Impact of Renal Function on Coronary Plaque Characteristics in Patients with Acute Myocardial Infarction: An Intravascular Ultrasound Analysis


Background: Previous studies have shown that renal insufficiency is an independent predictor of significant coronary artery disease and is associated with subclinical atherosclerosis.

Methods: We used intravascular ultrasound to assess plaque morphology and morphometry in 100 acute myocardial infarction (AMI) pts (39 ST segment elevation and 61 non-ST segment elevation MI) with varying degrees of renal dysfunction according to creatinine clearance (CrCl): Group I (CrCl > 70 ml/min, n=36); Group II (CrCl 30 to 69 ml/min, n=35); Group III (CrCl <30 ml/min, n=29, including 12 hemodialysis patients)).

Results: Group III pts were oldest and had most diabetes. Although no significant differences were found in lesion site plaque burden and remodeling pattern among the 3 groups, lesions were longest, reference segment plaque burden was greatest, culprit lesion plaque ruptures were more common, and rupture plaque cavities were largest in Group III (Table). Plaque rupture (n=0.258, p=0.010), reference segment plaque burden (n=0.358, p=0.001), and plaque cavity area (n=0.366, p=0.013) all correlated with CrCl.

Conclusions: A significant decrease in renal function (CrCl <30 ml/min) was associated with more diffuse atherosclerosis (longer lesions with larger reference segment plaque burden) and more unstable plaque morphology (more frequent single and multiple plaque ruptures) in pts with AMI. This may contribute to the worse acute and chronic outcomes in these pts.
Results: Overall, 90% of the patients presented with 2 or more severe comorbidities. All patients were successfully implanted with the device. There was no intra-procedural death. The 30-day mortality was 6% (2 deaths post procedure and one after discharge). Adverse event rates were low, similar to what has been reported elsewhere (stroke 0%, limb ischemia 2%, bleeding requiring transfusion 4%, severe infection 2%, vascular complication 8%).

Conclusions: This study demonstrated that the Impella 2.5 is safe and potentially effective in supporting patients during high risk PCI procedures. The ease of use of the technology and high survival rate provide a compelling incentive to implement the Impella 2.5 for circulatory support during high risk PCI procedures.

Successful Thermal Coapation of Patent Foramen Ovale: First Experience and Temporal Histopathologic Heating in a Porcine Model

Hirotaka Hara, Elena LaDich, Renu Varma, David Ahuj, Joseph Eichinger, Deborah Sheffield, Mark Rosman, Robert S. Schwartz, Minneapolis Heart Institute Foundation, Minneapolis, MN

Background: Percutaneous patent foramen ovale (PFO) closure with implantable devices is now routine, and limits embolic complications. A novel method for PFO closure without an implantable device uses radiofrequency (RF)-based thermal energy to seal the PFO tunnel. We examined the healing response to temporal histopathologic events after thermal PFO closure in swine to characterize safety and efficacy of this strategy.

Methods: Domestic swine were studied over time following thermal PFO closure. Three animals were euthanized within 1 hour, 5 at 7, 28 days, and 5 at 60 days. Gross and histopathologic findings were examined.

Results: RF energy was successfully delivered in all cases. Acute results showed edema, hemorrhage and myocyte necrosis. Minimal thrombus formation occurred on the left atrial endocardial surface at the treatment site. At day 7, transmural thermal effects were seen through the atrial wall, and in 3 of 5 cases there was extension to the epicardial surface. At day 28, minimal thermal injury remained, with excellent scar formation. Collagen, matrix, and neoendothelialization occurred in all cases (Figure). No animal suffered adverse events prior to euthanasia at day 60.

Conclusions: RF based PFO closure device uses no implantable device, is feasible, safe, and effective in swine. Thermal tunnel healing is nearly complete by 4 weeks, consisting dense collagen formation and tunnel closure. This technique may allow effective PFO closure without a need for implanted devices.

Are Angiographic Restenosis Criteria Functionally Relevant In Evaluation Of Jailed Side Branch Lesions At Follow-up Angiograms?

Bon-Kwon Koo, Kyung-Woo Park, Eui-Keon Choi, Yong-Seok Cho, Woo-Young Chung, Han-Young Lee, Hyun-Jai Kang, In-Ho Chong, Dong-Ju Chi, Hye-Soo Kim, Byung-Hee Oh, Young-Bae Park, Youn-Shik Choi, Seoul National University Hospital, Seoul, South Korea

Backgrounds: Quantitative coronary angiography (QCA) is not always accurate in evaluation of angiographic restenosis. Previous study showed that angiographic evaluation of jailed side branch lesions overestimates the functional severity of these lesions. We performed this study to evaluate the relationship between QCA and functional significance of jailed side branch lesions at a follow-up angiogram.

Methods: Fractional flow reserve (FFR) was measured using RADI 4 pressure wire in patients with jailed side branch lesions (reference diameter<2mm, lesion length<10mm) after drug-eluting stent at routine 6 months follow-up angiogram. Patents with regional wall motion abnormalities and significant luminal narrowing at the parent vessel were excluded. FFR was measured at 5mm distal and proximal to the ostial lesion of the jailed side branches.

Results: Sixty-seven lesions (LAD 73%, Cypher 70%) were consecutively enrolled and FFR was successfully measured in 66 lesions (LAD 4%, LCX 12%, RCA 4%). Reference diameter, percent stenosis and lesion length of main branch side branch lesions were 2.9±0.42±0.3±0.3 mm, 18.3±18.7±15.1% and 27.9±21.7±2.2±7.7mm, respectively. FFR at main branch was 0.96±0.04 and side branch, 0.87±0.09. There was a negative correlation between FFR and percent stenosis at jailed side branch lesions (r=0.27, p=0.03). However, no lesion <75% stenosis was functionally significant and only 16% among lesions ≥75% stenosis had FFR<0.75. Restenosis rates by different criteria are as follows: 50% restenosis: 91%, 75% restenosis: 49% and functional criteria (FFR<0.75): only 8%. Conclusion: QCA overestimates the functional significance of jailed side branch lesions. More strict angiographic criteria should be applied in evaluation of treatment success of side branch lesion at a follow-up angiogram.

Safety and Efficacy of Desensitization Procedure in pts with Aspirin Sensitivity Undergoing Percutaneous Coronary Stenting

Roberta Rosini, Giuseppe Musumeci, Mario Scorci, Paolo Invernizzi, Paolo Ferrazzi, Antonello Gavazzi, Cardiovascular Dpt Ospedali Riuniti di Bergamo, Bergamo, Italy

Background: with the widespread of drug eluting stents (DES) in coronary percutaneous interventions (PCI), aspirin therapy has become mandatory. However, some patients (pts) are unable to tolerate acetylsalicylic acid (aspirin) due to sensitivity, which can limit percutaneous coronary revascularization.

Aim: to test safety and efficacy of a new standard desensitization procedure, using escalating low doses of aspirin in pts with acetylsalicylic acid sensitivity.

Methods and Results: Out of 721 pts with coronary artery disease, eighteen (age ≥82 yrs; 15 male) had a history of aspirin sensitivity (8.5%). They were divided into two groups, one for acute coronary syndrome (N=10) or stable angina (N=8). Six pts had respiratory sensitivity (asthma and/or rhinitis), and 12 had experienced cutaneous reactions (urticaria and/or angioedema). All pts underwent the challenge desensitization procedure. None received pretreatment with antihistamines or corticosteroids, and beta-blockers were withheld 24 hours before desensitization. Six sequential doses of aspirin (1, 5, 10, 20, 40, and 100 mg) were administered orally, with the procedure lasting 5.5 hours. Blood pressure, pulse, cutaneous, nasociliary, conjunctival and pulmonary reactions were monitored closely until 4 hours after the procedure. The desensitization procedure was successful in 15 pts (83.3%). No serious adverse reaction occurred: two pts (both with a history of chronic idiopathic urticaria) developed cutaneous reaction which resolved with corticosteroids and antihistamines; one pt (with frequent asthma attacks) experienced shortness of breath associated with bronchospasam, which resolved immediately after the administration of corticosteroids. All pts but 2 underwent PCI (1.5 stent, DES 75%, stent length 27.3±7.2 mm, multivessel PCI 37.5%) and were discharged on dual antplatelet therapy. At six month follow-up, all pts well tolerated aspirin. No major adverse cardiac event occurred.

Conclusions: this desensitization procedure seems to be safe and effective in the vast
Physiologic Evaluation Of Myocardial Bridging: A New Analysis For An Old Disease

Bon-Kwon Kang, Jung-Won Suh, Wook-Jin Chung, Hae-Young Lee, Hyun-Jae Kang, Young-Suk Cho, In-Ho Chae, Dong-Ju Choi, Hye-Soo Kim, Woon-Young Chung, Byung-Hee Oh, Young-Bae Park, Seoul National University Hospital, Seoul, South Korea

Background: Myocardial bridging is the most common congenital coronary anomaly. It is infrequently associated with mycardial ischemia; however, it is difficult to assess the functional significance of this lesion due to its dynamic nature. We performed this study to assess the hemodynamic relevance of myocardial bridges using a pressure wire.

Methods: 24 patients with lone myocardial bridging lesions were consecutively enrolled (systolic compression >50% by visual estimation). Baseline angiogram was obtained after intracoronary nitroglycerine administration and angiographic data of diastolic and systolic phases were obtained. Then fractional flow reserve (FFR) and pressure parameters were measured. Diastolic FFR was calculated by off-line analysis. Dobutamine stress-FFR (DS-FFR) was performed with intravenous dobutamine infusion while keeping the pressure wire across the lesion. Results: Mean age was 60±9 years and 63% were male. No lesion was functionally significant according to baseline FFR/diastolic FFR. After dobutamine infusion, percent stenosis and lesion length were aggravated and diastolic FFR was lowered. However, FFR was not changed (Table). Two lesions became functionally significant after dobutamine infusion. Conclusion: Dobutamine increased the morphologic and functional significance of myocardial bridging. This study should be used in functional assessment of myocardial bridging.

E-POSTER SESSION 902

P902-209 The Effect of Contrast Induced Nephropathy on Long-Term Renal Function

Hee-Suk Min, Ji-Hyun Kim, Bon-Kwon Koo, Jung-Won Suh, Hae-Young Lee, Hyun-Jae Kang, Young-Suk Cho, Woon-Young Chung, In-Ho Chae, Dong-Ju Choi, Hye-Soo Kim, Byung-Hee Oh, Young-Bae Park, Seoul national university college of medicine, Seoul, South Korea

Background: While even modest increases in serum creatinine (Scr) have been associated with an increase in long-term mortality, a pathophysiological link between the two is still unknown. The purpose of this study is to address whether contrast induced nephropathy (CIN) influences on long-term renal function and to find a new definition of CIN. Methods: Database from two prospective studies on CIN after coronary catheterization (RECOVER and PROMISE; total n=542) was reviewed. 253 patients (mean age: 65.26 years, female: 32%, mean CrCl: 51.68 ml/min per 1.73m2) with records of Scr values six months after the procedure were selected. Creatinine clearance (CrCl) was calculated by Cockcroft-Gault equation. CrCl levels of six months before the procedure were also analyzed in 130 patients. Results: When the patients were classified according to peak increment in Scr within 48hr after the procedure (ΔScr48hr), the change in CrCl during 6 month follow-up was significantly lower in patients with ΔScr48hr ≥0.2mg/dL than in those with <0.2mg/dL. The same findings were shown even when ΔScr48hr was calculated. Conclusions: There was no significant change in CrCl during 6 month follow-up was significantly lower in patients with ΔScr48hr ≥0.2mg/dL than in those with <0.2mg/dL. ΔScr48hr ≥0.2mg/dL can be a new definition of CIN that can predict the long-term renal function deterioration.

P902-210 Drug Eluting Stents in Patients With Diabetes Mellitus: a Meta-analysis of Randomized Trials

Giuseppe Paggi, Vincenzo Pasceri, Annunziata Nasca, Andrea D’Ambrosio, Germano Di Sciascio, Department of Cardiovascular Sciences, Campus Bio-Medico University, Rome, Italy, Interventional Cardiology Unit, San Filippo Neri Hospital, Rome, Italy

Background: The real impact of drug eluting stents (DES) on angigraphic and clinical endpoints in diabetic patients (pts) remains to be evaluated. In particular, no extensive data are available about the relative effect of DES vs bare metal stents (BMS) on the incidence of death and myocardial infarction (MI) during follow-up and there is a concern about the use of DES in insulin-dependent diabetic pts.

Methods: We searched data from randomized trials comparing DES and BMS in pts with diabetes mellitus during a follow-up of at least 6 months. Main clinical outcomes were: target lesion revascularization (TLR), death and MI. Angiographic outcome was the incidence of binary in-stent restenosis.

Results: A total of 8 randomized trials reporting post-hoc outcome analyses on the sub-population of diabetic pts and 1 trial specifically enrolling diabetic pts were found. TLR occurred in 8% of pts receiving DES vs 27% of those assigned to BMS (OR 0.23, 0.16-0.34; P=0.00001). In-stent restenosis was detected in 8% of pts randomized to DES vs 41% of those treated with BMS (OR 0.13, 0.09-0.20; P=0.0001). There was no significant difference in the incidence of death (2% in both groups, OR 1.04, 0.45-2.43; P=0.92). MI occurred in 3% of pts assigned to DES vs 7% of those assigned to BMS, with a significant 53% risk reduction in the first group (OR 0.47, 0.26-0.88; P=0.02). The benefit of DES in reducing in-stent restenosis was greatest in non-insulin-dependent diabetic pts (OR 0.17, 0.11-0.26; P<0.0001), but remained highly significant in insulin-dependent diabetic pts (OR 0.22, 0.13-0.37; P<0.0001).

Conclusions: Diabetic pts receiving DES have a significantly lower risk of restenosis and TLR compared with those treated with BMS. This reduction was observed both in non-insulin-dependent and in insulin-dependent pts. Use of DES in diabetic pts may decrease the incidence of MI during follow-up, whereas rates of death in DEB and BMS groups were similar.

9002-211 The Endeavor V Registry: ‘Real-world’ 12-month Safety and Efficacy Data for the Endeavor Zotarolimus-eluting Stent

Chaim Lotan, Ian T. Meredith, Martin T. Rothman, Medtronic, Inc, Santa Rosa, CA

Background: Endeavor V is an open-label, nonrandomized, multicenter global registry of patients receiving the Endeavor zotarolimus-eluting, phosphorlycholine-polymer stent (ZES) for the treatment of coronary artery disease. To reflect real-world clinical practice, consecutive patients are enrolled without clinical or angiographic exclusion.

Methods: Consecutive patients (maximum 100/site) undergoing any percutaneous coronary revascularization are enrolled at centers in Australia, Asia Pacific, Europe, India, Israel, New Zealand, and South America for a planned total enrollment of 8,000 patients treated with ZES. The primary endpoint is major adverse cardiac events (MACE) at 1 year. Secondary endpoints include MACE at 30 days and 6 months; device, lesion, and procedural success rates; and rates of stent thrombosis at 24 hours, <30 days, and >30 days postprocedure.

Results: Since October 2005, more than 5,000 patients receiving the Endeavor stent have been enrolled. At present, among 2,500 patients, clinical and angiographic characteristics include the following: diabetes mellitus, 34.6%; vessel caliper between mm, 38%; stent length > 30 mm, 20% in-stent restenosis, 15%; bifurcations, 16.5%. Lesion success was 99.5%, and procedural success was 95%. One-year results for 750 patients enrolled in the Endeavor V registry will be available in March 2007.

Conclusion: Interim analysis from the Endeavor V registry indicate high procedural and early clinical outcomes among patients treated with ZES in clinical settings beyond those previously studied in systematic trials. Clinical outcomes among over 750 patients with 1-year follow-up should provide confirmation of the safety and efficacy of the Endeavor stent in a broad, unselected patient population reflecting real-world clinical practice.

9002-212 The Radial Approach to Percutaneous Coronary Intervention is Associated with a Lower Risk for Complications Regardless of Radial Procedure Volume: A report from the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR)


Background: Studies comparing the radial (r)-PCI with the femoral (f)-PCI approach to percutaneous coronary intervention have not included centers with low r-PCI volume.

Methods: Data on 305,425 PCI procedures in the ACC-NCDR (2004-2006) were analyzed to evaluate variation in use of r-PCI and outcomes across centers. Logistic regression was used to evaluate the adjusted association between PCI site and r-PCI use and procedural complications (including bleeding, ischemic, & vascular outcomes).

Results: r-PCI accounted for 13.3% of the total procedures (N=40,674) & use varied across centers (0 to 71%). Patients who underwent r-PCI had higher BMI & more often had peripheral vascular disease. Compared with f-PCI, r-PCI had longer fluoroscopy time (13.20 vs. 11.50 min, p=0.0001) but did not involve more contrast use. r-PCI had significantly lower incidence of any bleeding or vascular complication (0.96 vs 2.38%, p=0.0001).
Innovation in Intervention: i2 Summit 2007

**Clinical and Angiographic Predictors of High Degree Atrio-Ventricular Block After Percutaneous Septal Myocardial Ablation: Multivariate Analysis of 65 Consecutive Patients**

Mario Araya, Federico De Marco, Thierry Leclercq, André Rosas Ramos, Yves Louvard, Marie-Christine Malergue, Bertrand Commer, Marie-Claude Morice, Institut Cardiovasculaire Paris Sud, Massy, France

**Background:** Transluminal Alcohol Septal Myocardial Ablation (TASH) bears a significant risk of atrioventricular block (AVB). Pre-procedural electrocardiographic (ECG) and procedural risk factors have been previously identified (left bundle branch block, type 1 AVB, no echocardiographic guidance, bolus injection). Aims of the study: To identify angiographic characteristics associated with post-procedural AVB.

**Methods:** Between 2001 and 2006, a group of 65 consecutive patients, without prior pacemaker implantation (PM), referred for a first TASH procedure were analyzed. The dominant septal (S) branch was defined as the biggest septal branch, and the distance between ostial LAD and the S was measured by QCA. We performed univariate and multivariate analysis to identify predictors of post-procedural AVB.

**Results:** High degree post-procedural AVB (HD AVB) incidence was 23/65 (35.4%). Permanent PM was required in 5/65 (7.7%). Predictors of HD AVB by univariate analysis:

<table>
<thead>
<tr>
<th>Model</th>
<th>OR (95% confidence interval)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>5.56 (0.44-7.0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Adjusted for patient differences</td>
<td>0.71 (0.57-0.89)</td>
<td>0.003</td>
</tr>
<tr>
<td>Adjusted for patient differences, procedure differences, and center clustering</td>
<td>0.69 (0.57-0.84)</td>
<td>0.001</td>
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</table>

**Conclusions:** Beyond standard predictors we identified for the first time the role of septal anatomy in predicting peri-procedural high degree AVB. Alcoholisation of a first Septal, dominant septal (S1) branch was defined as the biggest septal branch, and the distance between ostial LAD and the S was measured by QCA. We performed univariate and multivariate analysis to identify predictors of post-procedural AVB.

**Abstracts - Innovation in Intervention: i2 Summit 2007**

**Clinical Correlates of Restenosis Following Coronary Implantation of Drug-Eluting Stents**


**Background:** The efficacy of drug-eluting stents (DES) in reducing restenosis has not been uniform across all patient and lesion subsets. The study aims to identify clinical and procedural factors which correlate with DES restenosis.

**Methods:** The clinical and procedural characteristics of 171 (229 lesions) consecutive patients with DES restenosis were compared with 2522 (4564 lesions) consecutive DES patients without restenosis. Univariate and multivariate regression analysis were performed to detect predictors of DES restenosis.

**Results:** Patients with DES restenosis were more likely to be younger (62.70±11.04 vs. 65.23±11.61; p=0.001), and present with unstable angina (p=0.001), hypertension (p=0.001), and peripheral vascular disease (p=0.038). These patients underwent longer procedures (70.38±51.07 min vs.59.72±47.74; p=0.003) and had more renal insufficiency (p=0.001). There was less IVUS guided stent implantation (p=0.001), less primary stenting (p=0.001), and longer total stented length (35.21±19.48 mm vs.24.26±12.55 p=0.001) with more stents/patient (1.81±0.75 vs. 1.16±0.45; p=0.001) in the DES restenosis group. Multivariate analysis detected longer total stented length as the major correlate for DES restenosis. Other correlates were age, hypertension, longer procedural times, and IVUS guided stent implantation (Table).

**Conclusions:** Minimizing the number of stents and total stented length, along with utilizing IVUS guidance, may potentially reduce DES restenosis.

10:00 a.m.

**Outcomes of Bivalirudin in Moderate and High Risk Patients with Acute Coronary Syndromes and Renal Insufficiency: An ACUITY Substudy**

Ayu J. Kortang, Roxana Mehran, George Dangas, Steven Manoukian, Frederich Felt, Thomas Siaukay, Magnus Ohman, Martial Hamon, Angel Cequier, David Cohen, Charles Pollack, James Hoeckstra, Stuart Pocock, Bernard Gersh, Joseph Stella, Michel Bertrand, Walter Desmet, Gregg W. Stone, Columbia University Medical Center, New York, NY, Cardiovascular Research Foundation, New York, NY

**Background:** Renal insufficiency is an important predictor of adverse outcomes after PCI and in pts with ACS. The safety and efficacy of current anti-thrombotic regimens in this population have not been extensively studied.

**Methods:** In the ACUITY trial, 13,819 moderate and high risk ACS pts undergoing early invasive management were randomized to bivalirudin alone (BIV), BIV+glycoprotein IB/IIa inhibition (BIV+GPI), or heparin+GPI (H+GPI). Clinical outcomes in pts with baseline renal insufficiency (CrCl <60 ml/min) were compared by randomized treatment.

**Results:** Baseline renal insufficiency was present in 2486 (17.9%) pts, in whom the mean CrCl was 46.2±11.6 ml/min. Mean age was 74 yrs, 29% had diabetes, and 59% had elevated cardiac markers. As seen in the Figure, the 30 day rate of the composite net clinical endpoint of death/MI/unplanned revasc with major bleeding was similar among pts treated with BIV (16.1%), H+GPI (16.8%), and BIV+GPI (19.5%). Composite ischemia (death/MI/unplanned revasc) occurred with similar frequency among the 3 study arms, but the rate of major bleeding was not significantly lower with BIV compared to H+GPI (Figure).

**Conclusion:** Bivalirudin monotherapy compared to H+GPI results in significantly lower rates of major hemorrhagic complications and similar net clinical benefit at 30 days in the high-risk subgroup of pts with ACS and baseline renal insufficiency. One year adjudicated outcomes will be presented.

10:00 a.m.
We already reported that utilizing Sirolimus-eluting stent treatment of STEMI in patients with ESRD. Hypothesis: percutaneous coronary intervention (PCI) or thrombolysis.

Methods: ESRD patients with STEMI treated with primary PCI (n=573) or thrombolysis (n=120) during 1999-2000 were identified from the US Renal Data System (USRDS) database.

Results: Thrombolysis patients were older (70±10 vs 66±12 years, p=0.002), with a higher percentage of whites (80% vs 70%, p=0.016) compared with primary PCI patients.

Conclusions: Primary PCI is associated with improved survival compared with thrombolysis for treatment of STEMI in ESRD patients with a history of prior ischemic heart disease.
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11:00 a.m.

**903-213**

Immediate Improvement In Coronary Flow Reserve After Alcohol Septal Ablation In Patients With Hypertrophic Obstructive Cardiomyopathy

Wissem A. Jaber, Eric H. Yang, Rick A. Nishimura, Amir Lerman, Mayo Clinic, Rochester, MN

Background: Patients with hypertrophic obstructive cardiomyopathy (HOCM) are known to have reduced coronary flow reserve (CFR), the mechanism of which is not well understood. Alcohol-induced septal ablation (SA) reduces obstruction and improves symptoms in patients with HOCM. The objective of this study is to define the effect of SA on CFR.

Methods: Patients with symptomatic HOCM underwent coronary flow assessment with a Doppler flow wire placed in the mid left anterior descending coronary artery (LAD) distal to the septal perforator. CFR was determined with the use of intracoronary adenosine and was measured immediately before and after SA. Simultaneous left ventricular (LV) and aortic pressures were recorded.

Results: Eleven patients with symptomatic HOCM (age 81±14, 5 males, 4 hypertensive, 2 smokers) were studied, 7 of whom had CFR measured after SA. After SA, LV outflow tract gradient decreased in all patients. There was no change however in mean left atrial pressure or the time constant of relaxation. The CFR was low at baseline, and increased in all patients after SA, as did the diastolic/systolic flow velocity ratio. Coronary resistance increased, but LAD flow did not change (Table).

Conclusions: In patients with symptomatic HOCM, reduced CFR is at least in part due to decreased coronary resistance, rather than chronic remodeling. SA leads to immediate increase in CFR by reducing the contraction load on the LV, without improvement in diastolic function.

**903-214**

“Cone Crush”, A Variant of Modified T-Stenting Technique for Coronary Bifurcation Lesions: Bench Testing, Clinical Feasibility, and In-Hospital Outcomes

Sanjay Ravji, Alfonso Suarez, Kalgi A. Modi, Brigitta C. Bott, Raed A. Azpi, Vijay K. Misra, William B. Hillegass, University of Alabama at Birmingham, Birmingham, AL

Background: Multiple two stent techniques exist for coronary artery bifurcation lesion (CABL). Circumferential scaffolding of the side branch (SB) ostium without excessive main vessel (MV) provocation is optimal. We describe a simple technique to yield a trumpeted cone of ostial SB stent using two stents for CABL. One stent is placed over the ostial SB and the other is positioned distally using a balloon catheter. This technique is called “Cone Crush”.

Methods: Cone Crush Technique (CCT): The SB and MV are predilated. SB stent is placed over the ostium and intra-balloon inflation performed. The SB wire is removed if angiography confirms a satisfactory SB result. CCT in a waterlogged plexiglass bifurcation model with intravascular ultrasound. Clinical testing, clinical feasibility, and in-hospital outcomes

Results: Among 610 patients 283 (46%) had PCI. The primary endpoint was seen in 66 patients (11%). 903-214

**903-215**


Background: Access closure devices (ACD) use has increased following percutaneous transluminal coronary angioplasty (PTCA), however, their safety in patients with chronic kidney disease (CKD) is not known. Therefore, we evaluated the complication rates of ACDs among patients with CKD.

Methods: 610 consecutive patients who underwent PTCA and ACD were retrospectively studied. Patients were grouped according to their creatinine clearance (CCr) calculated by the Cockcroft-Gault formula using the National Kidney Foundation classification system: Stage I (CrCl > 90); Stage II (60-89); Stage III (30-59); Stage IV (15-29); and Stage V (<15). Primary endpoints were pseudoaneurysm, retroperitoneal hematoma, femoral artery thrombosis, surgical vascular repair and groin infection.

Results: Among 610 patients 283 (46%) had PCI. The primary endpoint was seen in 66 patients (11.0%) patients. Univariate predictor of primary outcome were lower CrCl (<0.001), and presence of PVD (p = 0.03). There were an inverse relationship between CrCl and complication rate (see graph). CKD was the strongest independent predictor for the primary endpoint (OR 1.032; 95% CI -1.019-1.046, p = 0.0001). For example, patients with 50% reduction in CrCl more had complication rate of 1.55±4.0 compared to 0.63±0.4 in those with normal CrCl. Patients with prior cardiac event had significantly higher complication rate compared to those without heart disease (p < 0.0001). Conclusions: Renal function plays a significant role in predicting the rate of vascular access site complications. Worsening renal function is associated with higher vascular access site complications largely driven by an increased infection rate.


### 903-215

**Rotational Atherectomy Prior to the Stenting with Sirolimus-Eluting Stent for Diffuse In-Stent Restenosis: Multicenter Registry in Asia**

Sunao Nakamura, Jang-Ho Bae, Yeo H. Cahyadi, Wasan Udadyachalerm, Damras Tesroskul, Sudaratana Tarsuphaswadikiul, 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.

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### 903-216

**Measures of Aspirin Resistance and Clopidogrel Resistance Do Not Correlate with Post Percutaneous Coronary Intervention Markers of Myonecrosis**

Ashesh N. Buch, Sumant Singh, Kimberly A. Smith, Rebecca Torguson, Zhenyi Xue, Natalie Gevorikian, Jana Fournadjieva, Lowell F. Satter, Kenneth M. Kent, William O. Suddath, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC

**Background:** Aspirin and clopidogrel protect against thrombotic events during percutaneous coronary intervention (PCI). CK-MB enzyme release after PCI has been identified as an adverse prognostic indicator. We aimed to determine if there was any correlation between measures of aspirin resistance, degree of thienopyridine specific P2Y12 platelet receptor inhibition, and post PCI CK-MB release.

**Methods:** We prospectively studied 330 elective PCI patients (drug-eluting stents), all pre-treated with aspirin and clopidogrel. Patients with acute coronary syndromes and those on GP IIb/IIIa inhibitors were excluded. Serum assays of aspirin resistance (Ultegra Rapid Platelet Function Assay-ASA, Accutest, CA) and clopidogrel resistance (Rapid Platelet RFFAPY212, Accutest, CA) were performed pre-PCI. Serum troponin-I and CK-MB were measured at 8, 16, and 24 hours after PCI.

**Results:** We detected only 12 patients (3.7%) with aspirin resistance unit (ARU) measurement of ≥ 550. Mean platelet reactivity unit (PRU, measure of inhibition of P2Y12 activity) was 192 ± 95.4. There was no correlation between the level of ARU or PRU and post PCI troponin-I or CK-MB release at any time point. A positive correlation was found between levels of ARU and PRU (Figure). TVR-MACE rate at 12 months was 8.2% with no post PCI troponin-I or CK-MB release at any time point. A positive correlation was found between ARU and PRU and the release of cardiac enzymes nor the occurrence of adverse cardiac events.

