To evaluate the frequency, severity, and clinical implication of the plaque
Remote ischemic preconditioning (remote IPC) is effective at attenuating
We used the POET
Twenty patients undergoing single vessel elective PCI had intraventricular
Coronary microvascular endothelial dysfunction can impede myocardial
The incidence of PP was similar in SES and PES. PP was not associated
Procedure related cTnI release ranged from <0.02 to 7.06 ng/mL. The incidence
PP were discovered at 18 sites (SES=5, PES=13, p=ns) in 17 stented
In the control group, the first coronary balloon occlusion did not significantly
High risk plaques demonstrate certain morphological characteristics
Methods: Eighteen patients with single vessel coronary artery disease awaiting PCI were
increased susceptibility to injury.
reperfusion injury. However, primary microvascular dysfunction may account for an
“no-reflow”. Traditionally this is believed to be secondary to an endothelial ischemia-
Background:
Cambridge, United Kingdom, Addenbrooke’s Hospital, Cambridge, United Kingdom
Seongin Oh, Byoung-Keuk Kim, Dong Woon Jeon, Joo-Young Yang, Woong Chil Kang, Taehoon Ahn, Jung-sun Kim, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, National Health Insurance Corporation Ilsan Hospital, Goyang, South Korea
Background: To evaluate the frequency, severity, and clinical implication of the plaque
Plaque Prolapse With Cypher and TAXUS Stents
Evaluated With Serial Intravascular Ultrasound Analysis
Seongin Oh, Byoung-Keuk Kim, Dong Woon Jeon, Joo-Young Yang, Woong Chil Kang, Taehoon Ahn, Jung-sun Kim, Young-Guk Ko, Donghoon Choi, Yangsoo Jang, National Health Insurance Corporation Ilsan Hospital, Goyang, South Korea
Background: To evaluate the frequency, severity, and clinical implication of the plaque
Remote Ischemic Preconditioning in Humans Does Not Attenuate Ischemic Left Ventricular Dysfunction, Measured Invasively During Coronary Artery Balloon Occlusion
Remote ischemic preconditioning (remote IPC) is effective at attenuating myocardial ischemia-reperfusion injury and necrosis but evidence of protection from ischemic left ventricular (LV) dysfunction and myocardial stunning is less convincing. We investigated if remote IPC could reduce ischemic left ventricular dysfunction in humans during coronary balloon occlusion.
Methods: Twenty patients undergoing single vessel elective PCI had intraventricular contractility indices measured by LV conductance catheter: ΔdP/dt max, ΔdP/dt min and Tau. Measurements were recorded after one minute of low-pressure coronary balloon occlusion and during recovery after balloon deflation, and then repeated again 30 minutes later. In 10 randomly selected patients, remote IPC was performed: 3 x 5-minute blood pressure cuff inflations to 200mmHg around the upper arm interspersed with 5-minute intervals of cuff deflation, in the intervening 30-minute period.
Results: In the control group, the first coronary balloon occlusion did not significantly attenuate the contractility changes seen during the second balloon occlusion (Figure A: ΔdP/dt min shown). Similarly, remote IPC administered after the first coronary occlusion did not reduce the ischemic LV dysfunction during subsequent coronary balloon occlusion for any of the three measured parameters of contractility (Figure B: ΔdP/dt min shown).
Conclusion: Remote IPC does not attenuate ischemic left ventricular dysfunction in Man.
Primary Coronary Microcirculatory Dysfunction Predicts Procedure-related Cardiac Troponin-I Release in Humans, After Elective Percutaneous Coronary Intervention
Stephen Hoole, Paul White, Patrick Heck, Cameron Densm, Sarah Clarke, Leonard Shapiro, Peter Schofield, Michael O’Sullivan, David Dutka, Papworth Hospital, Cambridge, United Kingdom, Addenbrooke’s Hospital, Cambridge, United Kingdom
Background: Coronary microvascular endothelial dysfunction can impede myocardial perfusion after percutaneous coronary intervention (PCI) - a phenomenon known as “no-reflow”. Traditionally this is believed to be secondary to an endothelial ischemia-reperfusion injury. However, primary microvascular dysfunction may account for an increased susceptibility to injury.
Method: Eighteen patients with single vessel coronary artery disease awaiting PCI were recruited. All were optimally medically treated and taking statins. Patients with diabetes were excluded. Simultaneous intracoronary distal pressure (Pd) and averaged peak velocity (APV), measured by Volcano® guide-wire, and central venous pressure (CVP) were recorded during successive low pressure balloon occlusions (BO1 and BO2), a high pressure balloon occlusion (POBA) and at stent implantation. Microvascular resistance (Rmicro) was calculated during coronary balloon occlusion: Rmicro = Pd (occl.) - CVP / APV (occl.). Serum cardiac troponin-I (cTnI) was measured at 24-hours. Mean microvascular resistance at each stage of PCI for cTnT tertiles were compared by one-way ANOVA.
Results: Procedure related cTnI release ranged from <0.02 to 7.06 ng/mL. The incidence of cTnI release after PCI was significantly associated with baseline microvascular resistance and this observation persisted on each successive balloon occlusion (Figure). Successive balloon occlusions did not increase microvascular resistance significantly (p = 0.82).
Conclusion: Pre-existing coronary microvascular dysfunction predicts procedure-related cTnI release and microvascular endothelial dysfunction does not appear to increase with successive PCI stages.
Correlation Between Morphological and Functional Characteristics of Culprit Lesions
Konstantinos Toutouzas, Virginia Markou, Sophia Vaina, Maria Drakopoulou, Manolis Vavouranakis, Elli Stefanidi, Christodoulos Stefanidis, 1st Department of Cardiology, University of Athens, Athens, Greece
Background: High risk plaques demonstrate certain morphological characteristics and increased local temperature. In this study we investigated the possible correlation between the IVUS morphological and the Thermography functional characteristics of
We enrolled 48 pts with ACS and 33 with CSA, undergoing percutaneous coronary intervention, matched for demographic and angiographic characteristics. We defined the ratio of lesion to reference external elastic membrane area as positive (pRi>1) or negative (nRi<1) remodeling index. Temperature difference (ΔT) between the culprit plaque and the proximal vessel wall was also measured.

Results: ΔT was greater in pts with ACS than CSA (0.08±0.03 vs 0.04±0.02°C, p<0.01). Similar was pRi (1.15±0.18 vs 0.90±0.11, p<0.01). ΔT was greater in pts with pRi than nRi (0.07±0.03 vs 0.04±0.02°C, p<0.01). Among pts with pRi, those with ACS had increased ΔT than pts with CSA (0.08±0.03 vs 0.04±0.02°C, p<0.01, figure). Similar were the findings in pts with nRi (0.05±0.03 vs 0.04±0.02°C, p<0.05, figure). There was a correlation between ΔT and Ri (p<0.01, r=0.59).

Conclusion: This study demonstrated a correlation of IVUS morphological and Thermography functional characteristics in culprit lesions. More specifically these results provide new insights regarding the pathogenesis and risk stratification of pts with ACS.

The Relationship Between Multiple Biomarkers and Coronary Plaque Vulnerability by Use of Optical Coherence Tomography

Duk-Woo Park, Myeong-Ki Hong, Jong-Pil Park, Jae Hyung Park, Jeong-Woo Lee, Won-Jang Kim, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Jae-Joong Kim, Seong-Wook Park, Seung-Jung Park, Asian Medical Center, Seoul, South Korea

Background: Many individual biomarkers have been related to high-risk coronary plaques and subsequent cardiovascular risk. Optical coherence tomography (OCT) is a high resolution imaging modality capable of identifying vulnerable plaque characteristics. We evaluated the relationships between multiple serum biomarkers and the morphologic features of coronary plaque characterized by OCT.

Methods: OCT was performed in the culprit lesions of patients undergoing cardiac catheterization. Lipid was semi-quantified as the number of quadrants on the cross-sectional image. Fibrous cap thickness was measured at its thinnest part. Thin-cap fibroatheroma (TCFA) was defined as lipid rich plaque (>2 quadrants) with a fibrous cap thickness < 65 μm. We measured 9 biomarkers at baseline: white blood cells (WBC) counts, C-reactive protein, erythrocyte sedimentation rate, fibrinogen, homocysteine, von Willebrand factor, lipoprotein (a), apolipoprotein A-1 and B-100. Logistic transformation was performed to normalize the distribution of the biomarkers.

Results: A total of 41 patients were enrolled in the study. Among the 8 multiple biomarkers, a significant correlation was found only between WBC count and fibrous cap thickness (r = -0.47, p=0.002). Also, WBC count was the only biomarker showing significant difference between plaque with TCFA and without TCFA (6.5±3 vs 5.2±1.7 x10^3/mm^3, p=0.036). In multivariate regression models adjusting for conventional risk factors, WBC count was independently associated with fibrous cap thickness (adjusted estimation effect size per 100/mm^3, -0.8±0.3; p=0.007) and the probability of TCFA (adjusted relative risk per 100/mm^3, 1.02±1.11; p=0.036).

Conclusion: Among the multiple biomarkers for stratifying the cardiovascular risk, WBC count was the most informative biomarker for predicting the vulnerable plaque characteristics identified by use of OCT. Further studies may be needed to evaluate the value of inflammatory risk stratification and vulnerable plaque features with OCT on the clinical prognoses in these patients.

Tissue Characterization of Coronary Plaque With Thin-Cap Fibroatheroma identified by Optical Coherence Tomography

Duk-Woo Park, Myeong-Ki Hong, Jong-Pil Park, Jae Hyung Park, Jeong-Woo Lee, Won-Jang Kim, Seung-Whan Lee, Young-Hak Kim, Cheol Whan Lee, Jae-Joong Kim, Seong-Wook Park, Seung-Jung Park, Asian Medical Center, Seoul, South Korea

Background: Optical coherence tomography (OCT) is a reliable and reproducible imaging modality for detailed coronary plaque characterization. Despite the high resolution of OCT imaging, the accurate assessment of the coronary plaque composition is limited. Therefore, we performed the tissue characterization of vulnerable plaque assessed by OCT, using virtual Histology (VH)-intravascular ultrasound (IVUS).

Methods: Pre-intervention OCT and VH-IVUS was consecutively performed in the culprit lesions. Lipid was semi-quantified as the number of quadrants on the cross-sectional image. The cross-sectional image with the highest number of lipid quadrants was used to assess TCFA. Fibrous cap thickness was measured at its thinnest part. Thin-cap fibroatheroma (TCFA) was defined as lipid rich plaque (> 2 quadrants) with a fibrous cap thickness < 65 μm. VH-IVUS analysis was performed at the site of the largest necrotic core. Plaque composition was classified as fibrous, fibrofatty, dense calcium, and necrotic core. All vulnerable plaque areas were negative percentages were reported.

Results: 41 coronary lesions were analyzed and OCT-derived TCFA was found in 23 plaques (56%). Plaque classified as TCFA had a larger P&M area than non-TCFA plaques (p=0.024). In VH-analysis, TCFA showed significantly larger necrotic absolute area as compared to non-TCFA without the difference of fibrous, fibrofatty and dense calcium components (Table). Conclusion: TCFA identified by OCT imaging showed more unstable tissue compositions with larger plaque and necrotic core area compared to non-TCFA.

<table>
<thead>
<tr>
<th>Variables</th>
<th>TCF A (n=23)</th>
<th>Non-TCFA (n=18)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEM area (mm^2)</td>
<td>15.7±3.5</td>
<td>13.6±3.1</td>
<td>0.076</td>
</tr>
<tr>
<td>Lumen area (mm^2)</td>
<td>5.4±2.2</td>
<td>5.3±1.7</td>
<td>0.8</td>
</tr>
<tr>
<td>P&amp;M area (mm^2)</td>
<td>10.3±2.6</td>
<td>8.4±2.3</td>
<td>0.024</td>
</tr>
<tr>
<td>Necrotic core</td>
<td>2.8±1.5</td>
<td>1.6±1.0</td>
<td>0.003</td>
</tr>
<tr>
<td>Fibrofatty</td>
<td>3.2±2.1</td>
<td>3.6±2.4</td>
<td>0.31</td>
</tr>
<tr>
<td>Fibrinolytic</td>
<td>3.2±2.1</td>
<td>3.6±2.4</td>
<td>0.31</td>
</tr>
<tr>
<td>Deme dense calcium</td>
<td>1.0±0.6</td>
<td>0.8±0.6</td>
<td>0.33</td>
</tr>
<tr>
<td>Necrotic core</td>
<td>2.8±1.5</td>
<td>1.6±1.0</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Vessel Shrinkage as a Mechanism of Atherosclerosis Progression in Diabetic Patients: A Serial Intravascular Ultrasound Study

Pilar Jiménez-Quevedo, Manel Sabet, Suzuki Nobuaki, Cecilia Corros, M. Cruz Ferrer, Marco Costa, Fernando Alfonso, Rosana Hernandez-Antolin, Esther Bernardo, Dominick Angiolillo, Camilo Banfueros, Javier Escaredo, Carlos Macaya, Hospital Clinico San Carlos, Madrid, Spain, University of Florida, Jacksonville, FL

Background: Negative remodeling plays a major role in coronary narrowing in diabetic patients. The aim of this study was to identify predicting factors of vessel shrinkage (VS) in diabetic patients, using serial IVUS analyses.

Methods: 235 coronary subsegments (45 patients) from the DIABETES I II III trial were included. Quantitative volumetric IVUS analyses from motorized pullbacks (0.5 mm/sec) after the index procedure and at 9-month follow-up were performed in the same coronary segment. Non treated minor lesions (angiographic stenosis <55%), with ≥0.5 mm plaque thickening and 5 mm of length assessed by IVUS were included. Subsegmental analysis was performed dividing the lesions into three sections of equal length (subsegments). VS was defined as a ratio ΔVessel area/Δatheroma area<1. Statistical adjustment by multiple subsegments and multiple lesions per patient (GEE method) was performed.

Results: Mean lesion length was 10.3 mm. VS occurred in 36.7% and was associated with a significant decrease in lumen area at 9-month: VS:10.5±3.8mm² vs no-VS:11.1±3.8; (p=0.04). Independent predictors of VS were: insulin-dependent diabetes (OR: 4.8; 95% CI: 1.4-1.5, p<0.01); glicated haemoglobin level (OR:1.5; 95% CI: 1.05-2.17, p<0.02); apolipoprotein B level (OR:0.98; 95% CI:0.94-0.98;p<0.001); hypertension (OR:3.7; 95% CI:1.4-10.3;p=0.009); number of diabetes-erosses (OR:5.8; 95% CI:2.5-12.5;p<0.001) and prior revascularization (OR:17.5; 95% CI:6.4-46.9;p<0.001).

Conclusions: The present serial IVUS study demonstrates that VS contributes to coronary stenosis progression in diabetic patients. VS is influenced by insulin treatment and metabolic levels and is more frequent in patients with multivessel disease and prior revascularization.

Assessment of Intra-coronary Inflammatory and Oxidative stress markers following percutaneous coronary interventions (PCI).

F. Khan Porto, Saurabh S. Dawan, Abdul Sheikh, Arshed A. Goyumy, Dean P. Jones, Syed T. Rabb, Habib Samady, Zayed B. Ghazzal, Emory University, Atlanta, GA

Background: A heightened inflammatory response to PCI is associated with a worse long term outcome. We investigated the mechanisms underlying the inflammatory response provoked by PCI with the hypothesis that it is triggered by an increase in oxidative stress.

Methods: In two separate studies we investigated changes in systemic markers of inflammation and oxidative stress. In study 1 of 220 patients with stable CAD, markers were measured before, 1 day, 1 week and 1 month after PCI and stenting. In study 2, these changes were measured in 13 patients with intracoronary sampling immediately before and after PCI. Arterial blood samples were obtained sequentially from the aorta, distal to target lesion pre-PCI, distal to target lesion post-PCI, and in a non-target vessel. Reduced (cysteine) and oxidized (cystine) levels reflected plasma oxidative stress, and inflammation was measured using CRP, IL-6 and MMP-9.

Results: In study 1 there was an increase in CRP (50%, p<0.001), IL-6 (100%, p<0.001), and MMP-9 (80%, p<0.001) 1 day after PCI. However, in study 2, there was no change in any of these markers of inflammation between pre- and post-PCI coronary arterial samples. Nevertheless, an increase in markers of oxidative stress was observed immediately post PCI; there was no difference between the aortic and post lesion cystine levels before PCI (58.2 and 56 MM, respectively, p=ns), however, after PCI, post lesion and non-target coronary arterial levels were significantly elevated (62.6MM and 67.3MM, respectively, p=0.02 compared to pre-PCI levels).

Conclusions: Oxidative stress increases immediately after PCI and subsequently (1 day) leads to an increase in systemic inflammatory response. Understanding the mechanisms underlying oxidation-mediated inflammatory activation by PCI will likely influence development of therapeutic strategies for improving outcomes after PCI.
Discrepancy of Calcium Detection Between Gray Scale Intravascular Ultrasound and Spectral Analysis of Radiofrequency Data

Task-Gun Kwon, Dae-Woo Hyun, Ki-Young Kim, Jang-Ho Bae, Konyang University Hospital, Daejeon, South Korea

Background: We sought to evaluate 1) the discrepancy of calcium detection between gray scale intravascular ultrasound (IVUS) and VH-IVUS and 2) the association between coronary calcium and plaque composition.

Methods: Study subjects consisted of 162 consecutive patients (119 males, mean 60.0 years old). Subjects were divided into 3 groups based on gray scale IVUS findings: No calcification group (n=50), Spotty group (n=56) who had a lesion containing only small calcium deposits within an arc of less than 90° and diffuse group (n=56) who had a diffuse calcific lesion with an arc of more than 90° in more than 1 transverse section of the lesion.

Results: With gray scale IVUS analysis, no calcification group was younger (54.4±13.0yrs vs. 61.1±10.7yrs and 64.2±9.9yrs, p=0.011 and p<0.001, respectively) than other groups, were likely to be male (84.5% vs. 62.5%, p=0.017), less smoker (50.0% vs. 23.2%, p=0.005) and less hypertension (48.0% vs. 71.4%, p=0.017) than diffuse group. With IVUS-VH analysis, fibrofatty plaque (n=1, 34±1%, p=0.039), fibrocalcific plaque (n=4, 97±1%, p=0.002) and necrotic core (n=1, 71±2%, p=0.022) volume was significantly lower in no calcification group than in other groups. There were no significant differences between diffuse and spotty group as well as dense calcified composition (5.7mm³ vs. 4.4mm³, p=NS). Calcium volume was correlated directly with plaque volume (r=0.80, p<0.001), fibrofatty volume (r=0.76, p<0.001) and lipoid core volume (r=0.72, p<0.001) in no calcification group and correlated with plaque volume(r=0.43, p<0.001), fibrofatty volume(r=0.34, P<.011) and lipoid core volume(r=0.70, P<.001) in spotty group and correlated with plaque volume(r=0.60, P<0.001), fibrofatty volume(r=0.48, P<0.001) and lipoid core volume(r=0.81, P<0.001) in diffuse group.

Conclusions: This study showed that coronary calcium can be present even if invisible in gray scale IVUS and correlated with plaque volume and lipid core volume in patients with invisible calcium by gray scale IVUS.

Relation of Plaque Size to Compositions as Determined by an in vivo Volumetric Intravascular Ultrasound

Table. Relation between plaque volume (mm³) and burden (%) vs. each plaque volume (r=0.573, p<0.001), fibrofatty volume (r=0.423, p<0.001) and dense calcium also significantly correlated with fibrotic volume (mm³) (r=0.714, p<0.001), necrotic core (r=0.233, p<0.001). However, there were no significant correlations between each plaque components between the 2 groups except lesser percentage of dense calcium in positive remodeling (Table). RI was significantly correlated with an area of fibrotic plaque (r=0.262, p<0.001), fibrofatty plaque (r=0.149, p=0.002), dense calcium (r=0.112, p=0.019) and necrotic core (r=0.233, p<0.001). However, there were no significant correlation between RI and percentage of each plaque components. In conclusions, the percentage of each plaque components was similar between positive and negative/fibrotic remodeling except lesser percentage of dense calcium in positive remodeling. Compared with negative/fibrotic remodeling, area of fibrotic plaque, fibrofatty plaque and necrotic core were significantly larger in positive remodeling due to a larger total plaque area.

Does Takotsubo Cardiomyopathy Result From Plaque Rupture? Insight From Intravascular Ultrasound Studies

Saqib Samee, Tania Chao, Teruo Okabe, Probal Roy, Tina L. Pinto Slottow, Daniel H. Steinberg, Rebecca Torgouson, Subosh B. Joshi, Lowell F. Satler, Kenneth Kent, William O. Suddath, Joseph Lindsay, Ron Waksman, Augusto D. Pichard, Washington Hospital Center, Washington, DC

Background: Takotsubo cardiomyopathy (TC) is a disorder characterized by typical clinical and ECG manifestations of acute myocardial infarction, a characteristic contraction abnormality ('ballooning' of the left ventricle (LV) apex) with absence of obstructive coronary disease. Its pathogenesis is poorly understood. Some have postulated its cause to be associated with transient occlusion of the left anterior descending (LAD) coronary artery. This study utilized intravascular ultrasound (IVUS) in patients with typical TC to detect coronary atherothrombosis to test this hypothesis.

Methods: From a cohort of 52 patients who presented to the cardiac catheterization laboratory with typical chest pain, ECG changes, positive cardiac enzymes, typical LV apical ballooning and angiographically normal coronary arteries, 7 patients underwent IVUS at the time of initial angiography. IVUS imaging was interpreted by an independent reviewer.

Results: All 7 patients had atherothrombotic lesions in the proximal LAD by IVUS with a mean obstruction of 67% (48%-70%), 5 of the 7 (71%) patients had evidence of acute plaque rupture, and 1 had a tight calcific stenosis. In all 7 patients, the LAD wrapped around the LV apex.

Conclusions: These IVUS findings support the hypothesis that TC can result from plaque rupture with transient occlusion of wrap-around LAD causing LV stunning.

We evaluated the relation between coronary plaque composition by virtual histology (VH) intravascular ultrasound (IVUS) and arterial remodeling pattern. The study included 121 patients (438 lesions) that underwent VH-IVUS study. There were 145 lesions with positive remodeling (remodeling index; RI > 1.05) and 293 lesions with negative/intermediate remodeling (RI < 1.05). Compared with negative/intermediate remodeling, positive remodeling have a larger area of fibrotic plaque, fibrofatty plaque and necrotic core. However, there were no significant differences of percentage of each plaque components between the 2 groups except lesser percentage of dense calcium in positive remodeling.

Remodeling pattern Positive (n=145) Negative/intermediate (n=293) p

<table>
<thead>
<tr>
<th>Component</th>
<th>Positive</th>
<th>Negative/intermediate</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute (mm³)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrotic (Dark-green)</td>
<td>4.5 ± 2.2</td>
<td>3.5 ± 2.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fibrofatty (Yellow-green)</td>
<td>0.5 ± 0.5</td>
<td>0.4 ± 0.5</td>
<td>0.024</td>
</tr>
<tr>
<td>Dense calcium (White)</td>
<td>0.7 ± 0.7</td>
<td>0.7 ± 0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>Necrotic core (Red)</td>
<td>2.7 ± 1.3</td>
<td>2.2 ± 1.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Percentages (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrotic</td>
<td>33 ± 13</td>
<td>51 ± 15</td>
<td>0.188</td>
</tr>
<tr>
<td>Fibrofatty</td>
<td>8 ± 5</td>
<td>5 ± 5</td>
<td>0.26</td>
</tr>
<tr>
<td>Dense calcium</td>
<td>8 ± 7</td>
<td>10 ± 8</td>
<td>0.046</td>
</tr>
<tr>
<td>Necrotic core</td>
<td>33 ± 12</td>
<td>34 ± 13</td>
<td>0.5</td>
</tr>
</tbody>
</table>

We evaluated the relation between calcium detection between gray scale IVUS and VH-IVUS and the association between coronary calcium and plaque composition. The study included 121 patients (438 lesions) that underwent VH-IVUS study. There were 145 lesions with positive remodeling (remodeling index; RI > 1.05) and 293 lesions with negative/intermediate remodeling (RI < 1.05). Compared with negative/intermediate remodeling, positive remodeling have a larger area of fibrotic plaque, fibrofatty plaque and necrotic core. However, there were no significant differences of percentage of each plaque components between the 2 groups except lesser percentage of dense calcium in positive remodeling.
Among Serum Lipid Profile Parameters High-Density Lipoprotein Cholesterol Is the Major Determinant of Coronary Plaque Burden: A Volumetric Intravascular Ultrasound Analysis

Eduardo Miesel, Gary S. Mintz, Hector Garcia-Garcia, Ryan K. Kaple, Celia Castellanos, Simon Broo, Jeffrey W. Moses, Gregg W. Stone, Martin B. Leon, Columbia University Medical Center, New York, NY, Cardiovascular Research Foundation, New York, NY

Background: Although statins are highly effective in reducing future adverse cardiovascular events, the effect on plaque burden (PB) measured by intravascular ultrasound (IVUS) is, at best, modest. We assessed the relationship of lipid profile to IVUS parameters in order to explain this paradox.

Methods: We performed volumetric IVUS analysis in a series of 625 patients and measured external elastic membrane (EEM), lumen, and plaque/media (P&M) areas and volumes and PB (EEM/PAM).

Results: Patient age was 62.3±11.1yrs with 75% males and 23% diabetics. There was a negative association between HDL-C levels and mean PB (r=-0.18, p<0.0001), mean P&M CSA (<0.16, p=0.0008), and P&M volume (<0.11, p=0.02). Total cholesterol LDL-C and triglycerides were not related to any of these IVUS parameters. Multiple regression analysis revealed that among lipid profile parameters, HDL-C was the only independent predictor of PB (p<0.0001). Patients with HDL-C<50mg/dl had higher mean P&M area (7.1±2.6 vs. 6.2±2.5mm2), P&M volume (349.7±203.7 vs. 293.8±173.5mm3, p=0.004), and mean PB (40.5±8.7 vs. 40.9±7.7, p=0.001) than with normal HDL levels. Patients with HDL-C levels in the 3rd tertile (>58mg/dl) had significantly lower plaque burden (40.7%) when compared to the 1st (44.6%, p=0.002) or 2nd (44%, p=0.006) tertiles. Decreasing TC/HDL tertiles was associated with a progressively smaller plaque burden as well (p=0.008) (Figure).

Conclusion: Among lipid parameters, HDL-C is the major determinant of coronary plaque burden. The modest benefits of statins in terms of plaque regression more likely result from the slight effect on increasing HDL-C levels than in reducing LDL-C levels.

Clinical, Angiographic and Morphologic Features and Post-PCI Complications in Patients With Acute Coronary Syndromes and Attenuated Plaques Detected by IVUS

Sung Yun Lee, Gary S. Mintz, Seok-Yeon Kim, Terun Bae, Young Joon Hong, Augusto A. Pichard, Lowell F. Satler, Ron Waksman, Kenneth M. Kent, William O. Suddath, Neil J. Weissman, Cardiovascular Research Institute/Medstar Research Institute, Washington Hospital Center, Washington, DC, Cardiovascular Research Foundation, New York, NY

Background: Attenuated plaques are unusual intravascular ultrasound (IVUS) findings in patients with acute coronary syndrome; their significance is not fully understood.

Methods: We reported clinical presentation and angiographic and pre-intervention IVUS findings in 293 patients with acute coronary syndrome undergoing percutaneous coronary intervention (PCI) without a distal protection device; 184 with non-ST elevation myocardial infarction (STEMI) and 109 with STEMI.

Results: Attenuated plaque (defined as deep echo attenuation without calcification) were discovered and underwent intravascular ultrasound (IVUS) examination. Among 625 patients and measured external elastic membrane (EEM), lumen, and plaque/media (P&M) areas and volumes and PB (EEM/PAM).

Results: Patient age was 62.3±11.1yrs with 75% males and 23% diabetics. There was a negative association between HDL-C levels and mean PB (r=-0.18, p<0.0001), mean P&M CSA (<0.16, p=0.0008), and P&M volume (<0.11, p=0.02). Total cholesterol LDL-C and triglycerides were not related to any of these IVUS parameters. Multiple regression analysis revealed that among lipid profile parameters, HDL-C was the only independent predictor of PB (p<0.0001). Patients with HDL-C<50mg/dl had higher mean P&M area (7.1±2.6 vs. 6.2±2.5mm2), P&M volume (349.7±203.7 vs. 293.8±173.5mm3, p=0.004), and mean PB (40.5±8.7 vs. 40.9±7.7, p=0.001) than with normal HDL levels. Patients with HDL-C levels in the 3rd tertile (>58mg/dl) had significantly lower plaque burden (40.7%) when compared to the 1st (44.6%, p=0.002) or 2nd (44%, p=0.006) tertiles. Decreasing TC/HDL tertiles was associated with a progressively smaller plaque burden as well (p=0.008) (Figure).

Conclusion: Among lipid parameters, HDL-C is the major determinant of coronary plaque burden. The modest benefits of statins in terms of plaque regression more likely result from the slight effect on increasing HDL-C levels than in reducing LDL-C levels.

Virtual Histology Intravascular Ultrasound Analysis of Thin-Capped and Thick-Capped Fibroatheromas in Autopsied Coronary Arteries


Thin fibrous cap can lead to plaque rupture. However, plaque characteristics and their mechanical properties also play an important role. We Methods: We harvested 123 coronary arteries from 43 autopsied cases. Virtual histology intravascular ultrasound (VH-IVUS) imaging was performed beginning 30mm distal to the ostium of each coronary artery. Thin-capped fibroatheroma (TCFA) was defined as necrotic core >10% of plaque area associated with a plaque burden of >40% with the necrotic core in contact with the luminal for at least 3 image slices. VH-IVUS derived fibroatheromas (FA) were validated histopathologically. Positive remodeling was defined as a remodeling index (lesion/reference EEM [external elastic membrane] area)>1.05. Results: Patient age was 49.2±9.12yrs and 82% were males. Four pts experienced sudden cardiac death and 39 non-cardiac death. Overall, 8% (10/123) of coronary arteries showed a thick-capped FA and 9% (12/123) showed a thin-capped FA. Grey-scale IVUS showed no a trend toward a larger EEM area (12.7±0.16mm2 vs 10.88±2.48mm2, p=0.064) and lumen area (5.19±1.00mm2 vs 5.37±0.96mm2, p=0.097, p<0.01) in TCFA, but did not difference in plaque burden (58.0±8.4% vs 59.8±8.1%, p=0.6), or remodeling index (1.15±0.24 vs 0.96±0.22, p=0.13). VH-IVUS showed relatively larger necrotic core and relatively more dense calcium in TCFAs, but relatively smaller necrotic core and relatively more fibrous plaque in thick-capped FAs (Table). Conclusion. VH-IVUS findings of TCFA and thick-capped FAs parallel histopathology. The role of calcium in the more-unsatable TCFA requires further study.

Quantitative Correlation of Colorimetry Thin Cap Fibroatheroma in Human Autopsy Specimens

Fumiyuki Ishibashi, Jennifer Lisasakas, Thomas Meese, Sergio Waxman, Lahey Clinic, Burlington, MA

Background: We reported that high yellow color intensity (HYCI) of human carotid/ femoral athereosclerotic plaques, measured with quantitative colorimetry during angioplasty, is associated with lipid cores underneath thin fibrous caps (cap thickness <100um, MCTCs). We hypothesized that these lipid parameters would define coronary lesions with MCTCs, including thin-cap fibroatheromas (TCFA), and performed angioplasty with colorimetry in human coronary artery autopsy specimens.

Methods: Angioplasty was performed in 40 non-severely stenotic coronary segments from 17 autopsy hearts which were pressure perfused. Each arterial cut was stained, and examined at 2 mm intervals for histopathologic analysis. Luminal surface diagrams were constructed from histology to define the regions with LCTCs (consecutive surface regions of lipid cores underneath fibrous cap <100um) and to compare with angiographic images. The surface color of LCTCs was measured from the angiographic pullbacks using quantitative colorimetry with the L*a*b* color space (positive a*=red, positive b*=yellow).

Results: 81 angiographic regions were defined (21 LCTCs and 60 non-LCTCs). The predominant histologic plaque types of 21 LCTCs were TCFA (n=14), fibroatheromatous plaque (n=7) and fibrocalcific plaque (n=1). A predefined HYCI b*>23) or (a*>15, b*>0) for LCTCs were 95% and 97%, and for TCFAs were 93% and 98% (Table). In 81 angioscopic regions, the sensitivity and specificity of (a* >0, b*>23) or (a*>15, b*>0) for LCTCs was 95% and 97%, and for TCFAs was 93% and 98% (Table). Among 33 HYCI stained, and examined at 2 mm intervals for histopathologic analysis. Luminal were discovered and underwent intravascular ultrasound (IVUS) examination.

Conclusions: Coronary angioplasty could be reliably identified as high yellow/red color intensity regions by quantitative colorimetry during postmortem angioplasty. Further validation of these parameters in vivo is necessary. Prospective identification of TCFAs could lead to prevention of cardiovascular events.

Incomplete stent apposition and Stent Fracture after Sirolimus-eluting stent implantation

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Background: Little is known about causes of stent fracture (SF) after sirolimus-eluting stent (SES) implantation. The present study investigated differences of the IVUS findings between segments with and without stent fracture in patients treated with SES.

Methods: Since January 2004, 25 (5 fractures in 24 patients) after SES implantation were discovered and underwent intravascular ultrasound (IVUS) examination.
IVUS parameters at the center of stent fracture were not different from the other sites (EEM area(mm^2); 16.4±3.0, 15.7±3.12, 15.9±3.64, 15.9±3.76, 15.7±2.64, 15.6±3.95, 15.60±4.18, p=NS). Stent area(mm^2); 8.46±2.28, 7.88±2.17, 7.79±2.26, 7.75±2.08, 7.75±2.09, 7.82±1.87, p=NS except Lumen area(mm^2); 8.15±2.01±0.01, 7.45±2.14±0.008, 8.14±8.09±0.054, 6.42±2.26, 6.54±2.28±p=NS, 6.99±2.169±p=NS, 7.50±2.00±p=0.007). Stent under-over expansion, regional vessel remodeling, or excessive P&M (possible NIH) accumulation were not observed (P&M; 7.98±2.22 vs. 7.85±2.15 vs. 8.18±2.75 vs. 7.83±5.04 vs. 7.98±3.23 vs. 7.98±2.60 vs. 7.78±2.77% NIH; 0.32±0.87 vs. 0.43±0.42 vs. 0.35±5.73 vs. 1.20±1.33 vs. 0.76±0.88 vs. 0.18±0.3). Incomplete stent appositions were more frequently found at the fractured stent edges compared with other sites (Table). Calcium profiles were not different between sites. Conclusion: Complete stent apposition is more frequently found at the fractured stent edges after SES implantation, suggesting a role in the pathogenesis of this adverse event.

<table>
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<tr>
<th>ISA and SF</th>
<th>0.5mm proximal to SF</th>
<th>2.5mm proximal to SF</th>
<th>Proximal edge of SF</th>
<th>Distal edge of SF</th>
<th>2.5mm distal to SF</th>
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<tr>
<td>ISA frequency</td>
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<td>3.12% (12.5%)</td>
<td>3.12% (12.5%)</td>
<td>0.0 (0.4)</td>
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<td>ISA depth (mm)</td>
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<tr>
<td>ISA arc (°)</td>
<td>103</td>
<td>203</td>
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<td>203</td>
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</tbody>
</table>

Coronary Microvascular Resistance Estimated by Intracoronary Hemodynamic Measurements Reflects Residual Myocardial Viability in Patients With Prior Myocardial Infarction

Koshipi Tamita, Atsushi Yamamuro, Syuyohiro Kaji, Minako Katayama, Takeshi Kitai, Takumiki Yamane, Yasuki Khira, Takashi Akasaka, Kobe General Hospital, Kobe, Japan, Wakayama Medical University, Wakayama, Japan

Background: Fractional flow reserve (FFR) and coronary blood flow velocity reserve (CFR) represent physiological quantities and are useful to evaluate coronary lesion severity. However, resistive vessel dysfunction may blunt the maximal hyperemic response in patients with prior myocardial infarction (MI). The aim of this study was to examine the effect of residual viability on intracoronary physiological assessments in the infarct-related coronary arteries.

Methods: FFR and CFR were assessed in 61 consecutive patients with 61 intermediate coronary lesions (between 40% and 70% diameter stenosis by visual assessment) in the infarct-related coronary artery. Microvascular resistance (MRV) index was defined as the ratio of mean distal pressure to averaged peak blood flow velocity during maximal hyperemia. Patients were divided into two groups based on myocardial viability assessed by thallium-201 SPECT; 45 patients with viable myocardium and 16 patients with nonviable myocardium in the infarcted area. Redistribution patterns or residual myocardial activity >50% are indices of tissue viability.

Results: Intra-coronary physiological assessments showed significantly lower hyperemic coronary blood flow velocity reserve (28.8±10.9 vs. 42.6±18.2 cm/s; p<0.0001) in nonviable myocardial group compared with viable group. The CFR did not differ between these two groups (2.37±1.07 vs 2.72±1.03; p=0.25). The optimal cutoff value of CFR was 2.5 indicating presence of residual myocardial viability.

Conclusions: The use of the MRV index whether is feasible and safe. In 88% of patients, IVMRI was able to obtain valuable data for lesion characterization. IVMRI may provide valuable information on plaque lipid characteristics for lesion assessment. Additional studies are warranted and are underway.

Lipid-Rich Plaque Adjacent to Stenosis in Coronary Autopsy Specimens: Implications for Selection of Stent Length

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Background: Selection of stent length is generally based on length of stenosis as determined by angiography. However angiography cannot identify lipid-rich plaque (LRP) which has limited re-endothelialization capacity and may contribute to late thrombosis at the edge of a stent. We studied the relationship between stenosis and LRP in autopsy specimens to determine if assessment of LRP by near-infrared (NIR) spectroscopy would be useful for selection of stent length.

Methods: Stenosis (by IVUS) and LRP (by histology at 2mm intervals) were measured in 124 coronary autopsy specimens from 51 donor hearts. The hearts were also scanned with a NIR catheter to identify LRP with a method suitable for clinical use.

Results: LRP were found adjacent to 30 of 70 stenoses. The adjacent LRP extended an average of 5.3 mm from the maximum stenosis (std dev = 3.1 mm). Many of the LRP's located at the stenotic site, also extended further in the vessel (see below).

Conclusions: LRP, which provides a poor substrate for re-endothelialization of a coronary stent, is frequently encountered 10 or more mm from the center of a stenotic lesion. Identification of LRP in patients, which is possible with a novel NIR system could help identify the length of stent needed to span both stenotic and lipid-rich regions.
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. The results were better than those with thrombin. Echo phonometry demonstrated restricted 25%-30% of left ventricular volume. The device could be placed with the Hybrid method and was effective in experimental aneurysms.

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.

The Frequency of Coronary Artery Compression and Management Using a Removable Mitral Annuloplasty Device in the Coronary Sinus
Steven L. Goldberg, Richard Van Bibber, Joachim Scholfer, Adrian Ebnner, Tomasz Simkaw, Uta C. Hoppe, Michael Haude, Jean-Paul R. Herman, Stephen J. Duffy, David Reuter, David M. Kaye, Cardiac Dimensions, Inc, Kirkland, WA

Background: The close relationship between the coronary sinus and the posterior mitral annulus has been used as a possible avenue for reducing mitral annular dimensions to treat functional mitral regurgitation (MR). One concern of this approach has been the potential for compromising the circumflex coronary artery which also runs in the atrioventricular groove.

Methods: Preliminary data from pts in the MADEUS, PERSEUS and VERITAS safety and feasibility trials of the CarionTM Mitral Contour SystemTM (CMCS) were evaluated for coronary artery compromise (CACCMP), defined as impingement of a ≥2 mm diameter coronary artery to >50% narrowing, and/or a reduction in TIMI flow. The CMCS is placed in the coronary vein and tension applied to cinch the mitral annulus. Coronary arteriography is then performed to assess for CACCMP while echo assessment for MR is being done. If impingement is noted and there is no CACCMP, the device is present the device can be recaptured. Coronary arteriograms were reviewed for evidence of coronary artery crossing and for CACCMP Post-procedure EGCS were obtained, and in a subset of patients, cardiac enzymes (CK's) were drawn. Patients were followed for subsequent clinical events.

Results: 63 pts underwent attempted implantation of the CMCS. Angiographic evidence of coronary artery crossing by the CMCS was seen in 52 (83%). However, CACCMP was only seen 15 pts (24%), which successfully resolved with removal of the device. In 5 of these pts a second device was successfully placed more proximally without CACCMP. In 15% of pts CACCMP limited utility of the CMCS. No pt developed Q-wave MI's, either at time of implant or with follow-up. 45 pts had CK or CK MB drawn. Only 2 had >3 X ULN, both with occlusions of <1 mm branches (one a distal branch of the right coronary artery, and one an AV groove branch of the left). Not considered to be important vessels by the operators at the time of implant.

Conclusions: Although a coronary sinus based annul remodeling device will frequently cross a coronary artery, coronary artery compromise is infrequent. Using a removable device allows for successful management of coronary artery compromises which may ensue.

Intracoronary Red Light Irradiation for the Treatment of High-risk Non-culprit Atheromatic Plaques
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Background: Intraluminal low-power red laser light (LPRLL) irradiation has been successfully applied to prevent restenosis after percutaneous coronary intervention. Recent studies have shown that LPRLL besides its antiproliferative effect induces redox-sensitive nitric oxide/nitrite production, promoting nitric cGMP production. Our study aimed to evaluate coronary thrombosis after LPRLL irradiation of high risk plaques.

Methods: Eleven patients with more than two angiographically significant lesions at different vessels were enrolled. Culprit lesions (CL) were identified by a combination of wall motion abnormalities, scintigraphic perfusion defects, and/or coronary angiogram. In non-CL (50-75% stenosis) coronary thermography was performed by a dedicated thermography catheter (Epiphany, Medisips S.W., ZUG, Switzerland) and temperature difference (ΔT) between the atherosclerotic plaque and the proximal vessel wall was assessed. If ΔT was >0.05°C irradiation with LPRLL was transmitted from a diode laser (660 nm) at an energy level of 10 mW at the end of LPRLL irradiation repeat temperature measurement was performed.

Results: The average stenosis of the non-CL was 67±12%. Temperature measurement in the non-CL and application of LPRLL irradiation was performed without any complication. The mean ΔT at baseline was 0.09±0.08°C. Immediately after LPRLL irradiation ΔT was reduced to 0.05±0.04°C (p<0.02). No major adverse cardiac events at 30 days were reported. Further clinical, angiographic, IVUS and thermographic follow-up will be soon available.

Conclusions: A promising first application of LPRLL for the treatment of high risk plaques, as recognized by coronary thermography is demonstrated in this study. Further studies are required to evaluate this method for the treatment of high risk plaques.

Ambulatory Radial Coronary Angioplasty: Is it a Feasible Approach?
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Background: The transradial access in the procedures of percutaneous coronary revascularization has arisen like an alternative to the femoral route with low risk of local and general complications. The possibility of realizing this procedure in ambulatory form in stable patients and not having an acute infarct, could be an reasonable alternative in our patients population.

Method. From January 2005 to March 2006, 326 percutaneous coronary angioplasty were done, 241 by femoral route, 85 by radial route. There were 11 failures. Of the radial procedures none were successful, of which 8 were considered as successful with discharged after 2 hours of observation (G1) and 39 hospitalized (G2). By femoral route always hospitalized, 147 were controlled (G3). Different variables for each group were analyzed. The statistic analysis was realized using nonparametric test, t student and tests Mantel-Haensel and of Fisher.

Results: Myocardial Infarction was the most frequent diagnosis (p < 0.05) in the G3 group and stable chronic angina in the group G1. Time of procedure (minutes): G3 = 78.6 versus G2 = 144.9 (p < 0.01), G3 = 78.6 versus G1 = 97.1 (p < 0.05) and G2 = 144.9 versus G1 = 97.1 (p > 0.01). The amount of contrast media was G3 = G1 (p > 0.01), G1 < G2 (p < 0.01), G2 < G3 (p > 0.01). There were not significant differences in relation to the number of utilized catheters, angioplastiled vessel and type of lesion. Neither differences were seen analyzing major complications: Death, acute coronary Syndrome, Stroke and Transient Ischemic Attack. We did not find also differences in complications related to the punction site.

Conclusions. Ambulatory radial coronary angioplasty is a feasible procedure, with low rate of local complications and similar major complications compared with the hospitalized radial coronary angioplasty and hospitalized femoral coronary angioplasty.

2000-25 Release of Bio-markers of Myocardial Damage After Direct Intramyocardial Injection of Gene and Stem Cells via the Percutaneous Transluminal Route
Federica Baltazari, Erik Jorgensen, Jens Kastrup, Cardiac Catheterization Laboratory Department of Cardiology, University Hospital Rigshospitalet, Copenhagen, Denmark

Background: We aimed to quantify the release of cardiac markers of myocardial damage, such as troponin I (T), creatine kinase (CK) MB mass and the cardiac enzyme Mb, in a subset of patients, cardiac enzymes (CK’s) were drawn. Patients were followed for subsequent clinical events.

Results: Plasma CKMB (upper normal laboratory limit=5 Mg/l) was 2.5Mg/l ±1.3 at baseline; increased to 9.2±8.9 after 8 hours (p < 0.001) and then normalized to 4.8±3.5 after 24 hours. TNN (upper normal limit=0.1 Mg/l) was 0.01 Mg/l±0.04 at baseline; 0.13±0.09 after 8 hours (p < 0.001); and 0.06±0.05 after 24 hours (p < 0.001). A total of 8 patients were treated (17%), receiving a volume of 0.3 ml per injection, had CKMB rises exceeding 10 times the upper limit, whereas no patient in the group receiving 0.2 ml had a more than two fold CKMB increase. No patient developed new ECG changes. There were no clinically important ventricular arrhythmias and no death. There was no relation between procedure time and enzyme release.

Conclusions: Direct Intramyocardial injections of stem cells or genes lead to measurable release of cardiac markers of myocardial damage, which is related to the injected volume.

Giuseppe Patti, Marco Miglioroni, Annunziata Nusca, Andrea D’Ambrosio, Germano Di Sciascio, Department of Cardiovascular Sciences, Campus Bio-Medico University, Rome, Italy

Background: Genous R-stentTM is a stainless steel coronary stent covered with antibodies specific to circulating endothelial progenitor cells (EPCs) surface antigens, designed to promote formation of a confluent functional endothelial layer over the device; conceivably this may prevent both stent thrombosis and restenosis. Aim of this study was to prospectively evaluate outcome with EPC capture stent implantation in a cohort of consecutive patients with high risk angiographic and/or clinical features.

Methods. From November 2005 to March 2007, 80 patients received 93 EPC capture stents at Campus Bio-Medico University of Rome. Patients had >2 of the following high risk features: diabetes mellitus (33%), unstable coronary syndromes (73%), left ventricular dysfunction (8%), multivessel intervention (9%), B2/C lesions (66%).

Results. Procedural success was achieved in 79/80 patients (98%); no post-procedural Q-wave myocardial infarction (MI), in-hospital death or emergency bypass surgery occurred. Despite 1 patient had acute or subacute stent thrombosis. Follow-up was available in 78 patients (mean 14±4 months): non cardiac death occurred in 1 patient, acute MI in 1 patient; no patient required by-pass surgery; 10 patients (13%) underwent percutaneous target lesion revascularization (TLR); 3 patients (4%) had re-intervention on a non-target vessel. Kaplan-Meier life-table analysis showed an event-free survival of 86% and a TLR-free survival of 90%.

Conclusions. The cell capture stent is safe and effective, with satisfactory immediate results and mid-term outcome, without stent thrombosis. Whether those devices would represent a viable alternative to currently available drug-eluting or bare metal stents will need to be evaluated in larger randomized studies.
Angiographic and Ultrasonographic Comparison of Sirolimus and Novolimus-Elluting Stents for the Treatment of Coronary Lesions: “Past and Future Head-to-Head”


Background: Despite the marked efficacy of 1st generation DES in reducing neointimal hyperplasia, long-term follow-up has shown that its efficacy may be impaired by slow release of paclitaxel and intimal dissection within the stent. A new DES system, the Novolimus-eluting stent (NES), preserves the safety profile of DES. The Novolimus-eluting stent (NES) combines a stainless steel platform with a methacrylate polymer eluting a Sirolimus-analogue anti-proliferative drug, the Novolimus. As potential advantages, it carries less drug than the Cypher (84μg of Novolimus vs. 140 μg of Sirolimus) requiring less amount of polymer. We aimed to compare the midterm efficacy of this device to the Cypher (SES) stent.

Methods: A total of 15 pts were consecutively treated with NES and compared to our 15-pts historical first-in-men cohort treated with SES. Only single, de novo, <15mm lesions in native coronary arteries of 2.7 to 3.5 mm in diameter were included. The primary end point was the comparison of lumino loss by QCA and % of obstruction by IVUS at 4-month follow-up (FU).

Results: Baseline clinical and angiographic characteristics were similar between the groups. Overall mean age was 60.8 years with 47% of diabetics. QCA and IVUS data are shown in the table. Conclusion: This preliminary analysis demonstrates the equivalence between the two DES systems in reducing NIH. The decrease in the dose of the anti-proliferative drug in the NES did not seem to impact the efficacy of this device. Long-term FU in larger and more complex cohorts of pts is necessary to confirm its safety profile.

<table>
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<th>Reference Vessel Diameter, mm</th>
<th>NES</th>
<th>SES</th>
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<tr>
<td>Lesion length, mm</td>
<td>1.6 ± 0.2</td>
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<tr>
<td>In-stent Late loss, mm</td>
<td>0.17 ± 0.09</td>
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<tr>
<td>IVUS % obstruction</td>
<td>3.9 ± 2.8</td>
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Differences in Intraventricular Pressure Can Account for the Variation in the Flow Velocity Profile Between the Left and Right Coronary Arteries

Nearther Heilbronn, Justin E. Davies, Darrel P. Francis, Arun J. Baksi, Iqbal Malik, Rodney Foale, Kim Parker, Alun Hughes, Jamil Mayet, International Center for Circulatory Health, Imperial College and St Mary’s Hospital, London, United Kingdom

Background: Despite having similar origins and perfusion pressures, flow velocity waveforms in the left main stem (LMS) and right coronary artery (RCA) are different. We speculate pressure differences originating from the distal (intramyocardial) bed account for this. We apply Wave Intensity to identify proximal- and distal-originating pressures, to explore the differences in these velocity waveforms.

Methods: In 20 subjects with unobstructed coronary arteries, sensor-tipped intra-arterial wires were used to measure simultaneous pressure and Doppler velocity in the LMS and proximal RCA. Wave Intensity was applied to derive proximal- and distal-originating waves and were examined with respect to structural and anatomical properties.

Results: Diastolic-systolic ratio of peak velocity was less in the RCA than LMS (1.2±0.3 versus 1.8±0.6, p<0.001).

The cause was lower diastolic velocity in RCA (36±17 cm/s) than LMS (55±35 cm/s), explicable by the lower distal-originating suction wave (5.9±1.5 x10^3 Wm^2s^-1versus 13.2±5.9 x10^3 Wm^2s^-1, p<0.03). Ventricular pressure correlated with the suction wave in the LMS (r=0.6, p<0.01 for LV pressure) and RCA (r=0.7, p<0.05 for RV pressure) but not with diameter, length or number of branches in these arteries.

Conclusion: Lower diastolic velocities account for the different velocity waveform in the proximal RCA and the LMS. This is due to a smaller distal-originating suction wave which is explained by lower pressure in the right than the left ventricle.
Intravascular ultrasound (IVUS) proved to be able to guide coronary intervention. Optical coherence tomography (OCT) is a novel high resolution imaging technique that has the potential to improve the results of IVUS but requires a complicated images acquisition process. The aim of the study was to evaluate a simplified non-occlusive technique of OCT acquisition (based on manual injection of iodoxanol 370) in guiding complex coronary intervention.

Methods: OCT was attempted in 20 patients (63 ACS and 27 stable angina). A questionable quantitative coronary angiography (QCA) result was the reason for the study in 15 patients: (8 cases with intermediate stenosis and 7 with hazziness) while in 5 patients had OCT to guide reintervention for DEB restenosis. The rest evaluations were performed in the OCT guided intervention and for significant >50% stenoses at QCA. In 15 cases OCT was repeated after stenting. Successful OCT images acquisition process was defined as images of sufficient quality as to measure vessel lumen and characterize the details of the plaque at target lesion and reference segment.

Results: OCT evaluation was successful in 66 (90%) of the patients. In 4/8 patients with intermediate lesions OCT avoided an interventional procedure by showing a non-significant lesion (minimal lumen area >4 mm²). In 6/7 cases with hazziness OCT revealed complicated plaques with thrombosis and were treated with PCI. In the remaining cases a calcified non significant plaque was present. In all 5 cases with in-stent DEB restenosis OCT quantified accurately the amount of neointimal tissue, detected stent underexpansion (in two cases) and, in presence of overlapping stent, measured the length of struts overlapping. After stenting implantation OCT revealed incomplete apposition and/ or dissection in the adjacent segments in 26.6% (5/19) and in 20% (3/15) of the patients respectively. Overall OCT led to additional balloon dilatation and/or further stent implantation in 4 patients.

Conclusions: OCT proved to be capable of guiding complex interventional procedures, detailing vessel anatomy, and adequacy of stent implantation.

A Model of Calcium Aortic Valve Stenosis: A Hybrid Model of Pig Aortic Root and Cadaver Heart Calcified Aortic Cusp

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Background: New technologies are available to treat calcific aortic stenosis. We describe a model of a calcified and stenotic aortic valve to test novel devices to treat calcific aortic stenosis.

Methods: Ten aortic roots were harvested from slaughtered pig hearts, and dissected free from ventricular septum and mitral valve. The ascending aorta was transected 1 cm above the sino-tubular junction. 30 non damaged calcified cusps were obtained from 10 human cadaver hearts of individuals with aortic stenosis. The calcified cusps were attached on the aortic surface of the pig leaflets using cyanoacrylate glue. The sino-tubular junction was stabilized with a plastic O-ring. The roots were inserted in a bench model of left heart. Transvalvar pressure gradients (variable flows from 0 to 10 L/min) were obtained at baseline and following balloon dilation.

Results: Mean annular diameter at baseline was 23±2.9 mm. Following the application of calcified human leaflets, variable pressure gradients were obtained according to the degree of calcification of the cadaver heart cusps. Gradients were halved following balloon dilation.

Conclusions: The model reproduces the anatomy and function of the stenotic, calcified, aortic valve. The behaviour of the simulated valves was similar to what observed in naturally occurring aortic stenosis, both at baseline and following balloon dilation. This model can be used to test new devices for the treatment of aortic stenosis both in bench and animal tests.
EXCELLA First-in-Man Study: Safety and Efficacy of Novolimus-Eluting Stent in De Novo Coronary Lesions

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Background: First generation drug-eluting stents (DES) have markedly reduced restenosis. However, there is a major interest in developing new DES with greater flexibility, radiopacity and safety profile. The Elixir Medical Drug Eluting Stent is a novel DES that combines a chromium-cobalt platform with Novolimus (an antiproliferative sirolimus analogue drug) and a polymer from methacrylate family. As potential advantages, it provides a lower drug dose as compared to Cypher® (85 mg of Novolimus vs. 140 mg of sirolimus) and has a lower polymer load. We sought to evaluate the safety and efficacy of this novel device in reducing neointimal hyperplasia as assessed by QCA and IVUS.

Methods: In April 2007 a consecutive cohort of patients with de novo native coronary artery lesions ≤14 mm in length, located in native coronaries of diameter from 3.0 to 3.5 mmm were consecutively enrolled in this First-in-Man study. By protocol, angiography and IVUS should be done at baseline and repeated at 4 and 9 months. Dual antiplatelet therapy was maintained for 6 months. Primary endpoint was QCA lumen loss at 4-month follow-up. Secondary endpoints included MACE, in-stent neointimal obstruction by IVUS and device success.

Results: A total of 15 patients were included with 67% female patients and diabetes detected in 47% of the cohort. Angiographic and procedural success was achieved in all patients. At 4-month angiographic follow-up there was minimum in-stent late lumen loss (0.15 ± 0.42 mm) by QCA and % volume obstruction (2.7 ± 2.7) by IVUS. Vascular positive remodeling and late ISA were not observed among these patients. No MACE was evidenced through six month follow-up. Nine month QCA and IVUS results will be presented at the meeting.

Conclusions: In this first-in-man study, implantation of the Novolimus-eluting stent was proven to be feasible, safe and elicited minimum neointimal proliferation. Additional large clinical trials are required to confirm these promising results.
Comparing the Outcomes Between Extracorporeal and Conventional Cardiopulmonary Resuscitation Among In-Hospital Adult Patients with Cardiac Arrest: Propensity-Matched Study

Jou-Wei Lin, Y-Yuh-Shiang Chen, Fang-Yue Lin, National Taiwan University Hospital, Taipei, Taiwan, ROC, National Taiwan University Hospital Yun-Lin Branch, Dou-Liou, Yun-Lin, Taiwan, ROC

Background: The objective of this study was to determine the survival difference between extracorporeal membrane oxygenation (ECPR) and conventional cardiopulmonary resuscitation (CCPR) in patients experiencing in-hospital cardiac arrest (IHCA) due to cardiac origin by means of well balance on measurable selection criteria.

Methods: During the period between 2004 and 2006, 59 adult patients receiving ECPR and 113 receiving CCPR due to cardiac etiologies were retrieved from a CPR registry in a tertiary medical center in Taiwan. A propensity-score matching process was performed to equalize potential prognostic factors in both groups, and to formulate well-balanced 1:1 matched cohort study.

Results: Unmatched patients who underwent ECPR experienced a better survival trend over those who received CCPR (p = 0.007). However, age, sex, underlying diseases, CPR duration, and initial cardiac rhythm could affect the predisposition for placing ECPR. The well-balanced ECPR (n = 46, age: 55±15) and CCPR (n = 46, age: 57±14) were composed of patients with equally distributed baseline characteristics. There was still a statistically significant difference in 30-day survival favoring ECPR over CCPR (log rank p = 0.042). Survival at 6 months and survival to discharge were probably higher in the CCPR group (p = 0.055 and p = 0.096, respectively).

Conclusions: A well-balanced design that equalized potential prognostic predictors has demonstrated a survival benefit with the supplement of ECPR over CCPR in the IHCA patients of cardiac origin. Further studies will be needed to identify potential subgroups that may benefit from ECPR.

Regional Differences in Carotid Plaque Morphology and Shear Stress Using Combined 3T MRI, Ultrasound and Patient-Specific Computational Fluid Dynamics and the Effects of Short-Term Statin Treatment

John LaDisa Jr., Robert Prost, Leanne Harmann, Tayyab Mohyuddin, Osama Zaidat, Jason J. J. V. Su, Mahazan Kaikobad, Megan Bright, Raymond Q. Mignino, Medical College of Wisconsin, Milwaukee, WI

Background: Computational fluid dynamics (CFD) is a specialized tool to study hemodynamics that can augment clinical evaluation from MRI and ultrasound (US). We tested whether CFD could quantify hemodynamics in the common (C), bifurcation (B) and internal (I) carotid arteries of patients with moderate to severe plaque undergoing stent treatment.

Methods: 5 subjects (1F, 66±8 yrs) had 3T MRI and US at baseline and 6 months after treatment. Between September 2005 and March 2007, 248 patients were treated with an 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, may prevent ST. In this single center study we report the 6 months clinical outcome and occurrence of ST in patients treated with an EPC-capturing stent.

Methods: Between September 2005 and March 2007, 248 patients were treated with an EPC-capturing stent for coronary artery stenosis. All patients were treated with statins for at least 4 weeks prior to PCI and antiplatelet therapy was described for at least 1 month. Clinical follow-up was obtained after 1 month and 6 months.

Results: Mean age of the population was 64 years and 73% were male. 16% of the patients were diabetic. A total of 299 lesions were treated of which 16% were CT and 23% were PCI. Mean PV and SS was higher in B compared to C and I (C, B, I: PV 117±25, 164±48, 87±22 mm3, p=0.002; SS 16±8, 35±15, 24±13 dyn/cm²; p=0.02). 6-month statin treatment reduced mean PV (131±52 vs. 115±38 mm³, p=0.02) without significant SS increments.

