ACUTE CORONARY SYNDROMES, MYOCARDIAL INFARCTION, THROMBECTOMY AND VULNERABLE PLAQUE

A-010

Title: Elevated Fibrinogen Level Without Systemic Inflammation is Associated with Increased Ischemic Risk During Percutaneous Coronary Intervention

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Lawrence Ang, M.D., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA; Khalid Bin Thani, M.D., M.A.S., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA; Khalid Bin Thani, M.D., M.A.S., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA; Manjusha Ilapakurti, M.B.B.S., M.P.H., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA; Vachaspathi Palakodeti, M.B.B.S., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA; Ehtisham Mahmud, M.D., University of California, San Diego Sulpizio Cardiovascular Center, United States, La Jolla, CA

Background: Elevated serum fibrinogen is associated with an increased risk of adverse cardiovascular events. The relationship between elevated fibrinogen with normal C-reactive protein (CRP), and ischemic cardiac events following percutaneous coronary intervention (PCI) is uncertain.

Methods: Elective PCI patients pretreated with clopidogrel (600 mg 12 hours prior or 75 mg daily for ≥7 days) were prospectively enrolled with measurement of baseline fibrinogen, CRP, creatine kinase-myocardial band (CK-MB)(normal 0-4.8 ng/ml), troponin I/T (normal troponin I 0-0.5 mg/ml, troponin T 0-0.03 mg/ml) and fasting lipid levels.

Results: The study enrolled 186 subjects (age 63.8±11.7 years, 74.2% male, 73.7% CRP <0.5 mg/dl) undergoing elective PCI (normal baseline cardiac markers). Periprocedural myocardial infarction (PPMI) occurring 24 hours following PCI was defined as CK-MB or troponin I/T level >3x upper limit of normal (5.9% CK-MB-defined PPMI, 14.1% troponin I/T-defined PPMI). Independent of CRP, the presence of elevated fibrinogen ≥345 mg/dl was associated with an increased incidence of PPMI [CK-MB- (11.3% vs 2.6%; p = 0.023) and troponin I/T-defined (21.2% vs 9.9%; p = 0.037)]. In the absence of increased CRP (<0.5 mg/dl), elevated fibrinogen ≥345 mg/dl was associated with an even higher incidence of PPMI [CK-MB- (16.2% vs 1.0%; p = 0.002) and troponin I/T-defined (27.8% vs 9.4%; p = 0.007)]. Among subjects with CRP >0.5 mg/dl, elevated fibrinogen level was not associated with either CK-MB- (5.9% vs 13.3%; p = 0.576) or troponin I/T-defined (13.3% vs 13.3%; p = 1.00) PPMI.

Conclusion: In the absence of systemic inflammation, fibrinogen ≥345 mg/dl is associated with increased risk of a PPMI following elective PCI.

Disclosures:
Lawrence Ang: This author has nothing to disclose.
Khalid Bin Thani: This author has nothing to disclose.
Manjusha Ilapakurti: This author has nothing to disclose.
Vachaspathi Palakodeti: This author has nothing to disclose.

A-016

Title: Diabetic Status is More Predictive of Necrotic Core Burden in Acute Coronary Syndromes Patients vs. Stable Patients Undergoing Percutaneous Coronary Intervention, as Quantified by Intravascular Ultrasound-Virtual Histology

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Sandeep Nathan, M.D., M.Sc., University of Chicago Medical Center, United States, Chicago, IL; Vikrant Jagadeesan, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Mark Gajjar, M.D., University of Chicago Medical Center, United States, Chicago, IL; Linda Lee, None, B.S., University of Chicago Medical Center, United States, Chicago, IL

Background: ACS plaque is thought to differ from non-ACS plaque by manifesting more inflammation/cellular debris and lower plaque volume. We used intravascular ultrasound-Virtual Histology (IVUS-VH) to validate reported plaque compositional differences pre- PCI in ACS vs. non-ACS patients (pts).

Methods: 2,579 IVUS-VH frames were acquired in 36 PCI pts (ACS: n = 15, 6 diabetic (DM); non-ACS: n = 21, 9 DM). Automated IVUS-VH pullbacks were performed using Volcano EagleEye Platinum 20 MHz probes with VH frames traced and blindly adjudicated. VH data
was divided into Fibrous (FI), Fibro-Fatty (FF), Necrotic Core (NC), and Dense Calcium (DC). Statistical analyses were performed in groups stratified by ACS and DM status.

Results: ACS pts overall had slightly higher plaque area/frame (Fig 1) with lower proportional NC (16% vs. 21%, \(p < 0.001\)) and absolute NC amount (1.6 vs. 1.9 mm\(^2\), \(p<0.0001\)) than non-ACS pts. NC/DC ratio, a known VH correlate of lesion instability, was higher however (3.2 vs. 1.9, \(P<0.0001\)) in ACS pts. DM status conferred opposite NC content signals when pts were divided by ACS status, with DM/ACS plaque having the greatest NC content of all.

Conclusions: ACS plaque does not uniformly contain greater NC but does evidence greater NC/DC ratio suggesting increased overall plaque vulnerability. DM status is more predictive of absolute NC burden in ACS patients than non-ACS patients. This raises the question of whether the impact of DM on NC content eclipses the impact of ACS and merits further study.

Disclosures:
Sandeep Nathan: Volcano, 5. Consulting Fees or Other Remuneration
Vikrant Jagadeesan: This author has nothing to disclose.
Mark Gajjar: This author has nothing to disclose.
Linda Lee: This author has nothing to disclose.

A-019

Title: FAST-PCI (Reduced-Dose Fibrinolytic Acceleration of STEMI Treatment Followed by Urgent Percutaneous Coronary Intervention) Reduces Infarct Size Assessed by Cardiac Magnetic Resonance Imaging

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Manuel Reyes, M.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^1\); Ashley Gunter, None, University of Texas Houston Medical School, United States, Houston, TX\(^2\); Ashley Gunter, None, University of Texas Houston Medical School, United States, Houston, TX\(^2\); Ashley Gunter, None, University of Texas Houston Medical School, United States, Houston, TX\(^2\); Mark Fasulo, M.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^6\); H. Vernon Anderson, M.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^7\); Ali E. Denktas, M.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^8\); Stefano Sdringola, M.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^9\); Colin Barker, M.D., Colin.M.Barker@uth.tmc.edu, University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^10\); James McCarthy, M.D., University of Texas Houston Medical School, United States, Houston, TX\(^11\); Richard Smalling, M.D., Ph.D., University of Texas Medical School at Houston, Division of Cardiology, United States, Houston, TX\(^12\)

Background: In STEMI patients, FAST-PCI reduces mortality and the combined endpoint of death, reinfarction, and stroke, without increased bleeding risk, compared to primary PCI (PPCI) alone. However, the impact of FAST-PCI on infarct size is unknown. We examined whether early application of FAST-PCI leads to significant infarct size reduction.

Methods: Between 8/2005 and 7/2010, 262 patients with STEMI were treated with either FAST-PCI (174 patients) or PPCI (88 patients). Patients underwent delayed hyperenhancement cardiac magnetic resonance imaging on day 3-5 to measure scar and microvascular obstruction

Figure 1. Scarc volume per ischemic time (FAST-PCI vs PPCI).
(MVO) volumes, and to determine the extent of transmural infarction (scar involving >50% of myocardial wall thickness). Total ischemic times (IT = symptom onset to TIMI 2-3 flow) were recorded and correlated with infarct size measurements. Patients were divided into groups according to IT (<120, 120-239, ≥240 min).

**Results:** Baseline demographics were similar in all groups. Average total IT was insignificantly shorter with FAST-PCI versus PPCI (IT: 232±183 min vs 263±201 min; p = NS). For total IT <120 min, the FAST-PCI group had a significant 34.2% reduction in infarct size when compared to the PPCI group (mean scar volume: 9.57 ± 3.1 vs. 14.56 ± 8.4 cc; p = 0.04, Figure). FAST-PCI also showed a trend towards fewer transmural infarcts and less MVO when compared to the PPCI group (transmural infarcts: 68% vs 83%, respectively, p = NS; MVO: 0.51 cc vs. 1.28 cc, p = NS).

**Conclusion:** FAST-PCI strategy for STEMI reduces infarct size compared to PPCI if total IT is <120 minutes. These findings complement previous data on FAST-PCI benefits, and support the early application of this strategy for optimum STEMI treatment.

**Disclosures:**
Manuel Reyes: This author has nothing to disclose.
Ashley Gunter: This author has nothing to disclose.
Nicoleta Daraban: This author has nothing to disclose.
Catalin Loghin: This author has nothing to disclose.
Mark Fasulo: This author has nothing to disclose.
Daniel Maland: This author has nothing to disclose.
Ali E. Denktas: This author has nothing to disclose.
Stefano Sdringola: This author has nothing to disclose.
Colin Barker: This author has nothing to disclose.
James McCarthy: This author has nothing to disclose.
Richard Smalling: This author has nothing to disclose.