**Conclusion:** This study does not support routine measurements of aspirin and clopidogrel resistance

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### 903-217

**Impact of Plaque Composition on Troponin Elevation After Percutaneous Coronary Intervention: Virtual Histology-IVUS Analysis**


**Background:** Percutaneous coronary intervention (PCI) is often complicated by postprocedural myocarial necrosis as manifested by elevated cardiac markers.

**Methods:** We investigated the relationship between preintervention coronary plaque characteristics determined by intravascular ultrasound-virtual histology (IVUS-VH); on troponin-I (TnI) elevation after PCI of 59 native coronary lesions in 59 consecutive pts (20 stable angina and 39 unstable angina) with normal pre-PCI TnI. Pts were divided into two groups according to the presence/absence of post-PCI TnI elevation more than 3 times upper limit of normal: TnI elevation (n=28) vs. no TnI elevation (n=31).

**Results:** There was a male predominance (75% vs. 48%, p=0.036) and LDL-cholesterol level was significantly higher in pts with TnI elevation vs pts without TnI elevation after PCI (108±46mg/dl vs. 86±31mg/dl, p=0.044). Lesion plaque burden and reference segment plaque composition and plaque burden were similar between the two groups. Lesion remodeling index and % lesion necrotic core area were significantly larger and lesion length was longer in pts with post-PCI TnI elevation than in pts without post-PCI TnI elevation (Table). Post-PCI TnI levels correlated with % lesion necrotic core area (r=0.290, p=0.026) and remodeling index (r=0.258, p=0.048).

**Conclusions:** IVUS-VH analysis demonstrates that post-PCI TnI elevation occurs in longer lesions with a larger necrotic core and more positive remodeling.

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### 904

**ePoster Session 904**

**Sunday, March 25, 2007, Noon-1:00 p.m.**

**Noon**

### 904-209

**The Effect of Nesiritide on Kidney Function in Patients with Advanced Chronic Kidney Disease Undergoing Contrast Angiographic Procedures**

Andrew R. Wainsroub, Carey Kimmelstiel, Marvin A. Konstant, James Udolison, Pamela Field, Christine Delano, John Griffith, Mark Sarnak, Tufts-New England Medical Center, Boston, MA

**Contrast-induced nephropathy (CIN) is a common cause of acute renal failure. Exogenous recombinant B-type natriuretic peptide (nesiritide, NSR) has been shown to have a salutary effect on kidney hemodynamics. The effect of NSR in patients with advanced chronic kidney disease (CKD) who are exposed to contrast medium (CM) is unknown. We explored the effect of NSR on kidney function in patients at high risk for CIN.**

**Methods:** 50 patients with CKD and a stable GFR 40 ml/min/1.73 m2 undergoing angiographic procedures were prospectively randomized in a double blind fashion to receive NSR (at FDA approved heart failure dosing) in conjunction with standard preventive therapy (ST) for CIN (n-acytetylcysteine and pre/post procedure hydration) vs. ST alone. The primary endpoint was defined as a 0.5 mg/dl increase in serum creatinine at 72 hours (hrs). Patients with heart failure exacerbation were excluded.

**Results:** Over a 72-hr follow-up, patients randomized to receive NSR experienced no significant effect on kidney function compared to ST alone (TABLE)

<table>
<thead>
<tr>
<th>Time</th>
<th>Nesiritide Serum Cr Mean (mg/dl) ± SD (n=24)</th>
<th>Control Serum Cr Mean (mg/dl) ± SD (n=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.32 ± 0.57</td>
<td>2.41 ± 0.63</td>
<td>0.6</td>
</tr>
<tr>
<td>24 Hours</td>
<td>2.24 ± 0.50</td>
<td>2.35 ± 0.70</td>
<td>0.97</td>
</tr>
<tr>
<td>48 Hours</td>
<td>2.19 ± 0.48</td>
<td>2.35 ± 0.70</td>
<td>0.4</td>
</tr>
<tr>
<td>72 Hours</td>
<td>2.16 ± 0.63</td>
<td>2.44 ± 0.75</td>
<td>0.17</td>
</tr>
<tr>
<td>8.5 mg/dl Serum Cr increase: % (n=25)</td>
<td>1 (4.2)</td>
<td>0 (11.2)</td>
<td>0.38</td>
</tr>
<tr>
<td>Absolute ∆ Serum Cr</td>
<td>-0.14 ± 0.37</td>
<td>0.03 ± 0.42</td>
<td>0.15</td>
</tr>
</tbody>
</table>

**Overall change in creatinine from baseline to 72 hrs (Control Mean ± SD: 0.03 ± 0.42 vs. NSR -0.14 ± 0.37 mg/dl p=0.15) trended favorably in the NSR group.**
Conclusion: In this pilot study, the addition of NSR to ST for CIN does not affect kidney function in patients with CKD undergoing contrast angiographic procedures. Event rates for CIN were low despite advanced CKD. Exploration of a salutary effect of NSR in CIN will require a larger clinical trial.

Clinical Results of Percutaneous Coronary Intervention for Chronic Total Occlusion: Predictive Factor for Procedural Failure in Recent Technical Development and New Stiff Guide wire

Masanori Shibata, Masato Nakamura, Masaki Hori, Makoto Utsunomiya, Nachiko Nemoto, Shingo Ito, Hiotaka Komatsu, Masamichi Wada, Rintaro Nakajima, Hissao Hara, kazuyuki Ishi, Yoshinori Nagashima, Kaoji Sugr, Takuro Takagi, Toho university showa medical center, tokyo, Japan

Background: Revascularization of chronic total occlusion (CTO) is one of the major remaining problems in the field of percutaneous coronary intervention (PCI). However, some new guide wire and recent technical development may have improved it. We investigated our procedural results, and clarified the predictive factor of procedural failure.

Methods: We studied 157 cases of PCI for CTO (defined as duration >3months). All procedures were guided by well-visualized distal vessel anatomy by bilateral simultaneous angiography. We used the Confinza Pro (tapered special stiff wire for CTO) in selected cases. If we struggled in sub-intimal space with single wire, parallel wire method (PWM) using second wire was chosen after that. And if it was hard to cross the CTO with balloon, anchor balloon technique (ABT) was attempted.

Results: Distribution of attempted CTO cases were RCA 48%, LAD 32%, LCX 20%. Lesion characteristics of CTO was reference vessel diameter 2.8±0.7mm, occlusion length 27.5±19mm, and 54% of cases with no determinable duration of occlusion. Details of Lesion morphology were tapered occlusion 40.1%, occlusion at side branch 25.4%, moderate or severe calcification 47.1%, marked tortuosity 42.6%, and bridge collaterals 31.8%. Confinza Pro was used in 60.5% of all cases. Total procedural success rate was 82.3% (including 7pts who required second session for revascularization). PWM was required in 47.1% of all cases, and succeeded with 68.8% in these selected cases. ABT was necessary for 13.7% of successful patients. During these procedures, amount of 23±7±7mm contrast media and 82±13±8mL of fluoroscopy time were required. In multivariate analysis, predictive factor for procedural failure is moderate or severe calcification (OR=5.8, 95% CI, 1.19-24.4, P=0.03)

Conclusions: Although more severe cases were attempted, we thought procedural success rate has improved than its historical rate. New stiff guide wire and PWM, ABT contributes to these results. However, calcification at CTO is the independent predictor for procedural failure still in this era.

Two-year Outcomes in Real World Experience With Taxus Paclitaxel-Eluting Stent in a Prospective, Multicenter, Consecutively-Enrolling US Registry: ARRIVE 1

John M. Lasala, J. Tiff Mann, Brian Armstrong, Mitie Kellett, Stephen Mascioli, Washington University St. Louis, St. Louis, MO

Objective: Whether the long-term safety and effectiveness of drug-eluting stents observed in clinical trials translates to wide-spread use in the more complex populations of patients currently being treated in interventional labs. The ARRIVE 1 registry has compiled data on real-world usage, safety, and clinical events for the Taxus Express®-paclitaxel-eluting stent.

Methods: Each of the 48 community-based US sites enrolled up to 75 consecutive patients receiving Taxus stents. Anti-platelet therapy included long-term aspirin and 6 months clopidogrel. Clinical follow-up was conducted at 1, 6, 12 and 24 months to collect data receiving Taxus stents. Anti-platelet therapy included long-term aspirin and 6 months clopidogrel. Clinical follow-up was conducted at 1, 6, 12 and 24 months to collect data

Results: Distribution of attempted CTO cases were RCA 48%, LAD 32%, LCX 20%. Lesion characteristics of CTO was reference vessel diameter 2.8±0.7mm, occlusion length 27.5±19mm, and 54% of cases with no determinable duration of occlusion. Details of Lesion morphology were tapered occlusion 40.1%, occlusion at side branch 25.4%, moderate or severe calcification 47.1%, marked tortuosity 42.6%, and bridge collaterals 31.8%. Confinza Pro was used in 60.5% of all cases. Total procedural success rate was 82.3% (including 7pts who required second session for revascularization). PWM was required in 47.1% of all cases, and succeeded with 68.8% in these selected cases. ABT was necessary for 13.7% of successful patients. During these procedures, amount of 23±7±7mm contrast media and 82±13±8mL of fluoroscopy time were required. In multivariate analysis, predictive factor for procedural failure is moderate or severe calcification (OR=5.8, 95% CI, 1.19-24.4, P=0.03)

Conclusions: Although more severe cases were attempted, we thought procedural success rate has improved than its historical rate. New stiff guide wire and PWM, ABT contributes to these results. However, calcification at CTO is the independent predictor for procedural failure still in this era.

Predictors of Major Vascular Complications in Patients Undergoing Percutaneous Coronary Intervention: Insights from the REPLACE-2 Trial

Reza Fazel, Michèle D. Voelitz, Frederick Feit, Michael J. Attubato, S. Tanweer Rab, Habb Samady, Sunil V. Rao, Steven V. Manoukian, Emory University School of Medicine, Atlanta, GA, New York University School of Medicine, New York, NY

Background: Major vascular complications (MVC) are associated with significant morbidity in patients undergoing percutaneous coronary intervention (PCI). We sought to determine the baseline and procedural predictors of MVC in contemporary PCI.

Methods: We reviewed the REPLACE-2 Trial and defined MVC as major bleeding at the vascular access site or surgical vascular repair. We used stepwise logistic regression to determine predictors of MVC. Candidate variables for inclusion in the model (based on P ≤ 0.05) were age, gender, systolic BP, GFR, urgent PCI, diabetes mellitus, LVEF, BMI, sheath dwell time, platelet count, pro-PCI thienopyridine or heparin, treatment group (bivalirudin [BIV] vs. GP IIb/IIIa inhibitor plus heparin [GPI+H]), vascular closure device use, and an interaction term of the latter two variables.

Results: 5667 (94%) patients had complete data and were included in our analysis. MVC occurred in 1.9% of patients and were less frequent for BIV vs. GPI-H (1.17% vs. 2.61%, unadjusted OR: 0.44, P < 0.0001). After multivariable adjustment, predictors of MVC included treatment group, vascular closure device use, sheath dwell time, GFR, and gender. The o-statistic was 0.71 and the test for goodness-of-fit indicated satisfactory fit.

Conclusions: In PCI, GPI+H use, vascular closure device use, sheath dwell time, impaired renal function, and female gender are independent predictors of MVC. Altering treatment strategy with regard to the three modifiable factors may reduce the risk of MVC in PCI.

Three-year clinical and echographic follow-up after Percutaneous Edwards Aortic Valve Implantation for Severe Aortic Stenosis in Compliant Patients.

Hélène Eltchaninoff, Christophe Tron, Fabrice Bauer, Damien Brunet, Sydney Tapiero, Ibrahim Baala, Alain Criber, Rouen University Hospital, Rouen, France

Background: The Edwards percutaneous heart valve (PHV) is an equine pericardium bioprosthetic sutured onto a balloon expandable stent. From February 2004 to April 2005, 37 patients with end-stage aortic stenosis, multiple comorbidities (Parsonnet score: 47+/–6), formally declined for surgical valve replacement, were included on compassionate use, and an interaction term of the latter two variables.

Methods: PHV was implanted by the antegrade approach in 30/37 cases. Clinical and echocardiographic outcomes were assessed serially at one year, one week, one month, 3 months and every 6 months thereafter. Results: Successful implantation was obtained in 27 patients with a final valve area (AVA) of 1.70 ± 0.10 cm² and a transvalvular gradient of 9.0 ± 2.0 mmHg. One month major adverse events were 26% including 6 death of non cardiac cause. PHV function was observed in no case. Despite critically ill at the time of implantation, 9 patients are currently alive with a follow-up > 18 mos (3 years in 2 patients), NYHA class I and return to normal life. As shown on the figure, PHV function remained unchanged during follow-up in the 27 patients.

Conclusions: Close clinical and echographic follow-up already demonstrate the 3 years durability of PHV. Ongoing prospective studies will further determine the place of this promising new therapeutic alternative in non operable patients with calcific AS.

Predictors of Irreversible Events After Percutaneous Coronary Intervention in Unprotected Left Main Lesions

Federico De Marco, Mario Araya, Jose Antonio Fernandez-Diaz, Olivier Darremont, Yves Lourdou, Philipp Garot, Thierry Untersetzer, Marie-Claude Morice, Thierry Leb weber, B. Cardiovaskuläres Institut Mainz, Mainz, Mainz, Germany

Background: Percutaneous treatment of left main (LM) lesions represents a high risk intervention. Objective of this study was to evaluate the impact of baseline clinical and angiographic characteristics on one year outcome.

Methods: A group of 291 consecutive patients treated in 4 French centers for unprotected LM stenosis was included in the LM TAXUS Pilot study between March 2003 and June 2005. We performed univariate and multivariate analysis to identify predictors of “irreversible events” at 1 year follow-up. Irreversible events were defined as the composite of death, stroke, Q-wave MI and CABG. Variables differing in the two groups with a P value < 0.10 were entered in multivariate analysis.

Results: At mean FU of 13.3 ± 2.1 months cumulative irreversible events occurred in 17/291 patients (5.8%), including CABG in 1.0%, Q-wave MI in 0%, stroke in 0.3% and death in 4.8%. Variables taken into account in the test were: age, EF, Euroscore, general risk factors, clinical indication, presence of 3- vessel disease and angiographic variables
before and after PCI.

<table>
<thead>
<tr>
<th>Patients (n)</th>
<th>No Irreversible Events Group</th>
<th>Irreversible Events Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>57.4 ± 11.5</td>
<td>72.9 ± 9.9</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>27%</td>
<td>59%</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>44%</td>
<td>13%</td>
</tr>
<tr>
<td>Family History (%)</td>
<td>31%</td>
<td>0%</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>6%</td>
<td>11%</td>
</tr>
<tr>
<td>EF (%)</td>
<td>51 ± 13</td>
<td>56 ± 12</td>
</tr>
<tr>
<td>NSTEMI (pts)</td>
<td>37 ± 3.4</td>
<td>33 ± 3.2</td>
</tr>
<tr>
<td>Vessel Disease (%)</td>
<td>35%</td>
<td>40%</td>
</tr>
<tr>
<td>Distal lesion (%)</td>
<td>77%</td>
<td>84%</td>
</tr>
<tr>
<td>Female (n)</td>
<td>40%</td>
<td>67%</td>
</tr>
<tr>
<td>Stenosis main branch (%)</td>
<td>93 ± 32</td>
<td>81 ± 30</td>
</tr>
<tr>
<td>Stenosis side branch (%)</td>
<td>93 ± 31</td>
<td>61 ± 30</td>
</tr>
<tr>
<td>Post PCI stenosis main branch (%)</td>
<td>7 ± 8</td>
<td>9 ± 9</td>
</tr>
<tr>
<td>Post PCI stenosis side branch (%)</td>
<td>7 ± 10</td>
<td>5 ± 9</td>
</tr>
</tbody>
</table>

By multivariate analysis, only diabetes (OR 3.32, 95% CI 1.07-10.24, p = 0.037) and no dyslipidemia (OR 0.32, 95% CI 0.08-0.82, p = 0.02) remained as independent predictors of irreversible events at one year follow-up.

Conclusions: The risk of irreversible events after LM stenting, using the TAXUS stent is relatively low in this high risk population. Diabetes appears as the strongest predictor of events at one year follow-up.

## 904-215

**Metabolic Syndrome as a Predictor of Restenosis in Diabetic Patients Presenting with Acute Coronary Syndrome or Angina**

Carlos A. Huie Jr., John M. Galla, Saif Anwaruddin, Samir Kapadia, Richard A. Kronis, Matthew C. Becker, Cleveland Clinic Foundation, Cleveland, OH

**Background:** The metabolic syndrome has been defined as a constellation of well-established cardiovascular risk factors and is common in the diabetic population. The effect of metabolic syndrome on rates of restenosis after percutaneous coronary intervention in this high risk population has not been clearly established.

**Methods:** 2561 patients who presented with acute coronary syndrome (ACS) or anginal symptoms and had previously received coronary artery stents were identified from a group of 5329 consecutive diabetic patients undergoing diagnostic angiography. World Health Organization (WHO) criteria were used to classify these patients as having metabolic syndrome (n=154) or as diabetic controls (n=59). Baseline characteristics and laboratory data were prospectively collected for all patients at the time of initial intervention. Bivariate analyses were performed comparing the prevalence of target vessel in-stent restenosis in both cohorts.

**Results:** Restenosis was present in 61.7% (n=95) of the metabolic syndrome cohort and 44.1% (n=26) of the controls (p=0.02). The WHO criteria for metabolic syndrome, both hypertension (p=0.01) and body mass index (p=0.05) correlated with restenosis, whereas hypertriglyceridemia (p=0.06) and low high-density lipoprotein levels (p=0.08) did not correlate with restenosis. Multivariate analysis controlling for common demographics and use of drug-eluting stents revealed a trend towards increased restenosis in the metabolic syndrome cohort (odds ratio 1.9, p=0.05).

**Conclusion:** The presence of metabolic syndrome suggests a nearly two-fold increase in the risk of restenosis in the diabetic population presenting with ACS or anginal symptoms. The majority of this effect may be the result of an increased prevalence of hypertension and elevated body mass index in this cohort. This supports early and aggressive intervention aimed at reduction of blood pressure and body mass index in this high risk population.

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**E-POSTER SESSION**

**905**

**Noon**

**Post-Coronary Intervention Recurrent Ischemia in the Presence of Adequate Platelet Inhibition by Dual Antiplatelet Therapy: What Are We Overlooking?**

Paul A. Gurbel, Kevin P. Biren, Irene Navickas, Udaya S. Tantry, Ellis Cohen, Sinai Center for Thrombosis Research, Baltimore, MD, Haemroscope Corporation, Niles, IL

**Background:** Despite therapy with COX-1 and P2Y_13 inhibitors, recurrent ischemic events occur suggesting that mechanisms other than inadequate aspirin and clopidogrel induced platelet inhibition may be involved. Here, we investigated the characteristics of enzymatic and platelet-fibrin interactions in addition to aspirin and clopidogrel responsiveness using the TEG hemostasis analyzer in patients who experienced recurrent ischemic events after stenting, despite dual antiplatelet therapy.

**Methods:** In 192 patients undergoing elective stenting, ADP- and AA-induced platelet aggregation measured by the TEG PlateletMapping assay, rate of enzymatic reaction (TEG R), and thrombin-induced platelet-fibrin clot strength (TEG MA) were measured before the procedure. Patients were followed for six months to determine the occurrence of adverse events (cardiovascular death, MI, stroke, or unstable angina).

**Results:** 36 patients experienced recurrent ischemic events. 7 patients (19%) with ischemic events had >75% platelet inhibition by both aspirin and clopidogrel, indicative of high responsiveness to dual antiplatelet therapy, as compared to >75% inhibition in the remaining patients with ischemia (p = 0.05). Patients with ischemic events and adequate platelet inhibition had a more rapid TEG R and a greater TEG MA (p < 0.05 for both) vs. ischemic patients with inadequate platelet inhibition.

**Conclusion:** Patients with adequate inhibition by dual antiplatelet therapy who experience recurrent ischemia after stenting are characterized by an enzymatic hypercoagulable state. These results would indicate that the achievement of an adequate level of protection against a recurrent thrombotic event may require the combination of antiplatelet and anticoagulant therapy in selected patients. These patients can be identified pre-procedure by TEG.

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**904-216**

**Noon**

**Post-Coronary Intervention Recurrent Ischemia in the Presence of Adequate Platelet Inhibition by Dual Antiplatelet Therapy: What Are We Overlooking?**

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**905-237**

**The Incidence of Contrast-Induced Nephropathy With Iomeprol is Similar to the Incidence of Contrast-Induced Nephropathy With Iopamidol**

Mitsuru Abe, Takeshi Kimura, Yoshitaka Nakagawa, Yutaka Furukawa, Masaharu Akao, Masanao Toma, Yoshihiro Tamura, Ryoi Taniguchi, Kozo Hoshino, Tamaki Suyama, Masao Imai, Takeshi Monimoto, Toru Kitah, Kyoto University Hospital, Kyoto, Japan

**Background:** Contrast-induced nephropathy (CIN) is defined as an elevation in serum creatinine (Cr) concentration ≥0.5mg/dl within 5 days after cardiac catheterization. CIN is the third leading cause of hospital-acquired renal failure accounting for 10% of all cases and has been associated with increased long-term mortality. Iomeprol is a newer nonionic iodinated contrast agent and is the most popular one in the European Union countries. Because the incidence of CIN with iomeprol is unknown at present, elucidating the incidence of CIN with iomeprol will help cardiologists to take preventive measures for high risk patients.

**Methods:** We retrospectively examined all patients who underwent cardiac catheterization in our department at Kyoto University Hospital from January 2003 to December 2004 and patients on hemodialysis before catheterization were excluded. We compared the incidence of CIN with iomeprol with the incidence of CIN with iopamidol because iopamidol is one of the most popular contrast agents in the world and the incidence of CIN with iopamidol was reported to be significantly lower than other contrast agents.

**Results:** Among 1159 patients, iomeprol was administered to 647 patients (55.8%) and iopamidol was administered to 512 patients (44.2%). The incidence of CIN with iomeprol (4.3%) (28 of the 647 patients, 95% CI: 3.0-6.2%) is similar to the incidence of CIN with iopamidol (3.2% (18 of the 512 patients), 95% CI: 2.2-5.5%). Baseline clinical and procedural characteristics, which had been reported as risk factors for CIN, were as follows (iomeprol vs iopamidol): male gender (72.8% vs 69.9%, p<0.03), older age (>70 years) (59.4% vs 53.9%, p=0.05), renal insufficiency (Cr ≥1.2mg/dl) (22.6% vs 21.1%, p=0.5), use of high volume contrast (≥200ml) (38.8% vs 34.3%, p=0.1), anesthesia (21.5% vs 19.2%, p=0.4), diabetes mellitus (32.9% vs 42.0%, p=0.01), cosmetic heart failure (19.8% vs 18.2%, p=0) and peripheral arterial disease (21.2% vs 24.4%, p=0.2).

**Conclusion:** Logistic regression model adjusting for these risk factors showed the odds ratio of CIN with iomeprol was 1.2 (95% CI: 0.6-2.3).

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**905-226**

**Noon**

**Robust Impact of Chronic Kidney Disease on Long-Term Survival in Patients Undergoing Revascularization of Severe Unprotected Left Main Coronary Artery Stenosis.**

John M. Galla, Matthew C. Becker, Saif Anwaruddin, Thomas P. Carrigan, Sachin S. Gos, Marlene Goormastic, Nicholas G. Smirida, A. Michael Lincott, Arman T. Askari, Cleveland Clinic, Cleveland, OH

**Background:** Chronic kidney disease (CKD) has been associated with adverse events in patients with coronary artery disease. However, the effect of CKD on treatment-related outcomes in patients with severe unprotected left main coronary artery (ULMCA) stenosis remains poorly defined.

**Methods:** Consecutive patients with severe (≥50%) ULMCA stenosis were prospectively identified between January 2004 and May 2006. We sought to assess the relationship between CKD as defined by the Kidney Disease Outcomes Quality Initiative (KDOQI) and revascularization procedure in this cohort of patients. Proportional hazards regression analyses was performed to evaluate the effect of CKD on 1-year survival in this cohort.

**Results:** 1415 patients were found to have severe ULMCA stenosis and of these 471 (33.3%) were unprotected and received consideration for revascularization. Median serum creatinine (mg/dl) and creatinine clearance (CrCl; C/Cr) by Cockroft-Gault in mL/min/1.73m² for patients managed medically (MM), or undergoing percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) group were 1.39, 1.753 and 1.278 (p=0.04) respectively. Kaplan-Meier estimates of 1-year survival for each group by K/DOQ CKD stage are presented in Table 1.

**Conclusions:** Kidney function is a powerful predictor of long-term survival in patients with ULMCA stenosis in the MM and CABG groups. The absence of an association between more severe CKD and PCI is an interesting finding worth further exploration.
Two strategies were selected according to the operators’ discretion. We compared one-
year clinical outcome of both strategies.

Results: 293 lesions (42%) were true bifurcations. Only 34 lesions (5.7%) among those
which were treated with provisional stenting of the side branch crossed to the group C
and no lesion crossed to group S from elective two stenting. 516 patients (656 lesions)
were included in group S and 126 patients (135 lesions) in group C. 4 methods of two
stenting were used: Y-stenting (58.6%), Culotte stenting (21%), Crush stenting (18.0%),
and Kissing stenting (2%). There was no significant differences between group S
and group C in cardiac death (1.9% vs 4.0%, p=0.021), myocardial infarction (2.1% vs
1.6%; p=0.69) at one-year. However, the incidence of target lesion revascularization
(8.7% vs 2.1%; p=0.001), cumulative major adverse cardiac events (13.5% vs 5.2%; p=0.001)
and stent thrombosis (3.2% vs 0.4%, p=0.012) was significantly higher in group C than
in group S.

Conclusions: For SES placement in bifurcation lesions, one stent technique suggests
a good long-term outcome compared with two stent technique regarding TLR, stent
thrombosis and MACE.
Pathologic Findings of Coronary Bifurcation Stenting - DES vs BMS

Gaku Nakazawa, Michael Joner, Elena Ladich, Frank Kolding, Alisse V. Finn, Herman K. Gold, Renu Virmani, CVPath, Institute, Inc, Gaithersburg, MD, Massachusetts General Hospital, Boston, MA

Background: Sites of maximal atherosclerotic plaque formation are frequently observed in coronary bifurcations as a result of the flow disturbances. We aimed to investigate whether the morphological differences observed at autopsy translate into distinguishing outcomes following implantation of bare-metal stents (BMS) and drug-eluting stents (DES), respectively.

Methods: Twenty-six atherosclerotic non-stented coronary bifurcation lesions were examined longitudinally for plaque formation. From our registry of 206 autopsy stented cases, 28 bifurcation lesions (18 with BMS and 10 with DES) were identified and analyzed by morphometry.

Results: Atherosclerotic plaque formation was predominantly observed in the lateral wall (low shear regions), while the flow divider wall was spared in most cases (72% vs 31%, p<0.001). Stenosis (ST) was found in 11 lesions (44%) with BMS and 8 (80%) with DES, while restenosis was documented in 7 lesions (39%) with BMS and 3 with DES (30%). Although neointimal thickness was significantly less at the flow divider site as compared to the lateral wall in DES, this difference was not observed in BMS cases (Table).

Conclusions: Plaque formation in native coronary bifurcations and neointimal growth following DES implantation showed substantial differences between the flow divider and the lateral wall site. The greater prevalence of late ST in DES compared to BMS is likely related to an exaggerated delay of arterial healing at sites of flow disturbance.

Morphometric Analysis of Bifurcation Stenting

<table>
<thead>
<tr>
<th>Flow divider</th>
<th>Lateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES</td>
<td>BMS</td>
</tr>
<tr>
<td><strong>p value</strong></td>
<td>0.09±0.07</td>
</tr>
</tbody>
</table>

Late restenosis was defined as the in-stent restenosis at 18- to 20-month follow-up (FU) which occurred in the lesions without restenosis at 6- to 8-month FU after the stent implantation. We compared the late restenosis rate in 462 lesions treated with SES with that in 2675 lesions treated with BMS for de novo lesions including complex lesions, retrospectively. Furthermore, we investigated the difference in the late stenosis site (in stent or stent edge), the late stenosis type (local or diffuse), and the time course pattern of progression (newly developed type; less than 25% stenosis at mid-term FU, or gradually progressed type; 25% to 50% stenosis at mid-term FU) between the lesions treated with SES and BMS.

Results: Results are shown in the Table.

Conclusions: The lesions treated with SES would have higher incidence of late restenosis than those treated with BMS. The results suggested that the mechanism of the late restenosis would be different between SES and BMS. There is a possibility that the difference in the late restenosis might affect the long-term clinical outcome.
Innovation in Intervention: i2 Summit 2007

E-POSTER SESSION

906-211 A Prospective Multicenter Randomized Comparison of Paclitaxel versus Sirolimus-Eluting Stents For Long Coronary Lesion: 6 Month 12-Month Follow-Up Study (Long-DES II Study): Impact of Cilostazol on Neointimal Hyperplasia

Seung-Whan Lee, Cheol Whan Lee, Myung-Ki Hong, Seung-Jung Park, Hyun-Sook Kim, Jae-ki Ko, Jae-Hwan Lee, Joo-Hyeong Park, Si-Wan Choi, In-Whan Seong, Nae-Hoe Lee, Youn-Haeng Cho, Jun-Hong Kim, Asan Medical Center, Seoul, South Korea, Chonbuk National University Hospital, Chung-ju, South Korea

Background: The impact of cilostazol after drug-eluting stent (DES) implantation for long coronary lesion (lesion length ≥2.5mm, requiring long DES ≥32 mm) has not been evaluated.

