among those who first discontinued thienopyridine after 6 months, stent thrombosis rate was relatively lower

in EES than in PES. To further corroborate these observations in a larger population, we performed a pooled analysis of 2-year clinical data from SII and SIII.
Methods: The SII (n=300) and SIII (n=1,002) trials randomized 1,302 patients with a maximum of 2 de novo coronary artery lesions either to EES or PES. Poolability was justified on the basis of comparable inclusion and exclusion criteria with similar demographic, and angiographic characteristics and endpoint definitions. Major adverse cardiac events (MACE) were defined as the composite of cardiac death, MI, or ischemia-driven TLR, TVF as cardiac death, MI or ischemia-driven TVR.
Results: At 2 years, MACE rates were 7.4% for EES vs. 13.2% for PES (p=0.002) and TVF rates were 10.4% for EES vs. 14.7% for PES (p=0.03). The observed reduction in MACE and TVF were driven by lower rates of ischemia-driven TLR by PCI (3.3% vs. 6.3%, p=0.02) and non-QMI (2.6% vs 5.0%, p=0.04) in EES patients. Between 1 and 2 years, there were no differences in occurrence of MACE in both groups (EES 2.3% vs. PES 3.0%, p= 0.55). At two years, ARC definite or probable stent thrombosis occurred in 1.2% with EES vs. 1.6% with PES. (p=0.59) Amongst those who first discontinued thienopyridine after 6 months , definite or probable stent thrombosis was 1.1% in EES vs. 1.3% in PES.
Conclusions: In the pooled 2 year data from SII and SIII, EES demonstrated superiority over PES for MACE, MI, TLR and TVF. Despite a late catch-up observed in EES, this may not be representative of the whole population as there is no difference in occurrence of MACE between 1 and 2 years. In addition, there are no difference in occurrence of stent thrombosis among those who first discontinued thienopyridine after 6 months.

9:30 a.m.

2501-515 Correlation of Stented Segment Length on Target Lesion Revascularization and Stent Thrombosis: From Two-Year Clinical Outcome of The j-Cypher Registry

Shinichi Shirai, Kenji Ando, Yoshimitsu Soga, Katsuhiro Kondo, Koyu Sakai, Takeshi Arita, Kyohei Yamaji, Masahiko Goya, Hiroyoshi Yokoi, Masashi Iwabuchi, Hideyuki Nosaka, Masakiyo Nobuyoshi, Takeshi Kimura, Kazuaki Mitsudo, Kokura Memorial Hospital, Kitakyushu, Japan

Background: A longer stented segment resulted in a high restenosis rate in Bare Metal Stent (BMS). The advent of Sirolimus Eluting Stent (SES) reduced the rate of restenosis as compared with BMS. In this sub-analysis of the j-Cypher registry, we evaluate the relation between the total stented segment length (TSL) and target lesion revascularization (TLR), and between TSL and stent thrombosis.
Methods: Design of the j-Cypher Registry was multi-center prospective enrollment of consecutive patients (pts) receiving SES from 39 centers in Japan. By the end of March, 2008, two-year clinical follow-up data was completed in 11323 pts (14712 lesions) underwent successful implantation of SES.
Results: Angiographical follow-up was completed in 9507 lesions (64.6%). Overall angiographic restenosis rate through 2years was 699 lesions/ 9507 lesions (7.4%). Overall TLR rate was 886 lesions/ 14712 lesions (6.0%). Stent thrombosis was occurred in 57 pts (early in 36 pts, late in 18 pts and very late in 3 pts). Each 1mm of stented segment length increased TLR rate by 0.1% (Figure-1). Stent thrombosis rate was not accociated with stented segment length (Figure-2).
Conclusions: Total stented segment length affected the restenosis rates and the need for TLR. However, stent thrombosis rate was not related to the total stented segment length.

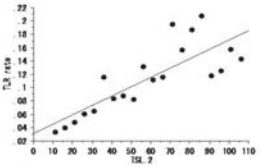


Figure-1
Relationship between Total Stented Segment Length and TLR rate.
TLR rate =0.031+0.001*TSL
R2=0.656, p<0.0001

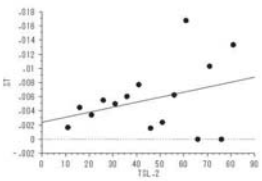


Figure-2
Relationship between Total Stented Segment Length and Stent thrombosis rate.

P=0.2380

9:30 a.m.

2501-516 Abluminal Deposition of Sirolimus on Anti-CD34 Coated Stents Controls Neointimal Proliferation and Promotes Enhanced Endothelialization in Porcine Coronary Arteries

Michael S. Aboodi, Juan F. Granada, Carlos Alviar, Martin B. Leon, Greg L. Kaluza, Stephen Rowland, Sherry Parker, Frank Kolodgie, Gaku Nakazawa, Renu Virmani, Cardiovascular Research Foundation, Orangeburg, NY

Background: There is substantial clinical potential for stents integrating the antiproliferative effect of sirolimus elution with endothelial progenitor cell capture (anti-CD34). Functional endothelialization increases natural healing while reducing thrombotic potential and the need for anti-platelet therapy. We hypothesize that by separating EPC capture from sirolimus delivery through application of the drug to the abluminal surface of the stent, the safety profile of these devices could be improved.
Methods: 35 stents (18 with anti-CD34 and abluminal sirolimus deposition (AS), 18 with anti-CD34 and uniform sirolimus coating (US)) were implanted in 12 pigs using a 10% overstretch ratio. Animals were sacrificed at 3 (n=4), 14 (n=4), and 28 days (n=4). Terminal IVUS analysis was performed in all stents. All stents were harvested and examined by conventional histology, surface electron microscopy (SEM) and confocal microscopy to assess the degree of neointimal formation and device endothelialization.
Results: SEM analysis demonstrated that the amount of strut coverage was similar between both devices at 3 (AS:47±13% versus US:45±21%) and 14 days (AS:97±2.4% versus US:96±2.6%). Confocal microscopy (PECAM) analysis at 14 days demonstrated an increased presence of functional endothelium in AS stents (70±35%) compared to US stents (27±35%, p=0.06). At 28 days, the degree of neointimal thickness (AS: 0.094±0.068mm versus US:0.087±0.021mm) and percentage area of stenosis (AS:17.19±4.35%, US:18.57±6.43) were similar between both stent groups.
Conclusion: Partitioning sirolimus abluminally effectively maintains its antiproliferative effect on neointimal formation while allowing the recruitment of functional endothelial cells to the adluminal side of the device. These biological effects could potentially translate to a clinical advantage over stents with uniform sirolimus coating.

9:30 a.m.

2501-517 Recurrent Restenosis After Reimplantation With Sirolimus-eluting Stent for Restenosis After Sirolimus-eluting Stent Implantation

Masakazu Miyamoto, Kazushige Kadota, Kazuaki Mitsudo, Tsuyoshi Gotoh, Hiroyuki Yamamoto, Satoki Fujii, Yasushi Fuku, Shingo Hosogi, Hiroyuki Tanaka, Seiji Habara, Daiji Hasegawa, Masao Imai, Suguru Ohtsuru, Kurashiki Central Hospital, Kurashiki, Japan

Background: Reintervention cases for restenosis after implantation of Sirolimus-eluting stent (SES) have increased as the indication for SES has expanded. However, the prevalence and predictors of recurrent restenosis after SES implantation for SES restenosis remains unclear. In this study we evaluated the prevalence of recurrent restenosis after reintervention with SES for restenosis after SES restenosis.
Methods: From November 2002 to January 2008, 3840 patients with 5049 lesions underwent implantation with SES. Of these lesions, 86 patients with 95 lesions were treated with SES for recurrent restenosis after SES implantation and underwent the follow-up coronary angiography after reintervention at 8 months.
Results: The recurrent restenosis rate was 41.1% (39/95 lesions). The table shows the relationships between recurrent restenosis and clinical, angiographical, and procedural factors. The recurrent restenosis rate of diffuse restenosis lesion was significantly higher than that of focal restenosis lesion (61.5% vs. 38.5% p = 0.0032). Of focal restenosis lesion, recurrent restenosis rate of lesion treated with shorter stenting (<=13mm) was lower than that with longer stenting (=>14mm) (9.1% vs. 43.1% p= 0.0058).
Conclusion: The effect of reimplantation with SES for SES restenosis lesion was limited, especially in diffuse restenotic lesion. Considering the stenting length, shorter stenting at any procedure could be beneficial to prevent recurrent restenosis.

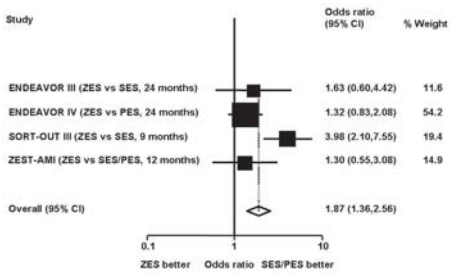
	total	Re-restenosis(+)	Re-restenosis(-)	p value
total	95	39 (41.1%)	56 (58.9%)	
initial ISR lesion	23 (24.2%)	25.6%(10)	23.2%(13)	p=0.7859
DM	43 (45.3%)	48.7%(19)	42.9%(24)	p=0.5734
HT	60 (63.2%)	64.1%(25)	62.5%(35)	p=0.8734
Hemodialysis	5 (5.3%)	7.7%(3)	3.6%(2)	P=0.3983
Restenosis pattern				
diffuse	22 (23.2%)	38.5%(15)	12.5%(7)	p=0.0032
focal	73 (76.8%)	61.5%(24)	87.5%(49)	p=0.0032
initial lesion length (mm)	20.5±12.6	21.3±12.2	20.0±12.9	p=0.637
initial stent length				
per each lesion (mm)	30.2±18.1	32.8±20.4	28.4±16.1	p=0.270
per whole lesion (mm)	35.8±21.9	41.9±25.2	31.8±18.5	p=0.035
re PCI stent length (mm)	19.7±7.83	23.4±9.99	17.1±4.40	p=0.001

9:30 a.m.

2501-518 Zotarolimus-Eluting Stents vs. Sirolimus-Eluting Stents or Paclitaxel-Eluting Stents: Meta-Analysis of Randomized Trials

Alban Dibra, Antoinette de Waha, Laureta Sulcaj, Tritan Keta, Julinda Mehilli, Albert Schömig, Adnan Kastrati, Deutsches Herzzentrum, Munich, Germany, University Hospital Center "Nene Tereza", Tirana, Albania

Background: Clinical trials comparing zotarolimus-eluting stents (ZES-Endeavor) versus the most frequently used drug-eluting stents - the sirolimus-eluting stents (SES-Cypher) or paclitaxel-eluting stents (PES-Taxus), have reported conflicting results regarding their relative clinical efficacy and safety.
Methods: We performed a meta-analysis of 4 randomized trials comparing ZES with SES or PES and reporting the outcomes of interest during a follow-up period of 9 to 24 months. A total of 4635 patients were enrolled in these trials. The primary endpoint was target lesion revascularization. Secondary endpoints were mortality, myocardial infarction, and stent thrombosis rates. Odds ratios (ORs) were used as summary estimates. The pooled ORs were calculated using the DerSimonian and Laird method for random effects.
Results: Use of ZES was associated with a marked increase in the odds of target lesion revascularization compared to the use of SES or PES (OR 1.87, 95% confidence interval [CI]: 1.36 to 2.56, *P*<0.001). On the other hand, there was no significant difference between the respective groups of patients regarding the odds of death (OR 1.20, 95% CI: 0.70 to 2.04, *P*=0.52), myocardial infarction (OR 0.69, 95% CI: 0.44 to 1.08, *P*=0.10) or stent thrombosis (OR 1.53, 95% CI: 0.76 to 3.07, *P*=0.24).
Conclusions: Zotarolimus-eluting stents are less effective and similarly safe compared to sirolimus-eluting or paclitaxel-eluting stents.



9:30 a.m.

2501-519 **Incidence, Correlates and Predictors of Stent Thrombosis (ST) up to 6 Years Follow-up Following Implantation of Drug-Eluting Stents (DES) in Unselected Patients with Complex Coronary Lesions - Results from the Large, Prospective DESIRE (DES In the REal World) Registry**

Ricardo A. Costa, Amanda Sousa, Adriana Moreira, J. Ribamar Costa, Jr., Galo Maldonado, Manuel Cano, Fausto Feres, Luiz A. Mattos, Rodolfo Staico, Alexandre Abizaid, Mariana T. Carballo, Cantídio Campos, Ricardo Pavanello, Otávio Berwanger, J. Eduardo Sousa, Hospital do Coração - Associação do Sanatório Sírio, São Paulo, Brazil

Background: Recent reports have suggested that ST after DES could be increased in complex subsets and overtime.
Methods: In the DESIRE trial, 2,500 unselected undergoing routine or emergency PCI with DES implantation were consecutively enrolled at 1 center from Mar/02-May/08. Clinical FU (98%) was performed at 1 and 6 months, and yearly up to 6 years. ST was defined according to the ARC propositions.
Results: Mean age was 64 years, 29% had diabetes, 22% had prior MI, and 52% had prior revascularization; 41% presented with ACS (15% STEMI); and 66% of lesions were type B2/C, including 27% mod/severe calcium, 5% ISR, 6% SVG, 5% ostial location, and 3% thrombus. Overall, there were 40 cases of ST (1.6%) during the follow-up period (median time: 3.4 years). Of the 40 ST, 9 (23%) were classified as subacute (1-30 days), 18 (45%) late (1-12 months), and 13 (33%) very late (>12 months). The majority of ST were angiographically documented (60% definite ST), and 53% (21/40) were associated to a fatal event.
Conclusions: In this large, prospective "real-world" registry, unselected patients with complex coronary lesions undergoing DES implantation had low cumulative incidence of ST (1.6%) up to 6 years FU; however, a fatal event was associated in half of pts. In this study, significant predictors of ST were acute MI at presentation, smoking, diabetes, multiple stenting procedure, complex lesion morphology, and stent underexpansion.

Variable	Hazard Ratio	95% Confidence Interval	P value
Acute MI	3.58	1.35 - 9.52	0.010
Smoking (current)	2.58	1.19 - 5.61	0.017
Multiple DES implanted	2.11	1.28 - 3.47	0.003
Diabetes mellitus	1.95	1.03 - 3.69	0.041
Lesion postdilatation	0.50	0.29 - 0.86	0.013
Calcium (mod/severe)	1.97	1.17 - 3.34	0.011
Eccentric lesion morphology	1.60	0.95 - 2.71	0.079
In-stent residual stenosis (per % unit increase)	1.04	1.02 - 1.07	<0.001

9:30 a.m.

2501-520 **SPIRIT II Study: A Clinical Evaluation of the XIENCE V Everolimus Eluting Stent**

Patrick W. Serruys, on behalf of the SPIRIT II Investigators, Erasmus University Thorax Center, Rotterdam, The Netherlands

Background: SPIRIT FIRST results demonstrated continued safety of the XIENCE V Everolimus Eluting Stent in a limited number of patients. The SPIRIT II study is a continuation in the assessment of the safety and performance of the XIENCE V Stent in the treatment of patients with a maximum of 2 de novo native coronary artery lesions.
Methods: The XIENCE V stent is compared to the TAXUS Paclitaxel-Eluting Stent. The primary endpoint is in-stent late loss at 180 days. Ischemia Driven Major Adverse Cardiac Events (MACE) are assessed through 5 years.
Results: Three hundred patients were randomised in the proportion of 3:1 (XIENCE V: TAXUS) at 28 sites in Europe, New Zealand and India. At 180 days, the mean in-stent Late Loss (analysis lesion, intent-to-treat population) was significantly lower for the XIENCE V group compared to the TAXUS group, 0.11±0.27mm vs. 0.36±0.39mm (non-inferiority p<0.0001, superiority p<0.0001). Hierarchical analysis of 1-year clinical results showed that the total MACE rates for the procedure through the 1 year interval were 2.7% in the XIENCE V group and 9.2% in the TAXUS group [p=0.04 from two-sided Fishers's Exact]. At 2 year serial follow up the in-stent late loss was no longer significantly different; 0.33±0.37mm in the XIENCE V arm vs. 0.34±0.34mm in the TAXUS arm. IVUS results showed that in the XIENCE V arm the neo-intimal volume was 8.4 mm and the % volume obstruction was 5.2% vs 11.6 mm and 5.8 % in the TAXUS arm. However despite this modest increase in late loss and neo-intima in the XIENCE V arm, the total MACE rates for the procedure through the 2 year interval were 6.6% in the XIENCE V group and 11.0% in the TAXUS group. According to the ARC definition, stent thrombosis was 0.9% in the XIENCE V group and 1.4% in the Taxus group through 2 year follow-up.
Conclusion: Based on the protocol design and statistics, XIENCE V showed non-inferiority (primary endpoint) and superiority to TAXUS in terms of late loss. Additionally, SPIRIT II 2 year data shows a consistent reduction in clinical events for XIENCE V versus TAXUS and low stent thrombosis rate for XIENCE V. The three-year clinical results will be presented at ACC.

9:30 a.m.

2501-521 **Predictors of Major Adverse Cardiovascular Events in a Real-World Population receiving the Zotarolimus-eluting Stents: Data from the E-Five Registry**

Chaim Lotan, Ian T. Meredith, Peter Sick, Nakul Sinha, Praveen Chandra, Fausto Feres, Martin T. Rothman, For the E-FIVE Registry Investigators, Hadassah-Hebrew University Medical Center, Jerusalem, Israel

Background: Concerns regarding the safety of drug-eluting stents (DES) in patients with complex lesions and clinical characteristics typically excluded from randomized clinical trials highlight the need to identify predictors of major adverse cardiovascular events (MACE) that may guide patient selection for DES implantation.
Methods: E-Five, a prospective, multicenter, global registry enrolled patients with symptomatic coronary artery disease who underwent single or multi-vessel percutaneous coronary intervention (PCI) with the Endeavor zotarolimus-eluting stent (ZES). MACE (death, MI, emergency cardiac bypass surgery, or target lesion revascularization) events were adjudicated by a Clinical Events Committee. Multivariate logistic regression was used to identify significant predictors of MACE at 12 months.
Results: Twelve month data is available for 7832 of the 8314 patients enrolled at 188 centers across 4 continents. The 12-month rate of MACE was 7.5% (587/7832). The majority of these events occurred in complex patients (500/6189, 8.6%). Clinical characteristics predicting MACE include increasing age, diabetes, prior PCI, and renal impairment. MACE was also significantly associated with the presence of multivessel disease, long lesions, and bifurcated lesions.
Conclusions: Characteristics predicting MACE in the E-Five registry are consistent with observations from other clinical trials and confirm the higher risk of patients with complex clinical and lesion characteristics.

Characteristic	Odds Ratio	P-Value
Age	1.02	<.001
Diabetes (vs. Non diabetes)	1.52	<.001
Prior PCI (vs. Non)	1.59	<.001
Moderate/ severe renal impairment (vs. mild renal impairment)	1.66	<.001
Single lesion (vs. multiple lesions)	0.65	<.001
Lesion length ≤ 27 mm (vs. lesion length > 27 mm)	0.63	<.001
Bifurcation (vs. Non)	1.30	0.022
Logistic regression multivariate analyses were performed using stepwise selection with the following covariates: age, sex, smoking, diabetes, prior MI, hypertension, hypercholesterolemia, prior PCI, prior CABG, ACS (unstable angina or AMI <72 hr); renal impairment with no renal transplant (mod./severe [creatinine ≥140 µmol/L] vs. mild [creatinine < 140 µmol/l]; single vs. multiple lesions, lesion length > 27mm vs. lesion length ≤27mm, bifurcation.		

9:30 a.m.

2501-522 **Clopidogrel Use and Clinical Events After Drug-Eluting Stent Implantation: Findings From the HealthCore Integrated Research Database**

John L. Petersen, II, John D. Barron, Bradley G. Hammill, Mark J. Cziraky, Kevin J. Anstrom, Peter M. Wahl, Eric J. Eisenstein, Mitchell W. Krucoff, Robert M. Califf, Kevin A. Schulman, Lesley H. Curtis, Duke University Medical Center, Durham, NC, HealthCore, Inc., Wilmington, DE

Background: The relationship between use of dual antiplatelet therapy greater than 12 months and outcomes after drug-eluting stent implantation has not been well established.
Methods: We performed a retrospective cohort study using administrative data from the HealthCore Integrated Research Database from 9256 patients receiving drug-eluting stents between January 1, 2003, and August 31, 2006. We classified patients according to tertiles of clopidogrel use based on supply received during the 12-month landmark period after stent implantation. We adjusted for differences in baseline characteristics using Inverse Propensity Weighted models and adjusted for intervening clinical events and concomitant medication use between baseline and 12 months using Cox proportional hazards models to evaluate death, death or nonfatal myocardial infarction, and bleeding events. .
Results: There were 3102 (33.5%) patients in the high-use clopidogrel group, 3069 (33.2%) in the medium-use group, and 3085 (33.3%) in the low-use group. Use of clopidogrel in the 12 months after stent implantation was highly correlated with clopidogrel use at 24 and 36 months. Compared with the high-use clopidogrel group, risk of death or nonfatal myocardial infarction was significantly greater in the medium-use group (hazard ratio [HR], 1.46; 95% confidence interval [CI], 1.09-1.99; *P* = .01) and the low-use group (HR, 1.59; 95% CI, 1.18-2.14; *P* = .002) (Table). There were no significant differences for mortality alone. Compared with the high-use clopidogrel group, the risk of bleeding events was significantly lower in the medium-use group (HR, 0.84; 95% CI, 0.71-0.98; *P* = .03) and the low-use group (HR, 0.77; 95% CI, 0.65-0.90; *P* = .002).

Conclusion: High use of clopidogrel in the 12 months after drug-eluting stent implantation is associated with a higher risk of bleeding events. Low use of clopidogrel is associated with a greater risk of death or nonfatal myocardial infarction.

Table

Characteristic	Adjusted HR (95% CI)*	P Value
Death		
Clopidogrel use		
Low	1.28 (0.79-2.06)	.31
Medium	1.36 (0.86-2.15)	.18
High	1.00	
Other medication use		
ACE inhibitor	0.82 (0.55-1.22)	.327
Beta-blocker	0.90 (0.61-1.30)	.57
Statin	1.02 (0.70-1.49)	.93
Events during landmark period		
Bleeding event	2.30 (1.49-3.53)	<.001
Myocardial infarction	2.62 (1.41-4.88)	.002
Revascularization	0.80 (0.48-1.33)	.39
Transfusion	4.34 (2.23-8.45)	<.001
Death or Nonfatal Myocardial Infarction		
Clopidogrel use		
Low	1.59 (1.18-2.14)	.002
Medium	1.46 (1.09-1.96)	.01
High	1.00	
Other medication use		
ACE inhibitor	1.04 (0.82-1.33)	.73
Beta-blocker	0.91 (0.72-1.15)	.45
Statin	0.83 (0.65-1.04)	.11
Events during landmark period		
Bleeding event	1.69 (1.27-2.25)	<.001
Myocardial infarction	2.19 (1.44-3.33)	<.001
Revascularization	0.97 (0.71-1.31)	.82
Transfusion	2.41 (1.39-4.17)	.002
Bleeding Events		
Clopidogrel use		
Low	0.77 (0.65-0.90)	.002
Medium	0.84 (0.71-0.98)	.03
High	1.00	
Other medication use		
ACE inhibitor	1.01 (0.88-1.17)	.84
Beta-blocker	0.88 (0.77-1.01)	.08
Statin	0.82 (0.71-0.94)	.004
Events during landmark period		
Bleeding event	2.79 (2.40-3.25)	<.001
Myocardial infarction	0.91 (0.66-1.27)	.60
Revascularization	1.05 (0.88-1.25)	.58
Transfusion	2.12 (1.50-2.98)	<.001

9:30 a.m.

2501-523 Late Progression After Sirolimus-Eluting Stent Implantation: Comparison with Bare Metal Stent Implantation

Nobuo Shiode, Kinya Shirota, Yukihiro Fukuda, Yasuko Katou, Fumiyo Tsunoda, Mai Fujiwara, Asao Mimura, Matsue Red Cross Hospital, Matsue, Japan

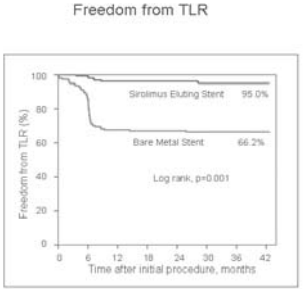
Background: In previous studies, minimal luminal diameter (MLD) of lesions treated with bare metal stent (BMS) was shown to improve from 6 months to 3 years. However the long-term response to Sirolimus-Eluting Stent (SES) implantation remains unclear. **Methods:** To evaluate 6-month, 12-month and 3-year outcomes, angiographic follow-up data were analyzed for 531 patients (812 lesions) who underwent successful SES implantation compared to follow-up data for 703 patients (903 lesions) who underwent BMS implantation. **Results:** Angiographic follow-up was performed at both 6 and 12 months for 655 SES-treated lesions and 628 BMS-treated lesions and at 3 years for 148 SES-treated lesions and 210 BMS-treated lesions. The angiographic restenosis rate within 12 months was significantly lower for SES-treated lesions than for BMS-treated lesions (8.4% vs. 26.4%, $p < 0.01$), but from 12 months to 3 years, the new restenosis rate was significantly higher for SES-treated lesions than for BMS-treated lesions (11.5% vs. 4.8%, $p < 0.05$). Among lesions without revascularization neither at 6 and 12 months, MLD increased significantly from 2.01 ± 0.62 mm at 6 months, to 2.09 ± 0.58 mm at 12 months ($p < 0.05$) and to 2.20 ± 0.57 mm at 3 years ($p < 0.05$) in BMS lesions. However, MLD decreased significantly from 2.60 ± 0.50 mm at 6 months to 2.44 ± 0.55 mm at 12 months ($p < 0.01$) and to 2.35 ± 0.58 mm at 3 years ($p < 0.01$) in SES-treated lesions. **Conclusions:** From 6 months to 3 years, stenosis of BMS-treated lesions regressed, but stenosis of SES-treated lesions progressed.

9:30 a.m.

2501-524 Long-Term Outcome of Sirolimus-Eluting Stents for Off-Label Indications. Data from the Randomized SCANDSTENT Trial.

Henning Kelbæk, Lene Kløvgaard, Steffen Helqvist, Jens Lassen, Lars Krusell, Thomas Engstrøm, Hans Erik Bøtker, Erik Jørgensen, Kari Saunamäki, Samir Aljabbari, Per Thayssen, Anders Galløe, Gunnar Jensen, Leif Thuesen, Rigshospitalet, Copenhagen, Denmark

Background: While sirolimus-eluting stents (SES) have proved to be effective in patients with simple coronary artery lesions, there are limited data of long-term outcome of their use in patients with off-label lesion characteristics.
Methods: We randomly assigned 322 patients with total coronary occlusions or lesions located in bifurcations, ostial or angulated segments of the coronary arteries to have SES or bare-metal stents (BMS) implanted.
Results: At 3 years, major adverse cardiac events had occurred in 20 patients (12%) in the SES group and in 59 patients (38%) in the BMS group ($p<0.001$). Four versus 2 patients suffered a cardiac death in the SES versus the BMS group (NS). Six patients in the SES group versus 15 patients in the BMS group suffered a myocardial infarction ($p<0.05$) during the 3-year observation period, and target lesion revascularization was performed in 8 patients (4.9%) versus 53 patients (33.8%), respectively ($p<0.001$) (Figure); of these 4 in the SES versus 7 in the BMS group was performed between 1 and 3 years after the index treatment (NS). Stent thrombosis occurred in 5 patients (3.1%) in the SES group and in 7 patients (4.4%) in the BMS group (NS). The lower rate of events was recorded in all subgroups of patients who had a SES implanted and in all types of lesions albeit most pronounced in occluded lesions.
Conclusions: Implantation of SES for off-label lesion indications can be done with a high level of efficacy and safety as indicated from these 3 years results of the SCANDSTENT Trial.



9:30 a.m.

2501-525 Comparison of Vessel Response Between Zotarolimus- and Paclitaxel-eluting Stents: Global and Focal Vessel Responses as Assessed by Serial Intravascular Ultrasound

Katsuhisa Waseda, Akiyoshi Miyazawa, Takao Hasegawa, Ichizo Tsujino, Ryota Sakurai, Junya Ako, Paul G. Yock, David E. Kandzari, Martin B. Leon, Peter J. Fitzgerald, Yasuhiro Honda, The ENDEAVOR IV Trial Investigators, Stanford University, Stanford, CA

Background: The aim of this study was to compare chronic vessel responses to zotarolimus-(ZES) versus paclitaxel-eluting stent (PES) implantation.
Methods: In ENDEAVOR IV (a randomized trial of zotarolimus-eluting, phosphorylcholine-coated, DRIVER stent for the treatment of *de novo* coronary lesions), serial IVUS analyses (baseline and 8 months) were available in 38 ZES and 32 PES. Volumetric analyses were performed for vessel (VVI), lumen, plaque (PVI), stent, and neointima. Changes in vessel and plaque areas were analyzed at every matched 1-mm sub-segment throughout the stent. Significant focal positive remodeling was defined as >20% vessel area increase during follow-up in at least 3 consecutive subsegments.
Results: In overall analysis, ZES had no significant change in peri-stent vessel dimensions, whereas PES showed a significant increase in VVI and PVI during follow-up. Delta VVI was significantly larger in PES than ZES (0.7±0.9 mm^3/mm versus 0.1±0.9 mm^3/mm, $p<0.05$). In subsegment analysis, significant focal positive remodeling was observed in 5% of ZES and 25% of PES ($p<0.01$). Delta VVI at maximum remodeling site was significantly larger in PES than ZES (2.2±1.4 mm^3/mm versus 1.6±0.8 mm^3/mm, $p<0.05$). When compared with in-stent vessel response, changes in peri-stent dimensions did not correlate with neointimal volume in either stent type.
Conclusions: Global and focal vessel responses appear to be different between ZES and PES, particularly within the vessel wall surrounding the stent.

	ZES (N=38)		PES (N=32)		p*
Entire Stent Segment Analysis (mm3/mm)					
	Baseline	Follow-up	Baseline	Follow-up	
VVI	12.8±3.6	13.0±3.5	13.8±4.0	14.5±4.2†	NS
PVI	6.2±2.2	6.3±2.1	6.5±2.6	7.2±2.7†	NS
Subsegment Analysis					
Incidence of focal positive remodeling (%)	5		25		<0.01
%VVI change at max. remodeling site (%)	13.7±6.8		18.2±9.2		<0.05
%PVI change at max. remodeling site (%)	28.3±20.3		47.2±29.8		<0.01
* p value for ZES vs. PES † p<0.05 for baseline vs. follow up					

9:30 a.m.

2501-526 Effect of Gender on One Year Outcomes in the Synergy between Percutaneous Coronary Intervention and Cardiac Surgery (SYNTAX) Trial

Marie-Claude Morice, Helene Eltchaninoff, Patrick Serruys, Pieter Kappetein, Friedrich Mohr, Katrin Leadley, Keith Dawkins, Elisabeth Stahle, Institut Cardiovasculaire - Paris Sud, Massy, France, Boston Scientific Corporation, Natick, MA

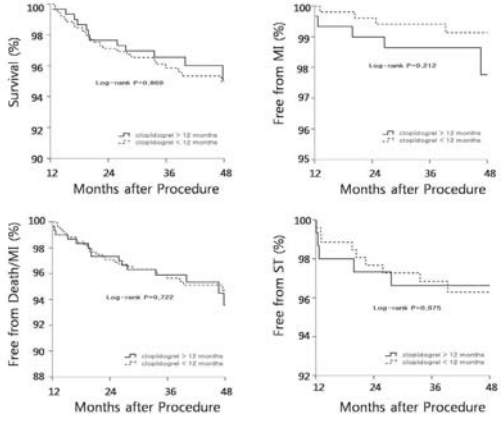
Background: Women undergoing coronary revascularization are at an increased risk for adverse outcomes compared with men due to a higher prevalence of risk factors and co-morbidity. This study assesses gender differences in one year outcomes between coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) in the SYNTAX trial which enrolled the most challenging patients with three vessel and/or left main disease.
Methods: SYNTAX is a prospective, multinational trial with an intended 'all-comers' design. Consecutive patients were screened by a Heart Team (cardiothoracic surgeon and interventional cardiologist) to determine suitability for PCI or CABG. Patients amenable for equivalent revascularization using either treatment option were randomized 1:1 to TAXUS Express² paclitaxel-eluting stent system or CABG. The primary endpoint was 12-month MACCE (major adverse cardiac and cerebrovascular events; death, stroke, MI, and revascularization).
Results: A total of 1800 patients were randomized, of which 402 (22%) were women. Although the baseline characteristics were well matched between the treatment groups, women were older, had more unstable angina, diabetes, hypertension, metabolic syndrome, and chronic lung disease compared with men. Similar to the men, the 12-month MACCE rate in women was significantly higher in the TAXUS group compared with CABG (men, 12.7% vs 17.5%, *P*=0.0132; women, 11.1% vs 19.0%, *P*=0.0348). The rate of revascularization was significantly higher in the TAXUS group compared with CABG in both cohorts (men, 6.2% vs 13.2%, *P*<0.001; women 4.7% vs 14.2%, *P*=0.0020). The overall safety (death, stroke and MI) rate was comparable in CABG and TAXUS for men and women (men, 7.8% vs. 6.8%, *P*=0.46; women 7.0% vs 10.4%, *P*=0.24). The rate of stroke however was higher in the CABG group for men (2.5% vs 0.3%, *P*<0.001 but comparable in both groups for women (1.2% vs 1.4%, *P*<0.99).
Conclusions: In the most challenging group of patients with three vessel and/or left main disease in the SYNTAX trial, relative differences in outcomes between CABG and PCI at 12 months were similar for men and women despite gender related differences in baseline co-morbidity.

9:30 a.m.

2501-527 Long-Term Outcomes by Clopidogrel Duration in a Diabetic Patients treated with Drug-eluting stent

Jeong-Sook Seo, Duk-Woo Park, Sung Sik Kim, Sung-Hwan Kim, Myung-Zoon Yi, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Seong-Wook Park, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: Data are limited regarding uniform evaluation of stent thrombosis (ST) and the influence of clopidogrel continuation beyond 12 months on late events after drug-eluting stent (DES) treatment in diabetic patients. Therefore, this study evaluated the long-term risk of ST, cardiovascular events, and the benefits of extended clopidogrel use after DES implantation in these patients.
Methods: We identified 865 patients with diabetes who received DES implantation between February 21, 2003 and March 16, 2006. A total of 833 patients surviving 12 months without adverse cardiovascular events event were analyzed according to clopidogrel continuation at 12 months after the procedure. We compared long-term adverse outcomes including death, MI, and ST up to 4 years.
Results: Patients with extended use of clopidogrel beyond 12 months had more complex clinical and angiographic characteristics as compared to those with limited duration of clopidogrel <12 months after the procedure. During the 4 years of follow-up, extended continuing clopidogrel beyond 12 months was not associated with a reduced risk for ST (definite or probable, HR: 1.12, 95% CI: 0.37-3.42). In addition, the adjusted-risk of death (HR: 1.24, 95% CI: 0.62-2.47) and death or MI (HR: 1.02, 95% CI: 0.54-1.94) were also similar in the both groups.
Conclusion: In diabetic patients treated with DES, extended continuation of clopidogrel beyond 1 year did not appear to reduce ST and death or MI during the long-term clinical follow-up.



9:30 a.m.

2501-528 Impact of Drug-Eluting Stents on the Peristent Plaque Compositions: A Serial Volumetric Analysis Using Quantitative Integrated Backscatter Intravascular Ultrasound

Mitsuaki Endo, Kiyoshi Hibi, Naohiro Komura, Fumiyuki Otsuka, Takayuki Mitsuhashi, Noriaki Iwahashi, Naoki Nozawa, Jun Okuda, Kengo Tsukahara, Masami Kosuge, Toshiaki Ebina, Tsutomu Endo, Satoshi Umemura, Kazuo Kimura, Saiseikai Yokohama-city Southern Hospital, Yokohama, Japan, Yokohama City University Medical Center, Yokohama, Japan

Background: Although drug-eluting stents (DES) are effective in inhibiting neointimal hyperplasia, concern about vasculo-toxic effects of DES still remains to be resolved. Several autopsy studies revealed enhanced inflammatory responses of peristent plaque when treated with DES. However, little data are available regarding tissue characteristics of peristent plaque after DES implantation in vivo. Recently, integrated backscatter intravascular ultrasound (IB IVUS) was developed for tissue characterization of coronary plaques. The aim of this study was to investigate serial change in peristent plaque compositions after DES implantation using quantitative IB IVUS.
Methods: We enrolled 42 consecutive patients (pts) with angina pectoris who received elective stenting with DES (22 pts; 16 sirolimus-eluting and 6 paclitaxel-eluting stents) and bare-metal stents (BMS) (20 pts). Serial IB IVUS analyses were performed after stent implantation and at 10 month follow-up (f/u). The tissue characterization of peristent plaque was analyzed in the 10 mm stent segment with the largest peristent plaque volume at baseline, and the occupancy rate of four tissue types (lipid, fibrous, dense fibrous, calcified) within peristent plaque was evaluated.
Results: In the DES group, a significant increase in vessel volume (143 to 154 mm^3, p<0.001), which was mainly caused by an increase in peristent plaque volume (56 to 65 mm^3, p<0.001), was observed during f/u. %lipid volume of peristent plaque became greater from baseline to f/u (28 to 35%, p=0.02), whereas %fibrous volume (58 to 56%, p=0.08), %dense fibrous volume (10 to 8%, p=0.01), and %calcified volume (4 to 3%, p=0.003) decreased. In contrast, vessel volume (144 to 140 mm^3, p=0.21), peristent plaque volume (53 to 50 mm^3, p=0.17), and each tissue compositions of peristent plaque in the BMS group did not change during f/u.
Conclusions: DES caused expansive remodeling and altered tissue characteristics of peristent plaque as assessed by IB IVUS, which may represent inflammatory response and delayed healing process around stent struts. Development of new generation DES without this potentially deleterious effect is required to reduce long term adverse outcomes.

9:30 a.m.

2501-529 Elevated Circulating Endothelial Progenitor Cells in Stent Thrombosis Patients is not Correlated With Platelet Reactivity Index

Mickey Scheinowitz, Tina L. Pinto Slottow, Rajbabu Pakala, Richard Baffour, Laurent Bonello, Rebecca Torguson, Augusto D. Pichard, Lowell Satler, Rekha Gavini, Patricia Beauzile, Shari Lawler, Udaya Tantry, Paul Gurbel, Ron Waksman, Washington Hospital Center, Washington DC, DC

Background: Limited data is available regarding the association between endothelial progenitor cells (EPCs) and platelet reactivity among patients post drug-eluting stent (DES) implantation. We aimed to investigate the level of circulating EPCs in post stent thrombosis (ST) patients treated with clopidogrel and correlate these data with platelet reactivity index (PRI). **Methods**: Forty patients (19 ST - ARC definition, 21 controls) with prior DES implantation in the past 3 years were enrolled in this study. The number of circulating EPCs (positive for CD34/CD133; CD34/VEGFR; and CD133/VEGFR) were counted using flow cytometry. PRI (%), as a measure of clopidogrel responsiveness, was assessed using vasodilator stimulated phosphoprotein (VASP)/P2Y12 assay.
Results: Baseline characteristics were similar between groups. The average time to presentation with ST was 157±308 days (ranging between 0 to 1148 days) post DES implantation. PRI were similar: 66.5%±20.0% and 57.4%±20.7%, for ST and control patients, respectively (p=0.408). No correlation was found between elevated EPCs among ST patients and PRI values at any given time during the follow-up.
Conclusion: Stent thrombosis is associated with significant elevation of circulating EPCs, however, this is not correlated with the responsiveness to clopidogrel therapy. The increased EPCs even long after stent implementation suggest an active, ongoing process which may be unrelated to initial thrombus formation.

Variables	Acute ST patients n=5	Sub-acute ST patients n=7	Late ST patients n=7	Control patients n=21	p value
Days to thrombosis	0.8±1.1	10.3±5.4	416.1±401.9	-----	
PRI, %	60.6±14.4	67.5±28.4	69.8±14.7	57.4±20.7	0.408
CD34/CD133, %	1.7±2.3	1.0±1.2	0.9±0.8	0.17±0.23	0.001
CD133/VEGFR, %	3.0±2.7	2.3±1.2	2.4±2.5	0.34±0.61	0.004
CD34/VEGFR, %	11.7±6.4	8.7±8.8	5.2±4.7	0.34±0.64	0.0001

9:30 a.m.

2501-530 Outcomes of Small Vessel Stenting in the Bare Metal Stent vs. Drug Eluting Stent Eras: Results from the NHLBI Dynamic Registry

Shailja V. Parikh, Tayo Addo, Faith Selzer, Oscar C. Marroquin, Suresh Mulukutla, J. Dawn Abbott, Elizabeth Holper, University of Texas - Southwestern, Dallas, TX

Background: While randomized trials of drug-eluting stents (DES) vs bare metal stents (BMS) demonstrate reduced target vessel revascularization, it is unclear if similar outcomes are seen in unselected patients after PCI for small vessel disease.
Methods: Utilizing patients from the NHLBI Dynamic Registry Waves 1-3 for BMS (1997-2002) and Waves 4-5 for DES (2004 and 2006), demographic, angiographic, and one year outcome data of patients with small vessel disease treated with BMS (n= 550) vs DES (n= 643) were evaluated. Small vessel was defined as 2.5 - 2.75 mm in diameter.
Results: Patients undergoing small vessel PCI with DES vs BMS had a higher prevalence of diabetes (38.5% vs 31.0%, p = 0.007) and were more likely to have a prior PCI (35.9% vs 26.9%, p<0.001), but less likely to have a prior MI (24.1% vs 32.1%, p=0.003). Compared to BMS-treated patients, the mean number of significant lesions was higher in the DES-treated group (3.0 vs 2.8, p=0.04). Among DES-treated lesions, the mean lesion length was longer (16.7 vs 13.6 mm, p<0.001) and the mean reference vessel size was smaller (2.56 vs 2.59 mm, p<0.001) vs BMS-treated lesions. Adjusted one year adverse outcomes are in Table 1.
Conclusions: Despite a higher clinical and angiographic risk profile, in this real-world registry, patients with small vessel disease treated with DES had lower rates of repeat revascularization and lower rates of death and MI vs patients treated with BMS. These data confirm the efficacy and safety of DES over BMS in common clinical practice.

Adjusted HR of One Year Adverse Events for pts w/ Small Vessel Disease Undergoing PCI w/ DES vs. BMS

	Hazard Ratios	95% CI	p-value
Death	0.82	0.41 - 1.61	0.56
MI	0.55	0.29 - 1.05	0.07
CABG	0.20	0.10 - 0.41	<0.001
Death or MI	0.58	0.36 - 0.93	0.02
Repeat PCI	0.48	0.32 - 0.70	<0.001
Repeat Revascularization	0.44	0.31 - 0.61	<0.001

9:30 a.m.

2501-531 Incidence and Predictor of Stent Thrombosis in Japanese Patients with Acute Coronary Syndrome in the Real World. -From the j-CYPHER Registry-

Ren Kawaguchi, Shigeru Oshima, Takeshi Kimura, Kazuaki Mitsudou, j-CYPHER Registry Investigators, Gunma Prefectural Cardiovascular Center, Maebashi, Japan

Background: Acute coronary syndrome (ACS) has been identified as a strong predictor of stent thrombosis (ST) after Sirolimus-Eluting Stent (SES) implantation. We aimed to estimate the incidence and predictors of ST for the ACS lesions after SES implantation in the real world of Japanese intervention.
Methods: 2440 Patients with 2800 lesions of ACS (ST-elevation myocardial infarction: 666, Non ST-elevation myocardial infarction: 318, unstable angina: 1816) which enrolled in j-Cypher Registry were investigated. ST was defined as definite or probable of Academic Research Consortium.
Results: One year and two years follow up have completed for 96% and 86 % of the patients respectively. Emergent procedure was performed in 1146 cases (47.0%). Dual antiplatelet therapy (APT) before procedure had given in 1328 cases (54.4%), oppositely 272 cases (11.1%) had not given either both aspirin and thienopiridine before procedure. All course of death was observed in 184 patients (7.5%) and cardiac death was 114 cases (4.7%). TLR was performed in 155 cases (8.3%). Overall ST occurred in 38 lesions (1.36%) and late ST (LST) was observed in 12 lesions (0.43%) through 2 years. Diabetes, severe renal insufficiency, hemodialysis, low EF (<40%) and two stent approach to the bifurcation lesion were significantly associated to the overall ST in univariate analysis. Discontinuation of both APT, premature discontinuation of thienopiridine, severe renal insufficiency and LMT lesion were significantly associated to the LST in the univariate analysis. Furthermore, the multivariate analysis identified that discontinuation of both APT (O.R. 5.47 95%CI: 1.08-23.29) was the strongest predictor of the LST. The pretreatment of dual APT before procedure was not associated to either ST or LST.
Conclusions: The incidence of ST seems lower in Japanese patients with ACS than previously reported in the world. Pretreatment of APT was not associated to ST. However, similar to the previous report, discontinuation of dual APT is the strong predictor of both overall ST and LST for the ACS lesion treated with SES.

9:30 a.m.

2501-532 Comparison of Neointimal Coverage of Zotarolimus-Eluting Stents With Paclitaxel-Eluting Stents Using Optical Coherence Tomography at 9 Months After Implantation

Sang Min Park, Jung-Sun Kim, Chunyu Fan, Tae Hoon Kim, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, Yonsei cardiovascular center, Seoul, South Korea

Background: Optical coherence tomography (OCT) could afford the detection of thin layer of neointimal hyperplasia (NIH) and malapposition of stent with high-resolution. We intended to compare the stent strut coverage and malapposition between Zotarolimus-eluting stent (ZES) and paclitaxel-eluting stent (PES) using OCT.
Methods: Sixty-one patients (33 ZES vs. 28 PES) undergoing follow-up coronary angiography at 9 months after stent implantation were enrolled on the list of study population. We performed OCT to evaluate the degree of NIH inside each strut and stent apposition.
Results: 15,190 struts in 1,492 mm single-stented segments in total were analyzed. OCT analysis showed trend that ZES had greater mean NIH thickness (247 ± 111 μm vs. 210 ± 119 μm, $p = 0.06$) and percentage of mean NIH area (28 ± 9% vs. 24 ± 14%, $p = 0.05$). In addition, there were significant differences in percentage of malapposition (ZES 0.1 ± 0.5% vs. PES 1.4 ± 3.9%, $p = 0.02$) and exposed struts (0.50 ± 1.37% vs. 4.62 ± 7.85%, $p = 0.001$). Interestingly, thrombi were more frequently observed in ZES than in PES [3 patients (9 %) vs. 8 patients (30 %), $p = 0.05$].
Conclusions: The magnitude of NIH was greater in ZES while malapposition, exposure of stent struts and thrombi were more frequently observed in PES at 9 months follow-up. These findings might elucidate higher rate of late stent thrombosis in PES than ZES.

9:30 a.m.

2501-533 The Safety and Efficacy of the Zotarolimus-eluting Stent in Elderly Patients: 12-Month Outcomes from the E-Five Registry

Chaim Lotan, Eulogio Garcia-Fernandez, Nakul Sinha, Ian T. Meredith, Martin T. Rothman, For the E-FIVE Registry Investigators, Hadassah University Hospital, Jerusalem, Israel

Background: Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) in the elderly has not been well studied and outcomes are conflicting. The clinical outcomes of PCI with the Endeavor zotarolimus-eluting stent in a real-world population of elderly patients were examined.
Methods: The E-FIVE Registry, a prospective, multicenter, nonrandomized, global registry, enrolled 8314 patients at 188 centers. All patients with symptomatic coronary artery disease suitable for stenting were eligible. Patient characteristics and clinical outcomes at 12 months were stratified by age and analyzed for patients >75 and >85 years. Logistic regression analysis was used to adjust for differences in baseline characteristics. All MACE events, death, myocardial infarction (MI), and ARC defined stent thrombosis events were adjudicated by a Clinical Events Committee.
Results: Data was available for 1172 and 56 patients over age 75 years and 85 years respectively. Elderly patients were more likely to be female and for those >75 years, more likely to have complex lesions, and comorbid conditions. Patients >75 and >85 years had significantly more cardiac deaths. Among patients >75 there was a greater proportion of MACE, cardiac death, non-Q wave MI, and cardiac death plus MI, but similar TLR rates. (Table)
Conclusions: We found that patients over 75 in the E-Five Registry experienced a higher rate of MACE and its components, consistent with other reports of DES in this age group, however TLR rates were similar.

Clinical Outcome	≤75 years N=7142	>75 years N=1172	P-value*	≤85 years N=8258	>85 years N=56	P-value*
MACE, %	6.8	11.5	<.001	7.5	12.0	0.250
Cardiac death, %	1.3	4.2	<.001	1.7	6.0	0.027
MI (all), %	1.5	2.4	0.077	1.6	2.0	0.819
Q-wave MI, %	0.4	0.3	0.604	0.4	0.0	0.989
Non-Q-wave MI, %	1.1	2.2	0.028	1.2	2.0	0.647
Cardiac death + MI, %	2.5	6.0	<.001	3.0	6.0	0.227
ARC Def/Prob ST, %	1.0	1.9	0.054	1.1	2.0	0.495
TLR	4.4	4.8	0.875	4.4	8.0	0.242

*P-values were calculated using logistic regression adjusted for propensity scores for age > 75 vs. ≤75, or age >85 vs. ≤85. Propensity scores were calculated using: sex, prior MI, prior PTCA, prior CABG, diabetes, acute MI (<72hrs), hypertension, hypercholesterolemia, smoking, LAD (vs. Non LAD), B2C (vs. AB1), lesion length (≥27mm vs. <27mm), RVD (> 3.5mm, vs. ≤ 3.5mm).

9:30 a.m.

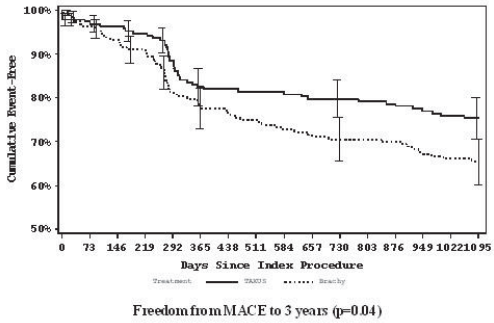
2501-534 Paclitaxel-Eluting Stents for the Treatment of Bare Metal Stent Restenosis: Three-Year Results of the TAXUS V ISR Trial

Stephen G. Ellis, Saif Anwaruddin, Charles D. O'Shaughnessy, Kenneth M. Kent, Kenneth M. Kent, Steven L. Martin, Thomas F. McGarry, Dean J. Kereiakes, Donald S. Baim, Gregg W. Stone, Cleveland Clinic, Cleveland, OH

Introduction: In the TAXUS V-ISR trial at 2 years, TAXUS Express, a paclitaxel-eluting stent (PES), demonstrated similar safety and less clinical restenosis than vascular brachytherapy (VBT) for treatment of bare metal stent (BMS) in-stent restenosis (ISR). Whether these benefits are sustained long-term at the 3-year follow-up is unknown.
Methods: Patients (N=396) with BMS ISR were prospectively randomized to either beta source VBT or PCI with PES. The primary endpoint was ischemia-driven target vessel revascularization (TVR) at 9 months. Thienopyridine use at 3 years was 59.3% in the PES group and 66.3% in the VBT group.
Results: At 3 years, PES compared to VBT resulted in a decrease in TVR (21.5% vs 32.6%, P=0.02) and target lesion revascularization (TLR) (11.2% vs 25.6%, P<0.001). This reflects a further differential reduction with PES vs. VBT in TVR (3.8% vs 9.9%, P=0.02) and TLR (1.1% vs 6.6%, P=0.006) between 2 to 3 years. No differences in

estimated rates of cardiac death (2.8% PES vs 2.2% VBT, *P*=0.76), myocardial infarction (4.2% PES vs 7.6% VBT, *P*=0.20) or target vessel thrombosis (2.7% PES vs 4.3% VBT, *P*=0.40) were observed at 3 years. The significant decrease in MACE (cardiac death, MI or TVR) with PES (24.7%) over VBT (34.5%, *P*=0.04) appears driven primarily by a progressive relative reduction in TVR throughout follow-up (Figure).

Conclusion: The treatment of BMS ISR using PES rather than VBT improves event free survival through 3 years, with benefits improving over time due to reduced late catch-up.



Freedom from MACE to 3 years (p=0.04)

9:30 a.m.

2501-535 **"Late catch-up" in Restenosis Following Sirolimus-Eluting Stent Implantation**

Masashi Kimura, Osamu Matsuda, Nobuyoshi Tanaka, Kenya Nasu, Mariko Ehara, Yoshihisa Kinoshita, Mitsuyasu Terashima, Etsuo Tsuchikane, Hitoshi Matsuo, Yasushi Asakura, Osamu Katoh, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Despite the suppression of intimal hyperplasia (IH) in coronary arteries with drug eluting stents (DES) compared with bare-metal stents at 6 months postprocedure, there appears to be a "late catch-up" in IH growth among patients treated with DES after 1 year. However, late restenosis after sirolimus-eluting stent (SES) implantation has not been sufficiently evaluated. The aim of our study was to determine whether in-stent restenosis (ISR) occurring >1 year after SES implantation is a real clinical entity.

Methods: We analyzed data on all SES implanted in patients treated from June 2004 to April 2007 and evaluated the incidence, clinical presentation, and angiographic ISR pattern after SES implantation. "Late catch-up" required demonstration of a patent stent at 6 to 9 months, with restenosis demonstrated on repeat angiography after 1 year.

Results: There were 3,420 lesions in 2,414 patients treated with SES over the length of the study period at our institution. Of this population, angiographic follow-up was performed in 1,763 patients (73.0%) with 2,506 lesions (73.3%). Angiography was performed after 1 year because of patient symptoms or to treat other vessels. Overall, ISR occurred in 265 lesions (10.6%). "Late catch-up" in ISR was observed in 20 lesions (0.80%) at second angiographic follow-up (median 23.5 months; range of 17.7 to 29.3 months). Of 20 lesions, 13 (65%) were located at the stent edge. Almost all cases of "late catch-up" (92.8%) expressed a focal angiographic ISR pattern. Clinical presentation of late target lesion revascularization (TLR) included silent ischemia (43%) and recurrent angina (57%). Late TLR was performed in 18 patients with 19 lesions. Serial quantitative coronary angiographic analysis of these lesions showed a minimal lumen diameter of 2.71±0.55 mm immediately after SES implantation, 2.44±0.59 mm at 9-month follow-up, and 1.04±0.26 mm at second follow up (p<0.001).

Conclusions: "Late catch-up" is an infrequent but real entity. The clinical presentation of late TLR was either silent ischemia or recurrent angina, but not acute coronary syndrome. Careful clinical and angiographic follow-up 1 year after SES implantation should be considered.

9:30 a.m.

2501-536 **Intravascular Ultrasound Analysis of Vessel Response in Acute Coronary Syndrome Treated with Zotarolimus-Eluting Stents**

Daisaku Nakatani, Katsuhisa Waseda, Hiromasa Otake, Bon-Kwon Koo, Ryota Sakurai, Akiyoshi Miyazawa, Masao Yamasaki, Junya Ako, Hyeonsoo Chang, Jean Fajadet, Richard E. Kuntz, William Wijns, David E. Kandzari, Martin B. Leon, Paul G. Yock, Yasuhiro Honda, Peter J. Fitzgerald, Stanford University Medical Center, Palo Alto, CA, Clinique Pasteur, Toulouse, France

Background: First-generation drug-eluting stents demonstrated conflicting results in the treatment of acute coronary syndrome (ACS). The aim of this IVUS study was to elucidate detailed vessel response to Endeavor zotalolimus-eluting stents (ZES) in patients with ACS versus stable angina.

Methods: We analyzed serial (baseline and 8-9 month follow-up) volumetric IVUS in 297 patients treated with a ZES for *de novo* coronary lesions. Volume index (volume/length) was calculated for vessel (VVI), plaque (PVI), neointima (NIV), and lumen (LVI). Percent neointimal volume (%NIV) was calculated as (NIV/SVI)×100. Cross-sectional narrowing (CSN) was defined as neointimal area divided by stent area (%).

Results: Despite larger VVI, PVI, and SVI in ACS patients, %NIV and max CSN at follow-up were similar among groups with stable angina (SA, n=142), unstable angina (UA, n=125), and recent myocardial infarction (MI, n=30) (Table). The rate of significant narrowing (maximum %CSN >50%) was also comparable among the 3 groups. With adjustment for difference in baseline characteristics by multiple regression analysis, ACS (UA and MI) showed no significant correlation with %NIV (β=0.044, P=0.702) or max CSN (β=0.094, P=0.382). The incidence of late acquired incomplete stent apposition (ISA) was also similar among the 3 groups.

Conclusion: The efficacy of ZES in patients with ACS on neointimal hyperplasia appears to be comparable to those with stable angina.

	Stable AP	Unstable AP	AMI	P value
Baseline (BL)				
VVI (mm3/mm)	12.9±4.1	14.4±3.6	16.6±5.0	0.001
PVI (mm3/mm)	6.3±2.7	7.1±2.4	8.6±3.1	0.004
LVI (mm3/mm)	6.7±1.9	7.3±2	7.7±2.3	0.022
Follow-up (FU)				
VVI (mm/mm3)	13.2±4.1	14.9±3.6	15.8±4.8	0.002
Delta-VVI (mm3/mm)	0.203±1.027	0.174±1.18	-0.276±1.208	0.279
PVI (mm3/mm)	6.5±2.5	7.4±2.3	8.2±3.3	0.006
Delta-PVI (mm3/mm)	0.163±0.932	0.119±0.935	-0.159±0.671	0.436
LVI (mm3/mm)	5.7±1.9	6.0±1.8	6.6±1.8	0.032
Delta-LVI (mm3/mm)	-1.007±1.007	-1.351±1.054	-1.216±1.362	0.066
% NIV (%)	16.9±11.8	18.9±10.7	16.6±9.5	0.292
% Max CSN (%)	31.7±14.9	35.4±14.9	34.0±16.5	0.135
Patinets with Max CSN >=50% (%)	12.0	15.2	16.7	0.666
Late acquired ISA (%)	1.5	0	0	0.322

9:30 a.m.

2501-537 **Six-Month Clinical Outcomes of Sirolimus-Eluting Stents with a Biodegradable Polymer for the Treatment of Unselected Patients with Complex Coronary Lesions - Preliminary Results from the Prospective, Multicenter E-Series Registry**

Ricardo A. Costa, Alexandre Abizaid, Andrea S. Abizaid, J. Ribamar Costa, Jr., Dimytri Siqueira, Fausto Feres, Costantino Costantini, Ayrton Arruda, Fábio S. Brito, Maurício Prudente, Expedito Ribeiro, Cadiovascular Research Center, São Paulo, Brazil, Institudo Dante Pazzanese de Cardiologia, São Paulo, Brazil

Background: The Supralimus sirolimus-eluting stent, S-SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), is a new DES technology incorporating a biodegradable drug-carrier component. Preliminary data with the S-SES has shown promising results, however, its impact in unselected pts is still unknown.

Methods: Between Nov/2006-Sep/2008, 1,045 pts were prospectively enrolled in 35 sites in South America. Inclusion criteria were all comers for routine or emergency PCI. Clinical follow-up was scheduled at 1, 6, 12, and 24 months. We report the preliminary outcomes at 6-month.

Results: Baseline characteristics included mean age 64 years, 32% female, 79% hypertension, 40% diabetes, 32% smoking, 23% previous MI, and 35% previous PCI. Overall, 37% presented with ACS (5% AMI). Lesion morphology included 29% mod/severe calcium, 16% in-stent restenosis, 12% bifurcation, 6% total occlusion, 5% ostial, 4% thrombus, and 63% classified as type B2/C. LAD was the predominant location (43%); glycoprotein inhibitors were used in 11%, there were 1.03 lesions per patient, and final TIMI 3 flow was achieved in 97%. Baseline reference diameter and lesion length were 2.92 and 23.26 mm, respectively. Clinical outcomes are shown in the Table.

Conclusions: The novel S-SES DES with a biodegradable polymer demonstrated excellent results in unselected pts with complex lesions. In the mid-term FU, there were only 2% TLR, and no safety concerns including stent thrombosis <1%. Longer-term follow-up is warranted.

Outcome	In-hospital	6-month (Out-of-hospital)
Death (all cause)	0.3%	2.1%
MI	1.7%	1.2%
TLR	0.1%	2.2%
Stent thrombosis	0%	0.8%

9:30 a.m.

2501-538 **The Initial Extent of Incomplete Stent Apposition in ST-Elevation Myocardial Infarction Treated with Drug-Eluting Stent: The Usefulness of Optical Coherence Tomography**

Ung Kim, Jung-Sun Kim, Jin-Sun Kim, Jung-Myung Lee, Jung-Woo Son, Jaedeok Kim, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, Inje University Paik hospital, Busan, South Korea

Background: The aim is to identify the extent of initial incomplete stent apposition (ISA) using optical coherence tomography (OCT) in ST-elevation myocardial infarctions (STEMI) treated with different types of drug-eluting stents (DES) and to compare the results.

Methods: Twenty four STEMI patients underwent primary percutaneous coronary intervention (PCI) were enrolled. The OCT was performed within 72 hours after the primary PCI. Distances between the endo-luminal surface of the strut reflection and the vessel wall and the extent of ISA were measured and analyzed.

Results: Sirolimus-eluting stents (SES), paclitaxel-eluting stents (PES) and zotarolimus-eluting stents (ZES) were deployed in 7 patients (29%), 7 patients (29%) and 10 patients (42%). In total, 4951 struts in 620 mm single-stent segments were analyzed. 1463 struts in SES, 1522 in PES, and 1966 in ZES were analyzed and measured distances were found to be significantly different (134±48 μm in SES, 89±29 μm in PES and 76±26 μm in ZES, p=0.001) and the frequency of ISA were also significantly different (28% in SES, 11% in PES, 10% in ZES, p=0.001).

Conclusions: Considerable rates of ISA using OCT were detected in STEMI after primary PCI with DES implantation and SES has especially higher rates of ISA.

9:30 a.m.

2501-539 Stent fracture after "full metal jacket" using drug-eluting stents as cause of in-stent restenosis

Masashi Kimura, Tsuyoshi Ito, Mariko Ehara, Nobuyoshi Tanaka, Kenya Nasu, Yoshihisa Kinoshita, Etsuo Tsuchikane, Yasushi Asakura, Hitoshi Matsuo, Mitsuyasu Terashima, Osamu Katoh, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Stented segment length and multiple stents are predictive factors for restenosis after drug-eluting stent (DES) implantation; coronary stent fracture has been noticed as a cause of in-stent restenosis (ISR). Nonetheless, clear visualization of in-vivo stent structure is not currently feasible with conventional technology. Therefore, we investigated the morphological characteristics of the stent fracture site and the correlation with ISR using multislice computed tomography (MSCT). Specifically, we looked at very long segments (ie, ≥64 mm of stented length) treated by DES, an approach colloquially referred to as a "full metal jacket."
Methods: From January 2007 to April 2008, we performed MSCT coronary angiography in 512 consecutive patients. In these patients, a total of 21 stented lesions were treated, with at least 64 mm of overlapping DES scanned using MSCT. Stent fracture was defined as a spontaneous injury to the structure of the in vivo stent strut in the absence of any artificial process. Lesions were divided according to the presence or absence of fracture. Frequency of overlapping, vessel bending and severe calcification of the native artery were compared between the 2 groups, as well as the ISR rate.
Results: Of the entire population, lesions with "full metal jacket" had more stent fractures than those without "full metal jacket" (30% vs. 7%, P<0.0001). The average stented length in these lesions was 83.9 ± 19.0 mm, with stent fracture detected in 10 sites (30%) and observed more frequently in the right coronary artery (RCA). There were no significant differences between groups in the rate of bending of the native coronary artery or in severe calcification. The ISR rate was higher in the fracture group (73% vs. 30%, P=0.03.
Conclusion: Coronary stent fracture was detected in 30% of stented lesions after aggressive stenting. "Full metal jacket" was the main predictor of stent fracture, resulting in in-stent restenosis. MSCT is a feasible modality capable of providing essential information regarding stent fracture.

9:30 a.m.

2501-540 The Impact of Age on One Year Outcomes in the Synergy Between Percutaneous Coronary Intervention and Cardiac Surgery (SYNTAX) Trial

Antonio Colombo, Pieter Kappetein, Patrick Serruys, Marie-Claude Morice, Katrin Leadley, Keith Dawkins, Friedrich Mohr, Ospedale San Raffaele, Milan, Italy, Boston Scientific Corporation, Natick, MA

Background: Although advanced age is known to induce adverse outcomes following percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), limited data are available on the relative differences in outcomes between these procedures as a function of age. This study compares one year outcomes between CABG and PCI in patients ≤70 and >70 years in the SYNTAX trial which enrolled the most challenging patients with three vessel and/or left main disease.
Methods: SYNTAX is a prospective, multinational trial with an intended 'all-comers' design. Consecutive patients with *de novo* three vessel and/or left main disease were screened by a Heart Team (cardiothoracic surgeon and interventional cardiologist) to determine suitability for PCI or CABG. Patients amenable for equivalent revascularization using either treatment option were randomized 1:1 to TAXUS Express² paclitaxel-eluting stent system or CABG. Patients deemed amenable for only one treatment option were entered into the appropriate registry. The primary
endpoint was 12-month MACCE (major adverse cardiac and cerebrovascular events; death, stroke, MI and revascularization).
Results: Of the 1800 randomized patients, 1225 (68%) were ≤70 (CABG, 612; TAXUS, 613) and 575 patients were >70 (CABG, 285; TAXUS, 290). The12-month, MACCE rate was significantly higher in the TAXUS group (11.4% vs 17.4%, *P*=0.0034) in patients ≤70 but was comparable between CABG and TAXUS in patients >70 (14.4% vs 18.8%, *P*=0.18). The overall safety (death, stroke, MI) rate was comparable between the groups in both cohorts (≤70, 6.1% vs 5.8%, *P*=0.81; >70, 11.0% vs 11.5%, *P*=0.87). The rate of stroke however was significantly higher in the CABG group (1.7% vs 0.2%, *P*=0.0055) in patients ≤70 but comparable between the two groups in patients >70 (3.4% vs 1.4%, *P*=0.12). The revascularization rate was significantly higher in the TAXUS group compared with CABG in both cohorts (≤70, 6.5% vs 13.9%, *P*<0.001; >70, 4.6% vs. 12.5%, *P*=0.001).
Conclusions: In the SYNTAX trial, patients ≤ 70 had a significantly higher MACCE rate in the Taxus group compared with CABG. However, patients >70 years had comparable MACCE rates in TAXUS and CABG at 12 months.

9:30 a.m.

2501-541 To Be Dead or Alive After Stent Thrombosis? Clinical and Angiographic Correlates of Drug-eluting Stent Thrombosis Presented with Deaths

Byeung-Keuk Kim, Seung Jin Oh, Dong Woon Jeon, Joo Young Yang, Jung-Sun Kim, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, Bum Kee Hong, Hyuck Moon Kwon, Kyung-Hoon Lee, Seung-Hwan Lee, Byoung Kwon Lee, Choong Won Goh, Jae-Hun Jung, National Health Insurance Corporation Ilsan Hospital, Goyang-si, South Korea

Background: The stent thrombosis (ST) following drug-eluting stents (DES) implantation has a fatal clinical course and shows the various initial clinical presentations including deaths. The aim of this study is to evaluate the clinical and angiographic correlates of ST presented with death.
Methods: Between March 2003 and July 2006, a total of 6,592 patients underwent percutaneous coronary intervention with DES in a Korean Multicenter Angioplasty Team (KOMATE) Registry. Of these patients, using the database from Korea National Statistical Office and hospital network, we identified 97 patients with ST, by Academic Research Consortium definition. The ST presented with a death, which developed initially or during the in-hospital periods, occurred in 60 (62%) patients. We compared the clinical, angiographic, and procedural variables of these patients with other patients with ST without deaths (n=37), who survived after ST. Multivariate regression analysis was performed to determine the correlates of ST presented with a death.
Results: The patients with deaths after ST were older [mean age; 69 vs. 62, p=0.002], more female gender [25 (42%) vs. 8 (22%), p=0.040], and lower left ventricular ejection fraction [45±16 vs. 53±14 %, p=0.019] and had a higher frequency of chronic renal failure [16 (27%) vs. 2 (5%), p=0.014] and acute myocardial infarction [35(58%) vs. 14 (38%), p=0.042], as compared with those without deaths after ST. There was no difference in the frequency of diabetes or hypertension between the 2 groups. In angiographic and procedural variables, the patients with ST presented with deaths were treated more frequently for chronic total obstructive lesions (20% vs. 7%, p=0.044), compared with those without death after ST. The types, length, and diameter of used DES did not differ between the groups. The most independent predictor for the occurrence of a death in patients with ST after DES implantation was older age [odds ratio (OR) = 1.08, 95% confidence interval (CI)=1.01-1.15, p=0.029].
Conclusions: This study suggested that the patients with ST following DES might be frequently presented with death. The major determinant for death after ST was older age.

9:30 a.m.

2501-542 Two Year Outcomes Following Off-Label Use of Drug-Eluting Stents in the Real-World: Insights from the HMO Research Network- Stent Registry (HMORN-Stent)

Thomas T. Tsai, P. Michael Ho, Nikki M. Carroll, Susan M. Shetterly, Stanley Xu, J. David Powers, Alan S. Go, Karen Margolis, David J. Magid, Denver VA Medical Center, Denver, CO, University of Colorado Denver, Denver, CO

Background: Most drug-eluting stents (DES) are implanted for non-FDA-approved "off-label indications". The degree to which off label use and clopidogrel treatment duration impacts long term post-stent outcomes remains unclear.
Methods: We evaluated 5679 patients from the HMORN-Stent Registry from January 2004-June 2006 stratified by on versus off-label indications. Off-label DES indications included use in bypass grafts, chronic total occlusions, left main artery, bifurcations, multi-vessel intervention, myocardial infarction (MI), and vessel diameter <2.5 mm or >4.0 mm or lesion length >30 mm.
Results: Of 5679 patients with DES, 3893 (68.6%) received stents for off-label indications. At 2 years of follow-up, those receiving off label DES had significantly higher rates of death and MI (12.6% vs 7.2%)[**Figure**]. After adjustment for confounders, off-label use was associated with a significantly higher risk of death, MI, or revascularization (adjusted HR, 1.32; 95% CI, 1.15-1.53; P=0.005). Mean duration of clopidogrel therapy was longer in off-label patients (264 days vs. 222 days, P<0.0001).
Conclusion: Most DES in real world practice are placed for off-label indications. There are increased adverse events with off-label DES implantation at 2 years despite longer clopidogrel treatment. Optimal clopidogrel duration and DES use in this patient subset requires further study.

9:30 a.m.

2501-543 Outcome of Non-cardiac Surgical Procedure and Brief Interruption of Dual Anti-platelet Agents within 12 Months Following ENdeavor™ Stent (Zotarolimus-eluting Stent) Implantation (SENS): a Multicenter Study

Jin Won Kim, Woong Chol Kang, Ki Seok Kim, Soo Joong Kim, Chang-Wook Nam, Chul-Min Ahn, Bong-Ki Lee, Sang Yup Lim, Hyun Sook Jung, Jin Ho Choi, Young Joon Hong, Dong Joo Oh, Korea Univ Guro Hosp, Seoul, South Korea

Background: Bare-metal stent is preferable to 1st generation drug-eluting stent (DES) in patients who need non-cardiac surgery within 12 months from coronary stenting despite restenosis. However, data are lacking regarding the safety of Endeavor™ stent which has been known to carry a lower risk of stent thrombosis due to rapid re-endothelialization.
Methods: A total of 3099 consecutive patients treated with Endeavor™ stent (Zotarolimus-eluting stent;ZES) since January 2006 were retrospectively analyzed in Korean 11 teaching hospitals. The primary endpoint was the 30-day major adverse cardiac events (MACE) including death, non-fatal myocardial infarction (MI) and target lesion revascularization.
Results: 194 patients (6.2 %, 194/3099) (male 54.9 %, mean age 63.5 years, diabetes

29.7 %) with brief interruption of dual anti-platelet agents (DAP; both aspirin and clopidogrel) due to non-cardiac surgical procedure within 12 months following ZES implantation were identified. Four patients (2.1 %) experienced a MACE (2 patients: fatal, 2 patients: non-fatal MI with identified thrombus). The incidence of MACE was higher in the early-surgery group (within 3 months following stent implantation) than in the late-surgery group (3 months to 12 months after stent implantation) (p<0.001, Table).
Conclusion: ZES appears to be safe and feasible in patients undergoing non-cardiac surgical procedure after 3 months following stent implantation.

Variables	Early surgery group (0-3 months, n=34)	Late surgery group (3-12 months, n=160)	p-value
Age(yrs)/Male(%)	62.2/63.5	63.1/50.9	NS
Lesion type (B2/C) (%)	73.6	72.8	NS
Stent number	1.4	1.5	NS
Mean stent diameter (mm)	3.11±0.52	3.08±0.47	NS
Total stent length (mm)	33.0±16.7	29.2±19.5	NS
Major surgery (%)	20.5	22.8	NS
Days from stenting to surgery	56.5	233.7	<0.001
DAP withdrawal (days)	13.4	14.8	NS
MACE (%)	8.9 (2 Death, 1 MI)	0.6 (1 MI)	<0.001

9:30 a.m.

2501-544 **A Year of Drug Eluting Stent Failure: Results From a Single Institution Registry**

Giuseppe Gioia, MariaFrancesca Gioia, Dawn Christensen, Jackie White, Howard Levite, William Mathhai, AtlantiCare Regional Medical Center, Pomona, NJ

Background: In January 2007 we created a prospective registry of patients presenting to AtlantiCare Regional Medical Center with DES in-stent restenosis or thrombosis (DES failure) to identify potential risk factors, and to assess the early and long term outcome of these patients.
Methods: Patients previously implanted with any DES who presented to the cath lab from January to December 2007 with a DES failure (defined as either in-stent restenosis or thrombosis) were enrolled.
Results: Fifty-five patients were identified and treated for DES failure. Mean age was 61 ± 13 years. Mean time to DES failure was 550 ±389 days. Twenty-eight patients (51%) presented with angiographic evidence of stent thrombosis (ST cohort) and clinical presentation with either STEMI (22 patients, 79%), non-STEMI (5 patients, 18%) or unstable angina (1 patient, 4%). Twenty-seven patients (49%) presented with in-stent restenosis (ISR cohort) and clinical presentation with either unstable angina (16 patients, 59%) or stable angina (11 patients, 41%). Thirteen (46%) patients with ST were still on dual antiplatelets therapy (DAT). A strong association was noted between the initial DES clinical indication and subsequent clinical DES failure presentation. Out of 22 patients presenting with ST and STEMI, 19 (86%) were initially implanted because of a STEMI. and only 3 (14%) were implanted for a non-MI syndrome (p<0.001). In contrast out of 27 patients presenting with ISR, 22 (81%) of them were initially implanted for a non-MI syndrome (stable or unstable angina) and only five of them were implanted because of a STEMI (p<0.001). Patients with ST were younger (55±12 vs. 66±10 yrs, p=0.001), more frequently current smokers (50% vs. 15%, p=0.008) and less likely to be on dual antiplatelets therapy (DAT) than patients with ISR (45% vs. 78%, p=0.02).
Conclusions: A strong association was noted between the initial DES clinical indication and subsequent clinical DES failure presentation. Patients presenting with ST were likely to have had their implant because of a STEMI and patients with ISR likely to have had their implant because a non-MI syndrome, suggesting that the implantation of DES for STEMI is a risk factor for subsequent stent thrombosis

I2.POSTER CONTRIBUTIONS

2502

New Technologies/Innovations

Sunday, March 29, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2502-545 **Stroke Prevention in Non-valvular Atrial Fibrillation: Long-Term Results of the WATCHMAN Left Atrial Appendage Occlusion Pilot Study**

Peter B. Sick, Zoltan G. Turi, Eberhard Grube, Gerhard Schuler, Karl E. Hauptmann, Gregory Mishkel, Steven Yakubov, Steven Almany, David R. Holmes, Hospital Barmherzige Brüder, Regensburg, Germany

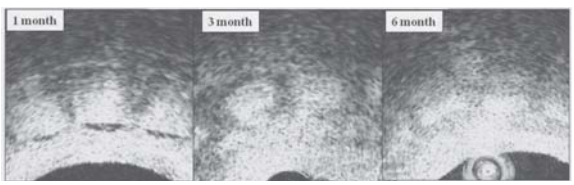
Background: Patients with non-valvular atrial fibrillation (NVAF) are at enhanced risk of embolic stroke; 90 % of left atrial thrombi in NVAF patients are found in the left atrial appendage (LAA).
Methods: The WATCHMAN LAA Closure device (Atritech, Plymouth, MN) is made of nitinol, incorporates fixation barbs around its perimeter and has a porous membrane on its atrial surface. A multi-center pilot study commenced in August 2002. Patients were assessed at 45 days, 6 months and one year with transesophageal echo (TEE) and clinically assessed annually for up to 5 years.
Results: Of 75 patients enrolled, the device was implanted successfully in 66. Anatomic limitations prevented implantation in 7, failure of venous access and an earlier generation delivery cable resulted in the other 2. Mean follow up was 46 ± 14 months. Mean age was 68.5±8.0 years. The acute results have been published previously. After 6 months, 91% had discontinued warfarin therapy. On routine 6 month TEE follow-up, 4 patients were noted to have a thrombus layer along the atrial face of the implant, one of whom developed a transient ischemic attack (TIA). Warfarin was restarted in these patients and stopped 3 months later without further evidence of thrombus. In long term follow up, 63 of 66 patients (95%) were off anticoagulation. There was one additional TIA. One patient had an embolic stroke at 39 months in the setting of severe concurrent carotid disease. These data reflect an actual stroke rate of 1 in 251 patient years (0.4%); the expected stroke rate given a mean CHADS2 Score of 1.8 ± 1.1 would have been 5.75%. Eight patients have died (mean 36± 15 months), all deaths were non-device and non-procedure related.
Conclusions: The data suggest that WATCHMAN LAA Closure is safe and feasible, with one embolic stroke through 5 year follow up. A randomized study comparing the WATCHMAN device with warfarin for stroke prevention in NVAF is ongoing.

9:30 a.m.

2502-546 **Novel Fully Bioabsorbable Salicylate-Based Sirolimus-Eluting Stent: OCT Assessment of Stent Degradation in Pig Coronary Artery Implants**

Daisuke Matsumoto, Toshiro Shinke, Sarah Geva, Nicolas Chronos, Keith Robinson, Refat Jabara, Saint Joseph's Translational Research Institute, Atlanta, GA, Saint Joseph's Hospital of Atlanta, Atlanta, GA

Background: Fully biodegradable stent is an attractive alternative strategy for current permanent metallic stents. We evaluated a novel, fully bioabsorbable sirolimus-eluting stent (8.3µg sirolimus/mm stent) synthesized entirely from salicylic-acid polymer in a clinically relevant animal model.
Methods: Bioabsorbable balloon-expandable stents (n=21) were implanted in pig coronaries using QCA to optimize stent apposition. *In vitro* studies demonstrated sirolimus elution over 30 days and complete stent degradation in 9-12 months. Animals underwent restudy and terminated at 1 month (1M), 3 month (3M), and 6 month (6M). Thickness and area of each strut (implantation: 1273 struts, 1M: 689 struts, 3M: 585 struts, and 6M: 292struts) were measured. Brightness of struts was semiquantitatively classified into 3 groups: 1) high 2) moderate 3) low signal intensity with or without clear strut border.
Results: Average strut thickness and area at 1M was similar to post implantation (implant: 0.27±0.025mm, 0.14±0.018mm^2, 1M: 0.26±0.002mm, 0.12±0.002mm^2, respectively, P=NS,). Strut Thickness and area gradually decreased over time (3M: 0.230±0.002mm and 0.093±0.002mm^2, P<0.0001; 6M: 0.227±0.003mm and 0.085±0.002mm^2, respectively, P<0.0001). OCT signal intensity was decreased with higher frequency of unclear border at 6M (P<0.01).
Conclusions: Degradation of a novel fully bioabsorbable salicylate-based stent was demonstrated by OCT. The size of this stent was remarkably decreased from 1M to 3M and 6M.



9:30 a.m.

2502-547 **In-Vivo Intravascular Imaging of Novel Fully Bioabsorbable Salicylate-Based Sirolimus-Eluting Stent**

Refat Jabara, Daisuke Matsumoto, Toshiro Shinke, Sarah Geva, Nicolas Chronos, Nicolas Chronos, Keith Robinson, Hadassah-Hebrew University Medical Center, Jerusalem, Israel, Saint Joseph's Translational Research Institute, Atlanta, GA

Background: Recent advances in bioabsorbable stent technology have contributed to awakened interest in their role as alternatives to current metallic drug-eluting stents. We sought to evaluate a novel, fully bioabsorbable sirolimus-eluting stent (SES) synthesized entirely from salicylic-acid polymer, in a clinically relevant animal model.
Methods: Bioabsorbable balloon-expandable stents (n=32) were implanted in pig coronaries using quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) to optimize stent apposition. Dose density of sirolimus was 8.3 µg/mm stent length with *in-vitro* studies demonstrating elution over 30 days and complete stent degradation in 9-12 months. Animals underwent QCA and IVUS restudy and were terminated at 7, 14, 30, 90, and 180 days for histologic assessment. Optical coherence tomography (OCT) was also performed for the 90- and 180-days samples.
Results: All stents were deployed successfully without notable mechanical difficulties. No edge dissection or vasospasm was observed during implant. No stent migration was observed at any time. Angiographic diameter stenosis (DS) was 20±16%, 24±4%, and 23±17%, at 1, 3, and 6 months, respectively. In parallel, IVUS showed good apposition of the stent to the vessel wall with DS of 21±9%, 25±7%, and 18±3%; and area stenosis (AS) of 35±13%, 33±7%, and 32±4% at 1, 3, and 6 months, respectively. OCT demonstrated good apposition of the stent with DS of 28±7% and 20±6%, and AS of 37±10% and 33±13% at 3 and 6 months, respectively. OCT showed reduction of stent thickness by 23% from 3 to 6 months. Histologic analysis confirmed these in-vivo findings and revealed a favorable healing process of absorbable stent incorporation into the arterial wall, without excessive thrombotic or inflammatory reactions.

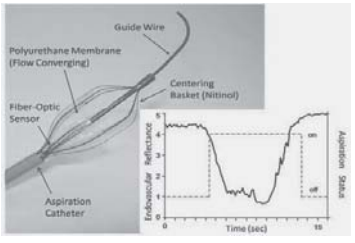
Conclusions: This study shows favorable vascular compatibility and efficacy for a novel fully bioabsorbable salicylate-based SES. This device has good mechanical performance during deployment and stays well-apposed to the vessel wall at long term follow-up. These initial results are highly encouraging and support progress into more extensive preclinical studies as well as early clinical testing.

9:30 a.m.

2502-548 A Novel Technique For Endovascular Detection and Automated Removal of Radiographic Contrast During Angiography

Hyeonsoo Chang, Ali H.M. Hassan, Young L. Kim, Bon-Kwon Koo, Junya Ako, Yasuhiro Honda, Peter J. Fitzgerald, Center for Cardiovascular Technology, School of Medicine, Stanford University, Stanford, CA

Background: Increasing complexity of current PCI may be associated with growing incidence of contrast-induced nephropathy. To address this clinical problem, a novel method of endovascular detection and automated removal of contrast has been developed, comprised of a catheter-based system with a reflectance-type optical sensor.
Methods: To test the feasibility of in-vivo detection and removal of contrast, a prototype aspiration catheter equipped with a fiber-optic sensor (Figure) was inserted into the coronary sinus (CS) of 5 canines. Contrast (5 cc per injection) was administered into the coronary artery, and reflectance signals were recorded at the CS (n=33 signal samples). The removal rate was analyzed through 10 blood specimen collections using spectrophotometric absorbance assay.
Results: Upon detection of contrast in the CS, the sensor signal dropped by 79.5±9.9% (range 54.1~92.9%) from the baseline reflectance signal at pre-injection (Plot, left axis). The signal change was highly reproducible and was significantly greater than the baseline noise level (2.5±0.9%; range 0.9~4.3%), enabling automatic activation of the aspiration system (Plot, right axis). Quantification of contrast removal ranged from 46~76% of the total injection volume.
Conclusions: The present study demonstrated the feasibility of an in-vivo, catheter-based detection and automated removal of contrast using reflectance sensing technology.



9:30 a.m.

2502-549 Responders and Mechanism of Clinical Benefit in AMADEUS Trial of the CARILLON™ Mitral Contour System™ to Treat Functional Mitral Regurgitation

Steven L. Goldberg, Joachim Schofer, Tomasz Siminiak, Uta C. Hoppe, Michael Haude, Jean-Paul Herrman, Richard Van Bibber, Ludwik Firek, David Reuter, Justina C. Wu, Cardiac Dimensions, Inc, Kirkland, WA

AMADEUS evaluated pts with CHF (NYHA ≥ 2), cardiomyopathy (EF < 40%), and functional mitral regurgitation ≥ 2+. The CARILLON™ Mitral Contour System™ (CMCS) is a device placed percutaneously into the coronary sinus/great cardiac vein, and manual tension applied to "cinch" the posterior annulus of the mitral valve. This analysis compares improvements in clinical and echo parameters at 1 mo fu after placing a CSMC.
Methods: 30 pts successfully received a CMCS. 1 patient died 3 weeks after implant of progressive CHF. The others returned at 1 month for clinical and echo fu. Quantitative measurements were performed on baseline and 1 mo echos, including mitral jet area to left atrial area, vena contracta, EROA, regurgitant volume, regurgitant fraction as well as MR grade. A pt was identified as a responder (RESP) by 2 different echo criteria or by 3 different clinical criteria (see TABLE below):
Results: The Table shows the different RESP rate per the different definition of RESP. There were 21 pts who improved their NYHA class by > 1 and 8 who did not. The MR grade in the 21 pts who improved their NYHA class decreased from a mean of 3.1 to 2.0, whereas those that did not improve their NYHA decreased from a mean of 3.1 to 2.7 (p = 0.03 comparing the RESP and non-RESP).
Conclusions: There were similar numbers of RESP using echo and clinical definitions. There was a correlation between echo and clinical improvement, suggesting a mechanistic explanation for the clinical benefits which were seen after a CARILLON implant was performed.

Responders in AMADEUS

Definition of Responder	Percent Responder
Improvement in > 1 MR grade	67%
Improvement in > 1 grade in 2 or more quantitative MR measurements	76%
Improvement in > 1 NYHA class	75%
Improvement in 6 MWT > 30 meters	75%
Increase in KCCQ by > 5 points	81%

9:30 a.m.

2502-550 Long Term Safety, Angina Relief and Improvement in Quality of Life in Patients with Refractory Angina Treated with the Neovasc Coronary Sinus Reducer

Keyur H. Parikh, Milan Chag, Urmil Shah, Hemang Baxi, Anish Chanadarana, Ajay Naik, Satya Gupta, Shmuel Banai, The Heart Care Clinic, Ahmedabad, India, Cardiology Department, Tel Aviv Medical Center, Tel Aviv, Israel

Background: Increased coronary sinus (CS) pressure redistributes collateral blood flow into ischemic territories of the myocardium, reduces ischemic damage and infarct size. First-in-Man Study for the feasibility and short term (12 months) safety for CS Reducer™ (Neovasc Inc, Canada) in patients with refractory angina have demonstrated promising results. The following study was conducted to assess the long term safety, quality of life (QoL) and cardiac status among patients implanted with CS Reducer™.
Methods: Ten patients with coronary artery disease (CAD), severe angina, and reversible ischemia were electively implanted with the CS Reducer™. Angina class assessment, echocardiography, exercise stress test, and quality of life assessed by the Seattle Angina Questionnaire (SAQ) were performed at baseline and at 3 year follow-up.
Results: At 3 years after implantation of the CS Reducer™, all 10 patients were alive. Average angina class (by Canadian Cardiovascular Class, (CCS)) was significantly improved compared to baseline (P<0.0001). SAQ at 3 year follow-up demonstrated significant (P<0.001) improvement compared to baseline in physical limitation, angina frequency, treatment satisfaction and QoL. Improvement in the Angina Stability was also statistically significant at 3 years follow up (P=0.0288). Mean ejection fraction by echocardiography and exercise duration by stress test were unchanged as compared with baseline (P=0.9627 and P=0.3097 respectively)
Conclusions: Long term follow up after implantation of the Neovasc CS Reducer™ in 10 patients with refractory angina demonstrates the safety and efficacy of the Reducer™. No mortality was recorded, and the improvement in CCS class, angina relief and QoL was sustained for 3 years after implantation of the Reducer™.

9:30 a.m.

2502-551 A Novel Transcatheter Suture Technique for PFO Closure: The Heart Stitch Pilot Study

Anita W. Asgar, Arif Khan, Niki Walker, Anthony Nobles, Michael J. Mullen, Royal Brompton Hospital and Harefield HNS Trust, London, United Kingdom

Background: Patent foramen ovale (PFO) has been implicated in the etiology of embolic stroke, transient ischemic attack, migraine with aura, and decompression sickness in divers. Transcatheter PFO closure is a safe procedure however, current devices implant material that may obstruct future access to the left atrium. The Sutura Heart Stitch is a novel bidirectional suture device which allows direct suturing of the PFO without the need for an open surgical approach. We describe our preliminary results.
Methods: The study was a prospective non-randomized feasibility study of the Heart Stitch to determine safety and efficacy of the device in patients with a PFO and indication for closure. Inclusion criteria were as follows: patients 18 years and older, diagnosis of a PFO and indication for closure, and no previous history of device closure for PFO. The procedure was performed in the cardiac catheterization lab using general anesthetic and transesophageal echocardiographic guidance. If device implantation failed, closure was performed using another device at the discretion of the operator.
Results: From April 2008 to October 2008, sixteen patients underwent attempted PFO closure using the Sutura Heart Stitch device. Indications for PFO closure were; previous thromboembolic stroke or transient ischemic attack (11 patients), intractable migraine headaches (4 patients) and cryptogenic MI (one patient). Of those enrolled, the Heart Stitch was successfully deployed in ten patients . Inability to deploy the device was secondary to failure to capture the secundum septum in four patients, and the suture being pulled through the septum in two patients. In those patients, the PFO was closed using a Biostar (n=5) and Premere device (n=1). One procedural complication, a hemothorax occurred was managed successfully. Follow up contrast echocardiography in device success patients (n=10) following the procedure demonstrated; no residual shunt (n=5), Grade 1 (n=2), and Grade 3 shunt (n=3) at rest and no shunt (n=2), Grade 1 (n=3) and Grade 2 shunt (n=1) at valsalva.
Conclusions: This feasibility study demonstrates that the Heart Stitch is both safe and effective for PFO closure and provides a novel option for patients.

9:30 a.m.

2502-552 Mid-term Safety and Efficacy of Patent Foramen Ovale Closure Using the Bioabsorbable Septal Repair Implant

Ben Van den Branden, Marco Post, Jurrien ten Berg, Maarten-Jan Suttorp, St. Antonius Hospital, Nieuwegein, The Netherlands

Background: The use of permanent synthetic implants for closure of a patent foramen ovale (PFO) has a number of possible disadvantages including erosions, thrombus formation and allergic reactions. These might be absent using a bioabsorbable closure device because it will be absorbed and replaced by healthy native tissue.
Methods: All consecutive patients who underwent a percutaneous PFO closure with the bioabsorbable closure device between November 2007 and September 2008 were included. We report the safety and efficacy of closure in-hospital and at 1 month and 6 months follow up.
Results: In total 44 patients (50% female, mean age 49.1±10.9 years) underwent a PFO closure. The in-hospital complications were a surgical device retrieval from the femoral vein in one patient (2%) and a minimal inguinal haematoma in four patients (9%). The short-term complications at one month follow up (n=34) were a transient ischemic attack in the presence of a residual shunt in one patient (3.0 %) and paroxysmal supraventricular

tachycardia in three patients (9.0 %). There were no mid-term complications at six months follow up (n=21). Using contrast transthoracic echocardiography, a mild or moderate residual shunt was present in 49%, 40%, and 32% at 0, 1, and 6 months follow up respectively. A large shunt was present in 9%, 6%, and 0% at 0, 1, and 6 months follow up respectively.
Conclusion: Percutaneous PFO closure using the bioabsorbable device seems to be safe during mid-term follow up. A high percentage of residual shunting is present at short-term follow up which decreased importantly at mid-term follow up. Long-term follow up data are necessary to evaluate the residual shunting and safety of this new device.

9:30 a.m.

2502-553 **Clinical Experience with a Novel Multi-functional Percutaneous Assist Device**

Ehab S. Kasasbeh, David Webb, Jayant Bagai, Joseph Salloum, Marshall Crenshaw, David X. Zhao, Vanderbilt University Medical Center, Nashville, TN

Background: In 1968, the first clinical application of the intra-aortic balloon pump -the first mechanical assist device- was reported in treating patients with cardiogenic shock after acute myocardial infarction. Since then, multiple mechanical assist devices have been developed. Percutaneous ventricular assist devices (pVAD) have been in use since 2003.
Objective: Here, we present our clinical experience with a newly developed pVAD, named the Vanderbilt multifunctional percutaneous heart (MPH). Our objective is to evaluate the feasibility and safety of implanting the Vanderbilt MPH in comparison to a currently available pVAD, the TandemHeart.
Methods: From February to September 2008, we used the Vanderbilt MPH device in 18 patients. All patients were clinically assessed to be at high of a risk for circulatory collapse without maximal hemodynamic support. In 9 of these patients, the device was used as an extra-corporeal membrane oxygenator (ECMO) device. In the remaining 9 patients, it was used as a left pVAD. Procedural success was 100%. During the same period, Tandem Heart pVAD was used in 20 patients.
Results: Average age was similar between the two groups (65.1 in the TandemHeart group versus 61.8 in the Vanderbilt MPH group). Death at 5 and 21 days was 10% (2 patients) and 25% (5 patients) respectively in the TandemHeart group versus 11% (2 patients) and 28% (5 patients) respectively in the Vanderbilt MPH group. One patient who underwent TandemHeart implantation developed a stroke and two patients required renal replacement therapy. Vascular complications were similar in both groups (one in each).
Conclusions: Our clinical experience with this device has shown that it is simple and easy to deploy. Our device is unique because it can function as an ECMO as well as a VAD. The switch can be made quickly and with a few short steps. Its small size and few components make it portable and it can be utilized at the referring institution or in the field if needed. It is significantly cheaper than currently available pVADs. Therefore, it is an effective, versatile, and economical VAD, and can aid in providing the necessary support required to enhance procedural success and safety during high risk cardiac procedures.

9:30 a.m.

2502-554 **Does The Absence of Polymer Really Impact The Efficacy of Drug-Eluting Stents? A Serial Angiography and Intravascular Ultrasound Comparison of Sirolimus-Eluting Stents With and Without Polymeric Coating**

Daniel Chamié, J. Ribamar Costa, Jr., Alexandre Abizaid, J. Fábio Almiro, Fausto Feres, Luiz Alberto Piva Mattos, Rodolfo Staico, Ricardo Costa, Andréa Abizaid, Luiz Fernando Tanajura, Amanda G.M.R. Sousa, J. Eduardo Sousa, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil

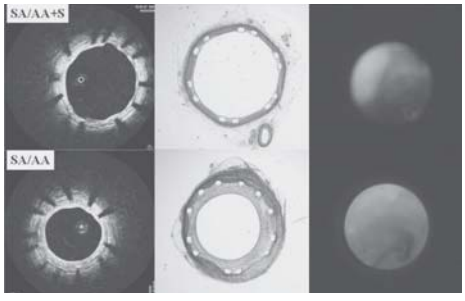
Background: Although synthetic polymers in DES may provide better release kinetics of the drug, their long-term presence in the vessel has been related to intense inflammatory response and late adverse events. Moreover, it is believed that the lesser the drug dose, the lower the toxic effect to the vessel wall. However, absence of polymer may compromise drug dose and release kinetics, leading to some efficacy issues. The Vestasync Sirolimus-eluting stent (VES) combines a stainless-steel platform with a nanothin-microporous hydroxiapatite surface coating, impregnated with a polymer-free, low-dose Sirolimus formulation (55 µg), eluting the drug for 3 months. We aimed to compare, by means of serial QCA and IVUS, the efficacy of this novel device with the permanent polymer, high-dose (140 µg) Cypher sirolimus-eluting stent (CYP).
Methods: 15 pts with single, *de novo* lesions <14 mm length, in native vessels of 3.0-3.5 mm in diameter, were consecutively treated with VES in May/2007, and compared to a historical cohort of 15 pts treated with the CYP with the same inclusion criteria. QCA and IVUS data were obtained post-procedure and serially at 4- and 10-month FU, and were analyzed by 2 operators blinded to the type of DES used. Primary end-points were the comparison of in-stent late loss (LL) by QCA and % of intimal hyperplasia (IH) by IVUS.
Results: Clinical characteristics were similar between groups. The VES group had smaller vessels (2.67 ± 0.32 vs. 2.98 ± 0.4 mm, p=0.02). Success of the procedure was obtained in all pts. At 4-month FU, the VES group had similar in-stent LL (0.30 ± 0.25 vs. 0.09 ± 0.3, p=0.08) and IVUS % IH obstruction (2.8 ± 2.2 vs. 2.2 ± 3.8, p=0.60). At mean 10.5 ± 1.5 months, in-stent LL was 0.37 ± 0.24 (VES) vs. 0.16 ± 0.36 (CYP), p=0.074, and the IVUS % IH obstruction was 3.8 ± 2.3 (VES) vs. 2.37 ± 3.8 (CYP), p=0.22. There were no cases of binary restenosis in both groups.
Conclusions: This analysis shows that the VES is safe and effective in reducing IH formation up to 10-month FU. The absence of polymer, as well as the lower drug dose, did not impact on the efficacy of the VES compared to the CYP. Whether these changes will impact the safety profile of this novel DES has to be confirmed in a larger cohort of pts and a longer FU.

9:30 a.m.

2502-555 **Novel Sirolimus-Eluting Stent Coated with Bioabsorbable Salicylate-Based Polymer: Optical Coherence Tomography and Angioscopic Evaluation of Pig Coronary Artery Stent Implants**

Daisuke Matsumoto, Toshiro Shinke, Sarah Geva, Nicolas Chronos, Keith Robinson, Refat Jabara, Saint Joseph's Translational Research Institute, Atlanta, GA, Saint Joseph's Hospital of Atlanta, Atlanta, GA

Background: Permanent polymers used in current DES can trigger chronic inflammation and hypersensitivity reactions, which may contribute to late thrombosis and rebound restenosis. We evaluated sirolimus-eluting stent coated with novel bioabsorbable salicylate-based polymer using OCT, angioscopy and histology.
Methods: Bare metal stents (BMS, n=14), salicylic acid/adipic acid bioabsorbable polymer-only coated metal stents (SA/AA, n=15), biostable polymeric sirolimus-eluting stents (Cypher®, n=13) and SA/AA containing sirolimus (SA/AA+S, n=17) were randomly implanted in pig coronary arteries using QCA to optimize stent apposition. Diameter stenosis (DS) was evaluated by angiography, OCT, and histology (aDS, oDS, and hDS). Intimal area was assessed by OCT and histology (oIA and hIA). Angioscopic and histological mural thrombus (aMTand hMT) was also assessed.
Results: aDS was significantly lower in SA/AA+S (-13.2±4.3%) than the other groups (BMS: 6.7±5.6%, SA/AA: 8.1±4.2%, and Cypher: -3.4±6.2%, respectively, P=0.01). oIA and hIA were lower in SA/AA+S and Cypher compared to SA/AA group (SA/AA+S: 1.65±0.18mm^2, BMS: 2.11±0.32mm^2, SA/AA: 2.99±0.36mm^2, and Cypher: 1.88±0.34mm^2, P=0.017). aMT and hMT were observed slightly higher in SA/AA+S and Cypher compared to BMS and SA/AA.
Conclusions: This sirolimus-eluting stent coated with novel bioabsorbable salicylate-based polymer showed favorable vascular compatibility and suppression of neointimal growth by different modalities.



9:30 a.m.

2502-556 **TIMI Myocardial Perfusion Grade Predicts Abnormal Single Photon Emission Computed Tomography and Endocardial Electrical Activity in Patients with Advanced Chronic Coronary Artery Disease**

Ricardo Sanz-Ruiz, Pilar Jimenez-Quevedo, Guilherme Silva, Marlos Fernandes, Cristiano Cardoso, Fred Braimbridge, Edie Oliveira, Yi Zheng, James Willerson, Emerson Perin, Texas Heart Institute, Houston, TX

Background: in the setting of chronic CAD, we aimed to assess the ability of abnormal TIMI Myocardial Perfusion Grade (TMPG) scores to identitfy patients with impaired myocardial perfusion by SPECT imaging and decreased endocardial voltage at electromechanical mapping (EMM). **Methods:** Nineteen consecutive pts with chronic stable CAD were included. TMPG was assessed from coronary angiography utilizing a 17-segment polar map of the LV (normal, TMPG=3; impaired, TMPG=0-1-2). Perfusion was studied with Tc-99m sestamibi (normal: grades 3-4; impaired: grades 0-1-2) and EMM was performed with the NOGA system. All studies were performed and analyzed by independent observers blinded to the results of the other techniques.
Results: Mean age was 59±7 years and 73% were male. A total of 357 SPECT and EMM segments were correlated with the corresponding angiographic data. Abnormal TMPG was associated with impaired perfusion by SPECT and segments with normal TMPG showed normal SPECT perfusion more frequently (figure 1A). Segments with abnormal TMPG had lower unipolar voltage (UV) than segments with normal TMPG (figure 1B). Moreover, segments with impaired perfusion by SPECT had lower UV (9.6±4.3mV vs 11.9±4.7mV, p<0.01) and local shortening (8.4±7.1% vs 11.4±6.8%, p<0.01) than segments with normal perfusion.
Conclusions: For the first time, we have demonstrated that TMPG may be a reliable method to study myocardial perfusion in chronic CAD pts, and that TMPG is associated with voltage values as assessed by EMM.

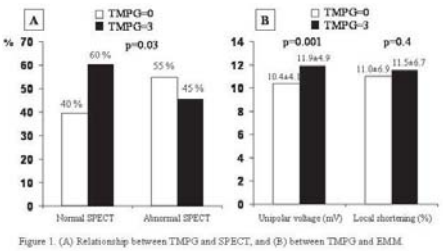


Figure 1. (A) Relationship between TMPG and SPECT, and (B) between TMPG and EMM.

9:30 a.m.

2502-557 **First In Man Assessment of Orbital Atherectomy System in Treating De Novo Calcified Coronary Lesions (ORBIT I)**

Keyur H. Parikh, Ashok Seth, Hemang Baxi, Anish Chandarana, Satya Gupta, Urmil Shah, Milan Chag, Sandhya Nair, Praveen Chandra, The Heart Care Clinic, Ahmedabad, India, Max Heart and Vascular Institute, New Delhi, India

Background: Calcific coronary artery disease (CCAD) remains a significant clinical problem for interventional cardiologists, requiring different treatment strategies. Various debulking strategies have been tried over the years with mixed results. This study was sought to evaluate the safety and performance of the Diamondback 360°™ Orbital Atherectomy System (OAS) in treating *de novo* calcified coronary lesions

Methods: ORBIT I study is a prospective, non randomized, multi-center trial. Fifty patients with *de novo* calcified coronary lesions were enrolled in the study. The Orbital Atherectomy included a sterile single use device, guidewire and a console. The diameter of the crowns used in the study was 1.25, 1.5, 1.75 and 2 mm. All devices had 30 µ grit size. Angiographic and intravascular ultrasound (IVUS) images before and post procedure were recorded. The primary end point was target vessel failure (TVF) whereas secondary end points were target lesion revascularization (TLR), procedural success and device performance.

Results: Of the fifty patients enrolled in the study, one patient was withdrawn since the IVUS catheter could not pass the lesion. Debulking measured by percent change in diameter stenosis using angiography and IVUS were significantly achieved. No major angiographic complications were seen while in 9 cases minor complications were observed (minor dissection- 5, minor perforation- 2 and bradycardia-2). TVF was observed in 3 cases (Q wave MI in 1 and non Q wave MI in 2 patients) and TLR (PTCA) was done in 1 case at 30 days. Both procedural success as well as device success were achieved in 48 out of 49 cases .There were no serious acute in-hospital complications such as deaths and emergency coronary artery bypass graft surgery.

Conclusion:

This study demonstrates that the Diamondback 360°™ Orbital Atherectomy System safely and effectively debulks heavily calcified plaque in patients with *de novo* calcified coronary lesions improving stent expansion and apposition .

9:30 a.m.

2502-558 **Long-Term Results (> 1 Year) of the Vestasync I Trial With a Novel, Third-Generation, Hydroxyapatite Polymer-Free Sirolimus-Eluting Stent**

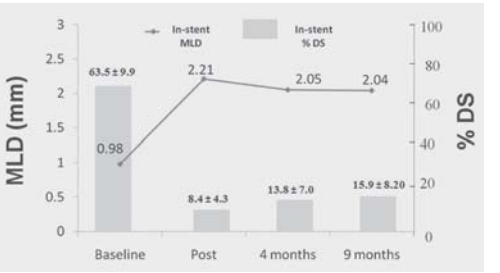
Jose de Ribamar Costa Jr, Alexandre Abizaid, Ricardo A. Costa, Fausto Feres, Luiz Fernando Tanajura, Andrea Abizaid, Rodolfo Staico, Dimytri Siqueira, Galo Maldonado, Raoul Bonan, Amanda Sousa, J. Eduardo Sousa, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, Cardiovascular Research Center, São Paulo, Brazil

Background: Durable polymers in 1st-generation DES have been linked to local inflammatory reactions. Stent thrombosis (ST) secondary to positive vessel remodeling and late-acquired incomplete stent apposition (ISA) is a possible clinical translation of this local adverse effect. We sought to assess the safety, and efficacy of the novel VESTAsync Eluting Stent (VES) combining a SS platform with a nanothin-microporous hydroxyapatite surface coating impregnated with a polymer-free low-dose of Sirolimus (55µg). All sirolimus is released within 3 months of the procedure.

Methods: 15 pts with single de novo lesions in native coronary arteries with 3.0-3.5mm diameter and ≤ 14mm in length were enrolled in this FIM study. Primary endpoint was in-stent late lumen loss (LL) at 4 and 9 months.

Results: Baseline characteristics included mean age of 63 years-old and 33% of diabetics. RVD and lesion length were 2.7 ± 0.3mm and 10 ± 2.0mm, respectively. Procedure success was obtained in all cases. Lifelong AAS and 6-month clopidogrel were prescribed to all pts. At 4 months, in-stent LL and % of NIH were 0.3±0.25mm and 2.6±2.2%, with a non-significant increase at 9 months (0.36 ± 0.23mm and 4.0 ± 2.2%). Serial IVUS did not show late ISA. The chart displays the variation of MLD and % of stenosis along the months. There was no MACE within 1 year of FU.

Conclusion: The novel VES was effective in reducing LL and NIH at 4 and 9 months, with no evidence of late catch-up by QCA or IVUS. Two-year clinical results will be available during the meeting.



9:30 a.m.

2502-559 **Quantitative Analysis of Myocardial Perfusion After Primary Percutaneous Coronary Intervention in Patients With ST-Elevation Myocardial Infarction: Computer Assisted Myocardial Blush Results From a Randomized Controlled Trial**

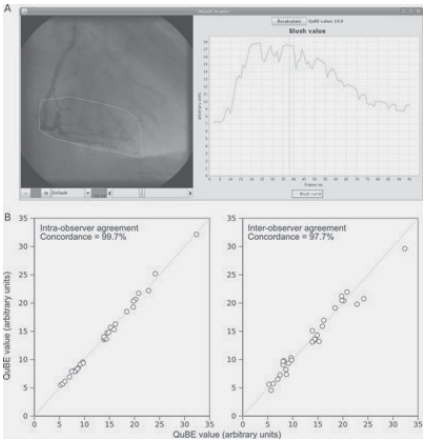
Youlan L. Gu, Marieke L. Fokkema, Mathijs Vogelzang, Pieter J. Vlaar, Felix Zijlstra, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

Background: Although visually scored myocardial blush grade (MBG) is an established marker of myocardial perfusion after primary percutaneous coronary intervention (PCI) in patients with ST-elevation myocardial infarction (STEMI), computer assisted quantitative analysis may allow better reproducibility, and a more fine-grained evaluation. We sought to validate the applicability of the Quantitative Blush Evaluator (QuBE) in a randomized clinical trial.

Methods: In the ADenosine Administration during Primary percutaneous coronary intervention in acute myocardial infarction Trial, patients were randomized to 2 intracoronary (IC) injections of adenosine (2x0.12mg in 20ml sodium chloride) or placebo (2x20ml sodium chloride), administered before and after stenting. QuBE values were quantified on angiograms recorded before and after the second injection.

Results: QuBE values had an excellent intra- and interobserver variability (see Figures). In total, 448 patients were randomized to IC adenosine (n=226) or placebo (n=222). So far, paired angiograms have been analyzed in 318 (71%) patients. There was no difference in QuBE values before and after the first injection between the adenosine and placebo groups (-0.067±2.3 versus -0.15±1.9, *p*=0.738).

Conclusions: QuBE provides a reproducible quantitative measure of myocardial perfusion, and is an attractive method in future studies in STEMI patients. IC adenosine does not improve MBG as assessed by QuBE (Dutch trial register ID NTR1073).



9:30 a.m.

2502-560 **Coronary Revascularization Approaches Combining Total Endoscopic Bypass Grafting and Percutaneous Interventions using Different Timing Protocols**

Guy J. Friedrich, Nicos Bonaros, Thomas Schachner, Guenther Laufer, Otmar Pachinger, Johannes O. Bonatti, Medical University Innsbruck, Innsbruck, Austria

Background: LIMA grafting is known to be the optimal revascularization strategy in LAD lesions unsuitable for PCI. Total endoscopic bypass surgery (TECAB) is a minimal invasive procedure reducing surgical trauma. The sequence of both strategies has not yet been defined or compared regarding follow up (FU). We sought to investigate this "hybrid" approach combining PCI and TECAB using different timing protocols.