**A-021**

**Title:** Bivalirudin for 2 Hours after STEMI PCI: A Comparison to HORIZONS

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

**Authors:** William Prabhu, M.D., FAHC-UVM, United States, Burlington, VT; Enkhhuuva Mueller, M.D., FAHC-UVM, United States, Burlington, VT; Preeth Sundaran, M.D., FAHC-UVM, United States, Burlington, VT; Michael DeSarno, M.D., FAHC-UVM, United States, Burlington, VT; Harold Dauerman, M.D., FAHC-UVM, United States, Burlington, VT

**Background:** Bivalirudin is superior to UFH/GPI strategy for STEMI PCI for net adverse cardiovascular events, albeit with an increased risk of acute stent thrombosis. A prolonged bivalirudin infusion that continues until clopidogrel load becomes effective, may help ameliorate this risk. We hypothesized a STEMI bivalirudin protocol with 2 hour extended infusion after PCI (Bival +2) could be utilized in a regional STEMI program without increased bleeding risk.

**Methods:** We analyzed a 6 center (5 non-PCI, 1 PCI) regional protocol involving routine therapy with ASA, 600 clopidogrel, bolus UFH followed by primary PCI for STEMI using bivalirudin. All consecutive patients during the study period (January 1, 2009 to June 30, 2011) presenting with STEMI requiring PCI were included in the analysis. We compared baseline characteristics as well as outcomes of the current Bival +2 registry to the historical groups of Bival +0 or Heparin/GPI from the HORIZONS trial.

**Results:** Among 346 undergoing PCI for STEMI, all but 7 received bivalirudin during PCI. 82% of patients received Bival +2 after PCI, and 13.3% received GPI bailout. The overall mortality in the entire STEMI registry was 3.1% including patients with shock/arrest. Compared to HORIZONS bival arm, Bival + 2 patients were more likely to have diabetes, prior PCI and prior CABG, as well as more likely to have received higher dose clopidogrel (Table). Bival + 2 patients were less likely to have had a bolus of UFH (58 vs 66%, p = 0.01). Bleeding rates were 50% less in the Bival + 2 group than in the Horizons GPI arm and similar to Horizons bival arm. Acute stent thrombosis occurred in 3 of the Bival + 2 patients; two of these events occurred while receiving bailout GPI.

**Conclusions:** Bival +2 is a feasible pharmacologic algorithm for STEMI PCI; 2 hour post PCI infusion of bivalirudin for STEMI PCI is not associated with increased bleeding risk and warrants further study as a mechanism of mitigating very early thrombosis risk.

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William Prabhu: This author has nothing to disclose.
Enkhhuuva Mueller: This author has nothing to disclose.
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Michael DeSarno: This author has nothing to disclose.
Harold Dauerman: The Medicines Company, 5. Consulting Fees or Other Remuneration

**A-027**

**Title:** An Analysis of Door-To-Balloon Time Delays in ST-Elevation Myocardial Infarction (STEMI) - A Single Center Experience

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

**Authors:** Gian Carlo Giove, M.D., Gagnon Cardiovascular Institute, United States, Morristown, NJ; Joon Dong Kim, M.D., Gagnon Cardiovascular Institute, United States, Morristown, NJ; Youlan Tang, None, Gagnon Cardiovascular Institute, United States, Morristown, NJ; Roberto Lopez, M.D., Gagnon Cardiovascular Institute, United States, Morristown, NJ; Donald Casey, M.D., FACC, Gagnon Cardiovascular Institute, United States, Morristown, NJ; Linda Gillam, M.D., FACC, Gagnon Cardiovascular Institute, United States, Morristown, NJ; Barry Cohen, M.D., FACC, Gagnon Cardiovascular Institute, United States, Morristown, NJ

**Background:** Delays in the door-to-balloon (D2B) times STEMI (ST-elevation myocardial infarction) patients undergoing Primary Percutaneous Coronary Intervention (PCI), are associated with increased risk of in-hospital mortality. The accepted goal for D2B time is < 90 minutes. The purpose of this study is to analyze factors which prolong D2B time.

**Methods:** We analyzed 387 consecutive STEMI patients presenting to a single center 12/06-11/11 (34% females). Each patient was assessed for 3 segments of time. Benchmark time goals (minutes) were assigned to three major groups to analyze retrospectively causes of delay for performance improvement. They include: Door to ECG (D2E) diagnosis
S4  Abstracts

(Goal ≤ 9 min), MD page to patient on table (Goal ≤ 50 min) and Table to reperfusion (Goal ≤ 29 min).

Results: Overall, the median D2B was 75 minutes (Range: 25 – 202 min). 81% achieved D2B ≤ 90 minutes. D2B was 63.5 min for patients presenting during working hours (M-F, 7AM – 7 PM) compared to 82 min for off call hours. (P = 0.001) Seventy-one patients did not meet the goal of D2B ≤ 90 minutes. In patients with a D2B ≤ 90 min, 82% achieved the D2E goal, as compared to only 65% in D2B>90 minutes. Patients who did not meet the benchmark time goals, had worse D2B times (Table 1, p<0.001). Factors that significantly affected D2B times included the presence of a Pre-Hospital ECG (Mean D2B 66 vs. 85 min, p<0.001), delays in performing (80%) and interpreting (20%) an ECG upon arrival (30 pts), personnel delays (20 pts) and prolonged catheterization times (21 pts).

Table1. Comparison of Door-To-Balloon Time (D2D) in the 3 assigned groups. Includes percentage in each group who achieved D2B ≤ 90 minutes (Dx: Diagnosis; RFP: Reperfusion, Min: Minutes) * Mann Whitney U Test

<table>
<thead>
<tr>
<th>D2B ≤ 90 min</th>
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<tr>
<td></td>
<td>Door-to-Do (≤ 9 min)</td>
<td>Door-to-Do (≤ 9 min)</td>
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<tr>
<td></td>
<td>Mean</td>
<td>50</td>
<td>Median</td>
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<tr>
<td>D2B Time (minutes)</td>
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<td></td>
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</tr>
<tr>
<td>69.6</td>
<td>20.1</td>
<td>64.0</td>
<td>92.8</td>
</tr>
<tr>
<td>D2B ≤ 90 min</td>
<td></td>
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<tr>
<td>74.9</td>
<td>23.1</td>
<td>72.0</td>
<td>90.8</td>
</tr>
<tr>
<td>D2B Time (minutes)</td>
<td></td>
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<tr>
<td></td>
<td>Table-RFP (&lt; 29 min)</td>
<td>Table-RFP (&lt; 29 min)</td>
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<tr>
<td></td>
<td>Mean</td>
<td>50</td>
<td>Median</td>
</tr>
<tr>
<td>D2B Time (minutes)</td>
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<td></td>
<td></td>
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<tr>
<td>60.5</td>
<td>16.3</td>
<td>63.5</td>
<td>83.0</td>
</tr>
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</table>

Figure 1. D@B_delays.giove.

Conclusion: We observed that D2E > 9 min, Page-Table > 50 min and Table – Reperfusion > 29 min are associated with inferior D2B times. Performance improvement protocols addressing these issues would be of benefit.

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Gian Carlo Giove: This author has nothing to disclose.
Joon Dong Kim: This author has nothing to disclose.
Youlan Tang: This author has nothing to disclose.
Roberto Lopez: This author has nothing to disclose.
Donald Casey: This author has nothing to disclose.
Linda Gillam: This author has nothing to disclose.
Barry Cohen: This author has nothing to disclose.

A-035

Title: Clinical Predictors of Elevated Radiation Dose in Patients with Myocardial Infarction Undergoing Percutaneous Coronary Intervention

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

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Background: X-ray imaging and its associated radiation are an essential component of performing percutaneous coronary intervention (PCI). We sought to assess the radiation dose received by patients with myocardial infarction undergoing PCI and to determine if clinical and procedural characteristics were predictive of elevated radiation dose.

Methods: The study population included 1,121 patients who underwent PCI for an MI between January 2007 and December 2008 at a tertiary care teaching hospital. Total area dose (TAD) (measured in milli-gray per meter squared [mGy/m2] units) was selected as a measurement of patient radiation burden. Several clinical and procedural variables were analyzed in a multiple logistic regression model with elevated TAD (defined as greater than or equal to 20 mGy/m2) as the clinical end point.

Results: Of the 1,121 patients studied, 202 (18%) had elevated TAD exposures while 919 (82%) did not. Patients with elevated TAD were more often male (82% vs 68%, p<0.001) with higher body mass index (BMI) (33 vs 29 kg/m2, p<0.001). They also had lower left ventricular ejection fraction (0.47 vs 0.50, p = 0.008) and had more comorbidities including prior coronary artery bypass surgery (23% vs 12%, p<0.001) and diabetes (40% vs 25%, p<0.001). Patients with elevated TAD were less likely to present with a ST-elevation MI (STEMI) (32% vs 47%, p<0.001), and were more likely to have multivessel disease with more vessels intervened. In multivariate analysis, independent predictors of TAD included age (OR 1.03, 95%CI 1.01-1.05), male gender (OR 3.23, 95%CI 1.74-5.98), BMI (OR 1.14, 95%CI 1.10-1.19), STEMI presentation (OR 0.54, 95%CI 0.32-0.90) and multivessel disease (OR 2.83, 95%CI 1.51-5.33).

Conclusions: Several clinical predictors of patient radiation dose during PCI for MI were identified in this study. Appropriate radiation-protection measures in patients with characteristics predictive of higher radiation burden should be instituted to help minimize radiation dose to the patient and operator.

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Puja Parikh: This author has nothing to disclose.
Usman Tahir: This author has nothing to disclose.
Sheena Prakash: This author has nothing to disclose.
Luis Gruberg: This author has nothing to disclose.
Allen Jeremias: This author has nothing to disclose.