Methods: We enrolled the 500 patients with long coronary lesion suitable for five centers in korea. These patients were randomly assigned to a two-by-two factorial design to receive either triple therapy (aspirin plus clopidogrel plus cilostazol, group I, n=250) or dual antiplatelet therapy (aspirin plus clopidogrel, group II, n=250) for 6 months, and either paclitaxel-eluting stent (PES, n=250) or sirolimus-eluting stent (SES, n=250). The primary end point was in-stent late loss and the secondary end point was angiographic restenosis at 6 months and major adverse cardiac events (myocardial infarction, death, target lesion revascularization at 9 months).

Results: The baseline clinical and angiographic characteristics were similar between the 2 groups. The lesion in the TR group (34.1±11.8 mm in group I and 34.1±11.8 mm in group II, p=0.731) and mean stent length (41.4±13.6 mm in group I and 40.3±12.9 in group II, p=0.348) were also similar between the 2 groups. In-segment binary restenosis rate was similar between two groups (6.7% in group I vs. 1.2% in group II, p=0.104). The in-stent (0.21±0.49 mm vs. 0.32±0.50, p=0.031) and in-segment late loss (0.34±0.46 mm vs. 0.51±0.49 mm, p=0.001) were smaller in group I than group II. Stent thrombosis at 9 months was similar between two groups (0.4% vs. 0.4%, p=1.0). Incidences of 9-month death (0% in group I vs. 0.8% in group II, p=0.499), myocardial infarction (9.2% in group I vs. 10.4% in group II, p=0.662), or major adverse cardiac events (11.2% in group I vs. 16.8% in group II, p=0.071) were not statistically different between the two groups. But target lesion revascularization (2.8% vs. 6.8%, p=0.036) was lower in group I than group II.

Conclusions: The cilostazol significantly reduced neointimal hyperplasia after DES implantation in patients with long coronary lesions and the need of target lesion revascularization.
906-213  The QuantumCor Device for Mitral Regurgitation: A Radiofrequency Alternative to an Annular Ring
Richard R. Heuser, David T. Cragun, Patricia A. Takada, Thomas Witzel, Duane Dickens, Phoenix Heart Center, Phoenix, AZ

Background: Ischemic mitral regurgitation (MR) is a common problem occurring in nearly 20% of all myocardial infarctions and results in harmful ventricular remodeling and an increase in morbidity and mortality. The QuantumCor device uses radiofrequency (RF) energy at sub-ablative temperatures to produce contraction of the mitral valve annulus and thereby reduce mitral regurgitation.

Methods: Eleven healthy sheep (6 with naturally-occurring MR) had RF energy applied for 60 seconds at sub-ablative temperatures to replace a surgical mitral annuloplasty. Four segments of the posterior mitral valve annulus were heated while on cardiopulmonary support via a left thoracotomy with access via the atrial appendage.

Results: Nine sheep measured with intracardiac echo (ICE) before and after RF therapy experienced reduction of the anterior to posterior (AP) annulus distance by a mean of 5.0 +/- 2.1 mm (P<.001). In 7 sheep, circumferential measurements were performed during surgery at each of the four treated segments of the posterior mitral valve annulus yielding a mean reduction of 17.3% +/-6.6% (P<.05). The 6 sheep with non-ischemic mitral regurgitation had the MR eliminated.

Conclusions: In a sheep model, RF energy applied at sub-ablative temperatures in four quadrants of the posterior mitral valve annulus can reduce the anteroposterior and circumferential annular distance significantly and eliminate non-ischemic MR. This rapid, less than 4 minute, treatment will need to be confirmed in a chronic animal model to determine its safety and efficacy. If successful, it could lead to a novel percutaneous method of mitral valve annuloplasty with lower risk and morbidity than current surgical techniques.

906-214  Drug-Eluting Stents for the Treatment of Left Main Coronary Artery Disease: A Comparison of Serial Angiographic Follow-Up With Sirolimus, Paclitaxel, Zotarolimus and Tacrolimus-Euting Stent: Multicenter Registry in Asia
Sunao Nakamura, Jang-Ho Bae, Yeo H. Cahyadi, Wasan Udadyachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

Background and Purpose: Drug-eluting stent have been proven to be effective in reducing restenosis in patients with left main coronary arteries (LMT). However, no studies comparing different drug-eluting stents in this complex subset are yet available. The aim of this study is to compare the safety and efficacy of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES) and Tacrolimus-eluting stent (TES) on the outcome of patients with LMT stenosis.

Methods: A prospective analysis of 501 patients with 501 LMT stenosis (248 SES, 172 PES, 52 ZES, 29 TES) in five high volume Asian centers after successful stenting in LMT stenosis. The study endpoints were 30 days and 9 months major adverse cardiac events (MACE), 9 months angiographic restenosis and target lesion revascularization (TLR).

Results: The baseline clinical characteristics between 4 groups are similar. 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 showed lesser rate of restenosis compared with other drug-eluting stents.

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>PES</th>
<th>ZES</th>
<th>TES</th>
</tr>
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<tbody>
<tr>
<td>Number of patients</td>
<td>248</td>
<td>172</td>
<td>52</td>
<td>29</td>
</tr>
<tr>
<td>Procedural success (%)</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>MACE at 30 days (%)</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Proximal reference diameter (mm)</td>
<td>3.6</td>
<td>3.3</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Stereology procedure: single/crush</td>
<td>75/87/89</td>
<td>24/90/14</td>
<td>12/16/14</td>
<td>14/10/5</td>
</tr>
<tr>
<td>Minimum lumen diameter post procedure (mm)</td>
<td>3.5</td>
<td>3.5</td>
<td>3.2</td>
<td>3.4</td>
</tr>
<tr>
<td>Restenosis rate at 9 months (%)</td>
<td>3.2</td>
<td>4.7</td>
<td>7.7</td>
<td>10.3</td>
</tr>
<tr>
<td>TLR at 9 months (%)</td>
<td>3.2</td>
<td>3.5</td>
<td>7.7</td>
<td>10.3</td>
</tr>
</tbody>
</table>

*P<0.05 vs ZES, TES

906-215  Detection of In-Stent Restenosis by 64 Detector Computed Tomographic Angiography: Comparison with Quantitative Selective Coronary Angiography.
Harvey S. Hecht, Maja Zanic, Vladimir Jelnin, Lev Lubarsky, Manish Prakash, Lenox Hill Heart and Vascular Institute, New York, NY, Lenox Hill Hospital

Background: Detection of in-stent restenosis (ISR) by computed tomographic angiography (CTA) remains problematic.

Methods: To evaluate the ability of 64 detector CTA to accurately detect in-stent restenosis (ISR), 90 stents in 40 patients who underwent quantitative selective coronary angiography (QCA) were analyzed. Stents were subjectively evaluated by visual inspection as totally occluded, moderate to severe hyperdensities, mild hyperdensities and normal; abnormal was defined as occluded or moderate to severe. Using a quantitative analysis, the average Hounsfield unit in a 2 mm length prior to and after the stent was measured. The lowest Hounsfield unit in 4 separate 0.5 mm slices in the stent (IS) were averaged and compared to the pre stent (PS) values; abnormal was defined as IS-PS. In the QCA analysis, performed by a separate observer, ISR was classified as normal, 1-25%, 25-50%, 50-75%, 75-99%, and 100%.

Results: 8 stents were 100%, 1 was 75-99%, 2 were 50-75%, 7 were 25-50%, 34 were 1-25%, 38 were normal. Visual analysis was superior to quantitative at all levels of ISR. The best results were for detection of >50% ISR: 100% sensitivity, 76% specificity, 37% positive and 100% negative predictive values.

Conclusions: 1) Visual analysis of CTA produces the best results for the evaluation of ISR. 2) Quantitative analysis was inaccurate; partial volume and beam hardening are problematic. 3) 64 detector CTA is excellent for the detection and exclusion of >50% ISR, at the expense of positive predictive value.

906-216  Responses to Clopidogrel Measured By A Point-of-Care Assay Following Percutaneous Coronary Intervention Is Associated With Stent Thrombosis Over 6-Month Follow-up
Matthew J. Price, Rafael Valencia, Raghaiva R. Gollapudi, Sarah Endemann, Curtis Stiles, Justin P. Levitt, Paul S. Teirstein, Scripps Clinic, La Jolla, CA

Background: We examined the association of clopidogrel (CLOP)-induced platelet inhibition measured by a point-of-care assay following sirolimus-eluting stent (SES) implantation with stent thrombosis (ST) at 6-month follow-up (FU).

Methods: Platelet function in patients (pts) not receiving glycoprotein inhibitors was measured with the VerifyNow P2Y12 assay (Accumetrics, Inc) at baseline prior and 12 hours post-procedure. Pts not on CLOP received 600-mg at the time of the procedure, and all received 75-mg daily for at least 3 months. ADP-induced aggregation is reported by the assay using P2Y12 Reaction Units (PRU). In pts receiving a loading dose, % inhibition (%I) due to CLOP was defined as 1-PRU(post-CLOP)/PRU(pre-CLOP). In pts on CLOP without a baseline value, the reference channel was used to determine %I.

Results: P2Y12 assays were complete in 280 pts. The procedural indication was stable angina/ischemia in 93%. In 25% of patients, the %I was <10%. To date, ST has occurred in 5 pts (1.7%): 1 acute, 3 sub-acute, and 1 late (> 30 days). All ST pts were taking aspirin and CLOP CLOP NONRESP was found in 4 of the 5 pts with ST (p=0.013).

Conclusions: Clopidogrel NONRESP was defined as the lowest quarter of %I. ST was defined as an angiographic demonstration of thrombosis or unexplained sudden death. FU was obtained at 6 mss. Univariate analysis was performed with Fisher’s Exact Test.

Results: P2Y12 assays were complete in 280 pts. The procedural indication was stable angina/ischemia in 93%. In 25% of patients, the %I was <10%. To date, ST has occurred in 5 pts (1.7%): 1 acute, 3 sub-acute, and 1 late (> 30 days). All ST pts were taking aspirin and CLOP CLOP NONRESP was found in 4 of the 5 pts with ST (p=0.013).
Background: sPLA2 enzymes are involved in key immunoinflammatory processes and enhance the atherogenic potential of low-density lipoproteins. We showed recently that circulating sPLA2 enzyme activity, which encompasses several types of sPLA2, was an independent predictor of coronary events in patients with acute coronary syndrome. The relationship between the risk of incident CAD in people free of disease and plasma sPLA2 activity is unknown.

Methods: We investigated this association in a nested case-control study among the 25,663 healthy subjects included in EPIC-Norfolk cohort. Cases (n = 991) were subjects who developed CAD during the 6 years of mean follow-up. Controls (n=1806) matched by age, sex, and enrolment time remained free of any cardiovascular disease during follow-up, in EPIC-Norfolk cohort.

Results: The risk of incident CAD was associated with increasing quartiles of sPLA2 activity (p<0.001). After adjustment for risk factors, CRP and sPLA2 type IIa concentration, the odds ratios of incident CAD in the second, third and fourth quartiles of sPLA2 activity were 1.41, 1.33, and 1.56 (p = 0.003), compared with the lowest quartile. The corresponding odds ratio for CRP after adjustment for sPLA2 activity was 1.55 (95%CI, 1.20 to 1.99). sPLA2 activity and CRP were poorly correlated (r= 0.15), suggesting each biomarker identifies different high-risk groups. Their combined values were more informative for incident risk of CAD than either biomarker alone. Subjects in the highest quartiles of sPLA2 activity and CRP had an adjusted odds ratio of 2.89 (95%CI, 1.78 to 4.68, p<0.001) for CAD compared with those with the lowest quartiles of both markers. Conclusions: Serum sPLA2 activity provides additive value to traditional risk factors and CRP in predicting incident CAD.

<table>
<thead>
<tr>
<th>Variable</th>
<th>RI</th>
<th>No RI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>70.6 ± 8</td>
<td>72.4 ± 10.5</td>
<td>0.0001</td>
</tr>
<tr>
<td>Ejection Fraction, %</td>
<td>47.7 ± 10.8</td>
<td>53.2 ± 9.8</td>
<td>0.0001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>31.3% (66)</td>
<td>15.5% (199)</td>
<td>0.002</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>41% (34)</td>
<td>25.7% (308)</td>
<td>0.004</td>
</tr>
<tr>
<td>Insulin-requiring diabetes</td>
<td>22.9% (19)</td>
<td>8.3% (76)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Multi-vascular disease</td>
<td>63.1% (69)</td>
<td>74.5% (893)</td>
<td>0.08</td>
</tr>
<tr>
<td>Intra-aortic balloon pump</td>
<td>7.2% (6)</td>
<td>9.9% (35)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Outcomes

- Periprocedural myocardial infarction: 0% (0) vs. 2.6% (31) (p = 0.001)
- 30-day death: 8.8% (9) vs. 3.2% (2) (p < 0.001)
- 30-day MACE: 5% (5) vs. 3.4% (5) (p = 0.001)
- MACCE: 90.7% (328) vs. 74.4% (345) (p = 0.001)
- Death: 10.8% (9) vs. 2.1% (25) (p < 0.001)
- Cardiac death: 8.4% (7) vs. 1.7% (20) (p = 0.001)
- Myocardial infarction: 2.5% (2) vs. 1.7% (25) (p = 0.001)
- Target vessel revascularization: 22.9% (19) vs. 18.2% (218) (p = 0.3)
- Target lesion revascularization: 14.5% (12) vs. 15.3% (184) (p = 0.7)

Conclusions: Serum sPLA2 activity adds significant independent value in risk prediction of ischemic events in patients undergoing PCI.
Background: Transcatheter aortic valve placement by intravascular routes can be lengthy and the incidence of restenosis compared to bare metal stents, although restenosis still occurs. However, to date, there are concerns about the safety of DES, in particular with respect to delayed healing, chronic inflammatory reaction, and late stent thrombosis. The Genous® Endothelial Progenitor Cell (EPC)-capturing stent is coated with an antibody (CD34+) that binds circulating EPC's which differentiate into a functional endothelial layer. This accelerated healing may reduce in-stent restenosis by reducing neointimal hyperplasia and smooth muscle cell proliferation and, in addition, prevent stent related thrombosis by platelet aggregation. Furthermore, it has been shown that stent therapy increases the EPC number in the peripheral blood.

In this single center study, we report the 6 months clinical outcome after percutaneous treatment with the Genous® EPC-attracting stent in patients treated with statins for at least 2 weeks prior to intervention.

Methods: All patients were treated with a Genous® EPC-attracting stent for coronary artery stenosis. All patients were treated with statins for at least 2 weeks prior to PCI. Clinical follow-up was obtained after 6 months.

Results: Mean age of the population was 64 years and 72% were male, 31% of the lesions were bifurcation lesions and 64.5% of the patients had multivessel disease. Mean stent length was 15 ± 10 mm. Patients received an average of 1.5 stents and a mean stent length was 19 ± 6 mm and mean stent diameter was 3.16 ± 0.4 mm. TIMI flow 3 flow was achieved in 99.3% of all treated lesions. There was one side branch failure, relating to an in-hospital MI. During 6 months clinical follow-up, there was 1 additional MI. Target vessel revascularization was 3.7% (2 patients had a repeat PCI, 1 patient had a CAGB and a repeat PCI, 2 patients had a non-target vessel revascularization, and no patients died.

Conclusion: The percutaneous treatment of coronary artery stenosis with a Genous® EPC-attracting stent in statin-treated patients shows excellent procedural success and 6 months clinical results.

3:00 p.m.

Transcatheter Restriction of Left Ventricular Cavity in Piglets

Eleftherios B. Sideris, Savvas Toumanides, Demetrios Bramos, Efthoratos Christianakis, Basilos Sideris, Spyridon Moulopoulos, Athenian Institute of Pediatric Cardiology, Athens, Greece, Department Clinical Therapeutics University of Athens, Athens, Greece

Background: Surgical resection of left ventricular aneurysms, is not always possible in high risk patients. Purpose of this study is to access an alternative to surgery in eliminating post-infarction left ventricular (LV) aneurysms in high risk patients. Transcatheter restriction of LV aneurysms could improve morbidity and mortality associated with surgery, maintaining the benefits of improved ejection fraction and wall tension.

Methods: The procedure was performed in 15 piglets, 12-16 kg, after ketamine anesthesia. A transcatheter patch/balloon device was introduced in the left ventricle, through a 12F sheath after antegrade and retrograde apical needle puncture. The device consists of a balloon catheter, with a sleeve type polyurethane patch mounted on the balloon and a floppy disk attached on the tail of the patch. The patch was inflated in diameters of 15-20 mm using normal saline or whole blood and contrast; it was pulled to the apex of the LV with the tail of the patch occluding the residual myocardial hole and the floppy disk immobilizing the patch on the epicardium. Fluorescopy and echocardiography and continuous monitoring were used for the device placement and the animals were followed for periods of 4 days to 3 months, when they were euthanized and had autopsies.

Results: All devices were successfully placed, restricting the left ventricular apical region. There was no significant change on the EKG or the blood pressure during the procedure. There was no case of tamponade. On follow-up all animals, except for two who developed severe infection did well. In autopsy the LV apical region was restricted although most balloons lost part of their initial volume. The residual balloon size was larger if it was inflated with whole blood. The patches were fully endothelialized within 2 weeks. They were free of thrombus.

Conclusion: Percutaneous restriction of the left ventricular apical region is feasible, simple and relatively safe in piglets. The method could be applicable in high risk patients. Feasibility clinical studies are justified.

3:00 p.m.

Predictors For Diffuse In-stent Restenosis After Taxus Stent Implantation: Analysis From The Taxus IV and V Trials

Masashi Kimura, Roxana Mehran, Ajay Kirtane, Jeffrey J., Stephen G. Ellis, Joerg Koglin, Donald S. Baim, Gregg W. Stone, Columbia University Medical Center, Cardiovascular Research Foundation New York, New York, NY

Background: Diffuse in-stent restenosis (ISR) is less common with drug-eluting stents (DES) than with bare metal stents (BMS). The clinical and angiographic predictors of diffuse restenosis after DES have not been described.

Methods: In the TAXUS IV and V trials, 1517 pts were randomized to receive either a paclitaxel-eluting stent (PES) or an identical BMS. Excluding stent thrombosis, 297 ISR lesions were identified (78 with PES and 219 with BMS). The primary angiographic restenosis (defined as diameter stenosis of more than 50%) rate. Secondary endpoint was clinical outcome by 1 year. Results: In Japanese 17 centers, 99 patients were enrolled (until Oct, 2005). Lesion locations were as follows; LMT: 81, LAD: 16, LCx: 2. DCA provided the reduction of percent plaque area stenosis from 82.3 to 55.8% in IVUS examination for main vessels without any procedural complication. Then, crossover stenting was performed in 83 and non-crossover stenting in 16 lesions. Additional stenting of side branch was required only in 2 lesions. No major adverse cardiac event was observed in hospital stay. DCA has been collected in 76 patients to date. Angiographic restenosis was 1.3% (1/76) for main branch and 2.6% (2/76) for side branch, and target lesion revascularization rate was 1.3% and 1.3%, respectively. Conclusion: PES and BMS stents in diffuse ISR lesions is safe and enables simple DES stenting so that it may provide a good long-term outcome. Final Fu data will be presented.

3:00 p.m.

Perventricular non Surgical Aortic Valve Placement with Subsequent Use of Myocardial Plugs

Eleftherios B. Sideris, Demetrios Bramos, Efthoratos Christianakis, Basilos Sideris, Spyridon Moulopoulos, Athenian Institute of Pediatric Cardiology, Athens, Greece

Background: Transcatheter aortic valve placement by intravascular routes can be lengthy and difficult. Perventricular entry is technically easier, but it usually requires surgical assistance. We will assess the safety and efficacy of perventricular non surgical aortic valve placement using myocardial plugs.

Methods: A self-expandable nitinol cage with a mono-leaft biologic valve was inserted in ten piglets 10-12 kg, through 13-14 Fr sheaths, after left ventricular (LV) apical needle puncture. The valve function was assessed by fluoroscopy, angiography and echocardiography under continuous monitoring. A myocardial plug was placed through the same sheath after aortic valve placement and release. The myocardial plug consists of a balloon/balloon with the tail going through the residual opening, immobolizing the plug disc on the epicardium. The valve diameter was 15 mm and the balloon/patch diameter varied between 12 and 20 mm. Follow-up was performed up to 2 weeks and all animals had autopsies.

Results: All valves were deployed in the ascending aorta. Three with placement on the natural valve had fast deterioration, because of aortic insufficiency or coronary interference. The rest were placed above the coronaries and had good outcome. There was one case where the mono-cusp valve was too large and obstructive (40 mm LV Aortic gradient). In the rest of the animals there was good leaflet movement without insufficiency or residual stenosis. There was no hemopericardium after myocardial plug placement; however in one case the sheath was pulled out by mistake prior to myocardial plug insertion, resulting in hemopericardium and death. Minimal bleeding and transient EKG changes were noticed in all cases. In autopsy all valve cages were in place with the aortic mono-cusp leaflet mobile. The myocardial plugs were effectively occluding the residual openings and the patch was partially endothelialized.

Conclusion: Perventricular aortic valve placement is fast and fairly easy, without need of surgery if myocardial plugs are used. The supravalvar aortic position was safer. Further animal testing is required prior to the use of the valve in human trials.

3:00 p.m.

The Efficacy of Pre Drug Eluting Stent Debubling by Directional Atherectomy for Bilurcated Lesions: A Multicenter Prospective Registry (PERFECT Registry)

Etsuo Tsuchida, Tadatoshi Azawa, Hideo Tamai, Yasumi Igarashi, Kenji Kawajiri, Noriyuki Oka, Shigeru Nakamura, Yui Oku, Minoru Kikugawa, Yui Hamazaki, Toyohashi Heart Center, Toyohashi, Japan, Cardiovascular Institute, Tokyo, Japan

Background: Drug eluting stent (DES) significantly controls restenosis, however the efficacy for bilurcated lesions is still unsatistied. These lesions sometimes require complex 2 stenting so that restenosis occurs particularly in side branch. Pre stent plaque debulking by directional atherectomy controls plaque shift and consequently enables simple stenting. Pre DES DCA has not yet been examined.

Methods: PERFECT (PHE Rapamyacin eluting stent Flexi-CUT) is a multicenter prospective registry aimed to examine the efficacy of pre DES debulking by DCA. Lesions located in left main trunk (LMT) bifurcation, or proximal left anterior descending (LAD) or left circumflex (LCx) artery with a major side branch were enrolled. Intravascular ultrasound (IVUS) guided DCA using Flexi-Cut was conducted for main vessel. DCA of side branch was also performed if possible. Then Cypher stenting for main branch with/without kissing balloon technique was conducted. Provisional Cypher stenting for side branch was allowed when necessary. Serial quantitative angiography (QCA) was performed at the procedure and 9 month follow-up (Fu). The primary angiographic restenosis (defined as diameter stenosis of more than 50%) rate. Secondary endpoint was clinical outcome by 1 year. Results: In Japanese 17 centers, 99 patients were enrolled (until Oct, 2005). Lesion locations were as follows; LMT: 81, LAD: 16, LCx: 2. DCA provided the reduction of percent plaque area stenosis from 82.3 to 55.8% in IVUS examination for main vessels without any procedural complication. Then, crossover stenting was performed in 83 and non-crossover stenting in 16 lesions. Additional stenting of side branch was required only in 2 lesions. No major adverse cardiac event was observed in hospital stay. Fu data has been collected in 76 patients to date. Angiographic restenosis was 1.3% (1/76) for main branch and 2.6% (2/76) for side branch, and target lesion revascularization rate was 1.3% and 1.3%, respectively. Conclusion: PES and BMS stents in diffuse ISR lesions is safe and enables simple DES stenting so that it may provide a good long-term outcome. Final Fu data will be presented.

3:00 p.m.

ABSTRACTS - Innovation in Intervention: i2 Summit 2007
Background: Elevation of cardiac enzyme after percutaneous coronary intervention (PCI), especially creatine kinase-MB (CK-MB), has been associated with early and late cardiac event and mortality. The aim of our study is to assess whether pretreatment with rosuvastatin before PCI in patients with stable angina can reduce periprocedural myocardial injury after PCI in a randomized study.

Methods: Seventy-six patients with stable angina without previous statin treatment were enrolled. Patients scheduled for elective PCI were randomized to rosuvastatin (n=38, 20 mg/d) or control (n=38) group 7 days before the procedure. CK-MB (upper normal limit [UNL] 4.0 ng/ml) and cardiac troponin I (cTnI, UNL 0.2 ng/ml) levels were measured at baseline and at 6, 12, and 24 hours after PCI. Primary end-point of this study was elevation after PCI was rosuvastatin pretreatment (OR=0.075; 95% CI=0.006-0.878; p=0.025).

Results: Of 18,623 Patients In A Community Setting.

Conclusion: Among elderly community patients with HF, D is frequent and is independently associated with a poor clinical outcome.
Results: Patients with stable angina undergoing PCI had markedly elevated levels of specific MPs (MMP-2, MMP-9), and MMPs (alpha-2 macroglobulin, TIMP-1) compared to asymptomatic patients, whereas MMP-9 was higher in asymptomatic patients. CRP and TNF-β were higher in the group undergoing PCI (9.3±14.6 mg/L vs. 4.0±8.8 mg/L, p<0.01 and 44±35 vs. 30±20 mg/L, p<0.001).

Conclusion: Our data indicate that patients coming to PCI with "stable" angina are not stable; their disease is very metabolically active and is indicated by a specific biomarker fingerprint of heightened inflammation and rapid plaque transformation that is distinctly different than asymptomatic patients. MMP-2 and MMP-9 should be prospectively investigated as markers of plaque growth and destabilization identifying the patient with progressing disease.

4:00 p.m.

908-211 Efficacy and Safety of Pimecolimus-Eluting Stents in Porcine Coronary Arteries
Ron Wakaman, Rajabu Pakala, Richard Baffour, Rufus Seabron, David Hellinga, Fermin Tio, Eric Wittchow, Sonja Hartwig, Michael Tittelbach, Claus Harder, Washington Hospital Center, Washington DC, DC, BIOTRONIK GmbH, Erlangen, Germany

Background: Pimecolimus (PL) is an ascomycin derivative with anti-inflammatory and immunomodulatory capabilities, which binds specifically to the cytosolic receptor, pimecolimus receptor 1 (PMR-1), and blocks transcription pathways in T cells and the inhibition of the synthesis of inflammatory cytokines. This study aimed to examine the safety and efficacy of a novel PL-eluting stent with a biosorbable polymer in the coronary model of restenosis.

Methods: Domestic swine randomly underwent intracoronary implantation of PL-eluting stents coated with PLLA containing 320 (n = 9), 750 (n = 9), or 1200 (n = 10) µg of PL/mm of stent length, stents coated with PLLA alone (n = 9), and bare metal stents BMS (Vision, Guidant, Santa Clara CA, n = 8). At 28 days vessels were harvested, fixed, stained and analyzed by histomorphometry.

Results: PLLA and PL-eluting stents had similar endothelialization, intimal, and adventitial fibrin scores when compared to BMS. Vessel, stent, and lumen areas were larger in the vessels deployed with PLLA and PL. The percentage occlusion of the PL-eluting stents was lower when compared to the BMS (p<0.05). Though the intimal area and inflammation score in the vessels with PL-eluting stents were smaller, they did not attain statistical significance and there was no dose response effect.

Conclusion: The present data suggest that PL-eluting stents are safe, have similar healing profile to BMS, and may suppress inflammation leading to reduced intimal hyperplasia in porcine coronary arteries.

Effect of Pimecolimus Eluting Stent on Vessel parameters in Porcine Coronary Arteries

<table>
<thead>
<tr>
<th>Vessel Parameters</th>
<th>Vision</th>
<th>PLLA</th>
<th>1200µg PL</th>
<th>750µg PL</th>
<th>320µg PL</th>
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</thead>
<tbody>
<tr>
<td>Stent area (mm²)</td>
<td>5.3±0.36</td>
<td>6.13±0.55</td>
<td>6.23±0.49</td>
<td>6.14±0.52</td>
<td>6.20±0.67</td>
</tr>
<tr>
<td>Lumina area (mm)</td>
<td>3.12±0.53</td>
<td>4.03±0.86</td>
<td>4.43±0.85</td>
<td>4.36±0.69</td>
<td>4.39±0.90</td>
</tr>
<tr>
<td>Intimal area (mm²)</td>
<td>2.26±0.64</td>
<td>2.10±0.77</td>
<td>1.80±0.68</td>
<td>1.78±0.52</td>
<td>1.81±0.60</td>
</tr>
<tr>
<td>% occlusion</td>
<td>41.76±12.30</td>
<td>42.27±11.96</td>
<td>48.94±10.26</td>
<td>49.04±10.25</td>
<td>49.04±10.26</td>
</tr>
<tr>
<td>Injury score</td>
<td>1.25±0.46</td>
<td>1.70±0.74</td>
<td>1.69±0.62</td>
<td>1.93±0.56</td>
<td>1.53±0.74</td>
</tr>
<tr>
<td>Inflammation score</td>
<td>1.08±0.75</td>
<td>1.67±0.29</td>
<td>1.78±0.24</td>
<td>1.85±0.47</td>
<td>1.97±0.40</td>
</tr>
<tr>
<td>Intimal fibrin</td>
<td>0.08±0.15</td>
<td>0.15±0.24</td>
<td>0.18±0.24</td>
<td>0.00±0.00</td>
<td>0.13±0.23</td>
</tr>
<tr>
<td>Endothelialization</td>
<td>2.28±0.52</td>
<td>2.29±0.20</td>
<td>2.16±0.34</td>
<td>2.44±0.37</td>
<td>2.37±0.27</td>
</tr>
<tr>
<td>p&lt;0.05 compared to Vision</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

4:00 p.m.