Conclusions: The percutaneous treatment of coronary artery stenosis with a Genous™ EPC-capturing stent in statin treated patients shows a good 6 month clinical outcome regarding stent thrombosis.

Percutaneous Creation of an Arteriovenous Fistula: A Novel Approach at Treat Patients With Severe Chronic Obstructive Pulmonary Disease

Stephanie Klecshewer, Peter Kardos, Nina Wunderlich, Horst Sievert, CardioVascular Center, Frankfurt am Main, Germany

Background: COPD is one of the leading causes of disability and death. In the last stages of the disease long-term oxygen therapy is necessary. To create an arteriovenous fistula is a new method which allows blood rich in oxygen to flow from an artery to a vein. This leads to an increase in oxygenated blood returning to the lung, so the oxygen content of the circulating blood also increases. This method utilizes the cardiovascular reserve to overcome a respiratory insufficiency. The arteriovenous fistula is percutaneously created by the RAO AC1 system by delivering a self-expanding nitinol clip to the puncture site between the external iliac artery and vein.

Methods: Since July 2007 in three long-term oxygen therapy dependent patients (age 49-58 years) with severe COPD (post-bronchodilator FEV1 <50%, post-bronchodilator FEV1/FVC < 70%) an arteriovenous fistula was created percutaneously under local anesthesia. Follow-up will be performed in regular intervals which include NYHA functional assessment, MMRC (Modified Medical Research Council Dyspnea Scale), SGRQ (St. George’s Respiratory Questionnaire) as well as ECG, echocardiography, Doppler ultrasound and right heart catheterization and 6 minutes walk test.

Results: In all patients the AC1 system was successfully placed and the arteriovenous fistula was created without complications. Patients were discharged on the following day. Up to now, one patient has completed the 12 week follow up. At this visit the fistula was open, PaO2 improved from 57.6 mmHg to 60.6 mmHg, PaCO2 from 52.0 mmHg to 49.8 mmHg, 6 min walk distance without oxygen increased from 420 m to 540 m. 6 min walking distance with supplemental oxygen increased from 510 m to 540 m. In the SGRQ an improvement by 4 points was observed. The patient reported a reduction of supplemental oxygen increased from 510m to 540m. In the SGRQ an improvement by 4 points was observed. The patient reported a reduction of supplemental oxygen increased from 510m to 540m. In the SGRQ an improvement by 4 points was observed. The patient reported a reduction of supplemental oxygen increased from 510m to 540m. In the SGRQ an improvement by 4 points was observed. The patient reported a reduction of supplemental oxygen increased from 510m to 540m. In the SGRQ an improvement by 4 points was observed. The patient reported a reduction of supplemental oxygen increased from 510m to 540m.
As of 10/31/2007, 10 subjects have been enrolled at 2 U.S. sites and 18 lesions Artery segments (n=126) from 51 donor hearts were perfused with whole 0.91 1.94 ± 0.80 2.61 0.56 ± 0.20 Percutaneous closure of patent foramen ovale (PFO) is frequently 47.8% and all the lesions were dilated with IKAZUCHI 10 balloon catheter as prime choice for consecutive 23 CTO lesions with methods: For another 12 lesion, after failing to penetrate the lesion with this 0.010 wire, we changed for procedural anticoagulation (ACT>200) and cephalexin for antibiotic prophylaxis. Cummidow (n=2) or aspirin and clopidogrel (n=1) was used for procedural anticoagulation. Results: Fenestration closure was successfully performed via the femoral (n=1) or internal jugular (n=2) vein under fluoroscopic control (fluoro time 11.3-19.1 (mean 15.3 min)). Fontan pressure increased by ≤ 3 mm Hg (range 10-14 (12.3) mm Hg to 10-16 (14) mm Hg); and there was either an increase or no change in the mixed venous saturation [50-67 (58%) to 64-67 (65%)] during balloon occlusion. Systemic saturation increased from 80-93 (85.7%) to 96-97 (96.3%) immediately and at 6 weeks. There were no complications. There was no residual shunt by trans-thoracic echocardiography at 24 hours and 6 weeks. Conclusion: This first pediatric in-humanexperience demonstrates feasibility, safety and efficacy of a novel bioabsorbable implant for Fontan fenestration closure. The short term results are encouraging. The low-profile and predicted absorption of the device and replacement with native tissue will hopefully minimize hemodynamic perturbations in the Fontan circuit. Larger series with longer follow-up and comparison with other devices is needed.

Initial Results of PFO Closure With the Coherex Flat Stent Isabel C. Reiffenstein, Cardio Vascular Center, Frankfurt, Germany, Washington Hospital Center, Washington DC, WA

Background: Percutaneous closure of patent foramen ovale (PFO) is frequently performed to prevent stroke and decompression sickness caused by recurrent paradoxical embolism. The corpus of currently available closure devices extends into both atria. The Coherex FlatStent is a flat self-expanding stent which can be positioned in the tunnel of PFOs. With its micro-tined anchors it is placed selectively into the tunnel of the PFO. This is a report about the results in the first 6 patients in whom a PFO was closed with this novel device. Methods: The purpose of this multicenter study is to evaluate the safety and efficacy of the Coherex FlatStent PFO Closure System. The first use of the Coherex FlatStent in a human was performed on October 2, 2007. As of this writing, six patients with history of paradoxical embolism (age 18-65 years) have had their PFOs closed with this device. The Coherex FlatStent PFO Closure System comprises a self-expanding FlatStent with integrated polyurethane foam in the intra-tunnel cells of the device. The foam is intended to stimulate tissue growth inside the tunnel. The FlatStent can be unsheathed in the PFO tunnel where it expands laterally. This process brings the walls of the septum primum and the septum secundum into apposition. Radionuclide markers allow for visualization of the arms during implant placement. All patients received 100 mg of aspirin for 6 months and 75mg clopidogrel for 3 months post-procedure. Results: In all six patients the Coherex FlatStent was successfully placed. Mean stretched balloon diameter was 7.1 mm (range 3.9 - 9.6 mm). The mean tunnel length measured by TEE was 10.8 mm (range 8.4 - 14 mm), the mean tunnel width measured by TEE was 3.1 mm (range 2 - 6 mm). No arrhythmias or other events were noted during follow-up. Conclusions: This initial experience demonstrates that PFO Closure using the Coherex FlatStent PFO Closure System seems to be highly feasible and safe. A more detailed statement regarding the efficacy of the Coherex FlatStent PFO Closure System will be necessary to perform more interventions and to consider the outcomes of the 1 month, 3 month and 6 month Follow up.

Results: Of 32 anatomists, 24 (75%) correctly determined the sex of the body donor and the sex of the heart. Conclusions: Anatomists can correctly determine the sex of the heart in an anatomic body donation.

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Conclusions: In prospective, blinded validation, NIR-LBI accurately predicted the presence and average volume of fibroatheroma in human coronary artery segments and showed trends that were consistent with gender and cause of death. Because the catheter-based system used in this study has been used in over 100 patients, a method is now available to determine the lipid burden of coronary arteries in living patients. This index may be helpful in identifying patients at greater risk of cardiac events.

2900-52
A Novel Anti-Inflammatory Salicylate-Based Bioabsorbable Polymer for Use in Fully Biodegradable Coronary Stents
Refet Jabara, Nicolas Chronos, Patrick Rivelli, Olek Hnojewy, Keith Robinson, Saint Joseph’s Hospital, Atlanta, GA

Background: Permanent polymer platforms used in current DES have been shown to reduce restenosis and in-stent neointima formation, unique histological effects were observed that support further investigation of 117mSn effects in the circulatory system to understand the interaction of this unique conversion electron emitting radioisotope with the vascular tissue.

Results:
Patient Age(s) (n) Sex Target vessel Reference Diameter (mm) Minimal luminal diameter (mm) Lesion length (mm) Lesion overlap Time to SF
1 40 M RCA 3.34 0.74 27.4 No At discharge
2 56 M RCA 3.43 0.90 27.0 No At discharge
3 71 M RCA 2.79 1.12 46.2 Yes At 1 month
4 66 M RCA 3.33 0.58 45.2 Yes At discharge
5 64 M RCA 2.87 0.84 30.2 No At discharge
6 52 M RCA 3.11 1.13 48.0 Yes At 1 month
7 62 F RCA 2.73 0.95 49.0 Yes At 1 month
8 70 M RCA 3.24 0.37 28.1 No At 2 months

Conclusions: In this study we demonstrated the usefulness of fluoroscopic surveillance for detecting SF in another study. We performed serial prospective fluoroscopic exam in high risk stent(33mm long stent) for SF at all follow-up sub-periods(at hospital discharge and 3weeks, 1month, 3months and 6months after intervention). All patients suspicious of SF were requested to undergo follow-up angiography and IVUS confirmation. Clinical, procedural and angiographic characteristics were analyzed at the time of 8month follow-up angiography.

Results: From August 2005 to January 2007, 121patients(92.4%) completed 8month fluoroscopic surveillance. Total eight SF were discovered(6.6%) and their profiles were presented at the table. All stents were those implanted at right coronary artery and showed high prevalence of stent fracture(90%). SF was found at 1-2 wks in 5 patients and at 2 months in 1 patient.

Background: The present study was designed to determine the occurrence of stent fracture(SF) after sirolimus-eluting stent(SES) is usually discovered.

Results: All diabetic patients undergoing a 1st DES placement from 5/1/03 to 12/31/06 and showed trends that were consistent with gender and cause of death with respect to injury were not noted exactly when this adverse finding occurs.

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Background: The present study was designed to determine the occurrence of stent fracture(SF) after sirolimus-eluting stent(SES) is usually discovered.
were included. Clinical follow-up was obtained at 6 months, 1-year, and annually thereafter. Three-year endpoints were all-cause mortality, non-fatal myocardial infarction (MI), stent thrombosis (ST), and clinically-driven target vessel revascularization (TVR).

Results: The study cohort consisted of 1540 patients (2376 lesions). DES usage was 82.1% SES; 17.9% PES. Clinical follow-up was obtained on 97% of patients (average 681.7 ± 374.6 days). Groups were similar at baseline with regards to gender, age, renal insufficiency, smoking history, and STEMI presentation. SES were placed more often in patients that had a prior PCI (33.5% vs 25.7%; p=0.013) and with unstable angina at presentation (37.6% vs 26.6%; p=0.001). PES were utilized more in lesions that were high risk (ACC defined) (46.4% vs 37.4%; p=0.001), involving a bifurcation (20.5% vs 19.0%; p=0.001), and longer length (21.1 ± 13.3 vs 19.2 ± 9.7; p=0.001). See table for Kaplan-Meier results.

Conclusions: All 3-year PES event rates were lower than SES, although not statistically significant. Despite PES use in more complex lesions, there was a trend toward decreased TVR. Choice of DES platform in diabetes warrants further study.

<table>
<thead>
<tr>
<th>Three-year Kaplan-Meier event rates % (95% CI)</th>
<th>PES (n=276)</th>
<th>SES (n=1264)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>12.7 (7.8-20.3)</td>
<td>14.2 (11.9-17.0)</td>
<td>0.697</td>
</tr>
<tr>
<td>Non-fatal MI</td>
<td>4.9 (2.2-10.5)</td>
<td>6.8 (5.1-9.1)</td>
<td>0.643</td>
</tr>
<tr>
<td>TVR</td>
<td>8.8 (5.4-14.3)</td>
<td>16.0 (13.7-18.8)</td>
<td>0.054</td>
</tr>
<tr>
<td>Def/Pref ST</td>
<td>1.2 (0.4-3.8)</td>
<td>1.8 (1.0-3.3)</td>
<td>0.814</td>
</tr>
<tr>
<td>MACE</td>
<td>25.3 (18.1-34.7)</td>
<td>32.4 (29.1-35.9)</td>
<td>0.148</td>
</tr>
</tbody>
</table>

**2900-56**

An optimal bare-metal stents (BMS) expansion with intravascular ultrasound (IVUS) guidance may serve as a similar long-term outcomes as drug-eluting stents (DES) implantation in patients without diabetes mellitus.

Katsuo Noda, Shuichi Oshima, Seiji Hokimoto, Kumamoto chuo hospital, Kumamoto, Japan

Background and Methods: DES may be effective to reduce repeat percutaneous coronary intervention and some important problems (prolonged anti-platelet drugs administration, increase in stent thrombosis every-year) have been concerned continuously. Thus, DES indication has been changing from most of all patients to some specific patients like diabetes, small vessels, or long lesions in the real world. Recently, some reports showed that BMS has become similar better long-term outcomes as DES in patients without diabetes. So we investigated the long-term outcomes of BMS implants in patients with diabetes in comparison with DES. Routinely, IVUS guidance and a high pressure post-dilatation was performed due to achieve optimal BMS expansion. The optimal BMS expansion was defined as a minimum stent area of over 6.5 mm² by IVUS.

Results: A consecutive series of 457 patients was divided into 2 groups (DES: 92, BMS: 365). There were no significant differences of clinical characteristics except for the condition of unstable angina (DES 13% vs. BMS 32%; p<0.01), LAD just-proximal lesion (DES 23% vs. BMS 9%; p<0.01), and severe calcified lesion (DES 1% vs. BMS 10%; p<0.05). The 30-day MACE was not different between 2 groups (DES 2.2% vs. BMS 0.6%; p=NS). The minimum stent area was larger in BMS than in DES, significantly (6.6 mm² vs. 6.1 mm²; p<0.01). After 1-year, TLR occurred in 3.3% in DES versus 5.8% in BMS (p=NS), and the incidence of MACE was not different between DES and BMS (5.4% vs. 7.0%; p=NS). The stent thrombosis occurred 1.1% (n=1) in DES and 0.3% (n=1) in BMS. The optimal BMS expansion group was significantly lower incidence of 1-year MACE than the non-optimal BMS group (2.9% vs. 11.5%; p<0.05), and the incidence of MACE in optimal BMS expansion group was similar to that in DES group (2.9% vs. 5.4%).

Conclusions: With diabetes, the early and long-term outcomes of BMS are acceptable in DES era. Particularly, if the optimal BMS expansion could be achieved, the long-term outcomes of BMS were equal to those of DES implantation. In view of the DES problems associated with thrombotic events or antplatelet drugs administration, BMS implantation may be safe and effective in non-diabetic patients.

**2900-57**

Optimal Late Loss May be Desirable for Neointimal Healing Following Stenting: Angiographic Comparison Between Sirolimus- and Zotarolimus-eluting Stents

Masaki Aoyagi, Shinshu University Ueda hospital, Ueda, Nagano, Japan

Background: Delayed healing of the neointima following drug-eluting stent implantation may play a role in late stent thrombosis. Zotarolimus-eluting stent (ZES) appreciates the neointimal healing following stenting. Methods: Follow-up angiography and angioplasty were performed 8±1 months after 16 imaging studies, Thrombi tended to be more frequent with SES (ZES: 7%; SES: 69%, p=0.814). Compared to a strategy of utilizing only BMS, strategies of selective or predominant DES use (74% one or more paclitaxel stents). Safety, (death, MI, hospitalization for bleeding) and total revascularization events, percutaneous coronary interventions (PCI) and coronary artery bypass grafting (CABG) were tracked using a comprehensive 28- hospital registry database and the Social Security death index. Events were analyzed using Kaplan-Meier techniques; p-values are from log-rank tests.

Results: Two-Year Safety and Revascularization Rates

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>Composite Safety Events</th>
<th>Death</th>
<th>MI</th>
<th>Bleeding</th>
<th>Total Revasc.</th>
<th>PCI</th>
<th>CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMS only</td>
<td>2,801</td>
<td>23.5%</td>
<td>10.1%</td>
<td>12.5%</td>
<td>4.4%</td>
<td>19.1%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Selective-DES</td>
<td>1,233</td>
<td>18.7%</td>
<td>7.4%</td>
<td>7.4%</td>
<td>3.6%</td>
<td>19.5%</td>
<td>17.3%</td>
</tr>
<tr>
<td>Predominant-DES</td>
<td>1,344</td>
<td>18.9%</td>
<td>7.6%</td>
<td>7.6%</td>
<td>4.3%</td>
<td>16.9%</td>
<td>15.9%</td>
</tr>
</tbody>
</table>

Conclusions: Compared to a strategy of utilizing only BMS, strategies of selective or predominant DES use were associated with less frequent death and MI and no difference in rates of serious bleeding at two years. Total revascularization rates were not decreased with either DES strategy, although there was a decrease in CABG, especially with the predominant DES strategy.

**2900-58**

Complete Versus Incomplete Revascularization in Patients with Multivessel Disease Undergoing Percutaneous Coronary Intervention with Drug-Eluting Stents

Piero Capranzano, Dominick J. Angiolillo, Rossella Barbagallo, Alessio La Manna, Francesco Taglialeni, Konstantinos Dimopoulos, Rita Bucalo, Anna Caggese, Alfredo R. Galassi, Theodore A. Basta, Corrado Tamburino, University of Catania, Catania, Italy

Background: Recent reports have shown that patients with multivessel disease (MVD) treated with coronary artery bypass grafting (CABG) have better outcomes when complete revascularization is achieved. There is limited data from the pre-drug-eluting stent (DES) era on the prognostic implications of complete versus incomplete revascularization of MVD patients undergoing percutaneous coronary intervention (PCI) and there is no data currently available utilizing DES. The aim of this study was to evaluate the long-term outcomes of complete versus incomplete revascularization in MVD patients undergoing PCI with DES. The primary endpoint measures were cardiac death and need for repeat revascularization.

Methods: Patients (n=508) with MVD undergoing PCI with DES (sirolimus- or paclitaxel-eluting stent) were included. Revascularization was defined as complete when all segments with a stenosis ≥50% and diameter ≥2.25 mm were revascularized. Study endpoints, including prior history of any type of revascularization or PCI with POBA or BMS, were excluded. Baseline characteristics of patients with complete and incomplete revascularization meeting study inclusion criteria were compared. After adjustment for
baseline characteristics, comparisons of outcomes between groups were made.

**Results:** Complete and incomplete revascularization was achieved in 42% and 58% of patients, respectively. There was higher prevalence of chronic renal failure in incomplete revascularization (p < 0.0001) and presence of a total occlusion (p = 0.001) in patients with incomplete revascularization. All patients were followed for 26.5 (interquartile range: 21.8-36.3) months. After adjustment for different baseline characteristics, the adjusted hazard ratio (HR) (95% CI) for the association between complete revascularization outcomes were 0.37 (0.15-0.92; p = 0.03) for cardiac death and 0.48 (0.28-0.68; p < 0.001) for the need for subsequent revascularization.

**Conclusions:** Complete revascularization of patients with MVD treated with DES is associated with better long-term outcomes. Higher mortality rates and need for revascularization were observed in patients with incomplete revascularization.

### 2900-20 Intravascular Ultrasound Findings in Very Late Stent Thrombosis After Implantation of Sirolimus- and Paclitaxel-Eluting Stents

Pharamee Choe, Parham Ehtehadi, Mario Torgi, Rolf Vogel, Peter Wenzesser, Michael Billinger, Christian Seiler, Otto M. Hess, Bernhard Meier, Stephan Windeneker, Swiss Cardiovascular Center, Bern, Bern, Switzerland

**Background and Purpose.** Very late stent thrombosis (ST) after drug eluting stent (DES) implantation has been associated with complete stent apposition and vessel remodelling. Necropsy studies suggest differences in the pattern of healing and chronic inflammation between sirolimus- (SES) and paclitaxel-eluting stents (PES). The purpose of the present study was to investigate differences of arterial structure between SES and PES in patients presenting with very late DES ST.

**Methods.** Intravascular ultrasound (IVUS) was systematically performed in 32 very late DES-stented patients, presenting 963±368 days after DES implantation (14 (4) SES; 14 (3) PES). IVUS imaging was performed in the ST-stage (48% LAD, 12% RCA, 39% RCA) using motorized pullback (0.5 mm/s) prior to emergency percutaneous coronary intervention. Stent expansion was defined as minimum cross-sectional area (MSA) divided by reference lumen area. Stent malapposition was defined as lack of contact between any strut and the vessel wall. Results. Stent length (SES: 29.6±21.6 mm; S: 28.2±14.0 mm, p = 0.25) and number of lesions per patient (SES: 1.4±0.8; PES: 1.6±0.6mm, p=0.41) were similar for SES and PES. IVUS findings are summarized in the table below.

<table>
<thead>
<tr>
<th>Reference Segment</th>
<th>** SES**</th>
<th>** PES**</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEM-CSA, mm²</td>
<td>14.4±5.6</td>
<td>15.8±7.0</td>
</tr>
<tr>
<td>Lumen-CSA, mm²</td>
<td>7.7±2.3</td>
<td>9.1±3.6</td>
</tr>
<tr>
<td>** p-value**</td>
<td>0.76</td>
<td>0.19</td>
</tr>
</tbody>
</table>

**Stent Segment**

| EEM-CSA, mm²      | 23.7±11.4| 19.7±9.2 |
| Lumen-CSA, mm²    | 6.1±2.4   | 6.8±2.1  |
| Stent-CSA, mm²    | 6.5±2.5   | 7.9±2.5  |
| Minimal Stent-CSA, mm² | 5.8±2.4 | 6.8±2.2 |
| ** p-value**      | 0.95    | 0.73    |

**Stent Expansion**

| Maximal NIH-CSA, mm² | 0.9±1.2 | 0.7±0.6 |
| Lumen-CSA, mm²      | 5.7±6.0 | 6.8±4.1 |
| Stent Expansion     | 0.77±0.05| 0.80±0.24|
| ** p-value**        | 0.19    | 0.12    |

**Incomplete stent apposition (ISA), % (n)**

| max CSA, mm² | 89% (16) | 97% (6) |
| Max. area, mm² | 7.8±6.2 | 8.4±1.6 |
| Length, mm     | 9.6±10.5 | 4.4±2.0 |
| ** p-value**   | 0.04    | 0.06    |

Conclusion. In patients with very late ST, SES shows a higher prevalence of ISA and larger ISA size than PES. The structural differences appear to be related to differential vessel remodelling in response to these devices, suggesting different inflammatory processes.

### 2900-61 Long-term Prognostic Implications of Treatment of Multivessel Coronary Artery Disease with Drug-eluting Stents Implantation


**Background:** Drug eluting stents (DES) are associated with reduced need for repeat revascularization. This has led to hypothesis that percutaneous coronary intervention (PCI) with DES may be equivalent to surgical revascularization (CABG) in multivessel disease (MVD) patients. However, there are no definitive data to support this hypothesis, which has been recently shadowed by the ray of concerns regarding the long-term safety of DES, particularly in complex patients. The aim of this study was to evaluate long-term clinical outcomes of patients undergoing multivessel PCI with DES.

**Methods:** Patients undergoing PCI with at least one DES (sirolimus- or paclitaxel-eluting stents) were enrolled in the Ferrarotto Hospital DES Registry (n=1612). For the purpose of this analysis, patients undergoing multivessel PCI only with DES were included. Patients with any previous revascularization and with concomitant bare metal stent implantation were excluded. Major adverse cardiac events (MACE) including cardiac death, non-fatal myocardial infarction (MI), need for repeat target vessel revascularization (TVR), and possible in 6 (1.9%) patients. The multivariate analysis showed that independent predictors of MACE were: triple- vessel disease (HR 2.02 CI: 1.39-2.45, p=0.0001), diabetes (HR 1.74, CI 1.19-2.52, p=0.004) and left ventricle ejection fraction <35% (HR 1.86 CI 1.06-3.26, p= 0.03). LST occurred as follows: definite 0%, probable in 1 (0.3%) and possible in 3 (0.9%) patients. VLST occurred as follows: definite in 1 (0.3%), probable in 1 (0.3%) and possible in 2 (0.6%) patients.

**Conclusions:** Multivessel DES implantation can be safely performed on patients with complex coronary artery disease, among whom MACCE more commonly occur in patients with diabetes, triple-vessel disease, and low left ventricle ejection fraction.

### 2900-62 Long-term Outcomes of Sirolimus-Eluting Versus Bare-Metal Stents in Patients Undergoing Percutaneous Coronary Intervention: A Single, Tertiary Care Hospital Experience

Anuj R. Shah, Jeffrey D. Mather, Jill Courtier, Deborah Murphy, Athanasios Kapetanopoulos, Bhupinder Singh, Rameez T. Sayed, Shafeeq Ahmed, Francis J. Kienan, Raymond G. McKay, Hartford Hospital, Hartford, CT

**Background:** The long-term safety of drug-eluting stents remains controversial. We sought to determine long-term outcomes of sirolimus-eluting stents (SES) compared to bare-metal stents (BMS) in patients undergoing percutaneous coronary intervention (PCI).

**Methods:** A total of 4448 consecutive PCI patients treated with either SES (n=2976) or BMS (n=1472) between 12/2002 and 2/2007 were included in a propensity analysis to adjust for baseline clinical, demographic and angiographic differences between the cohorts. The matched-pairs (SES, n = 991; BMS, n = 1027) were compared for long-term outcomes (mean follow-up = 20.3 months; interquartile range 9.4 - 36.2), including mortality, myocardial infarction (MI) or repeat target lesion revascularization (TLR).

**Results:** In follow-up over 3 years in an unadjusted or adjusted Cox regression analysis, SES demonstrated a significant benefit over BMS for the composite end point of death, MI or repeat TLR (p<0.001: Hazard Ratio (HR)=1.6; 95% CI = 1.3 - 2.2), as well as for combined death or MI (p = 0.02: adjusted HR = 1.5; 95% CI = 1.1 - 2.1). The stent groups did not differ for mortality alone in the adjusted analysis (p = 0.08: adjusted HR = 1.4; 95% CI = 0.9 - 1.9).

**Conclusions:** In this single-center registry, sirolimus-eluting stents demonstrated a significant protection over bare-metal stents for the composite outcome of death, MI and TLR and the combined endpoint of death or MI over a 3-year period. There were no long-term mortality differences between the stent types.

### 2900-63 Polymer Integrity and Focal Platelet Deposition on Paclitaxel-Eluting Stent After Failure of Direct Stenting in Complex Coronary Lesions

Giuilio Quagliuolo, Giuseppe Mucchiocci, Roberto Rossini, Frank Kolodge, Patricia Johnson, Vaghele Sirdo, Robert Nolan, Lauren Mikhailik, Ana Volyodic, Orazio Valsecchi, Renata Virmani, Ospedali Riuniti di Bergamo, Bergamo, Italy, CVPath Institute Inc, Gaithersburg, MD

**Aim:** To evaluate the short term mechanical integrity of paclitaxel-eluting stents (PES) and bare metal stents (BMS) following failure of direct stenting in complex coronary lesions.

**Methods:** We studied 26 patients with 43 lesions (24:3:8) referred for coronary angioplasty. Test subjects, randomized 1:1:2 to BMS Libertè (BMS, n=5), Taxus Express2™ (TE2, n=5) and Taxus Libertè™ (TL, n=10), had direct stenting failures (DSF). Control group (BMS 2, TE2 2 and TL 2) were inserted into the guide catheter of control pigs for 2 minutes. All stents were analyzed by Scanning-Electron Microscopy (SEM) for a qualitative and semi-quantitative analysis in terms of coating displacement/scratching and platelet deposition.

**Results:** SEM analysis showed no loss of mechanical integrity on DSF. In BMS, a low amount of scratches were seen in both controls and DSF. In terms of coating displacement 3 TE2 test subjects (60%) had coating displacement at strut surface. Both TL test and control subjects displayed bare spots on connecting struts. Four TL test group showed a tear-like coating displacement on the strut surface (40%: Fig. 1). There was a non significant trend of higher platelet density on TL stents compared to others. Conclusions: DSF does not influence the mechanical integrity of BMS or PES units, but does not seem to be associated with a higher amount of scratches/scratching displacement. Fig. 1 Tear-like coating displacement, present on 4 of the TL test subjects.
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**B37**

**2000-06**

Balancing the Risks of Restenosis and Stent Thrombosis in Bare-metal Versus Drug-eluting Stents: Results of a Decision Analytic Model

Pallav Gang, David Cohen, Thomas Gaziano, Laura Mauri, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, Saint Luke’s Mid-America Heart Institute, University of Missouri-Kansas City, Kansas City, MO

**Background:** While there are robust data on the restenosis benefit of drug-eluting (DES) vs. bare metal stents (BMS), the incremental risk of stent thrombosis, a rare but serious complication of percutaneous coronary intervention (PCI), is not well known. We sought to define what incremental risk of very late stent thrombosis (VLST; >1 year) in DES would outweigh the restenosis benefit.

**Methods:** We developed a decision analytic Markov model comparing DES vs. BMS strategies for a contemporary PCI population. Procedure-related morbidity and mortality data from published literature were used to derive the model probabilities. Over a range of incremental risk and duration of risk of VLST, we identified the net benefit of DES vs. BMS in terms of quality-adjusted life expectancy (QALE).

**Results:** Beyond the first year of follow up, the threshold excess risk of very late DES thrombosis compared with BMS, above which BMS would be the preferred strategy, was 0.14% per year (over 4 years of follow up). Under an assumption of equal stent thrombosis rates beyond year one, the DES strategy was superior to BMS in terms of quality-adjusted life expectancy (16.26 vs. 16.248 QALYs, difference = 0.014), but under the assumption of an incremental risk difference of 0.13% per year, the net benefit was substantially reduced (difference = 0.001 QALYs). This threshold increased as the population risk of restenosis increased and decreased as the vulnerable time window lengthened.

**Conclusions:** A small absolute increase in DES thrombosis compared with BMS after year 1 (>0.14% per year) would result in BMS being the preferred strategy for the overall PCI population. Larger clinical trials with longer follow-up are needed to estimate the risk of very late stent thrombosis with greater certainty for existing and new drug-eluting stents.

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**2000-07**

Clinical Correlates of Definite Drug-eluting Stent Thrombosis a Matching Case Control Analysis

Tina L. Pinti Slottow, Daniel H. Steinberg, Probal Roy, Tenuo Okabe, Sqabub Sames, Rebecca Torgerson, Kimberly Smith, Zhenyi Xue, Joseph Lindsay, Augusto D. Pichard, Lowell Saltier, William O. Sadduth, Kenneth Kent, Ron Waksman, Washington Hospital Center, Washington, DC

**Background:** Stent thrombosis (ST) is a concerning but rare adverse outcome of drug-eluting stent (DES) placement. Accurate determination of potential predisposing factors is challenging.

**Methods:** Each of the 80 patients with definite DES ST was matched to 5 patients without ST, who underwent initial DES implant on the same day as the ST patient. Implant characteristics were compared and a conditional logistic regression model was created, controlling for age; sex; diabetes; hypertension; dyslipidemia; current smoking; history of restenosis, myocardial infarction (MI) during admission; restenosis lesion; and stent number, diameter, and length.

**Results:** Baseline demographics were similar with a population that were 64% male and 36% 1 diabetic with a mean age of 63.6±13.1. The ST group had a higher incidence of current smokers, patients with MI during admission, and patients with restenosis lesions when compared to the no ST group. DES length and diameter were similar, but significantly more stents were implanted in the ST group. A multivariate model found ST to be independently associated with MI during admission, DES placement in a restenotic lesion, and number of stents deployed.

**Conclusions:** DES ST is an infrequent but highly morbid occurrence independently associated with MI during admission, DES placement in a restenotic lesion, and number of stents deployed. Careful consideration is warranted when using DES in these settings.

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**2000-08**

Do Cobalt Chrome Stent and Paclitaxel-Euting Stent Have Equivalent Clinical Result in Noncomplex Lesion? Two-Year Follow-up

Hyoen-Chool Gwon, on behalf of COPE study investigators, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea

**Background:** Recent study suggested excessive risk of late stent thrombosis after drug-eluting stent (DES) implantation. This study was to compare the long-term safety of DES comparing bare metal stent (BMS).

**Methods:** This study was designed as a multicenter prospective randomized trial comparing VISION® stent (group V) and TAXUS® stent (group T) in a low risk group. Inclusion criteria were 1) stable or unstable angina or acute ischemia 2) treated lesion number ≤ 2 in separate vessels 3) target lesion stenosis was 50 - 95%, 3) native vessel stentable with at least 3.0-4.0 mm stent, and 4) lesions fully covered by one stent (length ≤ 28 mm).

**Results:** Total 481 patients from 11 centers in Korea were included in this study. Two-year clinical follow-up was completed in 472 patients (98.1%). The baseline characteristics were similar between group V and T, except higher proportion of left anterior descending artery location in group T (V 34.6%, T 51.0%, p=0.001). Major adverse cardiac event and stent thrombosis rate (definite or probable stent thrombosis by ARC definition) was statistically not different between 2 groups for 2 years, and also between 1 and 2 years after the procedure. Target vessel revascularization rate was significantly lower in group T at 1 year (V 6.9%, T 1.3%, p=0.002), and also at 2 years (V 7.0%, T 2.6%, p=0.03).

**Conclusions:** Overall safety of DES seems to be similar to BMS for 2 years, without excessive risk of death or myocardial infarction as well as stent thrombosis, even in low risk patients.

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**2000-09**

Clinical and Angiographic Predictors of Restenosis and Target Lesion Revscularization After Implantation of Sirolimus-Eluting Stents in Bifurcation Lesions from the j-Cypher Registry

Toshioh Tamura, Kazuaki Mitsudo, Takeshi Kimura, Kazushige Kadota, Hideo Abe, Osamu Doi, Seichi Haruta, Yasuhiko Hayashi, Kazuo Hazi, Yoshikazu Hisaka, Takashi Honda, Naoto Inoue, Takeshi Iishki, Kazuya Kawai, Atsushi Atsushi, Tomohiro Kawasaki, Yuki Kazatani, Masumori Matsuzaki, Taichiro Megumi, Akira Miura, Toshiyua Muramatsu, On behalf of the j-Cypher Registry investigators, Kyoto University Hospital, Kyoto, Japan

**Background:** The factors associated with the occurrence of restenosis after sirolimus-eluting stent (SES) implantation in bifurcation lesions are currently unknown.

**Methods:** Design of the j-Cypher Registry was multi-center prospective enrolment of consecutive patients receiving SES from 41 centers in Japan. As of July 31, 2007, long-term follow-up data were available in 1052 patients underwent successful implantation of SES. Target lesion revascularization (TLR) was defined as any revascularization procedure involving the target lesion. Among them, we identified 1736 patients (1854 lesions) who were treated with SES in bifurcation lesions excluding left main coronary artery, left anterior descending artery ostium and circumflex coronary artery ostium. 1395 lesions (1500 lesions) were assigned in group C (finally stenting main vessel and side branch). Two strategies were selected according to the operators discretion. We analyzed clinical and angiographic predictors of restenosis and TLR at long-term (follow-up period was 462±222.7 days).

**Results:** 763 lesions (43.4%) were true bifurcations. Follow-up angiography was performed on 59.4% lesions. Restenosis rate was 20.1% (main vessel: 8.6% and side branch: 14.1%) and TLR rate was 6.5%. There was no significant differences in restenosis rate between group C and group S (16.0% vs 20.6%, p=0.39). However the incidence of TLR was significantly higher in group C than group S (11.6% vs 5.3%, p=0.001). With regard to angiographic restenosis, postprocedural side branch diameter stenosis was associated with a higher risk among baseline angiographic parameters. In the multivariable analysis of TLR, hemodialysis, total stent length, two stent approach and postprocedural main branch reference diameter were the strongest predictors.

**Conclusions:** For SES placement in bifurcation lesions, there was no significant differences in restenosis rate between group C and S. However hemodialysis, total stent length, two stent approach and postprocedural main vessel reference diameter were the most important predictors of TLR.

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**JACC March 11, 2008**
In the bare metal stent (BMS) era, stent fracture was reported mostly for lesions in the majority of stented patients. However, since drug-eluting stent introduction, stent fracture started to be highlighted as a new potential mechanism of coronary restenosis after sirolimus-eluting stent (SES) implantation. The aim of this study was to evaluate the incidence and clinical features of stent fracture after SES implantation versus BMS implantation.

Methods: We identified consecutive 462 patients who underwent revascularization with sirolimus-eluting Bx Velocity® stent from August 2004 to January 2007 (SES group). A control group was composed of 453 patients treated with standard Bx Velocity® stent preceding 30 months before the introduction of SES (BMS group). Stent fracture was identified by fluoroscopic evidence at follow-up angiogram.

Results: Angiographic follow-up rate was 92.0% (425/462) and 89.4% (405/453) in SES group and in BMS group, respectively. There were no significant differences in baseline patient characteristics between both two groups. The incidence of stent fracture in SES group was significantly higher (4.6% vs. 0.3%, p<0.001). The frequency of type B2/C lesion in SES group was significantly higher (76.1% vs. 67.8%, p=0.012). Especially, the frequency of total occlusion was 4.3% in SES group and 0.3% in BMS group (p<0.001). Maximum stent inflation pressure in SES group was significantly higher (19.6 ± 2.96 atm vs. 14.1 ± 1.97 atm, p<0.001). Implanted stent length per lesion in SES group was significantly longer (28.9 ± 16.3 mm vs. 15.9 ± 4.66 mm, p<0.001). And the frequency of patients with multiple overlapping stenting in SES group was significantly higher (30.2% vs. 3.0%, p<0.001).

Conclusions: Incidence of stent fracture of SES group was significantly higher than BMS group. However, rather than a specific problem with SES, stent fractures might be caused by complex lesion morphology and/or stenting techniques such as higher stent inflation pressure, long stenting, multiple overlapping stenting. Future studies should evaluate treatment strategy for SES restenosis with stent fracture.

Clinical Outcomes Among 210 Patients With Definite/ Probable Stent Thrombosis

Tina L. Pinto Slottow, Daniel H. Steinberg, Prabhu Roy, Terao Okabe, Saquib Samee, Zhenyi Xue, Kimberly Smith, Rebecca Torgeson, Joseph Lindsay, Augusto D. Pichard, Lowell Satter, William O. Suddath, Kenneth Kent, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Stent thrombosis (ST) is the most concerning adverse outcome of drug-eluting stent (DES) placement.

Methods: Clinical outcomes of patients experiencing definite and definite/probable ST by the Academic Research Consortium definitions among the 8403 patients undergoing unrestricted percutaneous coronary intervention (PCI) with DES since April 2003 were examined. Clinical outcomes to 2 years of the patients with definite or probable ST were compared to those without ST.

Results: Baseline demographics were similar; the population was 65.4% male with a mean age of 64.5±12.2 years. 83 patients presented with 84 definite DES events. 210 patients were adjudicated to have experienced definite or probable ST events. Outcomes in both groups were uniformly poorer with a much higher incidence of death, Q-wave myocardial infarction, and target vessel revascularization up to 2 years when compared to patients who did not experience definite or probable ST. (Table)

Conclusions: DES is an infrequent but highly morbid occurrence.

Long-term Struts Coverage of Paclitaxel Polymer-eluting Stents Implanted During ST Elevation Myocardial Infarction

Giulio Guagliumi, Vaskle Sirbu, Giuseppe Musumeci, Alexander Mallasshivli, Roberta Rosatti, Ana Veyovic, Alexandr Mikhailov, Marco A. Costa, Orozio Valsecchi, Osamu Kitamura, Kyoto Second Red Cross Hospital, Kyoto, Japan

Background: The use of drug eluting stents in ST elevation myocardial infarction (STEMI) remains controversial due to the risk of stent thrombosis. Uncovered stent struts were identified by pathology as the main predictor of late stent thrombosis. This study aimed to evaluate long-term stent strut coverage in patients (pts) treated with paclitaxel polymer eluting stents (Taxus Express2TM; PES) during STEMI using high resolution optical coherence tomography (OCT), which allows accurate assessment of in-vivo stent strut coverage at a micron-scale resolution (10 μm).

Methods: We studied 30 consecutive STEMI pts with baseline TIMI 0-1 flow who underwent primary angioplasty with DES (n=51) and completed 12 month follow-up assessment with OCT imaging of the target vessel. OCT was performed with an automatic pullback at 15 frames/sec (1 mm per sec). Quantitative analysis of neointimal thickness, stent strut coverage and apposition was performed throughout the entire stent at every 0.5 mm. Stent coverage was graded as: covered (>0.01 mm thickness) and uncovered (≥0.01 mm thickness) and uncovered struts (>0.01 mm). Clopidogrel and aspirin were maintained for one year in all pts.

Results: All 51 PES (mean length 21±6.9 mm) were evaluated by OCT. A total of 15217 struts were analyzed. There were 92 (0.6%) malapposed struts and 247 (1.6%) uncovered struts. Mean neointimal thickness was 330±400 Mm. On average, 98.8% struts per stent were covered (range: 90.8-100). There were 28 PES (54.5%) which showed all struts to be completely covered. Two pts (6.6%) had at least one cross section image with >30% of struts uncovered. There was no evidence of intraluminal thrombus. No stent thrombosis occurred during the study.

Conclusions: Strut coverage of PES implanted in the setting of primary PCI was almost complete at long-term follow-up as assessed by OCT and malapposition rate was relatively low. Whether the frequent finding of at least one uncovered stent strut has any clinical implication remains to be evaluated in large prospective clinical trials.

The Incidence of Stent Thrombosis in Patients With Acute Coronary Syndrome and Stable Angina After Drug-eluting Stents Implantation

In Hyun Jung, Seong-wook Park, Jong-Pil Park, Jae Hyung Park, Jeong-wo Lee, Won-Jang Kim, Duk-Woo Park, Seung-Whan Lee, Yong-Hak Kim, Cheol Whan Lee, Myeong-Ki Hong, Jae-joong Kim, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: Despite the substantial benefit of drug-eluting stents (DES) on the suppression the neointimal growth, the long-term safety regarding stent thrombosis (ST) has been questioned recently. Data on the difference of the incidence of ST between acute coronary syndrome (ACS) and stable angina is limited in patients who underwent DES implantation.

Methods: We identified 3,153 patients who underwent DES implantation at our institution between Feb. 2003 and Mar. 2006, in whom 1,494 patients (47%) were presented with stable angina and 1,585 patients (53%) with ACS. Mean follow up duration was 29.6 ± 10.0 months.

Results: Stent thrombosis occurred in 66 patients (the cumulative incidence of ST up to

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to 3 years was 2.1%, ST developed more frequently in patients with ACS, as compared with those with stable angina (441/585 pts (2.8%) vs. 221/494 pts (1.5%), p=0.013). Mean durations of development of ST in stable angina and ACS group were 30.1 ± 9.7 and 28.9 ± 10.5 months, respectively. Cox-regression analysis showed that the incidence of ST was significantly higher in patients with ACS than that of patients with stable angina according to time duration (p=0.010, HR=0.51; 95% CI 0.30-0.85) (Figure).

Conclusion: These results demonstrate that the long-term cumulative incidence of ST is significantly higher in ACS than in stable angina patients. Additional pharmacological efforts should be necessary to prevent ST in patients with ACS after DES implantation.

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<table>
<thead>
<tr>
<th>Unadjusted Values, % (n)</th>
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<tr>
<td>Non-Diabetic</td>
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<tr>
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<td>All-cause Death</td>
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<td>Stent thrombosis (per protocol)</td>
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<td>ARC ST (definite or probable)</td>
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</table>

*Patients with the following characteristics were excluded: vein graft stenting, percutaneous intervention, left main stenting, cardiogenic shock, severe calcification, dissection, and thrombus present, severe tortuous vessels, or a total stent length >64 mm.*

**9200-75**

**Greater Healing Is Observed in Very Late Versus Late Drug-eluting Stent Lesions in Man**

Gaku Nakazawa, Elena Ladich, Alodie V. Finn, Erik K. Mont, Robert Kutys, Allen P. Burke, Frank D. Kolotie, Renu Virmani, CVPath Institute, Inc, Gaithersburg, MD.

**Background:** Delayed arterial healing is the hallmark of drug eluting stents (DES) however, it remains unknown when healing is complete. We therefore examined our DES autopsy registry to investigate the differences in late and very late DES lesions.

**Methods:** From a total 181 DES lesions, 86 were late (360-360 days), and 47 were very late (360-360 days). Analysis for fibrin deposition, strut coverage, inflammation score, and presence of giant cells was compared between late and very late lesions in those with and without acute stent thrombosis (ST).

**Results:** The incidence of ST was equal in late and very late lesions (23% vs. 26%). Patient (non-ST) very late DES lesions showed better healing with significantly less uncovered struts and fibrin deposition compared to patient late DES lesions. Among ST lesions, delayed arterial healing was observed in both late and very late lesions with poor strut coverage and moderate fibrin deposition (Table). The underlying pathologic risk factors specific for very late ST lesions were bifurcation, hyperactivity reaction, and penetration of necrotic core in acute myocardial infarction patients.

**Conclusions:** DES healing was greater in very late versus late lesions in patient lesions. Stents with late and very late ST did not show significant differences in healing except for a decrease in fibrin score. The main underlying morphologic findings of very late ST are bifurcation, hyperactivity reaction, and penetration of necrotic core in acute myocardial infarction patients.

**Comparison between Late vs. Very Late DES Lesions in those with and without stent thrombosis**

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<th></th>
<th>Non-ST Late</th>
<th>Non-ST Very Late</th>
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<th>ST Late</th>
<th>ST Very Late</th>
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<td>(360-360days)</td>
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<td>EEL, mm²</td>
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**9200-74**

**Paclitaxel-eluting Stents Blunt the Effect of Diabetes on Clinical Restenosis: A Pooled Analysis of the ARRIVE Program**

D. Lynn Morris, John M. Lasala, David A. Cox, Lazar Mandlov, Donald S. Baim, Albert Einstein Medical Center, Philadelphia, PA.

**Background:** Diabetes (DM) is associated with an increased risk of cardiovascular events and increased incidence (up to 60%) of restenosis following percutaneous coronary interventions compared to non-diabetic (non-DM) patients. In vitro, paclitaxel inhibits smooth muscle cell proliferation even in the presence of insulin resistance. We thus assessed whether the paclitaxel-eluting TAXUS Express (TE) stent reduces clinical restenosis as effectively in DM as in non-DM patients.

**Methods:** TE patients (1530 DM and 3242 non-DM) from the ARRIVE 1 and 2 registries were pooled, excluding patient characteristics globally contraindicated for TE. Clinical events were evaluated at 1 year (95.5% follow-up) for DM and non-DM. Baseline differences were adjusted by propensity score.

**Results:** DM patients had more cardiac risk factors and comorbidities than non-DM, with an anticipated increase in 1-year mortality. However, TE-related cardiac death, MI, and ST were similar in DM and non-DM. TVR and TE-related TVR were nearly identical between groups. These findings were maintained following propensity score adjustment.

**Conclusion:** This study suggests that despite the known higher mortality rate for DM vs. non-DM, the TE stent has similarly low rates of stent-related death, MI, ST, and MCE in DM and non-DM. Moreover, the incidence of TVR and TAXUS-related TVR in indicated patients with or without DM suggest that the TE stent can mitigate the adverse effect of diabetes as a risk factor for restenosis.
Surgical Treatment with Left Internal Mammary Artery Grafting versus Percutaneous Coronary Intervention with Drug Eluting Stent Implantation in Patients with Proximal Left Anterior Descending Artery Stenosis, Suffering from Chronic Stable Angina - Long-term Results
Konstantinos Toutouzas, Chrysovalia Patsia, Sophia Vaina, Eleftherios Tsimas, Anastasios Spanos, Eli Stefanidis, Manolis Vavouranakis, Eustratios Pattakos, Mathaios Panagiotou, Dimitrios Filipou, Ioannis Chlorgiaanis, Christodoulos Stefanidis, Hippocrates hospital, Athens, Greece

Background: Drug eluting stent (DES) implantation and left internal mammary artery (LIMA) are two well-accepted treatment options for significant lesions of the proximal left anterior descending artery (pLAD). A limited number of small studies comparing the two procedures have shown conflicting results. In our study we performed a comparison between LIMA and DES for a single pLAD plaque, in patients (pts) suffering from chronic stable angina (CSA).

Methods: We enrolled 317 pts with a lesion in the pLAD, who suffered from CSA: 207 underwent DES implantation and 110pts LIMA grafting. Primary end points were the occurrence of major adverse cardiac events (MACE), MACE was defined as: Death, myocardial infarction and target lesion revascularization (TLR). The recurrence of angina was also evaluated. The pts were followed-up clinically

Results: The incidence of MACE was 5.31% in the DES and 2.72% in the LIMA group (p=0.39) during the 26.3±10.15 months follow-up period. TLR was 3.88% after DES and 0% after LIMA (p=0.10). Recurrent angina occurred in 11pts (4.38%) in the DES group and in 7pts (6.36%) in the LIMA group (p=0.60), which were treated medically. The event-free survival curve was similar in both groups: 94.68% for the DES group versus 97.27% for the LIMA (p=0.14) (Figure).

Conclusion: We demonstrated that DES use in pLAD lesions has comparable long-term results with LIMA due to the decreased rate of TLR. Further, large scale, randomized trials will establish whether DES will be the treatment of choice.

Safertiy of Protamine After Percutaneous Intervention With Drug-eluting Stent: A Retrospective Study
Dmitry Chuprun, Ephron Shohat, Scott Frankel, Mehndi Haran, Nancy Schulhoff, Robert Frankel, Maimonides Medical Center, Brooklyn, NY

Background: Reversal of anticoagulation with intravenous Protamine after percutaneous intervention (PCI) is a simple and inexpensive method permitting early sheath removal. Despite several studies showing the safety of Protamine after percutaneous balloon angioplasty or bare metal stent, routine use of Protamine after drug-eluting stent (DES) placement has not been adequately evaluated.

Methods: Outcomes in 372 patients who underwent PCI during 2005 and received Protamine to normalize activated clotting time for manual sheath removal were reviewed. Those patients who underwent Angioseal placement without reversal of heparin during the procedures were considered to have a sheath removal. Postprocedural events in the subsequent 30 days were analyzed.

Results: The two groups of patients were well matched according to demographic, clinical and procedural characteristics. A majority of the patients (92.5%) had successful placement of DES and 2.6% had balloon angioplasty alone. Fifty seven percent of the procedures were emergent or urgent. Two or more stents were placed in 40% of the patients and PCI of more than one vessel was performed in 29%. The incidence of cardiovascular complications was not significantly different between the groups. No adverse reactions to Protamine were observed.

Outcomes

- Proximal graft
  - DES: p=0.72
  - LIMA: p=0.35
  - P value
- Periprocedural MI
  - DES: 10 (3.7%)
  - LIMA: 12 (3.4%)
  - 0.852
- Acute/subacute thrombosis
  - DES: 0 (0.4%)
  - LIMA: 4 (1.1%)
  - 0.384
- Death
  - DES: 0 (0.4%)
  - LIMA: 2 (0.43)
- Stroke 24 hr after PCI
  - DES: 1 (0.4%)
  - LIMA: 0.435
- Peripheral vascular injury
  - DES: 5 (1.8%)
  - LIMA: 0.35

Conclusion: Administration of Protamine after DES placement is not associated with an increased incidence of adverse cardiovascular events, even in the setting of high-risk procedures.

Is Coronary Stent Fracture after Sirolimus-Eluting Stent Implantation an Adverse Event?
Yoshitaka Nishibori, Hiroshi Fujita, Akiko Matsuo, Yasutusu Shiono, Kiyonari Matsuo, Nakihiko Nakashima, Shin-ichiro Yamaguchi, Keiji Iinoue, Tetsuya Tanaka, Makoto Kitamura, Kyoto Second Red Cross Hospital, Kyoto, Japan

Background: Stent fracture is considered as a new potential mechanism of restenosis after sirolimus-eluting stents (SES) implantation. The aim of this study was to evaluate the prevalence and clinical impact of coronary stent fracture after SES implantation.

Methods: From our prospective institutional database, 336 patients were treated solely with SES from June 2004 to August 2006. Among 336 patients, 315 (93.8%) patients with a total of 377 lesions underwent follow-up angiography on an average of 240 days after the procedure.

Results: Stent fractures were observed in 17 lesions (4.5%). Of the 17 lesions with stent fracture, 7 were chronic total occlusion, 4 were diffuse long lesion, and 4 were in-stent restenosis lesion. In patients with stent fracture, the number of implanted SES per lesion was 2.18±1.29, the mean diameter and length of SES per lesion were 3.01±0.34mm and 50.9±36.6mm, respectively. Fifteen of the 17 stent fractures were adjacent to the edge of previously implanted or overlapping stenting. One stent thrombosis case (1/17) and two coronary artery aneurysm cases associated with stent fracture (2/17) were seen in patients with stent fracture. Independent predictors of stent fracture were RCA location (OR 10.2, 95% CI 2.01-52.57, p=0.005), implanted SES length (>30mm) (OR 11.16, 95% CI 4.30-36.70, p=0.001), and overlapping stenting (OR 59.5, 95% CI 1.53-75.4, p=0.004). In-stent binary restenosis rate was 47.1% (8/17) and 15.0% (5/426) in lesions with stent fracture and without stent fracture, respectively (p=0.001). Whereas 26 (7.2%) lesions without stent fracture underwent target lesion revascularization (TLR), 5 (29.4%) lesions with stent fracture underwent TLR (p=0.001). In all lesions underwent TLR, only 16.1% (5/31) was with stent fracture.

Conclusions: Stent fracture was associated with complex coronary lesions, long stenting and/or multiple overlapping stenting. Stent fracture might be associated with the high incidence of TLR. However, lesions with stent fracture underwent TLR were small minority group in whole SES restenosis. Coronary stent fracture after SES implantation showed relatively favorable long-term prognosis.

Left Main Bifurcation Percutaneous Treatment: Is Restenosis Influenced by the Type of Drug-eluting Stent?
Mario Elena Di Salvo, Gian Paolo Ussia, Piera Capranz, Giambattista Barrano, Anna Ciggeghi, Alessio La Mania, Carmelo Sgri, Alfon Monaco, Corrado Tamburino, Ferrarorotto Hospital, Catania, Italy

Objective: Percutaneous transluminal angioplasty (PTA) of unprotected left main coronary artery (ULMCA) stenting bifurcations is a challenge for interventional cardiologists. Drug eluting stents (DES) showed a lower rate of restenosis related to the different techniques.

The objective of this analysis is to evaluate the mid-term results of bifurcation treatment by DES and to study whether restenosis is influenced by the type of implanted DES.

Method and Result: From June 2002 to August 2007 in our Institute PCI with DES of ULMCA bifurcations stenosis was performed in 326 consecutive patients and 139 bifurcations were treated: 106 (82%, male, mean age 65.5 ± 9.2 years). Clinical presentation was acute myocardial infarction in 58%, acute coronary syndrome in 25%, stable angina in 10%. Stenting of bifurcated lesions was performed during the index PCI in 55 patients. procedural success was 99%. In hospital adverse major cardiac events occurred in 4 patients (3.9%). One patient died for cardiac arrest during PCI. One patient died at three months for non cardiac death. At six months clinical follow up was obtained in 113 patients, angiography was performed in 83 patients with 10.8% of in-stent restenosis.

Conclusions: PCI of ULMC bifurcation with DES is a safe procedure, with good immediate and mid term results. The best bifurcation stenting technique has to be identified and follow up is not differentially influenced by the use of Sirolimus or Paclitaxel stent.

Large Registry Analysis of Patients Treated with Drug-eluting Stents for Off-label Indications: A Comparison to Bare-metal Stents
John M. Gatz, Sorin J. Brener, Stephen G. Ellis, Cleveland Clinic, Cleveland, OH

Background: The use of drug-eluting coronary stents (DES) for other than FDA approved indications has been associated with worse outcomes versus when they are applied for on-label indications. Comparisons of outcomes for off-label DES vs. bare-metal stents (BMS) use have not been reported. This analysis compared outcomes of DES to BMS in lesions categorized as off-label for DES.

Methods: Four thousand and two consecutive patients received coronary stents for an off-label DES indication at our institution since the commercial introduction of DES in April 2003 to July 2007. Off-label indications included ST-segment elevation myocardial infarction (STEMI), chronic total occlusion (CTO), bypass graft, in-stent restenosis (ISR), long lesions (>30mm for paclitaxel-eluting (PES) or > 28mm for sirolimus-eluting stents (SES)) and vessel diameter (3.75mm for PES and 3.5mm for SES). Patients were prospectively followed for 3 years for death, myocardial infarction and target lesion revascularization. Cox proportional hazard analysis was performed including pertinent variables and a propensity score for receiving DES vs. BMS (c-statistic = 0.75).
Results: 2959 (73.9%) patients with at least one off-label indication received at least one DES. Predictors of stent choice (odds ratio >1 favors DES) included STEMI (OR=1.03, 95% CI 0.99-1.07, p=0.02), female sex (OR=0.95, 95% CI 0.92-0.98, p<0.0001), lesion located within the proximal left anterior descending artery (1.49, 1.12-1.98, p=0.006) and larger vessel diameter (0.43, 0.38-0.49, p<0.0001). Compared to BMS, DES was associated with a significant reduction in mortality (HR=0.53, 0.42-0.67, p<0.0001). There was a trend toward fewer recurrent myocardial infarctions in the DES group (HR=0.66, 0.38-1.13, p=0.13) with no observed difference in total and non-target vessel revascularization rates.

Conclusions: When used in an off-label setting, DES appear to perform at least as well, and possibly better, than BMS in similar lesions. Further prospective studies are needed to verify these findings. If confirmed, could alter the indications for DES use.

2900-81 Overlapping Drug-eluting Stents: Intravascular Ultrasound Insights From Cobalt Chromium Stent With Anti-proliferative for Restenosis II (COSTAR) II Trial
Yunja Ahn, Ichiro Tsujino, Tomomi Kozumi, Katsuhisa Waseda, Yashiro Honda, Paul G. Yock, Dean J. Kereiakes, Mitchell W. Krucoff, Peter J. Fitzgerald, Stanford University, Stanford, CA, Duke University, Durham, NC
Background The safety and efficacy of overlapping drug-eluting stents (DESs) remain to be elucidated. In a subset of patients in COSTAR II trial (a randomized trial comparing CoStar cobalt chromium paclitaxel-eluting stent with TAXUS stents), the effects of overlapping DESs were examined. The aim of this intravascular ultrasound (IVUS) study was to compare the vascular responses of overlapping stenting.

Methods: The degree of neointimal proliferation at 9 months follow-up was assessed by IVUS. Complete stent apposition (IPA) was defined as apposition of all stent struts from the vessel wall at follow-up, where post-procedure IVUS revealed complete apposition. Impaired strut continuity was defined as interrupted continuity of the stent struts. Percent lumen area (%LA) and mean minimum lumen area (MMA) were assessed in the single stent group and overlapping group. Percent neointimal volume (%NV) and mean neointimal volume (MV) were calculated in the single stent group and overlapping group.

Results: Maximum %neointimal area was 47.5 ± 19.9 (P = 0.95) in the single stent group and 37.8 ± 15.4 (P = 0.04) in the overlapping group. Mean neointimal volume was 4.2 ± 1.5 mm³ in the single stent group and 6.8 ± 1.9 mm³ in the overlapping group. Mean neointimal area was 3.6 ± 1.7 mm² in the single stent group and 5.5 ± 2.1 mm² in the overlapping group.

Conclusions: As compared with single stenting, overlapping stents equivalently reduced neointimal hyperplasia without excess LISA in both stents. Impaired strut continuity was more frequently observed in overlapping stent.

Clinical Implications of Drug-eluting Stent Fracture
Jong Kim, Jong-Seon Park, Won-Jae Lee, Sang-Hee Lee, Geu-Ru Hong, Dong-Gu Shin, Young-Jo Kim, Bong-Sup Shim, Yoon-Kyung Cho, Hyoung-Seop Kim, Chang-Wook Nam, Sun-Wook Han, Seung-Ho Hur, Kwon-Bae Kim, Yoon-Nyun Kim, Sang-Boon Choi, Sang-Hoon Seol, Tae-Hyun Yang, Dae-Kyung Kim, Sung-Man Kim, Do-Il Kim, Dong-Soo Kim, Tae-Kim, Yeungnam University Medical Center, Daegu, South Korea
Background: Stent fracture (SF) has been suggested as a cause of restenosis and cardiac events after sirolimus-eluting stent (SES) implantation. However, we do not have any data about its prognosis and optimal therapeutic strategies. We have performed this study to understand the clinical outcomes of SF fracture.

Methods: A total of 52 SFs from 42 consecutive patients who implanted with SES in 4 centers were included in this registry. All therapeutic modalities (no treatment, balloon angioplasty, stent) were decided by the operator’s decision. Patients were followed up to evaluate major adverse cardiac events such as death, myocardial infarction and repeat revascularization. Follow-up angiography was performed in selected patients.