A-047

Title: Revisiting Pre-Hospital Fibrinolitics in STEMI Care

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Neel Bhatt, M.B.B.S., The University of Texas School of Public Health, United States, Houston, TX1; Prakash Balan, M.D., J.D., University of Texas Health Science Center at Houston, United States, Houston, TX2; H. Vernon Anderson, M.D., University of Texas Health Science Center at Houston, United States, Houston, TX3; Ali Denktas, M.D., University of Texas Health Science Center at Houston, United States, Houston, TX4; Richard Smalling, M.D., Ph.D., University of Texas Health Science Center at Houston, United States, Houston, TX5

Background: While “facilitated PCI” using full-dose fibrinolitics has not been useful in ST elevation myocardial infarction (STEMI) care, we and others have shown that pre-hospital reduced dose fibrinolitics followed by urgent percutaneous coronary intervention (PCI) is...
associated with reductions in mortality compared to primary PCI (PPCI) alone.

**Objective:** We compared in-hospital outcomes of STEMI patients treated with pre-hospital reduced dose fibrinolytics followed by urgent PCI (FAST-PCI) against outcomes of STEMI patients treated with PPCI alone.

**Methods:** The pre-hospital fibrinolytic group consisted of 253 STEMI patients treated with reteplase 10 units once prior to urgent PCI between 2003 and 2009. The PPCI group consisted of 124 STEMI patients treated with PPCI alone between 2000 and 2011 following an interruption due to shortages of reteplase. In-hospital mortality constituted the primary endpoint with reinfarction, stroke, and GUSTO major bleeding during the index hospitalization constituting secondary endpoints. Other endpoints included Killip class on hospital arrival and TIMI flow at start of PCI.

**Results:** In-hospital mortality was considerably lower in the FAST-PCI group as compared to the PPCI group (2.77% versus 10.47%, \( p = 0.0017 \)). Rates of reinfarction, stroke, and GUSTO major bleeding were not different between the two groups. Patients treated with FAST-PCI were less likely to arrive at the hospital with Killip class IV shock (2.5% vs. 20.96%, \( p < 0.0001 \)) and significantly less likely to have TIMI 0 flow in the infarct related artery at the start of PCI (20.11% vs. 56.56%, \( p < 0.0001 \)).

**Conclusion:** Pre-hospital reduced dose fibrinolytics followed by urgent PCI compared to primary PCI alone results in reduced in-hospital mortality likely due to earlier patency of the infarct related artery without a significant increase in bleeding. Reduced dose fibrinolytic administration in the field prior to urgent PCI thus remains a potential tool as part of a coordinated STEMI system of care.

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Neel Bhatt: This author has nothing to disclose.
Prakash Balan: This author has nothing to disclose.
H. Vernon Anderson: This author has nothing to disclose.
Ali Denktas: This author has nothing to disclose.
Barker Colin: This author has nothing to disclose.
James McCarthy: This author has nothing to disclose.
Stefano Sdringola: This author has nothing to disclose.
Amol Rajmane: This author has nothing to disclose.
Armen Bareketain: This author has nothing to disclose.
Richard Smalling: This author has nothing to disclose.

**A-050**

**Title:** Gradual Decline in the In-Hospital Mortality of Type 2 Diabetes Patients Presenting with Acute ST Segment Elevation Myocardial Infarction Over Last 20 Years

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Mohammad Reza Movahed, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Borut Jug, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Jenny Papazian, D., Harbor UCLA Medical Center, United States, Torrance, CA; Harpreet Bhatia, M.D., Cardiovascular Medical Group of Southern California, United States, Beverly Hills, CA; Ronald Karlsberg, M.D., Cardiovascular Medical Group of Southern California, United States, Torrance, CA; Matthew Budoff, M.D., Harbor UCLA Medical Center, United States, Torrance, CA

**Background:** Gradual decline in the in-hospital mortality of patients with ST elevation myocardial infarction has been reported. The goal of this study was to evaluate this effect in type 2 diabetes mellitus (DM) patients presenting with ST elevation myocardial infarction (STEMI).

**Method:** The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted mortality rate of patients with type 2 diabetes presenting with STEMI from 1988 to 2006 using ICD-9 coding.

**Results:** A total population of 308,297 patients of over the age of 40 with type 2 diabetes presenting with STEMI were available between 1988-2006 for our analysis. We found that age adjusted mortality rate steadily declined to a lowest level in 2006. Age adjusted mortality from type 2 DM patients presenting with STEMI 469 per 100,000 in 1988 vs. lowest rate of 283 per 100,000 in 2006 (p < 0.01). Mortality in non-DM patients also showed gradual decline starting in 1995

**Conclusion:** Mortality rate from STEMI in patients with type 2 DM showed gradual decline from 1988 until end of study in 2006 suggesting persistent advancement in the care of DM patients has led to improved outcome.

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Mohammad Reza Movahed: This author has nothing to disclose.
Mehrtash Hashemzadeh: This author has nothing to disclose.
Mehrooosh Hashemzadeh: This author has nothing to disclose.

**B-002**

**Title:** Effect of Coronary Artery Calcification on Diagnostic Accuracy of 64-Slice Multi-Detector Coronary Computed Tomographic Angiography

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Mohit Gupta, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Borut Jug, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Jenny Papazian, D., Harbor UCLA Medical Center, United States, Torrance, CA; Harpreet Bhatia, M.D., Cardiovascular Medical Group of Southern California, United States, Beverly Hills, CA; Ronald Karlsberg, M.D., Cardiovascular Medical Group of Southern California, United States, Torrance, CA; Matthew Budoff, M.D., Harbor UCLA Medical Center, United States, Torrance, CA

**Background:** Measurement of coronary artery calcium (CAC) score on coronary computed tomographic angiography (CCTA) is predictive of future coronary events. Diagnosis of coronary artery stenosis on 64 slice Multidetector CT (MDCT) in patients with extensive CAC has been challenging, but only a few studies with limited number of participants have specifically investigated the accuracy of 64 slice MDCT in detection and exclusion of CAD in these patients with invasive coronary angiography as the reference.

**Methods:** We included 427 patients who underwent both CCTA and invasive coronary angiography within 6 months for workup of anginal symptoms, at two Los Angeles medical centers from September 2006 to May 2010 or as part of the multicenter ACCURACY trial. Sensitivity, specificity, positive (PPV) and negative predictive value (NPV), and likelihood ratios (LR) of 64 slice MDCT to detect coronary artery stenosis with invasive coronary angiography as the reference were calculated in different groups based on CAC.

**Results:** Out of total 427 patients, 97 had a CAC score of 0 (mean age 51.8 ± 9), 97 had a CAC score of 1-100 (mean age 58 ± 8), 98 had a CAC score of 101-400 (mean age 58 ± 12) and 135 had a CAC score >400 (mean age 64 ± 11). On a patient based model, the sensitivity, specificity, PPV, NPV, and likelihood ratios of 64 slice MDCT to detect 50% coronary artery stenosis in each group are shown in the table.
Abstracts

Table 1. Baseline differences between patients with D2B time < and > 90 mins

<table>
<thead>
<tr>
<th></th>
<th>D2B Time</th>
<th>D2B Time</th>
<th>p value</th>
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<tbody>
<tr>
<td></td>
<td>&lt;90 mins</td>
<td>&gt; 90 mins</td>
<td></td>
</tr>
<tr>
<td>n=10,837</td>
<td>n=2,542</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Off-hours presentation, n (%)</td>
<td>5,692 (53)</td>
<td>1,777 (70)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ECG within 10 mins of hospital arrival, n (%)</td>
<td>8,476 (78)</td>
<td>1,162 (46)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Prior CABG, n (%)</td>
<td>550 (5.1)</td>
<td>222 (8.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Black race, n (%)</td>
<td>745 (6.9)</td>
<td>285 (11)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Age (years), median</td>
<td>58 (50, 66)</td>
<td>59 (50, 68)</td>
<td>0.003</td>
</tr>
<tr>
<td>Female gender, n (%)</td>
<td>2,418 (22)</td>
<td>743 (29)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Conclusion: The sensitivity of 64 slice MDCT remains preserved through all levels of CAC, however the specificity decreases with increased CAC due to blooming and beam hardening artifact created by vessel wall calcification. In patients with no CAC, MDCT is highly accurate in ruling out significant CAD with a NPV of 100%, largely obviating the need for any further testing.

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Matthew Budoff: GE, 8. Speaker’s Bureau

B-009

Title: Predictors of Reperfusion Delay in Walk-in STEMI patients from the ACTION GWTG Registry

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: David Shavelle, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA1; Anita Y Chen, None, Duke Clinical Research Institute, United States, Durham, NC2; Ray Matthews, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA3; Matthew T Roe, M.D., Duke Clinical Research Institute, United States, Durham, NC4; James A de Lemos, M.D., University Of Texas - Southwestern, United States, Dallas, TX5; James Jollis, M.D., Duke Clinical Research Institute, United States, Durham, NC6; Jay Thomas, M.D., LA Biomed Research Inst At Harbor-UCLA Medical Center, United States, Torrance, CA7; William J French, M.D., LA Biomed Research Inst At Harbor-UCLA Medical Center, United States, Torrance, CA8

Background: Primary percutaneous coronary intervention (PPCI) for STEMI is beneficial if performed in a timely manner. Walk-in STEMI patients have prolonged treatment times compared to paramedic transported patients. We therefore sought to evaluate walk-in STEMI patients and identify factors associated with prolonged door to balloon (D2B) times.