Methods: Patients (pts, n=57, mean age 58, 47 male, mean EuroSCORE 1) with stable angina and 2 - or 3 vessel disease were included. All presented type C lesions of the LAD, type A/B lesions of non LAD vessels. PCI timing in relation to TECAB was investigated using 4 timing protocols. LIMA bypass (54 LAD, 6 DG, 4 CX, including jump grafts) was performed using the robotically assisted TECAB technique (da VINCI™, Intuitive Surgical Inc., Sunnyvale, Ca). The non LAD lesions were treated by PCI either simultaneously

or in a staged intervention protocol (7 PCI before,16 after TECAB,16 simultaneously). One group (n = 18) underwent TECAB only, PCI(small caliber of non LAD vessels, no robust evidence of related ischemia) was postponed and planned to be performed only in clinically driven indications.
Intraoperative coronary angiography (ICA) in simultaneous revascularization was performed with a mobile C-arm (OEC 9800™, GE Healthcare).
Results: Surgery was performed as 1 vessel arrested heart (1V-AH) TECAB in 45 pts, 2 V-AH TECAB in 8 and 1 V beating heart TECAB in 4 pts. In 30/39 pts PCI with stenting was performed (13 BMS, 17 DES). Mean PCI timing in pts before TECAB was 60 days, after TECAB 90 days. ICA showed patent TECAB grafts in 50 pts, 7 were converted to open surgery (12.3%). Peri-and postoperative mortality was 0%. Mean FU time was 24 months including clinical investigation and invasive CA: mortality rate was 0%, freedom from angina 97%, MACCE rate 9%, PCI target vessel reintervention rate 4%.
Conclusions: Our preliminary experience shows that TECAB LIMA bypass surgery combined with PCI, performed using different timing protocols, is feasible and safe. Intermediate term survival and freedom from angina are excellent.

9:30 a.m.

2502-561 Safety and Feasibility of a New Biodegradable Drug Eluting Stent for the Inhibition of Neovascularization: Assessment with Optical Coherence Tomography

Konstantinos Toutouzas, Andreas Synetos, Antonis Karanasos, Eleutherios Tsiamis, Elli Stefanadi, Christodoulos Stefanadis, 1st Cardiology Clinic, University of Athens, Medical School, Hippokration Hospital, Athens, Greece

Background: Neovascularization seems to play an important role in the development of the vulnerable plaque. Vascular endothelial growth factor (VEGF) appears to be the most important mediator of neovascularisation. We assumed that inhibition of VEGF, using local delivery of bevacizumab, a monoclonal antibody specific for VEGF, could affect neovascularization and intimal hyperplasia in hypercholesterolemic rabbits.
Methods: We used 12 New Zealand white rabbits under atherogenic diet for 3 weeks. Thirteen bevacizumab-eluting stents were implanted in the distal aorta. The stents were coated with a biodegradable polymer which was loaded with bevacizumab, after immersion into a solution of 4 ml of the drug. All animals were treated with aspirin and clopidogrel for 4 weeks. Follow-up angiography and Optical Coherence Tomography (OCT) study were performed at 4 weeks. OCT images of each stent taken at 1 mm intervals were analysed and each strut was examined for apposition. A strut was defined as embedded when it was buried in the intima for more than half its thickness, protruding when apposed to the intima but not embedded, and malapposed when there was no intimal contact. A stent was defined as well apposed when all struts were either embedded or protruding. Mean neointimal area for each arterial segment was measured.
Results: Angiography in all stented arteries revealed no acute or subacute thrombosis or restenosis. OCT image acquisition was successful in all cases. OCT revealed no severe stenosis or thrombus. We acquired 143 cross-sectional images from 130 mm of 13 stents in 12 arteries. Images with poor quality and images located in a major side branch were excluded. From the total of 1303 struts analysed, 1271 (97.5%) were embedded, while only 32 (2.5%) struts were protruding and none malapposed. All stents were well apposed. Mean neointimal area was 0.30±0.30 mm2 comprising 5.31% of the lumen area.
Conclusions: This study demonstrated the safety of the bevacizumab-eluting stent implantation in animal models. The bevacizumab-eluting stent inhibits intimal hyperplasia. Further clinical trials are needed in order to show its efficacy as a potential treatment of vulnerable plaques.

9:30 a.m.

2502-562 Fully Automated Iterative 3D Reconstruction of Rotational Coronary X-Ray Angiograms: A Feasibility Study

Anne M. Neubauer, Joel A. Garcia, John C. Messenger, Eberhard Hansis, Michael S. Kim, Andrew J. Klein, Gert A. F. Schoonenberg, John D. Carroll, Michael Grass, Philips Research, Briarcliff Manor, NY, University of Colorado, Denver, CO

Background: The lack of 3D data from typical angiography has limited its use for accurate lesion characterization, quantification of vessel properties (curvature and bifurcation angles) and interventional roadmapping. Existing methods for generating 3D representations require user interaction or suffer from significant motion artifacts. We describe and evaluate a strategy which overcomes these limitations.
Methods: 23 patients referred for diagnostic coronary angiography underwent a 7.2 s acquisition of the LCA and RCA during a 180° rotational run (Philips Allura Xper FD20). *Fully automatic* processing of the images consisted of: least motion cardiac phase determination, gated iterative reconstruction, and 2D motion compensation within the gating window (see Figure). Two interventional cardiologists qualitatively evaluated the 2D and 3D images of 23 LCAs and 17 RCAs for image quality and clinical utility.
Results: No adverse events resulted from the extended injection and the 2D images were adequate for CAD screening. The quality of the reconstructions was rated 3.7±1.1 (LCA) and 4.3±0.9 (RCA) and the average clinical utility score was 3.0±1.4 (LCA) and 3.0±0.92 (RCA) out of 5 with good agreement between the two observers. The 3D reconstructions allowed the evaluation of more segments than the 2D data in 85% of cases.
Conclusion
These results show the that the 3D reconstruction algorithm is not only feasible but also helps compensate for the limitations of 2D angiography.

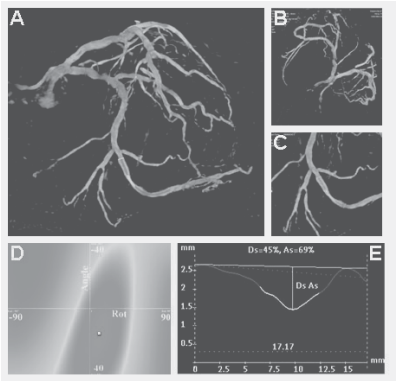


Figure: A) Sample 3D reconstruction of an LCA with an in-stent restenosis lesion (blue and yellow). This was assigned a quality and clinical utility score of 3.5 by the two observers. **B**) View of 3D reconstruction (RAO 97 Cran 38) optimized to show the left main-LAD-LCX bifurcation. **C**) Magnified view of the lesion in A. **D**) Optimal viewing angle map which minimizes foreshortening of the segment. **E**) 3D lesion quantification.

9:30 a.m.

2502-563 Development of Novel Adenosine Polymers for Coating Medical Devices

Mervyn B. Forman, Jianying Zhang, Zaichuan Mi, Edwin K. Jackson, St. Joseph Translational Research Institute, Atlanta, GA

Background: Percutaneous coronary intervention (PCI) procedures in ST segment elevation myocardial infarction (STEMI) and acute coronary syndromes (ACS) are frequently complicated by vascular and organ damage secondary to reperfusion injury, no-reflow phenomenon (NRF), and microembolization. Adenosine (ADO) is an endogenous nucleoside that ameliorates many of the adverse processes activated during PCI and significantly reduces infarct size in STEMI. ADO's therapeutic potential is compromised during PCI due to its ultra-short half life (~ 1-2 seconds) and dilutional effects with catheter administration. Prophylactic and continuous local infusion of ADO during PCI would optimize its cardioprotective effects.
Methods: We embarked on a project to develop a number of unique polymers with special characteristics to allow ADO to be covalently bonded. The goals were: (i) the polymers should consist of physiological components, rapidly release ADO, and degrade into non-toxic substances; (ii) the polymers can be coated onto medical devices such as guide wires and stents; (iii) a continual release of pharmacological amounts of ADO should occur during the duration of a PCI procedure (30-60 minutes).
Results: A number of unique polymers were developed composed of adenosine, lysine methyl esters, and either glycerol or cysteine. These polymers undergo non-enzymatic hydrolysis rapidly in contact with aqueous solutions. A significant release of ADO occurred in an in vitro system with coated guide wires within 10 minutes and continued for another 50 minutes. In vivo experiments utilizing a small animal model infused with potent vasoconstrictors to mimic NRF exhibited a significant increase in arterial blood flow over 50 minutes with the ADO-coated wire compared to controls. Pilot studies in the porcine model revealed that the coated wire produced a striking increase in coronary blood flow and prevented vasoconstriction induced by intracoronary infusion of endothelin-1.
Conclusion: The development of unique polymers containing adenosine and non-toxic monomers that can be coated onto guide wires and stents may significantly improve outcomes in patients with STEMI and ACS undergoing PCI procedures.

9:30 a.m.

2502-564 Percutaneous Coronary Intervention using a Novel 4-French Coronary Accessor "KIWAMI"

Satoshi Takeshita, Shinji Tanaka, Takaaki Shiono, Saeko Takahashi, Shigeru Saito, Shonan Kamakura General Hospital, Kamakura, Japan, Shonan Atsugi Hospital, Atsugi, Japan

Background: Percutaneous coronary intervention (PCI) using a guiding catheter with small diameters may have a favorable impact on vascular access complications and patient morbidity. Here, we report the initial results of PCI using a 4-Fr coronary accessor "KIWAMI".
Methods: Between July 2007 and September 2008, a total of 58 patients underwent 4-Fr PCI. Exclusion criteria were (1) lesions associated with side branches requiring wire protection and (2) planned use of angioplasty devices not compatible with 4-Fr catheter.
Results: Forty six patients were male (79%) and the average age was 71.6 ± 9.7 years (range, 38 to 85 years). Sixty eight lesions, including 6 chronic total occlusions (CTO), were treated. Access sites included radial artery in 43 patients (74%), brachial artery in 8 (14%), and femoral artery in 7 (12%). PCI was successful in 64 of 68 lesions (94%) in 56 of 58 patients (97%). Reasons for unsuccessful PCI included 2 CTOs,1 tortuous right coronary artery, and 1 cannulation failure. Among successfully treated 64 lesions of the 56 patients, coronary stents were deployed in 58 lesions (91%). There were no stent dislodgements or inadequate contrast opacification. No access-site related complications including radial artery occlusion were observed.
Conclusions: PCI using a 4-Fr coronary accessor is a viable alternative to the use of

larger guide catheters. The advent of this system may afford a less invasive approach for the treatment of patients with coronary artery disease.

Procedural Characteristics

Number of lesions treated per patient	1.2+0.4
Ad hoc coronary intervention	7 (12%)
Number of catheters used per patient	1.1+0.4
Number of pts crossed-over to 5 or 6 Fr	3 (5%)
Stent diameter (mm)	2.9+0.5
Stent length (mm)	18.1+7.2
Deep vessel intubation	48 (63%)
Direct stenting	5 (7%)
Fluoroscopy time (min)	12.1+12.2
Contrast dye volume (mL)	80.3+46.1

9:30 a.m.

2502-565 An Innovative Non-Invasive Respiratory Stress Test Indicates Significant Coronary Artery Disease

Ron Waksman, Steven Sushinsky, Petros Okubagzi, Patricia Landry, Rebecca Torguson, Anh Bui, Arthur Shiyovich, Amos Katz, Washington Hospital Center, Washington, DC

Background: Respiratory maneuvers can uncover manifestations of myocardial ischemia. Some pulse wave (PW) characteristics are strongly associated with significant coronary artery disease (S-CAD). An innovative test, using the respiratory stress response (RSR), has been developed for the detection of S-CAD. It is based on spectral analysis of finger pulse wave oscillations measured by photoplethysmography (PPG) during deep, paced breathing at a rate of 6 breaths per minute (0.1Hz) over 70 seconds. We aimed to investigate the value of RSR as a noninvasive tool for identification of S-CAD.
Methods: RSR was assessed, prior to the procedure, in 150 consecutive patients referred for coronary angiography. It was calculated by analyzing the relative spectral power of the respiratory peak area at 0.1 Hz using proprietary software. The coronary angiograms were analyzed by quantitative coronary angiography (QCA) by a cardiologist who was blinded to the RSR results. S-CAD was defined as luminal stenosis >70% of at least 1 coronary artery with a diameter ≥2 mm, or left main stenosis >50%.
Results: A valid RSR was obtained in 150/153 patients (98%) with a mean age of 58.7 ± 10.6 years (67% males). S-CAD was found in 36 patients (24%). S-CAD patients had significantly lower RSR compared to patients without S-CAD, (6.7% ± 5.1 vs. 17.4% ± 10.6, p<0.001, respectively). RSR ≤10.2% yielded a sensitivity of 86%, a specificity of 81%, and positive and negative predictive values of 59% and 95%, respectively for the detection of S-CAD. Multivariate logistic regression analysis, adjusted for known CAD risk factors, showed that RSR is a strong independent indicator of S-CAD (OR 41.2, 95% CI 12.2-139.3, p<0.001).
Conclusion: The innovative RSR test is a simple, non-invasive bedside or office-based tool for the detection of S-CAD.
Figure 1. Reduced Respiratory Stress Response in Significant CAD.

9:30 a.m.

2502-566 Comparison of Intravascular Ultrasound and Optical Coherence Tomography for the Evaluation of Stent Segment Malapposition

Noah Rosenthal, Giulio Guagliumi, Vasile Sirbu, Giuseppe B. Zoccai, Luigi Fioca, Giuseppe Musumeci, Alexandre Mathiasvili, Antonio Trivisonno, Hiro Kyono, Satoko Tahara, Daniel I. Simon, Marco Costa, Hiram G. Bezerra, University Hospitals Case Medical Center, Cleveland, OH

Background: Stent malapposition has been associated with stent thombosis. IVUS can be used to evaluate stent apposition, but has weaker resolution than Optical Coherence Tomography (OCT) which allows in-vivo evaluation of stent struts and coronary lumen to 10 microns.
Methods: Data were obtained from the ODESSA trial, a single center, randomized, controlled OCT study comparing luminal impact of overlapping drug eluting stents vs. bare metal stents. IVUS and OCT of stented vessels were performed 6 months post-implantation. Each stent was divided into proximal, overlap and distal segments. Malapposition by IVUS was defined as visible blood between a strut and luminal contour. Two methods were used by OCT: qualitatively (every 0.067mm) counting free struts without luminal apposition; and quantitatively (every 0.33mm), using a strut-to-lumen distance corrected for strut thickness. An arbitrary threshold to detect malapposition was used: ≥5 free floating struts in ≥3 frames. Cross sections at bifurcations were excluded. When OCT and IVUS disagreed, 3 experienced independent observers reviewed images for consensus. Sensitivity of IVUS and OCT to detect malapposition was evaluated against cases where both IVUS and OCT agreed.
Results: 43 coronary segments with matched IVUS and OCT images for analysis. IVUS identified 17/43 (40%) segments with strut malapposition vs. 40/43 (93%) by OCT. IVUS failed to identify malapposition in 23 cases (57%) detected by OCT. There were 5 segments with malapposition by IVUS but not by OCT: in 2, OCT identified struts at a bifurcation missed by IVUS; OCT missed malapposed struts in 2 cases from poor images; 1 was due to bridging coverage of malapposed struts.
The sensitivity of IVUS to detect malapposition was 39.5% with a specificity of 99.2% vs. OCT with 93.0% and 100.0% respectively. IVUS was 25.0% sens. and 99.0% spec. for malapposition in stent overlap segments, and 45.2% sens. and 99.4% spec. at non-overlapping sites.
Conclusions: Using the present strut-level malapposition criteria, OCT demonstrates more accuracy than IVUS in detecting stent strut malapposition. However, the extent of malapposition associated with increased risk of adverse outcome is still unknown.

9:30 a.m.

2502-567 How Do Intracardiac Devices Integrate into the Heart? Histopathologic Healing in Left Atrial Appendage Closure is Analogous to Intravascular Stent Healing

Robert S. Schwartz, David R. Holmes, Robert A. Van Tassel, Ray Matthews, Shepal Doshi, Renu Virmani, Minneapolis Heart Institute Foundation, Minneapolis, MN

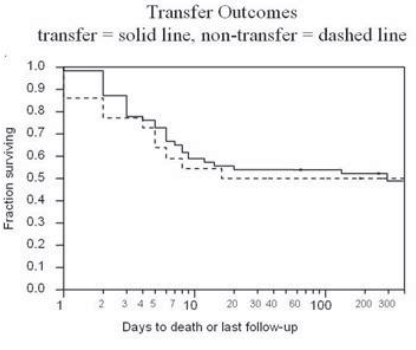
Background: Intracardiac devices integrate into the heart through poorly understood mechanisms. We studied healing of Left Atrial Appendage (LAA) obliteration and compared results with stent healing.
Methods: 9 dog hearts were examined at 3, 49 and 91 days after LAA implant, and the results compared with 2 human necropsy hearts with LAA obliteration.
Results: At 3 days, struts were apposed to the LAA wall. The atrial fabric mesh was covered by a fibrin film. Fibrin sealed gaps between the LA wall and the device. Thrombus filled the LAA body. Device contact sites showed submyocardial hemorrhage and edema. At 49 days, endocardial cells completely covered exposed surfaces. Continuous endocardial growth effectively sealed the device-LA interface. Prior fibrin deposition was replaced by endocardium that surrounded metal and fabric elements. Disorganized thrombus occurred within the device in the LAA body and at the periphery near the appendage walls. Granulation tissue and neovascularization occurred at the periphery. Mild inflammation was seen as the thrombus resorbed. No inflammation was found at metal strut contact sites. At 91 days, fibrous connective tissue covered the former LAA ostium with complete endocardial lining. Organizing thrombus had transformed into fibrous connective tissue, and no residual inflammation was evident.
The human necropsy hearts had similar findings. In both hearts (139 and 200 days post procedure) the fabric membrane was covered with organized endocardium. Organizing thrombus covered the under-surface. No significant inflammation occurred at the struts or fabric. Organizing fibrous tissue was seen inside the LAA, prominent at and near the atrial wall. The device interior contained RBC and organizing fibrin thrombus.
Conclusions: This temporal study of intracardiac device integration delineated stages of 1) early thrombus deposition, 2) thrombus organization, inflammation and granulation tissue, and 3) final healing by mature fibrous connective tissue, and endocardialization. These healing histopathologic stages are similar to those of intravascular stents that integrate into coronary and peripheral arteries.

9:30 a.m.

2502-568 "Cool It": Therapeutic Hypothermia as a New Standard of Care in Treating Transfer Patients Following Out-of-Hospital Cardiac Arrest

Leah Swanson, Kalie Edelstein, William Parham, Daniel O'Laughlin, Barbara T. Unger, David Page, Tony Sundholm, Eric Gage, James Hodges, Wes R. Pedersen, William T. Katsiyiannis, Timothy D. Henry, Michael R. Mooney, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: Recent trials have shown that therapeutic hypothermia (TH) reduces mortality and improves neurological outcome in comatose survivors out-of-hospital cardiac arrest (OOHCA). Widespread implementation of TH in the United States is limited by the lack of data supporting the safe transfer and treatment of these high risk pts by organized systems of emergency care.
Methods: The Cool It program established a regional TH system transferring pts up to 200 miles from the TH capable center. OOHCA pts were cooled to 33ºC for 24 hours. Cerebral function after TH was measured by the five point Pittsburgh Cerebral Performance Category (CPC) scale. CPC 1 and 2 are positive neurological outcomes.
Results: From 2/06 to 5/08, 85 pts were treated with TH; 63 were transferred from outstate hospitals. Comparing non-transfer pts to transfer pts, no difference occurs in survival rate (50% vs. 54%, p=0.81) or positive neurological outcome among survivors (82% vs. 97%, p=0.14). For each hour TH was delayed, the relative risk of death increased by 20%.
Conclusions: The transfer of TH pts does not compromise survival or neurological recovery following OOHCA. This program relies on rapid initiation of TH with ice packs in the field, organized protocols, and intensivist management. With this data, TH becomes a more relevant standard of care for OOHCA and should be a part of every large acute MI and cardiovascular emergency transfer program.



9:30 a.m.

2502-569 **The Same Day Discharge after Coronary and Peripheral Percutaneous Interventions. Bivalirudin and Catalyst II Wire System Strategy (GO HOME Study)**

R. Stefan Kiesz, Pawel E. Buszman, Barbara K. Wiernek, Szymon L. Wiernek, Martin G. Radvany, George V. Nazarewicz, Jack L. Martin, San Antonio Endovascular & Heart Institute, San Antonio, TX

Background: The majority of coronary and peripheral interventions are performed with an overnight stay. That increases the cost and adds little if any to patient safety. Bivalirudin has been shown to decrease bleeding complications in comparison to heparin. Cardiva Catalyst II Wire device facilitates site closure after intervention and leaves nothing behind. We hypothesized that by combining Bivalirudin with the Catalyst II Wire System we can safely discharge patients within 5 hours after interventions.
Methods: Since January 2008 in our outpatient cath lab we performed 110 interventions on 71 consecutive patients (46 male, mean age 62.4 ± 10.2, range 43-83). All procedures, 45 (40.1%) coronary, and 65 (59.9%) peripheral were performed exclusively with Bivalirudin. Thirty three (46.5%) patients were diabetic, 15 (21.1%) on dialysis, 65 (91.5%) had hypertension, 64 (90.1%) had hyperlipidemia and the average BMI was 30.3 ± 6.5 (range 20.1-47.9). The primary endpoint was assessment of major adverse events (death, stroke, myocardial infarction [MI], target lesion revascularization [TLR], severe GUSTO bleeding) in short term follow-up.
Results: The average time of observation was 4.9 ± 2.6 months. Procedural success was achieved in 44 (97.7%) coronary and 63 (96.9%) peripheral procedures. Thirty two (96.7%) procedures below the knee, were done with antegrade 4 French access. The Catalyst II Wire System device was applied successfully after 107 (97.2%) procedures. All patients were discharged home the same day in up to 5 hours after the intervention. No major adverse events were noted in short term follow-up. Site echymosis was noted after 30 (27.2%) procedures, haematoma (2-5cm) after 5 (4.54%), retroperitoneal bleeding after 1 (0.9%) and pseudoaneurysm after 1 (0.9%).
Conclusions: The same day discharge after coronary and peripheral percutaneous interventions in a selected group of patients appears to not increase the risk of the procedure. The Catalyst II Wire System is a safe and effective device in achieving hemostasis and in combination with Bivalirudin allows patients to go home the same day.

I2.POSTER CONTRIBUTIONS

2503

Vascular Access, Closure Devices and Complications

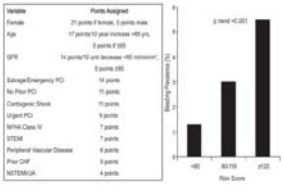
Sunday, March 29, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2503-570 **A Clinical Risk Prediction Tool for Post-PCI Bleeding From the National Cardiovascular Data Registry® (NCDR®)**

Jason B. Lindsey, Sameer K. Mehta, Andrew D. Frutkin, John A. Spertus, Sunil V. Rao, Fang-Shu Ou, Matthew T. Roe, Eric D. Peterson, Steven P. Marso, Mid America Heart Institute, Kansas City, MO, Duke Clinical Research Institute, Durham, NC

Background: Bleeding after percutaneous coronary intervention (PCI) is associated with increased morbidity and mortality. A clinical tool to estimate bleeding risk may enable physicians to tailor peri-PCI therapy and mitigate risk.
Methods: PCI procedural data at 440 U.S. centers in the NCDR® from 2004-06 were examined. Bleeding was defined as resulting in transfusion, increased length of stay, and/or >3gm/dL decrease in hemoglobin occurring at vascular entry site, retroperitoneal, gastrointestinal, genitourinary or other location. A random sample of 80% of patients was used to develop a model to estimate risk of post-PCI bleeding; the remaining 20% comprised a validation cohort. Variables in the risk model were assigned a weighted integer based on the z-score to develop a simplified risk score.
Results: There were 302,152 patients with a bleeding rate of 2.4%. The model using pre-PCI variables associated with post-PCI bleeding performed adequately overall (c-statistic = 0.73). Independent predictors of bleeding and risk score assignment are shown in the figure (left). Bleeding rates increased with increasing risk score category (figure, right).
Conclusions: Using data from the NCDR, we developed a clinical tool that estimates post-PCI bleeding. This tool is potentially actionable, enabling physicians to consider alternative strategies in high risk patients that are associated with lower rates of bleeding e.g., radial PCI, smaller sheath size and alternative anticoagulation strategies.

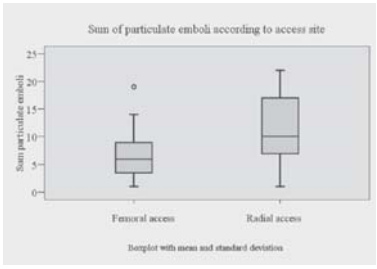


9:30 a.m.

2503-571 **Cerebral Embolism is Related to Access Site at Coronary Angiography**

Juliane Jurga, Jesper Nyman, Nondita Sarkar, Per Tornvall, Maria N. Mannila, Peter Svenarud, Jan van der Linden, Dep of Cardiology, Karolinska University Hospital, Karolinska Institutet, Stockholm, Sweden, Dep of Cardiothoracic Surgery and Anesthesiology, Karolinska University Hospital, Karolinska Institu, Stockholm, Sweden

Background: Stroke is an unusual but severe complication of coronary angiography (CA). Its cause is not entirely explained, but the choice of access site might be of importance. The aim of this study was to investigate if the number of particulate cerebral emboli during CA is related to the access site. **Methods**: Fifty patients with stable angina pectoris referred for CA and with normal hand collateral blood flow were randomized to right femoral or right radial access site. A transcranial Doppler with bilateral probes was used to automatically register the number of particulate emboli passing each middle cerebral artery (MCA) during every part of the procedure. The Mann-Whitney U test was used for comparisons. **Results:** Eight patients were converted to the femoral approach due to problems cannulating the left coronary artery. The number of particulate emboli was significantly higher with radial than with femoral access site 10.9±6.3 (n=19) versus 6.9± 4.7 (n=23, p= 0.036, Figure). More emboli passed the right MCA with radial (6.8±4.7) than with femoral access (3.0±2.4, p=0.007), whereas there was no difference on the left side. Specific parts of the CA procedure showed to be embogenic such as change of catheters. **Conclusion:** The present study provides novel evidence indicating that the vascular access site and certain procedural steps have a substantial impact on the number of particulate cerebral emboli. The finding that more particles passed the right MCA with the right radial approach denotes a causal linkage.



9:30 a.m.

2503-572 **Are neurologic complications following percutaneous coronary diagnostic or interventions more common in transfemoral versus transradial approach?**

Helena Tizon-Marcos, Gerald barbeau, Jacques Rouleau, Louis Roy, onil gleeton, Guy proulx, J-Pierre Dery, olivier Bertand, cM nguyen, bernard Noel, josep Rodés-Cabau, eric larose, stephane Rinfret, robert De Larochellière, Laval hospital, quebec, QC, Canada

Introduction: Neurologic complications (NC) have been described as a rare but potentially catastrophic complication following transfemoral coronary angiography and interventions. Recently, transradial approach is showing less incidence of complications with similar per-procedural succeed.
Objectives: Determine the incidence and characteristics of neurological complications between transradial and transfemoral approach.
Methods: Retrospective review of all charts of patients with coronary angiography or interventions from April 1990 to October 2007 and per-procedural NC in our center. Analysis was performed comparing multiple clinical and procedural variables.
Results: NC occurred in 54 of the 83,409 patients (0.06%).

	Radial patients	Femoral patients	p
N patients with NC	26/52191	28/31218	0.029
% of entire population	(0.05%)	(0.09%)	
NC in diagnostic procedures	9/28411 (0.03%)	24/23607 (0.1%)	0.0024
NC in interventional procedures	17/23780 (0.07%)	4/7611 (0.05%)	0.799
Type of NC,%			
- Non hemorrhagic stroke	65.5	68	
- Hemorrhagic stroke	11	3.5	
- AIT	23.5	28.5	
Inhospital mortality, %	23	3.6	0.047

Conclusions: In this large series, per-procedural cerebrovascular accident was an uncommon complication of both coronary angiography and interventions. Compared to transfemoral approach, transadial approach is associated with a lower incidence of per-procedural CVA (0.049% vs 0.089%, p= 0.029). No differences between type of stroke and approach were found. Mortality of patients with transradial approach and NC was higher in our series.

9:30 a.m.

2503-573 Lower Concentration of Heparinized Flush Solution is Associated With a Higher Incidence of Femoral Sheath Clot Following Diagnostic Cardiac Catheterization

Kristen E. Casale, Michael A. Horst, Angela S. Anderson, Richard B. Devereux, Lancaster General Hospital, Lancaster, PA, Weill Cornell Medical College, New York, NY

Background: The concentration of heparinized saline flush solution used in catheters and sheaths during diagnostic cardiac catheterization varies by laboratory. It is unknown if lower heparin concentration in flush solution is associated with a higher incidence of femoral sheath clot.
Methods: 853 patients (pts) undergoing diagnostic cardiac catheterization were randomized to receive either 2 unit/ml (group 1) or 6 unit/ml (group 2) of heparin in the saline flush solution for catheters and sheaths. Clinical and procedural variables were analyzed by multiple logistic regression analysis to identify independent predictors of post-procedure femoral sheath clot.
Results: 212 of 404 pts.(52.5%) in group 1 developed femoral sheath clot compared to 133 of 448 pts.(29.7%) in group 2, p<.001. Of the clinical and procedural variables analyzed, procedure time ≥16 minutes, sheath size ≥5 French, no flushing of sheath between catheter exchanges and older age were associated with a higher incidence of femoral sheath clot. After adjustment for these variables, lower heparin concentration was associated with a 2.7-fold higher incidence of femoral sheath clot (Table 1).
Conclusions: Femoral sheath clot was identified more frequently when 2 unit/ml heparinized saline flush solution was used compared to 6 unit/ml after adjusting for clinical and procedural variables. The 63% lower incidence of sheath clot with 6 unit/ml heparin may help guide decisions regarding heparin concentration for flush solutions.

Table 1: Multivariate Logistic Regression Analysis

Variable	odds ratio	confidence interval	p value
2 unit/ml heparin	2.67	1.97-3.63	<.001
sheath size ≥5 French	6.00	2.87-12.52	<.001
procedure time ≥16 min.	1.56	1.14-2.13	<.001
no flushing of sheath between catheter exchanges	3.75	2.66-5.28	<.001
age (per 10 yrs)	1.22	1.07-1.38	<.01

9:30 a.m.

2503-574 Unsuccessful Transradial Approach for Percutaneous Coronary Interventions: Predictors and Mechanisms of Radial Access Failure

Payam Dehghani, Tony Hong, Colin M. Suen, Waseem Sharieff, Atif Muhammad, Robert J. Chisholm, Michael J.B. Kutryk, Neil P. Fam, Asim N. Cheema, St. Michael's Hospital, Toronto, ON, Canada

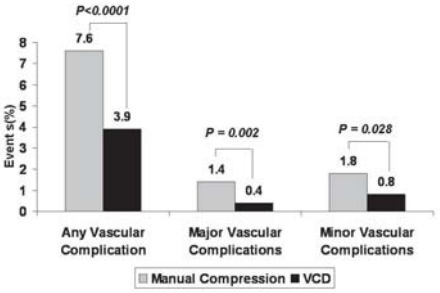
Background: Radial access for percutaneous coronary intervention (PCI) results in early ambulation and a lower risk of vascular access site complications. However, the mechanism and predictors of radial access failure (RF) in a diverse patient population are poorly understood. In this study, we sought to determine the mechanisms and predictors RF in a large cohort of patients undergoing transradial PCI.
Methods: All patients undergoing transradial PCI at our center between June 2002 and June 2005 were included in the study. Baseline clinical characteristics, procedural details, and clinical outcomes were prospectively collected. RF was defined as an inability to complete PCI procedure by the radial approach. Logistic regression analysis was applied to determine the predictors of RF.
Results: A total of 2100 patients underwent transradial PCI during the study period and were included in the analysis. The mean age was 62±10 years, 83% were male, 38% presented with an acute coronary syndrome and 66% were treated with GPIIb/IIIa antagonist. Vascular complications occurred in 18 (0.9%) and 9 (0.5%) patients received blood transfusion. A total of 98 (4.7%) patients experienced RF. This was due to unsuccessful arterial puncture in 13 (13%), inability to advance equipment beyond brachial artery in 50 (51%) due to spasm in 33 (66%) followed by radial artery dissection in 10 (20%), inability to maneuver the tortuous subclavian artery in 18 (18%), and poor guide catheter support for PCI in 17 (17%) patients. Of those with RF, the PCI was completed successfully in 94 (96%) of patients through a femoral approach. On multivariate regression analysis, age >75 (OR=3.86; CI=2.33, 6.40, p<0.0001), previous CABG (OR=7.48; CI=3.45, 16.19, p<0.0001) and short stature (OR=2.55; CI=1.22, 5.32, p = 0.02) were independent predictors of RF.
Conclusions: Radial access for PCI in a diverse patient population is associated with a low rate of failure (<5%) and vascular complications (<1%). Predominant mechanisms of RF were radial artery spasm, subclavian artery tortuosity, and an anatomy with unsuitable back-up for PCI. Advanced age, precious CABG and short stature were independent predictors of RF.

9:30 a.m.

2503-575 Prevention of Vascular Access Site Complications with Vascular Closure Devices in Patients with Diabetes Undergoing Cardiac Catheterization

Sripal Bangalore, Nipun Arora, Kevin Bainey, Thomas Todoran, Pallav Garg, Pinak B. Shah, Frederick S. Resnic, Brigham and Women's Hospital, Boston, MA

Background: The efficacy of VCDs in patients with diabetes, who are considered to be at increased risk of vascular complications, is not well defined.
Methods: We evaluated 3398 consecutive diabetic patients undergoing cardiac catheterization. Major vascular complications was defined as any retroperitoneal hemorrhage, limb ischemia, or any surgical repair. Minor vascular complications was defined as any groin bleeding, hematoma (>=5 cm), pseudoaneurysm, and arteriovenous fistula. 'Any' vascular complications was defined as either a major or minor vascular complication.
Results: Among the 3398 patients, 2600 (76.5%) received a VCD while the rest had manual compression. Compared to manual compression, VCDs were associated with a significant reduction in the risk of any, major or minor vascular complications (Figure). Use of VCDs was the strongest predictor [Chi^2 = 22.6; OR = 0.43 (0.30-0.61); P <0.0001] for decrease in the risk of any vascular complications even after controlling for age, female gender, history of peripheral arterial disease, chronic renal insufficiency, use of GP IIB/IIIA, a emergent or an urgent procedure, MI on presentation and using a 7.0 Fr or greater arterial sheath size, which were all multivariable predictors of vascular complications.
Conclusions: VCD use is the strongest predictor of decrease (57%) in the risk of vascular access site complication in patients with diabetes. VCD benefit extends beyond mere reducing the time to ambulation in patients with diabetes.



9:30 a.m.

2503-576 Left Radial Versus Femoral Approach in Primary Percutaneous Coronary Intervention - Prospective Comparison

Ivo Bernat, Jiri Koza, Jan Pesek, Jitka Tesarova, Richard Rokyta, University Hospital, Plzen, Czech Republic

Background: Transradial approach reduces access site bleeding complications. Right radial artery is routinely used for coronary interventions although 90% of the population is right handed. The aim of this study was to compare left radial (LR) and femoral approach (FA) in primary percutaneous coronary intervention (PCI).
Methods: From January to December 2007, 297 consecutive patients (pts) with acute myocardial infarction (STEMI) were treated by primary PCI in our institution. 255 pts were enrolled to this prospective non randomized study: LR 129 pts versus (vs) FA 126 pts. Exclusion criteria were: cardiogenic shock (n=22), right radial approach (n=18) and brachial approach (n=2). Both groups did not differ significantly in age (63,7±11,3 vs 64,4±10,9 years), gender (75% vs 67% males), body mass index (28±4 vs 29±5) and Killip class I (105 vs 107), II (21 vs 12), III (3 vs 7).
Results: Procedural duration (45±21 vs 43±19 min), fluoroscopy time (10,3±7,4 vs 9,2 ±6,3 min) and technical procedural success (96% vs 97%) were not significantly different (p=NS). Contrast consumption was lower in LR group (144±52 vs 162±53ml, p<0,05). Serious access site bleeding complications occured only in FA group (0 vs 5 pts, p<0,05). In hospital mortality was 2,3% in LR and 4,0% in FA group (p=NS). Conversion to FA was necessary in two (1,6%) pts. At discharge three (2,3%) pts had asymptomatic loss of the left artery pulsation.
Conclusions: Left radial approach for primary PCI is safe, feasible and effective in STEMI patients without cardiogenic shock. Minimal risk of serious access site bleeding complications is the main advantage in comparison with femoral approach. Postprocedural immediate normal right hand mobility is an added benefit for right handed patients.

9:30 a.m.

2503-577 Quality of Life after Same-day Discharge or Overnight Hospitalization after Transradial Coronary Stenting and Maximal Antiplatelet Therapy. Results of the Randomized EASY Trial.

Olivier F. Bertrand, Javier Courtis, Stéphane Rinfret, Olivier Costerousse, Éric Larose, Rodrigo Bagur, Helena Tizon-Marcos, Can M. Nguyen, Robert De Larochellière, Paul Poirier, Louis Roy, Josep Rodes-Cabau, Laval Hospital, Quebec Heart-Lung Institute, Quebec, QC, Canada

Background: : It is unknown whether same-day home discharge after PCI impacts differently health-related quality of life (HRQOL) measures compared to standard overnight hospitalisation.
Objective : To compare early and late HRQOL in acute coronary syndrome (ACS) patients discharged home the same-day (SD) or after overnight hospitalisation (OH) after transradial coronary stenting and maximal antiplatelet therapy in the randomized EASY trial.
Methods : We administered the Medical Outcomes Study Short-Form Survey (SF-36) at baseline, 1, 6, and 12 months after uncomplicated transradial PCI in patients randomized to SD (n =504) or OH (n = 501). The questionnaire contains 36 items that, when scored, yields 8 domains (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). All patients were pretreated with ASA and

clopidogrel (90% > 12h) and received abciximab bolus prior the first balloon inflation.
Results : At baseline, no differences were noted between the 2 groups. After 1 month, significant improvement was observed in 7 domains in both randomized groups ($P < 0.05$) but no change was detected in the general health domain. The amplitude of improvement was similar in both groups. Between, 1 month and 6 months, further significant ($P < 0.05$) and similar improvement was observed in role-physical and -emotional and social-functioning domains whereas other domains remained stable until 12 months. There was no change in any domain between 6-months and 12-months.
Conclusion: After transradial PCI and maximal antiplatelet therapy in ACS patients, several dimensions of health status improve during the first 6 months of follow-up and remained stable up to 1 year after PCI. The duration of hospitalization after uncomplicated trans-radial PCI has no impact on health recovery.

9:30 a.m.

2503-578 Impact of Micropuncture on Vascular Access Site-Related Complication Rates in Percutaneous Coronary Interventions

Louie Kostopoulos, Babak Haddadian, Mohamed Rahman, Alfred J. Anderson, Joaquin Solis, Ramagopal Tumuluri, Anjan Gupta, Tanvir Bajwa, Suhail Allaqaband, Aurora Sinai/Aurora St. Luke's Med Ctrs, Univ Wisconsin School of Medicine and Public Health-MCC, Milwaukee, WI

Background: Vascular access site-related complications during percutaneous coronary interventions (PCI) are known to increase morbidity and mortality. In spite of its widespread use, the ability of micropuncture to lower these complication rates has not been validated. We reviewed our access-site complication rates from 2005 to 2007 in patients undergoing PCI; access via the traditional 18-gauge thin-wall needle (TWN) versus the 21-gauge micropuncture kit (MPK).
Methods: Data was extracted from the ACC-NCDR CathPCI Registry. Event rates of 1,706 patients who underwent PCI with TWN access from 1/05 to 1/06, and 1,997 patients with MPK from 7/06 to 7/07 were reviewed. Primary endpoints included ACC-defined vascular complications of bleeding and pseudoaneurysm confirmed by ultrasound.
Results: Overall bleeding rates using TWN versus MPK were 1.5% (26/1706) and 1.9% (41/1997) (p=0.5) and pseudoaneurysm rates were 0.8% (14/1680) and 1.3% (25/1974) (p=0.25), respectively. There was a trend towards a higher mean clopidogrel loading dose in the MPK group (360 mg for MPK vs. 297mg for TWN); the highest loading dose of 600 mg was observed more frequently in the MPK group (39% versus 8%). Test for linear trend in proportions among the varied loading doses between the two groups was not found to be statistically significant (p<0.08).
Conclusion*:* Use of MPK for gaining vascular access in PCI did not contribute to reduced site-related complication rates.

BLEEDING EVENT RATES

Hematoma >10cm diameter + either	Thin-Walled Needle (n=26)	Micropuncture (n=41)	p-value
Need for transfusion	12 (46.2%)	19 (46.3%)	0.47 (ns)
Prolonged length of stay	10 (38.5%)	18 (43.9%)	0.35 (ns)
Hb decrease > 3g/dl	4 (15.4%)	4 (9.8%)	1.0 (ns)

9:30 a.m.

2503-579 Randomized comparison of Angio-seal vs. Starclose for closure of femoral artery access in coronary catheterization

Jong-Young Lee, Sung Sik Kim, Myung-Zoon Yi, Sung-Hwan Kim, Duk-Woo Park, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Myeong-Ki Hong, Seong-Wook Park, Seung-Jung Park, Asan medical center, Seoul, South Korea

Background: Percutaneous vascular closure devices (VCDs) decrease the time to ambulation and decrease complications for patients undergoing invasive cardiovascular procedures via femoral artery access. Currently, the collagen-anchor-suture mediated device (Angio-Seal) and clip-mediated device (Starclose) were most commonly used. We compare the safety and efficacy of these two devices for patients receiving cardiac cauterization via femoral access.
Methods: Patients undergoing coronary intervention via femoral approach were randomly assigned to receive either AngioSeal or StarClose VCD. Study end points were success of hemostasis and major vascular complication within 1 month. Success of hemostasis was defined as absence of pulsatile blood leakage directly after device placement. Major vascular complication was defined as puncture site bleeding necessary transfusion, distal device embolization, aggravated claudication, AVF, pseudoaneurysm and femoral artery compromise.
Results: Total 238 patients (Angioseal, N = 116 versus Starclose, N = 122) were enrolled from August 2007 through February 2008 in Asan Medical Center. There was no significant differences in baseline characteristics including antiplatelet medication, baseline coagulation level, and sheath size. Successful hemostasis was not achieved in 4 (3.2%) patients of Starclose group and no in Angioseal group (p=0.12). The rate of oozing necessitating immediate manual compression was significantly higher in Starclose group than in Angioseal group (37.4% vs. 20.0%, p=0.003). The incidence of early hematoma (≤12 hours) (13.8% vs. 11.3%, p=0.56) and bruising area (67 ± 70cm^2 vs 31 ± 29 cm^2, p=0.08) were not significantly different. However, late hematoma formation (≥12 hours) was significantly higher in Angioseal group than in Starclose group (8.7% vs. 0, p=0.001). There were no significant major vascular complications.
Conclusions: Two different VCD are simialry safe and effective for percutaneous occlusion of femoral access. However, the rate of oozing with additive manual compression was significantly higher in Starclosure group than Angioseal group, whereas the incidence of late hematoma was vice versa.

I2.POSTER CONTRIBUTIONS

2504

Aortic and Pulmonic Valve Intervention

Sunday, March 29, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2504-580 Assessment of Aortic Valve Performance After Transcatheter Aortic Valve Replacement: Interim Report from the REVIVE II and REVIVAL II Clinical Trials

Mathew Williams, William O'Neal, Helene Eltchaninoff, Susheel Kodali, George Hanzel, Thierry Lefevre, Michael Pichard, Craig Smith, Linda Gillam, Samir Kapadia, John Webb, Jeffrey Moses, Martin Leon, Columbia University, New York, NY

Background: Transcatheter aortic valve replacement (TAVR) has been an investigational procedure for several years and although clinical outcomes have been encouraging, little is known about bioprosthetic valve function over time. This analysis was designed to examine a consecutive series of TAVR patients (Edwards-Sapien valve) with serial echocardiographic studies to assess mean valve gradients (MVG), effective orifice areas (EOA), paravalvular aortic regurgitation (pAR), and other signs of prosthetic valve deterioration.
Methods: All patients were enrolled in the REVIVE II (EU) and REVIVAL II (US IDE) non-randomized feasibility studies for high surgical risk or non-operable patients with severe aortic stenosis (AS). Patients had transfemoral implantation of the balloon-expandable bovine pericardial Edwards-Sapien stent valve (sizes = 23mm and 26mm). Bioprosthetic valve function was assessed by serial echocardiograms which were interpreted in a single core laboratory.
Results: 161 patients were enrolled of whom 61 had echo data available at one year. Patients had a significant reduction in MVG and improvement in EOA (MVG: from 42.8±17.1 to 10.7±4.0 mmHg, p<0.001 and EOA: from 0.57±0.14 to 1.54±0.46 cm2, p<0.001) which was sustained at one year (MVG: 9.5±3.6 mmHg and EOA: 1.54±0.46 cm2). After TAVR, 62.4% had 0/1+, 34.6% had 2+, and 3% had 3/4+ pAR, which was unchanged at mean follow-up of 268 days (53.5% 0/1+, 36.6% 2+, and 9.9% 3/4+ pAR). Of those patients with 2+ or greater pAR, LV diastolic and systolic volumes trended to become smaller (LVEDS: 99.5 ml v. 86.5 mm, p=0.18 and LVESV: 46.8 ml v. 35.8 mm, p=0.22) and LVEF improved (51.8% v. 57.6%, p=0.05) over time. There were no cases of bioprosthetic valve deterioration.
Conclusion: TAVR using the Edwards-Sapien valve results in excellent hemodynamic valve performance which is sustained for at least one year. pAR does not progress over time and there is no evidence of LV remodeling or dysfunction in patients with ≥ 2+ pAR. Continued echocardiographic surveillance is required to assess long-term TAVR durability.

9:30 a.m.

2504-581 Percutaneous Mitral Valvuloplasty During Pregnancy

Hung Manh Pham, Oanh Ngoc Pham, Hieu Lan Nguyen, Quang Ngoc Nguyen, Loi Doan Do, Viet Lan Nguyen, Khai Gia Pham, Hanoi Medical School, Hanoi, Viet Nam, Vietnam Heart Insitute, Bachmai Hospital, Hanoi, Viet Nam

Background: Circulatory changes in gestation, a hyperdynamic adaptive state in general, cause an additional burden on the cardiovascular system of women with rheumatic mitral stenosis (MS). Percutaneous Mitral Valvuloplasty (PMV) has emerged as an effective nonsurgical technique for the treatment of patients with symptomatic MS during pregnancy.
Methods: From November 1999 to Dec. 2007, 95 pregnant women (among 4700 PMV patients) were performed PMV using Inoue balloon at Vietnam Heart Institute. The transthoracic echocardiography was used in combination with intermittent fluoroscopy to limit the radiation exposure time. A detailed clinical, echocardiographic, hemodynamic assessment was analyzed pre, post procedure, at every 3 months for the first year and at 6-month interval thereafter. The pregnancy and newborn babies outcomes were also followed.
Results: MS pregnant women were 27,6 years old on average (ranged 22-42) and the mean length of pregnancy was 24,2 ± 5,6 weeks. Echo score of mitral valve was 7,1 ± 2,3. The procedure was technically successful in all cases without any complications. The good result (MVA post PMV greater than 1.5cm^2) was obtained in 85 cases (89.5%). The total mean duration of the procedure was 35,25 ± 14,28 min and that of fluoroscopy 2,55 ± 1,28 min (from 1 min 59 sec to 3 min 15 sec). The fluoroscopy time was significantly shorter than that of usual patients not using echo guided (2 min 23 sec vs. 7 min 23 sec, p< 0.01). The mitral valve area increased from 0,7 ± 0,3 to 1,9 ± 0,4 cm2 (on 2D echocardiography) and from 0,8 ± 0,4 to 2,0 ± 0,4 cm2 (on PHT) (p< 0.01). A reduction in mean transmitral valve gradient (MVG) was from 22 ± 6 to 8 ± 2 mmHg. There were no maternal or fetal deaths. All patients delivered at full term but 9 (without major complications), 37 vaginally and 49 by caesarean section. After average 36 months follow-up (range, 3 to 60) all children had normal growth.
Conclusions: During pregnancy, Percutaneous Mitral Valvuloplasty could be considered as the treatment of choice of severe pliable mitral stenosis which are refractory to medical treatment. Using echocardiography guided can reduce the fluoroscopy time.

9:30 a.m.

2504-582 **Comparison of Transapical and Transfemoral Aortic Valve Replacement for High Risk Patients With Severe Aortic Stenosis Using the Edwards Sapien Balloon-Expandable Bioprosthesis: In-Hospital and Medium Term Outcomes**

Mark D. Osten, Christopher Feindel, Barry Rubin, Kristeen Chamberlain, Joan Ivanov, Massimiliano Meineri, Melitta Mezody, Eric M. Horlick, University Health Network, Toronto General Hospital., Toronto, Canada

Background: Transcatheter aortic valve replacement (TCAVR) is an emerging alternative therapy to conventional open heart surgery in high risk surgical patients with symptomatic aortic stenosis. We sought to compare our experience with the transfemoral (TF) and transapical (TA) Edwards Sapien bioprosthesis (Edwards lifesciences, Irvine,Calif). **Methods:** Patients with severe aortic stenosis (area<0.8cm^2 and/or mean gradient >40mmHg) with NYHA class >2 and an operative mortality risk of >15% as assessed by a cardiologist and two surgeons were eligible for TCAVR. Two valve sizes were available:23- and 26-mm diameter using a 22Fr and 24Fr sheath system via the TF approach and a 24Fr sheath via the TA approach. **Results:** :A total of 30 patients(18-TA, 12-TF) with a mean valve area of 0.6+/-0.1cm^2,a mean age of 80.8+/-7.9,a mean logistic euroscore of 25.3+/-10.7, and a mean STS score of 8.0+/-4.4 were analyzed. Discharge home occurred at a median of 8 days in the TA group (range 5 to 47) and 14 days in the TF group (range 6 to 21). The mean follow up period was 164 days. Procedural success was 89% in the TA group and 92% in the TF group. There were 2 (1-TA, 1-TF) procedural deaths. Overall in-hospital mortality was 16% (2-TA, 3-TF). There was 1 procedural stroke in the TF group. Successful valve replacement was associated with an increase in valve area from 0.6+/-0.1cm^2 to 1.4+/-0.1cm^2 in the TA group and 0.6+/-0.1cm^2 to 1.2+/-0.1cm^2 in the TF group. At discharge, there was a significant improvement in mean gradient (p<0.0001), mitral regurgitation (p<0.01) and NYHA functional class (p<0.0001) in both groups. At medium term follow up the valve area was maintained (1.4cm^2 in both groups) (p<0.0001),and there remained an improvement in functional class in both groups compared to baseline (p<0.0001). At medium term follow up, there were no cardiac related deaths in either group. There were two late strokes in the TA group. Mild paravalvular regurgitation was common in both groups.**Conclusions:**:We observed similar in-hospital and medium term outcomes using the two currently available TCAVR techniques with the Edward Sapien bioprosthesis for the treatment of severe aortic valve stenosis in this high-risk population.

9:30 a.m.

2504-583 **Use of Balloon Aortic Valvuloplasty to Size the Aortic Annulus Prior to Implantation of a Balloon Expandable Transcatheter Heart Valve**

Vasilis Babaliaros, David Liff, Vinod Thourani, Edward Chen, Robert Guyton, Zahid Junagadhwalla, Stamatios Lerakis, Jacob Green, Kush Agrawal, Collins Kwarteng, Jason Guyotte, Ateet Patel, Roy Abrahamian, Thomas Vassiliades, Peter Block, Emory University, ATLANTA, GA

Background: Annulus sizing by balloon aortic valvuloplasty (BAV) during transcatheter heart valve (THV) procedures has not been studied and may aid in selecting appropriate THV size.
Methods: Patients (pts, n=20) with aortic stenosis (< 1.0cm2) scheduled for THV implantation were enrolled. Pre and post procedure echo measurements were made by TEE. A valvuloplasty balloon of known size and inflatable pressure was inserted into the aortic valve and inflated. The development of intra-balloon pressure in addition to the nominal inflation pressure (AIBP) reflected apposition of balloon and aortic annulus. THV implantation with a device ≥ 1mm than the balloon size that generated AIBP was subsequently performed.
Results: Intra-balloon pressure measurements were performed in 18 pts during BAV (unable to stabilize balloon for measurement, n=2), Table 1. In 1 pt, no AIBP was generated during BAV and THV size was chosen >3mm than TEE annulus size. Using the THV size based on balloon results, no valve embolization occurred or significant paravalvular leak was observed.
Conclusions: Intra-balloon pressure measurements during BAV can help size the aortic annulus and may help select the size THV that should be implanted. These data suggest a strategy of THV sizing ≥ 1mm + the Balloon size that generates AIBP.

Table 1. Patients Undergoing Aortic Annulus Sizing by BAV Before THV Implantation

Patient Number	TEE Annulus (mm)	Balloon Size (mm)	AIBP (atm)	THV Size (mm)
1	20	20	1	23
2	21	22	2	23
3	20	20	1	23
4	22	23	2	26
5	19	20	1	23
6	20	21	2	23
7	22	23	0.5	26
8	20	20	N/A	23
9	20	20	0.5	23
10	23	23	0	26
11	20	20	0.5	23
12	24	24	0.5	26
13	23	22	N/A	26
14	22	22	0.5	23
15	20	22	1	23
16	22	22	0.75	23
17	24	24.5	0.5	26
18	24	24	0.5	26
19	20	23	0.5	26
20	24	24.5	0.5	26

I2.SYMPOSIUM

2609

i2.Iliofemoral Disease: Evaluation, Treatment, Follow-up

Sunday, March 29, 2009, 10:30 a.m.-Noon
Orange County Convention Center, Room W414C

11:30 a.m.

2609-8 **In-Hospital Outcomes and Cost Comparison of Femoropopliteal Revascularization Strategies**

David M. Safley, Jason B. Lindsey, John A. House, Katherine Robertus, Keith B. Allen, Elizabeth Mahoney, David J. Cohen, Mid America Heart Institute, Kansas City, MO, University of Missouri - Kansas City, Kansas City, MO

Background: For patients undergoing femoropopliteal (FP) revascularization, atherectomy (ATH) has recently emerged as an alternative to angioplasty (PTA) with or without stenting or bypass surgery. Despite the increased use of ATH, there are few comparative studies of these alternative approaches to FP revascularization and no direct cost comparisons.
Methods: Consecutive patients (n=199) undergoing FP PTA (n=70), ATH (n=91) or surgical bypass (n=42) from 1/05 - 4/06 were included in this analysis. Hospital costs were calculated from detailed hospital cost accounting records. Professional fees were calculated from CPT codes and the Medicare Physician Fee Schedule. Between group differences were evaluated using Fisher's Exact Test for complication rates and the Wilcoxon rank-sum test for costs.
Results: Among the 3 treatment groups, there were no significant differences in baseline characteristics. Complication rates did not differ between groups except for higher rates of urgent repeat procedures after bypass (table). Total costs were similar for PTA and ATH but higher for bypass (table), due to longer length of stay.
Conclusions: For patients undergoing FP revascularization, initial clinical outcomes are comparable for PTA, ATH, and surgery but costs are higher with surgery. These findings suggest that either PTA or ATH may be acceptable initial treatment strategies if the anatomy is suitable. Long-term follow-up will be needed to determine if an initial surgical strategy can be justified.

In-Hospital Outcomes and Costs of Femoropopliteal Revascularization					
In-Hospital Outcomes	PTA (n=70)	Atherectomy (n=91)	p value*	Surgical Bypass (n=42)	p value†
Bleeding	8.7%	4.3%	0.33	7.1%	0.90
Urgent Revascularization	0.0%	2.2%	0.51	9.5%	0.02
Costs					
Total Costs	$10,945	$10,783	0.57	$14,947	<0.0001
Procedural	$7,396	$7556	0.75	$3,564	<0.0001
Non-Procedural	$2,655	$2347	0.57	$9,519	<0.0001
Professional Fees	$893	$880	0.78	$1,863	<0.0001
Length of Stay (procedural related)	0.46 ± 1.82	0.27 ± 0.96	0.40	3.48 ± 4.44	0.0001
*p-value is PTA vs atherectomy †p-value is PTA vs surgical bypass					

I2.SYMPOSIUM

2613

i2.Vascular Access and Closure

Sunday, March 29, 2009, 10:30 a.m.-Noon
Orange County Convention Center, Room W315B

11:30 a.m.

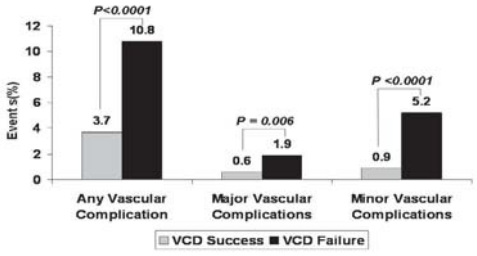
2613-8 **Vascular Closure Device Failure: Frequency and Implications**

Sripal Bangalore, Nipun Arora, Thomas M. Todoran, Kevin Bainey, Pallav Garg, Piotr S. Sobieszczyk, Frederic S. Resnic, Brigham and Women's Hospital, Boston, MA

Background: The frequency and consequence of failure of VCDs is not well defined.
Methods: 9838 consecutive patients who received either a collagen-plug (Angioseal) based or a suture-based (Perclose) VCD were selected. VCD failure was defined as unsuccessful deployment or failure to achieve hemostasis. Major vascular complications was defined as any retroperitoneal hemorrhage, limb ischemia, or need for surgical repair. Minor vascular complications was defined as any groin bleeding, hematoma (>=5 cm), pseudoaneurysm, or AV fistula. 'Any' vascular complication was defined as either a major or minor vascular complication.
Results: VCD failed in 268 (2.7%) patients. The VCD failure group had significantly increased risk of any (10.8% vs. 3.7%), major (1.9% vs. 0.6%) or minor (5.2% vs. 0.9%) vascular complications compared with the group with successful deployment of VCD (Figure). Univariable predictors of VCD failures were older age, female sex, history

of diabetes, peripheral arterial disease, presentation with NSTEMI, lower creatinine clearance, use of suture-based VCD (8.9% vs. 1.5%) and undergoing PCI. Multivariable predictors were older age, use of suture-based VCD (OR = 7.30; 95% CI = 5.59-9.52; P<0.0001) and undergoing PCI.

Conclusions: In contemporary practice, VCD failure is rare but when it does fail, it is associated with significant increase in the risk of vascular complications. Patients with VCD failure should be closely monitored.



I2.ORAL CONTRIBUTIONS

2903

Interventional Pharmacology

Sunday, March 29, 2009, 10:30 a.m.-Noon
Orange County Convention Center, Room W414D

10:30 a.m.

2903-5 Impact of Different Antithrombotic Regimens on Ischemic and Hemorrhagic Outcomes Following Percutaneous Coronary Intervention in Elderly: Pooled Analysis from the REPLACE-2, ACUITY and HORIZONS-AMI Trials

Eugenia Nikolsky, Roxana Mehran, Helen Parise, Alexandra J. Lansky, George D. Dangas, Steven V. Manoukian, Michele Voeltz, Karen P. Alexander, E. Magnus Ohman, Darius Dudek, A. Michael Lincoff, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Among patients (pts), undergoing percutaneous coronary interventions (PCI), elderly represent vulnerable population due to higher rates of ischemic and bleeding complications. Our aim was to assess impact of different antithrombotic regimens on outcomes of elderly pts with stable or acute coronary syndromes treated with bivalirudin (Biv) alone versus heparin+GPIIb/IIIa inhibitors (Hep+GPI) in three contemporary PCI trials.

Methods and Results: Among a total of 14,325 pts undergoing PCI in the patient-based pooled analysis from REPLACE-2, ACUITY and HORIZONS-AMI trials, 2,235 (15.6%) were elderly (≥ 75 years of age). Elderly compared to younger pts had significantly higher rates of composite ischemic endpoint (death, myocardial infarction, or revascularization) [10% vs. 6.7% p<0.001] and protocol-defined major bleeding (8.3% vs. 3.8%, p<0.001). At 30 days, elderly assigned to Biv vs. Hep+GPI had similar rates of composite ischemic endpoint but significantly lower rates of bleeding (Table).

Conclusions: Older age is associated with notably increased risk of PCI-related ischemic and bleeding complications. Elderly patients benefit from bivalirudin by a marked reduction in bleeding with similar rates of ischemic complications.

Clinical endpoints (%)	Heparin + GPI (N=1,144)	Bivalirudin (N=1,091)	P value
Composite ischemia	9.5%	10.5%	0.43
Death	2.5%	3.3%	0.23
Myocardial infarction	6.3%	7.0%	0.58
Revascularization	2.3%	2.0%	0.69
Non-CABG TIMI bleeding (major + minor)	9.5%	7.0%	0.03

10:42 a.m.

2903-6 Is There a Rebound Effect After Clopidogrel Cessation in Patients Undergoing Percutaneous Coronary Intervention and Drug-Eluting Stent Implantation?

Gilles Lemesle, Laurent Bonello, Axel De Labriolle, Itsik Ben-Dor, Gabriel Maluenda, Sara D. Collins, Asmir I. Syed, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

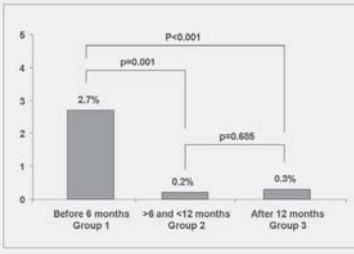
Background: Clopidogrel discontinuation within the first 6 months after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation has been reported to be a strong predictor of early events. Nevertheless, it is currently debated if clopidogrel cessation after 6 months is also related to an increased short-term risk of adverse events. This study aimed to determine the link between clopidogrel cessation and adverse cardiovascular events after PCI.

Methods: From 2002 to 2007, 2254 patients underwent PCI with DES implantation. We compared patients who stopped their clopidogrel within the first 6 months (group 1, n=442), between 6 and 12 months (group 2, n=510) and after 12 months after the PCI (group 3, n=1302). We indexed the primary composite endpoint death - myocardial infarction - stent thrombosis at 30 days after the clopidogrel cessation.

Results: Baseline characteristics were similar among groups. The rate of the composite criteria at 30 days after clopidogrel cessation was significantly higher in group 1 vs groups 2 and 3: 2.7% vs 0.2% and 0.3%, respectively (p=0.001).

Conclusion: This study confirms that clopidogrel cessation is strongly associated with an increased short-term risk of adverse events when it occurred within the first 6 months after the PCI. By contrast, clopidogrel cessation was no longer associated with such a risk after 6 months. This suggests that cardiac events seen immediately after clopidogrel cessation are not related to a rebound phenomenon.

Figure: Rates of primary composite endpoint death - myocardial infarction - stent thrombosis in the 3 groups at 30 days after the clopidogrel discontinuation.



10:54 a.m.

2903-7 Proton Pump Inhibitor and Clopidogrel Combination Is not Associated With Adverse Clinical Outcomes After PCI: The NHLBI Dynamic Registry

Jose F. Ramirez, Faith Selzer, Rinita Chakaprani, William D. Anderson, Joon S. Lee, Conrad Smith, Suresh R. Mulukutla, Kevin E. Kip, Sheryl F. Kelsey, Oscar C. Marroquin, Cardiovascular Institute, University of Pittsburgh Medical Center, Pittsburgh, PA

Background: In vitro studies have suggested that Proton Pump Inhibitors (PPI's) could influence the antiplatelet effect of Clopidogrel, by decreasing its inhibitory effect on the platelet P2Y12 ADP receptor. The clinical impact of this combination has not been well characterized. Therefore, we investigated the effect of this therapeutic combination on clinical outcomes in patients undergoing percutaneous coronary intervention (PCI).

Methods: Data from 535 patients enrolled at the University of Pittsburgh as part of the NHLBI Dynamic Registry waves 4 (2004) and 5 (2006) was analyzed. Patients discharged alive from their index PCI and on clopidogrel were included. They were divided onto those PPI users and those PPI nonusers. One-year rates of death, MI, and repeat revascularization were collected.

Results: Of the 535 patients taking clopidogrel, 138 (25.80%) were PPI users and 397 (74.20 %) patients were PPI nonusers. There were no significant baseline differences between PPI users and nonusers in age, baseline prevalence of diabetes, hypertension, renal dysfunction, smoking habits, or procedural success. At one year, there were no differences between PPI users and nonusers in univariate rates of death, MI, death/MI, or repeat revascularization.(table)

Conclusion: In patients undergoing PCI and discharged on clopidogrel therapy, the concomitant use of PPI's did not result in adverse cardiovascular outcomes at one year. This suggests that this combination is safe in patients who have undergone PCI.

Cumulative 1-year outcomes

Adverse Outcome (%)	PPI non-users(n=397)	PPI users(n=138)	p-value
Death	5.9	3.0	0.18
MI	4.2	3.7	0.83
CABG	4.1	3.1	0.53
Death/MI	9.6	6.7	0.32
Repeat PCI	10.1	13.4	0.23
Repeat Revascularization	14.2	15.8	0.65

11:06 a.m.

2903-8 Carriage of the CYP2C19*2 Allele Increases One-Year Risk of Myocardial Infarction Among Recipients of Drug-Eluting Stents Treated With Clopidogrel.

Jeffrey L. Anderson, Chrissa P. Mower, Benjamin D. Horne, Joseph B. Muhlestein, James J. Park, Tami L. Bair, John F. Carlquist, Intermountain Medical Center, Murray, UT

Background: Drug-eluting stents (DES) reduce the rate of restenosis but increase the risk of in-stent thrombosis with consequent myocardial infarction (MI) from delayed endothelialization. At least 1 y dual anti-platelet therapy (clopidogrel plus aspirin) is recommended after DES as premature thienopyridine discontinuation (at < 6 months post-DES) increases risk for late stent thrombosis and MI. From 29-56% of the population achieve suboptimal inhibition of platelet aggregation (IPA) with clopidogrel and up to a three-fold increase in risk for MI or death (D) at 1 y. The reduced-function *2 variant of the p450 cytochrome oxidase CYP2C19 gene was shown to predict impaired IPA with clopidogrel (5.4% reduction for carriers vs. 27.3% for non-carriers). However, a CYP2C19*2 association with clinical risk has not been shown. We prospectively tested the hypothesis that carriage of the CYP2C19*2 allele increases risk for myocardial infarction (MI) in the first y after DES in a large cohort.

Methods: Consenting patients (pts; N=1250) enrolled in the Intermountain Heart Collaborative Study, receiving a DES, and discharged with a prescription for clopidogrel from January 1

2003 - June 30, 2006 were studied. Pts were genotyped for CYP2C19*2 using 5' nuclease technology. Electronic medical records and national databases were analyzed at 1 year for incident MI, D, and combined MI/D following stent placement and at 2 y.
Results: Pt age averaged 63 y, and 27% were women. Genotype frequencies were *1*1=72%, *1*2=27%, and *2*2=1%. By 1 y, MI had occurred in 11.9% of *2 carriers and 8.3% of non-carriers (OR=1.50, 95% CI=1.00, 2.24; p=0.048) and was not affected by adjustment for age and sex (OR=1.49, CI=0.99, 2.23; p=0.054); a similar trend was found for MI/D (13.7% vs. 9.9%, OR=1.43, CI=0.98, 2.09; p=0.06). Rates of D were low (2.0% vs. 1.9%, p=0.86). The effect of *2 carriage on MI risk was maintained at 2 y (OR=1.42, CI=0.99, 2.02; p=0.055).
Conclusion: Carriage of a CYP2C19*2 allele not only decreases in vitro (IPA) responsiveness to clopidogrel, but increases (by 50%) the 1-2 y risk of MI or MI/D among DES recipients. If confirmed, these findings may lead to pre-DES stent genotyping to optimize DAT therapy and reduce MI risk.

11:18 a.m.

2903-9 Modified Clopidogrel Desensitization Following Percutaneous Coronary Intervention (PCI): A Novel Approach to the Management of Clopidogrel Allergy

Hasan Jilaihawi, Rose-Pascale Paul, Martin Blaquière, Denis Brouillette, Marc-André Lavoie, Pierre Théroux, Raoul Bonan, Philippe L'Allier, Réda Ibrahim, Montreal Heart Institute, Montreal, QC, Canada

Background: Allergic reactions to clopidogrel affect around 6% of patients. In patients after PCI, where a period of dual antiplatelet therapy is fundamental to reduce the risk of stent thrombosis, ticlopidine is used as a traditional replacement drug when clopidogrel allergy is seen. We sought to assess the safety and efficacy of a locally modified clopidogrel desensitization protocol.
Methods: Patients post PCI were regarded as having probable clopidogrel reaction in the absence of alternative causes. They were treated symptomatically in the first instance by a modified desensitization approach, with a course of oral corticosteroid/antihistamine combination with continued clopidogrel. In the setting of a persistent rash despite this, the clopidogrel was temporarily changed to ticlopidine and a graded rechallenge protocol was initiated. This consisted of rapidly incremental doses of plavix given at 30 min intervals; 0.75mg, then 7.5 mg, then 75 mg. Clopidogrel was continued thereafter and patients were assessed for symptoms at 1-2 weeks and 3 months follow-up.
Results: 45 consecutive patients with probable clopidogrel allergy underwent modified desensitization (steroids/antihistamines with continued clopidogrel) between March and June 2008; these comprised 13 STEMI (29%), 14 UA/NSTEMI (31%) and 18 stable angina (40%) cases. 37 (82%) were male and mean age was 61.9 years (SD 12.4). Of these cases, 20 had undergone PCI with DES (44%), 21 with BMS (47%), 1 POBA (2%) and 3 diagnostic coronary angiograms only (7%). Reactions were observed a mean of 7.6 days (SD 5.4, range 1-21) post clopidogrel exposure and in all cases were cutaneous reactions with no anaphylactic reactions observed. Full graded rechallenge was necessary in 4 patients (9%). At 1-2 weeks, 5 cases had minimal residual rash or pruritis (11%) with 40 no residual symptoms (89%). Of the 30 cases with documented 3 month follow-up thus far, only 2 had minimal residual rash/pruritis (7%).
Conclusion: A modified desensitization approach to clopidogrel allergy, with continued clopidogrel and a course of a corticosteroid/antihistamine combination, is a safe and effective strategy to this important clinical problem.

11:30 a.m.

2903-10 Impact of Gastrointestinal Bleeding on Outcomes of Patients Treated With Contemporary Antithrombotic Strategies: Pooled Analysis From 3 Randomized Trials

Eugenia Nikolsky, Roxana Mehran, Alexandra Lansky, Adriano Caixeta, George D. Dangas, Giora Weisz, Iulian Benetato Giuran, Martin Fahy, A. Michael Lincoff, Bernhard Witzenbichler, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Gastrointestinal bleeding (GIB) is a potential complication of antithrombotic therapy. Our aim was to assess incidence and impact of GIB on outcomes of patients with coronary artery disease treated with contemporary antithrombotic regimens.
Methods: We performed a patient-level pooled analysis from 3 contemporary multicenter, randomized trials (REPLACE-2, ACUITY and HORIZONS-AMI) assessing outcomes of patients assigned to heparin+GP IIb/IIIa inhibitors, bivalirudin+GP IIb/IIIa inhibitors, or bivalirudin monotherapy. GIB events adjudicated to CABG were excluded from analysis.
Results: Of the 22,283 patients in the dataset, in-hospital GIB occurred in 253 patients (1.1%). Multivariable predictors of major bleeding included older age (OR=1.03, P=0.0004), prior cerebrovascular accident (OR=2.20, P=0.008), baseline hematocrit (OR=0.91, P<0.0001), positive biomarker (OR=1.55, P=0.023), and treatment with any GP IIb/IIIa inhibitors regimen (OR=2.17, P=0.003). Thirty-day and 1-year clinical outcomes are presented in the Table. At 1 year, GIB was an independent predictor of death (OR=4.66, P<0.0001).

Clinical outcomes, %	GIB (+) N=253	GIB (-) N=22,030	P-value
30-day events			
Death	7.8%	1.1%	<0.0001
Reinfarction	11.0%	4.6%	<0.0001
Q Wave	2.8%	0.8%	0.0003
Non-Q Wave	8.6%	3.8%	0.0002
Target vessel revascularization	2.4%	1.2%	0.09
Blood product transfusion	36.6%	0.2%	<0.0001
1-year death	16.4%	2.9%	<0.0001

Conclusions: Although infrequent, GIB is a serious complication of contemporary antithrombotic therapy, associated with high rates of transfusion, reinfarction and strikingly increased mortality at 30 days and 1 year. Future investigation is warranted to determine effective measures to prevent GIB in high-risk populations.

I2.SYMPOSIUM

2612

i2. Acute Myocardial Infarction

Sunday, March 29, 2009, 2:00 p.m.-3:30 p.m.
Orange County Convention Center, Room W415D

3:00 p.m.

2612-9 Randomized Comparison of Primary Percutaneous Coronary Intervention With Combined Proximal Embolic Protection and Thrombus Aspiration and Primary Percutaneous Coronary Intervention Alone in ST-segment Elevation Myocardial Infarction

Joost D. Haeck, Karel T. Koch, Luc Bilodeau, René J. Van der Schaaf, José P. Henriques, Jan Baan, Jr., Marije M. Vis, Krischan D. Sjauw, Jan J. Piek, Jan G. Tijssen, Mitchell W. Krucoff, Robbert J. De Winter, Academic Medical Center – University of Amsterdam, Amsterdam, The Netherlands, Duke Clinical Research Institute, Duke University Medical Center, Durham, NC

Background: Distal embolization during primary percutaneous coronary intervention (PCI) occurs in at least 15% of patients and is a strong predictor of more extensive myocardial damage and a poor prognosis. A novel approach of preventing distal embolization is the use of the Proxis system (St. Jude Medical, St Paul, MN, USA), a combination of proximal embolic protection and thrombus aspiration, during primary PCI.
Methods: We performed a randomized trial assessing whether primary PCI with combined proximal embolic protection and thrombus aspiration was superior compared to primary PCI alone. A total of 284 patients were randomly assigned to primary PCI with Proxis system or primary PCI alone after coronary angiography. The primary endpoint was complete (≥ 70%) ST-segment resolution (STR) after the procedure, performed in a blinded manner at Duke Clinical Research Institute Virtual Electrocardiogram Core Laboratory (Durham, North Carolina, USA).
Results: Complete STR at time of last contrast occurred in 66% (85/129) of patients receiving combined proximal embolic protection and aspiration and in 50% (67/135) of control patients (absolute difference, 16.3% [95% confidence interval, 4.3% to 28.2%]; P=0.009).The difference between the 2 groups in the rate of complete STR at the time of last contrast injection was statistically significant. The mean percent STR at last contrast in the both arms was also statistically significant different (73.2% vs 63.4%, respectively; P=0.009). A significant lower ST-segment curve area (0 - 3 hours after primary PCI) was observed in the Proxis arm (5192 µV-minutes vs 6250 µV-minutes, P=0.037). Debris was confirmed on pathology in 75% (84/112) of patients.
Conclusions: The results of the PREPARE trial showed that primary PCI with combined proximal embolic protection and thrombus aspiration is feasible and safe and leads to more complete STR which suggest better immediate microvascular flow in STEMI patients.

I2.SYMPOSIUM

2614

i2.Infrapopliteal Disease: Evaluation, Treatment, Follow-up

Sunday, March 29, 2009, 2:00 p.m.-3:30 p.m.
Orange County Convention Center, Room W414C

3:00 p.m.

2614-8 Presence of Critical Limb Ischemia Rather Than Vessel Run-off Determines Restenosis in the Femoro-popliteal Artery in the New Nitinol Stent Era

Kuniyasu Ikeoka, Osamu Iida, Shinsuke Nanto, Masaaki Uematsu, Takakazu Morozumi, Tetsuya Watanabe, Masaki Awata, Toshinari Onishi, Fusako Sera, Hitoshi Minamiguchi, Shin Okamoto, Seiki Nagata, Kansai Rosai Hospital, Hyogo, Japan

Background: Severity of limb ischemia, lesion length, and outflow lesions are raised as restenosis factors following endovascular therapy (EVT) in the superficial femoral artery (SFA) in TASC 2. However, factors influencing restenosis in the new era of nitinol stents are unclear. We sought to investigate factors influencing restenosis following EVT with nitinol stents in the femoro-popliteal artery (FPA). **Methods:** Provisional stenting was performed with a nitinol stent (Smart Control, Cordis)in the FPA of 163 patients (227 limbs), including diabetes mellitus (DM, 63%), hemodialysis (20%), critical limb ischemia (CLI, 24%). Thirty-seven % of patients showed less than 1 vessel distal run-off below the knee. Mean lesion length was 139±90mm; TASC classification A/B/C/D was 91/42/23/71; 46% of lesions were chronic total occlusion (CTO); 40% were with severe calcification; 43% received multiple stents. Either angiography (diameter stenosis > 50%) or duplex ultrasound (peak systolic velocity ratio >2.5) were used at follow up to define restenosis.
Results: Restenosis rate at 15±6.7 months of follow up was 17%. Seventeen % of the lesions had stent fractures. Presence of CLI, TASC C/D, CTO, multiple stenting, lesion

length > 100mm(P=0.005, 0.001, 0.01, 0.0009, 0.002, respectively) were chosen as significant variables related to restenosis by single regression analysis, while DM, hemodialysis, poor run-off, stent fracture were not chosen (P=0.66, 0.76, 0.71, 0.15, respectively). CLI was chosen as the only significant variable by multivariate regression analysis (P=0.009). **Conclusion: Presence of CLI was the strongest independent predictor of restenosis in the femoro-popliteal artery in the new nitinol stent era.**

I2.ORAL CONTRIBUTIONS

2904

Complex Patients

Sunday, March 29, 2009, 2:00 p.m.-3:30 p.m.
Orange County Convention Center, Room W414D

2:00 p.m.

2904-5 Impact of PCI vs. CABG on the Development of Acute Renal Failure in Patients With Acute Coronary Syndromes: Insights From the ACUITY Trial

Giora Weisz, Roxana Mehran, George Dangas, Eugenia Nikolsky, Leroy Rabbani, Yanai Ben-Gal, Martin Fahy, Varinder Singh, Alexandra Lansky, Jeffrey W. Moses, Gregg W. Stone, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, NY, Cardiovascular Research Foundation, New York, NY

Background: In patients with acute coronary syndrome (ACS) and CAD requiring revascularization, concerns about contrast induced nephropathy often lead to referral to CABG over PCI. We studied the effect of revascularization mode (PCI vs CABG) on the rate of in-hospital acute renal failure (ARF) in patients with ACS in the ACUITY trial.
Methods: All patients underwent angiography within 72 hours of presentation, followed by triage to PCI or CABG. Serum creatinine (SCr) was measured throughout hospital stay, and ARF was defined as SCr increase of ≥25% or ≥0.5mg/dl from baseline
Results: Data on revascularization and SCr were available on 8087 patients. Following angiography, 6731 patients (83.2%) were managed by PCI, and 1356 (16.8%) with CABG. Baseline characteristics and rates of ARF are presented in Table. Independent predictors of ARF were CABG (RR 3.92, p<0.0001), female gender (RR 1.43 p<0.0001), diabetes (RR 1.41, p<0.0001), ST-segment deviation (RR 1.26, p=0.04), (RR 1.02, p<0.0001) and baseline creatinine clearance (RR 1.01, p<0.0001).

	PCI (n=6731)	CABG (n=1356)	p-value
Mean Age, years	63	65	<0.0001
Diabetes	27.6%	34.2%	<0.0001
Baseline Creatinine clearance, ml/min	88.1	84.1%	<0.0001
Baseline renal insufficiency	18.4%	18.8%	0.726
ST deviation	35.8%	49.5%	<0.0001
TIMI Risk score ≥3	47.5%	50.4%	0.049
# lesions per pt	4.4 ± 2.6	6.1 ± 2.8	<0.0001
LVEF, %	65.2	63.6	<0.003
In-hospital acute renal failure	11.6%	32.2%	<0.0001

Conclusions: In patients with moderate and high risk ACS requiring revascularization, the patients that were referred to CABG had higher rates of diabetes and more extensive CAD than patients treated by PCI. As compared with PCI, surgical revascularization resulted in significantly higher rates of in-hospital ARF. When considering the mode of revascularization in patients with CAD, the significantly increased risk of ARF with CABG should be considered.

2:12 p.m.

2904-6 Higher Adverse Events After PCI in Patients With Pulmonary Disease: Insights From the NHLBI Dynamic Registry

Jonathan R. Enriquez, Shailja V. Parikh, Faith Selzer, Alice K. Jacobs, Elizabeth M. Holper, Rush University Medical Center, Chicago, IL, University of Texas Southwestern Medical Center, Dallas, TX

Background: Previous studies have demonstrated that patients with pulmonary disease are at higher risk for mortality after PCI, but the cause of this association remains poorly understood.
Methods: Utilizing Waves 1-5 (1999-2006) of the NHLBI Dynamic Registry, patients with pulmonary disease (n= 860) and without (n= 10,048) were compared. Baseline demographics, angiographic characteristics, in-hospital and 1-year adverse events were compared.
Results: Patients with pulmonary disease were older (mean age 66.8 vs 63.2, p<0.001), more likely to be female, and more likely to present with diabetes, prior MI, peripheral arterial disease, renal disease, and smoking. Patients with pulmonary disease also had a lower mean ejection fraction (49.1% vs 53.0%, p<0.001) and a greater mean number of significant lesions (3.2 vs 3.0, p=0.006). Rates of in-hospital death (2.2% vs 1.1%, p=0.003) and major entry site complications (6.7% vs 4.4%, p=0.001) were also higher in pulmonary patients. At discharge, pulmonary patients were significantly less likely to be prescribed aspirin (92.4% vs 95.3%, p<0.001), β-blockers (55.7% vs 76.2%, p<0.001), and statins (60. 0% vs 66.8%, p<0.001). Adjusted one year adverse outcomes are shown in Table 1.
Conclusions: Pulmonary disease is associated with higher mortality and need for repeat revascularization 1-year after PCI. Possible causes of these findings include greater unmeasured comorbidities and lower rates of guideline class I recommended medications post-procedure.

Adjusted Hazard Ratios of One Year Adverse Events for Patients with Pulmonary Disease

	HR	95% CI	p-value
Death	1.30	1.01-1.67	0.04
MI	0.96	0.70-1.30	0.77
CABG	1.28	0.94-1.76	0.12
Death or MI	1.16	0.95-1.42	0.14
Repeat PCI	1.12	0.91-1.38	0.27
Repeat Revascularization	1.22	1.02-1.46	0.03

2:24 p.m.

2904-7 Safety and Efficacy of Three Strategies of Multi-Vessel Percutaneous Coronary Intervention: Same Session vs. Multi-Session vs. Multi-Hospitalization

James C. Blankenship, Richard E. Shaw, Joseph D. Babb, Geisinger Medical Center, Danville, PA, Sutter Pacific Heart Centers, San Francisco, CA

Background: Multi-vessel coronary intervention (MVPCI) may be performed during 1 session, different sessions during 1 hospitalization, or different hospitalizations. US federal agencies are concerned that economic factors may bias treatment strategies toward multiple admissions.
Methods: The American College of Cardiology National Cardiovascular Data Registry (NCDR) was queried to identify all patients undergoing elective MVPCI during 2001-2003. Patients were assigned to groups based on strategy: 1 session (1-session, N = 32,246), 2 sessions during 1 hospitalization (2-session, N = 1,932), or sessions during different hospitalizations (2-hosp, N = 6,474). Complications and success rates were calculated on a per-patient basis. Expected mortality was calculated using a model based on demographic and angiographic characteristics.
Results: 2-session patients (vs 1-session vs 2-hosp) had more co-morbidities: current CHF: 10.6% vs 7.7% vs. 5.6%; unstable angina: 58.8% vs. 49.2% vs 40.0%; prior renal failure: 7.0% vs. 4.6% vs. 4.7%, EF<40%: 19.5% vs. 14.4% vs. 13.4%. Lesions/ patient were 2.1 vs 2.5 vs 2.3. Observed/expected mortality was lower for 2-hosp (0.27) than for 1-session (1.17) or 2-session (1.28) (p <0.0001).
Conclusions: A strategy of 2-session MVPCI, used in the sickest patients, does not reduce mortality below expected levels. MVPCI on different hospitalizations, used in the least sick patients, is effective and may be safer than MVPCI during 1 admission.

Complications and Success Rates of Multi-Vessel PCI Strategies

	1 Session	2 Sessions, 1 Hospitalization	2 Hospitalizations
In-hospital mortality	0.54%	0.69%	0.08%
Expected mortality	0.46%	0.53%	0.29%
Peri-procedural MI	1.69%	1.55%	0.82%
Unplanned CABG	0.47%	0.41%	0.36%
Vascular site bleeding	1.58%	1.50%	0.69%
Success in all lesions	91.1%	93.4%	94.0%

2:36 p.m.

2904-8 Patients With Coronary Artery Disease not Amenable to Traditional Revascularization: Prevalence and 3-Year Mortality

Benjamin Williams, Madhav Menon, Daniel Hayward, Daniel Satran, James Hodges, Timothy D. Henry, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: A growing number of patients have severe coronary artery disease (CAD) not amenable to traditional revascularization. Many have ongoing angina despite optimal medical therapy. Prevalence and mortality data for these patients are scarce.
Methods: Clinical and angiographic data were reviewed for 493 consecutive patients undergoing coronary angiography at the Minneapolis Heart Institute in 2005. Patients were categorized into six groups: 1) normal coronary arteries 2) CAD <70%, 3) CAD >70% with complete revascularization (CR) by percutaneous intervention (PCI) or coronary artery bypass grafting (CABG), 4) CAD >70% with partial revascularization (PR) (by PCI or CABG), 5) CAD >70% treated medically and 6) CAD >70% on optimal medical therapy with no revascularization option. All-cause mortality at 3 years was determined.
Results: Prevalence and 3 year mortality for each group are shown (Table). Mortality for patients not undergoing complete revascularization (groups 4-6, n = 142) was significantly higher than for completely revascularized patients (groups 1-3, n = 351): 14.8% vs. 6.6% (p=0.004).

Prevalence and Mortality by CAD Group

Group	Total n=493 (% of 493)	Deaths (% of group n)
1. Normal	73 (14.8)	2 (2.7)
2. CAD <70%	96 (19.5)	6 (6.3)
3. CAD >70% (CR)	182 (36.9)	15 (8.2)
4. CAD >70% (PR)	63 (12.8)	8 (12.7)
5. CAD >70% (medical)	46 (9.3)	8 (17.4)
6. CAD >70% (“no option”)	33 (6.7)	5 (15.2)

Conclusions: In a contemporary series of patients undergoing coronary angiography, 28.8% (142/493) of patients had CAD and did not undergo complete revascularization, including 12.8% partially revascularized, 9.3% managed medically, and 6.7% with “no option.” These patients had higher risk for mortality at 3-years (14.8% vs. 6.6%, p=0.004)

compared to completely revascularized patients.

2:48 p.m.

2904-9 **Will the Net Clinical Benefit of the Prophylactic Use of the Impella LP 2.5 Device Demonstrate Superiority Over the Intra-Aortic Balloon Pump for High-Risk Percutaneous Coronary Intervention?**

Asmir Syed, Amit Kakkar, Yanlin Li, Sara Collins, Itsik Ben-Dor, Gabriel Manuela, Gilles Lemesle, Mickey Scheinowitz, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, Joseph Lindsay, Kenneth Kent, Lowell Satler, William O. Suddath, Augusto Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

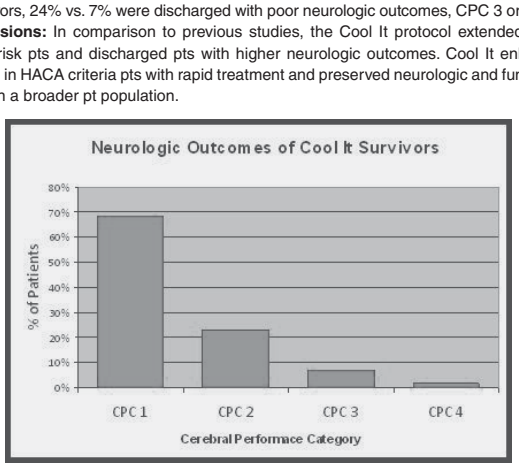
Background: For patients (pts) undergoing non-emergent, high-risk percutaneous coronary intervention (HRPCI) the current practice is to use prophylactic intra-aortic balloon pump (IABP) (8 Fr) for hemodynamic support. The aim of this analysis was to detect the event rates in this population supported with IABP and to evaluate in what conditions the prophylactic use of the Impella LP 2.5 device (12 Fr) would demonstrate superiority over IABP in the high-risk population.
Methods: Among our general PCI population 73 pts were identified as receiving prophylactic IABP support for HRPCI and who met the inclusion/ exclusion criteria of the PROTECT II study, which is evaluating the prophylactic use of the Impella LP 2.5 device in this population. HRPCI was defined as PCI to the last patent coronary conduit or an unprotected left main or EF < 35% with 3-vessel disease. Pts with STEMI, cardiac arrest within 24 hours, or cardiogenic shock were excluded. The primary endpoint was the composite of death, myocardial infarction, stroke, TIA, revascularization, renal failure, severe hypotension, CPR, ventricular arrythmias, and angiographic failure at 30 days.
Results: Baseline characteristics of the cohort included a mean age of 68 years, 78% male, 84% with hypertension, 24% acute coronary syndrome, 50% diabetes, and 35% chronic renal insufficiency. The in hospital and 30 day event rates were low for this population (5.7% and 21.4%, respectively) with a low major vascular complication rate of 3.0%. With a 30 day event rate of 21.4% and a treatment effect size of 33.3% aimed in the PROTECT II trial a total of 924 patients would be required to evaluate superiority with 80% power. Additionally, with this event rate the PROTECT II, with a total sample size of 654 patients, would have 60% power to detect a treatment effect size of 33.3%.
Conclusion: Prophylactic use of IABP for HRPCI is associated with a low event rate in hospital and at 30 days. The current PROTECT II study will be underpowered to detect superiority of the Impella LP 2.5 device over IABP in this high-risk population. These data question the net clinical benefit of the relatively high-profile Impella LP 2.5 device over IABP for this high-risk population.

3:00 p.m.

2904-10 **"Cool It": Therapeutic Hypothermia for Recovery of Neurologic Function in High Risk Patients Following Cardiac Arrest**

Leah Swanson, Kalie Edelstein, William Parham, Jon Hokanson, Richard Shronts, Barbara T. Unger, Wendy George, Ivan J. Chavez, Timothy D. Henry, Michael R. Mooney, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: Survival to discharge following out-of-hospital cardiac arrest (OOHCA) is uncommon. Among survivors, neurologic deficits from anoxic encephalopathy are common and disabling. The Hypothermia after Cardiac Arrest (HACA) Study Group reported that pts randomized to therapeutic hypothermia (TH) had improved survival (59% vs. 45%; p=0.02) and neurologic outcome (55% vs. 39%; p=0.009).
Methods: OOHCA pts due to ventricular fibrillation, ventricular tachycardia, asystole, and pulseless electrical activity (PEA) were cooled to 33ºC for 24 hrs. Pts in cardiogenic shock were included. Cerebral function after TH was measured by the five point Pittsburgh Cerebral Performance Category (CPC) scale. CPC 1 and 2 are positive neurologic outcomes, 3 and 4 are poor outcomes, and 5 is death.
Results: From 2/06 to 5/08, 85 pts were treated with TH, and 45 (53%) of pts survived. Applying the HACA Study Group exclusion criteria eliminated 43 pts with cardiogenic shock or PEA/asystole rhythms. HACA criteria pts had a higher survival rate than non-HACA criteria pts (71% vs. 35%; p=0.001). Comparing HACA Study Group survivors with all Cool It survivors, 24% vs. 7% were discharged with poor neurologic outcomes, CPC 3 or 4.
Conclusions: In comparison to previous studies, the Cool It protocol extended TH to higher risk pts and discharged pts with higher neurologic outcomes. Cool It enhanced survival in HACA criteria pts with rapid treatment and preserved neurologic and functional status in a broader pt population.



I2.POSTER CONTRIBUTIONS

2505

PCI - Diabetes

Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2505-649 **Clinical and Angiographic Predictors of Death or Myocardial Infarction in Diabetics with Acute Coronary Syndromes Undergoing Percutaneous Coronary Intervention: An ACUITY Subanalysis**

Kenji Goto, Alexandra J. Lansky, Ecatarina Cristea, Martin Fahy, Frederick Feit, Magnus E. Ohman, Harvey D. White, Karen P. Alexander, Michel E. Bertrand, Walter Desmet, Martial Hamon, Steven V. Manoukian, Ramin Ebrahimi, Carles V. Pollack, Michael J. Attubato, Roxana Mehran, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Backgrounds Despite pharmacologic and technical advances, diabetic pts with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) have a poor prognosis. We sought to determine the rates and predictors of cardiac ischemic events in diabetics with ACS undergoing contemporary PCI.
Methods The ACUITY trial randomized 13,819 pts with moderate- and high-risk ACS to unfractionated or low molecular weight heparin + glycoprotein IIb/IIIa inhibitors (GPI), bivalirudin + GPI, or bivalirudin alone; 7000 pts were included in a formal angiographic substudy. Clinical and angiographic predictors of death or myocardial infarction (MI) at 30 days and 1 year were identified by univariate and multivariable analysis using logistic regression analysis.
Results Following angiography, 7,789 (56.4%) pts were treated with PCI, including 2,137 patients (27.4%) with diabetes. Pts with vs. without diabetes had more hypertension (83.5% vs. 58.7%), hyperlipidemia (70.2% vs. 50.8%), renal insufficiency (20.7% vs. 17.6%), and 3-vessel disease (51.8% vs. 44.5%) (all p<0.01). The rates of death/MI were similar at 30 days in diabetics compared to non-diabetics (7.3% vs. 6.8%, p=0.56). However, death/MI was significantly more frequent at 1 year in diabetics (14.3% vs. 10.7%, p<0.0001). Among diabetics, independent predictors of death/MI at 30 days included renal insufficiency (OR 1.84 [1.06, 3.19], p=0.03), elevated biomarkers (OR 1.71 [1.02, 2.86], p=0.04) and the number of diseased vessels (OR 1.18 [1.08, 1.29], p=0.0003). Death/MI at 1-year was independently predicted by insulin treatment (OR 1.66 [1.10, 2.51], p=0.02) and renal insufficiency (OR 1.76 [1.11, 2.79], p=0.02).
Conclusions: Among diabetics with ACS undergoing PCI with contemporary techniques and pharmacologic regimens, the rates of death or MI are not increased at 30 days compared to non-diabetics, but are significantly worse at 1 year. While the extent of CAD and clinical syndrome acuity contributes to adverse 30 day outcomes in diabetics, at 1 year renal insufficiency and the requirement for insulin are the most powerful factors contributing to death and MI in diabetics with ACS undergoing PCI.

3:30 p.m.

2505-650 **The Effects of Pioglitazone on Neointima Volume and Atherosclerosis Progression at Eight Months after Zotarolimus-Eluting Stent Implantation in Diabetic Patients**

Soon Jun Hong, Wan Joo Shim, Seong Mi Park, Jae Suk Park, Yong Hyun Kim, Chul Min Ahn, Do-Sun Lim, Korea University Anam Hospital, Seoul, South Korea

Background: Diabetic patients showed increased late lumen loss and rates of restenosis compared with nondiabetic patients even after drug-eluting stent implantation. Pioglitazone has been known for anti-inflammatory and antiproliferative effects in patients with coronary artery disease. We compared the effects of pioglitazone and placebo on neointima volume and atherosclerosis progression with intravascular ultrasonography (IVUS) after zotarolimus-eluting stent (ZES) implantation in diabetic patients.
Methods: This was a prospective, randomized, single-blinded, 8 months follow-up study including diabetic patients with significant coronary artery stenosis assigned to the Pioglitazone Group (n=44) and the Placebo Group (n=43). Neointima volume and atherosclerosis progression beginning 5 mm distal to and extending 5 mm proximal to the stented segment were analyzed by repeat IVUS examination. Inflammatory markers such as IL-6, IL-18, TNF- and high sensitive C-reactive protein (hsCRP) were measured. Major adverse cardiovascular events such as death, myocardial infarction, and target vessel failure were evaluated.
Results: Total plaque volume 5 mm proximal (7.7 ± 4.2 vs. 8.3 ± 4.8 mm^3 per 1-mm vessel segment, p<0.05) and distal to the stent (4.8 ± 3.2 vs. 5.2 ± 2.9 mm^3 per 1-mm vessel segment, p<0.05) were significantly lower in the Pioglitazone Group compared with the Placebo Group at 8 months. Neointima volume was also significantly lower in the Pioglitazone Group (1.5 ± 1.0 vs. 2.0 ± 1.1 mm^3 per 1-mm stented segment, p<0.05) at 8 months. Inflammatory markers such as IL-6 (0.76 ± 0.70 vs. 1.32 ± 1.21 pg/ml, p<0.05), IL-18 (153.9 ± 99.1 vs. 172.4 ± 107.4 pg/ml, p<0.05), TNF- (2.02 ± 1.66 vs. 2.73 ± 1.93 pg/ml, p<0.05) were significantly lower in the Pioglitazone Group at 8 months; however, no significant differences were found for hsCRP level between the 2 groups. Major adverse cardiac events were similar between the 2 groups.
Conclusions: Adding pioglitazone was associated with significant decrease in the total neointima volume and total plaque volume 5mm proximal and distal to the stent after ZES implantation in diabetic patients with significant coronary narrowings.

3:30 p.m.

2505-651 **Impact of Longitudinal Geographic Miss in the Clinical Outcomes of Diabetes Population Treated With Drug Eluting Stent: Sub-analysis of the STLLR Trial.**

SATOKO TAHARA, Hiram Grando Bezerra, Hiroyuki Kyono, Noah Rosenthal, Nobuaki Suzuki, Marco Aurelio Costa, University Hospitals Harrington-McLaughlin Heart & Vascular Institute, Cleveland, OH

Background: Longitudinal geographic miss (LGM) frequently occurs during stent implantation and is associated with an increased risk of target lesion revascularization (TLR) at 1 year. Diabetes mellitus (DM) is recognized as a risk factor for coronary restenosis, even when treated with drug eluting stent
(DES). However it is unknown how technical aspects like longitudinal geographic miss influence the outcomes of DM population.
Methods: The STLLR trial (**S**tent deployment **T**echniques on c**L**inica**L** outcomes of patients treated with the cyphe**R** stent) was the first prospective, multicenter (41 US hospitals), large (n=1557) study to evaluate clinical outcomes associated with sirolimus-eluting stent (SES) deployment techniques in real world practice. Quantitative coronary analysis and assessment of LGM, defined as balloon injured or diseased segment uncovered by SES, was performed and adjudicated by an independent blinded core lab. We analyzed the impact of LGM in a sub-population of DM.
Results: A total of 1336 lesions were assessed and classified as DM (28.8%) group or non-DM (71.2%) group. TLR was only slightly higher in the DM population compared to non-DM (4.7% vs. 2.8%, p=NS). However in the LGM population (n=632, 47.3%), TLR was significantly higher in DM (8.0% vs. 3.8%, p=0.03). When LGM was represented by balloon injury, it had a higher impact on TLR in the DM population (8.5% vs. non-DM 1.9%, p=0.012). On the other hand when LGM was the result of uncovered diseased segments, it did not show significant difference between the DM and non-DM (7.3% vs. 7.6%, p=NS).
Conclusion: The higher incidence of TLR in the DM population is mostly explained by LGM, especially balloon injury during stent implantation.

3:30 p.m.

2505-652 **Similar Prognostic Significance of Impaired Glucose Tolerance and Diabetes Mellitus in Patients with Acute Myocardial Infarction Treated Invasively**

Zbigniew Kalarus, Jacek Kowalczyk, Radoslaw Lenarczyk, Teresa Zielinska, Agnieszka Sedkowska, Patrycja Pruszkowska-Skrzep, Andrzej Swiatkowski, Beata Sredniawa, Joanna Stabryla-Deska, Oskar Kowalski, Lech Polonski, Krzysztof Strojek, 1st and 3rd Dept. of Cardiology, Medical University of Silesia, Silesian Center for Heart Diseases, Zabrze, Poland, Department of Internal Diseases, Diabetology and Nephrology, Medical University of Silesia, Zabrze, Poland

Background: The prognostic role of impaired glucose tolerance (IGT) is still little known. The aim of the study was to evaluate the impact of diabetes mellitus (DM) and IGT on long-term outcome in patients (pts) with acute myocardial infarction (AMI) treated invasively.
Methods: Single-centre study encompassed 2733 survivors of acute AMI phase. In all pts without history of DM standard oral glucose tolerance test was performed before hospital discharge. Our study population was divided into 3 major groups: 560 pts with IGT, 809 pts with DM diagnosed prior or during index hospitalization and 1158 pts without IGT and DM, defined as controls. Long-term outcomes were compared with log-rank test. Independent predictors of death were selected with multivariate Cox-regression model.
Results: Remote mortality was significantly higher in DM and IGT pts compared to controls, but not in DM vs. IGT group (Table 1). DM and IGT groups had more unfavorable baseline characteristics in comparison with controls. Neither IGT nor DM was independent risk factor for death. The independent death predictors in the entire population were: age >=70, cardiogenic shock, chronic kidney disease, incomplete revascularization, ejection fraction <35%, contrast-induced nephropathy.
Conclusions: Prognosis in AMI pts with IGT, who were treated invasively is similar to those with DM. Both DM and IGT are associated with significantly reduced long-term survival compared to controls. Neither IGT nor DM was independent risk factor for death.

Table 1.

Mortality	DM group (n=809)	IGT group (n=560)	Control group (n=1158)	P value (DM and IGT vs. controls)
30-day mortality	1.5%	0.9%	1.0%	NS
1-year mortality	7.3%	6.6%	3.3%	<0.05
Total mortality	11.6%	9.3%	6.2%	<0.05
all P = NS for DM vs. IGT				

3:30 p.m.

2505-653 **Outcomes of patients with diabetes mellitus undergoing PCI treated with bivalirudin versus heparin plus a glycoprotein IIb/IIIa inhibitor: Pooled analysis from the REPLACE-2, ACUITY and HORIZONS-AMI Trials**

Frederick Feit, Hitinder S. Gurm, Bernhard Witzenbichler, Helen Parise, A. Michael Lincoff, Steven V. Manoukian, Harvey D. White, Stuart J. Pocock, Roxana Mehran, Gregg W. Stone, New York University School of Medicine, New York, NY

Background: Bivalirudin monotherapy (Biv) was associated with similar rates of ischemic events and significantly reduced bleeding compared to Heparin+ GP IIb/IIa inhibitors (GPI) in patients (pts) undergoing PCI for stable or unstable angina (in REPLACE-2), NSTE-ACS (in ACUITY), and STEMI (in HORIZONS). However, pts with diabetes mellitus (DM) undergoing PCI are at increased risk of ischemic events. A pooled analysis of these 3 pivotal trials was performed to provide a more accurate estimate of the treatment effects of Biv vs Hep+GPI across a broad spectrum of pts with DM undergoing PCI.
Methods: The REPLACE-2, ACUITY, and HORIZONS trials randomized pts to Biv or Hep+GPI. We assessed the rates of 30-day composite ischemia (death, MI, or urgent revascularization), non-CABG TIMI bleeding (major/minor), and net adverse clinical outcomes (NACE, composite ischemia or protocol-defined bleeding) in pts with DM undergoing PCI, by randomized treatment.
Results: Of 14,280 randomized pts undergoing PCI, 3540 (24.8%) were diabetic. In pts with DM undergoing PCI, Biv vs Hep+GPI resulted in a significant reduction in 30-day NACE due to significantly reduced major bleeding with no significant difference in composite ischemia (Table).
Conclusions: These results indicate that Biv is a safe and effective antithrombotic strategy for pts with DM undergoing PCI across a broad spectrum of clinical presentations.

30-day adverse events	Hep + GPI N=1750	Biv N=1790	p-value
NACE	12.6%	10.2%	0.03
Composite Ischemia	8.0%	6.8%	0.20
- Death	1.5%	0.9%	0.21
- MI	5.4%	4.9%	0.49
- Revascularization	2.5%	2.7%	0.66
TIMI Major or Minor Bleeding (Non-CABG)	5.9%	3.5%	0.001

3:30 p.m.

2505-654 **Three-Year Clinical Outcome of Paclitaxel- and Sirolimus-Eluting Stents Versus Bare Metal Stents in Patients with Diabetes Mellitus. From Western Denmark Heart Registry**

Lisette Okkels Jensen, Anne Kaltoft, Per Thayssen, Michael Maeng, Hans Henrik Tilsted, Jens Flensted Lassen, Knud Noerregaard Hansen, Klaus Rasmussen, Klaus Rasmussen, Morten Madsen, Soeren Paaske Johnsen, Henrik Toft Soerensen, Leif Thuesen, Odense University Hospital, Odense, Denmark

Background: Patients with diabetes mellitus have an increased risk of restenosis after coronary stent implantation. Drug-eluting stents have reduced this risk of restenosis but the long-term outcome after paclitaxel-(PES) or sirolimus-eluting (SES) stents compared to bare metal stents (BMS) is unknown. Therefore, we examined stent thrombosis, myocardial infarction (MI), mortality and target lesion revascularisation (TLR) in diabetic patients treated with PES, SES or BMS implantation in Western Denmark.
Methods: From January 2002 to June 2005 all consecutive diabetic patients who had SES, PES or BMS implantation were identified in the Western Denmark Heart Registry. All patients were treated with dual antiplatelet therapy for 12 months and followed for 36 months.
Results: A total of 1,580 diabetic patients were treated: 228 with PES, 370 with SES and 982 with BMS. Very late definite stent thrombosis (between 12 and 36 months after implantation) did not differ significantly between DES (0.2%) or BMS (0.1%) treated patients [adjusted RR=0.53 (95% CI: 0.0.04-6.78)]. MI [adjusted RR 1.11(95%CI: 0.76-1.62)] and mortality [adjusted RR=0.91 (95% CI: 0.69-1.19)] did likewise not differ significantly between DES and BMS treated diabetic patients. The risk profiles were similar according to DES type. TLR was reduced significantly in DES treated patients [adjusted RR=0.67 (95% CI: 0.50-0.91)]. Compared to BMS treated diabetic patients SES reduced TLR significantly [adjusted RR=0.62 (95% CI: 0.43-0.89)], whereas this attenuated after 36 months in PES treated diabetic patients [adjusted RR=0.77 (95% CI: 0.52-1.14)].
Conclusion: In diabetic patients a sustained effectiveness and safety were found after SES treatment. TLR was not reduced in PES treated patients after 3 years. The safety profiles did not differ between DES type and BMS.

3:30 p.m.

2505-655 **Lack of Prognostic Value of HbA1C in Diabetic Patients Undergoing Percutaneous Coronary Intervention With Drug-eluting Stent Implantation**

Gilles Lemesle, Laurent Bonello, Axel De Labriolle, Gabriel Maluenda, Sara D. Collins, Asmir I. Syed, Yanlin Li, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: The optimal HbA1C target among diabetic patients (pts) is a subject of ongoing controversy that may be especially pertinent among diabetic pts with coronary artery disease (CAD). This study aimed to determine the prognostic value of HbA1C levels in diabetic pts undergoing percutaneous coronary intervention (PCI).
Methods: From 2003 to 2007, 952 consecutive diabetic pts underwent PCI with drug-eluting stent implantation. We compared pts with a normal HbA1C (≤7%, n=429) to pts with an elevated HbA1C (>7%, n=523). The 1-year rate of major adverse cardiovascular events (MACE) including death, myocardial infarction (MI), and target vessel revascularization (TVR) was indexed.
Results: Baseline characteristics were similar between both groups except for the body mass index that was higher in the High-HbA1C group: 32.2 vs 31.2, p=0.03. Pts in the High-HbA1C were more likely insulin dependents: 45.5% vs 26.3%, p<0.001. The rate of cardiovascular events was similar between both groups. By multivariate analysis age, renal failure, clinical presentation as MI and history of congestive heart failure were independently associated with MACE. By contrast, HbA1C was not associated with patient outcome.
Conclusion: This study suggests that HbA1C is not a predictor of cardiac events in

diabetic pts with advanced CAD. These results could explain at least in part the recent findings of randomized trials suggesting the absence of benefit in terms of macrovascular complications of a strict glycemia control.

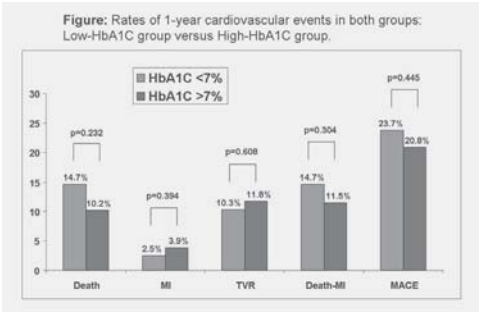


Figure: Rates of 1-year cardiovascular events in both groups: Low-HbA1C group versus High-HbA1C group.

3:30 p.m.

2505-656 **Comparison of Subsequent Vascular Response in Diabetic Patients Following Coronary Stenting Between Sirolimus- and Paclitaxel-Eluting Stents: Optical Coherence Tomography Analysis**

Kenya Nasu, Etsuo Tsuchikane, Osamu Katoh, Masashi Kimura, Yoshihisa Kinoshita, Mariko Ehara, Mitsuyasu Terashima, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Diabetes mellitus is one of the major predictors for target lesion revascularization even in drug-eluting stent era. The aim of this study is to evaluate the differences of chronic vascular response in patients with diabetes mellitus (DM) following coronary stenting between sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES) using optical coherence tomography (OCT).
Methods: We examined non-restenotic 60 SESs and 60 PESs were imaged with motorized OCT pull-back system (1 mm/s) at 9-month follow-up and analyzed at interval of 1 mm. Neointimal coverage of stent struts and the incidence of stent malapposition were evaluated.
Results: A total of 20526 struts were analyzed (10336 SES struts and 10190 PES struts). Exposed struts and malapposed struts of SES were observed more frequently in non-diabetic patients than those in diabetic patients. However, in PES group, both incidences of exposed struts and malapposed struts were not different between diabetic and non-diabetic patients. SES in diabetic patients also had less averaged neointimal thickness compared with SES in non-diabetic patients. However, in PES group, averaged neointimal thickness was similar between diabetic and non-diabetic patients (See table).
Conclusions: SES could not prevent neointimal growth in DM group. However, subsequent vascular response after PES implantation in DM group was similar to that in non DM group.