908-212 Can Inflammatory Markers Predict Major Adverse Cardiac Events (MACE) in Patients undergoing Non-Coronary Vascular Surgery?
Syed U. Ahmed, Eveline Lee, Omogoriuwa Williams, Paul Browning, Michael Fisher, Royal Liverpool University Hospital, Liverpool, United Kingdom

Background: Inflammatory markers have been shown to be associated with acute coronary syndrome and inflammatory insults e.g. chest infection however little is known regarding the inflammatory response to vascular surgery. No data are available on whether this response can predict these cardiac events.

Methods: We performed a prospective observational study on patients undergoing non-coronary vascular surgery. This is defined as any form of peripheral arterial surgery and aortic aneurysm surgery including endovascular repair (EVAR). Blood samples for high sensitivity CRP, Interleukin-1 (IL-1), Interleukin-6 (IL-6), and soluble intercellular adhesion molecule -1 (sICAM-1) were collected pre-operatively and on day-1 post operatively. MACE were recorded on post-op days 1-3, defined as a rise in cardiac troponin T >0.06 or new ischaemic ECG changes. Statistical analyses were performed using paired t-test. Data are shown as mean ± S.E.M.

Results: 47 patients were included in the study. 21 patients underwent peripheral arterial surgery, 16 had EVAR and 9 patients had open AAA repair. There were 11 (23%) MACE. The Eagle risk score was 1.3±0.12 and there was no significant difference between the MACE and non-MACE groups. Peri-operative rise in CRP (2.33±0.19 vs 3.36±0.22 pre and post operatively respectively p=0.001) and IL-6 (8.47±0.90 vs 42.67±5.39 pre and post operatively respectively p<0.001) was highly significant throughout the group but IL-1 and sICAM-1 did not show significant change. The normalised peri-operative rise at all day 1 in CRP (0.83±1.79 vs 0.74±0.29 in MACE and non-MACE groups respectively) was highly significantly different (p<0.008).

Conclusions: 1-There is selective increase in the inflammatory response peri-operatively. 2-The degree of rise in CRP predicts those who will have MACE. 3-The mechanisms underlying this selective inflammatory activation require further study as they may identify a high risk sub-group requiring treatment to forestall MACE.

4:00 p.m.

908-213 Comparative Analysis of Neointimal Growth on the Stent Struts of Sirolimus-Eluting Stents and Bare Metal Stents Crossed a Side Branch Using Optical Coherence Tomography
Mitsuaki Terashima, Tatsuya Ito, Yoshihiro Takeda, Jean-François Surmely, Osamu Katoh, Tetsuo Matushita, Etsuo Tsukihane, Mariko Ebara, Yoshitaka Kinoshita, Kenya Nasa, Nisho Naka, Yoshiyuki Tanaka, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Late stent thrombosis following sirolimus-eluting stent (SES) implantation is a severe complication, and could be related to delayed neointimal stent coverage and disturbed laminar blood flow at the site of a bifurcation or a residual stenosis. Existing imaging tools have limitations for visualizing a thin neointimal layer. Optical coherence tomography (OCT) is a novel high resolution imaging technology. Using OCT, we examined differences in neointimal growth on the stent struts crossing a side branch between SES and Bare Metal Stent (BMS).

Methods: Of the 21 lesions in 20 cases treated with single stent implantation to the lesion involving side branches (>1 mm), 36 struts of 14 SES and 10 struts of 7 BMS, which crossed over a side branch, were analyzed 8 months after stent implantation using OCT. Neointimal coverage of stents was classified into either complete or incomplete coverage (Figure). Neointimal thickness on the covered strut was also measured.

Results: Neointimal growth was found on all stent struts both of SES and of BMS. Complete coverage was observed in 24 struts of SES (66.7%) and in all 10 struts of BMS (100%) (p < 0.05). Mean neointimal thickness for SES was significantly less than that for BMS (0.09 ± 0.03 mm vs 0.15 ± 0.06 mm, p < 0.01).

Conclusions: Using OCT, neointimal growth was observed on the struts both of SES and of BMS that were crossing a side branch. However, neointimal coverage of struts was delayed in SES, compared to BMS at 8 months after stent implantation.

4:00 p.m.

908-214 What Kind of Polymer Is Better for Bifurcation Stenting?
Yoshitaka Kinoshita, Osamu Katoh, Yasuyoshi Suzuki, Jean-François Surmely, Hiroshi Fujita, Tetsuo Matushita, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Aichi, Japan

Background: The incidence of in-stent restenosis of bifurcation stenting (BS) remains high even with drug-eluting stents. One of the mechanisms is polymer damage which prevents a homogeneous drug distribution. We postulated that the degree of damage depends on the type of polymer.

Methods: BS Veloxyfl® stents, either coated with a permanent polymer (PEVA + PBMMA: Cypher®, Cordis Corporation, Warren, NJ), or a bioabsorbable polymer (siacrylic acid/stearyl acrylate/poly acrylamide + poly lactide anhydride: BI7 stent, Biosensors Therapeutics, Menlo Park, CA) were implanted in a bifurcation phantom model, and final kissing-ball dilation was done. BS techniques included T-stenting, culottes-stenting, conventional crush-stenting, reverse crush-stenting, and flower-stenting (Panel A). Polymer damage was evaluated by electron microscopy.

Results: For both type of stents, polymer damage were observed at stent-overlapping...
Innovation in Intervention: i2 Summit 2007

308-215 Pacitaxel-eluting Stents For In-stent Restenosis of Sirolimus-eluting Stents: 12 Month Outcomes

Justin P. Levisay, Steve Lee, Curtis T. Stenis, Matthew J. Price, Raghava R. Gollapudi, Raphael Valencia, Garrett B. Wong, Richard A. Schatz, Paul S. Tenenstein, Scripps Clinic, LaJolla, CA

**Background:** The optimal treatment for in-stent restenosis (ISR) of sirolimus-eluting stent (SES) is not known.

**Methods:** From March 2004 to October 2005, paclitaxel-eluting stents (PES) were implanted in 148 patients with 162 lesions containing SES restenosis. Acute and 12 month clinical outcomes were determined through telephone contact and review of the medical record.

**Results:** Mean patient (pt) age was 66±12 years, 50 pts (34%) had diabetes, and 36% of lesions had been previously treated with bare metal stenting prior to initial SES implantation. Clinical FU was obtained in 100% of pts at a mean of 17±4.8 months (range 30 months to 12 months). In-hospital major adverse cardiac events (cardiac death, MI, stent thrombosis, and TLR) were 23.6%.

**Conclusions:** PES implantation for SES failure provides excellent outcomes at 12 month follow-up. Our TLR rate of only 14% in pts with de novo SES restenosis is particularly encouraging. Efficacy is reduced in the setting of multiple prior target lesion interventions, total SES occlusions, and longer PES length.

Table 1: Out of Hospital MACE and Determinates of TLR in Taxus for Cypher ISR

<table>
<thead>
<tr>
<th>Cause</th>
<th>Subgroups</th>
<th>TLR Rate (N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>50 (35.6) %</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>1 (1%)</td>
<td></td>
</tr>
<tr>
<td>SAT</td>
<td>2 (1.3%)</td>
<td></td>
</tr>
<tr>
<td>TLR total</td>
<td>32 (21.6%)</td>
<td></td>
</tr>
<tr>
<td>TLR Subgroups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- PES for de novo SES ISR</td>
<td>9 (14%)</td>
<td></td>
</tr>
<tr>
<td>- Any previous Brachytherapy</td>
<td>9 (40%)</td>
<td>0.01</td>
</tr>
<tr>
<td>- Occlusive SES restenosis</td>
<td>12 (63%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>- Prior POBA of SES restenosis</td>
<td>13 (42%)</td>
<td>0.048</td>
</tr>
<tr>
<td>- Any previous TLR</td>
<td>37 (37%)</td>
<td>0.009</td>
</tr>
</tbody>
</table>
Methods: In 1142 pts undergoing PCI, we assessed incidence of post-PCI RF using 5 definitions (the old and new ACC-NCDR definitions; post-PCI increase in serum creatinine (Cr) >1.0 mg/dL, Cr>0.5 mg/dL, and Cr>0.5% above the baseline value) and the correlation of each definition with 6-mon death, 6-mon MACE (death, target vessel revascularization, or infarction), and long-term (median 859 days) death.

Results: The incidence of post-PCI RF varied widely depending on the definition (table). Only 2 definitions (Cr>0.5 mg/dL and Cr>0.5%) showed consistent univariate and multivariate correlations with study outcomes. After adjustment for other baseline characteristics, occurrence of Cr>0.5 mg/dL increased 6-mon death, MACE, and long-term death by 6.1, 2.1-, and 2.7-fold, respectively (p<0.05 for all). The respective odds ratios for Cr>25% were 3.6, 1.6, and 2.0 (p>0.05 for all). The Cr>0.5 mg/dL criterion discriminated well between all pts and high-risk pts, but the Cr>25% criterion occurred frequently in all groups (table).

Conclusions: The incidence and prognostic value of post-PCI RF vary widely depending on the definition used, highlighting the need for a universal definition. Of the 5 temporary definitions, Cr>0.5 mg/dL appears to be the optimal definition.

<table>
<thead>
<tr>
<th>Vessel Parameters</th>
<th>BMS</th>
<th>AMS</th>
<th>BVT + AMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent area (mm²)</td>
<td>5.31 ± 0.61</td>
<td>3.50 ± 0.67</td>
<td>3.97 ± 0.79</td>
</tr>
<tr>
<td>Lumen area (mm²)</td>
<td>7.96 ± 0.93</td>
<td>7.73 ± 0.51</td>
<td>9.19 ± 0.82</td>
</tr>
<tr>
<td>Intimal area (mm²)</td>
<td>2.34 ± 0.64</td>
<td>1.30 ± 0.62</td>
<td>1.49 ± 0.34</td>
</tr>
</tbody>
</table>

Background: Obstructive lesions of the subclavian artery can result in arm claudication, steal syndrome, or subclavian steal syndrome. Aims: To evaluate the safety, efficacy and durability of endovascular stenting for treating 340 obstructive lesions of subclavian artery.

Methods: We performed 340 cases of endoluminal stenting for 320 patients (217 males, 63±12 years). All procedures were performed with Palmaz stents (225 cases) and Wall stents (115 cases), 220 cases (64.7%) were used transradial approach. Indications for stenting were arm claudication in 196 cases, subclavian steal syndrome in 80 cases and symptomatic ischemia secondary to compromised flow through internal mammary grafts in 64 cases.

Results: Procedural success (defined as abolition of pressure gradient across the aorta and subclavian artery and a residual diameter stenosis<20%) without major complications was achieved in 337 patients (99.1%). Only one patient had a major complication (medastinal hematome due to subclavian artery rupture). Baseline diameter stenosis was reduced from 89.7% to 13.8±9.0%, mean systolic pressure difference was reduced 46.9±14.9 mmHg to 4.5±4.8 mmHg (p<0.01). There was no cerebral or distal embolization. In 318 of 340 patients (93.5%) we performed, follow-up angiography ranged from 6 months to 8 years (mean, 48 months). Primary angiographic patency at 5 years was 99% (only 3 restenoses: 1.2%).

Conclusions: Endoluminal stenting of the subclavian artery is safe and effective with high technical success and these clinical benefits are durable at least 5 years.

9:00 a.m.

9:09-217

Long-Term Durability of Endoluminal Stenting for Obstructive Lesions of the Subclavian Artery: Multicenter Registry in Japan


Background: Obstructive lesions of the subclavian artery can result in arm claudication, steal syndrome, or subclavian steal syndrome. Aims: To evaluate the safety, efficacy and durability of endovascular stenting for treating 340 obstructive lesions of subclavian artery.

Methods: We performed 340 cases of endoluminal stenting for 320 patients (217 males, 63±12 years). All procedures were performed with Palmaz stents (225 cases) and Wall stents (115 cases), 220 cases (64.7%) were used transradial approach. Indications for stenting were arm claudication in 196 cases, subclavian steal syndrome in 80 cases and symptomatic ischemia secondary to compromised flow through internal mammary grafts in 64 cases.

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Conclusions: Endoluminal stenting of the subclavian artery is safe and effective with high technical success and these clinical benefits are durable at least 5 years.

9:09 a.m.

9:09-217

Morphologic Feature and Frequency of Coronary Pre-Rupture Thin-cap Fibroatheroma in Patients With Acute Myocardial Infarction and Stable Angina Pectoris: A Three-Vessel Optical Coherence Tomography Study

Kosho Fujii, Motomaru Masutani, Tsuyoshi Sakoda, Tohru Masuyama, Mitsumasa Ohyangayi, Hyogo College of Medicine, Nishinomiya, Japan

Background: It has been recognized that thin-cap fibroatheroma (TCFA) is the precursor of plaque rupture, which accounts for a majority of acute myocardial infarction (AMI). However, characteristics of TCFA have not been well assessed because TCFA’s are a thin fibrous-cap (<65μm) that cannot be identified by current imaging modalities due to their insufficient resolution. We evaluated the incidence and features of TCFA using optical coherence tomography (OCT) that is a new high-resolution (approximately 10μm) imaging modality.

Methods: OCT and intravascular ultrasound (IVUS) examinations were performed using motorized pullback in all 3 coronary arteries for 14 AMI and 8 stable anginous patients (SA). Quantitative OCT analysis for each focal atherosclerotic plaque was performed using the previously validated criteria. OCT criteria for TCFA were lipid-rich plaque with cap thickness<65μm. Quantitative IVUS measurements were also performed for each plaque.

Results: No procedure-related complications occurred. OCT identified 22 culprit and 73 non-culprit focal plaques. The frequency of TCFA’s at culprit site was 57% in AMI and 0% in SA patients (p=0.02). At least 1 TCFA was found somewhere other than on the culprit site in 64% for AMI and 13% for SA patients (p=0.03). OCT and IVUS analyses revealed that TCFA’s had greater vessel and plaque area and a higher remodeling index than non-TCFA’s (p<0.001, p=0.001, and p=0.002, respectively). In all cohorts, TCFA’s were clustered mainly in the proximal segments in the left coronary artery or the entire segments in the right coronary artery. Multiple TCFA’s were identified in 36% for AMI and 13% for SA patients (p=0.4). In AMI patients, serum high-sensitivity C-reactive protein (hsCRP) level was significantly higher in patients with multiple TCFA’s than in patients without multiple TCFA’s (p<0.01).

Conclusions: Pre-rupture TCFA’s were observed more frequently both at culprit and non-culprit sites. The use of OCT may allow a better identification of high-risk plaques with thin-cap fibroatheromas.
non-culprit sites in AMI than SAP patients. TCFAs were mainly located in the proximal segments and had large remodeling index and plaque burden compared with non-TCFAs.

In AMI patients, the prevalence of multiple TCFAs was associated with a higher hs-CRP level.

9:00 a.m.

**109S145**  
Culotte versus T-Stenting in Bifurcation Lesions: Immediate Clinical and Angiographic Results and Mid-term Clinical Follow-up

Peter Bartis, Sahin Kaplan, Konstantinos Dimopoulos, Omer Goktekin, Alessio La Manna, Jun Tanigawa, Carlo Di Mario, Royal Brompton Hospital, London, United Kingdom

**BACKGROUND** Stenting of the main vessel with provisional stent implantation of the side branch (SB) is the technique of choice for treating most bifurcation lesions, since no advantage on restenosis has been shown by universal use of kissing stents and the concern for the development of sub-acute or late thrombosis in the drug-eluting stent (DES) era. There is no consensus however on the best technique when the provisional approach fails and a second stent is needed. Two possible methods are T-stenting and the culotte technique, but no studies have addressed the relative merits of these techniques. The purpose of this study was the comparison of immediate angiographic and mid-term clinical results of the culotte and T-stenting techniques for bifurcation lesions using DES.

**METHODS** Between February 2004 and October 2005, 80 patients with bifurcation lesions were treated with either culotte (n=45) or T-stenting (n=35). Coronary angiograms were analyzed using a new dedicated system (Quantitative Vascular Arteriography). All patients were treated with DES, either sirolimus-eluting (Cypher and Cypher Select; Cordis Johnson & Johnson, Warren, New Jersey, USA) or paclitaxel-eluting (Taxus and Taxus Lible, Boston Scientific; Natwick, Massachusetts, USA). Only patients with stable and unstable angina or non-ST elevation myocardial infarction were included.

**RESULTS** Acute procedural success was 100% for both groups. One patient in the culotte group had a myocardial infarction at 2 days related to sub-acute thrombosis and underwent repeat revascularization. Residual diameter stenosis of the SB ostium was 3.4±2.4% in the culotte group versus 12.5±11.5% in the T-stenting group (P<0.001). The culotte group had a lower target lesion revascularization rate compared to T-stenting (8.8% versus 25.7%, P=0.034) and a trend towards lower major cardiac adverse events at 9 months (20.0% versus 31.4%, P=0.087).

**Conclusion** Both culotte and T-stenting of bifurcation lesions using DES achieve high procedural success with low complication rates. The culotte technique, nevertheless, results in a better angiographic result at the side branch ostium with improved clinical outcome at 9 months.

9:00 a.m.

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**109S146**  
Illicit Drug Use Is An Independent Risk Factor For Coronary In-stent Restenosis

Dinesh Kumar, Neeraj Arora, Faisal Bahadur, Stephen Simpson, Gloria Calditto, Praphul Misra, LSU Health Sciences Center, Shreveport, LA

**BACKGROUND** Percutaneous coronary interventions (PCIs) are one of the accepted treatments for coronary artery disease (CAD) with a history of illicit drug use (IDU). Post PCI outcomes in stented patients with IDU have not been previously studied. We hypothesized that IDU is associated with poor outcomes in such patients.

**METHODS** 89 Patients with angiographic diagnosis of instent restenosis (ISR) were identified from the catheterization laboratory data base with 16 of these patients were treated with DES, either sirolimus-eluting (Cypher and Cypher Select; Cordis Johnson & Johnson, Warren, New Jersey, USA) or paclitaxel-eluting (Taxus and Taxus Lible, Boston Scientific; Natwick, Massachusetts, USA). Only patients with stable and unstable angina or non-ST-elevation myocardial infarction were included.

**RESULTS** Illicit drug users were more likely to be African-Americans (56 vs. 21%) with a mean age of 55 vs. 60 years old (P=0.01). They were more likely to have a history of premature CAD (19 vs. 72%) (p<0.01 for all). Other than smoking, number of other traditional risk factors were lower among drug users (1.4±1.3 vs 3.0±0.8, p<0.01) They were also more likely to be female (56% vs 28%) (p<0.01). 63% of the illicit drug users were lost to follow up (p<0.05). 68% of the IDU patients required repeat revascularization compared to 45% of the non-IDU patients (p<0.01). 46% of the IDU patients required cardiac revascularization compared to 31% of the non-IDU patients (p<0.05). They had significantly lower levels of high sensitivity C reactive protein (10.4±3.6 vs 15.7±3.3, p<0.01).

**CONCLUSION** Illicit drug use is an independent risk factor for poor outcomes in such patients with a history of illicit drug use. It is associated with high levels of traditional and non-traditional risk factors. More aggressive management is needed to decrease the high rates of poor outcomes after PCI in this high risk group. More research is needed to determine the relative impact of different risk factors on post PCI outcomes. More effective management strategies are needed to decrease the high rates of repeat revascularization and poor outcomes in patients with a history of illicit drug use. Further studies are needed to determine the relative impact of type of drug use, frequency of drug use and type of drug use on post PCI outcomes.

9:00 a.m.

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**109S147**  
Vanilla vs. Culotte Stenting in Bifurcations: Immediate Clinical and Angiographic Results and Midterm Clinical Follow-up

John C. Gurley, Guillermo Pinto, Abhishek Beshmukh, Kiran Saraff, University of Kentucky, Lexington, KY

**BACKGROUND** The ALARA principle calls for x-ray doses to be kept to the lowest levelachievable. Needless exposure occurs when an operator activates the fluoroscopy foot switch while glancing at interventional equipment or physiologic data. Methods. A head-tracking, Automatic Fluoroscopy Lockout (AFL) system was based on a miniature infrared camera and a reflective dot (Figure). X-ray exposure was enabled only when the reflector was directed toward the live display. The efficacy of AFL was evaluated during 57 unselected procedures. Foot switch and x-ray “ON” times were logged electronically during 1,912 sessions comprising 1,110,5 minutes of fluorescence.

**Results** AFL reduced the exposure time in 80% of procedures. Mean exposure times were significantly lower with AFL (actual 1,162.5 sec vs. predicted 1,243.9 sec, P<0.001). On average, fluorescence was automatically disabled during 14.6±9.5% of the foot switch “ON” time (range 1.2 to 56.3%). A resulting x-ray dose reduction of at least 20% occurred in 23% of patients.

**Conclusions** Fifteen percent of the x-ray exposure during routine fluoroscopy is unnecessary, occurring while the operator is not viewing the display. AFL eliminates this unnecessary fraction of x-ray exposure and minimizes the risk of radiation injury.
We proposed that an atrial decompression device positioned across the interatrial septum increase after successful PCI is rare.

CONCLUSIONS: rises occurred in 28% of MC vs 3% of no MC pts (p<0.0001). (Figure).

RESULTS: MC were evaluated prospectively in 550 pts and CKMB measured pre- and post PCI. DU derived PSV increased significantly following placement of the X-Act stent (80±26 cm/sec [pre] vs. 102±29 cm/sec [post], p=0.002), while FW derived PSV did not change. The Precise stent did not influence DU derived PSV.

Background: The Plaque Destabilization Of Non-culprit Lesion In Acute Myocardial Infarction: An Optical Coherence Tomography Study

Hironori Kitabata, Takashi Kubo, Yu Arita, Hideyuki Iijima, Kashi Otkochi, Hiroto Tsujpika, Akio Kuroi, Satoshi Ueno, Takashi Tanimoto, Takashi Yamano, Yoshih Matusuo, Takashi Masrho, Shigeho Sakurada, Toshio Imanishi, Yoshihki Tomobushi, Takashi Akasaka, Wakyama medical university, Wakyama, Japan

Background: Recent intravascular ultrasound (IVUS) studies frequently demonstrated multiple plaque rupture in cases with acute coronary syndrome. Optical coherence tomography (OCT) is a new intravascular imaging method with a high resolution of approximately 15-20 micron, which is 10-fold greater than that of IVUS. This may allow us to observe the pathophysiology of the atherosclerosis in the vessel wall in detail in vivo, and to estimate the vulnerable plaques. The present study sought to assess atherosclerotic plaque destabilization by intracoronary OCT in acute myocardial infarction (AMI) compared with stable angina (SA).

Methods: The OCT examination of culprit-vehicle was performed in 51 patients: 33 had AMI and 18 had SA. We evaluated not only culprit plaques by OCT, but also non-culprit plaques (AMI: n=33, SAP: n=18) but not with the Precise or Acculink stent. Larger scale clinical comparison of various stent types and their impact on SA are needed in order to clarify the value of DU surveillance following carotid artery stenting.
those in SAP. Furthermore, the fibrous-cap thickness of non-culprit plaque in AMI was significantly thinner than that in SAP (109 +/- 55.5 vs. 194 +/- 81.9 μm, p<0.001), and the incidence of the cap fibroatheroma (fibrous cap thickness <65μm) of non-culprit plaque in AMI patients was significantly higher than that in SAP (25 vs. 8%, p<0.01). 

Conclusions: The OCT examination demonstrates the plaque destabilization not only in culprit lesion but also in non-culprit lesion in AMI. Intracoronary OCT provides abundant information regarding plaque microscopic morphology, which is thought to be essential in the identification of high-risk lesions.

310A14
One Year Follow-up Of Left Ventricular Function And Remodeling After Intracoronary Infusion Of Bone Marrow - Derived Progenitor Cells After Acute Stemi; MRI Substudy of the Double-blind, Randomized, Placebo-controlled Multicenter Repair-AMI Trial.

Andreas Roll, Thorsten Dill, Susanne Moellmann, Guido Conradi, Volker Schroechinger, Andreas Zehier, Christian W. Hamm, Kerckhoff-Heart Center, Bad Nauheim, Germany

Background: The Repair-AMI trial demonstrated a positive effect of intracoronary infusion of bone marrow derived stem cells (BMC) on left ventricular function by LV angiography 4 months after acute myocardial infarction. An MRI substudy to assess myocardial function, wall motion, and infarct size/transmurality was performed and the follow-up data after 12 months are presented.

Methods: Consecutive patients (pts) with STEMI and primary PCI were enrolled (n=204) and randomly assigned to either stem cell therapy or placebo after bone-marrow aspiration. 74 pts participated in the MRI substudy, 60 pts were available for 4 month (mo) follow up (fup), 39 pts for 12 mo fup, respectively. Image analysis was performed at a central core lab.

Results: There is no significant difference in EF between both groups at baseline. After 12 mo EF significantly increased in the BMC group (3% vs. 2.5%, p<0.04, difference 0.31 ± 0.43, placebo 0.17 ± 0.24, p<0.43), 0.48% (95% CI 0.240 - 0.720, p<0.001). Improvement was more pronounced in pts with EF below median of 49.5% (BMC 0.240 - 0.430, difference 0.19 ± 0.32, p<0.001) vs. placebo 0.17 ± 0.24, p<0.43). There was no significant difference in EDV between both groups at baseline. After 12 mo BMC treated patients showed no significant increase (130 ml ± 68.8 to 150.6 ml ± 68.8, p=0.09, difference 20.8 ml ± 30.5, p=0.095), whereas placebo patients showed a significant increase (126.7 ml ± 66.0 to 150.6 ml ± 68.8, p<0.001, difference 23.9 ml ± 43.9, p<0.001). There was no significant difference between both groups regarding infarct size at baseline. After 12 mo BMC 75.6% ± 16.8% to 69.2% ± 14.9%, p=0.08, difference 6.4% ± 10.9%, p=0.13), whereas placebo 71.4% ± 17.0% to 83.2% ± 15.4%, p<0.001, difference 11.8% ± 10.9%, p<0.001). Improvement was more pronounced in pts with EF below median of 49.5% (BMC 9.2% ± 5.9% to 3.1% ± 3.2%, p<0.001), whereas placebo 9.2% ± 4.6% to 10.9% ± 6.7%, p=0.03).

Conclusions: Preliminary analysis of 12 mo fup data confirms the beneficial effects of BMC treatment on EF and EDV that could be demonstrated after 4 mo. The positive additional effect of BMC treatment on infarct volume and transmurality could not be demonstrated with this limited number of 12 mo fup data.

310B16
Troponin Elevation After Percutaneous Coronary Intervention Predicts Major Cardiac Adverse Outcomes in Patients with Non-ST-Segment Elevation Acute Coronary Syndromes: Results From the SYNERGY Trial


Background: The importance of troponin (Tn) elevation following PCI is still unclear. The prognostic role of peak Tn post-PCI among non-ST-segment elevation (NSTE) myocardial infarction (MI) patients with post-PCI Tn rise (pre-PCI Tn normal or stable) is still not well understood. The SYNERGY trial demonstrated a positive effect of PCI using SES in this population. Therefore, we sought to determine whether peak Tn post-PCI among NSTE MI patients is related to clinical outcomes.

Methods: Consecutive NSTE MI patients with pre-PCI Tn <0.2 ng/mL, post-PCI Tn rise >1 or post-PCI Tn >2.5 ng/mL were included from SYNERGY trial sites. The relationship between peak Tn post-PCI and 12 month clinical outcomes were assessed using Cox regression analysis.

Results: 2510 patients were included in this study, of whom 2111 (84%) had peak Tn post-PCI available. Overall, peak Tn post-PCI was >1ng/mL in 38% and >2.5ng/mL in 14%. The overall cumulative survival for 12 months was 91%. The cumulative survival for Tn <1ng/mL was 93% vs. 87% for Tn >1ng/mL (p<0.001), and for Tn <2.5ng/mL was 92% vs. 84% for Tn >2.5ng/mL (p<0.001). In patients with Tn <1ng/mL, mortality (HR 1.01-1.16; p<.001) but not Tn >1ng/mL was associated with adverse outcomes at 12 months. Tn >2.5ng/mL was associated with adverse outcomes at 12 months (HR 1.5 [1.27-1.70]; p<.001), and Tn >2.5ng/mL was associated with adverse outcomes at 12 months (HR 1.12 [1.01-1.16]; p<.001).

Conclusions: In NSTE MI patients with post-PCI Tn rise (pre-PCI Tn normal or stable) higher peak Tn post-PCI was associated with worse short- and mid-term ischemic outcomes but not 1-yr mortality. Further studies are needed to clarify the clinical significance of these results.
difference in the incidence of death (9% vs. 3%, p=0.36) and myocardial infarction (2% vs. 0%, p=0.99) between the BMS and SES group. Follow-up angiography was performed in 80% of lesions. There was no stent thrombosis in the SES group while it was observed in 1 patient (2%) in the BMS group (p=0.99).

Conclusion: Restenosis rate was high in patients on hemodialysis who received either BMS or SES.