Results: Average SF number was 1.2 per patient. Mean follow up duration from stent implantation to Fx detection was 277±153 days. SF was found with restenosis in 19 of 52 SF lesions (37%). Ten patients (24%) presented with chest pain and 9 of them showed restenosis associated with SF. Twenty-seven patients (62%) were treated by maximal medical therapy and 15 patients (38%) were treated by intervention (sten 10, balloon 5). At long term follow up (469±291 days), total 5 MACE have occurred. Four patients (15%) had myocardial infarction, and 3 of these were related with very late stent thrombosis in mediacion arm. Otherwise, only 1 patient (7%) had TLR without myocardial infarction in PCI arm. No death was found. Conclusions: SF, even if it’s silent, is not safe and careful examination to find out the SF and close attention for the cardiac events are needed.

2900-83 Proximal Calcium May Influence Performance of Polymer-based Drug-eluting Stents: A Detailed Intravascular Ultrasound Analysis
Ryota Sakurai, Masao Yamasaki, Junya Ako, Yoichiro Hongo, Akiyoshi Miyazawa, Seung-Ho Hur, Yashiro Honda, Paul G. Yock, Peter J. Fitzgerald, Stanford University, Stanford, CA
Background: Polymers used in drug-eluting stents may be susceptible to mechanical damage during stent delivery. We sought to investigate the potential impact of proximal calcification on the efficacy of the phosphorylcholine-coated zotarolimus-eluting Driver stent (ZES). Methods This study enrolled 243 patients who underwent phosphorylcholine-coated ZES (n=187) and uncoated Driver stent (BMS, n=56) deployment with baseline and 8 months intravascular ultrasound (IVUS) examination. Proximal calcified plaque was defined as any plaque with superficial calcium arc >180° between the coronary ostium and the proximal stent edge defined by baseline IVUS. Results The prevalence of proximal calcified plaque was similar between BMS and ZES (21.4% vs. 19.3%, p = 0.71). In each stent, baseline characteristics were comparable between patients with (px-Ca+) and without (px-Ca-) proximal calcified plaque. At 8 months, IVUS measurements were similar between the 2 groups in BMS. In ZES, although maximum %neointimal area, defined as the maximum of (neointimal area / stent area x 100), was greater and minimum lumen area was smaller in the px-Ca+ group than the px-Ca- group, volumetric IVUS measurements and angiographic in-stent restenosis rates were comparable between the 2 groups, as well as in BMS. Conclusion: Despite the slight increase in focal neointimal proliferation, moderate proximal calcification may not significantly attenuate the overall efficacy of phosphorylcholine-coated ZES.
Discrepancy Between Intravascular Ultrasound and Coronary Pressure Measurement Criteria to Assess Optimal Implantation of Sirolimus-eluting Stent
Hong-Seok Lim, Myeong-Ho Yoon, Hyung-Mo Yang, Seong-Il Woo, Un-Jong Choi, Jung-Won Hwang, Soo-Jin Kang, Byoung-Joo Choi, So Youn Choi, Gyo-Seung Hwang, Joon-Han Shin, Seung-Jea Tak, Ajou University Medical Center, Suwon, South Korea

Background: Determination of pressure derived myocardial fractional flow reserve (FFR) has been proposed as a means to assess stent deployment. However, data comparing morphologic and functional criteria of optimal drug-eluting stent deployment are still limited. We investigated the relative value of FFR by comparing it with the intravascular ultrasound (IVUS) for optimizing optimal sirolimus-eluting stent (SES) implantation.

Methods: In 46 patients, a SES was implanted in 51 lesions located at proximal to mid coronary arteries followed by optional adjuvant dilation with non-compliant high-pressure balloon. IVUS assessment and FFR measurement were performed before and after the interventional procedure.

Results: Receiver operator characteristic analysis defined a optimal FFR cut point at ≥0.94 for the prediction of optimal stent deployment based on validated IVUS criteria (final minimal lumen area (MLA) ≥5.0mm2; at this threshold, the sensitivity, specificity, and predictive accuracy of FFR were 50%, 76%, and 62%, respectively. Both optimal IVUS and FFR results were achieved in 27 lesions (group A) but, 15 lesions had optimal IVUS and suboptimal FFR results (group B). Plaque burden, reference lumen area, final MLA and final minimal lumen diameter were not different between both groups. Length of stented segments was longer (56 ± 43mm; p=0.023) in B group than in A group.

Conclusions: An FFR > 0.94, measured after SES deployment, predicts an optimal result, however, an FFR ≤0.94 does not reliably predict a suboptimal stent result. In patients treated with multiple long SES implantation, an FFR might underestimate the stent result, compared with IVUS.

Prospsective Randomized Six-Month Comparison of Coronary Vasomotor Response Associated with Zotarolimus- Versus Sirolimus-Eluting Stent: Differential Recovery of Coronary Endothelial Dysfunction
Jin Won Kim, Byung Won Cheon, Jin Oh Na, Ji Hoon Kim, Cheol Ung Choi, Soong Suh, Eung Ji Kim, Seung-Woon Rha, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Cardiovascular Center, Korea University Guro Hospital, Seoul, South Korea

Background: Zotarolimus-eluting stent (ZES: EndeavorTM) have been known to induce less intimal hyperplasia (IH) than SESs (CypherTM) implantation. However, the predictive accuracy of FFR was limited. We investigated the relative value of FFR by comparing it with the intravascular ultrasound (IVUS) for optimizing optimal sirolimus-eluting stent (SES) implantation.

Methods: In 55 patients (male 21, 54±6.9 yrs) randomly treated with IVUS guided intervention using single stent to the mid segment of left anterior descending artery (20 ZES, 20 SES, 15 BMS: bare metal stent: DriverTM), endothelial function was estimated at pre-intervention and post-intervention 6 months follow-up, by incremental acetylcholine (Ach: 10, 20, 40, 50: 100 μg/ml) and nitrate (200 μg/ml) infusion into the left coronary ostium. The vasoactive response was quantitatively measured in the segment 5 mm proximal and distal to stent. All anti-anginal agents were withheld for at least 72 hours prior to coronary angiography. Results: At 6 months of follow-up, significant vasoinhibition to Ach was observed in DES groups over the BMS group (Figure). There was a lesser vasoinhibition to Ach in the segments distal to ZESs than SESs (Figure). Conclusions: Vasoinhibition to Ach was present in the segments distal to ZESs than SESs. The difference was significant (p<0.01).

Treatment of Drug-Eluting Stent Restenosis With the Same or Different Drug-Eluting Stent: To Switch or Not to Switch
Kimberly A. Smith, Rebecca Torguson, Zhenyi Xue, Daniel H. Steinberg, Tina L. Pinto Slottow, Probah K. Rey, Saqib Sameem, Joseph Lindsay, Augusto D. Pichard, Lowell Satler, William O. Suddath, Kenneth Kent, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Drug-eluting stents (DES) have been proven as an effective treatment for bare metal in-stent restenosis (ISR). This study aimed to evaluate treatment of DES ISR with the same type versus an alternate DES type for the failed DES.

Methods: A cohort of 166 patients previously treated with a sirolimus-eluting stent (SES) or a paclitaxel-eluting stent (PES) who presented with restenosis and angina were treated with repeat DES implantation. Of these, 132 had a SES failure and 34 had a PES failure. At the time of restenosis, in the SES group 81 patients were treated with repeat SES while 51 were treated with PES, and in the PES group 9 patients were treated with repeat PES and 25 with SES. Overall, 90 patients were treated with the same DES and 76 received the other type of DES. Of these, 138 completed 12-month follow up.

Results: Baseline clinical and angiographic characteristics were similar among the groups. At 12 months the TVR-MACE rate for the SES patients treated with repeat SES was 25.4%. For SES patients treated with repeat PES was it was 17.8%. For PES patients treated with repeat PES it was 28.6% and for SES patients treated with SES it was 26.1% with no difference between the groups (p=0.769). The 12-month clinical outcomes were similar among the groups (Table). Conclusions: Switching the DES type for the treatment of DES restenosis does not yield better outcome when compared to the same DES, thus other modalities for treatment of DES restenosis should be considered.

Table 1: Table 12-Month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Same DES</th>
<th>Other DES</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR MACE</td>
<td>18 (25.7)</td>
<td>14 (20.6)</td>
</tr>
<tr>
<td>All Death</td>
<td>2 (2.9)</td>
<td>3 (4.4)</td>
</tr>
<tr>
<td>Q Wave Myocardial Infarction</td>
<td>3 (4.3)</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>TVR</td>
<td>16 (22.9)</td>
<td>11 (16.2)</td>
</tr>
<tr>
<td>Stent Thrombosis</td>
<td>1 (1.4)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Multiple Versus Single Drug-Eluting Stenting in Patients With Small Coronary Lesion
Zhe Jin, Seung-Woon Rha, Kang-yin Chen, Yoshiausu Minami, Jin Oh Na, Soong Suh, Cheol Ung Choi, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Cardiovascular Center, Korea University Guro Hospital, Seoul, South Korea

Background: Percutaneous coronary intervention (PCI) in patients (pts) with small vessel and diffuse disease is challenging because of the higher chance of recurrence even in the drug-eluting stent (DES) era. The efficacy and safety of multiple DES implantsations in pts with diffuse long and small vessel is largely unknown.

Methods: From Sep, 2004 to Dec 2006, a total 104 pts with small vessel (diameter≤2.5mm), de novo coronary artery lesions were treated with DES. Two or more DESs were implanted in 24% of the enrolled pts. Mid-term angiographic outcomes, clinical outcomes, and the survival and freedom from MACEs of the Multi-stenting group (25 pts, 53 lesions) were compared with those of Single stent group (79 pts, 79 lesions).

Results: In this study, 25 pts received two or more DESs (DESs≥2:12±0.33). The baseline characteristics were matched between the two groups. The percentage of procedure success was high and there was no difference between the two groups (100% vs. 97.3%, P=0.517). At 6-month, the overall incidence of binary restenosis was in 23.1%. However, there was no significant difference between the two groups. Overall clinical outcomes were similar (Table) and during the 6-month follow up, the survival and freedom from MACEs was similar between DM and non DM group (96.0% vs. 96.2%, p=1.000).

Conclusion: Multiple DES implantsations in pts with small vessels and diffuse long disease are safe and effective. Although the implanted stent number might not impact on the survival and freedom from MACEs after PCI at mid-term follow up, but the incidence of binary restenosis remained high, which need long-term follow up with larger study population.

Table 2: Clinical and angiographic outcomes at 6 Months

<table>
<thead>
<tr>
<th>Variables, n (%)</th>
<th>Multi-stenting group (n=25 pts, 53 lesions)</th>
<th>Single stenting group (n=79 pts, 79 lesions)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binary restenosis, %</td>
<td>36.7</td>
<td>29.8</td>
<td>0.552</td>
</tr>
<tr>
<td>Late lumen loss, mm</td>
<td>0.83±0.70</td>
<td>0.74±0.73</td>
<td>0.564</td>
</tr>
<tr>
<td>Total death</td>
<td>1 (4)</td>
<td>2 (2.5)</td>
<td>0.566</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>-</td>
</tr>
<tr>
<td>TLR</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>-</td>
</tr>
<tr>
<td>TVR</td>
<td>0 (0)</td>
<td>1 (1.3)</td>
<td>1.000</td>
</tr>
<tr>
<td>Total MACE, n (%)</td>
<td>1 (4)</td>
<td>3 (3.8)</td>
<td>1.000</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>1 (3.3)</td>
<td>0 (0)</td>
<td>0.240</td>
</tr>
</tbody>
</table>

Midterm Outcomes of Drug-Eluting Stent Implantation in Patients With Small Vessel Disease
Zhe Jin, Seung-Woon Rha, Kang-yin Chen, Yoshiausu Minami, Jin Oh Na, Soong Suh, Cheol Ung Choi, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Cardiovascular Center, Korea University Guro Hospital, Seoul, South Korea

Background: Drug-eluting stents (DES) have provided a significant innovation for preventing in-stent restenosis. Small vessel diameter is a risk factor of in-stent restenosis following percutaneous coronary intervention (PCI). In this study, we evaluated the efficacy of PCI with DES in patients (pts) with small coronary lesions.

Methods: From Sep 2004 to Dec 2006, a total of 735 pts (1064 lesions) with coronary artery lesions were treated with DES (Cypher or Taxus). The enrolled pts were divided into two groups according to the target vessel diameter: Small vessel group (<2.5mm) and Non-small vessel group (≥2.5mm). The procedural, angiographic and clinical outcomes
were compared up to 6 months. Results: In this study, 176 pts (200 lesions) were included in small vessel group and 582 pts (620 lesions) in non-small vessel group. The clinical and angiographic baseline characteristics were similar between the two groups. The percentage of procedure success was high and there was no difference between the two groups (97.9% vs. 97.6%, p = 0.820). At 6 month, although the incidence of binary restenosis was higher in the small vessel group, but the clinical outcomes were not different between the two groups (Table). At 6-month follow up, the survival and freedom from MACES was similar between the two groups (95.6% vs. 95.8%, p = 0.549). Conclusion: The procedural success, survival and freedom from MACES were high in pts who had small coronary lesions undergoing PCI with DES up to mid-term follow up despite the incidence of binary restenosis in the small vessel group. The long-term clinical outcomes of this particular subset of patients should be evaluated with a larger study population.

Table. Clinical and angiographic outcomes at 6 Months

<table>
<thead>
<tr>
<th>Variables, n (%)</th>
<th>Small vessel group (n=176 pts, 200 lesions)</th>
<th>Non-small vessel group (n=559 pts, 864 lesions)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binary restenosis, %</td>
<td>21.3</td>
<td>9.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Late loss, mm</td>
<td>0.76 ± 0.68</td>
<td>0.69 ± 0.66</td>
<td>0.174</td>
</tr>
<tr>
<td>Total death</td>
<td>6 (3)</td>
<td>28 (3.3)</td>
<td>0.697</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>4 (2)</td>
<td>17 (2.2)</td>
<td>0.976</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>0</td>
<td>0</td>
<td>0.82 ± 2.88</td>
</tr>
<tr>
<td>TVR</td>
<td>1 (0.5)</td>
<td>9 (1.7)</td>
<td>0.47</td>
</tr>
<tr>
<td>Total MACE</td>
<td>7 (3.5)</td>
<td>37 (4.3)</td>
<td>0.118</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>1 (0.5)</td>
<td>0</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Late Restenosis After Sirolimus-Eluting Stent Implantation: The Implication of Lesion Complexity

Kazushige Kadota, Kazuaki Mitsuoka, Katsumi Inoue, Tsuyoshi Goto, Satoki Fujii, Hiroyuki Yamamoto, Masao Yamashita, Ichiro Tsugino, Ali H. M. Hassan, Takao Hasegawa, Ryuji Sakurai, Katsuhiro Waseda, Paul G. Yock, Yasuhisa Hiro, Krishnan Hothi, Gregg W. Stone, Peter J. Fitzgerald, Stanford University Medical Center, Stanford, CA

Background: Although drug-eluting stents markedly reduce neointimal hyperplasia in coronary lesions, diabetes remains a risk factor for restenosis after stenting. The aim of this study was to evaluate vessel response to the XIENCE V everolimus-eluting stent implantation in the treatment of diabetic patients.

Methods: Eight-month IVUS follow-up was performed in 115 lesions (36 DM: 79 non-DM) treated with XIENCE V. Volume index (volume/length) was calculated for vessel (V), plaque (PV), neointima (IV), and lumen (L). Cross-sectional narrowing (CSN) was defined as neointimal area divided by stent area (%). To evaluate the length of severe narrowing, IH50 (% stent length with CSN > 50% along the stented segment) was calculated. Neointima-free frame ratio was defined as the number of frames without IVUS-detectable neointima divided by the total number of frames.

Results: No difference was observed in %NIV (NIV/stent volume) or max %CSN between the DM and non-DM groups, resulting in equivalent LVI and minimum lumen area (MLA) at 8 months. IH50 and neointima-free frame ratio were also similar between the 2 groups. Both groups showed no significant post-stent remodeling (VVI and PVII) during 8 months. One subject with late-acquired incomplete stent apposition was observed in the DM group.

Conclusions: The XIENCE V everolimus-eluting stent demonstrated significant suppression of neointimal hyperplasia with no increased adverse vessel response in diabetic patients up to 8 months.

Meta-Analysis of Percutaneous Coronary Intervention Versus Coronary Artery Bypass Surgery: A New Analysis Incorporating Drug-Eluting Stent Data

Damian J. Kelly, Najam I. Siddiqui, Martin Holt, Kamal Chikara, Anthony H. Gershlick, University of Leicester, Leicester, United Kingdom

Background: No meta-analysis has been published incorporating results of multi-vessel Percutaneous Coronary Intervention (PCI) with Drug-Eluting Stents (DES) versus Coronary Artery Bypass Surgery (CABG).

Methods: We conducted a meta-analysis, using fixed and random-effects analyses, of 6 trials in 4731 patients comparing PCI with CABG to determine whether DES reduced adverse outcomes. The Arterial Revascularization Therapies Study (ARTS); Stent or Surgery Trial; Argentine Randomized Trial 2 (ERACI 2); and Medicine, Angioplasty or Surgery Study involved PCI with Bare-Metal Stents (BMS); while ARTS 2 and ERACI 3 used DES versus non-randomized historical CABG controls. The primary outcome measure was the combined incidence of death, myocardial infarction. The secondary end point was the incidence of repeat revascularization.

Results: There was no difference in the primary clinical end-point between the BMS (n=1515) and CABG (n=1533) groups at one or five years: at one year this was reached by 9.4% of the PCI group and 10.7% of the CABG group (HR 0.94, p=0.46); and at 5 years by 17.7% of the BMS group and 20% of the CABG group, RR 0.99, p=0.89. Revascularization was required at one year in 16.1% of BMS and 3.3% of CABG patients, RR 4.83, p=0.001; and at five years in 30.3% of BMS and 7.5% of CABG patients, RR 4.06, p=0.001. Among the DES patients (n=830), the primary end-point was reached by 6.4% of patients at one year vs 9.8% of CABG controls (n=830), RR 0.61, p=0.003, although this follow-up period does not assess any potential risk of very late stent thrombosis. At one year 8% of DES patients required repeat revascularization vs 4.0% of CABG controls, RR 1.94, p=0.002. Combining the BMS and DES trials, PCI
reduced the incidence of the primary endpoint at one year vs CABG (8.3% vs 10.3%, RR 0.80, p=0.016), driven entirely by the DES trials. Repeat revascularization occurred more frequently following PCI than CABG (14% vs 3.8%, RR 3.66, p=0.0001).

Conclusions: Compared with multi-vessel PCI using BMS, there was no difference in the combined rate of death, myocardial infarction or stroke at one or five years following CABG. The need for repeat revascularization following PCI was attenuated by DES.

Application of Newly Developed Virtual Discrete Model of Platelet Adhesion and Aggregation for Asessment of Stent Thrombosis
Shinya Goto, Hitoshi Kawahara, Mayumi Kajimura, Noriko Tamura, Yota Kawamura, Makoto Suematsu, Tokai University School of Medicine, Isehara, Japan, Keio University School of Medicine, Tokyo, Japan

Background. Late stent thrombosis raise caution with the use of drug eluting stents. Yet, the mechanism of platelet accumulation around stent is still to be elucidated.

Methods. We have developed a new discrete model of platelet adhesion and aggregation at various blood flow condition. Virtual platelet we generated possess the function of three key adhesive platelet specific proteins of glycoprotein (GP) IIb, GPIIb/IIIa and GPVI. Adhesive force of GPIIb/IIIa and von Willebrand factor (VWF) changed with shear stress as previously demonstrated. Adhesive function of GPIIb/IIIa or both fibronogen and VWF appeared only when platelets are activated after multiple GPIIb interaction with VWF or by GPVI stimulation by collagen. We have perfused this virtual platelet with various blood flow condition on a virtual arteries implanted with various shapes of stents modeled (A).

Results. Upon perfusion of virtual blood containing our newly developed vorgit model of platelet on virtual coronary arteries exposing virtual thrombogenic matrix of collagen and VWF, platelet started to adhere on them, get activated and form platelet thromb. Platelet accumulation were augmented when stents were implanted on the injured arteries, especially downstream sites of stents (B). By comparison of the same stent in various opening opening width of stent (56 degree, 67 degree, 76 degree), number of platelets accumulated downstream of stent was the most with 67 degree at constant flow and 56 degree at pulsatile flow condition mimicking real coronary arterial blood flow (Figure). Conclusion. We have developed a virtual system to predict thrombogenicity of various shape of stents.

The Efficacy of Coronary Stenting at Lower Inflation Pressure Using the 2.5-mm Sirolimus-Eluting Stents in Very Small Vessels
Shinji Miyata, Hisashi Umeda, Tomoyuki Ota, Mitsunori Iwase, Ryoi Ishiki, Haruo Inagaki, Hideo Izawa, Toyoko Mochihara, Toyota Memorial Hospital, Toyota, Japan, Nagoya University Graduate School of Medicine, Nagoya, Japan

Background: Although coronary interventions for very small vessels are common in a clinical practice, the 2.25-mm sirolimus-eluting stents (SES) have not been available in Japan. The purpose of the present study was to assess the clinical and angiographic benefits of the 2.5-mm SES implantation at lower inflation pressure in very small coronary arteries.

Methods: A series of 110 consecutive patients with the reference diameters of <2.5 mm undergoing the 2.5-mm SES implantation at lower initial inflation pressure (<10 atm) were compared with the historical group of 141 consecutive patients (>2.5 mm) treated by balloon angioplasty and/or bare-metal stenting (control group).

Results: The clinical and lesion characteristics were similar the 2 groups. (See Tables).

Conclusions: With lower rates of restenosis and adverse cardiac events, SES implantation at lower inflation pressure might be a superior strategy in this particular population.

Angiographic and clinical outcomes in the 2 groups

<table>
<thead>
<tr>
<th></th>
<th>SES (n=110)</th>
<th>Controls (n=141)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference diameter at baseline (mm)</td>
<td>2.2±0.21</td>
<td>2.26±0.20</td>
<td>0.089</td>
</tr>
<tr>
<td>Initial inflation pressure (atm)</td>
<td>7.7±1.0</td>
<td>7.8±2.6</td>
<td>0.666</td>
</tr>
<tr>
<td>Post dilatation (%)</td>
<td>84.5</td>
<td>85.0</td>
<td>&lt;0.999</td>
</tr>
<tr>
<td>Late loss (mm)</td>
<td>0.18±0.60</td>
<td>0.53±0.52</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In-segment restenosis (%)</td>
<td>14.5</td>
<td>38.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stent thrombosis / abrupt closure (%)</td>
<td>0.9</td>
<td>2.8</td>
<td>0.389</td>
</tr>
<tr>
<td>TLR at 360 days (%)</td>
<td>9.1</td>
<td>28.2</td>
<td>0.001</td>
</tr>
<tr>
<td>MACE at 360 days (%)</td>
<td>9.1</td>
<td>29.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values are mean ± SD or percentages. SES = sirolimus-eluting stents; TLR = target lesion revascularization; MACE = major adverse cardiac events.

Multivariable predictors of restenosis

<table>
<thead>
<tr>
<th>Predictors</th>
<th>OR</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5-mm SES use</td>
<td>0.22</td>
<td>0.10-0.49</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lesion length</td>
<td>1.10</td>
<td>1.05-1.15</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Postprocedural MLD</td>
<td>0.25</td>
<td>0.10-0.64</td>
<td>0.004</td>
</tr>
<tr>
<td>Prior bypass surgery</td>
<td>3.67</td>
<td>1.23-10.95</td>
<td>0.020</td>
</tr>
<tr>
<td>Ostial location</td>
<td>3.08</td>
<td>1.18-8.03</td>
<td>0.021</td>
</tr>
</tbody>
</table>

SES = sirolimus-eluting stents; MLD = minimal lumen diameter.

Paclitaxel-Eluting Stents Are Effective in Higher Risk Patients: Gender and Age Specific Sub-Group Analyses of the TAXUS OLYMPIA Registry
Oscar Mendiz, Martyn R. Thomas, Waqar H. Ahmed, Stephen Mascioli, Donald S. Baim, Fundacion Favaloro, Buenos Aires, Argentina

Background: Previous studies have shown that women and the elderly have a higher risk during and after coronary revascularization with bare metal stents. Data following the use of drug-eluting stents, however, is limited.

Methods: TAXUS OLYMPIA is a global, post-approval registry capturing baseline and outcomes data in patients (pts) receiving the TAXUS Liberté paclitaxel-eluting stent in routine clinical practice.

Results: Of the first 7124 pts enrolled in OLYMPIA 23% were women and 12% were >75 yrs. Compared to men, women were older and more likely to be diabetic or hypertensive, while fewer smoked, had prior intervention or MI. Pts >75 tended to be female, hypertensive and have complex lesions, but less likely to smoke or have had a CABG versus younger pts. At 1 yr, event rates were higher in both subgroups. Significant increases in death, stent-related cardiac death and MI were seen in elderly pts, with no increase in stent thrombosis (ST) or TAXUS-related TVR for either group. Multivariate analysis revealed that thienopyridine termination (<6 months), age, diabetes, cardiogenic shock, prior stroke or PCI, acute MI, long lesions and multivessel disease were all predictors of death whereas multiple stenting, restenosis, RVD and thienopyridine termination were predictors of TVR.

Conclusions: The TAXUS Liberté stent, as used in this real-world registry, has excellent outcomes data in patients (pts) receiving the TAXUS Liberté paclitaxel-eluting stent in routine clinical practice.

Table 1: Characteristics and Clinical Outcomes in the OLYMPIA registry by gender and age*.

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=7124)</th>
<th>Female (N=1619)</th>
<th>Male (N=5505)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range)</td>
<td>62.3±11.1</td>
<td>66.2±10.5</td>
<td>61.3±11.0</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Age &gt;75</td>
<td>28.4</td>
<td>31.3</td>
<td>24.8</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Male (%)</td>
<td>77.3</td>
<td>73.7</td>
<td>78.1</td>
<td>ns</td>
</tr>
<tr>
<td>Cardiac History (%)</td>
<td>25.7</td>
<td>29.2</td>
<td>22.9</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>28.4</td>
<td>24.9</td>
<td>26.5</td>
<td>0.83</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>10.6</td>
<td>8.1</td>
<td>11.4</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*Significant differences: <0.05; ns, not significant.
ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts B45

2900-56 Lower Mortality With Drug-Eluting Stent in the “Real World” at Two Years
Albert E. Alahmg, Mohammed Andron, Khalel Albouaini, Mohamed Egred, Elved Roberts, Billal Patel, Khashif Bashir, Moazet Eldakhd, Rodney Stables, Raphael A. Perry, Cardiothoracic Centre Liverpool, Liverpool, British Virgin Islands, Royal Liverpool University Hospital, Liverpool, British Virgin Islands

Background: Long-term mortality following drug-eluting stent implantation in daily practice is still a concern.

Methods: We carried out retrospective analysis of prospectively collected data on All patients undergoing PCI with stent implantation at our institution between January 2003 and December 2004. To account for differences in patient characteristics, logistic regression was used to produce a propensity score for DES group membership using age, smoking status, New York Heart Association class, diabetes, priority, left main stem, restenotic lesion, vessel diameter, and length of lesion. Patients receiving DES were then matched to patients receiving bare metal stents (BMS) with identical propensity scores using the greedy match technique. We were able to match 777 patients in each group (DES= BMS) which then compared with respect to the incidence of Death. Results: During the study period 995 patients received DES. Of these, 82 patients had combined DES and BMS use and were therefore excluded, leaving 913 DES patients compared to 2105 BMS patients. Patients who received DES were more likely to be diabetic (p<0.001), restenotic lesions (p<0.001), LMS interventions (p<0.001), long lesions (p<0.001), small diameter lesions (p<0.001), and AHAC-type lesions (p<0.001). Two years mortality was lower in the DES group before (2.0% vs 4.1% p<0.003), and after matching (1.8% vs 4.0% p<0.01).

Conclusions: In our “Real world” series, DES implantation was associated with lower mortality compared with BMS.

2900-57 Two-Year Survival Advantage in Medicare Patients Receiving Sirolimus-Eluting Stents (SES) Compared With Bare-Metal Stents (BMS)
Barry F. Uretsky, Dong Zhang, Sharon H. Giordano, Fen Wei Wang, The University of Texas Medical Branch, Galveston, TX

Background: Concerns have been raised regarding late mortality from drug-eluting stents (DES). We evaluated survival in the first 2 years after DES implantation, specifically with the sirolimus eluting stent (SES), Cypher, vs BMS in “real world” older patients using the Medicare claims database from May-Dec 2003.

Methods and Results: BMS (n=4149) and SES (n=3418) groups had similar baseline characteristics except for small but statistically significant differences with BMS patients being somewhat older, having more males and African Americans, and a higher percentage of peripheral artery disease and heart failure while SES patients had a higher percentage of diabetics and patients with prior revascularization procedures. A significant decrease in 2-year mortality using both unadjusted and adjusted analyses was observed for SES (16.8% BMS vs 10.7% SES, p<0.0001; hazard ratio 1.65, 95% CI 1.5, 1.9). Controlling for comorbidity, extent of disease and other characteristics by multivariable analysis or by propensity analysis had little impact on these results. If analysis was limited to 12-month survivors and 12-24 mortality analyzed, there was decreased mortality with SES (6.1% BMS vs 5.0% SES, p=0.05). To understand potential interaction of unknown selection biases, Medicare pts from calendar year 2002 (n=6890, all BMS) were compared with all 2003 pts (BMS used in 55%), 24-month mortality was similar (14.6%, 2002 vs 14.0% 2003), suggesting unidentified selection biases may have affected survival results in 2003.

Conclusion: A 2 year survival benefit for SES vs BMS in 2003 was observed, suggesting the safety of DES. The similar 2-year survival between 2002 (pre-DES) and 2003 despite 46% SES use in 2003 suggests unidentified selection biases may have accounted for some the survival differences between SES and BMS in 2003.

2900-97 Assessing the Correlation Between In-Stent Neointimal Proliferation and Plaque Progression in the Target Vessel: An Intravascular Ultrasound Analysis in the Drug-Eluting Stent Era
Andre F. Brito, Jose de Ribamar Costa, Jr., Alcar M. Cunha, Jr., Fausto Feres, Alexandre Alizaid, Ricardo Costa, Rodolfo Staico, Dmytri Siqueira, Luiz Alberto Mattos, Amanda Sousa, J Eduardo Sciosa, Instituto Dante Pazanzen de Cardiologia, Sao Paulo, Brazil

Background: Local inflammatory response in the treated segment (in-stent and 5 mm proximal and distal edges) has been described after PCI resulting in a variable amount of neointimal hyperplasia (NIH) formation. Whether this response is limited to the treated segment and/or if it correlates with the degree of plaque progression outside the stent limits is still to be demonstrated.

Methods: Between January and March 2006, 36 consecutive unscored patients with 40 lesions in native coronary were treated with 45 Zotarolimus-eluting stent (Endeavor™) and submitted to IVUS after the procedure and at 6-month follow-up (FU). Segments

<table>
<thead>
<tr>
<th>Known Previous MI (%)</th>
<th>37.3</th>
<th>90.1</th>
<th>39.4</th>
<th>&lt; .01</th>
<th>34.8</th>
<th>37.7</th>
<th>ns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known Smoking (%)</td>
<td>54.5</td>
<td>26.1</td>
<td>62.8</td>
<td>&lt; .01</td>
<td>37.1</td>
<td>56.9</td>
<td>&lt; .01</td>
</tr>
<tr>
<td>Known Diabetes (%)</td>
<td>33.4</td>
<td>39.5</td>
<td>31.6</td>
<td>&lt; .01</td>
<td>34.8</td>
<td>33.2</td>
<td>ns</td>
</tr>
<tr>
<td>Known Melitus (%)</td>
<td>9.3</td>
<td>15.1</td>
<td>7.5</td>
<td>&lt; .01</td>
<td>10.1</td>
<td>9.2</td>
<td>ns</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>66.7</td>
<td>76.5</td>
<td>63.8</td>
<td>&lt; .01</td>
<td>75.9</td>
<td>65.4</td>
<td>&lt; .01</td>
</tr>
<tr>
<td>Acute MI (%)</td>
<td>17.8</td>
<td>16.1</td>
<td>18.3</td>
<td>&lt; .01</td>
<td>18.2</td>
<td>17.7</td>
<td>ns</td>
</tr>
</tbody>
</table>

Target Lesion Reference Vessel Diameter (mm)* | 2.9 | 2.9 | 2.9 | ns | 2.9 | 2.9 | ns |

Target Lesion Length (mm)** | 17.8 | 17.4 | 17.9 | ns | 17.6 | 17.8 | ns |

AHAC ACC class B2/C (%) | 56.6 | 55.1 | 57.1 | ns | 62.5 | 55.8 | < .01 |

Severe Lesion Calcification (%) | 4.0 | 3.9 | 4.1 | ns | 7.4 | 3.6 | < .01 |

12-Month Reviewed Cardiac Events (%)

Death | 2.0 | 2.4 | 1.9 | ns | 6.2 | 1.5 | < .01 |

TAXUS Liberté Stent Related (%)

Composite CE | 3.9 | 4.9 | 3.7 | 0.04 | 6.3 | 3.6 | < .01 |

Cardiac Death | 1.1 | 1.4 | 1 | ns | 3.3 | 0.8 | < .01 |

MI | 0.9 | 0.9 | 0.9 | ns | 1.6 | 0.8 | 0.03 |

TVR (per patient) | 2.5 | 3.1 | 2.4 | ns | 2.8 | 2.5 | ns |

SI (per patient) | 0.8 | 0.8 | 0.8 | ns | 1.1 | 0.8 | ns |

*unadjusted numbers  **IVUS visual estimate
beyond the 5mm proximal and distal edges of the stent were matched in the baseline and FU IVUS for each patient. These segments had their vessel, lumen and plaque volumes calculated using a dedicated IVUS software and were correlated to NIH volume in-stent at follow-up. After testing the main variables for normality using the Kolmogorov-Smirnov Test, Pearson’s correlation test was used to compare the degree of NIH in-stent and plaque progression in the matched segments.

Results: Most patients were men (69.5%) and diabetes was detected in 25% of the cohort. A total of 69 segments (37 distal and 32proximal to the stent) were properly identified and matched at baseline and FU (mean length = 11.1±4.7mm). At FU, % of in-stent obstruction was 14.5±14.9%. Atheromas located proximally to the stent markedly progressed more than those located distally to it (plaque volume difference of 0.6±2.8 mm^3/mm vs. 0.009 ± 1.5 mm^3/mm, p<0.001). However, there was no correlation between the amount of NIH in-stent and the degree of plaque progression in the proximal (Pearson’s correlation of -0.113, P = 0.237), distal (Pearson’s correlation of -0.066, P = 0.379) and both segments (Pearson’s correlation of -0.18, P = 0.2).

Conclusion: NIH formation after Endeavor deployment was low and did not correlate to plaque progression outside the treated segment. However, the more pronounced plaque progression proximal to the treated segment may be a consequence of the more aggressive/traumatic manipulation of that area at the time of the stent deployment.

2900-107

Endothelialization Responses to Abluminally-Directed Ultrathin Film Stent-Based Paclitaxel Administration to the Coronary Artery Wall in Pigs

Toshiro Shinke, Art Rosenthal, Retal Jabara, Nicolas Chronos, Keith Robinson, Saint Joseph’s Research Institute, Atlanta, GA; Labcoot, Galway, Ireland

Purpose: To assess effects of bioabsorbable polymer (D,L polyactic acid (PLA) applied abliminally as ultrathin film surface dots) based paclitaxel delivery from stents into porcine coronary arteries by scanning electron microscopy (SEM) and histology.

Methods: Vascular responses to PLA coated stent (P), low (L: 5mg/stent) and high (H: 10mg/stent) dode paclitaxel-eluting stents were compared to bare metal stent (BMS). Morphological analysis of re-endothelialization was assessed by SEM at 1-mo in 3 pigs. Gaps between endothelial cells (ECgap; % images ≥ 1 gap/1KX field) and leukocyte adhesion to luminal surface (WBC; 0–none to 3→severe) were scored. %area stenosis (%AS) and inflammation score (IS: 0–3) were assessed 1-mo and 3-mo in 20 and 9 pigs respectively.

Results: 1-mo %AS was slightly lower in H (25.7±3.3%) compared to L (31.0±3.5%), P (31.0±3.5%) and BMS (31.1±4.5%), accompanied by higher IS (P<0.001), which were abolished at 3-mo, P was indistinguishable from BMS. SEM showed consistent coverage of luminal surface with endothelial-like cells in all groups. H and L revealed higher ECgap appearance (H: 85%; L: 81%; P: 35%; P=0.005) and higher WBC compared to P (P<0.001).

Conclusions: PLA bioabsorbable polymer is biocompatible for stent-based abliminally-targeted delivery of paclitaxel and endothelialization is complete at 1-mo Paclitaxel-exacerated leukocyte adhesion to the endothelial luminal surface in dose-dependent fashion and was associated with interendothelial defects.

2900-102

Drug-Eluting Stents vs. Bare-Metal Stents for Transplant Abluminog Vascupathoy

LeRoy E. Rabbani, Anuj Gupta, Mark Applebaum, Susheel Kottali, Martin Leon, Jeffrey W. Moses, Donna M. Mancini, Columbia University Medical Center, New York, NY

Background: Drug eluting stents (DES) are associated with significant reduction in restenosis and target vessel revascularization (TVR) compared with bare metal stent (BMS) in patients with native coronary artery disease. The safety and efficacy of DES in cardiac transplant angioplasty (TAV) is not established.

Methods: We performed a retrospective analysis of all patients with TAV at a single center undergoing stenting between 1/97 to 9/07. Significant clinical outcomes analyzed included (TVR) as well as retransplantation and/or death. BMS patients were followed for three years, while DES patients were followed for one year.

Results: 25 patients received 25 bare metal stents; 30 patients received 51 DES (paclitaxel 3, sirolimus 48). The average age at transplant was 47 years old (±13) for BMS patients and 46 years old (±14) for DES patients. Average time from transplant to stent placement was 6.8 years (±3.9) for BMS patients and 8.5 years (±5.4) for DES patients. 15 DES patients had angiographic follow-up (average follow-up time, 6 months ±3mo); 3 patients developed in-stent restenosis (20%), 2 patients underwent TVR. Three DES patients had definite stent thrombosis (ARC definition). Mortality or retransplantation at three years, while DES patients were followed for one year.

Conclusion: NIH formation after Endeavor deployment was low and did not correlate to NIH volume in-stent and plaque progression in the proximal and distal segments. However, the more pronounced plaque progression proximal to the treated segment may be a consequence of the more aggressive/traumatic manipulation of that area at the time of the stent deployment.

2900-103

The Impact of Mandatory Angiographic Follow-up on the One-Year Clinical and Angiographic Results From Endeavor IV: A Randomized Comparison of the Endeavor Drug (ABT-578) Eluting Stent System vs. Taxus in De Novo Native Coronary Lesions

Martin B. Leon, Jeffrey Pocock, Charlie O’Shaunessy, Paul Overlie, Brent McLaurin, Stuart Solomon, Ajay Kirtane, Laura Mauri, Peter Fitzgerald, Kweli Thompson, Columbia University Medical Center, New York, NY

Background: While routine angiographic follow up has been demonstrated to impact revascularization rates in early bare metal stent (BMS) trials and in drug-eluting (DES) vs. BMS trials, the impact of routine follow-up angiography in DES vs. DES trials is less understood.

Methods: In the ENDEAVOR IV trial of the Endeavor vs Taxus DES, the first 328 enrolled patients (21.2%) underwent protocol-mandated follow up angiography at 8 months; outcomes among these patients were compared to those of the subsequent 1200 patients with no routine angiographic follow up.

Results: Trial enrollment was completed in July 2006. The 12 month target lesion revascularization rates stratified by assignment to routine angiographic or clinical follow-up are as follows (see table).

While there was a trend toward reduced TLR with Taxus compared to Endeavor among patients undergoing routine angiography, this was not observed in the larger clinical-only follow-up cohort. Complete one-year data describing baseline characteristics, procedural and angiographic data for these two cohorts of the ENDEAVOR IV trial will be presented in detail.

Conclusions: The low overall rate of protocol-mandated angiographic follow up in the ENDEAVOR IV trial allows assessment of the degree to which protocol-mandated angiographic follow up can impact outcomes in head-to-head DES studies, which has implications for future clinical trial designs.
Two-year Outcome After Repeat Intervention for Restenosis After Unprotected Left Main Stenting: A Report From the French Left Main Taxus Registry

Thierry Leffere, Beatriz Vaquerizo, Olivier Darremon, Marc Silvestri, Philippe Garot, Helen Routledge, Yves Louvard, Pierre Dumas, Marie-Claude Morice, Institut Cardiovasculaire Paris Sud, Massy, France

Background: Repeat coronary artery bypass surgery (CABG) is associated with a higher complication rate compared to de novo surgery. At present, the outcome of repeat PCI for the treatment of restenosis after unprotected left main (LM) stenting in the drug-eluting stent (DES) era, remains unknown.

Methods: We conducted a retrospective analysis of the long-term outcome of patients (Pts) included in the French LM registry who underwent target vessel revascularization (TVR).

Results: 291 consecutive Pts were included; acute myocardial infarction (MI) or death within 30 days following PCI was present in 27.6% of cases. Overall mortality was 9.3% (cardiac in 5.2%). Repeat angiogram was performed in 186/291 Pts (64%) at 7.5±4.0 months, 23.5% were symptomatic and 8.6% had silent ischemia. Restenosis was observed in 25/186 (13.4%): 14 in LM stem, 10 in distal LM stent segment, 1 inostial LM, 1 at the LM stent and 3 at the LM ostium, untreated, 6 at ostial LCX, 2 inunostial ostial Cx and 4 in stented ostial Cx), and 5 at ostial LAD (1 in an unostented ostial LAD and 4 in the stented ostial LAD). In total, TVR was performed in 7.9% of cases, 6.2% by re-PCI (all with DES) and 1.4% by CABG. At the time of reintervention, 62.6% of Pts were symptomatic (stable angina 52.2%, unstable angina 13.0%) or had documented silent ischemia (17.4%). Two years after repeat intervention (follow-up completed in 22/23 Pts), 3 Pts (13.6%) had repeated re-intervention (2 by re-PCI, 1 by CABG) and 1 (4.5%) died, from pulmonary infection 7 months after the last PCI.

Conclusion: Effective ULM PCI using paclitaxel eluting stent with a strategy of provisional side branch T stenting in cases of distal LM disease is associated with 7.9% TVR rate at 2 years. Repeat PCI with DES seems to be safe and effective at 2 years' follow-up.

The Impact of Bifurcation Type and Treatment Strategy on the Risk of Stent Thrombosis After Drug-Eluting Stent Implantation

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Background: Bifurcation lesion is known to be one of the major risk factors for stent thrombosis (ST) after drug-eluting stent (DES) implantation. However, whether this is due to complex intervention or bifurcation lesion itself increases the risk is not well-defined.

Methods: KoST (Korea Stent Thrombosis) registry was a 10-center prospective registry that enrolled ST patients after DES implantation. 98 patients with ST were compared to a control group of 1,295 patients from a core center who had up to 18 months of follow-up.

Results: Pathological analysis of ST revealed damage to the polymer but the stent may not be suitable for BS on structural grounds. Polymer damage was less marked in Taxus stents, particularly for the stent-struts in some BS techniques (Panel A). When the strut was dilated with balloon only, a stent strut and polymer damage was observed using an optical microscope, an electron microscope and multi-slice computed tomography. BS strategy entailed cutout-stenting, conventional crush-stenting, reverse crush-stenting, conventional T-stenting and modified T-stenting.

Results: In Taxus stents, the carina of the bifurcation was not sufficiently covered by stent-struts in some BS techniques (Panel A). When the strut was dilated with balloon catheter to make side branch access, Taxus stents suffered more damage to structure, especially around the carina (Panel B). For both type of stents, polymer damage were observed at stent-overlap sites. The degree of damage varied according to BS strategy and polymer type. Polymer damage was less marked in Taxus stents, particularly for the crush BS technique (Panel C).

Conclusion: When using Taxus stents for BS strategies, the stent may undergo less damage to the polymer but the stent may not be suitable for BS on structural grounds.

The Effect of Debulking Pre-Drug Eluting Stent for Bifurcated Corona Lesions in Unprotected Left Main -Sub Analyses of PERFECT Registry-

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Background: Percutaneous coronary intervention for bifurcated coronary lesions (BCL) using DES alone remains challenging, although drug-eluting stent (DES) significantly reduces restenosis and repeated revascularization. The purpose of this study was to evaluate the safety and efficacy of plaque debulking with directional coronary atherectomy (DCA) before DES implantation for BCL in unprotected left main coronary artery (ULMCA).

Methods: Sixty two patients with BCL in ULMCA were enrolled in this prospective multicenter registry (PRe Rapamycin eluting stent FiEx-CUT Registry). All patients were scheduled to undergo a 9-month coronary angiography. The primary end point was the 9-month binary angiographic restenosis rate. Secondary end points included procedure-related events and major adverse cardiac events (MACE) at 1 year.

Results: DCA was performed successfully in all cases without any complications. Simple stenting was achieved in all cases. Angiographical findings are shown in Table. No in-hospital MACES were observed. The 9-month binary restenosis rates in the main branch and side branch were 0% and 0%, respectively. No target lesion revascularization, no deaths, no coronary artery bypass grafting, and no myocardial infarction were reported in the patients within the first year.

Conclusion: DCA before DES implantation is safe and effective for the treatment of ULMCA without complex stenting. These results may provide excellent long-term outcomes in patients with BCL in ULMCA.

Cypher or Taxus: Which is Better for Bifurcation Stenting?

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Background: The incidence of in-stent restenosis for bifurcation stenting (BS) remains high even with drug-eluting stents. We postulated that some of the mechanisms depend on polymer damage and stent structure.

Methods: We deployed Cypher and Taxus stents in a silicon "phantom" vessel with a 3.5mm diameter main branch and a 3.0mm side branch. Kinetic-balloon dilatation was then performed, and stent-structure and polymer damage observed using an optical microscope, an electron microscope and multi-slice computed tomography. BS strategy entailed cutout-stenting, conventional crush-stenting, reverse crush-stenting, conventional T-stenting and modified T-stenting.

Results: In Taxus stents, the carina of the bifurcation was not sufficiently covered by stent-struts in some BS techniques (Panel A). When the strut was dilated with balloon catheter to make side branch access, Taxus stents suffered more damage to structure, especially around the carina (Panel B). For both type of stents, polymer damage were observed at stent-overlap sites. The degree of damage varied according to BS strategy and polymer type. Polymer damage was less marked in Taxus stents, particularly for the crush BS technique (Panel C).

Conclusion: When using Taxus stents for BS strategies, the stent may undergo less damage to the polymer but the stent may not be suitable for BS on structural grounds.
We treated 100 consecutive patients with unprotected LMS bifurcation disease using the SKS technique and Taxus stents. Dual anti-platelet therapy was continued lifelong. We recorded clinical status at baseline, in-hospital and at medium term follow-up using hospital and catheter laboratory records and telephone contact.

**Results:**
Mean age was 66 (45-88) years, 75% were male, 8% were emergency cases, 23% urgent and 69% elective. The mean New York PCI Risk Score was 4.2. The procedure was successful in 100% cases. Apart from the LMS, there was 2.0 ± 0.9 vessel disease and 1.8 ± 0.8 vessels were successfully treated. There were 4 in-hospital deaths all of which were in patients with cardiogenic shock or a recent myocardial infarction. At a median follow-up of 26 months, there were 6 deaths and 6 cases of restenosis involving either of the vessels treated (TVR). Despite drug eluting stents (DES), bifurcation coronary disease is associated with higher rates of restenosis than that of simple lesions. This may discourage the choice of an initial percutaneous strategy.

**Conclusions:**
This is the first substantial series of patients with unprotected LMS bifurcation disease treated with SKS technique and it shows that this technique is safe, feasible and associated with good medium term clinical results.

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**First Clinical Experience of “Flower Petal” Stenting: A Novel Technique for the Treatment of Bifurcated Lesions**

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**Background:**
The best stenting technique for bifurcated lesions has yet to be defined. **Objective:** To report the results of both bench-testing and our first clinical experience with this novel technique.

**Methods:**
This technique works by fixing the proximal side of the stent in the side branch (SB) out like petals (Panel A). We tested it in vitro and the resultant stent-structure and stent polymer damage was observed in both main branch (MB) and SB with an optical microscope, multi-slice computer tomography, IVUS, endoscope and an electron microscope (EM). We also applied this technique in 20 patients and assessed patient outcomes up to 9 months prospectively. Drug-eluting stents were used for the bench-tests and for all patients.

**Results:**
Bench-testing showed complete coverage of the bifurcation with minimal stent-layer overlapping (Panel B). There was little polymer damage by EM (Panel C). Procedural success was achieved in 19 cases and restenosis occurred in 2 cases. In both restenosis cases, “petal” stenting technique was done provisionally after another stent had already been deployed in the main branch prior to any stenting of the side-branch. There were no incidences of restenosis when we used this technique electively.

**Conclusions:**
In terms of damage to the polymer and of ostial strut coverage, this new “flower petal” stenting technique may well be superior to other available techniques.

**Increased Neointimal Hyperplasia, but not Minimum Lumen Area, is Associated With Restenosis in the Side Branch Ostium After Percutaneous Coronary Intervention on Bifurcation Lesions**

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**Background:**
Restenosis rates are high after percutaneous coronary intervention (PCI) on bifurcation lesion, especially at the ostium of the side branch (SB). However, the mechanism of restenosis in the SB ostium has not been fully understood.

**Methods:**
We evaluated 84 bifurcation lesions with SB ≥2.5 mm, which were treated successfully by provisional T stenting and small protrusion technique using drug-eluting stents under intravascular ultrasound (IVUS) guidance. Postintervention IVUS was performed in both branches and 9-month angiographic follow-ups were performed. IVUS analysis of the SB included 2 distinct locations: SB ostium (≤5 mm distal to the neo-ostia), and SB distal stent (≥5 mm distal to the neo-ostia).

**Results:**
SB stenting was performed in 56 lesions (67%). Post-procedural MLA at the MB distal stent in the same (4.8±0.6 mm²) and 4.8±0.2 mm² respectively, p = 0.76. Regarding the SB, angiographic restenosis (diameter stenosis ≥50%) developed in 8 patients (9%). Of these, 6 cases occurred at the ostium of the SB and focal (SB ostium restenosis group). There was no significant difference in post-procedural MLA at the SB ostium between the SB ostium restenosis group and the SB ostium non-restenosis group (4.6±1.8 mm² versus 4.4±1.7 mm², p = 0.88). However, the SB ostium restenosis group showed a significant larger late lumen loss compared with the SB ostium non-restenosis group (5.4±1.6 mm² versus 4.8±1.7 mm², p = 0.49). Again, the SB ostium restenosis group showed a significant larger late lumen loss compared with the SB ostium non-restenosis group (1.9±1.0 mm versus 0.5±0.7 mm, p = 0.001).

**Conclusions:**
The SB ostium may show a high restenosis rate due to increased neointimal hyperplasia rather than small post-procedural MLA.

**Increased Neointimal Hyperplasia, but not Minimum Lumen Area, Is Associated With Restenosis in the Side Branch Ostium After Percutaneous Coronary Intervention on Bifurcation Lesions**

Maria Elena Di Salvo, Piera Capranzano, Gian Paolo Ussia, Anna Caggegi, Giambattista Barrano, Alessio La Marra, Alfredo Ruggiero Galassi, Corrado Tamburino, Ferrarotto Hospital, Catania, Italy

**Background:**
Coronary artery bypass graft surgery (CABIG) is up to now the treatment of choice for unprotected left main artery stenosis (ULM) and it has proven better results over long-term outcomes. The treatment of unprotected left main (ULM) is one of the most challenging lesion subset in percutaneous coronary intervention (PCI). Several studies on drug eluting stent (DES) showed low mortality and MACCE in hospital and at follow-up, but they reported a limited sample size and a short follow-up duration. We report our institutional experience and very long term follow up of patients undergoing LM PCI with DES.

**Methods:**
From June 2002 to August 2007, 256 consecutive patients (pts) with ULM stenosis were treated with PCI with Sirolimus (29%), Paclitaxel (64%) or ABT 578 (8%) eluting stents in our institution. Mean age was 63 ± 10 y, the ejection fraction was 49 ± 11%; 88 pts (34%) were diabetic, 162 pts (63%) had unstable angina and 16 pts (6%) had acute myocardial infarction. Bifurcation lesion was treated in 130 pts (51%). The clinical follow-up was performed at 1, 6 months and every year and angiography follow-up was mandatory at 6-8 months.

**Results:**
Procedural success was achieved in 99%. One pt with ostial stenosis had ostial recoil at the end of the procedure and one pt for periprocedural acute stent thrombosis were referred for coronary artery bypass graft surgery. During hospitalization 3 patients (1.2 %) died, one pt for cardiac cause not stent-related. Acute myocardial infarction occurred in three patients (1.2 %). At 1 year follow-up (184 pts, 72%) 3 pts (1.6%) died, one for sudden death, one for not stent-related cause and one died for non cardiac disease. At angiography follow-up was performed on 156 pts (61%), restenosis occurred in 12 pts (7.7%) with the need of a new PCI. At long term follow-up (> 1 year) (99 pts, 39%) 1 pt (1 %) died for sudden death and 2 for chronic cardiac failure (2%); 6 pts (6 %) underwent target lesions revascularization. Conclusions: In-hospital data of our population show PCI as an effective and therapy with low incidence of periprocedural thrombosis, cardiac death and MACE. These results are maintained at long term follow-up with only one suspected very late stent thrombosis.

**The Impact of Restenosis After Percutaneous Treatment of Coronary Bifurcation Lesions With Drug-eluting Stents**

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**Background:**
Despite drug eluting stents (DES), bifurcation coronary disease is associated with higher rates of restenosis than that of simple lesions. This may discourage choice of an initial percutaneous strategy. Aim: To investigate the impact of restenosis in patients treated for bifurcation lesions with DES.

**Methods:**
Analysis of data from a prospective registry of 477 consecutive patients treated with DES and a default provisional side branch (SB) T -stenting strategy.

**Results:**
At 29 (±8) months revascularization involving either of the vessels treated (TVR) had been undertaken in 42 patients (8.8%). This included the index bifurcation in 25 cases (5.2% TVR). Treatment of a Medina 0, 0.1 lesion was the only independent predictor of TVR. Indications for repeat intervention in the ostial lesion were stable angina in 44%, silent ischemia in 23% and unstable syndromes in 23%. Of the re-PCI patients, 10% were treated with balloon angioplasty, 64% with a DES in the main vessel (MV) 23% with a SB DES and 3% with DES in both branches.

In 37 of 39 patients restenosis was uncomplicated 2 patients died following TVR, 1 (1 MI, 1 Tamponade. Re-revascularization occurred in 4.8% of TVR group. The risk of death or MI at 2 years was no different in patients who required TVR or TVR. Conclusion: The need for TVR or TVR at 2 years after using DES and provisional T-stenting for bifurcations is low. Restenosis is relatively benign and repeat PCI is associated with a high rate of success and a low rate of repeat revascularization.
have a lower restenosis rate than lesions treated with T-stenting. Compared with single stenting, T-stenting does not increase the 3-year risk of death and MI, regardless of whether BMS or DES were implanted. Although there were no significant differences, the observed 3-year incidences of death and MI favored DES as compared with BMS.

Long-term Clinical Outcomes Between Percutaneous Versus Surgical Revascularization for the Treatment of Ostial and Shaft Lesions of Unprotected Left Main Coronary Artery

Jung Soon Kim, Duk-Woo Park, Young-Hak Kim, Won-Jang Kim, Myeong-Ki Hong, Jong-Pil Park, Cheol-Woo Lee, Seung-Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, MYEO-Geun Park, Seoul National University Hospital, Seoul, South Korea

Background: The long-term clinical outcomes after percutaneous coronary intervention (PCI) versus coronary artery bypass grafting (CABG) has not been known in patients with non-bifurcation (ostium and shaft) lesions of unprotected left main coronary artery (ULMCA).

Methods: Between Jan, 2000 and June, 2006, a total of 1090 patients with ostium and shaft ULMCA stenosis were collected from 12 academic institutions in Korea. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) were performed in 577 patients and 513 patients, respectively.

Results: Compared to patients with PCI, patients with CABG were significantly older and showed a higher incidence of previous myocardial infarction (MI), peripheral vascular disease, hyperlipidemia, poor LV function (LVEF<40%), and high Euroscore (≥6) and more presented with acute coronary syndrome. During long-term follow-up of median 35.4 months, there was no difference of death or Q-wave myocardial infarction (MI) between PCI and CABG group. However, patients with PCI showed a significantly higher incidence of target vessel revascularization than those with CABG. This trend was persistent in comparison between drug-eluting stents and CABG (Table). Conclusion: There was no difference in death or Q-MI in patients with ostial and shaft ULMCA disease, compared to PCI and CABG. However, percutaneous revascularization without regard to stent type was significantly associated with target vessel revascularization than bypass surgery. Table. Cumulative 3-year incidence of clinical events

Comparison of Long-Term Outcomes Between Percutaneous Coronary Intervention Versus Bypass Surgery for Treatment of Isolated Unprotected Left Main Coronary Artery Disease

Duk-Woo Park, Young-Hak Kim, Won-Jang Kim, Myeong-Ki Hong, Jong-Pil Park, Cheol-Woo Lee, Seung-Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Seung-Jung Park, MAIN-COMPARE Investigators, asan medical center, Seoul, South Korea

Background: The differential long-term outcome of percutaneous coronary intervention (PCI) versus coronary artery bypass grafting (CABG) is not well known in patients with isolated unprotected left main coronary artery (ULMCA).

Methods: Between Jan, 2000 and June, 2006, a total of 354 patients with isolated ULMCA lesions were collected from 12 academic centers in Korea. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) were performed in 267 patients and 87 patients, respectively.

Results: Compared to patients with PCI, patients with CABG were significantly older and showed a higher incidence of previous myocardial infarction (MI), peripheral vascular disease, hyperlipidemia, poor LV function (LVEF<40%), and high Euroscore (≥6) and more presented with acute coronary syndrome. During long-term follow-up of median 35.4 months, there was no difference of death or Q-wave myocardial infarction (MI) between PCI and CABG group. However, patients with PCI showed a significantly higher incidence of target vessel revascularization than those with CABG. This trend was persistent in comparison between drug-eluting stents and CABG (Table). Conclusion: There was no difference in death or Q-MI in patients with ostial and shaft ULMCA disease, compared to PCI and CABG. However, percutaneous revascularization without regard to stent type was significantly associated with target vessel revascularization than bypass surgery. Table. Cumulative 3-year incidence of clinical events
Over an average follow-up of 2.3 years (SD=1.3 years), 68 (38%) patients had experienced an MI (19 ST-elevation MI and 34 non-ST-elevation MI) underwent ULMCA PCI with DES.

Results: The mean age was 71 ± 11 years. The mean peak CKP was 1367 ± 1397 U/L. Cardiogenic shock was present in 25%. Mean EuroSCORE was 10 ± 8. Distal bifurcation was involved in 31 patients (58%). Silomimus-eluting stents were implanted in 43 patients (81%). angiographic success with TIMI 3 flow was achieved in all patients. Overall in-hospital major adverse cardiac event (MACE) rate was 9%. In-hospital mortality was 8% for all patients (16% for ST-elevation MI and 3% for non-ST-elevation MI) all due to refractory cardiogenic shock. At one year, the overall MACE rate was 30%, the total mortality rate was 15%, and the cardiac mortality rate was 11%. Two patients required target vessel revascularization, both of whom had distal bifurcation involvement, and subsequently underwent bypass surgery. The definite and probable/stable stent thrombosis were 0% and 6%, respectively.