	SES non-DM	SES DM	p value	PES non-DM	PES DM	p value
No. of patient	29	27		28	25	
No. of stent	35	25		36	24	
No. of analyzed strut	5650	4686		5503	4687	
Exposed strut (%)	17.3	2.1	<0.0001	2.3	2.2	0.67
Malapposed strut (%)	6.3	1.6	0.002	0.7	0.3	0.51
Neointimal thickness (μm)	81±83	124±96	0.001	162±123	185±131	0.17

3:30 p.m.

2505-657 **Myocardial Function Improves Equally in Diabetes following both Multivessel PCI and CABG - Results from a CARDia Trial Substudy**

Akhil Kapur, Ayesha C. Qureshi, Malcolm Finlay, Jeremy Butts, Iqbal S. Malik, Marcus Flather, Jamil Mayet, Kevin J. Beatt, Roger J. Hall, Petros Nihoyannopoulos, Barts and the London NHS Trust, London, United Kingdom, Imperial College Healthcare NHS Trust, London, United Kingdom

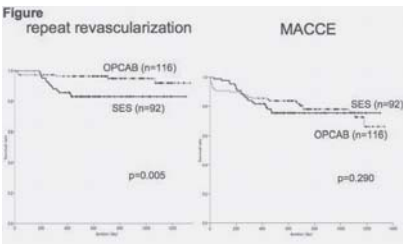
Background: The optimal form of revascularisation in diabetic patients with multivessel coronary disease has been controversial since the subset analysis of BARI (Bypass Angioplasty Revascularisation Investigation) in 1995. The CARDia (Coronary Artery Revascularisation in Diabetes) Trial presented at the ESC in 2008 and is the first study in patients with diabetes comparing Coronary Artery Bypass Grafting (CABG) and optimal Percutaneous Coronary Intervention (PCI) with abciximab and drug eluting stents.
Aim: A sub-study was undertaken in 3 centres recruiting to CARDia. It assessed comparative improvement in reversible ischaemia following revascularisation.
Methods: 71 patients underwent stress echo at baseline and 6 months. A wall motion score index [WMSI] was assigned at baseline [WMSI(pre)] and six months[WMSI(post)]. These were calculated as the sum of individual segment scores (1-4, where 1 = normal and 4 = akinetic) divided by the number of segments. Individual patients were defined as: improvement in reversible ischaemia, no change from normal, no change from positive ischaemia or worsening of reversible ischaemia. An overall score defined this difference: WMSI(∂) [= WMSI(pre) - WMSI(post)].
Results: 71 patients were recruited. 42 underwent PCI and 29 CABG. 39 PCI patients demonstrated ischaemia, 31 had a significant improvement in reversibility (79%), 5 showed no improvement in ischaemia, 3 demonstrated worsening of ischaemia. 23 CABG patients demonstrated ischaemia, 20 had a significant improvement in reversibility (87%), 2 showed no improvement in ischaemia, 1 demonstrated worsening of ischaemia.
The mean WMSI(pre) in the PCI group was 1.63 and mean WMSI(post) was 1.32. In the CABG group the mean WMSI(pre) was 1.69 and mean WMSI(post) was 1.46. The PCI WMSI(∂) was 0.31 and CABG WMSI(∂) was 0.23, (p=NS).
Conclusion: The optimal form of revascularisation in diabetic patients with multivessel disease has been controversial for many years. This subset analysis of the CARDia Trial in patients undergoing stress echo at baseline and at 6 months post revascularisation shows that both PCI and CABG achieve similar improvement in myocardial function.

3:30 p.m.

2505-658 **A Three-year Clinical Outcome after Percutaneous Coronary Intervention using Sirolimus-eluting Stent versus Off-pump Coronary Artery Bypass Grafting for Diabetic Patients with Multivessel Disease**

Yu Kataoka, Ken-ichirou Yamagata, Nobuaki Kokubu, Yoichirou Kasahara, Mitsuru Abe, Hiroyuki Nakajima, Junjiro Kobayashi, Yoritaka Otsuka, National Cardiovascular Center, Osaka, Japan

Background: BARI study showed that diabetic patients with multivessel disease (MVD) had the survival benefit by coronary bypass surgery compared with balloon angioplasty. Recently, sirolimus-eluting stent (SES) and off-pump coronary artery bypass grafting (OPCAB) have improved the outcomes of patients with coronary artery disease. However, there are few data to compare the long-term efficacy of SES and OPCAB for diabetic patients with MVD.
Methods: Two-hundred and eight diabetic patients with MVD were examined (SES: n=92, OPCAB: n=116). The occurrence of major adverse cardiac and cerebral events (MACCE: all-cause death, heart failure, non-fatal myocardial infarction, cerebral events, repeat revascularization) were compared between 2 groups.
Results: During the follow-up period (mean periods: 36 ± 8 months), the rate of revascularization was significantly higher in the SES group than the OPCAB group (figure-right panel, 20% vs 6%, p=0.005). On the other hand, significant high occurrence of in-hospital cerebral event could be seen in the OPCAB group. In the SES group, there were no stent thrombosis. Finally, there were no significant differences of MACCE between 2 groups (figure-left panel, 21% vs 24%, p=0.290).
Conclusion: At a three-year clinical follow-up, although some significant differences exist, the prevalence of MACCE was comparable between the SES group and the OPCAB group for diabetic patients with MVD, and SES seems to be effective therapeutic option for this particular category.



Figure

3:30 p.m.

2505-659 **Diabetes Mellitus Is Associated With Inadequate Platelet Inhibition After Clopidogrel Measured by a Point-of-Care Assay and With Poorer Peri-Procedural Outcome in Patients Undergoing Percutaneous Coronary Intervention**

Fabio Mangiacapra, Giuseppe Patti, Laura Gatto, Annunziata Nusca, Vincenzo Vizzi, Elisabetta Ricottini, Andrea D'Ambrosio, Germano Di Sciascio, Department of Cardiovascular Sciences, Campus Bio-Medico University of Rome, Rome, Italy

Background: Diabetes mellitus (DM) is associated with high platelet reactivity and impaired response to clopidogrel. A threshold of platelet reactivity ≥240 P2Y12 reaction units (PRU) after clopidogrel loading, as measured by the VerifyNowTM assay, is associated with a significantly higher risk of peri-procedural myocardial infarction (MI) in patients undergoing percutaneous coronary intervention (PCI). In this study we prospectively evaluated the influence of diabetes mellitus on residual platelet reactivity and peri-procedural outcome after PCI.
Methods: A total of 254 patients (96 diabetics, 38%) receiving clopidogrel and undergoing PCI were prospectively enrolled. Platelet reactivity was measured before intervention by the VerifyNowTM P2Y12 assay. Creatine kinase-MB and Troponin-I levels were measured at baseline and at 8 and 24 hours after the procedure.
Results: Diabetic patients showed higher platelet reactivity by PRU values (210±82 vs. 190±70 in patients without DM; P=0.040). A PRU value ≥240 was more frequently observed in patients with DM than in non-diabetic patients (34% vs. 21%; P=0.017). Patients with pre-procedural PRU levels in the fourth quartile had a higher prevalence of DM (49% vs. 34% in quartiles 1 to 3; P= 0.031). Among patients with DM, a PRU value ≥240 was associated with higher incidence of peri-procedural MI (15% vs 2% in those

with PRU <240; P=0.017), while this association was not observed in the non-diabetic population (P=0.159).
Conclusions: DM is associated with impaired platelet response to clopidogrel, as assessed by a point-of-care assay, and poorer peri-procedural outcome in patients undergoing PCI. In patients with DM more aggressive antithrombotic strategies may be indicated in order to reduce peri-procedural complications in the setting of PCI.

3:30 p.m.

2505-660 Four years follow-up of DIABETES trial

Pilar Jimenez-Quevedo, Lorenzo Hernando, Joan Antoni Gomez-Hospital, Andres Iñiguez, Alberto SanRoman, Rosana Hernandez Antolin, Fernando Alfonso, Camino Bañuelos, Javier Escaned, Carlos Macaya, Manel Sabate, Hospital Clínico San Carlos, Madrid, Spain, Hospital de Bellvitge, Barcelona, Spain

Background: The DIABETES trial is a prospective, multicenter, randomized, controlled trial aimed to demonstrate the efficacy of sirolimus-eluting stent (SES) implantation as compared to bare metal stent (BMS) in diabetic patients (pts). The aim of this study was to assess the 4 years clinical follow-up of the patients included in this trial.
Methods: From January to November 2003, 160 pts (222 lesions) were included in the trial: 80 pts were randomized to SES and 80 pts to BMS. Patients were eligible for the study if they were identified as non-insulin or insulin-dependent diabetics, with significant coronary stenoses in ≥1 vessel. There was a sub-randomization according to the type of diabetes. The use of abciximab during the procedure was recommended per protocol, and dual antiplatelet therapy (aspirin indefinitely and clopidogrel for 1 year) was routinely prescribed.
Results: Four-year clinical follow-up was obtained in 95% of the pts included in the trial. Between 2 and 4 years very few events have been recorded. After the second year follow-up there was not any additional target lesion revascularization (TLR) due to very late restenosis or any new episodes of myocardial infarction (MI) in the SES group. However, one additional TLR and MI was observed in the BMS group. One patient in the SES group (sudden death) and one patient in the BMS group (refractory heart failure) suffered cardiac death . The TLR rate at 4 year was still significantly lower in the SES group (8.1% vs. 37.7%, p<0.001), whereas the MI rate and the cardiac death rate were similar between groups (4,1% vs 10.4;P=0.21), (4.1% vs 6.5%, p=0.50), respectively. In addition, one patient presented a possible stent thrombosis in the SES group and 1 patient presented a definitive stent thrombosis in the BMS group.
Conclusions: After 4 years SES implantation continues to demonstrate the safety and efficacy in diabetic patients.

3:30 p.m.

2505-661 Triple Versus Dual Antiplatelet Therapy in Diabetic Patients with Acute Myocardial Infarction Undergoing Percutaneous Coronary Intervention with Drug-Eluting Stent

Kang Yin Chen, Seung-Woon Rha, Yong Jian Li, Kanhaiya L. Poddar, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong*, Other KAMIR Investigators, Korea University Guro Hospital, Seoul, South Korea, ChonNam National University Hospital*, Gwangju, South Korea

Background: Whether the triple antiplatelet strategy is superior or similar to dual antiplatelet strategy in diabetic patients (pts) with acute myocardial infarction (AMI) undergoing percutaneous coronary intervention (PCI) with drug-eluting stents (DES) remains unclear.
Methods: A total of 2,074 diabetic pts with AMI underwent PCI with DES received either dual (aspirin plus clopidogrel, Dual group, n=1,220) or triple antiplatelet therapy (aspirin plus clopidogrel plus cilostazol, Triple group, n=854). Total major adverse cardiac events (total MACE) included total death, revascularization, and myocardial re-infarction. The bleeding complications and clinical outcomes at 7 days, 1 and 8 months were compared between these two groups.
Results: Triple group was associated with significantly lower incidence of total death and total MACE up to 8 months compared with Dual group. However, the incidence of myocardial re-infarction, revascularization and TIMI major bleeding were similar between these two groups throughout 8 months clinical follow up period (Table).
Conclusions: The triple antiplatelet therapy appears to be superior to the conventional dual antiplatelet therapy in reducing early mortality and MACE without increasing the major bleeding in diabetic AMI pts undergoing PCI with DES.

Table: Clinical Outcomes at 7 Days, 1 Month and 6 Months

Variable, n (%)	Dual group (n= 1,220 pts)	Triple group (n= 854 pts)	P value
At 7 days			
Total death	69 (5.7)	16 (1.9)	<0.001
Re-infarction	3 (0.2)	1 (0.1)	0.648
Revascularization	12 (1.0)	6 (0.7)	0.497
Total MACE	84 (6.9)	23 (2.7)	<0.001
TIMI-major bleeding	8 (0.7)	4 (0.5)	0.771
At 1 month			
Total death	95 (7.8)	23 (2.7)	<0.001
Re-infarction	8 (0.7)	5 (0.6)	0.845
Revascularization	24 (2.0)	9 (1.1)	0.102
Total MACE	127 (10.4)	37 (4.3)	<0.001
At 8 months			
Total death	106 (8.7)	39 (4.6)	<0.001
Re-infarction	14 (1.1)	11 (1.3)	0.773
Revascularization	62 (5.1)	36 (4.2)	0.360
Total MACE	182 (14.9)	86 (10.0)	0.001

3:30 p.m.

2505-662 Late Outcomes of Patients with Diabetes Mellitus and Acute Myocardial Infarction Undergoing Primary Angioplasty: One Year Results from The HORIZONS AMI trial

Bernhard Witzenbichler, Roxana Mehran, Giulio Guagliumi, Ran Kornowski, Martin Desaga, Janusz Kochman, Dennis W. Nilsen, Ariel Finkelstein, Morris Mosseri, Helen Parise, Eugenia Nikolsky, Alexandra J. Lansky, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) compared to unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding, comparable composite major adverse cardiovascular events (MACE) (although with decreased cardiac mortality), and enhanced freedom from net adverse clinical events (NACE) in pts with AMI undergoing primary PCI. Whether the beneficial effects of Biv are independent of diabetic status has not been reported.
Methods and Results: A total of 3602 pts at 123 centers in 11 countries with AMI undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802) and followed up to one year. Outcomes were analyzed according to the presence of known diabetes mellitus (DM) at the time of admission. At one year in the entire study population, Biv compared to UFH+GPI resulted in a 39% reduction in major bleeding (5.8% vs. 9.2%, P<0.0001), similar MACE (11.9% vs. 11.9%, P=1.0), and a 16% reduction in NACE (15.7% vs. 18.3%, P=0.03). Compared to pts without DM, those with DM (n=593; 16.4%) had greater rates of major bleeding (9.8% vs. 7.1%, P=0.027), MACE (15.4% vs. 11.2%, P=0.003), mortality (6.3% vs. 3.7%, P=0.003), and NACE (21.3% vs. 16.1%, P=0.002). Impact of biv was independent of DM (Table).
Conclusions: In pts with DM and AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events and cardiac mortality.

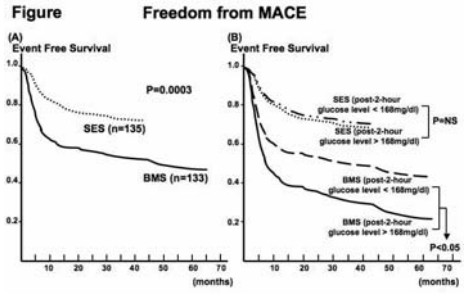
	Diabetes (n=593)		
	Biv mono	UFH+GPI	RR [95%CI]
Major bleeding	8.7%	10.7%	0.81 [0.48, 1.36]
MACE*	14.5%	16.2%	0.87 [0.57, 1.32]
NACE**	20.6%	22.0%	0.91 [0.64, 1.31]
Cardiac Death	2.5%	7.1%	0.35 [0.15,0.82]

3:30 p.m.

2505-663 The Efficacy of Sirolimus-eluting Stent in Patients with Impaired Glucose Tolerance and Coronary Artery Disease

Yu Kataoka, Nobuaki Kokubu, Yoichirou Kasahara, Mitsuru Abe, Yoritaka Otsuka, National Cardiovascular Center, Osaka, Japan

Background: Patients with impaired glucose tolerance (IGT) have small vessel, diffuse coronary narrowing similar to diabetic patients, and higher cardiovascular events compared with patients with normal glucose tolerance. Although sirolimus-eluting stent (SES) has improved the outcome of PCI, there are few data about the efficacy of SES for this category. In the present study, we examined the clinical efficacy of SES in patients with IGT and compared with IGT patients treated by BMS.
Methods: A total of 268 IGT patients with CAD were examined (BMS group n=133, SES group n=135). IGT was defined by the oral glucose tolerance test. The occurrence of MACE (death, non-fatal myocardial infarction, heart failure and repeat revascularization) was compared between 2 groups. In addition, these two groups were divided on the basis of median post-2-hour glucose level of oral glucose tolerance test (168mg/dl).
Results: In SES group, reference diameter was smaller and lesion length was longer than BMS group. (reference diameter 2.9mm vs 3.2mm, lesion length 55mm vs 28mm, p 168mg/dl) had higher MACE than that with lower post-2-hour glucose level (< 168mg/dl). However, in SES group, this difference of MACE was disappeared (Figure-B).
Conclusions: In BMS group, patients with IGT, especially patients with post-2-hour hyperglycemia, have high cardiovascular events. However, SES has improved these worse clinical outcomes regardless of post-2-hour glucose level.



I2.POSTER CONTRIBUTIONS

2506

PCI - Left Main Disease

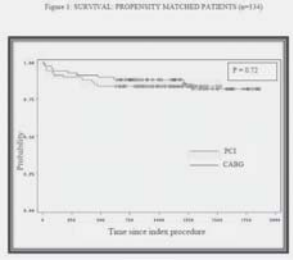
Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2506-608 **Comparison of Coronary Artery Bypass Surgery (CABG) and Percutaneous Drug-eluting Stent Implantation (PCI) for Treatment of Unprotected Left Main Coronary Artery (ULMCA) Stenosis: 3-year follow-up analysis by Propensity Score Adjustment**

Tarun Chakravarty, Anthony J. White, James S. Forrester, James M. Mirocha, Hursh Naik, Ulrich Luft, Saibal Kar, Lawrence Czer, Gregory Fontana, Alfredo Trento, Prediman K. Shah, Raj R. Makkar, Cedars Sinai Medical Center, Los Angeles, CA

Background: ACC/AHA guidelines indicate CABG is the appropriate treatment of ULMCA. Recent studies suggest that drug-eluting stents (DES) may achieve comparable outcomes.
Methods: 343 patients undergoing PCI or CABG for ULMCA stenosis were analyzed using an 18 variable propensity score model with multivariate logistic regression. Hazard ratios (HR) for death and major adverse cardiac and cerebrovascular events (MACCE) were calculated by Cox proportional hazards. Freedom from death and MACCE was compared in propensity score matched patients. The effect of operative risk on survival was assessed, using Parsonnet and Ellis scores.
Results: In 223 CABG (follow-up 1298 days) and 120 PCI patients (follow-up 973 days), death (HR 1.60 CI 0.84-3.05, p=0.155) was not statistically significant, but there was a higher risk of MACCE in the PCI group (HR 2.13, 95% CI 1.32-2.41, p=0.002). In the 134 propensity matched individuals, neither survival (log-rank p=0.72, Fig. 1) nor MACCE-free survival (log-rank p=0.17) was different. Survival was similar in low-risk surgical candidates (Parsonnet score ≤ 15, log-rank p=0.70; Ellis category I, II or III, log-rank p=0.28), but PCI had a tendency to worse survival in high-risk surgical candidates (Parsonnet score >15, log-rank p=0.017; Ellis category IV, log-rank p=0.053).
Conclusions: When ULMCA patients are treated by physician judgment rather than randomization, long-term mortality is similar for PCI and CABG, suggesting that ACC/AHA guidelines should be revisited.



3:30 p.m.

2506-609 **Drug-Eluting Stents for the Treatment of Left Main Coronary Artery Disease with Sirolimus, Paclitaxel, Zotarolimus, EPC Capture and Everolimus-Eluting Stent: Multicenter Registry in Asia**

Sunao Nakamura, Shotaro Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the safety, efficacy and durability of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES), EPC capture (ECS) and Everolimus-eluting stent (EES) on the outcome of patients with left main coronary arteries (LMT) stenosis.
Methods: A prospective analysis of 616 patients with 628 LMT stenosis (248 SES, 172 PES, 104 ZES, 42 ECS 50 EES) in five high volume Asian centers after successful stenting in LMT stenosis was performed. The study endpoints were 30 days and 9 months major adverse cardiac events (MACE), 9 months angiographic restenosis and target lesion revascularization (TLR) in those 4 groups and 24 months MACE in SES and PES groups.
Results: See table for clinical results.
Conclusion: The use of drug-eluting stents in patients with LMT stenosis was safe with low acute complication. Patients treated with SES and EES showed lesser rate of restenosis compared with other drug-eluting stents.

	SES	PES	ZES	ECS	EES
Number of patients	248	172	104	42	50
Procedural success (%)	100	100	100	100	100
MACE at 30 days (%)	0	0	0	0	0
Proximal reference diameter (mean: mm)	3.6	3.5	3.5	3.7	3.5
Stenting procedure: culotte/single/crush	75/87/86	52/40/80	36/39/29	10/29/3	4/30/16
Minimum lumen diameter post procedure (mean: mm)	3.5	3.5	3.3	3.5	3.4
Minimum lumen diameter at 9 months (mean: mm)	3.4	3.0	2.9	3.1	3.3
Restenosis rate at 9 months (%)	7.3*	9.9	16.3	16.7	6.0*
TLR at 9 months (%)	6.0*	8.7	14.4	14.3	6.0*
MACE at 2 years (%)	6.0*	8.7	14.4	14.3	6.0*

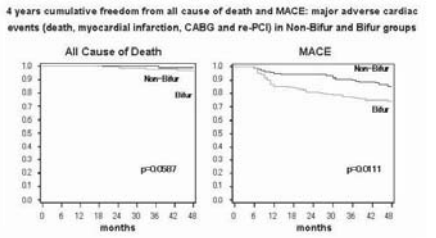
*p<0.05 vs ZES, ECS

3:30 p.m.

2506-610 **Comparison of 4 Years Efficacy and Durability of Drug-Eluting Stent Implantation in Non-Bifurcation and Bifurcation Lesion of Unprotected Left Main Coronary Arteries: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the 4 years safety and durability of drug-eluting stent implantation in non-bifurcation (ostium and/or mid shaft) (Non-Bifur) and bifurcation (Bifur) lesion of unprotected left main coronary arteries (LMT). **Methods**: A prospective analysis of 448 patients with LMT stenosis (324 Bifur and 124 Non-Bifur) in five high volume Asian centers after successful stenting in LMT was performed. LMT was treated with 5 strategies (single stenting 195 cases, T-stenting 47 cases, crush stenting 38 cases, Mini-crush stenting 93 cases, culotte stenting 54 cases, kissing stenting 21 cases). Complete clinical follow-up to 4 years is being analyzed for all 448 patients. **Results**: The baseline clinical characteristics between 2 groups were similar. Angiographic and clinical success were achieved in all patients without any major complication. At 4 years overall cardiac events of Non-Bifur (14.5%) were significantly lower than Bifur (28.0%) (p=0.011). See figure for clinical results. **Conclusion**: The use of drug-eluting stent in patients with LMT was safe and feasible with low acute complication and low incidence of restenosis. Drug-eluting stent implantation in non-bifurcation lesion of LMT showed lesser incidence of cardiac events (death, myocardial infarction, CABG and PCI) compared with those of bifurcation lesion at 4 years clinical follow-up.

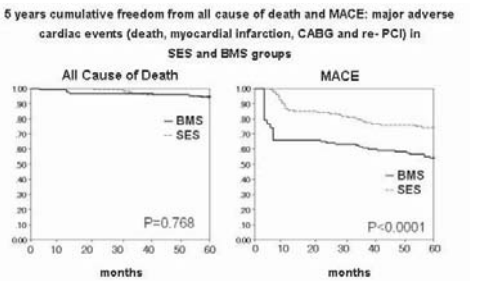


3:30 p.m.

2506-611 **Five-Year Durability of Sirolimus-Eluting Stent in Patients with Unprotected Left Main Coronary Arteries Compared with Bare Metal Stents: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the safety and efficacy of Sirolimus-eluting stent (SES) and bare metal stent (BMS) on the outcome of patients with unprotected left main coronary arteries (LMT). **Methods**: Complete clinical follow-up to 5 years is being analyzed for 241 patients who received 120 SES and 121 BMS in patients with LMT (male 71.7%, mean age 70.5 yrs) in five high volume Asian centers. Lesion location of LMT was ostial 24 cases (10.0%), mid shaft 38 cases (15.8%) and distal 179 cases (74.3%). **Results**: The baseline clinical characteristics between 2 groups were similar. Angiographic and clinical success were achieved in all patients. At 5 years overall cardiac events occurred in 12.5% of SES patients and 38.0% of BMS patients (p<0.001). See figure. **Conclusion**: The use of Sirolimus-eluting stent is effective in preventing cardiac events compared with bare metal stent associated with low acute complication and these benefits is durable at least 5 years.

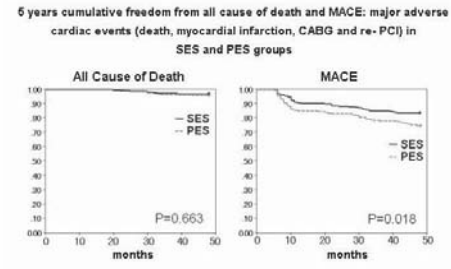


3:30 p.m.

2506-612 **Comparison of Efficacy and Four-Year Durability between Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent in Unprotected Left Main Coronary Arteries: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the safety and durability of Sirolimus-eluting stent (SES) and Paclitaxel-eluting stent (PES) on the outcome of patients with unprotected left main coronary arteries (LMT). **Methods**: A prospective analysis of 448 patients with LMT stenosis (248 SES and 200 PES) in five high volume Asian centers after successful stenting in LMT was performed. Lesion location of LMT was ostial 38 cases (8.5%), mid shaft 56 cases (12.5%) and distal 354 cases (79.0%). Complete clinical follow-up to 4 years is being analyzed for 448 patients. **Results**: The baseline clinical characteristics between 2 groups were similar. Angiographic and clinical success were achieved in all patients without any major complication. At 4 years overall cardiac events of SES (16.5%) were lower than PES (25.5%) (p=0.045). See figure for clinical results. **Conclusion**: The use of SES and PES in patients with LMT was safe and feasible with low acute complication and low incidence of restenosis. SES showed lesser incidence of cardiac events (death, myocardial infarction, CABG and PCI compared with PES).



3:30 p.m.

2506-613 **Drug-Eluting Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease: Mid- to Long-Term Results of a Two-Center Registry**

Si-Hyuck Kang, Kyung Woo Park, Seung-Jung Park, Il-Young Oh, Hae-Young Lee, Hyun-Jae Kang, Young-Seok Cho, Tae-Jin Yeon, Bon-Kwon Koo, Woo-Young Chung, In-Ho Chae, Dong-Ju Choi, Byung-Hee Oh, Young-Bae Park, Hyo-Soo Kim, Department of Internal Medicine and Cardiovascular Center, Seoul National University Hospital, Seoul, South Korea

Background: Recent results from the SYNTAX trial and MAIN-COMPARE registry suggest the comparability of percutaneous coronary intervention (PCI) with coronary-artery bypass grafting (CABG) regarding hard endpoints in patients with left main coronary artery disease. This study aimed to compare outcomes of the two strategies in an unselected 'real-world' two-center registry.
Methods: From March 2003 and June 2007, a total of 463 patients were treated by PCI with drug-eluting stents (DES) (N=205) or CABG (N=258) at Seoul National University Main and Bundang Hospital in Korea.
Results: Baseline characteristics were mostly comparable between the groups. However, patients in the CABG group were older and had more complex coronary anatomy, and ST-elevation myocardial infarction was more frequent in the PCI group. After a median follow-up of 31.2 months, the composite of death, stroke, and myocardial infarction was similar between the two groups (20.2% vs. 20.5%, *P*=0.662), while the needs of repeat revascularization was significantly higher in DES group (TVR rate: 21.0% vs. 4.6%, *P*<0.001). Although event rates of repeat revascularization at 6 months did not differ significantly (3.4% vs. 1.6%, *P*=0.191), most of the revascularization events occurred between at 6 to 12 months in PCI group (13.8% vs. 1.7%; *P*<0.001). The results were similar after adjustment of various factors, (Hazard ratio for death, stroke, MI, 1.03; 95% CI, 0.63-1.67, for death, stroke, MI, and TVR, 1.67; 95% CI, 1.13-2.48). Definite stent thrombosis occurred in 6 patients (2.9%) in the PCI group.
Conclusions: PCI using DES in patients with left main coronary artery disease showed comparable outcomes compared with CABG especially regarding hard endpoints. However, CABG was significantly associated with reduced needs for repeat revascularization.

3:30 p.m.

2506-614 **Left main bifurcation lesion and non left main bifurcation lesions : Comparison in terms of One month and six month MACE outcome**

Kanhaiya L. Poddar, Seung-Woon Rha, Kang Yin Chen, Yong Jian Li, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Korea University Guro Hospital, Seoul, South Korea

Background: Bifurcation lesions are a challenging pathology to deal with, during intervention procedure. Depending upon the location , vessel size and type of lesions , bifurcation lesions may be associated with different early and medium term outcome.
Methods: A total of 515 (male 69.7%, age 61.61 with SD 10.64) patients who underwent PCI for bifurcation lesions (left main or non left main) between October 2003 and December 2007 were evaluated for Major Adverse Cardiac Event (MACE) in one month and six month period .The factor studied were matched for other significant risk factors.
Results: -In our study population baseline characteristics were similar in left main bifurcation and non left main bifurcation groups. Difference in MACE in one month post procedure period was not statistically significant (3 out of 44 pts as compared to 10 out of 471 pts with p value 0.116 after adjustment , OR 3.317 , CI 0.755-13.030).Six month post procedure period showed significant statistical difference in terms of MACE (8 out of 44 pts as compared to 30 out of 471). Age (p value - 0.013 , OR 1.048 with 95% CI 1.010-1.088) and Left main bifurcation lesion (p value - 0.007 , OR 3.356 with CI 1.399-8.050) were independent predictors for MACE in six month period with Left main bifurcation lesion a much stronger predictor.
Conclusion: As per our study population , bifurcation lesion at left main is not associated with higher adverse cardiac event in short term outcome but is a strong predictor for higher adverse cardiac events in mid term outcome as compared to non left main bifurcation lesions.

3:30 p.m.

2506-615 **Outcome in Very High Risk Patients with Unprotected Left Main Coronary Artery Stenosis Treated with Percutaneous Coronary Intervention and Stent Implantation. Results from the Western Denmark Heart Registry.**

Lisette Okkels Jensen, Kirsten Vilan Mikkelsen, Michael Maeng, Anne Kaltoft, Hans Henrik Tilsted, Per Thayssen, Evald Hoej Christiansen, Knud Erik Pedersen, Jens Flensted Lassen, Morten Madsen, Klaus Rasmussen, Knud Noerregaard Hansen, Leif Thuesen, Odense University Hospital, Odense, Denmark

Background: Percutaneous coronary intervention (PCI) of left main coronary artery lesions may be an alternative to coronary artery bypass grafting in very high risk surgical patients. We examined mortality, risk of myocardial infarction and target lesion revascularization rate in very high risk patients with unprotected LM PCI in Western Denmark.
Methods: From January 2005 to May 2007 all consecutive patients who had unprotected LM PCI with stent implantation where identified in the Western Denmark Heart Registry. The indications for PCI were: (1) ST segment elevation myocardial infarction (STEMI), (2) non-STEMI or unstable angina, and (3) stable angina. All patients were followed for 18 months
Results: A total of 344 patients were treated with LM PCI. Drug-eluting stents were used in 88.4% of the patients. The number of stents pr. lesion was 1.2 ± 0.5. Fifty-six (16.2%) patients were diabetics. Glycoprotein IIb/IIIa inhibitors were used in 146 (42.3%) patients. Forty-two (12.2%) patients underwent intravascular ultrasound.
Conclusion: Patients with STEMI and LM culprit lesion have a high mortality risk in the acute phase whereas long term outcome is comparable to other very high risk surgical patients with unprotected left main lesions. Further, TLR rates were low and risk of stent thrombosis minimal.

	STEMI	Non-STEMI/ Unstable Angina	Stable Angina	p-value
Number of patients	71	157	116	
Age, (years)	69.3 ± 12.6	73.3 ± 10.7	68.8 ± 10.8	0.002
Euroscore (Logistic)	28.4 ± 20.4	18.6 ± 17.9	8.4 ± 10.3	<0.001
Euroscore >6, (%)	95.8	68.2	40.5	<0.001
Drug-Eluting stents, (%)	88.7	86.6	91.4	NS
Distal LM Lesion, (%)	60.6	69.4	62.9	NS
Bifurcation stenting, (%)	29.6	22.3	31.0	NS
Endpoints:				
Mortality, (%)	40.8	23.1	12.9	<0.001
Mortality < 30-days, (%)	31.0	6.4	3.4	<0.001
Mortality 30 days -18 months, (%)	9.8	16.7	9.5	NS
Myocardial Infarction, (%)	9.9	6.4	5.2	NS
Definite Stent Thrombosis, (%)	0.6	0	0	NS
Target Vessel Revascularization, (%)	2.8	4.5	5.2	NS

I2.POSTER CONTRIBUTIONS

2507

PCI - Renal Insufficiency

Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2507-664 **Randomized Clinical Trial to Compare the Nephrotoxic Effects of Iso-osmolar vs. Low-osmolar Contrast Medium in Patients with Impaired Renal Function Undergoing Coronary Angiography**

Tobias Koppara, Rainer Wessely, Adnan Kastrati, Christian Bradaric, Stefanie Schulz, Marc Vorpahl, Julinda Mehilli, Albert Schömig, Deutsches Herzzentrum München, Munich, Germany, Klinikum rechts der Isar der TU München, Munich, Germany

Background: Exposure to contrast medium for coronary angiography increases the risk of contrast induced nephropathy (CIN) in patients with renal failure. The purpose of the CONTRAST trial (COntrast media and NephroToxicity following coronary Revascularization by AngioplaSTy) was to compare the nephrotoxic effect of Iodixanol 320, an iso-osmolar

contrast medium (IOCM), and Iomeprol 350, an low-osmolar contrast medium (LOCM), in 975 patients with impared renal function undergoing coronary angiography (CAG) with or without percutaneous coronary intervention (PCI). The outcomes of 324 patients who underwent PCI have been presented as a late-breaking clinical trial at ACC 2008.

The present work assesses the outcomes of 651 patients randomly assigned to either Iodixanol 320 or Iomeprol 350 who underwent diagnostic CAG without subsequent PCI.

Methods: A prospective, randomized, double blind, comparative clinical trial was performed in two university heart centers. Patients with impaired renal function (MDRD calculated glomerular filtration rate ≤ 60 ml/min and/or S-creatinine ≥ 1.5 mg/dl) undergoing CAG were randomized to receive either Iodixanol 320 or Iomeprol 350. N-acetylcysteine was not administered.

Primary endpoint of the study is the peak increase in S-creatinine during index hospitalization. Secondary endpoints are cardiovascular events within 6 months.

Results: The cohort contained 30% diabetics of whom one third were treated with insulin and 65% patients with multivessel disease. Baseline GFR was 49.2 ± 13.0 ml/min in the IOCM group and 49.1 ± 10.9ml/min in the LOCM group. The mean change of S-creatinine was not significantly different between the groups and amounted to 0.08±0.29 mg/dl in the iodixanol and 0.06±0.27 mg/dl in the iomeprol group (P=0.47). CIN occurred in 9% in the IOCM group and 8% in the the LOCM group. There was no significant difference in mortality after a 180 days follow-up.

Conclusion: The outcomes of this trial, the largest randomized clinical trial in patients with impaired renal function undergoing coronary angiography, do not support a benefit of iodixanol to reduce nephrotoxicity associated with contrast medium injection in these high-risk patients.

3:30 p.m.

2507-665 Bivalirudin Therapy Reduces 30-Day Bleeding Complications in Patients with Chronic Renal Insufficiency: A Pooled Analysis of the REPLACE-2, ACUITY, and HORIZONS Trials

Roxana Mehran, George D. Dangas, Alexandra J. Lansky, Eugenia Nikolsky, Derek P. Chew, A. Michael Lincoff, Eric Topol, Stuart J. Pocock, Bernhard Witzenbichler, Helen Parise, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Chronic renal insufficiency (CRI) is an independent marker of ischemic and hemorrhagic events in patients (pts) undergoing PCI. This analysis assessed impact of two different antithrombotic regimens (bivalirudin [Biv] vs. heparin+GP IIb/IIIa inhibitors [Hep+GPI]) on outcomes of pts with CRI treated with PCI in 3 contemporary PCI trials (REPLACE-2, ACUITY and HORIZONS-AMI).

Methods: We assessed 30-day outcomes including composite ischemic endpoint (death, myocardial infarction, or revascularization), non-CABG related major+minor bleeding by TIMI definition, and net adverse clinical events (composite ischemic endpoint + protocol-defined major bleeding) in pts with CRI (creatinine clearance [CrCl] <60 mL/min) undergoing PCI.

Results: Among a total of 13,708 pts with baseline CrCl data, 2,295 pts (16.7%) had CRI. Pts with vs. without CRI had significantly higher rates of composite ischemia (10.5% vs. 6.6% p<0.001) and major bleeding (7.9% vs. 3.8%, p<0.001). Ischemic complications occurred with similar frequency in pts assigned to Biv vs. Hep+GPI, while rates of bleeding complications were notably lower in the Biv treated pts yielding a relative reduction of 41% (Table).

Conclusions: Presence of CRI is associated with remarkably worse short-term prognosis. In a broad spectrum of pts with stable/acute coronary syndromes and CRI, treatment with Biv compared with Hep+GPI provides significant benefit in reduction of bleeding complications without increasing rates of ischemic events.

Endpoints (%)	Heparin + GPI (N=1,179)	Bivalirudin (N=1,116)	p-value
Composite ischemic endpoint	10.0%	11.1%	0.39
Death	3.0%	3.1%	0.74
Myocardial infarction	6.4%	7.0%	0.59
Revascularization	2.8%	2.6%	0.77
Non-CABG TIMI bleeding (major + minor)	9.9%	5.8%	0.0003
Net adverse clinical events	17.9%	16.6%	0.41

3:30 p.m.

2507-666 Contrast-Induced Nephropathy Occurs Frequently and is a Powerful Independent Predictor of Morbidity and Mortality In Patients With Acute Myocardial Infarction Undergoing Primary PCI

Giora Weisz, Roxana Mehran, Leroy Rabbani, Eugenia Nikolsky, Ran Kornowski, Franz Hartmann, S. Chiu Wong, Alexandra Lansky, Helen Parise, Gregg W. Stone, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, NY, Cardiovascular Research Foundation, New York, NY

Introduction: Patients undergoing primary PCI for ST-elevation myocardial infarction (STEMI) may be at increased risk to develop contrast-induced nephropathy (CIN) due to insufficient time for protective hydration as well as other high risk features. We studied the predictors and outcomes of CIN after PCI in pts enrolled in the HORIZONS-AMI trial.

Methods: In HORIZONS-AMI, pts presenting within 12 hours of symptom onset were randomized to different anticoagulation regimens and stent types. Serum creatinine (SCr) was assessed at baseline and daily post PCI for at least 2 days. CIN was defined as SCr increase of ≥25% or ≥0.5 mg/dl from baseline.

Results: Among 2775 pts available for analysis, 422 (15.2%) developed CIN. Baseline features and outcomes in pts with and without CIN are presented in the Table.

	CIN (n=422)	No CIN (n=2353)	P value
Baseline			
Age (yrs, mean)	65.0	59.4	<0.0001
Diabetes mellitus	21.8%	15.2%	0.0007
Baseline SCr (mg/dl)	0.9	1.0%	<0.0001
CHF (Killip 2-4)	14.2%	8.1%	<0.0001
Multivessel PCI	6.8%	3.8%	0.007
Contrast dose (ml, mean)	248	225	0.0001
30-day events			
Death	7.8%	0.9%	<0.0001
Cardiac death	7.4%	0.9%	<0.0001
Reinfarction	3.6%	1.8%	0.02
Ischemic TVR	5.0%	2.4%	0.003
MACE*	11.8%	4.0%	<0.0001
Major Bleeding	17.6%	7.3%	<0.0001
1-yr events			
Death	11.4%	2.2%	<0.0001
Cardiac death	8.8%	1.5%	<0.0001
Reinfarction	6.0%	4.0%	0.057
Ischemic TVR	10.3%	6.7%	0.008
MACE*	20.5%	10.2%	<0.0001
Major Bleeding	18.6%	7.9%	<0.0001

*MACE = Death, reinfarction, ischemic TVR or stroke

Independent predictors of CIN included diabetes (RR 1.43, p<0.005), presentation with Killip class 2-4 (RR 1.37, p=0.013), and age (RR 1.03, p<0.0001). By multivariate analysis CIN was a powerful independent predictor of death (RR 6.21 and 4.2) and MACE (RR 2.97 and 1.96) at 30 days and 1 yr follow-up (all p<0.0001) .

Conclusions: CIN develops frequently in patient with STEMI undergoing primary PCI, and is more common in the elderly, diabetics, and in pts presented with CHF. The development of CIN is associated with markedly increased rates of mortality and adverse cardiovascular events and major bleeding in these high risk pts.

3:30 p.m.

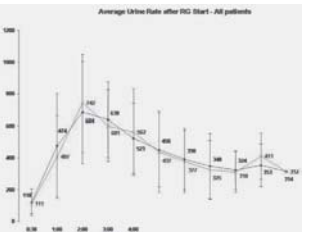
2507-667 Prevention of Contrast Induced Nephropathy Using High Volume Matched Diuresis Using the RenalGuard System: First-In-Man Study

Frederic S. Resnic, Charles J. Davidson, Richard Zelman, Simon R. Dixon, Robert Rudko, Jean-Francois Dorval, Brigham and Women's Hospital, Boston, MA

Background: Studies have suggested that high urine flow can reduce the risk of contrast induced nephropathy (CIN) by creating a lower concentration of contrast in the renal tubules. However, preventing dehydration and volume overload are challenging.

Methods: : A multicenter study was performed using a novel hydration balancing device, the RenalGuard™ System (system), to assess the safety of high urine flow rates with matching fluid input in patients at high risk for CIN (with estimated glomerular filtration rate (eGFR) < 50cc/min) undergoing angiography. The system replaces patient urine output with intravenous normal saline. Patients were given 250cc saline over 30min and then 0.5 ml/kg Furosemide. After achieving urine rates greater than 300 ml/hr, the patient underwent angiography.

Results: A total of 23 patients with mean sCR of 1.67±.69 mg/dl and eGFR of 46±13 were enrolled. Mean urine flow rate at initial contrast administration was 584±272 ml/hr. Mean contrast administered was 184±107 ml. There were no major device related complications. At 48-60hrs following the procedure mean sCr=1.82±.78 and eGFR was 40±12 with 2 patients (9%) developing CIN. The system accurately matched fluid input to output with 99.9% as shown.



Conclusions: In this first in man study, the system demonstrated effective high volume fluid balancing with acceptable safety. Further evaluation of system efficacy at preventing CIN is warranted.

3:30 p.m.

2507-668 Impact of Renal Insufficiency on Prescription of Discharge Medication after Percutaneous Coronary Intervention

Andrew O. Maree, Faith Selzer, Hani Jneid, Rene Quiroz, Oscar C. Marroquin, Suresh R. Mulukutla, Warren K. Laskey, Alice K. Jacobs, Boston University Medical Center, Boston, MA, University of Pittsburgh, Pittsburgh, PA

Background: Renal insufficiency strongly predicts death and cardiovascular events in a dose-dependent fashion after percutaneous coronary intervention (PCI). Little is known about how varying degrees of renal insufficiency impact the prescription of cardiovascular medication in PCI patients.

Methods: This was a prospective, multi-center, cohort study of consecutive patients undergoing PCI during three NHLBI Dynamic Registry recruitment waves (2001-2006). Rates of prescription of statin, aspirin, thienopyridine, beta blocker, ACE inhibitor and Coumadin were determined based on estimated glomerular filtration rate (eGFR) in discharged patients.
Results: Patients with renal insufficiency who underwent PCI were less likely to be prescribed cardiovascular medication on discharge. The percentage of patients discharged on statins, antiplatelet therapy, beta blockers and ACE inhibitors was inversely proportional to the degree of renal insufficiency (table).

Prescription Rates of Discharge Medication in Patients with Renal Insufficiency Undergoing PCI

	eGFR (ml/min/1.73m2)					
Medication on discharge	<45 (n=639)	45-59 (n=1,004)	60-74 (n=1,534)	≥ 75 (n=2,815)	p-value overall	p-value trend
Statin (%)	73.6	76.4	81.9	81.6	<0.001	<0.001
Aspirin (%)	93.7	95.5	96.7	96.9	<0.001	<0.001
Clopidogrel / Ticlopidine (%)	93.4	93.9	95.6	96.4	<0.001	<0.001
Beta blocker (%)	80.8	76.0	80.5	81.5	0.003	0.03
ACE Inhibitor %)	45.9	52.3	52.9	51.5	0.02	0.10
Coumadin (%)	11.7	10.0	7.4	6.3	<0.001	<0.001

Conclusions: Patients with even mild or moderate degrees of renal insufficiency are less likely to receive optimal discharge pharmacotherapy after PCI despite higher cardiovascular risk. An incremental decline in the prescription rate of all guideline recommended Class I medications is evident, and not only those with relative contraindication in patients with renal impairment.

3:30 p.m.

2507-669 Major Adverse Cardiac Events in Patients With Moderate to Severe Renal Insufficiency Treated With Sirolimus-Eluting Stent Versus Paclitaxel-Eluting Stent

Tarunjit Singh, Chandrasekar Palaniswamy, Rishi Sukhija, Wilbert S. Aronow, Kumar Kalapatapu, Anthony L. Pucillo, Craig E. Monsen, Carmine Sorbera, Fausan Tsai, Sastry Prayaga, Diwakar Mohan, Savneek S. Chugh, Melvin B. Weiss, New York Medical College, Valhalla, NY, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Background: There is a dearth of data comparing the long-term outcome of sirolimus-eluting stent (SES) versus paclitaxel-eluting stent (PES) in patients with moderate to severe renal insufficiency.
Methods: The incidence of major adverse cardiac events (MACE) - death, myocardial infarction, and target vessel revascularization during long-term follow-up were studied in patients with a glomerular filtration rate less than 60 ml/min/1.73 m^2 by the Modification of Diet in Renal Disease (MDRD) study equation, who underwent percutaneous coronary intervention (PCI) with either SES or PES. Out of 428 patients studied, PES was placed in 287 patients and SES in 141 patients. Stepwise Cox regression analyses were performed to identify significant independent risk factors for MACE using the variables age, gender, race, length of stents, width of stents, indications for PCI, coronary artery disease burden, complexity of lesion, prior coronary artery bypass surgery, smoking, hypertension, diabetes, dyslipidemia, body mass index, and use of drugs which included aspirin, clopidogrel, thrombolytics, glycoprotein IIb/IIIa inhibitors, beta blockers, statins, and angiotensin-converting enzyme inhibitors or angiotensin receptor blockers.
Results: At 47 ± 19-month follow-up, MACE occurred in 49 of 287 patients in the PES group (age 71.3 ± 10.5 years, 54.7% males) versus 31 of 141 patients in the SES group (age 70.6 ± 11.8 years, 53.2% males). There was no significant difference in MACE in the PES versus the SES group (17% vs. 22%, p value=0.8). This persisted even after controlling for length of the stent, complexity of lesion and other co-morbidities. All-cause mortality was not significantly different in the PES group versus the SES group (7.1% vs. 8.5%, p value = 0.7).
Conclusions: At long-term follow-up of patients with moderate to severe renal insufficiency, the rate of major adverse cardiac events and the all-cause mortality were similar in the PES and SES.

3:30 p.m.

2507-670 Peripheral Ultrafiltration for the Prevention of Contrast Induced Nephropathy: A Pilot Study

Alice A. Perlowski, Michael S. Lee, Jonathan M. Tobis, UCLA Medical Center, Los Angeles, CA

Background: Peripheral ultrafiltration (PUF) is an effective method for fluid removal in heart failure patients. This pilot study evaluated the feasibility and safety of a PUF/ hydration protocol for the prevention of contrast induced nephropathy (CIN) in patients with moderate to severe kidney dysfunction undergoing elective percutaneous coronary intervention (PCI).
Methods: Patients with serum creatinine (Cr) ≥ 1.8 mg/dL scheduled for elective PCI were recruited. A 16 Ga, 35 cm extended length catheter and 18 Ga IVs were placed in peripheral veins for blood withdrawal and return, respectively. PUF was performed with the *Aquadex FlexFlow* system (CHF Solutions, Inc.) at goal rate 500 mL/hour (hr). IV hydration with either NS or ½ NS with ½ ampule of $NaHCO_3$ was infused at a rate equal the amount of fluid withdrawn. PUF/ hydration was performed for 4-6 hrs before PCI, continued during PCI, and for 4-6 hrs post PCI. Serum Cr was measured at baseline, 12 hrs, 48 hrs and 7 days post PCI. Serum electrolytes and hemodynamics were monitored during PUF. Incidence of CIN was defined as the increase in Cr from baseline of an absolute of 0.5 mg/dL or 25% from baseline.
Results: Nine patients completed the protocol: 78% were male, with mean age of 74.9 (±10) years. Mean baseline Cr was 2.47 (± 0.8) mg/dL (Mean GFR 28.5 mL/min/1.73 m2) with mean contrast received 123 ± 52 cc. PUF was conducted for a mean duration of 4.8 ± 1.1 hr pre-PCI, 1.6 ± 0.5 hr during PCI, and 5.2 ± 0.6 hr post-PCI. In all patients, electrolytes remained stable, with the exception of serum bicarbonate, which decreased by a mean of 21% in the first 4 patients, prompting the addition of a small amount of $NaHCO_3$ to the hydration fluid in the remaining patients. No patients suffered adverse reactions, hemodynamic compromise, or significant discomfort from the protocol. 3 out of 8 patients had CIN at 48 hours, where Cr increased by mean 0.77 mg/dL; in 2 of these patients Cr normalized at 7 days. No patients required hemodialysis.
Conclusions: Peripheral ultrafiltration is a safe, well tolerated approach for the prevention of CIN. A randomized trial comparing PUF with maximum medical therapy will be performed to evaluate its efficacy.

3:30 p.m.

2507-671 Impact of Renal Insufficiency on Bleeding Events in Patients Undergoing Percutaneous Coronary Intervention

Andrew O. Maree, Faith Selzer, Brian Adams, Neal Patel, Hani Jneid, Oscar C. Marroquin, Suresh R. Mulukutla, Warren K. Laskey, Alice K. Jacobs, Boston University Medical Center, Boston, MA, University of Pittsburgh, Pittsburgh, PA

Background: Access site hematoma requiring blood transfusion predicts mortality in patients undergoing PCI. Patients with renal insufficiency undergoing PCI have increased risk of adverse cardiovascular events. Little is known about the relationship between degrees of renal insufficiency and bleeding in patients undergoing PCI.
Methods: This was a prospective, multi-center, cohort study of consecutive patients undergoing PCI during three NHLBI Dynamic Registry recruitment waves (2001-2006). In-hospital major and minor bleeding events and access site bleeding requiring transfusion were determined based on estimated glomerular filtration rate.
Results: Bleeding events and access site bleeding requiring transfusion were significantly associated with renal insufficiency (table). Patients with renal insufficiency were more commonly female (p<0.0001) and less likely to receive peri- and post-procedural anticoagulation and antiplatelet therapy.

Event Rates and Odds Ratios for Bleeding Events in Patients with Renal Insufficiency Undergoing PCI

Glomerular Filtration Rate. (ml/min/1.73m2)	Event Rate (%)	Adjusted Odds Ratio	95% CI	p-value
	Bleeding*			
<45 (n=661)	4.8	1.49	0.94-2.37	0.09
45-59 (n=1023)	5.1	1.58	1.06-2.36	0.03
60-74 (n=1544)	2.8	1.05	0.70-1.57	0.80
≥75 (n=2822)	2.7	1.00	reference	n/a
	Access site transfusion*			
<45 (n=661)	2.7	2.67	1.29-5.52	0.008
45-59 (n=1023)	1.5	1.41	0.67-2.99	0.37
60-74 (n=1544)	1.1	1.50	0.74-3.04	0.26
≥75 (n=2822)	0.6	1.00	reference	n/a
Event rate comparisons (overall and trend): *p<0.001				

Conclusions: Renal insufficiency predicts in-hospital bleeding events in patients undergoing PCI. Even moderate levels of impairment are associated with increased bleeding risk after adjustment for all other measured variables. Whether renal insufficiency imparts an added risk of mortality in patients with bleeding requiring transfusion requires further study.

3:30 p.m.

2507-672 Improved Outcomes Post Coronary Revascularization with Drug Eluting Stents Compared to Coronary Artery Bypass Surgery in Patients with End Stage Renal Disease on Hemodialysis

Syed A. Hussain, Alan C. Wilson, Abel E. Moreyra, UMDNJ-Robert Wood Johnson Medical School, New Brunswick, NJ

Background: Patients with Stage 5 renal failure on hemodialysis (HD) have increased cardiovascular risk and mortality. Historically revascularization with coronary artery bypass graft surgery (CABG) as compared to bare metal stents (BMS) has yielded better outcomes. There are few data on revascularization using drug eluting stents (DES) in this patient population.
Methods: We used the statewide MIDAS data of patients admitted with renal failure on HD who also had diagnosis of coronary heart disease (CHD) or myocardial infarction (MI) in New Jersey between 2003 and 2006. Outcomes included frequency of readmission for revascularization procedures, MI, stroke, 30-day, 1 and 2 year mortality were analyzed.
Results: A total of 9839 patients were identified. Of these 571 had revascularization at the index admission; 227 CABG, 217 DES, 91 BMS and 36 percutaneous balloon angioplasty (PTCA). The two-year mortality rate for the DES vs CABG group was 20% vs 34%, adjusted hazard ratio (HR) of 0.687 (95% CI 0.469 - 1.006). The adjusted two-year composite MACE (cardiovascular death, readmission for MI, CABG and stroke) for the DES vs CABG group was 24% vs 20%. This difference was not statistically significant.

Conclusions: Patients with Stage 5 renal failure on hemodialysis have high cardiovascular mortality. Revascularization using drug eluting stents has a lower mortality with no difference in MACE as compared to coronary artery bypass graft surgery in this population.

3:30 p.m.

2507-673 Can Contrast Induced Nephropathy be Prevented via a Renal Pleotropism Effect from Statins?

Valentyna Ivanova, Jennifer Spotti, Diane A. Vido, David M. Lasorda, Robert W. Biederman, Allegheny General Hospital, The Gerald McGinnis Cardiovascular Institute, Pittsburgh, PA

Introduction: Statins are extensively used for treatment of dyslipidemia and CAD prevention. Current controversy exists regarding possible pleotropic effect of statins with many vascular and nonvascular beds appearing to benefit from their administration. To date, little data exists to support possible nephroprotective effects of the non-lipid effects of statins.
Hypothesis: We hypothesize that pre-PCI administration of statins may be beneficial in preventing contrast induced nephropathy (CIN) post-PCI.
Methods: A retrospective study of 4000 pt charts who underwent PCI for standard clinical reasons was performed. Pts were categorized into those who developed CIN (based on serum creatinine (SCr) level elevation by ≥0.5mg/dL from baseline) and those with normal renal function after PCI. Pts with CIN were further grouped into statin (-) and statin (+) prior to PCI. Multivariate analysis against HTN, DM, age, sex, baseline SCr, BUN, contrast dose, WBC and lipid levels was performed and related to statin +/- therapy.
Results: SCr was measured within 1 week prior to or day of PCI in 806 pts: 516 (64%) male, 289 (36%) female and within 1 week post PCI. Statin therapy was initiated in 328 (41%) pts ≥week prior to PCI. When classified by statin therapy ((+) or (-)), there was no significant difference in the incidence of CIN (29 vs. 39, p=0.8). However there was a significant number of pts who had rise to over 2.5mg/dL in the statin (-) pts (p<0.05). When limited to the absolute rise in SCr, the mean rise in SCr was 0.64 in statin (-) vs. 0.16mg/dL in statin (+) subgroup, representing a 3-fold nephroprotective effect of statins (p<0.001). Interestingly, HTN, age, sex, baseline SCr or BUN, LDL/total cholesterol/ triglyceride level, WBC or contrast load were *not* a significant variable in predicting the rise in SCr; while only statin+ therapy was nephroprotective.
Conclusion: Renal pleotropism due to statin therapy to prevent against CIN appears to have important clinical benefits. A strong signal supporting additional statin capability as a nephroprotective agent emerged. Early pre-PCI use of statins therapy was independently reno-protective *despite* the strong presence of otherwise high risk co-morbidities.

3:30 p.m.

2507-674 Paclitaxel Eluting Versus Sirolimus Eluting Stents for Patients with Pre-existing Chronic Renal Insufficiency.

Asmir Syed, Itsik Ben-Dor, Sara Collins, Yanlin Li, Gilles Lemesle, Gabriel Manuela, Mickey Scheinowitz, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, Joseph Lindsay, Kenneth Kent, Lowell Satler, William O. Suddath, Augusto Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Chronic renal insufficiency (CRI) is associated with increased incidence of restenosis and stent thrombosis. Drug Eluting Stents (DES) reduce the incidence of restenosis, compared to BMS in these pts. This study aimed was to examine whether there are differences in clinical outcomes between paclitaxel eluting stents (PES) versus sirolimus eluting stents (SES) in patients with CRI who were subjected to coronary intervention.
Methods: A cohort of 570 patients with CRI who underwent intervention with DES (346 with SES and 224 with PES) were followed clinically up to 1 year and the clinical events were recorded and compared between the two groups.
Results: Baseline and procedural characteristics were similar with slightly higher number of diseased vessels in the SES group as compared to PES (2.3±0.9 vs. 2.1±0.9, p=0.06). The overall MACE and the stent thrombosis were similar between the groups. The PES group had less revascularization when compared to SES (Table). However, after covariate adjustment there was no difference seen in target vessel revascularization between stent types (HR: 2.5 [0.9-6.9], 0.083). The strongest independent predictor of Death and MACE at 1 year was number of diseased vessels.
Conclusions: Patients with CRI who are undergoing PCI with either PES or SES have low restenosis and acceptable stent thrombosis rates. Patients CRI who present with multi-vessel disease should be considered for surgical revascularization.

Baseline Characteristics (n=1033)	Cypher n=346	Taxus n=224	p value
Age, years	69.4 +/- 12	68.5 +/- 11.6	0.383
Male, %	59.0	60.7	0.677
Diabetes, %	58.1	57.2	0.826
Hypertension, %	95.7	95.1	0.748
Hyperlipidemia, %	92.8	87.3	0.031
Peripheral Vascular Disease, %	36.4	35.6	0.851
Presnetation with AMI, %	13.6	10.3	0.241
Baseline Creatinine Clearance	2.50 +/- 2.42	2.68 +/- 2.49	0.306
On Dialysis, %	18.8	21.4	0.440
LAD disease, %	35.3	28.6	0.034
Proximal Disease, %	48.1	39.0	0.008
Procedure Related ARF, %	12.2	13.5	0.535
Outcomes at 1 Year			
MACE, %	27.2%	20.1%	0.535
Death, %	18.2%	17.9%	0.535
TVR, %	10.6%	2.9%	0.001
Stent Thrombosis, %	1.4	0.4	0.411

I2.POSTER CONTRIBUTIONS

2508

Restenosis/Instent Restenosis - Prevention and Management

Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2508-616 Impact of Cilostazol on Angiographic and Clinical Outcomes After Cobalt-Chromium Alloy Stent Implantation

Hiroshi Ueda, Hiroki Sakamoto, Akira Miura, Japanese Red Cross Society Wakayama Medical Center, Wakayama, Japan

Background: The impact of cilostazol on neointimal hyperplasia after cobalt-chromium alloy stent (CCS) implantation has not been evaluated. We performed a prospective randomized trial to evaluate the angiographic and clinical impact of cilostazol after CCS implantation.
Methods: From August 2006 to March 2008, a total of 220 patients who underwent CCS (Vision™ or Driver™) implantation were randomly assigned to receive aspirin plus thienopyridine plus cilostazol (triple group, n=110) or aspirin plus thienopyridine (dual group, n=110). The primary end point was in-stent late loss at 6 months. The secondary end points were in-segment late loss and binary restenosis rate at 6 months, target lesion revascularization, target vessel revascularization (TVR), and major adverse cardiac events, including death, myocardial infarction, and TVR at 1 year.
Results: Follow-up angiography was performed in 89.5% of patients. Baseline clinical and angiographic characteristics were similar between the two groups. The in-stent (0.49±0.56mm vs. 0.85±0.52mm, p<0.001) and in-segment (0.23±0.51mm vs. 0.49±0.54mm, p=0.001) late loss were significantly smaller in the triple group compared with the dual group. The incidence of in-segment binary restenosis was also significantly lower in the triple group compared with the dual group (4.3% vs. 15.5%, p=0.01). Multivariate analysis showed that the use of cilostazol was the only independent predictor of 6-month in-segment binary restenosis (OR 0.09, 95% CI 0.02-0.58, p=0.01). One-year clinical follow-up data will be presented at the meeting.
Conclusions: Triple antiplatelet therapy with aspirin, thienopyridine, and cilostazol after CCS implantation resulted in a significantly smaller late loss and a significantly lower binary restenosis rate compared with standard dual antiplatelet therapy.

3:30 p.m.

2508-617 Predictors of Clinical Restenosis in Real-World Clinical Practice: An Analysis of Drug Eluting Stents in the EVENT Multicenter Registry

Joshua M. Stolker, Jason B. Lindsey, Steven P. Marso, Kevin F. Kennedy, Michael J. Pencina, Donald E. Cutlip, Neal S. Kleiman, David J. Cohen, Mid-America Heart Institute, Kansas City, MO, Methodist DeBakey Heart & Vascular, Houston, TX

Background: Drug eluting stents (DES) reduce restenosis compared with bare metal stents, but data are limited regarding predictors of target lesion revascularization (TLR) in DES-- particularly in the absence of angiographic follow-up.
Methods and Results: We used data from the EVENT study-- a prospective registry of the practice and outcomes of contemporary PCI at 50 US centers-- to examine incidence and predictors of TLR among DES recipients. Between 7/04 and 6/06, EVENT enrolled 7,587 patients of whom 6,871 received at least 1 DES. Over 1-year follow-up, the incidence of TLR in DES was 3.93% (on a per lesion basis), which decreased to 3.47% when early repeat PCI (<30d) and definite stent thrombosis were excluded. Independent predictors of TLR were identified from 18 candidate clinical and angiographic variables using logistic regression and are summarized in the Table. Consistent with studies from the pre-DES era, smaller stent diameter and longer stent length were independent predictors of TLR along with SVG location, while advanced age and current smoking were associated with a lower need for subsequent TLR. Diabetes was not associated with TLR in either univariate or multivariate analyses.
Conclusion: Among unselected patients undergoing PCI with DES, the per lesion incidence of TLR is <4% and is associated with several clinical and angiographic factors. Although several predictors of TLR are conserved from the pre-DES era, the absence of diabetes is noteworthy and should be validated in future studies.

Independent predictors of 12-month target lesion revascularizaton

Variable	Odds Ratio	95% C.I.	p-value
Patient age (per 10-year increment)	0.77	0.68-0.87	<0.0001
Female gender	1.62	1.23-2.14	0.0007
Prior percutaneous coronary intervention	1.58	1.21-2.07	0.0009
Current smoker	0.60	0.42-0.86	0.0050
Average stent diameter (per mm increase)	0.61	0.43-0.88	0.0077
Total stent length (per 10 mm increment)	1.15	1.06-1.25	0.0010
DES placement in saphenous vein graft	3.30	2.25-4.83	<0.0001

3:30 p.m.

2508-618 Comparison of Sirolimus versus Paclitaxel-eluting Stents for Treatment of Sirolimus-Eluting Stent Restenosis

Seiji Habara, Kazushige Kadota, Kazuaki Mitsudo, Tsuyoshi Goto, Satoki Fujii, Hiroyuki Yamamoto, Harumi Kato, Naoki Oka, Yasushi Fuku, Shingo Hosogi, Akitoshi Hirono, Toru Kawakami, Takeshi Maruo, Hiroyuki Tanaka, Daiji Hasegawa, Masao Imai, Hiroshi Tasaka, Chinatsu Yamada, Yoji Okamoto, Suguru Otsuru, Masakazu Miyamoto, Naoki Saito, Kentaro Shibayama, Yuki Tsujimoto, Kurashiki central hospital, Kurashiki, Japan

Background: Although the rate of restenosis is quite low after sirolimus-eluting stent (SES) implantation, recurrent restenosis may still occur in some cases. The next major question is what the effective treatment of recurrent restenosis in a SES will be. We evaluated the efficacy of repeat stenting (stent-in-stent) in patients with in-stent restenosis (ISR) of SES.
Methods: From December 2004 to February 2008, 123 consecutive patients (69.2±10.4 yrs) with 145 lesions after repeat drug-eluting stent (SES or Paclitaxel-eluting stent (PES)) implantation for ISR of SES were enrolled. All of the initial SES were implanted in de novo lesions. Follow-up angiogram was obtained 8 months after implantation. We compared characteristics of lesions between the two groups (the SES group (n=89) and the PES group (n=56)).
Results: There were no significant differences in clinical, lesional, or procedural characteristics between two groups. The incidence of restenosis was higher in SES group than PES group (27.0% vs 16.1%, p=0.03).
By multivariate analysis, reference diameter of less than 2.5mm (odds ratio [OR]: 1.54, 95% confidence interval [CI]: 1.1 to 3.3, p=0.05), the use of SES (OR: 1.82, CI: 1.21 to 4.56, p=0.01) and diffuse type restenosis (OR: 3.10, CI: 1.29 to 8.36, p=0.002) were independent predictors of recurrent restenosis.
Conclusions: PES is superior to SES in reducing the incidence of recurrent restenosis in lesions with ISR of SES.

3:30 p.m.

2508-619 Clinical Outcomes of Target Lesion Revascularization after Bare-Metal or Sirolimus-Eluting Stenting. Five Year Follow-up from SIRIUS

Victor Novack, Michael C. Nguyen, Meredith Mulhearn, Riya Chacko, Lena Novack, Michael Pencina, Laura Mauri, Sidney A. Cohen, Jeffrey Moses, Martin B. Leon, Donald E. Cutlip, Harvard Clinical Research Institute, Boston, MA

Background: The association of restenosis requiring target lesion revascularization (TLR) following either drug-eluting stent (DES) or bare-metal stent (BMS) placement and subsequent late cardiac outcomes has not been previously assessed.
Methods: The study objective was to assess the long-term outcomes of patients undergoing clinically driven TLR associated with restenosis (TLR group) compared to those without TLR (non-TLR group). Of the 1057 patients with one native coronary lesion randomized to sirolimus-eluting (SES) or BMS in the SIRIUS trial, those who survived free from TLR or MI for the first 30 days were followed for the primary outcome of cardiac death or MI (defined by the universal definition) for 5 years (983 subjects). Events either occurring at time of or after TLR for restenosis were assigned to TLR group. Events related to stent thrombosis occurring before a first TLR were assigned to non-TLR group. Cox proportional hazard risk model with time dependent variable (TLR) adjusted for baseline clinical and demographic covariates was used to assess the independent effect of requirement for TLR on the primary outcome.
Results: TLR occurred at least once in 160 (16.3%) patients. Primary endpoint was reached by 66 subjects during assignment to non-TLR group (24 MI and 22 cardiac deaths) and in 26 subjects in TLR group (21 MI and 5 cardiac deaths) . Of these 26 events 7 presented at time of first TLR, 3 events were periprocedural complications of TLR and 16 events occurred later during the follow-up. Multivariate analysis showed that TLR was an independent predictor of the primary endpoint (Hazard ratio [HR] 2.8, 95% CI 1.7-4.5). Other independent predictors of CD/MI were RVD (HR 0.5, 95% CI = 0.3-0.8), diabetes (HR 1.5, 95% CI 1.0-2.3) and prior MI (HR 2.1, 95% CI 1.4-3.1) however use of BMS was not (HR 0.9, 95% CI = 0.6-1.4). Brachytherapy performed in 77 cases (48.1%) was not associated with an increase risk of CD/MI following the TLR.
Conclusions: Restenosis requiring TLR after 30 days following successful initial stenting is associated with an increased risk of adverse long-term outcomes such as cardiac death/MI in subsequent years.

3:30 p.m.

2508-620 A Prospective Randomized Comparison of Vision Versus Driver Stents in De Novo Coronary Lesions

Hiroshi Ueda, Hiroki Sakamoto, Akira Miura, Japanese Red Cross Society Wakayama Medical Center, Wakayama, Japan

Aim: The aim of this study was to evaluate the relative efficacy and safety of 2 commonly used cobalt-chromium alloy stents (CCS): the Vision™ stent and the Driver™ stent.
Methods: From August 2006 to March 2008, 220 consecutive patients with de novo coronary lesions (<30 mm in length, 3.0-4.0 mm in diameter), who had angina pectoris or acute coronary syndrome, were randomly assigned to receive a Vision™ stent (n=107) or a Driver™ stent (n=113). The primary end point was in-stent late loss at 6 months. The secondary end points included in-segment late loss and binary restenosis rate at 6 months, target lesion revascularization (TLR), target vessel revascularization (TVR), and major adverse cardiac events (MACE), including death, myocardial infarction (MI), and TVR at 9 months.
Results: Procedural success rate was 100% in both stents. Follow-up angiography was performed in 89.5% of patients. Baseline clinical and angiographic characteristics were similar between both stents. Angiographic and clinical outcomes are shown in the table.
Conclusions: The use of CCS in patients with de novo coronary lesions is safe and effective. Both Vision™ and Driver™ stents provide similar angiographic and clinical outcomes in a real-world setting.

Angiographic and Clinical Outcomes

	Vision (n=107)	Driver (n=113)	p-value
In-stent late loss (mm)	0.69±0.64	0.67±0.49	0.82
In-segment late loss (mm)	0.38±0.57	0.35±0.51	0.71
In-stent binary restenosis (%)	10.4	8.9	0.91
In-segment binary restenosis (%)	10.4	9.9	1.00
TLR (%)	3.7	4.4	1.00
TVR (%)	4.7	6.2	0.77
MI (%)	0.0	0.0	N/A
Death (%)	0.0	1.8	0.50
MACE (%)	4.7	8.0	0.41

3:30 p.m.

2508-621 Long-term safety and efficacy of using drug-eluting stents to treat previous bare-metal and drug-eluting stents restenosis: insights from the DESIRE-ISR Registry

Jose de Ribamar Costa Jr, Amanda Sousa, Adriana C. Moreira, Ricardo A. Costa, Manuel N. Cano, Galo Maldonado, Cantídio Campos, Mariana Carballo, Marcos Barbosa, Ricardo Pavanello, Otávio Berwanger, J. Eduardo Sousa, Instituto de Ensino e Pesquisa do Hospital do Coração, São Paulo, Brazil

Background: Currently, DES are the 1st choice to treat BMS restenosis, replacing all other available percutaneous approaches. Although markedly reduced, DES restenosis still occurs and has been often treated with the another DES, despite the lack of robust data supporting the safety and efficacy of this approach. We sought to compare the long-term clinical outcomes of pts with BMS and DES restesnosis treated with another DES deployment.
Methods: Between May 2002 and May 2008 a total of 158 pts with BMS restenosis and 58 pts with DES restenosis were consecutively treated with a DES and enrolled in this single-center registry. Pts treated in the setting of AMI and lesions in SVG were excluded.
Results: Baseline clinical aspects did not significantly differ between the groups. The exception was the higher incidence of DM in the DES cohort (36% vs. 33%, p=0.04). Mean time between first procedure and restenosis was significant longer in the DES population (178±61 days vs. 140±38 days, p=0.02). LAD was the most frequent treated vessel (37% in the BMS and 38% in the DES, p=0.7). Main pts characteristics as well as clinical outcomes are displayed in the table. Clinical FU was obtained from all pts.
Conclusions: Percutaneous treatment of BMS or DES restenosis with the implant of another DES represents a simple, efficient and safe approach with sustained long-term results. However, the recurrence of restenosis is considerably higher among patients with prior DES restenosis.

Clinical, angiographic and procedural characteristics			
-Female gender, %	27%	29%	0.2
-Age, years	62.6±11.5	59.5±9.8	0.06
-DM, %	33%	36%	0.04
-Unstable angina, %	38%	42%	0.09
-Focal ISR(10mm), %	36%	83%	<0.01
-Diffuse ISR (>10mm),%	58%	17%	<0.01
-Lesion length,mm	16.6±7.3	14.33±5.8	0.02
-RVD,mm	2.99±0.5	2.8±0.5	0.02
-Use of Cypher to treat ISR,%	93%	79%	<0.01
Clinical outcomes (median 3.6 years)			
-MACE	8.6%	13.7%	<0.01
-Cardiac death	2.8%	0.4%	0.4
-Non-fatal MI	2.8%	1.8%	0.8
-TLR	3.0%	11.5%	<0.01
-Stent thrombosis	0.6%	0	0.8

3:30 p.m.

2508-622 U-Shape Relationship of Pre-procedural Blood Glucose Levels With In-stent Restenosis in Patients Undergoing Coronary Angioplasty

Annunziata Nusca, Giuseppe Patti, Antonio Abbate, Andrea D'Ambrosio, Fabio Mangiacapra, Germano Di Sciascio, Campus Bio-Medico University, Rome, Italy, Virginia Commonwealth University, Richmond, VA

Background. Hyperglycemia and hypoglycemia are associated with increased long-term mortality in patients with acute myocardial infarction, irrespective of diabetic state. Moreover, neointimal hyperplasia after coronary stent implantation is increased in the presence of suboptimal glycemic control. Both hypoglycemia and hyperglycemia may have a pathogenic role in endothelial dysfunction and inflammation, potential mechanisms for adverse outcome following percutaneous coronary intervention (PCI). The aim of this study was to evaluate the relationship between pre-procedural blood glucose levels and long-term outcome in patients undergoing PCI.
Methods. We retrospectively enrolled 573 patients who underwent coronary stenting at our Institution. In all patients, blood glucose levels were measured before PCI and,

according to these, patients were classified in four pre-defined groups: hypoglycemia ≤ 80 mg/dl; euglycemia 81-99 mg/dl; mild hyperglycemia 100-149 mg/dl; hyperglycemia ≥ 150 mg/dl. Primary end point was the occurrence of clinically driven in-stent restenosis, defined as stenosis of at least 50% of the luminal diameter.
Results. After a median of 15±8 months, incidence of in-stent restenosis was significantly higher in patients with hypoglycemia (27%) and hyperglycemia (24%) compared with the euglycemic (13 %) and mild hyperglycemic groups (8%) (P for trend = 0.006). Incidence of death and myocardial infarction was not different between the four groups (P = 0.10 and P = 0.22). All patients with angiographic evidence of in-stent restenosis were treated with re-PCI. A U-shaped relationship of blood glucose with in-stent restenosis was also observed both in diabetic and non diabetic subgroups.
Conclusions. In patients undergoing PCI, hypoglycemia and hyperglycemia are associated with increased incidence of in-stent restenosis. These results suggest that optimal glucose control remains an important target in diabetic and non-diabetic patients undergoing PCI.

I2.POSTER CONTRIBUTIONS

2509

Basic Science, Cell Therapy

Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2509-623 Hepatocyte Growth Factor Gene Therapy for Patients With Critical Limb Ischemia: Results of a Phase I Dose-Escalation Trial

Timothy D. Henry, JoAnne Goldman, Yale L. Wang, Daniel L. Lips, Daniel Dulas, William D. McMillan, Sue Duval, Thomas A. Biggs, Alan T. Hirsch, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: Angiogenic growth factors represent a novel treatment for patients with critical limb ischemia (CLI) who are not amenable to revascularization. We evaluated the safety and tolerability of increasing doses of IM delivery of a novel non-viral plasmid encoding 2 isoforms of hepatocyte growth factor (pCK- HGF-X7) in patients with CLI.
Methods: 12 patients with CLI, and not eligible for revascularization based on angiography performed within 12 months, were randomly assigned to increasing doses (2 mg to 16 mg) of pCK- HGF-X7 at days 0 and 14 administered into the ischemic calf. Serum HGF levels, plasmid biodistribution, transcutaneous oxygen ($TCPO_2$), ankle-brachial index (ABI), pain severity score by a 100mm visual analog scale (VAS), and ulcer size assessment were obtained at baseline and at 1, 2, 3, and 6 months. MRA was performed at baseline, 3 and 6 months.
Results: pCK- HGF-X7 was well tolerated with no serious adverse effects, amputations, or deaths through 1 year of followup. 9 patients have completed 3 months follow-up. A significant reduction in pain was reported by 8/9 patients, with mean VAS decreasing from 63.8 to 36.9 (p=.02). ABI increased from 0.34 to 0.44 (p=.056), though $TCPO_2$ decreased from 30.2 to 23 (p=NS). HGF levels remained unchanged and there was no HGF plasmid detectable via biodistribution studies after 59 days. Complete 6 month results will be available by 03/2009.
Conclusions: This first trial using HGF gene therapy in CLI patients demonstrates excellent safety with encouraging initial subjective and objective clinical results. These results support performance of a randomized, double-blind, placebo-controlled trial in patients with CLI using pCK-HGF-X7.

3:30 p.m.

2509-624 Hypertrophic Obstructive Cardiomyopathy-Alcohol Septal Ablation vs. Myomectomy: A meta-analysis

Mahboob Alam, Hisham Dokainish, Nasser Lakkis, Baylor College of Medicine, Houston, TX

Objectives: We conducted a meta-analysis of all published studies comparing alcohol septal ablation (ASA) and myomectomy (MM) for hypertrophic obstructive cardiomyopathy (HOCM).
Background: ASA is a less invasive alternative to MM for relief of symptoms in patients with drug refractory HOCM.
Methods: An extensive PubMed search identified 5 studies (351 patients) comparing outcomes of patients undergoing ASA and MM.
Results: 183/351 patients underwent ASA and 168/351 underwent MM. ASA group was older (54.4±6.3 vs. 45.0±4.4 years, p=0.02). All patients were in NYHA class II-IV. Baseline left ventricular outflow tract (LVOT) gradient was comparable (81.4 ± 14.3mmHg in ASA vs. 77.4±15.5mmHg in MM, p=0.2). Although resting LVOT gradient after ASA or MM in both groups was <20mmHg, MM group had lower LVOT gradient (18.2±6.7mmHg vs. 10.8±6.3mmHg, p<0.001). Patients in both groups had comparable improvement in NYHA class (1.5 ± 0.3 in ASA vs. 1.3 ± 0.2, p=0.2) at follow-up. A higher percentage of ASA patients required permanent pacemaker (PPM) implantation for complete heart block (18.4 ± 7.9 vs. 3.3 ± 3.9%, p=0.04). There was no significant in-hospital mortality difference between the 2 groups.
Conclusions: ASA provides similar reduction in NYHA class and LVOT gradient on a mid-term follow-up. A higher percentage of patients required PPM after ASA.

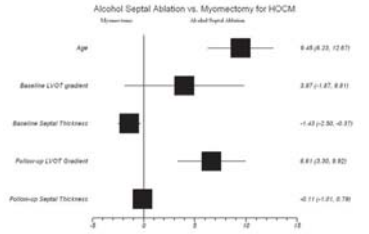


Figure-1 shows that MM patients had thicker basal septum (1.4mm on average) compared to ASA patients. Follow-up septal thickness was similar in two groups.

3:30 p.m.

2509-625 Effects of Alcohol Septal Ablation on Inflammation and Signal Peptides in Hypertrophic Cardiomyopathy

Francesco Pelliccia, Cinzia Cianfrocca, Lucia Gatta, Vincenzo Pasceri, Antonio Auriti, Christian Pristipino, Giulio Speciale, Giuseppe Rosano, San Filippo Neri Hospital, Rome, Italy, San Raffaele Pisana, Roma, Italy

Background: Alcohol septal ablation (ASA) has become a diffuse therapeutic approach in hypertrophic cardiomyopathy (HC) leading to reduced obstruction, relief of symptoms, and improvement in global LV function. It remains unknown, however, if ASA exerts favorable effects on markers of inflammation and signal peptides. Accordingly, we prospectively assessed whether changes in biochemical indexes occur after ASA in HC.
Methods: We studied 20 patients (12 women, 66±13 years) with obstructive HC who underwent ASA. Before ASA and 6 months later, erythrocyte sedimentation rate (ESR), high-sensitivity C-reactive protein (hsCRP), nuclear factor-kappa B (NF-kB), interleukin (IL)-6, tumor necrosis factor-alpha (TNF-alpha), and the glycoprotein carbohydrate antigen 125 (CA125) were evaluated in all patients. Measurements were done according to standard techniques. NFkB was quantified by a sensitive multi-well colorimetric assay for active NF-kB.
Results: ASA was successful in all patients, with NYHA functional class decreasing from 3.5±1.1 to 1.6±1.0 and LV outflow tract gradient reducing from 101±45 to 18±12 mm Hg. Procedural complications included only the need of permanent pace-maker in 3 patients. Over follow-up, no death occurred and obstruction recurred in 1 patient who underwent myectomy. Hematologic evaluation at 6-month follow-up did not show any significant change in ESR (from 15±3 to 12±5 mm/h, p<0.05), hsCRP (from 3.2±2.1 to 2.9±2.0 mg/l, p<0.05), and IL-6 from 4.2±3.1 to 4.0±2.7 pg/ml, p<0.05). Conversely, there was evidence of significant decreases in NF-kB (from 10.5±6.5 to 4.1±3.9 ng/µg cell protein, p<0.05), TNF (from 3.5±2.9 to 1.1±1.9 pg/ml, p<0.05), and CA125 (from 13.4±9.8 to 7.9±8.9 U/ml, p<0.05).
Conclusions: Signal peptides, but not markers of inflammation, decrease significantly after ASA in patients with obstructive HC. These findings suggest that symptomatic and functional improvement after the procedure can be ascribed, at least partly, to favorable changes that occur in some biochemical indexes.

3:30 p.m.

2509-626 Combination Stem Cell Therapy for the Treatment of Severe Limb Ischemia

Gabriel P. Lasala, Jose A. Silva, Philip A. Gardner, Denise Gonsior, Rebecca Lorino, Jose J. Minguell, TCA Cellular Therapy, Covington, LA

Background. A source of endothelial progenitor cells (EPCs) has been used to increase blood flow in patients with severe limb ischemia. Results have shown that infusion of this single cell type is safe and may stimulate angiogenesis; however the long-term clinical benefits have not been established. Vasculogenesis involves the interaction of EPCs with many other cell types, including mesenchymal stem cells (MSCs)-derived pericytes. Following this rationale, we used a combination of autologous EPCs and MSC to treat patients with severe limb ischemia.
Methods. Ten patients (Fontaine, stage 2b-4) were enrolled in a Phase I, randomized, open label, safety/efficacy clinical trial. MSC and EPCs, obtained by bone marrow aspiration were mixed and infused in the most hypoperfused area of the gastrocnemius muscle. Follow-up included evaluation of pain-free walking test (WT), ankle brachial pressure index (ABI), transcutaneous oxygen pressure, angiography, 99mTc-TF perfusion scintigraphy and Quality of Life (QOL).
Results. No adverse events occurred after infusion. Efficacy assessed periodically after infusion demonstrated a time-dependent improvement in all clinical parameters. A comparison of baseline values and 6 month follow up showed that ABI improved from 0.34 ± 0.19 to 0.69 ±18 (p ≤0.001), QOL increased from 1.09 ± 0.40 to 2.39 ± 0.65 (p ≤0.001) and WT improved 2.92 ± 1.64 fold.
Conclusions. Improvement in all variables as well as a concomitant increase in collateral vessels suggests that the combination cell therapy is safe and effective. The outcome of this study could be due to either a cell-dependent stimulation of pre-existing collateral vessels or the development of new mature and stable capillaries (vasculogenesis). The latter is strongly supported by the persistence of clinical effects after 8-13 months of cell infusion and by an increase in radionuclide uptake in the ischemic areas.

3:30 p.m.

2509-627 **Oxytocin Accelerates Transmigration of Umbilical Cord Blood-derived Mesenchymal Stem Cells via MMP-2 and MMP-9**

Youngkeun Ahn, Yong Sook Kim, Moon Hwa Hong, Chang Hun Song, Myung Ho Jeong, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, Chonnam National University Hospital, Gwangju, South Korea, Gwangju, South Korea

Background: Oxytocin (OT), a cardiac hormone, is reported as the cardiomyogenic factor for embryonic stem cells. It also stimulates the differentiation of cardiac progenitor cells to cardiomyocytes. We found that oxytocin receptor (OTR) was highly expressed in UCB-MSCs in compared with bone marrow (BM)-MSCs, and we designed this study to elucidate whether OT play important roles in UCB-MSCs cellular events.
Methods: MSC were isolated and cultured from UCB and BM. MSCs were treated with OT (100 nM). Angiogeneic potential was evaluated by tube formation, and cell migration was assessed by wound healing assay. The transwell migration activity was determined by using modified Boyden chamber assay. The expressions of OTR, vWF, angiopoietin (Ang)-1, vascular endothelial growth factor (VEGF), matrix metalloproteinase (MMP)-2 and MMP-9 were determined by reverse transcriptase-polymerase chain reaction (RT-PCR) or Western blot analysis. To assay the enzymatic activities of MMP-2 and MMP-9, MSCs cultured media were analyzed by zymography.
Results: The expression level of OTR was higher in UCB-MSCs than BM-MSCs. The proliferation rate of UCB-MSCs was not changed during treatment with OT (0, 10, 100, 1000 nM). Tube formation was attenuated by OT, and cell migration rate was not changed by OT treatment. On the other hand, transmigration activity was drastically accelerated by OT treatment. To examine whether MMP expression was induced by OT, mRNA level of MMP-2 and MMP-9 was determined by RT-PCR. OT increased the MMP-2 mRNA in proportion to OT concentration (10, 100, 1000 nM) in 1 hr. MMP-9 mRNA, not expressed in UCB-MSCs, was increased by 100 nM and 1000 nM OT treatment in 1 hr and prolonged to 24 hr. To examine whether MMP-2 and MMP-9 activity was increased by OT, the UCB-MSCs were cultured for 24 hr in the presence or absence of OT (100 nM), and cultured media was analyzed by zymograph. Both MMP-2 and MMP-9 activities were increased by OT treatment.
Conclusions: OT accelerated the transmigration activity of UCB-MSCs, and OT could be utilized to improve the efficient targeting of UCM-MSCs to injured heart tissue.

3:30 p.m.

2509-628 **Real Time 3D Echo Guided Intramyocardial Delivery of Mesenchymal Precursor Cells in a Chronic Myocardial Infarct Ovine Model Using a Novel Catheter**

Yanping Cheng, Warren Sherman, Genghua Yi, Gerard Conditt, Alexander Sheehy, Timothy Martens, Michael Schuster, Silviu Itescu, Armando Tellez, Anguo Gu, Greg L Kaluza, Shubhayu Basu, Juan Granada, The Skirball Center for Cardiovascular Research Foundation, Orangeburg, NY

Background: Allogeneic mesenchymal precursor cells (MPCs) provide a new treatment for heart failure. Previous studies delivered MPCs either surgically or used electromagnetic mapping and guidance for percutaneous injection. We evaluated the safety and feasibility of 3D echo guided, transendocardial delivery of MPCs (Angioblast Systems Inc, NY) in a chronic myocardial infarct (MI) ovine model using a novel injection catheter (Abbott Vascular, CA).
Methods: MI was induced by LAD 90 min occlusion-reperfusion. 4wks after MI, the infarct area was identified by echocardiography. Allogeneic MPCs ($225x10^6$ cells, n=9) or media (n=10) were injected into the infarcted myocardium. The catheter was positioned by fluoroscopy and catheter tip location and target area was confirmed by 3D echo. Cardiac function was evaluated 8 wks following injections in all animals.
Results: The average procedure time in each animal was 44±10 minutes. No adverse cardiac events occurred during and after procedure. 8 wks after cell injection when compared to baseline, EF was increased 8±7% while decreased 11±9% in control group (P<0.001). Anterior wall circumferential (S_{circ}) and radial (S_{rad}) strain were improved after MPC treatment.
Conclusions: Transendocardial injection of allogeneic MPCs was safe and effectively preserved of cardiac function in a model of chronic myocardial infarction. Real time 3D echo guided injections using a novel catheter provides a quick, safe, and effective method for percutaneous delivery of cells.

	LVEDV(ml)	LVESV(ml)	EF%	Scirc (%)	Srad (%)
Baseline (4 wks Post MI)	56±8	33±5	42±4	-8.7±4.8	12.3±9.9
8 wks MI-Media	74±20*	47±15*	37±3*	-8.5±3.3	9.2±4.1
Baseline (4 wks Post MI)	63±12	38±9	40±6	-9.9±4.4	4.6±12
8 wks MI-MPCs	74±18*	43±14	43±5*†	-15.3±3.6†	17.9±8.9*†
Mean ± SD. *P<0.05 vs. 4 wks post MI; †P<0.05 vs. MI-Media					

3:30 p.m.

2509-629 **Four Years Follow Up of Intracoronary Delivery Autologous Bone Marrow Mononuclear Cells in Patients with ST-Segment Elevation Myocardial Infarction**

Feng Cao, Dongdong Sun, Chengxiang Li, Li Zhao, Haichang Wang, Deparment of Cardiology, Xijing Hospital, FMMU, Xi'an, People's Republic of China

Background: The benefit of current reperfusion therapies for ST-elevation myocardial infarction (STEMI) is limited by post-infarction left ventricular (LV) dysfunction. Many clinical trials showed the short term outcome of bone marrow stem cell transplantation for MI patients, but few report demonstrated the long-term follow-up results.The purpose of this study was to evaluate 4-year efficacy and LV functional improvement of autologous bone marrow mononuclear cells (BMMNC) transplantation in patients with ST-segment elevation myocardial infarction.
Methods: 86 patients with STEMI who had successfully undergone percutaneous coronary intervention (PCI) were randomized to receive intracoronary injection of BMMNC (n=41) or saline (n=45) 7 days after PCI. Left ventricular function and myocardial viability were assessed by echocardiography, single-photon emission computed tomography (SPECT) and coronary angiography up to 4 years' follow-up.
Results: LV ejection fraction was markedly improved compared with control group 6 months after the procedure [(48.4±0.5)% in BMMNC group vs (45.7±0.6)% in control group, *P*<0.05], and this benefit was still evident in 4 years' follow-up [(50.5±0.8)% in BMMNC group vs (47.6±0.9)% in control group, *P*<0.05] evaluated by echocardiography. However, the current cell therapy didn't improve the myocardial viability of the infarcted area assessed by SPECT 4 years after the transplantation (0.263±0.007 in BMMNC group *vs* 0.281±0.008 in control group, *P*>0.05). During the four years' follow-up period, 1 case (2.2%) of in-stent restenosis in control group was confirmed by coronary angiography which subjected to repeat PCI. 1 patient (2.4%) of transient acute heart failure in BMMNC group and 1 death (2.2%) in control group were reported.
Conclusions: This study indicates that intracoronary delivery of autologous BMMNC is safe and feasible for STEMI patients who have undergone PCI, which can also lead to long-term benefits on heart functional improvement. The mechanism by which the functional improvement occurs still needs more dedicate investigation.

3:30 p.m.

2509-630 **Assessment of Safety, Accuracy and Human CD34+ Cell Retention After Intramyocardial Injections With a Helical Needle Catheter in a Porcine Model**

Arun Kumar, Micah Hughes, Roberto Pacheco, Christian Spies, Didier Rouy, Nate Cresswell, Ryan Braun, David Turner, David Amrani, Delara Motlagh, Sharon Pokropinski, Gary L. Schaer, Rush University Medical Center, Chicago, IL

Background: Percutaneous intramyocardial delivery of biotherapeutic agents must be accomplished in a safe and accurate manner and adequate retention is an important goal. A unique delivery system (Helix, Biocardia Inc., S. San Francisco CA) has been developed to improve maneuverability and stability of the catheter-needle-myocardium intersection using a separate deflectable guiding catheter, and an injection catheter with a helical needle at its tip and two injection ports.
Methods: In part A, 12 anesthetized swine received 6 intramyocardial injections of colored dye (at least 5 mm apart) into prespecified LV territories using fluoroscopic guidance. The hearts underwent gross and histologic evaluation to assess safety and accuracy. In part B, cell retention was assessed by labeling human CD34+ cells with iron oxide and fluorochrome. The cells were injected into 6 pigs using the same technique as part A. The animals were euthanized after 2 hours, and hearts were formalin fixed. MRI was performed on the 6 treated hearts and 4 untreated controls. Blinded analysis was performed by 2 MRI radiologists. Two treated hearts underwent immunohistologic analysis.
Results: In part A, 71 of 72 total injections (98.6%) were within the pre-specified target zone and 65 of 72 injections (90.3%) were at least 5 mm apart. No malignant arrhythmia, perforation, pericardial effusion, or death occurred. In part B, iron-oxide labeled cells were identified by MRI in all treated hearts. Antibody staining and fluorescence microscopy also confirmed retention of human CD34+, and histology suggested cell viability.
Conclusions: The Helix percutaneous intramyocardial delivery system was highly accurate and safe in this animal model using only fluoroscopic guidance. Retention of human CD34+ cells was confirmed by MRI and immunohistology. Future studies are needed to confirm accuracy, safety, and cell retention in patients. Further preclinical studies are needed to characterize cell retention over time and quantify efficiency of cell delivery.

I2.POSTER CONTRIBUTIONS

2510

PCI - DES II

Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2510-631 **Long Term Effectiveness of Drug Eluting Stents in the Treatment of In-stent Restenosis**

W T Yeo, S G Teo, C H Lee, Y T Lim, H C Tan, A F Low, National University Heart Centre, Singapore, Singapore

Background: In-stent restenosis (ISR) rate vary from 20% to 40% following implantation of a bare metal stent in coronary intervention. Drug-eluting stents (DES) is now the preferred option in managing ISR. Long-term efficacy beyond 2 years is however uncertain.
Methods: We conducted a prospective analysis of a cohort of patients presenting to a tertiary hospital with ISR who were treated with DES. All patients were followed-up for major adverse cardiac events (MACE), defined as death, myocardial infarction (MI), or target lesion revascularization (TLR). Patient's clinical information, lesion characteristics and intervention details were evaluated. They were followed up by telephone and outpatient reviews during the study period.
Results: A total of 127 patients with 135 target lesions were evaluated from 1st June 2002 to 31st July 2006. The average age of the patients was 56.9 ± 10.4 years with a male predominance (81.1%). 27.6% of patients had a myocardial infarction and 6.3% had

coronary artery bypass grafting prior to the use of DES for ISR. The target vessel was the left anterior descending artery in the majority of patients (59.3%), followed by the right coronary artery (25.9%), and left circumflex artery (9.6%). The type of stenoses according to the Mehran Classification were Pattern I (5.2%), Pattern II (33.3%), Pattern III (43.7%) and Pattern IV (17.8%). Most patients were treated with 1 DES (77.8%). Cypher, Taxus and Endeavor stents were used in 51.1%, 46.7% and 2.2% of the cases respectively. The median follow up duration was 38 months (Range from 24 to 72 months). A total of 21 (16.5%) patients experienced MACE on follow-up of at least 2 years: death 1.6%, MI 5.5% and TLR 9.4%. Patients with MACE had longer ISR length (33.6mm vs 25.0mm, p=0.009), higher grade stenosis (mean lesion diameter = 0.28mm vs 0.49mm, p=0.04), and vessel calcification [OR = 3.86 (95% CI 1.23 - 12.09)] when compared to those without MACE.
Conclusions: DES implantation is a reasonable long-term treatment for ISR. Our study demonstrates a MACE-free rate of 83.5% with median follow up to 38 months. Calcified, diffuse ISR with high grade stenoses predispose to clinical failure regardless of preexisting cardiovascular risk factors.

3:30 p.m.

2510-632 Off-label and On-label Uses of Sirolimus-eluting Stent: Angioscopic Comparison

Masamichi Yano, Masaki Awata, Shinsuke Nanto, Masaaki Uematsu, Takakazu Morozumi, Tetsuya Watanabe, Toshinari Onishi, Osamu Iida, Kenji Kawamoto, Fusako Sera, Hitoshi Minamiguchi, Kuniyasu Ikeoka, Shin Okamoto, Nobuaki Tanaka, Haruyo Yasui, Takayuki Ishihara, Tomoharu Dohi, Seiki Nagata, Kansai Rosai Hospital Cardiovascular Division, Amagasaki, Japan

Background: Off-label use of sirolimus-eluting stent (SES) may have an increased risk of late stent thrombosis. However, neointimal surfaces following off-label and on-label use of SES have not been explored by angioscopy. We compared the angioscopic findings of on-label and off-label uses of SES to explore differences in arterial healing.
Methods: We retrospectively enrolled 44 patients with 70 SES who underwent coronary angioscopy between 6 and 12 months after stenting. Neointimal coverage was angioscopically compared between off-label and on-label uses. Neointimal coverage was graded as complete/incomplete, depending on whether stent struts were embedded by the neointima.
Results: Study subjects included 56 off-label and 14 on-label uses. Incomplete coverage was more common in off-label use than in on-label use (71% versus 36%, p<0.05). Although not statistically significant, exposed struts was found in 16 stents in off-label use, whereas in only 1 stent in on-label use (29% versus 7%). Incidence of thrombus tended to be higher in incomplete coverage than in complete coverage (24% versus 8%). Among off-label use, bifurcation lesions were significantly associated with exposed struts by multivariate analysis (p<0.05).
Conclusion: Compared with on-label use, off-label use of SES was significantly associated with incomplete coverage. Bifurcation lesions were strongly associated with exposed struts.

3:30 p.m.

2510-633 TAXUS ARRIVE Program: The Utility of a Comprehensive Drug-Eluting Stent Registry

John M. Lasala, David A. Cox, Keith D. Dawkins, Donald S. Baim, ARRIVE Program Participating Physicians, Washington University School of Medicine, St. Louis, MO

Background: Randomized clinical trials (RCT) of drug-eluting stents (DES) generally involve highly selected patients (pt) that exclude many treated in routine practice. Conversely, registry studies include the broadest pt subsets but lack concurrent controls and may lack rigorous ascertainment of endpoints.
Methods: The ARRIVE 1 and 2 Postmarket Surveillance Registries were designed to enroll consecutive TAXUS-treated pts with no other inclusion/exclusion criteria at procedure start. Data were captured via web-based reporting and verified against source documents for all cardiac events. Clinical monitors assessed an additional 10-20% per site sampling of pt to ensure data accuracy and completeness. An independent Clinical Events Committee determined the relationship of cardiac events to study device.
Results: Of 7,492 total pts, 64% represented expanded use beyond the simple-use (single vessel, single stent) characteristics found in the TAXUS pivotal RCT. Two-year follow-up was 94%. ARRIVE simple-use pt outcomes mirrored those of similar pt in the RCT TAXUS arms and outcomes for acute myocardial infarction pt were similar to results in the HORIZONS-AMI RCT (Table 1).
Conclusion: The close parallels in findings for simple-use and expanded-use pts between ARRIVE and RCT data validate the high event ascertainment in ARRIVE and show that a high-quality registry can provide rigorous and reliable data to guide physician decisions when analogous RCT data are not available.

Table 1: Comparison of ARRIVE Subgroup Data with RCT Data

Parameter	TAXUS RCTa TAXUS Arm	ARRIVE Program Simple-use Subgroupb	HORIZONS AMI TAXUS Armc	ARRIVE Program AMI Subgroupd
Baseline Characteristics	N=1,400	N=2,698	N=2,257	N=954
Male (%)	71.5	65.9	77	66.6
Age (mean)	62.8	63.0	59.9	62.2
Smoker (%)	22.0	24.2	46.3	36.2
Hyperlipidemia (%)	70.1	74.4	42.2	59.7
Hypertension (%)	72.1	75.4	51.2	63.9
Diabetes (%)	25.4	29.8	16.1	24.6
Previous MI (%)	31.6	26.9	9.1	67.1
Outcomes at 1 Year (Kaplan-Meier Analysis)				
All death (%)	2.0	2.3	3.5	3.8
Cardiac death (%)	1.1	1.3	2.4	2.6
MI (%)	0.6 (Q-wave)	0.5 (Q-wave)	3.7	2.8
TVR (%)	5.3e	4.9	5.8	5.8
ARC STf (%)	0.9	0.9	3.1	2.6

a: Includes TAXUS I, II-SR, IV, and V-de novo
b: Simple-use cases excluded one or more of the following: AMI; bifurcation, cardiogenic shock, chronic total occlusion, failed brachytherapy, vein graft stenting, in-stent restenosis, large vessel (RVD>3.75), left main disease/stenting, long lesion (>28 mm), moderate/severe calcification, multivessel stenting, ostial lesion, renal disease, severe tortuosity, small vessel (RVD<2.5 mm).
c: Stone GW, HORIZONS AMI: A prospective, randomized comparison of paclitaxel-eluting TAXUS stents versus bare metal stents during primary angioplasty in acute myocardial infarction-one year results; Presented at TCT 2008; downloaded 16Oct08 from http://www.crtonline.org
d: ARRIVE AMI population was more inclusive than HORIZONS AMI due to no exclusion criteria in the registry.
e: Non-angiographic subset (N=287)
f: ARC definite plus probable (Cutlip, et al. Circulation. 2007;115:2344)
Abbreviations: AMI=acute myocardial infarction; RCT=randomized clinical trial; ST=stent thrombosis; TVR=target vessel revascularization

3:30 p.m.

2510-634 Evaluation of Bioabsorbable Polymer Coated Paclitaxel-Eluting Stent by Optical Coherence Tomography; STELLIUM First-in-Man Study

Amane Kozuki, Junya Shite, Toshiro Shinke, Yusuke Tanino, Daisuke Ogasawara, Takahiro Sawada, Hiroyuki Kawamori, Yuki Kato, Naoki Miyoshi, Naoki Yoshino, Damian Conway, Ken-ichi Hirata, Kobe University Graduate School of Medicine, kobe, Japan, Disa Vascular Ltd, Cape Town, South Africa

Background: Recent reports suggest durable polymers used for first generation drug-eluting stent (DES) as potential contributors to persistent inflammation and late DES thrombosis. In this study, we evaluated the vascular response to STELLIUM stent, which is coated with absorbable polymer for slow releases of low dose paclitaxel.
Methods: Sixteen patients with stable angina were implanted with 21 STELLIUM stents in South Africa. Quantitative coronary angiography (QCA) was performed at baseline and QCA and optical coherence tomography (OCT) analysis were done at 6 months post-implant on 12 of these patients (15 stents). Offline OCT analyze was fulfilled with every 1 mm cross section. Strut apposition to the vessel wall and thickness of neointima on each strut surface was evaluated. Frequency of intravascular thrombus was also evaluated.
Results: In-stent and analyzed late luminal loss was 15.33±10.22mm and 17.33±6.60mm (binary restenosis: 0%). By OCT, 3015 struts were visualized and average neointimal thickness was 148.93±154.44μm . Well-apposed strut with and without neointima overlay was 2725 (90.38%) and 273 (9.05%). Malapposed struts were observed in 7 (0.23%), 5 of those (0.17%) were uncovered with neointima. Thrombus attached to struts was observed in 1 stent but no angiographic obstruction.
Conclusions: This first-in-man study of STELLIUM shows feasibility and safety of bioabsorbable polymeric surface coating paclitaxel-eluting stent. Additional large clinical trials are warranted.

3:30 p.m.

2510-635 Difference in Neointimal Coverage on the Stent Strut Between Sirolimus- and Paclitaxel-Eluting Stents: Optical Coherence Tomography Analysis

Kenya Nasu, Etsuo Tsuchikane, Osamu Katoh, Mariko Ehara, Yoshihisa Kinoshita, Masashi Kimura, Sudhir Rathore, Mitsuyasu Terashima, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Optical coherence tomography (OCT) is a novel imaging technique with high resolution, which is able to evaluate microscopic vascular response after drug-eluting stent implantation. The aim of this study is to evaluate the differences of chronic vascular response following coronary stenting between sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES).
Methods: Non-restenotic 60 SESs (56 patients) and 60 PESs (53 patinets) were imaged with motorized OCT pull-back system (1 mm/s) at 9-month follow-up and analyzed at interval of 1 mm. The stent with malapposed strut observed by intravascular ultrasound at the time of stent implantation was excluded from analysis. Neointimal coverage of stent struts and the incidence of stent malapposition were evaluated.
Results: A total of 20526 struts were analyzed (10336 SES struts and 10190 PES struts). Exposed struts and malapposed struts were observed more frequently in SES group than PES group (10.5% vs. 2.3%, p<0.0001, 4.2% vs. 0.7%, p<0.0001). SES also had less averaged neointimal thickness compared with PES (101±92μm vs. 179±130μm, p<0.0001).
Conclusions: Although neointimal growth was more strongly suppressed by SES, both exposed and malapposed struts were observed more frequently in SES group. This study suggested that dual antiplatelet therapy should be recommended for even patients with non-restenotic SES at 9-month follow-up.

3:30 p.m.

2510-636 Gender-Specific Outcomes after Paclitaxel-Eluting Stent Implantation in Routine Practice

John M. Lasala, David A. Cox, Ruth M. Starzyk, Takahiro Uchida, Keith D. Dawkins, Donald S. Baim, ARRIVE Program Investigators, Washington University School of Medicine, St. Louis, MO

Background: Pivotal randomized controlled trials (RCT) of drug-eluting stents (DES) have included small numbers of women and have been limited to a highly selected patient (pt) population excluding many treated in routine practice. Adverse outcomes have not been independently correlated with gender in RCT as women and men have derived similar benefit through 1 year with DES compared to bare metal stents. This study assessed the association of gender with 2-year outcomes in a large cohort of unselected patients.
Methods: The ARRIVE Postmarket Surveillance Program was designed to enroll at procedure start consecutive pts treated with the TAXUS Express^2 Stent System with no other inclusion/exclusion criteria. Clinical monitors assessed 100% for cardiac events and an extra 10-20% per site sampling of pt to confirm data accuracy and completeness. An independent Clinical Events Committee determined the association of cardiac events to study device.
Results: Women, representing 33% of 7,492 analyzed pts, were older with more diabetes and by unadjusted analysis had significantly higher 1- and 2-year rates for mortality and target lesion revascularization (TLR, Table 1). By multivariate analysis, gender was a significant factor for TLR at 2 years (Male: HR 0.75 [0.63-0.90] *P*=0.002) but not for death/cardiac death/MI.
Conclusion: Unlike in pivotal RCT, in the US real-world ARRIVE registry women had slightly higher mortality and TLR through 2 years. By multivariate analysis gender was a significant factor for TLR.

Table 1:
ARRIVE Baseline Characteristics and Outcomes in Men and Women

	Men	Women	P-valuea
Baseline Characteristics			
Simple Useb	35.2% (1777/5043)	37.6% (921/2449)	0.045
Age	62.92±11.48 (5043)	66.99±11.73 (2449)	<0.001
Smoker at baseline	25.0% (1259/5043)	20.6% (505/2449)	<0.001
Hypercholesterolemia	76.0% (3833/5043)	75.3% (1844/2449)	0.50
Hypertension	73.3% (3698/5043)	81.4% (1993/2449)	<0.001
Diabetes mellitus	30.0% (1511/5043)	35.0% (857/2449)	<0.001
Oral medication	22.3% (1125/5043)	24.2% (593/2449)	0.07
Previous MI	38.3% (1929/5043)	32.4% (793/2449)	<0.001
Previous stroke	5.4% (270/5043)	8.0% (197/2449)	<0.001
Previous CABG	22.6% (1138/5032)	14.9% (364/2439)	<0.001
Previous PCI	38.1% (1902/4994)	34.1% (823/2414)	0.001
CHF	6.4% (321/5043)	7.8% (190/2449)	0.03
Multivessel stenting	16.1% (814/5043)	16.1% (394/2449)	0.95
Mean RVD (mm)	3.04±0.42 (5043)	2.95±0.40 (2448)	<0.001
Mean lesion length (mm)	15.84±9.01 (5033)	15.33±8.29 (2442)	0.02
Outcomes (Unadjusted Analysis)			
1 Year (97% follow-up)			
Death	3.2% (157/4884)	4.2% (100/2390)	0.04
Cardiac death	2.0% (97/4884)	2.6% (62/2390)	0.10
MI	2.1% (102/4884)	2.2% (53/2390)	0.72
Q-wave MI	0.7% (34/4884)	0.5% (12/2390)	0.33
TVR	6.3% (310/4884)	7.6% (182/2390)	0.04
TLR	4.6% (225/4884)	6.2% (148/2390)	0.004
ARC ST (definite/probable)c	1.8% (86/4884)	1.8% (42/2390)	0.99
2 Years (94% follow-up)			
Death	6.1% (288/4706)	7.4% (173/2329)	0.04
Cardiac death	3.4% (161/4706)	4.3% (99/2329)	0.08
MI	3.2% (152/4706)	3.3% (77/2329)	0.87
Q-wave MI	1.1% (52/4706)	0.8% (18/2329)	0.19
TVR	9.8% (461/4706)	10.9% (254/2329)	0.15
TLR	7.2% (341/4706)	8.8% (204/2329)	0.03
ARC ST (definite/probable) c	2.7% (127/4706)	2.4% (57/2329)	0.53

Values are % (count/sample size) or mean±SD (n)
a: P values are two-sided from Student t -test for continuous variables and from the chi-square test for binary proportion.
b: Simple-use cases excluded one or more of the following: AMI; bifurcation, cardiogenic shock, chronic total occlusion, failed brachytherapy, vein graft stenting, in-stent restenosis, large vessel (RVD>3.75), left main disease/stenting, long lesion (>28 mm), moderate/severe calcification, multivessel stenting, ostial lesion, renal disease, severe tortuosity, small vessel (RVD<2.5 mm).
c: Cutlip, et al., Circulation 2007;115:2344
Abbreviations: CABG=coronary artery bypass graft; CHF=congestive heart failure; MI=myocardial infarction; PCI=percutaneous coronary intervention; RVD=reference vessel diameter; ST=stent thrombosis; TLR/TVR=target lesion/vessel revascularization

3:30 p.m.

2510-637 Does the Therapeutic Option Used for a Drug-eluting Stent Failure Impact the Clinical Outcomes?