### Table: MLD-minimum lumen diameter, TLR-target lesion revascularization

<table>
<thead>
<tr>
<th>Stents length (mm)</th>
<th>BMS</th>
<th>SES</th>
<th>P-value</th>
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<tbody>
<tr>
<td>29.6±18.8</td>
<td>19.8±10.1</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Max. inflation pressure (atm)</td>
<td>16.2±3.35</td>
<td>13.6±3.19</td>
<td>&lt;0.001</td>
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<tr>
<td>Lesion length (mm)</td>
<td>19.49±12.45</td>
<td>13.86±3.19</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Reference diameter (mm)</td>
<td>2.75±0.67</td>
<td>2.87±0.59</td>
<td>0.34</td>
</tr>
<tr>
<td>Pre-MLD (mm)</td>
<td>0.9±0.34</td>
<td>0.78±0.34</td>
<td>0.10</td>
</tr>
<tr>
<td>Final MLD (mm)</td>
<td>2.48±0.47</td>
<td>2.58±0.45</td>
<td>0.28</td>
</tr>
<tr>
<td>Follow-up MLD (mm)</td>
<td>1.6±0.84</td>
<td>1.6±0.88</td>
<td>1.6</td>
</tr>
<tr>
<td>Binary restenosis (%)</td>
<td>17</td>
<td>44</td>
<td>0.22</td>
</tr>
<tr>
<td>TLR (%)</td>
<td>17</td>
<td>27</td>
<td>0.26</td>
</tr>
</tbody>
</table>

#### 911-210
**Time Delay To Rescue PCI And Clinical Endpoints. Results From The React Study.**

Neil Swanson, Amanda Carver, Sarah Hughes, Gail Richardson, Anthony Gershlick, Glenfield Hospital, Leicester, United Kingdom

**Background:** REACT was a 428 patient trial of STEMI with failed reperfusion (<50% ST resolution) 90min after thrombolysis. Patients were randomised to repeat thrombolysis, conservative treatment, or rescue PCI. The composite endpoint (death, reinforcement, stroke or severe heart failure) at 6th month occurred in 15% for PCI v. 29.3% conservative v. 31.3% thrombolysis overall (P=0.004, published data).

In primary PCI, outcomes have been related to delay to PCI. Till now, no such data exist for rescue PCI.

**Methods:** Data on the timing of symptom onset, randomisation and PCI were examined in 97/115 patients who had data for timing of PCI. These patients had an 11.3% endpoint (death, reinforcement, stroke or severe heart failure) at 6th month.

**Results:** 97/115 patients had data for timing of PCI. These patients had an 11.3% endpoint rate. Median time to PCI from randomisation was 1.9hr (18min to 19hr 25min). Median time to PCI from initial pain was 7hr (3hr 8min to 22hr 20). Hour by hour analysis showed no clear time point where benefit of PCI was lost, although at >12hr from randomisation, time to PCI from initial pain was 7hr (3hr 8min to 22hr 20). Hour by hour analysis showed no clear time point where benefit of PCI was lost, although at >12hr from randomisation, time to PCI from initial pain was 7hr (3hr 8min to 22hr 20).

**Conclusion:** In REACT, rescue PCI was expected to be performed speedily. This analysis has not shown a clear cut-off time beyond which rescue PCI is ineffective (although the very limited data for patients treated >12hr suggest they may be at increased risk).

**Performance:** Performed promptly, rescue PCI remains the best treatment for failed thrombolysis and very limited data for patients treated >12hr suggest they may be at increased risk.

**Conclusions:** No clear time point where benefit of PCI was lost, although at >12hr from randomisation, time to PCI from initial pain was 7hr (3hr 8min to 22hr 20). Hour by hour analysis showed no clear time point where benefit of PCI was lost, although at >12hr from randomisation, time to PCI from initial pain was 7hr (3hr 8min to 22hr 20).

**Preliminary data show that acute stent recoil of the BVS stent is comparable to that of the metal stent. We will show the stent recoil data on all patients at the time of the presentation.**

#### 911-211
**Acute Stent Recoil of Bioabsorbable Everolimus-Eluting Coronary Stent and Everolimus-Eluting Coronary Metal Stent: Insight from the ABSORB and SPIRIT Trials**

Shinzo Tanino, Patrick W. Serruys, Leif Thuesen, Dukdik Dariusz, Bernard de Bruyne, Bernard Chevalier, John A. Ormiston, Thoracic Erasmus MC, Rotterdam, The Netherlands, Auckland City Hospital, Auckland, New Zealand

**Background:** The bioabsorbable everolimus-eluting coronary stent (BVS) is composed of a poly-L-lactic acid backbone, expected to be totally metabolized and absorbed. When compared with metallic stents, the BVS may have less radial strength, which can result in more acute recoil post stent implantation. The aim of this study was to evaluate and compare acute stent recoil results of the BVS and metal stents.

**Methods:** A total of 60 patients, who underwent elective stent implantation for single de novo native coronary artery lesions, were enrolled: 30 patients treated with BVS from the ABSORB trial and 30 consecutive patients treated with the everolimus-eluting cobalt chromium stent from the SPIRIT trials. Acute stent recoil was measured by quantitative coronary angiography and defined as the difference between mean diameter of the last inflated balloon at the highest pressure (x) and mean lumen diameter of the stent immediately after the last balloon inflation divided by x and expressed as a percentage.

**Results:** At the time of abstract submission, 27 ABSORB trial patients and 20 SPIRIT trial patients were analyzed. Disease segments were relatively simple. As preliminary data, mean acute stent recoil of the BVS and the metal stent was 6.9 ± 7.0% and 4.4 ± 7.6%, respectively (p = 0.407).

**Conclusion:** Preliminary data show that acute stent recoil of the BVS stent is comparable to that of the metal stent. We will show the stent recoil data on all patients at the time of the presentation.

#### 911-213
**Multiple Thin-cap Fibroatheromas Assessed By Three Vessel Histological and Optical Coherence Tomographic Study**

Takahiro Kume, Hiroichi Okura, Takahiro Kawamoto, Takashi Aoki, Eiji Toyota, Noriomi Watanabe, Yoshihisa, Renan Sukurnaw, Ryotaro Yamada, Kiyoji Yoshida, Kawasaki Medical School, Kurashiki, Japan

**Background:** Recently, three vessel intravascular ultrasound studies have shown that plaque rupture may be present not only in the culprit lesion but also in non-culprit lesions. Such a plaque rupture most commonly arise from the disruption of thin-cap fibroatheromas (TCFA), known as the thickness of fibrous cap < 65 m. The purpose of this study was to evaluate the incidence of TCFA by histological examination and investigate the feasibility of using optical coherence tomography (OCT) to detect of TCFA.

**Methods:** We examined 108 coronary arterial segments from 38 human cadavers (24 male and 14 female, mean ages 74 ± 7 years). Coronary arteries were imaged with intravascular OCT system. We evaluated the incidence of TCFA by histological examination and investigated the feasibility of using OCT to detect of TCFA.

**Results:** Thirty distinct TCFA were detected by histological examination. Patients with TCFA had significantly higher incidence of ischemic heart disease than in patients without TCFA (34% vs. 0%, p=0.003). Complete histological examination of all 3 coronary arteries suggests that TCFA had significantly higher incidence of ischemic heart disease than in patients without TCFA (34% vs. 0%, p=0.003). Among 32 patients, 6 (19%) had 1 TCFA, 6 (19%) had 2 TCFA, and 13 (41%) had 3 TCFA (Figure). OCT showed a high sensitivity and specificity for detecting TCFA (sensitivity 90% and specificity 84%).

**Conclusion:** Multiple TCFA were observed in about one-thirds of cadavers by histological examination. OCT could provide a high sensitivity and specificity for detection of TCFA.

#### 911-214
**The Critical Role of Magnetic Resonance Angiography in Evaluation of Anomalous Coronary Arteries**

Vvasu K. Rathi, Ronald M. Razmi, Mark Doyle, Agostino Meduri, Tony G. Farah, Benigno Soto, Gerald M. Pohost, Robert W. Biederman, Allegheny General Hospital, Pittsburgh, PA, PA, University of Alabama at Birmingham, Birmingham, AL

**Background:** X-ray angiography (CATH) has been the imaging modality of choice for assessment of the coronary arteries (CA). However, due to its 2D projectional nature, it does not reliably delineate the proximal course of anomalous CA. This information is critical to pt management. CT angiography is 3D with excellent spatial resolution but high radiation and contrast side effects. Preliminary data indicate that CA MRA is effective in defining the origin and proximal course when intraluminal stenosis is not a primary aim. We compared the accuracy of MRCA to CATH in pts referred with an anomalous CA diagnosis.

**Methods and Results:** Pts (37) referred for anomalous CA underwent MRCA (1.5T GE Signa CVI, Milwaukee WI). No contrast was used.
Stent Thrombosis in the Modern Drug-eluting Stent Era compared to the Bare-Metal Stent Era: A Comparison from a Large Clinical Registry

Kent G. Meredith, Rodney S. Badger, Anwar Tandar, Heidi T. May, Tami L. Bar, Douglas L. Cosmides, Andrew D. Michaels, Jeffrey L. Anderson, Benjamin D. Horne, Joseph B. Muhlestein, LDS Hospital, Salt Lake City, UT, University of Utah, Salt Lake City, UT

BACKGROUND: Concern for a potential risk of late stent thrombosis (ST) associated with drug-eluting stents (DES) has prompted a shift toward prolonged dual anti-platelet therapy in patients with DES. We compared outcomes in patients who received DES since 2003 to patients who received bare-metal stents (BMS) in the pre-DES era to determine whether ST has increased in clinical practice.

METHODS: We analyzed 11,642 patients (N=6142) from a single center who received coronary stents between 1993-2006 were included. In order to control for biased stent selection in modern practice (i.e. BMS typically are used only in very small or large vessels, or when anti-platelet therapy is contraindicated), we compared patients stented with DES after 2003 to patients who received BMS stents before DES became available (1993-2002). ST during the first 36 months after stent placement was studied, using multivariate regression to adjust for standard risk factors. Timing categories were: acute/subacute (AST) within 30 days, Late (LaST) 1-6 months, and very late (VLaST): 6-36 months.

RESULTS: Compared to BMS (N=6193), patients with DES (N=1949) were more likely to have diabetes, hypertension, and hyperlipidemia. ST was more frequent in BMS patients than DES (137 [2.2%] vs. 12 [0.6%], p=0.001). Multivariate analysis showed a greater risk for ST (OR=3.78, p<0.001) in BMS. ST timing compared as follows: AST: DES 0.3%, BMS 2.0%; LaST: DES 0.3%, BMS 0.8%; VLaST: DES 0.1%, BMS 1.6%. In multivariate analysis, there was no difference for AST (OR=1.20, p=0.72), but BMS were more likely to have LaST (OR=3.76, p<0.001) and VLaST (OR=22.3, p=0.002).

CONCLUSION: The incidence of ST remains very low for DES compared to BMS placed in the pre-DES era. Although not assessed in this study, the greater ST among BMS may be due to the lesser duration of intensive antiplatelet therapy whereas current strategies for prolonged dual anti-platelet therapy in the DES era may maintain equivalent or even superior ST rates regardless of the DES compared to BMS treatment strategy. However, the long-term risk for ST in DES after discontinuing antiplatelet therapy remains uncertain.

Radiation Exposure during Flat Detector Fluoroscopy: Recognition of a Unique Hazard to Obese Patients

John C. Curley, Guillermo Pineda, Kiran Saraff, University of Kentucky, Lexington, KY

Background. Modern flat detector (FD) fluoroscopy systems provide superior contrast resolution, enabling operators to work with heavier patients and steeper projections. It is generally assumed that FD systems are safe, the potential for excessive x-ray exposure is unknown.

Methods. Measurements of x-ray dose and image quality were obtained in clinical catheterization laboratories, using acrylic blocks to simulate patients of varying size. FD and image intensifier-based (II) fluoroscopy systems were compared by analyzing image quality and x-ray dose as functions of attenuator thickness.

Results. FD fluoroscopy provided superior image quality during obese-patient simulations, but at the cost of escalating x-ray doses (Figure). II and FD image quality scores were equivalent when penetrating 30 and 38 cm of attenuator, respectively (27% greater for FD). Entry skin dose rates at this point of equivalency were 5.86 R/min for II and 16.4 R/min for FD fluoroscopy. (2.8 times higher for FD). At these rates, FD fluoroscopy could cause skin injury in 12 minutes.

Conclusions. FD fluoroscopy presents a unique hazard for radiation skin injury in obese patients. Since image quality is preserved, operators may not be aware of high skin dose rates. FD systems should be used with caution in heavy patients.
Methods: Reported P values are based on Fisher’s Exact test. Numbers needed to harm (NNH) are derived as inverse of absolute risk difference. Probability of harm is estimated at 1 minus one-sided P value based on Bayesian principles; threshold probability of significance = 97.5%.

Results: The meta-analyses revealed a nonsignificant increase in death or MI with DES, with a significant increase in these outcomes with sirolimus-eluting stents (SES) at last follow-up. Even though the differences in death or MI were not statistically significant in any one of the individual trials (due to inadequate power), the NNH with DES ranged from 12 to 111 and the probability of harm ranged from 68% to 96%.

Conclusion: These findings suggest a potential for increased risk of death or MI with DES presumably related to stent thrombosis. Given these observations, an adequately powered prospective trial to reliably estimate the true excess risk of death or MI is urgently warranted.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Endpoint</th>
<th>Follow-up</th>
<th>Incidence (%)</th>
<th>P value</th>
<th>Probability of harm</th>
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<tr>
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<td>Death</td>
<td>3 y</td>
<td>2.3</td>
<td>0.02</td>
<td>71</td>
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<tr>
<td></td>
<td>Death or MI</td>
<td>3 y</td>
<td>4.6</td>
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<td></td>
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<td>Meta-analysis PES vs BMS (n=3445)</td>
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<td>RAVEL</td>
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<td>26</td>
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<tr>
<td>BASKET</td>
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<td>18 months of follow-up</td>
<td>7.1</td>
<td>0.03</td>
<td>13</td>
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<tr>
<td></td>
<td>Death or MI</td>
<td>7.1</td>
<td>2.6</td>
<td>0.03</td>
<td>13</td>
</tr>
</tbody>
</table>

Quantitative Analysis of Vulnerable Plaque Color Using LCH Color Space

Yasunori Ueda, Nobuyuki Iwagawa, Jota Oyabu, Kazuaki Okada, Kazunori Kashiwase, Atsushi Hayama, Kazuhiisa Kodama, Osaka Police Hospital, Osaka, Japan

Background: Although yellow plaque is regarded vulnerable, the evaluation of yellow color has been subjective. Therefore, we have analyzed quantitatively the characteristics of yellow color that is regarded a sign of vulnerable plaques.

Methods: Color of yellow plaques was quantitatively analyzed using LCH color space and was presented by the maximum values of lightness (Lmax), chroma (Cmax), and hue (Hmax). Effect of light intensity on these parameters was experimentally examined (5 plaque models, 6 light intensities). Relation between conventional yellow color grade and LCH parameters was examined (31 plaques). Color analysis with LCH color space was applied to compare the culprit lesions of unstable angina (8 patients) and of stable effort angina (5 patients), and to evaluate the regression of yellow plaque by 80-weeks statin treatment (4 patients, 19 plaques).

Results: Cmax and Hmax were not influenced by light intensity so far as it was within appropriate range. Cmax (13±3, 25±5, and 28±4) became higher and Hmax (178±26, 99±69, and 178±26) became lower as the grade became higher (>90%). Culpit lesions of unstable angina had higher Cmax (22.8±7.9 vs. 14.8±7.5, p=0.04) and lower Hmax (73.3±19.7 vs. 168.0±71.5, p=0.00) than stable effort angina. Statin treatment reduced Cmax (21.3±6.9 vs. 14.6±3.1, p=0.04) and increased Hmax (82.5±25.8 vs. 142.3±54.1, p=0.005).

Conclusions: Plaque color was consistently and quantitatively measurable using LCH color space unfluenced by light intensity of appropriate range. Vulnerable yellow color had high chroma and low hue, indicating vivid and reddish yellow color.

Coronary Stent Assesability by 64 Slice Multi-Detector Computed Tomography

Toni Shelt, Jonathan Dodd, Alok Finn, Herman Gold, Ricardo C. Curv, Massachusetts General Hospital, Boston, MA

Background: We evaluated the assessability of contemporary stent platforms by 64-slice MDCT.

Methods: Patients undergoing coronary stenting were included in a prospective protocol of MDCT imaging within 48 hours of stent implantation. MDCT data were acquired using a Sensation 64 MDCT scanner (Siemens Medical Solutions, Forchheim, Germany). Stent assessability was assessed by two independent blinded observers and disagreement was resolved by a third observer. Assessability was defined as visualization of the in-stent lumen without influence of partial volume effects, beam hardening, motion, calcification, or contrast to noise limitations.

Results: 54 stents (Cypher n=25, Vision/Minivision n=19, Taxus Express n=8, Liberte n=1, Driver n=1) in 44 patients were included in the study. The two independent observers classified 30 of 54 stents (56%) as assessable by any degree of artifact. Stent interobserver reproducibility was high with kappa =0.66. Stent size was the most important determinant of assessability. Consistently assessable stents were 3.0 mm or larger, whereas those under 3 mm were mostly non-assessable (see figure).

Conclusions: Contemporary stent designs evaluated on a 64-slice MDCT scanner showed artifact free assessability only in larger stents. Increase in spatial resolution or modifications in stent design will be necessary in order to evaluate stents less than 3 mm in diameter, where in-stent restenosis is more frequent.

Renal Frame Count Can Identify the Good Responder of Stent Placement in Patients with Atherosclerotic Renal Artery Stenosis Which Induced Renal Dysfunction

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Background: There is considerable need and interest to identify who will benefit from revascularization in patient with atherosclerotic renal artery stenosis (ARAS) which induced renal dysfunction. Recent data suggest that renal frame count (RFC) using renal angiogram demonstrate the renal perfusion status. We evaluated results of renal artery stent placement by quantitative angiography and RFC. And we investigated the ability of RFC to identify the good responder of this therapy.

Methods: A total of 33 patients with renal dysfunction (serum creatinine >1.3mg/dl) due to ARAS (angiographically >70% stenosis by visual estimation) who underwent stent placement without restenosis were evaluated. We divided it into the two groups by reaction to this treatment, and we compared it. Patients who has improved or stabilized the serum creatinine value categorized into group A. renal frame count (RFC) was measured immediately after procedure as previously described.

Results: Good responder group has lower RFC number immediately after stent placement. In multivariate analysis, RFC numbers are independent predictor for good response of this therapy (odds ratio, 0.88; 95%CI, 0.77-0.99; P=0.04).

Conclusions: RFC is independent predictor for identifying the good responder of renal artery stent placement. Well-perfused kidney could contribute to preservation of renal function. Lower frame count number is better.

Intravascular Delivery of Sirolimus with Two Biodegradable Polymers Using Novel Electro-Grafting Technology

Thierry Lebret, Eric J. Pacheco, Patrice Guerin, Ross Elloy, Fétal Haroun, Katina Lesieux, Renaud Decrop, Christophe Bureau, Renu Varmans; CVPath Institute, Inc., Gaithersburg, MD, Acmeate SA, Massy, France

Background: This study examined the feasibility of local drug release with biodegradable polymers applied to bare metal stents using an electro-grafting eGTM technique (Alchimer SA, Massy, France) creating a ultra-thin layer (100-150 nm) of stable and reproducible binding of polymer matrix to metal surfaces.

Methods: Rabbits were fed a high fat diet (1% cholesterol) for 2 months, during which animals underwent bilateral iliac artery stent implantation at 28 days. Balloon-expandable stainless steel stents (18 × 3 mm) were coated with sirolimus incorporated in two different biodegradable matrices, PC1 & PC2. The arteries were randomized to one of five groups: uncoated stents (n=8); PC1 stents (n=8); PC2 stents (n=10); PC1/Sirolimus-eluting stents (n = 9); and PC2/Sirolimus eluting stents (n=7). At the completion of the 8-11e phase, stented vessels were removed and processed for histomorphometry.

Results: Percent stenosis was significantly lower in drug-loaded stents (PC1/Sirolimus eluting= 17.3±6.27 and PC2/Sirolimus eluting= 21.29±4.78) compared to uncoated (25.3±4.19, PC1 (32.5±12.25) or PC2 (29.6±7.89) stents (p=0.0034). Intimal inflammation was minimal in all groups. Re-endothelialization was near complete (>90%) with the exception of PC1/Sirolimus stents, where cell coverage was significantly less (70.0±20.2, p<0.0001). The degree of endothelialization may be influenced by the release kinetics. In vitro liberation of sirolimus from moderate release PC1/Sirolimus eluting stents at 3, 14 and 28-days was 48.6±3.3%, 55.9±2.2%, and 64.0±1.4%, respectively while for slow release PC2/Sirolimus eluting stents, elution rates were 1.6±0.3%, 3.7±0.6%, and 5.9±0.7%.

Conclusion: Sirolimus eluted from biodegradable polymer-coatings significantly reduced neointimal growth in 28-day iliac stents without promoting inflammation. These preliminary results demonstrate the potential clinical value of electro-grafting eGTM technology in stent-based drug delivery. Further studies are necessary to determine the influence of drug-release kinetics on luminal re-endothelialization and to assess the long-term effects of sirolimus-elution with biodegradable polymers.
Conclusions: PCI (OR 2.43; 95CI: 1.11 - 5.34).

Results: We analysed DNA-polyomorphisms within IL-1 gene clusters: IL-1B (-511), IL-1B (+3954) and IL-1α variable number tandem repeat (VNTR) in 135 patients undergoing intravascular ultrasound (IVUS) guided PCI. Clinical, angiographic and IVUS follow-up was performed at 6 months. We compared combined heterozygous and homozygous carriers of the allele T with homozygous carriers of the allele C in IL-1B (-511), IL-1B (+3954) and homozygous and homozygous carriers of the allele 2 with homozygous carriers of the allele 1 in IL-1RN (VNTR).

Conclusions: Allele 2 of IL-1RN (VNTR) polymorphism was associated with significant lower stented segment late loss in MLD and MSA at 6 months. This finding supports the hypothesis that genetic programming of the inflammatory response may be relevant to the pathogenesis of restenosis.

Background: Contrast-induced nephropathy (CIN) is an important cause of mortality and morbidity in patients undergoing cardiac angiography. Aim of this study was to investigate whether statins reduce the incidence of contrast-induced nephropathy (CIN) in the setting of percutaneous coronary intervention (PCI) and to evaluate the influence of such therapy on long-term clinical outcome.

Methods: A total of 434 patients undergoing PCI were prospectively enrolled and followed at least 4 years after the procedure. Patients were stratified according to pre-procedural statin therapy (260 statin-treated and 174 without statins). Blood samples were drawn before and 24 hours after PCI for detection of serum creatinine and other hematomatological parameters. CIN definition was as post-procedural increase in serum creatinine ≥0.5 mg/dL or >25% from baseline. Follow-up assessment included the 4-year occurrence of major adverse cardiac events (MACE).

Results: Statin-treated patients had a significantly lower incidence of CIN (3% vs. 27% in patients without statins; P<0.001), corresponding to a 90% risk reduction (Odds ratio 0.10, 95% CI 0.02-0.18; P=0.0001), and had higher post-procedural creatinine clearance (82±25 vs. 65±19 mL/min; P<0.001). Benefit of pre-treatment with statins was observed in all subgroups, except in patients with pre-existing renal failure (OR 0.42, 1.0-2.8; P=0.37). During follow-up statin therapy was independently associated with lower risk of MACE, and CIN was a predictor of poorer outcome; 4-year event-free survival was highest in patients statin-treated and no CIN (95%, P=0.015) and lowest in those without statins and CIN (53%, P=0.018).

Conclusions: Patients treated with statin therapy prior to percutaneous coronary intervention have a significantly lower incidence of contrast-induced nephropathy; importantly, this protective effect translates into a better long-term cardiac event-free survival. These data may support routine utilization of statins as adjuvant pharmacological therapy before percutaneous coronary revascularization.

Monday, March 26, 2007, 1:00 p.m.-2:00 p.m.
**Background:** Cryoangioplasty has been shown to prevent restenosis in lower extremity atherosclerotic lesions by reducing smooth muscle proliferation and extracellular matrix synthesis. Percutaneous coronary revascularization of coronary bifurcation lesions remains a challenge due to plaque shift into small side vessels after stenting to the main vessel. Here, we report on the outcome of cryoangioplasty for the treatment of side branches after plaque shift from main vessel percutaneous intervention.

**Methods:** Eleven male veterans (age=60.6 ± 8.6 years) with complex bifurcation lesions who were enrolled in a side branch cryoangioplasty study were reviewed. Percutaneous coronary intervention after cryoangioplasty was performed to correct side branch stenosis.

**Results:** Bifurcation lesions involved the left anterior descending/diagonal branch arteries in 55% of patients and the circumflex/obtuse marginal branch arteries in 45% of patients. The initial maximal luminal diameter (MaxLD) of the side branches was 1.5 ± 0.4 mm. The minimal luminal diameter (MinLD) of the side branch decreased significantly after plaque shift from main vessel angioplasty from 1.0 ± 0.3 mm to 0.6 ± 0.2 mm (p<0.0001). After cryoangioplasty the MinLD was increased significantly to 1.2 ± 0.3 mm (p<0.0001). Plaque shift increased the initial side branch stenosis from 33 ± 7.3% to 67 ± 19% (p<0.0001). After cryotherapy side branch stenosis was not significantly different from the pre intervention value (31 ± 4.1%, p>0.18). Patients were followed for an average of 7 ± 3.6 months. One patient had target vessel revascularization (TVR) with stent placement at the cryoangioplasty site. None had angina or ischemia on nuclear perfusion study.

**Conclusions:** Cryoangioplasty is a novel treatment of stenosis of small side branches after plaque shifts in coronary bifurcation lesions. Small coronary side branch cryotherapy was technically successful in all patients, with low incidence of TVR at 7 month follow-up.

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**CT Scan Versus EndoSure™ For Endoleak Detection After Endovascular Repair of Abdominal Aortic Aneurysm**

Joaquín Solis, Daniel Hemsworth, Suresh Ramamurthy, Mohamed Djemai-Hani, Fareed Shahi, Ashok Kumar, Tanvir Bajwa, Aurora Sinaí/St. Luke’s Medical Ctr, Univ of Wisconsin School of Medicine and Public Health-MCC, Milwaukee, WI

**Background:** Endovascular repair (EVAR) is an alternative to open surgical repair for abdominal aortic aneurysm (AAA). Post-procedure follow up requires CT scan for early detection of endoleaks which may be deleterious in patients with renal impairment. We compared CT scan with the EndoSure™ Wireless AAA Pressure Measurement System (CardioMEMS, Inc, Atlanta, GA) in the detection of endoleaks.

**Methods:** We present our experience in 30 patients who underwent EVAR of AAA with implantation of EndoSure device. Pressure measurement was compared with angiogram immediately after procedure and with CT scan at one month.

**Results:** All 30 patients had successful EVAR of AAA. Average pulse pressure inside the aneurysm sac decreased from 64.6 to 29.5 (range 2 to 78) immediately after the procedure. Five endoleaks resulted in minimal pressure drop. Type I and III endoleaks, were repaired successfully resulting in decreased pressure. Type II endoleaks required no additional procedures. At follow up average pulse pressure was 19.7 ± 24. Patients in whom the pressure decreased, CT scan showed no endoleak. Patients with elevated pressure had Type II leak (2 patients) or no leak (2 patients).

**Conclusion:** Non-invasive evaluation of sac pressure during EVAR of AAA is reliable for evaluating procedure success and predicting endoleaks at follow up. Correlation with CT scan in patients who had decrease pressure is 100%.

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**Drug-eluting Stents: Have We Made Any Progress?**

Tereza Pucelíková, Ajay J. Kirtane, George Dangas, Eugenia Nkosi, Emilia Solinas, Alexandra J. Larssen, Theresa Franklin-Bond, Paul Boland, Andy Morales, Masahiro Kimura, Jiro Aoki, Young-Hak Kim, Matthew Williams, Abdi Agahshiri, Issam Moussa, William Gray, Michael Collins, Edward Keps, Giora Weisz, Susheel Kodali, Gregg W. Stone, Jeffrey W. Moses, Martin B. Leon, Roxana Mehran, Columbia University Medical Center, Cardiovascular Research Foundation, New York, NY

**Background:** Percutaneous treatment of saphenous vein grafts (SVGs) is associated with peri-procedural complications and higher incidence of restenosis. The safety and efficacy of DES in SVG PCI had not been established.

**Methods and Results:** From August 2004 to the December 2005, 116 SVGs (113 pts) were treated with DES (82.3% men, mean age 69.2±13.9 y, 39.6% diabetics, 12.7% on admission, 21.6% restenotic lesions, mean graft age 11.5±6.2 y). Cypher, Taxus, and bare metal stents were implanted in 62.9%, 31.9%, and 8.6% of grafts, respectively. At one year, 9.2% had required target lesion revascularization; however, the overall major adverse cardiac events were high (41.5%), driven mostly by death or MI, especially in patients with treated with longer (>40mm) stent lengths (see table).

**Conclusion:** Even with usage of DES and EPD, treatment of saphenous vein grafts is associated with unfavorable outcomes, especially when the grafts are treated with long and/or multiple stents.**
Non Polymer Elution Of Biolimus From A Stent Inhibits Intimal Hyperplasia In A Porcine Model

Sabeel Kay, Vladimir Royter, Gordon Grant, John Shulze, Douglas Savage, Michael C. Foose, Cedars Sinai Medical Center, Los Angeles, CA, University of California, Los Angeles, Los Angeles, CA

Background: Recent data suggest that even though first generation drug eluting stents reduce restenosis, there is a slight increase in late stent thrombosis and concurrent mortality. Persistent polymer and/or drug may be causal. Local delivery of a Biolimus A9 (B), an engineered rapamycin derivative from a specially designed porous stent not coated with Polymer can inhibit hyperplasia.

Methods: We compared a specially designed porous metal BioMatrix III Stent containing 225 µg of B versus Bare metal BioFlex II (C). Seven C and 4 B stents were deployed in the coronary arteries of 4 farm swine. All animals were sacrificed at 1 month. Endpoints were assessed by quantitative coronary angiography, histomorphometry and histology. Histology assessment of each of the stented segments were analyzed by an experienced cardiovascular pathologist who was blinded to the groups.