Methods: Between January 2007 and March 2011, data for 113,305 STEMI patients from 597 hospitals participating in the ACTION GWTG Registry were evaluated. Transfer-in, paramedic transported, LBBB and STEMI equivalents and those with incomplete data were excluded yielding 13,379 "walk-in" patients from 432 PPCI capable hospitals for analysis. Patients with a D2B time > 90 mins were compared to those with D2B time < 90 mins. Factors associated with prolonged D2B (> 90 mins) were explored using logistic general estimated equations method.

Results: The median (25th, 75th percentile) D2B time for the entire cohort was 72 (58, 86) mins and 19% had a D2B time > 90 mins. There were significant baselines differences between patients with a D2B time < and > 90 mins (Table). The top 6 factors associated with prolonged treatment time were off-hours (weekends and 7PM-7AM weeknights) presentation, not obtaining an ECG within 10 mins of hospital arrival, prior CABG, black race, older age and female gender.

Conclusions: While prolonged times for ECG acquisition is a modifiable factor contributing to prolonged D2B times among walk-in patients with STEMI, other factors (age, race, and gender) indicate that historic disparities for cardiovascular care still persist in terms of contemporary metrics for reperfusion for STEMI patients.

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William J French: This author has nothing to disclose.

B-010

Title: Optimal STEMI Therapy

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Ramesh Adiraju, M.D., FACC, Renu-CA Research Institute, United States, bristol, PA1; Anita Y Chen: This author has nothing to disclose.

Background: Intra-coronary (IC) thrombus is present in >85% of STEMI cases. Large thrombus burden causes more complications during PCI and has poor prognosis longterm. Time to re-canalization is crucial, however optimal myocardial perfusion is of paramount importance.

Methods: STEMI patients were front loaded in ED with eptifibatide or bivalrudin en-route to catheterization. Heparin bolus was given IC in patients receiving eptifibatide. All patients received 300mg of clopidogrel. Filling defect >70% of vessel lumen, TIMI 0 flow and no dye flow after guide wire crossing the lesion indicated significant thrombus burden. Optimal thrombectomy was performed using Essizer, Pronto or Export catheters. Resolution of the filling defect, TIMI 2 or 3 distal flow and residual stenosis <30% were accepted as final result. Balloon dilation was minimized to prevent embolization and no-reflow state. Stenting was for significant underlying disease or unstable lesions only.

Results: 81 patients were enrolled between 5/2006-7/2011.36/81 had primary thrombectomy without stents. 45/81 had partial recanalization at the time of angiography. Infarct vessel recanalization was 100%. 9/81 were in-stent thrombosis. There were no in-hospital abrupt closures, re-infarctions or major bleeding. 2/81 patients had restenosis. 2/81 presented in cardiogenic shock, died despite recanalization, autopsy showed
extensive myocardial necrosis. 3/81 had minor perforations, during Exsizer thrombectomy, successfully managed in the cath lab. One patient had distal LM stenosis with large LAD thrombus treated with LAD thrombectomy and LM stenting (fig).

**Conclusions:** Optimal treatment for STEMI with large thrombus is thrombus management. Avoiding stents and ballooning prevents no-reflow state, minimizes LV dysfunction, preserves endothelial integrity and reduces restenosis. Front loading allows for partial recanalization and reduces thrombus burden during PCI. This approach in our limited experience has proven to be cost affective and safe.

**Disclosures:**
Ramesh Adiraju: This author has nothing to disclose.

**B-045**

**Title:** Specific ECG Patterns Predict Door-to-Balloon Time in Primary PCI for STEMI

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Mercy Chandrasekaran, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Jeffrey Cook, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Rajinder Marok, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Carlos Arrieta Garcia, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Kathleen Magurany, R.N., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Peter Stecy, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL; Lloyd Klein, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL.

**Background:** A rapid evaluation of patients presenting with STEMI is based on the accurate and timely assessment of the presenting electrocardiogram (ECG), which is critical to shorter door-to-balloon (DTB) times and improved outcomes. We prospectively studied whether specific ECG patterns predicted a more rapid DTB time.

**Methods:** The study group was comprised of 209 consecutive patients with STEMI treated by primary PCI in a single teaching hospital center. Presenting ECGs were reviewed for reciprocal ST deviation, patterns of localization, presence of multiple ischemic distributions and amplitude of ST deviation. These changes were compared with mean DTB time as well as door to catheterization (DTC) times.

**Results:** The involvement of >1 ischemic distribution was associated with earlier DTB time (82 vs. 106 minutes, p < 0.05). Presence of anterior MI was associated with delayed DTB time, OR for achieving DTB time < 90 minutes 0.50 (0.27-0.94). Patients with DTB time < 90 minutes demonstrated greater mean STE than those with door-to-balloon time > 90 minutes, 3.0 +/- 1.5 vs. 2.4 +/- 1.4, (p < 0.01), were more likely to have had inferior/posterior MI (67.2% vs. 45.1%, p = 0.01)(Figure 1), as well as reciprocal ST deviation (71.6% vs. 43.7%, p < 0.01). When adjusted for other variables, reciprocal depression was a strong multivariate predictor of DTB time < 90 minutes, HR 3.4 (1.76-6.98) (p = 0.001).

**Conclusion:** The number of ECG leads with ST deviation, the presence of reciprocal ST deviation specifically and >1 ischemic distribution was associated with shorter DTB time and opening of infarct vessel faster. This data suggests that particular ECG characteristics impart a sense of urgency to the responding team more than others, independent of ST elevation.

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Kathleen Magurany: This author has nothing to disclose.
Peter Stecy: This author has nothing to disclose.
Lloyd Klein: This author has nothing to disclose.
C-018

Title: Obesity does not Predict 30-day Mortality After Coronary Angiography for STEMI

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

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Introduction: Obesity has been shown to increase the risk of coronary artery disease and to shorten overall life expectancy. The impact of obesity on short-term outcomes in patients with acute ST elevation myocardial infarction (STEMI) receiving coronary catheterizations is not known.

Methods: A retrospective analysis was conducted using data from the Maimonides Medical Center Cardiac Catheterization registry. Patients who underwent cardiac catheterization for acute STEMI between 2007 and 2011 were included in the study. Based on Body Mass Index (BMI), these patients were classified into normal weight (BMI <24.9), overweight (BMI 25-29.9) and obese (BMI >30). Primary outcome measure was 30-day mortality, and duration of hospital stay was a secondary outcome measure. Bivariate analysis was conducted using Chi square, T-tests with a P-value for significance set at 0.05. Multivariate analysis was also conducted using Multiple logistic regression and Multiple linear regression to explore the influence of obesity on 30-day mortality duration of hospital stay. This analysis controlled for age, gender, ejection fraction, history of prior PCI (Percutaneous Coronary Intervention) and a history of CABG (Coronary Artery Bypass Graft).

Results: This registry contained 898 patients who underwent coronary angiography for STEMI during this time period (2007-11). 77% were male, with a mean age of 61 years (SD 13). The median Ejection fraction in this population was 40%. Most of these patients were overweight (45%), while 33% were obese; the median BMI was 27.9. Overall 30-day mortality was about 3% with a median duration of hospital stay of 5 days. On Bivariate analysis, obese patients were noted to have been younger (Mean age 58 vs. 63 years P <0.01), they had slightly higher ejection fractions (43 vs. 41%); but there was no difference in mortality (P = 0.601) and duration of hospital stay (P = 0.240). On multivariate regression analysis, controlling for the aforementioned confounders, Obesity was shown to not be associated with increased mortality (OR 1.38, P = 0.555) or duration of hospital stay (P = 0.977).

Conclusion: Although obese patients suffer from STEMI earlier than non-obese patients, they do not appear to be more likely to sustain more adverse events after cardiac catheterization.

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as hwad afzal: This author has nothing to disclose.
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Robert Frankel: This author has nothing to disclose.
Jacob Shani: This author has nothing to disclose.

C-020

Title: Non-Atherosclerotic Coronary Artery Disease in Young Women

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Jacqueline Saw, M.D., Vancouver General Hospital, Canada, Vancouver, BC1; Christopher Buller, M.D., St. Michael’s Hospital, Canada, Toronto, ON2; Andrew Starovoytov, M.D., Vancouver General Hospital, Canada, Vancouver, BC3; John Mancini, M.D., Vancouver General Hospital, Canada, Vancouver, BC4; Donald Ricci, M.D., Vancouver General Hospital, Canada, Vancouver, BC5

Background: Non-atherosclerotic CAD (NACAD) is an important cause of myocardial infarction (MI) in young women but is often misdiagnosed. Spontaneous coronary artery dissection (SCAD) appears to be the most commonly observed NACAD, and our group has observed an association between SCAD and fibromuscular dysplasia (FMD). We suspect that underlying coronary FMD predispose these patients to SCAD causing MI. We sought to assess the prevalence of SCAD, coronary FMD, and other NACAD among young women.

Methods: We retrospectively reviewed all women aged ≤50 who underwent coronary angiography at Vancouver General Hospital over the past 2 years from Dec 1/2009 to Nov 30/2011. The baseline characteristics and medication use were recorded. The angiograms were reviewed meticulously by 2 experienced interventional cardiologists, and reported as normal or mild CAD (<30% stenosis), atherosclerotic CAD (ACAD), or NACAD. NACAD is further characterized as SCAD, coronary FMD (diffuse obliterative disease from mid to distal segment), ectasia, vasculitis, embolism, congenital anomaly, or unclear etiology.