Gabriel Maluenda, Gilles Lemesle, Itsik Ben-Dor, Sara D. Collins, Asmir Syed, Yanlin Li, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Treatment of in-stent restenosis (ISR) of drug eluting stents (DES) is challenging. There are several therapeutic options for this condition including repeat DES, intravascular radiation (IRT) or conventional plain-old balloon angioplasty (POBA), but the optimal treatment has not yet been defined. This study aimed to assess the predictors for recurrence of DES restenosis and to detect optimal therapeutic strategy.
Methods: A cohort of 476 patients who were previously treated with DES and presented with angiographic restenosis was identified. 266 patients were treated with new-DES implantation, 87 with IRT and 123 with POBA. Of these 340 patients completed 12 month follow-up. The composite endpoint of death-MI-target lesion revascularization (MACE) and target lesion revascularization were assessed up to 1-year follow up.
Results: This population presents a high prevalence of co-morbidities: diabetes (44.5%), chronic renal failure (18.9%) and congestive heart failure (17.8%). There was not significant difference between the 3 groups regarding their baseline clinical and angiographic characteristics. The rate of diffuse and proliferative restenosis (length > 20 mm) at baseline was 22.2% for repeat DES group, 18.4 % for IRT group, and 34.7% for POBA. The overall incidence of recurrent DES failure was 13.4 % (n=45). The rate of the composite MACE was 14.9% for DES, 19.4% IRB, and 18.0% for POBA (p=0.63). The univariate assessment of covariate association with recurrent restenosis up to 1 year revealed no predictors, however, chronic renal failure trended towards an association (HR: 1.8[0.9-3.3], p=0.074).
Conclusion: Recurrence of ISR after treatment of DES failure is not benign and remains challenging independent of the treatment modality. Chronic renal insufficiency remains the most important adverse prognosis marker for failure of treatment in this population.

3:30 p.m.

2510-638 Frequency and Risk of Noncardiac Surgery After Drug-Eluting Stent Implantation

Nainesh K. Gandhi, Subhash Banerjee, Emmanouil S. Brilakis, VA North Texas Healthcare System, Dallas, TX, University of Texas Southwestern Medical Center, Dallas, TX

Background: Limited data exist on the frequency of noncardiac surgery and the incidence of perioperative complications after coronary drug-eluting stent (DES) implantation.
Methods: We evaluated the perioperative outcomes of all patients who underwent noncardiac surgery after receiving a DES at our institution between 1/2005 and 7/2008.
Results: Of the 823 patients receiving a DES during the study period, subsequent noncardiac surgery was required in 131 (16%) patients. Mean age was 60 years and 96% were men. A total of 191 surgeries were performed (34% general surgery, 18% dermatologic, 15% vascular, 8% urologic, 8% orthopedic, 7% head and neck, 5% colorectal, 3% ophthalmologic, 2% dental) after a mean and median time of 17 ± 10 and 15 months, respectively from DES implantation.
A complication occurred in 19 surgeries (10%): excessive bleeding in 11 patients (6%), myocardial infarction in 4 patients (2%), acute renal failure in 1 patient (0.5%), hypotension and syncope in 1 patient (0.5%) and postoperative death in 2 patients (1%). Stent thrombosis occurred in only 1 patient (0.5%). A complication occurred in 3 of 27 (11%) surgeries done within 6 months vs. 16 of 164 surgeries (10%) done greater than 6 months post DES implantation (p=0.83). Clopidogrel was continued during the perioperative period in 58 surgeries (30%). A complication occurred in 6 of 58 surgeries (10%) in which patients received perioperative clopidogrel vs. 13 of 133 surgeries (10%) in which patients did not receive perioperative clopidogrel (P=1.0).
Conclusions: Patients receiving a DES often require noncardiac surgery afterwards. The risk of perioperative myocardial infarction or stent thrombosis appears to be low.

3:30 p.m.

2510-639 Prevalence and Predictors of Early and Late Restenosis After Sirolimus-Eluting Stent Implantation for De Novo Lesion

Kazushige Kadota, Kazuaki Mitsudo, Katsumi Inoue, Tsuyoshi Goto, Satoki Fujii, Hiroyuki Yamamoto, Harumi Kato, Naoki Oka, Yasushi Fuku, Shingo Hosogi, Hiroyuki Tanaka, Seiji Habara, Daiji Hasegawa, Masao Imai, Suguru Ootsuru, Youji Okamoto, Masakazu Miyamoto, Naoki Saito, Kentaro Shibayama, Kurashiki Central Hospital, Kurashiki, Japan

Background: Recently, the concern about late restenosis after drug eluting stent implantation has emerged. However, the prevalence and predictors of late restenosis after Sirolimus-eluting stent (SES) implantation remain unclear. We evaluated the prevalence of early and late restenosis after SES implantation for de novo lesion by serial follow-up angiography (f/u CAG). **Methods:** From November 2002 to December 2006, 1913 patients (3025 de novo lesions) were treated with SES exclusively and successfully. Of these lesions, 2430 lesions underwent early f/u CAG at 6-8 months after PCI (early f/u rate, 80.3%). Of these lesions, 1830 lesions without restenosis underwent late f/u CAG at 12 months after early f/u CAG (late f/u rate 82.8 %). Early and late restenosis were defined as restenosis at early f/u and restenosis at late f/u without early one respectively.
Results: Early and late restenosis rate were 9.0 % and 6.3 % respectively. Early and late target lesion revascularization (TLR) after SES implantation was 5.9 % and 4.1 % respectively. By multivariate analysis, the predictors of early and late restenosis were

shown in the table. **Conclusions:** Late restenosis after SES implantation was not a rare phenomenon for de novo lesion. There were some differences between the predictors of early and late restenosis. These results suggested that the mechanism of early and late restenosis could be different.

Predicctors of Early and Late Restenosis

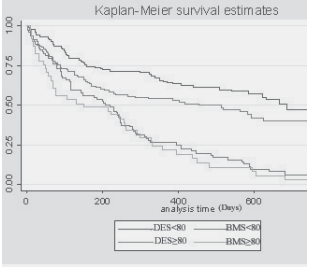
Predictors of Early Restenosis				Predicotrs of Late Restenosis			
	OR	95%CI	P Value		OR	95%CI	P Value
Hemodialysis	5.25	3.00-9.18	<0.0001	Longer stenting (>36mm)	2.61	1.33-5.13	0.0055
LMT stenting	2.27	1.49-3.49	0.0002	Saphenous vein graft	5.43	1.10-26.9	0.0381
Saphenous vein graft	7.43	2.28-24.3	0.0009				
Diabetes Mellitus	1.71	1.23-2.38	0.0015				
Aorto-ostial lesion	3.25	1.51-6.97	0.0026				
Bifurcation lesion	1.59	.112-2.26	0.0101				
Longer stenting (>36mm)	1.81	1.11-2.97	0.0179				

3:30 p.m.

2510-640 Drug Eluting Stents (DES) versus Bare Metal Stents (BMS) in Octogenarians: A Comparative Outcome Analysis

Nitin Mahajan, Ashok Kondur, Rajeev Sudhakar, Vikas Veeranna, Ashutosh Niraj, Luis Afonso, Wayne State University, Detroit, MI

Background: Despite the increasing number of elderly, octogenarians (≥80 years) are underrepresented in percutaneous coronary intervention (PCI) trials. Limited data on comparative clinical outcomes following PCI with DES or BMS in octogenarians exist.
Methods: Retrospective screening of 3960 consecutive patients that underwent PCI at a tertiary medical center (Jan 2000 -Dec 2006) identified 220 octogenarians (83.6±3.4 years) and 376 elderly (<80 yrs) patients (71.3±4.3 years). End points included all cause mortality and major adverse cardiovascular outcomes (MACE) defined as recurrent MI, CHF, revascularization or death at 30 days and 2 years of follow up. The patients were stratified into 4 groups a) elderly (<80 yrs) DES PCI (n=176), b) octogenarian DES PCI (n=146), c) elderly BMS PCI (n=202) and d) octogenarian BMS PCI (n=74).
Results: Cumulative 2 year mortality was higher in octogenarians compared to elderly <80 (24% vs. 22% p <0.05). After adjustment of confounding variables, age≥80 years remained a significant predictor of mortality (hazard ratio 1.33, 95% CI 0.92-1.92) and MACE (HR 1.40, 95% CI 1.06-1.85). On multivariable analysis, BMS was associated with higher (Figure) MACE (HR 1.31, 95% CI 1.13-1.51 p<0.01), and mortality (HR 2.72, 95% CI 1.15-6.51, p=0.02) in octogenarians at 2 years. No differences were seen at 30 days.
Conclusions: Octogenarians have a high mortality risk following PCI. However, compared to BMS, DES use confers a significant survival benefit and longer MACE free period.



3:30 p.m.

2510-641 Gender-based Outcomes Following Treatment with Zotarolimus-Eluting Stents: Analysis of 6 Clinical Trials

Marcus L. Williams, Ryan A. Brown, Colin M. Barker, Minglei Liu, Laura Mauri, Ian Meredith, Jean Fajadet, William Wijns, Paul S. Teirstein, Martin B. Leon, David E. Kandzari, Scripps Clinic, La Jolla, CA

Background: Whether outcomes differ according to gender among patients treated with zotarolimus-eluting stents (ZES) has not been characterized.
Methods: In a patient level analysis of the Endeavor ZES clinical trials program (N=2,132), angiographic and clinical findings were compared at baseline and over late-term follow-up according to gender.
Results: Among 2,132 patients treated with ZES and enrolled in 6 Endeavor clinical studies, 608 (28%) were women. Compared with men, women treated with ZES had significantly older age (*P*<0.001) and a higher prevalence of diabetes and hypertension (*P*<0.001 for both). Women less commonly had a history of recent (*P*=0.006) or prior myocardial infarction (*P*<0.001), prior percutaneous coronary revascularization (*P*=0.009) and smoking (*P*<0.001). Reference vessel diameter was significantly smaller for women compared with men (2.7±0.4 mm versus 2.8±0.5 mm, *P*<0.001). Risk-adjusted outcomes at 1 and 2 years according to gender are represented in the Table.
Conclusion: Despite greater baseline risk and a numerically higher incidence of stent thrombosis among women treated with ZES, late-term composite outcomes of TVF and MACE are significantly lower in women due to decreased rates of target lesion and target vessel revascularization. These findings inform the need to better understand the interaction of gender with safety and efficacy outcomes following percutaneous revascularization with ZES.

	1 year			2 years		
	Female (N=608)	Male (N=1,524)	P value	Female (N=608)	Male (N=1,524)	P value
Cardiac Death	1.0	0.5	0.16	1.4	1.0	0.12
Myocardial Infarction	2.0	2.4	0.17	2.4	2.6	0.34
Target Lesion Revascularization	4.8	5.6	0.04	5.8	6.4	0.07
Target Vessel Revascularization	6.7	8.7	0.007	8.2	10.4	0.005
ARC Definite/Probable Stent Thrombosis	1.2	0.4	0.13	1.4	0.5	0.06
Major Adverse Cardiac Events	7.4	8.3	0.02	8.8	10.2	0.01
Target Vessel Failure	8.5	10.7	0.008	10.0	12.8	0.004
All values expressed as percent.						

3:30 p.m.

2510-642 A Risk Score For Predicting Major Adverse Cardiovascular Event Within 30 Days After Percutaneous Coronary Intervention With Drug-Eluting Stent, Results From The STENT Registry

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Background: Previous risk models predicting in-hospital major adverse cardiovascular event (MACE) after coronary intervention may underestimate actual post-procedure complications due to the trend toward early discharge of patients. In addition, these studies were not exclusive to drug-eluting stent (DES).
Methods: Using a subset (N 10,679) from the STENT registry, a logistic regression model was developed to predict 30day MACE which includes death, myocardial infarction, target vessel revascularization and stroke. A risk score was created from the model and validated in another subset (3,099).
Results: In the study subset, there was significant difference between in-hospital and 30day MACE 2.0 vs. 4.2% (p <0.01). Univariate analyses comparing patients with vs. without 30day MACE showed that female (33.2 vs. 34.1%), mean age (63.2±11.9 vs. 62.7±11.7years), age ≥75 years (17.2 vs. 16.5%), diabetes mellitus (33.0 vs. 30.6%), and previous coronary bypass surgery (16.7 vs. 15.8%) were not significant predictors, which contrasts previous studies. The c-statistics of the final model were 0.653 and 0.650 in the study and validation subset, respectively.
Conclusion: In this large real world registry of DES, in-hospital MACE did not represent short-term post-procedure prognosis, and some demographic risk factors were not consistent with previous studies. It may be valuable to see if another prediction rule such as recursive partitioning fits better in our dataset.
Multivariate predictors of 30day MACE

Variables in the final model	Integer score	Coefficient	OR (95% CI)	p value
Hemoglobin <10	4	0.85	2.4 (1.8-3.1)	<0.001
Left main disease	3	0.63	1.9 (1.1-3.4)	0.034
Acute congestive heart failure	2	0.49	1.6 (1.1-2.4)	0.017
Shock or cardiac arrest	8	1.75	5.7 (3.4-9.8)	<0.001
IABP or cardiopulmonary support	6	1.25	3.5 (2.0-6.3)	<0.001
Coronary thrombosis	2	0.47	1.6 (1.0-2.5)	0.039
Ostial lesion	3	0.58	1.8 (1.4-2.4)	<0.001
Post-procedure TIMI <3	5	1.14	3.1 (1.6-6.0)	<0.001
High ACC/AHA lesion risk	1	0.22	1.3 (1.0-1.5)	0.038

3:30 p.m.

2510-643 Rates of Aspirin and Plavix Resistance Among Patients With and Without Definite Drug-Eluting Stent Thrombosis

Ron Waksman, Tina L. Pinto Slottow, Rekha Gavini, Mickey Scheinowitz, Patricia Beauzile, Petros Okubagzi, Kimberly Kaneshige, Zhenyi Xue, Rebecca Torguson, Udaya Tantry, Augusto Pichard, Lowell Satler, William Suddath, Kenneth Kent, Paul Gurbel, Washington Hospital Center, Washington, DC

Background: Drug-eluting stent thrombosis (DEST) has multifactorial causes. Variable responsiveness to antiplatelet therapy likely contributes to its pathogenesis.
Methods: Aspirin (ASA) and clopidogrel (CLOP) responsiveness was measured in 26 pts (ST group) who experienced angiographically-proven DEST and 15 pts (control group) who had not experienced ST at least 1 year following DES implantation. ASA resistance was defined as ASA resistance units (ARU) >550 by VerifyNow Aspirin assay. CLOP resistance was defined as either P2Y12 response units (PRU) >263 by VerifyNow assay or P2Y12 reactivity ratio (PRR) >65% by Biocytex vasodilator-stimulated phosphoprotein phosphorylation assay.
Results: Median time to DEST after implant was 17 days (range 0-1312). Clinical presentation was STEMI in 77% and acute coronary syndrome in 16%. At the time of ST, 82% of ST pts were taking ASA and 71% were taking CLOP. More ST pts than controls

were ASA and CLOP resistant as determined by PRU. There was no difference in CLOP resistance by PRR between the ST and control groups. Approximately 40% of ST pts were CLOP resistant. 14 pts (early ST) had early DEST (median 6 days after implant) and 12 (late ST) had late DEST (median 492 days after implant). Rates of ASA and CLOP resistance were similar between pts in the early and late ST groups.

Conclusions: Pts who experienced DEST demonstrated significantly higher rates of CLOP resistance when compared to controls by PRU but not PRR. ASA resistance was only present in ST pts.

Antiplatelet Responsiveness	ST (n=26)	Control (n=15)	p value
Mean ARU	477 ± 89	409 ± 41	0.002
Mean PRU	226 ± 110	173 ± 80	0.023
Mean PRR (VASP)	64 ± 20	53 ± 22	0.11
ASA resistant (%)	23 (6/26)	0 (0/15)	0.07
CLOP resistant (%)			
By PRU	40 (10/25)	7 (1/15)	0.03
By PRR	43(9/21)	43 (6/14)	--

3:30 p.m.

2510-644 Two-Year Extended Follow-up in Patients Receiving a Zotarolimus-eluting Stent in the E-Five Registry

Martin T. Rothman, Ian T. Meredith, Keyur Parikh, Peter Sick, Fausto Feres, Chaim Lotan, For the E-FIVE Registry Investigators, The London Chest Hospital, London, United Kingdom

Background: The use of drug-eluting stents (DES) for percutaneous coronary intervention (PCI) effectively reduces restenosis rates in patients with symptomatic ischemic heart disease and *de novo* coronary artery lesions, however, long-term safety and late stent thrombosis (ST) rates remain a concern. The Endeavor zotarolimus-eluting stent (ZES) has been found to successfully treat patients with a range of clinical and angiographic characteristics. Long-term follow-up in real-world populations is essential to establish the safety of the ZES in patients with both simple and complex lesions.

Methods: The E-Five Registry is a prospective, nonrandomized, global registry of 8314 patients from 188 centers on 4 continents. There were no angiographic or clinical exclusion criteria for patients with single or multi-vessel disease amenable to stenting. The primary endpoint was rate of major adverse cardiac events (MACE) at 1 year. Compliant centers who enrolled at least 40 patients continued to follow a subset of patients through 2-years. MACE, myocardial infarction (MI), and ST using ARC criteria were adjudicated by an independent Clinical Event Committee.

Results: Twelve month results for 7832 (94.2%) have been reported and revealed a high proportion of patients with complex clinical and lesion characteristics (74.4%). The overall rate of MACE was 7.5% and late ARC definite/probable stent thrombosis (31 to 365 days) was 0.4%. The 12-month rates for overall death was 2.4%, cardiac death plus MI was 3.0%, and TLR, TVR and TVF were 4.5%, 4.9% and 7.2% respectively. Extended two-year follow-up data on approximately 2000 patients will be reported for each of these key secondary endpoints.

Conclusions: Long-term follow-up of registry patients with a range of clinical and angiographic characteristics will further enhance our understanding of the extended effects of ZES treatment for patients undergoing PCI.

3:30 p.m.

2510-645 Long-Term Clinical Impact of Bleeding After Percutaneous Coronary Intervention With Drug-Eluting Stent In Real World Practice

Jong-Young Lee, Young-Hak Kim, Won-Jang Kim, Sung-Hwan Kim, Sung Sik Kim, Myung-Zoon Yi, Duk-Woo Park, Seung-Whan Lee, Sung-Cheol Yun, Cheol Whan Lee, Myeong-Ki Hong, Seong-Wook Park, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: The impact of bleeding or transfusion on long-term clinical outcomes after percutaneous coronary intervention (PCI) with drug-eluting stent (DES) is not clear in real world practice.

Methods: Consecutive 3,170 patients (mean age of 60 ± 10 years) undergoing PCI with DES between February 2003 and March 2006 were enrolled. Occurrence of cardiac death, myocardial infarction (MI), bleeding, or transfusion was prospectively evaluated. The primary end point was the episode of major bleeding defined as the STEEPLE criteria indicating fatal, retroperitoneal, intracranial or intraocular bleeding, bleeding requiring any transfusion ≥ 1 unit of packed red cells or whole blood, bleeding causing a decrease in hemoglobin of ≥ 3 g/dl (hematocrit ≥ 10%), or bleeding requiring intervention or specific treatment.

Results: Major bleeding occurred in 148 patients (4.7%) during follow-up (median, 1366 days). Adjusted Cox model was created using the patients' clinical, procedural and angiographic characteristics. Patients with major bleeding had higher incidences of adverse outcome (Table). When the patients were stratified according to the presenting symptom, in either acute MI (adjusted HR 3.93, 95% CI 1.64 - 9.42) or angina (adjusted HR 3.18, 95% CI 2.05 - 4.93), major bleeding was significantly associated with cardiac death.

Conclusions: Bleeding complication is a significant predictor of long-term cardiac mortality and MI after daily practice of DES placement for either stable or unstable patients.

Outcomes	Hazard Ratio (95% CI)
Unadjusted cardiac death	6.16 (3.60 - 10.54)
Unadjusted MI	4.73 (2.39 - 9.34)
Unadjusted cardiac death/MI	5.18 (3.26 - 8.24)
Adjusted cardiac death	3.36 (1.79 - 6.31)
Adjusted MI	3.06 (1.50 - 6.26)
Adjusted cardiac death/MI	3.19 (1.89 - 5.37)

3:30 p.m.

2510-646 Multicenter First-In-Man Study With the Lowest Known Dose Elixir Myolimus-Eluting Coronary Stent System With Durable Polymer: 12-month Clinical and Six Month Angiographic and IVUS Follow-Up

Wolfgang Rutsch, Helmut Schühlen, Bernhard Witzenbichler, Lynn Meredith, Vinayak Bhat, John Yan, Peter Fitzgerald, Charité, University Clinic Berlin, Campus Berlin Mitte, Department of Cardiology, Berlin, Germany, Stanford Cardiovascular Core Analysis Laboratory, Stanford University, Stanford, CA

Background: The Elixir Myolimus-Eluting Stent with Durable Polymer (Elixir Medical, Sunnyvale, CA, USA) is comprised of a balloon expandable cobalt chromium alloy stent coated with a low, 40 mcg total dose of myolimus, delivered by a thin, single layer methacrylate polymer.

Methods: The Elixir Myolimus-Eluting Stent FIM trial evaluated safety and effectiveness through a combination of clinical, angiographic, and IVUS endpoints. A total of 15 patients with single, de novo coronary artery lesions were enrolled. The primary endpoint was in-stent late lumen loss assessed by angiography at 6 months. Secondary endpoints included acute success, major adverse cardiac events (MACE) and clinically-driven TLR at 1, 6, 9, 12, 24 months and 6-month binary restenosis and in-stent % volume obstruction.

Results: Acute device success was 100% with a low MACE rate through 9 months (Table 1). Twelve (12) month clinical follow-up and detailed 6-month angiographic and IVUS data will be presented.

Table 1: Major Adverse Cardiac Events

Major Adverse Cardiac Events (MACE) to 9 months	
Cardiac Death	0.0% (0/15)
Myocardial Infaction (MI)	6.7% (1/15)
Q-Wave	0.0% (0/15)
Non-Q-Wave	6.7% (1/15)
Target Lesion Revascularization (TLR)	0.0% (0/15)
Cumulative MACE	6.7% (1/15)
Stent Thrombosis	0.0% (0/15)

Conclusion: The Elixir Myolimus-Eluting Stent loaded with the lowest known dose of myolimus, in combination with a durable polymer, demonstrated excellent safety and effectiveness to 9 months. Clinical data through 12 months and 6 month angiographic and IVUS data will be presented.

3:30 p.m.

2510-647 Influence of Drug-eluting Stent Implantation With Lipid Lowering Therapy to the Plaque Regression Located Apart From the Stented Segment, Sub-analysis of JAPAN-ACS Trial

Yoshihisa Nakagawa, Takeshi Kimura, Takeshi Morimoto, Takafumi Hiro, Katsumi Miyauchi, Yukio Ozaki, Masakazu Yamagishi, Tetsu Yamaguchi, Satoshi Saito, Kazuo Kimura, Hiroyuki Daida, Masunori Matsuzaki, for the JAPAN-ACS Investigators, Tenri Hospital, Tenri, Japan

Background: Location of focal restenosis after drug-eluting stent (DES) implantation is more common in proximal-edge than in distal-edge, such a phenomenon was not observed with bare metal stent (BMS). It is unclear that the influence of DES to the plaque located apart from the stenting site.

Methods: JAPAN-ACS trial showed a significant regression of non-culprit plaque volume (PV) with early aggressive lipid lowering therapy for patients with acute coronary syndrome (ACS). In this study, PV was measured with intravascular ultrasound at baseline and at 8-12 months follow-up after stenting for the treatment of culprit plaque. All measured plaques were located in proximal or distal of the same coronary arteries of stenting, and at least 5 mm apart from the stent edge. Percentage change in plaque volume (%change in PV) and change in percent plaque volume (change in %PV) were compared between the stent types (DES or BMS) and between plaque locations (in proximal or distal of stenting site).

Results: As shown in the table, the plaque located in DES distal had significantly larger regression of %change in PV of -22.6±11.4%, compared to that of in DES proximal (p=0.0064) and in BMS distal (p=0.013). **Conclusion:** The degree of plaque regression with aggressive lipid lowering therapy was larger in the plaque located in DES distal, and this data suggest that DES has an influence to the plaque apart from and located in distal of the stented segment.

Plaque Volume Data

variable	DES proximal	DES distal	p value: DES proximal vs distal	BMS proximal	BMS distal	p value: DES distal vs BMS distal
n	62	18		108	58	
PV at baseline(mm3)	56.1 ±32.7	40.1 ±31.8	0.070	64.6 ±31.8	50.0 ±30.0	0.23
%PV at beseline (%)	50 ±11	52.4 ±13	0.42	49.5 ±8.8	50.2 ±11.1	0.47
PV at follow-up(mm3)	45.8 ±28.3	30.5 ±23.8	0.039	54.1 ±28.9	43.5 ±30.0	0.096
%PV at follow-up (%)	44.2 ±12.1	41.9 ±11.5	0.47	44.3 ±9.9	44.4 ±11.2	0.41
%change of PV (%)	-18.7 ±15.2	-22.6 ±11.4	0.31	-17.2 ±12.9	-15.2 ±15.6	0.067
change in %PV (%)	-5.78 ±6.1	-10.5 ±7.36	0.0064	-5.29 ±5.45	-5.76 ±6.86	0.013

3:30 p.m.

2510-648 **Inflammatiory Markers Predict Cardiovascular Outcomes in Patients Undergoing Coronary Drug Eluting Stenting**

Kreton Mavromatis, Nima Ghasemzadeh, Konstantinos Aznaouridis, Zohreh Forghani, Padi K. Reddy, Christine De Staercke, W. Craig Hooper, Arshed A. Quyyumi, Emory University, Atlanta, GA, Atlanta VA Medical Center, Decatur, GA

Abstract: Circulating inflammatory markers (IMs) have been associated with outcomes in patients with unstable coronary artery disease (CAD). We investigated the association of a broad array of IMs and clinical factors on outcomes in patients with stable CAD undergoing coronary stenting (CS) with drug eluting stents (DES).
Methods: Stable CAD patients had circulating IMs measured before and after (1 day, 1 week and 1 month) CS, and were followed for cardiovascular death and myocardial infarction (MI) for 23 (range 13-43) months. Patients with inflammatory diseases were excluded.
Results: 191 patients (male: 84%; age: 61±9 years; DM: 44%; DES 92%) were studied. IMs that increased after CS included CRP (158%), Il-6 (273%), MMP-9 (182%), MMP-3 (143%), MCP-1 (130%), sCD40L (125%) (all p≤0.05 vs baseline), and TNF- (126%) (p=0.07). Death + MI was increased in patients with higher baseline values of CRP, IL-10, IL-6, sCD40L, and MCP-1. (Table) Multivariate analysis including the baseline IMs and clinical factors showed only Il-6, Il-10 and sCD40L (p=0.01, 0.07, 0.03 respectively) to be independent predictors of death + MI. After CS, only 1 day and 1 week post-CS CRP levels correlated with the risk of death + MI.
Conclusion: Higher baseline levels of Il-6, Il-10 and sCD40L, but not clinical factors, predict death + MI in patients with stable CAD undergoing CS.
Table. Univariate analysis: Death + MI in stable CAD patients

Baseline Inflammatory Markers (median)	Low (< median)	High (> median)	P	OR
CRP (2.96)	3.5%	15.1%	0.009	4.86
TNF- (2.96)	5.7%	12.0%	0.14	2.24
IL-10 (0.31)	14.6%	3.7%	0.018	0.23
IL-6 (1.23)	2.3%	15.4%	0.003	7.59
SCD40L (2964.5)	3.5%	13.7%	0.01	4.37
MCP-1 (128.8)	3.4%	14.2%	0.01	4.66
MMP-3 (9.4)	7.2%	11.2%	0.36	1.62
MMP-9 (76.4)	11.7%	7.1%	0.30	0.57
Age (61)	8.0%	8.6%	NS	1.08
Diabetes*	10.4%	6.0%	0.27	0.54
HTN*	6.4%	9.0%	0.64	1.44
HLP*	15%	7.8%	0.28	0.48
Active smoking*	6.2%	14.5%	0.07	2.54
History of MI*	7.0%	10.4%	0.46	1.52
LV Function**	15.3%	7.5%	0.19	0.45

*Data presented as without vs.with the risk factor
** Data presented as EF≤40% vs. EF>40%

I2.POSTER CONTRIBUTIONS

2511

Interventional Outcomes

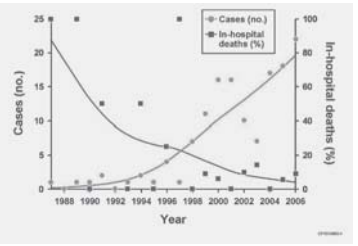
Sunday, March 29, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2511-584 **Temporal Trends and Improved Outcomes of Percutaneous Coronary Revascularization in Nonagenarians**

Aaron Matthew From, Charanjit S. Rihal, Ryan J. Lennon, David R. Holmes, Jr., Abhiram Prasad, Mayo Clinic, Rochester, MN

Objectives: There is a paucity of outcomes data among nonagenarians undergoing percutaneous coronary intervention (PCI). The aim of this study was to describe the clinical characteristics and the outcomes of patients 90 years of age or older who were treated with PCI.
Methods: We evaluated the outcomes of all patients 90 years of age or older in the Mayo Clinic PCI registry and examined trends over time.
Results: Over a period of 19 years we identified 138 nonagenarians (66% female; age 92.2± 2.0 years). Mean duration of hospitalization was 3.7 ± 3.1 days and the median follow-up duration was 3.6 years. 91% of patients presented with an acute coronary syndrome and underwent urgent or emergent revascularization. Technical success rate was 91%. Overall, the frequency of in-hospital death, Q-wave MI, and MACE (composite of death, Q-wave MI, urgent or emergent CABG, and cerebrovascular accident) were 9.4%, 0.7% and 12.3%, respectively. The long term survival of the cohort was not significantly different than that of an age, gender, and calendar year of birth matched Minnesota cohort. The cohort was divided into 2 groups according to the time of their intervention: pre 2000 (n=32) and 2000-2006 (n=106). The in-hospital mortality decreased markedly:22% to 6% (p=0.006), respectively. **Conclusions:** Our study demonstrates that advanced age alone must not be a contraindication for performing coronary angiography and PCI when clear indications are present.

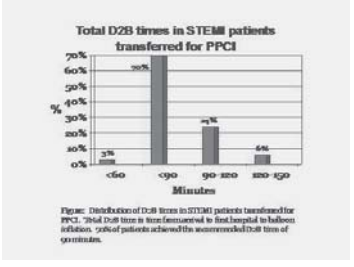


3:30 p.m.

2511-585 **Achieving Door to Balloon Times of Less Than 90 Minutes for STEMI Patients Transferred for Primary PCI**

Bina Ahmed, Stefan Lischke, Faye Straight, Prospero Gogo, Stephen Leffler, Marc Kutler, David J. Schneider, Harold L. Dauerman, University of Vermont, Burlington, VT

Background: Recent data from large national registries show that <10% of STEMI patients transferred for primary PCI (PPCI) actually meet the door to balloon (D2B) goal of <90 minutes, and only one third achieve D2B time of < 120 minutes. We established a single point of activation and simplified pharmacology system to allow rapid transfer of STEMI patients for PPCI to meet the D2B goal < 90 minutes. **Methods**: Per established protocol, 33 consecutive patients from February 2007 to August 2008 presenting with STEMI to a community hospital in Vermont were transferred 26 miles to our PCI center for PPCI. No patients received thrombolysis during this time period. Three time intervals were evaluated: door to door time (presentation to first hospital to arrival at PCI center); PCI delay time (arrival at PCI center to first balloon inflation) and total D2B time (presentation to first hospital to first balloon inflation). **Results:** The majority of transfers (69%) occurred off-hours. All patients received aspirin, clopidogrel and heparin pre-PCI. Mean door to door time, PCI delay and total D2B times were 66(40-109), 20 (9-35) and 86 minutes (58-129) with 70% of patients achieving D2B of less than 90 minutes and 94% achieving D2B < 120 minutes. **Conclusions**: For patients in a rural setting who present with STEMI, transfer of approximately 30 miles for timely PPCI can be achieved in nearly 75% of patients using a simplified activation and pharmacology system.



3:30 p.m.

2511-586 **Low Blood Pressure Is Associated With Increased Cardiovascular Morbidity (J-Shaped Curve) in Treated Hypertensive Patients With Increased Cardiovascular Risk: The VALUE Randomized Trial**

Franz H. Messerli, Giuseppe Mancia, Michael A. Weber, Sverre E. Kjeldson, Bjorn Holzhauer, Tsushung A. Hua, Dion Zappe, Stevo Julius, St. Luke's-Roosevelt Hospital Center, New York, NY

Background: Previous studies have debated the notion that low blood pressure (BP), particularly diastolic, is associated with increased risk for cardiovascular (CV) disease. We evaluated the impact of low BP on CV outcomes in a high risk population of 15245 hypertensive patients almost half of whom had a coronary artery disease (CAD) history.
Methods: In the prospective VALUE study, patients were randomized to valsartan or amlodipine regimens and followed for 4.2 years (mean). A Cox proportional hazards model was used to evaluate the relationship between average on-treatment BP and clinical outcomes. The relationship between BP and CV events was adjusted for baseline covariates such as age, BMI, history of CHD, history of stroke, LVH, diabetes mellitus, current smoking, high total cholesterol and proteinuria.
Results: Diastolic BP >90 mmHg was associated with increased incidence of the primary endpoint (figure); however, diastolic BP <70 mmHg also was associated with increased incidence (J-shaped curve). Similar trends were observed for death, total MI, heart failure but not for stroke. Nadir for MI was at a diastolic BP of 76 mmHg and for stroke 60 mmHg, respectively. The ratio of MI to stroke increased as diastolic BP decreased below 70 mmHg. In CAD patients the J curve was more pronounced than in patients without CAD whereas there was no J curve relationship for stroke regardless of CAD history. Also, systolic BPs >140 and <110 mmHg similarly were associated with increased risk for primary endpoint.
Conclusion: Patients in BP strata >140/90 mmHg, as well as <110/70 mmHg, were at increased risk for adverse outcomes in this hypertensive, high risk population. The preponderance of MIs over strokes in low diastolic pressure strata suggests a J-shaped curve with regard to diastolic BP and CAD but not with regard to diastolic BP and stroke.

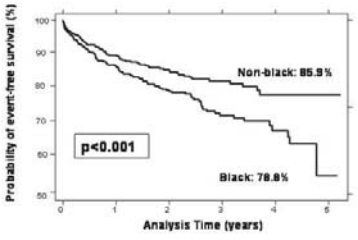
3:30 p.m.

2511-587 **Influence of gender and race on post-percutaneous coronary intervention (PCI) outcomes in an open cohort of public health system patients**

Sandeep Nathan, Steve Attanasio, Amit P. Amin, Arun Kumar, Ravilla Mahidhar, University of Chicago Medical Center, Chicago, IL, Cook County Hospital, Chicago, IL

Background: Racial and gender differences influence various cardiovascular outcomes however the impact of these variables on post-PCI outcomes, remains unclear.
Methods: 1,410 consecutive pts undergoing PCI at a large public health system hospital (PHS) were analyzed as an open cohort. Pts were included if complete clinical and procedural data were available and uniform access to healthcare was provided through planned follow-up in the PHS. Pts were grouped based on gender and race and followed for occurrence of MACE (death, MI, urgent TVR). Multivariate models were constructed and survival data were analyzed via Kaplan-Meier analysis and Log-rank test.
Results: 1,410 pts meeting inclusion criteria (57±10 yrs, 32% female, 46% Black) underwent PCI for STEMI (17.1%), NSTEMI (27.9%), unstable angina (26.0%) or stable CAD (29.1%) over 56 mos. Clinical follow-up was obtained in 97.2% (n=1,370, mean 1.7 yrs ± 1.3 yrs). Event-free survival was similar for males and females (83.5% vs 81.9%, p=0.44). Black pts evidenced lower MACE-free survival than non-blacks (78.8% vs 85.9%, p<0.001) [Figure 1]. After multivariate analysis controlling for all risk and therapy covariates, there was a strong trend towards a higher MACE hazard for black pts (p=0.06).
Conclusions: While healthcare disparities exist in PHS pts, gender differences do not seem to confer incremental risk in this population. Racial differences however, accounted for a trend towards poorer outcomes and warrant further investigation.

Figure 1. Kaplan-Meier MACE-free survival by race



3:30 p.m.

2511-588 **Outcomes of Patients with Acute Coronary Syndromes and Non-obstructive Coronary Artery Disease: Analysis from the Randomized ACUITY Trial**

Eugenia Nikolsky, Alexandra Lansky, Roxana Mehran, Adriano Caixeta, George D. Dangas, Iulian Benetato Giuran, Walter Desmet, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Coronary angiography in patients (pts) presenting with acute coronary syndromes (ACS) may reveal non-obstructive coronary artery disease (CAD). Outcomes of these pts have not been systematically studied. We analyzed data from the randomized ACUITY trial to assess outcomes of pts with moderate/high-risk ACS and non-obstructive CAD on baseline coronary angiography triaged to medical therapy (Tx).
Methods and Results: Among a total of 6,921 pts with analyzed baseline coronary angiogram, non-obstructive CAD (maximal diameter stenosis <50% in any of the major epicardial coronary arteries/main branches) was present in 904 (13%) pts (median age: 57 years; 53% men) triaged to medical Tx. Non ST-segment elevation MI was present in 35.5% of pts, and the rest had unstable angina. In-hospital composite ischemic outcome* occurred rarely (0.2%) [death and unplanned revascularization, one case each]. At 30-day F/U, 82.6% of the pts were taking aspirin, 39.8% - thienopyridines, 65.4% - statins, 57.2% - β-blockers and 47.3% were taking ACE-inhibitors. Outcomes at F/U are presented in the Table. By multivariable analysis, 1-year mortality was predicted by older age (OR=1.13, P=0.001), smoking (OR=7.41, P=0.02), and lack of aspirin Tx at 30-day F/U (OR=0.13, P=0.007).

Clinical endpoints, n (%)	Follow-up	
	30 days	1 year
Death	7 (0.8%)	18 (2.1%)
Cardiac death	2 (0.2%)	6 (0.7%)
Q wave myocardial infarction	0 (0.0%)	0 (0.0%)
Non-Q wave myocardial infarction	2 (0.2%)	5 (0.6%)
Unplanned revascularization	2 (0.2%)	14 (1.6%)
Composite ischemic endpoint*	11 (1.2%)	35 (4.0%)
* Death, myocardial infarction or unplanned revascularization		

Conclusions: Pts presenting with ACS and non-obstructive CAD have favorable 1-year outcomes. However, secondary prevention of CAD is necessary including smoking cessation and continued aspirin Tx to improve survival of these pts at 1 year.

3:30 p.m.

2511-589 **Risk Of Major Adverse Events Associated With Non-Cardiac Procedures Among Patients With Drug-Eluting Coronary Artery Stents**

Scott Beach, Charles Salters, Hussam Hamdalla, David Booth, Ahmed Latif, Pareena Bilkoo, Debabrata Mukherjee, David Moliterno, Khaled Ziada, VA Medical Center, Lexington, KY, University of Kentucky, Lexington, KY

Background: and Objectives. Prolonged dual anti-platelet therapy after use of drug-eluting stents (DES) represents a clinical challenge when patients subsequently require non-cardiac procedures. We sought to evaluate the prevalence of such occurrences, the incidence of adverse events, and the current management of anti-platelet therapy at the time of these procedures.
Methods. Records of patients who received DES at the Lexington VA Medical Center between 1/1/2004 and 12/31/2007 were searched for evidence of planned or performed non-cardiac procedures. Adverse cardiac events and/or serious bleeding complications during the peri-operative period were recorded.
Results. During the study, 601 patients received DES. Of those, 130 (22%) underwent or were planned to undergo a non-cardiac procedure: major procedures in 45 and minor procedures in 85 patients. Time from DES implantation to the procedure was 427 ± 24 days. In 53 (9%) patients, the procedure was within the 1st year. Definite stent thrombosis occurred in 3 (2%) patients: 2 events before minor procedures and 1 after an abdominal surgery. Two events were in the 1st year after DES and one after 13 months. All resulted in myocardial infarctions; one was eventually fatal. All 3 patients were taken off ASA and clopidogrel prior to the procedure. Serious bleeding events were documented in 4 (3%) patients on dual anti-platelet therapy that were related to or resulted in non-cardiac procedures: 1 subarachnoid bleed after carotid surgery, 1 vitreous bleed requiring vitrectomy, and 2 GI bleeds requiring transfusion. Peri-procedural management of anti-platelet therapy was variable: 26 patients stopped both ASA and clopidogrel and 65 patients were on ASA alone. Detailed data was not available in the remaining cases.
Conclusions. Non-cardiac procedures following DES implantation are frequent (22% overall, 9% within 1 year). Discontinuation of dual anti-platelet therapy before a non-cardiac procedure carried a small (2%) but devastating risk of stent thrombosis. Dual therapy was associated with a small (3%) risk of serious bleeding. Optimal anti-platelet therapy management during non-cardiac procedures after DES needs further prospective study.

3:30 p.m.

2511-590 **Staged PCI for Residual Multi-Vessel Disease Following Primary PCI Is Associated with Low Mortality**

Kurt G. Barringhaus, David D. McManus, Philippe G. Steg, Gilles Montalescot, Frans Van de Werf, Jose López-Sendón, Rebecca Dedrick, Joel M. Gore, for the GRACE Investigators, University of Massachusetts, Worcester, MA

Background: CABG and PCI are effective means for revascularization of patients with multi-vessel coronary artery disease, but previous studies have not focused on treatment of patients that first undergo primary PCI.
Methods: Among patients enrolled in the Global Registry of Acute Coronary Events (GRACE), clinical outcomes for patients presenting with STEMI treated with primary PCI were compared according to whether residual stenoses were treated medically, surgically, or with repeat PCI. Clinical characteristics and data pertaining to major adverse cardiac events during hospitalization and 6 months after discharge were collected.
Results: Of the 2768 patients included, 2375 (85.8%) patients were treated medically, 331 (12.0%) underwent staged PCI, and 62 (2.2%) underwent CABG following primary PCI. Hospital mortality was lowest among patients treated with staged PCI (Medical=3.4%; PCI=0.9%; CABG=4.8%; *p=0.04*) as was the risk adjusted mortality (Odds Ratio: PCI=0.26 [0.08-0.86]; *p=0.03*; CABG=1.81[0.53-6.24]; *p=0.35*). Patients presenting with LAD occlusion as the culprit for primary PCI tended to have a lower mortality when residual disease was treated with PCI (Medical=4.0%; PCI=0.7%; CABG=7.7%; *n=1304; p=0.08*). Six-month post-discharge mortality (Medical=1.3%; PCI=1.6%; CABG=0.0%; *p=0.62)* and MI (Medical=2.2%; PCI=2.9%; CABG=0.0%; *p=0.36*) were similar among the three groups. However, fewer unplanned catheter-based procedures were performed in patients revascularized surgically (Medical=10%; PCI=14%; CABG=1.6%; *p=0.01).*
Conclusions: The results of this multinational registry suggest that hospital mortality in patients who undergo percutaneous revascularization of multivessel coronary disease following primary PCI is low. Patients undergoing CABG following primary PCI require fewer unplanned catheter-based procedures.

3:30 p.m.

2511-591 **Red Blood Cell Storage Duration and Transfusion Volume Affects Mortality In Patients Undergoing Percutaneous Coronary Intervention (PCI)**

Simon D. Robinson, Christian Janssen, Eric B. Fretz, Alexander J. Chase, Brian Berry, Anthony J. Della Siega, W. Peter Klinke, J. David Hilton, Victoria Heart Institute Foundation, Victoria, BC, Canada, Morriston Cardiac Centre, Swansea, United Kingdom

Background: Despite being widely used to treat blood loss, red blood cell (RBC) transfusion has been associated with increased morbidity and mortality. Although the reasons for this remain unclear, it may be related to the structural and functional changes occurring within RBCs during storage. We investigated whether duration of RBC storage was associated with 30 day mortality in patients undergoing PCI.
Methods: We collected data on all RBC transfusions (excluding those related to CABG) occurring within 10 days of PCI using an electronic linkage between the British Columbia Cardiac Registry (BCCR) and Central Transfusion Registry (CTR). Out of 38,952 cases in the BCCR between 1999 and 2005, 909 patients received at least 1 unit of RBC post

PCI. Mortality was determined from the provincial Vital Statistics records and transfusion details compared according to 30 day survival.
Results: Mean transfusion volumes were significantly lower in patients surviving 30 days (2.8±2.1 vs 3.8±2.9 units, p=0.002). The average storage duration of RBC prior to transfusion was 25.2±10.0 days. Compared to survivors, patients dying within 30 days more often received blood stored for >28 days (65.3 vs 52.9%, p=0.02). In a Cox regression model to adjust for baseline risk factors, RBC storage age >28 days (odds ratio 1.71 [95% CI 1.04-2.80], p=0.04) and higher transfusion volumes (OR 1.12 [1.03-1.22], p=0.008) both predicted 30 day mortality.
Conclusion: Transfusion of red cells stored for more than 28 days and higher transfusion volumes are associated with increased mortality in patients undergoing PCI. Further work should assess whether reducing the storage duration of blood improves clinical outcomes in those patients requiring transfusion.

3:30 p.m.

2511-592 Lipoprotein-Associated Phospholipase A2 Predicts 28-Day and 1-Year Adverse Events Following PCI: A CREDO Substudy

Herbert D. Aronow, Steven R. Steinhubl, WH Wilson Tang, Danielle Brennan, Robert L. Wilensky, Steven P. Marso, Michael Wegner, Eric J. Topol, Michigan Heart & Vascular Institute, Ann Arbor, MI

Background: Lipoprotein-associated phospholipase A2 (Lp-PLA2) mass and activity predict major adverse cardiovascular events (MACE) among patients with established coronary artery disease including those with stable and acute coronary syndromes. Little is know about the prognostic utility of Lp-PLA2 in the setting of percutaneous coronary intervention (PCI).
Methods: We related pre-procedure Lp-PLA2 mass and activity to 28-day and 1-year MACE in 1422 patients who underwent PCI in the Clopidogrel for the Reduction of Events during Observation (CREDO) trial. Lp-PLA2 mass was measured with the diaDexus PLAC test while activity was measured by the diaDexus Colorimetric Activity Method (CAM). Bootstrapping was employed for model selection; 28-day logistic regression and 1-year Cox proportional hazards models were adjusted for demographic and clinical characteristics, clinical presentation and randomization to clopidogrel vs. placebo. Odds and hazard ratios were calculated per 1 standard deviation (SD) of Lp-PLA2 levels.
Results: Mean age was 62 years and 28% were women; 15% presented with recent myocardial infarction (MI), 54% with unstable angina and 26% with stable angina. Mean (SD) Lp-PLA2 mass and activity were 481 (193) ng/mL and 166 (41) nmol/min/mL, respectively. Death, MI, stroke or any revascularization occurred in 156 and 388 patients at 28 days and 1 year, respectively. Increasing Lp-PLA2 mass and activity levels were independent predictors of this endpoint at 28 days (OR 1.22 [95% CI 1.03, 1.44], p=0.019 and OR 1.20 [95% CI 1.01, 1.43], p=0.044, respectively) but not at 1 year. At 1 year, there were 25 patients who died, 129 with death or MI and 109 with non-fatal MI; Lp-PLA2 mass independently predicted death (HR 1.48 [95% CI 1.03, 2.13], p=0.035) while Lp-PLA2 activity independently predicted death or MI (HR 1.25 [95% CI 1.04, 1.50], p=0.015) and non-fatal MI (HR 1.27 [95% CI 1.04, 1.55], p=0.017).
Conclusion: Lp-PLA2 mass and activity significantly predict the risk of death, MI, stroke and any revascularization during the initial 28-days following PCI; Lp-PLA2 mass and activity differentially predict the risk of atherothrombotic events 1 year post-PCI.

3:30 p.m.

2511-593 The Association of Serum Uric Acid Levels with Outcomes Following Percutaneous Coronary Intervention

Daniel B. Spoon, Amir Lerman, Abhiram Prasad, Ryan Lennon, David R. Holmes, Jr., Charanjit S. Rihal, Mayo Clinic, Rochester, MN

Background: Serum uric acid may serve as a marker for the activation of oxidative stress and may serve as a marker for cardiovascular events. Our goal was to assess the association of serum uric acid levels and the outcomes of patients who have undergone Percutaneous Coronary Intervention (PCI).
Methods: We preformed a retrospective cohort study of patients who underwent PCIs between 1/2000 and 1/2007 at the Mayo Clinic in Rochester MN. Data was retrieved from the Cardiac Lab Interventional Clinical Database as well as the medical record. In-hospital and long-term mortality, as well as Major Adverse Cardiac Events (MACE) were obtained. There were 10632 unique patients who had a PCI and allowed use of their records for research. Of these, 1916 had a uric acid measure within 2 years prior to the day of PCI.
Results: Of the 1916 patients in our cohort, 1353 had normal uric acid levels and 563 had elevated uric acid. Mortality was significantly higher in patients with elevated uric acid (p=0.034) after adjusting for other risk factors associated with elevated uric acid. The adjusted association with mortality/MI was not quite significant (p=0.058) and the association with MACE was not significant (p=0.42)
Conclusions: This study represents the first analysis examining the association of uric acid levels and outcomes of patients who have undergone PCI. The current study further supports a role for uric acid as a participant and/or an independent predictor of increased morality in PCI patients.

Multivariable Associations Between Hyperuricemia and Mortality

Variable	Hazard Ratio	95% CI	P-Value
Elevated Uric Acid	1.291	(1.02,1.63)	0.0338
Diabetes	1.721	(1.37,2.17)	<0.0001
CHF on presentation	2.450	(1.94,3.1)	<0.0001
Hypertension	0.869	(0.65,1.16)	0.3417
History of MI (>7 days)	1.302	(1.05,1.61)	0.0155
Peripheral Vascular Disease	1.462	(1.12,1.91)	0.0053
Moderate to Severe Renal Disease	1.408	(1.03,1.92)	0.0311
COPD	1.654	(1.29,2.12)	<0.0001
CVA/TIA	1.315	(1.02,1.7)	0.0365

3:30 p.m.

2511-594 Characteristics, Incidence, Management, Immediate and Long-Term Outcome of Coronary Artery Perforation During PCI in the Current Era Practice: Analysis of 23,399 PCIs

Ioannis A. Stathopoulos, Marcelo Jimenez, EJ Kwak, Monica Losquadro, Howard Cohen, Sriram Iyer, Carlos Ruiz, Gary Roubin, Kirk Garratt, Lenox Hill Hospital, New York, NY

Background: Technical improvements permit the performance of PCI reliably and safely. Yet, adverse events have not been eliminated. Coronary perforation (CP), although rare, remains an important complication during PCI.
Methods: Prospectively collected LHH data from 23,399 PCIs performed during an 8-year period (1999-2006) identified 73 CP cases. Records and angiograms were retrospectively reviewed. Long term patient survival data (median f/u 2090 days) were secured from the USSSDI database. Cox proportional hazard model was applied. An analysis was done to determine if incident rates and outcomes differed over time.
Results: CP occurred in 0.31% of PCI patients (pts). Type 1, 2, 3 and 4 occurred in 14%, 37%, 38% and 3% of CP pts. In 8% of pts the type of CP could not be determined. Mean age was 69.48 ± 12.13. Males represented 60.7% of pts. Type C lesions was noted in 72.6% of the CP and 27.4% were type B. CTOs were 33% of the lesions. PCI target vessels were the LAD (43.8%), the LCx (24.7%), the RCA (26%), the RI (2.7%) and grafts (2.8%). Vessels were found to be calcified in 84.6% and tortuous in 41.5%. Presumed causes of CP were: the balloon (46.6%), the wire (37%), cutting balloon (5.5%), or use of other devices (5.4%). In 5.5% no likely cause was identified. Pericardiocentesis was required in 36% of CP. PTFTE stents were deployed in 34% of CP. Coils embolization was used in 13%. Emergent cardiac surgery was required in 5%. In hospital mortality was 5.5% (of which 75% occured after type 3 CP). CP that occurred during emergent PCI was more likely to be complicated by tamponade (p=0.04). Significantly more PTFE stents were used in the most recent period (2003-2006). Length of stay was significantly longer in patients with type 2 and 3 CP. Long term survival was similar for all types of CP. Furthermore, tamponade did not affect long term survival. Perforation rate decreased in the most recent period.
Conclusions: CP rate remains low in the current era practice and decreased over the last four years of the study. Non surgical management is associated with a high success rate. Tamponade did not affect long term survival.

3:30 p.m.

2511-595 The Obesity Paradox Revisited in a Large Contemporary Percutaneous Coronary Intervention Database: Overweight and Obese Patient Have Better Outcomes

Luis Gruberg, Srihari Naidu, Richard A. Shlofmitz, Sorin Brenner, Allen Jeremias, Thomas Pappas, Kevin Marzo, David L. Brown, Stony Brook University Medical Center, Stony Brook, NY, Winthrop University Hospital, Mineola, NY

Background: Prior studies have shown that patients with increased body mass index (BMI) have better outcomes following percutaneous coronary intervention (PCI)(*obesity paradox*). We re-assessed these results in a large contemporary database.
Methods: Baseline clinical, angiographic and procedural characteristics, as well as in-hospital outcomes were prospectively collected among all patients undergoing elective, urgent and emergent PCI at four New York State medical centers. Patients were divided into three groups according to BMI: normal BMI <25, overweight with a BMI between 25 and 30 and obese with a BMI >30. The primary clinical endpoint was freedom from major adverse cardiac and cerebrovascular events (MACCE).
Results: A total of 15,116 patients underwent PCI between 1/2004 and 12/2007. Overweight and obese patients (83.4%) were more often male, younger and had diabetes when compared to normal BMI patients. Rates of anterior wall infarction, shock and left ventricular ejection fraction were similar among the three groups. Clinical characteristics and in-hospital outcomes including MACCE (death/stroke/re-infarction) rates are shown in the Table.

	Normal BMI (n=2,503)	Overweight (n=6,901)	Obese (n=5,712)	p
Age (yrs)	68.0	65.5	66.5	NS
Gender male (%)	59.6	72.1	65.1	<0.05
ST EMI (%)	9.8	8.4	6.7	NS
Diabetes (%)	22.3	26.8	43.2	<0.05
Death (%)	0.9	0.5	0.04	NS
Stroke (%)	0.4	0.2	0.2	NS
Re-infarction (%)	0.3	0.06	0.05	NS
MACCE (%)*	1.6	0.8	0.6	<0.05

Conclusions: Overweight and obese patients still constitute the large majority of patients undergoing PCI. These patients have better in-hospital outcomes when compared to normal BMI patients. This difference is mainly driven by a lower rate of the individual endpoints.

3:30 p.m.

2511-596 Impact of Mental Health Disorders in U.S. Veterans on Cardiovascular Revascularization Strategies and Outcomes

Jane T. Luu, Shaun J. Cardozo, Anupama Shivaraju, Dean Ferrera, Herman Kado, Clay Shaker, Adhir R. Shroff, John A. Kao, University of Illinois-Chicago, Chicago, IL, Jesse Brown Veterans Affairs Medical Center, Chicago, IL

Background: Percutaneous coronary intervention (PCI) requires mandatory antiplatelet therapy for up to 1 year. Because medication compliance is critical, many providers are hesitant to perform PCI in patients with mental health disease. Currently, 31% of all U.S. Veterans are diagnosed with a mental health disorder after active duty; how this impacts cardiac revascularization strategies and outcomes is not known.
Methods: All veterans at our institution receiving a PCI (n=487) or CABG (n=140) between 2004- 2007 were retrospectively studied. The primary endpoint was a composite of death, myocardial infarction, and revascularization at 1 year. PCI was compared to CABG, which has no mandatory antiplatelet requirement.
Results: Mental health disease was prevalent in 31.4% of veterans receiving PCI and 23.6% receiving CABG. There was no difference in major adverse cardiac events after revascularization between veterans with mental health disease and those without. This was true regardless of revascularization strategy (PCI, p= 0.689; CABG, p= 0.638).
Conclusions: Mental health disorders affect a large number of veterans. We did not find an association between mental health and cardiovascular outcomes after PCI. The decision to pursue PCI in these patients should be individualized, but mental disease should not be a stigma, and revascularization with PCI in this population should not be automatically precluded.

Outcomes after Revascularization

Outcomes	PCI (n=487)		CABG (n=140)	
	Mental Disease, PCI (n=152)	Control, PCI (n=335)	Mental Disease, CABG (n=33)	Control, CABG (n=107)
Death, % n	11.8 (18)	15.5 (52)	13.5 (5)	23.3 (24)
Cardiac Death, % n	0.65 (1)	3.2 (11)	3.0 (1)	1.9 (2)
Myocardial Infarction, % n	5.2 (8)	4.4 (16)	3.0 (1)	0.9 (1)
Revascularization, % n	18.4 (28)	15.5 (52)	9.1 (3)	3.7 (4)
Total Composite, % n	28.9 (44)	31 (104)	12.1 (4)	5.6 (6)
P-Value for Composite Endpoint	0.689		0.638	

3:30 p.m.

2511-597 Non-Red Blood Cell Transfusion Is Associated with Increased Early Mortality in Patients Undergoing Percutaneous Coronary Intervention (PCI)

Simon D. Robinson, Christian Janssen, Eric B. Fretz, Brian Berry, Alex J. Chase, Anthony Della Siega, W. Peter Klinke, J. David Hilton, Victoria Heart Insitute Foundation, Victoria, BC, Canada

Background: PCI related bleeding is common and may lead to blood transfusion and death. Previous work has suggested non red blood cell (RBC) transfusions may be harmful in critically ill patients. We investigated whether blood component type was related to clinical outcome in patients requiring transfusion following PCI.
Methods: All subjects receiving a transfusion following PCI were identified using the British Columbia Cardiac Registry (BCCR) and BC Central Transfusion Registry (CTR). Between 1999 and 2005 there were 38952 PCI cases in the BCCR - 975 (2.5%) of these were associated with at least 1 transfusion; patients undergoing CABG following PCI were excluded. Patient demographics and transfusion details were compared against 30 day mortality using the provincial Vital Statistics registry.
Results: The 30 day mortality was 1.3% in the non-transfused and 12.7% in the transfused subjects (p<0.001). Baseline characteristics of the transfused patients dying (TD30) and surviving 30 days (TLA30) were similar. Over 70% of all transfusions given to survivors were RBCs compared to 45% of those given to TD30 (p<0.001). In contrast, patients dying within 30 days received substantially more plasma and platelet transfusions (p<0.001 for all, Table 1).
Conclusion: In patients requiring transfusion post PCI, use of non-RBC products is associated with increased 30 day mortality. Our findings suggest transfusion of plasma and platelets may be detrimental in those at risk of coronary thrombosis.

Table 1 Distribution of blood products according to survival at 30 days

	Total Number of transfusions	Transfusions Patients Dead at 30 days (TD30)	Transfusions Patients Alive at 30 days (TAL30)	χ^2 P
Red blood cells	2644 (66.4)	403 (44.6)	2241 (72.9)	<0.001
Plasma	481 (12.2)	213 (23.6)	268 (8.7)	<0.001
Platelets	746 (18.7)	235 (26.0)	511 (16.6)	<0.001
Cryoprecipitate	108 (2.7)	52 (5.8)	56 (1.8)	<0.001
Total no. of units	3979 (100)	903 (100)	3076 (100)	

n, (%) of units transfused within group. Pearson Chi-square test according to 30 day survival.

3:30 p.m.

2511-598 Association of Target Lesion Revascularization with Outcome in Patients with Sirolimus-Eluting Stent Implantation: Insights From j-CYPHER Registry

Kazuhiro Nakao, Mitsuru Abe, Takuya Taniguchi, Futoshi Yamanaka, Nobuhito Yagi, Nobuaki Kokubu, Yoichiro Kasahara, Yu Kataoka, Yoritaka Otuka, Takeshi Morimoto, Takeshi Kimura, Kazuaki Mitsudo, Hiroshi Nonogi, National Cardiovasculer Center, Osaka, Japan

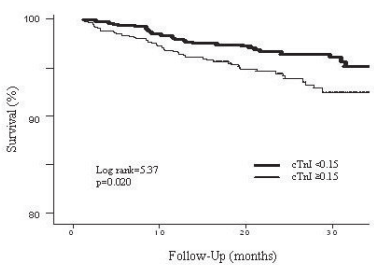
Background: Sirolimus-eluting stents (SESs) reduce restenosis and target lesion revascularization (TLR) compared with bare metal stents (BMSs). Although previous studies reported BMS restenosis was relatively benign event, the outcome of patients with TLR after SES implantation remains unknown at present.
Methods: Design of j-CYPHER registry was multi-center prospective enrollment of consecutive patients receiving SES implantation from 37 centers in Japan. From August 2004 to November 2006, 12812 patients with 17545 lesions were implanted with SES. Among 10778 patients treated exclusively with SES, we identified 694 patients referred for TLR within 1 year after index SES implantation or 9602 patients without TLR followed for 1 year. Among patients performed TLR, percutaneous coronary intervention was performed in 674 patients and coronary artery bypass grafting in 20 patients. We evaluated the event rates of death, myocardial infarction (MI), and cerebrovascular accident (CVA). MI occurring within 24 hours after index SES implantation or TLR procedure was excluded in our analysis.
Results: Compare to patients free from TLR, patients with TLR were younger (67.4+-10.2 vs. 68.4+-10.1, p= 0.01), more likely to be male gender (80.6% vs. 75.1%, p=0.001), lower ejection fraction (56.4+-13.4% vs. 58.2+-13.3%, p= 0.001), higher prevalence of diabetes (54.2% vs. 39.9%, p<0.0001), and multivessel disease (63.1% vs. 49.1%, p= p<0.0001). Among 694 patients performed TLR within 1 year after SES implantation, the rates of death, MI, and CVA were 1.9%, 0.0%, and 0.4%, respectively, at 30 days, and 11.1%, 1.3%, and 3.8%, respectively, at 1 year. The incidences of cardiac death and sudden cardiac death were 1.7% and 0.1%, respectively, at 30 days, and 7.4% and 1.1%, respectively, at 1 year. The combined event rate of death, MI, and CVA was 2.3% at 30 days, and 13.9% at 1 year after TLR. Among 9602 patients without TLR within 1 year after SES implantation, the incidences of death, MI, and CVA were 3.8%, 0.7%, and 1.7%, respectively, at 1 year after index SES implantation.
Conclusion: TLR within 1 year after SES implantation seemed to be associated with high mortality, but low incidences of MI and CVA in our study population.

3:30 p.m.

2511-599 Isolated Elevation in Troponin I Following Elective Percutaneous Coronary Intervention Is Predictive of Higher Long-Term Mortality

Dmitriy N. Feldman, Robert M. Minutello, Geoffrey Bergman, Issam Moussa, S. Chiu Wong, New York Presbyterian Hospital - Weill Cornell Medical Center, New York, NY

Background: Elevations of CK and CK-MB after elective PCI have been associated with an increased risk of cardiovascular events during follow-up. However, there is little known about the prognostic significance of an isolated elevation of troponin I (cTnI) without a rise in CK-MB following PCI.
Methods: Using the 2004/2005 Cornell Angioplasty Registry, we evaluated the outcomes of 1,601 pts who had normal pre-procedure cTnI and CK-MB, underwent elective or urgent PCI, and had normal CK-MB after the procedure. Mean follow-up was 24.6 ± 7.6 months.
Results: An elevation in cTnI was observed in 831 pts (51.9%) (median 0.50 ng/ml, range 0.2 to 52.8 ng/ml). Patients with cTnI elevations had a greater incidence of multivessel PCI (17.0% vs. 9.7%, p<0.001). DES were used in 88% of patients. The incidence of in-hospital MACE (death, CVA, emergent CABG/PCI) was 0.1% vs. 0% (p=1.00) in patients with vs. without cTnI elevations, respectively. By 2-years of follow-up, Kaplan-Meier survival rates were 94.1% vs. 96.4% (p log rank=0.020) in those with vs. without cTnI elevations, respectively (Figure). By multivariate Cox analysis, an elevation in post-PCI cTnI (HR 1.68, 95% CI 1.04-2.71, p=0.035) was an independent predictor of increased long-term mortality.
Conclusions: An isolated elevation in cTnI with normal CK-MB following non-emergent PCI is common and is not associated with more frequent adverse in-hospital outcomes. Importantly, patients with an elevated cTnI and normal CK-MB, have a higher long-term mortality.



3:30 p.m.

2511-600 Racial Disparities in Percutaneous Coronary Intervention In-hospital Outcome: Results from the Long Island Angioplasty Network

Luis Gruberg, Srihari S. Naidu, Richard A. Shlofmitz, Sorin Brenner, Allen Jeremias, Thomas Pappas, Kevin Marzo, David L. Brown, Winthrop University Hospital, Mineola, NY, Stony Brook University Medical Center, Stony Brook, NY

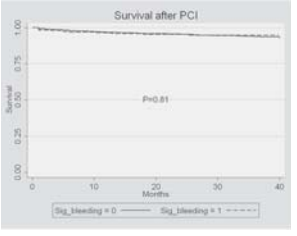
Background: Recent advances in percutaneous coronary intervention (PCI) technique, technology and pharmacotherapy have improved in-hospital outcomes. Whether racial disparities in PCI outcome persist in the current era remains unclear.
Methods: Baseline demographic, procedural and clinical characteristics, as well as in-hospital death, myocardial infarction and stroke were prospectively collected among consecutive patients undergoing PCI at Winthrop University Hospital and Stony Brook Medical Center as part of the Long Island Angioplasty Network. Baseline characteristics and in-hospital outcomes were compared across races.
Results: A total of 9,339 patients underwent PCI between January 1, 2004 and December 31, 2006. 8,349 patients (89.4%) were White, 401 (4.3%) Black, 358 (3.8%) Hispanic, and 216 (2.3%) Asian. There were no differences between groups with respect to gender, age, indication for PCI, hemodynamic instability or shock, ejection fraction, known coronary disease, diabetes, lesion location or extent of disease (p=NS for all). In-hospital death was highest among Hispanics (1.7%) when compared to Whites (0.4%), Blacks (0.5%) and Asians (0.5%). The combined endpoint of in-hospital death, myocardial infarction and stroke was likewise two-fold higher among Hispanics (2.2%) when compared to Whites (0.9%), Blacks (1.2%) and Asians (1.4%). Due to low absolute event rates, statistical significance was not reached.
Conclusions: Despite ongoing advances in interventional cardiology, there appear to remain significant racial disparities in PCI outcome, particularly among Hispanics. Further studies are warranted to more fully evaluate this association.

3:30 p.m.

2511-601 Does Peri-Procedural Significant Bleeding Impact Long-Term Mortality in Patients Undergoing Percutaneous Coronary Interventions? A Real-World Analysis

Salman A. Haq, Michael Anigobu, Morteza Tavachol, Shehzeen Ahmad, Terrence J. Sacchi, Sorin J. Brener, NY Methodist Hospital, Brooklyn, NY

Background: Recent data from randomized clinical trials (RCT) of patients undergoing percutaneous coronary interventions (PCI) have highlighted peri- PCI bleeding as an independent predictor of short- and long-term mortality, more powerful even than peri-procedural ischemic events. These patients, because of enrollment in RCT were observed with great scrutiny for bleeding complication. We sought to evaluate these findings in patients undergoing PCI in the real-world setting.
Methods: We prospectively evaluated all patients undergoing PCI in our institution from April 2004 to December 31, 2007. Significant bleeding was defined as a drop in hemoglobin of greater than 3 grams or bleeding requiring blood transfusion within 48 hours of PCI. Mortality data was obtained through the social security death index.
Results: A total of 2509 consecutive patients were evaluated. The mean age was 66±11 years, 37% had diabetes mellitus and 3.8% had significant chronic kidney disease (CKD). The mean ejection fraction was 50±12%. Urgent or emergency PCI was performed in 16%. The average Hb before PCI was 13.4±3 g% and it declined to 12.6±2 g% after PCI. Significant bleeding occurred in 11.9%. Of these, 1% had both a drop in Hb >3 g% and required transfusion, an equivalent of major bleeding. Death occurred in 5.7% during an average follow-up period of 29 ± 13 months. By multivariable analysis, significant bleeding was not an independent predictor of mortality in patients undergoing PCI (p = 0.81, Fig.). Factors predicting mortality were increasing age, urgency of procedure, lower ejection fraction, CKD and use of bivalirudin.
Conclusions: This study suggests that significant bleeding is not an independent predictor of mortality in patients undergoing PCI in routine clinical practice.



3:30 p.m.

2511-602 Periprocedural Bleeding and Myocardial Infarction are Associated with Increased Mortality after PCI: Results from the EVENT Registry

Jason B. Lindsey, Steven P. Marso, Michael Pencina, Joshua M. Stolker, Kevin F. Kennedy, Charanjit Rihal, Robert N. Piana, Steven L. Goldberg, Donald L. Cutlip, Neal S. Kleiman, David J. Cohen, Mid America Heart Institute, Kansas City, MO, Methodist DeBakey Heart Center, Houston, TX

Background: In randomized trials, major bleeding after PCI and periprocedural MI (pMI) are both associated with increased mortality. Whether similar associations exist among unselected PCI patients is unknown.
Methods: We used data from EVENT, a multicenter registry of patients undergoing PCI between July 2004 and June 2006 to examine the association between periprocedural ischemic and bleeding complications and 1-year mortality. pMI was defined as a CK-MB value ≥3x the upper limit of normal and was based on routine assessment of cardiac enzyme levels (available in 97% of subjects). Post-PCI bleeding was classified by TIMI criteria.
Results: After excluding patients with elevated pre-PCI CK-MB values or STEMI at presentation, the study cohort consisted of 5,961 subjects. Rates of post-PCI bleeding and pMI were 3.0% and 7.1%, respectively; 1-year mortality was 2.8% (1.6% cardiac). Compared to those without bleeding, subjects with any post-PCI bleeding (combined TIMI major and minor) had increased mortality at 1-yr (15.6% vs 2.4%, p<0.0001). Subjects with pMI also had increased mortality (5.2% vs 2.7%, p= 0.002). After multivariable adjustment, any post-PCI bleeding and pMI were both independently associated with mortality at 1-yr (Table).
Conclusions: In a "real-world" setting among unselected patients, both post-PCI bleeding of any severity and pMI remain relatively common and are independently associated with increased mortality. Continued efforts to reduce both complications are warranted.

Adjusted Hazard Ratios for the Association of Periprocedural Events with 1-year Mortality

Models	Any Bleeding (95% CI)		Periprocedural MI (95% CI)
Unadjusted	6.83 (4.55 - 10.24)		2.00 (1.27 - 3.10)
Model 1*	5.81 (3.83 - 8.83)		1.89 (1.20 - 2.95)
Model 2†	3.84 (2.48 - 5.94)		1.87 (1.19 - 2.94)
Fully Adjusted‡	3.83 (2.48 - 5.90)		1.84 (1.17 - 2.89)

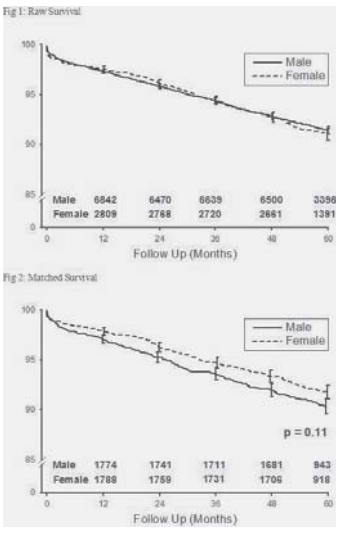
*Model 1: adjusted for age, gender, BMI; †Model 2: model 1+ DM, HTN, hyperlipidemia, smoking, CHF, PAD, GFR, prior MI, prior CABG, ACS at presentation; ‡Fully Adjusted: model 2 + multivessel CAD, PCI of SVG; PCI of proximal LAD

3:30 p.m.

2511-603 Influence of gender on long term mortality following percutaneous coronary interventions in the present era

SUDHIR RATHORE, Matthew Shaw, Anthony D. Grayson, Mark Jackson, Raphael A. Perry, Liverpool Heart and Lung Hospital, Liverpool, United Kingdom

Background: Earlier data has suggested that mortality after percutaneous coronary interventions (PCI) was greater for women than men.
Objective: The aim of our study is to evaluate the influence of gender on long term mortality among patients undergoing PCI in the North West of England.
Methods: We conducted a retrospective analysis of prospectively collected data on 9914 consecutive patients undergoing adult PCI between 1 Aug 2001 and 31 Dec 2003 at all centres undertaking PCI in the North West of England. All cause mortality at 30 day, 12 months and up to five years was compared by gender.
Results: Of the 9914 patients, 2880 (29%) were women. Women were significantly older than men (63.2 vs. 59.7, P <0.001) and are more likely to present with unstable angina (32.8% vs. 29.6%, P=0.002). Previous bypass surgery (3.8% vs. 8.0%, P< 0.001), Ejection fraction < 50% (14.7 vs. 8.2, P<0.001), and multivessel disease (7.5 vs. 10.7, P <0.001) were less common among women. AHA type C lesions (39.9 vs. 43.3, P<0.001), graft lesions (1.8 vs. 4.4, P <0.001) and multivessel PCI (21.5 vs. 23.3, P=0.04) was also less common in women. Stent usage was high with 93%.Using Cox proportional hazard analysis to adjust for baseline variables the 30 d mortality was similar in women and men (1%) and 12 month mortality was 2.1% in women and 3.0% in men (P= 0.12). Unmatched and matched Kaplan Meier survival curve up to5 yrs are shown in Figure 1 &2.
Conclusions: Long term mortality up to 5 years was similar in both genders after accounting for baseline factors.



3:30 p.m.

2511-604 Percutaneous Coronary Intervention for Treatment of Symptomatic Ischemic Heart Failure With Normal Left Ventricular Systolic Function

Scott J. Denardo, Mustafa HM Hassan, Richard S. Schofield, James A. Hill, Keith E. Davis, James E. Tcheng, North Florida/South Georgia Veterans Affairs, Gainesville, FL, University of Florida, Gainesville, FL

Background: Current guidelines recommend coronary revascularization for heart failure patients (HF pts) with normal left ventricular systolic function (NLVSF) and symptomatic or demonstrable myocardial ischemia (Recommendation: Class IIa; Level of Evidence: C). However, there are no systematic reports of the outcomes of those pts who actually undergo revascularization.
Methods: We assessed outcomes of 160 consecutive pts undergoing revascularization using percutaneous coronary intervention (PCI) for treatment of symptomatic ischemic HF with NLVSF. Each pt initially received conventional HF medical therapy, and pts were selected for study who continued to experience HF symptoms, demonstrate a pulmonary capillary wedge pressure of ≥18mmHg and a left ventricular ejection fraction of ≥50%.
Results: The technical success rate for PCI was 100%. During the first 24 hours, there were no major adverse cardiovascular events (MACE: death; Q wave myocardial infarction (MI); repeat revascularization). There were 2 (1.3%) non-Q wave MIs, 3 (1.9%) bleeding complications, and 2 (1.3%) episodes transient thrombocytopenia. During the first 30 days, there were no MACE and no hospitalizations for medical therapy of decompensated HF. During the first year, there were 33 (20.6%) MACE: 4 cardiovascular deaths (2.5%); 2 non-cardiovascular deaths (1.3%); 23 PCIs (14.4%); 4 coronary bypass graft surgeries (2.5%). Additionally, there were 11 (6.9%) hospitalizations for decompensated HF. Female sex (P=0.019), pre-PCI low diastolic blood pressure (P=0.045), and high cardiac index (P=0.028) were each associated with any event at 1 year (MACE or hospitalization). History of prior MI (P=0.017) was associated with 1 year death; higher HF class (P=0.011) and high pulmonary artery pressures (P=0.045) were each associated with 1 year hospitalization; no clinical or hemodynamic variable was associated with repeat revascularization.
Conclusions: PCI for treatment of ischemic HF with NLVSF appears safe and may prove efficacious. The HF death and decompensation rates for this cohort at 30 days and 1 year post-PCI were substantially lower compared to published reports consisting of medical therapy alone.

3:30 p.m.

2511-605 Regionalized Care with STEMI Centers Decreases Mortality and Improves Door to Balloon Times

Vikas K. Patel, Samip Vasaiwala, Mladen Vidovich, Adhir Shroff, John Kao, University of Illinois at Chicago, Chicago, IL, Advocate Christ Medical Center, Oak Lawn, IL

Background: ACC/AHA guidelines support the use of percutaneous coronary intervention (PCI) as the preferred treatment for ST elevation myocardial infarction (STEMI), with a goal door to balloon time (D2B) of ≤ 90 minutes. We compared D2B times and mortality rates of hospitals participating in regional STEMI networks to hospitals not participating in such networks utilizing publicly available data from the Hospital Compare and American Heart Association Mission: Lifeline ™ websites.
Methods: Of all 4, 470 hospitals listed on the Hospital Compare website providing D2B data for STEMI and mortality data for acute myocardial infarction, those with at least 10 or more patients were analyzed. STEMI Center hospitals were defined as hospitals registered on the Mission: Lifeline™ website. Non-STEMI Center hospitals were defined as those without a registered program. A student-t test was used to analyze both the mortality and D2B data.
Results: Review of the Mission: Lifeline™ website identified 92 STEMI Centers, of which 86 met criteria for mortality analysis and 75 for D2B analysis. Review of the Hospital Compare website, after removal of STEMI Centers, left 2,754 Non-STEMI Center hospitals providing mortality data and 1,233 providing D2B data. Primary findings are listed in Table 1.
Conclusion: STEMI Centers have significantly better D2B times and lower mortality rates compared to Non-STEMI hospitals. Our findings support the formation of dedicated STEMI networks for the treatment of patients with STEMI.

Table 1: Mortality and D2B ≤90 Minute Rates for STEMI and Non-STEMI Center Hospitals

Variable (%)	Mean ± Standard Deviation		P-value
	STEMI Centers (n=86)	Non-STEMI Centers (n=2754)	
Mortality rate	15.80±1.19	16.09±1.16	0.0214
	STEMI Centers (n=75)	Non-STEMI Centers (n=1233)	
D2B ≤ 90 minutes	74±21	69±19	0.021

3:30 p.m.

2511-606 Enrollment in STEMI PCI Trials Is Possible Without Increase in Door to Balloon Times

James C. Blankenship, Jennifer A. Sartorius, Deborah K. Zimmerman, Kimberly A. Skelding, Kimberly A. Skelding, Thomas A. Scott, Lynn M. Belles, Amy Temple, Peter B. Berger, Geisinger Medical Center, Danville, PA

Background: Current guidelines emphasize door-to-balloon times (D2B) under 90 minutes. Enrollment in randomized trials of STEMI PCI may delay D2B.
Hypothesis: Enrollment in STEMI PCI trials can be accomplished without delaying D2B.
Methods: From 10/17/04 to 12/31/07, 581 patients within 12 hours of the onset of STEMI were treated with direct PCI at our medical center. Of these, 123 were enrolled into a randomized STEMI PCI trial (ERASE-MI, AMIHOT II, HORIZONS-AMI, or APEX-AMI). Patients were enrolled if (1) a study was actively enrolling, (2) they met inclusion/exclusion criteria, (3) study nurse was available, (4) the interventionist thought enrollment was appropriate, (5) the patient signed informed consent. We compared patients enrolled in a trial ("Enrolled") to patients not enrolled in a trial ("Not Enrolled") with respect to D2B and cath-lab-arrival-to-balloon time (CL2B). Regression (including 12 demographic and 6 procedural factors) was used to adjust for time differences in characteristics between the Enrolled and the Not Enrolled groups.
Results: Unadjusted times (Table) for D2B and CL2B tended to be shorter for Enrolled pts than Not Enrolled pts. The Enrolled and Not Enrolled groups differed in frequency of presentation during on- versus off-hours, interventionist performing PCI, and culprit artery. After adjustment for these differences, Enrolled versus Not Enrolled pts did not differ significantly in overall D2B or CL2B (Table). This was true for both pts *transferred* from a non-PCI center (n = 423) and patients presenting *directly* to the PCI center (n = 158). Enrollment was 17% during off-hours and 30% during on-hours, although D2B times were almost identical for pts presenting on-hours versus off-hours.
Conclusions: In our system, with median D2B well under 90 minutes for non-transferred patients, enrollment did not delay D2B or CL2B, either in patients transferred from a non-PCI center or in patients presenting directly to the PCI center.

Median D2B and Cath Lab to Balloon Times

	Transferred from Non-PCI Center, ENROLLED (n = 96)	Transferred from Non-PCI Center, NOT ENROLLED (n = 327)	adjusted p-value	Presented to PCI Center, ENROLLED, (n = 27)	Presented to PCI Center, NOT ENROLLED (n = 131)	adjusted p-value
Door-to-Balloon Time (minutes)	104	107	.74	43	56.5	.83
Cath Lab Arival to Balloon Time (minutes)	17	18	.46	17	16	.06

3:30 p.m.

2511-607 Four-year Outcomes of Complex Coronary Intervention at a Single, High Volume Center Without On-Site Surgical Backup

Najamul H. Ansari, Almas Kherani, Bernadette Speiser, Stephanie Murray, John A. Kao, Adhir Ramesh Shroff, Jesse Brown VA Medical Center, Chicago, IL, University of Illinois at Chicago Medical Center, Chicago, IL

Objective: Current ACC/AHA Percutaneous Coronary Intervention (PCI) guidelines classify PCI without on-site cardiac surgery for elective and primary PCI as class III and IIb /III, respectively. Limited data regarding PCI outcomes in a single, high-volume center exists. We report the characteristics and outcomes of a consecutive group of unselected patients undergoing elective and primary PCI in a center that fulfills the criteria established by the ACC/AHA for the Performance of Angioplasty at Hospitals without On-Site Cardiac Surgery.
Methods: From 9/2004 to 9/2008, 729 patients (1081 lesions) were analyzed from a database at the Jesse Brown VA Medical Center. Lesions and procedural success were classified according to SCAI/ACC/AHA guidelines. Myocardial infarction (MI) post-PCI was defined as troponin-I elevation at or above the level defined as definite MI.
Results: Lesion types, characteristics and outcomes are shown in Table 1. There were no significant differences in rates of success, peri-procedural MI or death from the SCAI, ACC-NCDR, and NHLBI Registries. There were two deaths in-house after PCI and one emergent transfer for CABG after coronary dissection, for which the patient survived.
Conclusion: PCI on predominantly complex (B2/C) coronary lesions without on-site surgery was safely performed with complication rates comparable to national averages. The established transfer plan was proven successful in the single instance it was required.

Table 1.

Characteristics and Complications of Lesions				
Lesion Type	Number	Success	Myocardial Infarction	Emergent CABG/Death
A	175 (16.2%)	172 (98.2%)	5 (2.9%)	0 (0%)
B1	318 (29.4%)	313 (98.4%)	16 (5.0%)	0 (0%)
B2	323 (29.9%)	313 (96.9%)	17 (5.3%)	0 (0%)
C	262 (24.2%)	214 (81.7%)	16 (6.1%)	2 (0.7%)
Data Missing	3 (0.3%)			
Total Lesions	1081 (100%)	1012 (93.6%)		
Specific Lesion Subsets				
CTO	68 (6.3%)	46 (67.6%)	2 (2.9%)	0 (0%)
Bifurcation	165 (15.3%)	147 (89.1%)	7 (4.2%)	0 (0%)
STEMI	48 (4.4%)	43 (89.6%)	5 (10.4%)	0 (0%)
SVG/LIMA	76 (7.0%)	68 (89.5%)	6 (7.9%)	0 (0%)

I2.ORAL CONTRIBUTIONS

2906

Complex Lesions

Sunday, March 29, 2009, 4:30 p.m.-6:00 p.m.
Orange County Convention Center, Room W414D

4:30 p.m.

2906-5 Rate of Major Cardiac Adverse Events 14 Months After Coronary Bifurcation Stenting With Culotte vs. Crush Techniques in the Nordic Bifurcation Stent Technique Study

Kari Kervinen, Matti Niemelä, Andrejs Erglis, Indulis Kumsars, Michael Maeng, Jens F. Lassen, Pål Gunnes, Sindre Stavnes, Jan S. Jensen, Anders Galløe, Inga Narbute, Dace Sondore, Evald H. Christiansen, Jan Ravkilde, Terje K. Steigen, Jan Mannsverk, Per Thayssen, Knud Nørregaard Hansen, Kari Virtanen, Steffen Helqvist, Saila Vikman, Rune Wiseth, Jens Aarøe, Leif Thuesen, University of Oulu, Oulu, Finland, Aarhus University Hospital, Aarhus, Denmark

Background: Risk of stent thrombosis and other cardiac adverse events have been reported to be increased in bifurcation lesions, especially if a two-stent technique is used. Here we report the pre-specified secondary end-point of 14-month major adverse cardiac events (MACE) in patients with bifurcation lesions treated with Culotte versus Crush techniques using Sirolimus eluting stents (SES).
Methods:A total of 424 patients with a coronary artery bifurcation lesion were randomized to stenting of both main vessel and side branch using culotte or crush techniques. Recommended post-procedural clopidogrel treatment duration was 6-12 months. Stent thrombosis was defined according to the ARC criteria. MACE was defined as the composite of definite stent thrombosis, cardiac death, non-procedure related myocardial infarction and/or target lesion revascularization.
Results: Mortality data was available in 423 (99.8%) patients and clinical follow-up data in 417 (98.3%) patients. The two treatment groups were well balanced concerning preprocedure patient and lesion related characteristics. After 14 months, the rates of MACE were 6.4% versus 8.7% (ns) in the Culotte and Crush treated patients, respectively. The individual components of MACE are shown in the table.
Conclusions: Rates of stent thrombosis and MACE were low and similar in patients treated with culotte or crush technique using SES in bifurcation lesions.

	Crush	Culotte	p-value
Death, n(%)	6/209 (2,9)	3/214 (1,4)	ns
Cardiac death, n(%)	5/209 (2,4)	2/214 (0,9)	ns
MI, n(%)	7/206 (3,4)	6/211 (2,8)	ns
TLR, n(%)	11/206 (5,3)	10/211 (4,7)	ns
Stent thrombosis, n(%)	3/206 (1,5)	6/211 (2,8)	ns

4:42 p.m.

2906-6 Long-Term Clinical Outcome and the Efficacy of Final Kissing Balloon Technique After Sirolimus-Eluting Stent Implantation Using Only Main Branch Stenting Technique in Coronary Bifurcation Lesions

Toshihiro Tamura, Kazuaki Mitsudo, Takeshi Kimura, Kazushige Kadota, j-Cypher Registry Investigators, Kyoto University Hospital, Kyoto, Japan

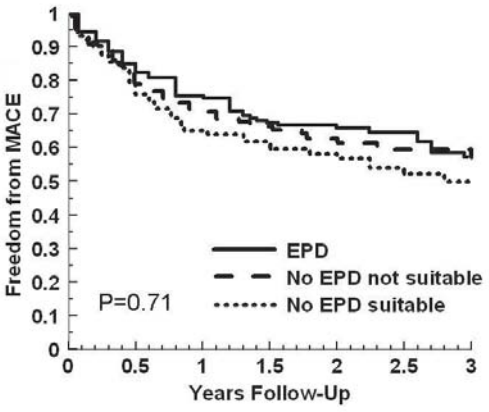
Background: Only main branch stenting in coronary bifurcation lesions seems to be better clinical outcome compared to the main and side branch stenting also in the drug eluting stent era.However the efficacy of final kissing balloon(FKB) technique and predictor of target lesion revascularization(TLR) after only main branch stenting technique remain unclear.
Methods: Design of the j-Cypher Registry was multi-center prospective enrollment of consecutive patients receiving sirolimus-eluting stent(SES) from 37 centers in Japan. Between August 2004 and November 2006, 12824 patients were enrolled in this registry. Among them, we identified 2250 non-LMCA native bifurcation lesions using only SES. Of these. 1871 lesions were treated with only main branch stenting(one-stenting) technique. We investigated long-term clinical outcome(follow-up period was 525.4±174.8days) and efficacy of FKB after implantation of SES with one-stenting technique.
Results: 741 lesions(39.6%) were true bifurcations. Wire protection of side branch before main branch stenting was performed in 1461lesions(78.1%) and the FKB was performed in 938lesions(50.1%). The incidence of death, TLR and ARC definite stent thrombosis were 5.7%, 7.6% and 0.38%.
In the multivariable analysis, gender, hemodialysis, DM, total stent length and post main vessel diameter were the predictor of TLR.
After stent implantation in main branch, 1053 lesions were >50% diameter stenosis in side branch. Even among them, there was no significant differences regarding TLR between the FKB group and non-FKB group(log-lank test; p=0.40).
Conclusions: For SES placement in bifurcation lesions, one-stenting technique suggests a good long-term clinical outcome. Gender, hemodialysis, DM, total stent length and post main vessel diameter were the only predictor of TLR. Even if the side branch %diameter stenosis was more than 50% after main branch stenting, the FKB did not provide the benefit regarding TLR.

4:54 p.m.

2906-7 Long-Term Outcome After Selective Use of Embolic Protection Devices During Saphenous Vein Graft Interventions

Shahar Lavi, Joan Ivanov, Clare A. Appleby, Karen Mackie, Eric M. Horlick, Chris Overgaard, Peter Seidelin, Douglas Ing, Vlad Dzavik, University Health Network, Toronto, Canada

Background: PCI to saphenous vein graft (SVG) is associated with increase risk and it is recommended to use embolic protection devices (EPD) in this setting. We tested the hypothesis that selective use of these devices is associated with acceptable risk.
Methods: Angiographic and clinical outcome were prospectively obtained from 534 consecutive patients that underwent PCI to SVGs, with or without EPD from January 2001 to December 2007 at a large tertiary cardiac referral center. Long term outcome was obtained by linkage to provincial registry.
Results: EPD were deployed in 198 of 373 SVGs (53%) that were suitable for deployment of a distal EPD. EPD were used more often in ectatic (33% vs 19%, p=0.003), ulcerated (17% vs 9%, p=0.03), thrombotic (25% vs 8%, p<0.0001) vein grafts, with longer degenerated segments (p=0.002), and in lesions involving the body of the graft (85% vs 66%, p<0.0001). In hospital death and myocardial infarction were similar with and without EPD(1.5% vs 1.7%, p=0.89, and 2% vs 5%, p=0.11). Long term event free survival was high and similar in both groups (figure). Independent predictors of death included urgency of the procedure (HR=2, p=0.027), left ventricular dysfunction (HR=5.5, p<0.0001) and renal dysfunction (HR=2.9, p=0.0003). Use of EPD was not a predictor of long term survival.
Conclusions: Selective use of EPD during PCI to SVG is associated with low in hospital cardiovascular event rates. Long term outcome is poor and determined by co-morbidities whether EPD is used or not.



5:06 p.m.

2906-8 Long-Term Outcomes of Drug Eluting vs. Bare Metal Stent Implantation for Patients With Chronic Total Coronary Artery Occlusions

Yaling Han, Jian Zhang, Yi Li, Shouli Wang, Quanmin Jing, Shenyang Northern Hospital, Shenyang, People's Republic of China

Background: There are limited data on the efficacy of drug eluting stents (DES) for treatment of chronic total occlusions (CTO). The aim of the study was to evaluate the long-term clinical outcomes of DES implantation for CTO compared with bare metal stents (BMS) implantation.
Methods: Between June 1995 and December 2006, a total of 1184 patients with successful recanalization of at least one CTO lesions were consecutively registered, including 660 (55.7%) received DES and 524 (44.3%) received BMS implantation. All patients were followed up to 5 years for occurrence of major adverse cardiac events (MACE). Long-term survival rates were estimated with Kaplan-Meier method.
Results: The baseline clinical and angiographic characteristics were comparable between the two groups except that patients in DES group received longer dual antiplatelet therapy (7.4±2.5 months *vs.* 1.7±0.8 months). The average follow-up periods were 4.7±0.89 years in the BMS group and 3.2±1.3 years in the DES group, respectively. There was no significant difference in 5-year survival rate between the two groups (90.3% for DES group *vs* 89.6% for BMS group, log-rank *P*=0.38),but the 5-year TVR-free survival rate in the DES group was significant higher than that in the BMS group (81.6% *vs* 73.5%, log rank *p*<0.001). The cumulative MACE-free survival in the DES group was also significantly higher than that in the BMS group (80.6% *vs* 71.5%, log-rank *p*<0.001). The rates of re-admission caused by cardiovascular disease (27.0% *vs* 37.8 %, *p*<0.001) and the need for CABG were significantly lower in the DES group (1.5% *vs* 3.4%, *P*<0.05). By multivariable analysis, DES implantation could significantly lower the long-term MACE risk of PCI for CTO patients (HR: 0.492; 95%CI 0.396~0.656, *P*<0.001). Heart failure and elderly (≥ 65-year) were identified as independent predictors of long-term MACE during follow-up.
Conclusions: This study demonstrates the long-term (up to 5 years) efficacy of DES for treatment of CTO, which is superior to BMS implantation in reducing the rates of TVR and MACE, as well as the need of re-admission and CABG.

5:18 p.m.

2906-9 **The Safety and Efficacy of Retrograde Approach for Percutaneous Recanalization of Chronic Total Occlusions of the Coronary Artery: Toyohashi Heart Center Experience From 157 Patients**

SUDHIR RATHORE, Hitoshi Matsuo, Mitsuyasu Terashima, Nobuyoshi Tanaka, Yoshihisa Kinoshita, Masashi Kimura, Kenya Nasu, Etsuo Tsuchikane, Mariko Ehara, Yasushi Asakura, Keiko Asakura, Osamu Katoh, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Successful percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) has shown improved survival, improvement in LV function and symptom relief. Retrograde approach through the collateral channels has become popular recently and has a potential to improve the success rate in CTO PCI.
Objective: To define the safety and efficacy of retrograde approaches used for percutaneous recanalization of the CTO PCI in a consecutive series of "real world" patients.
Methods: All consecutive patients undergoing CTO PCI of more than 3 months duration between 2003 and 2008 by retrograde approach were identified from dedicated database and were evaluated retrospectively.
Results: Total of 157 (17%) out of 925 CTO procedures were attempted in retrograde fashion during this period. Septal branch collateral was used in 67.5% and epicardial collaterals and saphenous vein grafts were used in 24.8%& and 7.6% cases, respectively. The occluded vessel was RCA in 59.2%, LAD in 31.8%, LCx in 7.6% and 0.6% each were LMS and vein graft. Collateral channel was crossed by guide wire successfully in 115(73.2%) cases and the procedure was successful by retrograde approach in 103 (65.6%) cases. Controlled antegrade and retrograde tracking (CART) was performed in 64 (40.8%) cases and retrograde wire entered the proximal true lumen in 39(24.8%) cases to achieve recanalization. The reasons for failure by retrograde approach was inability to cross the collateral channel (48 pts), CART not attempted (2 pts) and inability to pass balloon or micro catheter (4 pts). Final procedural success was achieved in 133 (84.7%) cases. Five patients developed septal perforation, one of which needed coil embolisation and rest were managed conservatively. One patient needed emergency CABG (0.6%) and, one (0.6%) and five patients (3.1%) had QMI and NQMI, respectively with no in hospital mortality.
Conclusions: Retrograde approach by different strategies is effective in recanalizing CTO in previously failed antegrade attempts. As shown here the success rate by retrograde approach was 65.6% and final success was 85% with low overall adverse events. Further studies are needed to evaluate the predictors of retrograde success.

5:30 p.m.

2906-10 **Acute Results From the INSPIRE Trial With the Novel MGuard™ Stent System Containing a Protection Net to Prevent Distal Embolization**

Felipe Maia, Sr., Jose Ribamar Costa, Sr., Ricardo Costa, Sr., Vinicius Esteves, Sr., Rodolfo Staico, Sr., Galo Maldonado, Sr., Fausto Feres, Sr., Luis Alberto P. Mattos, Amanda GMR Souza, J Eduardo Sousa, Sr., Alexandre Abizaid, Sr., Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil, Cardiovascular Research Center, Sao Paulo, Brazil

Background: Disturbances of coronary flow due to distal embolization of thrombus/ platelet agreggates are associated with worse immediate and long-term prognosis after PCI. Treatment of SVG and PCI in the setting of acute coronary syndromes (ACS) are often related to this complication. Although protection devices (filterwires) have been shown to reduce distal embolization, they add time and cost to PCI. The newly developed balloon-expandable Mguard™ stent system is a combination of an ultra-thin polymer mesh sleeve attached to the external of a bare metal stent surface designed to provide embolic protection during PCI
Methods: Between Nov/2007-Sep/2008, 23 patients were included. Inclusion critirea included *de novo* lesions in SVG or native vessels with angiographic evidence of instability with potential to provoke flow disturbance and/or distal embolization. Use of filterwires was not allowed. Primary endpoint included the incidence of MACE (composite of cardiac death, non-fatal MI and TLR) up to 30 days of the procedure and TIMI flow right after the PCI. Angiographic/ IVUS analysis were performed at independent core laboratories
Results: Mean population age was 63 years and 38% had diabetes. Overall, 55% presented with ACS, and 57% of lesions were located in a SVG. The majority of lesions had complex morphology including 50% eccentric, 26% thrombus and 20% ulcer. The Mguard™ stent was successfully delivered in all cases, there was no angiographic/ clinical complications including distal embolization and final TIMI-3/blush-3 was achieved in 100%. Preprocedural QCA data demonstrated lesion length=8.16±4.8mm, vessel size=3.19±0.46mm and diameter stenosis=70.2±9.47%; at final procedure, residual stenosis was 8.2±3.0mm with acute gain=2.06±0.32mm. There was no cardiac enzimatic elevation postprocedural and no MACE up to 30-day follow-up (FU)
Conclusions: In this preliminary evaluation, the MGuard™ device demonstrated excellent performance in a highly complex lesion subset, including absence of angiograhpic/ procedural complications and no adverse events up to 30-day FU. Complete six-month QCA, IVUS and clinical outcomes will be available during the meeting

I2.POSTER CONTRIBUTIONS

2512

PCI - Acute MI

Monday, March 30, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2512-675 **Coronary Flow Velocity Pattern Immediately After Reperfusion Predicts True Left Ventricular Aneurysm in Patients with Acute Anterior Myocardial Infarction Who Achieve TIMI Grade 3 Flow**

Atsushi Yamamuro, Shuichiro Kaji, Koichi Tamita, Minako Katayama, Makoto Kinoshita, Natsuhiko Ehara, Takeshi Kitai, Takafumi Yamane, Yoshimori An, Kite Kim, Syunsuke Funakoshi, Noriyuki Kimura, Tomoko Tani, Shigefumi Morioka, Yutaka Furukawa, Kobe General Hospital, Kobe, Japan

Background: Aggressive management of acute myocardial infarction (AMI), including prompt reperfusion, may diminish the incidence of true left ventricular (LV) aneurysm; however, it has been reported that even if successful reperfusion is achieved in epicardial coronary arteries, microvascular dysfunction causes insufficient reperfusion of the infracted myocardium, leading to LV dysfunction. Recent studies have shown that microvascular damage can be assessed quantitatively from coronary flow velocity (CFV) patterns immediately after successful reperfusion. The purpose of this study was to examine whether the CFV patterns may predict the risk of true LV aneurysm formation in patients with AMI achieving TIMI 3 flow.
Methods: Consecutive 168 patients with first anterior AMI who underwent successful percutaneous coronary intervention (<50% residual stenosis with TIMI grade 3 flow) were subjected to CFV measurement with Doppler guidewires. The CFV spectrum provided systolic peak velocity (cm/s, SPV) and diastolic deceleration time (ms, DDT). Left ventriculogram obtained 6 months after the infarction was analyzed to measure the LV volume index. True LV aneurysm was defined as a deformity of the infarct segment that was apparent during diastole as well as during systole, and demonstrated diastolic contour abnormality. Patients were divided into the two groups: those subsequently complicated by true LV aneurysm (n=26; group 1) and those without true LV aneurysm (n=142; group 2)
Results: CFV analysis showed significantly lower SPV (-24 ± 18 vs. 7 ± 21 cm/s; p<0.001) and shorter DDT (355 ± 165 vs. 685 ± 191 ms; p<0.001) in group 1 than in group 2. The optimal cutoff values to predict true LV aneurysm formation were -20 cm/s for SPV and 400 ms for DDT (sensitivity=0.77, specificity=0.85; and sensitivity=0.77, specificity=0.89, respectively). SPV and DDT correlated to the LV end-diastolic volume index obtained 6 months after AMI (r= -0.63; p<0.001 and r= -0.76; p<0.001, respectively).**Conclusions:** CFV pattern of infarct-related artery immediately after reperfusion predicts true LV aneurysm formation, and enables accurate risk stratification in patients with anterior AMI achieving TIMI grade 3 flow.

9:30 a.m.

2512-676 **Prognostic Utility of TIMI Flow After Primary PCI in Acute Myocardial Infarction: Insights from the HORIZONS-AMI Trial**

Adriano Caixeta, Alexandra J. Lansky, Eugenia Nikolsky, Roxana Mehran, George D. Dangas, Bernhard Witzenbichler, Giulio Guagliumi, Jan Z. Peruga, Bruce Brodie, Dariusz Dudek, Ran Kornowski, Hartmann Franz, Helen Parise, Gregg Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY, Adriano Caixeta, New York

Background: Restoration of normal epicardial flow has been strongly related to survival following reperfusion therapy during evolving AMI. The prognostic utility of restored TIMI flow has not been examined in a large-scale multicenter prospective study after contemporary interventional strategies in pts with AMI.
Methods: The HORIZON-AMI trial randomized 3602 pts with STEMI undergoing primary PCI to bivalirudin (n=1800) vs. UFH+GPI (n=1802), with a second 3:1 randomization in 3006 stent eligible pts to the Taxus stent (N=1348) vs. the bare metal Express stent (N=452). An independent angiographic laboratory assessed all angiograms for baseline and final lesion and flow characteristics. Clinical outcomes including composite major adverse cardiovascular events (MACE) (death, reinfarction, ischemic target vessel revascularization, and stroke) and stent thrombosis (ARC definite or probable).
Results: A total of 3,276 lesions were treated with core lab analysis; 2,815 lesions (86%) had final TIMI 3, 360 (11%) had TIMI 2, and 101 (3%) had TIMI 0/1. The 30-day and 1-year outcomes stratified by the post-procedure TIMI flow are summarized in Table.

Variable	Final TIMI 0/1 (N=101)	Final TIMI 2 (N=360)	Final TIMI 3 (N=2815)	P-Value All Groups
30-day Outcomes				
Death	16.8%	4.7%	1.5%	<0.0001
Reinfarction	4.0%	1.1%	1.1%	0.04
TVR	10.2%	2.6%	2.3%	<0.0001
Stroke	3.0%	0.8%	0.4%	0.001
MACE	26.7%	8.1%	4.1%	<0.0001
Stent thrombosis	8.6%%	4.0%	2.0%	0.0005
1-Year Outcomes				
Death	19.9%	7.3%	2.8%	<0.0001
Reinfarction	13.5%	3.2%	3.8%	<0.0001
TVR	15.2%	6.2%	6.8%	0.002
Stroke	3.1%	0.8%	0.9%	0.05
MACE	36.7%	14.3%	10.6%	<0.0001
Stent thrombosis	11.4%	4.7%	3.0%	0.0009

Conclusions: In this large-scale contemporary multicenter prospective randomized trial, restoration of normal TIMI flow after primary PCI in STEMI was achieved in 86% of lesions and was strongly associated not only with markedly lower rates of death, but also of reinfarction, TVR, stroke, stent thrombosis and MACE at 30-days and 1-year follow-up.

9:30 a.m.

2512-677 Thin Cap of the Culprit Lesion, as Assessed by Optical Coherence Tomography, is Associated with the Outcome of Fibrinolytic Therapy in Patients with STEMI

Konstantinos Toutouzas, Maria Riga, Andreas Synetos, Eleutherios Tsiamis, Antonis Karanasos, Dimitrios Tousoulis, Elli Stefanadi, Costas Tentolouris, Costas Tsioufis, Christodoulos Stefanadis, 1st Cardiology Clinic, University of Athens, Medical School, Hippokration Hospital, Athens, Greece

Background: Thrombolysis is successful in approximately 60% of patients (pts) with acute ST elevation myocardial infarction (STEMI). There are no data regarding the morphology of the culprit plaque, predicting the success of thrombolysis. Optical coherence tomography (OCT) can accurately measure the thickness of the fibrous cap of the atheromatic plaque. We hypothesized that there is a correlation between the success rate of thrombolysis and the cap's thickness of the culprit lesions (CL) in pts with STEMI.
Methods: We included 21 pts with STEMI (mean age 59.9±5.6 years), who underwent thrombolysis with tenecteplase 1-4 hours after the initiation of chest pain. Coronary angiography was performed within 24 hours after thrombolysis and TIMI flow was observed. Successful thrombolysis was assigned as TIMI flow III. Then all CL were investigated with OCT. In cases of complete obstruction, aspiration of the thrombus was performed before OCT examination. Fibrous cap thickness at the site of the greatest stenosis (FCT) of the CL was measured.
Results: OCT wires were successfully advanced through all lesions. We examined 21 CL of 21 pts (100%). In 13 out of 21 pts (61.9%) TIMI flow grade III was achieved. Analysis of OCT images showed that mean FCT in all pts was 97±19μm. FCT in pts with successful thrombolysis was 116±40μm, whereas in pts with failed thrombolysis FCT was 65±18μm ($p<0.01$). After the categorization of the plaques according to plaque thickness (thin <65μm; thick >65 μm) we found that 92.3% of pts with successful thrombolysis had thick caps, while only 25% of pts with failed thrombolysis had CL with FCT > 65μm ($p<0.01$).
Conclusions: In pts with STEMI, successful thrombolysis is associated with thicker fibrous cap at the site of the greatest lumen stenosis, as measured with OCT. This study demonstrates that in pts with STEMI the outcome of the thrombolytic therapy could be predicted by specific morphological characteristics of the culprit lesions.

9:30 a.m.

2512-678 ST-Segment Resolution after Primary Percutaneous Intervention is Strongly Associated with Improvement of Cardiac Function Only in Anterior Myocardial Infarction

Hiroyuki Shibata, Shinichiro Yamada, Takatoshi Hayashi, Yasuyo Yaniguchi, Kazuo Mizutani, Sachiyo Iwata, Katsunori Okajima, Akira Shimane, Masahiro Kumada, Kensuke Matsumoto, Yasue Tsukishiro, Takumi Inoue, Teishi Kajiya, Himeji Cardiovascular Center, Himeji, Japan

Background: Complete ST-segment resolution is well-recognized predictor of good myocardial salvage after primary percutaneous coronary intervention (pPCI) for ST segment elevation myocardial infarction (STEMI). However, regional difference of effect of ST resolution has not been well-evaluated.
Methods: We investigated 264 patients who underwent successful pPCI between 2005 and 2007 (120 anterior STEMI and 144 non-anterior). ECG-gated ^{99m}Tc-Tetrofosmin (TcTF) and ^{123}I-BMIPP SPECT were performed between 7-10 days (Acute) and TcTF was repeated 3 months (Chronic) after onset. Myocardium was divided into 25 segments and segmental score was graded by 5 degrees according to the relative activity (0:normal, 4:defect). Sum of defect scores (S-DS) were calculated from SPECT, and ejection fraction (LVEF) / left ventricular volume from QGS software.
Results: In anterior STEMI, both myocardial perfusion evaluated by TcTF and fatty acid metabolism by BMIPP were significantly improved in complete ST resolution group. LVEF is significantly greater in both acute and chronic phase. However, in non anterior STEMI, There parameters did not differ significantly between complete ST resolution group and no/partial ST resolution group.
Conclusions: Complete ST-resolution after primary-PCI was less frequent in anterior STEMI. However, it is strongly associated with preserved myocardial perfusion, fatty acid metabolism, and ejection fraction, and also prevents from LV remodeling only in anterior STEMI.

	Anterior STEMI			Non-Anterior STEMI		
	Complete ST Resolution	No/Partial ST Resolution	P	Complete ST Resolution	No/Partial ST Resolution	P
N (%)	24(20%)*	96(80%)		68(47%)	76(53%)	
Male Gender (%)	79	82	N.S.	78	76	N.S.
Peak CK-MB	231	458	0.004	250	267	N.S.
BMIPP S-DS	23.7	32.3	0.001	12.2	14	N.S.
Tc-TF S-DS, acute	19.4	29.3	0.002	11.5	12.5	N.S.
Tc-TF S-DS, chronic	15.4	25.9	0.001	10.8	11.1	N.S.
LVEF, acute (%)	48.1	40.8	0.003	49	50.1	N.S.
LVEF, chronic (%)	53.9	48.5	0.05	56.2	57.8	N.S.
LVEDV, acute (ml)	105	123.5	0.04	100.3	99.3	N.S.
LVEDV, chronic (ml)	104	126.7	0.03	97.7	94.2	N.S.

P<0.01 vs. Non-Anterior STEMI

9:30 a.m.

2512-679 The Effect of Intra-coronary Nicorandil prior to Reperfusion in Acute ST Segment Elevation Myocardial Infarction

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Background: Intravenous nicorandil infusion with percutaneous coronary intervention (PCI) has been reported to reduce reperfusion injury events and improve cardiac function in patients with an acute myocardial infarction. However, there is limited information on the use of intra-coronary nicorandil. A prospective randomized single center study was designed to evaluate the efficacy of intra-coronary nicorandil.
Methods: Seventy-three patients with acute ST segment elevation myocardial infarction were randomly assigned to the nicorandil group (n=37) or a control group (n=36); all patients had a PCI. In the nicorandil group, 4 mg of intra-coronary nicorandil was infused directly into the infarct area prior to reperfusion (2 mg before ballooning, 2 mg before stenting). The primary study endpoint was a composite of the incidence of a reperfusion arrhythmia, no-reflow and slow reflow. The secondary study endpoint was the post TIMI grade and the myocardial blush grade.
Results: The baseline characteristics were similar in both groups. A significant difference was observed in the primary study endpoint in the nicorandil group compared to the control group ($p=0.037$). The post TIMI grade 3 was significantly higher in the nicorandil group ($p=0.019$). The myocardial blush grade 1 was not observed in the nicorandil group; however, it was observed in five patients in the control group ($p=0.019$).
Conclusion: Intra-coronary nicorandil infusion reduced the occurrence of no reflow, slow reflow, reperfusion arrhythmia and improved the myocardial brush grade and TIMI flow during PCI. The results of this study showed that intra-coronary nicorandil improved the clinical outcomes in patients with an acute myocardial infarction.