Results. There was a 57% reduction of area stenosis of B versus C. There was complete endothelialization in both groups, with a slight increase in fibrin in the drug group. There was no significant medial or intimal inflammation in either group. There was a 57% reduction of area stenosis of B versus C. There was complete endothelialization in both groups, with a slight increase in fibrin in the drug group. There was no significant medial or intimal inflammation in either group.

Conclusions. BiolimusA9 delivered from a non polymer coated porous metal stent inhibits intimal hyperplasia in a porcine model. There is normal healing of treated arteries at 28 days and no inflammation as compared to controls. Long term animal studies are ongoing to confirm the safety and efficacy of this novel non polymer coated drug eluting stent.

The Impact of an Acute Percutaneous Coronary Intervention on Survival Rates for Women With and Without Diabetes Admitted to a Community Hospital With Acute Myocardial Infarction

Aaron D. Kugelmann, Alan Anderson, Lynn G. Tarkington, Margaret Lanham, Steven D. Cutter, April W. Simon, Henry Ford Healthcare System, Detroit, MI, HCA CCMN, Nashville, TN

Background: Women who sustain acute myocardial infarction (AMI) have worse risk-adjusted outcomes than men, however, the basis for this is poorly understood. This study investigates whether acute PCI in the setting of AMI is beneficial for women.

Methods: Between October 2005 and August 2006, 55 patients with 57 CTO lesions (28 LAD, 6 LCx, 30 RCA, and 1 left main) underwent the retrograde approach at our institution. Baseline lesion characteristics were calcification (38.6%), moderate to severe tortuosity (14.0%), length >20mm (52.6%), abrupt morphology (38.6%), and bridging collateral (40.4%). The intercoronary collaterals used for the retrograde approach were septal in 32 lesions, epicardial in 20, and bypass graft with stenosis in 5. The retrograde guidewire reached the distal point of the occluded segment in 37 lesions, of which we created a channeling (Group A, n=15), and we used the retrograde guidewire as a landmark for antegrade wiring (Group B, n=22). In the other lesions, the retrograde guidewire did not reach the target vessel because of excessive tortuosity and impassably tightness of collateral circulation, then we performed the antegrade approach (Group C, n=20). The procedural success rate was 93.3%, 68.2%, and 46.0% for Group A, B, and C, respectively (Group A vs. C, p=0.003, B vs. C, p=0.130). There were 2 cases of extravasation by balloon inflation of septal connection, and 1 case of O-wave myocardial infarction of the collateral vessel occlusion.

Conclusions: This technique appears a promising approach for cases, in which the retrograde guidewire reached the distal point of the occluded segment. If a balloon dilation of the occluded segment retrogradely is possible, it is especially an effective method in treating CTO lesions. The retrograde approach technique was safe and feasible percutaneous coronary intervention for CTO.

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through to 2 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. The in-stent late loss for the analysis lesions was 0.11 mm for the XIENCE V versus 0.36 mm for the TAXUS® arm. For all lesions the in-stent late loss was 0.12 mm versus 0.37 mm for the XIENCE V and the TAXUS® respectively. In the XIENCE V group the in-stent diameter stenosis was 16%, the in-stent binary restenosis 1.3%, the neointimal volume 3.8 mm and the % volume obstruction was 2.5%. In the TAXUS® group the in-stent diameter stenosis was 21%, the in-stent binary restenosis 3.5%, the neointimal volume 14.4 mm and the % volume obstruction was 7.4%.

Conclusions: Based on the protocol design and statistics, XIENCE V showed non-inferiority (primary endpoint) and superiority to TAXUS® in terms of late loss. Additionally, at 6 months a low MACE and stent thrombosis rate were observed. The one-year clinical results will be presented at ACC.

2:00 p.m.

914-211

Preliminary Experience of the MACH 2 trial: Safety and Feasibility of Left Ventricular Support with the Impella LP 2.5 device in patients with acute ST-segment elevation myocardial infarction

Krishan D. Baweja, Maurice Rempelink, Jan Blaan, Jr., René J. van der Schaaf, Manjie M. Vis, Karel T. Koch, Jan G.P. Tissen, Robbert J. de Winter, Jan J. Piek, José P.S. Henriques, Academic Medical Centre, Amsterdam, The Netherlands

Background: Unloading the left ventricle may in addition to reperfusion therapy reduce mortality in STEMI patients, particularly in cardiogenic shock (CS) patients. Hypothetically it gives the myocardium time to recover from ischemic stunning, which is especially important with a large ischemic area at risk. The Impella LP 2.5 device is a percutaneous implantable left ventricular assist device capable of unloading the left ventricle. Before initiation of a trial in CS patients the safety and feasibility of Impella support should be determined in haemodynamically ill patients.

Methods: The study concerns a single centre non-randomized controlled open trial. 20 consecutive patients with large anterior STEMI were immediately post-PCI alternately assigned to either 3 days support with the Impella or no support (or IABP on a intention to treat basis). Co-primary endpoints are safety and feasibility of Impella support, and left ventricular recovery at 4 months follow-up.

Results: The Impella group constituted a sicker group; It scored higher on conventional risk factors, admission hsCRP, NTproBNP and echo and MRI data are under evaluation.

Conclusions about the more pathophysiological endpoint of left ventricular recovery will be determined in haemodynamical less ill patients.

2:00 p.m.

914-212

True Lumen Re-Entry Catheter Availability Improves Procedural Success in Endovascular Intervention of Peripheral Chronic Total Occlusions

John A. Riddick, Caroline J. Cates, Khurshov Niazl, Christopher U. Cates, Emory University, Atlanta, GA

Background: Inability to re-access the true lumen is the most common cause of failure during percutaneous transluminal angioplasty (PTA) of long chronic total occlusions (CTO). We examined the relationship between the availability of the Pioneer catheter, an IVUS-guided re-entry catheter, and procedural success.

Methods: 52 consecutive cases of PTA to a lower extremity CTO were identified. 25 cases (2001-03) were performed prior to Pioneer availability while 27 cases (2004-06) were performed with Pioneer availability. In all cases attempts were made to cross the lesion with a guidewire and support catheter. Adjunctive devices (i.e. laser or blunt microdissection catheter vs. Pioneer) were used only after wire failure. Lesion characteristics were evaluated with QCA and calcium was scored visually.

Results: Procedural success was higher with Pioneer availability (100% vs. 76%; p<.009) while the mean number of adjunctive devices used per case was lower. Pioneer-available cases tended to be longer lesions with significantly more calcium. Significantly less contrast volume was required in Pioneer cases. Complications were similar in both groups and there were no cases of death, limb loss, or emergency surgery. Long term outcomes favored Pioneer-available cases but were not statistically different.

Discussion: Availability of the Pioneer catheter allows for more aggressive wiring with higher true lumen re-entry and improved procedural success compared to standard CTO techniques alone.

2:00 p.m.

Characterization of the Intravascular Ultrasound Radiofrequency Signal within Regions of Acoustic Shadowing Behind Calcium

Kazuo Tanaka, Stephane G. Carlier, Amin Katouzian, Gary S. Mintz, Cardiovascular Research Foundation and Columbia University, New York, NY

Background: Acoustic shadowing limits grey-scale intravascular ultrasound (IVUS) plaque assessment behind calcium (Ca). VH (Virtual Histology) IVUS derives plaque composition from spectral analysis of radiofrequency (RF) signal. However, the effect of Ca and acoustic shadowing on the RF signal and VH analysis has not been reported.

Methods: 20 lesions with a significant dense Ca (arc>90°) imaged at 20 MHz were analyzed. ROIs behind Ca were traced, and the corresponding RF signals were compared to the noise signal far behind a perfect reflector (tip of guiding catheter).

Results: RF signals had high amplitude (>1000, arbitrary units) for the brightest Ca echoes. Noise amplitude was ~10. More than 80% of the ROIs within the acoustic shadowing were classified as signal of very low amplitude; however, a coherent periodic pattern between successive scan lines and a slight signal increase in the region of adventitia indicated that these ROIs contained not only noise, but also reflected ultrasound waves. (Figure) However, the possibility of secondary echoes and reverberation against the calcium could not be excluded. In 20% of the ROIs, there was only noise, without any coherent pattern, coded as fibrofatty tissue (light green) by VH.

Conclusion: Although there are coherent RF signals within zones of acoustic shadowing, these are low amplitude signals close to the noise level. Therefore, the accuracy and specificity of the VH plaque characterization algorithm in these regions requires further specific histological validation.
Randomized Evaluation of the Effect of Thrombus Aspiration by two different Thrombectomy devices on Myocardial Blush during Primary PCI

Gennaro Santella, Massimo Mancone, Riccardo Colantonio, Giulia Conti, Angelo Di Roma, Francesco Fedele, Dept.of Cardiovascular Sciences-Policlinico Umberto I, Rome, Italy

Background: In STEMI pts impairment of microcirculatory function is a negative independent predictor of myocardial infarction recovery. Compared with conventional stenting pretreatment with thrombectomy during primary PCI improves the parameters of myocardial tissue perfusion reducing the incidence of left ventricular remodelling at 6 months. In the present single-center, prospective randomized study we sought to evaluate the safety and efficacy of two different manual thrombectomy devices (Over-Invatec® and Export-Medtronic®) in STEMI patients undergoing to primary angioplasty.

Methods: We randomized 103 pts (mean age 64.3±10.2, 85 male) referred to our Hospital with STEMI in order to undergo primary PCI (<9 hours from symptoms onset), to Invatec (n=52) (I) and Export (n=51) (E) devices. The primary end points of the study were the comparison of TIMI ≥ II post thrombectomy, thrombus score (TS) ≤ 1, MBG ≥ 2 and ST-segment resolution (STFR): 70% post-stenting, between patients randomized to I or to E. Secondary end points were peak of creatine kinase-MB and direct stenting.

Results: No differences on baseline, clinical and angiographic preprocedural findings were observed between the two groups. Presence of an intracoronary thrombus at basal angiography was observed in all pts. (Pre-thrombectomy TS 3.57±0.66 (I) vs. 3.65±0.72 (I) =NS). At baseline TIMI 0 flow was found in 71.1%(I) vs 82.3%(E), and TIMI I 29.9%(I) vs 17.7%(E) =NS post-procedurally. After thrombectomy, we observed a TIMI II flow in 38.6%(I) vs 19.6%(E) p=NS). TIMI III was 30.7%(I) vs 72.5%(E) (p=0.0017). Patients treated with E had a highly significant reduction in the culprit artery thrombus burden (12.7±5.8 vs 2.15±0.75 (I) >0.001). The patients enrolled in E group had a significantly higher incidence of TS 1 post-thrombectomy (40.9±21.65 E vs 13.3±7.7(I) p=0.001). No difference was observed between two groups in postprocedural MBG and STFR no difference were observed in the secondary endpoints.

Conclusions: The procedural and clinical final result is identical but a pretreatment with the Export provides greater epicardial flow in STEMI patients, suggesting that this thrombectomy device could remove more thrombotic burden.

A Prospective Randomized Antiplatelet Trial Of Cilostazol Versus Clopidogrel In Patients With Diabetic Patients Who Underwent Drug Eluting Stent Implantation

Youngae Ahn, Myung Ho Jeong, Tae Hoon Ahn, Chang-Gyu Park, Jong Hyn Kim, In-Ho Chae, Seung Ho Hur, Jang Ho Bae, Seok Kyu Oh, Chonnam National University Hospital, Gwangju, South Korea

Background: Previous studies have shown that cilostazol not only prevent subacute stent thrombosis, but also have positive effect in the prevention of restenosis in bare stent. However, the effect of cilostazol on restenosis after successful deployment of drug eluting stent (DES) in patients with diabetes mellitus was not evaluated. The prospective randomized trial was designed for this purpose.

Methods: A total of 320 patients at 8 clinical sites were included. The patients who underwent successful stenting were randomized to aspirin (100 mg/day) and cilostazol (200 mg/day) group (n=160, 60.1±9.8 years old) vs. aspirin and clopidogrel (75mg/day) (group II, n=160, 62.8±8.9 years old) after one month of aspirin, cilostazol, and clopidogrel group (p=NS).

Results: Baseline patient characteristics were not different between the groups. The type of DES implanted was different between the groups. There were no differences in angiographic and procedural characteristics between the groups. Acute (within 24 hours) and subacute (from 24 hours to 30 days) stent thrombosis were not observed. Late stent (>30 days) thrombosis by angiographic evidence were observed in two patients in both groups. There were no differences in bleeding, myocardial infarction, rehospitalization, or death between the groups during 1-year follow-up time. The follow-up quantitative coronary angiography (mean time = 6.7±1.2 months) was performed in 154 patients until now. The angiographic in-stent restenosis occurred in 5.3% of patients in cilostazol group and in 13.3% of patients in clopidogrel group (p=0.03). Follow-up minimum lumen diameter were 2.84±0.56 mm in cilostazol group and 2.68±0.61 mm in clopidogrel group (p=NS). Late lumen loss were 0.32±0.18 mm in cilostazol group and 0.37±0.31 mm in clopidogrel group (p=NS)

Conclusions: Our results demonstrated that the effects of combination therapy with aspirin and cilostazol for the prevention of restenosis were compatible or superior to those of aspirin and clopidogrel.

Rescue Angioplasty after Failed Fibrinolysis for Acute Myocardial Infarction: Predictors of a Failed Procedure and One Year Mortality

Babu Kunadig, Andrew P. Thornley, Kunadinan Vijayalakshmi, Joel Dunning, Andrew GC Sutton, Douglas F. Mui, Robert A. Wright, James A. Hall, Mark A. de Belder, The James Cook University Hospital, Middlesbrough, United Kingdom

Background: Rescue angioplasty (rPCl) for failed fibrinolysis is associated with a low mortality if successful, but a high mortality if it fails. The latter may reflect a high-risk group or harm in some patients. Predictors of success or failure of rPCI may aid selection of patients to be treated.

Methods: Unselected patients referred for PCI from March 1994 to March 2005 were studied to determine the predictors of a failed procedure and 1 yr mortality.

Results: Of 440 pts undergoing emergency coronary angiography for failed fibrinolysis (1 yr mortality 18%), 101 had TIMI flow grade (TFG) 3 in the infarct related vessel (IRV). rPCI was attempted in 318/339 patients with >TFG 3 flow but not in 21 patients [angiography produced TFG 3 (n = 7) or unsuitable anatomy (n = 14)]. Of the rPCI cohort, 77% had a successful procedure (no in-lab death or emergency CABG and TFG 3 in the IRV); rPCI failed in 23%, 1 yr mortality rates for successful and failed rPCI were 14% and 43% respectively. Patients with failed rPCI were older and more likely to be diabetic, have anterior MI, be inter-hospital transfers, be in cardiogenic shock and less likely to be a current smoker. Shock was the only independent predictor of failed rPCI. Age group >75 yrs, shock and final TFG < 3 were independent predictors of 1 yr mortality.

Conclusions: Cardiogenic shock is an independent predictor of a failed rPCI. Age group >75 yrs and shock were the only independent clinical predictors of 1 yr mortality. These variables may help select patients for a strategy of rPCI.

Independent predictors of 1yr mortality after rPCI

E-POTER Session 915

Monday, March 26, 2007, 3:00 p.m.-4:00 p.m.


915-210  
**Angiographic Presentation of Stent Thrombosis in the Drug-Eluting Stent Era**  
Gregory Mishkel, Anna Moore, Christopher Slater, Marc Shelton, Prairie Heart Institute, Springfield, IL, Prairie Education & Research Cooperative, Springfield, IL  

**Background:** Whether or not implantation of drug eluting stents (DES) is associated with an increased incidence of stent thrombosis (ST) compared to bare metal stents (BMS) remains to be proven. We sought to evaluate the clinical presentation and outcomes of ST at our institution in the DES era.  

**Methods:** We retrospectively identified all patients who received a DES at our single center tertiary care center between 5/1/03 - 7/1/06. Clinical follow-up is routinely collected at 6 months, 1 year and annually thereafter. Time to ST was categorized as acute (AST; <24 hrs), subacute (SST; 24 hrs - 30 days), late (LST; 1-6 months) or very late (VLST; >6 months).  

**Results:** During our study period, a total of 10848 (10556 DES, 792 BMS) stents were implanted in 8601 patients (10113 lesions). DES distribution was 81% sirolimus and 19% paclitaxel. A total of 351 events were recorded in follow-up, 41 patients (42 lesions) presented to the cath lab with ST. Prior to discharge, ST adverse events included: 4 deaths, 1 per-procedural MI, 1 acute renal failure and 1 vascular bleed.  

**Conclusions:** From a cath lab perspective, ST occurs in <1% of DES patients. Furthermore, VLST may also occur in BMS and not all ST are associated with STEMI. Previous studies have shown that fluctuations in pulse wave amplitude (PWA) may predict coronary artery disease (CAD). Recently, we introduced a noninvasive parameter, respiratory modulation response (RMR), derived from spectral analysis of PWA, during controlled breathing at 0.1Hz. We evaluated RMR as an indicator of coronary artery disease.  

**Methods:** RMR was calculated as respiratory peak area divided by total peak area of the pulse wave spectrum. RMR results of 124 consecutive pts (mean age 63±12 years, 81% male) referred for coronary angiography were compared with their angiography results. Patients undergoing PCI or CABG were classified as having significant CAD. RMR was analyzed after baseline 20 secs spontaneous breathing, followed by 70 secs of guided breathing at 0.1Hz. The test was repeated post procedure in 93 pts.  

**Results:** RMR was significantly lower in pts with significant CAD (n=85) vs. pts with nonsignificant CAD (n=39) (18±20 vs. 39±16, P<0.001). The improvement in post procedure RMR was significantly higher in pts undergoing successful PCI compared to pts undergoing diagnostic catheterization only (25±24 vs. 0±18, P<0.001). RMR was lowest at the subgroup of pts with recent MI (8±1 vs. 27±1, P<0.001). By using a receiver operating characteristic analysis, we identified an RMR<30% (sensitivity 0.75, specificity 0.85) to be the optimal cutoff value for predicting significant CAD.  

**Conclusions:** The RMR is a novel noninvasive parameter for the physiologic assessment of significant CAD.
J. D. Haack, K. T. Koch, J. P. Henriques, A. C. Van der Wal, R. J. Van der Schaaf, J. G. Tijsen, G. Sutsh, R. J. De Winter, Academic Medical Center, Amsterdam, The Netherlands

**Background:** Distal embolization may occur during recanalization of thrombotic coronary occlusion, leading to poor results during PCI. The Proxis device (St. Jude Medical, St. Paul, Minnesota), a novel proximal embolic protection system that completely blocks antegrade flow during PCI, may prevent this complication and thus improve outcome.

**Methods:** Between February 2004 and October 2005, 174 patients with STEMI underwent primary PCI with combined embolic protection and thrombectomy. The Proxis device consists of a short flexible catheter attached to a helix-type catheter shaft, with a short circumferential balloon at the distal tip. This 8 or 7 French guiding catheter compatible device was advanced just proximal of the occlusion and the balloon at the tip of the Proxis was inflated. The wire-crossing of the occlusion and balloon dilatation/stenting was carried out under total proximal blockage of the vessel. After withdrawal of dilatation/stent-balloons, aspiration of the stagnant column was performed and continued when coronary flow was restored during deflation of Proxis. Temporary proximal vessel occlusions and aspirations were repeated during PCI. Procedural success and angiographic recovery parameters (TIMI and MBG), ST-segment elevation resolution (STRES) and the retrieved embolic material were analysed. Follow-up of MACCE was collected until 1 year after PCI.

**Results:** The Proxis device was used in all 174 patients during primary PCI. 96% of patients had TIMI-3 flow; 3% had TIMI-2 flow, 1% had TIMI-1 flow and MBG-2B was present in 97% of patients. The mean immediate STRES was 61.7±24; immediate STRES > 50% was in 75% and > 70% in 43% of patients. The mean STRES at 1 hour was 75.3±19; STRES > 50% in 91% and > 70% in 68% of patients. Debris was retrieved from 77% of patients. The 30-day, 6-months and 1-year cumulative MACCE-rate was 4, 9.1 and 10.3%.

**Conclusions:** The Proxis® is feasible and safe in the setting of primary PCI. The results suggest that this device is effective for aspiration of embolic material during PCI. Moreover, angiographic and myocardial recovery with Proxis® are excellent. Randomized trials are needed to prove whether these observations can be reproduced on a larger scale.

916-209

**Impact of Glycoprotein Ib/IIa Inhibitors on Outcomes of Diabetic Patients Undergoing Percutaneous Coronary Interventions with Sirolimus-Eluting Stents**

Eugenia Nikoloudi, David R. Holmes, Roxana Mehran, George Dangas, Eric Schampaert, Marie-Claude Morice, Joachim Schofer, J. Eduardo Sousa, Dennis Donnhofer, Jeffrey W. Moses, Martin B. Leon, Columbia University Medical Center, New York, NY, The Cardiovascular Research Foundation, New York, NY

**Background:** There has been ongoing debate whether glycoprotein (GP) Ib/IIa inhibitors improve prognosis of patients with diabetes mellitus treated with percutaneous coronary intervention (PCI). We assessed the outcomes in diabetic patients undergoing PCI using sirolimus-eluting stents (SES) as a function of treatment with GP Ib/IIa inhibitors.

**Methods and Results:** Of 551 diabetic patients treated with a SES in 9 trials (RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS, REALITY, SVELTE, DIRECT, SIRIUS 2.25, and SIRIUS 4.0), 187 patients (33.9%) were administered GP Ib/IIa inhibitors during PCI. In the entire cohort, GP Ib/IIa blockade was associated with lower rates of myocardial infarction (MI) at 30 days (1.1% vs. 3.3%, P=0.12) and 1 year (1.1% vs. 4.7%, P=0.04) and composite endpoint of cardiac death/MI at 1 year (2.2% vs. 6.2%, P=0.05). Benefit from GP Ib/IIa inhibitors was confined to 128 insulin-treated diabetics who had remarkable reduction in MI and cardiac death/MI at 1-year (Figure). There were no significant differences in outcomes as a function of GP Ib/IIa blockade in diabetics not treated with insulin.

**Conclusion:** In this analysis, 1-year outcomes of insulin-requiring diabetic patients undergoing PCI with SES were considerably improved with adjunctive GP Ib/IIa inhibitors by decreasing the rates of MI and composite endpoint of cardiac death/MI.
Are Drug-Eluting Stents Superior to Bare Metal Stents in Large Coronary Arteries?


Background: The benefit of drug-eluting stents (DES) over bare metal stents (BMS) is driven primarily by restenosis, especially in high-risk patients and those with small (<3.0mm) coronary vessels; however, they are associated with increased cost and the need for prolonged antiplatelet therapy. This study aimed to investigate whether DES remain advantageous in large coronary vessels (>3.5mm).

Methods: 233 patients undergoing single vessel percutaneous coronary intervention (PCI) in vessels >3.5mm with DES were compared to 233 propensity-matched patients with similarly sized vessels undergoing PCI with BMS. Patients were followed for up to 1-year with respect to major adverse cardiovascular events (MACE: Death, myocardial infarction, and target lesion revascularization (TLR).

Results: Baseline characteristics of these groups were similar. At 1-year, overall cardiac events were low and comparable between the two groups. Overall MACE occurred in 7.7% of BMS patients and 8.5% of DES patients (p=0.80). TLR occurred in 3.5% of BMS patients and 3.4% of DES patients (p=1.00). Death and Q-wave myocardial infarction occurred in 4.2% in the BMS patients and 5.7% in the DES patients (p=0.70). No subacute or late thrombosis occurred in either group.

Conclusions: In patients with large coronary vessels (>3.5mm), BMS perform as well as DES regarding both clinical outcomes and TLR. As DES offer no advantage to BMS in this setting, BMS should be the treatment of choice for patients with large coronary vessels.
316-214

Drug Eluting Stents in the Treatment of Saphenous Vein Graft Disease: Poor Outcome in Diffusely Diseased Grafts

Nicholas J Ruggiero, II, Stuart Gould, Deborah DeLugau, Heath Saltzman, Abhijit DasGupta, David L. Fischman, Paul Walinsky, J. David Ogby, Michael Savage, Thomas Jefferson University Hospital, Philadelphia, PA

Background: Although drug eluting stents (DES) have been demonstrated to be superior to bare metal stents in native coronary vessels, there is a paucity of data defining the long-term outcome of DES in saphenous vein grafts (SVG). The goal of this study was to evaluate the outcome of DES in diseased SVG.

Methods: 70 consecutive patients (75 SVG) treated with DES were evaluated. Procedural outcomes and major adverse cardiac events (MACE) were assessed at a mean follow-up of 17 +/- 9 months. MACE was defined as death, MI, stent thrombosis, or target vessel revascularization (TVR).

Results: The study population consisted of 61 men and 9 women with a mean age of 70 +/- 8 years. 28 (40%) patients had diabetes, 43 (61%) patients had an acute coronary syndrome. Mean SVG age was 12 +/- 2 years. Diffuse disease (defined as >30 mm of disease or >3 lesions in 1 vessel) was present in 29 grafts (39%). A total of 94 lesions were treated with 114 stents: 104 (91%) Cypher and 10 (9%) Taxus. Total stent length was 31 +/- 5 mm. Distal protection was utilized in 65% of interventions. PCI was successful in all patients, with no peri-procedural deaths. CABG or stent thrombosis. There was a single acute non-Q wave MI (1.3%). At 1 year, actuarial TVR free survival was 84% in all patients. TVR free survival was 97% in focal disease versus 64% in diffuse disease (p <0.01). Freedom from any MACE is shown in the Figure.

Conclusions: In contrast to the excellent results achieved with focal SVG disease, the long-term outcome of PCI in diffuse SVG disease remains poor despite DES.

316-215

Optimal Platelet Inhibition in Patients undergoing PCI: Data from the Multicenter Registry of High-Risk Percutaneous Coronary Intervention and Adequate Platelet Inhibition (MR PCI) Study

H. M. Mardikar, M. S. Hiramath, David J. Mollohen, Ronny Mathew, Rangolee Aroa, Dhananjay Deo, J. S. Hiremath, Niteen V. Deshpande, Aziz Khan, Jacob Joseph, Debrata Mukhejee, Spandan Heart Institute, Nagpur, India, University of Kentucky, Lexington, KY

Background: The primary objective was to test several antplatelet regimens in elective high-risk PCI comparing different combinations of IV (GP IIb/IIIa inhibitors) and oral (thienopyridine loading) antiplatelet agents. 

Methods: Patients were randomized to one of four groups: Group A: Tirofiban; Group B: Epitifibatide; Group C: Tirofiban+Clopidogrel 600 mg loading; and Group D: Epitifibatide+Clopidogrel 600 mg loading. All patients received a clopidogrel maintenance dose of 75mg daily.

Results: Inhibition of platelet aggregation (IPA) was calculated as (IPA at baseline - IPA at time t/Aggregation at baseline) X 100. A 600-mg loading dose of clopidogrel did not initially increase IPA with a trend towards higher IPA at 24 hours. There were no significant differences in in-hospital events among the different groups (p=0.55).

Conclusions: This is the first head-to-head study comparing high-dose tirofiban with double-bolus eptifibatide and demonstrates greater platelet inhibition with high-dose tirofiban. Clinical outcomes at 30-days are now being collected.

Inhibition of Platelet Aggregation (IPA) in the four Groups at 10-mins, 6-8 hours and at 24 hours

<table>
<thead>
<tr>
<th></th>
<th>Tirofiban</th>
<th>Tirofiban + 600 mg</th>
<th>Clopidogrel</th>
<th>Epitifibatide + 600 mg</th>
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<tr>
<td>IPA-10 min (%)</td>
<td>95.7 ± 5.2</td>
<td>89.4 ± 8.6</td>
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<td>IPA-6-8 hours (%)</td>
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<td>IPA-24 hours (%)</td>
<td>71.7 ± 2.4</td>
<td>84.7 ± 15.7</td>
<td>28.3 ± 28.6</td>
<td>31.1 ± 28.6</td>
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E-POSTER SESSION

917
ePoster Session 917

Tuesday, March 27, 2007, 9:00 a.m.-10:00 a.m.

912209

New Value of Intraseptal Collateral for Percutaneous Coronary Intervention to Chronic Total Occlusion With Retrograde Approach

quanzhu zheng, Osamu Katoh, Mitsuuyasu Terasihima, Tetsuo Matsubara, Etsuo Toyohashi, Yoshitsha Kinoshiba, Kenya Nasu, Takahiko Suzuki, Toyohashi Heart Center, Toyohashi, Japan

Background: Despite of improvement in percutaneous coronary intervention(PCI), techniques and materials, chronic total occlusion (CTO) recanalization success rate is still suboptimal. Recently we have developed a new PCI technique for CTO lesions at the proximal to mid LAD or RCA, we evaluated the anatomy of intraseptal collateral, identified the feasible channel for retrograde approach, and examined the frequency of such a feasible intraseptal collateral channel.

Methods: Angiographic retroprospective investigation was performed in 515 patients with consecutive CTO lesions at proximal to mid LAD or RCA eligible for PCI. The condition of septal collateral was evaluated based on the following collateral connection (CC) grades: grade CC 0: no continuous connection, grade CC 1: threadlike continuous connection, grade CC 2: threadlike continuous connection, grade CC 3: more than threadlike continuous connection.
At autopsy, no macroscopic or histological abnormalities were observed. There were no branch lesions. We explored the possibility of using a paired sample test to determine if there were any differences between the two groups.

**Background:**

Mechanical endovascular thrombectomy is effective for removing thrombus and reducing the risk of late stent thrombosis. The aim of this study was to assess the degree of strut apposition of the 2 most commonly used DESs: Cypher Select and Taxus Liberte using Optical Coherence Tomography (OCT).