Results: Of 760 coronary angiograms performed, 177 were done in women ≤50 years old. The mean age was 45.4 ± 4.92 (range 31-50), and 76 (42.9%) presented with acute coronary syndrome (ACS), of which 66 were troponin-positive (37.3%). There were 95 (53.7%) women with normal or mild CAD (3 had Takotsubo cardiomyopathy), 53 (29.9%) with ACAD, and 25 (14.1%) with NACAD. Four had coronary stenoses that were not discernable between ACAD or NACAD. Among patients with troponin-positive ACS, 18/66 (27.3%) had normal or mild CAD, 22/66 (33.3%) had ACAD, and 21/66 (31.8%) had NACAD. The most commonly observed NACAD were suspected vasculitis 2/25 (pulmonary aspergillosis plus eosinophilia, and SLE) and coronary ectasia 4/25.

Conclusion: Non-atherosclerotic CAD is an important cause of MI accounting for about one third of young women ≤50 years old presenting with troponin-positive ACS, SCAD or coronary FMD is the most commonly encountered NACAD in young women, and better characterization and greater awareness is pertinent.

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C-021

Title: Impact of Hemoglobin A1C Levels on In-Hospital Outcomes in Patients with Acute ST-Elevation Myocardial Infarction

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Purushothaman Mathusamy, M.D., Grand Rapids Medical Education Partners, United States, Grand Rapids, MI1; Shivanshu
Background: Admission and stress hyperglycemia are associated with increased risk of mortality after myocardial infarction. While HbA1C levels are relatively unaffected by acute fluctuation in glucose levels, its role as a marker predicting adverse outcomes in acute ST-elevation myocardial infarction (STEMI) warrants further investigation. Our objective is to determine if HbA1C is an independent predictor of in-hospital mortality and major adverse cardiac events (MACE) in patients with acute STEMI.

Methods: A retrospective analysis was performed comparing HbA1C levels and its outcome in patients with acute STEMI admitted between January 2006 and April 2011. Using 2010 American Diabetes Association criteria, patients were stratified into three groups: group 1 (HbA1C ≤ 5.6%, n = 206); group 2 (HbA1C 5.7–6.4%, n = 340); and group 3 (HbA1C ≥ 6.5%, n = 309). In hospital mortality and MACE were assessed for each stratum. Statistically significant effects were assessed at P < 0.05.

Results: HbA1C levels were available for 855/2271 (37.7%) patients. Of these 609 (71.2%) males; the average age in years was 60.8 ± 13.2 (mean ± SD). Group 3, compared to groups 1 and 2, was associated with higher glucose levels (251 ± 118 vs 156 ± 73 vs 165 ± 85; P < 0.001), more insulin use (87% vs 29% vs 36%; P < 0.001), a higher rate of DM diagnosis (84.7% vs 83.8% vs 22.6%; P < 0.001), lower incidence of dysrhythmias (20.1% vs 33.5% vs 32.9%; P < 0.001), higher prevalence of renal insufficiency (11% vs 3.4% vs 7.9%; P = 0.008) and hypertension (78% vs 52.4% vs 61.2%; P < 0.001) and a lower number of MACE (0.62 ± 1.06 vs 0.93 ± 1.28 vs 0.97 ± 1.27; P < 0.001). There was no significant difference in HbA1C concentration between survivors and non-survivor (P = 0.95). Subjects with MACE had lower HbA1C as compared to those without MACE (7.0 ± 2.0 vs. 6.5 ± 1.5, respectively; P < 0.001). After adjusting for age and gender, these findings were corroborated by logistic regression, where HbA1C remained a strong predictor of in-hospital MACE (coefficient = -0.174, P < 0.001), but not in-hospital mortality (P = 0.80)

Conclusions: In patients with acute STEMI, HbA1c was an independent predictor of MACE, but not in-hospital mortality. This suggests that HbA1C level could be used as a novel prognostic marker to risk-stratify acute STEMI patients. Our findings support recent studies in which lower HbA1C is associated with a higher incidence of macrovascular complications.

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David Wolnus: This author has nothing to disclose.

C-022

Title: Primary Percutaneous Coronary Intervention Results in Nonagenarians with ST-elevation Myocardial Infarction

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: David Larson, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; David Hildebrandt, R.N., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Ross Garberich, None, Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Marc Newell, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Scott Sharkey, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Wes Pedersen, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Timothy Henry, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN

Background: Recent census data indicate the number of people ≥90 in the US has tripled since 1980 to nearly 2 million. There is almost no data regarding the outcome of percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) in these elderly patients.

Methods: Using a comprehensive prospective regional STEMI program database, we evaluated the outcome of STEMI patients ≥90 years old undergoing PCI.

Results: Of 3,367 consecutive STEMI patients who presented to or were transferred to the Minneapolis Heart Institute at Abbott Northwestern Hospital for PCI from 4/03 to 10/11, 65 (1.9%) were ≥90 years old. The baseline characteristics and outcomes for patients ≥90 compared to other age groups are shown in Table 1. PCI was performed in 50 (76.9%) patients while 8 (12.3%) had no clear culprit and 7 (11%) received medical management. Prior to admission, 52 (83.1%) were living independently (home or assisted living). Following a median length of stay of 4 (2.7) days, 33/55 (60%) were discharged to independent living.

Conclusions: Nonagenarians with STEMI have reasonable outcomes with PCI and should be considered for reperfusion therapy.

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Marc Newell: This author has nothing to disclose.
Wes Pedersen: This author has nothing to disclose.
Timothy Henry: This author has nothing to disclose.
Title: Utility of Early Platelet Reactivity Measurements on Clinical Outcomes in Patients Undergoing Percutaneous Coronary Intervention

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

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Background: Platelet inhibition has been shown to play a significant role in the prevention of early myocardial ischemic complications. Recent data have suggested that in specific cohorts undergoing percutaneous coronary intervention (PCI), high on-treatment platelet reactivity (HTPR) is associated with poor outcomes. We sought to evaluate the clinical utility of point-of-care measurements of platelet inhibition using the VerifyNow P2Y12 assay, in a general population immediately prior to PCI.

Methods: Patients who presented with acute coronary syndromes (ACS) or electively for PCI in 2009 were prospectively evaluated. Individual cohorts were further analyzed based on clopidogrel loading times (<12 hours, 12-24 hours and > 24 hours). Platelet reactivity was measured immediately prior to angioplasty using the VerifyNow P2Y12 assay, in a general population immediately prior to PCI.

Results: Of the 315 consecutive patients, 74.9% presented with ACS (13.3% STEMI, 16.5% NSTEMI, 45.1% UA) and 25.1% for elective PCI, with an average clopidogrel loading dose of 326mg. Average platelet reactivity unit (PRU) was 297 and did not differ significantly between presentation groups. Overall, 78% of patients had PRU <120. Patients who received pravastatin >12 hours pre-PCI had a higher rate of PRU <230 (29.6%) compared to those receiving clopidogrel <12 hours prior to PCI (17.5%, p≤0.044). Overall rate of all-cause mortality at discharge, 30 days and 1 year was 0%, 0% and 0.6%, with a composite rate of major adverse cardiac events (MACE) of 1.9% at 30 days and 2.5% at 1 year. MACE occurred in 2.4% of patients with PRU >230 vs. 0% PRU <230 at 30 days (p = NS) and mean PRU did not significantly differ between those with satisfactory outcome and those with MACE.

Conclusion: In this single center “real life” observational study we did not find significant pre-PCI clinical utility nor cost effectiveness in point of care platelet reactivity testing of clopidogrel in patients presenting for PCI. Given the pharmacokinetic variability of clopidogrel, larger randomized trials would be useful in evaluating utility, timing and cost effectiveness of point of care testing of clopidogrel in said patients when compared to newer P2Y12 inhibitors with improved pharmacodynamics.

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Title: Hypothermia Improves Left Ventricular Function and Attenuates LV Remodeling in Acute Myocardial Infarction

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Elizabeth Juneman, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ; Steven Goldman, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ; Hoang Thai, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ

Background: This study was designed to determine if induction of hypothermia immediately after acute myocardial infarction (MI) improves hemodynamic parameters, preserves left ventricular (LV) function and attenuates LV remodeling.

Methods: We ligated the left coronary artery of adult male Sprague Dawley rats to induce MI. LV hemodynamics, function and chamber dimensions were measured 3 weeks after induction of hypothermia (< 28°C). A normothermic group (> 34°C) served as controls. The hypothermia groups were divided into immediate (IH, within 60 minutes) and delayed (DH, > 60 minutes).

Results: The IH group had lower LV end diastolic pressure (LVEDP) compared to controls (10.7±1.7 vs 22.2±4.4 mmHg, p < 0.05). The LVEF ejection fraction in the IH group was also preserved compared to controls (58±5.0 vs 37±3.3 %, p < 0.05). LV remodeling was also attenuated in the IH animals. In the DH group there was no differences in LVEDP, LV function and chamber dimensions compared to controls after MI.

Conclusion: Early hypothermia following myocardial infarction demonstrated an improvement in LV hemodynamics, function and attenuated LV remodeling compared to normothermic or delayed hypothermia.

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Elizabeth Juneman: This author has nothing to disclose.
Steven Goldman: This author has nothing to disclose.
Hoang Thai: This author has nothing to disclose.