	Nicorandil group (N=37)	Control group (N=36)	p-value
Thrombus score			
3	10(27%)	15(41.7%)	0.281
5	27(73%)	21(58.3%)	0.188
Myocardial Blush grade			
1	0	5(13.9%)	0.019
2	11(29.7%)	10(27.8%)	0.854
3	26(70.3%)	21(58.3%)	0.287
Pre/Post TIMI grade			
0	1(2.7%)	2(5.6%)	0.538
1	1(2.7%)	4(11.1%)	0.155
2	0	3(8.3%)	0.173
3	35(94.6%)	27(75%)	0.019
Primary endpoint	2(5.4%)	8(22.2%)	0.037
No reflow	1(2.7%)	2(5.6%)	0.538
slow reflow	1(2.7%)	4(11.1%)	0.155
reperfusion arrhythmia (VT/VF)	0	2(5.6%)	0.146
re-myocardial infarction	1(2.7%)	0	0.321
Shock	3(8.1%)	2(5.6%)	0.666

9:30 a.m.

2512-680 Coronary Flow Velocity Pattern Immediately After Percutaneous Coronary Intervention Predicts Left Ventricular Remodeling and Ischemic Mitral Regurgitation in Patients with Acute Myocardial Infarction

TAKAFUMI YAMANE, Atushi Yamamuro, Yoshimori An, Kite Kim, Takeshi Kitai, Natuhiko Ehara, Makoto Kinoshita, Atushi Kobori, Koichi Tamita, Shuichiro Kaji, Tomoko Tani, Yutaka Furukawa, Kobe City Medical Center General Hospital, Kobe, Japan

Background: Studies using the Doppler guidewire have shown that coronary flow velocity (CFV) pattern in recanalized infarct-related arteries can evaluate microvascular dysfunction and predicts recovery of regional left ventricular (LV) function, in-hospital complications and long-term cardiac events. The purpose of this study was to examine whether the CFV patterns predict the risk of LV remodeling and ischemic mitral regurgitation (IMR) in patients with acute myocardial infarction (AMI).
Methods: Consecutive 173 patients with first anterior AMI underwent successful PCI (<50% residual stenosis with TIMI flow grade 2-3) and coronary flow measurement with the Doppler guidewire. We defined microvascular dysfunction as a diastolic deceleration time (DDT) ≤600 ms and the presence of systolic flow reversal. Based on CFV patterns, patients were divided into those without microvascular dysfunction (Group 1, n=100) and those with microvascular dysfunction (Group 2, n=73). LV end-diastolic volume index (LVEDVI), LV end-systolic volume index (LVESVI) and the severity of MR were evaluated by echocardiography at least 6 months after the infarction. A qualitative index of regurgitant severity was provide by the relative size of a regurgitant jet to the receiving chamber on a mild to severe scale. IMR was regarded as significant when moderate or severe MR was present.
Results: LVEDVI(62.2±20.9 ml/m^2 VS 48.0±13.9 ml/m^2, $p<0.0001$) and LVESVI(34.0±15.8 ml/m^2 VS 21.4±9.33 ml/m^2, $p<0.0001$) were greater in group 2 than in the Group1, and significant IMR was more frequently observed in Group 2 than in Group 1 (9.7% VS 1.0%, $p=0.017$).
Conclusions:CFV pattern of infarct-related coronary artery immediately after PCI predicts LV remodeling and ischemic mitral regurgitation, and enables accurate risk stratification in patients with anterior AMI.

9:30 a.m.

2512-681 **A Non-invasive Strategy for the Treatment of Myocardial Infarction is Associated with 1-Year Mortality After Correction for Differences in Baseline Characteristics.**

Kimberly A. Skelding, Vernon Mascarenas, Peter Berger, Christopher Good, Thomas Scott, Jeremy Buckley, Craig Wood, Jennifer Sartorius, James Blankenship, Geisinger Medical Center, Danville, PA

Background: Many randomized trials have demonstrated that an invasive strategy for myocardial infarction (MI) improves outcome. Data supporting an invasive approach in the general population, a much broader population than is enrolled in randomized trials, are lacking.
Methods: We queried our electronic medical health record and identified 3,015 pts admitted to a rural tertiary care center who suffered an MI (a CK-MB >3x upper limit of normal with a positive relative index) between 1/1/01 to 12/31/06. Multivariate logistic regression including 28 baseline clinical variables and risk factors was used to identify independent correlates of mortality at one year.
Results: Of the 3,015 pts, 2,066 were treated with an invasive strategy (coronary angiography during the initial hospitalization, followed by revascularization if appropriate), and 949 pts were not. The overall 1-year mortality rate was 15.7%. After adjusting for baseline clinical variables and risk factors, those that received non-invasive therapy were 4.44 times more likely to die within 1-year (95% CI=[3.45, 5.78], p<0.0001).
Conclusions: Among unselected pts suffering an MI, a non invasive strategy appears to be an independent correlate of 1 year mortality, even after adjustment for other measured variables.

9:30 a.m.

2512-682 **Gender is an Independent Risk Factor for Mortality when a Non-Invasive Strategy is Employed in the Setting of Acute Myocardial Infarction**

Kimberly A. Skelding, Peter Berger, Vernon Mascarenas, Christopher Good, Thomas Scott, Jeremy Buckley, Jennifer Sartorius, Craig Wood, James Blankenship, Geisinger Medical Center, danville, PA

Background: Gender has been reported to be an independent risk factor for mortality following acute myocardial infarction (AMI). However the issue has not been evaluated taking into account if and when an invasive strategy was pursued.
Methods: All patients with AMI between January 1, 2001 and December 31, 2006 at our center were included. Demographic and clinical characteristics including treatment modality and outcomes were captured through a comprehensive electronic medical health record. A propensity analysis was incorporated into a logistic regression model to determine likelihood of 1-year mortality.
Results: Males (n=1968) were more likely to have a history of smoking (49% vs. 31%, p<0.0001); females (n=1047) were older, had more obesity, hypertension, diabetes, hyperlipidemia, anemia, and chronic kidney disease (p value <0.0002 for each). After adjustment for risk factors, when invasively treated, there was no difference in one-year mortality between females to males (OR=0.90, 95% CI 0.63-1.29, p=0.55). However, among patients not undergoing an invasive evaluation females had a significantly higher mortality than males (OR=1.49, 95% CI 1.10-2.01, p=0.010).
Conclusions: Women treated conservatively for AMI are at highest risk for mortality. Prospective studies of AMI with increased representation of female patients ought to be performed in order to identify cohorts of females who may have a mortality benefit from more aggressive therapy.

9:30 a.m.

2512-683 **Improvements in Door to Balloon Time with Use of Prehospital ECG: The Vancouver Coastal Health Experience.**

Graham Christopher Wong, Michael Tsang, Michele Perry, Ron G. Carere, Anthony Y. Fung, John G. Webb, Monita Sundar, Christopher E. Buller, Krishnan Ramanathan, Vancouver Coastal Health Authority, Vancouver, BC, Canada, University of British Columbia, Vancouver, BC, Canada

Background: Use of prehospital ECGs (PHECG) has resulted in significant improvements in first medical contact to balloon time (FBT) and door to balloon time (DBT) for patients undergoing primary PCI for ST elevation myocardial infarction (STEMI). However, its widespread use is limited. Our health care region (Vancouver Coastal Health Authority [VCHA]) recently adopted the routine use of PHECG as part of a regional approach to STEMI reperfusion. We report on our initial experience with routine use of PHECG for STEMI identification and subsequent in-field redirection of patients for primary PCI.
Methods: VCHA has utilized a region-wide approach to STEMI reperfusion since June 1st, 2007. As part of this program, VCHA has implemented wireless transmission of paramedic acquired ECGs for all suspected STEMI patients seen by BC Ambulance Service (BCAS) since May 21st 2008. Patients so identified are redirected from community hospitals in the region towards one of 2 PCI capable hospitals. Activation of the cardiac catheterization team for primary PCI was made by the emergency department (ED) physicians upon receipt of the PHECG and clinical information supporting a diagnosis of STEMI. We compared the median first medical contact to balloon time (FBT) and hospital door-to-balloon time (DBT) amongst consecutive STEMI patients, before (n=68) and after (n= 48) initiating the PHECG program.
Results: Complete clinical and temporal data including was available for 116 patients. Patients were well matched for age, % male sex and % age >75 yrs. Use of PHECG was associated with a significant reduction in FBT (149 vs. 86 min, p< 0.001) and DBT (105 vs. 46 min, p<0.001). Absolute in hospital mortality was reduced from 13.2% to 8.3% (P<0.001).
Conclusion: Use of PHECG dramatically reduces FBT and DBT amongst STEMI patients undergoing primary PCI within the context of a regional STEMI reperfusion strategy. This approach was associated with a 4.9% reduction in inhospital mortality. Use of PHECG should be encouraged to improve reperfusion times and reduce mortality in STEMI patients.

9:30 a.m.

2512-684 **Will Bivalirudin Outperform Heparin Alone During Primary PCI for STEMI?**

Sanjay Kaul, Babak Azarbal, Prediman K. Shah, George A. Diamond, Cedars-Sinai Medical Center, Los Angeles, CA, UCLA Medical Center, Los Angeles, CA

Background: The HORIZON trial reported that in STEMI patients undergoing primary PCI, bivalirudin (Bv) significantly reduces major bleeding and increases event-free survival compared to abciximab + heparin (Hep). However, previous trials have failed to yield advantage for abciximab + Hep over Hep alone during primary PCI, thereby questioning the choice of the comparator in HORIZON.
Objective: Because the addition of abciximab to Hep may potentially increase bleeding without improving efficacy, we compared Bv vs Hep alone using an indirect comparison (IC). IC have previously been validated for evaluating competing interventions in absence of direct comparison.
Methods: Data from abciximab-treated cohort in HORIZON (Bv vs abciximab + Hep) and stented cohort in CADILLAC (abciximab + Hep vs Hep) were combined to yield the Bv vs Hep risk ratio (RR) according to the formula:
$RR_{Bv\ vs\ Hep} = (RR_{Bv\ vs\ abciximab\ +\ Hep}) \times (RR_{abciximab\ +\ Hep\ vs\ Hep})$
Trials were comparable in terms of patient population, lesion complexity, stent use, clopidogrel pretreatment, and outcomes.
Results (Table): Compared with Hep alone, Bv did not significantly reduce ischemic composite endpoint, mortality, blood transfusion or severe bleeding (all P >0.05).
Conclusion: The results of this IC indicate that Bv did not significantly improve efficacy or reduce bleeding compared with Hep alone during primary PCI for STEMI. A randomized controlled trial directly comparing bivalirudin vs heparin alone during primary PCI is warranted.

Bivalirudin vs Heparin Alone During Primary PCI for STEMI

Endpoints (30 days)	Bivalirudin vs Abciximab + heparin (HORIZON)	Abciximab + heparin vs heparin (CADILLAC)	Bivalirudin vs heparin (Indirect Comparison)
Death/MI/TVR/CVA	0.91 (0.61-1.36)	0.76 (0.44-1.34)	0.69 (0.35-1.37)
All-cause mortality	0.66 (0.44-1.00)	1.24 (0.57-2.71)	0.82 (0.34-1.98)
Transfusion rate	0.59 (0.39-0.88)	1.21 (0.69-2.12)	0.71 (0.36-1.43)
Severe bleeding	0.73 (0.29-1.81)	3.91 (0.44-34.85)	2.85 (0.78-10.42)

MI: reinfarction; TVR = target vessel revascularization for ischemia; severe bleeding (GUSTO criterion)

9:30 a.m.

2512-685 **Incidence and clinical consequences of distal embolization on the coronary angiogram after primary percutaneous coronary intervention for ST-elevation myocardial infarction.**

Marieke L. Fokkema, Pieter J. Vlaar, Tone Svilaas, Mathijs Vogelzang, Diny Amo, Gilles F. Diercks, Albert J. Suurmeijer, Felix Zijlstra, University Medical Center Groningen, Groningen, The Netherlands

Background: Primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) may be complicated by distal embolization (DE), which can be visible on the angiogram as a distal filling defect with abrupt cut-off distal to the culprit lesion. The aim of this study was to investigate the incidence and clinical consequences of angiographically visible DE after primary PCI in STEMI patients treated with triple anti-platelet therapy.
Methods: DE was analysed as part of the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study as a predefined secondary endpoint.
Results: Angiograms of 880 patients were evaluated for the presence of DE after primary PCI. DE was visible on 5.7% of the post-procedural angiograms. DE was associated with significantly worse outcomes, as shown in table. In patients with DE, the thrombus aspirate more often contained erythrocytes (47.1% vs. 15.7%, p<0.001) and the size of the aspirated thrombus was larger (p=0.02) compared to patients without DE.
Conclusions: In this patient group with triple anti-platelet therapy, the incidence of DE after primary PCI is low, compared to previous reports. Nevertheless, DE is still strongly associated with impaired myocardial reperfusion and poor outcome. Thrombus composition and size are related to angiographically visible DE after primary PCI.

Comparison of patients with and without distal embolization on the coronary angiogram after PCI

	No distal embolization (N = 830)		Distal embolization (N = 50)		P
Thrombus aspiration (%)	421/830	(50.7)	25/50	(50.0)	ns
TIMI flow 3 post PCI (%)	727/830	(87.6)	33/50	(66.0)	<.001
MBG 3 post PCI (%)	360/825	(43.6)	2/49	(4.1)	<.001
ST-seg. resolution >70% (%)	418/771	(54.2)	9/44	(20.5)	<.001
New Q-waves (%)	605/771	(78.5)	42/44	(95.5)	.004

9:30 a.m.

2512-686 **The Role of Coronary Artery Bypass Grafting in ST-Segment Elevation Myocardial Infarction: a Substudy From the Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study**

Youlan L. Gu, Iwan C. van der Horst, Yvonne Douglas, Tone Svilaas, Felix Zijlstra, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

Background: While primary percutaneous coronary intervention (PCI) is the treatment of choice for ST-segment elevation myocardial infarction (STEMI), coronary artery bypass grafting (CABG) may be indicated during the acute and subacute phase of STEMI for anatomic and ischemic reasons. In this study, we sought to investigate the clinical and surgical characteristics and long term outcome of patients treated with CABG within 30 days after presentation in a contemporary cohort of STEMI patients.
Methods: All 1071 patients enrolled in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS) were included in this analysis. The decision to perform CABG was made by a joint heart team consisting of a clinical cardiologist, interventional cardiologist and cardio-thoracic surgeon according to the current guidelines.
Results: CABG was performed in 59 (5.5%) STEMI patients within 30 days of presentation. Of these patients, 13 (22%) were operated within 24 hours, 8 (14%) between 1 and 3 days, and 38 (64%) between 4 and 30 days. Compared with patients not treated with CABG, CABG patients had multivessel disease more often (p<0.001), underwent PCI and stent implantation less often (70% vs. 95% and 50% vs. 94%, respectively, both p<0.001), needed more intra-aortic balloon pump support (33% vs. 5%, p<0.001), and experienced more major bleeding (39% vs. 4%, p<0.001). Rethoracotomy was performed in 9/59 (15%) patients. When CABG was performed within 3 days, the incidence of rethoracotomy and major bleeding was higher than when it was performed after 3 days (33% vs. 5%, p=0.004, and 62% vs. 26%, p=0.007). At 1 year follow up, cardiac mortality did not differ between the CABG and non-CABG group (1.7% vs. 5.3%, HR 0.31, 95% CI 0.043 - 2.26, p=0.248).
Conclusions: Despite multiple high risk features, and a high incidence of major bleeding and rethoracotomy in STEMI patients treated with CABG, especially when it was performed within the first 3 days after presentation, surgical patients have a favorable long term outcome similar to non-surgical patients.

9:30 a.m.

2512-687 **Clinical Outcomes of Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction due to Left Main Coronary Artery Occlusion**

Shingo Sakamoto, Norimasa Taniguchi, Yasuo Sato, Syunsuke Nakajima, Akihiko Takahashi, Sakurakai Takahashi Hospital, Kobe, Japan

Background: Acute myocardial infarction (AMI) due to left main coronary artery (LMCA) occlusion has a poor prognosis. However, data on the clinical outcome of primary percutaneous coronary intervention (PCI) of acute LMCA occlusion has been scarce. The purpose of this study was to determine the clinical features and outcomes of patients who underwent primary PCI for AMI due to LMCA occlusion.
Methods: Between January 1997 and December 2007, a total of 1219 patients with AMI admitted to our hospital. Of these, 37 patients (3.0%) who underwent PCI for LMCA occlusion were enrolled. Clinical outcomes were determined by reviewing hospital records or via telephone contact. Survival free of all-cause death was estimated by the Kaplan-Meier method. A multiple Cox proportional hazard model analysis was performed to identify independent variables associated with all-cause death.
Results: Most patients presented with critical hemodynamic status on arrival including 18 cardiogenic shocks and 8 cardiac arrests. Nineteen patients required percutaneous extracorporeal life support to maintain hemodynamic status and 35 patients required intra-aortic balloon counter pulsation. Success reperfusion was achieved in 97.3%. In-hospital mortality rate was 40.5%. Twenty-two patients (59.5%) survived to hospital discharge. During follow-up period, an additional 6 patients died. Multivariate analysis showed an independent predictor of all-cause mortality to be cardiopulmonary arrest on arrival (RR, 4.39; 95% CI, 1.53 to 12.6; P = 0.01).
Conclusions: Patients with AMI due to LMCA occlusion showed a high mortality, however, our data revealed high rate of successful reperfusion and better outcome than previous reports. Cardiopulmonary arrest on arrival was the only independent predictor of all-cause death. Advanced therapy for the patients with cardiopulmonary arrest on arrival may further improve the prognosis.

9:30 a.m.

2512-688 **Time-to-Treatment in STEMI Patients Undergoing Inter-hospital Transfer in Massachusetts**

Murtuza J. Ali, Zoran S. Nedeljkovic, Katya Zelevinsky, Ann Lovett, Sharon-Lise T. Normand, Alice K. Jacobs, Boston University School of Medicine, Boston, MA, Harvard Medical School, Boston, MA

Background: Primary percutaneous coronary intervention (PCI) is the preferred reperfusion strategy for ST-elevation myocardial infarction (STEMI) if delivered in a timely fashion. Because many STEMI patients require inter-hospital transfer to a PCI-capable hospital, the importance of time to treatment has gained increased recognition. To study the impact of efforts to reduce time to treatment in Massachusetts, we evaluated 6008 STEMI patients undergoing primary PCI between 2005 and 2007. **Methods:** We used prospectively collected data compiled, audited, and analyzed by the Massachusetts Data Analysis Center, the state mandated PCI registry. **Results:** The mean age of the population was 61 years, with 29% women and 6.5% in cardiogenic shock. In patients admitted directly to a PCI hospital, mean door-to-balloon (DTB) time decreased from 2005 to 2007, with an increase in patients achieving a DTB time ≤90 minutes (73.2% in 2007). For patients requiring inter-hospital transfer, mean DTB time also improved but fewer patients achieved total DTB time ≤90 minutes (8.7% in 2007), as shown in the table below. Most of the delay was due to the time required for inter-hospital transfer (102 min in 2007).

	Mean DTB time (no transfer) N=3695	Mean DTB time (with inter-hospital transfer) N=2313	DTB time ≤ 90 minutes (no transfer)	DTB time ≤ 90 minutes (with inter-hospital transfer)
2005	92.4 min	170.5 min	56.6%	4.5%
2006	87.5 min	159.6 min	62.6%	6.5%
2007	79.3 min	146.1 min	73.2%	8.7%

Conclusion: Although DTB time has improved in STEMI patients in Massachusetts, delays still persist primarily in patients requiring transfer to a PCI hospital with < 10% achieving the recommended target. The impact of the recently mandated Statewide STEMI Triage (Point of Entry) System will require further study.

9:30 a.m.

2512-689 **Beneficial Diastolic Effects of Mechanical Left Ventricular Unloading by Impella During High-Risk PCI and Primary PCI for Acute Myocardial Infarction**

Maurice Remmelink, Krischan D. Sjauw, José P. Henriques, Robbert J. de Winter, René J. van der Schaaf, Marije M. Vis, Karel T. Koch, Walter J. Paulus, Bas A. de Mol, Jan G. Tijssen, Jan J. Piek, Jan Baan, Jr., Academic Medical Center - University of Amsterdam, Amsterdam, The Netherlands, VU University Medical Center, Amsterdam, The Netherlands

Background: Limited clinical information is available on the direct left ventricular (LV) dynamic consequences of LV unloading in patients undergoing high-risk percutaneous coronary intervention (PCI) and primary PCI for acute ST-elevation myocardial infarction. We studied online LV dynamic effects of mechanical LV unloading during PCI.
Methods: The effects of the Impella LP2.5 device on LV dynamics were studied in 11 patients (elective high-risk PCI, n=6; primary PCI, n=5). LV pressure and volume were continuously assessed by a pressure-conductance catheter at 4 different support levels of the Impella, from 0 L/min at baseline to 2.5 L/min at maximal support.
Results: The response to increased LV unloading was not different between both groups of patients. The pooled data showed no change on global and systolic LV function during increased LV unloading, while diastolic function showed improvement as indicated by an increased LV compliance in all patients. There was a decrease in end-diastolic pressure from 22±4 to 13±3 mm Hg (p=0.0001), in end-diastolic elastance from 0.134±0.021 to 0.091±0.021 mm Hg/mL (p=0.009), and in end-diastolic wall stress from 84±18 to 47±13 mm Hg (p=0.004).
Conclusions: LV unloading decreases end-diastolic wall stress and improves diastolic compliance dose-dependently. Our results indicate beneficial LV unloading effects of Impella during high-risk and primary PCI.

9:30 a.m.

2512-690 **Clinical and Angiographic Factors Predicting Development of the No-Reflow/Slow Flow Phenomenon during Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction**

Hyoung-Mo Yang, Seung-Jea Tahk, Hong-Seok Lim, Byoung-Joo Choi, So-Yeon Choi, Myeong-Ho Yoon, Gyo-Seung Hwang, Jin-Sun Park, Soo-Jin Kang, Joon-Han Shin, Ajou University Medical Center, Suwon, South Korea

Background: The development of the no-reflow/slow flow phenomenon during percutaneous coronary intervention (PCI) is associated with unfavorable outcomes in patients with acute myocardial infarction (AMI). We aimed to identify the patient at high risk for developing the no-reflow/slow flow phenomenon in AMI.
Methods: We studied 122 patients who underwent primary PCI for AMI within 12 hours of symptom onset. The patients were divided into the no-reflow/slow flow group (thrombolysis in myocardial infarction (TIMI) 0,1,2) and reflow (TIMI 3) group, and compared clinical,

laboratory, echocardiographic, angiographic and procedural parameters.
Results: The incidence of the no-reflow/slow flow phenomenon was 31% (38 patients). Reperfusion after 6 hours (65.8 vs. 26.2%, p<0.001), the frequency of balloon pre-dilation ≥3 times (21.1 vs. 8.3%, p=0.048), ≥2 stents at culprit vessel (44.7 vs. 20.2%, p=0.005), lesion length ≥20 mm (71.1 vs. 33.3%, p<0.001), troponin-T ≥0.25 ng/ml (57.9 vs. 22.6%, p<0.001) were more common in the no-reflow/slow flow group. Multivariate logistic regression analysis revealed that reperfusion time ≥6 hours (odds ratio: 5.389, p=0.001), lesion length ≥20 mm (odds ratio: 4.065, p=0.005), and troponin-T ≥0.25 ng/ml (odds ratio: 5.178, p=0.001) were independent predictors for developing the no-reflow/slow flow phenomenon.
Conclusions: During primary percutaneous coronary intervention in patients with acute myocardial infarction, reperfusion time more than 6 hours, high troponin-T level and long lesion length were independent predictors for developing the no-reflow/slow flow phenomenon.

9:30 a.m.

2512-691 Impact of Clopidogrel Loading Dose on the Effectiveness of Bivalirudin in Primary Angioplasty for Acute Myocardial Infarction: The HORIZONS-AMI Trial

George D. Dangas, Giulio Guagliumi, Bernhard Witzenbichler, Deepak Bhatt, Frederick Feit, Magnus Ohman, S. Chiu Wong, Eugenia Nikolsky, Adriano Caixeta, Helen Parise, Alexandra J. Lansky, Roxana Mehran, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background. In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) compared to unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced 30-day rates of major bleeding, reduced cardiac mortality with comparable composite major adverse cardiovascular events (MACE), and enhanced freedom from net adverse clinical events (NACE; MACE or major bleeding) in pts with AMI undergoing primary PCI. Whether the observed effects of Biv are dependent on the clopidogrel loading dose is unknown.
Methods and Results. In HORIZONS, 3602 pts with AMI at 123 centers in 11 countries were randomized to Biv (n=1800) vs. UFH+GPI (n=1802). Per protocol, all pts were to receive a clopidogrel loading dose in the ER, either 300 mg or 600 mg per the treating physician, and randomization was stratified by this decision. As shown in the table, the effects of Biv were independent of the clopidogrel loading dose (interaction p values = nonsignificant for major bleeding, MACE and NACE respectively).
Conclusions. In patients with AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events, independent of the clopidogrel loading dose.

	Clopidogrel 300mg			Clopidogrel 600mg		
	Biv n=569	UFH+GPI n=584	RR [95%CI]	Biv N=1097	UFH+GPI N=1061	RR [95%CI]
Major bleeding	7.5%	11.9%	0.61 [0.41,0.89]	5.0%	8.2%	0.59 [0.42,0.84]
MACE*	13.7%	11.4%	1.22 [0.88,1.70]	10.5%	11.6%	0.90 [0.70,1.16]
NACE**	17.8%	19.4%	0.89 [0.68,1.17]	14.1%	17.4%	0.79 [0.64,0.98]

* MACE = death, reinfarction, ischemic TVR or stroke;
**NACE (Net Adverse Clinical Events) = MACE or major bleeding

9:30 a.m.

2512-692 Triple versus Dual Antiplatelet Therapy in Patients with Acute Non-ST-Segment Elevation Myocardial Infarction Undergoing Percutaneous Coronary Intervention

Kang Yin Chen, Seung-Woon Rha, Yong Jian Li, Kanhaiya L. Poddar, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong*, Other KAMIR Investigators, Korea University Guro Hospital, Seoul, South Korea, ChonNam National University Hospital*, Gwangju, South Korea

Background: Whether the triple antiplatelet therapy is superior to the dual antiplatelet therapy in patients (pts) with acute non-ST-segment elevation myocardial infarction (NSTEMI) undergoing percutaneous coronary intervention (PCI) is still unclear.
Methods: A total of 1,700 NSTEMI pts undergoing PCI received either dual antiplatelets (aspirin plus clopidogrel, Dual group, n=1,075) or triple antiplatelets (aspirin plus clopidogrel plus cilostazol, Triple group, n=625) therapy. The patients in Triple group received additional cilostazol for 1 month, then, changed to receive dual antiplatelet therapy.The bleeding complications and clinical outcomes up to 8 months were compared between these two groups.
Results: The baseline characteristics were similar between these two groups. The incidences of total death, recurrent MI and major bleeding events were similar between these two groups. Triple group showed a lower incidence of in-hospital revascularization, but it was not well maintained up to 8 months. Although there was a trend toward lower incidence of All MACE in the Triple group at 1 month, but not maintained at 8 months (Table).
Conclusions: Despite numerically lower incidences of early revascularization and MACE, the triple antiplatelet therapy appears to be similar to the dual antiplatelet therapy in pts with NSTEMI undergoing PCI.

Table: Clinical outcomes of the Study Population

Variables, n (%)	Dual group (n=1,075 pts)	Triple group (n=625 pts)	P value
In-hospital			
Total death	18 (1.7)	8 (1.3)	0.523
Reinfarction	2 (0.2)	3 (0.5)	0.364
Revascularization	18 (1.7)	2 (0.3)	0.013
All MACE	38 (3.5)	13 (2.1)	0.090
TIMI-major bleeding events	1 (0.1)	1 (0.2)	1.000
At 1 month			
Total death	20 (1.9)	12 (1.9)	0.939
Reinfarction	8 (0.8)	3 (0.5)	0.755
Revascularization	32 (3.0)	8 (1.3)	0.025
All MACE	60 (5.7)	23 (3.7)	0.076
At 8 months			
Total death	26 (2.5)	18 (2.9)	0.562
Reinfarction	12 (1.1)	5 (0.8)	0.528
Revascularization	55 (5.2)	22 (3.6)	0.127
All MACE	93 (8.8)	45 (7.3)	0.292

9:30 a.m.

2512-693 Direct Presentation, Field-Referral, and Interhospital Transfer in a Network-Based System for Primary Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction Result in Similar 1-Year Mortality

Wichert J. Kuijt, Karel T. Koch, Joost D. Haeck, Niels J. Verouden, José P. Henriques, Jan Baan, Jr., René J. Van der Schaaf, Marije M. Vis, Jan G. Tijssen, Jan J. Piek, Mitchell W. Krucoff, Robbert J. De Winter, Academic Medical Center-University of Amsterdam, Amsterdam, The Netherlands, Duke Clinical Research Institute, Durham, NC

Background: Guidelines describe a systems-based first medical contact (FMC) to balloon time of 90 minutes as the goal for standard of care in primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI). In our regionalized STEMI network, infrastructural measures such as single-call activation of the catherization laboratory, short touchdown in the emergency department of referring hospitals, and direct ambulance transmission of an electrocardiogram (ECG) have been implemented. We investigated whether these measures would lead to guideline adherence and if route of presentation had an impact on 1-year mortality in an all-comer STEMI population.
Methods: Data was prospectively acquired in a dedicated database. Between 2000 and 2006, 2507 patients with a complete dataset underwent primary PCI. Time of symptom onset, FMC, call to activate the catherization laboratory, arterial puncture (needle) and balloon inflation were recorded and time-intervals were calculated for patients presenting directly, through interhospital transfer or direct field-referral. Field-referral FMC was time of acquisition of ambulance ECG.
Results: Time-intervals are medians in minutes with interquartile ranges, in order of direct presentation, interhospital transfer, and field referral. Time of symptom-onset to FMC was 90.5 (60-165), 90 (54-155), and 69 (33.5-128) (p<0.001). FMC to call time was 17 (10-34), 22 (14-40), and 19 (10-36) (p<0.001). Call-to-needle time was 40 (27-49), 50 (40-61), and 41 (30-50) (p<0.001). Needle-to-balloon time was 12 (8-19), 13 (9-20), and 15 (11-23) (p<0.001). Unadjusted 1-year mortality was 9.6% for direct presentation, 9.1% for interhospital transfer and 9.3% for field-referral (p=0.95). The adjusted hazard ratios for route of presentation were 0.95 (p=0.76, 95% CI 0.69-1.31) and 0.77 (p=0.34, 95% CI 0.45-1.31), respectively.
Conclusion: In STEMI patients, fast reperfusion was achieved in all routes of presentation and there was no significant difference in unadjusted and adjusted 1-year mortality. These results support primary PCI as the preferred treatment in STEMI if these infrastructural measures can be successfully implemented.

9:30 a.m.

2512-694 Effect of Gender on Outcome Following Percutaneous Coronary Intervention for Acute Myocardial Infarction

Victoria Fratto, Lakshmi Venkitachalam, Faith Selzer, Alice Jacobs, Ruchira Glaser, J. Dawn Abbott, Kevin E. Kip, Suresh R. Mulukutla, Sheryl Kesley, Elizabeth M. Holper, Oscar C. Marroquin, University of Pittsburgh School of Medicine, Pittsburgh, PA, Center for Interventional Cardiology Research, Pittsburgh, PA

Background: Mortality rates from coronary artery disease, specifically acute myocardial infarction (AMI), have decreased over time in men, but not in women. Percutaneous coronary intervention (PCI) has proven beneficial for the treatment of AMI, but its impact in women is less clear.
Methods: The study population consisted of 2856 patients who underwent PCI for AMI enrolled in the National Heart, Lung, and Blood Institute Dynamic Registry in five waves from 1997 to 2006. Gender differences in baseline patient, procedural, and in-

hospital outcomes were calculated using Chi-square and Wilcoxon rank-sum tests for categorical and continuous variables, respectively. Cumulative one year event rates for death, MI, and repeat revascularization (PCI or bypass) were compared using the log rank test. Univariate and adjusted risks of one year events for women (reference: men) were computed using Cox proportional models. Temporal trends were assessed using the interaction term of gender with wave.

Results: Women undergoing PCI for AMI (35.4% of cohort) were older (mean age 65.5 vs 59.5 years, p<0.001), with a higher prevalence of diabetes (32.8% vs 23.5%, p<0.001), hypertension (71.6% vs 58.4%, p<0.001) and congestive heart failure (10.8% vs 7.1%, p=0.001) compared to men. Women also presented with more single vessel disease (44.8% vs 39.0%, p=0.01) and calcified lesions (27.3% vs 23.4%, p=0.02). In-hospital event rates were similar in both groups [death (3.7% women vs 3.2% men, p=0.51), MI (1.4% vs 2.0%, p=0.27), emergency bypass surgery (0.4% vs 0.2%, p=0.39)]. Cumulative one year event rates were as follows - death (7.1% women vs 6.6% men, p=0.53), MI (4.7% both genders), and repeat revascularization (11.7% vs 11.9%, p=0.91). Adjusted risks of death, MI and repeat procedures in women were similar to men in the overall cohort (non-significant hazard ratios were 0.93, 1.08, 1.12, respectively). Interaction of gender with wave did not reach statistical significance for any event.

Conclusions: Despite more adverse profiles at baseline, women treated with PCI for AMI experience similar procedural and one year outcomes as men with AMI. These results support the continued use of PCI to treat AMI in women and in men.

9:30 a.m.

2512-695 Fibrinolytic Acceleration of STEMI Treatment Coupled with Urgent PCI (FAST-PCI) in an Urban Setting Improves Infarct Vessel Patency, Decreases Ischemic Time, and Reduces Peak Biomarker Levels without a Bleeding Penalty

Troy Weirick, Ali Denktas, Vernon Anderson, Richard Smalling, University of Texas at Houston, Houston, TX

Background: Although theoretically attractive, the safety and efficacy of pre-hospital fibrinolysis prior to planned PCI for acute MI remains uncertain, particularly in an urban setting with short transport times. Early trials suggest improved outcomes when fibrinolytic therapy was given prior to hospital admission; however, a recent meta-analysis questions the safety of fibrinolytic therapy prior to planned PCI.

Methods: From November 2005 thru December 2006, over 200 patients presented to a large, urban hospital with presumed STEMI. In this cohort, 131 patients could reliably report the time of symptom onset to within six hours of presentation. Forty-nine of these patients were part of an ongoing evaluation of pre-hospital reduced-dose fibrinolytic therapy prior to planned PCI. Data were analyzed according to treatment strategy, FAST-PCI vs. primary PCI.

Results: Age and time to presentation are similar in these groups. Measures of early target vessel patency significantly favor the pre-hospital treated group. Peak biomarker levels are reduced in FAST-PCI patients, and mean ischemic time is lower in the lytic pretreated group. However, no significant difference in bleeding occurred, and there were no intracranial bleeds.

	FAST-PCI (n=49)	Primary PCI (n=82)	P-value
Age (yrs)	57 std +/-12	57 std +/-12	0.97
Time to Presentation (hrs)	2.21	2.17	0.89
Ischemic Time (hrs)	3.0	3.4	0.18
TIMI Flow Pre-procedure (Mean)	2.0	1.3	0.001
TIMI Flow Post-procedure (Mean)	2.9	2.8	0.76
Infarct Artery Patent at Presentation, (TIMI Flow 2 or 3)	73% (36/49)	48% (39/82)	0.003
Peak CK, U/L (Mean)	1664 std +/-1809	2431 std+/-2208	0.04
Peak Troponin-T, ng/dL (Mean)	6.3	8.1	0.19
Average Hb loss (g/dL)	2.5	2.8	0.37
MACE - Death, MI, Stroke (N)	2	5	0.62

Conclusions: In this well-matched, urban population of patients presenting within six hours of chest pain onset, FAST-PCI improves infarct artery patency, decreases peak biomarker concentrations and reduces ischemic time without increased bleeding compared to primary PCI.

9:30 a.m.

2512-696 Long-term Outcomes of Culprit Only versus Complete Coronary Revascularization During Primary Percutaneous Coronary Intervention

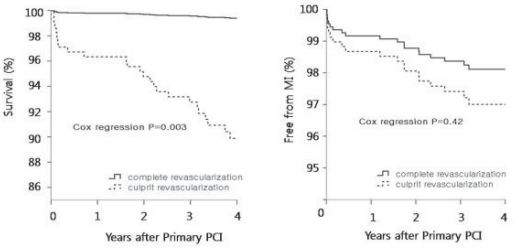
Jeong-Sook Seo, Duk-Woo Park, Sung Sik Kim, Sung-Hwan Kim, Myung-Zoon Yi, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Seong-Wook Park, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: The optimal percutaneous interventional strategy for dealing with significant non-culprit lesions in patients presented with acute ST elevation myocardial infarction (STEMI) and concomitant multivessel disease remains to be controversial.

Method: A total of 299 patients presented with acute STEMI and multivessel disease underwent percutaneous coronary intervention. Among the overall patients, 82 patients (27%) underwent simultaneously complete revascularization for culprit, infarct artery and the other significantly narrowed arteries and 217 (73%) had underwent revascularization for culprit lesion and the other disease artery were left during the primary percutaneous coronary intervention (PCI).

Result: During the 4 years of follow-up, patients with complete revascularization during the primary PCI showed the improved long-term mortality as compared to those with only culprit intervention (4.9 vs. 20.9%, adjusted HR, 0.06, 95% CI 0.01-0.38, P=0.003). However, the risk of MI (4.9 versus 7.9 %, adjusted HR, 0.63, 95% CI 0.20-1.94, P=0.42) and stent thrombosis (4.9 versus 5.5%, adjusted HR, 0.34, 95% CI 0.06-1.84, P=0.21) were similar in the both groups.

Conclusion: In the setting of primary PCI for STEMI with concomitant multivessel disease, simultaneous complete revascularization for culprit and non-culprit lesions was associated with improved long-term mortality.



9:30 a.m.

2512-697 Clopidogrel Pretreatment in ST-Elevation Myocardial Infarction Patients Transferred for Percutaneous Coronary Intervention

David M. Larson, Sue Duval, Scott W. Sharkey, Christopher Solie, Barbara T. Unger, Timothy D. Henry, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Background: Pretreatment with clopidogrel prior to percutaneous coronary intervention (PCI) reduces ischemic complications, but there are limited data in patients (pts) undergoing primary PCI for ST-elevation myocardial infarction (STEMI).

Methods: The Minneapolis Heart Institute at Abbott Northwestern (ANW) performs PCI for all STEMI that present directly or are transferred from 35 community hospitals as part of the "Level 1 MI" program. Zone 1 hospitals are <60 miles and Zone 2 are 60-210 miles away from ANW. STEMI pts receive aspirin, unfractionated heparin and clopidogrel (600 mg) in the emergency department of the presenting hospital within 15 minutes of diagnosis. Zone 2 pts also receive reduced dose fibrinolytic unless contraindicated. This analysis included all STEMI pts from 4/03 to 6/08 pretreated with clopidogrel and stratified by zone as a surrogate for pretreatment time. Median door to PCI time was 123 minutes in Zone 2, 96 minutes in Zone 1 and 65 minutes at ANW.

Results: There was significantly improved coronary patency (TIMI 2/3 flow) and less reinfarction at 30 days in pts treated in Zone 2 and 1 compared to ANW with no significant increase in bleeding and no difference in mortality (Table).

	Reinfarction, 30 days	Pre-TIMI flow 2/3 (excluding lytics)	Bleeding	Death, 30 days
ANW	14/371 (3.8%)	122/313 (38.9%)	14/371 (3.8%)	11/371 (3.0%)
Zone 1	9/850 (1.1%)	362/758 (47.8%)	19/850(2.2%)	28/850(3.3%)
Zone 2	6/604 (1%)	57/100 (57%)	21/604 (3.5%)	28/604 (4.6%)
P-value	0.001	0.002	0.23	0.29

Conclusions: STEMI pts who received earlier pretreatment with clopidogrel had significantly less ischemic complications and improved patency without increased bleeding or 30-day mortality. This study supports administration of clopidogrel (600 mg) for STEMI pts at the point of first medical contact.

9:30 a.m.

2512-698 Impact of Vascular Disease on In-Hospital Mortality Following Percutaneous Coronary Intervention for Acute Myocardial Infarction

Jignesh Patel, David L. Brown, Stony Brook University Medical Cener, Stony Brook, NY

Background: The impact of vascular disease on the survival of patients presenting with acute myocardial infarction (AMI) is not well understood. The purpose of the present study is to analyze the effect of vascular disease on in-hospital mortality of patients with AMI treated with primary percutaneous coronary intervention (PPCI).

Methods: This retrospective cohort study analyzed all patients undergoing PPCI for AMI from 1997-1999 in New York State. Vascular disease was defined as disease of the carotid, aorto-iliac or femoral-popliteal circulations. The primary outcome of interest was in-hospital mortality.

Results: PPCI was performed in 9015 patients with AMI of whom 529 patients (5.9%) had vascular disease. Vascular disease patients were older (69 vs. 60 years, P<0.001) and more commonly female (40% vs. 28%, P<0.001). Patients with vascular disease were more likely to have diabetes (28% vs. 17%, P<0.001), hypertension (72% vs. 55%, P<0.001) or chronic kidney disease (3.6% vs. 0.9%, P< 0.001). A history of stroke (15% vs. 3.2%, P<0.001), heart surgery (19% vs. 6%, P<0.001) and heart failure (7.6% vs. 2%,

P<0.001) was more common in vascular disease patients. Patients with vascular disease were more likely to develop heart failure (23% vs10%, P<0.001), cardiogenic shock (7.6% vs. 3.7%, P<0.001) and hemodynamic instability (11% vs. 5.1%, P<0.001). Patients with and without vascular disease had similar ejection fractions (37.3% vs. 40.4%, P=NS) Vascular disease patients had a longer length of stay (9.6 vs. 6.2 days, P<0.001), higher incidence of post-PCI stroke (1.9% vs. 0.6%, P<0.001), access site injury (2.3% vs. 0.8%, P<0.001) and acute vessel occlusion (2.5% vs. 0.8%, P<0.001). In-hospital mortality was 13% for patients with vascular disease vs. 3.8% for patients without vascular disease (P<0.001). After multivariate logistic regression analysis, vascular disease remained an independent predictor of increased in-hospital mortality (Odds Ratio 2.2, 95% Confidence Interval, 1.592 to 2.893, P<0.001).

Conclusion: Vascular disease is independently associated with doubling of the mortality risk in patients undergoing PPCI for AMI.

9:30 a.m.

2512-699 Does Coronary Dominance Affect Coronary Blood Flow and Mortality after Percutaneous Coronary Intervention for Acute Myocardial Infarction?

Jason Golub, Vikas Aggarwal, Dimitrios Bliagos, Seth Sokol, Jaime Ghitelman, Mark Menegus, Mark Greenberg, V. S. Srinivas, Montefiore Medical Center, Bronx, NY, Albert Einstein College of Medicine, Bronx, NY

Background: Coronary dominance is reported to independently predict mortality in acute myocardial infarction, although mechanisms underlying this relationship are yet to be elucidated. Whereas global flow reductions are noted during myocardial infarction, whether coronary dominance influences global flow in this setting is unknown.

Methods: In 278 patients undergoing primary Percutaneous Coronary Intervention (PCI), pre and post corrected TIMI frame count was measured in 159 when either the left anterior descending (LAD) or left circumflex (LCx) was the infarct related artery (IRA). Global flow was calculated as the mean frame count in the LAD & LCx; abnormal flow defined as frame count ≥28. The LCx was Dominant (DLCx) when it supplied the posterior descending artery and Non Dominant (NDLCx) otherwise. Statistical comparisons were performed using student-t test or suitable non-parametric tests for continious variables and chi-square test for categorical variables. Vital Rate ratios were calculated with Mantel-Haenszel methods. Multivariate analysis was performed using stepwise logistic regression.

Results: Overall, 27% had DLCx circulation and post-PCI flow improved from 57±16 to 31±14 frames (P<0.001).However, the improvement among DLCx was less than NDLCx (34±10 vs. 27±15, P=0.07).Post-PCI, global flow was normal in 51% and it was achieved less often in DLCx than NDLCx circulations (39.5% vs. 55.2%, p=0.08). Regardless of the location of IRA, post-PCI flow was slower in the DLCx compared to NDLCx; It was 37±17 vs. 31±14, P=0.05 for LAD and 43±18vs. 35±26,P=0.02 for LCx as IRA. At 90 days, normal global flow was associated with decreased mortality [RR 0.19; 95%CI 0.42-0.90]. Multivariate analysis identified DLCx (OR 0.35; 0.13-0.98), presence of thrombus, (OR 0.25; 0.07-0.84) and normal flow in non-IRA (OR 42.7; 15.4-118.4) as predictors for normal global flow post-PCI.

Conclusions: A DLCx independently predicted abnormal global flow, seen in almost half the patients, following primary PCI. Since normal global flow was associated with lower short term mortality, our results suggest that the effect of coronary dominance on mortality is likely to be explained by its effect on global flow.

9:30 a.m.

2512-700 Impaired Coronary Flow in Non-infarct Related Artery after Primary Angioplasty for Acute Myocardial Infarction: Predictors and clinical outcomes

Vikas Aggarwal, Jason Golub, Dimitrios Bliagos, Swapnil Rajpathak, Nassim Krim, Seth Sokol, E.Scott Monrad, Mark Greenberg, V.S Srinivas, Montefiore Medical Center, Bronx, NY, Jacobi Medical Center, Bronx, NY

Background: Global slowing of epicardial flow has been noted during acute myocardial infarction. Although Primary Percutaneous Coronary Intervention (PCI) improves infarct related artery (IRA) flow, the frequency of concurrent flow improvement in the non-IRA and its effect on clinical outcome is unknown.

Methods: Therefore, using standard techniques, we measured pre and post-PCI corrected TIMI frame counts (cTFC) in 159 patients with LAD (left anterior descending) or LCX (left circumflex) as IRA. Normal flow was defined as cTFC <28 frames and slow flow as cTFC ≥28 frames.Statistical comparisons were performed with t-test for continuous and χ^2 for categorical variables. Multivariate analysis was performed using stepwise logistic regression.

Results: Following primary PCI, prevalence of slow flow decreased from 93% to 35% (P<0.001) in the IRA and from 67% to 43% (P<0.001)in the non-IRA. In the non-IRA, post-PCI cTFC improved from 36.2 ± 13.3 to 30.5 ± 14.5 frames (p <0.001). However, 36% of patients who achieved normal flow in the IRA post-PCI also had slow flow in the non-IRA , wheras 58% failing to achieve normal flow in the IRA had slow flow in the non-IRA. Patients with slow flow in the non-IRA were older, more were males, had LAD as IRA, and had larger infarcts (higher Peak CK-MB and lower ejection fraction) compared to those with normal flow in the non-IRA. In multivariable analysis, independent predictors of normal post-PCI flow in non-IRA were age <60 yrs (OR 2.38; 95% CI 1.1 - 4.9, p = 0.02), female sex (2.24; 1.01-4.99, p=0.05), LCX as IRA (8.64; 2.7 - 27.6, p <0.001) and normal flow in the IRA after PCI (4.29; 1.87 - 9.85, p = 0.001). Among patients who achieved normal flow in the IRA, 30-day survival was better when non-IRA flow was also normal compared to when non-IRA flow was slow (0% vs. 8.1%, P=0.01). However, among those with slow flow in the IRA, 30 day outcome was similar in patients with either slow or normal flow in the non-IRA (9.4% vs. 13%, P=0.65).

Conclusions: Even in patients with normal flow in the IRA after Primary PCI, those with normal flow in the non-IRA recieved additional short term benefit. Whether abnormal flow in the non-IRA should be a target for therapy during primary PCI bears further investigation.

9:30 a.m.

2512-701 Equivalent Improvement of Cardiac Function after Late Reperfusion by Primary Percutaneous Coronary Intervention for ST-Segment Elevation Myocardial Infarction

Shinichiro Yamada, Takatoshi Hayashi, Sachiyo Iwata, Kazuo Mizutani, Yasuyo Taniguchi, Masahiro Kumada, Katsumori Okajima, Yasue Tsukishiro, Gaku Kanda, Takumi Inoue, Hiroyuki Shibata, Teishi Kajiya, Himeji Cardiovascular Center, Himeji, Japan

Background: Efficacy of primary percutaneous intervention (pPCI) for ST-segment elevation myocardial infarction (STEMI) >12 hours after the symptom onset is controversial.

Methods: We investigated 62 consecutive patients with STEMI who had undergone pPCI 12-48 after symptom onset (Late Reperfusion group). They were compared with age, gender and culprit lesion matched patients who received pPCI <6 hours after onset (Early Reperfusion). TIMI grade >2 at the time of diagnostic coronary angiography were excluded. ECG-gated ^{99m}Tc-Tetrofosmin (TcTF) and ^{123}I-BMIPP SPECT were performed between 7-10 days (Acute) and TcTF was repeated 3 months (Chronic) after onset. Myocardium was divided into 25 segments and segmental score was graded by 5 degrees according to the relative activity (0:normal, 4:defect). Sum of defect scores (S-DS) were calculated from SPECT, and ejection fraction (LVEF) / left ventricular volume from QGS software.

Results: There were no significant differences of prevalence of final TIMI grade or ST resolution between two groups. Baseline myocardial perfusion evaluated by TcTF, fatty acid metabolism by BMIPP, LVEF at acute and chronic phase also did not differ significantly. Only improvement of myocardial perfusion score from acute to chronic phase was significantly greater in Early Reperfusion group.

Conclusions: Primary PCI for STEMI provides the improvement of cardiac function including perfusion, metabolism and wall motion even when performed over 12 hours after the onset.

	Late Reperfusion	Early Reperfusion	P
Male Gender (%)	79	79	(matched)
Age	69.5	68.6	(matched)
Final TIMI grade	2.73	2.75	0.85
ST resolution (%)	43	37	0.58
TcTF S-DS, acute	17.4	20.1	0.29
TcTF S-DS, chronic	17.6	15.6	0.42
TcTF S-DS, change	-0.15	4.73	0.01
BMIPP S-DS	21.1	22.1	0.67
LVEF, acute (%)	45.5	47	0.51
LVEF, chronic (%)	51.8	54.4	0.21

9:30 a.m.

2512-702 Impact of Gender on the Safety and Effectiveness of Bivalirudin in Patients with Acute Myocardial Infarction Undergoing Primary Angioplasty: The Horizons-AMI Trial

Liliana Grinfeld, Alexandra J. Lansky, Jorge Belardi, Bernhard Witzenbichler, Giulio Guagliumi, Krzyszto Zmudka, Martin Moeckel, Andrzej Ochala, Witkowski Ruzyllo, Iulian Benetato Giuran, Helen Parise, Roxana Mehran, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) vs. unfractionated heparin (UFH) + glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding, comparable composite major adverse cardiovascular events (MACE), and enhanced freedom from net adverse clinical events (NACE) in pts with AMI undergoing primary PCI. Whether the beneficial effects of biv. are present in women, a high risk group after primary PCI in AMI, has not been reported.

Methods and Results: A total of 3602 pts at undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802). In the entire study population at 1 year Biv compared to UFH+GPI resulted in a 39% reduction in major bleeding (5.8% vs. 9.2%, P<0.0001), reduced cardiac mortality (2.1% vs. 3.8%, p=0.0.005), similar MACE (11.9% vs. 11.9%, P=1.0), and a 16% reduction in NACE (15.7% vs. 18.3%, P=0.03). At one year, compared to men, women (n=842; 23.4%) had greater rates of major bleeding (11.7% vs. 6.3%, P<0.001), MACE (15.5% vs. 10.8%, P=0.002) and NACE (23.5% vs. 15.0%, P<0.0001). Outcomes were analyzed according to gender. The impact of Biv was independent of gender.

Conclusions: In patients with AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events, effects which are consistent in women and men. However, compared to men, women continue to have worse outcomes at one year despite therapies which reduce important complications in the total population studied.

Female pts (n=842)	30-days			One Year		
	Biv mono	UFH+GPI	RR [95%CI]	Biv mono	UFH+GPI	RR [95%CI]
Major bleeding	7.5%	12.3%	0.61 [0.40, 0.93]	9.7%	13.6%	0.68 [0.45, 1.02]
MACE*	7.3%	7.4%	0.98 [0.61, 1.58]	16.7%	14.4%	1.15 [0.82, 1.63]
NACE**	13.6%	17.4%	0.78 [0.57, 1.07]	23.3%	23.7%	0.95 [0.71, 1.25]
Cardiac Death	2.2%	4.4%	0.55 [0.26,1.13]	2.7%	5.6%	0.48 [0.23,0.97]

* MACE = death, reinfarction, ischemic TVR or stroke;
**NACE (Net Adverse Clinical Events) = MACE or major bleeding

9:30 a.m.

2512-703 **Extracorporeal Membrane Oxygenation as an Adjunct to Primary Percutaneous Coronary Intervention and a Bridge to Decision in Acute Coronary Syndromes Complicated by Cardiogenic Shock**

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Background: Acute coronary syndromes (ACS) complicated by cardiogenic shock (CS) portends a poor prognosis despite advances in early invasive strategies. The role of extracorporeal membrane oxygenation (ECMO) as an adjunct to primary percutaneous coronary intervention (PCI) and a bridge to clinical stability and decision in this population is unknown.
Methods: Fifteen consecutive patients referred for emergent cardiac catheterization who presented with ACS complicated by CS and in whom ECMO was utilized early in their course for hemodynamic stabilization were evaluated. The expected mortality at 30 days was calculated using a validated scoring system. Primary outcome of observed 30-day mortality was then compared to expected mortality using a one-sample binomial test.
Results: Baseline characteristics included a mean age of 55±11 years, 93% male, mean arterial pressure 54±13 mmHg, cardiac index 1.8 ± 0.2 L/min/m^2, pulmonary capillary wedge pressure 29±8 mmHg, and 2.6±0.9 pressors. Ten patients had a cardiac arrest either before or during PCI. All patients received an intra-aortic balloon pump but remained hemodynamically unstable, necessitating early ECMO utilization. The culprit lesion most often involved the left anterior descending coronary artery (53%) while most had 2- or 3-vessel disease (93%). Reperfusion was established by PCI in 67% of patients. Six patients (40%) had PCI during ECMO support. Mean duration of ECMO support was 81±68 hours. The observed 30-day mortality in our cohort was lower at 53% compared to the calculated expected 30-day mortality of 75% (Z-statistic at 0.05 level:-1.97). Of the 8 patients who died, 4 had no neurological recovery post cardiac arrest, requiring withdrawal of support. Among survivors of ECMO support (n=12), 41% were bridged to a left ventricular assist device, 25% to coronary artery bypass surgery, and 17% to recovery. Three patients ultimately received heart transplantation.
Conclusions: ECMO may be an effective adjunct to primary PCI among carefully selected patients with ACS complicated by cardiogenic shock. ECMO support may facilitate clinical and hemodynamic stability in order to provide time for clinical decision making.

9:30 a.m.

2512-704 **Impact of Transfer Delays on Clinical Outcomes in Patients Undergoing Primary Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction**

Philippe Lachance, Jean-Pierre Déry, Gérald Barbeau, Éric Larose, Josep Rodés-Cabau, Olivier F. Bertrand, Can M. Nguyen, Bernard Noël, Louis Roy, Guy Proulx, Onil Gleeton, Robert De Larochellière, Laval Hospital, Québec, QC, Canada

Background: Shortened treatment delays have been associated with better outcomes in patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI). Patients presenting to hospital without PCI facilities experience longer reperfusion times compared to patients presenting directly to an hospital providing on-site primary PCI. The aim of this prospective study was to determine the impact of transfer delays on clinical outcomes of patients undergoing primary PCI for STEMI.
Methods: All STEMI patients undergoing primary PCI at a tertiary care center between May 2006 and June 2007 were included in the study. Treatment delays and clinical outcomes of patients presenting directly to the tertiary care center were compared to those of patients presenting to hospitals within a radius of 50 km and transferred for primary PCI. The primary endpoint was the composite of in-hospital death, myocardial infarction, revascularization, and stroke (MACE). One year event-free survival was also evaluated.
Results: During the study period, 199 patients presented directly (Group 1) and 462 patients were transferred (Group 2). Median door-to-balloon time was 60 (39, 82) minutes in group 1 compared to 91.5 (77,123) minutes in group 2 (p<0.0001). In-hospital MACE occurred in 21 patients (10.5%) in group 1 compared to 33 patients (7.2%) in group 2 (p=0.10). There was no difference in the occurrence of in-hospital death (3.5% vs 2.8% for group 1 and group 2, respectively, p=0.70). After a median follow-up of 1 year, 30.2% of patients in group 1 and 26.5% in group 2 experienced a MACE (p=0.40).
Conclusion: Despite delayed intervention, STEMI patients transferred from nearby community hospitals for primary PCI experience in-hospital and long-term clinical outcomes similar to those of patients presenting directly to the hospital providing primary PCI.

9:30 a.m.

2512-705 **Triple versus Dual Antiplatelet Therapy in Patients with Acute ST-Segment Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention**

Kang Yin Chen, Seung-Woon Rha, Yong Jian Li, Kanhaiya L. Poddar, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong*, Other KAMIR Investigators, Korea University Guro Hospital, Seoul, South Korea, ChonNam National University Hospital*, Gwangju, South Korea

Background: Whether the triple antiplatelet strategy is superior to the dual antiplatelet strategy in patients (pts) with acute ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) is still unclear.
Methods: A total of 2,404 STEMI pts underwent primary PCI received either dual antiplatelets (aspirin plus clopidogrel, Dual group, n=1,432) or triple antiplatelets (aspirin plus clopidogrel plus cilostazol Triple group, n=972) therapy. The pts in Triple group received additional cilostazol for 1 month, then, changed to receive dual antiplatelet therapy. The clinical outcomes up to 8 months were compared between the two groups.
Results: The baseline characteristics were similar between these two groups. The incidence of in-hospital cardiac death was significantly lower in Triple group (2.0% vs. 3.4%, *P*=0.041) but was not well maintained up to 1 and 8 months. The Triple group showed a trend toward lower total death up to 8 months. Both groups had similar incidences of in-hospital major bleeding, revascularization and recurrent MI. The Triple group showed lower incidences of All MACEs throughout the 8 months' follow-up (Table).
Conclusions: The triple antiplatelet therapy for 1 month appears to be superior to the dual antiplatelet therapy reducing early mortality and MACE without increasing the major bleeding events in pts with STEMI undergoing primary PCI.

Table: Clinical outcomes of Study Population

Variables, n (%)	Dual group (n=1,432 pts)	Triple group (n=972 pts)	P value
In-hospital			
Total death	54 (3.8)	23 (2.4)	0.055
Revascularization	18 (1.3)	6 (0.6)	0.122
All MACE	80 (5.6)	34 (3.5)	0.018
TIMI-major bleeding	8 (0.6)	2 (0.2)	0.333
At 1 month			
Total death	67 (4.9)	32 (3.4)	0.080
Revascularization	34 (2.5)	13 (1.4)	0.064
All MACE	114 (8.3)	51 (5.4)	0.007
At 8 months			
Total death	79 (5.8)	39 (4.2)	0.078
Revascularization	82 (6.1)	43 (4.6)	0.133
All MACE	178 (13.2)	89 (9.5)	0.008

9:30 a.m.

2512-706 **The Safety and Efficacy of Drug-Eluting Stents Compared With Bare-Metal Stents In Patients with Acute Myocardial Infarction**

Youngkeun Ahn, Myung Ho Jeong, Hae Chang Jeong, Young Jo Kim, Chong Jin Kim, Myeong Chan Cho, Chonnam National University Hospital, Gwangju, South Korea

Background: Although drug-eluting stent (DES) limits in-stent restenosis (ISR) and target vessel revascularization, their application in acute myocardial infarction is unclear. Specific DES comparisons with BMS for patients with acute MI remains controversial. We investigated the safety and efficacy of DES in patients with acute myocardial infarction (MI) and compared them with those of bare-metal stents (BMS) in routine clinical practice.
Methods: We recruited patients from 50 high-volume centers with facilities for primary percutaneous coronary intervention (PCI). All were participants in the Korea Acute MI Registry (KAMIR) from Nov 2005 to Dec 2006. Patients who received at least one DES (n=5,563) were retrospectively compared with patients who received at least one or more BMS (n=478) during one-year clinical follow-up.
Results: Patients receiving DES had more diabetes mellitus, more left anterior descending coronary lesions, and had lower left ventricular ejection fractions. At one-year, composite major adverse cardiac events (MACE) were 10.5 % in DES- and 18.0 % in BMS-treated patients (p<0.001). The one-year rate of target lesion revascularization was 1.5 % in DES- and 4.5 % in BMS- treated patients (p<0.001) and the one-year rate of re-PCI was 3.9 % in DES- and 6.8 % in BMS-treated patients (p=0.002). In multivariate analysis of all clinical and angiographic parameters, multi-vessel disease, use of BMS, door to balloon time were the only independent predictors of one-year MACE.
Conclusions: The use of DES in patients with acute MI was safe and associated with better one-year clinical outcomes than that of BMS, mainly due to the decreased re-PCI.

9:30 a.m.

2512-707 **Incidence and Long-term Outcomes of Plaque Prolapse After Stent Implantation in Patients Undergoing Primary PCI**

Yun-Kyeong Cho, Seung-Ho Hur, Bo-Ram Kim, Shin-Keun Kim, Hong-Won Shin, Hyoung-seob Park, Hyuck-jun Yoon, Hyungseop Kim, Chang-Wook Nam, Seong-Wook Han, Yoon-Nyun Kim, Kwon-Bae Kim, Division of Cardiology, Department of Internal Medicine, Keimyung University, Dongsan Medical Center, Daegu, South Korea

Background: Plaque prolapse (PP) has been reported to be 15 to 20% of cases after stenting and has a benign course at long-term follow-up. However, the influence of PP after stent implantation in STEMI patients has yet to be investigated. The aim of this study was to evaluate the incidence and long-term outcomes of PP after stenting in patients undergoing primary percutaneous coronary intervention (PCI).
Method: The study population consisted of 53 BMS (51 patients) and 87 DES (84 patients) cases undergoing IVUS examination after primary PCI. PP was defined as an intraluminal tissue (thrombus or atheroma) through the stent strut observed by IVUS. Patients were divided into two groups according to the presence/ absence of PP. Cumulative incidence of major adverse cardiac events (MACE) including death, MI, and TLR and stent thrombosis (ST) were evaluated at 1 year after index procedure.
Result: The incidence of PP after stenting was 44.3% (62/140) in patients undergoing primary PCI. PP was frequently observed in RCA lesion and presence of intracoronary thrombus by coronary angiography (all for p<0.05). The rates of MACE and ST were not different between the 2 groups at 1-month and 1-year follow-up (all for P=NS) (Table). By multivariate analysis, RCA lesion was the only independent predictor of PP (odds ratio: 2.25, p=0.033).

Conclusion: PP after stenting was detected in 44% of patients undergoing primary PCI. The presence/absence of PP was not found to affect short and long term clinical outcomes in this patient subset.

	-PP (n=78)	+PP (n=62)	P
Age, year	60 ± 11	61 ± 10	0.39
DM	15(19.5%)	8(13.8%)	0.49
DES	53(67.9%)	34(54.8%)	0.12
RCA lesion	24(30.8%)	33(53.2%)	0.009
TIMI 0/1	39(50.0%)	40(64.5%)	0.09
QCA Thrombus	30(38.5%)	38(61.3%)	0.01
Ref. VD, mm	3.22 ± 0.40	3.30 ± 0.40	0.27
Lesion Length, mm	28.5 ± 15.4	26.4 ± 14.5	0.42
Peak CK-MB, mg/dl	180 ± 186	214 ± 195	0.30
MACE			
1 month	2(2.6%)	1(1.7%)	1.00
1 year	5(6.5%)	6(10.3%)	0.53
Stent thrombosis			
1 month	0(0.0%)	1(1.7%)	0.43
1 year	0(0.0%)	2(3.4%)	0.18

9:30 a.m.

2512-708 **Early, Elective Percutaneous Coronary Intervention Is Safe and Beneficial After Successful Thrombolytic Therapy for Acute Myocardial Infarction**

Doo Sun Sim, Myung Ho Jeong, Youngkeun Ahn, Young Jo Kim, Sung Chull Chae, Taek Jong Hong, In Whan Seong, In Whan Seong, Jei Keon Chae, Chong Jin Kim, Myeong Chan Cho, Ki Bae Seung, Seung Jung Park, Chonnam National University Hospital, Gwangju, South Korea

Background: Early, elective PCI after successful thrombolysis is controversial. In case an invasive route is chosen, how early a PCI should be performed still remains elusive. The aim of this study was to assess the safety and benefits of early, elective percutaneous coronary intervention (PCI) after successful thrombolytic therapy for acute myocardial infarction (MI).
Methods: Employing data from the Korea Acute Myocardial Infarction Registry (KAMIR; November 2005 to June 2007), a total of 383 patients with acute MI who underwent elective PCI within two weeks of successful thrombolytic therapy were grouped based on time between thrombolysis and PCI: group 1: < 24 hours (N=81, 71 men, 59.5±10.5 years of age); group 2: ≥ 24 hours and < 48 hours (N=79, 72 men, 59.5±11.6 years); group 3: ≥ 48 hours and < 72 hours (N=79, 65 men, 61.0±10.8 years); group 4 > 72 hours (N=144, 109 men, 61.7±12.8 years). Primary study outcomes include major bleeding complications, in-hospital death, major adverse cardiac events (MACE: cardiac death, MI, repeat PCI, and coronary artery bypass surgery) at one, six and 12 months after the index procedure.
Results: There were no differences between the four groups in the baseline clinical characteristics and angiographic findings. Symptom onset to needle time was similar between the four groups: 4.0±3.2 hours in group 1; 5.8±7.4 hours in group 2; 5.4±9.6 hours in group 3; and 4.4±4.4 hours in group 4, p=0.226. There were no differences in the incidence of major bleeding, in-hospital mortality, and one-month outcomes between the groups. The rates of composite MACE and repeat PCI at 6 and 12 months were significantly lower in patients who underwent PCI within 48 hours of thrombolytic therapy, compared with those who underwent PCI later (6-month MACE: 0.7% vs. 7.3%, p=0.005; 6-month repeat PCI: 0% vs. 5.2%, p=0.006; 12-month MACE: 2.2% vs. 8.9%, p=0.017; 12-month repeat PCI: 0.7% vs. 5.7%, p=0.017).
Conclusion: Early, elective PCI within 48 hours of successful thrombolytic therapy for acute MI is safe and more beneficial, compared with PCI performed later.

9:30 a.m.

2512-709 **Transfusions after Percutaneous Coronary Intervention for Acute Myocardial Infarction Patients are Associated with Increased Long Term Mortality: A Statewid Registry Study**

Tudor Dumitru Vagaonescu, Abel E. Moreyra, Alan C. Wilson, Nora M. Cosgrove, John B. Kostis, UMDNJ Robert Wood Johnson Med Sch, New Brunswick, NJ

Background. Percutaneous coronary intervention (PCI) is the method of choice to reestablish coronary flow in acute myocardial infarction (AMI). Anticoagulation used during PCI may be associated with bleeding complications requiring, if severe, transfusions. Transfusions after PCI have been associated with a grim prognosis and outcome.
Methods. To identify predictors of transfusion during primary PCI for STEMI and its consequences on subsequent long term clinical outcomes we performed a retrospective analysis of the Myocardial Infarction Data Acquisition System (MIDAS) of the State of New Jersey between 2003 and 2004 with subsequent median follow-up over 3 years.
Results. Out of 5588 PCI performed, 207 (3.70%) received transfusions during the index hospitalization. Significant predictors for transfusion during the index PCI were advanced age (p<0.0001), female sex (p=0.002), renal disease (p=0.002) and anemia (p<0.0001) on admission. Use of Gp2b/3a during PCI did not predict transfusion (p=0.20). Over a median follow-up of 1000 days the patients who were transfused had significantly lower all cause survival (73.4% vs. 89.5%; p=0.04) than the patients who were not transfused. In the Cox multivariate analysis including age, sex, race, diabetes, hypertension, renal disease, anemia, cancer, cerebro-vascular disease and left ventricular dysfunction, use of Gp2b/3a inhibitors, type of stents used, transfusion during PCI for STEMI (vs. non transfusion) was significantly correlated with all cause mortality: adjusted HR 1.36 (1.03-1.83) and non cardiovascular mortality : adjusted HR 1.72 (1.11-2.65), but not with cardiovascular mortality: adjusted HR 1.13 (0.75-1.72).
Conclusions. The occurrence of transfusions in the setting of STEMI was associated with significant increase of 3 year all cause mortality.

2513

CTA/MRI - - Interventional Aspects

Monday, March 30, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2513-710 **Balloon pre-dilatation in percutaneous coronary intervention. A cardiovascular magnetic resonance imaging and cardiac biomarker study of myocardial injury**

Didier Locca, Giuseppe Ferrrante, Chiara Bucciarelli-Ducci, Francesca Del Furia, Peter Barlis, Agata Grasso, Alessio La manna, Sanjay Prasad, Dudley Pennell, Carlo Di Mario, Royal Brompton Hospital, London, United Kingdom

Background: In patients undergoing percutaneous coronary intervention (PCI) Troponin elevation is observed in 29-48% of patients in a standard daily practice. Little is known about the influence of balloon pre-dilatation before stent implantation in term of myocardial injury. The aim of this study was to assess the impact of balloon pre-dilatation in contributing to new areas of late gadolinium enhancement (LGE) measured by CMR and post-procedural troponin elevation.
Methods: Patients admitted with stable/unstable angina pectoris or silent ischemia were enrolled. LGE CMR scan was performed 24hours pre- and 24 hours post- PCI. Troponin I was measured at baseline, 12 and 24 hours after PCI. TIMI flow grade, TIMI perfusion myocardial grade (TMPG) (score 0,1,2,3) were assessed before/after balloon dilatation, after stenting and at the end of the PCI. No patient with baseline TnI elevation or baseline LGE evidence in the territory of the vessel treated was included.
Results: 45 patients had a successful PCI and pre and post CMR scan. Mean age was 61.6 ± 12.1 years, 73% male, 84% presenting with stable angina. Increased postprocedural TnI above the upper normal limit (0.04 ng/ml) occurred in 26 patients (57.7%) 0.51 ng/ml (0.05-4.93) (min-max). New LGE was detected in 15 patients (33.3%). All were in the group with TnI elevation. Patients undergoing pre-dilatation showed more frequent elevation of TnI (65.7% vs 14.3%, p=0.03), but no significant difference in the occurrence of LGE (36.8% vs 14.3%, p=0.39). Pre-dilatation was an independent predictor of TnI elevation, after adjusting for the presence of more than one lesion treated per patient and the occurrence of a reduction of TMPG score from baseline during PCI (OR 11.4, 95% CI (1.2-117.6), p=0.036), although it was not associated with new area of LGE (OR 3.45, 95% CI (0.4-32.8), p=0.28).
Conclusions: This study demonstrated the accuracy of TnI in identifying potential consequences of periprocedural myocardial necrosis after PCI with balloon pre-dilatation. Larger studies are needed to assess if pre-dilatation might be associated with LGE postprocedural myocardial injury.

9:30 a.m.

2513-711 **Detection and evaluation of myocardial bridging with multi-detector computed tomography (MDCT), coronary angiography (CAG) and myocardial scintigraphy**

Osamu Kuboyama, Takeshi Tokunaga, Daisuke Ueshima, Kazuo Kobayashi, Toride Kyodo General Hospital, Toride, Japan

Background: Myocardial bridging (MB), a congenital coronary anomaly, is clinical condition with several possible manifestations, and its clinical relevance is debated. The estimated frequency of MB with CAG was 1.5 to 16%, but it is as high as 80% in some autopsy series. It is reported that the proximal segment of MB is more susceptible to develop of atherosclerotic lesions because of haemodynamic disturbances. We investigated to evaluate the prevalence and characteristics of MB with MDCT, and comparative assessment of MB using CAG and myocardial scintigraphy.
Methods: We studied 157 patients (67.0 ± 9.3 years, 108 men), who underwent CT angiography and 154 (98%) patients were evaluable. In evaluable 154 patients, 90 patients with CAG and 92 patients with myocardial scintigarphy by TI-201 were also performed (28 patients were underwent both modalities). We evaluated prevalence and location of MB with MDCT and CAG. Atherosclerosis in segment immediately proximal to MB in MDCT was assessed. In myocardial scintigraphy, we searched ischemic change at the regions of MB
Results: The prevalence of MB was 31.2% (48/154) with MDCT and 6.7% (6/90) with CAG. The location of MB in MDCT was 72.9% (35/48) at LAD and 27.1% (13/48) at LCX. Especially, the rate of LAD mid-portion was high (66.7%, 32/48). In CAG, all MB were located in LAD (6/6). The atherosclerotic plaque in segment immediately proximal to MB was observed in 68.6% (24/36) at LAD and 15.4% (2/13) at LCX. (P=0.001). At the LAD proximal segment without MB, atherosclerotic plaque was observed in 46.7% (49/105). The rate of segment with plaque was significant higher in segemnet with MB than without MB (P=0.03). In 92 patients who underwent both MDCT and myocardial scintigraphy, 33 patients showed MB and 4 patients indicated ischemic changes. In 4 patients, 3 patients observed severe stenosis proximal to MB and only 1 patient (3.0%) indicates ischemic change without plaque.
Conclusion: The rate of myocardial bridging was higher in MDCT than in CAG and we frequently observed myocardial bridging at LAD. The incidence of plaque at proximal segment to myocardial bridging of LAD was higher. Ischemic change in myocardial bridging without atherosclerotic plaque was low.

9:30 a.m.

2513-712 **Coronary Artery Calcium Score for the Use of Rotational Atherectomy prior to Sirolimus-eluting Stent Implantation**

Naoyuki Yokoyama, Kumiko Konno, Hiroyuki Kyouno, Yasunari Ueno, Shigeru Suzuki, Ryu Iino, Akiyoshi Miyazawa, Kozuma Ken, Takaaki Isshiki, Teikyo University School of Medicine, Tokyo, Japan

Background: Even in the era of drug-eluting stents, Rotational atherectomy device (Rotabulator) is an effective tool which modifies calcified lesions to facilitate stent delivery and expansion. However, indications of Rotabulator have not yet been fixed as far as the levels of calcification in target lesion are concerned. Coronary artery calcium score (CACS) by non-contrast enhanced multi-detector computed tomography (MDCT) can quantify calcified coronary plaque. The aim of this study was to evaluate the ability of MDCT to measure the levels of calcification to determine indications of Rotabulator prior to sirolimus-eluting stent (SES) implantation.
Methods: A total of 36 patients (mean age 71.5 ± 6.2 years, 21 males) with stable angina underwent ECG-triggered MDCT scan (Mx8000 IDT Phillips Medical Systems) prior to SES implantation. CACS was measured by Agatston method in each vessel. The target vessels with chronic total occlusion or CACS of zero were excluded. Fifty-two calcified lesions (27 in LAD, 13 in LCX, 12 in RCA and 3 in LMT) were included. Selection of Rotablator was at the operator's discretion mainly based on the inability to cross IVUS catheter.
Results: Of 52 lesions, 17 were treated by SES implantation after rotablation (Rota+SES). SES implantation without rotablator (SES) was performed for 35 lesions. SES implantation was angiographically successful in all lesions. CACS of the target vessel in the Rota+SES group was significantly higher than that in the SES group (586.5±322.5 vs. 264.3±384.0; p = 0.004). ROC analysis revealed that CACS of >300 was the best cutoff value for detecting the heavily calcified plaque which was required with Rotablator prior to SES implantation. Sensitivity and Specificity in CACS of >300 was 82.4% and 77.8%, respectively. At 8 months, the target lesion revascularization rate was 5.9% in Rota+SES group vs. 0% in SES group (p = ns). Death and non-fatal MI were not occurred in all patients.
Conclusions: CACS of >300 was associated with the heavily calcified vessel which needed lesion modification with Rotablator. CACS measured by MDCT could be used as a novel guidance tool to determine the strategy of PCI for calcified lesions.

9:30 a.m.

2513-713 **The Role of 64-Slice Multidetector Computed Tomography in Detection of Subclinical Atherosclerosis of Coronary Artery**

Youngkeun Ahn, Hae Chang Jeong, Young Joon Hong, Doo Sun Sim, Nam Sik Yoon, Hyun Ju Youn, Kye Hun Kim, Hyung Wook Park, Ju Han Kim, Myung Ho Jeong, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, Chonnam National University Hospital, Gwangju, South Korea

Background: Multidetector computed tomography (MDCT) has high diagnostic value for detecting or excluding coronary artery stenosis in symptomatic patients. But, the role of MDCT for routine health examination in asymptomatic patients is not established. We hypothesized that MDCT could be a valuable method to detect subclinical coronary artery stenosis.
Methods: In a prospective, single-center, observational study, 1649 volunteers were underwent MDCT for routine health examination from Nov 2005 to Apr 2008. 120 patients were excluded due to their past history of coronary artery disease, typical chest pain, or evidence of myocardial ischemia on laboratory data, electrocardiogram, or echocardiography. 1529 patients (56.4 ± 8.3 years, 1353 males) were enrolled in our study.
Results: 969 (63.4 %) patients were presented with normal findings and 560 (36.6 %) patients were presented with abnormal findings in MDCT. The patients with abnormal findings was classified into two groups, the one was presence of coronary calcium, but luminal diameter stenosis of coronary artery < 50 % (n = 508, 33.2 %). These patients were treated by medication. And, the other was luminal diameter stenosis of coronary artery ≥ 50 %, presence or absence of coronary calcium (n = 52, 3.4 %). These patients were underwent conventional coronary angiogram and intravascular ultrasound. 29 patients (1.9 %) were presented with insignificant stenosis or myocardial bridge. These patients were treated by medication. 23 patients (1.5 %) were presented with significant stenosis. 17 patients were one vessel, 4 patients two, 2 patients three. The lesion artery was left anterior descending artery in 18 patients, left circumflex artery 6, and right coronary artery 6, and left main artery 1. They underwent percutaneous coronary intervention according to the basis of the coronary anatomy. The major adverse cardiac events were occurred in 2 patients during 387.4 ± 252.8 days (mean clinical follow-up period).
Conclusions: The incidence of subclinical significant coronary stenosis examined by MDCT in general population was 1.5 % in our study. 64-Slice MDCT can be an useful tool for noninvasive evaluation of coronary arteries in asymptomatic patients.

9:30 a.m.

2513-714 **Impact of aortic knob calcification on plaque composition in patients with coronary artery disease using coronary CT angiography**

Jae-Sik Jang, Young-Phil Bae, Byoung-Do Lee, Busan St. Mary's Hospital, Busan, South Korea, Busan, South Korea

Background: Atherosclerosis of the aorta has been associated with coronary artery disease. There are few data about the influence of aortic knob calcification on the severity of coronary artery disease and its relationship with coronary plaque composition. We evaluated differences in plaque composition and clinical significance in coronary artery disease according to the presence or absence of aortic knob calcification using coronary CT angiography (CTA).
Methods: A total of 452 consecutive coronary CTA examinations were performed between July 2007 and June 2008. Of these, 55 patients underwent invasive coronary angiography because they have significant coronary artery disease. The aortic knob calcification was assessed via chest posteroanterior view. On coronary CTA, plaques were classified into soft plaque, calcified plaque, and mixed plaque. Significant coronary narrowing was defined as > 60% luminal narrowing.
Results: Aortic knob calcification was present in 20 patients (36.4%). Presence of coronary plaque (100% vs. 80%, p=0.040), multi-vessel disease (65% vs. 28.6%, p=0.012), critical coronary stenosis (40% vs. 11.8%, p=0.013), and AHA/ACC B2/C lesions (80% vs. 37.1%, p=0.004) were higher in patients with aortic knob calcification than in patients without calcification. The plaque distribution was as follows: 5.0% soft plaques, 40.0% calcified plaques, and 55.0% mixed plaques in patients with aortic knob calcification vs. 39.9% soft plaques, 25.0% calcified plaques, and 35.7% mixed plaques in patients without calcification (p=0.025).
Conclusions: Aortic knob calcification in patients with coronary artery disease can be a marker of more severe coronary artery disease and it may also provide information about coronary atherosclerotic plaque composition.

9:30 a.m.

2513-715 **Computed Tomography Angiography vs. Coronary Angiography: A 3 Dimensional Vessel Feature Comparison**

Marvin H. Eng, Onno Wink, Philip Li, James Chen, Adam Hansgen, John D. Carroll, Joel A. Garcia, University of Colorado Denver, Aurora, CO

Background: Vessel spatial relationships in computed tomography angiograms (CTA) and coronary angiograms (CA) have not been rigorously studied, therefore we sought to validate CTA 3-dimensional (3D) vessel data against coronary angiography by forward projecting 3D CTA based centerlines to standard angiograms.
Methods: An initial validation was performed by comparing CTA datasets and X-rays of cardiac phantoms. We then retrospectively analyzed 20 patients undergoing both CA and CTA. First, CTA 3D reconstructions were imported into a coronary modeling software environment enabling centerline extraction, forward projection, and optimal view map generation. Centerline comparison from each dataset was performed via automated overlay of their respective centerlines (forward projection) and measuring the root mean squared difference (RMS) in error for each CA view. Offline working view selection using the CTA reconstructions versus operator selected working views were then compared in terms of foreshortening.
Results: There were minimal differences in the RMS for each vessel (Table 1A). Offline CTA working view selection was found to have less foreshortening compared to operator selected views (Table 1B).
Conclusion: The vessel centerline data from CTA is not significantly different to that of CA. Use of CTA to facilitate pre-procedural PCI working view selection may reduce foreshortening.

Table 1A. CTA Centerline Deviation from the Angiographic Centerlines of 20 patients.

	All vessels	LAD/LM/SB	Cx	LCA overall	RCA	RCA overall
Mean(mm)	2.09	2.08	2.74	2.42	1.9	3.42
Median (mm)	2.02	1.89	2.79	3.57	1.8	3.47
SD	± 0.77	± 0.88	± 1.0	± 1.55	± 0.66	± 1.25
Range	0.9-3.74	0.78-3.75	1.47-4.89	2-6.25	1.25-2.75	1.86-4.89

Table 1B. Difference in Vessel Foreshortening in Operator-Selected Working Views Compared to Off-line CTA Facilitated Optimal View Selection.

Foreshortening	Angiography	CTA
Mean	9.28 %	1.42 %
SD	± 6.66 %	± 0.93 %

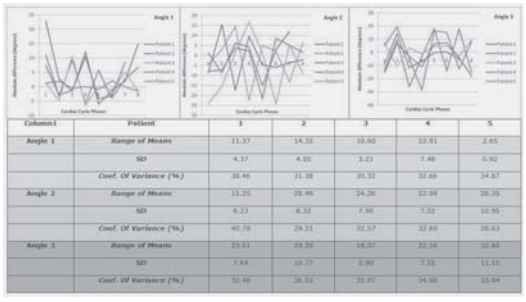
p value <0.005

9:30 a.m.

2513-716 **Four Dimensional, Multidetector Computed Tomographic Assessment of Dynamic Changes in Coronary Bifurcation Anatomy**

John E. Coletta, Pieter Kitslaar, Bruno Bruno Nascimento, Nobuaki Suzuki, Hiram Bezerra, Noah Rosenthal, Robert Gilkeson, J. Hans Reiber, Daniel I. Simon, Marco A. Costa, University Hosptials Case Medical Center, Cleveland, OH, Leiden University Medical Center, Leiden, The Netherlands

Background - Clinical outcomes of percutaneous approaches for bifurcation coronary artery disease remain unsatisfactory. Dynamic variation in the three dimensional (3D) anatomic configurations of coronary bifurcations during the cardiac cycle is a potential cause of bifurcation coronary device failure.
Methods & Results - We analyzed 10 anonymous technically adequate multidetector computed tomography (MDCT) coronary images of the Left Main (LM), Left Anterior Descending (LAD), and Left Circumflex (LCx) bifurcation. Images were obtained throughout the cardiac cycle. RR interval was divided into 10 segments (10% increments). Data was cropped in 8 phases to produce a dynamic data set. Angles, defined as (1) LAD-LCx, (2) LCx-LM, and (3) LAD-LM, were automatically determined. Each angle was determined in 3D (x, y, and z planes). We calculated the mean angle for each phase, the range of the means (RM) and standard deviation (SD), the absolute variation between each phase, and the coefficient of variance (CV=SD/RM). The results of 5 initial cases are shown.
For all patients, absolute angle variation between cardiac phases varied widely in an unpredictable pattern.
Conclusions - This is the first report on a novel quantitative method to access coronary bifurcation anatomy in 4D (x, y, z axes + time). Our results demonstrate the dynamic nature of coronary bifurcation. Future studies are warranted to establish the clinical impact of such findings and potential use of 4D-imaging to guide bifurcation PCI strategies.



Column1	Patient	1	2	3	4	5
Angle 1	Range of Means	11.37	14.35	10.60	22.91	2.65
	SD	4.37	4.50	3.21	7.46	0.92
	Coef. Of Variance (%)	38.46	31.38	30.32	32.66	34.87
Angle 2	Range of Means	15.25	28.46	24.26	22.99	28.35
	SD	6.23	8.32	7.90	7.52	10.95
	Coef. Of Variance (%)	40.78	29.21	32.57	32.69	38.63
Angle 3	Range of Means	23.51	29.50	16.37	22.16	32.85
	SD	7.64	10.77	3.90	7.35	11.15
	Coef. Of Variance (%)	32.49	36.51	32.87	34.08	33.94

I2.POSTER CONTRIBUTIONS

2514

PCI - ACS

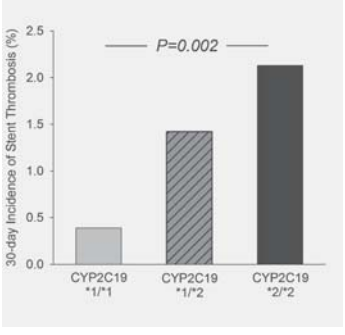
Monday, March 30, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2514-717 **Cytochrome P450 2C19 loss-of-function polymorphism and stent thrombosis following percutaneous coronary intervention**

Dirk Sibbing, Julia Stegherr, Wolfgang Latz, Werner Koch, Julinda Mehilli, Katharina Dorrler, Tanja Morath, Albert Schomig, Adnan Kastrati, Nicolas von Beckerath, Deutsches Herzzentrum Munchen, Munich, Germany

Background: Several studies have demonstrated that the mutant *2 allele of the *CYP2C19* 681G>A loss-of-function polymorphism is associated with diminished metabolization of clopidogrel into its active metabolite and an attenuated platelet response to clopidogrel. It is not known whether patients carrying the mutant *CYP2C19*2* allele have a higher risk of stent thrombosis (ST) compared to homozygous *CYP2C19*1* wild-type allele carriers following percutaneous coronary intervention (PCI). The aim of this study was to assess the impact of the *CYP2C19* 681G>A loss-of-function polymorphism on ST following PCI in clopidogrel treated patients. **Methods:** The study population included 2485 consecutive patients undergoing PCI after loading with 600 mg clopidogrel. Genotypes were determined with a TaqMan assay. The primary end point of the study was the incidence of definite ST within 30 days after PCI. **Results:** 1805 (73%) patients were *CYP2C19* wild-type homozygotes (*1/*1) and 680 (27%) carried at least one *2 allele (*1/*2 or *2/*2). The cumulative incidence of ST was significantly higher in *CYP2C19*2* allele carriers [10 (1.5%) in *CYP2C19*2* allele carriers vs. 7 (0.4%) in *CYP2C19* wild-type homozygotes (*1/*1), OR 3.81, 95% CI 1.55-9.36, P=0.003]. The risk of ST was highest in patients carrying two of the mutant *CYP2C19* alleles (*2/*2 genotype) (P=0.002, test for trend; see Figure). **Conclusions:** *CYP2C19*2* carrier status is significantly associated with an increased risk of ST following PCI.

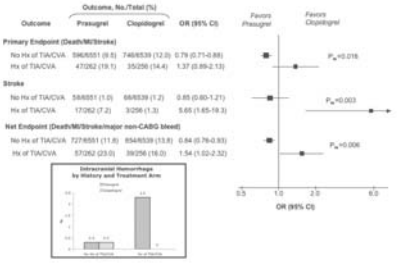


9:30 a.m.

2514-718 **Lack of Benefit and Evidence for Harm with Prasugrel as Compared to Clopidogrel in Patients with a History of TIA/CVA Undergoing PCI: Insights from TRITON-TIMI 38**

Nihar R. Desai, Elliott M. Antman, Sabina A. Murphy, Stephen D. Wiviott, TIMI Study Group, Brigham and Women's Hospital, Boston, MA

Background: Recent clinical trials of dual anti-platelet therapy (DAPT) for secondary stroke prevention have shown limited efficacy and potentially harm. Little is known about the impact of DAPT in patients with prior TIA/CVA presenting with ACS and undergoing PCI.
Methods: We compared the effect of DAPT on outcomes in 13608 patients according to history of prior TIA/CVA in TRITON-TIMI 38. Logistic regression models were used to adjust for baseline differences and formal interaction terms were used to test for differential outcomes by treatment assignment.
Results: The 518 patients with prior TIA/ CVA were older, more likely to have a history of hypertension, hyperlipidemia, and renal dysfunction, while less likely to receive glycoprotein IIB/IIIA inhibitors. After adjustment, those with prior TIA/CVA had significantly higher rates of the primary endpoint (CVD/MI/CVA) (HR 1.30 [1.04-1.64], p=0.02), CVA (HR 3.08 [1.89-5.00], p<0.0001), and intracranial hemorrhage (HR 4.10 [1.67-10.07], p=0.002). There were significant interactions between prior TIA/CVA, treatment and outcomes (Fig).
Conclusion: While prasugrel significantly reduces the risk for thrombotic events as compared to clopidogrel for patients with ACS undergoing PCI, its utility in combination with aspirin, in patients with prior TIA/CVA, is limited. These findings extend previous observations of the risk of DAPT for secondary stroke prevention to management of ACS in patients with cerebrovascular disease.



9:30 a.m.

2514-719 **Bivalirudin Therapy Reduces 30 Day Bleeding Complications in Women Undergoing PCI for Acute Coronary Syndrome: Results of the REPLACE-2, ACUITY and HORIZONS Pooled Analysis**

Alexandra J. Lansky, Helen Parise, Liliana Grinfeld, A. Michael Lincoff, Stuart J. Pocock, Roxana Mehran, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: Female gender is an independent marker of adverse events and bleeding in pts undergoing PCI. In the REPLACE-2, ACUITY and HORIZONS trials, bivalirudin (Biv) provided similar rates of ischemic events and significantly reduced bleeding compared to heparin+GPIIb/IIIa inhibitors (Hep+GPI) in pts with stable and unstable angina, NSTE-ACS, and STEMI undergoing PCI. This analysis provides more robust estimates of the impact of gender in pts receiving Biv or Hep+GPI across the spectrum of cardiovascular risk.
Methods: The 3 trials randomized pts to Biv or Hep+GPI. We assessed rates of 30-day composite ischemia (death, MI, or revascularization), non-CABG TIMI bleeding (major/ minor), and net adverse clinical events (NACE, composite ischemia or protocol-defined bleeding) in women undergoing PCI, overall and by randomized treatment.
Results: 3652 (25.5%) of 14,325 pts undergoing PCI were women. Women had similar rates of composite ischemia (7.7% vs 7.1% p=0.25) as men, but higher rates of major bleeding (6.6% vs 3.8%, p<0.001). In women, Biv vs Hep+GPI resulted in a significant reduction in 30-day NACE due to reduced major bleeding (Table).
Conclusions: Women had similar rates of 30-day ischemic outcomes as men, but significantly more bleeding. In women, Biv resulted in significantly lower NACE and major bleeding than Hep+GPI, with no significant difference in composite ischemia. These results indicate that Biv is a safe and effective strategy in women undergoing PCI across the spectrum of ACS.

	Heparin + GPI (N=1842)	Bivalirudin (N=1810)	p-value
NACE	15.0	12.4	0.02
Composite ischemia	7.4	7.9	0.61
- Death	1.3	1.1	0.61
- MI	5.3	5.7	0.64
- Revascularization	2.2	3.1	0.06
Non-CABG TIMI bleeding (major + minor)	8.5	4.6	<0.0001

9:30 a.m.

2514-720 **Clinical and Angiographic Risk Score to Predict Ischemic Outcomes at 1 Year in Acute Coronary Syndromes: The ACUITY Risk Score**

Alexandra J. Lansky, Kenji Goto, Martin Fahy, JungAh Jung, Eugenia Nikolsky, Magnus E. Ohman, Harvey D. White, Michel E. Bertrand, Micheal Lincoff, Jeffrey Moses, Roxana Mehran, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Background Risk assessment of ACS pts does not take into account angiographic factors. We sought to create a practical risk score based on both clinical and angiographic criteria to predict cardiac events at 1 year.
Methods The risk model was developed from 7000 ACS pts enrolled in the ACUITY angiographic substudy. Logistic regression was used to identify clinical and angiographic predictors of death/MI. Based on the Z score value, an integer score was assigned to each predictor; the sum comprising the total risk score.
Results Multivariable predictors of 1 year death/MI were determined from 3,740 pts with no missing covariates (61% PCI, 14% CABG, 25% medical); death/MI occurred in 414 pts (11.9%) (table). Death/MI risk increased as the score increased (p<0.0001). Pts

were categorized into low (score ≤10; 1677 pts; 44.8%), moderate (score 11 to 16; 1,295 pts; 34.6%), and high (score ≥17; 768 pts; 20.5%) risk, with increasing 1 year death/MI (low 5.6%; moderate12.3%; and high 21.1% risk, p=0.0001). The model was validated by multiple bootstrap resampling (Hosmer-Lemeshow goodness-of-fit, p=0.65) and c statistic=0.68 indicating good risk discrimination. The risk score was validated for pts triaged to PCI, CABG and medical therapy (p=0.001).

Conclusions The ACUITY Risk score, derived from 4 clinical and 4 angiographic baseline variables, provides reliable predictive risk of 1 year death/MI in pts with ACS undergoing early invasive management, and is applicable irrespective of selected treatment strategy.

Multivariate Predictors	Integer score	Z score	Odds Ratio[95% C.I.]	P value
Previous MI	2	2.4531	1.32 [1.06, 1.64]	
Number of diseased vessels = 3	2	2.2953	1.33 [1.04, 1.69]	0.02
Cardiac biomarker elevation	3	2.6982	1.36 [1.09, 1.71]	0.007
ST-segment deviation	3	2.644	1.36 [1.08, 1.70]	0.008
Jeopardy Score ≥6	4	4.3152	1.98 [1.45, 2.71]	0.0001
Calcification: Mod/severe	4	3.8392	1.52 [1.23, 1.88]	0.0001
Renal insufficiency	5	4.9888	1.85 [1.45, 2.35]	0.0001
Extent of disease, mm	2 when 0> to <20mm 4 when 20 ≥ to < 40mm 6 when 40 ≥ to < 60mm 8 when ≥ 60mm	2.3958	1.00 [1.00, 1.01]	0.02

9:30 a.m.

2514-721 **One year follow-up of the Thrombus Aspiration during Primary percutaneous coronary intervention in Acute non-ST-elevation myocardial infarction Study (TAPAS-II) - pilot - trial.**

Pieter J. Vlaar, Gilles Diercks, Tone Svilaas, Mathijs Vogelzang, Bart de Smet, Ad van den Heuvel, Gillian Jessurun, Eng-Shiong Tan, Albert Suurmeijer, Felix Zijlstra, University Medical Center Groningen, Groningen, The Netherlands

Background: Myocardial necrosis in patients with acute coronary syndromes may be a sign of microvascular obstruction, owing to spontaneous or intervention-induced embolization of atherothrombotic material. Thrombus aspiration results in improved myocardial reperfusion in patients undergoing percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction. Currently, scarce data on thrombus aspiration in patients with Non-ST-elevation myocardial infarction (NSTEMI) are available.

Methods: As part of a prospective cohort study, 70 patients undergoing PCI for NSTEMI were treated with thrombus aspiration (Export, Medtronic). Histopathological analysis was performed on aspirated material. Vital status at or beyond 1 year after inclusion was available for all patients.

Results: Thrombus aspiration was effective in 58 patients (83%), see table. Aspiration resulted in a marked reduction of TIMI-thrombus score 4/5 (40% pre- versus 7% post-aspiration) and increase of the rate of TIMI-flow 3 (36% pre- versus 66% post-aspiration). The incidence of Myocardial Blush Grade 3 was 45%. Distal embolization was visible in 3 patients (4%). At 1 year follow-up, the rate of target vessel revascularization, reinfarction and death were 5.7%, 2.9% and 1.4%, respectively.

Conclusions: This study demonstrates that thrombus aspiration in most NSTEMI patients is feasible and safe, is associated with a high rate of retrieval of thrombotic material, and results in excellent clinical outcome.

Histopathological analysis of aspirated material

		Total	Age (yrs)		Initial TIMI flow		Thrombus visible on initial angiogram	
			>60	≥60	0/1	2/3	no	yes
Total -no.		70	31	39	23	47	34	36
Effective aspiration - no. (%)		58 (83%)	29 (94%)	29 (74%)	21 (91%)	37 (79%)	26 (76%)	32 (89%)
Thrombus	White platelet thrombus	44 (76%)	72%	79%	57%	86%	92%	63%
	Red erythrocyte-rich thrombus	14 (24%)	28%	21%	43%	14%	8%	38%
Plaque	Thrombus with plaque	14 (24%)	28%	21%	33%	19%	15%	31%
Size	Small (<0.5mm)	37 (64%)	59%	69%	38%	78%	85%	47%
	Medium (0.5-2mm)	10 (17%)	17%	17%	29%	11%	8%	25%
	Large (>2mm)	11 (19%)	24%	14%	33%	11%	8%	28%

9:30 a.m.

2514-722 **Impact of Thrombus Aspiration Device use for the Treatment of In-stent Thrombosis on Early Patient Outcome**

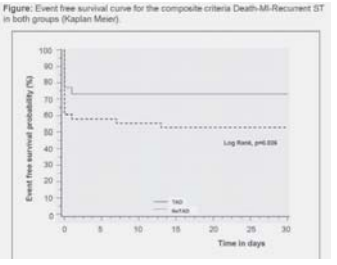
Gilles Lemesle, Axel De Labriolle, Laurent Bonello, Gabriel Maluenda, Itsik Ben-Dor, Sara D. Collins, Asmir I. Syed, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Recent data suggest a benefit with the systematic use of a thrombus aspiration device (TAD) for the treatment of ST-elevation myocardial infarction (STEMI). Nevertheless, the impact of TAD use for the treatment of stent thrombosis (ST) is unknown. This study aimed to analyze the impact of TAD use for the treatment of ST on patient outcome.

Methods: From 2003 to 2008, 91 consecutive patients presenting with a first definite ST were included. We compared procedural success rates and incidences of the composite criteria death-MI-ST at 30 days in patients who benefited from TAD use (TAD group, n=36) vs those who did not (No TAD group, n=55).

Results: Baseline characteristics were similar between groups except for body mass index: 26.2 vs 29.3 in the TAD and No TAD groups, respectively (p=0.03). The ST presented more likely as STEMI in the TAD group: 86% vs 67% (p=0.04). Except for TAD use, there was no difference in the treatment therapeutics between groups. The rate of procedural success was higher in the TAD group: 89% vs 71% (p=0.04). The incidence of the endpoint death-MI-ST was significantly lower in the TAD group: 22% vs 47% (p=0.03). By multivariate analysis, the TAD use was independently associated with a decrease in the composite criteria (HR=0.45, p=0.04).

Conclusion: The use of a TAD as part of the initial strategy for ST treatment is associated with a reduced incidence of subsequent death-MI when compared to conventional PCI. The use of a TAD should be considered for all patients presenting with ST.



9:30 a.m.

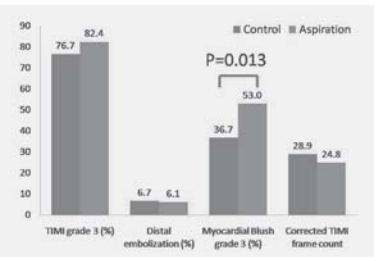
2514-723 **Thrombectomy Improves Angiographic Outcome in ST-Segment Elevation Myocardial Infarction Cases without Visible Thrombus: Subanalysis from the VAMPIRE trial.**

Hiroyuki Kyono, Ken Kozuma, Yuji Ikari, Kenshi Fujii, Masami Sakurada, Hideki Hashimoto, Takaaki Katsuki, Kazuo Kimura, Takahiko Suzuki, Takaaki Isshiki, On behalf of the VAMPIRE investigators, Teikyo University Hospital, Tokyo, Japan

Background: The efficacy of thrombus aspiration for STEMI patients who have no angiographically visible thrombus during PCI is still unclear. We sought to clarify the effectiveness of thrombectomy for this patient subset.

Methods: 355 consecutively enrolled patients in the VAMPIRE (Vacuum Aspiration Thrombus Removal) trial were analyzed. This trial was a multicenter prospective randomized trial, designed to evaluate the safety and efficacy of thrombus aspiration using a thrombus aspiration catheter in patients with STEMI. From this population, we analyzed all 65 patients who had coronary stenosis but no visible thrombus. We assessed angiographic parameters such as TIMI flow grade, distal embolization, Myocardial Blush Grade and corrected TIMI frame count (CTFC) post-procedure with thrombectomy compared to without thrombectomy. **Results:** Thirty one patients did not receive thrombectomy (control group) whereas 34 underwent thrombectomy (aspiration group). The incidence of TIMI 3 flow, CTFC, and distal embolization post procedure did not show a significant difference. However, Myocardial Blush Grade 3 post-procedure was achieved significantly more frequently in aspiration group compared to control group (36.7 vs. 52.9%, P=0.013).

Conclusions: Myocardial Blush Grade 3 was obtained more frequently in the aspiration group even if visible thrombus did not exist. This finding suggests that thrombectomy may be beneficial to myocardial perfusion beyond the effect of simple thrombus removal.



9:30 a.m.

2514-724 Short- and Long-term Outcomes in Patients Undergoing Rotational Atherectomy for Complex Coronary Lesions in the Current Era of Drug-Eluting Stents

Dmitriy N. Feldman, Robert M. Minutello, Geoffrey Bergman, Issam Moussa, S. Chiu Wong, New York Presbyterian Hospital - Weill Cornell Medical Center, New York, NY

Background: Patients requiring rotational atherectomy (RA) for complex calcific coronary lesions have been excluded from recent large randomized trials of drug-eluting stents (DES). The impact of RA in the current era of DES on short- and long-term outcomes in complex coronary lesions is unknown.
Methods: Using the 2004/2005 Cornell Angioplasty Registry, we analyzed 2,504 consecutive patients undergoing urgent or elective PCI. Patients were divided into 2 groups: (1) 82 pts (3.3%) undergoing RA; (2) 2422 pts (96.7%) undergoing PCI without RA. Patients presenting with an acute MI ≤24 hours, hemodynamic instability/shock, thrombolytic therapy ≤7 days were excluded. All-cause mortality was obtained for 100% of patients, with a mean follow-up of 24.8 ± 7.7 months.
Results: Patients undergoing RA were older (72.3 ± 9.3 vs. 66.6 ±11.8 yrs, p<0.01), more frequently had multivessel PCI (23.2% vs. 14.6%, p=0.04), or multilesion PCI (73.2% vs. 46.7%, p<0.01) performed. Drug-eluting stents were used in 86.8% of PCI; glycoprotein IIb/IIIa inhibitors were used in 52.7%. Angiographic success was 99.6% in both groups. The incidence of in-hospital death (0% vs. 0.2%, p=1.00) was similar, but the incidence of myocardial infarction (14.6% vs. 7.1%, p=0.02), and MACE (death, CVA, emergent CABG/PCI, myocardial infarction) (14.6% vs. 7.3%, p=0.03) was higher in the RA group. After multivariate analysis, RA was associated with a strong trend towards being an independent predictor of post-PCI myocardial infarction (OR 1.87; 95%CI 0.97-3.58, p=0.06). However, post-PCI cardiac enzymes elevation did not impact the length of stay during hospitalization (2.8 ± 3.3 vs. 2.9 ± 3.7 days, p=ns). By 2-years of follow-up, there was no difference in mortality: 4 (4.9%) deaths in the RA+ group vs. 125 (5.2%) deaths in the RA- group (HR 0.94; 95%CI 0.35-2.53, p=ns).
Conclusions: Patients undergoing rotational atherectomy in contemporary PCI with drug-eluting stents have a higher incidence of post-PCI myocardial infarction, but, importantly, a good long-term prognosis. These results suggest that a strategy of rotational atherectomy and DES is a safe and practical strategy in complex calcific coronary lesions.

9:30 a.m.

2514-725 Predictors of Filter No Reflow Prior to Percutaneous Coronary Intervention

Takayuki Ishihara, Masaaki Uematsu, Masaki Awata, Takaaki Morozumi, Tetsuya Watanabe, Toshinari Onishi, Osamu Iida, Fusako Sera, Hitoshi Minamiguchi, Kenji Kawamoto, Masamichi Yano, Kuniyasu Ikeoka, Shin Okamoto, Nobuaki Tanaka, Haruyo Yasui, Tomoharu Dohi, Shinsuke Nanto, Seiki Nagata, Kansai Rosai Hospital, Amagasaki, Japan

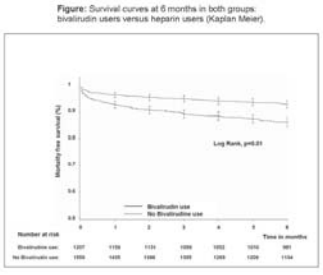
Background: A filter device is used to avoid microembolization during percutaneous coronary intervention (PCI). Under the use of filtering devices, filter no reflow (FNR) occurs in one-third of patients. We sought to investigate the predictors of FNR using intravascular ultrasound (IVUS). **Methods:** Between January 2007 and July 2008, PCI assisted with a filter device (Filtrap, NIPRO) and IVUS was performed in 62 patients (mean age 63±12, male 83.9%). FNR was defined as reduced flow that is reversible following removal of the filter. Before PCI, we measured reference external elastic membrane cross-sectional area (EEM-CSA), reference lumen CSA, calcification, and echo luminance of plaque by IVUS. Plaque burden was defined as (EEM-CSA - lumen CSA) / EEM-CSA. After implantation of the stent, we measured minimum stent area (MSA) by IVUS, and evaluated stent expansion (MSA / reference lumen CSA). Patients were divided into 2 groups: FNR(+) and FNR(-) groups. **Results:** FNR was found in 23 patients (37%). Significant differences were not found except for hyperlipidemia (21% versus 51%, P=0.030) and initial TIMI flow grade (TIMI 0: 43% versus 30%; TIMI 1 17% versus 3%; TIMI 2: 9% versus 3%; TIMI 3: 30% versus 64%; P=0.031) in the baseline patient, lesion and procedural characteristics. Before PCI, superficial calcification was more frequent in FNR(+) group (70%) than in FNR(-) group (31%, P=0.004) and low echoic plaque tended to be detected more frequently in FNR(+) group (48%) than in FNR(-) group (23%, P=0.054). Plaque burden and stent expansion were similar between the groups. Reference EEM-CSA and reference lumen CSA were smaller in FNR(+) group than in FNR(-) group (reference EEM CSA, 17.11±4.0mm² versus 20.43±6.2mm²; P=0.026; reference lumen CSA, 8.99±2.7mm² versus 11.39±3.7mm² ; P=0.0086, respectively). **Conclusions:** Superficial calcification, low echoic plaque, small reference EEM-CSA, and small reference lumen CSA assessed by IVUS may be predictors of FNR prior to PCI.

9:30 a.m.

2514-726 Impact of Bivalirudin on In-hospital Bleeding and 6-month Outcomes in Octogenarians Undergoing Percutaneous Coronary Intervention

Gilles Lemesle, Axel De Labriolle, Laurent Bonello, Gabriel Maluenda, Asmir I. Syed, Sara D. Collins, Itsik Ben-Dor, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Bivalirudin has been identified as able to prevent bleeding after percutaneous coronary intervention (PCI), which is associated with poor outcomes. Nevertheless, elderly people who are most susceptible to bleeding and subsequently to early and late mortality were excluded from randomized trials. This study aimed to analyze the impact of bivalirudin on in-hospital bleeding and 6-month mortality in octogenarians undergoing PCI.
Methods: From 2000 to 2007, 2766 consecutive patients, at least 80 years of age, underwent PCI with stent implantation. We compared rates of in-hospital bleeding and 6-month mortality between patients treated by bivalirudin for the PCI (n=1207) and patients treated by heparin (n=1559).
Results: The overall in-hospital bleeding and 6-month mortality rates were 4.6% and 11.8%, respectively. By multivariate logistic regression and after adjustment by propensity score analysis, bivalirudin was associated with a significant decrease in in-hospital bleeding (HR=0.4; p=0.003). By multivariate Cox analysis and after adjustment by propensity score analysis, bivalirudin was also associated with a significant decrease in the 6-month mortality (HR=0.6, p=0.01).
Conclusion: This study shows that bivalirudin use in octogenarians undergoing PCI as compared to heparin use was associated with a significant decrease in not only in-hospital bleeding but also in 6-month mortality. These results suggest that bivalirudin use is preferable to heparin in such a population.



9:30 a.m.

2514-727 The effect of high dose intracoronary ADenosine Administration during Primary percutaneous coronary intervention in acute myocardial infarction - a randomized controlled Trial (ADAPT).