**Methods:**

Twenty-one lesions in 18 patients immediately after implanting DESs (13 Cypher and 8 Taxus) for complex lesions (type B: 15 and C: 6) were included (mean age 65, 83% male). Distance of struts from the intima was assessed using OCT and adjusted for strut thickness of each stent type (160 μm for Cypher and 130 μm for Taxus). Stent apposition was defined as follows: embedded with more than half its thickness buried in the intima, protruding when apposed to the intima but not embedded and malapposed with no contact with the intima, and expressed as % of total struts examined.

**Results:**

No significant differences were detected in demographic, lesion, and procedural characteristics. Cypher Select stent struts were less likely to be embedded and more likely to be protruding or malapposed compared with Taxus Liberte stents (Figure). Cypher Select stent struts were less likely to be embedded and more likely to be protruding or malapposed compared with Taxus Liberte stents (Figure).

**Conclusions:**

The use of Taxus Liberte stent was associated with greater apposition and presence of side branches, respectively. Feasible intraseptal collateral for retrograde approach was defined as CC 1 or CC 2 with mild to moderate tortuosity and without branches. The incidence of significant carotid stenosis following head and neck irradiation ranges from 30% to 50%. Carotid endarterectomy (CEA) for radiation associated stenosis is often technically challenging and carries a high surgical risk. We sought to determine outcomes for carotid artery stenting (CAS) in patients with a prior history of neck irradiation (XRT).

**Methods:**

We evaluated 30-day outcomes of 823 patients who underwent CAS between Feb 1998 and Aug 2005 at our institution, according to whether they had a history of neck irradiation.

**Results:**

This cohort contained 62 patients with a history of XRT. Patients with a history of XRT were younger (67 vs. 71, p=0.008) and less likely to have diabetes mellitus, chronic renal failure, peripheral arterial disease, or hypertension. There was no difference in the groups with respect to contralateral occlusion, chronic obstructive pulmonary disease, or history of tobacco use. The 30-day incidence of stroke was 1.6% in patients with a history of XRT compared to 2.5% in those without (p=0.67). The composite endpoint of death, MI, or stroke was 4.8% for patients with a history of XRT compared to 6.4% for patients without (p=0.62). On multivariate analysis, a history of XRT was not an independent predictor of major adverse events (OR 0.97, 95% CI 0.28-3.39, p=0.97). In long term follow-up, there was a trend for higher target vessel revascularization rates in patients with a history of XRT (3.23% vs. 1.31%, p=0.23).

**Conclusion:**

CAS is safe and efficacious for treatment of carotid artery stenosis in patients with a history of XRT. We found no significant difference in the risk factors of restenosis that are associated with angioscopy and OCT.

**Background:**

At risk patients with diabetes mellitus (DM), hypertension, and hypercholesterolemia. Patients with XRT were less likely to have the use of embolic protection devices (EPD) (51% vs. 68%, p<0.009). There was no difference in the groups with respect to contralateral occlusion, chronic obstructive pulmonary disease, or history of tobacco use. The 30-day incidence of stroke was 1.6% in patients with a history of XRT compared to 2.5% in those without (p=0.67). The composite endpoint of death, MI, or stroke was 4.8% for patients with a history of XRT compared to 6.4% for patients without (p=0.62). On multivariate analysis, a history of XRT was not an independent predictor of major adverse events (OR 0.97, 95% CI 0.28-3.39, p=0.97). In long term follow-up, there was a trend for higher target vessel revascularization rates in patients with a history of XRT (3.23% vs. 1.31%, p=0.23).

**Conclusion:**

CAS is safe and efficacious for treatment of carotid artery stenosis in patients with a history of XRT. We found no significant difference in the risk factors of restenosis that are associated with angioscopy and OCT.

**Background:**

Levels of endothelial progenitor cells (EPCs) expressing surface markers of endothelialization (i.e. CD34 and CD133) have been shown to relate to restenosis after percutaneous coronary intervention (PCI). No previous investigation, conversely, has investigated if restenosis is associated also with an abnormal neo-angiogenesis. Accordingly, we tested the hypothesis that higher level of CD105 expressing EPCs, that are the more powerful markers of neovascularization in malignancies, are also associated with the occurrence of restenosis after PCI.

**Methods:**

Out of the 569 patients who underwent PCI and had ≥1 bare metal stents in 2004, we selected 25 patients who had restenosis 8 months after PCI (Gr. A) and compared them with 25 age- and sex-matched patients who had no restenosis at follow-up angiography (Gr.B). Peripheral blood samples were drawn before PCI in all patients. FACScalibur flow-cytometer was used for EPCs assay and absolute number of mononuclear cells, as well as of CD34+, CD45+, CD105+, and CD133+ cells were evaluated.

**Results:**

Comparison of the two groups did not show any difference in risk factors, cardiac function, extension of coronary artery disease, and pharmacologic treatment. Also, there were no differences in treated vessel, quantitative coronary angiography data and procedural characteristics. Flow cytometry showed that the two groups had similar absolute numbers of mononuclear cells (8.8±0.1 vs. 6.7±0.2 × 10³/mL, NS). Compared with Gr.B, Gr.A patients showed significantly lower absolute numbers of CD34+ (7.4±0.3 vs. 3.2±0.4 × 10³/mL, p=0.01), CD45+ (162±5 vs. 76±4 × 10³/mL, p=0.005), and CD133+ (0.8±0.2 vs. 0.3±0.2 × 10³/mL, p=0.001).

**Conclusions:**

The results of our study provide evidence that restenosis at 6-month
Despite Safety and Benefit, Distal Embolic Protection is Associated with Reduced Distal Embolic Protection Device Failure After Percutaneous Coronary Intervention (SVG-PCI): An Analysis of 19,562 Patients From the NCDRTM.

Sanjeev K. Mehta, Andrew D. Frutkin, Sarah Milford-Beland, Steven P. Marso, The Mid America Heart Institute, Kansas City, MO, Duke Cardiovascular Research Institute, Durham, NC

Background: Use of distal embolic protection devices (EPDs) in SVG lesions decreases the incidence of no reflow and post PCI myocardial infarction (MI), which are associated with late cardiac mortality. Previous studies estimate that 50% of SVG lesions meet ACC Class I indications for EPD deployment. However, the actual use of EPDs in SVG-PCI is unknown.

Methods: We determined whether an EPD was deployed in the 19,562 patients who underwent SVG-PCI at 452 centers in the ACC-NCDR from 1/1/2004 to 3/30/2006. Patients with ST elevation MI were excluded. Baseline characteristics and outcomes were compared between two groups, those who received EPD (EPD) and those who did not (No EPD).

Results: EPDs were used in 22% of patients who underwent SVG-PCI. EPDs were used more often in men (22.9% vs. women, 19.6%, P=0.001) and patients with increased age (P for trend <0.001), worse renal function (P for trend 0.001), and LVEF <45% (36% vs. 32%, P=0.008). SVG lesions with decreased pre-procedure TIMI flow (TIMI 0-2) were treated less often with EPDs (P=0.001). The prevalence of decreased post-procedure TIMI flow (TIMI 0-2) was less in the EPD group (2.7% vs. 4.2%, P=0.005) as was final TIMI flow (0.5% vs. 1.2%, P=0.001). EPD and No EPD groups had similar rates of in-hospital death (1.0% both groups, P=NS), vessel dissection (1.5% vs. 1.0%, P=NS), and perforation (0.5% vs. 0.4%, P=NS). Total fluoroscopic time was increased in the EPD group (P for trend <0.001).

Conclusions: Compared to estimates of SVG lesions suitable for EPD deployment, EPDs are currently underutilized in SVG-PCI. Although EPD use is associated with increased fluoroscopic time, EPD use appears safe and beneficial. To improve patient outcomes during SVG-PCI, efforts should be made to increase the use of EPDs.

Prevalence of Aspirin and Clopidogrel Resistance in Patients Undergoing Percutaneous Coronary Intervention: Comparison of Triple versus Dual Antiplatelet Therapy

Chi Yong Shin, Se-Jung Yoon, Sungha Park, Young-Guk Ko, Donghoon Choo, Yangsoo Jang, Nam-Joo Chung, Won-Heum Shin, Seung-Yun Cho, Yonsei Cardiovascular Center and Research Institute, Seoul, South Korea

Background: Triple antiplatelet therapy might have additional beneficial effect on prevention of thrombotic complication through additional suppression of platelet function in patients undergoing coronary stenting. We investigated the prevalence of aspirin and clopidogrel resistance in patients with dual antiplatelet and triple antiplatelet therapy after percutaneous coronary stenting.

Methods: A total 251 consecutive patient scheduled for elective coronary stenting was enrolled. Patients undergoing successful coronary stenting were divided into dual antiplatelet therapy (aspirin 100 mg plus clopidogrel 75 mg, group I, n = 86) and triple antiplatelet therapy (aspirin 100 mg plus clopidogrel 75 mg plus cilostazol 200 mg, group II, n=165) groups. At 2 weeks after coronary stenting, aspirin resistance was assayed with the VerifyNowTM-ASA and clopidogrel resistance with the VerifyNowTM-P2Y12 (Accumetrics, San Diego, California).

Results: Eight (9.3%) patients were resistant to aspirin and 13 (16%) to clopidogrel in group I. Seventeen (10.3%) were resistant to aspirin and 11 (7.0%) to clopidogrel in group II. The ARU was not different between groups (436±71 vs. 440±66, p=0.591), but the % inhibition was higher in group II (53±39.4 %, p=0.022) compared with that of group I (44.5±28.2 %). Conclusions: With triple antiplatelet therapy, the prevalence of aspirin resistance was not reduced, but that of clopidogrel resistance was significantly reduced compared with dual antiplatelet therapy.

Blood Transfusion is Independently Associated with Death in Acute Myocardial Infarction: Insights from APEX-AMI (Assessment of Pexelizumab in Acute Myocardial Infarction) Trial

William W. O’Neill, Paul W. Armstrong, Hussein R. Alkhalidi, Christian W. Hamm, David R. Holmes, Jr., Thomas G. Tovoar, Peter X. Adams, Frans J. van de Werf, Christopher B. Granger, for the APEX Investigators, University of Miami, Miami, FL, Duke Clinical Research Institute, Durham, NC

Background: Blood transfusion is related to worse outcome in acute coronary syndromes, but this relationship in acute myocardial infarction (MI) is controversial.

Methods: To define the relationship of transfusion and mortality in contemporary treatment of MI, we used the database of the APEX-AMI trial that enrolled 5,745 patients with ST elevation MI treated with primary PCI in 17 countries in 2004 to 2006.

Results: Mean age was 62 yrs, 23% were female. Pts were randomized to pexelizumab (an inhibitor of complement) or placebo. Six percent of pts received blood transfusion during admission, who had median length of hospital stay of 10 days compared to 6 days for non-transfused pts. Transfusion was most common in the US (10.7%) and least common in Europe (3.3%). Transfused pts were older (mean=68 yrs vs. 61 yrs), more commonly females (42% vs. 22%) and more commonly diabetic (23% vs. 15%) as compared to those who were not transfused. Using multivariable Cox regression (figure), transfused pts had a hazard ratio (HR) of 30-day death of 3.7 (95% CI 2.7 - 5.1; p<0.0001) compared to those who did not receive transfusion after adjustment for age, MI location, sex, and diabetes. Excluding 199 CABG pts (62% of whom received transfusion) from the analysis, the HR was 6.8.

Conclusions: In this acute MI population, transfusion was strongly and independently associated with death. Strategies to reduce bleeding and transfusion should be studied, as well as strategies to improve outcome in patients requiring transfusion.
Efficacy and Safety of Carotid Artery Stenting in Patients Scheduled for Cardiac Surgery
Use Zeymer, Ralf Zahn, Mathias Hochadel, Bernd Mark, Jochen Benges, for the ALKK-Study Group, Herzentrum Ludwigsafen, Ludwigsafen, Germany

Background - There is still debate about the optimal treatment strategy for a high grade carotid stenosis in patients scheduled for coronary artery bypass grafting or cardiac valve replacement procedures. Therefore we analysed data from a large registry to evaluate outcomes and complications of carotid artery stenting (CAS) in asymptomatic patients scheduled for cardiac surgery.

Methods - In a retrospective analysis of the prospective CAS registry of the ALKK all asymptomatic patients were included in this analysis. Concomitant diseases, procedural data and hospital complications were prospectively recorded and analyzed centrally.

Results - A total of 1096 patients fulfilled our inclusion criteria for this analysis. Mean age was 71 years, 74% were men, 31% diabetics, 5% had previous carotid endarterectomy. The median degree of the stenosis was 90%, CAS of the A. carotis interna was performed in 95% and of the A. carotis communis in 5% of the patients. The inhospital events are shown in the table.

Conclusions - In clinical practice in unselected patients with high grade carotid stenosis and planned cardiac surgery CAS is safe and effective. Therefore this approach is an alternative to combined or staged cardiac and carotid surgery. A randomized clinical trial seems warranted to determine the optimal strategy in these patients.

Should Bivalirudin be the Preferred Antithrombotic Agent of Choice During Elective or Urgent Percutaneous Coronary Intervention? A Bayesian Analysis of REPLACE-2 and ACUITY Trials
Sanjay Kaul, Jayanta R. Das, George A. Diamond, Cedars-Sinai Medical Center, Los Angeles, CA

Background: A recent trial, ACUITY, concluded that bivalirudin (Bv) alone is noninferior to heparin/epifibatide (hep/epi) + glycoprotein IIb/IIIa inhibitor (GPI) in preventing ischemic complications in ACS patients undergoing early intervention.

Objective: To perform a Bayesian analysis of noninferiority (NI) with regards to efficacy (E) and efficacy + safety (E+S).

Methods: Evidence from ACUITY was integrated with prior data from REPLACE-2 trial to generate an updated posterior using the Bayes’ theorem. A conservative NI margin...
Conclusions: Despite the investigators claims to the contrary, we conclude that Bv has not been shown to be noninferior to hep+GPI with respect to efficacy using conservative interpretative criteria. These analyses are consistent with the FDA's conclusion regarding REPLACE-2 and call into question the enthusiastic claims for considering Bv as the antithrombotic  

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### ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction (STAT-MI) Trial

Vivek N Dhruva, Samir Abdelhadi, Ather Anis, William Gleckman, Hosseinali Shahidi, Samir Ahuja, Suzanne Atkin, Marc Klapholz, UMDNJ-New Jersey Medical School, Newark, NJ

**Background:** Studies have shown the benefit of early angioplasty in decreasing morbidity and mortality in ST-segment elevation myocardial infarction (STEMI). The use of wireless technology has helped to decrease door to balloon (D2B) times but has unrealized potential.

**Methods:** A fully automated wireless network that transmits ECGs simultaneously to Emergency Department (ED) and offsite cardiologists via smart phones was developed. This system is automatically activated through a combination of preconfigured bluetooth devices and pre-programmed receiving and transmitting stations. The network allows direct communication between the offsite cardiologist and EMS facilitating patient triage directly to the cath lab from the field. Demographic, laboratory and time interval data were prospectively collected and compared to prior 12-month data.

**Results:** From June to August 2006, 50 ECGs with suspected STEMI were transmitted via the STAT-MI network. Ten patients with confirmed STEMI were triaged to the cath lab. Cardiology notification was earlier and mean door to needle, first angiographic injection via the STAT-MI network. Ten patients with confirmed STEMI were triaged to the cath lab. Results: prospectively collected and compared to prior 12-month data.

**Conclusions:** Despite the investigators claims to the contrary, we conclude that Bv has not been shown to be noninferior to hep+GPI with respect to efficacy using conservative interpretative criteria. These analyses are consistent with the FDA’s conclusion regarding REPLACE-2 and call into question the enthusiastic claims for considering Bv as the antithrombotic agent of choice during elective urgent PCI.

### Platelet Activation and Deposition Patterns After Exposure to the Surface of Paclitaxel Eluting Stents: An In Vitro Flow Chamber Study

Carlo A. Malvar, Juan F. Granada, Matthew O'Steen, David Wallace-Bradley, Armando Tellez, Greg L. Kalliuza, Angela Bules, Albert E. Razner, Neal S. Kleinman, El I. Lev, The Methodist Hospital, Houston, TX

**Background:** Drug eluting stents (DES) are suspected of higher stent thrombosis risk than bare metal stents (BMS). We hypothesized that DES may increase platelet activation and deposition compared with bare metal stents (BMS). We, therefore, quantified platelet activation and deposition in a flow chamber model with DES vs. BMS.

**Methods:** Anticoagulated blood drawn from volunteers was circulated in a flow chamber at 10 m/min (tubing diameter 3 mm) for 60 min. Stents (3.0 mm) were deployed inside the tubing system - DES (Paclitaxel)(n= 19), BMS (Express)(n = 14) or no stent (Control group, n= 6). Blood was extracted at 0, 10, 30 and 60 min. Platelet activation was evaluated by flow cytometric detection of P-selectin expression, PAC-1 binding and platelet-monocyte complexes (PMC) formation. Following 60 min perfusion, stents were fixed and surface coverage by platelets was quantified by electron microscopy.

**Results:** PMC formation and PAC-1 binding increased after 60 min perfusion in the DES group but not the BMS or control groups. Levels of PMC and PAC-1 binding were higher after exposure to DES vs BMS (Table). There were no differences in P-selectin expression. Percentage of the stent surface covered by clusters of platelets was higher in the DES than BMS group (2.28±4.1% vs. 1.11±1.6%, P=0.024).

**Conclusions:** DES placement in an in vitro flow chamber is associated with higher platelet activation markers and increased deposition over the stent surface, compared with BMS.
### Platelet activation markers, expressed as % of baseline, in DES vs. BMS

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<th>BMS (% of baseline)</th>
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<tr>
<td>10 min</td>
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<td>PAC-1</td>
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### P-selectin DES (% of baseline)

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### P-selectin BMS (% of baseline)

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### 919-211 Initial Clinical Experience with Right Ventricular Endocardial Thermography in Transplanted and Corony Artery Disease Patients.

Athanasios Manginas, Elias Andreoudes, Evangelos Leontiadis, Petros Styakis, Peter A. Alivizatos, Dennis V. Cokkinos, Onassis Cardiac Surgery Center, Athens, Greece

**Background:** Invasive temperature measurement (thermography) has been previously used to detect increased thermal heterogeneity in vulnerable coronary atheromatous plaques. Intracavitary right ventricular (RV) endocardial thermography, however, has not yet been evaluated to assess temperature differences between transplanted and hearts with coronary disease. Aim: To examine the safety of RV endocardial thermography and to document differences between native and transplanted hearts.

**Methods:** Using a validated catheter with a tip thermometer connected to commercially available software, we measured temperature difference (ΔT) between contact RV endocardial septum temperature (ET) and circulating blood (BT), in 2 groups of patients. Group 1 consisted of 20 patients (17 males, aged 40±25.8 years) with an orthotopic heart transplantation (OHT) performed 563±95 days before the procedure, who underwent 52 RV thermography measurements immediately prior to endomyocardial biopsy. Group 2 included 16 patients (15 males, aged 40±25.8 years) with documented history of coronary artery disease (CAD), who underwent RV thermography before coronary angioplasty (16 procedures).

**Results:** No complications were noted during RV thermography. Three procedures in Group 1 were unsuccessful due to technical reasons. BTs were similar in both groups (36.87±0.67°C and 36.89±0.21°C in Group 1 and Group 2 respectively, p=0.89). ΔTs, however, were significantly lower in Group 1 compared to Group 2 (0.05±0.06°C vs 0.19±0.11°C respectively, p=0.002). Group 1 only 2 patients had documented mild cellular rejection.

**Conclusion:** RV thermography is safe and feasible using a dedicated commercial catheter. The right RV endocardium is significantly cooler compared to the native endocardium of patients with CAD. A possible relation to cardiac denervation or impaired subendocardial flow in transplanted hearts remains to be elucidated. The relation between temperature changes and rejection needs further evaluation with larger group of patients.

### 919-212 Feasibility and Safety of Drug Eluting Stent Implantation in The Treatment of Stenosis of Vertebrobasilar Arteries

Santhosh K.G. Koshy, Vijay K. Misra, University of Alabama at Birmingham, Birmingham, AL, Baylor College of Medicine, Houston, TX

**Background:** Despite widespread use of drug eluting stents (DES) in percutaneous coronary interventions, the feasibility of its use in vertebrobasilar and other cerebrovascular interventions is limited. Hence, we analyzed the feasibility and safety of DES implantation in the treatment of vertebral and basilar arterial stenoses.

**Methods:** This was a prospective single center study on patients who underwent DES implantation for vertebral and basilar arterial stenosis. Baseline and follow up data were collected on symptoms and signs during complete clinical examination of these patients. Procedure related events and complications were also collected in these patients.

**Results:** Out of a total of 156 consecutive patients (from 1999 to 2005) who underwent stent implantation for the vertebral or basilar arterial stenoses, 13 patients (mean age 66.5 years; 7 males and 6 females) were treated with DES (Sirolimus eluting) after percutaneous angioplasty. Eight patients were implanted with sirolimus eluting stent (SES) and five patients with paclitaxel eluting stent (PES). Of the 13 patients, 10 patients had documented mild to moderate atherosclerotic disease. All patients had documented history of ischemic attacks (TIA) in 8 patients, history of stroke in 4 patients and asymptomatic severe stenosis on non-invasive imaging in 1 patient. The stenosis was located in V1 segment of left vertebral artery (LVA) in 8 patients, V1 segment of right vertebral artery (RVA) in 1 patient, basilar artery in 2 patients and V4 segment of LVA and RVA in one patient each. Technical success was obtained in all patients and there were no inhospital neurological events or mortality (median hospital stay 1 day; range 1-2 days). One patient with LVA stent showed major dissection warranting stenting of V2 segment. Clinical follow up (mean 489 days; range 395 to 550 days) was available in 12 patients and none had recurrence of neurological symptoms or new deficits. At follow up, 11 patients were on clopidogrel and aspirin and one patient on ticlopidine.

**Conclusions:** To date, this is the first report on the feasibility and safety of drug eluting stent implantation in the treatment of vertebral/ basilar stenosis. Percutaneous drug eluting stent implantation for treatment of vertebral/ basilar stenosis is feasible and safe. However, long term safety of this strategy needs to be tested in a larger cohort.

### 919-213 Bifurcation Lesion Intervention with Cypher and Endeavour Drug Eluting Stents-A Comparison.

Gaurav Minscha, Rajesh Jindal, Praveen Agarwal, Sanjukt Kumar, Sanjeev Bharadwaj, Asseem Dhill, Madhukar Shah, Atul Mathur, Babir Singh, Suman Bhandari, T. S. Klier, Escorts heart institute and Research Centre, New Delhi, India

**Background:** Drug Eluting Stents (DES) have improved outcomes in patients undergoing coronary interventions including those with bifurcation lesions. Cypher and Endeavour stents are DESs but have fundamental differences in stent design including cell architecture and polymer apart from the drug coating.

**Method:** We randomized 110 patients with bifurcations lesions in a single artery to treatment with either Cypher (n= 55) or Endeavour (n= 55) stent. Side Branch (SB) intervention with kissing balloon or stenting was done at operator's discretion. The 2 groups were compared for procedural outcomes, inhospital complications and follow up at 30 days and 6 months.

**Results:** Baseline clinical and lesion characteristics were similar between the 2 groups. Diabetics constituted 32.7% in Cypher versus 36.6% in Endeavour arm (p=0.84). There was no difference in patients with baseline SB stenosis ≥ 70% between the 2 groups (49% versus 54.5%; p = 0.70). During the procedure, SB intervention was required more often in the Cypher arm (63.6% vs 36.3%; p = 0.008) because of worsening SB stenosis or reduced TIMI flow. Procedure time was more in the Cypher arm (60 ± 18 vs 45 ± 20 mins; p > 0.001). There was however no difference in the procedure success between the two groups (96.3% vs 98.1%; p = 1.00). There was no death or in hospital target vessel revascularisation (TVR) in either group. 9% patients in the Cypher arm versus 5.4% in the Endeavour arm had significant enzyme elevation following the procedure (p = 0.71). At 30 days, any patient in the Cypher arm versus 1 in the Endeavour arm had subacute thrombosis (p = 1.00). There was no difference in major adverse events in the two arms (1.8% vs 3.6%; p = 1.00) at 30 days. On follow up at 6 months there was no difference in TVR (1.8% vs 3.6%; p = 1.00 or composite major (7.2% vs 9.0%; p = 1.00) between the two groups.

**Conclusion:** Bifurcation lesion treatment with Cypher and Endeavour DESs are associated with good clinical outcomes at mid-term follow up. SB intervention is required more often with Cypher compared to Endeavour stent because of worsening of SB stenosis or TIMI flow. There is no difference in inhospital complications, procedural success and the clinical follow up at 30 days and 6 months.

### 919-214 Impact of Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent on the Outcome of Patients with Sirolimus-Eluting Stent Failure: Multicenter Registry in Asia

Sunaz Nakamura, Jiang-Ho Bae, Ye H. Cahyadi, Wasan Udayachalam, Dames Tresukosol, Sudarattama Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan

**Background and Purpose:** Sirolimus-eluting stent failure (restenosis after Sirolimus-eluting stent implantation: SES-F) remains challenging problem and optimal treatment has not been established.

**Methods:** A total of 308 patients with 396 SES-F lesions (male 71.4%, mean age 70.8%, LAD 45.1%, LCX 36.8%, RCA 18.7%, p = 0.5 vs 0.9%) were treated with SES (mean lesion length 25.9±12.2 mm, mean stent length 30.3±15.9 mm) and Paclitaxel-eluting stent (PES) (mean lesion length 28.8±11.9 mm, mean stent length 33.1±18.9 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.

<table>
<thead>
<tr>
<th>Number of patients/lesions</th>
<th>SES</th>
<th>PES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion/mortality (%)</td>
<td>156/198</td>
<td>152/161</td>
</tr>
<tr>
<td>Procedural success (%)</td>
<td>95.0%</td>
<td>95.0%</td>
</tr>
<tr>
<td>Minimum lumen diameter at 6 months (mm)</td>
<td>2.80±0.20</td>
<td>2.80±0.20</td>
</tr>
<tr>
<td>Restenosis (%)</td>
<td>5.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Target lesion recanalization (%)</td>
<td>7.5%</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

### 919-215 Association of Antiplaque and Anti thrombin Therapy With Ischemia on Holter Monitoring Following Percutaneous Coronary Intervention (PCI): A PROTECT TIMI 30 Analysis

C. Michael Gibson, Jacqueline L. Buros, Saumil Shah, Lauren Ciaglo, David Morrow, Benjamin Scirica, Peter H. Stone, Beth Israel Deaconess Medical Center, Boston, MA, Brigham & Women’s Hospital, Boston, MA

**Background:** While post PCI Holter ischemia has been associated with MI, the association of antiplaque & anti thrombin therapy (tP) with the magnitude & timing of ischemia on Holter monitoring post PCI has not been characterized.
**Direct Stenting is an Independent Predictor of 30-Day Survival in Unselected Patients Admitted for Acute Myocardial Infarction**

Philippe Gared, Thierry Leflèvre, Yves Louvard, Claude Pougès, Jean-Yves Le Tarnec, Alain Margenet, Thierry Unterseh, Jean-Claude Robart, Karim Tazourate, Pierre Dumas, Marie-Claude Morice, Institut Cardiovasculaire Paris Sud, Quincy, France

**Background**: Direct stenting (DS) has been shown to improve myocardial reflow by reducing the incidence and magnitude of post-ischemic myocardial injury.

**Objectives**: Between 1995 and 2005, a total of 2,300 pts were directly admitted to the cath-lab of our institute for acute MI and were treated by immediate PCI. In 1998, we have provided data from a randomized trial showing the benefit of DS in improving ST-segment resolution on ECG after immediate PCI for acute MI. Since 1998, DS has become routine in our practice. The objective of this work is to assess the benefit of DS in term of reduced mortality in AMI-patients.

**Methods and results**: A total of 2,300 patients presenting with acute MI were treated between 1995 and 2005. Their mean age was 62±14 and 78% were males. Infarct location was anterior in 45% and shock was present on admission in 11% of the pts. The mean time elapsed between chest pain onset and admission was 295±251 minutes and 22% of the pts were treated by prehospital lysis. Predictors of 30 day survival were by multivariate analysis as follows:

<table>
<thead>
<tr>
<th>Survival</th>
<th>Death</th>
<th>P</th>
<th>Variable</th>
<th>OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>81%</td>
<td>19%</td>
<td>&lt;0.0001</td>
<td>Age</td>
<td>1.03 (1.01-1.05)</td>
</tr>
<tr>
<td>2%</td>
<td>18%</td>
<td>&lt;0.0001</td>
<td>Resuscitated CA</td>
<td>2.09 (1.11-3.94)</td>
</tr>
<tr>
<td>8%</td>
<td>63%</td>
<td>&lt;0.0001</td>
<td>Killip 4</td>
<td>18.17 (11.28-29.27)</td>
</tr>
<tr>
<td>44%</td>
<td>53%</td>
<td>&lt;0.05</td>
<td>Anterior MI</td>
<td>1.00 (1.00-1.00)</td>
</tr>
<tr>
<td>23%</td>
<td>11%</td>
<td>&lt;0.0005</td>
<td>Pre-PCI TIMI-3</td>
<td>3.58 (0.37-0.91)</td>
</tr>
<tr>
<td>34%</td>
<td>13%</td>
<td>&lt;0.005</td>
<td>Direct stenting</td>
<td>5.89 (0.27-0.85)</td>
</tr>
</tbody>
</table>

**Conclusion**: Among classical variables, such as younger age, lower Killip class and final TIMI 3 flow, direct stenting is an independent predictors of 30 day survival in unselected pts treated by emergency PCI for acute MI.
Experience With the Self-Expanding 21 French Percutaneous CoreValve Aortic Valve Prosthesis in High-Risk and Inoperable Patients With Symptomatic Aortic Valve Stenosis

Eberhard Gruent, Jean-Claude Laborde, Ulrich Gerkenks, Raymond Carter, Patrick W. Semags, Peter De Jaegere, Lutz Bluelstedt, Gerhard Schuler, Carlos Ruiz, Raoul Biocan, HEI Heart Center Siegburg, Siegburg, Germany

Background: Percutaneous aortic valve replacement (PVAR) is an emerging, alternative to palliative medical therapy for high risk and non-surgical patients with severe aortic valve stenosis (AS). We report the experience of PVAR with the CoreValve Revalving™ system, 21 French generation 2, which evaluates a self-expanding porcine bioprosthesis within a nitinol frame.