Conclusions: Patients with MI and ULMCA disease represent a very high-risk subgroup of patients who are critically ill. PCI with DES is technically feasible and appears to be a reasonable alternative to surgical revascularization for MI patients with ULMCA disease. A randomized trial would be needed to determine the ideal revascularization strategy for these patients.
no side branch intervention in 37 (23%) patients. DES were used in the main branch in 73 (46%) patients, and a final kissing balloon angioplasty was used in 68 (55%) of patients receiving a side branch intervention. On multivariate analysis, the risk of a clinical event was significantly higher with increasing age (p=0.026), unstable angina at the index presentation (p=0.011) and a prior PCI (p<0.001). Risk was lower with a DES in the main vessel (p=0.004) and a final kissing balloon inflation if there was a side branch intervention (p=0.015). Long-term risk with side branch balloon distal angioplasty (HR=0.79, 95%CI=0.38, 1.65, p=0.53) or no intervention in the side-branch (HR=0.57, 95%CI=0.23, 1.45, p=0.24) was not different to side branch stenting.

Conclusions: The long-term outcomes with side branch intervention were no better than main vessel stenting alone. However, among those having side branch intervention, outcomes were better with a final kissing balloon inflation. Patients receiving a DES in the main branch had significantly better very long-term outcomes compared to BMS.

2900-125

Preliminary Results of the Novel TMI (TriRemed Medical Inc.) Antares Side Branch Adaptive System (Antares SASTM Stent) for the Treatment of De Novo Coronary Bifurcation Lesions

Riccardo A. Costa, Alexandre Abizaid, Andrea Abizaid, Fausto Feres, Rodolfo Staico, Luz A. Mattos, J Ribamar Costa, Jr., Amanda Sousa, Mary E. Russell, Eitan Konstantino, Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil

Background: The Antares SAS stent was designed to facilitate side branch (SB) access, improve positioning, and maximize ostial scaffolding. It is comprised of a low profile 6-Fr, balloon-expandable stent, and a SB Stabilizing Wire which allows direct SB wire and access after stent deployment into the main vessel (MV), without the need for stent re-crossing. Also, there are 4 markers at the device’s “Ostium Preservation” structure to improve positioning and complete coverage of the SB ostium (Figure). Methods: 11 pts/sessions were consecutively enrolled in a single center as a part of a multicenter prospective study; 91% of lesions had significant involvement of both branches, and LAD/Dia- Diag. was the prevalent lesion location (73%). Results: Baseline RD was 2.97±0.35mm and 2.18±0.37mm, and lesion length was 11.5±2.46mm and 5.0±3.32mm, for the MV and SB, respectively. The Antares SAS stent was successfully implanted in 100% (mean pressure 13.3±3.0 atm). Single balloon post dilation was performed in all MVs and in 82% in SB; 50% had FKBS. Stents were implanted in the SB in 2 sessions. All pts achieved TIMI 3 flow in both branches < +50% DS in the MV and SB access with low residual stenosis. There was no in-hospital MACE (death, MI, TLR). At 30-day clinical FU, there was 0% MACE. Conclusions: The Antares SAS dedicated stent demonstrated safety and excellent acute results; therefore, it may represent an alternative for the treatment of bifurcation lesions. Larger studies with long-term FU are warranted.

2900-126

Analysis of the Long-term Effects of Drug-eluting Stents on Coronary Arterial Healing by Virtual Histology Intravascular Ultrasonography


Background: Animal models show impairment of arterial healing after drug-eluting stents (DES) compared to bare-metal stents (BMS). Spectral analysis of intravascular ultrasound (IVUS), radiofrequency backscattered signals - known as Virtual Histology (VH) - offers an opportunity to assess lesion morphology in vivo. Methods and Results: We used VH-IVUS to assess long-term (mean=8 months) native vascular responses after 36 DES implantations compared with 13 BMS. Baseline clinical and grayscale and VH-VHUS characteristics were similar between DES and BMS. Although necrotic core (NC) volume was not significantly changed during the follow-up period in either group (Table), the frequency of NC abutting the lumen (i.e., vulnerable plaque) at follow-up (42% vs. 14%, p=0.037) was significantly greater in DES than BMS because of the lack of an overlying, protective neointimal hyperplasia in DES-treated lesions. Furthermore, at the stent edge the frequency of thin-capped fibroatheromas (TCFAs) decreased in BMS-treated lesions (7% vs. 4%, p=0.015) but not in DES (25% vs. 22%, p=0.695). Conclusion: Serial VH-IVUS analysis of DES-treated lesions show a greater frequency of unstable lesion morphology (TCFAs or vulnerable plaques) at follow-up compared to BMS. The apparent mechanism is a suppression of the protective neointimal hyperplasia layer coupled with a lack of TCFD resolution at stent edges.

Comparison VH-IVUS characteristics between DES and BMS:

<table>
<thead>
<tr>
<th>DES (n=38)</th>
<th>BMS (n=13)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Stent length, mm</td>
<td>22.8±6.2</td>
<td>18.3±5.7</td>
</tr>
<tr>
<td>Fibroatheroma at baseline, n (%)</td>
<td>24 (64)</td>
<td>23 (62)</td>
</tr>
<tr>
<td>Baseline NC volume, mm³</td>
<td>25.8±18.9</td>
<td>22.5±17.1</td>
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<tr>
<td>Late loss NC volume, mm³</td>
<td>15.8±18.7</td>
<td>15.8±18.7</td>
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<tr>
<td>LNCl volume, mm³</td>
<td>2.1±3.8</td>
<td>3.3±4.2</td>
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</tbody>
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2900-127

Single Plane Balloon Sizing of Atrial Septal Defects with Intracardiac Echocardiography is an Advantages Alternative to Cineangiography

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Background: Aiming to develop a safe alternative to conventional quantitative angiography (QCA) that does not expose patients to radiation, we sought to compare intracardiac echocardiography (ICE) and transeosophageal echocardiography (TEE) for QCA sizing of atrial septal defects (ASDs). Methods: In 43 patients (mean age 40±15 years) with ASD, defect size was routinely measured by TEE in two perpendicular planes. Prior to percutaneous device closure, native ASD size was also determined by ICE. Upon subsequent balloon sizing, the stretched balloon diameter was measured by both ICE and QCA. The latter was considered the gold standard. QCA measurements were completed in two perpendicular planes whereas ICE balloon sizing was completed in just a single standard cut plane. Results: Conventional QCA-based balloon sizing revealed diameters of 17.5±5.4 mm. Both echocardiographic methods underestimated the diameter, but to a different degree: TEE 11.8±3.3 mm, p<0.001; ICE sizing of native ASD: 13.5±4.1 mm, p<0.001; single-plane ICE balloon sizing: 16.9±5.2 mm, p<0.001. ICE-based balloon sizing underestimated defect size by less than 1 mm on average (Figure). Conclusions: Balloon sizing is still indispensable for choosing an adequately sized occluder. As a sizing tool, ICE is an accurate alternative to QCA and helps lower radiation exposure. With ICE, the occluder should be oversized by about 1 to 2 mm to account for the slight underestimation observed with ICE sizing.
Previous trials using intravascular ultrasound (IVUS) have demonstrated that the lipid lowering therapy with statin decrease plaque volume and increase plaque echogenicity in patients with coronary artery disease. We examined whether statins clinically alter the composition of coronary atherosclerotic plaques of humans by in vivo IVUS-Virtual Histology (VH) analysis.

Methods: This was a prospective, single-center study to assess the effect of 6 months of treatment with statin to induce the change of plaque composition in non-percutaneous coronary intervention (PCI) sites of the culprit vessel with <50% diameter stenosis among 26 patients with acute coronary syndrome (ACS). One target segment was determined in a non-PCI site (>5 mm proximal or distal to the PCI site) with a reproducible index side branch or from the ostium of target vessel.

Results: In 6 months after statin therapy, no change was demonstrated in mean percentage of the lipid core (15.6 ± 7.2% to 13.6 ± 7.7%, p=ns), whereas plaque volume and LDL-cholesterol level were significantly reduced. Of 26 patients, four different types of atherosclerotic plaque were identified: pathologic intimal thickening (PIT, n=5); fibrocalcific atheroma (FC, n=9); fibroatheroma with thick cap (non TCFA, n=3), or fibroatheroma without thick cap (TCFA, n=9). There was a significant reduction of lipid core percentage only in the type of TCFA (16.7 ± 4.2 % to 9.8 ± 5.7 %, p < 0.05).

Conclusions: IVUS-VH may be useful to evaluate effects of statin on plaque composition in vivo. Specifically, percentage of lipid core was significantly reduced in the type of TCFA which suggest that the change of plaque composition following statin therapy might be different according to plaque stability in patients with ACS.

Variable Left Anterior Descending Coronary Artery Anatomy in Stress-Induced (Takotsubo) Cardiomyopathy

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Stress-induced (Takotsubo) cardiomyopathy (SCM) is characterized by mid ventricular and apical wall motion abnormalities without obstructive coronary disease. It is unknown whether development of the apical ballooning pattern requires the presence of a ‘wrap-around’ left anterior descending (LAD) artery. The aim of this study was to characterize LAD anatomy and flow in patients with SCM.

Methods: Coronary angiograms and ventriculograms of 75 patients with SCM were compared to 75 case-matched normal controls. Coronary dominance, LAD distribution, hemodynamics, and Thrombolysis in Myocardial Infarction frame counts (TFC) were compared between groups. Results (Table One): No differences in coronary dominance or LAD distribution were observed. Myocardial bridging and coronary vasospasm were rare in SCM. TFC were abnormally high in 96% of SCM patients; 62% had involvement of all three epicardial vessels. Abnormal TFC of the LAD alone was not observed in any SCM patient. Using linear regression, TFC being in contact with the lumen; and TCFA definition required a plaque burden ≥ 40%.

Conclusions: IVUS-VH is consistent with a greater probability of plaque rupture in diabetic patients. We used virtual histology-intravascular ultrasound (VH-IVUS) to evaluate the plaque composition and the incidence of TCFA in diabetic patients (61 diabetic patients vs. 136 non-diabetic patients).

Methods: In 196 patients (155 acute coronary syndrome and 42 stable angina), de novo coronary lesions were studied and plaque components were analyzed. We classified TCFA lesions as foci, necrotic core-rich (≥ 10% of the cross-sectional area) plaques being in contact with the lumen; and TCFA definition required a plaque burden ≥ 40%.

Results: The percent necrotic core area was significantly greater at both minimum lumen sites (17.3±11.8% vs. 12.6±9.8%, p=0.023) and largest necrotic core sites (30.2±10.8% vs. 20.9±6.9%, p<0.001), and the percent necrotic core volume was significantly greater (16.6±9.4% vs. 13.8±7.9%, p=0.038) in diabetic patients compared with nondiabetic patients. The presence of at least one TCFA (59% vs. 37%, p=0.004) and multiple TCFAs (25% vs. 11%, p=0.014) within culprit lesions were significantly higher in diabetic patients compared with nondiabetic patients. The presence of at least one TCFA within culprit lesions was significantly higher in patients with both acute coronary syndrome (60% vs. 42%, p=0.035) and stable angina (55% vs. 19%, p=0.026). In the multivariate analysis, diabetes mellitus was the only independent predictor of the presence of TCFA (Odds ratio=2.179; 95% CI 1.075-4.416, p=0.031).

Conclusions: VH-IVUS analysis demonstrates that diabetic patients had a higher frequency of culprit lesion Thin-Cap Fibroatheroma Compared with Nondiabetic Patients Regardless of Clinical Presentations: A Virtual Histology-Intravascular Ultrasound Analysis

Young-Joon Hong, Myung Ho Jeong, Doo Sun Kim, Jong Won Chung, Ju Han Kim, Jae-Young Moon, Young Keun Ahn, Jeong Gwan Cho, Jong Chun Park, Jung Chae Kang, Chonnam National University Hospital, Gwangju, South Korea

Background: Thin-cap fibroatheroma (TCFA) lesions are the most prevalent substrate of plaque rupture. Pathological studies showed diabetic patients had a greater amount of macrophage-infiltrated lipid-rich plaque compared with nondiabetic patients. This is consistent with a greater probability of plaque rupture in diabetic patients. We used virtual histology-intravascular ultrasound (VH-IVUS) to evaluate the plaque composition and the incidence of TCFA in diabetic patients (61 diabetic patients vs. 136 non-diabetic patients).

Methods: In 196 patients (155 acute coronary syndrome and 42 stable angina), de novo coronary lesions were studied and plaque components were analyzed. We classified TCFA lesions as focal, necrotic core-rich ( ≥ 10% of the cross-sectional area) plaques being in contact with the lumen; and TCFA definition required a plaque burden ≥ 40%.

Results: The percent necrotic core area was significantly greater at both minimum lumen sites (17.3±11.8% vs. 12.6±9.8%, p=0.023) and largest necrotic core sites (30.2±10.8% vs. 20.9±6.9%, p<0.001), and the percent necrotic core volume was significantly greater (16.6±9.4% vs. 13.8±7.9%, p=0.038) in diabetic patients compared with nondiabetic patients. The presence of at least one TCFA (59% vs. 37%, p=0.004) and multiple TCFAs (25% vs. 11%, p=0.014) within culprit lesions were significantly higher in diabetic patients compared with nondiabetic patients. The presence of at least one TCFA within culprit lesions was significantly higher in patients with both acute coronary syndrome (60% vs. 42%, p=0.035) and stable angina (55% vs. 19%, p=0.026). In the multivariate analysis, diabetes mellitus was the only independent predictor of the presence of TCFA (Odds ratio=2.179; 95% CI 1.075-4.416, p=0.031).

Conclusions: VH-IVUS analysis demonstrates that diabetic patients had a higher frequency of culprit lesion Thin-Cap Fibroatheroma Compared with Nondiabetic Patients Regardless of Clinical Presentations (in both acute coronary syndrome and stable angina).
Identification of Stent Fracture by 64 Slice Multidetector Computed Tomographic Angiography
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Background: In the current era, in-stent restenosis (ISR) results from failure of drug elution to prevent neointimal hyperplasia. Stent fracture (SF), with lack of exposure of the fractured area to drug elution or lumen obstruction by disrupted stent material, is an alternative explanation which has not been adequately explored. Catheter based angiography (CBA) may not demonstrate SF unless the acquisition is absolutely perpendicular to the fracture line. Intravascular ultrasound may be revealing but is not used routinely, is invasive, and has not been systematically investigated in this context. 64 slice multidetector computed tomographic angiography (MDCT) may be ideally suited, by virtue of its ability to interrogate stents from a 360 degree perspective and provide cross sectional stent images. This study was designed to evaluate the ability of MDCT to detect SF.

Methods: 64 slice MDCT in 300 consecutive stent patients were evaluated. SF was diagnosed in either single or overlapped stents by clear separation of struts on both the curved and straightened multiplanar reconstruction, with discontinuity of strut structure on cross sectional images at the site of separation. CBA was performed in all patients with MDCT identified SF.

Results: SF was noted in 9 patients (3.0%), 7 in the LAD, 1 each in the left circumflex and right coronary artery. Stent separation was 2.0±0.5 mm. In all cases, CBA did not reveal SF. Seventy percent of SF was seen in 3 patients with CBA also confirmed by CBA, and represented 15.8% of the total ISR noted in our laboratory. Mild (<50%) ISR, confirmed by CBA, was found in 3 patients.

Conclusions: 1) MDCT revealed stent fracture in 3.0% of stented patients; none were apparent on CBA. 2) SF fracture, in addition to failure of drug elution, may contribute to in-stent restenosis; in the absence of significant ISR, more frequent monitoring by MDCT may be indicated. 3) Stent fracture should be considered in the evaluation of new stent designs.

Coronary Plaque Composition of Nonculprit Left Main, Assessed by in vivo Intravascular Ultrasound Radio Frequency Data Analysis, is Related to the Severity of Coronary Artery Disease
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Background: The identification of subclinical high-risk plaque is important. However, there are few data on the clinical significance of nonculprit left main coronary artery (LM) in patients with coronary artery disease(CAD). We aimed to assess the relationship between plaque composition of nonstenotic LM coronary disease determined by intravascular ultrasound virtual histology (IVUS-VH) and severity of coronary artery disease.

Methods: In 83 patients referred for coronary angiography, a nonculprit LM with ≤50% diameter stenosis was evaluated with IVUS-VH for the in vivo coronary plaque characterization. The images were reconstructed and set to radio frequency using IVUS-VH software. Cross-sectional measurements, volumetric data of the plaque of LM and the volume of 4 different plaque components (fibrous, Fi; fibrofatty, FF; dense calcium, DC and necrotic core, NC) were compared with the angioscopic severity of CAD assessed by Gensini scoring system.

Results: Mean Gensini score of the patients was 27±15 and minimal lumen area of LM was 16.5±5.4 mm2. The average lumen, vessel and plaque volume of the 83 vessels were 103±70, 153±97 and 50±38 mm3, respectively. Mean percentage of the different plaque components were Agg-10%, Fi<5%, FF<5%, DC, and NC<5%. Gensini score demonstrated significant positive correlations with the volume(%) of DC and NC (r=0.392, p<0.001; r=0.385, p<0.001) respectively in the LM plaque. At multivariate regression analysis, Gensini score resulted to be an independent predictor of relative necrotic core content [β=0.402 (95%CI:0.124, 0.680), r=0.385], together with age, unstable clinical presentation, and presence of diabetes mellitus.

Conclusions: In conclusion, plaque composition of IVUS-VH measurable atherosclerosis in nonstenotic LM associated with angiographic severity of CAD. The patients with severe CAD had more lipid and calcium content in the LM plaque. We recommend more intensive evaluation and treatment for nonculprit LM in the patients with severe CAD.

The Predictive Value of Computed Tomography Calcium Scores: A Comparison With Quantitative Volumetric Intravascular Ultrasound

Background: Coronary artery (CA) calcium scoring (CS) by cardiac computed tomography (CCT) may be ideally suited, by virtue of its ability to interrogate stents from a 360 degree perspective and provide cross sectional stent images. This study was designed to evaluate the ability of MDCT to detect SF.

Methods: We examined the relationship between CACS and intravascular ultrasound (IVUS) quantification in 44 pts undergoing CACS 18±23days before IVUS. Volumetric IVUS analysis included vessel, lumen, and plaque areas and volume and plaque burden. CACS used the Agatston 10-30 protocol.

Results: There were 106 calcified and 17 non-calcified lesions detected by IVUS. Eighty-five of the IVUS-calcified lesions (80%) were detected by the CACS protocol, but 38 lesions (38%) were missed entirely. 14/28 (50%) of the lesions with an IVUS arc of calcium below the 25% percentile (51.4°) were detected by CACS vs. 91% of lesions with an IVUS arc of calcium >51.4° (p<0.05). Similarly, only 21/36 (58%) lesions <3mm in length were detected vs. 91% of lesions >3mm in length (p<0.05). We divided CAC-detected lesions into 3 categories: CS <10, 10-499, and >400. Mean plaque burden, lesion length, and arc of calcium increased significantly, and minimum lumen area decreased significantly with increasing CACS (Table).

Conclusions: Lesion detection using CCT CACS is dependent on both lesion morphometry (specifically, the arc and location of calcium) and lesion severity (plaque burden, lesion length, and minimum lumen area) as assessed using IVUS.

Safety of Cardiovascular Magnetic Resonance Performed Immediately after Primary Percutaneous Coronary Intervention for STElevation Myocardial Infarction
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Background: Although cardiovascular magnetic resonance (CMR) is usually postponed to prevent theoretical stent heating or displacement. However, several studies have demonstrated CMR safety performed 3 days after PCI. To better evaluate myocardial perfusion, necrosis and viability in the hyperacute phase of STElevation myocardial infarction (STEMI), it would be useful to perform CMR earlier following coronary stenting. We investigated the early and long term safety of CMR performed immediately after primary PCI with stenting for STEMI.

Methods: We prospectively studied 128 patients undergoing primary PCI with stent...
implantation for STEMI. The study group was composed of 64 patients who underwent CMR (1.5 Tesla) within 12 hours after primary PCI including 105 stents. The control group, also composed of 64 patients, underwent primary PCI without CMR. Adverse events were reported during the early in-hospital period as well as during 6-month follow-up.

Results: Patient populations were comparable in both groups. Total ischemic times were 0.08 ± 0.071 and 1.35-28.5 ± 0.245 hours. The mean delay between PCI and CMR was 4.8 (interquartile range 4) hours. Duration of the CMR study was 22 minutes (75% confidence interval 1.24-29.0 minutes). No adverse events occurred during the imaging session. Immediate CMR was not associated with any in-hospital increase in death, myocardial infarction, urgent revascularization, or bleeding (p = ns for each). During 6-month follow-up, CMR performed immediately after primary PCI was not associated with a higher rate adverse events compared to primary PCI without CMR (respectively MACE 5 vs. 8%; p=0.16; repeat angina 6 vs. 8%; p=0.73; rehospitalization for cardiac cause 3 vs. 13%; p=0.05). On Kaplan-Meier estimates, event-free survival at 6 months was not decreased by performing CMR immediately after primary PCI with stenting. Conclusion: Cardiovascular magnetic resonance at 1.5 T performed immediately after primary PCI with coronary stent implantation has proven early and long-term safety, opening the door for improved risk stratification in the hyperacute phase of STEMI.

2900-136 Frequency and Predictors of Troponin-I Elevation After Non-Urgent Diagnostic Coronary Angiography: A Prospective Study

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Background: Microembolization during coronary intervention, as reflected by elevated cardiac troponin I (cTnI), has been shown to be a common event. However, no reliable data to date has definitively demonstrated this issue during coronary angiography (CAG). The aim of this study was to identify the incidence and predictors of cTnI elevation after CAG.

Methods: A series of 172 consecutive patients undergoing elective CAG because of chest pain or diagnostic referral.

Results: Baseline and post-procedural cTnI levels were 0.06±0.009 ng/ml and 0.068±0.000 ng/ml, respectively (P=0.066). Consequently, positive cTnI elevation was observed in 31 patients (10.3%). (See Table).

In the experienced operators, the frequency of positive cTnI elevation after CAG was markedly lower than the inexperienced operators, presumably due to less procedure time (32.0±15.3 min vs. 44.0±25.2 min, P=0.001) and contrast volume (172.8±40.4 ml vs. 207.5±188.5 ml, P=0.017).

Conclusions: The occurrence of mild myocardial injury during CAG might be relatively frequent, and associated with gender, left ventricular hypertrophy, and the operator’s skill.

Univariate and multivariate predictors of a positive cTnI elevation after CAG

Mean Scores (±SEM) p-value (t-test) Optimal Cutpoint AUROC 95% Confidence Interval p-value (ROC analysis) Sensitivity Specificity

2900-137 Quantitative Coronary Artery Computed Tomography Angiography is Highly Reproducible for Stenosis Measurements and for the Quantification of Plaque Components

Sanj Rinehart, Hunt Anderson, Jennifer LaCorte, Sizul Voros, Fuqua Heart Center of Atlanta, Atlanta, GA

Background. Interobserver agreement for the quantification of stenosis and plaque components by CT coronary angiography is unknown.

Methods. We evaluated 184 coronary segments by CTA using a highly standardized approach (Vitrea 4.0). 9 pts had a designated study lesion. Two independent observers measured each parameter. For study lesions, observers measured % diameter (D% and area stenosis (A%), minimal lumen diameter (MLD), minimal lumen area (MLA), calcified volume and percent (CaV, %Ca), high-density non-calcified plaque (>30 HU) volume and percent (HDNCP-V, %HDNCP) and low-density non-calcified plaque (<30 HU) volume and percent (LDNCP-V, %LDNCP). Similar parameters were measured in the left main and the proximal, mid and distal LAD, RCA and LCx. Interobserver agreement was determined by concordance correlation coefficient (CCC) and Pearson’s r (PPP).

Results. We report CCC, 95% confidence interval and PPP in lesions. %Ca: 0.99, 0.98-1.00, 0.012; %AS: 0.98-1.00, 0.08; MLD: 1.00, 1.00-1.00, 1.00; MLA: 1.00, 1.00-1.00, 0.001; CaV: 1.00, 0.99-1.00, 0.0; %Ca: 1.00, 0.98-1.00, 0.001; HDNCP-V: 0.99, 0.96-1.00, 0.09; %HDNCP: 1.00, 0.99-1.00, 0.001; LDNCP-V: 0.98, 0.94-1.00, 0.09; %LDNCP: 0.99, 0.95-1.00, 0.99. Same parameters for the 184 segments are shown in Figure.

Conclusions. Interobserver agreement is remarkably high with our highly standardized approach to CoRDTA databases for quantitative measurements of stenosis severity and for quantification of plaque components.

2900-138 Measured Vessel-Specific and Lesion-Specific Coronary Artery Calcium Scores Significantly Improve Prediction of Severely Obstructive Coronary Artery Stenoses

Hunt D. Anderson, Scott J. Rinehart, Jennifer A. LaCorte, Sizul Voros, Fuqua Heart Center of Atlanta, Atlanta, GA

Background: Total coronary artery calcium (CAC) scores (Agatston and volume scores) have poor correlation with obstructive (>70%) coronary artery disease (CAD). We hypothesized that vessel- and lesion-specific CAC scores are more accurate.

Methods: 44 patients with CAC and invasive angiography (XRA) data were studied. Agatston and volume scores were measured individually for each lesion in the four major epicardial coronary arteries and the lesion-specific values were recorded. Summation of these values resulted in vessel-specific and patient-specific values. Presence or absence of obstructive CAD on XRA was recorded for corresponding vessels. CAD values in patients with and without obstructive CAD were compared by two-tailed t-test; ROC curves were used to evaluate the performance of CAC values in predicting obstructive CAD.

Results: Of the 175 vessels included, 27 had obstructive CAD by XRA. Specificity of the vessel-specific Agatston score and maximum lesion-specific score dramatically improved compared to the total Agatston and volume scores (86% to 86% and 86% to 86%, respectively). AUC of lesion-specific scores was also higher than total scores (0.77 vs 0.71). Mean scores in patients with and without obstructive CAD and ROC values are shown in the Table.

Mean scores in patients with and without obstructive CAD and ROC characteristics

Conclusion: Vessel- and lesion-specific CAC scores are more accurate than total scores in predicting obstructive CAD. This novel, simple refinement could increase the accuracy of CAC for diagnostic referral.

2900-139 Prediction of major adverse cardiac events after percutaneous coronary intervention

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Background: Many models have been devised in the past to predict adverse outcomes after percutaneous coronary intervention (PCI), but with rapid advancements in this field, a new risk prediction model might be needed. The purpose of our study was to identify the clinical and angiographic variables associated with adverse cardiac events after PCI and construct a simple bed-side tool for risk stratification of the patients.

Methods: Using the Texas Heart Institute research database, we analyzed data from...
9494 patients who underwent PCI between January 1, 1996 and December 31, 2002 (i.e. during the bare metal stent era). Predictors of major adverse cardiac events—death, myocardial infarction, stroke, and repeat revascularization by emergent coronary artery bypass grafting or PCI—were identified by multivariate logistic regression analysis using baseline clinical, angiographic and procedural variables. A simple integer score was constructed by multiplying β coefficient for each variable by a constant and rounding off the result to the nearest integer. The score was validated on 5545 patients undergoing PCI from January 1, 2003 to December 31, 2006 (i.e. during the drug-eluting stent era).

Results: Multivariable regression analysis identified emergent procedure, urgent procedure, unstable angina, acute MI, renal insufficiency, hypertension, congestive heart failure, peripheral vascular disease, Type C lesion, presence of thrombus and number of stents placed as independent predictors of adverse events after PCI. The model had good overall discrimination (Area under the receiver operator characteristic 0.701) and the model fitted the validation cohort adequately.

Conclusions: Risk of complications after PCI can be assessed by this simple risk assessment tool, which may permit comparisons between different operators as well as different hospitals.

Nationwide Trends in the Utilization of Percutaneous Coronary Intervention (PCI) in the United States.

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Background: To evaluate nationwide trends in the utilization of Percutaneous Coronary Intervention (PCI) in the past in comparison to recent years, we used a large data base from 1988 to 2004.

Methods: The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted rate for PCI from 1988 to 2004. Specific ICD-9-CM codes for all PCIs were used to compile the data. Patient demographic data was also analyzed from the database.

Results: The NIS database contained 1,747,736 patients who had PCI performed from 1988 to 2004. The mean age for these patients was 63.76 ± 11.07 years old. Male underwent PCI twice than female (male: 66.27, female 33.73). From 1988, the age-adjusted rate for PCI gradually increased to more than double until 2001 [(80.39 per 100,000 (95%CI=71.86-88.92) in 1988 and 243.85 per 100,000 (95%CI=221.31-266.39, p<0.01) in 2001] but remained unchanged until end of the study in 2004 (232.17 per 100,000 (95%CI=211.25-252.66) in 2004, see figure).

Conclusion: The utilization of PCI has dramatically increased to more than double from 1988 to 2001 but remained unchanged thereafter. The reason for the lack of steady increase in PCI rate in the recent years is not known. It could be related to the approval of drug eluting stents or secondary to aggressive lipid lowering treatments.

Nationwide Trends in the Utilization of Multi vessel Percutaneous Coronary Intervention (MPCI) in the United States.

Mohammad Reza Movahed, Mehrshar Hashemzadeh, Mazen Jamal, University of Arizona Sarver Heart Center and Southern Arizona VA Health Care System, Tucson, AZ

Background: To evaluate nationwide trends in the utilization of Multi Vessel Percutaneous Coronary Intervention (MPCI) in the past in comparison to recent years, we used a large data base from 1988 to 2004.

Method: The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted rate for PCI from 1988 to 2004. Specific ICD-9-CM codes for Multi vessel PCI were used to compile the data. Patient demographic data was also analyzed from the database.

Results: The NIS database contained 241,319 patients who had MPCI performed from 1988 to 2004. The mean age for these patients was 64.89 ± 11.84 years old. Male underwent MPCI at the double rate in comparison to female (male: 67.87, female 32.13). From 1988, the age-adjusted rate for MPCI gradually increased to more than 3 times in 1998 [6.62 per 100,000 (95%CI=5.92-7.33) in 1988 and 23.92 per 100,000 (95%CI=21.62-26.22, p<0.001) in 1998] and accelerated to more than 6 times than original rate at the end of the study in 2004 (41.50 per 100,000 (95%CI=37.84-45.16) in 2004, see figure).

Conclusion: The utilization of multi vessel PCI has dramatically increased to more than 6 times from 1988 to 2004 with acceleration in the recent years. The cause of this acceleration is most likely related to advancement in the percutaneous coronary interventional techniques.

Deadly Quartet of Clinical Factors Among Patients With Diabetes Mellitus Undergoing Saphenous Vein Graft Interventions

Rejendra H. Mehta, Emily Honeycutt, Linda K. Shaw, Michael H. Sketxh, Jr., Duke University Medical Center, Durham, NC, Duke Clinical Research Institute, Durham, NC

Background: Less data exist on the long-term outcomes of patients with diabetes mellitus (DM) undergoing saphenous vein graft (SVG) interventions. Accordingly, our goals were to evaluate the long-term outcomes and identify baseline factors associated with decrease survival in DM patients undergoing SVG interventions. Methods: We analyzed 1160 patients undergoing SVG interventions from the Duke Cardiovascular Disease Database (1986-2003). Cox proportional hazards modeling was used to identify predictors of long-term death. The most significant model predictors were then used to construct a decision tree providing unanswered Kaplan-Meier survival estimates at the median follow-up of 4 years. Results: DM was present in 437 (37.7%) patients undergoing SVG interventions. Median survival was significantly lower in DM versus non-DM patients (66.7% vs. 81.9%, p<0.0001). A clinical decision tree depicting baseline features and survival in DM patients is shown in Figure. While 88% of patients without heart rate >/=80, heart failure, renal insufficiency or hypertension survived to 4 years, those with all these 4 factors had 100% mortality. Conclusion: Long-term survival of DM patients undergoing SVG interventions is significantly lower than non-DM patients with one-third of these individuals dying at 4 years. We identify a ‘deadly quartet’ of clinical risk factors associated with extremely poor 4-year survival (100% mortality) in diabetics undergoing SVG interventions that may help physician in risk stratifying and counseling these patients.
had no coronary obstruction this sex differential progressively decreased across the ACS spectrum. Importantly, the prevalence of single-vessel disease differed according to type of ACS.

Conclusions: Sex-based differences exist in clinical presentation and angiographic severity according to type of ACS. Appreciating these differences in clinical syndromes and anatomy may provide useful mechanistic insights into the pathogenesis of ACS in women and men, which may ultimately translate into improved patient care and outcomes.

**Table 1.** Complication rate: Early (1999-2002) vs Recent period (2003-2006)

<table>
<thead>
<tr>
<th>Complication</th>
<th>Absolute difference</th>
<th>Value</th>
<th>p value</th>
<th>CI %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke</td>
<td>0.002</td>
<td>3.94</td>
<td>0.001</td>
<td>0.001 - 0.004</td>
</tr>
<tr>
<td>Any MI</td>
<td>0.005</td>
<td>4.84</td>
<td>0.001</td>
<td>0.003 - 0.008</td>
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<tr>
<td>Vascular</td>
<td>0.004</td>
<td>3.52</td>
<td>0.001</td>
<td>0.002 - 0.006</td>
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<tr>
<td>CEP</td>
<td>0.007</td>
<td>4.26</td>
<td>0.001</td>
<td>0.004 - 0.011</td>
</tr>
<tr>
<td>CEPproST</td>
<td>0.009</td>
<td>5.41</td>
<td>0.001</td>
<td>0.006 - 0.012</td>
</tr>
<tr>
<td>Any complication</td>
<td>0.013</td>
<td>5.48</td>
<td>0.001</td>
<td>0.008 - 0.018</td>
</tr>
</tbody>
</table>

**Figure 1.** PCI complication rate: Early (1999-2002) vs Recent period (2003-2006)

**Figure 2.** PCI complication rate: Early (1999-2002) vs Recent period (2003-2006)

**Is High Sensitivity C-Reactive Protein Associated With Early or Late Cardiovascular Events Following Percutaneous Coronary Intervention?**

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Background: High-sensitivity C-reactive protein (hsCRP) has been shown to be an independent marker of vascular risk in primary and secondary prevention populations. Stratification by levels of <1, 1-3, and >10 mg/L has correlated with risk of myocardial infarction (MI), stroke, and cardiovascular death.

Methods: 1341 consecutive patients who underwent percutaneous coronary intervention (PCI) between April 2000 and August 2007 were stratified by baseline hsCRP levels. 305 had a hsCRP <1, 406 between 1 and 3, 400 between 3 and 10, and 230 >10. Death, MI, and target vessel revascularization were examined at 30 days and 1 year following PCI.

Results: Baseline demographics were similar except in the CRP ≥10 group where patients were more likely to be female, have a history of diabetes, smoking, renal disease, and heart failure, and present with acute MI. (p<0.001) Outcomes at 30 days and 1 year revealed no difference in MI or revascularization among groups. There appeared to be a trend towards increased all-cause death at 1 year in the highest hsCRP group, but after performing an adjusted regression analysis that accounted for MI during admission, cardiogenic shock, and history of diabetes, smoking, renal disease, and heart failure, there was no significant difference in all-cause death at 1 year (adjusted p value=0.054).

Conclusions: Higher hsCRP levels were not independently associated with increased risk of cardiovascular events or mortality following PCI in an unrestricted population.
The Swedish angiography and angioplasty registry (SCAAR) is a continuous national registry covering all Swedish patients undergoing coronary angiography and percutaneous coronary interventions in Sweden. A complete 15-year follow-up of patients treated between 1989 and 2006 was obtained by merging with other national registries of death, myocardial infarction, coronary artery by-pass surgery and hospital discharge diagnoses. Only the first intervention during the study period was included. Results: 67 000 procedures were included in the analysis. The re-intervention rate was almost 20% the initial year post PCI and thereafter app. 2% annually. After 15 years 50% of patients had undergone a new intervention (40% PCI and 10% with by pass surgery), almost 30% had experienced a myocardial infarction and 10% had suffered from stroke. Mortality increased continuously and reached almost 40% after 15 years. Conclusions: This large real world registry demonstrates the natural course after PCI with a high risk of other manifestations of cardiovascular disease after very long term follow-up.

Trends in the Association Between Age and In-Hospital Mortality Following PCI: Data From the NCDR
Mandeep Singh, Eric Peterson, Matthew Roe, Fang-Shu Ou, John Sperutz, John Rumsfeld, H Vernon Anderson, Lloyd Klein, David Holmes, Jr., NCDR, Washington DC, DC
Background: Temporal trends and contemporary data on the association between age and outcome of percutaneous coronary interventions (PCI) are lacking. We aimed to determine the in-hospital mortality of various age groups in the National Cardiovascular Database Registry (NCDR) and to evaluate the temporal trends.
Methods and Results: In-hospital mortality following PCI on 1,410,069 patients from 2001-2006 was evaluated, age-stratified into 4 groups, Group 1 (age<40, n=25,679), Group 2 (40-59, n=496,204), Group 3 (60-79, n=732,574), and Group 4 (80+, n=155,612). Overall in-hospital mortality was 1.22%, and was 0.96%, 1.05%, 1.26%, and 3.16% in groups 1 to 4 respectively. P<0.0001. Overall temporal improvement per calendar year in the unadjusted and risk-adjusted in-hospital mortality following PCI was noted in all the 4 groups (Fig), however, it was significant only in older age groups, group 3 (OR 0.93, 95% CI 0.93, 0.97) and group 4 (OR 0.96, 95% CI 0.93, 0.97). While relative mortality reduction was greatest in young patients, absolute mortality reduction was greatest in the elderly. Conclusions: In-hospital mortality following PCI has fallen for all age groups over the last six years; with the largest magnitude reductions seen among octogenarians.

Procedural And Clinical Outcomes Of Percutaneous Coronary Intervention For Ostial Lesions in proximal coronary arteries.
Freeman Melani, David Clark, Han S. Lim, Stephen J. Duffy, Nick Andrianopoulos, Angela Brennan, Kerrie Charter, James Shaw, Martin Sebastian, Andrew E. Ajani, Chris Reid, Mark Horrigan, Farouque Omar, Austin Hospital, Melbourne, Australia
Background: Ostial lesions (OL) are a difficult subset associated with suboptimal target vessel revascularisation. OL continue to present significant challenges. OL, p= 0.548), and target lesion revascularization (2.9% vs. 4.9%, p= 0.233), however, 12-month MACE was higher in the OL group (29% vs. 16%; p=0.036), largely driven by target vessel revascularisation. Conclusion: PCI for OL is associated with similar 30-day clinical outcomes, but worse 12-month outcomes than for NO lesions. OL continue to present significant challenges.
Background: Intense focus has been placed on strategies to reduce door-to-balloon (DTB) time in patients undergoing primary PCI for ST-elevation myocardial infarction (STEMI). Despite the use of DTB time as a national performance measure, the impact of prior CABG surgery on DTB time is unknown.

Methods: We analyzed 77,166 patients who had primary PCI for STEMI from 2004-2007 in the ACCSCAI National Cardiovascular Data Registry (NCDR). The median and distribution of DTB time in patients with and without prior CABG were analyzed. Logistic General Estimating Equation models were used to evaluate in-hospital mortality, adjusting for differences in baseline patient characteristics.

Results: During the study period, 4601 (5.8%) patients undergoing primary PCI for STEMI had a history of CABG. Median DTB time was significantly longer in patients with prior CABG (113 vs. 98 minutes; p < 0.0001). In addition, the highest proportion of patients with prior CABG had DTB times of > 100 minutes (46.1%), while the highest proportion of patients without prior CABG had DTB times of < 90 minutes (43.3%) (Figure). However, in-hospital risk-adjusted mortality was not statistically different between the two groups (OR= 1.07; CI 0.91-1.25).

Conclusion: Prior CABG was associated with prolonged DTB time in patients undergoing primary PCI. This finding did not translate into higher in-hospital risk-adjusted mortality, yet could substantially impact performance measurement depending on the case mix for a given hospital.

Conclusions: We used a model initially tested at Immanuel St. Joseph’s Hospital (ISJ) for the conduct of the PCI. The quality assurance model included a validated peer-review process, meeting minimum volume threshold standards for the operators, a fully equipped cardiac catheterization laboratory facility, participation in a PCI database, and strict protocol for case selection and transfers. In-hospital mortality, Q-wave myocardial infarction, and need for emergency CABG were analyzed and compared with a facility with on-site surgery. We evaluated the in-hospital outcomes of 928 PCI (737 elective) performed at Franciscan Skemp (FSH), La Crosse, WI and 1175 PCI (877 elective) at ISJ, Mankato, MN, a hospital without on-site surgery whose model of care was adopted by FSH. The cases were compared to one-to-one matched controls from procedures performed at St. Mary’s Hospital (SMH) in Rochester, Minnesota, which has on-site surgical capability. Baseline clinical characteristics were well balanced between groups. Within elective procedures, the procedural success and major in-hospital adverse cardiovascular outcomes at sites with and without on-site surgery were similar (Table). No patients at MHS undergoing elective PCI required emergent transfer for cardiac surgery. Results in patients undergoing primary PCI for acute myocardial infarction were also similar between cases and controls (data not shown).

Conclusions: In one of the largest studies, adoption of a quality assurance model demonstrated similar clinical outcomes for both elective PCI and primary PCI at two community hospitals without onsite cardiac surgery as compared with those at a tertiary center with onsite cardiac surgery.

In-Hospital Events

<table>
<thead>
<tr>
<th>Event</th>
<th>FSH</th>
<th>ISJ</th>
<th>SMH</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
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<td>Emergent CABG ≤24 hr</td>
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</tr>
<tr>
<td>p</td>
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Background: Disparities in healthcare and cardiovascular outcomes are evident in lower socioeconomic status (SES) patients (pts). Very limited data exist regarding lower SES outcomes in the low SES population. Very limited data exist regarding lower SES outcomes in the low SES population. We tested whether the publication of the COURAGE Trial has led to a decrease in the number of coronary angiograms (CA) and PCIs in 4 Southern California academic institutions.

Methods: We retrospectively analyzed the number of CAs and PCIs performed at four institutions performed during the period between 4/1/2005 to 8/31/2005 (Group 1); 4/1/2006 to 8/31/2006 (Group 2); and 4/1/2007 to 8/31/2007 (Group 3). Differences between the groups were compared using repeated measures ANOVA and were considered significant if the p value was < 0.05.

Results: In Group 1, there were 1397 CAs and 623 PCIs (44.6% PCI); Group two had 1549 CAs and 788 PCIs (50.9% PCI), and Group 3 had 1091 CAs and 594 PCIs (54.5% PCI). Compared to Groups 1 & 2, Group 3 had significantly fewer CAs (p<0.01). Group 3 had a 9.9% increase in the number of PCIs compared to Group 1 (p<0.01), and a 3.6% increase compared to Group 2 (p=0.02).

Conclusions: The COURAGE Trial and the widespread attention it received may be considered significant if the p value was < 0.05.

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Conclusions: The COURAGE Trial and the widespread attention it received may be considered significant if the p value was < 0.05.
Conclusions: Lower SES was a powerful independent predictor of increased long-term MACE. This novel finding persisted after adjustment for risk, therapy and medical compliance, and warrants further investigation.

Outcomes in African American versus non-African American Patients following Percutaneous Coronary Intervention With Drug Eluting Stents

Daniel H. Steinberg, Michael A. Gaglia, Jr., Rebecca Torguson, Tina L. Pinto Slottow, Probol Roy, Teruo Okabe, Saqib Samee, Kimberly A. Smith, Zhenyi Xue, William C. Suddath, Kenneth M. Kent, Lowell F. Satler, Augusto D. Pichard, Joseph Lindsay, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Previous research has suggested that African American (AA) patients experience adverse cardiac outcomes following percutaneous coronary intervention (PCI).

Methods: We identified 1123 AA patients referred for PCI and compared them to 3966 non-AA patients. Patients were followed for one year with regard to major adverse cardiovascular events (MACE) including death, q-wave myocardial infarction (MI) and target vessel revascularization. We performed multivariate Cox proportional hazards regression to adjust for confounding variables and assess the contribution of African-American race to one year outcomes.

Results: At one year AA patients experienced significantly higher rates of overall MACE (15.9% AA vs. 10.0% non-AA, p<0.001) as well as each individual component of death (7.1% AA vs. 4.5% non-AA, p<0.001), q-wave MI (3.7% vs. 1.6%, p<0.001) and TLR (8.2% AA vs. 5.1% non-AA, p<0.001). Stent thrombosis was also higher in the AA population at one year (2.8% AA vs. 0.7% non-AA, p<0.001). After multivariate analysis, AA remained a highly significant predictor of MACE (HR 1.3, 95% CI 1.1 - 1.6, p<0.003). AA did not predict stent thrombosis on multivariate analysis, but there was a trend toward increased thrombosis with decreased thienopyridine compliance.

Conclusions: After controlling for comorbidities with multivariable analysis, AA remains a highly significant and independent predictor of MACE following PCI.

Low Incidence of Stent Thrombosis in Asian Races: Multicenter Registry in Asia 3 Years Follow-Up Result

Sunan Nakamura, Shotoro Nakamura, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Sunao Nakamura, Shotaro Nakamura, Jang-Ho Bae, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan, Konyang University Hospital, Daejeon, South Korea

Background: There are limited data about stent thrombosis which is rare but devastating complication after drug-eluting stent (DES) implantation in unselected patients with a variety of coronary lesions. The aim of this study was to evaluate the frequency, predictors and the clinical outcome of stent thrombosis after DES implantation and bare metal stent (BMS) implantation in Asian races. Method: A total of 14,577 consecutive patients who underwent successful DES implantation (8,809 patients, 62% of the lesion with Sirolimus-eluting stent: SES, 38% of the lesion with paclitaxel-eluting stent: PES) and BMS implantation (5,768 patients) in 5 Asian high volume PCI center during March 2002 to March 2004 were included in this study. We evaluate the frequency, predictor and clinical outcome of stent thrombosis in our multi-center registry of Asian races.

Results: At a mean follow-up of 40.5±14.6 months in DES and 44.±16.4 months in BMS. The cumulative incidence of stent thrombosis was subacute stent thrombosis (SAT): 0.5% with DES and 0.6% with BMS, late stent thrombosis (LAST): 0.2% with DES and no with BMS, very late stent thrombosis (VLAST): 0.4% per 2 year with DES and no BMS. Independent predictors of stent thrombosis are bifurcation lesion (OR=1.90, 95% CI: 1.83 to 24.24, p<0.01) and ejection fraction (OR=0.80, 95% CI: 0.86 to 0.94, p<0.03). Only 0.2% of the patients were died because of the myocardial infarction after stent thrombosis in both groups. Conclusions: The incidence of stent thrombosis in Asian races is relatively low (0.5% with DES and 0.6% with BMS of SAT, 0.2% increase per year with DES of late stent thrombosis) at mean follow-up more than 3 years. Particular attention will need to be directed to this complication when the patients have bifurcation lesions or low ejection fraction.

Conclusions: In general, patients with DES have better outcomes than those with BMS, late stent thrombosis (LAST): 0.2% with DES and no with BMS, with a Trend toward increased thrombosis with decreased thienopyridine compliance.

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ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts B59


Aaron D. Kugelmiss, David J. Cohen, Phillip P. Brown, Matthew R. Reynolds, Steven D. Culler, April W. Simon, Cardiac Data Solutions, Inc., Atlanta, GA, Emory University Rollins School of Public Health, Atlanta, GA

Background: This study reports annual national trends in incidence rates, survival rates, and Medicare program spending for treating Medicare beneficiaries (MB) experiencing a primary ST-segment elevation myocardial infarction (STEMI). Methods: A retrospective analysis was conducted using annual MedPAR data files for fiscal years (FY) 2000 through 2006. The study sample consists of all MB hospitalized with a primary diagnosis of STEMI. Incidence rates were the number of admissions in each FY per 1,000 MB. Survival rates were the observed proportion of MB discharged alive. Reimbursement was the mean reimbursement for all STEMI hospitalizations during each FY. Program savings were calculated as the difference between actual reimbursement in the FY and the amount the Medicare program would have spent if the incidence rate of STEMI admissions had remained at the FY2000 level. Results: Between 2000 and 2006, the number of hospitalizations for STEMI among MB decreased by 38%, with a 32% reduction (p<0.001) in per capita incidence. This has been accompanied by a 3.1% improvement (p=0.001) in in-hospital survival rate. The final rows of the table summarize the fiscal impact of the decline in STEMI incidence rate on the Medicare program hospital expenditures. Conclusions: There has been a significant increase in survival rates for STEMI admissions, and a decrease in the incidence rate of STEMI admissions resulting in total cumulative program savings of $3.84 billion over the past six years in the Medicare program.

2900-158 Percutaneous Coronary Intervention and 30-Day Mortality: The British Columbia PCI Risk Score

Jaap N. Hamburger, Simon J. Walsh, Lillian Ding, Zhi Tan, Min Gao, Karin H. Humphries, Dewey Evans, Ronald Caree, Anthony Y. Fung, Richard R. Mildenberger, Gerald J. Simkus, John G. Webb, Christopher E. Buller, University of British Columbia, Vancouver, BC, Canada, Provincial Health Services Authority, Vancouver, BC, Canada

Background: Predictors of 30-day mortality are commonly used to aid the management of cardiac surgical patients. There is a need for an equivalent risk-score for 30-day mortality for percutaneous coronary intervention (PCI) patients to allow direct comparison between the 2 different methods of revascularization. Methods: The British Columbia Cardiac Registry (BCCR) is a population-based registry that collects information on all PCI procedures performed in British Columbia (BC). We used data from the BCCR to construct a calculator that predicts mortality risk for patients undergoing PCI. Results: A total of 32,899 BC residents had PCI performed during the years 2000 - 2005. These patients were divided into a training set (n=26350, PCI between 2000 - 2004) and validation set (n = 6549, PCI in 2005). Univariate predictors of mortality were identified. Multivariable logistic regression analysis was performed on the training set to develop a statistical model for prediction of 30-day mortality. This model was then validated in the validation set. Variables that were objective and available before PCI were included in the model. Results: At one year AA patients experienced significantly higher rates of overall MACE decreased by 38%, with a 32% reduction (p<0.001) in per capita incidence. This has been accompanied by a 3.1% improvement (p=0.001) in in-hospital survival rate. The final rows of the table summarize the fiscal impact of the decline in STEMI incidence rate on the Medicare program hospital expenditures. Conclusions: There has been a significant increase in survival rates for STEMI admissions, and a decrease in the incidence rate of STEMI admissions resulting in total cumulative program savings of $3.84 billion over the past six years in the Medicare program.

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We describe a large, contemporary cohort of consecutive patients. The adult population of Olmsted County in 2006 was 100,716. During this one year evaluation, 88 patients developed 100 episodes of CS. Median age of the patients with CS was 76 (IQR 63.5-81) of which 64% were females. The median BMI was 25.2 (IQR 22.7-34.1). The all cause in-hospital mortality following CS was 45% (95%CI 35-65). CS was caused by NSTE MI in 40%, STEMI in 20% and other causes (arhythmias, valvular disease, decompensated heart failure) in the remaining 40%. The cumulative incidence of CS was 89 episodes (95%CI 68-147) per 100,000 person-years at risk. This translates to one episode of CS for every 1007 patient years. For a 1-year evaluation, 88 patients developed 100 episodes of CS.

**Background:** The incidence of Cardiogenic Shock (CS) following an acute coronary syndrome has been described, the epidemiology of all-cause CS requiring an Intensive Care Unit (ICU) admission is not, to our knowledge, known. The purpose of this study was to evaluate the epidemiology of CS in residents of Olmsted county, MN.

**Methods:** This was a retrospective cohort study of all Olmsted County residents admitted to the ICUs of Mayo Clinic, Rochester, MN. This is the only center capable of providing continuous ICU services for patients in this demographic. A random sample of the population was selected for analysis. We excluded patients who denied research authorization, were less than 18 years of age and who needed vasopressor support in the immediate post-cardiopulmonary bypass period. Those with prior withdrawal of care orders or a “mixed” distributive and CS picture were also excluded. CS was defined as a patient having 1. A shock index >1 or Systolic Blood Pressure (SBP) persistently <90 mmHg or need for vasoactive infusions to maintain a SBP >90 mmHg. 2. Evidence of end organ hypoperfusion and 3. Evidence of elevated filling pressures.

**Results:** The adult population of Olmsted County in 2006 was 100,716. During this one year evaluation, 88 patients developed 100 episodes of CS. Median age of the patients with CS was 76 (IQR 63.5-81) of which 64% were females. The median BMI was 25.2 (IQR 22.7-34.1). The all cause in-hospital mortality following CS was 45% (95%CI 35-65).

**Conclusions:** The incidence of cardiogenic shock in the community appears to be higher than previously reported. This may be explained by our use of more sensitive shock criteria. The in-hospital mortality was lower than expected, possibly due to recent improvements in our therapeutic approach.

**2900-160 Treatment of Patients Previously Deemed “Unrevascularizable” Often Includes Revascularization**

Gregory W. Barness, Linda Tesmer, Ryan J. Lennom, Mayo Clinic, Rochester, MN

**Background:** There is a growing population of patients with severe ischemic chest pain who are considered poor candidates for traditional revascularization. These patients are often referred to as “no option” or “refractory angina” patients, although the true characterization is ill-defined, making determination of long-term outcome and comparison of treatment strategies difficult. We studied long-term outcome in severely symptomatic patients referred to a tertiary center for treatment of chronic unrevascularizable coronary disease.

**Methods:** Clinical characteristics, symptoms and follow-up events were recorded at baseline and at 6 month intervals in 200 consecutive patients with demonstrable coronary disease and CCS class 3 or 4 angina consenting to follow-up. All patients were on optimal medical therapy and deemed unrevascularizable by a referrals cardiologist due to comorbidities and/or unfavorable coronary anatomy.

**Results:** Patients were elderly (median 68 yrs), primarily men (80%), with a history of diabetes (44%), hypertension (76%), tobacco use (54%), heart failure (20%), MI (58%), and prior PCI (67%), CABG (82%), TMR (5%) and/or heart transplantation (1%). Mean LVEF was 50±14%. Initial treatment included traditional revascularization (3% PCI, 2% CABG), TMR (1%), ECP (63%) or continued medical therapy (30%). At 1 year, events included MI (10%), CVA (1%), urgent revascularization (11%) and death (6.5%), resulting in a 1-year event-free survival of 77%. By 1 year, 15.5% of patients in this cohort underwent PCI and/or CABG. Of patients selected to undergo early elective revascularization, there were no deaths at a median of 3 years follow-up.

**Conclusions:** Patients with symptomatic coronary artery disease deemed to be unrevascularizable by experienced cardiologists may, in fact, be candidates for traditional revascularization. While this referral cohort included many who are at high risk for subsequent non-fatal coronary events, overall mortality was low and did not seem to be increased in those selected for elective revascularization. Further effort is needed to better define appropriate invasive and non-invasive strategies for patients labeled “unrevascularizable.”

**2900-161 The Impact of Systemic Inflammation on Heat Production in Non-Culprit Lesions.**

Konstantinos Tzouroua, Maria Drakopoulou, John Karabelas, Sophia Vaina, Maria Riga, Christodoulos Stefanadis, 1st Department of Cardiology, University of Athens, Athens, Greece

**Background:** Coronary artery disease is related to enhanced systemic and diffuse coronary inflammation. Though, the impact of systemic inflammation on non-culprit lesions (NCL) has not been extensively investigated. We studied: 1) the relation between local plaque temperature and C-reactive protein (CRP), 2) the impact of diabetes (DM) and 3) statin intake on NCL heat production.

**Methods:** We included 40 patients (pts) with stable angina (SA) and 47 with acute coronary syndrome (ACS), who underwent percutaneous coronary intervention in the CL and had a second intermediate NCL. Systemic inflammation was assessed by CRP. Temperature difference (ΔΤ) was calculated by subtracting the maximal vessel wall temperature from the maximal one at the NCL.

**Results:** Pts with ACS had higher ΔΤ (0.10±0.07 vs. 0.05±0.05°C, p<0.01) and CRP (1.19±1.06 vs. 0.46±0.35mg/dL, p=0.01) than SA pts. Pts with DM (n=30) had higher ΔΤ than non-DM (0.10±0.08 vs. 0.06±0.03°C, p=0.01). Statin intake (n=40) lowered ΔΤ (0.05±0.04 vs. 0.12±0.07°C, p<0.01; SA: 0.04±0.04 vs. 0.08±0.07°C, p=0.02). There was a linear correlation of ΔΤ and CRP in the study population (figure) and in the ACS and SA groups (R=0.4, p=0.001, R=0.34, p=0.01, R=0.41, p=0.01 respectively). Multivariate analysis showed CRP and DM as independent predictors of ΔΤ.

**Conclusions:** Pts with ACS have increased NCL heat production compared to SA pts, possibly due to enhanced systemic inflammatory activation. Statin intake has a beneficial effect on NCL heat production.

**2900-162 Risk and Clinical Predictors for Patients with Unstable Angina and Non-ST Segment Elevation Myocardial Infarction Post Early Percutaneous Coronary Intervention.**

Eric Chong, Shien Liang, Kian Keong Poh, Huay Cheem Tan, The Heart Institute, National University Hospital, Singapore, Singapore, Biostatistics Unit, National University, Singapore.

**Background:** TIMI score has been used to predict outcomes in patients with unstable angina (UA) and non-ST elevation myocardial infarction (NSTEMI). We aim to look for clinical predictors for patients in this group undergoing early percutaneous coronary intervention (PCI).

**Methods:** A cohort of 3822 patients presented with UAP/NSTEMI from June 1996 to March 2007 to our center were recruited. All patients underwent PCI within the same admission. We analyzed the various clinical predictors for prediction of major adverse cardiac events (MACE) and death at 1 month and 6 month.

**Results:** Median Age was 56.22(97), 78.1% was men, 34.5% diabetics, 58.8% had hypertension. Coronary lesions involving left main and proximal left anterior descending artery was 27.6%, 36.1% had NSTEMI.

**Clinical predictors**

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<th>Death at 1 month</th>
<th>Odds ratio (p value)</th>
<th>Death at 6 month</th>
<th>Odds ratio (p value)</th>
<th>MACE at 1 month</th>
<th>Odds ratio (p value)</th>
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**ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts**

**2900-105**

**Culprit Vessel Primary Percutaneous Coronary Intervention for ST Elevation Myocardial Infarction: Shorter Door to Balloon Time**

Stacy H. Graham, Robert J. Applegate, Sanjay K. Gandhi, Matthew T. Sacrinty, Talat T. Baki, Renato M. Santos, William C. Little, Michael A. Kutcher, Wake Forest University School of Medicine, Winston-Salem, NC

**Background:** Shorter door-to-balloon for ST elevation myocardial infarction (STEMI) treatment is associated with better outcomes, and is generally achieved by shortening the door to vascular access time. Whether procedural improvements can shorten the vascular access to balloon time has not been examined. We hypothesized that by first performing culprit vessel primary percutaneous coronary intervention (PCI) for STEMI, and then completing coronary angiography we would shorten door-to-balloon times.

**Methods:** Door-to-balloon was assessed in 50 patients who underwent initial PCI of the culprit vessel for STEMI at Wake Forest University Baptist Medical Center and 85 patients who underwent traditional complete coronary angiography followed by PCI for STEMI. All other treatment strategies were used similarly in both groups.

**Results:** Procedural success was 100% in both groups. See Figure for time intervals. 92% of the culprit PCI group had a door-to-balloon time ≤90 minutes, compared to 76% in the traditional group, p = 0.023. Subsequent planned revascularization procedures were infrequent and similar in both groups.

**Conclusions:** Performing PCI of the culprit vessel for STEMI as initial treatment resulted in a significant decrease in the door-to-balloon time compared to traditional coronary angiography followed by PCI without sacrificing subsequent cardiac care.

**2900-106**

**20 Years Follow-Up Results Of Pulmonary Balloon Valvuloplasty In Adults And The Fate Of Concomitant Infundibular Stenosis And Tricuspid Regurgitation**

Mohamed Eid Fawzy, Adil Osman, Said El Almouzai, Omar Nowayhed, Iman Ibrahim, Shabir Shah, King Faisal Specialist Hospital, Riyadh, Saudi Arabia

**Background:** The goal of this study was to evaluate the long term (up to 20 years) outcome of pulmonary balloon valvuloplasty (PBV) for severe pulmonary valve stenosis (PS) in adults, and to determine its effects on concomitant severe infundibular stenosis and severe tricuspid regurgitation (TR).

**Methods:** PBV was performed in 90 consecutive patients (49 women) mean age 23 ± 9 years with severe congenital PS. Clinical and echocardiographic assessment were performed 2-20 years after PBV. Repeat cardiac catheterization was performed 6-24 months after PBV in 43 patients who had concomitant moderate to severe infundibular stenosis (infundibular gradient ≥ 30 mm Hg).