Marieke L. Fokkema, Pieter J. Vlaar, Mathijs Vogelzang, Youlan L. Gu, Marthe A. Kampinga, Bart J. de Smet, Rutger L. Anthonio, Gillian A. Jessurun, Ad F. van den Heuvel, Eng-Shiong Tan, Felix Zijlstra, University Medical Center Groningen, Groningen, The Netherlands

Background: Coronary microvascular dysfunction is frequently seen in patients with ST-elevation myocardial infarction (STEMI) after primary percutaneous coronary intervention (PCI). Previous studies have documented that the administration of intravenous adenosine resulted in an improvement of myocardial perfusion and a reduction in infarct size. The effect of intracoronary adenosine during primary PCI has not been investigated in a large randomized trial.
Methods: Patients presenting with acute STEMI were randomized to 2 bolus injections of intracoronary adenosine (2x 0.12 mg in 20 mL NaCl) or placebo (2x 20 mL NaCl). The first bolus injection was given before and the second after stenting of the infarct artery. The primary endpoint was the incidence of residual ST-segment deviation <0.2 mV 30 to 60 minutes after procedure. Secondary endpoints were myocardial blush grade (MBG), TIMI flow after PCI, ST-segment elevation resolution and outcome at 30 days.
Results: A total of 448 patients were randomized to intracoronary adenosine (N=226) or placebo (N=222). The incidence of residual ST-segment deviation <0.2 mV was similar in patients treated with adenosine (46.2%) and placebo (52.2%). In addition, secondary outcome measurements did not significantly differ between the treatment groups, as shown in the table.
Conclusion: In patients with STEMI, administration of intracoronary adenosine before and after stenting of the infarct artery did not result in improved myocardial perfusion. (Trial nr: NTR 1073)

Effect of intracoronary administration of adenosine or placebo on myocardial perfusion and outcome

		Adenosine (N = 226)		Placebo (N = 222)		p
Primary end point: ST-segment deviation <0.2 mV (%)		96/208	(46.2)	108/207	(52.2)	ns
MBG 3 (%)		64/224	(28.6)	77/218	(35.3)	ns
TIMI flow 3 (%)		212/225	(94.2)	208/222	(93.7)	ns
ST-segment elevation resolution >70% (%)		129/189	(68.3)	128/193	(66.3)	ns
Mortality at 30 days (%)		3/226	(1.3)	2/222	(0.9)	ns

9:30 a.m.

2514-728 Late Outcomes of Elderly Patients with Acute Myocardial Infarction Undergoing Primary Angioplasty: One Year Results from the HORIZONS-AMI Trial

Dariusz Dudek, Roxana Mehran, Krzyszto Zmudka, Bernhard Witzenbichler, Giulio Guagliumi, Jan Z. Peruga, Bruce R. Brodie, Ran Kornowski, Franz Hartmann, Martin , Mockel, Andrzej Ochala, Helen Parise, Eugenia Nikolsky, Alexandra J. Lansky, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background: In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) vs. unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding and mortality with comparable composite major adverse cardiovascular events (MACE), and enhanced freedom from net adverse clinical events (NACE) in pts with AMI undergoing primary PCI at 30 days and 1 year. Whether the beneficial effects of Biv are independent of age, an important determinate of outcomes after primary PCI, has not been reported.
Methods and Results: A total of 3602 pts at 123 centers in 11 countries with AMI undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802). Outcomes were analyzed according to age above or below the median of 60.2 years. Compared to young pts, elderly pts had greater (all P values <0.0001) rates of major bleeding (9.9% vs. 5.2%), MACE (14.6% vs. 9.3%), cardiac mortality (4.7% vs.1.2%), and NACE (21.3% vs. 12.7%). In the entire study population at 1 year Biv compared to UFH+GPI resulted in a 39% reduction in major bleeding (5.8% vs. 9.2%, P<0.0001), reduced cardiac mortality (2.1% vs. 3.8%, p=0.0.005), similar MACE (11.9% vs. 11.9%, P=1.0), and a 16% reduction in NACE (15.7% vs. 18.3%, P=0.03). The impact of Biv was independent of age (Table).
Conclusions: At 1 year, elderly pts with AMI undergoing primary PCI benefited from Biv monotherapy with significant reductions in major bleeding, net adverse clinical events, and cardiac mortality.

	Age <=60.2 year (n=1,808)			Age >60.2 year (n=1,794)		
	Biv mono	UFH+GPI	RR(95% CI)	Biv mono	UFH+GPI	RR(95% CI)
Major bleeding	3.8%	6.7%	0.56 (0.37,0.84)	7.9%	11.7%	0.66 (0.49, 0.89)
MACE*	10.1%	8.5%	1.20 (0.89, 1.64)	13.9%	15.2%	0.90 (0.71, 1.15)
NACE**	12.3%	13.2%	0.91 (0.70, 1.18)	19.2%	23.2%	0.81 (0.66, 0.99)
Cardiac death	0.8%	1.6%	0.48 (0.19, 1.18)	3.6%	5.8%	0.61 (0.39, 0.95)

*MACE = death, reinfarction, ischemic TVR or stroke
**NACE (Net Adverse Clinical Events) = MACE or major bleeding

9:30 a.m.

2514-729 One Year Outcomes with Bivalirudin vs. Unfractionated Heparin During Percutaneous Coronary Interventions in Patients With Stable and Unstable Angina Pectoris

Julinda Mehilli, Adnan Kastrati, Franz-Josef Neumann, Robert A. Byrne, Heinz Joachim Buettner, Ahmed A. Khattab, Stefanie Schulz, Juergen Pache, Melchior Seyfarth, Josef Dirschinger, Gert Richardt, Albert Schomig, Deutsches Herzzentrum, Munich, Germany

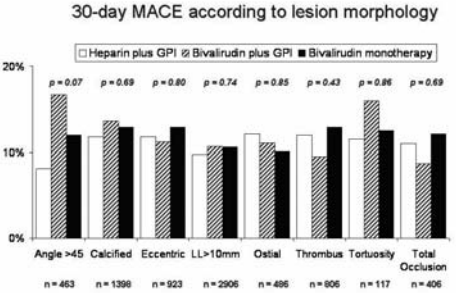
Background: Thirty-day results of the ISAR-REACT 3 trial, showed that bivalirudin reduced bleeding compared to unfractionated heparin, although net clinical benefit based on the quadruple endpoint was not improved by this drug. However, the 30-day period might not be long enough to identify the whole potential benefit with a certain drug. For example, reduction of bleeding in the early period may improve the long-term prognosis of the treated patients. One year outcomes with bivalirudin vs. unfractionated heparin are not evaluated so far.
Methods: In this randomized, double-blind study 4570 biomarker negative patients with stable or unstable angina who underwent a percutaneous coronary intervention after pretreatment with a 600 mg dose of clopidogrel were enrolled: 2889 patients assigned to bivalirudin and 2881 patients to unfractionated heparin. Aim of the present analysis is evaluation of one-year outcomes particularly in terms of mortality and myocardial infarction and their relation to the early 30-day events.
Results: Results will be available in February 2009.

9:30 a.m.

2514-730 Impact of Bivalirudin Monotherapy on 30-day Outcomes in Patients with Acute Coronary Syndromes and Complex Coronary Stenoses Undergoing Percutaneous Coronary Intervention

Kenji Goto, Alexandra J. Lansky, Ecaterina Cristea, Martin Fahy, Frederick Feit, Magnus E. Ohman, Harvey D. White, Karen P. Alexander, Michel E. Bertrand, Walter Desmet, Martial Hamon, Roxana Mehran, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Background: The ACUITY trial demonstrated that among moderate to high risk ACS pts undergoing PCI, bivalirudin monotherapy compared to heparin + GP IIb/IIIa inhibitors (GPI) achieves similar ischemic outcomes with fewer major bleeding complications. Whether these results are generalizable to ACS patients with complex coronary anatomy undergoing PCI is unknown.
Methods: ACUITY randomized 13,819 pts with moderate and high risk ACS to heparin (unfractionated or low molecular weight heparin) + GPI, vs. bivalirudin + GPI vs. bivalirudin alone. Independent blinded core laboratory analysis was performed in the first 7000 consecutive randomized US patients, 3664 of whom underwent PCI. Major adverse cardiac events (MACE) including death, MI, or unplanned revascularization for ischemia were compared for component ACC/AHA lesion type by treatment allocation.
Results: In the angiographic subset, a total of 1190 PCI pts were randomized to heparin + GPI, 1254 to bivalirudin + GPI, and 1220 pts received bivalirudin monotherapy. At 30 days, there were no differences in MACE for any of the complex lesion subgroups based on treatment allocation (Figure).
Conclusions: Compared with heparin + GPI or bivalirudin + GPI, bivalirudin monotherapy alone achieves similar rates of 30-day MACE across the spectrum of complex lesion types.

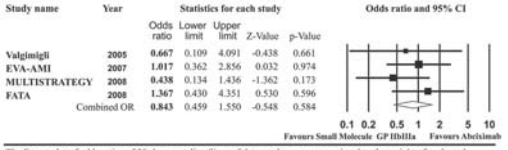


9:30 a.m.

2514-731 Safety and Efficacy of Small Molecule Glycoprotein IIb/IIIa Inhibitors compared to Abciximab in Patients undergoing Primary PCI: A Meta-Analysis of Randomized Controlled Trials

Umesh U. Tamhane, Pascal Meier, Paul Michael Grossman, Stanley Chetcuti, Hitinder S. Gurm, University of Michigan Medical Center, Ann Arbor, MI

Background: Recent "head to head" clinical trials comparing small molecule glycoprotein IIb/IIIa inhibitors (smGPI) with abciximab focused on surrogate endpoints and were not adequately powered to detect differences in clinical outcomes. The objective of our meta-analysis was to evaluate the survival benefit from smGPI compared to abciximab in ST elevation myocardial infarction (STEMI) patients undergoing primary PCI (PPCI).
Methods: Five randomized trials (n=2,138 patients) comparing smGPI (tirofiban or eptifibatide) with abciximab as an adjunctive therapy to PPCI were included in this meta-analysis. Summary odds ratios for 30-day death, reinfarction and major bleeding were calculated using fixed-effects models.
Results: There were no differences in 30-day mortality (1.9 % for small molecule versus 2.3% for abciximab, OR 0.84, 95% CI 0.46- 1.55, P =0.58), reinfarction (1.3% versus 1.2%), or major bleeding (1.7% versus 1.3%) between the two adjunctive strategies. There was no significant difference in the incidence of death or reinfarction on follow up at 8 months (3.9% versus 5% and 4.8% versus 4.6% for smGPI compared to abciximab).
Conclusions: In patients undergoing PPCI for STEMI, no difference in outcome could be identified in patients treated with smGPI or abciximab.



The Forest plot of odds ratios of 30-day mortality. Sizes of data markers are proportional to the weight of each study in the meta-analysis. Horizontal bars=95% CI

9:30 a.m.

2514-732 Clinical Outcomes of Percutaneous Coronary Intervention using Bivalirudin Versus Heparin plus Glycoprotein IIb/IIIa Inhibitors in the NHLBI Dynamic Registry

Sohah N. Iqbal, Faith Selzer, Frederick Feit, Ruchira Glaser, Suresh R. Mulukutla, Robert L. Wilensky, J. Dawn Abbott, David O. Williams, James Slater, New York University Langone Medical Center, New York, NY, University of Pittsburgh Medical Center, Pittsburgh, PA

Background: In randomized clinical trials, the use of bivalirudin monotherapy in percutaneous coronary intervention (PCI), as compared with heparin plus glycoprotein IIb/IIIa inhibitors (Hep-GPI), has been shown to reduce bleeding complications, while preserving protection from ischemic events. There is less data available on the effectiveness of bivalirudin in real world practice. We compared the outcomes of these two anticoagulation strategies as used in unrestricted, routine clinical practice.
Methods: Consecutive patients enrolled in 2 recruitment waves in the multi-center, prospective cohort study of the National Heart, Lung, and Blood Institute Dynamic Registry (2004 and 2006) were studied. Baseline characteristics, in-hospital events, and 1-year outcomes were compared based on the use of bivalirudin (n = 913) or Hep-GPI (n = 1282) during PCI. To account for factors affecting treatment selection bias, a propensity score adjustment was performed.

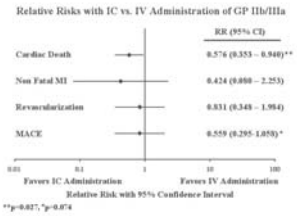
Results: Patients who received bivalirudin were more likely to be older (65 vs 62 years), have more diabetes (38.9% vs 30.2%), and have previous CABG or PCI (53.9% vs 33.6%) than Hep-GPI ($p < 0.001$). Patients who received Hep-GPI were more likely to present with an acute MI (46.9% vs 9.7%) ($p< 0.001$). In the propensity score adjusted model, risk for any reported bleeding was significantly lower in the patients treated with bivalirudin as compared with the Hep-GPI strategy during PCI (adjusted odds ratio [AOR] of 0.20, 95% CI 0.10-0.40, $p < 0.001$) as was bleeding requiring transfusion (AOR of 0.17, 95% CI 0.06-0.49, $p = 0.001$). Risk for in-hospital death, myocardial infarction (MI), or CABG was also significantly lower with bivalirudin therapy (AOR of 0.35, 95% CI 0.14-0.88, $p = 0.03$). There was no difference in risk of 1-year events including death, MI, CABG, or repeat PCI.
Conclusions: Our study demonstrates that in real world clinical practice, after adjusting for treatment selection bias, risk of bleeding complications is lower in PCI with bivalirudin as compared with Hep-GPI. Though unaccountable imbalances between the two groups may be present, there appears to be less in-hospital and similar 1-year ischemic events with bivalirudin use.

9:30 a.m.

2514-733 **Adverse Cardiac Events with Use of Intracoronary Compared to Intravenous Glycoprotein IIb/IIIa Inhibitor in Patients with Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention: A Meta-analysis**

Amol A. Bahekar, Rohit Bhuriya, Updesh Bedi, Param Puneet Singh, Ahmad Khraisat, Janos Molnar, Rohit Arora, Sandeep Khosla, Mount Sinai Hospital, Chicago, IL, Rosalind Franklin University, North Chicago, IL

Background: Recent studies have shown that intracoronary (IC) glycoprotein (Gp) IIb/IIIa inhibitor may improve myocardial microcirculation and reduce major adverse cardiac events (MACE). The aim of this meta-analysis was to assess the effects of IC versus intravenous (IV) Gp IIb/IIIa inhibitor bolus administration on the occurrence of MACE up to 6 months.
Methods: Systematic literature search revealed 7 clinical trials (N=2041) comparing IC versus IV Gp IIb/IIIa inhibitor in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI). Heterogeneity of the studies was analyzed by Cochran's Q statistics. The Mantel-Haenszel fixed-effect model was used to calculate endpoints for outcomes where studies were homogenous and random effect model when the studies were heterogenic.
Results: The relative risk (RR) for cardiac deaths decreased significantly 0.58; 95% CI: 0.35 - 0.94 p=0.03 in IC group as compared to IV group. There was a trend towards decreased RR of non fatal myocardial infarction(MI) 0.42; 95% CI: 0.08 - 2.25 p=0.31, rate of revascularization 0.83; 95% CI: 0.35 - 1.98 p=0.68 and MACE 0.56; 95% CI 0.3-1.06 p=0.07 in the IC group as compared to IV group but the results were not significant.
Conclusions: IC Gp IIb/IIIa inhibitor reduce the RR of cardiac death in addition to reducing the trend of non fatal MI & MACE in ACS patients undergoing PCI as compared to IV Gp IIb/IIIa inhibitor. Large scale prospective randomized trials are needed to assess this benefit further.

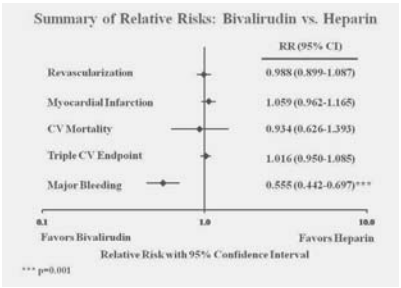


9:30 a.m.

2514-735 **Bivalirudin Versus Heparins in Acute Coronary Syndrome; with and without Percutaneous Coronary Interventions: A Meta-analysis**

Sarabjeet Singh, Rohit Arora, Janos Molnar, Param Puneet Singh, Rohit Bhuriya, Amol Bahekar, Ahmad Khraisat, Sandeep Khosla, Chicago Medical School and affilated Hospitals, Chicago, IL

Background: Heparin provides protection against cardiovascular events with fewer bleeding complications. Whether this advantage is consistent is not been fully defined. We evaluated cardiac outcomes with bivalirudin versus heparin in management of acute coronary syndrome (ACS), including patients undergoing percutaneous coronary interventions (PCI).
Methods: Seven randomized controlled trials (BAT, CACHET, REPLACE 1,REPLACE-2, ACUITY, HORIZONS-AMI, ISAR-REACT) comparing bivalirudin to heparin were identified. The meta-analysis consisted of 33,629 patients (bivalirudin, 1,9166; heparin, 1,4463). The combined relative risks (RR) across all the studies and the 95% confidence intervals of myocardial infarction (MI), and revascularization (bivalirudin versus heparin) were computed with using the Mantel-Haenszel fixed-effect model, while the random effect model was used for cardiovascular death and major bleeding.
Results: There were no significant differences in patient characteristics between the two groups. Compared to heparin, the risk of death, MI, revascularization and composite ischemic endpoints were similar with bivalirudin monotherapy. However, the risk of major bleeding was significantly lower with bivalirudin use p<0.001).
Conclusions: The present meta-analysis suggests that bivalirudin alone is noninferior to heparin in reducing composite ischemic endpoints. Additionally, bivalirudin significantly lowers rate of major bleeding compared with heparin.



I2.POSTER CONTRIBUTIONS

2515

Interventional Pharmacology

Monday, March 30, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2515-736 **Impact of Proton Pump Inhibitors on Platelet Response to Clopidogrel Treatment**

Dirk Sibbing, Tanja Morath, Julia Stegherr, Siegmund Braun, Martin Hadamitzky, Albert Schomig, Adnan Kastrati, Nicolas von Beckerath, Deutsches Herzzentrum Munchen, Munich, Germany

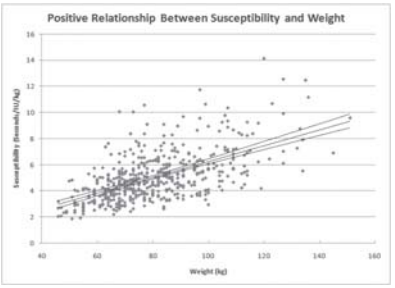
Background: Patients receiving dual antiplatelet treatment with aspirin and clopidogrel are commonly treated with proton pump inhibitors (PPIs) with the objective of minimizing the risk of gastrointestinal bleedings. Adverse effects on the platelet response to clopidogrel have been reported solely for the PPI omeprazole. PPIs differ in their metabolization properties as well as their potential for drug-drug interactions. Whether other PPIs such as pantoprazole or esomeprazole also attenuate the antiplatelet action of clopidogrel is unknown. The aim of this study was to investigate the impact of concomitant treatment with different PPIs on platelet response to clopidogrel in patients with previous coronary stent placement under dual antiplatelet treatment with clopidogrel and aspirin.
Methods: A total of 1000 consecutive patients under clopidogrel treatment and scheduled for a control coronary angiography were enrolled in this study. Adenosine diphosphate (ADP)-induced platelet aggregation was measured in whole blood with multiple electrode platelet aggregometry (MEA) on the Multiplate analyzer. Values of MEA are expressed as area under the curve (AUC=AU*min) of arbitrary units (AU).
Results: From the entire study population, 268 (26.8%) patients were under PPI treatment at the time point of platelet function testing (pantoprazole, n=162; omeprazole, n=64; esomeprazole, n=42). Platelet aggregation (median [interquartile range]) was significantly higher in patients with omeprazole treatment (295.5 [193.5-571.2] AU*min) compared to patients without (n=732) PPI treatment (220.0 [143.8-388.8] AU*min; P=0.001). Platelet aggregation was similar in patients with pantoprazole (226.0 [150.0-401.5] AU*min) or esomeprazole (209.0 [134.8-384.8] AU*min) treatment compared to patients without PPI treatment (P=0.69 and P=0.88, respectively).
Conclusions: Adverse effects of concomitant PPI treatment on platelet response to clopidogrel were restricted to the use of omeprazole. No adverse effects on platelet response to clopidogrel were observed for pantoprazole or esomeprazole.

9:30 a.m.

2515-737 **Less Heparin per Weight is Necessary for Obese Patients Undergoing Percutaneous Coronary Intervention**

Yuichi J. Shimada, Yumiko Kanei, Beth Israel Medical Center, New York, NY

Background: A weight-adjusted bolus heparin of 70 to 100 IU per kg is recommended to achieve adequate activated clotting time (ACT) during percutaneous coronary intervention (PCI) in ACC/AHA/SCAI Guideline. Since obese patients have lower proportion of lean body mass as a percentage of total body weight, heparin dosing based on total body weight could cause excessive anticoagulation.
Methods: In 500 consecutive PCI cases in our catheterization laboratory, the amount of initial heparin bolus (IU per kg) and ACT (seconds) using Hemochron at 5 minutes after heparin administration were retrospectively obtained. We hypothesized that patients with more weight requires less heparin per weight to achieve the same goal of ACT, and calculated susceptibility to heparin of each individual as the ratio of ACT to heparin dosing (IU per kg). Regression analysis was performed to determine relationship between weight and susceptibility.
Results: There was a statistically significant positive relationship between heparin susceptibility (y) and weight (x), showing that patients with more weight required less heparin per kilogram to achieve the same goal of ACT (Graph below; $y = 0.0603x + 0.2229$; 95% confidence interval of slope, 0.053-0.067>0; P<0.0001. 95% CI for the regression line is also shown).
Conclusions: For obese patients undergoing PCI, less heparin per weight should be given to avoid excessive anticoagulation.



9:30 a.m.

2515-738 **Comparison of addition of cilostazol versus increasing dose of clopidogrel in clopidogrel non-responders after drug-eluting stent implantation**

Hahn Joo-Yong, Young Bin Song, Sang-Yup Lee, Seung-Hyuk Choi, Jin-Ho Choi, Young Keun On, Sang Hoon Lee, Hyeon-Cheol Gwon, Samsung Medical Center, Seoul, South Korea

Background: Previous studies reported that triple antiplatelet therapy including cilostazol enhanced inhibition of platelet P2Y12 signaling compared with standard dual antiplatelet therapy. However, it is uncertain whether addition of cilostazol is superior to increasing dose of clopidogrel in clopidogrel non-responders after drug-eluting stent implantation.
Methods: This was a prospective randomized single-center trial. We enrolled 73 patients who showed a poor responsiveness to clopidogrel on standard dual antiplatelet therapy (aspirin 100 mg and clopidogrel 75 mg daily) more than 2 weeks. Clopidogrel responsiveness was evaluated using VerifyNow P2Y12 assay (Accumetrics Inc., San Diego, CA, USA). Patients were considered as clopidogrel non-responder when percent inhibition of P2Y12 reaction units (PRU) was less than 30%. Thirty-five patients were randomly assigned to receive additional cilostazol (aspirin 100 mg qd + clopidogrel 75 mg qd + cilostazol 100 mg bid daily: group A) and 38 patients to receive increased clopidogrel (aspirin 100 mg + clopidogrel 150 mg daily: group B). The primary endpoint was percent inhibition of PRU on follow-up VerifyNow P2Y12 assay at 4 weeks after the randomization. Secondary endpoints were PRU at follow-up and change in percent inhibition of PRU and PRU.
Results: Baseline percent inhibition of PRU and PRU was similar between 2 groups (13.3±10.5% versus 11.7±9.8%, p=0.50 and 296±54 versus 287±58, p=0.49, respectively). At follow-up, percent inhibition of PRU was significantly greater in group A than in group B (37.0±18.8% versus 27.3±17.1%, p=0.02). Change in percent inhibition of PRU was also significantly greater in group A compared with group B (23.6±17.6% versus 15.6±16.8%, p=0.04). Follow-up PRU and change in PRU showed a favorable trend toward group A compared with group B, but without a significant difference (212±71 versus 245±75, p=0.06 and -75±67 versus -51±66, p=0.13, respectively).
Conclusions: Addition of cilostazol on standard dual antiplatelet therapy improved clopidogrel responsiveness better than increase in clopidogrel dose in clopidogrel non-responders after drug-eluting stent implantation.

9:30 a.m.

2515-739 **Treatment of Clopidogrel Hypersensitivity Without Drug Interruption: Acute and Long-term Outcomes**

Kimberly L. Campbell, Rhaguram Mallya, Waseem Jaffrani, John R. Cohn, David L. Fischman, Paul Walinsky, Michael P. Savage, Thomas Jefferson University Hospital, Philadelphia, PA

Premature discontinuation of dual antiplatelet therapy after PCI is a major predictor of stent thrombosis. Clopidogrel hypersensitivity affects 6% of patients and results in drug discontinuation in 1.5%. Conventional clopidogrel desensitization protocols require a washout period to enable detection of reaction to desensitizing dose. This technique is problematic following stent placement since therapy interruption carries significant risk of stent thrombosis. The goals of the study were to assess a strategy for treating clopidogrel hypersensitivity using antihistamines and short-course corticosteroids without drug interruption and secondarily to assess long-term outcomes of this strategy. Review of PCI performed January 1, 2005 through September 30, 2008 identified 24 patients treated for clopidogrel hypersensitivity. Patients treated for hypersensitivity were followed for 487 ± 434 days (median 333) to ascertain duration of clopidogrel therapy, frequency of symptom recurrence, and incidence of adverse cardiovascular events. The study population included 18 males and 6 females with mean age 62 ± 9 years. Indications for PCI included STEMI (3), acute coronary syndrome (11), stable angina (1), and positive stress test (9). Drug eluting stents were used in 16 patients (67%). Clopidogrel hypersensitivity occurred on day 6 ± 2 of therapy. Treatment of hypersensitivity included corticosteroids (19) and antihistamines (20) with 15 receiving both. Patients treated with corticosteroids received tapering courses for 8 ± 5 days. Treatment of clopidogrel hypersensitivity was successful in 21 of 24 patients (87.5%). In these 21 patients, clopidogrel therapy duration was 115 ± 120 days for bare metal stents (median 92) and 511 ± 361 days for drug-eluting stents (median 454). During follow-up, there were no deaths, MI, CABG, or stent thrombosis. In-stent restenosis required repeat PCI in 3 patients. In conclusion, patients treated for clopidogrel hypersensitivity using antihistamines and short-course corticosteroids without drug interruption can be successfully maintained on prolonged clopidogrel therapy. This strategy confers a low risk of adverse cardiovascular events.

9:30 a.m.

2515-740 **Prognostic Implications of High Platelet Reactivity as Defined by Multiple Agonists in Diabetes Mellitus Patients on Dual Antiplatelet Therapy**

Dominick Angiolillo, Esther Bernardo, Piera Capranzano, Manel Sabate, Pilar Jimenez-Quevedo, Jose Luis Ferreiro, Fernando Alfonso, Rosana Hernandez, Carlos Macaya, Antonio Fernandez-Ortiz, Theodore A. Bass, University of Florida College of Medicine-Jacksonville, Jacksonville, FL, San Carlos University Hospital, Madrid, Spain

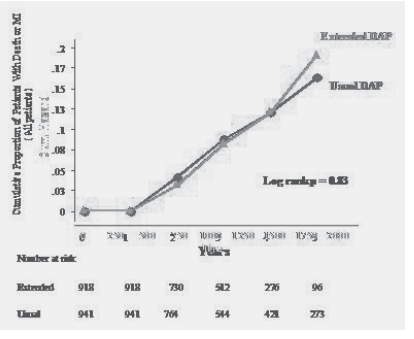
Background: High platelet reactivity (HPR) determined in patients while on dual antiplatelet therapy with aspirin and clopidogrel has been associated with an increased risk of major adverse cardiovascular events (MACE). Most studies have determined HPR using light transmittance aggregometry (LTA) with ADP stimuli. However, if concomitant assessment of platelet reactivity using others agonists can better define patients at an increased risk of MACE is unknown.
Methods: LTA with ADP (20 µmol/L) stimuli was used to define patients with HPR in a total of 173 diabetic patients on aspirin and clopidogrel therapy. LTA was also performed with the following agonists: collagen (6 µg/ml), epinephrine (20 µmol/L), and TRAP (25 µmol/L). Receiver-operating characteristics (ROC) analyses were computed in order to identify the best cut-off values of aggregation predicting MACE. MACE (cardiovascular death, acute coronary syndrome, stroke) occurring during 2-year follow-up were recorded.
Results: A total of 41 MACE occurred in 34 patients (19.6%) during the 2-year follow-up. ROC analysis identified ADP-induced aggregation >62% to best predict MACE. ROC analyses of aggregation values with other agonists (collagen, epinephrine, and TRAP) showed epinephrine-induced aggregation as the best to predict MACE for which a cut-off value >32% was identified. A total of 37 patients had both ADP and epinephrine aggregation above the ROC-defined cut-off values (group 1); 59 patients had only one of the aggregation parameters above the ROC-defined cut-off values (group 2); the remaining 77 patients had both ADP- and epinephrine-induced aggregation below the ROC-defined cut-off values (group 3). The 2-year MACE rate was 43.2%, 13.6%, and 13.0% in groups 1, 2, and 3, respectively (p=0.006). After adjustment for multiple confounders the hazard ratio for the association of >62% ADP- and >32% epinephrine-induced aggregation was 3.5 (95% CI 1.8-7.2, p=0.001).
Conclusions: Platelet function profiling using multiple agonists activating different signaling pathways allows to better discriminate individuals at increased risk of developing MACE while on antiplatelet therapy.

9:30 a.m.

2515-741 **Clinical Outcomes of Extended Duration of Dual Anti-Platelet Therapy After Percutaneous Coronary Intervention**

Kishore J. Harjai, Pamela Orshaw, Chetan Shenoy, Judith Boura, Guthrie Health System, Sayre, PA

Background: It is unknown whether DAP should be continued beyond 12 months after successful PCI. We assessed the impact of extended duration of dual-antiplatelet (DAP) therapy on long-term outcomes of patients undergoing PCI.
Methods: We identified 1859 patients who underwent successful native coronary stent procedures and survived event-free for ≥12 months. We assessed the impact of duration of DAP therapy ["usual" duration (≤12 mon, n=941; 51%) Vs. "extended" duration (>12 mon; n=918; 49%)] on the combined end-point of death or non-fatal myocardial infarction (MI) using actuarial survival analysis and propensity-adjusted multivariate Cox regression analysis. Similar analyses were then performed in the 2 stent subsets: BMS (n=835), DES (n=1024); and 3 high-risk subsets: diabetics (n=486), patients presenting with MI (n=713), and those with ACC/AHA type C lesions (n=717).
Results: Baseline characteristics were as follows: mean age 64±12 years, male 69%, diabetic 26%, presentation with MI 38%, ejection fraction 49±12%, mean vessel diameter 3.1±0.5 mm. Duration of DAP was 4.1±4.1 months in the 'usual' group and 27±11 months in the 'extended group (p<0.0001). At a median follow-up of 3.4 years after PCI, the 'usual' vs. 'extended' groups had similar incidence of death or MI (10 vs 9.4%, log rank p=0.83, figure). After multivariate adjustment, 'extended' DAP therapy was not associated with lower incidence of death or MI than 'usual DAP' therapy (adjusted HR=1.01; CI 0.74-1.37, p=0.95). Analysis of each of the 5 pre-defined subsets revealed similar results.
Conclusions: In patients who undergo successful native coronary PCI and survive event-free for at least 12 months, continuation of dual anti-platelet therapy beyond 12-months does not confer long-term protection from death or MI.



9:30 a.m.

2515-742 Point-of-Care Testing of Platelet Function at the Time of Percutaneous Coronary Intervention Identifies Patients at Risk for Early Post-Procedure Ischemia

Eric R. Powers, Andrew Fowler, Craig Thieling, Victor Diaz-Gonzales, Mitch Devlin, Valerian Fernandes, Robert Leman, Jacob Nunamaker, Bruce Usher, Andrea Boan, John Lazarchick, Christopher Nielsen, Randy Goodroe, Medical University of South Carolina, Charleston, SC

Background: The relationship between platelet reactivity at the time of PCI and late clinical outcomes remains controversial. However, the relationship between platelet reactivity at the time of PCI and early post-procedure ischemia has not been previously described. We hypothesized that aspirin resistance and low levels of P2Y12 platelet receptor inhibition measured using a point-of-care test performed in the catheterization laboratory would identify patients at risk for post-procedure ischemia assessed using an intracoronary ECG.
Methods: One-hundred consecutive patients undergoing PCI not treated with a glycoprotein IIb/IIIa inhibitor were included. PCI was performed according to standard clinical practice. Blood samples were drawn immediately prior to PCI. Aspirin resistance and P2Y12 receptor inhibition were assessed using The Ultegra Rapid Platelet Function Assay - VerifyNow (Accumetrics) and expressed as aspirin reaction units (ARU) and P2Y12 reaction units (PRU). Post-procedure ischemia was assessed using an intracoronary ECG and was defined as ST deviation >1mm two minutes following the completion of the PCI. Cardiac biomarkers were measured the morning after PCI.
Results: Post-procedure Ischemia was found in 49 of 100 patients. Aspirin resistance (ARU $\geq$ 550) was found in 17 patients and was not associated with post-procedure ischemia. A PRU >/= 314 (the median value) was associated with post-procedure ischemia (OR 3.89 (1.46, 10.35), p=0.007). The only other predictors of post-procedure ischemia were multivessel PCI (OR 6.22 (2.17, 17.85), p=0.001) and stent length (OR 2.69 (1.02, 7.09), p=0.045). Post-procedure ischemia was associated with an abnormal Troponin I the morning after PCI (OR 3.49 (1.25, 9.38), p=0.014).
Conclusions: Post-procedure ischemia following PCI is common and was associated with low levels of P2Y12 platelet receptor inhibition, as well as multivessel PCI and greater stent length but not aspirin resistance. Thus, pre-procedure point-of-care testing of platelet function can identify patients at risk for post-procedure ischemia and allows for targeting of these patients for additional anti-platelet therapies.

9:30 a.m.

2515-743 Changing Outcomes and Treatment Strategies for Wire Induced Coronary Perforations in the Era of Bivalirudin Use

Annapoorna S. Kini, Oana S. Rafael, Kunal Sarkar, Angelica Mares, Madhavi Jakkula, Michael C. Kim, Dheeraj Kaplish, Javed Suleman, Prakash Krishnan, Samin K. Sharma, Mount Sinai Hospital, NewYork, NY

Background: Technical advances in percutaneous coronary intervention (PCI) have facilitated its use in complex lesions like chronic total occlusion and calcified lesions. The resultant use of stiff/hydrophilic wires may lead to a higher incidence of coronary perforation (CP).
Methods: A single-center retrospective analysis of CP for the last 4 years with review of angiograms was performed. Wire perforation (WP) were identified and classified based on angiographic appearance as: Type I (myocardial stain, with no frank dye extravasation), Type II (myocardial fan: dye extravasation to pericardial cavity or cardiac chambers).All WP were divided into 2 groups based on anticoagulation used, heparin (group A) and bivalirudin (group B).
Results: Incidence of CP was 0.49% (82/16,859) of which 50 (61%) were identified as WP,30 in group A and 20 in group B. All WP occurred in type B2/C lesions (100%),commonly with hydrophilic guidewires (70%). All WP in group B responded to stopping anticoagulation and prolonged balloon inflation. However, type II perforations in group A frequently required additional procedures (pericardiocentesis, coil embolization or covered stent graft).(Figure1)
Conclusion: WP is a major cause of CP. With bivalirudin, most WP can be managed with discontinuing anticoagulation and balloon inflation. WP with heparin often needs procedures like pericardiocentesis and coil embolization. Bivalirudin may offer a safer alternative for anticoagulation in complex PCI.

	Figure 1						
Variable	Group A: Heparin (n = 30)			Group B: Bivalirudin (n = 20)			P value between group A and B
	Type I	Type II	Combined	Type I	Type II	Combined	
Number (%)	12 (40)	18 (60)	-	8 (40)	12 (60)	-	0.82
Pericardiocentesis/ Coil embolization/ Covered stent	0	12(66.6)	12(40)	0	0	0	0.002
Deaths (%)	0	3 (16.7)	3 (10)	0	0	0	0.55
Tamponade (%)	0	6 (33)	6 (20)	0	0	0	0.05
CABG (%)	0	1 (5.5)	1 (3.3)	0	0	0	0.55
MI (%)	1 (8.3)	5 (27.8)	6 (20)	0	0	0	0.23
MACE (%)	1 (8.3)	14 (78)	15 (50)	0	0	0	0.006

9:30 a.m.

2515-744 30-day outcomes of patients under anti-vitamin K treatment receiving sirolimus-eluting stent implantation in the world-wide e-Select Registry

Manel Sabate, Alexander Abizaid, Adrian Banning, Antonio Bartorelli, Vladimir Dzavik, Stephen G Ellis, Runlin Gao, David Holmes, Myung Ho Jeong, Victor Legrand, Franz-Josef Neumann, Christian Spaulding, Stephen Worthley, Philip Urban, Hospital Sant Pau, Barcelona, Spain

Background: Patients (pts) under anti-vitamin K (AVK) treatment before the implantation of a drug eluting stent remain a therapeutic challenge because of the potential bleeding risks associated with dual antiplatelet therapy (DAPT). We sought to identify the risk profile and the 30-day outcome of pts under AVK receiving sirolimus-eluting stent (SES) in the world-wide e-Select Registry.
Methods: Between 2006 and 2008, 15,217 pts from 321 hospitals in 56 countries were prospectively enrolled after implantation of at least one SES (Cypher Select™). Monitoring of 20% randomly selected enrolled pts is ongoing. All adverse events are adjudicated by an independent critical event committee. The main outcome measure will be the incidence of stent thrombosis (ST) at 3 years. Analysis of the subgroup of pts under AVK treatment was predefined and data regarding antiplatelet and anticoagulation therapy was prospectively collected.
Results: 293 pts (2%) were on AVK at the time of inclusion and were treated for 385 target lesions with SES. As compared with pts without AVK, these pts were older (68$\pm$10 vs. 62$\pm$11 years, p<0.001), had had more often prior revascularization (19% vs. 9%; p<0.001), myocardial infarction (43% vs. 32%; p<0.001), cerebrovascular accident (15% vs. 4%; p<0.001) and, presented a higher incidence of heart failure (19% vs. 4%; p<0.001) and comorbid conditions (Charlson comorbidity index $\geq$3 in 24.2% vs 10%; p<0.001). At 30 days, 98.2% of pts were still on AVK. The percentage of pts on clopidogrel was similar between groups (98% vs 98%). However, pts on AVK presented significantly less usage of aspirin (87% vs. 99%; p<0.001). There was a trend towards an overall higher incidence of bleeding at the expense of minor bleeding. The incidence of major bleeding and ST were comparably low between groups (0.7% vs. 0.3; p=NS and 0% vs. 0.4%, p=NS; respectively).
Conclusions: SES implantation in pts under AVK treatment led the physician to reduce the usage of aspirin at 30-day follow-up. However, this was not translated into any hazard in terms of major bleeding or ST. Further details on the interaction and discontinuation of these drugs at 6-months will be available in March 2009.

9:30 a.m.

2515-745 Dual Antiplatelet Plus Warfarin Therapy Following Coronary Stent Placement: An Evaluation of Long-Term Outcomes from the Prairie Data Registry

Anna (Moore) Plessa, Robert Trask, Marc Shelton, Gregory Mishkel, Prairie Heart Institute at St. John's Hospital, Springfield, IL, Prairie Education & Research Cooperative, Springfield, IL

Background: Dual antiplatelet (DA) therapy with aspirin + clopidogrel is the standard of care following coronary stent placement. Patients already on chronic warfarin require treatment with dual antiplatelet + warfarin (DA+W) therapy following stent placement. We wish to assess morbidity, mortality, and clinical outcomes of DA versus DA+W in the "real world".
Methods: We identified 3808 consecutive patients who underwent coronary stent placement between 1/1/05 and 3/29/08 and met the following criteria: a) this was the 1st stent procedure during that time; b) DA or DA+W was administered prior to hospital discharge. Clinical follow-up was obtained at regular intervals.
Results: DA was administered in 3520 patients, and DA+W in 288. Follow-up was obtained on 3519 patients (92.4%) at a mean of 631 ± 328 days. At baseline, the DA+W group had significantly more co-morbid conditions, including: diabetes (33.3 vs 27.3%, p=0.034), congestive heart failure (16.3 vs 4.8%, p<0.001), cerebrovascular disease (14.2 vs 7.3%, p<0.001), peripheral vascular disease (13.9 vs 9.0%, p=0.008), and prior myocardial infarction (25.3 vs 17.7%, p=0.002). Drug-eluting stents were used more than bare metal in the DA group (86.3 vs 79.2%, p=0.002). In-hospital outcomes were similar between groups.

Kaplan-Meier 12 Month Event Estimates

	DA (n=3520)	DA+W(n=288)	p value
At 12 months:			
All-cause death	3.0	6.7	0.004
Cardiac death	2.5	3.2	ns
Non-fatal MI	1.5	2.8	ns
Def + prob ST	1.0	1.9	ns
Rehosp for bleeding	5.8	6.8	ns

Conclusion: Although potentially explainable by baseline differences in co-morbidities, the significant increase in 1-year all-cause mortality for DA+W raises concerns regarding this practice and warrants further investigation.

9:30 a.m.

2515-746 Influence of Low Dose Aspirin (81 mg) on the Incidence of Definite Stent Thrombosis in Patients Receiving Bare Metal and Drug Eluting Stents

Jiang Cui, Amir Lotfi, Siddarth Wartak, Jesse Columbo, Scott Mulvey, Mary Davis, Marc Schweiger, Gregory R. Giugliano, Baystate Medical Center, Tufts University School of Medicine, Springfield, MA

Background: Dual antiplatelet therapy with aspirin plus clopidogrel is the mainstay of therapy in patients undergoing percutaneous coronary intervention (PCI). However, the optimal dose of aspirin following PCI has not been established.
Methods: Low dose (81mg) aspirin was used as part of a standard dual antiplatelet therapy in patients receiving bare metal or drug eluting stents at a large tertiary medical center. We retrospectively analyzed 4053 consecutive patients treated with stent placement and dual antiplatelet therapy from 01/01/2005 to 12/31/2007. All cases coded as stent thrombosis in our PCI database were reviewed and classified according to the ARC definition of definite stent thrombosis (DST). The incidence of DST at our institution was compared to DST as reported in a large, published cohort of 24 trials and 12973 patients using a Chi-squared test statistic.
Results: A total of 4053 patients underwent 5871 stent implantations during the study period (4534 DES and 1337 BMS). Thirty-four DSTs occurred during the study period (2 acute (<1 day), 17 subacute (1 day to 30 days), 8 late (30 days to 1 year) and 7 very late (>1 year)). The cumulative incidence of DST was 0.47% (95% CI 0.30%-0.73%) at 30 days and 0.67 % (95% CI 0.46%-0.97%) at 1 year. The incidence of DST was no different based on type of stent (0.53% for DES and 0.75% for BMS (p=0.36)). Compared to the historic, standard-dose aspirin (162-325mg) cohort, DST in our low dose aspirin (81mg) cohort was not significantly different at 30 days (0.47% vs 0.7%, p = 0.1) and significantly lower (0.67% vs 1.1%, p = 0.03) at 1 year.
Conclusion: Low dose aspirin therapy in combination with clopidogrel following implantation of either BMS or DES in our cohort does not appear to increase the risk of DST compared to a higher dose aspirin regimen. Given the known increased risk of bleeding with higher dose aspirin in combination with clopidogrel, low dose aspirin appears to be an effective and potentially safer alternative. Confirmation of these results deserves further study in a large scale randomized trial.

9:30 a.m.

2515-747 Triple versus Dual Antiplatelet Therapy in Patients with Acute Myocardial Infarction Undergoing Percutaneous Coronary Intervention

Kang Yin Chen, Seung Woon Rha, Yong Jian Li, Kanhaiya L. Poddar, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Young Keun Ahn*, Myung Ho Jeong*, Other KAMIR Investigators, Korea University Guro Hospital, Seoul, South Korea, ChonNam National University Hospital*, Gwangju, South Korea

Background: Whether the safety and efficacy of triple antiplatelet strategy is superior or similar to the dual antiplatelet strategy in patients (pts) with acute myocardial infarction (AMI) undergoing percutaneous coronary intervention (PCI) is still unclear.
Methods: A total of 4,892 AMI pts undergoing PCI received either dual antiplatelet therapy (aspirin plus clopidogrel, Dual group, n=2,974) or triple antiplatelet therapy (aspirin plus clopidogrel plus cilostazol, Triple group, n=1,918). All major adverse cardiac events (All MACE) included total death, revascularization, and myocardial re-infarction. The bleeding complications and clinical outcomes of in-hospital, 1 and 8 months were compared between the two groups.
Results: The baseline characteristics were similar between the two groups. The early mortality and revascularization rate were lower in Triple group up to one month and all MACE was significantly lower up to 8 months. Interestingly, Triple group also had a significantly lower in-hospital major bleeding (Table). This result might be due to the Triple group had less history of peptic ulcer disease (0.4% vs. 0.9%, *P*=0.034).
Conclusions: Triple antiplatelet therapy appears to be superior in preventing the MACE without increasing the major bleeding events in pts with AMI undergoing PCI compared with the conventional dual antiplatelet therapy.

Table: Clinical outcomes of study population

Variables, n (%)	Dual group (n=2,974 pts)	Triple group (n= 1,918 pts)	P value
In-hospital			
Total death	89 (3.0)	34 (1.8)	0.008
Reinfarction	12 (0.4)	9 (0.5)	0.730
Revascularization	41 (1.4)	12 (0.6)	0.013
All MACE	142 (4.8)	55 (2.9)	0.001
TIMI-major bleeding	12 (0.6)	3 (0.2)	0.023
At 1 month			
Total death	106 (3.7)	50 (2.7)	0.046
Reinfarction	25 (0.9)	10 (0.5)	0.175
Revascularization	71 (2.5)	26 (1.4)	0.008
All MACE	202 (7.1)	86 (4.6)	0.001
At 8 months			
Total death	124 (4.3)	65 (3.5)	0.147
Reinfarction	34 (1.2)	13 (0.7)	0.097
Revascularization	150 (5.2)	75 (4.0)	0.055
All MACE	308 (10.7)	153 (8.2)	0.004

9:30 a.m.

2515-748 Impact of Vascular Closure Devices and Antithrombotic/ Antiplatelet Therapy on Access Site Bleeding. Insights from the Acuity Trial

Timothy A. Sanborn, Ramin Ebrahimi, Steven V. Manoukian, Brent T. McLaurin, David A. Cox, Frederick Feit, Martial Hamon, Roxana Mehran, Gregg W. Stone, NorthShore University HealthSystems, Evanston, IL

Background: The ACUITY Trial demonstrated that bivalirudin monotherapy (BIV) had significantly reduced rates of major access site bleeding (ASB) compared to heparin or bivalirudin plus a glycoprotein IIb/IIIa inhibitor (H + GPI, BIV + GPI). However, it is unknown whether vascular closure devices (VCD) had an impact on ASB in this trial. Therefore, the incidence of major ASB with and without VCD was examined.
Methods: Major ASB was defined as hemoglobin drop > 3g/dL, retroperitoneal bleeding, operation for ASB, or hematoma > 5 cm. Stepwise logistical regression was performed to determine whether VCD usage was a predictor of ASB.
Results: Of the 11,278 patients undergoing angiography or percutaneous coronary intervention via the femoral approach, 4220 (37.4 %) received a VCD and 7058 (62.6 %) did not. Rates of major ASB were lowest with VCD compared to no VCD (2.1% vs. 2.9 %), OR (95 % CI) = 0.73 (0.57, 0.94) p = 0.0151) and rates of ASB were lowest in patients treated with BIV alone and a VCD (0.6 %). Stepwise logistical regression revealed a trend toward VCD usage and reduced ASB (OR 0.78 (95 % CI 0.60-1.03) p = 0.08).
Conclusions: Rates of major ASB were significantly lower with the use of a VCD and were also lower with the use of BIV compared to GPI containing regimens regardless of VCD usage. Lastly, rates of major ASB were lowest in patients who received both BIV and a VCD. These results suggest that the combined use of BIV and a VCD may be effective in minimizing major ASB in patients with ACS managed with an early invasive strategy.

Major Access Site Bleeding, (n, %)

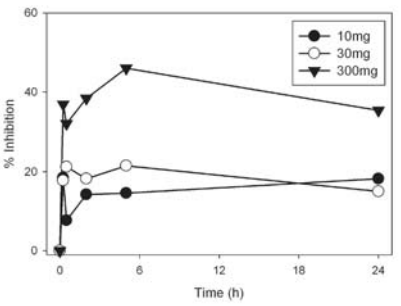
Category	H + GPI	BIV + GPI	BIV
VCD	41/1435 (2.9)	40/1344 (3.0)	9/1441 (0.6)
No VCD	81/2320 (3.5)	82/2413 (3.4)	41/2325 (1.8)
BIV vs. H + GPI, BIV + GPI: p < 0.0005			

9:30 a.m.

2515-749 Assessment of the pharmacokinetic and pharmacodynamic effects of intravenous clopidogrel in humans

Daniel Cushing, Raymond Lipicky, Peter Kowey, Christopher Cannon, Michael Adams, Warren Cooper, Gerold Mosher, Prism Pharmaceuticals, King of Prussia, PA

Background: Early administration of clopidogrel is recommended prior to diagnostic coronary angiography for ACS patients. Such dosing prior to angiography may increase bleeding complications if the patient requires CABG. Clopidogrel IV (CIV) is an IV formulation of clopidogrel that provides rapid inhibition of platelet aggregation. We present a pharmacokinetic (PK) and pharmacodynamic assessment of CIV in humans.
Methods: Healthy volunteers were enrolled in an open-label study and received CIV (n=12/dose). Blood samples were taken at baseline, 15 and 30 min, 2, 5 and 24 hr after dosing. Platelet aggregation (impedance method) and blood levels of clopidogrel, clopdiogrel-carboxylic acid, and the active clopidogrel-thiol metabolite (HPLC method) were assessed.
Results: CIV produced dose-dependent inhibition of platelet aggregation (Figure). Kaplan-Meier estimates of the cumulative percentage of subjects reaching first onset of maximum inhibition of ≥15% was 92% at 15min (300mg). Comparable inhibition was observed at 2h for a 300mg oral and IV doses. PK analyses indicated rapid dose-related exposure to clopidogrel, clopdiogrel-carboxylic acid, and clopidogrel-thiol. There were no serious adverse events or discontinuations. All doses were well tolerated with only mild to moderate adverse events.
Conclusion: CIV produced significant dose-dependent inhibition of platelet aggregation in human subjects with rapid onset (≤15min). Further studies are planned.

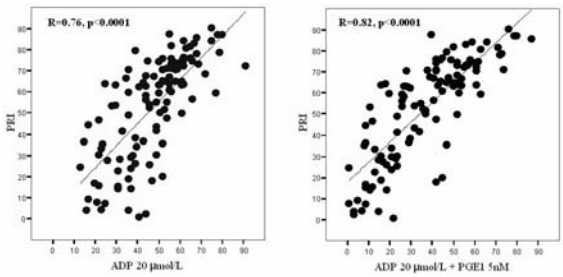


9:30 a.m.

2515-750 Evaluation of a Modified Light Transmittance Aggregometry Protocol to Assess $P2Y_{12}$ Blockade Induced by Clopidogrel

Piera Capranzano, Jose Luis Ferreiro, Sabrina Sumner, Bhaloo Desai, Ronald K. Charlton, Lyndon Box, Martin M. Zenni, Luis A. Guzman, Theodore A. Bass, Dominick J. Angiolillo, University of Florida College of Medicine-Jacksonville, Jacksonville, FL

Background: Although light transmittance aggregometry (LTA) with ADP stimuli is the gold standard to assess clopidogrel effects, this reflects both ADP ($P2Y_1$ and $P2Y_{12}$) receptors. The $P2Y_{12}$ reactivity index (PRI) determined by flow cytometric analysis of intraplatelet VASP specifically assesses $P2Y_{12}$ signaling by using PGE_1, which eliminates $P2Y_1$ effect, in addition to ADP. The aim of the study was to assess how PRI correlates with LTA performed with and without PGE_1.
Methods: Blood samples were collected from patients on chronic 75mg/day clopidogrel therapy (n=114). PRI was assessed using a commercially available kit. Maximal platelet aggregation by LTA was performed with 20 and 5 µmol/L ADP stimuli ("standard") and was repeated in the presence of 5nM PGE_1 ("modified").
Results: The PRI was 53±24%. Using the standard protocol, 20 and 5 µmol/L ADP-induced LTA values were 48±16% and 34±14%, and using the modified protocol, were 37±20% and 23±16%, respectively. The correlation coefficients between PRI and 20 µmol/L ADP-induced LTA were 0.76 and 0.82 using the standard and modified protocols, respectively (both p<0.0001; Figure). Improved correlations were also observed with the modified (r=0.72) compared to the standard (r=0.66) protocol with 5 µmol/L ADP.
Conclusions: Clopidogrel-induced antiplatelet effects assessed by LTA with ADP stimuli correlate well with PRI. A modified protocol in which PGE_1 is added to ADP makes the assessment more $P2Y_{12}$ specific, improving the correlation between assays.



9:30 a.m.

2515-751 Characterization of Clopidogrel Hypersensitivity Reactions and Response to Oral Steroids Without Clopidogrel Discontinuation

Asim N. Cheema, Atif Mohammad, St. Michael's Hospital, Toronto, ON, Canada

Background: Hypersensitivity reactions to Clopidogrel (CS) after coronary stenting are poorly characterized and present difficulty in management. Current treatment options include switching to Ticlopidine or Clopidogrel desensitization. In this report, we characterize CS and describe our experience with management of these patients using oral steroids.
Methods: Since July 2006, all patients with CS after stenting were referred to a Clopidogrel allergy clinic for desensitization or initiation and follow up of Ticlopidine therapy. From February 2007, all new patients referred received oral steroids after initial evaluation with close follow for CS.
Results: From February 2007 to August 2008, a total of 25 patients with CS were seen in clinic and completed a 2 week tapering course of prednisone starting at 30 mg BID X 5 days. Clinical characteristics are summarized in table. Complete resolution of CS was observed in all patients with no recurrence. 2 patients (4%) had normal platelet aggregation in response to ADP and were treated with higher dosage of Clopidogrel. Re exposure to Clopidogrel produced a recurrence of CS in 3 patients.
Conclusion: CS is characterized by a pruritic erythematous rash on day 3 to 5 in most patients. The cutaneous manifestation is not associated with Clopidogrel resistance as determined by platelet aggregation assays and can be successfully treated with short term course of oral steroids with concurrent Clopidogrel administration.

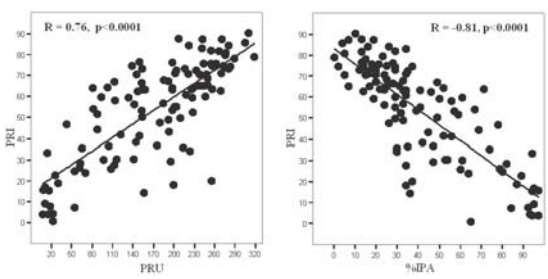
Baseline Characteristics	
Age	63±10
Male	18 (72%)
BMI	27±4
Cardiac risk factors	
Diabetes	11 (44%)
Hypertension	20 (80%)
Dyslipidemia	21 (84%)
Prior infarction	8 (32%)
Immunological history	
Asthma	0
Seasonal allergies	4 (16%)
Other environmental agent	5 (20%)
Family history	
Drug Allergy	2 (8%)
Seasonal Allergy	4 (16%)
Prior drug reactions	
Penicillin	3 (12%)
Sulfa drugs	3 (12%)
Ezetimide	1 (4%)
Nitrofurantoin	1 (4%)
Any drug	5 (20%)
Concurrent medications	
Beta blockers	17 (68%)
ACE inhibitors	12 (48%)
Aspirin	25 (100%)
Calcium channel blockers	4 (16%)
Clopidogrel loading	
300 mg	8 (32%)
600 mg	7 (28%)
None	10 (40%)
Stented vessel	
LAD	13 (52%)
RCA	5 (20%)
Cx	6 (24%)
SVG	1 (5%)
Drug eluting stent use	16 (64%)
Hypersensitivity manifestation	
Time to 1st symptom, days	4±2
Pruritic erythematous rash	25 (100%)
Rash Distribution	
Face	3 (12%)
Neck	8 (32%)
Trunk	25 (100%)
Limbs	18 (72%)
Shortness of breath	1 (4%)
Swelling of face or lips	2 (8%)
Fever	2 (8%)
Complete resolution of symptoms, days	5±2
All values are reported as n (%) or (mean ± SD)	

9:30 a.m.

2515-752 Clopidogrel-Induced Antiplatelet Effect Assessment by Flow Cytometry and Point-of-Care Based Assays: Correlation between VASP and VerifyNow $P2Y_{12}$ Testing

Piera Capranzano, Jose Luis Ferreiro, Sabrina Sumner, Bhaloo Desai, Ronald K. Charlton, Martin M. Zenni, Luis A. Guzman, Theodore A. Bass, Dominick J. Angiolillo, University of Florida College of Medicine-Jacksonville, Jacksonville, FL

Background: Flow cytometric assessment of VASP is the most specific assay to assess $P2Y_{12}$ receptor blockade in clopidogrel treated patients. Nevertheless, VASP analysis is time consuming, requires experienced personnel and it is not broadly available. The VerifyNow $P2Y_{12}$ assay is a point-of-care which, similarly to the VASP assay, specifically assesses $P2Y_{12}$ signaling, by using PGE_1 in addition to ADP. However, how these assays correlate is unknown.
Methods: Platelet function (n=115) was measured using the VASP and VerifyNow $P2Y_{12}$ assays according to standard protocols in patients on 75mg/day clopidogrel therapy. VASP measurements were used to define the $P2Y_{12}$ reactivity index (PRI). The VerifyNow $P2Y_{12}$ results are reported as $P2Y_{12}$ reaction units (PRU) and percentage inhibition (%IPA). Correlation analyses were performed between results obtained with the VASP and VerifyNow $P2Y_{12}$ assays.
Results: Using VASP analysis, the PRI was 54±23. Using the VerifyNow $P2Y_{12}$ assay, PRU and %IPA values were 172±85 and 40±26, respectively. The correlation coefficient between PRI and PRU was 0.76 and between PRI and %IPA -0.81 (both p<0.0001). The correlation was less strong at higher levels of inhibition (Figure).
There was a high degree of concordance between these assays in identifying suboptimal clopidogrel responders, defined as %IPA<50% and PRI > 50% (kappa 0.83).
Conclusions: A good correlation exists between the VASP and VerifyNow $P2Y_{12}$ assays used to assess clopidogrel-induced antiplatelet effects.



9:30 a.m.

2515-753 Does Transfusion for Major Bleeding After Percutaneous Coronary Intervention Impact Clinical Outcome in Patients Admitted With Normal Hematocrit?

Gabriel Maluenda, Gilles Lemesle, Asmir Syed, Sara D. Collins, Itsik Ben-Dor, Yanlin Li, Rebecca Torguson, Kimberly Kaneshige, Zehnyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Transfusion post percutaneous coronary intervention (PCI) has been associated with increased mortality and morbidity. Patients (pts) with pre PCI anemia are at higher risk for bleeding and transfusion post PCI which can result in an increase risk in adverse events. The present study aimed to assess the effect of red blood cell (RBC) transfusion post PCI on the incidence of adverse outcomes in a relatively healthy population with normal Hematocrit (Hct).
Methods: The records of 3738 pts with normal Hct (> 39% for men, > 36% for women) who underwent PCI were reviewed. Pts with cardiogenic shock were excluded. The one-year clinical outcomes were recorded and compared between pts who did or did not receive RBC transfusion.
Results: The 61 (1.6%) pts who required transfusion were older, more female, and had more renal failure and prior congestive heart failure. They had more frequently presented with acute MI and required intra-aortic balloon pump. Univariate analysis suggested that RBC transfusion was linked with death and MI (16.4% vs 3.7%, p<0.001), but after multivariate Cox adjustment, RBC transfusion did not persist as an independent predictor (p=0.1) [Table].
Conclusion: In pts with normal Hct, transfusion does not independently predict worse 1-year outcome. Although in an unselected population RBC transfusion is associated with worse outcomes, it is likely that the association with bleeding complications and co-morbid conditions are accounts for this complications and not the transfusion.

Clinical predictors for death and myocardial infarction at 1-year follow up

	Univariate Cox Proportional Model			Multivariate Cox Proportional		
	HR	95 % CI	p	HR	95 % CI	p
Age	1.05	1.0-1.1	< 0.001	1.03	1.02-1.05	< 0.001
Male	0.52	0.4-07	< 0.001	0.73	0.50-1.07	0.1
Diabetes Mellitus	2.52	1.8-3.4	< 0.001	2.03	1.39-2.97	< 0.001
Chronic renal failure	4.96	3.2-6.7	< 0.001	2.43	1.56-3.79	< 0.001
Congestive heart failure	4.4	3.1-6.3	< 0.001	2.74	1.80-4.17	< 0.001
IABP use	4.62	2.3-8.4	< 0.001	1.93	0.79-4.71	0.1
Transfusion	5.21	2.7-9.7	< 0.001	1.93	0.81-4.17	0.1

9:30 a.m.

2515-754 Efficacy of Triple Anti-platelet Therapy for Patients with Acute Myocardial Infarction Undergoing Drug-eluting Stent Implantation

Keun-Ho Park, Myung Ho Jeong, Min Goo Lee, Jum Suk Ko, Shin Eun Lee, Won Yu Kang, Soo Hyun Kim, Doo Sun Sim, Nam Sik Yoon, Hyun Ju Youn, Young Joon Hong, Hyung Wook Park, Ju Han Kim, Youngkeun Ahn, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, The Heart Center of Chonnam National University Hospital, Gwangju, South Korea, Cardiovascular Research Institute of Chonnam National University, Gwangju, South Korea

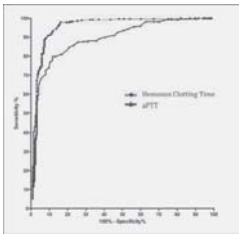
Background: It has been known that triple anti-platelet therapy prevents restenosis after drug-eluting stent (DES) implantation. However, there are few available data on efficacy of triple anti-platelet therapy for acute myocardial infarction (AMI).
Methods: We analyzed 784 consecutive patients with AMI undergoing DES implantation between Nov 2005 and Feb 2007. We compared clinical outcomes between triple anti-platelet therapy (group I, n=672: cilostazol adding to aspirin and clopidogrel at least one month) and dual anti-platelet therapy (group II, n=112: aspirin and clopidogrel).
Results: Mean ages were higher (62.1±11.86 vs. 59.3±11.61 years, p=0.02) and ST elevation MI (STEMI) and TMII flow 0 were more common (69.0% vs. 58.0%, p=0.02; 42.7% vs. 30.4%, p=0.014) in group I. Group I had lower incidences of 6-month target lesion revascularization (TLR) and major adverse cardiac and cerebro-vascular events (MACCE) than those of group II (9.0% vs. 18.3% and 12.0% vs. 21.1%, p=0.01 respectively). In subgroup analysis, lower incidence of 6-month TLR in patients with ACC/AHA B2 or C lesions and with non-STEMI (9.7% vs. 20.3% and 8.4% vs. 19.1%, p<0.05 respectively) were observed in group I than in group II. The rate of bleeding complications was not different between the two groups. In multivariate analysis, Killip III or IV and triple anti-platelet therapy were the independent predictors of 6-month MACCE (HR=2.805; 95% CI=1.464-5.375, HR=0.497; 95% CI=0.280-0.882).
Conclusions: Triple anti-platelet therapy is safe and efficacious, and prevents MACCE in patients with AMI, especially in patients with complex lesions and non-STEMI.

9:30 a.m.

2515-755 Monitoring of Enoxaparin Anticoagulation Immediately Before Catheterization Using a New Point-of-Care test

Johanne SILVAIN, Farzin Beygui, Dominique Costagliola, Ana Pena, Guillaume CAYLA, Olivier Barthelemy, Jean-Philippe Collet, Gilles Montalescot, INSTITUT DE CARDIOLOGIE - Univ Paris 06 - INSERM U856, PARIS, France, APHP - Pitie-Salpetriere

Background: : Inadequate anti coagulation in patients undergoing percutaneous coronary Intervention (PCI) is associated with the occurrence of ischemic events.
Methods: We sought to assess a new point-of-care test -HEMONOX- in monitoring enoxaparin anticoagulation in 296 unselected patients undergoing PCI. Chromogenic anti-Xa (AXA), Hemonox Clotting Time (HCT) and activated Partial Prothrombin Time (aPTT) were assessed at baseline (T1) and 10' after IV administration (T2) in patients receiving additional enoxaparin.
Results : The patients characteristics were: age:61±14 y/o; male: 75.7%, ACS: 41.3%, BMI >30:16.5%; creat cl <60ml/min: 25.2%. The Median (IQR) values were 0.16 (0.17) and 0.89 (0.28) IU/mL for AXA; 74 (11) and 155 (153) sec for HCT, and 46 (11) and 101 (92) sec for aPTT at T1 and T2 time points respectively. HCT strongly correlated with Anti-Xa level rho=0.78 (95% CI 0.75-0.82, p<0.0001). When comparing a total of 486 values to discriminate patients with AXA >0,5 IU/mL, the area under the receiver operating curve (AUC) (figure) for HCT was 0,95 ± 0,01 (95% IC; 0,93-0,97; p<0,0001) versus 0.89 ± 0,01 (95% IC; 0.86-0.92; p<0.0001) for aPTT. The HCT threshold of 80 seconds identified adequate anticoagulation (AXA >0.5 IU/mL) with a 98% sensitivity, 74% specificity and a likelihood ratio = 3.87.
Conclusion: Hemonox is a reliable point-of care test for monitoring the anticoagulation levels of enoxaparin with a high sensitivity to identify adequately anticoagulated patients undergoing PCI.



9:30 a.m.

2515-756 High Doses of Atorvastatin Before PCI in Patient With and Without Chronic Statin Therapy

Auguadro Carla, Angeletti Chiara, Manfredi Mariella, Scalise Filippo, Specchia Giuseppe, Dept of Cardiology, Policlinico of Monza, Monza, Italy

Background: previous studies documented a beneficial effect of chronic statins'therapy on the incidence of periprocedural myocardial injury in patients (pts) undergoing percutaneous coronary interventions (PCI). The first objective of this study was to verify in pts who were not on statins whether high doses of atorvastatin 12 hours before PCI reduces the occurrence and the extent of periprocedural myocardial damage. The second objective was to assess in pts who were on chronic statin therapy whether the addition of high doses of atorvastatin before PCI can potentiate the beneficial effect of these drugs.
Methods: statins' pre-treatment was performed with atorvastatin 80mg administered 12 hours before and 40mg 2 hours before the procedure. In all pts troponin I and CK-MB were evaluated in basal condition and 6-12-18-24 hours after PCI. Troponin I levels ≥ 1.0 ng/ml were considered indicative of post-procedural myocardial injury.
Results: The study population included 282 consecutive pts (215 males, mean age 65.4±11.4 years) who underwent PCI. 71 pts (G1) received high doses of atorvastatin before PCI whereas 211 (G2) did not received atorvastatin. The incidence of TnI ≥ 1.0 and CK-MB were significantly lower in pts who received high doses of atorvastatin (TnI 13% in G1 and 42% in G2, p=0.008; CK-MB 13% in G1 vs 43% in G2, p=0.009). Also the mean peak TnI and CK-MB values were significantly lower in G1 pts (TnI: 1.6±6.4 in G1 vs 4.8±11 in G2, p=0.02; CK-MB 25.2±39 in G1 vs 54.6±112 in G2, p=0.03). In the subogroup of pts who were on chronic statin therapy the addition of atorvastatin before PCI did not result in further reduction of TnI and CK-MB elevation.
Conclusions: This study documents that a pre-treatment with high doses of atorvastatin 12 hours before PCI significantly reduce the incidence of periprocedural myocardial damage at the time of PCI. On the other hand, the addition of high dose of atorvastatin in pts almost on chronic statin therapy did not potentiate the beneficial effects of statins.

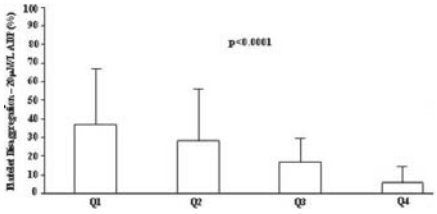
9:30 a.m.

2515-757 Platelet Disaggregation: a Novel Parameter of Clopidogrel Responsiveness?

Dominick J. Angiolillo, Esther Bernardo, Piera Capranzano, Manel Sabate, Jose Luis Ferreiro, Fernando Alfonso, Pilar Jimenez-Quevedo, Rosana Hernandez, Luis A. Guzman, Carlos Macaya, Antonio Fernandez-Ortiz, Theodore A. Bass, University of Florida College of Medicine-Jacksonville, Jacksonville, FL, San Carlos University Hospital, Madrid, Spain

Background: Light transmittance aggregomtery (LTA) using ADP stimuli is the gold standard to test for clopidogrel response. However, "maximum" or "late" aggregation values have been arbitrarily considered in LTA studies. The aim of this study was to evaluate

platelet disaggregation as a parameter to assess clopidogrel-induced antiplatelet effects.
Methods: LTA was performed using 20 µM/L ADP stimuli in 250 patients on clopidogrel 75mg/day therapy. Aggregation was measured at peak (Agg_{max}) and at 5 min (Agg_{late}). Percentage of platelet disaggregation considers both Agg_{max} and Agg_{late} and was defined as: 100 x (1 - Agg_{late}/Agg_{max}). Patients were divided into quartiles of Agg_{max} to assess profiles of platelet disaggregation
Results: In the overall population Agg_{max} and Agg_{late} were 51±15% and 42±19%, respectively. Agg_{max} quartile distribution (Q) was: Q1: <43% (n=61); Q2: 43-52% (n=63); Q3: 52-62% (n=65); Q4: >62% (n=62). The absolute change in platelet aggregation values between Agg_{max} and Agg_{late} progressively reduced from the lowest to upper quartile (Q1: 32±6% vs 21±12%; Q2: 46±2% vs 33±12%; Q3: 56±3% vs 47±8%; Q4: 70±7% vs 65±9%), indicative of reduced $P2Y_{12}$ inhibition. In accordance, platelet disaggregation was 22±24% in the overall population which reduced from the lowest to upper quartile (p<0.0001; Figure).
Conclusions: Platelet disaggregation is a novel parameter of clopidogrel response which, by combining maximal and late aggregation values, may represent a more objective determination.



9:30 a.m.

2515-758 **Dual Low Response to Acetylsalicylic Acid and Clopidogrel Is Associated With PCI-Related Myocardial Infarction and Ischemic Events Following Coronary Stenting**

Parham Eshtehardi, Stephan Windecker, Marcel Zwahlen, Stephane Cook, Michael Billinger, Mario Togni, Rolf Vogel, Ali Garachemani, Christian Seiler, Bernhard Meier, Otto M. Hess, Peter Wenaweser, Cardiology, Bern University Hospital, Bern, Switzerland

Background: An impaired response to antiplatelet therapy with acetylsalicylic acid (ASA) and clopidogrel (CLO) has been associated with adverse cardiovascular events following coronary stenting. We investigated whether patients with a low response to ASA (ASA-LR) or CLO (CLO-LR) are at risk for peri-interventional myocardial infarction (MI) or ischemic events during follow-up.
Methods: A total of 219 consecutive patients with stable coronary artery disease or acute coronary syndrome excluding ST-elevation myocardial infarction undergoing coronary stenting and pre-treated with ASA and CLO but not a glycoprotein IIb/IIIa inhibitor were prospectively included. Whole blood impedance platelet aggregometry was performed with the Multiplate analyzer to test for platelet aggregation in response to ASA (ASPI-test) and CLO (ADP-test) within 12-18 hours following PCI. Patients within the upper quartile of the ASPI-test area under the curve (AUC) and ADP-test AUC were defined as ASA-LR and CLO-LR, respectively.
Results: Dual ASA-LR and CLO-LR was present in 19 patients (8.6%). PCI-related MI, and 30-day cardiac death and MI were more frequent in dual ASA-LR and CLO-LR than the other patients (table). In multivariate analysis dual ASA-LR and CLO-LR was independently associated with 30-day composite of events (OR 10.08; 95% CI 3.07 to 38.52, p<0.001).
Conclusion: Dual ASA-LR and CLO-LR is associated with an increase of PCI-related MI and the risk for 30-day ischemic events following coronary stenting.

Clinical events during 30-day follow-up.

	Total population	Dual ASA-LR and CLO-LR vs. Controls	P value
Number of Patients, n	219	19 vs. 200	
PCI-related MI, n (%)	19 (8.7)	5 (26.3) vs. 14 (7.0)	0.004
30-day cardiac death and MI, n (%)	3 (1.4)	2 (10.5) vs.1 (0.5)	<0.001
Composite of PCI-related MI and 30-day cardiac death and MI, n (%)	21 (9.6)	7 (36.8) vs. 14 (7.0)	<0.001

9:30 a.m.

2515-759 **High Platelet Reactivity On Clopidogrel Is Driven Primarily By Non-Modifiable Risk Factors**

Matthew J. Price, Sarah Endemann, David E. Kandzari, Paul S. Teirstein, Scripps Clinic, La Jolla, CA

Background: High platelet reactivity (HPR) on clopidogrel (CLOP) has been associated with worse outcomes after percutaneous coronary intervention (PCI). The independent contribution of patient characteristics to HPR has not been well examined.
Methods: Patients on maintenance CLOP presenting for elective PCI were enrolled prospectively. Platelet reactivity was measured prior to PCI with the VerifyNow P2Y12 assay. HPR was defined as P2Y12 reaction units > 240, a level previously shown to optimally predict subsequent events. The following predictors were tested by univariate analysis (UA): age > 75, gender, ethnicity, body mass index > 30, DM, previous myocardial infarction, stroke, peripheral vascular disease, hypertension, hypercholesterolemia, renal function, smoking, Canadian Cardiovascular Society (CCS) class, LDL, HDL, triglycerides, and use of statins, beta-blockers (BBs), calcium channel blockers (CCBs), ACE inhibitors, ARBs, nitrates, or hormone replacement therapy (HRT). Multivariate analysis (MVA) was performed using forward stepwise logistical regression with candidate predictors having a p value of < 0.15 on UA.
Results: A total of 377 patients were studied. The average age was 66.8 + 10.6 years, 79% were male, and 34% had diabetes mellitus (DM). The univariate predictors of HPR entered into the MVA were ethnicity (univariate p=0.027), gender (p=0.034), renal dysfunction (p=0.041), HRT use (p=0.066). CCS class (p=0.076), BB use (p=0.078), smoking (p=0.11), and DM (p=0.11). Independent predictors of HPR were non-Caucasian ethnicity (odds ratio [OR] 2.6, 95% confidence interval [CI] 1.3-5.4, p=0.007), female gender (OR 1.8 [95% CI 1.8- 3.0], p=0.028), and smoking (OR 0.35 [95%CI 0.13-0.96], p=0.04).
Conclusions: In patients on maintenance CLOP, the only independent predictors of HPR were ethnicity, gender, and smoking status. Our findings are consistent with previous studies demonstrating a protective effect of smoking on platelet reactivity. We did not observe a relationship between HPR and concomitant medications, including CCBs. The independent contribution of ethnicity and gender to HPR suggest that HPR is driven primarily by genetic mechanisms in non-smokers.

I2.POSTER CONTRIBUTIONS

2516

Experimental Models

Monday, March 30, 2009, 9:30 a.m.-10:30 a.m.
Orange County Convention Center, West Hall D

9:30 a.m.

2516-760 **Decrease Of Neointimal Proliferation After Implantation of Activated Protein C (Xigris)-Coated Stent In Porcine Coronary Arteries**

Mariann Gyongyosi, Noemi Nyolczas, Aniko Posa, Zsolt Petrasi, Örs Petnehazy, Dietmar Glogar, Medical University of Vienna, Vienna, Austria, University of Kaposvar, Kaposvar, Hungary

Background: Activated protein C (APC) an endogenous protein that inhibits inflammation and thrombosis, promotes fibrinolysis and interrupts coagulation cascade. The aim of our study was to investigate the degree of neoinimal hyperplasia after stent implantation in pig coronary arteries after implantation of APC-coated stents
Methods: Ten domestic pigs underwent general anaesthesia and coronary angiography after loading dose of aspirin (100 mg) and clopidogrel (300 mg) and intravenous heparin. Five mg human recombinant APC (Drotrecogin alfa, Xigris, Eli Lilly) was prepared for 70% alcohol solution, followed by direct (non-polymeric) coating of 10 Yucon Pearl stents using the Translumina stent coating machine (T-SCM 2003) (2.6 ug/mm2 stent surface). The APC-coated and bare Yucon stents (BMS) were randomly implanted in the left anterior descending and circumflex arteries. During the 4-weeks follow-up (FUP), the animals were treated daily with dual antiplatelet therapy. After 1-month FUP, the development of neointimal hyperplasia was evaluated by angiography and histomorphometry. Coronary arteries were stained with mouse anti-human P-selectin antibody with a known cross-reaction with porcine to identifying activated endothelial cells at the injury site.
Results: There was no procedural complication or allergic reaction. Fibrin deposition and adventitial inflammation were significantly decreased in pigs with APC-coated stents as compared with BMS. Endothelialization was complete in both groups. At the FUP, significantly smaller neointimal area (0.98±0.92 vs 1.44±0.91 mm2, p=0.028) with higher lumen area (3.47±0.94 vs 3.06±0.91 mm2, p=0.046) and less %AS (22.2±21.2% vs 32.1±20.1%, p=0.034) was measured in APC-coated stents as compared with the BMS. P-selectin immunostaining revealed significantly less prevalence of activated endothelial cells in the neointima in the APC-group (4.6±1.9 vs 11.6±4.1/0.28 mm2, p<0.001).
Conclusions: Coating of stent with hrAPC (non-toxic, non-cytostatic drug) reduces thrombo-inflammatory responses, neointimal proliferation, and in-stent restenosis and offers a promising therapy to improve clinical outcomes of coronary stenting.

9:30 a.m.

2516-761 **Long-Term Biocompatibility of the Abluminally Coated Biolimus A9 Eluting Self Expandable Stent in a Porcine Coronary Artery Model**

Greg L. Kaluza, Gerard B. Conditt, Armando Tellez, Krzysztof Milewski, Akira Murata, Shigenobu Inami, David Wallace-Bradley, Kai Xu, Geng-Hua Yi, Jennifer C. McGregor, Brett Trauthen, Frank D. Kolodgie, Renu Virmani, Juan F. Granada, Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, New York, NY, CVPath Institute, Inc., Gaithersburg, MD

Background: The AXXESS stent is a novel self-expandable device specifically designed for bifurcation stenting. It is coated with a permanent primer layer consisting of parylene, and a bioabsorbable abluminal layer of polylactic acid and Biolimus A9 (~22 µg/mm of stent length). In this study, we aimed to determine the safety and vascular biocompatibility of the AXXESS Biolimus A9 (AxBA9) self-expandable nitinol stent in comparison to Cypher stent out to 180 days in the porcine coronary model.
Methods: A total of 147 coronary arteries in 56 animals were randomized to receive AxBA9, Axxess-BMS (AxBMS), Axxess-Parylene (AxP) and Cypher stents (SES). Ten animals were

terminated at 7 days, 15 at 30 days and 16 at 90 days (including 3 for SEM).
Results: At 7 days, SES and AxBA9 featured less endothelial coverage than AxBMS and AxP, but all stents were >75% covered, however, SES had significantly more uncovered struts than any Ax. At 30 days, the neointimal thickness was the lowest in AxBA9. The inflammation was minimal and the endothelialization nearly complete in all groups. Predictably, AxBA9 and SES had more residual fibrin that the other 2 Ax stents. At 90 and 180 days, the differences between SES and Ax stents were more evident. SES featured more luminal obstruction both angiographically (180-day % Diameter Stenosis 4±3% in AxBA9, 3±6% in AxBMS, 6±14% in AxP and 24±21% in the SES) and histologically (180-day neointimal thickness was the highest in SES (0.38±0.23), closely followed by AxP (0.22±0.19), AxBA9 (0.10±0.06) and AxBMS 0.10±0.04 (p=0.001)). This was predominatly due to higher prevalence of inflammation and granulomas in SES than in any Ax stent type,a difference even more pronounced at 180 days. Also, percentage of struts with residual fibrin at 90 days was higher in the SES (32.18±5.80%) compared to any of the Axxess stent groups (AxBA9= 7.44±9.45%, AxBMS= 0.77±1.85, AxP= 0.83±2.19, p=0.001); it normalized at 180 days.
Conclusion: In a porcine coronary model up to 180 days, the AXXESS Biolimus A9 self-expanding nitinol stent demonstrated at least comparable safety and efficacy as the benchmark Cypher stent.

9:30 a.m.

2516-762 **Vascular Safety of Overlapping Sirolimus-Eluting Reservoir Technology Stents in the Porcine Coronary Artery Model**

G. Sylvester Price, Jean-Martin Lapointe, Andrew Luk, Louis-George Guy, Gary Steese-Bradley, John Dooley, Campbell Rogers, Cordis Corporation, Warren, NJ, AccelLAB, Inc, Boisbriand, QC, Canada

Background: The Conor reservoir technology drug delivery stent platform uses biocompatible bioresorbable polymers programmed to erode safely within 90-120 days of stenting. Sirolimus has been incorporated into a poly-(lactic-co-glycolic) acid (PLGA) polymer matrix similar to that used in previous Conor stents. The sirolimus dose and in vivo release kinetics of NEVO™ prototype sirolimus-eluting stents (NEVO™; Menlo Park, CA) were tailored to be similar to CYPHER® stents (Cordis Corporation, Warren, NJ). Vascular healing of single NEVO™ prototype stents has been reported previously.
Methods: Overlapping pairs of NEVO™ prototype, of bare metal Conor (BMS; empty reservoir stents) and of CYPHER® stents were implanted in porcine left anterior descending, left circumflex and/or right coronary arteries for 30, 90, or 180 days. Quantitative coronary angiography, histopathology and histomorphometry were evaluated.
Results: All stents were endothelialized at 30 days. Peri-strut inflammation score in overlapping NEVO™ stent regions was minimal, and significantly lower than in BMS and CYPHER® controls at 30 days (NEVO™: 0.11 ± 0.06, CYPHER®: 1.14 ± 0.78, $p < 0.05$, BMS: 0.44 ± 0.13, $p < 0.05$). Inflammation remained minimal at 90 and 180 days; and did not differ between groups. There was no evidence of necrosis. As expected, peri-strut fibrin in overlapping NEVO™ stent regions was significantly greater than BMS but did not differ from CYPHER® stents at 30 days, and decreased progressively at 90 and 180 days. A similar pattern was observed in non-overlapping stented regions. Neointimal thickness in overlapping NEVO™ stent regions was significantly lower than BMS at 30 days (NEVO™: 0.28 ± 0.05 mm, CYPHER®: 0.41 ± 0.14 mm, BMS: 0.47 ± 0.12 mm, $p < 0.05$). At 90 and 180 days, there was no difference in neointimal thickness between stent groups.
Conclusions: NEVO™ prototype reservoir technology sirolimus delivery reduced intimal thickening and produced less inflammation than BMS, despite the presence at overlap sites of double sirolimus and bioresorbable polymer loads.

9:30 a.m.

2516-763 **Biolimus A9 Eluting Self Expandable Designated Bifurcation Stent in a Sheep Coronary Bifurcation Model: Long-Term Comparison to Provisional T-Stenting with Cypher Stents**

Greg L. Kaluza, Gerard B. Conditt, Armando Tellez, Krzysztof Milewski, Akira Murata, Shigenobu Inami, David Wallace-Bradley, Kai Xu, Geng-Hua Yi, Jennifer C. McGregor, Brett Trauthen, Frank D. Kolodgie, Renu Virmani, Juan F. Granada, Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, New York, NY, CVPath Institute, Inc., Gaithersburg, MD

Background: The AXXESS stent (AxBA9) is a novel self-expandable device aiming at a more anatomically correct reconstruction of the bifurcation than the current stenting techniques. It has a conical shape covering the entire proximal bifurcation area down to the carina, is coated with a bioresorbable abluminal top coat eluting Biolimus A9 (~22 µg/mm of stent length), and can be complemented with conventional stents in distal parent vessel and in side branch.
Methods: This 4-tier study evaluated by angiography and histology the structural integrity (fractures) of and arterial response to AxBA9/Cypher bifurcation stenting complemented by side branch PTCA or T-stenting vs. conventional Cypher stenting of the parent vessel complemented by side branch PTCA or T-stenting. In 45 sheep, 15 and 30 bifurcations were treated with one of these 4 options and followed up to 90 and 180 days, respectively.
Results: Collectively, out to 180 days, bifurcations receiving AXXESS/Cypher in the parent vessel and side branch PTCA had 0/12 stent fractures, while Cypher with side branch PTCA had 4/13 stent fractures. In bifurcations receiving AXXESS/Cypher in the parent vessel and side branch Cypher, there were 6/11 stent fractures, involving distal or side branch Cyphers only. Whereas, Cypher T-stented with another Cypher had 8/9 fractures. Fractures generally correlated with stenosis development and resulted in an increased incidence of side branch occlusions and aggravated stenosis in overlap areas and in Cypher stents used in distal vessels and/or side branches.
Conclusion: The sheep model allows for adequate simulation of complex stenting techniques commonly used clinically in bifurcation setting. AXXESS Biolimus A9 self-expanding nitinol bifurcation stent overlapped distally with Cypher shows superior structural integrity (no fractures) and favorable outcome in comparison to provisional T-stenting with Cypher stents out to 180 days in this model. As such, AXXESS stent seems an attractive, more anatomically compatible alternative to currently used stenting techniques with overlapping conventional stents.

I2.SYMPOSIUM

2624

i2.Complex Patients I: Diabetes, Renal Failure, Elderly, CHF

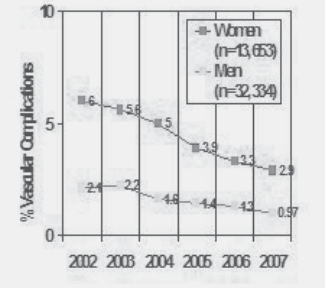
Monday, March 30, 2009, 10:30 a.m.-Noon
Orange County Convention Center, Room W415D

11:30 a.m.

2624-7 **Significantly Improved Vascular Complication Rates Among Women Undergoing PCI: Results From the Northern New England PCI Registry**

Bina Ahmed, Winthrop D. Piper, David Malenka, Peter VerLee, John Robb, Merle Kellet, Michael Hearne, Harold L. Dauerman, University of Vermont, Burlington, VT

Background: Female sex is associated with a higher risk for vascular complications (VC) and though the overall incidence of PCI related VC has declined, the impact of this decline specifically in women is unknown. **Methods:** We studied 13,653 female and 32,334 male consecutive cases, from 2002 to 2007, in the Northern New England (NNE) PCI Registry. Using multivariate regression, we compared absolute and adjusted rates of VC for women versus men over time and report clinical and procedural predictors of VC. VC was defined as any access site vessel injury requiring surgical intervention and/or any vascular site related bleeding requiring transfusion. **Results**: The overall risk of a VC was significantly higher in women versus men (4.5% ± 1.3 vs. 1.6% ± 0.5; $p<0.004$). Over time there was a significant (p trend < 0.001) 50% relative decrease in absolute VC rates in both women and men (see Figure). After adjustment for differences in baseline characteristics between men and women, women remained at a significant increased risk in 2007 (OR 2.6; CI 1.74-3.91). Predictors of increased risk of VC in women included older age, shock, renal failure, and larger sheath sizes while the use of routine fluoroscopy in obtaining vascular access and of closure devices were protective. **Conclusion:** Both women and men have had a significant 50% decline in VC rates over the last 6 years, though women remain at a two fold higher risk of VC. Use of routine fluoroscopy and closure devices are modifiable variables that are protective for both men and women.



I2.ORAL CONTRIBUTIONS

2907

AMI

Monday, March 30, 2009, 10:30 a.m.-Noon
Orange County Convention Center, Room W314B

10:30 a.m.

2907-5 **Impact of Chronic Kidney Disease on One-Year Outcomes of Patients With Acute Myocardial Infarction Undergoing Primary Angioplasty: Results From the HORIZONS AMI Trial**

Roxana Mehran, Eugenia Nikolsky, Alexandra Lansky, Bernard Witzenbichler, Giulio Guagliumi, Victor Guetta, Harry Suryapranata, Kurt Huber, Jochen Wöehrle, Chris Metzger, George D. Dangas, Iulian Benetato Giuran, Helen Parise, Gregg W. Stone, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

Background. In HORIZONS-AMI trial, bivalirudin monotherapy (Biv) vs. unfractionated heparin (UFH) + GP IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding and cardiac death, with comparable rates of composite major adverse cardiovascular

events (MACE), and enhanced freedom from net adverse clinical events (NACE; MACE or major bleeding) at 30 days and 1 year in pts with AMI undergoing primary PCI. Whether beneficial effects of Biv are independent of renal function has not been reported.
Methods and Results. A total of 3602 pts at 123 centers with AMI undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802). At 1 year in entire study population, Biv vs. UFH+GPI resulted in a 39% reduction in major bleeding (5.8% vs. 9.2%, P<0.0001), 43% less cardiac mortality (2.1% vs 3.8%, p=0.005), similar MACE (11.9% vs 11.9%, P=1.0), and a 16% reduction in NACE (15.7% vs 18.3%, P=0.03). Outcomes were analyzed according to the presence of baseline chronic kidney disease (CKD; calculated creatinine clearance ≤60 ml/min). Compared to pts with normal renal function, those with CKD (16% of pts) had greater rates (all P-values <0.0001) of major bleeding (16.2% vs 5.9%), MACE (20.8% vs 10.1%), cardiac mortality (8.6% vs. 1.8%), and NACE (30.3% vs 13.4%). No significant interactions were present between renal status and randomization arm (Table).
Conclusions. Patients with CKD and AMI undergoing primary PCI have significantly higher rates of major bleeding, cardiac mortality, and NACE at 1 year.

	Creatinine clearance >60 ml/min (n=2783)			Creatinine clearance ≤60 ml/min (n=554)		
	Biv mono	UFH+GPI	RR [95%CI]	Biv mono	UFH+GPI	RR [95%CI]
Major bleeding	4.3%	7.6%	0.50 [0.41, 0.77]	11.8%	14.7%	0.80 [0.52, 1.24]
MACE*	10.5%	9.8%	1.06 [0.84, 1.35]	12.6%	10.6%	1.19 [0.75, 1.88]
NACE**	13.3%	15.4%	0.84 [0.69, 1.02]	21.0%	21.2%	0.99 [0.72, 1.36]
Cardiac Death	0.9%	2.6%	0.35 [0.19, 0.67]	8.1%	9.0%	0.92 [0.51, 1.63]

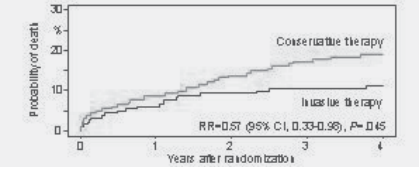
* MACE = death, reinfarction, ischemic TVR or stroke;
**NACE (Net Adverse Clinical Events) = MACE or major bleeding

10:42 a.m.

2907-6 Impact on Long-Term Mortality of Mechanical Reperfusion in Patients With Acute Myocardial Infarction Presenting 12 to 48 Hours From Onset of Symptoms

Julinda Mehilli, Gjin Ndrepepa, Adnan Kastrati, David Antoniucci, Albert Schomig, Deutsches Herzzentrum, Munich, Germany, 1. Med. Klinik rechts der Isar, Munich, Germany

Background: One-third of patients with acute ST-segment elevation myocardial infarction (STEMI) do not receive early reperfusion therapy mostly due to presentation >12 hours from the symptom onset and current guidelines do not recommend primary percutaneous coronary intervention in such patients (pts). The Beyond 12 hours Reperfusion AlternatiVe Evaluation (BRAVE-2) Trial showed that invasive treatment is associated with substantial reduction in infarct size in pts with STEMI presenting >12 hours after symptom onset. No studies to date have investigated the long-term prognosis after PPCI in such pts.
Methods: In BRAVE-2 trial 365 pts without persistent symptoms admitted with STEMI between 12 and 48 hours from symptom onset were randomly assigned to either an invasive treatment (PPCI) (n=182 pts) or a conservative treatment (n=183 pts). Primary outcome of the present analysis was 4-year mortality.
Results: At 4 years, significantly fewer pts died in invasive than in conservative treatment group (Figure). No difference in Kaplan-Meier estimates of myocardial infarction was observed (6.8% and 5.6%, RR=1.20, 95% CI 0.52 to 2.78, P=.66). Revascularization of the infarct-related artery was performed in 25.8% of pts treated inavsively and 69.1% of pts treated conservatively.
Conclusions: Reduction of infarct size and long-term mortality support the use of PPCI in pts with STEMI presenting between 12 and 48 hours after onset of symptoms.



10:54 a.m.

2907-7 Presentation and Outcomes After Percutaneous Intervention for Acute Myocardial Infarction in the NLHBI Dynamic Registry: Saphenous Vein Grafts Versus Native Coronary Arteries

Sohah N. Iqbal, Faith Selzer, Srihari S. Naidu, Serge Doucet, David Faxon, Alice Jacobs, James Slater, New York Langone Medical Center, New York, NY, University of Pittsburgh Medical Center, Pittsburgh, PA

Background: Percutaneous coronary intervention (PCI) of saphenous vein graft (SVG) lesions has a higher incidence of adverse events as compared with native coronary artery (NCA) interventions. Only limited data have been reported comparing interventions after myocardial infarctions (MI) in patients with SVG disease versus NCA lesions.
Methods: Consecutive patients enrolled in 4 recruitment waves (1999 -2006) in the multi-center prospective cohort study of the National Heart, Lung, and Blood Institute Dynamic Registry were studied. Baseline, angiographic and procedural data, in-hospital events, and 1-year outcomes of patients treated with PCI for acute MIs were compared based on whether the intervention was performed in a SVG (n = 101) or NCA (n = 2245).
Results: SVG patients were older (71 vs 61 years), had more renal disease (13.9% vs 6.0%), more peripheral arterial disease (22.8% vs 5.6%), more cerebrovascular disease (13.9% vs 6.1%), more diabetes (40.6% vs 25.5%) more previous MIs (54.2% vs 17.5%), more prior PCIs (37.6% vs 16.1%), more history of congestive heart failure (22.9% vs 7.5%), and lower mean % ejection fractions (44.3 vs 48.8) as compared with NCA interventions (p≤0.01 for all). The NCA patients presented more often with ST segment elevation MIs (55% vs 32%, p < 0.001). Peri-procedural use of ASA, thienopyridines, and glycoprotein IIb/IIIa inhibitors was similar in both groups. Angiographic success rate and stent use were similar, though more SVG lesions were treated with direct stenting as compared with NCA lesions (48.6% vs 22.5%, p< 0.001). In-hospital death, MI, and CABG were similar in both groups. At one year, there was no significant difference in repeat revascularization (hazard ratio [HR] = 0.96, p=0.89) and survival (HR for death = 1.66, p = 0.10), but there was a higher risk of MI (10.9% vs 4.7%, HR = 2.24, p = 0.01) in patients who had a SVG intervention.
Conclusions: Patients presenting with acute MI having PCI of SVGs are a higher risk population than patients having PCI of NCAs. Despite unfavorable baseline characteristics, there was no significant difference in in-hospital death or MI. At 1-year mortality is similar, but SVG PCI patients had two-fold higher risk for recurrent MI.

11:06 a.m.

2907-8 Abciximab in Patients With Acute Myocardial Infarction: One Year Outcomes in the BRAVE-3 Randomized Trial

K. Anette Birkmeier, Julinda Mehilli, Adnan Kastrati, Stefanie Schulz, Werner Moshage, Franz Dotzer, Jürgen Pache, Josef Dirschinger, Melchior Seyfarth, Albert Schömig, Deutsches Herzzentrum, Technische Universität, Munich, Germany, 1. Medizinische Klinik rechts der Isar, Munich, Germany

Background: In the Bavarian Reperfusion Alternatives Evaluation-3 (BRAVE-3) Trial, abciximab given after loading with 600 mg clopidogrel in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PPCI) within 24 hours after onset of symptoms was not associated with reduction of infarct size and thrombotic complications at 30 days. Previous studies investigating abciximab additional to PPCI in the era of ticlopidin therapy, have shown up to 30% mortality reduction at one year with abciximab. If this is also the case when abciximab is given after loading with 600 mg of clopidogrel is still not kown.
Methods: In BRAVE-3 study, which was a randomized , double-blind, placebo-controlled-trial, 800 patients with acute STEMI within 24 hours of symptoms onset, all treated with 600 mg of clopidogrel were assigned to receive either abciximab (=401) or placebo (n=399) in the intensive care unit before sent to the catheterization laboratory (96,4% underwent PPCI). Aim of the present analysis is assessment of all-cause mortality, recurrent myocardial infarction, stroke and reinterventions at one year after randomization.
Results: Results will be available in February 2009 and presented at the meeting.

11:18 a.m.

2907-9 Results of a Randomized Double-Blind Bolus Dose-Escalating Study Comparing Intracoronary to Intravenous Abciximab in Primary PCI : The EASY-MI Study.

Olivier F. Bertrand, Josep Rodes-Cabau, Eric Larose, Valérie Gaudreault, Rodrigo Bagour, Onil Gleeton, Can M. Nguyen, Guy Proulx, Gérald Barbeau, Bernard Noel, Louis Roy, Olivier Costerousse, Robert De Larochellière, Laval Hospital, Quebec Heart-Lung Institute, Quebec, QC, Canada

Background: Platelet aggregation inhibition (PAI) ≥ 95% has been associated with improved outcomes after PCI and GP IIb/IIIa inhibitors. Higher thrombotic burden in MI might require higher doses or intracoronary route of abciximab delivery to achieve optimal PAI. Whether these novel strategies would reduce myocardial necrosis is currently debated.
Objective: To compare Intracoronary (IC) to Intravenous (IV) routes of abciximab administration and to assess 2 bolus-doses : 0.30 mg/kg (bolus-only) vs 0.25 mg/kg bolus + standard 12 h infusion in patients referred for primary-PCI within 6 h of symptoms.
Methods: Using Verify Now (Accumetrics), PAI was assessed at baseline and 10 minutes post-bolus. All lesions were treated with Cypher Select® + stents. Assessment of cardiac necrosis and microvascular obstruction was performed using magnetic resonance imaging (MRI) within 12 hours of the procedure and at 6 months. Quantitative coronary analysis was performed after the index procedure and at 6 months.
Results:

Population Characteristics	Abciximab bolus dose and route				P
	0.30 mg/kg ic (n=25)	0.30 mg/kg iv (n=25)	0.25 mg/kg ic (n=28)	0.25 mg/kg iv (n=27)	
Age, yrs	59 ± 9	59 ± 11	59 ± 9	60 ± 7	0.99
Male	18 (72%)	19 (76%)	23 (82%)	24 (89%)	0.45
Symptoms-to-balloon, min	169 ± 88	188 ± 73	183 ± 58	162 ± 72	0.53
Culprit RCA	15 (63%)	10 (43%)	10 (38%)	18 (67%)	0.37
LAD	7 (29%)	12 (52%)	13 (50%)	8 (30%)	
CX	2 (8%)	1 (4%)	3 (12%)	1 (4%)	
TIMI flow (initial)					
0-1	17 (77%)	17 (77%)	19 (73%)	21 (81%)	0.99
Aspiration catheter	7 (28%)	12 (48%)	10 (36%)	11 (41%)	0.67
Primary End-points:					
Mean PAI 10 min, %	94.4 ± 6.1	94.0 ± 4.4	92.0 ± 8.1	94.0 ± 4.8	0.49
≥ 95% PAI 10 min	15 (60%)	13 (52%)	13 (46%)	15 (56%)	0.79

Conclusion: 10 minutes post-bolus, no difference in PAI was observed between standard or higher abciximab bolus dosing nor between intracoronary or intravenous delivery. Angiographic and MRI analyses will determine whether the standard abciximab infusion could be skipped and if intracoronary abciximab provides better myocardial salvage than intravenous delivery. Since the last patient was controlled in October 08, complete results will be available for presentation.

11:30 a.m.

2907-10 **Angiographic Findings and Door to Balloon Times at Hospitals With and Without Emergency Medicine Physician Cath Lab Activation: Insights From the National Cardiovascular Data Registry CathPCI Registry and the D2B Alliance**

Christopher Regan, Jeptha P. Curtis, Yongfei Wang, Elizabeth Bradley, Harlan Krumholz, Yale New Haven Hospital, New Haven, CT

Background: Allowing Emergency Medicine physicians to activate the catheterization lab reduces door to balloon (D2B) times. However, many hospitals have concerns that this policy would increase rates of inappropriate activation. To assess the overall impact of this strategy, we compared angiographic findings and D2B times of patients undergoing emergency catheterization for suspected STEMI at hospitals that did and did not allow EM activation.
Methods: We analyzed data from the NCDR CathPCI Registry to identify patients who underwent catheterization for suspected STEMI in hospitals enrolled in the D2B Alliance in 2006-7. The hospital's approach to activating the cath lab was classified as: cardiology alone makes the decision (EM Never), emergency medicine makes the decision in consultation with cardiology (EM Sometimes), and emergency medicine makes the decision without consultation with cardiology (EM Only). Outcomes, in separate models, included presence of significant stenosis or total occlusion, performance of a revascularization procedure, and proportion of patients with D2B time ≤90 minutes. To assess the independent association of ED activation with outcomes, we performed hierarchical multivariable analysis adjusting for demographics, cardiac status, comorbid conditions, and hospital characteristics.
Results: A total of 46,825 patients with suspected STEMI underwent catheterization at 513 CathPCI hospitals. In multivariable analysis, the strategy for activation was not associated with significant differences in the proportion of patients with a significant stenosis, the proportion with total occlusion, or the likelihood of undergoing revascularization (Table). In contrast, patients treated at "EM Only" hospitals, but not "EM Sometimes" hospitals, were more likely than patients treated at "EM Never" hospitals to have D2B times ≤90 minutes.
Conclusions: A strategy of EM cath lab activation is not associated with higher rates of false activation as assessed by measures of angiographic severity and need for revascularization. These findings support more widespread adoption of EM cath lab activation for STEMI patients.

	EM Never (n=17,357)	EM Sometimes (n=2,868)	EM Only (n=26,600)
Age (years)	61.0	60.4	60.6
Gender	28.5%	27.5%	28.3%
White	82.6%	83.6%	83.0%
Significant Stenosis	Ref	1.02 (1.00-1.03)	1.00 (1.00-1.01)
Total Occlusion	Ref	1.04 (1.00-1.07)	1.00 (0.98-1.02)
Revascularization	Ref	1.02 (0.99-1.03)	1.00 (0.99-1.02)
% D2B ≤90 min	Ref	1.01 (0.91-1.09)	1.08 (1.03-1.12)

I2.ORAL CONTRIBUTIONS

2909

Left Main

Monday, March 30, 2009, 2:00 p.m.-3:30 p.m.
Orange County Convention Center, Room W314B

2:00 p.m.

2909-5 **Sirolimus-Eluting Stent Versus Paclitaxel-Eluting Stent in Unprotected Left Main Coronary Artery Disease (MAIN-COMPARE Registry)**

Jong-Young Lee, Duk-Woo Park, Won-Jang Kim, Sung Sik Kim, Sung-Hwan Kim, Myong-Zoon Yi, Seung-Whan Lee, Young-Hak Kim, Cheol-Whan Lee, Myeong-Ki Hong, Seong-Wook Park, Seung-Jung Park, Asan medical center, Seoul, South Korea

Background: This study was aimed to evaluate outcomes of patients with unprotected left main coronary artery (LMCA) stenosis who were treated with most commonly used drug-eluting stent, Sirolimus-Eluting Stents (SES) and Paclitaxel-Eluting Stents (PES).
Methods: From May 2003 through June 2006, 858 consecutive patients with unprotected LMCA stenosis(50%>) in The MAIN-COMPARE registry were treated with SES in 669 (78%) patients and PES in 189 (22%) patients. Stent selection was decided on operator's discretion. Study end point were death, MI,Target Vessel Revascularization and MACE (composite of death, MI or TVR(TLR)).Mean follow-up duration was 864 ± 340 days. Procedural success was achieved in all patients.
Results: There were no significant differences in cumulative rates upto 3 years of death (SES vs PES : 9.1 vs 11.0%, Hazard Ratio 0.88, 95% Confidence Interval 0.49-1.56, p=0.66), Myocardial Infarction (7.8 vs 8.0%, HR 0.95, 95% CI 0.54-1.70, p=0.87), Target Vessel Revascularization (12.1% vs 10.6%, HR 1.27, 95% CI 0.64-2.51, p=0.49) and MACE (25.8 vs 25.7%, HR 1.02, 95% CI 0.71-1.49, p=0.90). After subsequent multivariable adjustment and/or Propensity-score adjustment, there were no significant differences. Renal failure (HR 3.28, 95% CI 2.00-5.39, p<0.001) was strongest independent preditors of MACE. Besides, Left Ventricular Ejection Fraction(%) (HR 0.99, 95% CI 0.97-1.00, p=0.04), IVUS guidance (HR 0.63, 95% CI 0.43-0.91, p=0.01), Total stent length (mm) (HR 1.01, 95% CI 1.001-1.02, p=0.03) and Complex bifurcation stenting (≥2 stents) (HR 1.54, 95% CI 1.02-2.34, p=0.04) were also meaningful independent predictors. The cumulative incidence of stent thrombosis (definite or probable by ARC definition) were 3 (0.6%) in the SES group versus 4 (1.6%) in the PES group (p=0.18).
Conclusions: There were no significant differences in cumulative rates of death, MI, TVR and MACE upto 3 years between patients with unprotected left main disease who underwent SES and those who underwent PES. Percutaneous coronary intervention with DES (SES or PES), acceptable long-term clinical results can be achieved, with no particular safety concerns about treatment of unprotected LM.

2:15 p.m.

2909-6 **Long-Term (4 Year) Outcome Following Drug Eluting Stent Implantation Versus Coronary Artery Bypass Surgery in Unprotected Left Main Coronary Artery Lesions**

Alaide Chieffo, Valeria Magni, Francesco Maesano, Alfonso Ielasi, Giorgio Bassanelli, Matteo Montorfano, Mauro Carlino, Azeem Latib, Cosmo Godino, Angela Ferrari, Giuseppe Sangiorgi, Ottavio Alfieri, Antonio Colombo, San Raffaele Scientific Institute, Milan, Italy

Background: One-year outcome following drug-eluting stent (DES) implantation versus coronary artery by-pass grafting (CABG) in unprotected left main coronary artery (LMCA) lesions have been previously reported from our center
Methods: All consecutive patients with an unprotected LMCA stenosis electively treated with DES implantation versus CABG in our Center, between March 2002 and July 2004, were analysed. Hierarchical study end points were occurrence at 4 years of: death; death and/or myocardial infarction (MI); death, MI and/or stroke; target vessel revascularization (TVR, defined as any revascularization in left coronary system); and major cardiac cerebrovascular events (MACCE). A propensity analysis was performed to adjust for baseline differences between the two cohorts.
Results: Two-hundred forty-nine patients were included in the study: 107 were treated with PCI and DES implantation and 142 with CABG. At 4 year-clinical follow-up, no difference was found between PCI and CABG in the occurrence of death (respectively 12.0% vs. 14.1%; adjusted OR=0.652; 95% CI=0.254 to 1.620; P=0.42). At adjusted analysis, PCI group showed a trend toward a lower occurrence of the composite endpoint of death and myocardial infarction (13.0% vs. 19.7%; adjusted OR=0.461; 95% CI=0.180 to 1.088; P=0.08). PCI was associated with a lower rate of the composite endpoint of death, MI and/or stroke (respectively 14.0% vs. 22.5%; adjusted OR=0.431; 95% CI=0.175 to 0.971; P=0.04). Indeed, CABG was correlated to lower TVR (8.4% vs. 28% ; adjusted OR= 5.928; 95% CI= 1.933- 38.0; p= 0.0003). No difference was detected in the occurrence of MACCE (in PCI 36.4% vs. 28.1% in CABG, adjusted OR=1.438; 95% CI=0.754 to 2.766; P=0.3007).
Conclusions: At 4 year-clinical follow-up, in this single-center experience, there was still no difference in the occurrence of MACCE between elective PCI with DES implantation and CABG in LMCA lesions. There was an advantage of PCI in the composite endpoint of death, MI and/or stroke, while a benefit in the need for reintervention was still found in CABG.

2:30 p.m.

2909-7 **Systematic Double Stenting Versus Simple Provisional T-Stenting for True Bifurcation Lesions of Left Main Coronary Artery Disease Using Drug Eluting Stents: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Purpose: The purpose of this study is to evaluate the long-term outcomes of systemic double stenting and provisional T-stenting technique that were used for treating true bifurcation lesions of left main coronary artery (LMT) disease with drug-eluting stents (DES, Sirolimus-eluting stent: SES and Paclitaxel-eluting stent: PES). **Methods**: A prospective Asian multicenter registry was set up in five high volumes Asian centers to evaluate the efficacy DES in the treatment of bifurcation lesions of LMT. A total of 507 patients, 507 lesions (male 72.0, mean age 68.9) with true bifurcation lesions (defined as a more than 50% stenosis in both LAD and LCX) were treated with 2 strategies: Systemic double stenting (n=306) (culotte 79, crush 21, mini-crush 122, kissing 8, T-stenting 76) and provisional T-stenting (n=201). All patients are evaluated immediate and long-term clinical results with 6 and 12 months coronary angiography. **Results**: The baseline clinical characteristics between 2 groups were similar. See table for clinical results. **Conclusion**: This study suggests that provisional T-stenting of the side branch is a feasible strategy associated with low MACE and low TLR in patients with LMT disease.

	Double stenting	Provisional stenting	p
Number of patients	306	201	-
30 days MACE (%)	0	0	-
6 months follow-up angiogram			
Restenosis (%)	15.7	12.4	NS
TLR (%)	13.1	6.0	0.03
12 months follow-up angiogram			
Restenosis (%)	17.0	14.9	NS
TLR (%)	15.0	8.3	0.04

2:45 p.m.