Methods: Patients with symptomatic, severe (area < 0.6 cm²/m²) AS aged ≥80 y. and/or Logistic Euroscore [LES] ≥20% and/or ≥65 y. and severe comorbidities were enrolled. A multi-disciplinary approach involved general anesthesia, surgical peripheral arterial access and femoral vein-femoral artery cardiopulmonary bypass (CPB). Aortic balloon valvuloplasty was performed first, then retrograde 21 Fr Core/Valve PAVR.

Results: Since August 2005, a total of 60 patients (pts) (49 high-risk pts, LES ≥ 23.4 ± 14%, 11 inoperable pts, LES ≥ 31.6 ± 16%) were recruited; mean age: 80.9 ± 6.5 years, 41 females, mean aortic valve area: 0.64 ± 0.2 cm². Technical failure happened in 5 cases, two inability to cross the valve and three misplacements with immediate conversions to surgery. Immediate results by TEE in 55 successful procedures showed mean AVA: 1.63 ± 0.4 cm² and 45 pts with paravalvular leak grade 0 or 1. Overall in-hospital mortality was 8/60 pts, 4/11 in the inoperable patient subgroup and 4/49 (8%) in the high risk patient subgroup. Follow-up (mean 5.0 ± 2.5 months; 1:1) confirmed hemodynamic and functional improvements in all discharged PAVR cases.

Conclusions: Percutaneous aortic valve replacement with the 21 French self-expandable CoreValve prosthesis is feasible and safe. When successful, the procedure results in marked hemodynamic and clinical improvement and follow-up up to 18 months confirms sustained clinical and hemodynamic benefit.
Fractional Flow Reserve-Guided Side Branch Intervention Versus Conventional Intervention in Bifurcation Lesions: Comparison of Long-Term Clinical Outcomes

Bion Won Koo, Jung-Won Suh, Kwon-Hee Park, Hae-Young Lee, Hyun-Jai Kang, Young-Suk Cho, Woo-Young Chung, In-Ho Chae, Dong-Chul Hye, Hye-So Kim, Byung-Nee Oh, Young-Bae Park, Yeon-Sik Choi, Seoul National University Hospital, Seoul, South Korea.

Backgrounds: Angiographic evaluation overestimates the functional significance of jailed side branch (SB) lesions. We performed this study to assess the clinical outcomes of fractional flow reserve (FFR)-guided jailed SB intervention strategy.

Methods: Patients with de novo bifurcation lesions with SB diameter >2.0mm and SB lesion length <10mm were consecutively enrolled. Patients with unstable clinical condition, ST-elevation myocardial infarction (MI) at target lesion territory, depressed LV function, chronic total occlusion and renal dysfunction were excluded. In FFR group (n=110), jailed SB FFR <0.75 and side branch stenting was permitted only in cases of < TIMI 3 flow. Conventional intervention group (n=118) was selected from SINUH database with the same patients’ selection criteria. All lesions were treated with drug-eluting stents. Nine-month major adverse cardiac events (MACE: cardiac death, MI and target vessel revascularization (TVR)) and 2-year event free survival rate were evaluated.

Results: There were no clinical and angiographic differences between 2 groups. In FFR group, SB intervention was performed in 24 lesions among 26 lesions with FFR<0.75. Conventional group had more SB intervention (45% vs. 30%, p=0.02) and less post-procedural SB residual stenosis (60% vs. 74%, p=0.01) and had a tendency of more peri-procedural MI (12% vs. 7%, p=0.32) than FFR group. Within 9 months, there was no difference in TVR rate between 2 groups (FFR-group: 4.6%, Conventional group: 3.7%). There was no death or MI. After 9 month, late MACE occurred in 4 patients (2 ST elevation MI due to stent thrombosis, 2 non-ST elevation MI) of conventional group. However, there was no difference in 2 year event free survival rate between 2 groups.

Conclusion: FFR-guided SB intervention strategy seems to be feasible and effective in reducing unnecessary complex interventional procedures in bifurcation lesions.

11:30 a.m.

Favorable One-Year Outcome Following Drug-Eluting Stent Implantation in Non-Bifurcational Lesions Involving Unprotected Left Main Coronary Artery: A Multicenter Registry

Aldaie Chieffo, Seung Jung Park, Marco Valgimigli, Young Hak Kim, Imad Sheiban, Joost Daemen, Flavio Arnoldi, Choi Chwan Lee, Myung Ki Hong, Seong Wook Park, Nuccio Morici, Claudio Moretti, Patrik Serruys, Antonio Colombo, San Raffaele Scientific Institute, Milan, Italy.

Background: The presence of a lumen narrowing at the ostium and the body of an unprotected left main coronary artery (LMCA), which does not require bifurcation treatment, is a class I indication to surgical revascularization. The aim of the study was to assess the safety and mid-term efficacy of drug-eluting stent (DES) implantation in the ostium and/or body of unprotected LMCA stenosis.

Methods: All consecutive patients (pts) who had a stenosis in the ostium and/or the midshaft of an unprotected LMCA (not requiring the treatment of the bifurcation) electively treated, from April 2002 to May 2005, with PCI and sirolimus (SES, Cypher, Cordis, Johnson and Johnson Company, Warren, NJ) or paclitaxel (PES, Taxus, Boston Scientific, MA)-eluting stents in 5 Centres (San Raffaele Hospital and EMO Centro Cuore Columbus in Milan, San Giovanni Battista Hospital in Turin, Italy; Erasmus Medical Center-Thoraxcenter, in the Netherlands and Asan Medical Center, in Korea).

Results: One-hundred forty four patients were included: 105 were treated with SES and 39 with PES. Fifty-two patients had ostial LMCA stenosis, 34 in the body and 11 in the midshaft of an unprotected LMCA. There were no clinical and angiographic differences between the 2 groups. In SES group, SB intervention was performed in 24 lesions among 26 lesions with FFR<0.75. Conventional group had more SB intervention (45% vs. 30%, p=0.02) and less post-procedural SB residual stenosis (60% vs. 74%, p=0.01) and had a tendency of more peri-procedural MI (12% vs. 7%, p=0.32) than SES group. Within 9 months, there was no difference in TVR rate between 2 groups (SES-group: 4.6%, Conventional group: 3.7%). There was no death or MI. After 9 month, late MACE occurred in 4 patients (2 ST elevation MI due to stent thrombosis, 2 non-ST elevation MI) of conventional group. However, there was no difference in 2 year event free survival rate between 2 groups.

Conclusion: FFR-guided SB intervention strategy seems to be feasible and effective in reducing unnecessary complex interventional procedures in bifurcation lesions.

11:30 a.m.
Delayed presentation to emergency department and increased door-to-balloon both contributed to longer symptom-to-balloon.

Conclusions: In the largest prospective, randomized, clinical trial of primary PCI for STEMI, we demonstrated that longer symptom-to-balloon is associated with worse survival and lower rates of TIMI grade 3 flow. Health care systems should strive to minimize total ischemic time in STEMI patients before and after hospital arrival to improve outcomes.

2:00 p.m.

2804-7 Impact of Techniques to Reduce or Prevent Distal Embolization During Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction: Meta-Analysis of Randomized Clinical Trials

Scott R. Martin, Daniel R. Montelittle, Luis Gruber, David L. Brown, Stacy Brock University Medical Center, Stony Brook, NY

Background: Distal embolization during primary percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI) may limit recovery of left ventricular function, increase infarct size, and reduce survival. Thrombectomy and distal embolic protection devices employing filters or occlusive balloons have been developed to prevent or limit distal embolization during PCI for AMI. However, studies of these devices have yielded inconsistent results.

Methods: We conducted a meta-analysis of all randomized, controlled trials investigating thrombectomy or distal protection devices (T-DPD) during PCI for AMI. Angiographic, electrocardiographic and clinical endpoints were extracted from each study. A random effects model was used to combine the results from individual trials.

Results: The 17 studies randomized 1,036 patients to T-DPD and 1,048 to control. Follow-up ranged from in-hospital to 6 months. Acute (60-90-minutes) resolution of ST-segment elevations was enhanced by treatment with T-DPD (OR: 1.64, 95% CI, 1.15-2.34, P<0.006). However, thrombectomy was significantly more effective than distal protection devices at achieving acute ST-segment resolution (P=0.04). The risk of no-reflow was reduced by T-DPD treatment (OR, 0.37, 95% CI, 0.19-0.73, P=0.004) with no significant differences between patients presenting with thrombectomy or distal protection devices (P=0.31). Distal embolization was reduced by treatment with T-DPD (OR, 0.61, 95% CI, 0.36-1.04, P=0.08). However, a significant reduction in distal embolization was only achieved with thrombectomy devices (OR, 0.52, 95% CI, 0.28-0.95, P=0.034). The achievement of TIMI-3 flow or TIMI-3 blush was not significantly impacted by T-DPD. The risks of mortality (OR, 1.03, 95% CI, 0.82-1.17, P=0.90) or reinfection (OR, 0.72, 95% CI, 0.39-1.33, P=0.29) were not altered by the use of T-DPD.

Conclusions: The use of T-DPD during PCI for AMI results in improvement in acute ST-segment resolution and reduces no-reflow. Thrombectomy devices reduce the risk of distal embolization. However, these electrocardiographic and angiographic benefits do not translate into a reduction in mortality or reinfection.

1:25 p.m.

2804-9 Quality Improvement: Reducing Door-to-Balloon Times in Patients With ST Elevation Myocardial Infarction - The Penn State HVI Heart Alert Program

Steven M. Ettinger, Charles Chambers, Ian Gilchrist, Mark Kozak, Craig Lauder, Lawrence J. Siroky, Penn State Heart and Vascular Institute, Hershey, PA

Background: Primary PCI for ST-segment elevation MI is superior to fibrinolytic therapy. While recent ACC/AHA PCI guidelines recommend a door-to-balloon (D2B) time of <90 mins, we reviewed the National Registry of MI (NORMI) study of 100% of all PCI cases done in our hospital within the time period.

Methods: We reviewed a database containing >3500,000 patients from 1999 to 2003 to determine the D2B time. We compared the D2B time of the last 6 months of the year with the first 6 months of the year for a total of 12 months of data.

Results: Our D2B time was 89 mins. Since implementation of the Heart Alert (HA) program, our D2B time has decreased significantly. The HA program was implemented in September 2005, and has continued to improve our D2B time. The HA program includes a comprehensive guide for physicians and nurses. The guide is available in the ED and includes the following steps:

1. Identification of STEMI patients
2. Activation of the HA
3. Communication with the cath lab
4. Documentation of the process
5. Follow-up of the patient

Conclusions: The HA program has been successful in reducing our D2B time. We have also seen an increase in the number of patients treated with PCI, and a decrease in the number of patients treated with fibrinolysis. The HA program has been a valuable tool in improving our door-to-balloon time.

1:45 p.m.

2804-10 Differential Predictors for Subacute, Late, and Very Late Drug-Eluting Stent Thrombosis: Results From the Multicenter "ESTROFA" Study

Jose M. de la Trone Hernandez, Felipe Hernandez, Marcelos San Martin, Iñigo Lozano, Juan Sanchez, Armando Perez de Prado, Jose R Rumoros, Juan M Ruiz Nodar, Javier Rodriguez Collado, Joselia Mauri, Jose M Vazquez, Jose A Diarte, Jose M Hernandez, Jose R Lopez Minguiz, Eduardo Pinar, Fernando Alforno, ESTROFA group, Santander, Spain

Background: Late stent thrombosis (LST), specifically very LST (>6 months after procedure), is a serious complication of drug eluting stents (DES). The incidence and predictors of these events are not clearly elucidated. Moreover, these predictors could be different to those described for acute/subacute thrombosis (SAT).

Methods: We performed a registry involving 16 Spanish centers in order to collect detailed data regarding angiographically documented DES thrombosis. Results: From a total cohort of 11,000 patients treated with DES since June 2002, 136 cases presented angiographic evidence of stent thrombosis (1.23%). The ST were: 76 with a DES ST). We used conditional logistic regression accounting for the matched design to determine the association of type of stent and ST for early (<30 days), late (30-180 days) and very late periods (>180 days). We estimated crude odds ratios (OR) and OR adjusted for diabetes, antiplatelet treatment, aspirin or clopidogrel, current smoking, revascularization, atheroembolic, left ventricular ejection fraction, number of stents and total stent length. The adjusted OR for early and late ST showed no increased risk for the use of DES. However, for ST occurring later than 180 days, the use of DES was associated with a significantly higher risk compared with the use of BMS (figure).

Conclusions: DES have a similar risk of ST during the first 6 months after stent implantation, but a significantly higher risk of very late ST (>180 days) compared with BMS.
discontinuation. These same predictors were also found for very LST. implantation in STEMI (OR 6.2; 95%CI 3.2 -12; p<0.0001) and stent in left anterior descending artery (OR 3.6; 95%CI 1.7-7.3; p<0.001).

Conclusions: LST and very LST after DES implantation although not frequent are a rareity and may occur over a extended period of time after procedure. Many of the variables involved in SAF are not predictive for LST. DES implantation in a setting of STEMI, stent in left anterior descending artery and antiplatelet therapy cessation resulted strong predictors for these late events.

11:00 a.m.

2804-C7 Late Thrombosis in Drug-Eluting Stents: Meta-Analysis of All Published Case Reports.

Ramin Arasht, Ghazanfar Khadim, Robert S. Dieter, Medical College of Wisconsin, Milwaukee, WI

Background: Drug Eluting Stents (DES) have significantly reduced the incidence of instant restenosis observed with bare metal stents. Several cases of late stent thrombosis (LAST) have been reported with discontinuation of clopidogrel as the major risk factor. The current guidelines for DES recommend dual anti-platelet therapy for 3-6 months. The aim of this study was to review all published cases of LAST in DES to explore possible trends.

Methods: With the key words “drug eluting stents” medline search was used to identify all case reports of LAST in DES defined as angiographic stent thrombosis at least 30 days after deployment. We included cases from randomized trials, observational registry reports and letters to editor. If information of the timing from stent deployment to clinical event, vessel, stent diameter and length, and antiplatelet regimen at the time of event were available.

Results: Baseline characteristics (table 1) were similar in both groups. There was a striking association between cessation of dual anti-platelet therapy and the occurrence of LAST, with discontinuation of clopidogrel alone resulting in significant delay in time to event.

![Table](data:image/png;base64,iVBORw0KGgoAAAANSUhEUgAAAPoAAAD2CAYAAADZNfVaAAAgAElEQVR42uA1Q4Q45AgAwAAAAABgA7QAAAABJRU5ErkJggg)

Conclusion: We present the largest collection of cases of LAST in DES published to date. This data supports the need for dual anti-platelet therapy beyond the current guidelines. The optimal duration of dual anti-platelet therapy remains to be determined. Efforts should be made to maintain patients at least on aspirin during routine surgical procedures.

11:15 a.m.

2804-D8 Four-Year Clinical Follow-Up of the Research Registry

Joost Daemen, Hector Garcia-Garcia, Neville Kukreja, Yvette van Gestel, Ron van Domburg, Patrick Serruys, Erasmus MC - Thoraxcenter, Rotterdam, The Netherlands

Background: Sirolimus-Eluting Stents (SES) proved to effectively reduce restenosis and target lesion revascularization as compared to bare metal stents (BMS). To date, little is known about the long term safety and efficacy, in particular mortality and stent thrombosis, of SES after 4 years of follow-up in a "real world" patient population.

Methods: Since April 2002, a cohort of 508 consecutive patients treated exclusively with sirolimus-eluting stents, has been followed. Prior to this, from October 2001 to April 2002, 450 consecutive patients were treated with standard bare metal stents and form the control group. Four-year follow-up is still ongoing and already complete for 87.5% of our patients (mean 1440 days). We will be able to present the complete follow-up at the meeting.

Results: Patients treated with SES had significantly more multivessel disease and more type C lesions, furthermore more stents per patient were implanted. The history of prior myocardial infarction was higher in the BMS group. Diabetes was present in 15% of the BMS population versus 18% in the SES population. Preliminary cumulative survival percentages are 88.9% in BMS population versus 89.1% in the SES population (log rank p-value = 0.959) (Figure). Major Adverse Cardiac Event (MACE) rates will be presented at the meeting.

Conclusions: Our preliminary results show that after 4 years of follow-up the use of SES in an unselected patient population remains safe with comparable mortality rates as BMS.

11:30 a.m.

2804-11 Comparison of Sirolimus-Versus Paclitaxel-Eluting Stents in an Unselected Population With Coronary Artery Disease: Two-Year Results From the REWARDS Registry

Probal Roy, Ashesh N. Buch, Vikram Raya, Teruo Okabe, Tina L. Pinto Sliotow, Daniel H. Steinberg, Kimberly Smith, Zhenyi Xue, Natalie Gevorkian, Lowell L. Satler, Kenneth M. Kent, Augusto D. Pichard, Ron Wiksman, Washington Hospital Center, Washington, DC

Background: Superiority has been established for both sirolimus- (SES) and paclitaxel-eluting stents (PES) over bare metal stents. A true difference between the 2 drug-eluting stents (DES) remains uncertain. We report 2-year results of the REWARDS registry comparing SES vs. PES in an unselected population undergoing percutaneous coronary intervention.

Methods: Consecutive patients undergoing DES implantation were entered into the REWARDS registry. Demographic, clinical, procedural, and follow-up data were collected. The 1-year outcomes of 2766 patients and outcomes from 1 to 2 years of 894 patients were analyzed.

Results: Patients receiving SES were more likely to have a greater number of diseased vessels (p<0.001), ostial lesions (p<0.04), in-hospital complications (p<0.03), tibia/ischial inhibitor use (p<0.002), and longer stent lengths (p<0.001). PES patients had higher unstable angina (p<0.001), type C lesions (p<0.02) and number of stents implanted per patient (p<0.001). A significantly higher rate of stent thrombosis with SES at 1 year (p<0.034) was observed. There were no other significant outcome differences at 1 year and from 1 to 2 years (Table).

Conclusions: Both DES types prove to be efficacious in reducing repeat revascularization with no appreciable difference in MACE between the two. A higher rate of stent thrombosis was observed in the SES group at 1 year. Stent thrombosis continued to be reported between 1 and 2 years in both groups.

Table. Outcomes for SES vs. PES in an unselected population with CAD at 1yr and between 1 to 2 yrs

<table>
<thead>
<tr>
<th>Outcomes at 1yr</th>
<th>SES (n=1932)</th>
<th>PES (n=842)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR-MACE</td>
<td>17.3%</td>
<td>17.4%</td>
<td>0.92</td>
</tr>
<tr>
<td>Death</td>
<td>6.6%</td>
<td>6.4%</td>
<td>0.09</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>2.8%</td>
<td>3.3%</td>
<td>0.97</td>
</tr>
<tr>
<td>Stable Thrombosis</td>
<td>1.9%</td>
<td>1.8%</td>
<td>0.03</td>
</tr>
<tr>
<td>Outcomes 1-2yrs</td>
<td>SES (n=652)</td>
<td>PES (n=242)</td>
<td>p-value</td>
</tr>
<tr>
<td>TVR-MACE</td>
<td>13.0%</td>
<td>13.0%</td>
<td>0.12</td>
</tr>
<tr>
<td>Death</td>
<td>5.2%</td>
<td>5.3%</td>
<td>0.23</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.49</td>
</tr>
<tr>
<td>Late Stable Thrombosis</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.49</td>
</tr>
</tbody>
</table>
Two-Year Outcomes From the ENDEAVOR III Trial: A Randomized Trial of the Endovascular Zotarolimus-Eluting Stent Compared With the Cypher Sirolimus-Eluting Stent

Martin B. Leon, David E. Kandzari, Medtronic, Inc, Santa Rosa, CA

Background: ENDEAVOR III is a randomized, multicenter trial comparing angiographic and clinical outcomes among patients randomized to treatment with either the Endovascular Zotarolimus-eluting stent (ZEI) or Cypher Sirolimus-eluting stent (SES). Whether disparities in angiographic measures at 8 months between the two stents translated into differences in late (1, 2 and 1 year) clinical outcome is uncertain.

Methods: A total of 436 patients were randomized to treatment with either ZE (N=216) or SES (N=220) in a single-blinded fashion. Clinical outcomes of composite endpoints and the individual rates of death, myocardial infarction, angiographically-determined stent thrombosis and clinically-driven repeat target lesion (TLR) and target vessel revascularization (TVR) were prospectively evaluated at 1 and 2 years following the index procedure.

Results: No significant differences in baseline reference vessel diameter, lesion length or the presence of diabetes were observed between ZEIS and SES cohorts. Despite higher 8-month angiographic late lumen loss with ZEI, at 12 months, rates of major adverse events were identical in both groups (8.2%), and there were no significant differences in the individual endpoints of death, MI or clinically-driven TLR. Stent thrombosis did not occur in either group at 1 year. The 2-year clinical follow-up data will be available in March 2007.

Conclusion: Despite differences in angiographic outcome at 8 month follow-up, rates of clinically-driven TLR and major adverse events appear similar between patients treated with ZES and SES. Long-term (2 year) follow-up will clarify further not only safety with ZES but also whether early angiographic disparities translate into differences in late clinical restenosis.

Arterial Revascularization Therapies Study Part II - Sirolimus-Eluting Stents for the Treatment of Patients With Multivessel De Novo Coronary Artery Lesions: Three-Year Clinical Outcomes

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Background: The Arterial Revascularization Therapies Study (ARTSII) was a randomized multicenter trial of 1205 patients with multivessel disease (MVD), comparing surgery (ARTSI-CABG, n=605) with bare metal stenting (ARTSI-BMS, n=600) on clinical outcome and cost effectiveness. At 1 year, survival free from major adverse cardiac and cerebrovascular events (MACCE) was 87.8% in the ARTSII-CABG vs 73.8% in ARTSI-BMS, driven by a 17.2% difference in repeat revascularization. As the sirolimus stent (SES) has reduced restenosis compared to BMS, further evaluation of MVD stenting with SES is warranted to compare outcomes with the two ARTSII-arms, CABG and BMS.

Methods: ARTSII is a multicenter (n=45), non-randomized, stratified trial of 607 patients treated with SES. Primary aim is to compare the effectiveness of SES with ARTSII-CABG measured as MACCE-free survival at 1 year. Secondary objectives are MACCE at 1 and 6 months, 1, 3 and 5 years, quality of life and cost effectiveness.

Results: In ARTSII the number of diseased vessels was 2.5 ± 0.5 vs 2.3 ± 0.5 in ARTSI-CABG and 2.2 ± 0.5 in ARTSI-BMS. The number of treated lesions was 3.2 ± 1.1 (ARTSII) vs 2.6 ± 1.0 anastomosed segments (ARTSII-CABG) and 2.5 ± 1.0 treated lesions (ARTSII-BMS). Postprocedural CK-MB release > 5 x upper normal limit was observed in 28% of ARTSII patients vs 43% in ARTSI-BMS. The number of treated lesions was 3.2 ± 1.1 (ARTSII) vs 2.6 ± 1.0 anastomosed segments (ARTSII-CABG) and 2.5 ± 1.0 treated lesions (ARTSII-BMS). The number of lesions treated was 2.5 ± 1.2 in ARTSII vs 2.3 ± 1.1 in ARTSI-CABG and 2.2 ± 0.5 in ARTSI-BMS. The number of treated lesions was 3.2 ± 1.1 (ARTSII) vs 2.6 ± 1.0 anastomosed segments (ARTSII-CABG) and 2.5 ± 1.0 treated lesions (ARTSII-BMS). Postprocedural CK-MB release > 5 x upper normal limit was observed in 28% of ARTSII patients vs 43% in ARTSI-BMS.

Conclusions: 3-year clinical outcomes will be presented at the meeting.

Chronic Kidney Disease Is Associated With Increased Mortality, Bleeding, and Ischemic Events in Moderate and High-Risk Patients With Acute Coronary Syndromes: An ACUITY Substudy

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Background: Chronic Kidney Disease (CKD) is an important predictor of adverse outcomes in pts with ACS, but there are incomplete data on this association among patients undergoing an early invasive treatment strategy treated with current anti-thrombotic regimens.

Methods: The ACUITY trial randomized 13,819 moderate and high risk ACS pts undergoing early invasive management to bivalirudin (BIV) alone, BIV + glycoprotein IIb/IIIa inhibition, or heparin + GPI. Clinical outcomes were compared among pts with creatinine clearance <60 ml/min (low CrCl) vs. ≥ 60 ml/min (normal CrCl).

Results: Pts with low CrCl were older, more frequently presented with ST-segment deviation, and were in general higher risk. Patients with low CrCl were slightly less frequently treated with PCI (54.7% vs. 57.3% for normal CrCl, p=0.02), though CABG was performed in similar proportions (11.0% vs. 11.2%, p=NS). The rate of death/MI/unplanned revascularization/major bleeding was significantly higher among pts with low CrCl (17.5% vs. 9.8%, p<0.001), (Table) in univariable and fully adjusted multivariable analyses. Importantly, CKD was an independent predictor of 30-day mortality (OR=2.7, CI=1.9-3.9).

Conclusion: Despite an early invasive strategy with a high rate of revascularization in ACUITY, baseline low CrCl was independently associated with mortality, adverse ischemic outcomes, and hemorrhagic complications. One year outcomes will be available for presentation.
Prevention of Radiocontrast Medium Induced Nephropathy Using High-Dose Statin in Patients Undergoing Coronary Angiography: The PROMISS Trial - A Randomized Controlled Study

Sang Ho Je, Ron-Kwon Koo, Jin-Shik Park, Hyun-Jae Kang, Young-Seok Cho, Yong-Jin Kim, Woo-Young Chung, In-Ho Chae, Dong-Ju Choi, Dae-Won Sohn, Byung-Hoe Dh, Young-Bae Park, Yun-Shik Choi, Hye-Soo Kim, Hallym University Sacred Heart Hospital, Gyeonggido, South Korea, Seoul National University Hospital, Seoul, South Korea

Background: Oxidative stress caused by contrast media has been suggested for one mechanism of contrast induced nephropathy (CIN). The statin has been reported to have pleiotropic effects one of which may be derived from its antioxidant property. We investigated to determine whether statin has preventive effect for CIN in patients with renal insufficiency undergoing coronary angiography.

Methods: We conducted a prospective, randomized, double-blind, placebo-controlled, 2-center trial. A total of 247 consecutive patients with chronic renal insufficiency (calculated creatinine clearance ≤ 60mL/min or serum creatinine ≥ 1.1mg/dL) who underwent coronary angiography were enrolled. Half iso-tonic saline was given intravenously at a rate of 1ml/kg/hour at least for 12hours before and 12hours after administration of contrast agent to both groups. Only iso-osmolar contrast medium-iodixanol was used in coronary angiography. Serum creatinine (Scr) was measured on the day1 and day2 after coronary angiography. Patients were randomly assigned to simvastatin group (n=124, simvastatin 40mg orally twice daily before and on the day [2 days] of coronary angiography) or placebo (n=123).

Results: The primary end point was peak increase of Scr from baseline within two days after coronary angiography, and secondary end point was development of CIN defined as increase of either ≥ 25% or ≥ 0.5mg/dL in Scr, length of hospital stay, 30-day and 6-month clinical outcomes. There were no differences in demographic and procedural characteristics between two groups. The mean peak increase of Scr was not different between simvastatin and placebo group (0.002±0.16 vs 0.02±0.23mg/mL respectively, p=0.56). In the secondary endpoint, CIN occurred in 2.5% (3 of 118 patients) in simvastatin group and 3.4% (4 of 118 patients) in placebo (p=1.0). The length of hospital stay, in-hospital, 30-day and 6-month clinical event rates were not different between two groups.

Conclusions: Simvastatin which have antioxidant property does not prevent renal function deterioration after administration of contrast medium in patients with baseline renal insufficiency undergoing coronary angiography.

2:15 p.m.

Effects of Aspirin Dose on Ischemic Events and Bleeding After Percutaneous Coronary Intervention: Insights From the PCI-CURE Study

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Background: Percutaneous coronary intervention (PCI) trials in the stent era have universally used high dose ASA (≥200 mg) in combination with thienopyridines to prevent stent thrombosis and ischemic events. The objective was to explore the safety and efficacy of low (≤100 mg), intermediate (101-199 mg) and high (≥200 mg) dose ASA after PCI in non-ST elevation acute coronary syndromes (ACS).

Methods: In the CURE trial, 2688 patients with ACS undergoing PCI were stratified according to most commonly used ASA dose after randomization. The crude event rates for cardiovascular (CV) death, MI or stroke as well as major bleeding were evaluated for each ASA dose group. These data were adjusted, using a cox proportional hazard model, for age, gender, weight, other components of TIMI risk score, hypertension and clopidogrel/placebo use.

Results: The composite of CV death, MI or stroke was similar in all the ASA dose groups at 30 days and 8 months. The incidence of major bleeding was not significantly different between the groups at 30 days, but the rate of major bleeding was significantly increased with high dose of ASA at 8 months.

Conclusion: In this large observational analysis, of patients with ACS undergoing PCI, low dose ASA appeared to be as effective as high dose ASA in preventing recurrent cardiac events with no significant differences in bleeding within 30 days. Longer-term treatment with high dose ASA demonstrated a similar efficacy benefit but significantly higher bleeding when compared with low dose ASA.