**Results:** There were no immediate or late deaths. The mean catheter peak pulmonary gradient (PG) before and immediately after PBV was 105 ± 34 and 39 ± 26 (p < 0.0001). The right ventricular pressure was 125 ± 58 and 58 ± 21 (p < 0.0001) mm Hg, respectively. The infundibular gradient (in 43 patients) immediately after PBV was 42.9 ± 24.8 (30 – 113) mm Hg and regressed at repeated catheterization to 13.5 ± 8.3 mm Hg (p < 0.0001). Doppler PG before and at one year and long term follow-up was 91 ± 33 (range 36 – 200), 28 ± 12 (p < 0.0001) and 26 ± 11 mm Hg (p = 0.2), respectively. New mild pulmonary regurgitation (PR) was noted in 24 patients (28%) after PBV. Significant TR in seven patients either regressed or disappeared after PBV.

**Conclusions:** Long term results up to 20 years of PBV in adults are excellent. Severe infundibular stenosis and severe TR regressed after successful PBV. No restenosis was encountered after successful PBV.

**2900-108**

**The Gender Difference In No Rerlow Phenomenon in Patients With ST segments elevation acute myocardial infarction**

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**Background:** The gender difference is established in epicardial coronary artery disease. However, it is not known whether or not there is any difference in coronary microcirculation and the occurrence of no reflow (NRF) phenomenon between the sexes.

**Methods:** All patients with ST elevation acute myocardial infarction (STEMI) admitted to a tertiary referral hospital from May 2001 to October 2005 who underwent percutaneous coronary intervention were reviewed. Patients with previous coronary artery bypass surgery and patients with unsuccessful intervention were excluded. NRF was diagnosed by using myocadial blush grade and TIMI flow score by a single reader blinded to the patients’ clinical data.

**Results:** Three hundred fifty patients met the inclusion criteria and form the basis of
The prevalence of cardiac risk factors was comparable in those with normal flow and those with NRF. Male patients were more likely to develop NRF (table 1). It was also observed that the presence of thrombus at the time of intervention was not different between males and females with 46% of male patients and 40% of female patients having thrombus. (P = 0.28).

<table>
<thead>
<tr>
<th>Table 1. Gender Difference in NRF</th>
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<tbody>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Fisher’s exact test</td>
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Conclusions: Male gender is a strong risk factor for development of NRF and that difference did not appear to be related to the presence of angiographically visible thrombus. These results are the first to demonstrate a gender difference in the coronary microcirculation following reperfusion therapy for STEMI.

Clinical Implications of the Choice of Therapy for Patients with Rheumatoid Arthritis and Lupus after Acute Myocardial Infarction

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Background: European studies have shown that rheumatoid arthritis (RA) patients have excessive risk of cardiovascular death after myocardial infarction (MI) and were less likely to receive percutaneous coronary intervention (PCI). The differential use of coronary revascularization procedures and its clinical implications in patients with RA and systemic lupus erythematosus (SLE) is unknown in United States.

Methods: Using Nationwide Inpatient Sample (2003-2004), we analyzed all patients admitted with diagnosis of MI. After adjusting for confounding factors which include age, gender, race, Charlson comorbidity index, hypertension, diabetes, hyperlipidemia, income, insurance, rural/urban residency, elective admission, and weekend admission, we examined patients with RA or SLE to determine the adjusted odds ratio of medical therapy, PCI and coronary artery bypass graft (CABG) compared to patients without RA or SLE. We then compared inhospital mortality of RA and SLE patients treated with medical therapy, PCI and CABG.

Results: Adjusted Odds Ratio for Choice of Therapy and In-Hospital Mortality (95% Confidence Intervals)

<table>
<thead>
<tr>
<th>Medical Therapy (n=119069)</th>
<th>CABG (n=29206)</th>
<th>PTCA (n=72599)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choice of therapy for RA</td>
<td>0.68 (0.61-0.76)</td>
<td>0.56 (0.81-1.13)</td>
</tr>
<tr>
<td>Choice of therapy for SLE</td>
<td>0.59 (0.81-1.21)</td>
<td>0.64 (0.45-0.9)</td>
</tr>
<tr>
<td>In-hospital mortality for RA</td>
<td>0.52 (0.78-1.09)</td>
<td>0.79 (0.41-1.52)</td>
</tr>
<tr>
<td>In-hospital mortality for SLE</td>
<td>0.97 (0.69-1.36)</td>
<td>0.27 (0.04-2.08)</td>
</tr>
</tbody>
</table>

Conclusions: In United States, RA and SLE patients with acute myocardial infarction were more likely to receive coronary revascularization procedures especially PCI. Furthermore, this treatment pattern appears to be justified since in-hospital mortality of RA patients undergoing PCI is significantly better than patients without RA.

Inflammation/Lipid Score May Outperform Timi Score in Acute Myocardial Infarction Treated by Primary Intervention.

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Background: Novel inflammatory and neurohumoral markers are potential prognostic factors after acute coronary syndromes. The aim of the study was to reassess the prognostic model after the first myocardial infarction (MI) treated with primary PCI (pPCI). Methods. 85 patients (20 females) aged 61±9 years admitted with first ST-elevation MI and treated with pPCI. Laboratory panel extended with IL-1, IL-10, MCP-1, sFAS, NT-proBNP, fibrinogen and CRP were sampled prior to intervention. Patients were followed-up with regard to the occurrence of death, MI or ventricular fibrillation during 12 month follow-up period.

Results. 37% pts reached the composite endpoint. We defined univariate predictors of 1-year prognosis: IL-10 (p=0.0014), HDL cholesterol (OR=7.5; 95% CI 1.9-30.1, p=0.0001), creatinine kinase (CK, p=0.007) and CK-MB (p=0.05). Left ventricular ejection fraction (p=0.02), TIMI risk score (p=0.027) and white blood count/WBC (p=0.029). In multivariate logistic regression model (86% correct, p=0.001) the independent prognostic factors were: HDL cholesterol; HR=0.89 (0.81-0.98), p=0.0001; IL-10; HR=1.39 (1.01-1.96), p=0.014, and WBC; HR=1.39 (1.03-1.88), p=0.038. A prognostic score based on 3 factors: HDL-31.2 mg/dl, IL-10-0.4 pg/ml, WBC>10800/mm³ yielded Kaplan-Meier's HR=10.4 (p<0.0001) when 2 or 3 factors were present (event rate 0%, 17% and 80% for scores 0, 1 and 2, resp.). TIMI score at optimal ROC-defined threshold-3 offered low HR=2.37 (p<0.002).

Conclusions. A simple prognostic score including white cell count, HDL-cholesterol and interleukin-10 concentration enabled optimized risk stratification and outperformed TIMI risk score in this study. These variables may better predict prognosis in patients referred with primary percutaneous intervention than Antman’s TIMI score.

Direct LV Dynamics During Primary Angioplasty for Anterior ST-Elevation Myocardial Infarction and Follow Up

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Background: We studied direct changes in left ventricular (LV) dynamics during primary percutaneous coronary intervention (PCI) and after a recovery period of 4 months, by pressure-volume (PV) loops.

Methods: Thirteen consecutive patients (8 males, mean age 60±11 years) were studied, who presented with their first acute anterior ST-segment elevation myocardial infarction within 6 hours after onset of symptoms (CK-MBmax 215±116 mg/L), and in whom angiography revealed an occluded left anterior descending artery. A pressure-conductance catheter was placed in the LV after which primary PCI was performed successfully. The patients were re-catherized at 3 days and 4 months.

Results: Before PCI, patients had depressed LV contractility, as indicated by a decreased ejection fraction (EF) 41±17%, an increased end-diastolic pressure (EDP) and volume (EDV), and reduced end-systolic volume (ESV), which improved immediately after successful reperfusion with TIMI 3 flow, EDP decreased by 9±5 mm Hg (p=0.007), while ESV and EDV showed a decrease after 3 days by 26±15 ml (p=0.009) and 38±23 ml (p=0.01), respectively, with a concomitant increase in EF by 14±5% (p=0.001). At 4 months EDV increased by 41±59 ml (p=0.02), while ESV and EF remained unchanged, indicating dilatation with a relatively preserved contractility. Levels of NT-proBNP increased up to 3 days and returned close to normal at 4 months. Conclusion: Coronary reperfusion during primary PCI directly reduces LV end-diastolic pressure, indicating an immediate partial relief of the stunned myocardium, which is followed by an increased contractile function at 3 days and 4 months contractile function was relatively preserved, despite myocardial dilatation.

Physician Experience Significantly Modifies The Effect of Hospital Primary Angioplasty Volume on In-Hospital Mortality

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Background: An inverse relationship between volume and outcome has been described for both hospitals and physicians during primary angioplasty (PA). However, whether physician experience of PA offsets the risk related to low volume hospitals and vice versa is not known.

Methods and Results: Using the 2000-2002 New York State PCI reporting system, we calculated the independent and joint effects of hospital, physician volume on risk-adjusted mortality in 7321 patients undergoing PA using logistic regression analyses. In these analyses, high volume hospitals (performing >50 PAs/year) and high volume physicians (>10 PA/year) had similar rates of in-hospital mortality compared to respective low volume counterparts after adjustment for underlying risk using the New York state PCI risk score.

Results: PA by high volume hospitals (OR 0.53; 95% CI 0.34 - 0.81) and by high volume physicians (0.66; 0.48 - 0.92) was independently associated with lower odds of mortality. In a logistic regression model of hospital and physician volume adjusted for underlying risk, the product interaction term for hospital and physician volume was significant with Wald ch2 of 417; P=0.02. Compared to PA in high volume hospitals and high volume physicians as reference, a low volume physician in low volume hospitals was associated with significantly higher odds of mortality (1.72; 1.04 - 2.85). Similarly, even within high volume hospitals, PA by high volume physicians was associated with significantly better outcomes compared to low volume physicians (OR 0.58; 95% CI 0.39-0.86).

Conclusions: A significant interaction exists between hospital and physician volume of PA such that the effect of low hospital volume on outcome is significantly modified by physician experience. These results would support the use of minimum volume thresholds for both hospitals and physicians performing PA.
2900-173
Impact of Round-the-Clock In-House Interventional Cardiologist on Door-to-Ballon Time in STEMI Patients
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Background: Prompt revascularization in ST-elevation myocardial infarction (STEMI) decreases in-hospital mortality. ACC/AHA recommends a goal of door-to-ballon time (D2B) <90 minutes in STEMI. We report the impact of round-the-clock in-hospital interventional cardiology team (24/7) on D2B time in our tertiary care hospital since April 2004.
Methods: Data was prospectively collected on all consecutive patients who presented to emergency room with STEMI and underwent primary percutaneous coronary intervention. We compared D2B time during the 2 years prior to 24/7 coverage (Pre 24/7) with D2B time for the 2 years since we started 24/7 (Post 24/7).
Results: In 587 patients (397 Pre 24/7 and 290 Post 24/7) mean D2B improved from 131.1± 281 min Pre 24/7 to 65.9±33.6 min Post 24/7 (p=0.0001). The target D2B <90 min was achieved in 39% of the Pre 24/7 group and 85.2% of the Post 24/7 group (p=0.001).
Conclusions: Round-the-clock in-house coverage by catherization laboratory staff and interventional cardiologist results in a significant improvement in door-to-balloon time.

2900-174
Intra Aortic Balloon Pumping Ineffective Against Systemic Inflammatory Activation During Myocardial Infarction Related Cardiogenic Shock
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Background: In patients with myocardial infarction complicated by cardiogenic shock (MI-CS) the use of IABP is recommended. MI-CS causes a systemic inflammatory response syndrome (SIRS) leading to further impaired hemodynamics and multi-organ dysfunction syndrome (MODS). This inflammatory response could be improved (by improvement of shock hemodynamics) or worsened (by exposure of the circulation to foreign material) with IABP use. No randomized clinical trial has examined whether IABP improves SIRS in MI-CS. We hypothesized that IABP use would ameliorate systemic inflammatory activation in MI-CS. The present IABP-shock trial was a monocentric, randomized, controlled prospective, parallel treatment trial to examine the role of IABP in treating MODS and inflammation in PCI treated patients with MI-CS.
Methods: Forty consecutive patients with acute MI-CS were randomized to receive therapy with or without IABP (for 48h) in addition to PCI centred care. APACHE II scores and inflammatory markers (Leukocyte count, IL-6, TNFα) were measured at enrolment and daily for 4 days. Results: The study population mean age was 64±9 years, 52% were mechanically ventilated, the mean LVEF was 27±2%, and 28 day survival was 67%. The global mean APACHE II score was 20±2.7 (illustrating the severity of disease) but was not affected by the implementation of IABP therapy. Conclusion: Although IABP therapy may exert pro- or anti-inflammatory influences, given the present data, we conclude that IABP use does not significantly improve markers of systemic inflammation or the development of SIRS / MODS in PCI treated MI-CS patients.

2900-175
Long-Term Clinical Outcome and Stent Thrombosis of Paclitaxel-Eluting Stent versus Sirolimus-Eluting Stent in Primary Percutaneous Intervention: multicenter registry in Korea
Seong-Wook Park, Seung-Whan Lee, Won-Jang Kim, Duk-Woo Park, Young-Hak Kim, Cheol Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Jae-Hwan Lee, Jae Hyung Park, In-Whan Seong, Hyun Sook Kim, Jae-Ki Ko, Jei Keon Chae, Seung-Jung Park, Asan Medical Center, Seoul, South Korea
Background: To compare long-term (3-year) safety and efficacy of paclitaxel eluting stents (PES) versus sirolimus eluting stents (SES) for the treatment of acute ST elevation myocardial infarction. Methods: The 549 consecutive patients were treated with PES (n=187) or SES (n=362) in the setting of primary percutaneous coronary intervention for acute myocardial infarction in this multicenter registry. Thirty-day and long-term clinical outcomes (28±10 months) were clinically assessed. The primary endpoint was incidence of stent thrombosis and major adverse cardiac events (MACE) including all cause mortality, myocardial infarction (MI), and target lesion revascularization (TLR). We applied a classification of stent thrombosis set by the Academic Research Consortium (ARC). Results: Both group had similar clinical and angiographic characteristics. At 30 days, the rate of target lesion revascularization (4.3% for PES vs. 4.1% for SES, p = 0.417) and MI (2.1% for PES and 1.4% for SES, p = 0.498) was similar between groups. Angiographic restenosis was significantly lower in SES (6.0% vs. PES, 14.4%; p=0.006). During the 3-year follow-up, no significant differences were seen between groups in terms of death (7.9% for PES and 6.0% for SES, p = 0.893), MI (4.0% vs. 3.4%, p = 0.632), TLR (8.3% vs. 4.0%, p = 0.318) and MACE (15.9% vs. 12.8%, HR 1.24; 95% CI, 0.72-2.12; p=0.441). Stent thrombosis (overall cumulative incidence; 1.9% at 30 days, 2.4% at 1 year, 2.6% at 2 years, and 3.3% at 3 years) occurred in 2.8% for PES versus 3.6% for SES during the 3-year follow-up (HR 0.95; 95% CI, 0.53-1.73; p = 0.798). Late stent thrombosis (>1 month) occurred in 0.6% for PES versus 2.2% for SES (p=0.259).
Conclusions: Despite significant reduction of angiographic restenosis in SES versus PES, no differences were seen in MACE and incidence of stent thrombosis between PES and SES for the treatment of acute myocardial infarction during 3-year follow-up.

2900-176
Myocardial Perfusion Grade (MPG) After Late Infarct Artery Recanalization Predicts Global and Regional LV Function at One Year; Analysis From The Total Occlusion Study of Canada-2
Tarek K. Steigen, Vinod Jorapur, Christopher E. Buller, Warren J. Cantor, Boban Thomas, James M. Rankin, John G. Webb, Bruce Barton, Deborah Jacinth, Gervasio A. Lamas, Judith S. Hochman, G. B. John Mancini, Vladimir Dzavik, Vancouver General Hospital, Vancouver, BC, Canada, University Health Network, Toronto, ON, Canada
Background: TOCSA-2 is an NHLBI-funded sub-study of the Occluded Artery Trial (OAT), an international randomized trial of PCI for occluded IRAe13-28 days post-MI. TOCSA-2 obtained paired ventriculograms at baseline and 1 year post-PCI, providing a unique opportunity to evaluate the association between myocardial perfusion grade (MPG) and global and regional functional recovery at one year following successful late IRA recanalization.
Methods: MPG was evaluable in 157 patients assigned to PCI (TIMI MPG scheme: 0-no blush, 1- stage, 2- slow entry/exit, 3-normal). Angiographic parameters, including MPG, were evaluated in a core lab.
Results: Lower blush grade post-PCI (MPG 0/1, n=33, 23 %) predicted lower LV ejection fraction (EF), higher end-systolic volume index (ESVI) and lower wall motion index (WMI) at one year (Table). In a logistic model from MI to reanimation (trend; OR 1.109 per day, 95% CI 1.019-1.206; P=0.017) and baseline ESVI (significant; OR 1.316, 95% CI 1.112-1.556; P=0.001) were positively related to MPG 0/1 at one year. For this analysis, n=151 was considered significant.
Conclusions: MPG is often preserved following late IRA recanalization and preserved MPG significantly relates to better global and segmental indices of LV function at 1 year. These observations extend prior analyses undertaken in acute MI settings indicating that MPG may represent preserved microvascular integrity and myocardial viability.

2900-177
Time Delay to Treatment and Long-term Outcome After Primary Angioplasty for ST-Segment Elevation Myocardial Infarction: A DANAMI-2 Substudy
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Background: In patients with ST-elevation myocardial infarction (STEMI) treated with primary percutaneous coronary intervention (pPCI) early reperfusion is believed to improve left ventricular systolic function and reduce mortality. However, long-term (>1 year) data are lacking.
Methods: In the DANAMI-2 study 666 patients were treated with pPCI. Long-term mortality was obtained three years follow-up. We grouped the patients according to symptom-to-balloon time <3 hours (early, n=223), 3-5 hours (intermediate, n=282) and ≥5 hours (late, n=181). These groups were compared using a Cox proportional hazards regression model adjusted for significant baseline differences between the groups. Left ventricular systolic ejection fraction (LVEF), mean arterial pressure and daily diuretic diuretic dose were recorded prior to discharge until hospitalization.
Results: There was no long-term mortality difference between the early and intermediate groups. The unadjusted mortality hazard ratio (HR) for symptom-to-balloon time ≤3 hours was highly significant (HR 2.36, 95% CI 1.51-3.70, p=0.0002) but after adjustment for differences in baseline characteristics only a trend remained (HR 1.55, 95% CI 0.98-2.44, p=0.063). There was a significant mortality interaction between age and time delay (p=0.047); the younger the patient the greater was the survival benefit of symptom-to-balloon time ≤3 hours. Symptom-to-balloon time was positively associated with LVEF (overall cumulative incidence; 80.3% early, 77.2% late, 66.9% ≥5 hours, p=0.036) and increased postPCI TIMI-3 flow (early 86.5%, intermediate 80.9%, late 75.7%, p=0.020).
Conclusions: A symptom-to-balloon time ≤3 hours is associated with improved three-year survival in STEMI patients treated with pPCI. This long-term survival benefit is age-dependent and associated with improved left ventricular function and improved postPCI coronary flow.
Early Initiation of Statins Immediately after Acute Myocardial Infarction Improves Mid-Term Clinical Outcomes

Young Joon Hong, Myung Ho Jeong, Doo Sun Sim, Jong Won Chung, Ju Han Kim, Jae Yoon Moon, Young Keun Ahn, Jeong Gwan Chi, Jong Chun Park, Jung Chaege Kang, Chonnam National University Hospital, Gwangju, South Korea

Background: Early initiation of statins in patients with acute myocardial infarction (AMI) on secondary cardiac events remain unclear. The aim of this study was to evaluate the beneficial effects of early initiation of statins on mid-term clinical events after AMI in a real-world setting.

Methods: Between October, 2005 and December 2006, 621 patients with AMI (439 ST segment elevation MI and 182 non-ST segment elevation MI) were registered and followed prospectively. Early initiation of statins was defined as prescription during hospitalization (statin group: 545 patients), and the control group was not prescribed statins during hospitalization or at discharge (76 patients). The primary end point was 6-month mortality rate.

Results: During 6-month follow-up, 22 patients died (3.5%), including 7 patients from the control group (9.2%) and 15 patients from the statin group (2.8%) (p<0.004). 6-month follow-up major adverse cardiac events (including cardiac death, MI, and target lesion revascularization) occurred less frequently in patients who were taken early statin therapy compared with patients who were not taken statin therapy (statin group: 78 (14.3%) vs. control group: 18 (23.7%), p=0.034). Baseline high-sensitivity C-reactive protein (hs-CRP) was significantly higher in died patients compared with live patients (12.8±10.2 mg/dl vs. 2.1±3.0 mg/dl, p<0.001). Multivariate logistic regression analysis showed that early initiation of statin therapy and baseline hs-CRP level were the independent predictors of 6-month mortality [hazard ratio (HR): 0.078, 95% CI: 0.008-0.808, p=0.032, and HR=1.314 (95% CI: 1.149-1.501, p<0.001, respectively).

Conclusions: In this analysis of 621 AMI patients, high inflammatory status is associated with poor prognosis, and early initiation of statins after AMI could decrease mid-term mortality rate.

Local Leukocyte Elastase Elastase at Site of Occlusive Plaque Rupture Predicts Downstream Microvascular Reperfusion Injury and Impaired Left Ventricular Function in ST Elevation Myocardial Infarction

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Background: Leukocyte elastase (LE) is a serine protease released from granules of activated neutrophils and associated with extracellular matrix breakdown and up-regulation of cycloxygenes and metalloproteinases. High levels of LE have also been found in monocytes/macrophages in morphologically vulnerable atheromatous plaques. We hypothesized that increased leukocyte activation locally at site of coronary plaque rupture may help predict a subgroup of patients that have impaired microvascular reperfusion following successful primary percutaneous coronary intervention (PCI) for ST elevation myocardial infarction (STEMI).

Methods: We enrolled STEMI patients presenting within 12 hours to undergo primary PCI. Following informed consent, samples were obtained from the coronary artery (CA) at site of occlusive plaque rupture pre (CApre) and post coronary angioplasty and stenting (CApost) using a multi-functioning probing catheter (BSC, Natwick, NJ). LE was measured by ELISA (IDK, Bensheim, Germany).

Results: Following informed consent, 34 patients with STEMI were enrolled. 32% anterior MI, 94% Final TIMI 3 flow, 42% with STR>70%, LE was higher at CApre 50.2 ng/ml (95% CI 29.2-74.3) compared to systemic 25.5 ng/ml (95% CI 21.8-36.2, p=0.001).

Conclusions: Increased LE elastase release locally at site of occlusive coronary plaque rupture, but not systemically, predicts downstream microvascular reperfusion injury and medium term LV myocardial dysfunction. Strategies to target intra-coronary elastase elastase and downstream products of activation may help improve outcome in patients undergoing primary PCI for STEMI.

Predictors of Slow Flow During Primary Percutaneous Coronary Intervention

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Background: Slow flow phenomenon is a serious complication of percutaneous coronary intervention (PCI) and associated with poor prognosis. We sought to evaluate the characteristics of lesions predisposing to slow/no-flow phenomenon during primary PCI in patients presenting with acute myocardial infarction.

Methods: The study subjects consisted of 57 consecutive patients (mean 58.5±14.5 years old, 45 males) who underwent primary PCI for acute myocardial infarction and intra-coronary ultrasonic-virtual histology (IVUS-VH) examination. Slow flow was defined as C-Phosphorylin myocardial infarction grade 2 after PCI.

Results: Slow flow was developed in 12 patients (8 males). Patients with slow flow was likely to be older (67.5±13.8 yrs old vs 56.2±19.9 yrs old, p=0.015), had more cardiogenic shock (16.7% vs. 2.2%, p=0.048), larger fibrofatty volume over the entire lesion length (36.7±25.5 mm3 vs. 18.0±18.6 mm3, p=0.006), higher remodeling index (1.10±0.17 vs. 0.99±0.16, p=0.043), larger plaque area (16.2±5.4 mm2 vs. 12.5±4.9 mm2, p=0.025), fibrous area (8.0±3.2 mm2 vs. 5.4±3.0 mm2, p=0.014), and fibrofatty area (2.7±2.2 mm2 vs. 1.3±1.6 mm2, p=0.016) at the minimal lumen site than those without slow flow (37 males). Multivariate analysis revealed that the fibrofatty volume over the entire lesion length was the only independent factor (beta=0.359, 95% confidence interval 0.002 to 0.012, p=0.006) for slow flow during primary PCI.

Conclusions: This study suggests that slow flow may be dependent on the tissue characterization (fibrofatty volume) of the underlying lesion at the time of the primary PCI for acute myocardial infarction.

One-Year Clinical Follow-Up of Endothelial Progenitor Cell Capture Stent versus Uncoated Stent in Patients Undergoing Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction

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Background: The endothelial progenitor cell (EPC) capture stent is a bioengineered R stent with immobilized antibodies on its stent struts which allows for capture of circulating EPCs to promote rapid endothelialization. We compared the mid-term efficacy and safety of this novel stent with bare metal stent in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).

Methods: Between January 2005 to September 2006, 234 consecutive patients presenting to our centre with STEMI and who underwent primary PCI with either EPC or bare metal stents were enrolled. The primary study end point was target vessel failure (death, recurrent MI or target vessel revascularization) at 1 year.

Results: The 2 groups were comparable in baseline demographic characteristics with males of 88.5% and diabetics 31.2%. The mean stent length deployed of EPC vs bare metal stents were 20.5±5.1 mm and 23.2±6.8 mm respectively (p=0.01). At 1 year, the primary end point was similar between the 2 groups (12.0% vs 11.3%, p=0.88). There was no significant difference in the rate of death (2.6% vs 5.7%, p=0.24), reinfarction (2.6% vs 2.8%, p=1.00) or target vessel revascularization (8.8% vs 8.2%, p=0.17). The rate of late stent thrombosis (0.9% vs 1.9%, p=0.50) was also similar.

Conclusion: The rate of EPC capture stent in patients undergoing primary PCI have comparable 1-year clinical outcomes with bare metal stents. Table. Clinical Events at 1 Year

Event | EPC Stent (N=120) | Bare Metal Stent (N=114) | P Value
---|---|---|---
Target vessel failure | 14 (12.0) | 12 (11.3) | 0.88
Clinically driven target vessel revascularization | 4 (3.3) | 3 (2.6) | 0.73
Death | 3 (2.6) | 6 (5.7) | 0.24
Cardiac causes | 3 (2.6) | 3 (2.9) | 1.00
Noncardiac causes | 0 | 0 | 0.07
Recurrent MI | 3 (2.6) | 3 (2.6) | 0.90
Stent thrombosis | 1 (0.9) | 2 (1.9) | 0.50
Acute | 0 | 0 | 0.00
Subacute | 0 | 1 | 0.50
Late | 1 (0.9) | 1 | 0.94

Drug-eluting Stents and Acute Myocardial Infarction: Experience from the TAXUS ARRIVE Registry Program

John M. Lusala, David Cox, Marc Schweiger, Donald Jenny, Nicholas Davakis, Stephen Mascioli, Donald Baim, Washington University School of Medicine Cardiovascular Division, St. Louis, MO, Lehigh Heart Village Specialists, Allentown, PA

Background: Patients (pts) with acute myocardial infarction (AMI) may have more adverse events after treatment than pts undergoing elective intervention. The risks when using drug-eluting stents (DES) are not well understood. Therefore, we examined pts in the ARRIVE program with all types of AMI.

Methods: In ARRIVE 1 and 2, investigators at 99 US sites collected safety and clinical outcomes data for pts receiving TAXUS Express2 Paclitaxel-eluting stents in routine clinical practice.

Results: AMI pts comprised 12.5% (n=917) of the total 7,307 pt cohort. Their baseline characteristics were similar to the overall study population in most respects, but the prevalence of prior intervention and diabetes were lower, while prior MI and smoking were higher. AMI pts had significantly higher (p<0.001) MI at p=0.01 and stent thrombosis (ST, p=0.01) at 1 yr with no difference in reintervention when compared to 2,641 pts treated for "simple" non-AMI indications. Independent predictors of outcomes at 2 yrs will be presented.

Conclusions: AMI pts treated with the TAXUS Express stent show comparable anti-restenotic benefits but have more death, MI and ST than Simple Use pts. This pattern has been reported with bare metal stents and a recent meta-analysis of AMI patients

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overall study population and AMI patient subgroup.

**Table 1: Characteristics and clinical outcomes in ARRIVE 1 and 2 pooled data: overall and AMI patient subgroup.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall Study Population (n=7307)</th>
<th>AMI Patients (n=917)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>64.3±11.7</td>
<td>62.1±12.9</td>
</tr>
<tr>
<td>Male (%)</td>
<td>67.3</td>
<td>66.6</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>31.5</td>
<td>24.0</td>
</tr>
<tr>
<td>Insulin-treated (%)</td>
<td>10.2</td>
<td>8.7</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>75.8</td>
<td>63.4</td>
</tr>
<tr>
<td>Previous PCI (%)</td>
<td>36.6</td>
<td>20.6</td>
</tr>
<tr>
<td>Previous CABG (%)</td>
<td>20.0</td>
<td>9.9</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>36.1</td>
<td>66.4</td>
</tr>
<tr>
<td>Known Smoker (%)</td>
<td>23.3</td>
<td>37.0</td>
</tr>
<tr>
<td>RVD (mm)</td>
<td>3.0±0.4</td>
<td>3.1±0.5</td>
</tr>
<tr>
<td>Lesion Length (mm)</td>
<td>15.7±9.2</td>
<td>16.6±9.5</td>
</tr>
</tbody>
</table>

**Outcomes**

- **Simple Use**
  - AMI (n=917)
  - p-value
  - Simple Use (n=2641)
  - p-value

- **All Death (%)**
  - Simple Use (n=2641)
  - p-value
  - Simple Use (n=874)
  - p-value

- **Cardiac Death (%)**
  - Simple Use (n=2641)
  - p-value
  - Simple Use (n=874)
  - p-value

- **MI (%)**
  - Simple Use (n=2641)
  - p-value
  - Simple Use (n=874)
  - p-value

- **Re-intervention (%)**
  - Simple Use (n=2641)
  - p-value
  - Simple Use (n=874)
  - p-value

- **ST (ΔMb≤1.0mm, total, #)*/
  - Simple Use (n=2641)
  - p-value
  - Simple Use (n=874)
  - p-value

**2000-184 Primary Coronary Intervention Without On-Site Surgery vs. Thrombolysis: A Rural Facility Cost Analysis**

Dane E. Sobek, Jennifer L. Kack, Blair D. Erb, Jr., Bozeman Deaconess Hospital, Bozeman, MT, Cardiology Consultants of Bozeman, PC, Bozeman, MT

**Background:** The current recommended approach to the ST elevation myocardial infarction (STEMI) patient at facilities without on-site cardiac surgery (non-SOS) is through emergency transfer to the nearest SOS facility. Many non-SOS facilities lack the country currently offer primary percutaneous coronary intervention (PCI) despite the current recommendations. Previous studies have generally shown good angiographic and clinical outcomes in this setting. The cost of the two approaches, however, is rarely discussed. We compare overall medical care costs for STEMI patients receiving primary PCI at our rural non-SOS facility to estimated costs for lysis and transfer.

**Methods:** Hospital charges for all STEMI patients, identified by hospital DRG, who underwent primary PCI during 2006 in an 86 bed rural non-SOS hospital. The nearest SOS facility is 150 miles away requiring helicopter transport. Cost for the lysis and transfer approach were calculated by adding emergency room costs (hourly rate for a 2 hour visit), thrombolytic (tPA) administration costs (by CPT Code), and helicopter flight costs (based on a 300 mile roundtrip) to the assumed similar costs for PCI at the nearest SOS facility.

**Results:** In 2006, 25 primary PCI’s were performed for STEMI. Mean door-to-balloon time was 69.6 minutes (12 - 146 minutes). Six (24%) of STEMI patients were in cardiogenic shock. Two patients underwent an induced hypothermia protocol for sudden cardiac death. Survival-to-discharge and 30 day survival rates were 100%. There were no major cardiovascular complications. Average hospital charges per STEMI patient was $34,971 ($18,397 - $57,572). The estimated cost for the lysis and transfer approach per patient was significantly higher at $49,629 ($33,055 - $72,230) (p<0.05). The estimated cost in health care dollars for STEMI care was decreased by 42% ($14,658) per patient with the primary PCI approach.

**Conclusions:** Initiation of a primary PCI program in a rural non-SOS community hospital resulted in a significant cost savings for acute STEMI care compared to thrombolysis and transfer. Clinical outcomes were not compromised, and PCI may have resulted in improved outcomes in patients with cardiogenic shock.

**2000-185 Late Recovery of Myocardial Reperfusion 24 Hours After a Primary PCI Predicts Long Term Outcomes**

Jorge L. Szafter, Miguel A. Riccitelli, Patricia Arce, Alejandro Garcia Escudero, Gerardo Gigera, Federico Blanco, Rodrigo Blanco, Andrea Rodriguez, Roberto Neme, Ricardo Sarmiento, Luis A. Vital, Hospital Argerich-Hemodinamia, Buenos Aires, Argentina

Late Recovery of Myocardial Reperfusion 24 Hours After a Primary PCI Predicts Long Term Outcomes

**Background:** The lack of Myocardial Reperfusion immediately after a primary PCI predicts worst long term outcomes. The effect of 24 hours (Hs) Myocardial Reperfusion Recovery assessed by Myocardial Blush Recovery (MBR) on long term Left Ventricular Function (LVF) and mortality is unknown. The aim of the study is to evaluate if Late (24 hs) MBR affects LVF evaluated 6 months (m.) after the procedure and 1 year survival.

**Methods:** End diastolic (EDV), end systolic (ESV) volumes and Ejection Fraction (EF) angiographically assessed through the area-length method, were prospectively evaluated pre procedure and 6 m. after a Primary PCI, in 405 consecutive patients (P) performed <12 hs. of symptoms onset. The corrected Timi Frame Count (cTFC) and Myocardial Blush (MB) according to the 0-3 grades described by Gibson were evaluated immediately and 24 hs. after Primary PCI. Patients were allocated to 3 groups according to the post procedure and 24 hs. MB: No reperfusion Group (NR): MB 0-1 immediately after and 24 hs (44P); Late reperfusion Group (LR) MB 0-1 immediately after and 2-3 at 24 hs (53P); Early reperfusion Group (ER) MB ≥2-3 immediately and 24 hs. after (308P)99.5% of patient completed follow up period.

**Results:** Cardiac death:

<table>
<thead>
<tr>
<th>ER: 14/44 (p=0.02)</th>
<th>LR: 8/144 (p&lt;0.001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LF: 1.7±2.4</td>
<td>2.2±3.9</td>
</tr>
<tr>
<td>EF: 45.1±10.4</td>
<td>43.9±10.5</td>
</tr>
<tr>
<td>cTFC: 32±17</td>
<td>32±17</td>
</tr>
<tr>
<td>EDV: 30.9±15.6</td>
<td>30.8±15.5</td>
</tr>
<tr>
<td>ESV: 21.7±15.6</td>
<td>21.7±15.6</td>
</tr>
<tr>
<td>EF: 52.2±11.3</td>
<td>52.1±11.3</td>
</tr>
<tr>
<td>cTFC: 32±17</td>
<td>32±17</td>
</tr>
<tr>
<td>EDV: 30.9±15.6</td>
<td>30.8±15.5</td>
</tr>
<tr>
<td>ESV: 21.7±15.6</td>
<td>21.7±15.6</td>
</tr>
<tr>
<td>EF: 52.2±11.3</td>
<td>52.1±11.3</td>
</tr>
<tr>
<td>cTFC: 32±17</td>
<td>32±17</td>
</tr>
</tbody>
</table>

Conclusions: Late Recovery of Myocardial Reperfusion improves long term LVF to similar levels achieved at the Early Reperfusion group, and could define a group of patients with intermediate prognostic risk at 1 year follow up.

**2000-186 Four-Year Follow-Up Patients with ST-Segment Elevation Acute Myocardial Infarction Treated with Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent: Multicenter Registry in Asia**

Sunao Nakamura, Jang-Ho Bae, Yeo Hans Cahyadi, Wasaen Udayachalerm, Damms Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan, Konyang University Hospital, Daejeon, South Korea

**Background:** Previous clinical study utilizing Sirolimus-eluting stent (SES) and Paclitaxel-eluting stent (PES) in simple coronary lesions demonstrated an impressive reduction in intimal hyperplasia and restenosis. However, clinical efficacy of SES and PES in treating patients with ST-segment elevation myocardial infarction (STEMI) has not been validated. 

**Methods:** We assessed baseline clinical and angiographic characteristics, in-hospital and AMI patient subgroup.

**Table 2: Characteristics and clinical outcomes in ARRIVE 1 and 2 pooled data: overall and AMI patient subgroup.**

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>BMS</th>
<th>SES</th>
<th>PES</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical success (%)</td>
<td>98.5</td>
<td>98.8</td>
<td>99.0</td>
</tr>
<tr>
<td>Death (%)</td>
<td>1.0</td>
<td>1.2</td>
<td>1.0</td>
</tr>
<tr>
<td>30 days to 12 mo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death (%)</td>
<td>0.5</td>
<td>0.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Angiographic restenosis (%)</td>
<td>6.5±1.0</td>
<td>6.7±1.0</td>
<td>0.0±0.0</td>
</tr>
<tr>
<td>Repeat PCI (%)</td>
<td>10.8</td>
<td>10.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Stent thrombosis (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>30 days to 36 mo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death (%)</td>
<td>0.8</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Angiographic restenosis (%)</td>
<td>17.5±5.3</td>
<td>17.4±5.2</td>
<td>0.0±0.0</td>
</tr>
<tr>
<td>Repeat PCI (%)</td>
<td>11.9</td>
<td>11.9</td>
<td>0.0</td>
</tr>
<tr>
<td>Stent thrombosis (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>30 years to 48 mo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death (%)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Angiographic restenosis (%)</td>
<td>17.8±5.0</td>
<td>17.7±5.0</td>
<td>0.0±0.0</td>
</tr>
<tr>
<td>Repeat PCI (%)</td>
<td>11.9</td>
<td>11.9</td>
<td>0.0</td>
</tr>
<tr>
<td>Stent thrombosis (%)</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Conclusions: Implantation of SES and PES in STEMI patients is not associated with any risk of adverse in-hospital events, and reduced the need for repeat PCI at follow-up.
Primary percutaneous coronary intervention (PPCI) is the preferred treatment for acute ST elevation myocardial infarction (STEMI). Shorter door-to-balloon times (DTB) are associated with improved outcomes. It is known that DTB vary by time of day and day of week, with longer DTB after hours. This study seeks to identify processes and factors that impact the timeliness of PPCI after hours.

**Methods:** This is a prospectively collected data registry of 171 STEMI patients who underwent PPCI between 08/2003 and 12/2006. The study population was divided into two cohorts: weekday (8AM - 6PM) versus after hours. After hours included holidays, weekends and weekdays. The following variables were studied: emergency department (ED) arrival to 1st electrocardiogram, electrocardiogram to catheterization laboratory (CL) activation, CL activation to sheath access, sheath access to 1st balloon inflation, CL arrival to 1st balloon inflation. Unpaired t-tests for different variables between each group were analyzed.

**Results:**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Weekday N = 86</th>
<th>After Hours N = 85</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median DTB (minutes)</td>
<td>75</td>
<td>107</td>
<td>0.19</td>
</tr>
<tr>
<td>DTB ≤60 minutes (percentage)</td>
<td>71</td>
<td>31</td>
<td>0.003</td>
</tr>
<tr>
<td>ED Arrival to 1st Electrocardiogram (mean in minutes)</td>
<td>13.47</td>
<td>11.58</td>
<td>0.0001</td>
</tr>
<tr>
<td>Electrocardiogram to CL Activation (mean in minutes)</td>
<td>19.68</td>
<td>15.90</td>
<td></td>
</tr>
<tr>
<td>CL Arrival to Sheath Access (mean in minutes)</td>
<td>12.09</td>
<td>16.25</td>
<td></td>
</tr>
<tr>
<td>Sheath Access to 1st Balloon Inflation (mean in minutes)</td>
<td>20.22</td>
<td>23.53</td>
<td></td>
</tr>
<tr>
<td>CL Arrival to 1st Balloon Inflation (mean in minutes)</td>
<td>32.29</td>
<td>39.52</td>
<td>0.0014</td>
</tr>
</tbody>
</table>

**Conclusion:** After hours presentation of STEMI is common, and their DTB times are worse. Although not reaching statistical significance, ED response times are actually better after hours. CL metrics are significantly worse after hours, primarily related to preprocedure performance, although procedure times are also longer. Improving DTB after hours requires CL focused solutions that could include, faster staff response times, 24-hour CL staffing or cross-training of non-CL staff.

**Quality of myocardial reperfusion according to ischemic time and infarct territory**

Fernando A. Cura, Samir Jozami, Lucio Padilla, Mariano Albertal, Marcelo Trivi, Jorge Thierer, Pablo Perez Balirio, Jorge Belardi, on behalf of the PREMIAR Investigators, Instituto Cardiovascular de Buenos Aires, Buenos Aires, Argentina

**Background:** The relationship of the ischemic time to primary angioplasty and the quality of myocardial reperfusion according to infarcted territory among patients with ST-segment elevation myocardial infarction (STEMI) is unclear.

**Methods:** This study comprised 140 patients with STEMI within 12 hours from symptom onset undergoing primary angioplasty from the Protection of Distal Embolization in High-Risk Patients with Acute ST-Segment Elevation Myocardial Infarction Trial (PREMIAR) clinical trial. ST-segment resolution (STR) at 60 minutes was analyzed by an independent corelab using a continuous ST monitoring. Patients were divided in anterior (n=76) and non-anterior (n=64) location according to quartiles in 4 groups (<90, 90-148, 148-241 and 241-635 minutes).

**Results:** Although there was no significant decrement in the extent of STR with the ischemic time in the entire population (74%, 51%, 72%, and 51%, respectively, p=ns), patients with anterior location have a significant reduction in the extent of STR after 90 minutes (p=0.005).

**Conclusions:** Patients with anterior STEMI appear to have a stronger impact of ischemic time on the quality of myocardial reperfusion compared to patients with non-anterior location. Efforts to reduce time to reperfusion should be emphasized among this high risk group of patients.
discharge left ventricular ejection fraction, cardiogenic shock were comparable among the 3 groups. Procedural success rate was high at a mean of 99.5%. Post-procedural TIMI 3 flow was achieved in EPC 91.6%, SES 96.2% and BMS 89.5%. The MACE results at 18-months were shown:

<table>
<thead>
<tr>
<th>Events</th>
<th>EPC (n=99)</th>
<th>SES (n=53)</th>
<th>BMS (n=218)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE (%)</td>
<td>13(13.7%)</td>
<td>8(15.1%)</td>
<td>35(16.1%)</td>
<td>0.985</td>
</tr>
<tr>
<td>Death (%)</td>
<td>9(9.5%)</td>
<td>2(3.8%)</td>
<td>22(11.5%)</td>
<td>0.208</td>
</tr>
<tr>
<td>Non-fatal MI (%)</td>
<td>1(1.1%)</td>
<td>1(1.9%)</td>
<td>4(1.8%)</td>
<td>0.916</td>
</tr>
<tr>
<td>TVR</td>
<td>3(3.2%)</td>
<td>5(9.4%)</td>
<td>6(2.8%)</td>
<td>0.070</td>
</tr>
<tr>
<td>Acute stent thrombosis</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Subacute stent thrombosis (SAT)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Late stent thrombosis (LST)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>2 (0.9%)</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion: The MACE rates among patients who underwent PCI were similar in all 3 stent groups at 18 months follow-up. There was no difference in TVR rate and stent thrombosis remains a low event occurrence.

2900-19T Impact of advanced age on the safety and effectiveness of bivalirudin in patients with acute myocardial infarction undergoing primary angioplasty: The HORIZONS AMI trial

Dariusz Dudek, Krzysztof Zmudka, Bernhard Witzenbichler, Giulio Guagliumi, Jan Z. Peruga, Bruce R. Brodie, Ran Kornowski, Franz Hartmann, Martin Mockel, Andrzej Ochala, Helen Parise, Roxana Mehran, Gregg W. Stone, Columbia University Medical Center/Cardiovascular Research Foundation, New York, NY

Background. In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) compared to unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding, comparable major adverse cardiovascular events (MACE) (though with decreased cardiac mortality), and enhanced freedom from net adverse clinical events (NACE) in pts with AMI undergoing primary PCI. Whether the beneficial effects of Biv are independent of age, an important determinant of outcomes after primary PCI, has not been reported.

Methods and Results. A total of 3602 pts at 123 centers in 11 countries with AMI undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802) and followed for 30 days. Outcomes were analyzed according to age above or below the median of 62.0 years. In the entire study population, Biv compared to UFH+GPI resulted in a 40% reduction in major bleeding (4.9% vs. 8.3%, P<0.0001), similar MACE (5.4% vs. 5.5%, P=1.0), and a 24% reduction in NACE (9.2% vs. 12.1%, P=0.006). Compared to pts without DM, those with DM (n=593; 16.4%) had greater rates of major bleeding (8.8% vs. 6.2%, P=0.02), MACE (8.1% vs. 5.0%, P=0.004) and NACE (14.2% vs. 10.0%, P=0.004). The impact of Biv was independent of DM (interaction P value for these 3 endpoints = 0.22, 0.10, and 0.90 respectively) (Table). Conclusions. In pts with AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events, effects which are independent of diabetic status.

2900-19S Safety and effectiveness of bivalirudin in patients with acute myocardial infarction undergoing primary angioplasty: The HORIZONS AMI trial

Gregg W. Stone, Bernhard Witzenbichler, Giulio Guagliumi, Jan Peruga, Bruce Brodie, Dariusz Dudek, Ran Kornowski, Franz Hartmann, George Dangas, Ajay Kirtane, S. Chiu Wong, Helen Parise, Roxana Mehran, Columbia University Medical Center/Cardiovascular Research Foundation, New York, NY

Background. In patients with stable angina and NSTEMI, bivalirudin (Biv) monotherapy has been shown to result in similar rates of composite ischemia as unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI), while significantly reducing major bleeding. Whether Biv has comparable safety and efficacy in patients with STEMI undergoing primary PCI in AMI is unknown.

Methods and Results. A total of 3602 pts at 123 centers in 11 countries with AMI within 12 hrs of symptom onset undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802) and followed for 30 days. Following angiography, primary PCI was performed in 3,340 pts (92.7%). Among these pts, baseline characteristics were well matched for age (median 60.1 yrs, gender (23% women), diabetes (16.3%), LAD PCI (40.7%), door to balloon time (median 99 mins), stent use (99.5%), TIMI-3 pre (18.7%) and TIMI-3 post (91.6%). Procedural GPI were used in 97.7% of UFH+GPI vs. 73% of Biv pts for bail-out. Thirty day results among pts undergoing PCI appear in the Table. Cardiac mortality 30 days after PCI occurred in 1.8% of Biv pts vs. 2.8% of UFH+GPI pts (RR [95%CI] = 0.63 [0.40, 0.99], P=0.049).

Conclusions. In patients with AMI undergoing primary PCI, at 30 days Biv monotherapy compared to UFH+GPI significantly reduces major bleeding and net adverse clinical events, including cardiac mortality.

Impact of advanced age on the safety and effectiveness of bivalirudin in patients with acute myocardial infarction undergoing primary angioplasty: The HORIZONS AMI trial

2900-19Z Impact of diabetes mellitus on the safety and effectiveness of bivalirudin in patients with acute myocardial infarction undergoing primary angioplasty: The HORIZONS AMI trial

Bernhard Witzenbichler, Giulio Guagliumi, Martin Desaga, Janusz Kochman, Dennis Nilsen, Ariel Finkelstein, Morris Mosseri, Helen Parise, Roxana Mehran, Gregg W. Stone, Columbia University Medical Center/Cardiovascular Research Foundation, New York, NY

Background. In the HORIZONS AMI trial, bivalirudin monotherapy (Biv) compared to unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI) resulted in reduced rates of major bleeding, comparable major adverse cardiovascular events (MACE) (though with decreased cardiac mortality), and enhanced freedom from net adverse clinical events (NACE) in pts with AMI undergoing primary PCI. Whether the beneficial effects of Biv are independent of diabetic status has not been reported.

Methods and Results. A total of 3602 pts at 123 centers in 11 countries with AMI undergoing primary PCI were randomized to Biv (n=1800) vs. UFH+GPI (n=1802) and followed for 30 days. Outcomes were analyzed according to presence of diabetic status. In the entire study population, Biv compared to UFH+GPI resulted in a 40% reduction in major bleeding (4.9% vs. 8.3%, P<0.0001), similar MACE (5.4% vs. 5.5%, P=1.0), and a 24% reduction in NACE (9.2% vs. 12.1%, P=0.006). Compared to pts without DM, those with DM (n=593) had greater rates of major bleeding (8.8% vs. 6.2%, P=0.02), MACE (8.1% vs. 5.0%, P=0.004) and NACE (14.2% vs. 10.0%, P=0.004). The impact of Biv was independent of DM (interaction P value for these 3 endpoints = 0.22, 0.10, and 0.90 respectively) (Table). Conclusions. In pts with AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events, effects which are independent of diabetic status.
reduce major bleeding and net adverse clinical events, effects which are consistent in women and men.

<table>
<thead>
<tr>
<th></th>
<th>Male (n=2760)</th>
<th>Female (n=842)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Biv mono UHF+GPI</td>
<td>RR [95% CI]</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>4.2%</td>
<td>7.0%</td>
</tr>
<tr>
<td>MACE*</td>
<td>4.9%</td>
<td>4.9%</td>
</tr>
<tr>
<td>NACE**</td>
<td>7.9%</td>
<td>10.4%</td>
</tr>
</tbody>
</table>

* MACE = death, reinfarction, ischemic TVR or stroke
**NACE (Net Adverse Clinical Events) = MACE + major bleeding

### 2900-195
Pre-Hospital 1/2-dose Fibrinolytic Therapy Coupled with Immediate PCI vs Primary PCI in Diabetics: AMICO Registry

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**Background:** Early treatment of STElevation myocardial infarction (STEMI) is not firmly established. Both fibrinolysis and primary PCI (PPCI) are advocated, yet time and transfer issues make definitive strategies elusive. Patients (pts) with diabetes are known to be at higher risk from STEMI, and clarify in early treatment options is especially needed.

**Methods:** The Alliance for Myocardial Infarction Care Optimization (AMICO) is a consortium of 5 high volume PCI centers. By local protocols, pts with STEMI may receive pre-hospital 1/2-dose fibrinolytic therapy coupled with transport to the center for immediate PCI (FAST-PCI). Our registry tracks and compares these pts with other STEMI pts at these centers treated with PPCI. For the period 1/1/2001-12/31/2006 we compared 1200 FAST-PCI pts with 1669 PPCI pts. We tested the hypothesis that STEMI pts with diabetes would have superior outcomes with FAST-PCI compared to PPCI.

**Results:** There were 223 (19%) FAST-PCI pts with diabetes, and 352 (21%) in PPCI group. 1st-medical-contact-to-balloon times were longer for FAST-PCI compared to PPCI (mean 196 min vs 166 min, p=0.012). Despite this, mortality at 30 days was significantly lower in diabetics treated with FAST-PCI compared to PPCI (5.8% vs 11.6%, p=0.01) and was more similar to non-diabetics. Also, non-diabetic pts had lower mortality with FAST-PCI.

**Conclusions:** STEMI pts with diabetes benefitted from a strategy of pre-hospital 1/2-dose fibrinolytic therapy coupled with immediate PCI instead of PPCI.

### 2900-196
Culprit-lesion Revascularization versus Complete Revascularization in Patients with Acute Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention with Drug-eluting Stents

Zhe Jin, Seung-Woon Rha, Kang-yin Chen, Yoshiyasu Minami, Jin Oh Na, Soon Yong Suh, Cheol Ung Choi, Jin Won Kim, Eung Ju Kim, Chang Gyu Park, Hong Seog Seo, Dong Joo Oh, Myung Ho Jeong, Korea University Guro Hospital, seoul, South Korea, Chonnam National University Hospital, GwangJuu

**Background:** Treatment guideline of STEMI has recommended opening the culprit infarct-related artery when primary PCI is required to patients (pts) with multivessel disease (MVD). The safety and efficacy of these two different PCI strategies of AMI with MVD in the DES era are largely unknown.

**Methods:** Study population is consisted of a total 1116 STEMI pts with MVD underwent primary PCI with DES enrolled in the Korean Acute Myocardial Infarction Registry (KAMIR) from Jan 2005 to Dec 2006. The pts were divided into two groups according to PCI strategy: Culprit-lesion revascularization group (Group 1, n=905) and Complete revascularization group (Group 2, n=215). In-hospital and 6-month clinical outcomes were compared between the two groups.

**Results:** The baseline and angiographic characteristics were similar between the two groups except that history of coronary heart disease was more common in Group 1 (10.3% vs 5.4%, p=0.005). The procedural success rate and in-hospital mortality rate were similar between the two groups (0.4% vs 1.4%, p=0.111, 91.5% vs 92.1%, p=0.846, respectively). At 6-month follow up, the survival and freedom from MACES were higher in Group 1 due to the incidence of TLR was higher in Group 2 (Table). Conclusion: Culprit-lesion revascularization strategy (infarct-related artery only) showed better mid-term clinical outcomes compared with those of complete revascularization strategy in AMI pts with MVD requiring multivessel angioplasty in the DES era. Table. Clinical Outcomes at 6-month

### 2900-197
Increased Endothelial Cell Mobility Following Stabilization of Hypoxia-Inducible Factor- Steps Towards Therapeutic Angiogenesis

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**Background:** Chronic total coronary occlusions (CTOs) are often resistant to treatment by percutaneous intervention. Clinical trials of therapeutic angiogenesis with systemic administration of protein growth factors such as Vascular Endothelial Growth Factor (VEGF) have been negative. Hypoxia-inducible factor (HIF) binds DNA sequences within the hypoxia response elements of multiple target genes involved in angiogenesis. In humans the protolytic stability of HIF is regulated via oxygen-dependent hydroxylases. We investigated the effect of a prolyl-4-hydroxylase inhibitor, Di-methyl oxalyl glycine (DMOG), on endothelial cell mobility and tube-formation in a matrigel-based angiogenesis assay with a view to developing a sterst-based angiogenic treatment for CTOs.

**Methods:** Hyperglycemic H9c2 human umbilical vein endothelial cells were grown in Dulbecco’s medium with 2% HAT and 2% FBS. 72 cells of a well plate were inoculated with 40,000 cells per well, passage 4, over 60% of reduced growth-factor matrigel. 100mM of culture medium was added with 125mM DMOG, 250g MVEG or 125mM Glycine (control). 160mM of a specific VEGF receptor inhibitor (VI) was added to alternate wells. Wells were photographed at 4, 8, 16, 24, 36 and 48 hours for evidence of cell migration. Blinded off-line digital image analysis using a 10x10 overlay-grid was performed to measure the proportion of grids squares containing ≥1 branching structure (GSB%).

**Results:** Minimal tube-like structures were present at 8 hours. By 16 hours DMOG culture produced similar GSB% to VEGF but more than control, Mean (SD): DMOG 38.7(3.6), VEGF 33.4(4.6), p=0.60; Control 4(1.7), p<0.001. DMOG reduced mean GSB% at 16 hrs in DMOG culture to 30.2(5.0) and abolished migration under VEGF culture, GSB% 0.5(0.7). Cell migration was complete in all cultures by 36 hours.

**Conclusions:** DMOG accelerates and enhances endothelial cell migration and tube formation in matrigel culture. This effect is in part mediated via VEGF. We are currently investigating the effect on antegrade collateral formation of stent-loaded HIF-stabilizing compounds in a novel porcine percutaneous model of coronary occlusion.

### 2900-198
The Protective Role of Human Coronary Collaterals: Prevention of QT Time Prolongation During Ischemia

Pascal Meier, Steffen Goeckler, Stefano De Marchi, Rainer Zbinden, Stephan Windecker, Bernhard Meier, Etienne Delacretaz, Christian Seiler, University Hospital, Bern, Switzerland

**Background:** Arrhythmogenesis during early myocardial ischemia is not well understood. Changes in action potential duration of ischemic regions may be important. The coronary collateral function has a beneficial role regarding all-cause and cardiac mortality. The aim of this study was to investigate the effect of acute ischemia on QT time and the protective influence of the coronary collateral function.

**Methods:** A total of 150 patients (mean age 63±11 years, 38 female) referred to our hospital for coronary angiography were prospectively included in this study. An ECG was recorded at baseline and during a 1-minute balloon occlusion. QT interval was measured in lead II before, at the end of and after a 1-minute balloon occlusion of a coronary vessel. QT time was corrected according to Bazett’s formula (QTc). Collateral flow index (CFI; no unit) expressing collateral flow relative to normal anterograde flow was determined by pressure guide wires using mean aortic, central venous and occlusive coronary wedge pressure.

**Results:** During occlusion of the left coronary artery (left anterior descending (LAD) or left circumflex artery (LCOX), QTc increased from 426±53 ms to 444±37 ms; p=0.001. QTc was not influenced by occlusion of the right coronary artery (RCA). Collateral flow index was inversely correlated with QTc prolongation during occlusion of the left coronary artery (r=-0.286, p=0.0038). In a multivariate regression analysis including CFI, gender, medication and cardiovascular risk factors, CFI was the only independent predictor of QTc change during vessel occlusion (p=0.0271).

**Conclusion:** Myocardial ischemia leads to QT prolongation during a controlled one-minute occlusion of the left but not the right coronary artery. QT prolongation is negatively correlated to collateral function indicating a protective mechanism of human coronary collaterals against cardiac death.

### 2900-199
Device Selection Guidelines for Transcatheter Closure of the Patent Ductus Arteriosus

Todd M. Guntupalli, Russell Hirsch, Philip R. Khoury, Robert H. Beekman, III, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH

**Introduction:** A variety of devices are available for transcatheter closure of the patent ductus arteriosus (PDA) but no guidelines exist to guide operator device choice. Therefore, to provide guidelines for device selection we retrospectively evaluated two consecutive closure strategies utilized in 132 patients at our center between January
Groups. Long-sheath used for stent implantation was larger in CS group compared to BS group (median 12 vs 10 French; p=0.01). Total complication rate was higher in BS (12% vs 7%; p=0.03). The following stents were used: Palmaz stents, Genesis stents, Cheatham-Platinum, covered Cheatham-Platinum. Bare stents were used in 71 patients, while covered stents were used in 33 subjects.

Results: There were no differences for age, gender, native coarctation/rectocatheteration rate, mean drop of peak systolic gradient, increase of diameter of coarcted segment, mean fluoroscopy and procedure times, between the two groups (BS: bare stent group vs CS: covered stent group). Stents were placed in the correct position in all subjects in both groups.

2000-202
OUTCOME AND COMPLICATIONS OF PERCUTANEOUS PERI-MEMBRANOUS VSD CLOSURE, MEDIUMTERM FOLLOW-UP

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Background: The safety, efficacy and indications of peri-membranous (PM) ventricular septal defect (VSD) percutaneous device closure are currently being in studies. There have been encouraging reports of the initial experience with the Amplatzer device; however, this has been hindered by reports of conduction system disturbances, to the extent of elective pause of the procedure

Methods: Retrospective analysis of all patients who successfully underwent (PM) VSD Amplatzer device closure in our institution, between May 2002 and June 2007. All patients were followed up with ECGs and echocardiograms. The mean FU duration was 30.3 ± 11.3 (9–48) months.

Results: We implanted 51 devices in 51 Patients, 25 males, and 26 females. Mean age (10.2 ± 7.5) years, with mean weight 28.6 ± 15.7 Kg. During catheterization, the average QP/QS was 1.9 ± 0.6, mean PA pressure was 18.5 ± 4.1 mmHg, and PVR was 1.0 ± 0.5 Wood units. The mean VSD size by transoesophageal echocardiography (TEE) was 7.2 ± 2.5 mm, and mean device size was 8 ± 2 mm. One patient developed complete right block immediately after, one needed permanent pacemaker, five patients developed right bundle branch block, three patients noticed to have trivial to mild AR on follow-up, and one device had to be removed surgically because of severe tricuspid regurgitation. Left ventricular end-diastolic diameter decreased from 44.1 ± 6.8 mm to 42.6 ± 6.0 mm after. There was no immediate or late mortality. There was immediate complete closure in 41 (80%) patients, and 49 (96%) late complete closure.