2909-8 **Left Main and Three Vessel Disease Stenting in Real World Settings: Results From the TAXUS OLYMPIA Registry**

Oscar A. Mendiz, Martyn R. Thomas, Waqar H. Ahmed, Katrin Leadley, Keith D. Dawkins, Fundación Favaloro, Buenos Aires, Argentina, Boston Scientific Corporation, Natick, MA

Background: Stenting of left main coronary artery (LM) or three vessel disease (3VD) is a topic of current debate. In the TAXUS OLYMPIA study, a prospective, web-based registry of patients (pts) receiving TAXUS Liberté stents, subgroups of LM and 3VD pts were enrolled. The outcomes of TAXUS Liberté stenting were examined in these pts.
Methods: OLYMPIA is a multi-center, post-approval registry capturing baseline data and outcomes in pts receiving the TAXUS Liberté paclitaxel-eluting stent in real world routine interventional cardiology practice. Enrollment and 12-month follow-up in 22,345 pts from 57 countries has been completed to date. Follow-up data are available for 692 pts with LM and 278 pts with 3VD stenting.
Results: Death was highest among pts following LM stenting (4.5%) (Table). The composite cardiac event (CE) rate, defined as cardiac death, myocardial infarction, or target vessel revascularization (TVR), was similar among pts with LM and 3-vessel stenting (7.7% vs 7.6%). In examining component CE, cardiac death was high in pts with LM stenting (3.3%) whereas revascularization rates were high in pts with 3-vessel stenting (6.5% TVR and 4.7% Target Lesion Revascularization, respectively). The rate of cardiac death was lowest in the 3-vessel stenting group (0.7%), even when compared with the overall cardiac death rate (1.4%).
Conclusions: These global registry data suggest that the TAXUS Liberté is safe and performs well in complex pts with LM and 3VD.

12-month outcomes of patients receiving TAXUS Liberté stents

	Overall (N=21,126)	LM Stenting* (N=692)	Three Vessel Stenting** (N=278)
Death	2.1	4.5	2.2
Composite CE***	4.4	7.7	7.6
Cardiac Death	1.4	3.3	0.7
MI	0.9	1.6	1.8
TVR (per patient)	3.1	4.8	6.5
TLR (per patient)	2.5	3.3	4.7
ST (per patient)	0.8****	1.0	1.4

Values reflect binary rates.
Outcomes adjudicated by an independent medical reviewer.
Abbreviations: LM=left main coronary artery; RCA=right coronary artery; LAD=left anterior descending artery; LCx=left circumflex artery; CE=cardiac event; MI=myocardial infarction; TVR=target vessel revascularization (reintervention of a target vessel); TLR=target lesion revascularization (TAXUS Liberté stent-related reintervention of a target vessel); ST=stent thrombosis (angiographically confirmed TAXUS Liberté stent thrombosis only)
*LM isolated stenting only
**Includes RCA, LAD, LCx, LM, and grafts
***A composite of cardiac death, MI (including Q- and non Q-wave MI) and reintervention of a target vessel (TVR)
****N=21,128 pts

3:00 p.m.

2909-9 **Three-Dimensional Bifurcation Angle in Patients With Left Main Disease: Impact on Long-Term Clinical Outcome Following Percutaneous Coronary Intervention**

Chrysafios Girasis, Yoshinobu Onuma, Neville Kukreja, Ron van Domburg, Patrick W. Serruys, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands

Background: Three-dimensional (3-D) quantitative coronary angiography (QCA) provides objective data on the bifurcation angle (BA). To appreciate their long-term prognostic value, we correlated the BA parameters to the 3-year clinical outcome of the Left Main (LM) population of the Thoraxcenter
Methods: Between January 1, 2000 and December 31, 2005, 207 consecutive patients underwent PCI for unprotected LM disease; 77 (37.2%) of them due to stable angina, 79 and 51 for unstable angina and myocardial infarction (MI) respectively. Cineangiograms were analyzed with 3-D QCA software (Cardiop-B, Paieon Medical Inc, Israel). The proximal BA (between LM and LCx) and the distal BA (between LAD and LCx) were computed in enddiastole and endsystole, both pre- and post-PCI. Annual follow-up on death and clinical events was collected for 3 years. The primary end-point was all-cause mortality. Secondary endpoints included MI, target vessel revascularization (TVR) and composite major adverse events (MACE: all-cause death, MI or TVR).
Results: Complete analysis was feasible in 136 (65.7%) patients. Only pre-PCI endsystolic distal BA predicted clinical outcome when stratified into tertiles, with a cut-off value of 71 degrees. Mortality and MACE rates were significantly lower in the first tertile, compared either to the third or to the pool of the other two tertiles. (table)
Conclusion: Pre-PCI endsystolic distal BA values wider than 71 degrees confer higher long-term mortality and MACE rates after PCI for LM disease.

3-year clinical event rates _ Pre-PCI endsystolic distal BA

	BA≤ 71°	BA=72-92°	BA≥93°	P value BA≤ 71° vs. BA≥93°	P value BA≤ 71° vs. BA>71°
All-cause mortality	16.4%	26.4%	36.9%	0.018	0.041
MI	9.8%	0.0%	4.7%	0.338	0.042
TVR	13.1%	23.0%	19.7%	0.297	0.183
Death+MI	20.2	26.4	38.9	0.037	0.102
MACE	28.4%	45.9%	52.6%	0.008	0.011

Log rank test, pairwise comparisons over strata, p<0.05 significant. BA values in degrees

I2.POSTER CONTRIBUTIONS

2517

PCI - Bifurcations

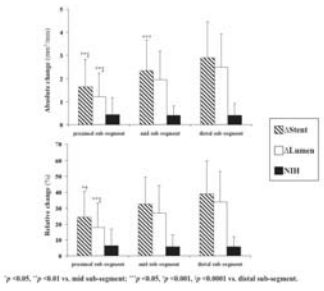
Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2517-764 **Intravascular Ultrasound Findings from the DIVERGE Trial: Serial Volumetric Analysis of the Biolimus A9-Eluting AXXESS Self-Expanding Stent for the Treatment of Bifurcation Coronary Lesions**

Takao Hasegawa, Junya Ako, Bon-Kwon Koo, Hyeonsoo Chang, Stefan Verheye, Joseph Dens, John Ormiston, Dougal McClean, Stephen Worthley, Yasuhiro Honda, Peter J. Fitzgerald, Stanford University Medical Center, Stanford, CA

Background: The AXXESS system is a Biolimus A9-eluting self-expanding stent, dedicated to the treatment of bifurcation coronary lesions. The aim of this study was to assess the efficacy of the AXXESS stent on the treatment of bifurcation coronary lesions using serial IVUS.
Methods: Data were obtained from the DIVERGE trial to evaluate the efficacy of the combination of AXXESS and sirolimus-eluting (SES) for the treatment of bifurcation coronary lesions. Nine-month follow-up IVUS was available in 60 cases, enabling 56 serial comparisons between post-procedure and follow-up. Volumetric and/or cross-sectional analyses within both the AXXESS stent and SES and cross-sectional analyses at the branch ostia were performed.
Results: At follow up, percent neointimal volume was 4.3 ± 5.0% within the AXXESS stent and minimal lumen area of 7.2 ± 2.3 mm^2. The self-expanding AXXESS stent volume increased 29.7% at follow-up compared with post-procedure (p<0.0001), leading to a corresponding 26% increase in lumen volume (p<0.0001). Absolute and relative stent volume changes during the follow-up period were greater in more distal part of the AXXESS stent, however this late stent enlargement did not exaggerate more neointimal growth (Figure). At follow-up, lumen area was 4.0 ± 1.3 mm^2 at main branch ostium and 3.6 ± 1.3 mm^2 at side branch ostium.
Conclusion: The combination of the AXXESS and SES demonstrated effective lesion coverage with significant neointimal suppression in the treatment of coronary bifurcation lesions.



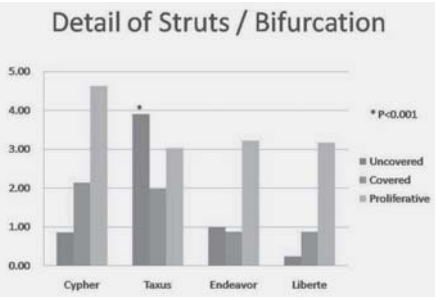
3:30 p.m.

2517-765 **Optical Coherence Tomography (OCT) for evaluation of strut healing at coronary bifurcations 6 months after deployment.**

Hiroyuki Kyono, Giulio Guagliumi, Vasile Sirbu, Noah Rosenthal, Satoko Tahara, Giuseppe Musumeci, Antonio Trivisonno, Hiram G. Bezerra, Marco A. Costa, University Hospitals Harrington-McLaughlin Heart & Vascular Institute, Cleveland, OH, Ospedali Riuniti di Bergamo, Bergamo, Italy

Background: Stent deployment in bifurcation lesions has been associated with a higher incidence of stent thrombosis in the drug eluting stent (DES) era. However, the mechanisms of this phenomenon are still unclear. We sought to evaluate coverage of floating stent struts located in bifurcated lesions by means of OCT.
Methods: The ODESSA trial was a prospective randomized trial designed to evaluate healing of overlapped drug-eluting vs. bare metal stents for de novo coronary artery stenosis. All cases underwent OCT imaging at a 6 month follow-up. Strut-level analysis was performed by an independent core laboratory. All floating struts at a bifurcation

segment were classified for coverage as: Uncovered (U), Covered (C), Proliferative (P), defined by tissue extending to an adjacent strut.
Results: 196 jailed bifurcations with 1416 floating struts from 75 patients (SES: 20, PES: 22, ZES: 22, Liberte BMS: 11) were analyzed. The average numbers of floating struts per bifurcation were: 7.62 in SES, 8.91 in PES, 5.11 in ZES, and 4.28 in BMS (p=0.090). PES showed larger number of uncovered struts (Graph).
Conclusions: This study suggests that delayed coverage at jailed bifurcations occurs more frequently in PES than in BMS and other DES platforms. Different DES drug properties and retention times might have impact on different levels of strut coverage. Coverage of floating bifurcation struts appears to follow a different pattern than that observed in struts deployed in non-bifurcation coronary segments.



3:30 p.m.

2517-766 **Serial Intravascular Ultrasound Analysis of Main and Side Branches in Bifurcation Lesions Treated with T-Stenting Technique**

Hahn Joo-Yong, Young Bin Song, Sang-Yup Lee, Seung-Hyuk Choi, Jin-Ho Choi, Young Keun On, Duk Kyung Kim, Sang Hoon Lee, Hyeon-Cheol Gwon, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea

Background: Restenosis rates after percutaneous coronary intervention on bifurcation lesions are high. However, the mechanism of restenosis, especially at the ostium of side branch (SB), has not been fully elucidated.
Methods and Results: We analyzed 73 bifurcation lesions treated with drug-eluting stents by T-stenting technique and with the available post-procedural and 9-month follow-up intravascular ultrasound images for both main vessel (MV) and SB. Analysis included 5 distinct locations: MV proximal stent, MV middle area, MV distal stent, SB ostium (<5 mm distal to the neo-carina), and SB distal stent. Stent expansion was less significantly in the SB than the MV (6.1±1.9 mm^2 versus 4.7±1.8 mm^2, P<0.001 and 87.1±20.4% versus 97.0±29.1%, P=0.007, respectively). The SB ostium was the most frequent site of post-procedural MSA. At the SB ostium, follow-up minimum lumen area (MLA) correlated with post-procedural MSA (r=0.81, P<0.001). Percentage of neointimal hyperplasia was higher at the SB ostium than the MV proximal, MV distal, and SB distal stent (23.8±18.9% versus 13.3±17.3%, 15.4±20.5%, and 12.5±17.2%, P<0.001). Optimal threshold of post-procedural MSA to predict follow-up MLA ≥4 mm^2 at the SB ostium was 4.83 mm^2 yielding an area under the curve of 0.88 (95% CI, 0.80 to 0.95).
Conclusions: Both inadequate post-procedural MSA and increased neointimal hyperplasia may make the SB ostium the most frequent site of restenosis after coronary bifurcation stenting. Our data suggest that obtaining adequate post-procedural MSA is crucial in avoiding restenosis at the SB ostium.

3:30 p.m.

2517-767 **Stent Strut Apposition in Coronary Bifurcation Lesions assessed with Optical Coherence Tomography.**

Giuseppe Ferrante, Nandakumar Ramasami, Pawel Tyczynski, Neville Kukreja, Pablo Aguiar-Souto, Francesca Del Furia, Peter Barlis, Kevin Beatt, Carlo Di Mario, Royal Brompton Hospital, London, United Kingdom, Mayday University Hospital, London, United Kingdom

Background: Several techniques have been introduced for the treatment of coronary bifurcation lesions, but there is still concern that malapposition may lead to an increased risk of late stent thrombosis. Optical coherence tomography (OCT), due to its high spatial resolution, allows accurate evaluation of strut apposition.
Methods: Consecutive patients, undergoing elective angioplasty for the treatment of coronary bifurcation lesions, with stenting of the main vessel only and kissing balloon dilatation of the side branch (simple strategy) or stenting of both main vessel and side branch with kissing balloon, were enrolled. Drug eluting stents and dedicated stents for the bifurcations: Tryton stent, Tryreme Antares stent were used. OCT was performed with a non-occlusive technique, with 1 to 3 mm/sec pullback speed. Cross-sectional images were analyzed every 450 microns. Strut apposition was assessed in three segments: bifurcation, divided into two 180 degrees quadrants: towards (1) or opposite (2) to the origin of the side-branch (SB), proximal segment and distal segment (both extending up to 2 mm from the first cross-section when the SB is visible). Stent struts were defined as malapposed if the strut/vessel wall separation distance was ≥ thickness of the strut.
Results: Twenty-nine patients, 33 bifurcation lesions, Left Anterior Descending-Diagonal (18), Left Circumflex-Obtuse Marginal (13), Left main (1), Posterior Descending-Posterolateral (1), 17 treated with the simple strategy, 15 with culotte technique, 1 with V-stenting were enrolled. Of 4871 stent struts assessed, 839 (17.2%) were malapposed. The prevalence of malapposition was higher in the bifurcation [23.2% (368/1585)] compared to the proximal [17.6% (297/1682)] or distal segment [10.8% (174/1604] (p<0.0001). The highest strut/vessel wall separation distance was detected in quadrant 1 [265 μ median, interquartile range (IQR) (180-430 μ)] compared to quadrant 2 [190 μ, IQR (140-255)], proximal [190 μ, IQR (160-250)] or distal segment [185 μ, IQR (160-280)] (p=0.0001).
Conclusions: In coronary bifurcation lesions, strut malapposition is more frequent at the bifurcation site and more severe towards the SB origin.

3:30 p.m.

2517-768 **Intravascular Ultrasound Evaluation of Complex Bifurcation Lesions Treated with Tryton Side-Branch Stent in Conjunction with Everolimus-eluting Stents.**

Daniela Trabattoni, Franco Fabbiocchi, Piero Montorsi, Stefano Galli, Paolo Ravagnani, Alessandro Lualdi, Luca Grancini, Antonio L. Bartorelli, Centro Cardiologico Monzino, IRCCS, Milan, Italy

Background: The Tryton Stent (TSBS) was designed to treat complex bifurcation lesions (BL). The results of FIM study demonstrated safety and feasibility and low restenosis at 6-month angiographic follow-up. **Methods:** TSBS is a balloon-expandable bare-metal stent with a distal zone that scaffolds the side-branch ostium and a proximal zone consisting of three fronds that terminate in a circumferential band. After deployment in the side branch, any stent can be advanced in the main branch across the TSBS proximal zone to complete the bifurcation architecture.TSBS was used in conjunction with Xience V stents in 9 LAD-diagonal and 1 LCx-obtuse marginal BL. By Medina classification, eight BL were 1,1,1, one was 1,1,0 and one 0,1,0. The lesion angle was <30° in 5, >30° and <45° in 4 and >45° in 1. Kissing balloon was performed in all cases. TSBS results were assessed by IVUS in 10 patients (7 men, age 66±11 years) and compared with those reported with the "crush" technique. **Results:** All TSBS and Xience V stents were correctly implanted in BL side branch and main vessel. Angiographic and procedural success was 100%. Table shows the postprocedural IVUS results in comparison to those previously published with the "crush" technique in BL. Six-month angiographic and IVUS follow-up will be presented. **Conclusions:** These IVUS results may explain the low restenosis rate observed in the FIM study and suggest that TSBS provides a reliable and reproducible strategy to stent the side branch and its origin.

	Tryton n=10	Crush# n=15
SB ostium MSA	4.71 ±1.05	4.2 ± 1.0
SB distal MSA	4.45 ±1.1	4.5 ± 2.3
SB Stent CSA <4 mm2	21%	55%
SB Stent CSA <5 mm2	66%	90%
SB Dmin/Dmax	0.83	N/A

#JACC 2005;46:599-605

3:30 p.m.

2517-769 **First Human Use of the TAXUS Petal Paclitaxel-Eluting Bifurcation Stent**

John Ormiston, Thierry Lefèvre, Eberhard Grube, Dominic Allocco, Keith Dawkins, Donald Baim, Mercy Angiography Unit Ltd, Auckland, New Zealand, Boston Scientific Corporation, Natick, MA

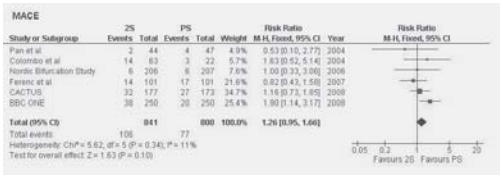
Background: Patients who undergo stenting for the treatment of coronary bifurcation lesions have an increased risk of subsequent adverse events compared with patients treated for non-bifurcation lesions. The TAXUS Petal paclitaxel-eluting bifurcation stent was specifically designed for the treatment of bifurcation lesions and may result in improved outcomes.
The aim of this single-arm, prospective, first-in-human study was to evaluate the safety and feasibility of this novel bifurcation stent.
Methods: A total of 28 patients with coronary bifurcation lesions were enrolled at three sites in Europe and New Zealand. Inclusion criteria were lesion length ≤20 mm and reference vessel diameter (RVD) between 3.0-3.5 mm in the main branch (MB) and lesion length ≤14 mm and RVD between 2.5-3.5 mm in the side branch (SB). Patients with stable or unstable angina and who had left ventricular ejection fraction ≥40 % were eligible for inclusion. The primary endpoint was a 30-day composite of death, myocardial infarction (MI), and target vessel revascularization (TVR). Complete 30-day results are reported below; six month clinical and angiographic follow-up is ongoing and will be available for all patients by ACC 2009.
Results: The mean age was 60.9±9.3 years with diabetes mellitus frequency of 17.9%. The treated lesion involved an LAD/diagonal bifurcation in 78.6% of patients. RVD, measured by an external core lab, was 2.91±0.28 mm in the MB and 2.23±0.33 mm in the SB. Seventy-five percent, 78.6% and 35.7% of patients had significant proximal MB, distal MB and SB disease, respectively. A Petal stent was successfully implanted in 25/28 (89.3 %) patients. A SB stent was placed in 25% of patients. Post procedure in-segment mean percent diameter stenosis was 23.6±9.1% in the MB and 23.1±13.7% in the SB. The rates of death, MI, and TVR at 30 days were 0%, 3.7% (1/27, NQWMI on day 0), and 0% respectively. No stent thromboses were reported.
Conclusions: Treatment of bifurcation lesions with the TAXUS Petal stent is feasible, with good clinical outcomes through 30 days. Further study in a larger number of patients is needed to better evaluate outcomes with this device.

3:30 p.m.

2517-770 **What is the optimal PCI strategy (two stents vs. provisional) for coronary artery bifurcation lesions? Meta-analysis of randomized trials**

Abdul Hakeem, Faisal M. Khan, Sabha Bhatti, Zainab Samad, Mark H. Eckman, Tarek Helmy, University of Cincinnati Hospital, Cincinnati, OH, Duke University Medical Center, Durham, NC

Background: To assess the optimal PCI approach for coronary bifurcation lesions (CBL), we conducted a meta-analysis of randomized trials comparing two stent (2S) to provisional (PS) strategy.
Data Sources: PubMed, Cochrane Register of Controlled Trials, conference proceedings, and Internet-based sources of clinical trials.
Results: Six randomized trials , including 1641 patients met the selection criteria for Meta analysis. There were no differences in clinical profile between the two groups. No significant heterogeneity was found across trials. There was no difference in the reference vessel diameters (mm) of main vessel (MV) [2.73±0.41(2S); 2.7±0.44 (PS) (p=0.77)] and side branch (SB) [2.31+0.33 (2S); 2.27+0.34 (PS) (p= 0.3)].Incidence of Myocardial infarction (MI) was significantly higher in the 2 S group compared to PS. (6.7% vs. 3.6%; RR 1.75 (1.14-2.68); p=0.01) however ,there was no difference in other outcomes between the two approaches (2S vs. PS) including total MACE [12.6% vs. 9.6%;RR 1.26 (0.95-1.66);p= 0.1] , death [1.07% vs. 1.1%;RR 0.93 (0.37 - 2.33);p=0.87,stent thrombosis(ST) (1.8% vs. 0.8%;RR 1.6(0.65-3.9);p=0.3) target lesion revascularization(TLR) [6% vs. 5.4%;RR 1.1 (0.73-1.64);p=0.66] ,MV restenosis [4.9% vs. 5%;RR 0.98 (0.58 to 1.67;p=0.93] and SB restenosis [13.8% vs. 13.8% ;RR 1 (0.68 - 0.98);p=0.9] at a mean follow up of 9 months.
Conclusion: A 2S strategy for CBL had a significantly higher risk of MI compared to PS group. Rates of death, ST, restenosis and TLR were similar.

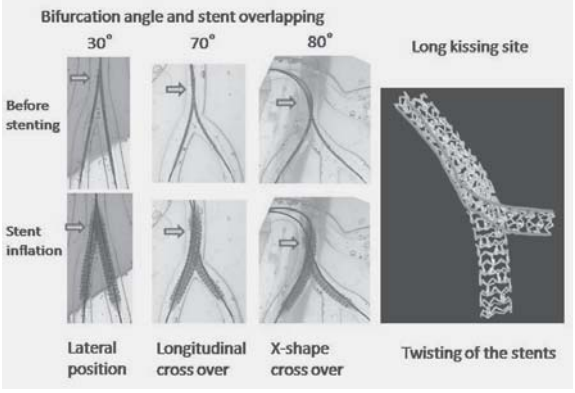


3:30 p.m.

2517-771 **Stent deformation and vessel dilation after simultaneous kissing stenting in the 3-dimensional coronary bifurcation model**

Yoshinobu Murasato, Yutaka Hikichi, Masataka Horiuchi, New Yukuhashi Hospital, Yukuhashi, Japan, Saga University, Saga, Japan

Background: We investigated how stents expanded in the proximal main vessel (MV) after simultaneous kissing stenting (SKS). We also compared the difference between SKS and single stenting with kissing balloon inflation (SSKB).
Methods: Various SKSs were performed in the 3-dimensional left main coronary artery (LMCA) models with the following conditions: same size stents; different size stents; long kissing site; 45 and 90 degrees of bifurcation angle. SKS and SSKB techniques were compared after the stent implantation in various models of bifurcation angles. The stents were analyzed by micro-focus CT or magnified macroscopic inspection.
Results: The lateral position of the two stents was maintained in the low-angle bifurcation model, whereas the stents overlapped longitudinally according to the degree of the bifurcation angle and finally becoming an x-shape. When the different size stents were used in the 3-dimensional LMCA model, the LCX stent overlapped the LAD stent and was compressed. However, when the same size stents were used, the compression was not observed. The long kissing site caused the twisting of the stents in the proximal MV area. In each experimental model, SKS showed higher values in both short axis distance and dilated area than those in SSKB.
Conclusions: Stent overlap in a high-angle bifurcation leads to a gap formation and stent distortion after SKS. SKS has a potential risk of over dilation in the proximal MV compared to SSKB.



I2.POSTER CONTRIBUTIONS

2518

PCI - Chronic Total Occlusions

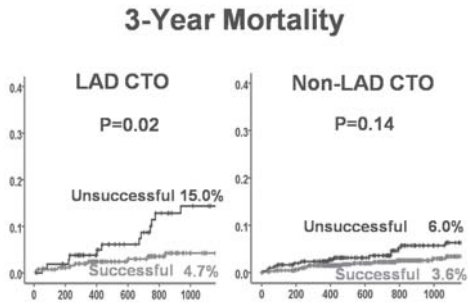
Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2518-772 **Clinical Impact of Percutaneous Coronary Intervention in Totally Occluded Left Anterior Descending Artery**

Cosmo Godino, Roxana Mehran, George D. Dangas, Kotaro Obunai, Martin B. Leon, Gregg W. Stone, Jeffrey W. Moses, Somjot Brar, Riccardo Colantonio, Matteo Montorfano, Mauro Carlino, Alaide Chieffo, Antonio Colombo, San Raffaele Hospital, Milan, Italy, New York Presbyterian-Columbia University Medical Center, New York, NY

Background: The clinical outcome after percutaneous coronary intervention (PCI) of chronic total occlusions (CTO) may differ according to the target myocardial distribution. We investigated whether PCI of left anterior descending artery (LAD) CTO has a greater clinical impact compared to the PCI of non-LAD CTO.
Methods: In a prospective PCI database, we analyzed clinical outcomes in 1,341 consecutive patients with 1,362 CTO who underwent PCI at three tertiary care centers in the US and Italy between January 2000 and May 2007.
Results: Successful PCI was achieved in 921 (67.7%) CTO cases. Of these, stents were used in 825 CTO (89.6%), including 555 CTO (60.3%) treated with DES. There were no significant differences in age, baseline left ventricular function, and history of prior myocardial infarction between groups. Kaplan-Meier analysis demonstrated low mortality rates during 3-year follow-up in both successful LAD CTO (4.7%) and successful non-LAD CTO groups (3.6%)(p=0.51). However, significantly higher mortality rate was observed in unsuccessful LAD CTO group compared to successful LAD CTO (15.0% vs. 4.7%, p=0.02) (Figure) and unsuccessful non-LAD CTO (15.0 vs. 6.0%, p=0.05) groups.
Conclusions: The LAD location appears to be important for clinical outcome after CTO PCI. Patients who had unsuccessful PCI of LAD CTO had significantly worse outcome than those with successful attempt, whereas the same was not detected in non-LAD CTO locations.



3:30 p.m.

2518-773 **Procedural and In Hospital Outcomes After Percutaneous Coronary Intervention for Chronic Total Occlusions of Coronary Arteries - 2002-2008: Impact of Novel Guide Wire Techniques**

SUDHIR RATHORE, Hitoshi Matsuo, Mitsuyasu Terashima, Masashi Kimura, Yoshihisa Kinoshita, Kenya Nasu, Mariko Ehara, Etsuo Tsuchikane, Yasushi Asakura, Osamu Katoh, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Objectives: The aim of this study was to examine the procedural success and in-hospital outcomes after percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) in current era during contemporary practice.
Background: The technique of PCI has improved over time with introduction of novel equipment and guide wire crossing techniques. However, there is limited data available from contemporary practice in the recent years.
Methods: We evaluated the procedural and in-hospital outcomes in consecutive series of 904 procedures between 2002 and 2008 performed at Toyohashi Heart Centre for PCI of CTO of > 3 months in duration.
Results: Technical and procedural success were achieved in 87.5% and 86.2% respectively. Baseline demographics was similar between successful and failure groups.86% patients had previous MI and 15% had previous CABG, and is similar in both groups. Target vessel was RCA in 38%, LAD in 28%, LCx in 20% and the branch vessel in 9% of the patients. Side branch at CTO site, severe calcification and severe tortuosity was seen in 15%, 11% and 5% cases, respectively. Single antegrade wire was the predominant strategy for guide wire crossing, however, retrograde guide wire crossing was used in 7.2% of the cases and controlled antegrade and retrograde sub-intimal tracking (CART) in 9.9% of the cases as the final strategy. Logistic regression analysis identified severe tortuosity (HR, 2.30; CI, 1.26-4.18, p=.006) and moderate to severe calcification (HR, 1.95, CI; 1.19-3.21, p=.008) as significant predictors of procedural failure. In- hospital MACE (Death, CABG, & QMI) occurred in 17(1.9%) and NQMI in 22 (2.4%) of the patients.

Conclusions: This is the first reported large series of patients undergoing PCI for CTO of the coronary arteries with improved wire crossing techniques. We have reported high success rate in recent years and low complication rates despite the use of more aggressive devices and techniques.

3:30 p.m.

2518-774 **Drug-Eluting Stents for the Treatment of Chronic Total Occlusion: A Comparison with Sirolimus, Paclitaxel, Zotarolimus, EPC Capture and Everolimus-Eluting Stent: Multicenter Registry in Asia**

Sunao Nakamura, Shotaro Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the safety and efficacy of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES), EPC capture (ECS) and Everolimus-eluting stent (EES) on the outcome of patients with chronic total occlusion (CTO). **Methods:** A prospective analysis of 1082 patients with 1183 CTOs (396 SES, 526 PES, 177 ZES, 41 ECS, 43 EES) in five high volume Asian centers after successful recanalization of CTO was performed. The study endpoints were 30 days and 9 months major adverse cardiac events (MACE), 9 months angiographic restenosis and target lesion revascularization (TLR). **Results:** See table for clinical results. **Conclusion:** The use of drug-eluting stents in patients with CTO was safe with low acute complication. Patients treated with SES and EES showed lesser rate of restenosis compared with other drug-eluting stents.

	SES	PES	ZES	ECS	EES
Number of patients/lesions	365/396	482/526	154/177	39/41	42/43
LAD/LCX/RCA (%)	54/26/20	52/22/26	89/138/50	21/9/9	25/7/11
Procedural success (%)	100	100	100	100	100
MACE at 30 days (%)	0	0.4	0.6	0	0
Proximal reference diameter (mean: mm)	2.86	2.80	2.83	2.90	2.88
Minimum lumen diameter post procedure (mean: mm)	2.65	2.54	2.59	2.60	2.68
Minimum lumen diameter at 9 months (mean: mm)	2.55	2.33	2.09	2.34	2.59
Restenosis rate at 9 months (%)	4.0*	6.7	12.3	12.8	4.8*
TLR at 9 months (%)	3.6*	6.7	10.4	10.3	2.4*
MACE at 9 months (%)	3.6*	6.7	10.4	10.3	2.4*

*p<0.05 vs ZES, ECS

3:30 p.m.

2518-775 **Serial Angiographic Follow-Up after Successful Implantation of Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent for Chronic Total Occlusions: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Purpose: To evaluate the long-term efficacy of Sirolimus-eluting stent (SES) and Paclitaxel-eluting stent (PES) on the outcome of patients with chronic total occlusions (CTO). **Methods:** A total of 210 patients with 232 CTO lesions (male 70.5%, mean age 70.8 yrs, LAD 50.9%, LCX 21.6%, RCA 25.0%, Others 2.5%) were treated with SES (102 patients 118 lesions, mean lesion length 36.1±12.9 mm, mean stent length 41.7±15.6mm) and PES (108 patients 114 lesions, mean lesion length 38.5±12.8 mm, mean stent length 43.9±19.5 mm). We conducted follow-up coronary angiogram in all patients after successful implantation of SES and PES (9, 12, 18, 24 months respectively) **Results:** The baseline clinical characteristics between 2 groups were similar. See table for clinical results. **Conclusion:** There is a different timing of late catch up phenomenon (late lumen loss) of SES and PES (SES: 12-18 months, PES: 9-12 months) after successful implantation of SES and PES in patients with chronic total occlusion. Patients treated with SES showed lesser loss of minimum lumen diameter compared with PES.

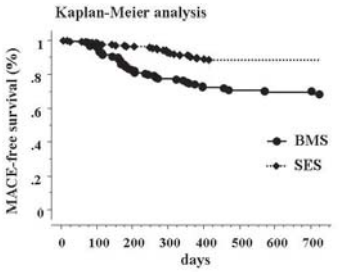
	SES	PES
Number of patients/lesions	102/118	108/114
Procedural success (%)	100	100
MACE at 30 days (%)	1.0 (1 Stent thrombosis)	0.9 (1 Stent thrombosis)
Proximal reference diameter (mm)	2.87±0.78	2.82±0.84
Minimum lumen diameter post procedure (mm)	2.62±0.77	2.60±0.79
Minimum lumen diameter at 9 months (mm)	2.50±0.80	2.29±0.74*
Minimum lumen diameter at 12 months (mm)	2.49±0.79	2.10±0.75*
Minimum lumen diameter at 18 months (mm)	2.31±0.83	2.08±0.79*
Minimum lumen diameter at 24 months (mm)	2.29±0.76	2.06±0.83*
*p<0.05 vs SES		

3:30 p.m.

2518-776 **The Long-Term Outcome for Patients with Chronic Total Occlusion Treated with Sirolimus-Eluting Stent:Japanese Multi-center Registry**

Hiroshi Fujita, Mitsuyasu Terashima, Masaharu Okada, Kunihiro Kosuga, Shigeru Nakamura, Tomoko Kobayashi, Ichiro Hamanaka, Etsuo Tsuchikane, Osamu Kato, Takahiko Suzuki, Eisho Kyo, Kinzo Ueda, Toyohashi Heart Center, Toyohashi, Aichi, Japan

Background: The long-term outcome for patients following successful percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) has not been well examined. This multi-center registry was conducted to investigate 2 years outcome for patients with CTO treated with DES, compared to BMS.
Methods: A total of 482 patients with CTO lesions (n=500) were treated with either Sirolimus-Eluting Stent (SES: n=337) or Bare Metal Stent (BMS: n=163). We compared the incidence of MACE (cardiac death, myocardial infarction, congestive heart failure, and target lesion revascularization: TLR) at 2 years follow-up between 2 groups.
Results: Overall MACE including TLR at 2-years was less frequent in DES group than that in BMS group (16% vs. 33% $p < 0.05$). The incidence of TLR was significantly lower in DES group than that in BMS group (12% vs. 31%; $p < 0.05$). Therefore, incidences of MACE without TLR were similar between 2 groups. The probabilities of freedom from MACE at 24 months were 71% in the BMS group and 89% in the DES group ($p < 0.0001$). (Figure)
Conclusions: Resulting from decrease in TLR, the introduction of DES in the treatment of CTO lesions was associated with reduction of incidence of overall MACE, compared to BMS.



I2.POSTER CONTRIBUTIONS

2519

PCI - Complex Lesions

Monday, March 30, 2009, 3:30 p.m.-3:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2519-777 **Impact of Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent on the Outcome of Patients with Sirolimus-Eluting Stent Failure: Multicenter Registry in Asia**

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Purpose: To evaluate the Sirolimus-eluting stent (SES) and Paclitaxel-eluting stent (PES) on the outcome of patients with SES failure (SES-F). **Methods:** A total of 520 patients with 609 SES-F lesions (male 74.8%, mean age 72.1 yrs, LMT 7.1%, LAD 47.6%, LCX 25.0%, RCA 16.2%, SVG 4.1%) were treated with SES (mean lesion length 26.1±12.6 mm, mean stent length 31.3±15.9mm) and PES (mean lesion length 28.3±12.2 mm, mean stent length 32.9±19.3 mm). We evaluate immediate and long-term clinical results by 6 and 12 months angiography. **Results:** The baseline clinical characteristics between 2 groups were similar. See table for clinical results. **Conclusion:** The use of SES and PES in patients with restenosis after SES implantation was safe with low complications. Patients treated with SES showed lesser rate of restenosis compared with PES.

	SES	PES
Number of patients/lesions	256/314	264/295
Procedural success (%)	100	100
MACE at 30 days (%)	0.6	1.1 (Stent thrombosis 2 cases)
Proximal reference diameter (mm)	2.96±0.79	2.83±0.80
Minimum lumen diameter post procedure (mm)	2.66±0.90	2.64±0.74
Minimum lumen diameter at 6 months (mm)	2.48±0.80	2.39±0.74
Minimum lumen diameter at 12 months (mm)	2.43±0.79	2.21±0.75
Restenosis rate (%)	7.0	15.2*
Target lesion revascularization (%)	6.6	15.2*
MACE at 12 months (%)	7.0	17.4*
*p<0.05 vs SES		

3:30 p.m.

2519-778 Drug-Eluting Stents for the Treatment of Small Coronary Artery with Sirolimus, Paclitaxel, Zotarolimus, EPC Capture and Everolimus-Eluting Stent: Multicenter Registry in Asia

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Aim: The aim of this study is to compare the safety and efficacy of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES), EPC capture (ECS) and Everolimus-eluting stent (EES) on the outcome of patients with small coronary artery disease. **Methods:** A prospective analysis of 1871 patients with small coronary artery stenosis (808 SES, 602 PES, 219 ZES, 153 ECS, 89 EES) in five high volume Asian centers after successful stenting for small coronary artery stenosis was performed. The study endpoints were major adverse events (MACE) at 30 days, 9 months restenosis rate and target lesion revascularization (TLR) at 9 months. **Results:** See table for clinical results. **Conclusion:** The use of drug-eluting stents in patients with small coronary artery stenosis was safe and feasible. Patients treated with SES and EES showed lesser rate of restenosis compared with other drug-eluting stents.

	SES	PES	ZES	ECS	EES
Number of patients	808	602	219	153	89
Procedural success (%)	99.8	99.7	100	100	100
Reference diameter (mean: mm)	2.40	2.42	2.37	2.35	2.33
Lesion length (mean: mm)	12.6	11.3	13.7	12.9	18.0
Minimum lumen diameter post procedure (mean: mm)	2.32	2.30	2.28	2.30	2.28
Minimum lumen diameter at 9 months (mean: mm)	2.10	2.01	1.70	1.72	2.10
Restenosis rate at 9 months (%)	7.4*	13.0	20.1	21.6	6.7*
TLR at 9 months (%)	7.4*	11.6	20.1	21.6	4.5*
MACE at 9 months (%)	7.9*	13.0	20.1	21.6	4.5*

*p<0.05 vs ZES, ECS

3:30 p.m.

2519-779 Rotational Atherectomy Prior to the Stenting with Sirolimus-Eluting Stent for Diffuse In-Stent Restenosis: Multicenter Registry in Asia

Sunao Nakamura, Hisao Ogawa, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Background: Diffuse in-stent restenosis (D-ISR) is still challenging problem and optimal treatment has not been established. **Methods:** To compare the efficacy and safety of stenting with Sirolimus-eluting stent (SES) versus rotational atherectomy (mean burr/artery ratio 0.70, mean burr size 1.97) prior to stenting with SES for the treatment of D-ISR, we assessed baseline clinical and angiographic characteristics, in-hospital and 12-month major adverse cardiac event (MACE) in 488 consecutive patients. Patients were divided into 297 patients, 347 lesions treated with one or more SES and 191 patients, 243 lesions treated with rotational atherectomy prior to SES. **Results:** The baseline clinical characteristics between 2 groups were similar. See table for the clinical results. **Conclusion:** Rotational atherectomy prior to Sirolimus-eluting stent provided an advantage in terms of long-term clinical and angiographic outcomes.

		SES	Rota+SES	p
Number of patients/lesions		297/347	191/243	-
In-hospital	Procedural success (%)	100	100	NS
	MACE (%)	0	0	NS
	Lesion length (mm)	30.5 ± 12.6	29.8 ± 13.8	NS
	MLD post procedure (mm)	2.68 ± 0.58	2.80 ± 0.70	NS
12-month	MACE (%)	0	0	NS
	Angiographic restenosis (%)	12.8	5.2	0.05
	Repeat PCI (%)	9.4	3.7	0.05
	In-lesion late loss	0.30 ± 0.29	0.10 ± 0.14	0.05

3:30 p.m.

2519-780 Clinical impact of treating complex lesions with drug-eluting stents: is lesion complexity still a predictor of worse outcomes - a long-term analysis (up to 6 years) of the DESIRE Registry

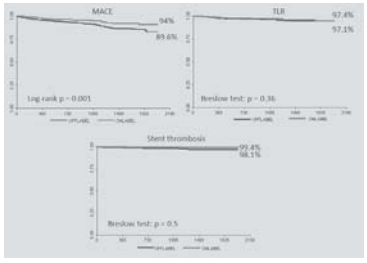
Jose de Ribamar Costa Jr, Amanda Sousa, Ricardo A. Costa, Adriana C. Moreira, Galo Maldonado, Manuel N. Cano, Mariana T. Carballo, Cantídio Campos, Enilton Egito, César Jardim, Otávio Berwanger, J. Eduardo Sousa, Instituto de Ensino e Pesquisa do Hospital do Coração, São Paulo, Brazil

Background: The superiority of DES over BMS in reducing repeat lesion revascularization has prompted physicians to expand the indications of PCI to very complex scenarios, not previously included in RCT. We sought to evaluate the very long-term clinical outcomes of DES in the off-label scenario.

Methods: Between May 2002 and May 2008 all consecutive pts treated solely with DES were prospectively enrolled in this single center registry and grouped according to their "label" status. Pts with STEMI and SVG lesions were excluded. On-label pts had de novo lesion <30mm in length, located in a native coronary artery of 2.5 to 3.5mm in diameter. All remaining pts were classified as off-label. The primary goal was the comparison of MACE and stent thrombosis (ST). Pts were evaluated at 1, 6 and 12 months and then annually up to 6 years.

Results: Most pts were off-label [1,725 (76%) of 2,265]. Complete FU data was obtained in 98.3% of the cases (median 3.5 years). During hospitalization, off-lable pts had more non-Q wave MI but similar rates of MACE and ST. Survival-free of MACE, TLR and ST curves are displayed in the chart. Off-label use of DES was an independent predictor of combined MACE (HR 2.5; 95% IC1.7-4.9) but did not impact MI and ST.

Conclusion: In this registry, DES in pts with increased complexity profile (off-label) was associated with low rates of MACE (<11%) and ST (<2.0%) in the very long-term FU; however, outcomes in this subset are still inferior compared to those with strict indications for DES (on-label).



3:30 p.m.

2519-781 Late Outcomes of Bare Metal or Drug-Eluting Stent Implantation in Standard and "Off-Label" Lesions

Kishore J. Harjai, Pamela Orshaw, Judith Boura, Daniel Sporn, Guthrie Clinic, Sayre, PA, William Beaumont Hospital, Royal Oak, MI

Background: Long-term outcomes from DES- vs. bare-metal stent (BMS) implantation in standard and off-label lesions are not available.

Methods: In 2345 patients undergoing PCI for standard (n=1540, 66%) or off-label (805, 34%) lesions, we assessed the time to occurrence of death, myocardial infarction (MI), death or MI, stent thrombosis, target vessel revascularization (TVR), and major adverse cardiovascular events (MACE, defined as composite of all study outcomes). Multivariable differences in outcomes between DES vs. BMS were assessed using propensity-adjusted Cox proportional hazards regression. To assess the impact of TVR on mortality, we constructed hazard curves for mortality in patients who suffered TVR vs. those who did not.

Results: The median duration of follow-up was 3.4 years. Stenting of off-label lesions was associated with uniformly worse outcomes than stenting of standard lesions. After adjustment for lesion classification, propensity to receive DES, and baseline differences, the use of DES was associated with statistically significant reductions in death, TVR, and MACE, without a detrimental impact on MI, death/MI, or stent thrombosis. Time to death was similar between patients who suffered TVR versus those who did not.

Conclusions: Compared to BMS, the use of DES is associated with clinical benefit in standard and off-label lesions at late follow-up. Reduction in elective TVR does not explain the apparent mortality benefit from DES implantation.

Multivariable Effect of DES Vs. BMS on Outcomes

Outcome	Adjusted HR	95% CI	P
Death	0.71	0.51-0.98	0.036
MI	1.22	0.84-1.75	0.29
Death or MI	0.81	0.63-1.05	0.11
Stent thrombosis	1.56	0.86-2.86	0.15
TVR (Off-label subset)*	0.58	0.39-0.85	0.0058
TVR (On-label subset)*	0.33	0.24-0.46	<0.0001
MACE	0.51	0.42-0.61	<0.0001

*In models relating to TVR, the interaction between DES and Off-label was significant. Hence, TVR analyses were performed separately for Off-label and standard groups

3:30 p.m.

2519-782 Temporal evolution in the Off-Label Use of Drug Eluting Stents: Observations from the EVENT Registry

Neal S. Kleiman, Chen-Hsing Yen, Peter B. Berger, John J. Lopez, Htut Win, David J. Cohen, Methodist DeBakey Heart and Vascular Center, Houston, TX, Harvard Clinical Research Institute, Boston, MA

Background: Since an FDA review in December 2006, there has been concern about the implant of drug-eluting stents (DES) for off-label indications. We previously reported from the EVENT registry that 54% of pts (excluding STEMI) received off-label DES. More recent data allowed us to compare implant practices before and after December 2006.

Methods: EVENT consisted of 4 yearly waves of approximately 2500 unselected pts with attempted stent implant from 2004 to 2007 at 61 centers. This analysis excluded

pts with STEMI or who did not have protocol mandated biomarkers collected. The in-hospital endpoint was a composite of death, MI (adjudicated), or urgent revascularization. Stratification as off-label required EF <.25, baseline CK-MB>3x ULN, >1 lesion stented, bypass graft target, unprotected LMCA or bifurcation, maximum balloon > 4 mm, stenosis = 100%, or total stent length > 36 mm.
Results: In the first 2 waves (2004-5) 54% of implants were off-label vs 49% in wave 4. Within wave 4 (2007), DES were used in 74% off-label and in 72% on-label pts. Among off-label pts in waves 1 & 2 vs wave 4, stent length was >36 mm in 54% vs 43%, bifurcation lesions were dilated in 26% vs 20%, and lesions were in bypass grafts in 10% vs 17%. Within wave 4, pts were more likely to receive a DES than a bare metal stent (BMS) for >1 lesion treated (OR 1.9), stent length > 36 mm (OR 2.4), lesion > 30mm (OR 1.7), bifurcation target (OR 1.9), and more likely to receive a BMS for EF <.35 (OR .55), or basal CK >3x nl (OR .4). In waves 1 & 2, death/MI, or UR occurred in 10.9% off-label and 5% on-label pts (adjusted OR 2.32; 95% CI 1.8, 3.1); in wave 4, the composite occurred in 9.2% and 4.1%, respectively, (adjusted OR 2.36; 95% CI 1.6, 3.4)
Conclusions: In 2007 compared with 2004-5, off-label implantation of stents decreased. Among pts with off-label indications there appeared to be a slight decrease in lesion complexity. Multilesion PCI, long lesions, and bifurcations were more likely to be treated with DES while pts with elevated CK-MB, or LV dysfunction were more likely to receive BMS. With more selective use of DES compared with earlier years, the absolute risk of ischemic complications for off-label use decreased, but the risk compared to on-label use was unchanged.

3:30 p.m.

2519-783 **Incidence of Early (30-day) Stent Thrombosis in Vein Graft Intervention: Results from the AMEthyst Study**

Srihari S. Naidu, Mark A. Turco, Janine Lane, Laura Mauri, Jeffrey Popma, Dean J. Kereiakes, Winthrop University Hospital, Mineola, NY

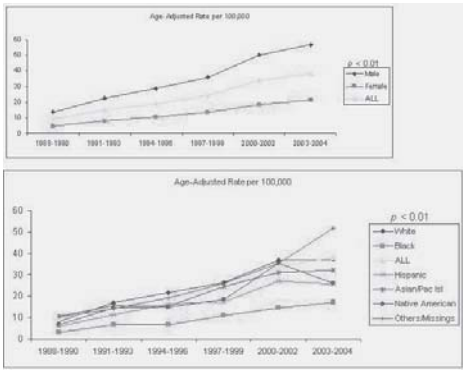
Background: The incidence of early stent thrombosis in contemporary saphenous vein graft (SVG) intervention remains unknown. Differences between individual drug-eluting stents (DES), and between DES and bare metal stents (BMS) in this setting, are uncertain. AMEthyst is the largest SVG intervention study with routine embolic protection.
Methods: Baseline demographic, procedural and clinical characteristics, as well as 30-day (early) incidence of stent thrombosis, were recorded on 786 patients undergoing SVG stenting. Stent thrombosis was defined as angiographic thrombus or subacute closure at time of clinically driven angiographic restudy, or cardiac death. **Results:** 60.2% (n=473) received DES (41.7% Taxus, n=195 and 58.3% Cypher, n=273) and 39.8% (n=313) received BMS. Compared to BMS patients, DES patients had lower glycoprotein 2b/3a receptor inhibitor use (35.5% vs. 51.1%, p<0.001), smaller reference vessel diameter (3.02 mm vs. 3.61 mm, p<0.001) and lower plaque volume (94.4 mm3 vs. 131.3 mm3, p<0.001). Compared to Cypher, patients who received Taxus were more likely male (82.1% vs. 73.6%, p=0.034) and trended older (70.2 vs. 68.3 years, p=0.053). Early stent thrombosis for all patients was 0.5%. Incidence of early stent thrombosis between DES and BMS patients did not differ, either prior to (0.4% vs. 0.7%, OR 0.65, p=0.67) or after adjustment (adjusted OR 1.10, p=0.93). Similarly, there were no differences in early stent thrombosis between Taxus and Cypher, either prior to (0.5% vs. 0.4%, OR 1.37, p=0.83) or after adjustment (adjusted OR 2.22, p=0.58). **Conclusions:** SVG stent thrombosis to 30 days appears infrequent with no apparent differences between drug-eluting stents and bare metal stents, or between different drug-eluting stents.

3:30 p.m.

2519-784 **Gender and race specifics Nationwide trends in the utilization of multivessel percutaneous coronary intervention (MVPCI) in the United State**

Mohammad Reza Movahed, Radhakrishnan Ramaraj, Ramin Ebrahimi, Mazen Jamal, Mehrtash Hashemzadeh, The Southern Arizona VA Health Care System and Sarver Heart Center, Tucson, CA, AZ

Background: We recently reported increases in the nationwide trends in the utilization of Multi Vessel Percutaneous Coronary Intervention (MVPCI). The goal of thisstudy was to evaluate this trend based on gender and ethnicity.
Method: The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted rate for PCI from 1988 to 2004 based on race and gender. Specific ICD-9-CM codes for Multi vessel PCI were used to compile the data. Patient demographic data was also analyzed from the database.
Results: According to the NIS database, MVPCI was performed in 241,319 patients from 1988 to 2004. From 1988, the age-adjusted rate for MPCI gradually increased to more than 6 times of 1988 in comparison to 2004. [(3.14 per 100,000 (95%CI=2.52-3.71) for female and [(9.83 per 100,000 (95%CI=7.7-11.86)] for male population for the year1988. In 2004 21.95 per 100,000 (95%CI=18.51-25.40) for female and 60.04 per 100,000 (95%CI=49.89-70.19) for male population (see figure). This trend was similar across different ethnicities except sudden decrease in MVPCI in the Native American population in the recent years.
Conclusion: The utilization of MVPCI has increased to 6 times that of 1988 in the year 2004, with much of the acceleration in the recent years in most races and both genders. The cause of this acceleration is most likely related to advancement in the percutaneous coronary interventional techniques.



I2.POSTER CONTRIBUTIONS

2520

PCI - Complex Patients

Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2520-785 **Combined antiplatelet therapy and oral anticoagulation for diagnostic and interventional coronary procedures.**

Helena Tizon-Marcos, Gerald Barbeau, Olivier Bertand, Jean Rock Boudreault, J-Pierre Dery, Onil Gleeton, Bernard Noel, CM Nguyen, Eric Larose, Guy Proulx, josep Rodés-Cabau, Jacques Rouleau, Guy Rossignol, Stephane Rinfret, Robert De Larochellière, Laval Hospital, Quebec, QC, Canada

Background: Based on ACCP guidelines, oral anticoagulation (OA) is usually stopped before interventional femoral procedures to avoid bleeding(B) and vascular complications (C). Bridging therapies (BT) are often used in patients with intermediate/high risk of thromboembolism. However, major B associated with BT and PCI is still high and thromboembolic C are abolished.
Objective: Evaluate the safety and feasibility of uninterrupted OA for diagnostic and interventional coronary procedures.
Methods: Prospective collection of patients (pts) chronically on OA admitted for acute coronary syndrome or stable angina from 12-2005 to 09-2008 who had a percutaneous coronary proc. with un-interrupted in OA group (OAG, n=73 pts with 76 procedures) or with interrupted OA and INR < 1.8 before procedure (control group, CG, n=22).
Results: Pts in the OAG group were older (71±10 vs 66±11, p=0.05), similar in gender, risk factors, CHADS2 score (2 in both groups), tendency for more prior CABG (28% vs 47%, p=0.06), similar left ventricular ejection fraction (46±14% vs 49±9%, p ns), similar indications for OA (atrial fibrillation 58% vs 50%) and similar indications for PCI (unstable angina 47% vs 59%, p=0.36). Radial approach was >90% in both groups. INR during proc. was 2.4±0.4 in the OAG group and 1.3±0.2 in the CG (p=0.04). Unfractionated heparin was used in 28% of OAG and in 95% of CG (p=0.03). ICP was performed in 47% of cases in OAG and 32% in CG (p=0.19). ICP in the OAG was more complex. No statistical differences were found in inhospital outcomes in death (0), per-PCI myocardial infarction (4% vs 0), bleeding site C (2.6% vs 0) and stroke (0) between OAG and CG.
Conclusions: Coronary diagnostic or interventional procedures with uninterrupted OA may be safe and feasible if radial approach is used as no differences in per-procedural and in-hospital outcomes were found between OAG and CG.

3:30 p.m.

2520-786 **Impact of Bivalirudin Use on Outcomes in Nonagenarians Undergoing Percutaneous Coronary Intervention**

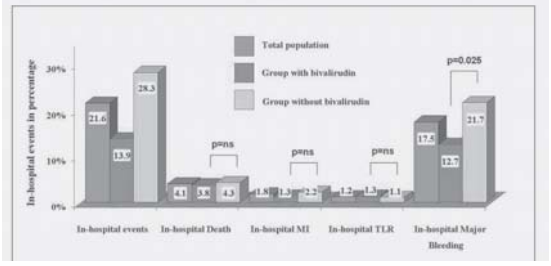
Gilles Lemesle, Laurent Bonello, Axel De Labriolle, Gabriel Maluenda, Sara D. Collins, Itsik Ben-Dor, Asmir I. Syed, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: With an aging population, nonagenarians constitute an increasing percentage of patients with coronary artery disease (CAD). We aimed to determine the predictors and outcome of nonagenarians undergoing PCI for symptomatic CAD.
Methods: From 2002 to 2007, 171 consecutive nonagenarians underwent PCI in our center. The 6-month rate of major adverse cardiovascular events (MACE) including death, myocardial infarction (MI), and target lesion revascularization (TLR) was indexed, as was in-hospital bleeding.
Results: The population was 52% female. Nearly 30% of patients had diabetes and >25% had renal failure. The mean LVEF was 45%. The clinical presentation was a MI in 59% of the cases. The in-hospital rate of bleeding was 18%. The 6-month rate of MACE was 14% and driven by death: 11%. Bivalirudin use was associated with a 42% decrease in in-hospital bleeding (Figure). Clinical presentation as MI or cardiogenic shock was associated with high rates of in-hospital death: 19% and 30%, respectively. Predictors

of 6-month MACE were clinical presentation as MI or cardiogenic shock, renal failure and stent length.

Conclusions: Nonagenarians represent a population with a high percentage of females and a high incidence of comorbidities. They have logically a worse prognosis than is reported in younger patients, with especially high rates of in-hospital bleeding. Bivalirudin use should be considered more often in the elderly since it reduces bleeding, and improves early outcome.

Figure: In-hospital outcomes in both groups: bivalirudin users versus heparin users.



3:30 p.m.

2520-787 **The Effect of Renal Impairment on Outcomes from the Real-World EFive Registry**

Martin T. Rothman, Ian T. Meredith, Nakul Sinha, Praveen Chandra, Antonio Merchan Herrera, Chaim Lotan, For the E-FIVE Registry Investigators, The London Chest Hospital, London, United Kingdom

Background: Renal impairment (RI) is a predictor of poor outcome in patients with cardiovascular disease, but its influence in the setting of percutaneous coronary intervention (PCI) and stent implantation is not well described. We evaluated clinical outcomes in patients with RI from the E-Five Registry.

Methods: E-Five was a prospective, multicenter, nonrandom, global registry of 8314 patients at 188 centers on 4 continents. All patients with symptomatic coronary artery disease amenable to stenting were eligible. Moderate/severe RI was defined as serum creatinine (SCr) ≥140 µmol/L, and mild RI included patients with SCr < 140µmol/L. Renal transplant patients were excluded. MACE (death, MI, emergency cardiac bypass surgery, or target lesion revascularization [TLR]) and stent thrombosis were adjudicated by a Clinical Events Committee. Events at 1 year were compared between groups using adjusted logistic regression.

Results: Baseline SCr was available in 6720 patients, and 437 had SCr ≥140 µmol/L. Patients with moderate/severe RI were more often male (81% vs. 76%, p = 0.02); were older (68 vs. 63 years), had more diabetes (52% vs. 31%) and hypertension (84% vs. 68%) (all *P*<0.001) and were more likely to have a previous MI or revascularization. Lesion characteristics were similar. Patients with moderate/severe RI had a higher rate of MACE, cardiac death, cardiac death plus MI and late stent thrombosis (Table).

Conclusions: RI is an important risk factor in patients undergoing PCI and stent implantation**.**

1-year Clinical Outcome	Moderate/Severe Renal Impairment (SCr ≥ 140 µmol/L) N=437	Mild Renal Impairment (SCr <140 mol/L) N=6283	P-Value*
MACE, % (n/N)	13.5 (56/416)	7 (414/5934)	0.003
Death (all), % (n/N)	9.9 (41/416)	1.8 (109/5934)	<0.001
Cardiac death, % (n/N)	5.3 (22/416)	1.4 (84/5934)	<0.001
MI (all), % (n/N)	2.9 (12/416)	1.5 (89/5934)	0.156
Q-wave MI, % (n/N)	0.7 (3/416)	0.3 (18/5934)	0.304
Non-Q-wave MI, % (n/N)	2.2 (9/416)	1.2 (72/5934)	0.295
Emergent CABG, % (n/N)	0	0	
TLR, % (n/N)	4.3 (18/416)	4.5 (269/5934)	0.355
Cardiac death + MI, % (n/N)	6.7 (28/416)	2.7 (159/5934)	0.003
ARC definite + probable stent thrombosis, % (n/N) 0-30 days 31-365 days	2.6 (11/416) 1.4 (6/416) 1.4 (6/416)	1.1 (63/5934) 0.7 (42/5934) 1.0 (22/5934)	0.039 0.347 0.008

*P-values were calculated using logistic regression adjusted for propensity scores for RI with no renal transplant [mod/severe creatinine≥ 140 µmol/l) vs. [mild (creatinine < 140 µmol/l). Propensity scores were calculated using: sex, age, prior MI, prior PCI, prior CABG, diabetes, acute MI (<72hrs), hypertension, hypercholesterolemia, smoking, LAD (vs. non-LAD), B2C (vs. AB1), lesion length (≥ 27mm vs. <27mm), and RVD (> 3.5mm vs. ≤3.5mm).

3:30 p.m.

2520-788 **Elective Percutaneous Coronary Intervention in the Elderly: Lessons From the Euro Heart Survey PCI Registry**

Timm Bauer, Christian Hamm, Anselm Gitt, Helge Möllmann, Matthias Hochadel, Franz Eberli, Ricardo Seabra-Gomes, Franz Weidinger, Jean Marco, Uwe Zeymer, Kerckhoff-Klinik, Bad Nauheim, Germany, Herzzentrum Ludwigshafen, Ludwigshafen, Germany

Background: The number of elderly patients undergoing elective percutaneous coronary intervention (PCI) has been increasing year by year. We evaluated age-related differences in clinical characteristics, adjunctive medical treatment, procedural details and in-hospital outcomes of patients with stable coronary artery disease (CAD) treated with PCI.

Methods: From 2005 to 2008, 40612 consecutive patients undergoing PCI were prospectively enrolled into the PCI-Registry of the Euro Heart Survey Programme (99 centres in 30 ESC-countries). For the present analysis we examined 19712 patients with stable CAD who were divided into two groups: >75 years (n=2747, 13.9%, 78.8 ± 3.1 years) and ≤75 years (n=16965, 86.1%, 60.6 ± 9.0 years).

Results: Elderly were more frequently female and had more comorbities, including diabetes, hypertension, renal insufficiency and a history of stroke and congestive heart failure. Coronary pathology was more severe. Among elderly the number of segments treated was higher and PCI of the left main stem was more often performed. Vascular closure devices were more frequently utilised in older patients, and arterial complications were also more prevalent. Guideline adherent adjunctive medication was commonly used and no age-related differences could be observed. The incidence of in-hospital death (0.5 versus 0.2%, p<0.01), major bleedings (0.8 versus 0.4%, p<0.0001) and elevated post procedural biochemical markers (5.1 versus 3.2%, p<0.0001) was higher among elderly, whereas there were no significant differences in the rate of non-fatal reinfarction (0.8 versus 0.7%), stroke (0.1% respectively) and renal failure requiring dialysis (0.5 versus 0.3%). Age >75 years was a strong predictor of hospital mortality (OR: 2.37, 95%-CI:1.27-4.41) by multivariate analysis. At discharge elderly patients were more likely to receive clopidogrel, while recommended duration of dual antiplatelet therapy was shorter.

Conclusions: In clinical practice the incidence of hospital complications among elderly undergoing elective PCI is low. Nevertheless, they face a higher risk than younger patients, strongly influenced by comorbidities and coronary status.

3:30 p.m.

2520-789 **Does Bleeding Impact the Outcomes in Patients Admitted Without Anemia After Percutaneous Coronary Intervention?**

Gabriel Maluenda, Gilles Lemesle, Itsik Ben-Dor, Sara D. Collins, Asmir Syed, Yanlin Li, Rebecca Torguson, Kimberly Kaneshige, Zhenyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Blood loss after PCI is linked with poor outcomes. Patients (pts) with bleeding are more often older and have co-morbidities. This study aimed to assess whether post PCI bleeding is associated with adverse outcomes in patients with normal baseline hematocrit (Hct).

Methods: 3727 consecutive patients with normal Hct (>39 men, >36 women) underwent PCI from 2003 to 2007. Of these, 58 (1.6%) had major bleeding (gastrointestinal bleeding, Hct drop >15, major hematoma and ≥2 red blood cell transfusions) and 1017 (27.3%) minor bleeding (Hct drop 5-15). Pts with cardiogenic shock were excluded. Death and myocardial infarction (MI) were systematically indexed at 1-year follow-up.

Results: Pts who presented with any bleeding were older and had more renal insufficiency and history of congestive heart failure. At 1 year, the composite death-MI was significantly lower in the no bleeding group vs the 2 other groups, minor and major bleeding: 3.0% vs 5.1% and 19.0% (p=0.003 and p<0.001, respectively). After adjustment for known covariates, major bleeding as compared to no bleeding remained independently associated with death and MI up to 1 year; however, minor bleeding was no longer associated after this adjustment. (Table)

Conclusions: This study showed that major bleeding, but not minor bleeding, predicts independently adverse outcomes in this selected, less ill population. This suggests that even if major bleeding is more frequent in older and sick pts, major bleeding by itself worsens the prognosis.

Clinical predictors for one year composite death and Q-wave myocardial infarction

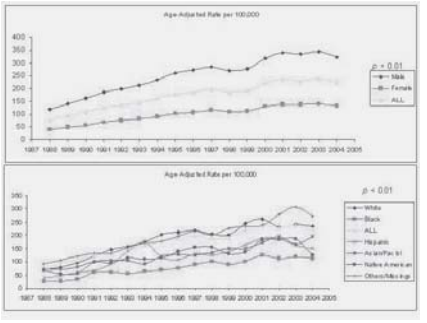
	Univariate Cox Proportional Model			Multivariate Cox Proportional		
	HR	95 % CI	p	HR	95 % CI	p
Age	1.0	1.0-1.1	< 0.001	1.0	1.0-1.1	< 0.001
Male gender	0.6	0.5-0.8	0.002	0.8	0.6-1.1	0.202
Diabetes Mellitus	2.2	1.6-3.0	< 0.001	1.8	1.3-2.5	0.001
Chronic renal failure	4.4	3.1-6.1	< 0.001	2.3	1.5-3.3	< 0.001
Congestive heart failure	3.8	2.7-5.4	< 0.001	2.6	1.8-3.7	< 0.001
Acute MI presentation	1.4	0.9-2.1	0.124	1.7	1.1-2.7	0.019
Major Bleeding	6.5	3.6-12.0	< 0.001	1.0	2.1-7.5	< 0.001
Minor Bleeding	1.7	1.3-2.4	0.001	1.3	0.9-1.8	0.341

3:30 p.m.

2520-790 Ethnicity and gender based Nationwide trends in the utilization of percutaneous coronary intervention (PCI) in the United State

Mohammad Reza Movahed, Radhakrishnan Ramaraj, Mazen Jamal, Ramin Ebrahimi, Mehrtash Hashemzadeh, The Southern Arizona VA Health Care System and Sarver Heart Center, Tucson

Background: We recently reported increases in the nationwide trends in the utilization of Percutaneous Coronary Intervention (PCI). The goal of this study was to evaluate this trend based on gender and ethnicity using a large data base from 1988 to 2004.
Methods: The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted rate for PCI from 1988 to 2004. Specific ICD-9-CM codes for all PCIs were used to compile the data. Patient demographic data was also analyzed from the database.
Results: The NIS database contained 1,747,736 patients who had PCI performed from 1988 to 2004. The From 1988, the age-adjusted rate for all PCI gradually increased to more than double until 2001 but remained relatively unchanged (slight decline in last few years of the study) until end of the study in 2004 for both gender. [For male in the year1988: 117.35 per 100,000 (95%CI=93.08-141.62, p<0.01). For female in 1988: 39.29 per 100,000 (95%CI=31.49-47.09, p<0.01). For male in the year 2004: 323.09 per 100,000 (95%CI=268.49-377.68, p<0.01).For female in the year 2004: .131.66 per 100,000 (95%CI=111.01-152.31, p<0.01). These trends were similar across the ethnicities. See figure.
Conclusion: The utilization of PCI has dramatically increased to more than double from 1988 to 2001 but remained unchanged thereafter regardless of ethnicity or gender. These trends could be related to the approval of drug eluting stents or secondary to improving in the secondary prevention.



3:30 p.m.

2520-791 Safety of Drug-Eluting Stents in Patients with Severe Left Ventricular Dysfunction: One Year Data from the NHLBI Dynamic Registry

Srihari S. Naidu, Faith Selzer, Helen Vlachos, Elizabeth Holper, Robert L. Wilensky, David Holmes, Winthrop University Hospital, Mineola, NY

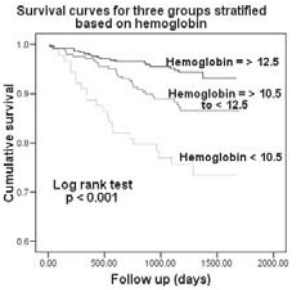
Background: Patients with left ventricular (LV) dysfunction may be at particular risk for ischemic events after percutaneous coronary intervention, including stent thrombosis. We utilized the NHLBI Dynamic Registry to evaluate whether drug-eluting stents (DES) are safe in patients with significant LV dysfunction. **Methods:** Baseline characteristics, as well as in-hospital and one-year outcomes were collected prospectively on 754 consecutive patients with ejection fraction < 40% undergoing stent placement during three successive Waves of enrollment between 2001 and 2006. BMS patients in Wave 3 (n=257), prior to the introduction of DES, were compared to DES patients in Waves 4 and 5 (n=497). **Results:** Mean ejection fraction was similarly reduced (DES 31.6% vs. 31.3%, p=0.58). DES patients were more often hypercholesterolemic (77.3% vs. 65.2%, p<0.001) with prior stent placement (28.8% vs. 21.0%, p<0.05), while BMS patients were more likely to present with positive troponin (62.3% vs. 51.3%, p<0.05), ST-elevation (29.2% vs. 21.5%, p<0.05), and prior coronary bypass (24.5% vs. 22.8%, p<0.05). DES lesions were longer (17.2 mm vs. 13.0 mm, p<0.001), more frequently calcified (30.7% vs. 18.4%, p<0.001), higher lesion class (Type C 30.9% vs. 17.5%, p<0.001), and more often elective (48.5% vs. 38.5%, p<0.05). Procedural success was similar (DES 97.6% vs. 95.7%, p=0.16), although DES patients more likely had post-procedure troponin elevation (34.1% vs. 24.1%, p<0.01). In-hospital death (DES 1.8% vs. 2.7%, p=0.41) and the combined endpoint death or myocardial infarction (MI, DES 3.6% vs. 4.3%, p=0.66) were similar. By one year, cumulative rates and adjusted risk (aHR) of death (DES 9.19 vs. 10.20%, p=0.64, aHR 0.65, 95% CI 0.38-1.13) and MI (5.01% vs. 5.88%, p=0.67, aHR 0.88, 95% CI 0.43-1.79) did not differ, nor did the combined endpoint death or MI (13.06% vs. 14.94%, p=0.48, aHR 0.76, 95% CI 0.48-1.20). Stent thrombosis in DES patients was 0.84% at one year. **Conclusions:** DES appear safe in moderate to severe left ventricular dysfunction, with similar procedural, in-hospital and one-year outcome compared to BMS, and low incidence of stent thrombosis.

3:30 p.m.

2520-792 Impact of Anemia on Long-term All Cause Mortality After Percutaneous Coronary Intervention in African-Americans.

Shyam Poludasu, Jonathan D. Marmur, Jeremy Weedon, Erdal Cavusoglu, SUNY Downstate Medical Center, Brooklyn, NY

Background: Anemia has been shown to be an independent predictor of long-term mortality after percutaneous coronary intervention (PCI). African Americans are known to have lower hemoglobin (Hgb) levels compared to Caucasians. The impact of anemia on long-term mortality in African Americans undergoing PCI is unknown.
Methods: We evaluated a total of 715 African Americans (313 with anemia and 402 without anemia as defined by WHO definition of anemia [Hgb < 13 g/dl for men; Hgb < 12 g/dl for women]).
Results: After a median follow up of 3.2 (interquartile range 2.4 to 3.8) years, there were a total of 72 (10%) deaths. The survival rate was 84% in the anemic group and 94% in the control group (Unadjusted p < 0.001 by log-rank test; hazard ratio [HR]: 2.8). After adjustment for baseline clinical and procedural characteristics using a Cox proportional hazards model, Hgb as a dichotomous variable was a strong and independent predictor of all-cause mortality (adjusted p = 0.003; HR for death: 2.2; 95% confidence interval : 1.3-3.7). Also, when Hgb was analyzed as a categorical variable having three groups with empirically determined cutoffs at <10.5, 10.5 to <12.5, and >=12.5 g/dl, the effect remained significant (p=0.001), with HR of 3.3 for the group with lowest hemoglobin when compared to the highest group and HR of 2.1 for the group with Hgb 10.5 to <12.5 compared to the highest Hgb group.
Conclusion: Baseline hemoglobin is a strong and independent predictor of all-cause long-term mortality in African Americans undergoing PCI.



3:30 p.m.

2520-793 Should Patients who Develop Anemia (Hematocrit ≤ 27%) After Percutaneous Coronary Intervention be Transfused?

Gabriel Maluenda, Gilles Lemesle, Asmir Syed, Sara D. Collins, Itsik Ben-Dor, Yanlin Li, Rebecca Torguson, Kimberly Kaneshige, Zehnyi Xue, William O. Suddath, Lowell F. Satler, Kenneth M. Kent, Joseph Lindsay, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Bleeding and blood transfusion after PCI are associated with higher mortality. Some have adopted a hematocrit (Hct) ≤27% as a threshold for transfusion post PCI. However, the impact of red blood cell (RBC) transfusion at this level of Hct is unknown. This study aimed to assess whether RBC transfusion at this threshold influences the frequency of adverse outcomes.
Methods: 379 patients whose Hct fell to ≤27 % after PCI were reviewed. We compared the patients who received RBC transfusion to those who did not. Death and myocardial infarction (MI) at 1-year follow-up were systematically indexed.
Results: The transfused patients (n = 203, 53.5 %) were more often female and more often presented with acute MI and cardiogenic shock. The average nadir Hct was similar for both groups (24.1 vs 24.2%). Univariate analysis suggested that those receiving transfusion had a greater incidence of death or MI (26.6% vs 17.2%, p = 0.048). After the multivariate Cox adjustment, no correlation between transfusion with the endpoint remained (p = 0.7).
Conclusion: This study does not support a beneficial effect of RBC transfusion in such a "high risk" population (Hct drop ≤ 27%). There are other stronger predictors that determine death and MI at 1-year follow-up.

Clinical predictors for death and myocardial infarction at 1-year follow up

	Univariate Cox Proportional Model			Multivariate Cox Proportional Model		
	HR	95 % CI	p	HR	95 % CI	p
Age	1.0	1.0-1.1	0.02	1.0	1.0-1.1	0.005
Diabetes Mellitus	1.8	1.2-2.6	0.005	1.9	1.2-3.0	0.003
Chronic renal failure	1.9	1.3-2.8	0.001	1.5	1.0-2.3	0.062
Chronic renal failure	1.9	1.3-2.9	0.001	1.8	1.2-2.7	0.005
Acute MI Presentation	1.7	1.1-2.5	0.01	1.8	1.1-2.8	0.02
Cardiogenic Shock	2.3	1.5-3.5	<0.001	2.0	1.2-3.1	0.004
Transfusion	1.5	1.0-2.1	0.048	1.1	0.7-1.6	0.7

3:30 p.m.

2520-794 **Angiographic and clinical outcomes of severe calcified lesions requiring rotational atherectomy in hemodialysis (HD) and non-hemodialysis patients after sirolimus-eluting stent (SES) implantation**

Hiroyuki Kyono, Ken Kozuma, Yoshitaka Shiratori, Shuichi Ishikawa, Kumiko Konno, Hirosada Yamamoto, Hidenori Watanabe, Akiyoshi Miyazawa, Takeshi Yamakawa, Naoyuki Yokoyama, Takaaki Isshiki, Teikyo University Hospital, Tokyo, Japan

Background: Severe calcified lesions and hemodialysis are both predictors for high rates of restenosis, even in the drug-eluting stent era. We sought to investigate the angiographic and clinical outcome in a population of hemodialysis vs. non-hemodialysis patients with severe calcified lesions requiring rotational atherectomy.
Methods: 100 consecutive lesions (28 lesions in HD group, 72 in non-HD group) from 94 patients that underwent rotational atherectomy prior to SES implantation were analyzed post-procedure and at 8 months. Clinical outcomes were assessed out to 8 months. Inclusion criteria were calcified lesions with > 270 degrees of superficial calcification on IVUS, lesions that IVUS could not cross, or undilatable lesions.
Results: There were no differences in patient characteristics except for age (HD 64.2±1.7, non-HD 72.7±6.99, P=0.003). Both baseline and post-procedure angiographic findings were similar between the two groups, late-loss and binary restenosis at 8 months were significantly higher in HD group. Also, HD group revealed significantly worse clinical outcomes (Table).
Conclusions: Mid-term results of highly complex, severely calcified lesions requiring rotational atherectomy in non-HD patients were acceptable. However, in HD patients, both angiographic and clinical outcomes were suboptimal in this lesion subset. Further approaches for HD patients, beyond plaque debulking and current DES, are warranted.

	HD (28 lesions, 26 patients)	Non-HD (72 lesions, 68 patients)	P value
Procedural Demographics			
Max. Burr Size (mm)	1.73±0.23	1.69±0.20	0.384
Number of Stent/Lesion	1.61±0.63	2.00±0.70	0.006
Total Stent Length (mm)	39.6±18.5	50.0±21.7	0.020
Before Procedure			
MLD (mm)	0.86±0.38	0.89±0.33	0.699
RD (mm)	2.37±0.51	2.27±0.49	0.411
Lesion length (mm)	19.2±13.2	23.8±15.0	0.159
Post Procedure			
In-Stent MLD (mm)	2.33±0.39	2.19±0.43	0.127
In-Stent RD (mm)	2.69±0.40	2.63±0.47	0.513
Acute gain (in-segment)	1.47±0.41	1.30±0.48	0.098
At 8 months			
In-Stent MLD (mm)	1.70±0.75	1.88±0.60	0.336
In-Stent RD (mm)	2.72±0.50	2.59±0.54	0.121
Late loss (in-segment)	0.69±0.74	0.34±0.50	0.050
Binary restenosis (%)	47.6	12.3	0.000
Clinical outcomes			
MACE (%)	63.2	19.0	<0.001
Death (%)	15.8	1.6	0.037
TLR (%)	39.3	9.7	0.001

MLD: Minimal lumen diameter, RD: Reference diameter

3:30 p.m.

2520-795 **Long-term(80mo) Clinical Follow-up After Drug-eluting Stents Implantation in patients with Chronic kidney disease in the DESIRE(Drug-Eluting Stents In the REal world) Registry**

Adriana Moreira, Amanda Sousa, J.Ribamar Costa, Jr., Ricardo Costa, Manuel Cano, Galo Maldonado, Fausto Feres, Luciano Cavalcante, Cantidio Campos, Mariana Carballo, Abrãao Cury, Otavio Berwanger, Marcos Barbosa, J.Eduardo Sousa, Hospital do coração - ASS, São Paulo, Brazil

Background: Chronic renal disease has been consistently shown to be an independent predictor of poorer long-term clinical outcomes after percutaneous treatment of coronary artery disease, even in DES era. We sought to evaluate the very long-term clinical outcomes after DES implantation in this high risk subset in a real world scenario.
Methods and Results: Between May/2002 and Nov/2008, 2,700 pts treated exclusively with DES were consecutively enrolled in the non-randomized, single-center DESIRE Registry. Recent STEMI (72h), lesions in SVG and patients with < 6months follow-up were excluded. The remaining pts (n=1500) were divided into 2 groups according to their creatinine clearance: Group I -Clearance ≤60 (n= 490) and Group II- clearance >60 (n= 1010). Primary endpoint included combined MACE and stent thrombosis (ST) rate. ST was classified according to ARC definitions. Clinical follow-up was obtained at 1, 6 and 12 months and then annually. Follow-up was achieved in 98% of the eligible cohort (median 3.6 years). Baseline characteristics and late outcomes are displayed in the table.

	Clearance ≤ 60 (n=490)	Clearance >60 (n= 1010)	p
Male gender, n(%)	286 (58.4%)	854 (84.55%)	< 0.0001
Age (years)	74.3 + 10.2	55.4 + 8.3	<0.0001
Diabetes, n(%)	136 (27.7%)	281 (27.8%)	0.973
Unstable angina, n(%)	171 (34.9%)	296 (29.3%)	0.03
Multivessel disease, n(%)	136 (27.7%)	269 (26.6%)	0.69
St / P ratio , n(%)	1.53	1.54	0.52
Cumulative events (late outcome) , n(%) Myocardial infarction	17 (3.5%)	27 (2.7%)	0.49
Target lesion revascularization	10 (2.0%)	33 (3.3%)	0.24
Cardiac death	15 (3.1%)	12 (1.2%)	0.019
Major adverse cardiac events	42 (8.6%)	72 (7.2%)	0.376
Stent thrombosis (ARC definitions)	5 (1.0%)	12 (1.2%)	0.97

Conclusions: In the DESIRE registry the negative impact of renal dysfunction was considerably minimized by the use of DES, resulting in very low and equivalent rates of myocardial infarction, TLR and ST when compared to patients with preserved renal condition. We especulate that the higher mortality among these very complex pts may reflect the severity of their co-morbities.

I2.POSTER CONTRIBUTIONS

2521

Endovascular

Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2521-796 **Contrast Induced Nephropathy in Patients Undergoing Peripheral Vascular Intervention: Incidence, Risk Factors, and Outcomes**

Paul Michael Grossman, Khan Munir, Hitinder S. Gurm, Paul G. Bove, Steven K. Wang, James M. Fox, Herbert D. Aronow, Timothy J. Nypaver, Arthur Riba, David Share, Mauro Moscucci, University of Michigan, Ann Arbor, MI

Background: This study was undertaken to determine the incidence, risk factors and outcomes associated with contrast induced nephropathy (CIN) after peripheral vascular intervention (PVI).
Methods: Data were analyzed from 3407 PVI cases prospectively collected in a multi-center database. Patients with prior renal failure were excluded. CIN after PVI was defined as an increase in serum creatinine (Cr) from baseline to post-PVI peak Cr of ≥ 0.5 mg/dl. A maximum weight and Cr adjusted contrast dose was calculated, (MACD = body weight in Kg X 5cc / pre-intervention Cr).
Results: CIN occurred in 3.8% of patients. The MACD was exceeded in 8.1% of the total cohort. Renal failure requiring dialysis occurred in 4.8% of CIN patients. CIN was associated with exceeding the MACD (13.9% vs. 7.9%, p=0.02) and age > 75 (42.7% vs. 34.3%, p=0.05). Clinical characteristics, in-hospital complications and outcomes are displayed (table). Independent predictors of CIN (c statistic=0.75) were: Cr clearance <30 ml/min (OR 5.3, 95% CI 2.0-13.6, p=0.0006), diabetes (OR 1.5, CI 1.0-2.5, p=0.05), anemia (OR 1.7, CI 1.1-2.8, p=0.01), CHF (OR 1.9, CI 1.2-3.0, p=0.009) and CVD (OR 1.6, CI 1.05-2.5, p=0.03).
Conclusions: CIN after PVI is relatively common and is associated with significant adverse events. CIN post-PVI is related to preexisting anemia, diabetes, CHF, CVD, lower Cr clearance, and exceeding MACD. These data suggest the need to limit CIN post-PVI, and to evaluate methods for doing so in multi-center, randomized clinical trials.

Clinical Characteristics, Post-PVI In-Hospital Outcomes and Complications

	CIN Group	Non-CIN group	P value
Anemia (%)	63.7	38.5	<0.0001
Diabetes (%)	55.6	41.5	0.002
Congestive heart failure (CHF) (%)	37.1	20.1	<0.0001
Cerebrovascular disease (CVD) (%)	41.9	27.1	0.0003
Death (%)	12.9	0.4	<0.0001
Myocardial Infarction (%)	10.5	0.5	<0.0001
Vascular Complication (%)	29.0	4.1	<0.0001
Transfusion (%)	39.5	6.3	<0.0001
Procedural success (%)	86.3	87.4	0.7

3:30 p.m.

2521-797 **Intravascular Ultrasound Imaging in First-In-Man Study with Bevacizumab-Eluting Stent. 12 Months Follow Up**

Konstantinos Toutouzas, Elli Stefanadi, Andreas Synetos, John Karampelas, Eleutherios Tsiamis, Dimitrios Tousoulis, Nicholas Kiphsidze, Christodoulos Stefanadis, 1st Cardiology Clinic, University of Athens, Medical School, Hippokration Hospital, Athens, Greece

Background: Bevacizumab is a monoclonal antibody against vascular endothelial growth factor (VEGF). Neovascularization of atherosclerotic plaque is mainly mediated by VEGF. Previous experimental results with bevacizumab-eluting stent showed inhibition of neovascularization in a rabbit atheromatic model. In this study we demonstrate the intravascular ultrasound (IVUS) findings of the first-in-man application of these stents.
Methods: Patients with acute coronary syndromes and >2 significant coronary artery stenoses were included in the study. The culprit lesions were successfully treated percutaneously. The targeted non-culprit lesions were 50%). Local delivery of bevacizumab was accomplished via BiodivYsio stents, which have a phosphorylcholine coating that adsorbs the drug. Patients were discharged under aspirin and clopidogrel for 12 months. All patients were scheduled for clinical and angiographic follow-up at 12 months, and intravascular ultrasound (IVUS) imaging of the target vessel immediately after the procedure and at 12 months. IVUS measurements included lumen Area (LA), neointimal hyperplasia area (NIHA), stent area (SA) and vessel area (VA).
Results: No acute or subacute thrombosis was observed. IVUS follow-up did not reveal any restenosis (50% vessel narrowing). Stent malapposition was not observed in any patient. Mean VA (13.3±0.9 vs 13.4±0.9 mm2), mean SA (6.4±0.5 vs 6.4±0.6 mm2) and

mean LA (6.4±0.5 vs 5.6±0.7mm2) were similar after the procedure of stent implantation and at follow up (p=NS). Mean NIHA at follow up was 0.8±0.5 mm2 (12.4±7.7%).
Conclusion: IVUS measurements indicate that bevacizumab-eluting stents are effective for the treatment of non-culprit de novo lesions in patients suffering from acute coronary syndromes.

3:30 p.m.

2521-798 Outcomes of Renal Artery Stenting in Patients With Severely Impaired Renal Function

Suresh Ramamurthy, Mubashir Ahmed, Abinet Boku, Samer Shuaib, Tonga Nfor, Anthony DeFranco, Anjan Gupta, Tanvir Bajwa, Suhail Allaqaband, Aurora Sinai/Aurora St. Luke's Medical Ctrs, Univ Wisconsin School of Medicine and Public Health-MCC, Milwaukee, WI

Background: Optimal management of renal artery stenosis (RAS) in patients with advanced renal failure is controversial. Our aim was to assess the effect of renal artery stenting in slowing progression to renal failure and in improving blood pressure (BP) control.
Methods: Three hundred nine patients with ≥70% single or dual RAS were stented between January 2002 and June 2007. Patients were grouped into those with creatinine < 2mg/dl (mild renal failure) **(N=233)** and those with creatinine ≥2.0 mg/dl (advanced renal failure) **(N=76)**. Pre and post intervention CR, BP, and number of antihypertensive medications were analyzed using T-test.
Results: Mean age was 73±9 yrs. There were more females in the group with mild renal failure (65% vs 45%, respectively). There were no significant differences between the groups for history of diabetes, hyperlidemia, smoking. During mean follow-up of 16 months post renal stenting, there was no significant change in renal function overall. Blood pressure control improved in both groups, but significantly more in the advanced renal failure group. Mean systolic blood pressure improvement (20 vs 15 mmHg) and diastolic blood pressure improvement (11 vs 6 mmHg) was seen in both groups post stenting.
Conclusions: Renal artery stenting for stenosis results in lower blood pressure in patients with mild renal failure, and even better blood pressure control in patients with advanced renal failure, regardless of any adjunct antihypertensive regimen.

creatinine < 2 mg/dl	pre intervention	post intervention	p value
systolic BP, mean ± SD	151±27	136±21	<0.0001
diastolic BP, mean ± SD	76±14	70±12	<0.0001
medications, mean ± SD	3±1.5	3±1.5	0.963
creatinine, mean ± SD	1.25±0.33	1.45±0.82	0.001
creatinine ≥ 2 mg/dl	pre intervention	post intervention	p value
systolic BP, mean ± SD	153±28	133±21	<0.0001
diastolic BP, mean ± SD	78±17	67±13	<0.0001
medications, mean ± SD	3.2±1.3	3.2±1.4	0.884
creatinine, mean ± SD	2.79±0.93	2.61±1.46	0.206

3:30 p.m.

2521-799 Longevity of Superior Mesenteric Artery Stents

Athar Saeed, Atif Saeed, Joaquin Solis, Anjan Gupta, Suhail Allaqaband, Tanvir Bajwa, Aurora Sinai/Aurora St. Luke's Medical Ctrs, Univ Wisconsin School of Medicine and Public Health-MCC, Milwaukee, WI

Background: Superior mesenteric artery stenosis (SMAS) can lead to incapacitating symptoms. Due to the low number of these procedures, there have been few studies that look at long-term patency.
Methods: All consecutive patients who underwent angioplasty and stenting of SMAS between 1/2003 and 12/2007 were included. All procedures were performed at the same center by an experienced interventional cardiologist or interventional radiologist. Patients were followed for an average of 22 months and restenosis was monitored both clinically, and by ultrasound, angiography, MRA, or CTA.
Results: A total of 28 patients were included. Clinical, angiographic, and procedural data are summarized in the table. A total of 32 procedures were performed, with a procedural success rate of 100%. In our population, we observed restenosis in 14 out of 32 total placed stents. There was a statistically significant relationship between restenosis and recurrence of symptoms (11/14 of restenosis) (p=0.003 by Yates correction) in contrast to no recurrence of symptoms in the patients with patent stents.
Conclusion: Our study showed a 44% rate of restenosis, with a majority of these patients showing a recurrence of symptoms, which was shown to be statistically significant. In addition, stent width (p=0.03) and age (p=0.012) were also defined as independent risk factors through multivariate analysis. Larger prospective studies with longer follow-up are required.

ANGIOGRAPHIC, PROCEDURAL AND F/U DATA	
	Mean ±sd, n(%)
Number of patients	28
Total stents	32
All in stent restenosis	14 (44)
Age	71± 9.7
Stent diameter (mm)	6 ± 0.94
Stent length (mm)	21 ± 9.17
Multi-vessel involvement	23 (72)
Procedural success	25(100)
Symptomatic improvement S/P stenting	100%
Duration of follow-up (m)	
Clinical follow-up (mean)	21 months
Diagnostic follow-up (mean)	13.5 months

3:30 p.m.

2521-800 Impact of Temporal Cessation of Vasodilators on Coronary Artery Spasm as Assessed with Intracoronary Acetylcholine Provocation Test

Kang Yin Chen, Seung-Woon Rha, Yong Jian Li, Kanhaiya L. Poddar, Jae Hyoung Park, Jin Oh Na, Cheol Ung Choi, Hong Euy Lim, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Korea University Guro Hospital, Seoul, South Korea

Background: Vasodilators are usually temporally stopped before the intracoronary acetylcholine (ACh) provocation test, a widely used method for detecting vasospastic angina. However, little has been known about the impact of temporal cessation on coronary artery spasm (CAS) as assessed with this method.
Methods: A total of 1199 patients (pts) presented with chest pain underwent coronary angiography were enrolled. Acetylcholine was injected into left coronary artery in incremental doses of 20μg/ min, 50μg/ min and 100μg/ min. Vasodilators were withheld 3 days before the test. Significant CAS was defined as a transient > 70% luminal narrowing with concurrent chest pain and/ or ischemic ST-segment change.
Results: After 3-day cessation, pts treated with nitrates, nicorandil, diatiazem and/ or molsidomine had significantly higher incidence of CAS than those without previous treatment (P<0.001). There was a trend toward significantly higher incidence of CAS in pts who stopped other calcium channel blockers (CCB) for blood pressure control (35.6% vs 29.2%, P=0.055). The incidences of CAS in pts who stopped angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB) and beta-blockers were similar to those in pts without previous treatment. Multivariate logistic analysis showed that the cessation of nitrates, nicorandil and diltiazem was significantly associated with the higher incidence of CAS, whereas, the cessation of beta-blockers was associated with reduced CAS. The cessation of other CCB, ACEI, ARB and trimetazine did not significantly influence on the incidence of CAS.
Conclusions: The temporal cessation of antianginal agents for 3 days was independently associated with higher incidence of CAS. Therefore, the cessation of antianginal agents should be cautious, and the confounding effect of vasodilator should be taken into account when we perform the ACh provocation test.

3:30 p.m.

2521-801 Cost Effectiveness of Angiography to Prevent Hemodialysis-Access Thrombosis

John A. Bittl, Ocala Heart Institute, Ocala, FL, Munroe Regional Medical Center, Ocala, FL

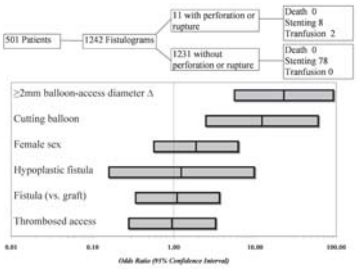
Background: Approximately $1B is spent annually in the U.S. for hemodialysis vascular access, but the optimal approach for maintaining the patency of arteriovenous fistulas and grafts is unknown. We sought to determine the value of pre-emptive angiography and angioplasty to prevent access thrombosis.
Methods: We conducted a cohort-based, cost-effectiveness analysis using data from a closed population of 560 hemodialysis patients referred for 1437 radiographic procedures during an 8.0-year period. Bottom-up microcosting methods provided measures of supply and personnel costs.
Results: Between 1999 and 2007, the rate of invasive surveillance for malfunctioning but non-thrombosed hemodialysis accesses rose from 18.8 to 48.3 angiograms per 100 hemodialysis patients per year (P<0.001). Stenosed accesses undergoing angiographic surveillance before thrombosis had a median patency of 348 days (interquartile range [IQR] 296, 400 days]), whereas thrombosed accesses undergoing de novo catheter-based thrombectomy had a median patency of 162 days (IQR 140, 184 days). Expansion of the invasive surveillance program was associated with a decline in the annual incidence of access thrombosis from 27.8 to 21.6 events per 100 hemodialysis patients (P=0.029). The incremental annual cost (in constant 2007 U.S. dollars) to prevent one access thrombosis was $14,286 per 100 hemodialysis patients. The estimated annual programmatic cost to prevent one access thrombosis in the average-sized cohort of 375 patients alive at any time was $53,571.
Conclusions: The increased use of angiographic surveillance of non-thrombosed hemodialysis accesses may have produced a small reduction in access thrombosis. The tradeoff between costs and clinical outcomes in an aggressive screening program remains uncertain.

3:30 p.m.

2521-802 Risk of Perforation or Rupture During Percutaneous Treatment of Hemodialysis Fistulas and Grafts

John A. Bittl, Ocala Heart Institute, Ocala, FL, Munroe Regional Medical Center, Ocala, FL

Background: Venous stenoses in the outflow limb of dialysis fistulas and grafts frequently require ultra-high balloon pressure or cutting-balloon angioplasty for optimal dilatation. The aim of this study was to analyze the risk and consequences of free perforation or rupture of hemodialysis accesses during catheter-based intervention.
Methods: Procedural characteristics and outcomes were analyzed for a consecutive series of patients treated by one operator over an 8-year period.
Results: In 1242 consecutive fistulograms referred for catheter-based treatment, free perforation or rupture occurred in 11 patients (0.9%). No patient with a perforation or rupture died, but 2/11 required transfusion (18.2%), and 8/11 required stenting (72.7%), of whom 6 required covered stents (75.0%). Vessel perforation was seen in 3 cases in which the balloon catheter was at least 2 mm larger than the diameter of the fistula or graft and in 3 separate cases where cutting balloons were used (Figure).
Conclusions: Rupture or perforation is a rare complication during catheter-based therapies for dialysis fistulas and grafts. The complication may be avoided by optimal balloon selection and sizing.



3:30 p.m.

2521-803 **Carotid Artery Stenting For Significant Carotid Stenosis in Patients With Contralateral Occlusion: The German ALKK CAS - Registry Experience**

Rajendra H. Mehta, Ralf Zahn, Matthias Hochadel, Harald Mudra, Thomas Ischinger, Karl E. Hauptmann, Jens Jung, Hubert Seggewiss, Uwe Zeymer, Jochen Senges, Duke Clinical Research Institute, Durham, NC, Institut für Herzinfarktforschung Ludwigshafen, University of Heidelberg, Ludwigshafen, Germany

Background: Data on the safety and efficacy of carotid artery stenting (CAS) in large number of patients (pts) with contralateral carotid occlusion (CCO) are less known.
Methods: We studied 3137 pts undergoing CAS enrolled in a German Registry (2000-2008, 31 sites). We compared the clinical and angiographic features and hospital outcomes of pts with and without CCO undergoing CAS.
Results: Of the 3137 pts undergoing CAS, 191 (6.1%) had CCO. Despite similar age of the 2 groups, those with CCO had a higher comorbidities, more complex carotid stenosis and more focal lesions on the contralateral side on CT imaging. In-hospital events including death (1.0% vs 0.5%), ipsilateral major stroke (1.1% vs 1.1%), death or major ipsilateral stroke (1.6% vs 1.4%), ipsilateral transient ischemic attack (2.7% vs 2.5%), and myocardial infarction (0.4% vs 0.1%) were all low and was not different between pts with and without CCO (p>0.05). Outcomes stratified by symptoms and CCO are shown in Table suggesting that most major adverse events were confined to symptomatic pts with CCO.
Conclusions: Our data in large number of pts undergoing CAS in contemporary practice attest to low risk of periprocedural events among pts with CCO. Most major adverse events were confined to symptomatic pts with CCO. This overall low risk of stroke and/or death together with its relatively less invasive nature and the ability to maintain uninterrupted cerebral perfusion during the procedure should make CAS an attractive option for the treatment of these pts.

In-hospital outcomes stratified by the presence of absence of symptoms

Variable	Symptomatic Patients with Carotid Occlusion	Symptomatic Patients without Carotid Occlusion	P value	Asymptomatic Patients with Carotid Occlusion	Asymptomatic Patients without Carotid Occlusion	P value
Ipsilateral Transient Ischemic attack	2.2%	2.3%	1.000	3.6%	2.6%	0.475
Ipsilateral Major Stroke	2.2%	1.5%	0.646	0%	0.6%	1.000
Contralateral Ischemic Events	3.3%	1.1%	0.096	1.2%	0.4%	0.305
In-hospital Mortality	2.2%	0.5%	0.103	0%	0.3%	1.000
Ipsilateral Major Stroke or In-hospital Mortality	3.3%	1.8%	0.413	0%	0.8%	1.000

3:30 p.m.

2521-804 **Incidence, Predictors and Prognostic Significance of Peri-Procedural Transient Ischemic Attack Associated With Carotid Stenting: Observations From the Cordis Carotid Stent Collaborative**

Herbert D. Aronow, Hong Wang, Jay S. Yadav, Kenneth Ouriel, Barry T. Katzen, Christopher J. Kwolek, Sidney Cohen, Michigan Heart & Vascular Institute, Ann Arbor, MI

Background: Although the incidence of peri-procedural death and stroke with carotid stenting has been well characterized, little is known about transient ischemic attack (TIA) in this setting.
Methods: We pooled data from 4 Cordis-sponsored carotid stent trials, including the Continued Access Registry, CASES, SAPPHIRE and ADVANCE to identify the incidence, predictors and prognostic significance of TIA within 30 days of the procedure. Independent predictors of peri-procedural TIA were determined from stepwise logistic regression. The primary endpoint was the 30-day incidence of neurological death + stroke.
Results: In 2,104 patients, median age was 74 years, 37% were women, 29% had prior TIA and 28% previous stroke. TIA occurred in 78 (3.7%) patients from the procedure through 30-day follow up; 73% of TIAs occurred on or before post-procedure day #1. Independent predictors of peri-procedural TIA included age, symptomatic status, number of stents implanted, use of GP IIb/IIIa inhibitors and absence of hypertension. The incidence of neurological death + stroke in patients who suffered peri-procedural to 30-day TIA colmpared with those who did not appears below (Table).
Conclusion: Peri-procedural TIA associated with carotid stenting is uncommon and is not associated with an increased incidence of the composite 30-day neurological death + stroke.

30-Day Outcome	No Peri-Procedural TIA	Peri-Procedural TIA	P-Value
Neurological death or stroke	3.6%	6.8%	0.14

3:30 p.m.

2521-805 **A Simple Method to Calculate Cerebral Blood Flow After Carotid Stenting by Using Carotid Frame Count and Guidewire Length**

waleed Y. kadro, Yaman Rai Balha, Maya Turkmani, Omar Shiekh Mouss, Tarek Alsaied, Hussam Eddin Alrahim, The Golden Cardiovascular Center, Damascus, Syrian Arab Republic

Background: The Carotid frame count (CFC) is a relative index of cerebral blood flow that measures time by counting the number of frames required for dye to travel from a beginning standardized carotid landmark (The point of common carotid artery bifurcation into internal and external branches) to an end standardized carotid landmark (The point of internal carotid artery bifurcation into anterior and middle cerebral branches) in an angiogram filmed at a known speed frames/s).
Methods: We describe a new method to measure distance along arteries so that absolute velocity (length ÷ time) and absolute flow (area × velocity) may be calculated in patients undergoing percutaneous carotid stenting (CS). After CS, the guidewire tip is placed at the end carotid landmark and a Kelly clamp is placed on the guidewire where it exits the Y-adapter. The guidewire tip is then withdrawn to the beginning carotid landmark and a second Kelly clamp is placed on the wire where it exits the Y-adapter. The distance between the 2 Kelly clamps outside the body is the distance between the beginning and the ending anatomic landmarks inside the body. Velocity (cm/s) may be calculated as this distance (cm) ÷ carotid frame count (frames) / film frame speed (frames/s). Flow ml/s) may be calculated by multiplying this velocity (cm/s) and the mean cross-sectional lumen area (cm2) along the length of the carotid artery between the two landmarks.
Results: In 25 patients, velocity increased from 9.9 ± 4.5 cm/s before to 14.8 ± 4.3 cm/s after CS (p <0.001). For all 25 patients, flow increased from 2.4 ± 0.2 ml/s before to 4.1 ± 0.3 ml/s after CS (p <0.001).
Conclusions: Distance along carotid arteries (length) can be simply measured using CS guidewire. This length may be combined with the Carotid frame count to calculate cerebral blood absolute velocity and flow that are sensitive to changes in perfusion.

3:30 p.m.

2521-806 **Percutaneous Renal Artery Revascularization versus Medical Therapy for Renal Artery Stenosis: A Prospective Randomized Trial**

Aaron W. Sweeney, Fadi Hage, Raed Aqel, George Phillips, Gilbert Perry, Gilbert Zogbi, David Calhoun, University of Alabama at Birmingham, Cardiovascular Disease, Birmingham, AL, Birmingham Veterans Affairs Medical Center, Division of Cardiology, Birmingham, AL

Background: Renal artery stenosis (RAS) accounts for around 10% of hypertension and 20% of end-stage renal disease. Data from randomized studies are lacking on the value of percutaneous revascularization (PR) in the management of RAS. We performed a prospective randomized trial comparing PR to medical therapy (MT) in patients with atherosclerotic RAS.
Hypothesis: Hypertensive patients with significant RAS who undergo PR along with MT will have better blood pressure control compared to MT alone.
Methods: Adult hypertensive patients on blood pressure medications were eligible for the study if they had a central aortic pressure of 135mmHg or more and RAS of 75% or more, or RAS of 50% or more with a gradient of no less than 10mmHg across the stenosis on renal angiography. Patients were randomized to either PR or MT after renal angiography if they provided informed consent.
Results: 71 patients have been randomized out of whom 36 have completed 6 months follow-up (19 patients in the PR arm and 17 patients in the MT arm). Both the systolic and diastolic blood pressures dropped in the PR arm (128.5 +- 4.3 mmHg versus 142.3 +- 3.6 mmHg, P<0.05 and 66.2 +- 2.2 versus 72.9 +- 2.0 mmHg, P<0.05) while they did not change in the MT arm (134.8 +- 4.1 versus 138.8 +- 3.3 mmHg, P=0.4 and 66.8 +- 2.0 versus 71.0 +- 3.1 mmHg, P=0.2). Number of BP medications did not significantly change from baseline to 6 months in both groups. In the MT group, 4 (24%) patients crossed over and underwent PR due to failure to achieve target blood pressure at 6 months with maximal medical therapy. 1 (6%) patient in the MT group and no patients in the PR group were hospitalized for non-protocol related cardiovascular events.
Conclusions: Preliminary findings from our ongoing randomization trial show that PR can lower blood pressure in patients with RAS and hypertension better than MT alone at 6 months. This is an on-going study to determine the usefulness of PR in the management of RAS.

I2.POSTER CONTRIBUTIONS

2522

Imaging in the Cath Lab: Angiography & QCA

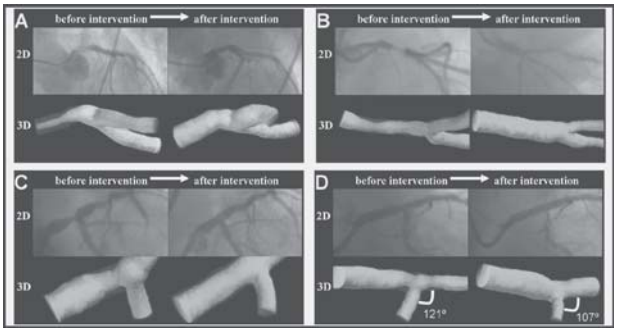
Monday, March 30, 2009, 3:30 p.m.-3:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2522-807 Percutaneous Interventions in Unprotected Left Main Lesions: Novel Three-Dimensional Imaging and Quantitative Analysis Before and After Intervention

Danny Dvir, Abid Assali, Eli Lev, Itsik Ben-Dor, Alexander Battler, Ran Kornowski, Rabin Medical Center, Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv, Israel

Background: Difficulties in performing percutaneous interventions in unprotected left main (LM) may be partly attributable to failure of conventional angiography to properly image vessel morphology and plaque distribution. The objective of this study was to examine the potential yield of three-dimensional (3D) reconstruction of LM coronary lesions.
Methods: 3D reconstruction of the coronary vessels was used to evaluate 302 angiographic images, before and after stenting, from 62 consecutive patients (age 73.5 ± 11.3 years) with unprotected LM lesions.
Results: 3D reconstructions significantly improved morphological analysis, especially for ostial and bifurcation lesions. In cases of bifurcation involvement, lesion length was significantly longer in the 3D reconstructions than in the 2D images (12.3±4.1 mm vs. 10.6±4.9 mm, p=0.003). The 3D analysis showed that procedures performed in distal LM were associated with a decrease in the bifurcation angle after intervention (from 82±27º to 72±28º, p=0.01). Elective interventions were associated with significantly lower mortality than emergent procedures (5% vs. 39% at 6 months).
Conclusions: 3D reconstruction adds insights on the morphology and lesion length of unprotected LM lesions, especially those involving the bifurcation, which may make it an important tool in planning interventional procedures and evaluating their results.



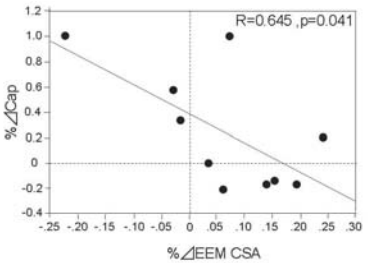
A. Ostial. **B**. Shaft **C**. Distal. **D**. Bifurcation (note a decrease in the bifurcation angle after intervention).

3:30 p.m.

2522-808 Relationship between the change of fibrous cap thickness and plaque morphology: Six months follow-up study of optical coherence tomography and intravascular ultrasound

Ryotaro Yamada, Hiroyuki Okura, Teruyoshi Kume, Takahiro Kawamoto, Yoji Neishi, Yoshinori Miyamoto, Akihiro Hayashida, Kiyoshi Yoshida, The Sakakibara Heart Institute of Okayama, Okayama, Japan, Kawasaki Medical School, Kurashiki, Japan

Background: Recently, in vivo assessment of a thin fibrous cap has become possible using high resolution optical coherence tomography (OCT). The pathological characteristics of vulnerable plaque prone to rupture are a positively remodeled vessel, a thin fibrous cap (<65μm) with macrophage infiltration into the cap and including a large necrotic core. Natural course of the fibrous cap and the relationship between serial arterial remodeling and changes in fibrous cap thickness is unknown. Therefore, the purpose of this study was to evaluate the relationship between changes in fibrous cap thickness and arterial remodeling by using OCT and intravasucular ultrasound (IVUS) during 6 months follow-up.
Methods: Three vessel IVUS and OCT examination was performed in 10 patients with angina pectoris. Thirteen fibroatheroma (plaque burden > 40 %) were detected by IVUS. Fibrous cap thickness of the fibroatheroma was measured by OCT. IVUS and OCT were repeated at 6 months follow up.
Results: Fibrous cap thickness was increased during 6 months follow-up (70.0±32.2→94.2±41.9μm). Percent change in fibrous cap thickness (%delta cap) was correlated negatively (r=-0.645, p=0.041) with the change in external elastic membrane cross sectional area (%delta EEM-CSA) (Figure).
Conclusions: Arterial remodeling may be related to change fibrous cap thickness.



3:30 p.m.

2522-809 Evaluation of Neointimal Coverage of Long-term Follow-up Evaluation after Sirolimus-Eluting Stents and Paclitaxel-eluting Stents Implantation by Optical Coherence Tomography

MIN ZHAO, Jan Minners, Thomas Comberg, Micheal Gick, Klaus Werner, Achim Buettner, Franz-Josef Neumann, Heart Center, Bad Krozingen, Germany, Heart Center of Beijing Friendship Hospital, Beijing, People's Republic of China

Background: Drug-eluting stents (DES) inhibit neointimal proliferation which may result in uncovered stent struts and predispose to the formation of stent thrombosis. Optimal coherence tomography (OCT) is a high-resolution imaging technique which can detect neointimal hyperplasia (NIH) in DES.
Methods: Patients who had DES more than 1 year ago and standard dual-antiplatelet therapy (long-term aspirin 100mg, clopidogrel 75mg daily for 6 months) after stenting were included. We used Modified OCT (non-occlusive) technique to evaluate the amount of neointimal coverage after DES implantation in consecutive stented coronary artery lesions.
Results: 36 DES (18 Sirolimus-Eluting Stent (SES), 18 Paclitaxel-eluting Stent (PES)) in 29 patients(68.21±12.43 years old, 17 male) were examined by OCT. The average follow up period is 642,31±248,94days. Totally 2199 struts in 358 cross-sectional images of 279mm single-stented segments were analysed. Mean neointimal thickness of all struts that with neointima was 176.31±79.59μM, which were similar in SES and PES (115.09±40.55 μM vs. 208.36±64.62 μM, p=0,12). It showed that 22% (483 of 2199) of total struts were still exposed without neointima even more than one year after DES implantation. Frequencies of non-neointima coverage was 21.15±16.61%, which showed 20.84±12.27% in SES and 22.17±17.41% in PES (p=0,28). The OCT identified 1 thrombus in 1 patient in SES group with neither abnormal findings on coronary angiograms nor clinical manifestations in this study.
Conclusions:DES had incomplete neointimal coverage even one year after stent implantation but resulted in no clinical events, there was no difference between SES and PES. 6 months duration of dual-antiplatelet therapy seems inadequate.

3:30 p.m.

2522-810 Three-Dimensional Bifurcation Angle Analysis in Patients With Left Main Disease: a Substudy of the SYNergy Between Percutaneous Coronary Intervention With TAXus and Cardiac Surgery (SYNTAX) Trial

Chrysafios Girasis, Yoshinobu Onuma, Marie-Claude Morice, Antonio Colombo, David R. Holmes, Ted E. Feldman, Keith D. Dawkins, Patrick W. Serruys, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands, Cardialysis BV, Rotterdam, The Netherlands

Background: Bifurcation angle (BA) is emerging as an independent predictor of outcome after PCI of bifurcation lesions. Three-dimensional (3-D) quantitative coronary angiography (QCA) eliminates the shortcomings of 2-D analysis, thus providing reliable data. We explore the variables describing the BA of the Left Main (LM) and the impact of PCI on this angulation.
Methods: This is a substudy of the SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery (SYNTAX) trial. We reviewed the cineangiograms of the 354 patients with LM disease who were randomized to PCI. Analysis was performed with 3-D QCA software (Cardiop-B, Paieon Medical Inc, Israel). The proximal BA (between LM and LCx) and the distal BA (between LAD and LCx) were computed in enddiastole and endsystole, both pre- and post-PCI; the variation of the BA during the heart cycle was also determined.
Results: Complete analysis with 3-D QCA was feasible in 266 (75.1%) patients. Post-PCI there was a significant reduction in the width of the distal angle. The proximal angle was not modified significantly (table). During systolic motion there was an enlargement of the proximal angle and a reduction of the distal angle (p<0.001 for both). The prognostic significance of these measurements will be presented at the time of the congress.
Conclusion: Left Main bifurcation angle analysis with 3-D QCA is feasible. PCI affects the distal angle, whereas both proximal and distal angles are affected by the heart's motion.