Title: Predictors of In-Hospital Outcome after Primary PCI of Left Main Coronary Artery Acute Myocardial Infarction with Cardiogenic Shock

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Koshi Matsuo, M.D., Osaka Police Hospital, Japan, Osaka; Yasunori Ueda, M.D., Osaka Police Hospital, Japan, Osaka; Yasuhiro Akazawa, M.D., Osaka Police Hospital, Japan, Osaka

Background: In patients with acute myocardial infarction (AMI) and cardiogenic shock, emergency revascularization improves long-time survival. However, predictors of in-hospital outcome after primary PCI of left main coronary artery (LMCA) AMI remain unclear.

Methods: Consecutive 19 patients with AMI admitted to our hospital presenting Killip IV heart failure and occluded LMCA on emergency coronary angiogram were enrolled. We performed primary PCI of LMCA. Patients’ clinical background, angiographic findings, results of primary PCI, laboratory data, usage of circulatory supporting devices (IABP and PCPS), and elapsed time (from onset to reperfusion)
were retrospectively examined. Patients who died in hospital and those who survived were compared.

**Results:** Successful reperfusion was achieved in 19 (100%) patients; IABP was used in 19 (100%) and PCPS in 6 (32%) patients; and 13 (68%) patients survived but 6 (32%) patients died in hospital. Prevalence of diabetes mellitus (83% vs. 23%; p < 0.05), elapsed time (5.8±2.6 vs. 2.8±1.0 hours; p < 0.05), and peak CK (1527±10263 vs. 6608±3612 U/l; p < 0.05) were larger in patients who died than in those who survived.

**Conclusion:** Short elapsed time, small infarct size, and non-diabetic patients were associated with good in-hospital outcome. Therefore, sooner primary PCI of LMCA should be an effective therapeutic strategy for LMCA AMI presenting cardiogenic shock.

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Koshi Matsuo: This author has nothing to disclose.

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**D-029**

**Title:** Manual Thrombectomy Use for the Treatment of ST-Segment Elevation Myocardial Infarction: Results from a Single-Centre Registry

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Luis Alvarez-Contreras, M.D., Interventional Cardiology Department, Hospital Clinic de Barcelona, Spain, Barcelona, Barcelona; Victoria Martin-Yuste, M.D., Interventional Cardiology Department, Hospital Clinic de Barcelona, Spain, Barcelona; Marta De Antonio, M.D., Hospital German Trias I Pujol, Spain, Barcelona; Salvatore Brugaletta, M.D., Interventional Cardiology Department, Hospital Clinic de Barcelona, Spain, Barcelona; Vicens Marti, M.D., Hospital de la Santa Creu i Sant Pau, Spain, Barcelona; Joan Garcia-Picart, M.D., Hospital de la Santa Creu i Sant Pau, Spain, Barcelona; Manel Sabate, Ph.D., Interventional Cardiology Department, Hospital Clinic de Barcelona, Spain, Barcelona.

**Introduction:** Thrombus burden remains one of the critical aspects in the technique when treating ST-segment elevation myocardial infarction (STEMI). Several studies have demonstrated the efficacy of an aspiration device before percutaneous coronary intervention (PCI) in patients with STEMI. Although now described in the guidelines as an IIa indication based on the TAPAS trial.

**Material and Methods:** From May 2006 to August 2008 we evaluated all the patients that presented with STEMI for primary or rescue PCI. From 542 patients, 66 were excluded because of lack of information; and in 30 patients the guidewire did not cross the lesion. A total of 456 patients were evaluated with a clinical visit or telephone contact at the longest follow-up available. Final TIMI grade flow as well as 2-year mortality, target lesion revascularization or recurrent myocardial infarction were compared between the two groups.

**Results:** From a total of 456 patients manual thrombectomy was performed in 156 patients previously to primary PCI, 300 were treated without manual thrombectomy. Clinical characteristics were similar at presentation for both groups with the exception of more shock patients, more history of dislipidemia and more often presentation of the left circumflex artery as the culprit artery in the non-thrombectomy group (NTG). TIMI 3 flow was achieved more often in thrombectomy group (TG) than in the NTG, 85.8% vs 77.3% p = 0.04. At the long term follow-up MACE presented a non-significant positive trend in the TG (17% vs 19.6%, p = 0.25). No statistical difference was found in global mortality between the two groups 17% (TG) vs 21.6% (NTG), p = 0.5.

**Conclusions:** The use of manual thrombectomy during primary PCI in patients with STEMI significantly improved TIMI flow in the infarct-related vessel and presented a trend for a more favourable long-term outcome.

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**D-035**

**Title:** Does radial artery access slow door-to-balloon time in primary PCI?

**Category:** Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Jim Beckmann, M.D., North Colorado Medical Center, Greeley, CO 1

**Background:** It has been suggested that radial approach may delay reperfusion in primary PCI. There is a learning curve for PCI with a tranradial approach but this has been variably characterized.

We sought to determine if there was a delay in reperfusion time using the radial approach in primary PCI, either in the preparation of the patient, or in the technique of radial puncture and coronary catheter use.

**Methods:** After the first 100 tranradial angiography cases were performed, primary PCI for STEMI was undertaken. The first 15 patients undergoing primary PCI via a right transradial approach were compared to those undergoing a femoral route, with the time interval from arrival in the cath lab to inflation of local anesthetic, and the time interval from local anesthetic until balloon time, being recorded. Only exclusion criteria were prior CABG, hypotension requiring vasoactive agents or mechanical support, or the need for temporary pacing. All patients underwent angiography of the non-infarct vessel first followed by PCI of the infarct-related artery.

**Results:** Radial access for primary PCI revealed cath lab entry to local anesthetic infiltration of 12 minutes (range: 3-17 minutes; ave: 11.4) and local anesthetic to balloon of 20 minutes (range: 11-33 minutes; ave: 20.1). Femoral access produced cath lab entry to local anesthetic infiltration of 10 minutes (range: 6-16 minutes; ave: 10.6) and local anesthetic to balloon of 15 minutes (range: 8-41 minutes; ave: 18.2). There were no crossovers from radial to femoral.

**Conclusions:** In a small cohort of patients undergoing primary PCI after 100 radial cases, compared to femoral access, there appears to be a potential for slightly prolonged times on (1) preparing the patient for PCI, and (2) on performing the radial technique. This minimal discrepancy may be less evident as the number of radial primary PCI cases increases.

**Abstracts S11**
Title: Prehospital ECG Use, Interpretation and Cardiac Catheterization Laboratory Activation by EMS for Acute Coronary Syndrome

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Thomas Culwell, P.A., Midwestern University, United States, Glendale, AZ; James Stoehr, Ph.D., Midwestern University, United States, Glendale, AZ; John Sweeney, M.D., Mayo Arizona, United States, Phoenix, AZ; Richard Lee, M.D., Mayo Arizona, United States, Phoenix, AZ; F. David Fortuin, M.D., Mayo Arizona, United States, Phoenix, AZ.

Purpose: Our aim was to characterize prehospital ECG use, interpretation, and communication by local Emergency Medical Services (EMS) treating patients presenting with acute coronary syndromes.

Background: Prehospital 12 lead ECGs are indicated for patients presenting with symptoms suspicious for acute coronary syndrome. Timely acquisition, accurate interpretation, and effective communication of the findings are necessary to minimize reperfusion times in patients with ST elevation MI (STEMI).

Methods: A retrospective analysis of patients evaluated at Mayo Clinic Hospital (Phoenix, AZ) for acute coronary syndromes arriving to the Emergency Department (ED) by EMS. Patients were identified by screening records with a presenting diagnosis of chest pain, shortness of breath, or myocardial infarction. Interhospital transfers were excluded.

Results: Between August 2009 and July 2010 we indentified 227 subjects fitting study criteria. A prehospital ECG was performed in 88% of cases. Compared to male patients, female patients were less likely to have had a prehospital ECG, however the difference was not statistically significant (93% for males vs 85% for females, p = 0.083). Agreement in ECG interpretation between EMS and the ED MD occurred 86% of the time for all cases. EMS classified 39 patients as cardiac alerts (STEMI or LBBB) of which the ED MD agreed with the diagnosis 27 times (69% of cardiac alerts). Conversely, the ED identified 9 additional ECGs with ST elevation that were not identified and/or communicated to ED by EMS.

Conclusions: This retrospective analysis suggests that in patients presenting with acute coronary syndromes there remain opportunities to improve prehospital ECG acquisition, interpretation, and communication with receiving hospitals. Potential solutions include continued EMS education and prehospital ECG transmission.

Disclosures: Thomas Culwell: This author has nothing to disclose.
James Stoehr: This author has nothing to disclose.
John Sweeney: This author has nothing to disclose.
Richard Lee: This author has nothing to disclose.
F. David Fortuin: This author has nothing to disclose.

Title: Strategic Cardiac Hajj Interventional Program (SCHIP) reduces mortality during Hajj

Category: Acute Coronary Syndromes, Myocardial Infarction, Thrombectomy and Vulnerable Plaque

Authors: Owayed Al Shammeri, M.D., King Fahad Military Medical Complex, Saudi Arabia, AlDahran; Khalid Al Faraidy, M.B.B.S., King Fahad Military Medical Complex, Saudi Arabia, AlDahran;

Purpose: Our goal was to analyze the impact of a cardiac care program during the Hajj, a religious pilgrimage to Saudi Arabia.