Conclusions: Amplatzer PM VSD device closure is feasible, effective and safe, but not free of complications. Careful patient’s selection, refinement of the technique, device, hardware and further miniaturizing could expand the use, safety and the effectiveness of PM VSD device closure. Our relatively low rate of conduction system disturbance could be related to precise device sizing

Pulmonary Valvuloplasty in Adults Using the Inoue Balloon Catheter

Hung Manh Pham, Hieu Lan Nguyen, Quang Ngoc Nguyen, Hung Minh Nguyen, Loi Doan Do, Viet Lan Nguyen, Khai Gia Pham, Vietnam Heart Institute, Hanoi, Viet Nam, Hanoi Medical School, Hanoi, Viet Nam

Background: Although pulmonary valvulostasis is not uncommon in adults. There are few reports of percutaneous pulmonary valvuloplasty in adults, especially using Inoue balloon. OBJECTIVES: This report describes the experience in adult patients undergoing Pulmonary valvuloplasty using Inoue balloon and evaluates its effectiveness and tolerance.

Methods: Over an 7-year period (2000-2006), pulmonary valvuloplasty using Inoue balloon was considered in 65 adults with mean age 29 ± 10.1 years (range 18-53 years) and mean peak-to-peak transvalvular gradient 91 ± 40 mmHg SD, with a mean right ventricular systolic pressure of 107 ± 41 mmHg SD.

Results: The procedure was technically successful in all but one patient (98.46%). One failure because balloon could not pass through pulmonary orifice valve due to very tight valvulostasis. Among all patients with technical success all tolerated well and free of major complications. The mean right ventricular systolic pressure and the pulmonary valvular peak-to-peak systolic gradient decreased from 107±41 to 56±19 mm Hg (p = 0.001) and 91±40 to 21±7 mm Hg (p = 0.0002), respectively. An infundibular peak-to-peak systolic gradient either developed (n = 13) or increased (n = 17). None of these patients were treated with beta-adrenergic blockers before or after the valvuloplasty. In contrast, this gradient decreased or did not develop in the remain patients who were on beta-blokers before procedures. All patients underwent echo follow up study for 6 - 60 months (mean 24) after treatment, and had no evidence of valvular restenosis. The mean right ventricular systolic pressure and the mean infundibular peak-to-peak systolic gradient decreased, compared to the values immediately after valvuloplasty (56 ± 47 mm Hg, p = 0.03, and 28 to 10 mm Hg, p = 0.03, respectively).

Conclusions: The study suggests that pulmonary valvuloplasty in adults using the Inoue balloon catheter technique is feasible, safe, and effective.
Preferred Management Strategies for Uncomplicated Atrial Septal Defects: A Physician Survey

Background: Transcatheter closure (TCC) and surgical closure (SC) of uncomplicated secundum atrial septal defects (ASD) are equivalent in terms of published success rates, and low mortality rates. The purpose of this survey was to determine physician treatment preferences for uncomplicated ASD closure in the current era, and to identify factors that influence preferences.

Methods: We performed an anonymous online survey of pediatric cardiologists in three geographic areas in the United States. Doctors were queried on personal demographics, treatment preference, risk perceptions, and knowledge of morbidity and mortality rates.

Results: The survey was completed by 61 (62%) of the 98 recipients. The majority practice in academic centers (89%), 55% have been in practice for >10 yrs, and 37% have a subspecialty interest in echocardiography (Echoc). TCC was preferred over SC by 87% while 13% preferred SC. Echo interest was associated with preferring SC (p = 0.006), but no other demographic variables were significant. Doctors who preferred SC reported a lower incidence of mortality for SC (0.10 ± 0.00 vs. 0.15 ± 0.15 %; p = 0.03) and a higher incidence of complications for TCC (3.0 ± 1.9 vs. 1.3 ± 1.5 %; p = 0.03) compared to those who prefer TCC. Those who preferred SC differed from those who preferred TCC in reporting the ‘most concerning’ potential complication for ASD closure (p = 0.02). Device erosion was the most concerning complication for 85% who preferred SC vs. 15% who preferred TCC. Those who preferred TCC were most concerned about ‘unforeseen long term risks’ (30%) and ‘death on the OR table’ (26%). ASD closure related complications were reported by 49%. Eighty-three percent who reported a TCC related complication in a pt preferred TCC, while only 11% whose pts had an SC related complication preferred SC (p = 0.01).

Conclusions: A majority of pediatric cardiologists surveyed prefer TCC to SC for treatment of ASD. Those who prefer SC were more likely Echo doctors, and reported higher incidence of complication with TCC than those who prefer TCC. Device erosion is the major concern of those who prefer SC.

Transcatheter Device Closure of Patent Foramen Ovale in Patients With Cryptogenic Stroke Secondary to Presumed Paradoxical Embolism
Monique A Ford, Guy S Reeder, Ryan J Lennon, Daniel J Crusan, Robert D Brown, Jr., George W Petty, Allison Cabalka, Frank Cetta, Donald J Hagler, Mayo Clinic, Rochester, MN

Background: The role of device closure of patent foramen ovale (PFO) in preventing recurrent cryptogenic stroke and transient ischemic attacks (TIA’s) remains highly controversial. We reviewed our experience with transcatheter device closure of PFO’s in selected patients after cryptogenic stroke or TIA to determine procedural safety and efficacy. We measured recurrent event rates and determined risk factors for recurrent stroke or TIA in this population.

Methods: Between December 2001 and June 2006, 402 patients at Mayo Clinic Rochester underwent transcatheter device closure of a patent PFO for cryptogenic stroke, TIA or peripheral embolization. Baseline characteristics, procedural details and complications were reviewed. Kaplan-Meier methods were used to estimate recurrent event rates. Simple Cox models were then used to identify risk factors for these recurrent events.

Results: We included 353 patients who presented with cryptogenic stroke (n=235) or TIA (n=118) in this analysis. The mean age was 53.4 years and 59% were male. The procedural complication rate was 2.8% and included atrial fibrillation (n=2), atrial flutter (n=2), cardiac perforation with tamponade (n=1), femoral bleed (n=1) and prostate reaction (n=1). There were no procedural deaths. The mean follow-up was 36 months (interquartile range 24 to 48 months). None of the 10 patients with residual shunts at follow up had recurrent events. Twenty recurrent events occurred in 17 patients: 7 strokes, 7 TIA’s, 3 peripheral embolizations. The recurrence rate at 1 year was 0.6% for stroke and 0.9% for TIA. At 4 years, the recurrence rate for stroke was 2.5% and 1.7% for TIA. Risk factors for recurrent events were hypertension (p=0.03), diabetes (p=0.001), right atrial pressure (p=0.002), pulmonary artery systolic pressure (p=0.001) and wedge pressure (p <0.001). Neither residual shunts nor hypercoagulable states were associated with recurrent events.

Conclusions: Transcatheter device closure of PFO is safe and effective. Recurrence rates of stroke or TIA are low. Predictors of recurrent events include significant stroke risk factors and elevated intracardiac pressures. Residual shunt is not associated with recurrent events.

Mid-Term Follow-up After Transluminal Alcohol Septal Ablation of Hypertrophic Obstructive Cardiomyopathy. A Real World Study
Kamaldeep Chawla, Thierry Lebey, Marie-Claude Morice, Aleem Khand, Ivan Laurent, Marie-Christine Malergue, Bertrand Cormier, Institut Cardiovasculaire Paris Sud, Massy, France

Introduction: Transluminal alcohol septal ablation (TASH) is now an alternative to surgery in patients (pts) with hypertrophic obstructive cardiomyopathy (HOCM). It is associated with good acute and mid-term results and an acceptable risk of atrio-ventricular block (AVB) requiring permanent pace maker (PM). To optimize the technique, perprocedural echo-guidance (ECHO) is recommended.

Objective: Assess the mid-term clinical outcome of TASH with systematic echographic guidance in the real world.

Method and Results:104 pts with symptomatic HOCM despite optimal treatment were prospectively enrolled. They were aged 56±17 years, 24% had a family history of HOCM, 8% previous syncope, 27% previous PM, 2% defibrillator, NYHA class 2.8±0.7. The septal thickness pre-procedure was 33±4 mm and basal gradient 97±48 mmHg. Injection of 2.1–0.8 ml of ethanol under ECHO was performed in 1.6±0.4 septal branches. Gradient decreased to 20±22 mmHg (p<0.001). Except conduction disturbance, no complications were observed during the procedure. Temporary PM was necessary in 25 % of cases and became definitive in 6%. The maximal CPK elevation after TASH was 1146±142 IU. Total hospital stay was 7.1±2.2 days (intensive care unit 5.2±1.9 days). In-hospital death occurred in 2 cases (1.9%) at day 2 (ventricular arrhythmia) and day 3 (atrio-ventricular block).

Follow-up was obtained in 98% of cases at 38±22 months. After hospital discharge, 2.8% of patients had PM implantation. Functional class was 1.1±0.3 (p<0.001). Eight death occurred, 6 cardiac (1 endocarditis, 2 sudden deaths, 3 heart failure) and 2 non cardiac. The Kaplan Meier survival curve is shown in the figure.

Conclusion: TASH using systematic ECHO is associated with a high rate of mid-term clinical success and a relatively low risk of irreversible AVB. The annual risk of cardiac death (1.5%) after successful TASH seems to be reasonable in this high risk population.
An increase in arrhythmias, specifically atrial fibrillation (AF) is a concern in patients (pts) following transcatheter closure of patent foramen ovale (PFO) following cryptogenic thromboembolic events (TE). Estimating the AF incidence following PFO closure has been difficult. We evaluated the frequency of AF following PFO closure.

Methods: We evaluated all pts who underwent PFO closure at our institution from 2/1994 until 9/2007. Pts were required to have at least one cryptogenic TE (Cerebrovascular accident (CVA), transient ischemic attack (TIA), or peripheral embolism) prior to PFO closure.

Results: During the 13 year period 862 pts underwent PFO closure. Median age was 51 years (range 17-83). Two hundred and fifty five patients had hypertension (30%) and 56 pts had coronary artery disease (CAD) (5.5%). Median follow-up time after PFO closure was 20 months (range 0-162). New onset AF was noted in 58 pts (6.7%); with 2065 cumulative follow up years this translates into an annual incidence of 2.8%. During more than 21 pts complained of palpitations (2.4%) and 7 pts of dyspnea (0.8%), of which only 6 were found to have AF on Holter monitoring. When comparing pts with and without new onset AF, there was no difference in the prevalence of hypertension (31% vs. 29%, p=0.633), CAD (5.1% vs. 0.5%), or residual shunt (13% vs. 9%, p=0.134). Conclusion: AF frequency following PFO closure in pts with cryptogenic TE is mildly increased compared to an age matched population, where the annual incidence has been estimated to be 1.1-1.5%. Importantly, pts only rarely had symptomatic AF following PFO closure.

Gian Paolo Anzola, Marco Berti, Francesco Casilli, Eustachio Onorato, G. Orsola Hospital, Bologna, Italy

Purpose: Patent foramen ovale (PFO) has been associated with embolic events secondary to paradoxical embolism and, more recently, also with migraine aura. The aim of our paper was to evaluate if the posture changes the amount of RLS across the PFO thus enhancing the likelihood of paradoxical embolism to the left heart chambers.

Methods: In a consecutive series of 26 patients (M/F= 6/20, age 44±14) with PFO, we used contrast-enhanced transcranial Doppler (c-TCD) to assess the bubble load in the right middle cerebral artery during normal breathing both in standing and in recumbent position. Half the pts were first tested while standing, half were tested in the reversed order. Data were analyzed with a repeated measure ANOVA with position (horizontal versus vertical) as within pts and order of testing (first while horizontal versus first while vertical) as between subjects factors.

Results: The position factor was statistically significant (F = 6587, P= 0.017) with an average of 12 and 29 bubbles detected during standing and recumbent position, respectively. The effect was independent of the testing order. Fourteen pts showed an increase in the bubble number from the horizontal to the upright position, 7 exhibited the same number, whereas in 5 the amount of shunt decreased on standing.

Conclusions: The amount of permanent RLS is posture-dependent in pts with PFO to an extent that may be variable between one individual and the other. Our results differ from previous reports in which the examination from supine to sitting resulted in a decrease of the median bubble count. We hypothesized that in upright position the neighbour vessels (sagittal and longitudinal) may exert a traction on the components of the tunnel-like PFO thus increasing the amount of RLS. It is conceivable that other factors, such as heart rate and stroke volume may influence the results of the c-TCD examination. Testing in upright position may thus be warranted in those cases in whom the usual assessment performed with the subject in horizontal position yields doubtful or inconclusive results.

Anatomy of Patent Foramen Ovale in Patients With Migraine Versus Stroke

Arif A. Khan, Mark Spence, Michael Mullten, Royal Brompton Hospital, London, United Kingdom

Background: Patent foramen ovale (PFO) has been implicated in transient ischemic attack (TIA), cryptogenic stroke (CS) and migraine (M). It is not known whether there is any difference in anatomy of PFO between migraine and stroke or TIA patients. This study assessed differences in shunt size and anatomy in patients with TIA/CS and Migraine undergoing device closure.

Methods: PFO shunt size was assessed by transthoracic contrast echocardiogram at rest and during valsais based on the highest number of contrast bubbles seen in the left heart. G 0, G 1, G 1+1/2/frame, G 2, G 2+1/2/frame, G 3, G 3+1/frame. Defect size and length were determined by inflation of a balloon. The site of constraint of the balloon allowed identification of the entrance (E1), exit (E2) and length (L).

Results: We reviewed all patients referred for percutaneous PFO closure for CS/TIA (n=40, 15= female) or severe migraine with aura (n=36, 24= female) mainly enrolled for their closure. ANP and BNP levels, 12 lead ECG, Chest X ray, transthoracic echocardiogram, and anatomical parameters in patients with TIA/CS and M that would impact on the effectiveness of device closure of PFOs. Ballon assessment of PFOs enhances the understanding of PFO morphology.

To Assess the Clinical Impact of Percutaneous Atrial Septal Defect Closure in the Older Population

Arif A. Khan, Jule Tan, Mark Spence, Michael Mullten, Royal Brompton Hospital, London, United Kingdom

Background: Atrial septal defect (ASD) is accounting for 10% of all congenital cardiac defects. The benefit of ASD closure in elderly is not well established we therefore aimed to prospectively assess the clinical status and functional class of patients after ASD device closure.

Methods: A prospective study of all consecutive patients age 40 or more who underwent device closure of secundum ASD between April 2004 and August 2006. Investigations including ANP and BNP levels, 12 lead ECG, Chest X ray, transthoracic echocardiogram, 6 MWT, and quality of life questionnaire (SF36v2) performed prior to and at 6 weeks and 1 year after the procedure.

Results: 23 patients had percutaneous device closure of ASD. Mean age was 69 year (range 43 - 93 years). Mean ASD size was 20 mm (range 10 to 30 mm) and mean device size was 24 mm (range 10 to 36 mm). At 1 year, NYHA class improved (p=0.004) in 18 patients with also significant improvement in 6MWT distance (p=0.001) and physical but not mental health score on the SF36v2 (p= 0.004). There were no major complications. Following ASD closure there was an increase in LV diastolic dimension (pre procedure 42 mm and 48 mm at 1 yr, p=0.002), long axis function (DTIs mm pre procedure 14, 9 at 1 yr, p= 0.009), and stroke volume but only a trend towards reduction in right heart dimensions.

Conclusions: Our results demonstrate significant improvements in symptoms and functional ability in elderly due to improvement in LV hemodynamics. These data support ASD closure at an advanced age.

Improvement in Myocardial Perfusion With Chronic Total Coronary Artery Occlusion Revascularization

Tarek Ghorab, Steven Marso, Vivek Goswami, Kevin Kennedy, John House, J. Aaron Grantham, Barry Rutherford, Mid-America Heart Institute, Kansas City, MO

Background: The benefits of revascularization for chronic total coronary occlusion (CTO) have been shown to improve longevity but there is a paucity of data regarding improvements in myocardial perfusion as assessed by radionuclide imaging.

Methods: Using a 20 segment model, the Sum Stress Scores (SSS) were examined for 2900-215 patients had percutneous device closure of ASD. Mean age was 69 year (range 43 - 93 years). Mean ASD size was 24 mm (range 10 to 36 mm). At 1 year, NYHA class improved (p=0.004) in 18 patients with also significant improvement in 6MWT distance (p=0.001) and physical but not mental health score on the SF36v2 (p= 0.004). There were no major complications. Following ASD closure there was an increase in LV diastolic dimension (pre procedure 42 mm and 48 mm at 1 yr, p=0.002), long axis function (DTIs mm pre procedure 14, 9 at 1 yr, p= 0.009), and stroke volume but only a trend towards reduction in right heart dimensions.

Conclusions: Our results demonstrate significant improvements in symptoms and functional ability in elderly due to improvement in LV hemodynamics. These data support ASD closure at an advanced age.

Results:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre device</th>
<th>6 weeks</th>
<th>1 yr</th>
<th>p value</th>
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<tbody>
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<td>ANP (ug/ml)</td>
<td>21</td>
<td>28</td>
<td>17</td>
<td>0.03</td>
</tr>
<tr>
<td>BNP (ng/ml)</td>
<td>43</td>
<td>55</td>
<td>32</td>
<td>0.13</td>
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<tr>
<td>Mental Health score</td>
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<td>47</td>
<td>53</td>
<td>0.13</td>
</tr>
<tr>
<td>Physical Health score</td>
<td>46/46v2</td>
<td>47</td>
<td>53</td>
<td>0.004</td>
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<tr>
<td>6 MWT distance (m)</td>
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<td>458</td>
<td>470</td>
<td>0.001</td>
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<tr>
<td>LVEDD(mm)</td>
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<td>49</td>
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<tr>
<td>LVEF(%)</td>
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<td>81</td>
<td>82</td>
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</tr>
<tr>
<td>DII LV s</td>
<td>14</td>
<td>8</td>
<td>9</td>
<td>0.009</td>
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Change in SSS from Baseline SSS

Table: Changes in SSS from Baseline SSS

<table>
<thead>
<tr>
<th>Shunt size</th>
<th>Migraine with aura (n=36)</th>
<th>TIA/CS (n=40)</th>
<th>p value</th>
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<tr>
<td>G 0</td>
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<td>6</td>
<td>NS</td>
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<td>G 1</td>
<td>6</td>
<td>6</td>
<td>NS</td>
</tr>
<tr>
<td>G 3</td>
<td>30</td>
<td>31</td>
<td>NS</td>
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<td>Aneurysm(%)</td>
<td>33%</td>
<td>35%</td>
<td>NS</td>
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<tr>
<td>E1(mm)</td>
<td>7.8</td>
<td>8.5</td>
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<tr>
<td>E2 (mm)</td>
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<td>8</td>
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<tr>
<td>PFO tunnel length (mm)</td>
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<td>Nalst (mm)</td>
<td>6.8</td>
<td>7.4</td>
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</table>

Conclusions: Opening CTO decreases ischemic burden in patients with at least moderate ischemia and increases ischemic burden in patients with normal myocardial perfusion. These data support that myocardial perfusion imaging should be used in screening CTO candidates.

Serum Retinol Binding Protein 4 and HbA1c level is associated with Target Lesion Revascularization in Type II Diabetes after Drug Eluting Stent Implantation

Yun Seok Choi, Wook-Sung Chung, Chul-Soo Park, Jeong-Hwan Park, Soo-Sung Oh, Dong-Hyeon Lee, Jong-Min Lee, Pum-Joon Kim, Sang-Hyun Im, Hee-Yul Kim, Yong-Seog Oh, Ho-Joong Youn, Ki-Bae Seung, Jae-Hyung Kim, The Catholic University of Korea, SEOUL, South Korea

Background: Retinol Binding Protein 4 (RBP4), a novel marker of insulin resistance and a key regulatory adipokine of Glucose Transporter 4 (GLUT 4) is predictive of vascular complication in type 2 diabetes. We examined the association between RBP4 or glycemic control determined by pre and post procedural hemoglobin A1c (HbA1c) level and target lesion revascularization rate (TLR) in diabetic patients

Methods: 90 patients(mean age 63±7%, and serum adiponectin and hsCRP levels were also compared between two groups respectively. Results: 1. Among the 90 patients, TLR at follow up was 12.2%. Serum RBP 4 level just before PCI was significantly higher in TLR group than no TLR group (40.5±5.9ug/ml vs 26.7±6.9ug/ml, p=0.008). Serum RBP 4 at follow up was...
not different between two groups (36.6±7.7 µg/ml vs 52.7±4.7 µg/ml). 4. Patients with HDLc>7% showed significantly higher TLR rate than those with HDLc<7% (17% vs. 11%, p=0.001). 5. Serum adiponectin were performed on total occlusion lesions. Compared to patients with non-CTO interventions, patients undergoing PCI were older, more likely to males, smokers, have lower left ventricular ejection fraction and a history of higher incidence of multi-vascular disease. The procedural success rate of PCI of CTO lesions was 73.5% compared to 97.0% in non-CTO lesions. Patients with PCI of CTO in their LAD artery had a significantly higher angiographic success rate than PCI of CTOs involving the RCA or LCX (77.1% vs. 72.2% vs. 69.3% respectively; P value for LAD vs. RCA<0.002, LAD vs. LCX<0.001, LCX vs. RCA=0.119). Patients with CTO had higher in-hospital major adverse cardiac events and cerebrovascular events (MACCE) (OR=0.9% vs. 0.6%, p=0.028). Multivariate regression analysis showed attempted PCI of a CTO was an independent predictor of MACCE (OR=1.7, 95% CI=1.2-2.3, p=0.004) and trended toward being a predictor of in-hospital mortality (OR=1.6, 95% CI=0.9-2.58, p=0.064).

**Conclusions:** In this comprehensive registry analysis involving a broad spectrum of clinical practices in New York State during a 2-year period, both the incidence and the treatment attempts of CTO lesions are considerably lower than previously reported. Importantly, patients undergoing PCI of a total occlusion have higher rates of in-hospital adverse events than patients with non-CTO interventions.


Sunao Nakamura, Jang-Ho Bae, Yeo Hans Cahuay, Wasan Udjayachalerm, Dammas Tresukosol, Sudaratana Tansuphaswadikul, New York Hospital, Chiba, Japan, Konyang University Hospital, Daejeon, South Korea

**Background:** Despite continued enthusiasm in the treatment of chronic total occlusions, their prevalence, recanalization attempts and peri-procedural outcomes are not well defined.

**Methods:** Using the 2000-2001 New York State Angioplasty Registry, we evaluated the prevalence of chronic total occlusion (CTO) and compared in-hospital clinical outcomes in patients undergoing percutaneous coronary interventions (PCI) of CTO vs. non-CTO lesions.

**Results:** Of the 82,140 patients undergoing angioplasty, 18,758 patients (22.8%) had at least one total occlusion in their main epicardial coronary arteries or major branches. After excluding patients with a history of CASG, this figure drops to 13.4% of all patients. CTO patients only had 7% of all occlusion lesions. Compared to patients with non-CTO interventions, patients undergoing PCI were older, more likely to males, smokers, have lower left ventricular ejection fraction and a history of higher incidence of multi-vascular disease. The procedural success rate of PCI of CTO lesions was 73.5% compared to 97.0% in non-CTO lesions. Patients with PCI of CTO in their LAD artery had a significantly higher angiographic success rate than PCI of CTOs involving the RCA or LCX (77.1% vs. 72.2% vs. 69.3% respectively; P value for LAD vs. RCA<0.002, LAD vs. LCX<0.001, LCX vs. RCA=0.119). Patients with CTO had higher in-hospital major adverse cardiac events and cerebrovascular events (MACCE) (OR=0.9% vs. 0.6%, p=0.028). Multivariate regression analysis showed attempted PCI of a CTO was an independent predictor of MACCE (OR=1.7, 95% CI=1.2-2.3, p=0.004) and trended toward being a predictor of in-hospital mortality (OR=1.6, 95% CI=0.9-2.58, p=0.064).

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### 2000-219 The Effect of Drug-Elluting Stents on Clinical and Angiographic Outcomes in Diabetic Patients: Multicenter Registry in Asia

Sunao Nakamura, Jang-Ho Bae, Yeo Hans Cahuay, Wasan Udjayachalerm, Dammas Tresukosol, Sudaratana Tansuphaswadikul, New York Hospital, Chiba, Japan, Konyang University Hospital, Daejeon, South Korea

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### 2000-220 Determining the Hardness of the Proximal and Distal Caps of Chronic Total Occlusions on 64-slice CT for the Retrograde Approach

Kazuhiro Ashida, Masahiko Ochiai, Shigeo Salt, Koichi Hoshimoto, Yuki Mikoshima, Naose Iwamura, Hiroshi Araki, Chika Obara, Showa University Northern Yokohama Hospital, Yokohama-shi, Kanagawa, Japan

**Background:** Recently, the retrograde approach has been used to cross of chronic total occlusions (CTOs). One of the differences between the antegrade and retrograde approaches is the hardness of plaque at the site of CTO, but little is known about differences in the hardness of these lesions.

**Methods:** Eighteen consecutive patients with CTO awaiting PCI underwent 64-slice CT coronary angioscopy between February and September 2007. We assessed the CT values of the proximal cap (PC) and distal cap (DC) of each CTO on the CT scans. We obtained accurate data on the duration of occlusion (DO) in 7 patients, and we investigated the relationship between DO and PC or DC hardness in these patients.

**Results:** All CTOs were successfully recanalized by the retrograde approach (n=16), or via the antegrade approach (n=2) in the patients without suitable collaterals for retrograde manipulation. The PC had a significantly higher CT value than the DC (378±217 vs. 292±135, p=0.0006). The CT value of the PC showed a significant correlation with DO (r=0.963, p<0.0001), while the CT value of the DC was not correlated with DO (r=0.379, n.s.).

**Conclusions:** From our data, the proximal cap of a CTO has harder plaque than the distal cap. A longer DO is not associated with the hardness of plaque in the DC, but is correlated with harder plaque in the PC. If the retrograde approach is available, a high success rate of crossing CTOs (without the guide wire taking the wrong course because of hard plaque) can be expected.

### 2000-221 Clinical and Angiographic Predictors for Successful and Unsuccessful Percutaneous Revascularization of Coronary Chronic Total Occlusions

Kotaro Obunai, George D. Dansag, Jeffrey W. Moses, Somjot Brar, Michael B. Collins, Edward M. Kreps, Arunj Gupta, Satya R. Almalnki, Sudhi Yagi, Martin B. Leon, Gregg W. Stone, Roxana Mehran, New York Presbyterian-Columbia University Medical Center, New York, NY

**Background:** Previous studies of PCI of chronic total occlusions (CTO) have reported angiographic features that correlate with enhanced ability to successfully cross a CTO. However, these predictors have not been validated in the current era with improved CTO techniques and equipment.

**Methods:** In a prospective PCI database, we identified 379 consecutive pts with 396 totally occluded native coronary vessels who underwent PCI of CTO between January 2005 and January 2007; the majority of pts were referred to our institution after failed attempts of CTO recanalization. Contra-lateral injections, multiple guidewires and retrograde techniques were used when indicated. Baseline angiograms of CTO
procedures were analyzed by QCA.

**Results:** Guidewire recanalization and successful PCI was achieved in 284 (72%) CTO vessels. The success rate of the guidewire across the target site was lower (43%) in the group with less likelihood of previous history of CABG (18% vs. 34%; p<0.001), shorter CTO length (18.9±12. mm vs. 26.9±14.63mm, p<0.001), lower prevalence of non-tapered stump (14% vs. 26%, p=0.01), absence of a side branch at CTO site (25% vs. 42%, p<0.01), lower rates of multiple occlusions in a vessel (5% vs. 16%, p<0.001), and absence of severe calcification by fluoroscopy (19% vs. 45%, p<0.001). There was no significant difference in presence of bridging collaterals (27% vs. 34%, p=0.23) between the two groups. Multivariate analysis identified independent predictors of unsuccessful PCI of CTO: longer CTO length (OR 1.06 per 1mm increase, 95% CI 1.03-1.09, p<0.01), severe calcification (OR 4.54, 95% CI 2.40-8.56, p<0.01), multiple occlusions in a vessel (OR 3.22, 95% CI 1.33-9.19, p<0.001), and presence of a side branch at the target site (OR 2.81, 95% CI 1.45-4.96, p<0.01).

**Conclusions:** In this large contemporary CTO cohort, greater lesion length, severe calcification, multiple occlusion sites in a vessel, and presence of a side branch at the target site predicted unsuccessful recanalization. Unlike historical reports, our study indicates that presence of bridging collaterals or a non-tapered stump should no longer discourage a CTO attempt from technical point of view. This observation may improve patient selection for CTO PCI.

**2900-225**

Left Ventricular Dysfunction Is Not a Predictor of Peri-procedural Complications in Patients Undergoing Carotid Artery Stenting


**Background:** Carotid artery stenting (CAS), with the use of embolic protection devices (EPD), is a minimally invasive alternative to carotid endarterectomy in high-risk patients. In patients with carotid artery stenosis (CAS), the risk of death, non-fatal stroke, and any cerebral or non-cerebral stenosis > 80%. These procedures were carried out as part of various study protocols at our institution. All patients had independent neurological evaluation pre and post procedure. We identified patients with severe LVSD (left ventricular ejection fraction (LVEF) <30%) and compared them with a cohort of patients with normal LVEF.

**Results:** 34% of the patients had LVSD. Rate of death and non-fatal strokes were similar at 30 days between the two groups (2.8% vs. 4.5%, p=ns). On one-year follow-up, there were no new ischemal strokes, however, in patients with severe LVSD, the rate of death was 37% compared to only 9% with normal LVEF (Kaplan-Meier curve, significance level, p<0.01).

**Conclusions:** Patients with severe LVSD who undergo CAS with EPD have a similar outcome at 30 days when compared to patients with normal LVEF. However, long-term outcome remains poor in such patients, mainly due to non-neurologic deaths.

**2900-226**

A Simplified Criteria for Determining Stroke Potential by TEE; Could it Herald an Earlier Septal Closure Policy?

Robert W. Biederman, Mark Doyle, Allegheny General Hospital, The Gerald McGinnis Cardiovascular Institute, Pittsburgh, PA

Introduction Multiple observations regarding the causality of PFO and stroke have been well established.

**Methods:** From January 2000 to April 2007, 202 patients underwent 216 CAS. They had Carotid stenting (CS) is evolving as an alternative to carotid endarterectomy (CEA) in the elderly. The CREST lead-in phase, octogenarians had an elevated 30-day stroke or death rate was 2.2%.

All had 30-day follow up. One additional patient had a TIA. Two of the 3 major strokes died; one had a transient ischemic attack (TIA). The other was a stroke and major death rate was 2.2%.

**Conclusion:** CS may be an option for carotid revascularization in these patients.
Identifying the High Endovascular Risk Patient with Carotid Stenosis: An analysis from the Cordis Carotid Stent Collaborative


Background: Comorbid and anatomic characteristics that portend higher procedural risk are well defined for carotid endarterectomy (CEA) but not for carotid stenting.

Methods: We pooled data from 4 Cordis-sponsored carotid stent trials (n=2104), including the Continued Access Registry, CASES, SAPHIRE and ADVANCE to identify predictors of neurological death, stroke, or transient ischemic attack (TIA) within 30 days of the procedure.

Results: Overall, median age was 74 years, 37% were women, 29% had prior TIA and 28% previous stroke. The composite outcome, neurological death, stroke or TIA occurred in 2.1% (95% CI 1.6-2.6%). Complete data was available for analysis in 99 CAS procedures performed in 74 patients. All patients underwent independent neurologic examination before and after the procedure, as well as all-cause mortality, new neurological deficit during the procedure of infra-popliteal arteries or planned amputation and with a reference vessel diameter of 1.5-3.5 mm were included.

Conclusions: We report a low MACCE rate with independent neurological assessment, in a patient population that has been reported to be at increased risk for CAS complications. Our excellent outcomes were despite the 52% use of embolic protection. We believe that experienced CAS operators and careful patient selection were critical to our success. Our data suggests that carefully selected elderly patients can undergo CAS with periprocedural mortality and morbidity within the current guidelines.

Safety of Carotid Artery Stent Placement in the Elderly


Background: Endovascular intervention of the carotid arteries is being evaluated as an alternative to carotid endarterectomy (CEA) for stroke prevention. Successful adoption of carotid artery stenting (CAS) depends on being able to perform the procedure safely enough to generate a cumulative stroke prevention benefit over time. Contrasting results regarding the safety of CAS in the elderly have been reported raising concerns about its overall benefit.

Methods: Between 1994 and 2007, 811 CAS procedures were performed at the Ochsner Clinic Foundation. Elderly patients (≥ 80 years of age) accounted for 128 (16%) of those procedures. All patients underwent independent neurologic examination before and after the CAS procedure. A dedicated database was developed and analyzed for data on in-hospital and 30-day major adverse cardiac and cerebrovascular events (MACCE).

Results: Complete data was available for analysis in 99 CAS procedures performed in 92 consecutive patients ≥ 80 years of age. The average age was 82.7 ± 2.7 years. Almost half (45%) were female and 38% were symptomatic. One-third of the elderly patients had neurological symptoms prior to stenting.

Conclusions: We report a low MACCE rate with independent neurological assessment, in a patient population that has been reported to be at increased risk for CAS complications. Our excellent outcomes were despite the 52% use of embolic protection. We believe that experienced CAS operators and careful patient selection were critical to our success. Our data suggests that carefully selected elderly patients can undergo CAS with periprocedural morbidity and mortality within the current guidelines.

Ischemia Postconditioning Protects Skeletal Muscle from Reperfusion Injury Through Calreticulin-regulated Emophilic Pathway in New Stent Era

Yun-Dong Wu, Yen-Zhang Zhang, Xiu-Hua Liu, Xiao-Sun Guo, Feng-Ying Liu, Chinese PLA General Hospital, Beijing, People’s Republic of China

Background: Reperfusion injury is the gold standard in treatment for acute limb ischemia. Sudden restoration of blood flow to the ischemic skeletal muscle may, however, also cause reperfusion injury. Ischemic preconditioning (IPC) and ischemic postconditioning (I-postC) are endogenous protective mechanisms capable of protecting the ischemic muscle against ischemia-reperfusion (IR) injury. IPC has been demonstrated previously to decrease infarct size and preserving endothelial function to an extent comparable to IPC. The fact that I-postC can be applied after a prolonged period of ischemia offers a novel approach to protection. The present study was designed to investigate the effects of I-postC on ischemia-reperfusion (IR) injury.

Methods: In vivo study: Wistar rats were divided into three groups (n=16) as follows: (1) IR group: Hind limb IR was induced by clamping right femoral artery for 4 h followed by 24 h reperfusion, (2) I-postC group: After 4 h of right femoral artery occlusion, reperfusion was initiated for 1 min of reperfusion followed by 1 min of reocclusion, repeated for three cycles, then subjected to 24 h reperfusion, (3) IPC group: the right femoral artery was occluded for 5 min followed by 5 min of reperfusion, repeated for three cycles, before the 4 h of prolonged occlusion. (4) Sham rats underwent the same surgical procedure without ligation. Lactate dehydrogenase (LDH) activity in plasma, Wet/dry ratio (W/D) and ultrastructure of skeletal muscle were detected by Western blotting. In vitro study: Cultured skeletal muscle cells (SMCs) from neonatal Wistar rats were divided into six groups (n=4) as follows: (1) hypoxia/reoxygenation (H/R) group: Cultured SMCs were placed into the hypoxia chamber for 2 h to induce hypoxia followed by reoxygenation (for 24 h). (2) hypoxia postconditioning (H-postC) group: SMCs were directly exposed to hypoxia (for 2 h) followed by 3 cycles of brief reoxygenation (5 min) and hypoxia (5 min) to induce H-postC. Then SMCs were incubated in cell incubator for 24 h to induce sustained reoxygenation. (3) Hypoxic preconditioning (HPC) group: SMCs were placed into the hypoxia chamber for 20 min to induce HPC prior to H/R. (4) Cyclosporine A (CsA) + H-postC group: SMCs were preincubated with CsA (a CaN inhibitor, 10 μM) for 60 min prior to H-postC. (5) CsA + H/R group: SMCs were preincubated with CsA prior to H/R. (6) Control group: SMCs were incubated in cell incubator for 24 h. Survival and apoptosis rate of SMCs were measured by Annexin V and PI FACS analysis.

Results: In vivo experiment, compared with IR group, I-postC significantly decreased LDH release, W/D ratio and ultrastructure damage induced by IR. I-postC upregulated CRT expression to 4-fold (reperfusion 12 h) and 102% (reperfusion 24 h) compared with IR group (P<0.05). The expression of CaN increased to 196% (reperfusion 12 h) and 63% (reperfusion 24 h) respectively (P<0.05). In in vitro study, H-postC attenuated H/R-induced apoptosis and induced cytoprotection of CRT and CaN, compared with H/R group. CaN inhibitor CsA abolished H/R-induced cytoprotection and up-regulation of CaN without affected CRT expression.

Conclusions: Both in vivo and in vitro results indicated that I-postC can protect the skeletal muscle against IR injury. I-postC may provide a potential alternative to carotid endarterectomy (CEA) for stroke prevention. Successful adoption of I-postC in CAS may provide a potential alternative to carotid endarterectomy (CEA) for stroke prevention. Successful adoption of I-postC in CAS may offer a potential alternative to carotid endarterectomy (CEA) for stroke prevention. Successful adoption of I-postC in CAS may offer a potential alternative to carotid endarterectomy (CEA) for stroke prevention.

Stent Fracture Does Not Affect the Long Term Patency in the Superficial Femoral Artery in the New Stent Era

Osamu Iida, Shinshuke Nanto, Masaaki Umetatsu, Takakazu Morozumi, Tetsuya Watanabe, Masaki Awata, Toshinari Onishi, Fusako Sera, Hitoshi Minamiguchi, Hiroki Akahori, Masamichi Yano, Kuniyasu Ieoka, Shin Okamoto, Nobuaki Tanaka, Haruyu Yasui, Seiki Nagata, Kansai Rosai Hospital, Amagasaki, Japan

Background: Stent fracture in the superficial femoral artery (SFA) has been related to poor long term patency. Although a new nitinol stent has been introduced to reduce stent fracture and restenosis in the SFA, whether stent fracture of the new stent still influences long-term patency remains unclear.

Methods: We studied 90 SFA lesions that underwent provisional stenting with a recently developed nitinol stent (Smart, J&J) in consecutive 77 patients who gave consent to receive follow-up arteriography 4 months later. Morphology of the stent fracture was classified based on the Cardiovascular Institute of the South Nitinol Stent Fracture classification system, evaluated by X-ray with multiple projections. Relation between...
follow-up restenosis (> 50% angiographic stenosis or peak systolic velocity ratio > 2.5 by Doppler ultrasound) and angiographic morphology of the fracture was explored.

Results: Stent fracture occurred in 28% lesions (25/90). Angiographic restenosis rate at follow-up was 24% (22/90). Restenosis rate neither correlated with the stent fracture (log-rank test, \( p = 0.36 \), Figure) nor with stent fracture morphology (\( \leq 35\% \), 6/17; \( > 50\% \), 24; \( < 5\% \), 0/2). None = 22%, 14/65, \( P = 0.5 \).

Conclusion: Stent fracture and fracture morphology of the new generation nitinol stent did not affect the long term patency following superficial femoral artery stenting.

2900-239 VIABAHN Stent-Graft for Percutaneous Revascularization of Long, Complex Lesions (TASC C/D) of Superficial Femoral Artery
Mohamed Dalman, Hamei, Raaid Musetil, Mohammed Taher, Nadh Chadda, Abdulsalam Hashem, Shareef Kazemi, Anjan Gupta, Ramagopal Tumuluri, Joseph Shavler, Suhail Allaqaband, Tarvir Bajea, Aurora Sinai/Aurora St. Luke’s Med Ctrs, Univ Wisconsin School of Med and Public Health-MCC, Milwaukee, WI

Background: Endovascular intervention for femoropopliteal occlusive disease poses a challenge due to a significant restenosis rate. We evaluated the primary and secondary patency rate of VIABAHN stent-graft (W. L. Gore, Flagstaff, AZ) in patients with long, high-grade de novo superficial femoral artery (SFA) lesions.

Methods: From August 2004 to March 2007, 123 patients at our institution underwent a total of 132 endovascular interventions for de novo, TASC grade C or D, SFA lesions, using VIABAHN stent-graft. All patients were discharged on ASA and clopidogrel. Patients were followed clinically and with duplex scans at 1, 3, 6 and 12 months postprocedure and longer, if clinically indicated. In-stent restenosis on duplex scan was defined as a lumen loss of \( \geq 50\% \) and confirmed with angiography.

Results: Mean age was 65 \( \pm 13 \) (59% male). Prevalence of diabetes, hypertension, renal failure, smoking and dyslipidemia was 45.5%, 82.1%, 37.6%, 36.6, and 72.3% respectively. Clinical presentation was Fontaine class IIb in 74.8%, class III in 4% and class IV in 21.2%. Lesions were TASC C class in 71% and D in 46.2% with a mean length of 21.10.9 cm. The initial technical success was 100%. All patients had at least 2-vesteck run-off. Primary patency rates are shown in the graph.

Conclusions: Percutaneous revascularization of de novo, long and high-grade SFA lesions/occlusions with VIABAHN stent-graft is safe, feasible with excellent long-term patency.

2900-240 Routine Stent Implantation Versus Percutaneous Transluminal Angioplasty in Femoropopliteal Artery Disease: A Meta-Analysis of Randomized Controlled Trials
Christos Kagiadakis, Peter K. Henke, Stanley J. Chetcuti, Gerald C. Koenig, John E. Rectenwald, P. Michael Grossman, Hitinder S. Gurm, University of Michigan Health System, Division of Cardiovascular Medicine, Ann Arbor, MI

Background: Clinical trials comparing routine stent (ST) implantation with percutaneous angioplasty (PTA) for superficial femoral-popliteal artery (SFA) disease have produced conflicting results. We performed a systematic meta-analysis of randomized controlled trials comparing ST vs. PTA in symptomatic SFA disease.

Methods: We searched the MEDLINE, Embase, ISI Web of Knowledge, Current Contents, International Pharmaceutical Abstracts databases, and the Cochrane Central Register of Controlled Trials up to August 31, 2007. We calculated the summary odds ratio (OR) for immediate technical success, restenosis and target vessel revascularization (TVR) using fixed-effect models.

Results: Data from nine randomized controlled trials (1,146 patients) were pooled. Patients were randomized to ST (N=627 limbs) or PTA with provisional stenting (N=618 limbs). The follow up period varied from 9-24 months. The immediate technical success was higher in patients treated with ST (OR=4.79, 95% CI 1.99-11.52, \( P = 0.001 \)) with 3% of the PTA patients undergoing stenting, because of suboptimal PTA result. There was a non-significant trend for lower restenosis in the ST group (OR=2.02, 95% CI 0.92-4.45, \( P = 0.081 \)), but no difference in the need for TVR (OR 1.01, 95% CI 0.75-1.4, \( P = 0.92 \)).

Conclusions: Despite the higher immediate success, routine stenting for SFPA disease was not associated with a reduction in rate of restenosis or TVR. Our data do not support use of routine stenting for SFPA lesions.
**2003-296**

**Renal Artery Stenosis and Proximal Tubular Injury**

Grant Reed, Katherine Hoeltz, Steven Haller, Pamela Brewster, Joseph I. Shapiro, Christopher J. Cooper, University of Toledo Medical Center, Toledo, OH

**Background:** Atherosclerotic renal artery stenosis (RAS) is associated with renal dysfunction in many patients. However, the mechanisms of renal injury are not well understood. In patients with proximal tubular injury N-acetyl-β-D-glucosaminidase (NAG) and β-2-Microglobulin (B2M) levels increase in the urine because of increased release and impaired reabsorption respectively. The present study evaluated proximal tubular function in patients undergoing renal artery stenting.

**Methods:** As a sub-study of the RESIST clinical trial 100 patients enrolled at 7 centers undergoing renal artery stenting were randomized to an embolic protection device (EPD). Angiogram, or a GP2b3a inhibitor, abciximab, in a 2x2 design. Urine was collected at baseline, 24hrs, and 1 month post procedure. Statistical analysis was performed on the natural log transformed data of matched pairs. NAG and B2M were corrected for creatinine.

**Results:** A substantial proportion of patients (54.86% (63%)) have evidence of proximal tubular dysfunction prior to revascularization. Elevated levels of NAG and B2M were highly correlated with overall renal function (MORD GFR, p<0.05). After stenting tubular function appeared to worsen acutely at 24 hours (NAG, -0.2 to 1.0 x 0.1 to 1.1 mLg, P<0.05, and B2M, -8.4 ± 4.3 vs. -7.8 ± 4.5 mLg, p=0.2). No change in tubular function was seen with an EPD, whereas without an EPD there was a trend towards worsening tubular injury at 24h (-5.0 ± 4.2 vs. 7.0 ± 4.5 mLg, p<0.05). Contrast dose did not have an effect on NAG or B2M.

Conclusion: Abnormalities of the proximal kidney tubule are important contributors to renal dysfunction in patients with renal artery stenosis, and may worsen 24hrs following revascularization. This effect may be lessened with the use of an EPD.

**2003-297**

**CASES-PSM Carotid Artery Stenting with Emboli Protection Surveillance Study: Outcomes at 1-Year**

Theodore Schreiber, William Bachinsky, Peter Faries, David Lewis, Steve Tyndall, Shenwood Dixon, Amit Patel, Christopher Cates, Peter Soukas, Charles Daly, Dennis Donchoe, Harper University Hospital, Detroit, MI

**Background:** CASES-PSM, a multi-center, prospective, single-arm, surveillance study assessed safety and efficacy outcomes of carotid artery stenting (CAS) using the Cordis PRECISE® Nitinol Stent and ANGIOGUARD®XP Emboli Capture Guidewire, when performed by physicians with varied experience in CAS utilizing a formal training program.

**Methods:** High surgical-risk patients with de novo atherosclerotic or post-endarterectomy restenotic lesions in native carotid arteries were enrolled. Inclusion and exclusion criteria matched those of the SAPPHIRE trial. Primary endpoint was composite 30-day major adverse events (MAE) including death, any stroke, or myocardial infarction.

**Results:** A total of 1,493 patients were enrolled at 73 sites from September 24, 2004 through October 7, 2005. 30-day results have been reported previously. At 1-year, Kaplan-Meier analysis of all stroke and death to 30-days plus ipsilateral stroke between 31 to 360 days with CASES-PSM (5.4%) was similar to rates seen with the SAPPHIRE trial stent cohort (5.4%). There were no significant differences in outcomes at 1 year by symptom status (high-risk vs. low-risk). Cognitogeners did have a significantly higher event rate compared with younger patients.

**Conclusions:** The durability of carotid artery stenting in high-surgical-risk patients seen in the SAPPHIRE trial has been reproduced with CASES-PSM. Subgroup analyses in this study suggest that patient population selection criteria for CAS and operator experience may help reduce event rates in patient subsets that are typically at higher risk for adverse events after carotid artery stenting.

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**ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts B77**

**2003-298**

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

Sunao Nakamura, Eiji Tada, Kensuke Fujinawa, Osamu Kakuda, Naoyuki Kurita, Mizuki Hirose, Shotaaro Nakamara, Satoko Tahara, Koji Hozawa, Hitoshi Nakamura, Kazutoshi Yamamoto, Seiji Ohnati, Nobuoaki Makishima, Jun Koyama, New Tokyo Hospital, Chiba, Japan, Chiba Central Medical Center, Chiba, Japan

**Background:** Obstructive lesions of the subclavian artery can result in arm claudication, symptoms of subclavian steal. Aim: To evaluate the safety, efficacy and durability of endovascular stenting for treating 405 obstructive lesions of subclavian artery. **Methods:** We performed 405 cases of endoluminal stenting for 383 patients (272 males, 67.1±10.9 years). All procedures were performed with Palmaz stents (272 cases) and Wall stents (133 cases), 262 cases (64.7%) were used transradial approach. Indications for stenting were claudication in 219 cases, subclavian steal syndrome in 90 cases and myocardial ischemia secondary to compromised flow through internal mammary grafts in 74 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 380 patients (99.2%). Only one patient had a major complication (mediastinal hemorrhage due to subclavian artery rupture). Baseline diameter stenosis was reduced from 88.9% to 12.9±9.2%, mean systolic pressure difference was reduced 45.9±14.8 mmHg to 4.7±4.9 mmHg (p<0.01). There was no cerebral or distal embolization. In 320 of 383 patients (83.6%) we performed, follow-up angiography ranged from 6 months to 9 years (mean, 56.8 months). Primary angiographic patency at 5 years was 99% (only 3 restenosis: 1.0%). **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.

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**2003-299**

**Differences in Nitinol Stent Characteristics for Clinical Decision Making**

Bruce H. Grzy, Anthony Ragheb, Greenville Hospital System University Medical Center, Greenville, SC, Medical Institute (Cook), Lafayette, IN

**Background:** There are a variety of nitinol stents available for use. Nitinol stents are not all the same, yet the clinician is provided little information besides selective marketing data. The purpose of this study was to compare some key characteristics of nitinol stents that may impact their ability to meet physiologic demands. **Methods:** The evaluations were performed using controlled test methods, and the various devices were tested under the same conditions. The table below summarizes the results.

**Results:**
Endovascular Exclusion of Popliteal Artery Aneurysms with Stent-Grafts - A Prospective, Single Center Experience.

Gary M. Iselstén, Leo Simpson, Kathryn G. Dougherty, Eduardo Hernandez, Ali Mortazavi, Neti E. Strickman, Zvonimir Krajcer, Texas Heart Institute at St. Luke’s Episcopal Hospital, Houston, TX, Baylor College of Medicine, Houston, TX

Background: Untreated popliteal artery aneurysms (PAAs) are associated with significant morbidity secondary to thrombosis and thromboembolization that may lead to limb loss. Due to the considerable morbidity and mortality related to surgical PAA repair, especially in symptomatic patients, we sought to determine the efficacy of percutaneously treating PAAs using self-expanding stent grafts.

Methods: Between October 2000 to September 2007, 32 patients underwent successful endovascular exclusion of 36 PAAs.

Results: Thirty-nine (91.7%) of the aneurysms were secondary to atherosclerotic disease, with three aneurysms occurring at sites of previous directional arterectomy. Twenty-nine PAAs (80.5%) were symptomatic and 4 patients presented with PAA-associated venous occlusion and thrombosis. Twenty-eight (77.8%) of the treated aneurysms had associated mural thrombus. The mean aneurysm diameter was 22.9 ± 16.2 mm. The mean lesion length was 48.4 ± 10.2 cm (range 15 to 422.3 cm). Average stent area per aneurysm treated was 1.9 ± 0.4, with a mean length of stent per lesion of 198.6 ± 105.3 mm (range of 50 to 450 mm). A total of 60 stent grafts were used, of which 15 were Wallgraft stents and 45 were Viabahn stents. All PAAs were successfully excluded. There were no death-associated complications, failures or deaths. Three (8.3%) patients had access site hematomas, one (2.7%) requiring surgical repair. Thrombosis occurred in two (5.6%) stent grafts at 24 hours and successfully recanalized. The mean length of hospitalization was 1.4 ± 1 days. Average follow-up was 35 ± 32.1 months. Primary and secondary patency rates were 94.4% and 100%, and 93.9% and 100%, respectively. One and 2-year primary and secondary patency rates were 89.3% and 96.4%, and 70.6% and 94.1%, respectively. In the patients with ≥ 5 years of follow-up, primary and secondary patency rates were 85.7% and 100%, respectively. There were no reinterventions, aneurysm ruptures or limb-loss at follow-up.

Conclusions: Percutaneous self-expanding stent graft exclusion of PAAs is safe and effective, with primary and secondary patency rates comparable to surgical repair.

Effects of Endovascular Stent-Graft Repair and Medical Therapy on True and False Lumen Volume in Type B Aortic Dissection

Sebastian Huptas, Holger Eggebrecht, Hilmar Kuehl, Uli Herold, Heinz G. Jakob, Rajendra H. Matha, Raimund Erbel, University of Duisburg-Essen, West-German Heart Center, Cardiology Department, Essen, Germany

Background: Endovascular aortic repair (EVAR) aims at non-surgical reconstruction of type B aortic dissection (AD). Obliteration of false lumen (FL) perfusion by implantation of a membrane-covered stent graft across the proximal entry tear is hypothesized to facilitate aortic remodeling characterized by FL thrombosis and enlargement of the true lumen (TL). So far, an analysis of the remodeling process in comparison with the medical management is, however, missing.

Methods and Results: Serial contrast-enhanced computed tomography (CT) aortic scans of 27 type B AD patients (60 patients ≥13 years) were analyzed; 17 of these underwent EVAR, while 10 patients received medical therapy. Volumes of TL and FL on CT performed at baseline and secondary patency rates of 3 and 6 months were obtained using 3D-reconstruction from the origin of the left subclavian artery to the abdominal aortic bifurcation. EVAR resulted in a significant immediate gain in TL volume (p<0.001) with before stenting whereas DT remained no changed. When the E/E’ ratio was of a significant increase from the origin of the left subclavian artery to the abdominal aortic bifurcation. EVAR resulted in a significant immediate increase in TL volume (p<0.001) with before stenting whereas DT remained no changed. When the E/E’ ratio was increased. E velocity, A velocity and E/A decreased significantly after stenting compared to before stenting and remained significantly (p<0.001) decreased to 10.8±2.7 at mean follow-up of 5.7±3.9 months, whereas ejection fraction and wall motion score index remained unchanged. E velocity and A velocity decreased significantly after stenting compared with before stenting whereas DT remained unchanged. The E/E’ ratio of a higher value, arterial remodeling was more beneficial. Subjects with improvement in hypertension and cardiac disturbance syndrome following renal artery stenting had significantly higher baseline E/E’ ratio than those without clinical improvement.

Conclusions: Renal artery stenting may contribute to an improvement in left ventricular diastolic dysfunction for RAS patients. Patients with pre-existing severe diastolic dysfunction are more likely to benefit from renal artery stenting. An enthusiastic evaluation of diastolic function in RAS patients is warranted.

Drug-Eating Stents versus Bare Metal Stents in Saphenous Vein Grafts at 2 Years

Robert J. Appleget, Matthew T. Sacrinty, Michael A. Kutcher, Sanjay K. Gardni, Renato M. Santos, William C. Little, Wake Forest University School of Medicine, Winston-Salem, NC

Background: Drug-eluting stents (DES) reduce restenosis compared to bare metal stents (BMS) in native coronary arteries. Recent data suggest that DES efficacy and safety in SVGs may be lower than with BMS. However, long term (>2 year) outcomes of DES in SVGs remain unclear.

Methods: 212 pts. at Wake Forest Baptist Medical Center between 4/02 and 4/05 underwent PCI of SVGs including 123 pts. with BMS and 89 pts. with DES. Clinical outcomes at 2 years were retrospectively reviewed.

Results: The baseline clinical characteristics of the two groups were similar. Procedural characteristics were also similar, except that embolic protection was used in 58% of BMS and 46% of DES cases, p=0.093. Anti-platelet therapy was similar in both groups at 2 years, with 50% using dual anti-platelet therapy. The hazard ratio for 2 years for DES compared to BMS for target vessel revascularization was 0.66 (0.32-1.38); for non-fatal MI was 0.26 (0.09-0.78); for all cause death was 0.55 (0.27-1.12); for stent thrombosis was 0.44 (0.09-2.20); and for non-fatal MI or death was 0.42 (0.22-0.79). The Kaplan-Meier plot of non-fatal MI or death is shown in the figure.

Conclusions: In this study of routine clinical practice, use of DES for PCI of SVGs was associated with lower need for repeat revascularization and non-fatal MI or death, with a similar incidence of stent thrombosis at 2 years. Thus, DES in SVGs have similar clinical efficacy as in native coronary arteries.
Histopathological Features in Primary PCI: A Large Single-Center Thrombectomy Study

Miranda C. Kramer, Allard C. van der Wal, Karel T. Koch, Johanna P. Ploegmakers, Rene J. van der Schaat, Jan Baan, Jr., Manjie M. Vis, Jose P. Henriques, Jan J. Pieck, Robbert J. de Winter, Academic Medical Center, Amsterdam, The Netherlands

Background: ST-elevation myocardial infarction is mostly due to plaque rupture or erosion and is frequently accompanied by occlusive thrombus. However, a heterogeneous composition in terms of thrombus age has been described suggesting a discrepancy between the time of onset of the thrombotic process and the occurrence of acute clinical symptoms. We aimed to describe the histopathological characteristics of thrombectomy material obtained in a large cohort of STEMI-patients treated with primary PCI.

Methods and Results: Intracoronary thrombectomy during primary PCI was performed in 1381 consecutive STEMI patients between August 2001 and September 2007. Patients were eligible if there was evidence of acute myocardial infarction with ≥2 mm ST elevation in ≥ 2 contiguous leads and symptoms of ≤ 12 hours duration. We collected 936 thrombus catheters: the Rescue®, and the Export® catheter and one proximal protection device: the Proxis® device. In 1307 of the patients (95%) thrombectomy was performed successfully and in 963 of these patients (75%) intracoronary-derived material was obtained. Thrombus age was classified as fresh (< 1 day), lytic (1 to 5 days) and organized (> 5 days), according to accepted definitions. We identified thrombus material in 936 patients (95%) and thrombus age could be classified in 916 of these patients. Thrombus older than 1 day was found in 369 of these patients (41%). Both thrombus and plaque components were found in 356 patients (39%) and only plaque components were found in 31 of the patients (3%).

Conclusions: This large single-center thrombectomy study confirms and extends our previous observation that in a significant proportion of the STEMI patients (40%) an acute coronary occlusion occurs to be the final stage in a series of successive thrombotic events in the preceding days or weeks.

Validation of Model Predicting 30-day Major Adverse Cardiac Events in Saphenous Vein Graft Percutaneous Coronary Intervention

Alanna Coolong, A. James O’Malley, Donald S. Baim, Richard E. Kunz, Donald E. Cutlip, Laura Mauri, Brigham and Women’s Hospital, Boston, MA, Harvard Clinical Research Institute, Boston, MA

Background: Saphenous vein graft (SVG) percutaneous coronary intervention (PCI) is associated with a high risk of peri-procedural morbidity. The use of embolic protection devices (EPD) has been shown to reduce 30-day major adverse cardiac events (MACE) by 50%. A post-hoc analysis of 3,958 patients enrolled in 5 randomized, controlled trials and one registry evaluating EPDs found angiographic measures of plaque burden to be the most potent predictors of adverse outcome. We attempted to confirm the predictive value of this multivariable model using an external dataset.

Methods: A multivariable logistic regression model predicting 30d MACE in SVG PCI was developed by combining patient data (N=3,958) from trials of EPD in SVG (SAFER, FIRE, CAPTIVE, SPIDER, and PROXIMAL randomized, controlled trials and the BLAZE II registry). The model identified estimated plaque volume, SVG degeneration score, age, tobacco use, and glycerciprotein IIb/IIIa inhibitor use as independent predictors of 30d MACE. Patients enrolled in the PRIDE randomized, controlled trial (N=693) and ASPIRE registry (N=113) of the TriActiv EPD in SVG were pooled to form an independent validation cohort. The multivariable logistic regression model was applied to the validation cohort and a goodness-of-fit estimate was performed using the Hosmer-Lemeshow statistic on ordered deciles.

Results: The Hosmer-Lemeshow test statistic was 4.75 (p=0.78) signifying good fit of the original model in the independent trial dataset.

Conclusions: A prediction model for 30d MACE in SVG PCI from 3958 patients was successfully validated in an independent dataset of 806 patients, confirming its reliability in predicting patient outcomes across devices and trials. This model may serve to develop a method to evaluate new EPDs against risk-adjusted models in future studies.

Impact Of Atrial Fibrillation On The Immediate And Long Term Results Of Mitral Balloon Valvuloplasty In 531 Consecutive Patients

Mohamed E. Fawzy, Walid Hassan, Adil Osman, Manzoor Memon, Iman Ibrahim, Souad El Amrasai, Abdolremonim El Dali, King Faisal Specialist Hospital, Riyadh, Saudi Arabia

Background: The aim of this study was to assess the effect of AF on the immediate and long-term results of balloon valvuloplasty (MBV) in 531 consecutive patients with MS.