Left Main Bifurcation Angles, pre- and post-PCI

	Pre-PCI	Post-PCI	p-value
Diast_prox_BA	106.1 ± 22.0	107.8 ± 21.6	0.142
Syst_prox_BA	113.9 ± 19.8	114.8 ± 19.0	0.409
Var_prox_BA	12.0 ± 9.7	11.0 ± 8.9	0.149
Diast_dist_BA	95.6 ± 23.9	91.0 ± 22.2	<0.001
Syst_dist_BA	86.7 ± 23.1	82.8 ± 21.1	<0.001
Var_dist_BA	11.7 ± 9.7	11.9 ± 9.2	0.737

Student's t-test, p<0.05 significant. Values are in degrees.

3:30 p.m.

2522-811 The Use of Transcranial Doppler in the Detection of Right-to-Left Shunt in the Catheterization Laboratory

Paul Poommipanit, Hohai Van, Mostafa Shalaby, Jonathan Tobis, UCLA, Los Angeles, CA

The purpose of this study was to determine the sensitivity of different methods of detecting right-to-left shunts. Transesophageal echocardiography (TEE) has traditionally been the most reliable diagnostic technique for assessment of intracardiac shunts. Some patients with a high clinical suspicion for patent foramen ovale (PFO) have inconclusive studies, in part due to a lack of cooperation with the Valsalva maneuver from sedation. Twenty seven consecutive patients were brought to the cardiac catheterization laboratory for PFO closure where simultaneous transcranial Doppler (TCD) and intracardiac echocardiography (ICE) were performed. Right atrial pressures were measured at rest, with Valsalva and with forced exhalation into a manometer to 40mmHg. Prior to PFO closure, the average right atrial pressures were as shown in the table below.
Of the 27 patients who had their PFOs closed, 3 had false-negative TEE studies with positive TCD studies. TCD was also more sensitive than intracardiac echo for estimating the degree of shunt. This study confirms that inadequate intrathoracic pressures are frequently generated with a voluntary Valsalva maneuver, thus confirming a potential mechanism for false negative agitated saline transesophageal echocardiograms in the assessment of intracardiac shunts.

Right Atrial Pressures

RA Pressure at rest	RA Pressure with Valsalva	RA Pressure against manometer
6.6 ± 2.7 mm Hg.	22.2 ± 13.6 mmHg*	37.2 ± 6.8 mmHg*
	*compared to rest (p<0.001)	during Valsalva maneuver (p<0.001)

3:30 p.m.

2522-812 Relation Between N-Terminal Pro-B-Type Natriuretic Peptide and Coronary Plaque Components in Patients with Acute Coronary Syndrome: Virtual Histology-Intravascular Ultrasound Analysis

Youngkeun Ahn, Young Joon Hong, Doosun Sim, Nam Sik Yoon, Hyun Ju Youn, Kye Hun Kim, Hyung Wook Park, Seung Uk Lee, Hyung Wook Park, Ju Han Kim, Myung Ho Jeong, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, Chonnam National University Hospital, Gwangju, South Korea, Gwangju, South Korea

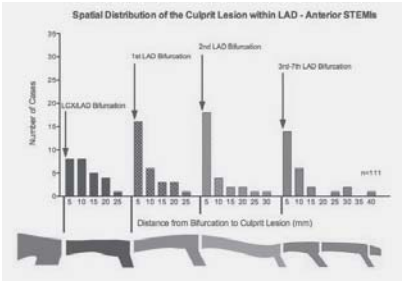
Background: The N-terminal pro-B-type natriuretic peptide (NT-pro-BNP) is a sensitive indicator of hemodynamic stress and its increased level is associated with higher mortality in acute coronary syndrome (ACS) patients. Virtual histology-intravascular ultrasound (VH-IVUS) can provide quantitative information on plaque components. We used VH-IVUS to evaluate the relation between NT-pro-BNP levels and plaque components in patients with ACS.
Methods: We measured pre-procedural serum NT-pro-BNP levels in 156 ACS patients with preserved left ventricular systolic function and normal serum creatinine. VH-IVUS classified the color-coded tissue into four major components: fibrotic; fibro-fatty; dense calcium; and necrotic core (NC). Thin-cap fibroatheroma (TCFA) was defined as focal, NC-rich (≥ 10% of the cross-sectional area) plaques being in contact with the lumen in a plaque burden ≥ 40%. We divided the patients into two groups according to the NT-pro-BNP levels [Group I: ≥ 200 pg/ml (n=58) vs. Group II: < 200 pg/ml (n=98)].
Results: The percent area of NC at the minimum lumen site (19.8±13.1% vs. 15.2±11.1%, p=0.027) and at the largest NC site (24.7±10.3% vs. 19.2±11.4%, p=0.015) were significantly greater in Group I than in Group II. Percent NC volume was significantly greater in Group I than in Group II (15.8±8.1% vs. 10.1±9.1%, p=0.008). The total number of TCFAs was 38 in group I and 56 in group II. The presence of at least one TCFA (58% vs. 38%, p=0.009) and multiple TCFAs (25% vs. 10%, p=0.005) within culprit lesions were observed more frequently in Group I than in Group II. The TCFAs were located more in proximal in Group I than in Group II [the length from coronary ostium to TCFA: 10.8±7.6 mm in Group I vs. 25.7±16.3 mm in Group II (p<0.001).] 85% of TCFAs was located within 20 mm from coronary ostium in Group I; conversely only 36% of TCFAs was located within 20 mm from coronary ostium in Group II (p<0.001).
Conclusions: VH-IVUS analysis demonstrates that ACS patients with high NT-pro-BNP levels had more vulnerable plaque component (more NC-containing lesions and higher frequency of culprit lesion TCFAs) and had more proximally located TCFAs.

3:30 p.m.

2522-813 Culprit Lesions in Patients With Anterior ST Elevation Myocardial Infarction Are Located Immediately Distal to Bifurcations

Ahmad M. Jeroudi, Omar R. Kashlan, Erin M. Galbraith, Eric L. Krivitsky, Michael C. McDaniel, Collins A. Kwarteng, Saurabh S. Dhawan, Jin Suo, Don Giddens, John S. Douglas, Habib Samady, Emory University, Atlanta, GA, Georgia Institute of Technology, Atlanta, GA

Background: Anterior ST elevation myocardial infarction (STEMI) culprit lesions are clustered in the proximal left anterior descending artery (LAD). Based on fluid dynamics principles, we hypothesized that these culprit lesions are located immediately distal to bifurcations where flow is non-laminar.
Methods: Emory University's contribution to the National Cardiovascular Data Registry was queried for STEMIs presenting from January 2006 to July 2008. Culprit lesions were defined as site of vessel occlusion or severe stenosis. Quantitative coronary angiography was used to measure distance from culprit lesion to LAD ostium and to the nearest proximal branch artery >1mm diameter.
Results: 111 of 469 STEMI patients had identifiable LAD culprit lesions (mean age 58±14 years, 69% male). Most culprit lesions, 93%, were located in the proximal 50mm of the LAD. Overall, culprit lesions were more likely to be located immediately distal to bifurcations: 52% within 5mm, 74% within 10mm, 85% within 15mm, p<0.01 (graph). Median distance from bifurcation to culprit lesions was 4.6 mm. We observed a positive correlation between side branch diameter and the distance from the culprit lesion to the bifurcation (r=0.49, p<0.01), with smaller diameter branches having LAD lesions closest to the branch artery.
Conclusion: Arterial bifurcations and branch artery diameter influence location of LAD culprit lesions, suggesting that disturbances in wall shear stress are implicated in plaque formation and rupture.



3:30 p.m.

2522-814 A Novel Approach to Quantitative Analysis of Intravsacular Optical Coherence Tomography Imaging

Nico Bruining, Kenji Sihan, Charl Botha, Frits Post, Nieves Gonzalo, Evelyn Regar, Ronald Hamers, Erasmus MC, Rotterdam, The Netherlands, TU-Delft, Delft, The Netherlands

Objectives and Background: Quantitative analysis on intracoronary optical coherence tomography (OCT) image data (QOCT) is currently performed by a time-consuming manual contour tracing process in many individual OCT images acquired during a pullback (frame-based method). In order to get an efficient quantitative analysis process, we developed a full-automated lumen contour detection method and evaluated the results against those derived by human observers.
Methods: The automated method has been developed using Matlab (The Mathworks, Natick, MA, USA) and uses an adapted Canny filter to detect the lumen borders. The process runs fully automated and allows the observer to change individual results in case of possible errors. OCT image data, acquirevd with a commercially available system (Lighlab imaging, Westford, MA, USA) in 20 randomly selected patients were used for this validation study.
Results: A total of 4137 individual OCT images were analyzed. There was no statistical significant difference in lumen areas between the two methods (5.03±2.16 vs. 5.02±2.21 mm2, p=0.6; respectively (human vs. automated)). Regression analysis showd a good correlation with an R value of 0.99 (Figure). The full automated analysis requires on average 2-5 seconds per frame and in only 3% of the contour data correction was necessary.
Conclusion: The present study shows that full-automated lumen contour detection in OCT images is feasible with only a sparse few frames showing an artifact, which can be easily corrected.
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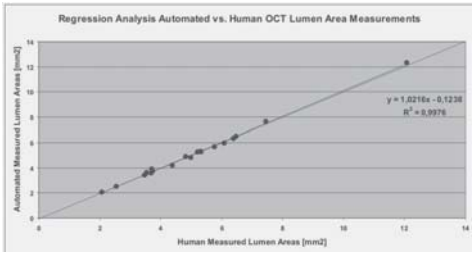


I2.POSTER CONTRIBUTIONS

2523

Intravascular Diagnostics

Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2523-815 Unraveling the Lack of Neointimal Hyperplasia Detected by Intravascular Ultrasound using Optical Coherence Tomography: Lack of Spatial Resolution or a True Biological Effect?

Hiram G. Bezerra, Giulio Guagliumi, O. Valescchi, N. Lortkipanidze, Noah Rosenthal, Satoko Tahara, Hiroyuki Kyono, Daniel Simon, Marco A. Costa, University Hospitals Harrington-McLaughlin Heart & Vascular Institute, Cleveland, OH, Ospedali Riuniti di Bergamo, Bergamo, Italy

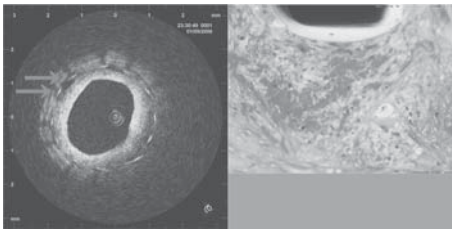
Introduction: Intravascular ultrasound (IVUS) frequently depicts absence of neointimal hyperplasia(NIH) after drug-eluting stents (DES). Histology studies suggest that IVUS may be unable to detect small amounts of NIH. OCT has a 10X higher spatial resolution compared with IVUS. The aim of this study was to evaluate the ability of OCT to detect NIH and malapposition in stented coronary segments showing no NIH or malapposition by IVUS at 6-month post-implantation.
Methods: A subanalysis of the ODESSA trial, a single-center prospective randomized, controlled study enrolling patients with long lesions requiring stent in overlap. Patients were randomized to drug eluting stents and bare metal stent in a 2:2:2:1 ratio. IVUS and OCT analyses were performed by an independent core laboratory. Stented coronary segments showing no (zero) NIH and no strut malapposition by IVUS were included. Detailed OCT strut level analysis was performed at every 0.3 mm intervals to determine NIH area and strut-level NIH thickness and malapposition.
Results: In 75 patients with complete follow-up imaging, 250 stented segments were analyzed by IVUS and OCT. Zero NIH and no malapposition were found in 20 segments in 11 patients (15%). There were 6968 cross-sections and 43096 struts analyzed by OCT. A significant correlation was observed between IVUS and OCT for stent lumen area r=0.8 (p=0.01). However, OCT measured an average of 0.72 mm^2 ± 0.63 of NIH per cross section and identified malapposition in 31% of segments. Indeed, 92.7% ± 15% of struts were covered by tissue. The degree of strut coverage varied considerably ranging from 35% to 100% coverage. There were no segments with complete absence of strut coverage by OCT, in contrast to a homogenous lack of NIH detected by IVUS. Of the 3146 uncovered strus detected by OCT, 96% were apposed.
Conclusion: All cases without identifiable NIH by IVUS have certain amount of tissue coverage detected by OCT strut-level analysis. In addition, undetected strut malapposition and heterogeneous pattern of strut tissue coverage were depicted by OCT. This study supports the need of high resolution imaging such as OCT to properly evaluate local vascular responses to potent drug-eluting stents.

3:30 p.m.

2523-816 Black Spot Surrounding Stent Struts Observed by Optical Coherence Tomography; What Do These Represent?

Tomohiko Teramoto, Fumiaki Ikeno, Jennifer Lyons, Hiromasa Ootake, Alan C. Yeung, Stanford University Cardiovascular Medicine, Stanford, CA

Background: Optical coherence tomography (OCT) has recently merged into the field of interventional cardiology.We have observed characteristic "black spot" images surrounding stent struts using OCT post drug eluting stent (DES) deployment (image 1 left, Arrow head). The purpose of this study is to reveal what these "black spot" represent .
Methods: A total of 36 stents (16 bare metal stent (BMS) and 20 DES) were deployed in the coronary arteries of 6 pigs. At one month, OCT was performed. The animals were then sacrificed and histological analysis was performed.
Results: The "black spots" appeared with significantly higher frequency in the DES group than BMS group (65% (13/20) vs. 19% (3/16), *p<0.001*). Percent neointimal volume on DES group was significantly higher in the "black spot" (+) group than "black spot" (-) group (45.5±18.3 vs. 27.6±18.9, *p=0.05*). Upon histological analysis, fibrin was mainly observed at the "black spot" site corresponding OCT image. Hyalironic acid and proteoglycan were also observed, and in small amounts, neutrophil and macrophage infiltration.
Conclusions: We currently think that these "black spots" surrounding stent struts might have some correlation with neointimal hyperplasia post DES deployment. According to the histological analysis, it seemed that hyaluronic acid and proteoglycan replaced fibrin. The "black spots" seemed to represent the process of fibrin resolution.

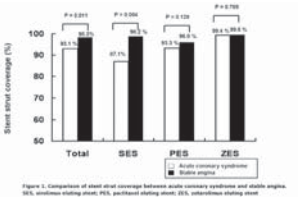


3:30 p.m.

2523-817 Rate of Neointimal Coverage is Different According to Initial Clinical Presentation and Types of Drug-Eluting Stents; Optical Coherence Tomography Findings

Jung-Sun Kim, Jung Myung Lee, Jin-Sun Kim, Yong Sung Seo, Sung Il Paik, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, Namsik Chung, Division of Cardiology, Yonsei University, Seoul, South Korea

Background: Acute coronary syndrome (ACS) has a different pathophysiology from stable angina (SA) and might has a different pattern of NC. Recently, optical coherence tomography (OCT) was introduced in clinical practice and could detect a NC with high resolution. Therefore, we compared NC patterns at 9 months after drug eluting stents (DES)implantation between ACS and SA using OCT. **Method:** OCT was performed at 9-month follow-up with 50 ACS (20 in sirolimus eluting stent (SES), 12 in paclitaxel eluting stent (PES) and 18 in zotarolimus eluting stent (ZES)) and 42 SA (15 in SES, 12 in PES and 15 in ZES). NIH thickness, percent NIH area and rate of malapposition were measured at each stent strut and corss section. **Results:** In total, 20842 struts in 2180-mm single-stented segments were analyzed. Overall, NIH thickness and percent NIH area were not different between ACS and SA (173 ± 100 vs. 163 ± 125 μm, p = 0.670 and 21 ± 11 vs. 18 ± 11 %, p =0.447). But rates of stent strut coverage (93.1 vs. 98.3 %, p=0.009, Figure 1) and rate of malapposition (1.8 vs. 0.4 %, p = 0.002) were significantly higher in ACS. According to the type of stents, SES has a different pattern of NC according to presence of ACS compared to other 2 DESs (Figure 1). **Conclusion:** Neointimal coverage rate at 9-month after stent implantation was significantly different between ACS and SA and especially, SES has a different pattern of NC. Therefore, present study suggested that NC might be influenced by initial clinical presentation and type of DESs.

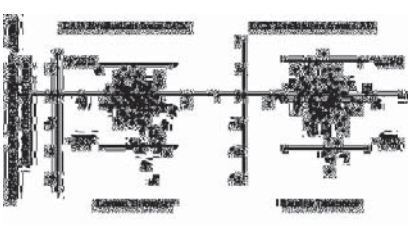


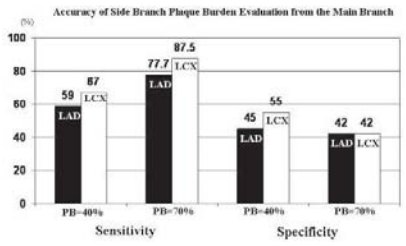
3:30 p.m.

2523-818 Is An Accurate Evaluation Of The Left Circumflex Ostium From The Left Anterior Descending-Left Main Possible? An Intravascular Ultrasound Study

Carlos Oviedo, Akiko Maehara, Gary S. Mintz, Damiana Fiscella, Kenichi Tsujita, Takashi Kubo, Hiroshi Doi, Celia Castellanos, Junqing Yang, Roxana Mehran, George D. Dangas, Martin B. Leon, Gregg W. Stone, Hiroshi Araki, Masahiko Ochiai, Jeffrey W. Moses, Cardiovascular Research Foundation - Columbia University Medical Center, New York, NY

Treatment of left main (LM) distal bifurcations can depend on ostial left circumflex (LCX) disease severity. We asked the question whether intravascular ultrasound (IVUS) assessment of the LCX ostium requires direct imaging or is accurate from the left anterior descending (LAD)-LM pullback.
Methods: In 126 patients with LM bifurcation disease (angiography diameter stenosis ≥50% and IVUS plaque burden (PB) ≥40%), we analyzed both pullbacks - from the LAD and from the LCX. (1) During the main branch pullback (i.e., from the LAD), we evaluated the side branch ostium (i.e., of the LCX) by estimating its lumen diameter and presence of significant plaque. We used 2 cut-offs for significant PB: 40% and 70%. (2) We then compared this oblique view with direct ostial measurements during LCX pullback. (3) Finally, we repeated this process imaging in the ostial LAD from the LCX.
Results: From the LAD, the estimated LCX ostial lumen diameter was 3±0,8mm compared to the actual diameter of 2,9±0,6mm. From the LCX, the estimated LAD ostial lumen diameter was 2,9±1,1mm vs. the actual diameter of 2,8±0,5mm. However, Bland-Altman plot (Figure) showed significant variation in these comparisons. The oblique view assessment of significant PB using 2 cut-offs (40% or 70%, Figure) showed good sensitivity, but poor specificity.
Conclusion: IVUS evaluation of the LCX ostium from the LAD-LM (or of the LAD ostium from the LCX-LM) is only modestly reliable. For an accurate assessment of the ostium of the side branch, direct imaging is necessary.



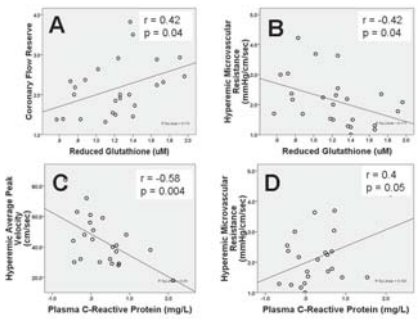


3:30 p.m.

2523-819 **Oxidative Stress and Inflammatory Markers are Determinants of Coronary Microvascular Function**

Saurabh S. Dhawan, Michael McDaniel, Collins A. Kwarteng, Kwan Lee, Ahmad M. Jeroudi, Omar R. Kashlan, Erin M. Galbraith, Vivek Nautiyal, Dean P. Jones, Arshed A. Quyyumi, Habib Samady, Emory University School of Medicine, Atlanta, GA

Background: Coronary flow reserve (CFR), defined as the ratio of hyperemic-to-baseline average peak velocity (APV) and hyperemic microvascular resistance (HMR), defined as the ratio of hyperemic distal pressure-to-hyperemic APV are indices of coronary microvascular resistance. We hypothesized that increased oxidative stress and inflammation are associated with lower CFR and higher HMR.
Methods: We performed invasive physiologic evaluation in 33 patients with moderate coronary lesions. Measurement of APV at baseline and hyperemia (Hyp-APV) induced by 140 mcg/kg/min of intravenous adenosine, CFR, FFR (fractional flow reserve) and HMR was performed using a combined pressure and Doppler wire. Four patients with significant epicardial stenoses (FFR< 0.80) were excluded. Plasma reduced glutathione (GSH) and high-sensitivity c-reactive protein (CRP) were measured as biomarkers of oxidative stress and inflammation, respectively.
Results: Mean age was 56 ± 11 years, 64% were male, 72% had hypertension, 88% had hyperlipidemia and 24% had diabetes. GSH correlated positively with CFR (r=0.42, p<0.05) [Fig.A] and Hyp-APV (r=0.47, p<0.05) and negatively with HMR (r=-0.42, p<0.05) [Fig.B]. CRP correlated negatively with Hyp-APV (r=-0.58, p=0.004) [Fig.C] and positively with HMR (r=0.4, p=0.05) [Fig.D].
Conclusions: Increased biomarkers of oxidative stress and inflammation are associated with reduced coronary microvascular function in patients with non-obstructive coronary atherosclerosis.



3:30 p.m.

2523-820 **Quantification of Calcified Plaque by Optical Coherence Tomography: Ex Vivo Validation and Predictive Value for Stent Expansion**

Teruyoshi Kume, Hiroyuki Okura, Takahiro Kawamoto, Ryotaro Yamada, Akihiro Hayashida, Yoji Neishi, Yoshinori Miyamoto, Koichiro Imai, Kiyoshi Yoshida, Stanford University, Palo Alto, CA, Kawasaki Medical School, Kurashiki, Japan

Background: Optical coherence tomography (OCT) can accurately delineate calcified plaque without acoustic shadowing. The aims of this OCT study were to evaluate: (1) the ability to quantify calcified plaque in *ex vivo* human coronary arteries; and (2) determine the impact of calcified plaque on stent expansion.
Methods: In an *ex vivo* study, 91 coronary segments from 33 consecutive human cadavers were examined. By intravascular ultrasound (IVUS), 32 superficial calcified plaques, defined as the leading edge of the acoustic shadowing appears within the most shallow 50% of the plaque plus media thickness, were selected and compared with corresponding OCT and histological examinations. Area of calcification (AC) was measured by planimetry. For this clinical study, 16 culprit lesions with IVUS-defined superficial calcified plaque were enrolled. OCT imaging was performed before intervention and AC was measured. Stent expansion was assessed as the minimal stent area (MSA) divided by the reference area.
Results: Ex vivo study showed that IVUS significantly underestimated AC compared with histology (y = 0.39 x + 0.14, r=0.78, p<0.001). Although OCT slightly underestimated AC (y = 0.67 x + 0.53, r=0.84, p<0.001), it showed a better correlation with histology than IVUS. In vivo study demonstrated that there was a significant correlation between AC by OCT and stent expansion (r = -0.59, p = 0.02), but not between AC by IVUS and stent expansion (r = -0.40, p = 0.13). AC > 2.0 cm^2 could predict stent underexpansion (MSA < 80% of the reference area) with a sensitivity of 71 % and a specificity of 78%.
Conclusion: Both OCT and IVUS underestimated AC, but OCT estimates of AC were more accurate than those estimated by IVUS. Thus, OCT may be a more useful clinical tool to quantify calcified plaque and predict stent expansion.

3:30 p.m.

2523-821 **Presence of a Ramus Intermedius is Associated with More Proximal LAD Culprit Lesions in Patients with Anterior ST Segment Elevation Myocardial Infarctions**

Erin Michelle Galbraith, Ahmad M. Jeroudi, Omar R. Kashlan, Eric Krivitsky, Michael C. McDaniel, Collins A. Kwarteng, Jin Suo, Don Giddens, Douglas C. Morris, John S. Douglas, Habib Samady, Emory University, Atlanta, GA, Georgia Institute of Technology, Atlanta, GA

Background: Fluid dynamic principles suggest that left main trifurcations result in greater flow disturbances in the very proximal left anterior descending (LAD) artery. We hypothesized that in patients presenting with anterior ST elevation myocardial infarction (STEMI), the presence of a ramus intermedius (RI) artery is associated with more proximal LAD culprit lesions resulting in larger infarcts.
Methods: Emory's contribution to the National Cardiovascular Data Registry was queried for STEMIs presenting from January 2006 to July 2008. Culprit lesions were defined as site of occlusion or severe stenosis. A RI was considered present when its diameter was ≥ 1mm. Quantitative coronary angiography was used to measure distance from LAD ostium to the culprit lesion in patients with and without RI. Peak troponin-I (TN-I), peak creatinine kinase MB (MB), and left ventricular ejection fraction by ventriculography were used as markers for infarct size.
Results: Among 469 STEMI patients, 137 had native LAD STEMI. Of these, 111 patients had identifiable culprit lesions (age 58±14 years, 69% male). Mean distance from LAD ostium to culprit lesion was 15.2 ± 11.0 mm in RI patients (n=27) and 27.8 ± 16.7 mm in non-RI patients (n=84), p<0.01. Culprit lesions within the LAD were more proximal in the RI vs. non-RI patients: 0-10mm: 37% vs. 12%, p<0.01, and 0-20mm: 67% vs. 33%, P<0.01. Those with RI tended to have higher peak TN-I values (74 ± 40 ng/ml vs. 60 ± 40 ng/ml, p<0.13) and were more likely to have peak TN-I values > 90 ng/ml (69% vs. 42%, p<0.02) compared to the non-RI patients. Similary, RI patients were more likely to have peak MB >200 ng/ml, (67% vs. 43%, p<0.05), with peak MB levels only slightly higher in the RI group compared to the non-RI group, 310 ± 250 ng/ml vs. 250 ± 240 ng/ml, p<0.25. Left ventricular ejection fraction was not significantly lower in patients with RI compared to those without RI, 36 ± 10% vs. 39 ± 11%, p<0.26.
Conclusions: In patients presenting with anterior STEMI, RI presence is associated with more proximal LAD culprit lesions and a trend towards larger myocardial infarctions. These data suggest that coronary anatomy and resulting flow disturbances may have important clinical implications.

3:30 p.m.

2523-822 **Histopathologic Validation of DICOM based-Ultrasound Signal Intensity: An Echoplaque Medical Imaging Bench(MIB) study in autopsied coronary arteries**

Sang-Wook Kim, Gary S. Mintz, Young-Joon Hong, Sung-Yun Lee, Wang-Soo Lee, Hyeong-Joong Kim, Gi-Hwan Kim, Kwang-Je Lee, Tae-Ho Kim, Chee-Jeong Kim, Wang-Seong Ryu, Neil J. Weissman, Chung-Ang Unversity Hospital, Seoul, South Korea, Washington Hospital Center, Washington, DC

We used histopathologically-validated intravascular Ultrasound (IVUS) Virtual Histology (VH) to evaluate the accuracy of processed reflected grayscale IVUS signal intensity to assess plaque composition. **Methods.** We harvested 123 coronary arteries from 43 autopsied cases. Greyscale IVUS and VH-IVUS imaging were performed beginning 30mm distal to the ostium of each coronary artery. Greyscale IVUS was processed; and the signal intensity determined from DICOM-stored images using a new MIB system (Echoplaque MIB, Indec, Mountain View, CA, USA). We compared 208 regions of interest (ROIs). The accuracy rate was expressed using the interpolation method and 95% confidence interval[CI]. **Results.** Pt age was 49±9.12yrs and 82% were males. Four pts had sudden cardiac death and 39 non-cardiac death. The grayscale IVUS signal intensity of dense calcium was 215±21.1 (95% CI: 207~223), of fibrosis was 75±17.8 (95% CI: 72~79), and of fibrofatty was 55±11.3 (95% CI: 52~59); however, necrotic core had a grayscale signal intensity between fibrous and dense calcium - 161±27.4 (95% CI:153~168, figure). As a result of interpolation method, the cut-off value of fibro-fatty was 0 ~ 65, fibrosis was 65< ~ 105, necrotic core was 105< ~ 187, dense calcium was over 187. MIB greyscale had a 78.1% sensitivity and 91.9% specificity vs histopathology. **Conclusion.** Plaque characterization using DICOM-based grayscale IVUS signal intensity may improve the major limitation of greyscale IVUS, its inability to assess plaque composition.

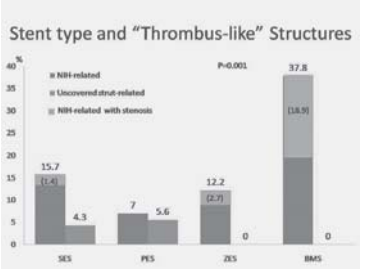
	ROIs	Predictive Accuracy	Sensitivity			Specificity		
			%	95% CI		%	95% CI	
FF	43	84.6%	83.7	72.7	94.8	84.8	79.4	90.3
FIBROUS	81	82.7%	64.2	53.8	74.6	94.5	90.5	98.5
NC	54	90.4%	77.8	66.7	88.9	94.8	91.3	98.3
CALCIUM	30	92.3%	86.7	74.5	98.8	93.3	89.6	96.9

3:30 p.m.

2523-823 High Frequency of Abnormal Intraluminal Tissue detected by Optical Coherence Tomography (OCT) 6 months after Deployment of Bare Metal (BMS) and Drug-eluting Stents (DES)

Vasile Sirbu, Hiroyuki Kyono, Giulio Guagliumi, Satoko Tahara, Noah Rosenthal, Giuseppe B. Zoccai, Teruyoshi Kume, Hiram G. Bezerra, Marco A. Costa, Ospedali Riuniti di, Bergamo, Italy, BergamoUniversity Hospitals Harrington-McLaughlin Heart & Vascular Institute, Cleveland, OH

Background: Previous reports suggest the ability of OCT to identify intravascular thrombus. However, this remains to be determined. We sought to evaluate the prevalence and characteristics of abnormal intraluminal tissue (ILT) detected by OCT at 6-month follow-up after stent implantation.
Methods: The ODESSA trial was a prospective randomized trial designed to evaluate healing of overlapped DES vs. BMS for de novo coronary artery stenosis. All 75 cases (20 SES, 22 PES, 22 ZES, 11 Liberte BMS) underwent OCT imaging at 6 month follow-up. A blinded strut-level analysis was performed at an independent core laboratory. ILT was defined as any intraluminal material with >0.25mm protruding into the lumen with light backscattering and attached to the vessel wall. ILT was stratified based on the presence or absence of neointimal hyperplasia (NIH).
Results: A total of 252 segments (OLP 86, non-OLP 166) were examined. ILT were found in 35 (21.1%) non-OLP and 11 (12.8%) OLP segments (P=0.26). Only SES and PES stents had ILT with uncovered struts (graph). BMS showed significantly higher incidence of ILT than DES. Half of BMS related ILT were observed in segments with severe NIH and lumen obstruction.
Conclusions: OCT detected a high incidence of abnormal ILT 6-months after implantation of both DES and BMS. Although ILT was defined based on known OCT thrombus properties, the clinical and pathological implication remains to be determined. Our results also illustrate the challenge in defining intravascular thrombus based on OCT.



3:30 p.m.

2523-824 PCI causes a Reduction in Microvascular Resistance in The Adjacent Vessel Territory

Billal Patel, Paul Browning, George Hart, Michael Fisher, Linda Smith, Royal Liverpool University Hospital, Liverpool, United Kingdom, Cardiothoracic Centre, Liverpool, United Kingdom

Background: Well developed collaterals play an important role in myocardial perfusion in patients with ischaemic heart disease. Coronary stenosis in one vessel is known to affect the haemodynamics of flow in the adjacent vessel bed. However the haemodynamic effect, of performing PCI in one vessel territory, has on the adjacent vessel bed has received little attention.
Methods: We measured the index of microvascular resistance(IMR) in the target vessel and a reference vessel (either left anterior descending or circumflex artery) using the thermodiltion technique and a pressure wire in patients with stable angina and single vessel disease. IMR was calculated at maximal hyperaemia during intravenous infusion of adenosine at 140ug/kg/min. Fractional flow reserve (FFR) and coronary flow reserve (CFR) were also recorded in both vessels before and after PCI. Data is presented as mean +/- SEM. Statistical analysis was performed using paired t-test.
Results: 22 patients were included in the study, mean age 61.2. FFR increased in the target vessel (0.61+/-0.03 vs 0.91 +/-0.01 p<0.0001). The CFR increased in the target vessel in response to PCI. (1.60 +/- 0.16 vs 2.56 +/- 0.28 p <0.001). There was no significant change in CFR post PCI in the reference vessel (3.04 +/- 0.36 vs 2.67 +/- 0.27 p=0.22). IMR reduced in response to PCI in the target vessel (31.71+/- 4.23 vs 20.68 +/- 2.51) and the reference vessel (27.06+/-3.28 vs 21.02+/-2.69 p=0.02).
Conclusions: IMR shows significant reductions in both vessel territories, although the reduction is to be expected in the target vessel since by performing the angioplasty flow will increase and hence a reduction in microvascular resistance would be expected. However the reduction in IMR in the reference vessel suggests a global reduction in IMR is acheived which is a novel finding. This data suggests another mechanism may be responsible,such as release of vasoactive mediators which are able to further vasodilate the microcirculation despite hyperaemia induced by adenosine.

3:30 p.m.

2523-825 The Nonuniform Strut Distribution is Associate with Intimal Hyperplasia in Patients with Drug Eluting Steent Implantation

Jin Bae Lee, Kee SIk Kim, So Yeon Kim, Young Soo Lee, Jae Kern Ryu, Ji Yong Choi, Sung Gug Chang, Daegu Catholic University Medical Center, Daegu, South Korea

Background: There is little data regarding the nonuniform strut distribution(NSD) and intimal hyperplasia(IH). The aim of this study was identify the impact of NSD on intimal hyperplasia in patients with drug eluting stent (DES) implamtation.
Methods: From January 2006 to May 2007, patients having IVUS guided intervention with DES implantation were consecutively registered. NSD was defined as interstrut angle > 90°, and NSD segment was defined as any segment observed for more than 0.5 mm longitudinally. Lesions were graded as follows: grade 1, none or slight intimal proliferation(≤25%); grade 2, intimal proliferation with no significant stenosis (<50%); grade 3, intimal proliferation with moderate stenosis (≥50%); and grade 4, intimal proliferation with severe stenosis (≥75%). Grade 2, 3 and 4 were considered IH, and Grades 3 and 4 were considered binary instent restenosis(ISR). NSD after stent implantation and followed intimal hyperplasia were assessesd.
Results: We performed IVUS in 120 patients after DES implantation, and 123 stented lesions were scanned. Of these, 71 (59.2%) had follow up analysis for intimal hyperplasia. The IH was more frequently occur in NSD patients(with NSD 17.4% vs without NSD 5.2%, p=0.045) and The ISR were more frequently occur in NSD patients without statistical significance(with NSD 15.4% vs without NSD 6.5%, p=0.253).
Conclusions: Patients with NSD after DES implantation have an increased IH rate compared to patients without NSD.

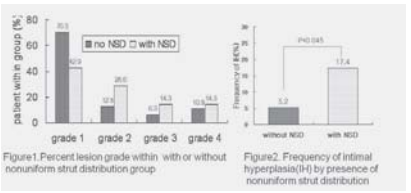


Figure1.Percent lesion grade within with or without nonuniform strut distribution group

Figure2. Frequency of intimal hyperplasia(IH) by presence of nonuniform strut distribution

3:30 p.m.

2523-826 Optical Coherence Tomography Analysis of Culprit Lesions of Patients with Acute Myocardial Infarction in Combination With Intracoronary Thermography: Excessive Macrophage Infiltration of Thin Fibrous Caps are Associated With Increased Local Temperature.

Konstantinos Toutouzas, Maria Riga, Andreas Synetos, Antonis Karanasos, Eleutherios Tsiamis, Dimitrios Tousoulis, Costas Tsioufis, John Karampelas, Athanasios Trikas, Elli Stefanadi, Christodoulos Stefanadis, 1st Cardiology Clinic, University of Athens, Medical School, Hippokration Hospital, Athens, Greece

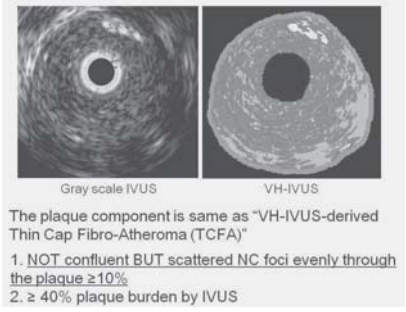
Purpose: Morphological characteristics of atherosclerotic plaques can be analysed by intracoronary optical coherence tomography (OCT) study. Intracoronary thermography (ICT) detects the functional situation of the atherosclerotic plaque by quantitative measurement of the local temperature. Moreover, OCT images reveal sites of the fibrous cap of the lesion with excessive macrophage infiltration. In this study we investigated the correlation between the morphological characteristics of the culprit lesion (CL) as analysed by OCT and its functional characteristics as measured by ICT in patients with acute myocardial infarction (AMI).
Methods: We studied 23 CL of 23 pts (20 men, 3 women, mean age 61±14 years) with AMI (ST and non-ST segment elevation). ICT and OCT were performed in patients undergoing coronary angiography. Temperature difference between the lesion and the healthy proximal vessel wall (ΔT) was measured with a dedicated thermography catheter. Thereafter, we measured the minimal thickness of the fibrous cap (mTFC) at CL by OCT. Lesions with mTFC < 65 μm were characterized as thin cap plaques, and CL with mTFC > 65 μm were characterized as thick cap plaques. The sites in the fibrous cap of CL with macrophage infiltration were identified in OCT images.
Results: We analyzed 23 CL. Sixteen CP (69.57%) had increased plaque temperature (ΔT> 0.05°C) and 7 CP (30.4%) had low plaque temperature (ΔT<0.05°C). All CL (100%, p<0.01) with low ΔT had thick cap (mTFC=98±22 μm). Three CL (18.7%) with high ΔT had thick cap (mTFC=78±9μm, p=0.02), while in 13 CL with high ΔT (80.9%) thin cap plaques were observed (mTFC=49±12μm, p=0.02). Among plaques with high ΔT, 15 (93.8%) had macrophage infiltration in OCT analysis, while only 1 plaque with low ΔT (6.3%) had macrophage infiltration of its fibrous cap.
Conclusions: In patients with AMI, the majority of culprit lesions with increased temperature have thin fibrous caps with excessive macrophage infiltration. OCT can also give reliable information about the functional characteristics of the atheromatic lesions. This study by using a combination of OCT and ICT examinations provides more information for the identification of high-risk plaques.

3:30 p.m.

2523-827 Intravascular Ultrasound Appearance of Scattered Necrotic Core Pattern as New Index for No-reflow Phenomenon During Intervention in Acute Coronary Syndrome

Kenji Sakata, Hidekazu Ino, Masa-aki Kawashiri, Takao Matsubara, Yoshihide Uno, Toshihiko Yasuda, Kenji Miwa, Honin Kanaya, Masakazu Yamagishi, Kanazawa University, Kanazawa, Japan, Ishikawa Prefectural Central Hospital, Kanazawa, Japan

Background: No-reflow (NRF) observed during interventional procedures in acute coronary syndrome (ACS) is associated with poor clinical prognosis. We often observed generally scattered necrotic core pattern (SNC) by VH-IVUS in ACS patients with NRF during intervention, and the pathological finding of materials in SNC collected by thrombectomy showed mixed thrombi and cholesterol clefts. The aim of this study was to evaluate the impact of SNC by VH-IVUS on NRF during intervention in ACS.
Methods: We prospectively studied 38 patients with ACS (30 males, mean age 65.9 ± 13.6 years) who underwent VH-IVUS before intervention. In addition to conventional VH-IVUS-derived indices, VH-IVUS plaque component patterns were evaluated. We defined SNC, which represents the ruptured thin-cap fibroatheroma derived from VH-IVUS as shown in Figure.
Results: Patients were divided into 2 groups with NRF (n=15) or normal reflow (n=23). The elastic membrane volume, plaque and media volume and fibrous volume were significantly greater in NRF than in normal flow ($p<0.05$). There was no significant difference in necrotic core volume between two groups. However, the incidence of SNC frame was significantly higher in NRF than in normal flow (11.7 ± 6.7 vs. 2.0 ± 4.3 frames, $p<0.0001$). Logistic regression analysis showed that the number of SNC frames was the most effective index for NRF in ACS patients (odds ratio 2.320, $P<0.05$).
Conclusion: Increased number of SNC frames with VH-IVUS is highly associated with NRF after intervention.



3:30 p.m.

2523-828 Tissue Characterization of Atherosclerotic Plaque in Coronary Artery Bifurcations: an Intravascular Ultrasound Radiofrequency Data Analysis in Humans

Seung Hwan Han, Joseph Puma, Hector M. Garcia-Garcia, Kenya Nasu, Pauliina Margolis, Martin B. Leon, Amir Lerman, Mayo clinic, Rochester, MN, Gil Hospital, Gachon University of Medicine and Science, Incheon, South Korea

Background: Coronary artery bifurcations are prone to atherosclerotic plaque accumulation. We assessed compositional characteristics of atherosclerotic plaques in coronary artery bifurcations with intravascular ultrasound radio frequency data analysis.
Methods: Using a global virtual histology registry, geometric and compositional characteristics of plaque in 3 segments (proximal, distal, and at the bifurcation) of major coronary bifurcation sites were analyzed.
Results: : A total of 256 major bifurcation sites were analyzed: left main (LM)-left anterior descending artery (LAD), 41; LAD-diagonal artery, 128; left circumflex artery-obtuse marginal artery, 34; and right coronary artery-acute marginal artery, 53. The percent (%) necrotic core at the bifurcation and distal segments at LM-LAD bifurcation sites was significantly greater than in proximal segments (6.75±5.09%, 7.36±6.01% vs. 4.89±4.78%, all $p<0.05$). In contrast, the % necrotic core in proximal segments of non-LM bifurcation sites was significantly greater than at the bifurcation and distal segments (8.08±6.21% vs. 6.47±5.11%, 6.28±5.05%, all $p<0.001$). The % necrotic core in proximal and distal segments of LM-LAD bifurcation sites was significantly correlated with the plaque plus media (P+M) burden ($r=0.45$, $p=0.003$; $r=0.42$, $p=0.006$, respectively). The % necrotic core in each segment of non-LM bifurcation sites showed a significant positive correlation with P+M burden and negative correlation with lumen cross sectional area ($0.51\leq r\leq 0.64$, all $p<0.001$; $-0.35\leq r\leq -0.31$, all $p<0.001$, respectively).
Conclusions: The results demonstrate significant differences of plaque composition among proximal, distal, at the bifurcation segments of the coronary bifurcations, especially according to their anatomical locations (LM-LAD vs. non-LM bifurcations). The investigation for the clinical efficacy of the imaging-guided therapeutic approach to complex coronary plaques such as bifurcation sites are warranted in the future.

3:30 p.m.

2523-829 Plaque Characteristics of Thin Cap Fibroatheroma evaluated by Optical Coherence Tomography and Integrated Backscatter Intravascular Ultrasound

Yoshinori Miyamoto, Hiroyuki Okura, Koichiro Imai, Ken Saito, Kosuke Kagamihara, Tomoko Maehama, Noriko Okahashi, Kikuko Obase, Akihiro Hayashida, Yoji Neishi, Takahiro Kawamoto, Kiyoshi Yoshida, Kawasaki Medical School, Kurashiki, Japan

Background: The purpose of this study was to assess optical coherence tomography (OCT)-derived thin cap fibroatheroma (TCFA) and to investigate plaque characteristics of the TCFA by conventional intravascular ultrasound (IVUS) and integrated backscatter intravascular ultrasound (IB-IVUS).
Methods: Twenty six coronary lesions from 18 patients with percent diameter stenosis > 50% were selected and analyzed using both IB-IVUS and OCT. OCT-derived TCFA was defined as a presence of thin fibrous cap (< 65 μm) overlying a low-intensity area with diffuse border representing a lipid-rich plaque. By conventional IVUS, external elastic membrane (EEM) cross-sectional area (CSA) and lumen CSA were measured. Plaque plus media (P+M) CSA was calculated as EEM minus lumen CSA. Plaque characteristics were further assessed by IB-IVUS and classified as follows: fibrous, mixed, calcification and lipid.
Results: OCT identified 9 TCFAs (34.6%). By conventional IVUS, EEM CSA, lumen CSA and P+M CSA were significantly larger in TCFA than non TCFA. Remodeling index was not significantly different between TCFA and non-TCFA. By IB-IVUS, % lipid area (=lipid area / P+M CSA x 100) was significantly higher in TCFA than non-TCFA (62.1 ± 8.3 vs 46.3 ± 18.9 %, $p < 0.05$). (Figure)
Conclusions: TCFA by OCT had larger plaque with predominant lipid component assessed by IB-IVUS. Combination of these 2 intracoronary imaging modalities may be helpful to identify vulnerable coronary plaque.

TCFA vs non-TCFA

	non-TCFA (n = 17)	TCFA (n= 9)	*p* value
EEM CSA, mm^2	10.8 ± 3.5	16.7 ± 5.8	<0.01
Lumen CSA, mm^2	3.2 ± 1.3	4.4 ± 1.3	<0.05
P+M CSA, mm^2	7.7 ± 2.9	12.3 ± 5.9	<0.05
Plaque burden, %	70.5 ± 8.7	72.9 ± 10.4	0.55
Remodeling index	0.98 ± 0.14	1.08 ± 0.26	0.21
Fibrous area, %	44.9 ± 13.0	34.8 ± 7.6	<0.05
Mixed area, %	6.2 ± 4.8	2.5 ± 1.4	<0.05
Calcified area, %	2.7 ± 3.3	0.6 ± 0.6	0.09
Lipid area, %	46.3 ± 18.9	62.1 ± 8.3	<0.05

EEM, external elastic membrane cross sectional area; CSA, cross-sectional area; P+M, plaque plus media; TCFA, thin cap fibroatheroma. Remodeling index was defined as ratio of lesion to reference EEM CSA.

3:30 p.m.

2523-830 Frequency of Lipid Core Plaque as Determined by Near-Infrared Spectroscopy at Target Lesion Sites in Patients Undergoing PCI

Philippe L. L'Allier, Jean-Claude Tardif, Simon R. Dixon, Jeffrey W. Moses, John L. Petersen, Giora Weisz, Donald E. Cutlip, Mitchell W. Krucoff, James E. Muller, Michael J. Hendricks, Stephen T. Sum, Gregg W. Stone, James A. Goldstein, Sergio Waxman, InfraReDx, Inc., Burlington, MA, Montreal Heart Institute, Montreal, QC, Canada

Background: Plaque characterization is of great interest to better understand the clinical pathophysiology of coronary artery disease. A catheter-based near-infrared spectroscopy (NIRS) system (previously validated in autopsy studies) was used to determine lipid core plaque (LCP) content of target lesions. The correlation between angiographic findings and NIRS indices of LCP has not been previously studied. The objective was to determine LCP content of target lesions and correlation with angiographic characteristics in patients (pts) undergoing PCI.
Methods: A retrospective analysis of SPECTACL study data (n=106) was performed to determine the prevalence of LCP at the target lesion site. Patients referred for coronary angiography were included (stable angina or acute coronary syndrome), and target lesions were identified by angiography combined with clinical data. Single (target) vessel NIRS scanning was performed in pts undergoing PCI. A LCP was defined as at least a 2mm segment of vessel exhibiting a clear lipid signal in the NIRS image. LCPs were considered distinct when separated by at least 6 mm. Angiographic characteristics of individual patients and respective target lesions were determined by a central QCA core lab.
Results: A total of 56 pts had NIRS data meeting study endpoint criteria and angiographically co-registered target lesions. LCP was detected at the target lesion in 23 pts (41%). The angiographic characteristics of the target lesions were ACC/AHA lesion type B2/C in 28 patients (50%); mean stenosis length was 15.0 mm, mean reference vessel diameter was 3.1 mm. LCP positive target lesions tended to be more severe (34.8% vs. 21.2%, N.S.), and longer (15.8 vs. 14.2 mm) than LCP negative lesions. Other angiographic characteristics associated with instability did not demonstrate differences between LCP positive and negative lesions.
Conclusion: LCP occurs in a significant proportion of target lesions. LCP status appears to be largely independent of conventional angiographic characteristics. The role of the identification of lesions with LCP content as determined by NIRS in the optimization of therapy requires evaluation in clinical studies.

3:30 p.m.

2523-831 Plaque Vulnerability at Coronary Bifurcations : A Study of Virtual Histology Intravascular Ultrasound

Hideo Amano, Division of interventional Cardiology, Cardiovascular Center, Toho University Omori Medical Center, Tokyo, Japan

Background: Ruptured plaque is often seen near the bifurcation, and it has been reported that endothelial cells near the bifurcation have reduced ability to repair damaged cells. However, since plaque properties cannot be discriminated by gray scale intravascular ultrasound(IVUS), the volume of vulnerable plaque associated with bifurcation plaque is unclear. Since Virtual Histology-IVUS(VH-IVUS) enables classification of plaque properties, VH was used to study the volume of vulnerable plaque associated with bifurcation plaque.
Objectives: To study the volume of vulnerable plaque with respect to the difference with bifurcation lesion and non-bifurcation by using VH-IVUS.
Subjects: Subjects were 165 patients with 171 lesions, undergoing stent implantation for coronary stenosis and observed by VH-IVUS prior to percutaneous coronary intervention.
Methods: 32 lesions revealed at the bifurcation were classified the bifurcation group, and 139 lesions that were not revealed at the bifurcation were classified the non-bifurcation group. Site of measurement was 1 slice at the bifurcation for the bifurcation group, and for the non-bifurcation group, a mean ratio was obtained by measuring the culprit lesion at 1 mm intervals. Necrotic core (NC), dense calcium (DC), and NC/DC ratio were calculated using VH-IVUS.
Results: The bifurcation group had significantly more NC with 14.1±7.2% in the bifurcation group and 11.0±6.7% in the non-bifurcation group ($p<0.05$). There was significantly less DC in the bifurcation group with 10.3±7.8% in the bifurcation group and 15.3±6.0% in the non-bifurcation group ($p<0.01$). NC/DC was significantly higher in the bifurcation group with 2.4±2.2 compared to 0.74±0.39 in the non-bifurcation group ($p<0.01$).
Conclusions: The high vulnerability of plaque at bifurcations was shown from the presence of less dense calcium and greater necrotic core by Virtual Histology intravascular ultrasound.

3:30 p.m.

2523-832 Long term Clinical Outcomes after Fractional Flow Reserve Guided vs. Intravascular Ultrasound Guided Percutaneous Coronary Intervention

Chang-Wook Nam, Hong-Won Shin, Yun-Kyeong Cho, Hyoung-Seob Park, Hyuck-Jun Yoon, Hyungseop Kim, Seong-Wook Han, Seung-Ho Hur, Yoon-Nyun Kim, Kwon-Bae Kim, Division of Cardiology, Department of Internal Medicine, Keimyung University, Dongsan Medical Center, Daegu, South Korea

Background: Even though intravascular ultrasound (IVUS) provides 3-D anatomic image of coronary artery, it might overestimate real functional significance of the coronary lesion during percutaneous coronary intervention (PCI). FFR-guided PCI strategy was reported to be safe and effective. The aim of this study is to evaluate the safety and efficacy of FFR-guided PCI strategy compared to IVUS guided PCI in daily practice.
Methods: Four hundred forty four patients (350 patients of IVUS guided, 94 of FFR) were consecutively included from Nov. 2006 to June 2007. All patients were divided to IVUS guided and FFR guided group. If both procedures were simultaneously used, that patients were included to FFR guided group. Major adverse cardiac events (MACE: cardiac death, myocardial infarction and target vessel revascularization (TVR)) were assessed at 12 months after the procedure.
Results: Mean age were higher in FFR guided group than IVUS guided group (63.5±8 vs. 61.2±10, $p=0.021$). IVUS guided group had more underwent revascularization therapy, also had more implanted stent number than FFR guided group (95.4% vs. 78.7%, $p<0.001$, 1.67±1.1 vs. 1.3±1.1, $p=0.003$). One year clinical follow-up was available in 98.6%. No difference was found in 12-month MACE rates between 2 groups (Table). There was no death or MI related to the lesions in FFR guided group.
Conclusions:FFR-guided PCI strategy resulted in excellent long-term outcomes, similar as IVUS guided PCI. However, FFR-guided strategy reduced the need for PCI.

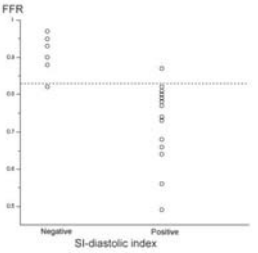
	FFR group	IVUS group	p value
Cardiac death	0 (0%)	3 (0.9%)	1
Myocardial infarction	0 (0%)	3 (0.9%)	1
Target vessel revascularization	5 (5.3%)	12 (3.5%)	0.38
Cumulative MACE	5 (5.3%)	18 (5.2%)	1
Stent thrombosis	0 (0%)	3 (0.9%)	1

3:30 p.m.

2523-833 Coronary Fractional Flow Reserve less than 0.83 is Useful Predictor of Myocardial Ischemia Compared with Postischemic Diastolic Dysfunction after Treadmill Exercise Stress Test

Motoyoshi Maenaka, Tamaki Suyama, Makoto Imai, Masaki Kawanami, Yasunaka Makino, Katsuhisa Ishii, Kansaidenryoku Hospital, Osaka, Japan

Background: In previous studies, coronary fractional flow reserve (FFR) of 0.75 lower was proved a useful index of myocardial ischemia. But it is seemed to sever cut-off line. To assess whether the coronary artery stenosis is responsible for myocardial ischemia, we reevaluated FFR by postischemic diastolic dysfunction after treadmill exercise test with strain image derived from 2-dimensional speckle tracking echocardiography.
Methods: In consecutive 33 consecutive patients with significant coronary stenosis, treadmill stress echocardiography was performed within 1 week of coronary angiography. FFR was measured after adenosine infused intravenously.Strain image was acquired in the LV midpapillary short-axis view. Radial strain was obtained and peak values of stain at the closure of aortic valve (A) and at the one third diastole duration (B) were measured. The strain image-diastolic index (SI-DI) was determined as (A-B)/A×100% and used to identify regional LV diastolic dysfunction. We defined SI-DI ≤40% as positive ischemic change, and compared FFR with these results.
Results: The result of FFR and diastolic dysfunction was showed in figure 1. Diastolic dysfunction was 75.8% (25 of 33 pts). The sensitivity of FFR <0.83 was 96% , the specificity 87.5%.
Conclusion: In patient with significant coronary stenosis, FFR<0.83 was a useful index of myocardial ischemia, that is new concept with postischemic diastolic dysfunction.



3:30 p.m.

2523-834 Gender Difference in Vessel Response in Coronary Artery Disease Treated with Zotarolimus-Eluting Stents

Daisaku Nakatani, Katsuhisa Waseda, Hiromasa Otake, Bon-Kwon Koo, Ryota Sakurai, Akiyoshi Miyazawa, Masao Yamasaki, Junya Ako, Hyeonsoo Chang, Jean Fajadet, Richard E. Kuntz, William Wijns, David E. Kandzari, Martin B. Leon, Paul G. Yock, Peter J. Fitzgerald, Yasuhiro Honda, Stanford University Medical Center, Palo Alto, CA

Background: Gender difference in outcomes of coronary interventions remains controversial in first-generation drug-eluting stents. The aim of this study was to examine potential gender difference in vessel response following Endeavor zotalolimus-eluting stent (ZES) implantation.
Methods: Serial volumetric IVUS analysis was performed in 305 patients (223 Men: 83 Women) treated with a single ZES for *de novo* native coronary lesions. Volume index (volume/length) was calculated for vessel (VVI), plaque (PVI), neointima (NIV), and lumen (LVI). Percent neointimal volume (%NIV) was calculated as (NIV/SVI)×100. Cross-sectional narrowing (CSN) was defined as neointimal area divided by stent area (%).
Results: Although women had worse baseline characteristics (older age, higher prevalence of coronary risk factors, and smaller vessel), max CSN at 8-9 months was significantly higher in men than in women (Table). %NIV also trended toward larger in men, resulting in significantly greater LVI loss in men compared with women. Multiple regression analysis revealed a correlation of male gender with %max CSN ($\beta=181$, $p=0.021$) and %NIV ($\beta=0.143$, $p=0.072$).
Conclusion: In patients treated with ZES, neointimal hyperplasia appears to be higher in men than in women. However, follow-up lumen dimensions may still be comparable due to larger vessel size in men.

	Women	Men	p
Baseline (BL)			
VVI (mm3/mm)	12.4±3.4	14.6±4.3	<0.001
PVI (mm3/mm)	5.6±2.0	7.5±2.8	<0.001
LVI (mm3/mm)	6.8±1.9	7.2±2.1	0.101
Follow-up (FU)			
VVI (mm3/mm)	12.6±3.3	14.9±4.2	<0.001
PVI (mm3/mm)	5.8±1.9	7.6±2.6	<0.001
LVI (mm3/mm)	5.7±1.8	6.0±1.9	0.297
%NIV (%)	15.7±10.3	17.8±11.1	0.128
Max CSN (%)	29.2±13.8	33.9±15	0.015
Patients with Max CSN >50% (%)	8.5	14.8	0.151
Changes (FU-BL)			
Delta-VVI (mm3/mm)	0.2±0.8	0.1±1.2	0.888
Delta-PVI (mm3/mm)	0.1±0.6	0.1±1.0	0.639
Delta-LVI (mm3/mm)	-0.9±1.0	-1.2±1.1	0.028

3:30 p.m.

2523-835 Angiographic, IVUS and OCT Evaluation of the Long-term Impact of Coronary Disease Severity at the Site of Overlapping Bare Metal and Drug-eluting Stents

SATOKO TAHARA, Hiram Bezerra, Giulio Guagliumi, Hiroyuki Kyono, Noah Rosenthal, Vasile Sirbu, Giuseppe Musumeci, Luigi Fioca, Giuseppe B. Zoccai, Daniel Simon, Marco A. Costa, University Hospitals Harrington-McLaughlin Heart & Vascular Institute, Cleveland, OH, Ospedali Riuniti di Bergamo, Bergamo, Italy

Background: Very long lesions are part of the daily interventional practice and often required implantation of overlapping (OLP) stents. Preclinical data suggest potential adverse vascular response at the site of OLP drug eluting stents (DES). The impact of disease severity at the location of OLP stents is unknown.
Objective: This study aims at evaluating the long-term impact of OLP stents in low grade stenosis (LGS) vs. high grade stenosis (HGS) using angiography, IVUS and OCT strut level analysis at 6-month follow-up.
Methods: The ODESSA trial was a single-center, prospective, randomized, controlled trial. We performed a subanalysis in 71/75 patients with 86 OLP stents (25 Sirolimus-SES, 24 Paclitaxel-PES, 26 Zotarolimus-ZES eluting stents; and 11 bare metal stents- BMS). Angiography, IVUS and OCT analyses were performed at an independent core laboratory. Based on angiographic stenosis severity at the site of OLP two groups were generated: >70% (HGS) or <70% (LGS). Endpoints were binary restenosis, % neointimal hyperplasia (NIH%), and degree of stent coverage by the OCT strut level analysis. Three categories were generated by the OCT strut level analysis: covered, uncovered and malapposed.
Results: OLP stents were implanted in 49 segments with HGS and 37 with LGS. Baseline characteristics were similar in both groups. Binary restenosis was observed in 9/49 (18%) in the HGS vs. 0/37 (0%) in the LGS (**p**=0.009). Five out of 6 HGS treated with OLP BMS had restenosis vs. 4/43 with OLP DES (**p**=0.01). IVUS and OCT showed similar degree of NIH in OLP DES implanted in HGS versus LGS. OCT strut level analysis identified uncovered or malapposed struts more frequently in the LGS vs. HGS groups, 48.6% vs. 27.1% (**p**=0.0236), which was driven primarily by a very high incidence of uncovered struts in the PES.
Conclusion: Severity of coronary disease at the site of OLP DES did not impact NIH response. However, OLP DES and BMS at segments with mild disease were associated with higher incidence of uncovered struts by OCT, particularly in patients treated with PES. OLP BMS at segments with HGS had a higher proliferative response. Future studies are required to guide proper positioning of DES in long lesions requiring stent overlap.

3:30 p.m.

2523-836 Microvascular Dysfunction Immediately after Percutaneous Coronary Intervention is Associated with Sustained Hemodynamic Abnormalities in Reperfused Acute Myocardial Infarction

Takeshi Kitai, Kobe City Medical Center General Hospital, Kobe, Japan

Background: Hemodynamic complications such as congestive heart failure (CHF) and cardiogenic shock often result in unfavorable outcomes of patients with acute myocardial infarction (AMI). Studies using intravascular Doppler guidewire (DGW) have shown that the microvascular dysfunction in infarct-related artery immediately after percutaneous coronary intervention (PCI) is an independent predictor of in-hospital mortality and morbidity. The aim of this study was to examine whether microvascular dysfunction was associated with sustained hemodynamic abnormalities in AMI.
Methods: The study population consisted of 201 consecutive patients with first anterior AMI successfully treated with PCI. We examined the coronary flow velocity (CFV) pattern immediately after PCI using a DGW. In accordance with previous findings, we defined severe microvascular injury as a diastolic deceleration time ≤600 ms and the presence of systolic flow reversal. We measured the pulmonary capirally wedge pressure (PCWP) and cardiac output index (CI) by thermodilution using pulmonary artery catheter. Patients were divided into the two groups: those with severe microvascular injury (n=74; group 1) and those without severe microvascular injury (n=127; group 2). Serial hemodynamic parameters have been compared between the groups.
Results: The results were shown in the Table. PCWP was significantly higher and CI was significantly lower in group 1 than in group 2 both on the day 1 and 3, despite extensive therapy for heart failure. CHF requiring mechanical ventilation or IABP, and in-hospital cardiac death occurred more frequently in group 1 than in group 2.
Conclusions: Microvascular dysfunction immediately after successful PCI for AMI was associated with sustained hemodynamic abnormalities and high cardiac mortality in AMI.

Results

	Group 1 (n=74)	Group 2 (n=127	P value
PCWP(day1), mmHg	14.1 ± 6.4	8.8 ± 4.4	<0.01
C.I.(day1), l/min/m2	2.3 ± 0.6	2.6 ± 0.6	<0.01
Forrester 2 or 4(day1), n(%)	21(28)	9(7)	<0.01
PCWP(day3), mmHg	13.9 ± 4.7	10.0 ± 3.6	<0.01
C.I.(day3), l/min/m2	2.6 ± 0.5	3.0 ± 0.6	<0.01
Forrester 2 or 4(day3), n(%)	8(11)	4(3)	<0.01
CHF requiring mechanical ventilation, n(%)	14(19)	4(3)	<0.01
IABP use, n(%)	14(19)	4(3)	<0.01
In-hospital death, n(%)	10(14)	0(0)	<0.01

3:30 p.m.

2523-837 Relation Between High-Sensitivity C-Reactive Protein and Coronary Plaque Components in Patients with Acute Coronary Syndrome: Virtual Histology-Intravascular Ultrasound Analysis

Young Joon Hong, Myung Ho Jeong, Yun Ha Choi, Jum Suk Ko, Min Goo Lee, Won Yu Kang, Shin Eun Lee, Soo Hyun Kim, Doo Sun Sim, Keun Ho Park, Nam Sik Yoon, Hyun Ju Youn, Kye Hun Kim, Hyung Wook Park, Ju Han Kim, Youngkeun Ahn, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, The Heart Center of Chonnam National University Hospital, Gwangju, South Korea

Background: An elevated high-sensitivity C-reactive protein (hs-CRP) is associated with an increased risk of future ischemic complications in acute coronary syndrome (ACS) patients. We used virtual histology-intravascular ultrasound (VH-IVUS) to evaluate the relation between hs-CRP levels and plaque components in ACS patients.
Methods: VH-IVUS classified the color-coded tissue into four major components: fibrotic, fibro-fatty, dense calcium, and necrotic core (NC). We divided the patients into two groups according to the hs-CRP levels [≥ 0.5 mg/dl (n=58) vs. < 0.5 mg/dl (n=188)]. Thin-cap fibroatheroma (TCFA) was defined as focal, NC-rich (≥ 10% of the cross-sectional area) plaques being in contact with the lumen in a plaque burden ≥ 40%.
Results: Elevated hs-CRP group was more diabetics (36% vs. 16%, p<0.001), and had lower ejection fraction (59±8% vs. 63±9%, p=0.011), higher white blood cell counts (9869±3110/mm^3 vs. 7906±2808/mm^3, p<0.001), higher glucose (160±60 mg/dl vs. 141±45 mg/dl, p=0.029), higher fibrinogen (314±82 mg/dl vs. 275±72 mg/dl, p=0.008), and higher N-terminal pro-B-type natriuretic peptide (681±864 pg/ml vs. 213±332 pg/ml, p<0.001) and longer IVUS lesion (22±13 mm vs. 18±12 mm, p=0.020). The absolute and percent areas of NC were significantly greater in elevated hs-CRP group at the minimum lumen sites (1.40±1.16 mm^2 vs. 0.89±0.73 mm^2, p=0.008, and 22.1±14.2% vs. 17.0±11.4%, p=0.005, respectively) and at the largest NC sites (2.01±1.26 mm^2 vs. 1.46±0.98 mm^2, p=0.003, and 28.3±10.3% vs. 23.2±11.2%, p=0.002, respectively). Absolute and percent NC volumes were significantly greater in elevated hs-CRP group (25.0±17.0 mm^2 vs. 15.2±10.5 mm^2, p=0.001, and 20.5±12.5% vs. 15.2±8.7%, p=0.004, respectively). The presence of at least one TCFA (62% vs. 35%, p=0.006) and multiple TCFAs (26% vs. 11%, p=0.016) within culprit lesions were observed more frequently in elevated hs-CRP group.
Conclusions: VH-IVUS analysis demonstrates that ACS patients with elevated hs-CRP had more vulnerable plaque component (NC-rich plaques and higher frequency of culprit lesion TCFAs) compared with ACS patients with normal hs-CRP.

3:30 p.m.

2523-838 Plaque Characteristics in Culprit Lesions in Diabetic Acute Coronary Syndrome Patients: Intravascular Ultrasound and Virtual Histology-Intravascular Ultrasound Analysis

Young Joon Hong, Myung Ho Jeong, Yun Ha Choi, Jum Suk Ko, Min Goo Lee, Won Yu Kang, Shin Eun Lee, Soo Hyun Kim, Keun Ho Park, Doo Sun Sim, Nam Sik Yoon, Hyun Ju Yoon, Kye Hun Kim, Hyung Wook Park, Ju Han Kim, Youngkeun Ahn, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, The Heart Center of Chonnam National University Hospital, Gwangju, South Korea

Background: Data of the relationship between diabetes mellitus and plaque characteristics in acute coronary syndrome (ACS) patients are lacking. The aim of this study was to assess the plaque characteristics in culprit lesions in diabetic ACS patients.
Methods: We performed grey-scale intravascular ultrasound (IVUS) analysis in 422 ACS patients. By subgroup analysis, we assessed the impact of diabetes mellitus on IVUS findings in 112 acute myocardial infarction (AMI) patients with plaque ruptures and also evaluated the relationship between diabetes mellitus vs. plaque composition and the incidence of thin-cap fibroatheroma (TCFA) using virtual histology (VH)-IVUS in 310 ACS patients.
Results: High-sensitivity C-reactive protein (hs-CRP) was significantly elevated (2.6±3.8 mg/dl vs. 0.6±1.4 mg/dl, p=0.008), multivessel disease was more common (65% vs. 29%, p<0.001), and plaque burden was greater (79.7±9.8 mm^2 vs. 74.2±8.9 mm^2, p<0.001) in diabetic group. In the subgroup analysis in 112 AMI patients with plaque rupture, the presence of multiple plaque ruptures (60% vs. 29%, p=0.001) and thrombus (72% vs. 52%, p=0.032) were more common in diabetic group, and diabetes mellitus was the independent predictor of hs-CRP elevation (HR: 3.030, 95% CI: 1.204-7.623, p=0.019) and multiple plaque ruptures (HR: 2.984, 95% CI: 1.311-6.792, p=0.009) by multivariate analysis. In 310 VH-IVUS subsets, the absolute and % necrotic core volumes were significantly greater (16.9±15.1 mm^3 vs. 11.5±11.4 mm^3, p<0.001, and 17.3±9.4% vs. 13.7±7.5%, p<0.001, respectively), and the presence of at least one TCFA (60% vs. 42%, p=0.003) and multiple TCFAs (28% vs. 11%, p<0.001) within culprit lesions were more common in diabetic group, and diabetes mellitus was the only independent predictor of TCFA by multivariate analysis (HR: 2.139, 95% CI: 1.266-3.613, p=0.004).
Conclusions: Diabetic ACS patients have more plaques, and have characteristics of plaque vulnerability and a different composition of plaques, and have elevated inflammatory status compared with non-diabetics for those presenting with ACS.

3:30 p.m.

2523-839 **Visibility and Quantitative Assessment of Biodegradable Magnesium Alloy Stents by Intravascular Ultrasound and Optical Coherence Tomography**

Holger Hetterich, Burcu Gül, Andreas König, III, Andreas Schober, Thomas Schiele, Volker Klauss, Johannes Rieber, Medizinische Poliklinik, University of Munich, Munich, Germany

Background: Biodegradable magnesium alloy stents (Mg) provide mechanical stability for weeks after PCI and demonstrate complete degradation without longterm impairment vessel function. Lately feasibility and safety of Mg was demonstrated. Since Mg are not visible by angiography, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are two imaging methods used for assessment of stent parameters. The aim of this study was to compare IVUS and OCT for the assessment of Mg and to compare the findings to bare metal stents (BMS).
Methods: Four mini pigs (55±7kg) were imaged with fluoroscopy, IVUS and OCT at implantation and after 4 weeks. Mg and BMS were randomly distributed in all three coronary vessels. Cross sectional images were obtained each millimeter, both by OCT and IVUS.
Results: 120 cross sections were analyzed by IVUS and OCT. By IVUS the number of Mg visible struts per cross section at implantation and harvesting was 6.62±0.83 and 4.70±1.11 (p=n.s.), strut thickness was 0.22±0.03mm and 0.15±0.03mm (p<0.05). In OCT the number of Mg struts was 8.0±1.0 and 6.20±0.8 (p<0.05), strut thickness was 0.05±0.01mm and 0.06±0.014mm (p<0.001). The values for BMS were similar to those for Mg at implantation. OCT was able to detect more struts (p<0.005) but was associated with a lower strut thickness (p<0.001) than IVUS, underestimating the original strut thickness. A moderate correlation between IVUS and OCT measurements was observed for lumen- (r=0.44, p<0.05), stent- (r=0.67, p=0.001) and vessel-area (r=0.71, p<0.05). However, all parameters were underestimated by OCT, when compared to IVUS. Blant-Altmann analysis revealed a mean difference of 0.71mm² for lumen area, 0.18mm² for stent area and 0.27mm² for vessel area. The differences between the measurements did not vary significantly for Mg or BMS.
Conclusion: Mg can be visualized by IVUS and OCT. Due to the better spatial resolution of OCT and the unique imaging characteristics, OCT should be the preferred method for qualitative assessment of Mg, e.g. to image the degradation process. Despite the higher resolution capacity of OCT, IVUS appears to be superior for quantitative measurements of vessel- and stent dimensions of Mg in-vivo.

3:30 p.m.

2523-840 **Hypoadiponectinemia Is Associated With Greater Atheroma Burden in Reference Segment of Coronary Artery**

Hideki Kitahara, Yoshio Kobayashi, Issei Komuro, Chiba University Graduate School of Medicine, Chiba, Japan

Background: There is little information about relationship between plasma adiponectin and plaque burden in reference segment of coronary artery.
Methods: Intravascular ultrasound (IVUS)-guided percutaneous coronary intervention (PCI) and measurement of plasma high-molecular weight adiponectin were performed in 80 patients. Lumen and external elastic membrane (EEM) areas in segment without significant stenosis (<50% stenosis) were measured at 1-mm intervals; the target lesion for PCI including 5-mm proximal and distal references were excluded. Median measured length was 23 mm. To compensate the difference in pullback length among coronary arteries, normalized total plaque and media volume (TPV) was calculated as TPV / number of slices in pullback × median number of slices in study population. Percent plaque and media volume (PPV) was calculated as TPV / $\sum$ external elastic membrane cross-sectional area × 100. Patients were classified into 2 groups according to adiponectin level: adiponectin ≥4 μg/mL (n=34) and <4 μg/mL (n=46).
Results: There was no significant difference in the incidence of diabetic patients between the normal adiponectin group and the hypoadiponectin group (32% vs. 26%, p=0.54). Table shows IVUS measurements. There was significant correlation between adiponectin level and normalized TPV (r=-0.26, p=0.02) and PPV (r=-0.46, p<0.001).
Conclusion: Hypoadiponectinemia may be associated with greater plaque burden in reference segment of coronary artery.

Results

Adiponectin level	≥4 μg/mL	<4 μg/mL	p Value
Normalized EEM volume (mm3)	280 ± 109	295 ± 114	0.55
Normalized lumen volume (mm3)	172 ± 58	157 ± 65	0.29
Normalized TPV (mm3)	108 ± 59	138 ± 60	0.03
PPV (%)	36.9 ± 8.4	46.2 ± 8.6	<0.001

I2.POSTER CONTRIBUTIONS

2524

Congenital and Pediatric Intervention

Monday, March 30, 2009, 3:30 p.m.-4:30 p.m.
Orange County Convention Center, West Hall D

3:30 p.m.

2524-841 **Hybrid procedures in the management of patients with CHD: Results of a multi-institutional registry**

Ralf Holzer, Lisa Bergersen, Joanne Chisolm, Sharon Hill, Russel Hirsch, Audrey Marshall, Jacqueline Kreutzer, Alistair Phillips, Mark Galantowicz, John Cheatham, Nationwide Children's Hospital, Columbus, OH, Boston Children's Hospital, Boston, MA

Introduction: Procedural cooperation between cardiac surgeon and interventional cardiologist to facilitate interventions, such as device delivery or angioplasty (Hybrid procedure) has become increasingly common in the management of patients with CHDz. Outcome data on these Hybrid interventions (Hybrids) is limited.
Methods: Data was prospectively collected using a multi-center registry (C3PO). Between 02/07 and 09/08, 7 institutions submitted details on 5941 cardiac catheterization procedures. Procedural data and adverse events (AE) of 71 Hybrids was evaluated.
Results: The median number of Hybrids per center was 5 (0 to 44). 55/71 (77.5%) Hybrids were performed at 2 centers. The median weight was 3.4kg (0.7-86kg). 49/71 (69%) cases were performed in patients with single ventricle, while 22/71 (30.9%) cases were performed in patients with 2-ventricle circulation. In 12/71 (16.9%) cases, patients were on inotropic support and 8/71 (11.2%) cases were performed within 30 days of previous cardiac surgery. Hybrids included PDA stent placement (n=41), pulmonary artery stent/balloon (n=13), BAS (n=7), VSD device closure (n=5), ASD/fenestration device closure (n=2), aortic stent/balloon (n=3), other stent/balloon (n=5), pulmonary valvuloplasty (n=1), and other procedures (n=5). The median fluoroscopy time was 3.7min (0-74min). 13 AE occurred in 11/71 (15.5%) Hybrids. Minor AE were documented in 8/71 (11.3%) cases, moderate AE in 3/71 (4.2%) cases, major AE in 1/71 (1.4%) cases, and catastrophic AE in 1/71 (1.4%) cases. The type of AE documented included arrhythmias (n=5), hypoxia or hypotension (n=2), vessel trauma (n=1), cardiac perforation (n=1), CNS event (n=1), and other events (n=3). 6/13 (46.1%) AE were classified as not preventable, 5/13 (38.5%) AE as possibly preventable, and 2/13 (15.4%) AE as preventable.
Conclusion: Hybrids are performed in many centers and include a large spectrum of interventions. They are often performed in the early postoperative period or in sick and unstable patients. Hybrids are safe with a low incidence of major or preventable adverse events. Procedural definitions of these innovative procedures are required to facilitate prospective data collection.

3:30 p.m.

2524-842 **Midterm Follow-up after Helex Device Closure of Patent Foramen Ovale for Prevention of Paradoxical Embolic Events**

John F. Rhodes, Jr., Amanda S. Green, Piers C.A. Barker, J. Curt Fudge, Duke University Medical Center, Durham, NC

Background: Patients (pts) with a paradoxical embolism as the potential etiology of their symptoms are at risk for recurrent events. Closure of a coexistent patent foramen ovale (PFO) eliminates paradoxical embolization as a mechanism for recurrence. Although midterm follow-up are available for other devices few data are available regarding the HELEX. **Methods:** All pts at a single center who underwent PFO closure using the GORE HELEX Septal Occluder between 10/06-10/08 were retrospectively reviewed. Procedures were performed as an outpatient using standard technique. All pts had anatomic assessment using a "stop-flow" balloon technique and intracardiac echocardiography. All pts were treated with Clopidogrel or warfarin for 1 month and aspirin for 6 mos. Follow-up was routinely performed at 12-24 hrs, 1month, 6 mos, and yearly including transthoracic echocardiography and upper extremity injection of agitated saline at rest and during valsalva. **Results:** There were 108 pts that underwent HELEX PFO device closure during the study period. The median age was 54.2 yrs (range: 22.1-75.9). Procedural indication included stroke (n=71), multiple transient ischemic attacks (n=23), migraine headache with aura (n=7), systemic embolic event (n=3), and systemic hypoxemia (n=4). Although each pt had a PFO; 38 had an atrial septal aneurysm (ASA), 9 had additional fenestrations, 3 had Chiari's network, and 18 had a tunnel length >18mm. The mean PFO balloon diameter was11.2±3.5mm (range: 7-20). The device was successfully placed in 107 pts with 1 pt having the device removed due to excessive mobility within the ASA. There were no procedure-related adverse events. With a Median follow-up of 10.8mos (range: 0.2 - 24) there have been no recurrent embolic events and 2 late adverse events including one pt with medically treated arrhythmia and one pt with a rash. Overall, 4 pts (3.7%) have a persistent right to left shunt including 3 with trivial and 1 with moderate. **Conclusions:** These data indicate that Helex device PFO closure is safe and effective in preventing recurrent paradoxical embolism and should be considered an alternate to life-long pharmacologic therapy or other available devices.

3:30 p.m.

2524-843 **Do we need to stent discrete (shelf-like) coarctation?**

Mohamed Eid Fawzy, Ahmed Fathala, Hani Sergani, Mohammed Kandeel, Amr Badr, Abdulaziz Al Ghamdi, Bruce Dunn, King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia

Background: Although the immediate and intermediate-term results of balloon angioplasty (BA) for patients with aortic coarctation (AC) have been encouraging, there is paucity of

data on long-term follow-up results. This study evaluated the long-term (up to 22 years) follow-up results of BA in adolescent and adult patients with discrete (shelf-like) aortic coarctation (AC) and compare the findings with the reported results of stenting of AC.
Methods: Follow-up data of 58 patients (mean age 24±9 years) undergoing BA for discrete AC at median interval of 13.4 years (range 1-22 years) including cardiac catheterization, magnetic resonance imaging, and Doppler echocardiography form the basis of this study.
Results: No early deaths occurred. Balloon angioplasty produced immediate reduction in peak AC gradient from 60±22 mmHg to 8.5±8 mmHg (P<0.0001). Follow-up catheterization 12 months later revealed a residual gradient of 5±6.4 mmHg (P=0.01). Five patients (8%) with suboptimal initial outcome (peak gradient>20 mm Hg) developed restenosis, and 4 of these had successful repeat angioplasty. Aneurysm developed at the site of dilatation in 4 patients (7%). Follow-up magnetic resonance imaging (up to 22 years) revealed no new aneurysm. In one patient, the aneurysm increased in size, but no recoarctation or appreciable changes in the Doppler gradient across the AC site was noted. The blood pressure had normalized without medical treatment in 29 (50%) of the 58 patients.
Conclusions: Long-term results of BA for discrete AC are excellent and compare favorably with the reported results of stenting, accordingly stenting is not necessary for discrete AC.

3:30 p.m.

2524-844 Balloon Aortic Valvuloplasty in Neonates: a Single-Center 10-year Experience

Christopher J. Petit, Frank F. Ing, Raphael Mattamal, Alan W. Nugent, Henri Justino, Baylor College of Medicine, Houston, TX

Background: Severe aortic valve stenosis in neonates is among the most challenging forms of congenital heart disease. Balloon aortic valvuloplasty is the treatment of choice, though rates of complications and need for surgical or catheter-based re-intervention have been reported to be high. We report a 10 year experience with this procedure.
Methods: The records of all neonates (age <33 days) who underwent balloon aortic valvuloplasty at Texas Children's Hospital from January 1, 1998 to October 30, 2008 were reviewed. Pre- and post-procedure echocardiographic, catheterization, and surgical data were obtained. Attention was paid to baseline and post-procedure valve gradient, aortic and mitral valve insufficiency, left ventricular systolic function, and need for repeat cath or surgical procedures, including valvotomy, Ross, or prosthetic valve replacement.
Results: 39 neonates underwent valvuloplasty at a mean age of 14.6 (±10.8) days and weight of 3.18 (± 0.61) kg. The peak and mean gradients by echo were 78.5 (±28.4) and 43.0 (±16.7) mmHg respectively. Catheterization demonstrated pressure gradient was 60.0 (±25.8) mmHg, which decreased to 16.5 (±8.5) mmHg following balloon valvuloplasty (p<0.01). Aortic insufficiency increased from a baseline of 0.17 (±0.38) to 0.85 (±0.66) based on a 4-point grading system (p<0.01). At a follow-up of 2.7 (± 3.0) years, the mean valve gradient by echo was 16.6 (±10.8) mmHg, and aortic insufficiency 1.8 (±0.9). 5 patients (12.8%) underwent repeat valvuloplasty 136 (±58) days following the initial catheterization and 4 other patients (10.2%) underwent Ross or prosthetic valve replacement. Of three patients who underwent prograde valvuloplasty, 2 experienced severe mitral injury, one requiring surgical replacement. Two patients experienced cardiac arrest. There were no deaths.
Conclusion: Balloon aortic valvuloplasty is an effective and safe therapy for critical and severe neonatal aortic valve stenosis. Aortic valve insuffiency commonly increases to a mild degree following intervention, and rarely, mitral injury can occur with prograde approach. Approximately one quarter of neonates will require repeat balloon or surgical intervention.

3:30 p.m.

2524-845 Pulmonary Valvuloplasty in Adults Using the Inoue Balloon Catheter

Hung Manh Pham, Hieu Lan Nguyen, Quang Ngoc Nguyen, Hung Minh Nguyen, Huong Nam Khong, Loi Doan Do, Viet Lan Nguyen, Khai Gia Pham, Hanoi Medical School, Hanoi, Viet Nam, Vietnam Heart Insitute, Bachmai Hospital, Hanoi, Viet Nam

Background: Although pulmonary valvular stenosis is not uncommon in adults. There are few reports of percutaneous pulmonary valvuloplasty in adults, especially using Inoue balloon. OBJECTIVES: This report describes the experience in adult patients undergoing Pulmonary valvuloplasty using Inoue balloon and evaluates its effectiveness and tolerance.
Methods: Over an 8-year period (2000-2007), pulmonary valvuloplasty using Inoue balloon was considered in 71 adult patients [43 men, 28 women; mean age 28.0 years ± standard deviation (SD) 10.3; range 16-53 years] with congenital pulmonary valve stenosis. Thirty-four patients were asymptomatic with pulmonary systolic murmurs, although 36 patients presented with dyspnea. Before the procedure, the peak-to-peak transpulmonary valve gradient was 91±40 mmHg SD, with a mean right ventricular systolic pressure of 107±41 mmHg SD.
Results: The procedure was technically successful in all patients but one (98.59%). One failure because balloon could not pass through pulmonary orifice valve due to very tight valve stenosis. Among all patients with technical success all tolerated well and free of major complications. The mean right ventricular systolic pressure and the pulmonary valvular peak-to-peak systolic gradient decreased from 107±41 to 56±19 mm Hg (p = 0.001) and 91±40 to 21±7 mm Hg (p = 0.0002), respectively. An infundibular peak-to-peak systolic gradient either developed (n = 23) or increased (n = 19). None of these patients were treated with beta-adrenergic blockers before or after the valvuloplasty. Incontrast, this gradient decreased or did not develop in the remain patients who were on beta-blokers before procedures. All patients underwent echo follow up study for 6 - 60 months (mean 24) after treatment, and had no evidence of valvular restenosis. The mean right ventricular systolic pressure and the mean infundibular peak-to-peak systolic gradient decreased, compared to the values immediately after valvuloplasty (56 to 47 mm Hg, p = 0.03, and 28 to 10 mm Hg, p = 0.03, respectively).
Conclusions: The study suggests that pulmonary valvuloplasty in adults using the Inoue balloon catheter technique is feasible, safe, and effective.

3:30 p.m.

2524-846 Adverse Event Rates in Congenital Cardiac Catheterization - A Multi-center Experience

Lisa Bergersen, Audrey Marshall, Kimberlee Gauvreau, John Moore, Susan Foerster, David Balzer, Robert Beekman, Russel Hirsch, William Hellenbrand, Julie Vincent, John Cheatham, Ralf Holzer, James Lock, Kathy Jenkins, Children's Hospital Boston, Boston, MA

Background: Single-center adverse event rates for patients with congenital heart disease undergoing cardiac catheterization vary considerably, due to non-comparable standards of data inclusion, and highly variable case mix.
Methods: A web based data entry application was developed for the Congenital Cardiac Catheterization Outcomes Project (C3PO) which prospectively captured case characteristics and adverse events (AE). Validity and completeness of data was independently audited. All AE were reviewed by two cardiologists for final classification of event severity.
Results: Between 2/1/07 and 4/30/08, the database captured 630 biopsy, 1099 hemodynamic, and 2126 interventional cases at 6 participating institutions. The median number of cases performed per site was 480 (308 to 1526). The data revealed two distinct cath lab practices with 3 institutions performing a higher frequency of interventions (excluding biopsies) during a case, 70 to 72% compared to 56 to 57% in the others. General anesthesia was used in median 70% of cases, varying from 28 to 99% between institutions. 22% (range 15 to 26%) of cases were non-electively or emergently performed. The median rate of AE reported by institution was 16%, ranging from 5 to 18%. For interventional cases the median rate of AE reported by institution was 19% (7 to 25%) and 10% for hemodynamic cases (6 to 17%). The incidence of adverse events was significantly higher for interventional compared to hemodynamic cases (20% vs 11%, p<0.001), as was the incidence of higher severity adverse events (9% vs 4%, p<0.001). Major or catastrophic adverse events occurred in 3% of interventional and 1% of hemodynamic cases, p<0.001. Adverse events in biopsy cases were uncommon, 4% overall, with <1% considered clinically significant.
Conclusions: In this multi-institutional cohort the incidence of AE is higher and includes more severe events among interventional cases compared to hemodynamic, and is very low among biopsy cases. It is likely that case mix diversity affects institutional AE rates and equitable comparisons will require risk adjustment methods.

3:30 p.m.

2524-847 Pediatric Interventional Cardiology in the U.S. is Dependent on the Off-Label Use of Approved Medical Devices

Jamie S. Sutherell, Russel Hirsch, Robert H. Beekman, III, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Background: The off-label use of approved medical devices is routine in pediatric interventional cardiology, but this practice is not well documented or described. Disadvantages of off-label use include: 1) lack of regulatory oversight to assure device safety and efficacy; and 2) inability of industry to refine devices for off-label pediatric applications. The purpose of this study is to evaluate the current prevalence and nature of off-label device use in an active pediatric interventional program.
Methods: A retrospective review of all non-investigational interventional cardiac procedures (excluding biopsies and EP ablations) performed at our institution between July 1, 2005 and June 30, 2008. Interventions performed were compared to the manufacturer's labeled indications for each device. Multiple coils were counted once.
Results: During this 3-year period 473 patients (median age 4 years) underwent 595 transcatheter interventions. An approved device was utilized for an off-label application in 63% of patients, and in 50% of all interventions performed. The most frequent off-label procedures were stent implantations (99% off-label) and balloon dilations (78%).

Device Type	Total Interventions	On-Label	Off-Label
Balloons (Angioplasty, Valvuloplasty)	243	54 (22%)	189 (78%)
Occlusion Devices (Septal, Ductal)	169	156 (92%)	13 (8%)
Embolization Coils	80	57 (71%)	23 (29%)
Stents (Biliary, Coronary, Bronchial)	67	1 (1%)	66 (99%)
Septostomy Catheters	18	18 (100%)	0 (0%)
Other Devices (e.g. IVC Filter, RF Wire, Blade, Cutting Balloon)	18	9 (50%)	9 (50%)

Conclusions: In our routine (non-investigational) practice of pediatric interventional cardiology, 63% of patients underwent procedures utilizing medical devices for off-label indications. These data underscore the need to enhance cardiac device review and approval processes in the U.S. to include pediatric applications.

3:30 p.m.

2524-848 Angiojet Rheolytic Thrombectomy in Infants With Congenital Heart Disease

Gregory Fleming, Khan Mohammed, Dana Janssen, Thomas Doyle, Vanderbilt Children's Hospital, Nashville, TN

Background: Thrombotic complications after pediatric cardiac surgery can be life threatening. Surgical thrombectomy and pharmacologic thrombolysis carry significant risk in these patients. Angiojet rheolytic thrombectomy (Possis Medical, Minneapolis, MN)

is a percutaneous method of thrombus removal with proven safety and efficacy in adults with acute myocardial infarctions, pulmonary embolism, and other indications. We present our experience with the Angiojet thrombectomy catheter for percutaneous thrombectomy in infants following congenital cardiac surgery.
Methods: We searched our institutional cardiac catheterization database for infants who underwent Angiojet thrombectomy, and we reviewed the medical records and angiograms of each patient identified. The Vanderbilt University Institutional Review Board approved this study.
Results: Between 11/2005 and 10/2008, ten procedures were performed in eight infants. The procedure was performed a mean of 23 days from surgery (range 1 to 76 days). The mean age was 74 days (range 1 to 276 days) with a mean weight of 4.3 kg (range 3.0 to 6.8 kg). All patients had life or limb threatening thrombosis. Indications for thrombectomy included severe cyanosis, chronic pleural effusions secondary to extensive venous thrombosis, and acute iliac artery thrombosis. Thrombus was evacuated from pulmonary arteries in three patients, systemic veins in four patients, a surgical aorto-pulmonary shunt in two patients, and an iliac artery in one patient. Balloon angioplasty following thrombectomy was performed in 75% of cases. All patients had significant improvement in flow across the affected area. Two patients required ECMO support at the time of the procedure and were successfully weaned from ECMO support following the procedure. 4F and 5F catheters were used in all procedures. There was one major complication and three minor complications with no procedural related deaths. Survival to discharge was 62.5%.
Conclusions: Angiojet thrombectomy is an effective treatment for life threatening postoperative thrombotic complications in infants with congenital heart disease.

3:30 p.m.

2524-849 Left lateral approach to pericardiocentesis in children and infants

Frank F. Ing, John Breinholt, Richard O'Brien, Christopher Petit, David Nelson, James Mathewson, Texas Children's Hospital, Houston, TX

Background: Pericardiocentesis in children & infants has traditionally utilized the subxiphoid approach originally described by Marfan over 100 years ago. However, the left lateral (LL) approach using echocardiographic guidance offers an equally effective but shorter, more direct & perhaps safer route, especially for those pericardial effusions (PCE) that are loculated &/or posterolaterally located. We report our experience with this approach.
Methods: The records of all pts who underwent pericardiocentesis using the LL approach from 1/07 to 9/08 at Texas Children's Hospital were reviewed. Pt profile included age & primary diagnosis. Pre-procedure echocardiographic measurements of the PCE were reviewed including size of effusion (mm) seen at the subxiphoid & the posterolateral locations. Procedural data included location of entry, depth of needle required to enter the pericardium, amount & type of fluid removed, & complications.
Results: 17 pts (19 procedures) underwent this approach during the study period. Median age was 8.8 yr (range:1mo-17.25 yr). Presumed etiology was related to blood dycrasias (7), post viral (4), post-op (2), and others (4). Mean effusion was 7.8 ± 4.2mm inferiorly and 19.3 ± 6.2 mm posterolaterally. Needle entry were all in the LL (15) or peri-apical region (2). Depth of needle entry before fluid was reached ranged from 5 to 20 mm. Single attempt was successful in 17 of 19 procedures while 2 required an additional attempt due to entrance into the pleural space. Amount of fluid drained averaged 220 ± 120 cc. Serous fluid was noted in all but 3 (serosanguious). Pericardial drains were left in place in 3. Minor complications included a small anterior pneumothorax (1) & inadvertent entrance into pleural space (2) without further sequelae. No major complications occurred.
Conclusion: The LL approach for pericardiocentesis is safe & effective when there is a significant posterolateral PCE. Entrance from skin to pericardium is no more than 2 cm thereby minimizing errors related to angle & distance of needle penetration. Rare minor complications include pneumothorax and entrance into pleural space. This approach should be considered in the majority of pts with PCE.

3:30 p.m.

2524-850 Incidence of Paradoxical Hypertension in Stent vs. Surgical Treatment for Coarctation of the Aorta

Priti Patel, Oluwatosin Fatusin, O'Brian Smith, Henri Justino, Frank F. Ing, Texas Children's Hospital, Houston, TX, Baylor College of Medicine, Houston, TX

Background: Paradoxical hypertension (HTN) has been reported following surgical (SU) repair of coarctation of the aorta (COA). This complication is not well defined in pts following stent (ST) treatment for COA.
Methods: Retrospective chart review was performed of pts who underwent either ST or SU treatment for COA from 1/98 to 8/08 at our institution. When adjusted for weight >20 kg, 79 pts were identified for the study (41 pts in the ST & 38 in the SU groups). 4-extremity systolic blood pressure (SBP) pre & post treatment as well as at 1st clinic follow up and use of anti-hypertensive medications were reviewed. SBP was defined as the average upper extremity SBP while SBP gradient was defined as the difference between the average upper & lower extremity SBP. HTN was defined as SBP ≥ 95th percentile for age and/or treatment with antihypertensives.
Results:

	Stent Group	Surgical Group	P value
Age (months) (median±range)	183.4 (56.7-628.9)	119 (55- 237)	0.001
Weight (kg) (median±range)	55.3 (24-100)	31.5 (20-74.3)	0.02
1st follow up (days) (median±range)	46.5 (6-630)	12 (7-223)	0.001
SBP(mmHg), preprocedure (mean± sd)	134.7 ± 16.0	130.89 ± 17.4	0.37
SBP(mmHg), postprocedure (mean± sd)	124.9 ± 16.4	128.05 ± 15.8	0.006
SBP(mmHg), follow up (mean± sd)	125.15 ± 13.4	109.65 ± 14.3	0.49
SBP gradient(mmHg), preprocedure (mean± sd)	23.4 ± 18.4	32.0 ± 21.0	0.08
SBP gradient(mmHg), postprocedure (mean± sd)	6.4 ± 11.3	22.27 ± 17.7	0.001
SBP gradient(mmHg), follow up (mean± sd)	7.0 ± 8.5	5.65 ± 8.9	0.35
Antihypertensives, postprocedure	7/41	25/38	0.0001
Antihypertensives, follow up	3/41	10/38	0.03

7/41 pts in ST group (17%) were treated with an oral anti-hypertensive while 25/38 in SU group (71.4%) were treated with IV medication followed by an oral regimen. At time of first clinic follow up, 3/41 ST pts (7.3%) and 10/38 SU pts (26.3%) continued to require antihypertensive medications.
Conclusion: Within 24 hours post procedure, the incidence of paradoxical HTN, the SBP gradient and use of antihypertensives were significantly higher in the SU group as compared to the ST group. By the time of 1st clinic follow up, SBP and SBP gradients were comparable for both groups, although the SU group continue to require more use of medications to control HTN.

I2.ORAL CONTRIBUTIONS

2911

Imaging

Monday, March 30, 2009, 4:30 p.m.-6:00 p.m.
Orange County Convention Center, Room W314B

4:30 p.m.

2911-5 Late Lumen Enlargement and Plaque Regression Following Use of the Bioabsorbable Everolimus Eluting Coronary Stent System --- 2-year IVUS and OCT Results of the ABSORB Study

Yoshinobu Onuma, Patrick W. Serruys, Evelyn Regar, Hector Garcia-Garcia, Nieves Gonzalo, Susan Veldhof, John A. Ormiston, the ABSORB investigators, Thorax center, Erasmus MC, Rotterdam, The Netherlands

Background: Metallic drug eluting stents have dramatically reduced restenosis rates after percutaneous coronary intervention. However, permanent metallic implants may predispose to late stent thrombosis, endothelial dysfunction, hinder surgical revascularization and impair coronary imaging with MRI or CT.
Methods: The purpose of the ABSORB Clinical Investigation is to assess the safety and performance of the fully absorbable everolimus-eluting stent (BVS EECSS, Abbott Vascular, Mountain View, CA) in the treatment of patients with a single de novo native coronary artery lesion. Follow-up with multiple imaging modalities including angiography, IVUS, IVUS-VH and optical coherence tomography (OCT), were obtained at the 6-month and 2-year time points.
Results: Enrolment of 30 patients at 4 clinical sites in Europe and New Zealand was completed in July 2006. At 2-year follow up the device was shown to be safe with no stent thromboses or ischemic driven target lesion revascularizations reportetd. The 2-year serial angiography demonstrated an acceptable in-stent late loss of 0.46 mm. The 2-year serial IVUS and OCT results, summarized below, are consistent in showing early lumen loss to 6 months, followed by late lumen expansion. IVUS also shows plaque regression at 2 years.
Conclusion: Use of a bioabsorbable everolimus eluting stent is associated with late lumen enlargement and late regression of plaque volume, which will be discussed along with results from additional imaging endpoints.

IVUS and OCT results

	Post procedure	6 months	2 years
Serial IVUS results			
Vessel Volume (mm3)	182.92	186.75	183.74
Plaque Volume (mm3)	99.11	116.49	100.73
Lumen Volume (mm3)	82.83	68.98	82.41
Serial OCT results			
Lumen volume (mm3)	84.1	58.0	74.1

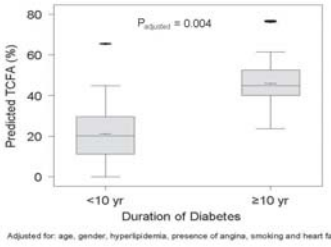
4:42 p.m.

2911-6 The Prevalence of IVUS-Assessed Vulnerable Plaque Increases With Diabetes Duration

Jason B. Lindsey, Joshua M. Stolker, John A. House, Steven P. Marso, Mid America Heart Institute, Kansas City

Background: Subjects with diabetes mellitus (DM) are at increased risk for MI. Longer duration of DM is associated with adverse cardiovascular (CV) events; however, the mechanism for this risk is unknown. Therefore, we describe the relationship between DM duration and the frequency of vulnerable plaque, defined as intravascular ultrasound-Virtual Histology™ (IVUS-VH)-derived thin cap fibroatheroma (TCFA).
Methods: Subjects were enrolled in an IVUS sub-study of a biomarker and gene banking registry. All patients underwent coronary angiography and IVUS-VH. The region of interest was the worst 10mm segment (greatest plaque volume over an axial distance of 10mm). TCFA was defined as plaque thickness>600 µm and >50% plaque burden with confluent necrotic core >14 pixels along the circumference of the lumen on 3 consecutive frames. DM duration was assessed by self report
Results: Of 63 diabetic subjects, 51% had DM ≥10 years. Patients with DM ≥10 years were older and less likely to smoke than those with DM <10 years. In univariate analysis, patients with DM >10 years had significantly more median (IQR) TCFA than those with DM <10 years (52.4% [5.7-77.5] vs 11.5% [0-26.1], p= 0.02). This relationship persisted after multivariable adjustment (Figure).
Conclusion: DM duration ≥10 years is independently associated with increased

prevalence of vulnerable plaque classified as TCFA. This finding may explain the increased CV risk associated with longer duration of DM, although further study is warranted.

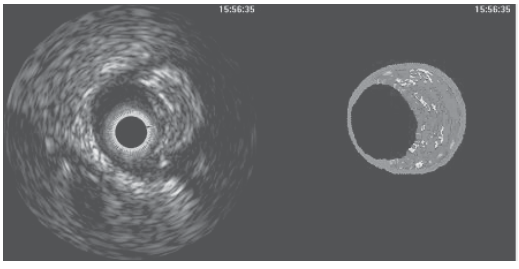


4:54 p.m.

2911-7 **Virtual Histology Intravascular Ultrasound Analysis of Attenuated Plaques Detected by Greyscale Intravascular Ultrasound in Patients With Acute Coronary Syndromes: A PROSPECT Substudy**

Xiaofan Wu, Akiko Maehara, Gary S. Mintz, Takashi Kubo, Hiroshi Doi, Kenichi Tsujita, Junqing Yang, Carlos Oviedo, Kai Xu, Yong He, Ning Guo, So-Yeon Choi, Celia Castellanos, Jeffrey W. Moses, Marin B. Leon, Bernard De Bruyne, Patrick W. Serruys, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

Background: Noncalcific, attenuated plaque identified by greyscale intravascular ultrasound (IVUS) is often seen in pts with acute coronary syndromes (ACS) and is associated with no reflow and CK-MB elevation post-PCI; Histopathology in a small number of patients has shown cholesterol clefts, microcalcification, or organized thrombus. The causes of this greyscale IVUS appearance are unknown.
Methods: We used virtual histology IVUS (VH-IVUS) to study 102 non-stented segments (which included 38 attenuated plaques) in 64 ACS pts from the PROSPECT trial; the minimum lumen area site not containing an attenuated plaque was used as control (n=64).
Results: VH-IVUS lesion phenotype included 30 thin-cap fibroatheroma (TCFA), 45 thick cap fibroatheroma (ThFA), and 27 pathological intimal thickening (PIT), but no fibrous of fibrocalcific plaques. Fibroatheromas - TCFA or -ThFA were more common at the site of attenuated plaques than at control sites (97.4% vs 59.4%, *P*<0.0001) and were associated with larger necrotic areas (1.4±0.7mm^2 vs 1.1±0.9mm^2, *P*=0.047) (example in the figure).
Conclusions: One cause of greyscale plaque attenuation appears to be a large amount of necrotic core. As a result, noncalcific, attenuated plaque identified by greyscale IVUS indicates the presence of a fibroatherma (TCFA or ThFA) assessed by VH-IVUS.



5:06 p.m.

2911-8 **Predictors of No-Reflow After Percutaneous Coronary Intervention in Acute Myocardial Infarction Patients With Plaque Rupture**

Young Joon Hong, Myung Ho Jeong, Yun Ha Choi, Jum Suk Ko, Min Goo Lee, Won Yu Kang, Shin Eun Lee, Soo Hyun Kim, Doo Sun Sim, Keun Ho Park, Nam Sik Yoon, Hyun Ju Youn, Kye Hun Kim, Hyung Wook Park, Ju Han Kim, Youngkeun Ahn, Jeong Gwan Cho, Jong Chun Park, Jung Chaee Kang, The Heart Center of Chonnam National University Hospital, Gwangju, South Korea

Background: Plaque rupture (PR) and subsequent thrombus formation is the most important mechanism leading to an acute myocardial infarction (AMI). Distal embolization and no-reflow during percutaneous coronary intervention (PCI) carries a poor prognosis in AMI patients. It is unclear which factors are associated with no-reflow after PCI in AMI patients with PR. The aim of this study was to investigate the predictors of the no-reflow phenomenon after PCI in AMI patients with PR.
Methods: The study group comprised 112 AMI patients who underwent stent implantation and pre- and post-PCI IVUS examinations. Angiographic no-reflow was defined as TIMI flow grade 0, 1, and 2. IVUS findings included multiple ruptured plaques (PRs separated by a >5-mm length of artery containing smooth lumen contours), thrombus (had a layered lobulated appearance, evidence of blood flow within the mass, and speckling or scintillation), and plaque prolapse (tissue extrusion through the stent struts).
Results: Of 112 patients who underwent pre- and post-stenting IVUS, no-reflow was observed in 17 patients (15.2%). High-sensitivity C-reactive protein (hs-CRP) was significantly higher (6.2±6.0 mg/dl vs. 2.2±2.9 mg/dl, p=0.002) and baseline TIMI flow grade was significantly lower in no-reflow group (TIMI flow grade <3: 59% vs. 18%, p<0.001). Lesion site plaque plus media area was significantly greater (12.9±2.6 mm^2 vs. 10.8±4.2 mm^2, p=0.009), remodeling index was significantly higher (1.14±0.17 vs. 1.03±0.20, p=0.031), and the presence of IVUS-detected thrombus (88% vs. 56%, p=0.012), culprit lesion multiple plaque ruptures (71% vs. 37%, p=0.009), and plaque prolapse (65% vs. 34%, p=0.015) were significantly more common in no-reflow group. In the multivariate analysis, plaque prolapse (HR=33.02; 95% CI 3.38-322.75, p=0.003), hs-CRP (HR=1.03; 95% CI 1.01-1.05, p=0.013), and culprit lesion multiple plaque ruptures (HR=15.73; 95% CI 1.61-153.46, p=0.018) were independent predictors of post-PCI no-reflow in AMI patients with PR.
Conclusions: Elevated hs-CRP and IVUS-detected multiple plaque ruptures and plaque prolapse are associated with post-PCI no-reflow in AMI patients with PR.

5:18 p.m.

2911-9 **New Index of Microvascular Resistance Reserve for Evaluating Residual Myocardial Viability in Patients With Prior Myocardial Infarction**

Koichi Tamita, Atsushi Yamamuro, Shuichiro Kaji, Minako Katayama, Makoto Kinoshita, Natsuhiko Ehara, Takeshi Kitai, Takefumi Yamane, Yoshimori An, Kite Kim, Yutaka Furukawa, Takashi Akasaka, Kobe General Hospital, Kobe, Japan, Wakayama Medical College, Wakayama, Japan

Background: Fractional flow reserve (FFR) and coronary blood flow velocity reserve (CFR) represent physiological quantities used to evaluate coronary lesion severity and to make clinical decisions. However, resistive vessel dysfunction may blunt the maximal hyperemic response in patients with prior myocardial infarction (MI). The aim of this study was to examine the effect of residual viability on intracoronay physiological assessments in the infarct-related coronary arteries.
Methods: FFR and CFR were assessed in 52 consecutive patients with 52 intermediate coronary lesions (between 40% and 70% diameter stenosis by visual assessment) in the infarct-related coronary arteries. Flow-derived microvascular resistance (MVR) was calculated as the ratio of mean distal pressure to average peak blood flow velocity. MVR reserve (MVRR) was defined as the ratio of MVR at rest to hyperemic MVR. Patients were divided into two groups based on residual myocardial viability assessed by thallium-201 SPECT; 38 patients with viable myocardium and 14 patients with nonviable myocardium in the infracted area. Redistribution patterns or residual maximal myocardial activity >50% are indices of tissue viability.
Results: Intracoronay physiological assessments showed significantly lower hyperemic averaged peak blood flow velocity (29.8±10.1 vs 41.7±16.8 cm/s; p=0.016), higher FFR (0.88±0.07 vs 0.82±0.09; p=0.026), lower CFR (2.15±0.79 vs 2.78±0.90; p=0.025), higher hyperemic MVR (2.63±0.92 vs 1.83±0.75 mmHg/cm/s; p=0.0051), and lower MVRR (2.47±1.03 vs 3.50±1.32; p=0.011) in nonviable myocardial group compared with viable group. The best cutoff value to predict residual viable myocardium was 2.3 for hyperemic MVR (sensitivity=0.89 and specificity=0.67).
Conclusion: These data indicate that the hemodynamic impact of intermediate coronary lesions depends on the amount of residual myocardial viability in patients with prior MI. The evaluation of MVR is clinically useful to assess residual myocardial viability in patients with prior MI.

5:30 p.m.

2911-10 **Near-Infrared Spectroscopic Detection of Lipid-Core Coronary Plaques Remote From the Target Lesion in Patients Undergoing PCI**

James A. Goldstein, Simon R. Dixon, Philippe L. L'Allier, Jeffrey W. Moses, John L. Petersen, Donald E. Cutlip, Giora Weisz, Robert D. Safian, Michael J. Hendricks, Stephen T. Sum, James E. Muller, Mitchell W. Krucoff, Jean-Claude Tardif, Sergio Waxman, Gregg W. Stone, William Beaumont Hospital, Royal Oak, MI, Montreal Heart Institute, Montreal, QC, Canada

Background: It has been observed that patients (pts) undergoing PCI often have multiple unstable plaques by angiography. A catheter-based near-infrared spectroscopy (NIRS) system has recently been cleared by the FDA for detection of LCP. We utilized this NIRS system to identify LCP remote from the target lesion that might be associated with a higher risk of a subsequent coronary event.
Methods: Scanning NIRS was performed in pts in the SPECTACL study undergoing PCI for stable angina or an acute coronary syndrome. Target lesions for PCI were identified by conventional angiography. The target vessel was then analyzed for the presence of LCP remote (≥10mm) from the target lesion.
Results: NIRS scans of a single vessel were performed in 56 patients. NIRS revealed remote LCP in 11 of the 56 pts. The remote LCP was associated with a significant stenosis (>50% diameter narrowing detected by angiography) in only 2 of the patients; in the remaining 9, the remote LCP was not associated with a stenosis and hence not detectable by conventional methods.
Conclusions: NIRS results indicate that the occurrence of LCP remote from the target lesion, and not associated with stenosis, is a relatively frequent finding. Figure 1. Chemogram from a subject enrolled in SPECTACL indicating LCP (yellow) proximal and distal (62mm, 50mm, and 2mm locations) at a location remote to the target stenosis (green). Angiographically, the vessel diameters at these remote LCP are not narrowed.