Methods: A retrospective analysis of patients evaluated at Mayo Clinic Hospital (Phoenix, AZ) for acute coronary syndromes arriving to the Emergency Department (ED) by EMS. Patients were identified by screening records with a presenting diagnosis of chest pain, shortness of breath, or myocardial infarction. Interhospital transfers were excluded.

Results: Between August 2009 and July 2010 we indentified 227 subjects fitting study criteria. A prehospital ECG was performed in 88% of cases. Compared to male patients, female patients were less likely to have had a prehospital ECG, however the difference was not statistically significant (93% for males vs 85% for females, p = 0.083). Agreement in ECG interpretation between EMS and the ED MD occurred 86% of the time for all cases. EMS classified 39 patients as cardiac alerts (STEMI or LBBB) of which the ED MD agreed with the diagnosis 27 times (69% of cardiac alerts). Conversely, the ED identified 9 additional ECGs with ST elevation that were not identified and/or communicated to ED by EMS.

Conclusions: This retrospective analysis suggests that in patients presenting with acute coronary syndromes there remain opportunities to improve prehospital ECG acquisition, interpretation, and communication with receiving hospitals. Potential solutions include continued EMS education and prehospital ECG transmission.

Disclosures: Owayed Al Shammeri: This author has nothing to disclose.
Khalid Al Faraidy: This author has nothing to disclose.

Title: Hemodynamic Characteristics of Cyanotic Adults with Single-Ventricle Physiology Without Fontan Completion

Category: Adult Congenital

Authors: Faysal Saab, None, David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Jamil Aboulhosn, M.D., Ahmanson/UCLA Adult Congenital Heart Disease Center, United States, Los Angeles, CA; Jamil Aboulhosn, M.D., UCLA, United States, Los Angeles, CA.
Background: The aim of the current study is to describe the long-term clinical and hemodynamic characteristics of adult patients with single ventricle physiology who have not undergone the Fontan operation and consequently have remained cyanotic.

Methods: Adult patients at the Ahmanson/UCLA Adult Congenital Heart Disease Center with non-Fontan single ventricle physiology that had undergone cardiac catheterization between 2005 and 2011 were included. Echocardiographic and cardiac catheterization data were reviewed.

Results: Mean estimated single ejection fraction was 56 ± 8%. Eight of 13 subjects had documented E'/E" data with a mean of 6.44. Seven subjects had both A' and E" data documented, of which two subjects exhibited A'>E". Mean ventricular end-diastolic pressure (MVEDP) was 15.77 ± 4.91mmHg and was >12mmHg in 8 of the 13 patients (62%). MVEDP was also analyzed by age, and in the single ventricle patients was 13.55 ± 4.12mmHg in those <50 years of age, compared with 20.75 ± 1.89mmHg in those >50 years of age. MVEDP prior to inhaled pulmonary vasodilator administration was 14.75 ± 5.5mmHg, compared to 15.00 ± 6.78mmHg in the post-vasodilator group (p = .48). Subjects with EDP <12 had a mean BNP of 108 ± 197 pg/mL, while subjects with EDP >12 had a mean BNP of 234.5 ± 127.36 pg/mL.

Conclusion: Cyanotic adult single-ventricle patients not palliated with Fontan completion have preserved single ventricle systolic function but develop elevated ventricular filling pressure with increasing age. Only invasive hemodynamic measurements demonstrated elevated ventricular filling pressures, while traditional echo/Doppler criteria for diastolic dysfunction were not met. Aging with cyanotic single ventricle physiology is associated with greater degrees of “diastolic” pressure elevations than in the general population. Single-ventricle patients with EDP >12 exhibited markedly elevated BNP compared to those with normal EDP.

Disclosures:
Faysal Saab: This author has nothing to disclose.
Jamil Aboulhouj: This author has nothing to disclose.
Jamil Aboulhouj: This author has nothing to disclose.

D-001

Title: Increased Prevalence of Patent Foramen Ovale in patients with Rheumatoid Arthritis: cause or effect?
Category: Adult Congenital

Authors: Mohit Gupta, M.D., St. Joseph Mercy Hospital, United States, Pontiac, MI; Jigar Kadakia, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Yalcin Hacioglu, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Taeyoung Choi, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Borut Jug, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; George Karpouzas, M.D., Harbor UCLA Medical Center, United States, Torrance, CA; Matthew Budoff, M.D., Harbor UCLA Medical Center, United States, Torrance, CA

Background: In some individuals after birth, a small communication may persist in the fossa ovalis region, giving origin to a patent foramen ovale (PFO). The prevalence of PFOs in the general population has been estimated at range of 15% to 35% in autopsy studies and 24.3% in a TEE based study. However, the prevalence of PFO specifically in Rheumatoid Arthritis (RA) patients has never been reported. In this study, we investigate the prevalence of PFO in adult RA patients in comparison with general population using coronary computed tomography angiography (CCTA).

Methods: In a study to evaluate atherosclerosis prevalence among RA patients, (n = 77; mean age 52.6 ± 10; 89% females); we compared prevalence of PFO (by CCTA) to an age-gender-matched control group without RA (n = 78; mean age 56 ± 15; 87% females). A PFO was defined as a channel like appearance of the inter-atrial septum with contrast agent jet from left atrium to right atrium.

Results: Out of the 77 patients with RA, a PFO was present in 45 resulting in a prevalence of 58.4%, while in the control group 31 patients had a PFO resulting in a prevalence of 39.7% (p value = 0.019). In all the patients with PFO, there was a left to right shunt and none of the right sided cardiac chambers were enlarged.

Conclusion: Our study clearly demonstrates a significantly increased prevalence of PFO in patients with RA compared to age and gender matched controls. Further research is warranted in order to determine the etiology and clinical importance of this association. With the association of PFO to cryptogenic stroke and migraine in general population, it might be responsible for causing similar symptoms in RA patients.

Disclosures:
Mohit Gupta: This author has nothing to disclose.
Jigar Kadakia: This author has nothing to disclose.
Yalcin Hacioglu: This author has nothing to disclose.
Taeyoung Choi: This author has nothing to disclose.
Borut Jug: This author has nothing to disclose.
George Karpouzas: This author has nothing to disclose.
Matthew Budoff: GE, 8, Speaker’s Bureau.

D-009

Title: Incidence of Patent Foramen Ovale and Migraine Headache in Adults with Congenital Heart Disease with no Known Cardiac Shunts
Category: Adult Congenital

Authors: M. Khalid Mojadidi, M.D., David Geffen School Of Medicine At UCLA., United States, Los Angeles, CA; Marat Volman, None, B.S., SUNY Upstate Medical University, United States, New York, NY; Rabine Gevorgyan, M.D., David Geffen School Of Medicine At UCLA., United States, Los Angeles, CA; Amy Kaing, None, B.S., David Geffen School Of Medicine At UCLA., United States, Los Angeles, CA; Harsh Agrawal, M.D., David Geffen School Of Medicine At UCLA., United States, Los Angeles, CA; Jonathan Tobis, M.D., FACC, David Geffen School Of Medicine At UCLA., United States, Los Angeles, CA

Background: There is an association between right-to-left shunting, usually through a patent foramen ovale (PFO) or pulmonary arterio-venous fistula, and migraine headache (MH) with aura. The frequency of PFO is 2.5 times higher in patients with MH with aura than in people without MH. It is hypothesized that an intermittent right-to-left shunt through the PFO provides a conduit for bioactive substances to bypass metabolism in the pulmonary circulation, enter the cerebral circulation, and trigger receptors in the brain of susceptible individuals to induce a MH. This concept is supported by the observation that adults who have congenital heart defects (ACHD) with a persistent or intermittent right-to-left shunt have an increased frequency of MH. It was also found that patients with ACHD but no obvious shunt also have a higher frequency of MH. The purpose of this study was to understand why ACHD patients with no known shunt have an increased frequency of MH.

Methods: ACHD patients with no known shunt, based on their echocardiographic or angiographic procedures, were tested for a right-to-left shunt using agitated saline contrast transcranial Doppler (TCD). Medical records of 2920 patients from the UCLA ACHD Center were screened to participate in a study to evaluate the prevalence of MH in adults with ACHD. 182 patients (6.23%) had ACHD without a known shunt; of these, 60 (30%) underwent a TCD.

Results: The frequency of MH was 43% in ACHD patients with no known shunt compared to 11% in a control population of 252 patients.
without ACHD (p<0.0001). There were 23 (38%) who tested positive for a right-to-left shunt compared to 20% in the controls (p = 0.01). TCD demonstrated right-to-left shunting in approximately 2/3 of patients with pulmonary stenosis. Marfan syndrome and congenitally corrected transposition of great vessels, 1/4 of patients with bicuspid aortic valve, 1/5 of patients with mitral valve prolapse and all patients with Ebstein’s anomaly. About half of the patients with right-to-left shunt experienced MH. Patients with MH did not show a higher frequency of right-to-left shunt when compared to those without MH [p = 0.57].

Conclusion: ACHD patients with conditions not associated with a shunt have a higher than expected prevalence of PFO which permits intermittent right-to-left shunting undetected by standard non-contrast TTE and TEE. The increased prevalence of right-to-left shunting may partially explain the higher than expected frequency of MH.

Disclosures:
M. Khalid Mojadidi: This author has nothing to disclose.
Marat Volman: This author has nothing to disclose.
Rubine Gevorgyan: This author has nothing to disclose.
Amy Kaing: This author has nothing to disclose.
Harsh Agrawal: This author has nothing to disclose.