Methods: The immediate and long-term (up to 17.8 years) clinical and echocardiographic results of MBV of 71 patients with AF at baseline were prospectively collected and compared with those of 460 patients in normal sinus rhythm (NSR).

Results: Patients with AF in the initial MBV were younger (42 ± 12 vs. 30 ± 10, p < 0.001), had higher echocardiographic score (echo score) 8.45 ± 1.14 vs. 7.95 ± 1 (P = 0.005) and MBV resulted in inferior immediate and long-term results as reflected in smaller immediate mitral valve area (MVA) 1.89 ± 0.23 cm² vs. 2.0 ± 0.39 cm² (P = 0.005) and smaller follow-up MVA (P = 0.005) and MVA by pressure half-time (PHT) and MVG by Doppler were compared using paired patient data.

Results: MVG increased slightly with treatment (1.8 ± 0.9 to 4.1 ± 2.2 mmHg, p<0.0001), and fell slightly from discharge to 12 months (4.2 ± 2.4 to 3.3 ± 1.7 mmHg, p<0.0001). MVA by planimetry showed an expected decrease after Clip repair (6.0 ± 1.3 to 3.5 ± 1.1 cm², p<0.0001), no change from discharge to 12 months (3.5 ± 1.3 to 3.4 ± 0.9 cm², p=NS), and no differences between patients who received one vs. two Clips (Figure). MVA by RHT showed similar results over time with a smaller MVA than by planimetry that also declined from discharge to 12 months (2.9 ± 0.8, baseline), 2.9 ± 1.2 (discharge), 2.8 ± 0.9 (12 month).

Conclusions: 1) Echocardiography demonstrates an expected decrease in MVA after percutaneous MitraClip repair without clinically significant mitral obstruction. 2) There is no significant difference in MVA or MVG between one and two Clips, and no evidence of progressive mitral infar obtruction from discharge to 12 months.
2900-250 18 Years Clinical And Echocardiographic Follow-up Results Of Mitral Balloon Valvuloplasty In 531 Consecutive Patients And Predictors of Long-term Outcome

Mohamed Eid Fawzy, Adil Osman, Omar Nowahy, Soudai El Amraoui, Shahib Shah, Iman Ibrahim, Abdulmonem El Dal, King Faisal Specialist Hospital, Riyadh, Saudi Arabia

Background: Long-term echocardiographic follow-up studies of mitral balloon valvuloplasty (MBV) are scarce. The aim of this study was to assess the long-term results (up to 18 years) of MBV and to identify predictors of restenosis and event-free survival.

Methods: We report the immediate and long-term clinical and echocardiographic results in 531 consecutive patients, (386 female) mean age 31 ± 11 years, who underwent successful MBV for severe mitral stenosis (MS) and were followed up for 1.5 - 18 (mean 8.5 ± 4.8) years after MBV.

Results: Mitral valve area (MVA) increased from 0.92 ± 0.17 to 1.95 ± 0.29 cm² (P < 0.0001). Restenosis occurred in 165 (31%) patients and it was less frequent in patients with low echo score (MVA ≤ 0.8) (19%). Actuarial freedom from restenosis at 10, 15, 18 years were (77 ± 2, 46 ± 3, 18 ± 4) respectively, and were significantly higher for patients with (MVA ≤ 0.8) (86 ± 2, 62 ± 4, 30 ± 7) respectively (P < 0.001). Event-free survival (death, redo MBV, MVR, NYHA Functional Class III or IV) at 10, 15, 18 years were 88 ± 1, 54 ± 4, 21 ± 5 respectively, and were significantly higher for patients with (MVA ≤ 0.8) (92 ± 1, 67 ± 4, 38 ± 8) respectively (P < 0.001). Cox regression analysis identified MVA > 8 (P = 0.0001), female gender (P = 0.021) as predictors of restenosis and MVA ≤ 8 (P < 0.0001), as predictors of event free survival.

Conclusions: MBV provides excellent long-term results for selected patients with MS. The long-term outcome of this procedure can be predicted from baseline clinical and echocardiographic characteristics of the mitral valve.

2900-251 Percutaneous Mitral Valvuloplasty During Pregnancy

Hung Manh Pham, Hieu Lan Nguyen, Quang Ngoc Nguyen, Loi Doan Do, Viet Lan Nguyen, Kha Giap Pham, Vietnam Heart Institute, Hanoi, Viet Nam

Background: Circulatory changes in gestation, a hyperdynamic adaptive state in general, cause an additional burden on the cardiovascular system of women with rheumatic mitral stenosis (MS). Percutaneous Mitral Valvuloplasty (PMV) has emerged as an effective nonsurgical technique for the treatment of patients with symptomatic MS during pregnancy.

Methods: From November 1999 to Dec. 2006, 75 pregnant women (among 4200 PMV patients) were performed PMV using Inoue balloon at Vietnam Heart Institute. The transendocardic echocardiography was used in combination with intermittent fluoroscopy to limit the radiation exposure time. A detailed clinical, echocardiographic, hemodynamic assessment was premed, post procedure, at every 3 months for the first year and at 6 month interval thereafter. The pregnancy and newborn babies outcomes were also followed.

Results: MS pregnant women were 27.6 years old on average (ranged 22-42) and the mean length of pregnancy was 24.2 ± 5.6 weeks. Echo score of mitral valve was 7.1 ± 2.3. The procedure was technically successful in all cases without any complications. The total mean duration of the procedure was 35.25 ± 14.28 min and that of fluoroscopy 2.55 ± 1.28 min (from 1 min 59 sec to 3 min 15 sec). The fluoroscopy time was significantly shorter than that of usual patients not using echo guided (2 min 23 sec vs. 7 min 23 sec, P < 0.01). The mitral valve area increased from 0.7 ± 0.3 to 1.9 ± 0.4 cm² (on 2d echocardiography) and from 0.8 to 2.0 ± 0.4 cm² (on PHT) (p< 0.01). A reduction in mean transmitral valve gradient (MVTG) was from 22 ± 6 to 8 ± 2 mmHg. There were no maternal or fetal deaths. All patients delivered at full term but 4 (without major complications), 34 vaginally and 41 by caesarean section. After average 36 months follow-up (range, 3 to 96) all children had normal growth.

Conclusions: During pregnancy, Percutaneous Mitral Valvuloplasty could be considered as the treatment of choice of severe pliable mitral stenosis which are refractory to medical treatment. Using echocardiography guided can reduce the fluoroscopy time.

2900-252 PERCUTANEOUS AORTIC VALUES: Predicting Appropriate Size

Vasilis Babaligoria, David Liff, Edward Chen, Jason Rogers, Ryan Brown, Vinod Thourani, Robert Guyton, Stamatis Lerakis, Arthur Stillman, Paolo Raggi, Jennifer Cheebers, Jake Green, Peter Block, Emory University Hospital, Atlanta, GA, University of California, Davis, Sacramento, CA

Background: Exact sizing of percutaneous aortic valve (PAV) is not clear. From November 1999 to Dec. 2006, 75 pregnant women (among 4200 PMV patients) were performed PMV using Inoue balloon at Vietnam Heart Institute. The transendocardic echocardiography was used in combination with intermittent fluoroscopy to limit the radiation exposure time. A detailed clinical, echocardiographic, hemodynamic assessment was premed, post procedure, at every 3 months for the first year and at 6 month interval thereafter. The pregnancy and newborn babies outcomes were also followed.

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Conclusions: During pregnancy, Percutaneous Mitral Valvuloplasty could be considered as the treatment of choice of severe pliable mitral stenosis which are refractory to medical treatment. Using echocardiography guided can reduce the fluoroscopy time.
in the KCCQ summary score was seen, but not in the summary scores of the SF-12. At 6 months, significant improvements were seen in all 3 scales. Study follow-up is ongoing, with 12 month results expected in early 2008.

**Conclusions:** In an elderly cohort of non-surgical candidates with critical AS, successful transcatheter aortic valve replacement was associated with large, clinically meaningful improvements in QOL over 6 months.

<table>
<thead>
<tr>
<th>Baseline (N=75)</th>
<th>30 Days (N=62)</th>
<th>P-value (Baseline - 30 days)</th>
<th>6 Months (N=36)</th>
<th>P-value (Baseline - 6 Months)</th>
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</thead>
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<tr>
<td>SF-12/ Physical</td>
<td>30.8±8.3</td>
<td>33.3±8.9</td>
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<tr>
<td>SF-12/ Mental</td>
<td>46.7±10.4</td>
<td>44.8±10.6</td>
<td>52.7±8.7</td>
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<tr>
<td>KCCQ</td>
<td>38.6±25.1</td>
<td>68.4±25.0</td>
<td>70.3±20.7</td>
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</table>

**Scores = mean ± s.d. *p-value from sign test; others from paired t-tests**

**2900-295**

**Prevalence of Diastolic Trans-mitral Valve Gradient in Patients with Severe Calcific Aortic Stenosis**

Gerald Yong, Aman Ali, Ted Feldman, Evanston Northwestern Healthcare, Evanston, IL

**Background:** During antegrade balloon aortic valvuloplasty (BAV), transvalvular pressure gradients (MVG) were noted frequently on hemodynamic assessment. Aim: Determine the prevalence and significance of a diastolic MVG in patients with aortic stenosis (AS) and no diagnosed mitral valve stenosis.

**Method:** Retrospective chart review of patients with severe non-rheumatic AS undergoing antegrade BAV. During antegrade BAV, direct left atrial (LA) and left ventricular (LV) pressure measurements were obtained allowing for accurate assessment of MVG. Significant MVG is defined as a LA-LV gradient of ≥5mmHg.

**Results:** 82 BAV patients were reviewed (mean age 84 years, Euroscore ≥6 in 100%). MVG ranged from 0 to 14mmHg, with mean 5.0±3.5mmHg. A significant MVG was seen in 54.9%, and was associated with significantly higher LA mean pressure, pulmonary arterial (PA) mean pressure and PA systolic pressure at baseline and post-BAV (see table). A weak but statistically significant correlation was seen between MVG and LA-LV mean pressure (r=0.49, p<0.001) and PA mean pressures (r=0.41, p<0.001). There was no association with cardiovascular risk factors, with presence or severity of mitral annular calcification (visually assessed on cinefluoroscopy) or with the presence of mitral regurgitation.

**Conclusion:** A significant MVG is common in elderly patients with severe AS. It is associated with higher LA and PA pressures. The clinical significance of this finding is yet to be determined.

<table>
<thead>
<tr>
<th>LA mean pressure</th>
<th>16.8 (6.6)</th>
<th>26.0 (6.0)</th>
<th>&lt;0.001</th>
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<tbody>
<tr>
<td>PA mean pressure</td>
<td>28.0 (11.4)</td>
<td>37.7 (10.4)</td>
<td>&lt;0.001</td>
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<tr>
<td>PA systolic pressure</td>
<td>43.1 (16.5)</td>
<td>59.3 (14.7)</td>
<td>&lt;0.001</td>
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<tr>
<td>POST-BAV</td>
<td></td>
<td></td>
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<tr>
<td>LA mean pressure</td>
<td>14.9 (5.9)</td>
<td>22.5 (7.7)</td>
<td>&lt;0.001</td>
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<tr>
<td>PA mean pressure</td>
<td>30.9 (8.8)</td>
<td>38.6 (9.4)</td>
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<td>PA systolic pressure</td>
<td>50.6 (16.5)</td>
<td>63.5 (13.8)</td>
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</tbody>
</table>

**2900-296**

**Bicuspid Aortic Valve in athletes: an echocardiographic follow up.**

Laura Stefani, Sr., Roberto Mercuri, Jr., Loira Toncelli, Sr., Vlerentina Di Tante, Jr., Maria Concetta Robertina Vono, Sr., Giorgio Galietti, Sr., Sport Medicine Cenyeter, Florence, Italy

Background: Bicuspid aortic valve (BAV) is a common congenital cardiac disease in the general population and in athletes. Data on the cardiac parameters are available in non-athletic BAV population. Though BAV is compatible with sports activity, the impact that regular training may have on the heart has not yet been investigated. We followed up with echocardiography a group of competitive athletes with BAV matched with tricuspid aortic valve (TAV) group.

**Methods:** A group of 120 consecutive athletes diagnosed with BAV were followed from January 1999 to December 2005 with yearly echocardiographic evaluations. 60 of these athletes had a full 5 years of follow up. The protocol study was performed at the University Teaching Hospital Specialist Clinic of Florence (Italy). **Results:** After five years, BAV athletes showed significant progression of left ventricular dimensions and aortic diameters (tab1) despite the values remain within the range of the general non-athletic BAV populations described in previous studies. In TAV athletes, the aortic and left ventricle dimensions did not increase significantly, and remained within physiological range. **Conclusions:** There is a significant progressive increase in aortic and left ventricular myocardial segments in competitive BAV athletes as compared to TAV athletes. The rate of the progression in BAV athletes is similar to that in the non-athletic BAV population. Sports activity does not have a deleterious impact on cardiac morphology in athletes with asymptomatic BAV.

**ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts B81**

**2900-258**

**Presence of Significant PAD in Patients Assessed for Percutaneous Aortic Valve Replacement: Implications for Feasibility of the Transfemoral Approach**

Srikanth Soli, Vikram Kura, Lars Svensson, Murat Tuzcu, Samir Kapadia, Roy Greenberg, Eric Rossell, Sandra Halliburton, Paul Schenkenhagen, Cleveland Clinic, Cleveland, OH

**Background:** Percutaneous aortic valve replacement (PAVR) is an emerging treatment option for selected patients with advanced aortic stenosis (AS) and may be done from a transfemoral or transapical approach. The prevalence of significant peripheral arterial disease (PAD)/unsuitable iliofemoral anatomy and the risk population is unknown. We evaluated the utility of cardiac multi-detector computed tomography (MDCT) in identifying suitable candidates for a transfemoral approach to PAVR.

**Methods:** We evaluated consecutive patients with calcific AS who were referred for PAVR. Patients with known peripheral vascular disease were excluded. All patients were scanned on a Siemens Definition Dual Source MDCT scanner after receiving iodinated contrast. Images of the chest, abdomen, and pelvis to the level of the mid thigh were reconstructed at 3 mm slice thickness to evaluate the aorta and iliofemoral vessels. The common iliac, external iliac, and common femoral arteries were evaluated for minimal luminal diameter < 8 mm, severe calcification, presence of dense calcification at the iliac bifurcation, and angulation of the external iliac to the common and internal iliac arteries.

**Results:** 45 patients (82±7 years, 55% male) were enrolled. The mean luminal diameter of the common iliac, external iliac, and common femoral arteries were 11.2±1.7 mm, 8.9±1.1 mm, and 9.4±1.0 mm, respectively. 10 patients had a minimal luminal diameter of < 8 mm and were excluded from the transfemoral approach. An additional 5 patients had adequate luminal diameters of the iliofemoral arteries but had severe circumferential (>60%) calcification or severe calcification at the external-internal iliac bifurcation that made a transfemoral approach unsuitable. In all, 15 of 45 patients (33%) were excluded from a transfemoral approach due to unsuitable iliofemoral anatomy.

**Conclusions:** PAD is common in the high-risk patient population currently evaluated for PAVR. Cardiac MDCT is useful to identify patients who are suitable candidates for a transfemoral approach to PAVR and allows preprocedural planning of arterial access strategies.

LA-LV≤3mmHg LA-LV>3mmHg p-value

<table>
<thead>
<tr>
<th>BASELINE</th>
<th></th>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LA mean pressure</td>
<td>16.8 (6.6)</td>
<td>26.0 (6.0)</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA mean pressure</td>
<td>28.0 (11.4)</td>
<td>37.7 (10.4)</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA systolic pressure</td>
<td>43.1 (16.5)</td>
<td>59.3 (14.7)</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**2900-259**

**Balloon valvuloplasty for native isolated rheumatic tricuspid stenosis**

Suree V. Sath., Manuel Donauraj, Rituparna Shinde, Chandrashekar Makhale, Shirish MS Hiremath, Archana Sath., Siddartha Gadage, Ravij B. Seth., Purvesh Grant, Grant Medical Foundation, Ruby Hall Clinic, Pune, India

**Background:** Incidence of native rheumatic tricuspid stenosis has been found to vary from 5-30% in clinical and pathological studies in cases of rheumatic valvular heart disease. Coexisting tricuspid stenosis in patients with significant mitral stenosis is often treated with concurrent balloon tricuspid valvuloplasty. Isolated balloon tricuspid valvuloplasty without hemodynamically significant mitral stenosis has not been reported extensively. We performed isolated balloon tricuspid valvuloplasty in 12 cases of isolated rheumatic tricuspid stenosis in 12 cases.

**Methods:** We performed balloon tricuspid valvuloplasty in 12 cases of isolated rheumatic tricuspid stenosis. 8/12 cases were previously treated with balloon mitral valvuloplasty, 2 had mitral valve replacement and 2 had open mitral valvotomy. All had mild to moderate mitral valve disease not requiring intervention. Inoue balloon was used in 8 cases. We used Mansfield double balloon catheter with double length wire in right pulmonary artery in 4 patients. **Results:** Good immediate results obtained in all cases. The mean gradient across the tricuspid valve reduced from 11mmH2O to 1.6±0.7mmHg after balloon valvuloplasty. **Conclusions:** Isolated balloon tricuspid valvuloplasty for rheumatic tricuspid stenosis is feasible and provides good reduction in the gradient across the tricuspid valve. With improving longevity following mitral valve intervention, this subgroup should be recognized and appropriately treated.

**2900-254**

**N-Acetylcysteine Enhanced Angiographic Contrast Provides Cardiorenal Protection**

Markus Meyer, Martin LeWinter, Stephen Bell, Zengyi Chen, Donald Selby, Dinender K. Singla, Harold L. Dauerman, University of Vermont College of Medicine, Burlington, VT

**Background:** We hypothesized that intravenous administration of N-Acetylcysteine (NAC) mixed with a radiographic contrast agent could provide both cardiac and renal protection in a pig model of ischemia-reperfusion.
Methods: Twelve pigs underwent coronary angiography followed by one hour of a mid left anterior descending artery (LAD) balloon occlusion. Each pig received a total of 200ml of iodixanol 320mg/l (in seven animals, NAC (1.13g/kg) was added to the contrast. The following end points were analyzed 24 hours after restoration of blood flow: area of myocardium at risk for myocardial infarction (MI), infarct size and morphology, apoptosis, ventricular arrhythmias and renal function.

Results: Intracoronary enhanced contrast alone did not result in arrhythmias or hemodynamic instability. There was no significant difference in the area at risk between control animals receiving contrast-only (C) and animals receiving NAC enhanced contrast (C-NAC). In comparison, MI size in C-NAC treated animals was significantly smaller compared with the controls (8.2±3.3% of ventricular weight versus 13.9±4.5%, p<0.05). In the control group 92 percent of the area at risk demonstrated a MI compared with 77 percent risk area in the C-NAC group (p<0.01). These observations may explain a higher incidence of peri-procedural ventricular arrhythmias in the C-NAC group (C-NAC: 6/7 animals; C: 1/5 animals). In addition, histological comparison of C-NAC versus C revealed that apoptosis in the area at risk was 20-fold reduced in C-NAC and C-NAC administration blunted the rise in serum creatinine levels from 37 percent in the control group to 15 percent in the C-NAC group (p<0.05).

Conclusions: N-Acetylcysteine enhanced contrast medium reduced MI size by about 15% toward an increase in the incidence of CIN was observed with increasing fluid. This strategy might be beneficial in patients undergoing coronary interventions.

Iodixanol versus Iopromide for Coronary Angiography

Background: Inflammation may play a central role in the pathophysiology of contrast-induced nephropathy (CIN). Although sirolimus-eluting stents (SES) have been shown to markedly reduce restenosis, there are still controversies about the safety issues in high-risk patients. The aim of this study is to compare long-term outcomes and stent thrombosis (ST) rates in patients with end-stage renal disease (ESRD) following SES versus bare-metal stent (BMS) implantation.

Methods: Between 2003 and 2005, a total 58 patient (80 lesions) with ESRD undergoing SES implantation (SES-ESRD group) were enrolled and compared with 50 patients (54 lesions) with ESRD receiving BMS (BMS-ESRD group) in a Korean Multicenter Angioplasty Team (KOMATE) Registry. We assessed the incidences of major adverse cardiac events (MACE; death, myocardial infarction (MI), target-vessel revascularization (TVR)) and ST by Academic Research Consortium definition, of the 2 groups.

Results: Although SES-ESRD group had more diabetes and longer lesion length with smaller vessel diameter, 1-year MACE rate of this group was significantly lower than that of BMS-ESRD group (See Table). However, during the long-term follow-up (mean; 34±19.9 months), there were no statistical differences in the mortality, overall MACE, and cumulative 3-year MACE-free survival rates between the 2 groups. The incidences of definite or probable ST were similar between both groups (See Table).

Conclusions: The use of SES did not increase the risks of death, overall MACE, and ST in patients with ESRD during the long-term follow-up, as compared with BMS.

Iloprost prevents Contrast-Induced Nephropathy in high-risk patients undergoing a coronary procedure.

Methods: Consecutive patients (n=203) undergoing coronary angiography and/or intervention who had a serum creatinine concentration ≥1.4 mg/dL, were randomized to receive intravenous iloprost at 1 ng/kg/min or placebo, beginning 30-90 minutes before and terminating 4 hours after the procedure. Iloprost was titrated to a maximum of 10 ng/kg/min.

Results: The patient randomized to placebo died before contrast exposure. None of iloprost requiring renal replacement therapy occurred during follow-up. The mean volume of contrast agent used in the study patients was 234±110 mL. Iloprost was given in 8 of the 102 patients (8%) in the iloprost group and in 24 of the 103 patients (23%) in the placebo group (p=0.05). Iloprost reduced the mean serum creatinine concentration increased significantly in the placebo group (from 1.59±0.49 to 1.73±0.66 mg/dL, p=0.001) but not in the iloprost group (from 1.63±0.49 to 1.66±0.73 mg/dL, p=0.51).

Conclusions: Prophylactic intravenous administration of the prostacyclin analogue iloprost appears to prevent CIN in high-risk patients undergoing a coronary procedure.
Risk Scoring System for Prediction of Contrast Induced Nephropathy In Patients With Preexisting Renal Impairment Undergoing Percutaneous Coronary Intervention

Eric Chong, Shen Liang, Kian Keong Poh, Huay Cheem Tan, The Heart Institute, National University Hospital, Singapore, Singapore, Biostatistic Unit, National University, Singapore, Singapore

Background: Renal impairment is the most recognized risk factor for developing contrast nephropathy (CIN) post percutaneous coronary intervention (PCI). We examine other risk factors in this group and develop a risk model for prediction of CIN.

Methods: A cohort of 770 patients with existing renal impairment (estimated glomerular filtration rate (GFR) < 60 ml/min/1.73m²) who received prophyllactic saline hydration and oral N-acetylcysteine while undergoing PCI between May 2001 to March 2007 in our centre were enrolled. The study endpoint CIN, is defined as >25% increase from baseline creatinine within 48 hours post PCI.

Results: Despite prophylaxis, CIN occurred in 11.4% of patients. Uni-variate tests showed that clinical predictors for CIN were age (OR 1.59 95% CI 1.20-2.02 p=0.049), anemia with hemoglobin < 11g/dl (OR 2.26 95% CI 1.41 - 3.61 p=0.001), post PCI creatinine kinase rise (OR 1.12 95% CI 1.07 - 1.16 for every 500 UI rise p=0.001), systolic hypotension with blood pressure <100mmHg (OR 2.53 95% CI 1.16 - 5.62 p=0.016), contrast volume (p=0.032) for every 50ml use. The incidence of CIN was significantly higher in patients with existing severe renal failure (6.3%, 17.4%, 40.8% in mild, moderate, severely impaired renal groups respectively, p=0.001). A prediction model was developed based on the findings:

<table>
<thead>
<tr>
<th>Clinical Predictors</th>
<th>Assigned score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 70</td>
<td>1</td>
</tr>
<tr>
<td>GFR (ml/min/1.73m²)</td>
<td>0 - 60</td>
</tr>
<tr>
<td>Mild (40 - 60)</td>
<td>2</td>
</tr>
<tr>
<td>Moderate (20 - 40)</td>
<td>4</td>
</tr>
<tr>
<td>Severe (&lt; 20)</td>
<td>6</td>
</tr>
<tr>
<td>CK (every 500 ul increase)</td>
<td>0.5</td>
</tr>
<tr>
<td>Contrast volume (every 50ml increase)</td>
<td>0.25</td>
</tr>
<tr>
<td>Score range</td>
<td>Risk, incident rate of CIN</td>
</tr>
<tr>
<td>0 - 4</td>
<td>Low, 2.0%</td>
</tr>
<tr>
<td>4.5 - 6.5</td>
<td>Moderate, 12.4%</td>
</tr>
<tr>
<td>7 - 8</td>
<td>High, 35.0%</td>
</tr>
<tr>
<td>8.5 and above</td>
<td>Extremely high, 97.4%</td>
</tr>
</tbody>
</table>

Conclusions: Patients with impaired renal function undergoing PCI are at high risk of developing CIN despite traditional prophylaxis. A model of risk prediction could be used to predict its occurrence.

Previous Chronic Renal Failure Affects Long-term Mortality in Patients With Cholesterol Crystal Embolization After Percutaneous Coronary Intervention

Yasushi Fuku, Kazuaki Mitsudosu, Tsuyoshi Goto, Kazushige Kadota, Satoki Fuji, Hiroyuki Yamamoto, kurashiki central hospital, kurashiki, Japan

Introduction: Little is known about the correlation of baseline renal function with the clinical outcomes in patients with cholesterol crystal embolization (CCE) after percutaneous coronary intervention (PCI). We evaluated the impact of previous chronic renal failure on long-term mortality in patients with CCE after PCI.

Methods: Clinical records of patients with clinical or histopathologic diagnoses of CCE seen from January 1999 through December 2006 at our hospital were reviewed. The clinical diagnosis of CCE was made when patients had peripheral cutaneous involvement (livedo reticularis, blue toe syndrome, and digital gangrene) with eosinophilia or renal dysfunction. Patients with history of diabetes mellitus (DM) were significant predictors. In patients with baseline renal impairment who received prophylaxis, baseline GFR confers significant risk. CIN occurred in 6.3%, 17.4% and 40.8% in patients with GFR of 40-60, 20-40 and < 20 ml/min/1.73m² respectively, p<0.001. Other significant predictors of CIN in this group include age, periprocedural MI and hypotension.

<table>
<thead>
<tr>
<th>Clinical predictors</th>
<th>Normal Baseline Renal Function (Odd ratio)</th>
<th>p value</th>
<th>Impaired Baseline Renal Function (Odd ratio)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.67(1.07-2.58)</td>
<td>0.02</td>
<td>1.59(1.02-2.52)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pre-PCI creatinine</td>
<td>1.43(1.04-1.96)</td>
<td>0.03</td>
<td>2.74(1.75-3.61)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female gender</td>
<td>2.07(1.48-2.9)</td>
<td>&lt;0.001</td>
<td>Not Sig</td>
<td></td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>1.41(1.03-1.90)</td>
<td>0.03</td>
<td>Not Sig</td>
<td></td>
</tr>
<tr>
<td>Antigen (Hemoglobin &lt;11g/dl)</td>
<td>1.82(1.04-3.16)</td>
<td>Not Sig</td>
<td>2.26(1.41-3.61)</td>
<td>0.001</td>
</tr>
<tr>
<td>Systolic BP &lt; 100 mmHg</td>
<td>Not Sig</td>
<td>Not Sig</td>
<td>2.53(1.16-5.52)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Conclusion: Different predictors of CIN exist between patients with and without existing renal impairment. DM is a predictor in those with normal renal function, whereas baseline GFR and periprocedural hypotension are important in those with impaired renal function.
Impact of renal insufficiency degrees, and mode of initial coronary revascularization on the long-term outcome for multi-vessel diseases without left main trunk diseases: from the Coronary Revascularization Demonstrating Effects of Multi-modal Treatment (CREDO-Kyoto) Ryuji Taniguchi, Natsuhiko Ebara, Satoshi Shizuka, Yoshishumi Haruna, Mitsuo Abe, Tatsuhiko Doi, Yutaka Furukawa, Yoshaki Takatsi, Shinichi Nomoto, Ryuji Nohara, Mitsuo Matsuda, Masahiko Ono, Misao Yamauchi, Takeshi Morimoto, Satoshi Teramukai, Masanori Fukushima, Toru Kita, Takeshi Kimura, Hyogo Prefectural Amagasaki Hospital, Hyogo, Japan.

Background: End-stage renal disease is an established predictor in patients (pts) undergoing coronary revascularization (CR). However, the differences in the long-term outcome of such pts depending on the severity of renal insufficiency (RI) and on the mode of CR have not been clearly shown.

Methods: CREDO-Kyoto is a multi-center registry in pts undergoing first CR (PCI or CAGB). Among 9877 pts enrolled (5564 PCI; 4286 [85% stent use], CAGB 1978 [39% off-pump]) pts were identified to have multi-vessel diseases excluding pts with left main trunk diseases. The study subjects were divided into the 5 groups by their renal functions; normal function (80 mL/min>GFR, n=1024) mild RI (60>GFR>80, n=2111), moderate RI (30>GFR>60, n=1857), severe RI (GFR<30 without hemodialysis, HD), (n=303), (n=265). Incidence of all cause death was compared.

Results: During follow-up (median period = 42.6 months), 670 pts died. There is no difference of all cause mortality rate between PCI and CAGB in all 5 groups. Mortality rates were significantly higher with each increasing degree of RI irrespective of mode of CR (p<0.0001). Multivariate analysis indicated that groups with a lower estimated GFR had worse outcomes than the normal function (reference) group (table) and the mode of CR had no influence on all cause mortality in varying degrees of RI.

Conclusions: In this cohort, RI degrees are strong predictors of all cause death in pts undergoing CR and the mode of CR had no influence on all cause mortality in pts with varying degrees of RI.

<table>
<thead>
<tr>
<th>Renal Function</th>
<th>Univariate</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Function</td>
<td>1.000*10</td>
<td>1.000*10</td>
</tr>
<tr>
<td>GFR&lt;30</td>
<td>1.11</td>
<td>1.11</td>
</tr>
<tr>
<td>GFR&lt;60</td>
<td>1.20</td>
<td>1.20</td>
</tr>
<tr>
<td>GFR&lt;90</td>
<td>1.32</td>
<td>1.32</td>
</tr>
<tr>
<td>GFR&lt;100</td>
<td>1.48</td>
<td>1.48</td>
</tr>
</tbody>
</table>

(Adjusted for age, sex, prior heart failure, prior myocardial infarction, prior ischemic stroke, prior peripheral arterial disease, diabetes, cancer, chronic obstructive pulmonary disease, chronic liver disease, anemia, current smoker, left ventricular dysfunction, mode of revascularization.)

Effects of Continuous Hemofiltration During Coronary Catherization on Renal Function in Patients with Chronic Kidney Disease

Yoshimiari An, Kouchi Tamita, Kite Kim, Takashi Kitai, Takahumi Yamane, Minako Katayama, Tomoyuki Oda, Natsuhiko Ebara, Makoto Kinoshita, Shuichiro Kaji, Atsushi Yamada, Tomohiro Takimi, Kazuaki Tanaka, Yasuhide Ikemori, Yasuyoshi Kihara, Yosuaki Matsushima, Yosuaki Matsushima, Ichrui Sakaki, Kobe City Center General Hospital, Kobe, Japan.

Background: Contrast-induced nephropathy (CIN) is one of the major complications of coronary catheter procedures in patients with chronic kidney disease (CKD). The effect of continuous hemofiltration (CHDF) and that of hemodialysis (HD) on the occurrence of CIN has not been fully elucidated. The aim of this study was to determine the efficiency of CHDF during the procedure on the occurrence of CIN as compared with prophylactic hemodialysis.

Methods: We investigated 28 consecutive patients with CKD (estimated GFR<60 mL/min/1.73m2) undergoing CHDF during the procedure (CHDF group; n=14) undergoing HD after the procedure (HD group; n=14). We intravenously administered isonitric-saline before and after procedures to all patients. CIN was defined as an increase in the serum creatinine level more than 0.5mg/dL or 25% above the baseline within 48 hours. Nondiagnostic and nonspecifically contrast media was used during the procedure. CHDF was performed through a double-lumen intravenous femoral catheter during the procedure, and HD was performed without fluid removal in the same way about three hours as soon as technically possible after the procedure.

Results: Mean estimated CHDF group and the HD group (26.8±10.7 mL/min/1.73m2 vs. 24.4±7.8 mL/min/1.73m2; p=0.433). The amount of contrast media was also similar between the two groups (140.5±68.1 mL vs. 140.3±64.1 mL, respectively; p=0.238). Among the CHDF group, no patients were suffered from CIN nor required regular hemodialysis at one month later. However, among the HD group, 4 of 14 patients (28.6%) were suffered from CIN and 1 patient required temporary hemodialysis during the hospitalization.

Conclusions: While CIN is common in patients with renal insufficiency, no patients among the CHDF group were suffered from CIN. CHDF during coronary catheter procedures is more effective than HD after the procedures on the prevention from CIN in patients with CKD. Advanced application of CHDF during coronary catheter procedures may prevent the deterioration of renal function due to CIN in patients with limited renal function.

The Association of Race/Ethnicity with Contrast Induced Nephropathy in Patients Undergoing Percutaneous Coronary Intervention


Background: Important racial/ethnic differences in chronic kidney disease have been described in patients with heart disease. However, little is known about the effect of race/ethnicity on the development of contrast induced nephropathy (CIN).

Methods: We prospectively identified 875 patients undergoing PCI between 2004-2007. CIN was defined as a 25% increase in serum creatinine level within 48 hours of the procedure. We developed unadjusted and adjusted models with development of CIN as the dependent variable and race/ethnicity as the independent variable. Caucasian race was used as the referent group for all analysis.

Results: Of the 857 patients, 59% were Caucasian, 11.4% Hispanic, 5.4% African American, and 24% were Other. The incidence of CIN for Caucasian, Hispanic, African American and Other were 4.6%, 14.0%, 13.6%, and 8.2%, respectively (p<0.001). Unadjusted and adjusted logistic regression models for contrast nephropathy appear in the Table.

<table>
<thead>
<tr>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American vs. White</td>
<td>3.14</td>
</tr>
<tr>
<td>Hispanic vs. White</td>
<td>3.54</td>
</tr>
<tr>
<td>Other vs. White</td>
<td>1.88</td>
</tr>
<tr>
<td>Adjusted*</td>
<td>1.88</td>
</tr>
<tr>
<td>African American vs. White</td>
<td>3.15</td>
</tr>
<tr>
<td>Hispanic vs. White</td>
<td>2.91</td>
</tr>
<tr>
<td>Other vs. White</td>
<td>1.81</td>
</tr>
</tbody>
</table>

*Adjusted for: age, gender, baseline GFR, body mass index, diabetes, congestive heart failure, myocardial infarction, days hospitalized, contrast type, contrast volume, N-acetylcysteine use, and systolic blood pressure.

Conclusion: There is marked racial variation in the incidence of CIN among patients undergoing percutaneous coronary interventions. Hispanics and African Americans are at particularly high-risk for this serious complication.

Percent Change in Renal Function After Contrast Exposure is Associated with Long-term Adverse Events in Patients Undergoing Percutaneous Coronary Interventions


Background: Data are limited on long-term outcomes of patients undergoing percutaneous coronary intervention (PCI) by periprocedural change in renal function.

Methods: We identified 778 consecutive patients with an estimated GFR <60 mL/
The mean age of the cohort was 71.6 +/- 9.8 years, and 43% were female. PCI was performed in the setting of an acute myocardial infarction (MI) in 43% of patients. Clopidogrel pre-treatment reduces the incidence of periprocedural events. We prospectively enrolled 419 consecutive patients (291 men, age 63±31yrs) undergoing elective percutaneous coronary intervention (PCI) were randomized to receive a 75mg or 150mg daily maintenance dose of clopidogrel for 30 days; afterwards, patients resumed 75mg dosing. All patients were on low dose aspirin. Platelet aggregation (PA) was performed using light transmittance aggregometry following ADP (20μM/80μL and 5μM/80μL) stimuli at 2 time points: 30 days after randomization (T1) and 30 days after resuming 75mg dosing (T2).

Results: There were no differences in baseline demographics observed between patients randomized to clopidogrel 75mg (n=20) or 150mg (n=20). At T1, patients randomized to clopidogrel 150mg had lower PA following 20μM/80μL ADP stimuli compared to patients on clopidogrel 75mg (52±10% vs 63±11%; p=0.002; primary endpoint). At T2, once all patients resumed 75mg dosing, there were no differences in PA between the 2 groups: 20μM/80μL ADP stimuli (61±10% vs 63±11%; p=ns). Inhibition of PA (IPA) calculated between the 2 time points in each group was significantly higher in the 150mg group following 20μM/80μL ADP stimuli (15±12% vs 4±17%; p=0.001). Patients with high platelet reactivity while on a 75mg dose (>68% using 20μg/L ADP), defined as the upper tertile of ADP-induced platelet aggregation in the steady state phase of clopidogrel 75mg therapy, had greater responsiveness to 150mg compared to patients with moderate or low platelet reactivity (p=0.01). Parallel findings were observed for all platelet function analysis using 5μM/80μL ADP stimuli. No bleeding events occurred.

Conclusions: A 150mg maintenance dose regimen of clopidogrel is associated with reduced platelet reactivity and enhanced platelet inhibition compared to that achieved with the currently recommended 75 mg maintenance dose in patients undergoing elective PCI.

**2000-274**

**Impact of High Clopidogrel Maintenance Dosing in Patients Undergoing Elective Percutaneous Coronary Interventions: Results of a Randomized Study**

Dominic J Angiolillo, Esther Bernardo, Marco A. Costa, Jorge Palazuelos, Bhaloo Desai, Ian Weisberg, Fernando Alfonso, Luis A. Guzman, Liudmila Rozum, Piers Capranzano, Rosana Hernández-Antolín, Martin Z. Zenni, Carlos Macaya, Antonio Fernandez-Ortiz, Theodore A. Bass, University of Florida-Shands Jacksonville, Jacksonville, FL, San Carlos University Hospital, Madrid, Spain

Background: In clopidogrel treated patients, inadequate dosing contributes to suboptimal antiplatelet effects. Numerous reports have demonstrated that high loading dose regimens improve clopidogrel-induced antiplatelet effects. However, limited data is available on the functional impact of a high maintenance dose regimen.

Methods: This is a prospective, randomized, platelet function study. Patients (n=40) undergoing elective percutaneous coronary intervention (PCI) were randomized to receive a 75mg or 150mg daily maintenance dose of clopidogrel for 30 days; afterwards, patients resumed 75mg dosing. All patients were on low dose aspirin. Platelet aggregation (PA) was performed using light transmittance aggregometry following ADP (20μM/80μL and 5μM/80μL) stimuli at 2 time points: 30 days after randomization (T1) and 30 days after resuming 75mg dosing (T2).

Results: There were no differences in baseline demographics observed between patients randomized to clopidogrel 75mg (n=20) or 150mg (n=20). At T1, patients randomized to clopidogrel 150mg had lower PA following 20μM/80μL ADP stimuli compared to patients on clopidogrel 75mg (52±10% vs 63±11%; p=0.002; primary endpoint). At T2, once all patients resumed 75mg dosing, there were no differences in PA between the 2 groups: 20μM/80μL ADP stimuli (61±10% vs 63±11%; p=ns). Inhibition of PA (IPA) calculated between the 2 time points in each group was significantly higher in the 150mg group following 20μM/80μL ADP stimuli (15±12% vs 4±17%; p=0.001). Patients with high platelet reactivity while on a 75mg dose (>68% using 20μg/L ADP), defined as the upper tertile of ADP-induced platelet aggregation in the steady state phase of clopidogrel 75mg therapy, had greater responsiveness to 150mg compared to patients with moderate or low platelet reactivity (p=0.01). Parallel findings were observed for all platelet function analysis using 5μM/80μL ADP stimuli. No bleeding events occurred.

Conclusions: A 150mg maintenance dose regimen of clopidogrel is associated with reduced platelet reactivity and enhanced platelet inhibition compared to that achieved with the currently recommended 75 mg maintenance dose in patients undergoing elective PCI.
### Effects of clopidogrel and aspirin in combination versus aspirin alone on platelet activation and major receptor expression in diabetic patients: The PLavix versus aspirin alone on platelet activation and major receptor expression in diabetic patients: The PLavix use for Treatment Of Diabetes (PLUTO-Diabetes) Trial.

**Victor Sametreyu, Alex Malinin, Alex Pokoz, Gregory Barness, Dan Hanley, John Harris, Medicine, University of Towson, MD**

**Background:** Clopidogrel is widely used in diabetic patients after vascular events; however, the ability of this thienopyridine to yield additional antiplatelet protection on top of aspirin has never been explored in a controlled study with comprehensive assessment of platelet activity. The objective of this study was to compare the antiplatelet profiles of clopidogrel + aspirin in combination (C+ASA) versus aspirin alone (ASA) in patients with Type 2 diabetes mellitus.

**Methods:** Seventy patients with documented diabetes already treated with antecedent aspirin were randomly assigned to C+ASA or ASA in the PLUTO-Diabetes trial. Platelet studies included ADP-, collagen- and arachidonic acid-induced aggregometry, PFA-100 and Utegra analyzers, and expression of 6 major receptors by flow cytometry at baseline and at 30 days after randomization.

**Results:** There were no differences in the baseline clinical and platelet characteristics between the C+ASA and ASA groups, or significant change in platelet biomarkers in the ASA group, except for diminished collagen-induced aggregation (p=0.02). In contrast, when compared with ASA group, therapy with C+ASA resulted in significant inhibition of platelet activity assessed by ADP-aggregation (p<0.0001); closure time prolongation (p=0.0003), and reduction of platelet activation units with Utegra (p=0.0001); expression of PECAM-1 (p=0.002), GPIIb/IIIa antigen (p=0.0002), and activity (p=0.0001).

**Conclusion:** Treatment with C+ASA for one month provides significantly greater inhibition of platelet activity than ASA alone in diabetics with Type 2 diabetes mellitus.

### Enoxaparin Clotting Times Monitoring During Percutaneous Coronary Intervention: The Sensitivity of Point of Care Tests to Different Dosages

**Jose G. Diez, Jay Alista, Soumaya El Roubey, Texas Heart Institute / Baylor College of Medicine, Houston, TX, ITC, Edison, NJ**

**Background:** Experience has been obtained on use of enoxaparin (EXP) during percutaneous coronary interventions (PCI). EXP acceptance during PCI has been limited by an increase in bleeding events and lack of monitoring. Monitoring may be required for high risk populations and/or transition from subcutaneous to intravenous administration before PCI.

**Objective:** To evaluate the sensitivity of 2 dot based point of care tests (POCT) Hemochron Signature™ HEMOXINXTM (H-C Titan Rapidpoint Enox® (CC) to different dosages of enoxaparin in patients (pts) undergoing PCI. **Methods:** Consecutive series of 28 pts received one IV bolus (see table). The 0.3 mg/kg IV dose was given to pts on prior subcutaneous (SC) EXP for ACS. Blood draws for POCT and chromogenic anti-Xa assay were obtained prior to PCI and post bolus. Results: Both CCT and H-C Titan achieved peak response 10 min post bolus. At any dose, peak H-C and CCT corresponded to therapeutic anti-Xa levels (~0.5 U/ml) in 100% of pts. The ranges for H-C and anti-Xa levels increased with EXP in a dose dependent fashion. Only pts on prior SC dosing for ACS yielded detectable anti-Xa level at baseline (0.18-0.45 U/ml) which corresponded to CCT and H-C of 183-309 and 62-127 secs respectively. Anti-Xa correlation was r=0.81 for H-C and 0.63 for CCT. There were no TIMI major or minor bleeding events.

<table>
<thead>
<tr>
<th>Dose (mg/kg)</th>
<th>0.30</th>
<th>0.50</th>
<th>0.75</th>
<th>1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range Peak Anti-Xa (U/ml)</td>
<td>0.50-0.69</td>
<td>0.64-0.69</td>
<td>0.68-0.84</td>
<td>0.85-1.89</td>
</tr>
<tr>
<td>Range Peak HEMOXINX (sec)</td>
<td>80-250</td>
<td>112-352</td>
<td>178-643</td>
<td>325-871</td>
</tr>
<tr>
<td>Range Peak Enox CT (sec)</td>
<td>427-647</td>
<td>340-609</td>
<td>538.1-538.3</td>
<td>398-654</td>
</tr>
<tr>
<td># of patients</td>
<td>6</td>
<td>2</td>
<td>3</td>
<td>18</td>
</tr>
</tbody>
</table>

**Conclusion:** POCT methods yield appropriate CT increase with EXP. Adequate monitoring may help to optimize outcomes by decreasing bleeding events while assuring anticoagulation during PCI.

### First Evidence of the Stepwise Relation Between On-Treatment Platelet Reactivity to ADP and Post-PCI Ischemic Events: First Evidence for a Potential Therapeutic Target for PL2Y12 Inhibitors

**Paul A. Gurbel, Kevin P. Bleden, Joseph DiChiaro, Mark J. Antonino, Thomas Suarez, Kutleva S. Tantir, Sinei Center For Thrombosis Research, Baltimore, MD**

**Background:** The relation between platelet reactivity to ADP (ADP-R) and ischemic event occurrence is unclear. It is unknown whether events begin to occur after a cutpoint in a stepwise fashion.

**Methods:** We examined whether there was a threshold level of on-treatment ADP-R measured by light transmission aggregometry assessment that was associated with the onset of ischemic events after percutaneous coronary intervention (PCI). Data from 4 clinical studies (Clopidogrel loading with epibatidine to arrest the reactivity of platelets (CLEAR PLATELETS I and II); Platelet reactivity in patients and recurrent events post-stenting (PREPARE POST-STEINTING), and Clopidogrel effect on platelets in patients with stent thrombosis (CREST) conducted at our center were analyzed.

**Results:** The age was 65±12 years. ADP-R (20uM) was 46±14% in patients without ischemia and 60±13% with ischemic events. Based on cumulative distribution curve analysis, we observed a threshold for the occurrence of periprocedural myocardial infarction (~50% mean platelet aggregation over 24 hours) for long-term ischemic events defined as the occurrence of death secondary to cardiovascular cause, myocardial infarction, unstable angina, and stroke that required rehospitalization (~48%-20uM ADP) and stent thrombosis (~40%-20uM ADP). ADP-R >40% identified 95% of all ischemic events.

**Conclusions:** A threshold of platelet reactivity to ADP exists that can identify 95% of patients at risk for post-PCI ischemic events, including stent thrombosis. These data have important implications for future prospective investigations to explore the concept of a therapeutic target for P2Y12 inhibitors.

### Determining the Optimal Duration of Dual Anti-platelet Therapy following Implantation of Drug-Eluting Stents by the Predictive Value of Clopidogrel Cessation for Stent Thrombosis

**Probul Roy, Rebecca Torgerson, Teru Okabe, Tina L. Pinto Sirottow, Daniel H. Steinberg, Kimberly Smith, Zhern Lu, Well F. Satter, Kenneth M. Kent, William O. Suddath, Augusto D. Pichard, Ron Waksman, Washington Hospital Center, Washington, DC**

**Background:** The optimal duration of dual anti-platelet therapy post drug-eluting stent (DES) implantation remains uncertain. Prolonged therapy remains limited by an increased bleeding risk. This study aimed to determine the predictive value of clopidogrel cessation for stent thrombosis (ST) over time.

**Methods:** Clinical and procedural characteristics of 61 patients who re-presented with definite stent thrombosis following successful DES implantation were compared with a cohort of 2688 unselected patients who remained free of ST. Predictors of cumulative ST were determined at 1, 6 and 12 months using the proportional hazards model.

**Results:** Patients with ST were more likely to be on dialysis (8.3% vs. 2.1% p=0.009) and have worse left ventricular function (40±16% vs. 48±14% p=0.002). Left anterior descending artery (50.0% vs. 37.1% p=0.02) and in-stent restenotic (12.2% vs.4.1% p=0.04) lesions were more common in patients with ST. ST group received more stents (2.0±1.1 vs. 1.6±0.8 p=0.01) and less intravascular ultrasound guidance (48.6% vs. 65.9% p=0.002). Independent predictors of cumulative ST are presented below. Clopidogrel cessation was no longer predictive of ST at 12 months. 73.8% of ST patients were clopidogrel complier at the time of presentation.

**Conclusion:** Clopidogrel compliance is not prohibitive of ST. Furthermore, clopidogrel cessation is not predictive of cumulative ST at 12 months. These findings question prolonged dual anti-platelet therapy beyond 12 months.
The Risk of Bleeding on Dual Antiplatelet Therapy After Drug-eluting Stent Implantation

Azeem Latib, Nuccia Morici, John Cosgrave, Asif Qasim, Flavio Airoldi, Nedy Brambilla, Erminio Bonizzoni, Cosmo Godino, Renata Rogacka, Davide Tavano, Enrico Romagnoli, Valeria Magni, Aldice Cheffo, Matteo Montorfano, Tiziana G. Aranuza, Francesco Bedogni, Alfredo Castelli, Carlos Briguori, Antonio Colombo, San Raffaele Scientific Institute, Milan, Italy, EMO Centro Cuore Columbus, Milan, Italy

Background: Prolonged periods of dual antiplatelet therapy (DAT) are currently recommended to prevent late drug-eluting stent (DES) thrombosis. The aim of this study was to assess the risk of bleeding associated with such prolongation in a large real-world population.

Methods: Observational cohort study examining 2355 consecutive patients undergoing successful DES implantation at 4 hospitals in Italy between June 2002 and December 2004. Bleeding events occurring on DAT and warfarin or in the first 30 days from stent implantation were excluded.

Results: The overall bleeding rate was 1.9% (45 patients) with major bleeding in 19 patients (0.8%) and minor bleeding in 26 patients (1.1%). The median time from stent implantation to any bleeding complication was 216 days (interquartile range, 97–396 days).

The median duration of DAT was 209 days (interquartile range, 179–444). Independent predictors of bleeding were: DAT (HR: 19.8; 95% CI: 3.96-106.34, p<0.001) and age < 65 years (HR: 2.15; CI 95% 1.16-4.00; P=0.02). In patients on DAT, the incidence rate of any bleeding event between 30 days and 18 months was 2.57 per 100 person-years (95% CI, 1.83-3.48), while the rate of major bleeding was 1.10 per 100 person-years (95% CI, 0.65-1.74). The risk of bleeding on DAT remained constant over the 18 month follow-up period (See Figure).

Conclusion: The risk of major and minor bleeding on DAT occurs at a constant rate up to 18 months with a very low risk of major bleeding. DAT and older age are independent predictors of bleeding.

A Comparison of Heparin Without Glycoprotein IIb/IIIa Inhibition Versus Bivalirudin in Elective Percutaneous Coronary Intervention

Christopher L. F. Gade, Dmitry N. Feldman, Michael Ross, Nichole Polin, Geoffrey Bergman, S. Chiu Wong, Robert M. Minutello, NY Presbytarian Hospital, New York, NY

Background: Recent evaluation of anti-coagulation strategies for low-intermediate risk patients undergoing percutaneous coronary intervention (PCI) demonstrate no differences in outcomes when comparing strategies of heparin plus GP IIb/IIIa inhibitors to bivalirudin. The efficacy of bivalirudin as an antithrombin agent in PCI was largely demonstrated in trials comparing it to heparin plus GP IIb/IIIa inhibitors. We compared short and long term outcomes in patients undergoing elective angioplasty and receiving intra-procedural bivalirudin vs. those receiving heparin alone.

Methods: We used the Cornell Angioplasty Registry to study 1222 patients undergoing elective PCI with intra-procedural use of only bivalirudin or bivalirudin. Patients with acute coronary syndrome within the preceding 14 days, chronic total occlusion or apriori contraindication to either heparin or bivalirudin were excluded.

Results: A total of 804 patients (65.8%) received bivalirudin and 418 patients (34.2%) received heparin alone. There was no in-hospital mortality. The incidence of in-hospital myocardial infarction (MI) (5.5% vs. 5.6%, p=ns), and major adverse cardiac and cerebrovascular events (MACCE) defined as in-hospital death, MI, stroke, emergent CABG or PCI (6.2% vs. 6.5%, p=ns) were similar in the bivalirudin and heparin groups respectively. The incidence of major (0.37% vs. 0.24%, p=ns) and minor bleeding (3.6% vs. 5.9%, p=0.082) were also not significantly different. At a mean clinical follow-up of 20.1 ± 8.7 months, there were 36 (4.5%) deaths in the bivalirudin group versus 16 (3.8%) in the heparin group (p=ns). Multivariate Cox analysis, showed neither bivalirudin nor heparin use to be independent predictors of short or long term adverse clinical outcomes.

Conclusions: When comparing peri-procedural antiagulation strategies of bivalirudin versus heparin alone, there were no significant differences in short term or long term clinical and safety outcomes and in long term mortality in patients undergoing elective angioplasty.

The Novel Factor Vila/Tissue Factor Inhibitor, Recombinant Nematode Anticoagulant Protein C2, Alters PT/INR in Dose-Dependent Manner Proportionate with Plasma Concentration in Patients with nSTE-ACS: Data from the ANTHEM-TIMI 32 Trial

Vibhuti N. Singh, Stephen Wiviott, Daniel Simon, Marc Schweiger, Massoud Leesar, Bergman, S. Chiu Wong, Robert M. Minutello, NY Presbyterian Hospital, New York, NY

Background: ACS involves tissue factor (TF) release and thrombosis yet unaddressed in primary PCI. Peri-procedural TF may affect the risk of major bleeding. The efficacy of bivalirudin as an antithrombin agent in PCI was largely demonstrated in trials comparing it to heparin plus GP IIb/IIIa inhibitors. Bivalirudin reduces ischemia and improves clinical outcomes when compared to heparin alone. The efficacy of bivalirudin as an antithrombin agent in PCI was largely demonstrated in trials comparing it to heparin plus GP IIb/IIIa inhibitors. Bivalirudin reduces ischemia and improves clinical outcomes when compared to heparin alone.

Results: Ascending doses of rNAPc2 (1.5, 5, 7.5, and 10 mcg/kg) caused increasing plasma levels between 2–6 and 48h, proportionate to PT/INR, and reduces ischemia without increase in bleeding. Thus, in patients with nSTE-ACS undergoing early invasive strategy, an additional blockade of coagulation cascade at an earlier step through FXa/TA inhibition with rAPC2 appears promising to improve PT/INR and reduce ischemia on Holter (Fig 1) without significant bleeding increase. These findings require confirmation in a larger trial to determine if rAPC2 improves clinical outcomes.

SafETY AND EFFECtIVENESS OF BIVRALIRUDIN COMPARED TO EITHER ABCIXIMAB OR EPIPTAFIBRIDE IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION UNDERGOING PRIMARY ANGIOPLASTY: THE HORIZONS AMI trial

Guilio Guagliumi, Bernhard Witzenbichler, Jan Peruga, Bruce Brodie, Dariusz Dudek, Ran Kornowski, Janusz Kochman, Yaron Almogar, Dennis Nilsen, Ajay Kirtane, Helen Paris, Roxana Mehran, Gregory W. Stone, Ospedali Riuniti di Bergamo, Bergamo, Italy

Background: In the HORIZONS AMI trial, 3,602 patients with STEMI undergoing primary PCI at 123 centers in 11 countries were randomized to bivalirudin (Biv) vs. unfractionated heparin (UFH) plus glycoprotein IIb/IIIa inhibitors (GPI). Either abciximab or double bolus epifibatide could be selected as the GPI per operator discretion, and randomization was stratified by this choice. As previously reported, Biv resulted in reduced 30 day rates of major bleeding, comparable rates of composite major adverse cardiovascular events (MACE) (though with decreased cardiac mortality), and enhanced freedom from net adverse clinical events (NACE). Whether the beneficial effects of bivalirudin are independent of GPI selection has not been reported.

Methods and Results. A total of 1,915 pts (53%) were randomized in the abciximab strata, and 1,687 pts (47%) were randomized in the epifibatide strata. In the entire study population, Biv compared to UFH+GPI resulted in a 40% reduction in major bleeding (4.9% vs. 8.3%, P<0.0001), similar MACE (5.4% vs. 5.5%, P=1.0), and a 24% reduction in net adverse clinical events (NACE) (5.4% vs. 6.5%, P=0.006). In patients randomized to the GPI strata, Biv compared to UFH+GPI resulted in a 46% reduction in major bleeding (4.9% vs. 8.3%, P=0.006), independent of GPI (interaction P for these 3 endpoints = 0.79, 0.58, and 0.67 respectively).

Conclusions. In patients with AMI undergoing primary PCI, Biv monotherapy significantly reduces major bleeding and net adverse clinical events compared to UFH with either abciximab or double-bolus epifibatide.
function (interaction P value for these 3 endpoints = 0.20, 0.43, and 0.31 respectively). Conclusions. In pts with AMI undergoing primary PCI, Blv monotherapy significantly reduces major bleeding and net adverse clinical events, independent of baseline renal function.

<table>
<thead>
<tr>
<th></th>
<th>Creatinine clearance (mL/min)</th>
<th>Creatinine clearance (mL/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>tIVU (n=2783)</td>
<td>UFH+GPI (n=554)</td>
</tr>
<tr>
<td>Major</td>
<td>3.7%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACE</td>
<td>4.1%</td>
<td>4.4%</td>
</tr>
<tr>
<td></td>
<td>0.94 [0.66, 1.34]</td>
<td>1.19 [0.75, 1.88]</td>
</tr>
<tr>
<td></td>
<td>12.6%</td>
<td>10.6%</td>
</tr>
<tr>
<td></td>
<td>21.0%</td>
<td>21.2%</td>
</tr>
<tr>
<td></td>
<td>0.70 [0.55, 0.90]</td>
<td>0.99 [0.72, 1.36]</td>
</tr>
</tbody>
</table>

* MACE = death, reinfarction, ischemic TVR or stroke; **NACE = Net Adverse Clinical Events = MACE or major bleeding

**ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts**

**2900-287** Major Adverse Events in STEMI Patients Treated with Primary Angioplasty Occur More Frequently at U.S. Compared with Non U.S. Sites: Analysis from the HORIZONS AMI Trial

Bruce R. Brodie, Thomas Stuckey, Berndt Wettenich, Giulio Guagliumi, Jan Z. Peruga, Dariusz Dudek, Ren Kornowski, Franz Hartmann, George Dans, S. Chiu Wong, Helen Parise, Roxana Mehran, Gregg W. Stone, LeBauer CV Research Foundation/Moses Cone Hosp., Greensboro, NC, Columbia University Medical Center/ Cardiovascular Research Foundation, New York, NY

**Background:** Whether adverse event rates following primary PCI for AMI vary in different geographies is unknown.

**Methods:** HORIZONS AMI was an international randomized trial evaluating bivalirudin (Blv) vs unfractionated heparin + GP IIb/IIIa platelet inhibitors (UFH+GPI) in 3,602 pts with STEMI treated with primary PCI; 814 pts (22.6%) were enrolled in the US. Major endpoints adjudicated by central committee using original source documents included major bleeding, major adverse cardiovascular events (MACE), and net adverse clinical events (NACE = major bleeding or MACE).

**Results:** US compared to non US pts had more diabetes (20.8% vs 15.2%; p=0.0003), hypertension (59.1% vs 51.8%, p=0.0003), prior MI (13.8% vs 10.1%, p=0.004), prior PCI (14.9% vs 9.5%, p<0.0001), prior CABG (5.5% vs 2.2%, p<0.0001), and higher BMI (28.0 vs 26.8, p<0.0001). Age and sex were similar. MACE and major bleeding events were significantly higher at US vs OUS sites (Table). Blv compared to UFH+GPI reduced NACE to a similar extent at US sites (RR: 0.80 [0.59-1.07]) and non US sites (RR: 0.74 [0.58-0.95] (p for interaction = 0.83).

**Conclusions:** Compared to non US pts, US pts with AMI undergoing PCI had a higher risk baseline profile and reduced event-free survival. Multivariable analysis will be reported at presentation to determine whether the baseline difference explains the varying prognosis. Regardless, Blv reduced NACE compared to UFH+GPI regardless of enrolment geography.

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>Non US</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>3.8%</td>
<td>2.2%</td>
<td>0.017</td>
</tr>
<tr>
<td>Reinfarction</td>
<td>2.3%</td>
<td>1.6%</td>
<td>0.23</td>
</tr>
<tr>
<td>Ischemic TVR</td>
<td>2.8%</td>
<td>2.1%</td>
<td>0.23</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.1%</td>
<td>0.5%</td>
<td>0.09</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>12.2%</td>
<td>5.0%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MACE**</td>
<td>8.0%</td>
<td>4.7%</td>
<td>0.0006</td>
</tr>
<tr>
<td>NACE**</td>
<td>17.8%</td>
<td>8.6%</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

**2900-288** Long Term Adherence to Dual Antiplatelet Therapy and Late Adverse Cardiovascular Events

Somjit S. Brar, Amala Chirumamilla, Roxana Mehran, George Syros, Varinder Singh, Biniy Singh, Gurkan Taviloglu, Laura Higginbotham, Gregg W. Stone, Jeffrey W. Moses, Martin B. Leon, George Dans, Columbia University, New York, NY, Cardiovascular Research Foundation, New York, NY

**Objective:** Clopidogrel non-adherence is an important predictor of adverse events after PCI with drug-eluting stents. However, data are lacking on the incidence of clopidogrel non-compliance and the impact of stopping therapy after prolong administration on late adverse cardiovascular events.

**Methods:** The MATRIX registry is a single arm study initiated in 2004 to evaluate the outcomes of 3,500 consecutive patients treated with sirolimus-eluting coronary stents in an unsampled population. Post PCI, all study participants receive the same instructions on dual anti-platelet therapy; aspirin 325 mg daily for 1 month and 81 mg indefinitely thereafter, plus clopidogrel 75 mg daily for 1 year, physician discretion thereafter. Results: The mean age was 64.8 ± 11.1 yrs. 74.6 ± 19.8% were male, 33.3 ± 25.5% had prior PCI and 33.7 ± 30.7% were diabetic. Adherence to aspirin therapy at 6 months, 1 yr, and 2 yrs was: 93.5%, 92.2%, and 89.1%. Adherence to clopidogrel therapy at 6 months, 1yr, and 2 yrs was: 78.7%, 74.0%, and 60.5%. The incidence of stent thrombosis (ARC definite and probable) at 6 months, 1yr, and 2 yrs was: 0.6%, 0.6%, and 1.0%. For patients with at least 1 year of clopidogrel use compared to <1 yr of use the event rates beyond 1yr post-PCI are shown in the Table.

<table>
<thead>
<tr>
<th></th>
<th>Death</th>
<th>MI</th>
<th>Stroke</th>
<th>TVR(vessels)</th>
<th>TLR(lesions)</th>
<th>MI</th>
<th>Stroke</th>
<th>TVR(vessels)</th>
<th>TLR(lesions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR(100)</td>
<td>1%</td>
<td>5%</td>
<td>5%</td>
<td>8.4%</td>
<td>0.9%</td>
<td>5%</td>
<td>8%</td>
<td>3.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>DES(100)</td>
<td>0.23</td>
<td>6.22</td>
<td>0.95</td>
<td>0.96</td>
<td>0.86</td>
<td>0.62</td>
<td>0.41</td>
<td>0.75</td>
<td>0.15</td>
</tr>
</tbody>
</table>

**2900-290** Plaque Progression in Neighboring Segment of Stent: Comparison between Drug-Eluting Stent and Bare Metal Stent

Yong Haan Park, Sang Yeob Lee, Bong Gun Song, Soo Jin Cho, Joo-Yong Hahn, Jin Ho Choi, Seung-Hyuk Choi, Hiwon-Seol Gwon, Sang Hoon Lee, Samsung Medical Center, SEOUL, South Korea

**Background:** Drug-eluting stent (DES) implantation was reported to be associated with paradoxical persistent vasodilatation in response to exercise or acetylcine suggesting endothelial dysfunction. Endothelial dysfunction can result in atherosclerosis progression. We investigated whether plaque progression is accelerated in the neighboring segments after DES implantation compared with bare metal stent (BMS).

**Methods:** We retrospectively evaluated 133 patients with stable angina who underwent successful stenting and completed follow-up coronary angiography (CAG). Patients were grouped into BMS (n=40) and DES (n=93). Late loss of minimal luminal diameter (MLD) in-stent, proximal and distal stent edges (5 mm from stent) and proximal and distal neighboring segments (10 mm from stent edges) were measured in post-procedural and follow-up CAG.

**Results:** Baseline clinical and angiographic characteristics were similar between 2 groups. Mean follow-up duration was 265±176 days. Late loss of MLD in neighboring segments was similar in DES group, whereas not significant in BMS group. In-segment late losses were significant in both groups. But target vessel revascularization in neighboring segments was similar between 2 groups (3% vs 3.4%, p=NS).

**Conclusions:** In contrast to BMS, DES implantation seems to be associated with plaque progression in the proximal and distal neighboring segment. But the clinical implication...
Design of j-CYPHER registry was multi-center prospective enrollment of

Baseline characteristics were as follows (SES vs BA): diabetes (50.2% vs

In this large real world registry there were large differences between

Results: From May 2004 to December 2006, 62822 stents were implanted at 39691

Methods: The Swedish angiography and angioplasty registry (SCAAR) is a continuous

The study is a pre-specified analysis of Japanese multi-center post-marketing

Background: To investigate the rate of acute occlusions in a large number of different

Conclusions: In this large real world registry there were large differences between
different types of stents among both BMS and DES which reinforces the need of larger
randomized trials with head-to-head comparisons between the different stent types.

Incidence and Clinical Impact of Longitudinal Geographical Miss following Sirolimus-Eluting Stent Implantation

Background: Restenosis of sirolimus-eluting stent (SES) is sometimes attributable to a
towards higher restenosis at distal edge in lesions with balloon injury.

Restenosis rates at the edges

<table>
<thead>
<tr>
<th>Segment</th>
<th>BMS(mm)</th>
<th>p-value</th>
<th>DES(mm)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal neighboring segment</td>
<td>0.08 ± 0.41</td>
<td>0.197</td>
<td>0.21 ± 0.47</td>
<td>0.001</td>
</tr>
<tr>
<td>Proximal stent edge</td>
<td>0.22 ± 0.54</td>
<td>0.009</td>
<td>0.23 ± 0.51</td>
<td>0.001</td>
</tr>
<tr>
<td>Distal stent edge</td>
<td>0.87 ± 0.57</td>
<td>0.001</td>
<td>0.21 ± 0.45</td>
<td>0.001</td>
</tr>
<tr>
<td>Distal stent edge</td>
<td>0.27 ± 0.50</td>
<td>0.001</td>
<td>0.08 ± 0.42</td>
<td>0.096</td>
</tr>
<tr>
<td>Distal neighboring segment</td>
<td>0.02 ± 0.45</td>
<td>0.719</td>
<td>0.12 ± 0.53</td>
<td>0.042</td>
</tr>
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Siroliimus-Eluting Stent vs Balloon Angioplasty for the Treatment of Post-Sirolimus-Eluting Stent Restenosis: Insights From j-CYPHER Registry

Methods: Design of j-CYPHER registry was multi-center prospective enrolment of

Results: Baseline characteristics were as follows (SES vs BA): diabetes (50.2% vs 58.3%, p=0.04), hemodialysis (13.7% vs 17.2%, p=0.2), treatment of in-stent restenosis (17.0% vs 29.5%, p=0.0005), long lesion length (>=30mm) (26.4% vs 27.3%, p=0.8), and small vessel size (<=2.5mm) (27.7% vs 31.2%, p=0.3). During median follow up of 174 days, target lesion revascularization occurred in 9.6% (30/313) of SES-treated lesions and 25.8% (84/326) of BA-treated lesions (Log-rank p=0.001). Cox proportional hazard model showed that only an additional SES-implantation (hazard ratio (HR): 0.60, 95% confidence interval (CI): 0.48-0.74) and long lesion length (HR: 1.28, 95% CI: 1.04-1.57) were independently associated with recurrence of post-SES restenosis after adjustment (Table).

Conclusions: In our study population, SES is superior to BA for the treatment of post-SES restenosis.

Methods: The Swedish angiography and angioplasty registry (SCAAR) is a continuous

Results: All available stents on the Swedish market used at least 500 times since 2005, were

Conclusions: The Swedish angiography and angioplasty registry (SCAAR) is a continuous

ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts

Large differences in rate of clinical restenosis between different stents - Long term follow-up from the Swedish angiography and angioplasty registry (SCAAR)

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Conclusions: In this large real world registry there were large differences between
different types of stents which reinforces the need of larger randomized trials with head-to-head comparisons between different stent types.

Abstracts - SCAI-ACCi2 Interventional E-Abstracts

Background: The rate of restenosis and acute occlusion in a large number of different

Conclusions: The Swedish angiography and angioplasty registry (SCAAR) is a continuous

Results: From May 2004 to December 2006, 62822 stents were implanted at 39691 procedures. Until August 2007 3402 restenosis have been reported. As expected, Drug eluting stents (DES) had a lower rate of restenosis as compared to bare metal stents (BMS). There was a great variation in the rate of restenosis between different DES and an even greater difference between different BMS.

Conclusions: This large real world registry there were large differences between
different types of stents among both BMS and DES which reinforces the need of larger randomized trials with head-to-head comparisons between the different stent types.

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Abstracts - SCAI-ACCi2 Interventional E-Abstracts

2900-293 Large differences in rate of clinical restenosis between different stents - Long term follow-up from the Swedish angiography and angioplasty registry (SCAAR)

Stefan K. James, Tage Nilsson, Jörg Carlsson, Ivar Sjögren, Per Tornwall, Fredrik Schersten, Bo Lagerqvist, Uppsala Clinical research center, Uppsala, Sweden

Background: The rate of restenosis and acute occlusion in a large number of different

Conclusions: The Swedish angiography and angioplasty registry (SCAAR) is a continuous

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Abstracts - SCAI-ACCi2 Interventional E-Abstracts

2900-294 Large differences in rate of acute stenocclusions between different stents - Long term follow-up from the Swedish angiography and angioplasty registry (SCAAR)

Bo Lagerqvist, Tage Nilsson, Jörg Carlsson, Ivar Sjögren, Tomas Kallert, Jens Jensen, Stefan James, Uppsala Clinical Research Center, Uppsala, Sweden

Background: To investigate the rate of acute occlusions in a large number of different

Conclusions: This large real world registry there were large differences between
different types of stents which reinforces the need of larger randomized trials with head-to-head comparisons between the different stent types.

Abstracts - SCAI-ACCi2 Interventional E-Abstracts

2900-292 Incidence and Clinical Impact of Longitudinal Geographical Miss following Sirolimus-Eluting Stent Implantation

Kenji Tanabe, Ken Koszumi, Toru Kataoka, Hitoshi Yasumoto, Shinshuke Nanto, Yui Ikari, Mitsu Memorial Hospital, Tokyo, Japan

Background: Restenosis of sirolimus-eluting stent (SES) is sometimes attributable to a mismatch of lesion and injured segment with the stent site (geographical miss), however, there have been a few studies to survey the incidence and sequel of the technical failure.

Methods: The study is a pre-specified analysis of Japanese multi-center post-marketing survey (PMS). From 2004 to 2005, the PMS enrolled 2501 patients (2459 lesions) who were treated with SES. Of the lesions, the study comprised 992 lesions which serial angiograms (baseline and 8 months) were analyzed at an independent core laboratory. Longitudinal geographical miss included "balloon injury" or "uncovered plaque". The "balloon injury" was defined as the presence of segment which was dilated by a balloon, but not covered with SES. The "uncovered plaque" was defined as the presence of proximal or distal edge segment of which diameter stenosis was greater than 30% post-procedure, or residual dissection. Results: The "balloon injury" and "uncovered plaque" were observed in 26.5% and 41.0%, respectively. The restenosis rate in lesions with uncovered plaque was higher compared to those without uncovered plaque (Table). However, there was no impact of balloon injury on restenosis at proximal edge. Conversely, there was a trend toward higher restenosis at distal edge in lesions with balloon injury. Conclusions: Geographical miss is associated with edge restenosis. There remains a room for technical improvement to achieve better outcomes of SES.
Early Development of Percutaneous Coronary Intervention lowered the Clinical need for Re-intervention More than Recent Advances - A 15 year of follow-up from the Swedish Angiography and Angioplasty Registry.

Fredrik Calais, Stefan James, Tage Nilsson, Per Albertsson, Peter Eriksson, Hans Ohlsson, Ulf Sterenstrand, Department of Medical Sciences Akademiska sjukhuset, Uppsala, Sweden

Background: Clinical need for re-intervention after percutaneous coronary intervention (PCI) on very long term is not investigated.

Methods: The Swedish angiography and angioplasty registry (SCAAR) is a continuous national registry covering all Swedish patients undergoing coronary angiography and percutaneous coronary interventions in Sweden since 1989. All re-interventions after the initial PCI were recorded. Event curves for different years of the initial treatment were adjusted for differences in all available background characteristics.

Results: 77,259 procedures were included in the analysis. There was a dramatic lower need for a new revascularization in patients treated during 1999 to 2000 as compared to 1996 to 1998 and 1989 to 1995 which timely corresponds to the introduction of, and wider use of, stents during these periods. In the time periods thereafter, the clinical need for a new revascularization was only marginally lower.

Conclusion: The early development of PCI techniques and the introduction of stents apparently had a larger impact on the clinical need of new revascularizations than the introduction of more recent techniques and devices such as drug eluting stents.

Do Drug-Eluting Stents have Similar Efficacy for the Treatment of Drug-Eluting Stent Restenosis as they are for Bare Metal Stent Restenosis?

Daniel H. Steinberg, Michael A. Gaglia, Jr., Tina L. Pinto-Slottow, Probol Roy, Teruo Okabe, Rebecca Torguson, Kimberly A. Smith, Saquib Samee, Zhenyi Xue, William O. Suddath, Kenneth M. Kent, Lowell F. Satler, Augusto D. Pichard, Joseph Lindsay, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Drug-eluting stent (DES) implantation is the standard treatment for bare metal stent (BMS) restenosis and is associated with lower rates of target-vessel revascularization (TVR). Outcomes in patients with DES ISR treated with repeat DES is less certain.

Methods: We evaluated 123 patients who presented with BMS ISR and 119 patients with DES ISR matched for baseline characteristics. Both groups of patients were treated with DES and they were compared with regard to major adverse cardiac events included death, myocardial infarction and target vessel revascularization (TVR) at one year.

Results: Baseline characteristics were similar between the two groups. Compared to patients with BMS ISR, those with DES ISR had similar one year rates of death (3.4% DES ISR vs. 4.9% BMS ISR, p=0.75) and myocardial infarction (3.4% DES ISR vs. 3.3% BMS ISR, p=1.00) when treated with DES. However, at one year, patients with DES ISR experienced significantly higher rates of TVR (20.2% DES ISR vs. 10.6% BMS ISR, p=0.04).

Conclusion: Patients with DES ISR treated by DES experience a high rates (20.2%) and significantly more TVR at one year than patients who present with BMS ISR treated by DES. The optimal treatment of DES restenosis remains to be defined.

Intravascular Radiation Therapy for Patients with Recurrences of In-stent Restenosis who Previously Treated with Either Radiation Therapy of Drug Eluting Stents

Ron Waksman, Rebecca Torguson, Kimberly Smith, Tina Pinto-Slottow, Daniel Steinberg, Probol Roy, Teruo Okabe, Saquib Samee, Augusto Pichard, Lowell Satler, William Suddath, Kenneth Kent, Washington Hospital Center, Washington, DC

Background: Treatment of in-stent restenosis is challenging especially for patients who failed the initial treatment and present with recurrences of in-stent restenosis. Intravascular radiation (IRT) and Drug eluting stents (DES) are effective treatment for patients with in-stent restenosis of bare metal stents (BMS). However, these treatments are associated with recurrences. This study evaluates and compares the safety and efficacy of repeat IRT for IRT failure versus IRT for drug-eluting stents (DES) failure.

Methods: Fifty-four consecutive patients treated with repeat IRT as adjuvant therapy to percutaneous coronary intervention (PCI) for in-stent restenosis (ISR) of a prior site treated with IRT were compared to 119 patients treated with IRT for ISR of a DES. Commercially available IRT systems were utilized. The angio-platelet regimen for both groups was life-long aspirin and at least 12 months of clopidogrel. Pts were followed up by telephone contact or clinical visit at 12 months.

Results: Baseline characteristics were comparable between the two groups except there were more current smokers in the IRT group (24.1% vs. 16.0%, p<0.001) and more patients who underwent prior coronary bypass surgery in the IRT for DES failure group (31.5% vs. 56.6%, p = 0.008). Beta radiation was used more frequently in the IRT for DES failure group (20.4% vs. 97.5%, p<0.001). There has been no report of subacute thrombosis in either group. (Table)

Conclusions: IRT for patients with multiple recurrences of in-stent restenosis who previously treated with either radiation therapy or drug eluting stents is safe and associated with acceptable results at 12 months. IRT should be considered as the treatment modality for this difficult subset of patients. (Table)

Drug-Eluting Stent for the Treatment of Small Coronary Artery with Sirolimus, Paclitaxel, Zotarolimus, Tacrolimus-Eluting Stent and EPC Capture Stent: Multicenter Registry in Asia

Sunam Nakanomy, Jang-Ho Bae, Yeo Han, Cadiyedi, Wasan Udayachalerm, Dammas Tresukool, Sudaratana Tansuphaswadi, New Tokyo Hospital, Chiba, Japan, Koryang University Hospital, Daejeon, South Korea

Aim: The aim of this study is to compare the safety and efficacy of Sirolimus (SES), Paclitaxel (PES), Zotarolimus (ZES), Tacrolimus-eluting stent (TES) and EPC capture
Constrictive Vascular Remodeling After Implantation of a Bioabsorbable Magnesium Alloy Stent in Porcine Coronary Arteries

Michael Maeng, Lisette O. Jensen, Leif Thuesen, Aarhus University Hospital, Aarhus, Denmark

Background: Bioabsorbable magnesium alloy stents (AMS) represent an alternative revascularization modality. There is, however, very little information on the arterial response to the AMS stent as compared to other stent types.

Methods: Absorbable magnesium stents (n=11), sirolimus-eluting stents (Cypher®, n=11), and bare-metal stents (n=11) were randomly implanted in 31 porcine coronary arteries (n=11 pigs). Mechanisms of lumen loss were assessed by serial intravascular ultrasound and histomorphometry at 90 days.

Results: By histomorphometry, lumen (median [quartiles]): AMS 1.76 (1.07-2.36), Cypher® 1.26 (0.89-1.88), BMS 1.05 (0.74-1.39). Area under the curve (AUC) 0.875 (0.84-0.91) and external elastic lamina (AMS 5.56 (4.09-6.95), Cypher® 7.95 (6.45-10.92), BMS 9.08 (7.85-11.63); p=0.014) areas were smallest in the absorbable magnesium stent group. By intravascular ultrasound, external elastic lamina area at follow-up (AMS 7.5±2.8, Cypher® 9.1±2.7, BMS 9.3±3.1; p=0.03) and change in external elastic lamina area from index intervention to follow-up (remodelling; AMS -1.0±0.3, Cypher® 1.0±0.83, BMS 0.9±1.2; p=0.30) were not statistically different between the groups. In a dichotomized intravascular ultrasound assessment, vascular remodeling, 6 AMS stents were remodelled (constrictive remodelling; n=5; positive remodelling: n=1) at 90 days follow-up (AMS versus SES-BMS: p=0.001). Necrotic area was smallest in the AMS group (histomorphometry: AMS 2.2±0.6, Cypher® 3.5±1.4, BMS 2.6±0.9; p=0.013; intravascular ultrasound: AMS 1.9±1.0, Cypher® 3.5±1.9, BMS 2.7±0.7; p=0.019).

Conclusion: Coronary implantation of absorbable magnesium stents, as compared to bare-metal and sirolimus-eluting stents, was associated with smaller lumen diameters and smaller external elastic lamina areas at follow-up despite less neointima formation. Constrictive vascular remodelling was the main cause of this result.
Background: Bare metal stent (BMS) restenosis often mimics pre-stent lesion morphology and location. However, sirolimus-eluting stent (SES) restenosis is more often focal than BMS restenosis. However, it is unclear whether angiographic DES restenosis occurs at the same location or at a different location compared to the original de novo coronary stenosis.

Methods: We used quantitative coronary angiography (QCA) to compare baseline vs in-stent restenosis (ISR) lesion locations in 35 pts (diameter stenosis [DS] >50%) after SES implantation. The distances between the minimum lumen site and the coronary ostia were measured, and the distance between baseline stenosis site and ISR site were calculated. Pts were divided into 2 groups: (1) ISR <5mm from baseline stenosis and (2) ISR >5mm far from baseline stenosis.

Results: Baseline %DS measured 67.5±19.3%, and follow-up %DS measured 63.0±15.8% (p=0.3). Baseline lesion length was longer than follow-up lesion length (12.0±7.1mm vs. 8.9±5.9mm, p=0.04). At follow up, the minimum lumen site was located 11.2±8.6mm remote from baseline minimum lumen site; and 26 (74%) were >5mm remote from baseline minimum lumen site. However, there were no QCA differences between the two groups (Table). Conclusion: Unlike BMS restenosis, SES restenosis is more focal; and 74% of SES restenosis lesions occur at sites remote (>5mm) from the original stenosis.

Conclusions: Scanning electron microscopy analysis of corrosion of Stainless Steel and Nitinol Stents from Autopsy Retrievals

Scanning Electron Microscopy Analysis of Corrosion of Stainless Steel and Nitinol Stents from Autopsy Retrievals

Methods: We obtained 9 autopsy stent-artery specimens and evaluated them with scanning electron microscopy (SEM) with energy dispersive spectroscopy (EDS). Examples of overlapping Nitinol (NiTi) and stainless steel (SS) stents, and a SS stent are shown.

Results: Overlapping regions of NiTi and SS stents and SS stent alone revealed significant corrosion along the stent surfaces. Regions of overlap of the NiTi stent revealed fretting wear. Conclusion: Stent corrosion exists in vivo, with particular prevalence in regions of stent overlap. Corrosion and release of metallic ions into surrounding tissue could impact in-stent restenosis and the structural integrity of stents.

Optimal criteria for stent edge landing zones: An integrated intravascular ultrasound analysis from the TAXUS IV, V, and VI Studies

Background: Stent edge restenosis can occur after implantation of either bare metal stents (BMS) or drug-eluting stents. Previous studies suggest that stent edge restenosis can be minimized by stenting from “normal to normal.” However, reference segments are rarely normal, and the optimal criteria for the stent edge landing zone have not been established.

Methods: In the combined TAXUS IV, V, and VI trials, intravascular ultrasound (IVUS) was performed at implantation and analyzed in 809 BMS and 810 paclitaxel-eluting stents (PES) that had quantitative coronary angiography (QCA) at 9 months. Follow-up QCA diameter stenosis (DS) was compared to baseline IVUS measurements of proximal and distal stent edge lumen area and plaque burden (plaque/external elastic membrane areas).

Results: Receiver operating curve (ROC) analysis of BMS showed that only the stent edge reference lumen area predicted edge restenosis; a lumen area of 7.3mm2 best separated edge restenosis (QCA DS >50%) from no edge restenosis (c=0.751, right figure) while stent edge plaque burden did not predict edge restenosis (c=0.497). Conversely, ROC analysis of PES showed that only the stent edge reference plaque burden predicted edge restenosis; a plaque burden of 42% best separated edge restenosis from no edge restenosis (c=0.673, left figure) while stent edge reference lumen area did not predict edge restenosis (c=0.551).

Conclusions: The optimal criteria for stent edge landing zones are different for BMS and PES. After BMS only the lumen area influences edge restenosis; after PES only the plaque burden influences edge restenosis. This difference also indicates that the causative mechanisms of stent edge restenosis are fundamentally different between BMS vs PES.

ENDOTHELIAL CELL APOPTOSIS AFTER CORONARY STENT PLACEMENT: IMPLICATION FOR RESTENOSIS

Background: Apoptotic endothelial microparticles have been described in several conditions of endothelial cell damage. Whether endothelial cells could represent an apoptotic target after coronary stent placement has not been investigated yet.

Methods: In this study, we have measured circulating endothelial cell apoptosis in 50 patients undergoing coronary stenting (25 bare-metal stents -BMS- and 25 sirolimus-eluting stents -SES). CD144+ cells (endothelial lineage) were analyzed by using a flow cytometry assay. Cells that were positive for both CD144 and Annexin V (CD144AnnV+; i.e., apoptotic cells) and negative for 7-amino actinomycin D (i.e., dead cells) were assessed.

Results: After bare-metal stenting, CD144AnnV+ cells increased, reaching a maximum on day 8 after stenting. By 6 months of follow-up, angiographic restenosis was seen in 4 of 25 patients treated with BMS and in 2 of 25 patients with SMS. The maximum change compared with baseline before stenting in CD144AnnV+ cell count (13.4 ± 4.3 cells/mL) was more striking in patients with restenosis (278±111%) compared to those without restenosis (137±37%; P<0.01). In contrast, CD144AnnV+ cells increased only slightly after sirolimus-eluting stent implantation (56±10% vs. baseline 40%, P<0.01). In vitro experiments showed that exposure of rat aortic rings to CD144AnnV+ cells isolated from patients undergoing BMS placement, but not from SES patients, selectively impaired vasorelaxation after acetylcholine exposure (P<0.01).

Conclusions: Altogether, our study shows that circulating CD144AnnV+ cells are augmented in patients undergoing BMS placement. More importantly, we have demonstrated that the count of circulating CD144AnnV+ cells predicts the angiographic restenosis rate at 6-month follow-up. We also observed that circulating CD144AnnV+ cells of patients undergoing BMS placement specifically impaired endothelium-dependent relaxation to acetylcholine in the rat aorta in vitro. From our results, we have identified a novel pathophysiological mechanism of restenosis. We propose circulating CD144AnnV+ as a new potential risk marker in the occurrence of restenosis after coronary stent placement.
Low levels of the endogenous cannabinoid arachidonylethanolamide and its metabolite anandamide are predictive of symptomatic in-stent restenosis after coronary implantation of drug-eluting stents. 


Background: It has been recently indicated a role for cannabinoids in neointimal hyperplasia and smooth muscle cell proliferation. Additionally, the endocannabinoid system, consisting of two cannabinoid receptors (CB1 and CB2) and the endogenous ligands anandamide (arachidonylethanolamide (AEA)) and 2-arachidonoylglycerol (2-AG), has been shown to control a number of immunomodulatory effects on lymphoid and myeloid cells at the vessel wall. Since impairment of the endocannabinoid system could influence restenosis risk, the goal of this study was to determine whether the plasma levels of AEA and 2-AG are impaired in patients with a history of symptomatic in-stent restenosis (ISR).

Methods: 707 patients who had a successful implantation of DES in native vessels for de novo lesions were eligible. After lipid extraction of venous blood, samples were analyzed for AEA and 2-AG levels by liquid chromatography-atmospheric pressure chemical ionization-mass spectrometry.

Results: Plasma concentrations of AEA resulted significantly lower in patients with ISR (odds ratio for the first quartile versus the top quartile, 2.11; 95% Cl, 1.63 to 2.88, P < 0.001) compared with the symptom-free stent group. The possible relationship between the AEA and the severity of ISR was also examined by comparing plasma levels with Mehran classification, percentage restenosis, and the number of stented segments with ISR in each patient. Patients with multiple sites of ISR had significantly lower levels of AEA compared with patients with only a single ISR lesion or no ISR (P < 0.01). No significant association was seen between the plasma levels of 2-AG and ISR in all the patients’ groups. The association between AEA levels and ISR retained its statistical significance even after controlling for index coronary disease extent and severity, number, diameter, and total length of stents, and plasma C-reactive protein.

Conclusions: These findings show that a derangement in the production of the endogenous cannabinoid AEA could be associated with ISR after DES implantation. Therefore the cannabinoid system may represent a potential therapeutic target for prevention of ISR after placement of DES.

Insulin Resistance Alters Neointimal Extracellular Matrix Composition After Arterial Injury: Role of Versican

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Background: Patients with type 2 diabetes are at increased risk for restenosis. Restenosis after angioplasty occurs secondary to smooth muscle cell accumulation and extracellular matrix deposition within the developing neointima, though the affect of diabetes and insulin resistance on extracellular matrix changes after arterial injury is unknown.

Methods: Using a rat carotid balloon injury model, we examined the extracellular matrix composition of insulin resistant Zucker Fatty (ZF) and non-insulin resistant Zucker Lean (ZL) rats by immunohistochemistry. Quantitative RT-PCR was also conducted on injured carotids from both types of animals to examine the effect of insulin resistance on versican mRNA upregulation.

Results: At 14 days after injury ZF animals had significantly greater percent stenosis (ZL 16.8±7.3% versus ZF 24.8±8.0%, P < 0.03) whereas there were no differences in hyaluronan (25.9±5.7 versus 31.9±5.7, P=ns). Quantitative RT-PCR of balloon injured arteries revealed significant upregulation of versican transcripts at 3 and 7 days after injury (figure).

Conclusions: Insulin resistance alters neointimal extracellular matrix composition after injury. Inhibition of versican production may be a promising avenue to decrease restenosis in patients with type 2 diabetes.
A profound adverse effect of PES on endothelium-dependent vasomotor relaxation in conduit vessel segments both proximal and distal to inflating implants, was observed both in vitro and in vivo and is related to increased oxidative stress. Endothelial dysfunction associated with PES likely contributes to pathophysiological clinical sequelae.

Results: Overall, BCA origin Type-B was found in 19% (n=184); Aortic root greater than 3.9cm was noted in 7% (n=68). With BCA of Type-B origin and aortic root diameter>3.9 cm TRCA procedure time increased to mean 17.3±4 mins from average of 8.5 ± 3.8 mins (p<0.03); incidence of spasm & pain increased to 9.1% from average of 1% (p<0.05); crossover to alternative access increased from average of 0 to 0.3% and catheter exchanges increased 13% from average of 3% (p<0.02).

Conclusions: BCA origin Type-B and aortic root diameter >3.9 cm on Echocardiogram are associated with greater procedure time & need for >1 catheter exchanges for TRCA, more patient discomfort & RAS and greater need for crossover to alternative access. It helps identify difficult anatomy for TRCA.

Background: Blood transfusion is independently associated with increased mortality in patients undergoing CABG. We sought to determine if a similar relationship exists with contemporary PCI.

Methods: We evaluated 4283 patients in the NHLBI Dynamic Registry waves 4 and 5 (2/04-5/04, 2/06-8/06). Demographics, procedural characteristics, in-hospital, and one-year outcomes were compared between patients who received T (n=80), 1.9% and no transfusion (NT) during hospitalization for PCI.

Results: Patients treated with T were older (70.4 vs. 63.7 years, p<0.001), more often female (66.3 vs. 32.0%, p<0.001), and smaller (body surface area 1.8 vs. 2.0m2, p<0.001). T patients were more likely to present non-electively (60.0 vs. 42.3%, p<0.001), with ST elevation 28.3 vs. 14.2%, p<0.001), and shock (6.3 vs. 1.3%, p<0.001). Ilioblocker use (45.0 vs. 33.1%, p=0.03) and major entry site complication (60.0 vs. 4.9%, p<0.001) were higher and mean length of stay longer (6.2 vs. 1.9 days, p<0.001) for T patients. Vascular access site location did not differ. In-hospital outcomes are below.

Conclusions: These data suggest that blood transfusion is independently associated with mortality and adverse outcomes in PCI and emphasize the importance of strategies to decrease the need for T.

**Can Echocardiography Guide Transradial Coronary Angiography?**

Sunita Chugh, Sanjay K. Chugh, Ravi Ratani Kasiwal, Navin C. Nanda, Naresh Trehan, Indraprastha Apollo Hospitals, New Delhi, India

Background: Transradial Coronary Angiography (TRCA) offers greater patient comfort and is associated with lower risk of vascular complications compared to Femoral access. However procedural difficulties occur in some cases. This prospective study was aimed at specifically identifying variations in origin of Brachiocephalic artery (BCA) and in size of aortic root by Color Doppler echocardiographic which could be associated with increased procedure time, incidence of radial artery spasm (RAS) and pain, rate of crossover to alternative access and catheter exchanges >1 during TRCA from right radial access (RRA).

Methods: A proposed classification of origin of BCA (on Color Doppler Echocardiogram) used in this study as follows: 1) Type-A: Origin of BCA from Proximal or middle third of aortic arch, pointing towards ascending aorta, (2) Type-B:Origin of BCA from or beyond middle third of aortic arch, directed to descending aorta. TIG (Terumo, Japan) catheters and wires were used via RRA in 970 consecutive patients prospectively. Procedure time, incidence of spasm, crossover to alternative access, need for alternative catheters and patient feedback was recorded in these patients.

Results: Overall, BCA origin Type B was found in 19% (n=184); Aortic root greater than 3.9cm was noted in 7% (n=68). With BCA of Type B origin and aortic root diameter>3.9 cm TRCA procedure time increased to mean 17.3±4 mins from average of 8.5 ± 3.8 mins (p<0.03); incidence of spasm & pain increased to 9.1% from average of 1% (p<0.05); crossover to alternative access increased from average of 0 to 0.3% and catheter exchanges increased 13% from average of 3% (p<0.02).

Conclusions: BCA origin Type-B and aortic root diameter >3.9 cm on Echocardiogram are associated with greater procedure time & need for >1 catheter exchanges for TRCA, more patient discomfort & RAS and greater need for crossover to alternative access. It helps identify difficult anatomy for TRCA.

**Blood Transfusion Associated with Death in Patients Undergoing Percutaneous Coronary Intervention in the NHLBI Dynamic Registry**

Marc Z. Krichavsky, Zoran S. Nedeljkovic, Faith Selzer, James N. Slater, Alice K. Jacobs, Boston Medical Center, Boston, MA

Background: Blood transfusion (T) is associated with increased mortality in patients undergoing CABG. We sought to determine if a similar relationship exists with contemporary PCI.

Methods: We evaluated 4283 patients in the NHLBI Dynamic Registry waves 4 and 5 (2/04-5/04, 2/06-8/06). Demographics, procedural characteristics, in-hospital, and one-year outcomes were compared between patients who received T (n=80, 1.9%) and no transfusion (NT) during hospitalization for PCI.

Results: Patients treated with T were older (70.4 vs. 63.7 years, p<0.001), more often female (66.3 vs. 32.0%, p<0.001), and smaller (body surface area 1.8 vs. 2.0m2, p<0.001). T patients were more likely to present non-electively (60.0 vs. 42.3%, p<0.001), with ST elevation 28.3 vs. 14.2%, p<0.001) and shock (6.3 vs. 1.3%, p<0.001). Ilioblocker use (45.0 vs. 33.1%, p=0.03) and major entry site complication (60.0 vs. 4.9%, p<0.001) were higher and mean length of stay longer (6.2 vs. 1.9 days, p<0.001) for T patients. Vascular access site location did not differ. In-hospital outcomes are below.

Conclusions: These data suggest that blood transfusion is independently associated with mortality and adverse outcomes in PCI and emphasize the importance of strategies to decrease the need for T.
**ABSTRACTS - SCAI-ACCi2 Interventional E-Abstracts**

2900-317

**Superiority of Real-time Ultrasound Guidance for Femoral Arterial Access: A Prospective Pilot Study**

Ardic H. Sehgal, William M. Suh, Alexander T. Harrison, Pranav Patel, Morton Kern, University of California, Irvine Medical Center, Orange, CA

**Background:** The common femoral artery (CFA) is the preferred point of access for cardiac catheterization to minimize vascular complications and allow for safe deployment of vascular closure devices. Real-time ultrasonic (US) guidance, a standard of care for central venous access, has not been adequately assessed for femoral arterial cannulation, despite its unique ability to localize the CFA bifurcation.

**Methods:** 71 consecutive patients undergoing cardiac catheterization by a single operator were prospectively randomized to fluoroscopic (n=36) or US guidance (n=35) for sheath insertion. US guidance was performed with a real-time freehand technique by a single operator. Time of insertion, number of needle advancements, and incidence of venipuncture were recorded. Two blinded readers analyzed the femoral angiograms for the point of sheath insertion relative to the femoral head and CFA. A third reader resolved any disagreements.

**Results:** Compared with fluoroscopic guidance, US guidance resulted in a higher first pass success rate (83% vs 47%, p=0.002), reduced venipunctures (0% vs 25%, p=0.002), and a higher rate of CFA insertion (89% vs 69%, p=0.048) (see Table). There was no difference in median access time (120 vs 132 sec for US, p=0.245), despite the inclusion of US probe setup time.

**Conclusion:** In this prospective pilot study, US guidance was superior to fluoroscopic guidance in femoral arterial access, without prolonging the time to sheath insertion. A larger multicenter study is warranted.

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2900-318

**Use of Collagen Based Device for Femoral Artery Puncture Site Closure Following Percutaneous Coronary Intervention is Equally Safe in the Hands of Trained Technologists/Nurses and Cardiologists**

Nicole Leone, Niksdar C. Puthiya, Nowwar Mustafa, Angela Hoban, Maria Albert, Angela Di Sabatino, James Hopkins, William Weintrob, Esharun Rahman, Christiana Care Health System, Newark, DE

**Background:** Deployment of collagen based closure device by trained technologists/nurses in the cardiac cath lab is an emerging practice. However, it is not known whether there is a difference in the complication rate in the deployment of this device between non-physicians and cardiologists. In our institution, technologists, nurses, and cardiologists have been trained to deploy this closure device.

**Methods:** Between April and September 2006, 978 patients underwent percutaneous coronary intervention (PCI) in our institution. Of these, 487 patients received the collagen based closure device (Angioseal™) and their records were reviewed. These patients were divided into two groups based on whether the technologists/nurses (Group 1) or cardiologists (Group 2) deployed the device. All patients received either heparin or bivalirudin. Additionally, some patients received IIb/IIIa inhibitors.

**Results:** Shown in Table 1. There was no difference in the baseline characteristics in the two groups and the complication rates also did not differ (Femoral artery dissections, loss of pulse, AV fistula or need for blood transfusions did not occur in either group).

**Conclusions:** For the deployment of this collagen based femoral artery closure device following PCI, we found no difference in vascular complication rate between trained technologists/nurses and cardiologists.

<table>
<thead>
<tr>
<th>Table 1 Baseline Characteristics/Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total patients</strong></td>
</tr>
<tr>
<td>Age (yr)</td>
</tr>
<tr>
<td>Male (%)</td>
</tr>
<tr>
<td>Body Surface Area</td>
</tr>
<tr>
<td>Elective (%)</td>
</tr>
<tr>
<td>IIb/IIIa Inhibitor (%)</td>
</tr>
<tr>
<td>Entry Site Bleed/Hematoma (%)</td>
</tr>
<tr>
<td>Pseudoaneurysm (%)</td>
</tr>
<tr>
<td>Retroperitoneal Bleed (%)</td>
</tr>
<tr>
<td>Total complications (%)</td>
</tr>
</tbody>
</table>

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2900-319

**Immediate and Long term Safety and Efficacy of Starclose for diagnostic and Interventional Cases**

Ramin Ebrahimi, James Lee, Hormoz Babaei, M. Reza Movahed, Edward G. Toggett, University of California Los Angeles-GLAVA, Los Angeles, CA, University of Arizona Medical Center, Tuscon, AZ

**Background:** Starclose is a new percutaneous arterial closure device that employs a circumferential nitinol clip. This device has been approved for use in diagnostic procedures such as coronary angiography. Long term safety and efficacy of Starclose has not been well documented. The purpose of this study is to evaluate immediate and long-term safety and efficacy of Starclose.

**Methods:** Data were collected on the first 600 consecutive cases using the Starclose device (including “start up” procedures) in a single academic center. The cases included diagnostic as well as interventional procedures. Deployment was performed by attending cardiologists or cardiologist fellows. Outcomes evaluated included: 1) Standalone success (immediate hemostasis without the need for manual or device compression). 2) Procedural success (Standalone success plus manual or device assisted hemostasis and no hematoma, transfusion, or vascular injury requiring any interventions). Patients were tracked over a six month period for late access site complications.

**Results:** Baseline Characteristics included average age of 63 years, Hypertension 53% (89%), Diabetes 272 (45%), Peripheral arterial disease 85 (14%). Of the 600 cases, 172 (29%) had coronary intervention (PCI), 2644 (44%) were obese (Ob) defined as a Body Mass Index of 30 or greater. Six french sheaths were used in all cases and bivalirudin nontherapy was used as the antithrombotic agent in 97% of interventional cases. 27/46% had received clopidogrel pre-procedurally. Outcomes are as follows: 1) Standalone success-Overall 89%, PCI 90%, Ob 91%. 2) Procedural success-Overall 97%, PCI 98%, Ob 98%, Hematoma: Overall 3%, PCI 1%, Ob 2%. No acute complications (leg ischemia, vascular injury requiring any interventions, or transfusion) occurred. There was one late vascular complication (pseudoaneurysm). Conclusion: Starclose is a safe and effective arterial closure device with good immediate and long term outcomes. This device may be used safely in Ob and PCI cases.

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2900-320

**The StarClose Arterial Closure Device is Associated with Higher Rates of Bleeding Complications than the AngioSeal Arterial Closure Device in Patients Undergoing Coronary Angiography**

Arman P. Shah, Victor Gabrielian, Grace Nam, David M. Shavelle, William J. French, Harbor-UCLA Medical Center, Torrance, CA

**Background:** Vascular closure devices (VCD) are used to enhance patient comfort in diagnostic and interventional procedures. More diabetics are undergoing percutaneous coronary procedures. Previous studies have shown that diabetics undergoing percutaneous coronary procedure have more complications than non diabetics.

**Methods:** A retrospective analysis was performed at a high volume cardiac catheterization laboratory. Patients who underwent CA and percutaneous coronary intervention (PCI) who were either diabetics (DM) or non diabetics (ND) were divided into two groups based on whether the AngioSeal (AS) or Starclose (SC) device was used. Outcomes evaluated included: 1) Standalone success (immediate hemostasis without the need for manual or device compression). 2) Procedural success (Standalone success plus manual or device assisted hemostasis). 3) Late complications.

**Results:** Of the 241 patients in the study (58.2 +/- 8.5 years, 71% male), AS was used in 138 cases and SC in 103 cases. DM were divided into two groups: 1) Diabetics undergoing coronary angiography (CA). This study investigated the safety and efficacy of two common VCDs, the AngioSeal (AS) and StarClose (SC) devices.**

**Conclusions:** DM were divided into two groups: 1) Diabetics undergoing coronary angiography (CA). This study investigated the safety and efficacy of two common VCDs, the AngioSeal (AS) and StarClose (SC) devices.
A cohort of 485 consecutive DMCD was retrospectively studied. Access related complications were analyzed. Patients were classified into two groups according to their prophylactic antibiotic therapy. Group A did not receive antibiotics whereas group B received either Ceftazolin or Vancomycin antibiotics during the procedure. The primary endpoint was cumulative in-hospital incidence of major vascular complications, defined as hematoma, femoral artery thrombosis, vascular repair, and groin infection. Secondary endpoint was incidence of groin infection rate.

Results: Group (B) had a higher admission glucose level (187±59 mg/dL vs 159±46; p<0.001), lower body mass index (25.5±7 vs 22.4±5; p<0.01), and more hypertension (91% vs 76%; p<0.001). The primary endpoint of vascular complications was seen in 33 (14%) patients in Group A, and 8 (3%) in Group B (p=0.0001). Multivariate analysis demonstrated that Antibiotic usage (OR 0.19; 95% CI= 0.08-0.42, P< 0.001) was the strongest negative predictor for the primary endpoint. However higher glucose level (OR 0.56; 95% CI= 0.38-0.81, P< 0.002) and a lower CCI was a positive predictors (OR 1.13; 95% CI= 1.001 to 1.029, P= 0.04) for groin complications. There was no significant difference in rate of complication between closure types. Higher rate of infection was the major contributor to the higher complication rate in group A (p=0.023). Interestingly, incidence of infection in group B was associated with subsequent in-hospital coronary bypass surgery.

Conclusions: Prophylactic antibiotic therapy in diabetic patients undergoing cardiac catheterization and treated with closure device can dramatically decrease access site infection rate . However, manual compression may be a better option for those subsequently undergoing coronary bypass surgery.

The Quick-CloseTM Vascular Suturing System for Closing the Femoral Arteries II (STITCHES II)

Scott B. Hacking, Stephen Minor, Chris Cove, University of Rochester Strong Memorial Hospital, Rochester, NY

Background: The Quick-Close™ Vascular Suturing System (QC) is a suture-based percutaneous vascular closure device. The device remotely deploys a single mono-filament suture into the femoral artery (FA) secured by a stainless steel clip. Previous generations of this device were shown to be safe and effective in the STITCHES I trial. Methods: STITCHES II is a multi-center, prospective, randomized, safety and efficacy trial including 367 patients(pts) at 8 US sites. The pts were randomized in a 2:1 fashion (QC:manual compression (MC)). All pts underwent a 5-8 Fr percutaneous diagnostic or interventional procedure via the FA. The primary efficacy end-points were time to hemostasis and hemostasis. The secondary efficacy end-points were time to dischargability (DC), procedural success, and device success. The primary safety end-point was the rate of major complications. The secondary safety end-point was the combined rate of minor complication.

Results: Time to hemostasis and ambulation was significantly improved by use of the QC device (p<0.001). The secondary efficacy end-points showed time to DC was not statistically significant. Device success was 98.4%. Procedural success was 97.9% with QC, 100% with MC (p=0.72). There were 4 major complications in the QC and 3 with MC (p=1.0). There were 14 minor complications in the QC and 14 in the MC group (p=1.0).

Conclusion: The use of QC resulted in improved time to hemostasis and ambulation. QC was safe and was associated with high procedural and device success.

Table 1

<table>
<thead>
<tr>
<th>Quick-Close™</th>
<th>Manual Compression</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Hemostasis all pts</td>
<td>10.4 min (n=243)</td>
<td>23.4 min (n=124)</td>
</tr>
<tr>
<td>Diagnostic pts</td>
<td>3.5 min (n=136)</td>
<td>16.6 min (n=70)</td>
</tr>
<tr>
<td>Interventional pts</td>
<td>19.1 min (n=107)</td>
<td>32.3 min (n=54)</td>
</tr>
<tr>
<td>Time to Ambulation all pts</td>
<td>4.4 hrs</td>
<td>6.9 hrs</td>
</tr>
<tr>
<td>Diagnostic pts</td>
<td>2.8 hrs</td>
<td>4.8 hrs</td>
</tr>
<tr>
<td>Interventional pts</td>
<td>6.3 hrs</td>
<td>9.5 hrs</td>
</tr>
<tr>
<td>Time to Discharge all pts</td>
<td>11.7 hrs</td>
<td>11.9 hrs</td>
</tr>
<tr>
<td>Diagnostic pts</td>
<td>5.4 hrs</td>
<td>6.7 hrs</td>
</tr>
<tr>
<td>Interventional pts</td>
<td>19.6 hrs</td>
<td>16.9 hrs</td>
</tr>
<tr>
<td>Device Success</td>
<td>98.4%</td>
<td>n/a</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>97.9%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Vascular Complications Following Cardiac Catheterization and Interventions: Persistence of Gender Gap in the Contemporary Era.

Kaija A. Mogi, Faisal Bahadur, Kavita Desouza, Lee Gibbs, Sujaeta Agnani, James Atherton, Michael Goebel, Gloria Caldito, Pratap Reddy, Louisiana State University Health Science Center, Shreveport, LA

Background: There are conflicting reports on gender difference in vascular complications following cardiac catheterization (CATH) and percutaneous coronary intervention (PCI). Earlier studies have shown that women experience more complications compared to men. While more recent reports have found no gender difference. Thus, we evaluated if vascular complications occur with greater frequency in women compared to men in the recent era.

Methods: A total of 1,287 (female n=648, male 669) consecutive CATH (938) and PCI (349) procedures performed via femoral access at our institution between 2005 to 2007 were evaluated to determine if a gender gap exists in the vascular complication. We compared complication rates between categories of factors observed to be significantly associated with using the chi-square test. Multiple logistic regression analysis was used to determine independent risk factors for complication and to calculate adjusted odds ratios (OR). A 5% level of significance was used for all statistical tests.

Results: For the entire study population the incidence of any vascular complication was 26%. For women it was 0.4% and for men 1.6%. Adjusted for the effect of each other in a multiple logistic regression analysis female gender was determined to be independent significant risk factors for vascular complication. The risk adjusted odds ratio for any vascular complications comparing women to men was 2.32 (95% CI 1.01 to 4.40, p=0.04) for CATH and 2.76 (p=0.01) for PCI.

Conclusions: Following CATH and PCI: 1) Women had more vascular complication than men 2) Female gender was an independent predictor of vascular complications 3) Gender gap for the vascular complications persist in the contemporary era.

Safety of Cardiac Catheterization in patients with End-Stage Liver Disease Prior To Orthotopic Liver Transplantation

Mayan Sharma, Celina Yong, Christian Zellner, Thomas Ports, Yerem Yeghiazarians, Andrew Boyle, University of California San Francisco, San Francisco, CA

Background: The morbidity and mortality of patients with coronary artery disease (CAD) who undergo orthotopic liver transplantation (OLT) is unacceptably high, necessitating pre-operative evaluation of coronary artery anatomy. Patients with liver failure are predisposed to bleeding complications due to thrombocytopenia, reduced synthesis of coagulation factors and increased fibrinolytic activity. Therefore, they are thought to be at high risk for vascular access site complications after cardiac catheterization. However, the exact incidence of vascular access site complications in this group remains unknown.

Methods: 89 consecutive patients with liver underlying left heart catheterization (LHC) prior to OLT from August 2004 to February 2007. 82 patients without known liver disease, but matched for age, sex and BMI who had left heart catheterization during the same period were chosen as the control group. Vascular complications were defined as hematoma > 5 cm, pseudoaneurysm, arteriovenous fistula or retroperitoneal bleeding.

Results: Liver failure patients had lower baseline Hct (32.3±6.0 vs 39.2±6.2, p<0.001) and platelet count (90.1±66.3 vs 236.1±77.1, p<0.001) compared to controls. They also had higher serum creatinine (1.9±7.1 vs 1.2±8.0, p=0.002) and INR (1.6±0.7 vs 1.1±0.2, p<0.001). There was a trend toward lower platelet counts in the patients with liver failure compared to 1.2 ±1 in controls (1.8±2 cases) p=0.12. The incidence of significant hematoma was 0 % (8/89 cases) in the patients with liver disease compared to 1.2 % (1/82) in controls p=NS. There were no retroperitoneal bleeds in either group. More liver failure patients required blood transfusion (24.7 % vs 7.4 %, p=0.001), fresh frozen plasma (51.7 % vs 12.2 %, p=0.001) and platelet transfusions (48.3 % vs 1.2 %, p=0.001).

Conclusions: Despite severe coagulopathy, LHC may be performed relatively safely in this patient population with rigorous correction of coagulopathy and meticulous attention to procedural technique. Strategies to reduce transfusion requirements and the incidence of pseudoaneurysms should be studied in this patient population.
Thoracic aortic disease has traditionally been treated by surgery. Endovascular stent grafting has emerged as an alternative approach. The aim of this study is to describe our clinical experience and results using percutaneous femoral closure devices for femoral arterial closure after thoracic aorta stent graft placement (TASGP).

Methods: Thirty-five consecutive patients were selected to use the Prostar XL® device for arterial closure after TASGP. According to pre-established criteria (femoral size, tortuosity, calcium), after arterial puncture two Prostar XL® devices in each patient were placed at the puncture site. The first is inserted using the conventional technique guided by a standard 0.038-inch guidewire and is left in the femoral artery after implantation of the 2 sutures. The artery is recanalized with a guidewire and the device is withdrawn. The second device is then inserted, implanting the 2 sutures after rotating 45 degrees clockwise from the position of deployment of the first device. The access site is gradually dilated to 20-22 French. The aortic endoprostheses are subsequently implanted and upon completion of the procedure, hemostasis is performed by closing the sutures of the 2 devices with a knot pusher. Patients were anticoagulated during the procedure with 10,000 U of IV heparin. Femoral sites were followed up (discharge-6 month). If a femoral murmur was detected, an echo-Doppler was performed.

Results: All femoral sites were correctly closed by the two devices. In one case surgery was needed because of occlusion of the iliac artery, due to intima disruption, not related with the closure device. In the other cases, predischarge physical examination revealed absence of major hematomas. At 6 months follow up, two echo-Dopplers were performed and one of them revealed the presence of a femoral pseudoaneurysm.

Conclusions: Our data suggest that in TASGP, hemostasis of large puncture sites can be successfully achieved with two Prostar XL® devices, when placed prior to arterial dilatation.
was used to identify the independent predictors of access site related complications. MACCE was defined as death, MI, abrupt vessel closure or coronary artery bypass graft.

Research: The transradial approach was associated with fewer vascular access complications than the transfemoral approach (1.5% vs. 0.6%; p < 0.001) and a shorter length of hospital stay. Multivariable analysis revealed transradial access (OR 0.39 95% CI 0.2, 0.7), to be an independent predictor of lower risk of access site related complications, with proximal PCI (OR 0.43 95% CI 1.4, 1.3), recent MI (OR 0.95 95% CI 1.2, 3.4), age (per 10 years increase: OR 1.37 95% CI 1.1, 1.7) and female gender (OR 2.78 95% CI 1.7, 4.6) were independent predictors of a higher risk of access site complications. A trend was also observed indicating transradial access to be independently associated with a lower risk (rate) of major adverse cardiac events (1.9% vs. 2.3%, p=0.018).

Conclusions: The use of transradial PCI is safe and is independently associated with a reduced rate of in-hospital access site complications and reduced length of hospital stay.

Outcomes of Non-physician Vascular Access and Closure: A Single Center Clinical Evaluation

Daniel Leg, Matthew Lee, Patrick Rim, Thomas Tomczak, Karen DiDonato, Bay Regional Medical Center, Bay City, MI

Background: Standard of care at most hospitals is for the physician to perform the femoral artery puncture required for vascular access, with the arteriotomy then being closed via manual compression or a VCD (vessel closure device). Clinical trials demonstrating safety and efficacy of VCDs have been mandated by the FDA, with participation restricted to interventional cardiology. Little to no data has been published regarding the utilization of non-physician cath lab staff for providing vascular access and closure.

Methods: This study was a single center, retrospective evaluation of 1000 consecutive femoral access punctures and closures using the Abbott Vascular (Redwood City, CA) StarClose® device between March 2006 and September 2006. The objective was to evaluate the safety and efficacy of the device in achieving hemostasis following diagnostic and PCI (percutaneous coronary intervention) procedures, where femoral arterial access and closure was obtained by a trained cath lab nurse, radiology technician or RCIS (Registered Cardiovascular Invasive Specialist). Device success was the primary endpoint and was defined as achievement of hemostasis in the catheterization lab allowing transfer to the cardiovascular holding unit.

Results: Of the 1000 patients analyzed, 749 (75%) were diagnostic catheterization and 251 (25%) were PCI. Overall device success rate for the combined population was 96.3% (963/1000). Diagnostic patients demonstrated a device success rate of 96.5% (723/749) while intervention patients were successfully closed with the StarClose device in 96% (240/251) of the time. There were a total of 34 failed closures; 26 of which occurred in the diagnostic population, and 11 in the interventional.

Conclusion: Successful femoral artery access and closure when performed by trained, non-physician cath lab staff is feasible and appears to be safe and effective based on this preliminary observational study in patients who underwent diagnostic and interventional catheterization procedures. Additional, prospective studies with the StarClose device utilizing a more formalized hypothesis testing should now be attempted.

Single Center Results of PFO Closure with a Non-Implantable Device Using Radiofrequency

Julia Wallenborn, Laura Schumpl, Christiane Bußmann, Nicolas Majurke, Corinna Heinisch, Andreas Baranowski, Wbke Zimmermann, Stephan Staubach, Niki Wawra, Evelyn Fischer, Michaela Leetz, Marijke Skowasch, Nina Wunderlich, Horst Sievert, CardioVascular Center, Frankfurt, Germany

Background: Percutaneous closure of patent foramen ovale (PFO) to prevent recurrent paradoxical embolism is frequently performed, however, currently available closure devices are not implantable, leaving a foreign structure in the atria. The PFOxTM Closure System (Cierra, Inc., Redwood City, CA) is a novel method employing radiofrequency energy to effect closure of a PFO by welding the tissues of the septum primum and septum secundum together without leaving foreign material in the body. The PFOxTM Closure System was applied before the first procedure. A 19mm device was introduced during the study and evaluated along with the 13mm. In 13 patients with a residual shunt a second procedure was performed which was successful in 10.

Conclusions: Initial experience demonstrates that PFO closure using radiofrequency energy is technically feasible and safe.

Coronary Angiography is Safe in Patients with Peripheral Arterial Disease: A Sub-Study of the Coronary Artery Revascularization Prophylaxis (CARP) Trial

Santiago Garcia, Brack Hatler, Thomas Moritz, Steven Goldman, Kendrick Shunk, Fred Lilloty, Domenic Rada, Herbert Ward, Edwards McPats, University of Minnesota, Minneapolis, MN

Background: The safety of diagnostic coronary angiography has not been systematically studied in a large cohort of patients scheduled for an elective vascular operation.

Methods: Between March 1, 1999 and February 28, 2003, 5398 patients were screened at 18 VA Medical Centers and considered for enrollment into the Coronary Artery Revascularization Prophylaxis (CARP) trial. Coronary angiography was performed in 1298 patients prior to vascular surgery and comprised the study cohort. Complications were assessed 24 hours post-procedure.

Results: Indications for vascular surgery included an expanding aortic aneurysm (AAA) (36%) or arterial occlusive disease with either claudication (36%), or rest pain with or without tissue loss (30%). A major complication occurred in a total of 16 patients (1.23%) and, as shown in the Table, tended to be more common in patients with arterial occlusive symptoms compared to those with expanding aneurysms (1.8% vs. 0.4%; p=0.07).

Conclusions: Coronary angiography is safe in patients with peripheral arterial disease undergoing preoperative screening prior to elective vascular surgery. Vascular access complications are more common in patients with arterial occlusive disease.

Table

<table>
<thead>
<tr>
<th>Complication</th>
<th>AAA (n=446)</th>
<th>PFO (n=1298)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MI</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Renal failure</td>
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<td>3</td>
</tr>
<tr>
<td>VT/VF</td>
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<td>5</td>
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<tr>
<td>Allergic reactions</td>
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<td>2</td>
</tr>
<tr>
<td>Vascular access</td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

Can Femoral Artery Angiography Reduce Vascular Complications of Cardiac Catheterization

Takeshi Ozintuka, Akio Kawamura, Shinisuke Yuasa, Takashi Kohno, Kentarou Hayashida, Yuichirou Maekawa, Satoshi Ogawa, Keio University School of Medicine, Tokyo, Japan

Objective: We sought to reveal whether femoral artery angiography (FAA) could reduce vascular access complications associated with trans-femoral arterial catheterization.

Background: Trans-femoral approach is widely used in cardiac catheterization and percutaneous coronary intervention. Despite meticulous care to reduce access site complications, vascular complications such as, retroperitoneal hemorrhage, pseudoaneurysm, arterio-venous fistula, remain to be serious problems related to trans-femoral approach.

Methods: Between September 2006 and August 2007, consecutive 580 patients underwent trans-femoral catheterization after FAA. The FAA was performed immediately after femoral arterial access. Unless any bleeding or arterio-venous fistula was found, heparin was administered and procedure was commenced. The incidence of vascular complications of this group was compared with that of consecutive 953 patients who underwent trans-femoral catheterization without FAA in preceding period between January 2005 and September 2007.

Results: Baseline demographics were similar between the 2 groups except that patients with FAA were less likely to have second arterial access on the same side of the femoral artery (5.1% vs. 1.2%, p < 0.05). The incidence of vascular complications was lower in patients with FAA than in patients without FAA (0.34% vs. 1.37%, p < 0.05). By performing FAA immediately after femoral access, 2 vascular complications (arterio-venous fistula and extravascular bleeding) were promptly recognized and treated before the procedure.

Conclusions: FAA immediately after femoral arterial access can reveal vascular complications in its early stage and facilitate swift treatment.