D-014

Title: Initial use of the new Gore® Septal Ocluder in Patent Foramen Ovale Closure

Category: Adult Congenital

Authors: Simon MacDonald, M.D., Ph.D., MRCP, John Radcliffe University of Oxford Hospitals NHS Trust, United Kingdom, Oxford, Oxfordshire; Matthew Daniels, M.D., Ph.D., MRCP, John Radcliffe University of Oxford Hospitals NHS Trust, United Kingdom, Oxford, Oxfordshire; Oliver Ormerod, M.D., DM FRCP, John Radcliffe University of Oxford Hospitals NHS Trust, United Kingdom, Oxford, Oxfordshire; Simon MacDonald, M.D., Ph.D., MRCP, John Radcliffe University of Oxford Hospitals NHS Trust, United Kingdom, Oxford, Oxfordshire.

Background: A number of devices are available for percutaneous closure of a clinically significant patent foramen ovale (PFO). The new GORE® Septal Occluder (GSO) is a non self centering device consisting of an expanded polytetrafluoroethylene (ePTFE) tube supported by a frame of nitinol wire conforming into a double disk. This study reports the first clinical GSO implantation experience at our centre.

Methods: GSO implantation in 30 consecutive patients is reported. Inclusion criteria were all patients referred with a significant PFO implicated in paradoxical embolism or transient right to left shunting causing desaturation. Procedures were performed under local anaesthesia and intracardiac echocardiography (ICE) in addition to fluoroscopy. Procedural data, acute and early closure rates were examined.

Results: All patients underwent successful day-case device implantation. Acute closure rates on IVC injection bubble testing were 97% (29/30) at implant and 100% (23/23) at 1 month. Average PFO balloon size was 8.1±3.5 (range 2.0-16.7) mm, mean fluoroscopic implantation time 2.5±1.6 (range 0.5-6.3) mins, radiation dose 244±295 (range 6-1431) μGyn2, and total procedural time 33.1±8.3 (range 20-53) mins. 9x20mm, 12x25m, 9x30mm GSO devices were implanted, aiming for device size at least twice balloon PFO size. Cases included aneurysmal septums with up to 30mm deviation and tunnels up to 12mm long. Removal and repositioning of 2 devices was performed on 2 occasions after uncertainty about device locking. At 1 month follow-up 4 patients had brief self-terminating episodes of palpitation suggestive of atrial tachycardia, all had normal resting ECGs. No thromboembolic/neurological events were reported.

Conclusion: The GSO can be implanted under local anaesthesia and ICE with low procedural and fluoroscopy times and high procedural success. Implantation times will improve with greater familiarity. Comparison with other occluders will be needed over the long-term but initial experience suggests it is a practical, safe and effective device for PFO closure.

Disclosures:
Simon MacDonald: This author has nothing to disclose.
Matthew Daniels: This author has nothing to disclose.
Oliver Ormerod: Dr Ormerod has a consultant agreement with WL Gore and associates, 5. Consulting Fees or Other Remuneration.

D-032

Title: Coronary Artery Fistula to Left Ventricle Presenting with Syncope and Ventricular Tachycardia

Category: Adult Congenital

Authors: Mohamed Morsy, M.D., UTMB Division Of Cardiology, United States, Galveston, TX; Wissam Khalife, M.D., UTMB Division Of Cardiology, United States, Galveston, TX; Abdelrahman Al Emam, M.D., UTMB, United States, Galveston, TX.

Coronary artery fistulae are abnormal communication between coronary arteries and other vessels or cardiac chambers; they may be congenital, or secondary to trauma or iatrogenic. It usually originates from right or left coronary artery system or, rarely, from both. In a descending order fistulae terminate in the right ventricle, right atrium, pulmonary arteries, and less frequently in SVC or coronary sinus, with the left atrium and ventricle being a very rare termination site.

We report a case of a 64 year old male patient with no past cardiac history who presented with dizziness and recurrent syncope. He had no chest pain or shortness of breath. On telemetry he had frequent runs of non-sustained VT. The cardiac workup included an echocardiogram which showed hyperdynamic LV function. Cardiac catheterization showed anomalous fistulous drainage of the left circumflex and Ramus intermedius into the left ventricle. The course of the fistula was confirmed by a coronary CT angiogram. The patient had right heart catheterization which showed significantly increased venous oxygen saturation throughout including femoral vein, IVC, SVC, and right atrium.

Figure 1. Fistula post coiling.
Methods: Medical records of 42 patients with Melody valve implantation at Ronald Reagan UCLA Medical Center and the Children’s Heart Center Nevada were reviewed (men: 25/42; mean age: 22.4 +/- 11.2 years; RVOT conduit: 23/42, BPV: 18/42; Pulmonic Stenosis: 6/42, Pulmonic Regurgitation 3/42, Both: 33/42). Detailed medical and surgical histories, as well as catheterization and echocardiography data were recorded and analyzed.

Results: The post-implantation RV-PA peak gradient measured by Doppler echocardiography (within 24 hours of valve implantation) was significantly higher than the measurements acquired by catheterization immediately following implantation (24.2 +/-16.3 mmHg vs. 11.6 +/-8.5 mmHg, p<0.0001). The relationship showed a statistically strong correlation (r = 0.65, p<0.0001) with regression analysis suggesting a predictable linear association between the two modalities in both directions (echo gradient = 1.24*cath gradient + 9.8, p<0.0001 vs. cath gradient = 0.34*echo gradient + 3.4, p<0.0001).

Conclusion: The Doppler echocardiography derived RV-PA peak gradient estimate within 24 hours of valve implantation significantly over-estimates the direct catheter measured peak gradient immediately following valve implantation. A regression equation was derived to define this important relationship.

Disclosures: Brenton Bauer: This author has nothing to disclose.
Sybil Zachariah: This author has nothing to disclose.
Abraham Rothman: This author has nothing to disclose.
Daniel Levi: This author has nothing to disclose.
Alvaro Galindo: This author has nothing to disclose.
Abdelrahman Al Emam: This author has nothing to disclose.

CO-002

Title: Comparison of Transesophageal Echocardiography and Transcranial Doppler in the Detection of Right-to-Left Shunt

Category: Adult Congenital

Authors: Rubine Gevorgyan, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA;
M. Khalid Mojadidi, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA;
Alice Perlowksi, M.D., The University of Chicago, United States, Los Angeles, CA;
Michael Shenoda, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA;
John Child, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA;
Jonathan Tobis, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA

Background: The optimal way to detect a right-to-left shunt (RLS) has yet to be determined. The aim of this study was to compare the relative sensitivity of transcranial Doppler (TCD) and transesophageal echocardiogram (TEE) using contrast agitated saline injections obtained during TEE and TCD studies that were performed simultaneously.

Methods: Patients presented to the Adult Non-Invasive Cardiac Laboratory for assessment of a suspected RLS or following PFO closure were enrolled in this single center, prospective study. Power M-mode Transcranial Doppler (Terumo 150 PMD) was conducted simultaneously during their TEE procedure.

Five injections of agitated saline were administered. The first two were done at rest and with straining using the standard echo lab protocol (mixture of 8 cc normal saline and 0.5 cc air). The injections were then repeated using our customary TCD protocol (mixture of 8 cc saline, 0.5 cc air, and 1 cc blood). The fifth injection was performed only with TCD after removal of the TEE probe; a mixture of agitated saline with blood was used with the Valsalva maneuver aided by visual feedback via manometer.

Results: Total of 81 patients participated in the study. The mean age was 52.0 +/- 14.6 years, 62% were female. The presence of RLS via a patent foramen ovale (PFO) was confirmed in 75/81 patients (93%) by
cardiac catheterization either before or after TEE and TCD. Primarily after PFO closure, 41 of the 81 (50.6%) patients tested negative for RLS with both TCD and TEE. Of the 40 patients who tested positive, 10 (25%) had a RLS with TCD (>grade 3) but were negative by TEE.

The use of blood in the agitated saline produced a significant change in TCD grade (p = 0.007) and TEE grade (p = 0.04) only in the subset of patients who had an atrial septal aneurysm. Using visual feedback with the manometer during the Valsalva maneuver increased the average TCD grade by 0.6±1.4 (p = 0.035).

The sensitivity of TCD was 94.6% while the sensitivity of TEE was only 71.4%.

Conclusion: The sensitivity for detecting RLS is higher by TCD than TEE. The addition of blood to the agitated saline mixture produced a significant increase in TCD grade. The ability of the patient to adequately perform and adjust their effort via visual feedback with a manometer during the Valsalva maneuver may also be responsible for the increased sensitivity of TCD over TEE. These results may help guide future protocols for determining the best screening test for identifying a PFO.

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Rubine Gevorgyan: This author has nothing to disclose.
M. Khalid Mojadidi: This author has nothing to disclose.
Alice Perlowksi: This author has nothing to disclose.
Michael Shenoda: This author has nothing to disclose.
John Child: This author has nothing to disclose.
Jonathan Tobis: This author has nothing to disclose.

COMPLEX PCI, RESTENOSIS, LEFT MAIN & MULTI-VESEL INTERVENTION
A-005

Title: Utility of the 0.010” Jailed Guidewire During Coronary Bifurcation Interventions via the 5 French Transradial Approach

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Justin Ratcliffe, M.D., Beth Israel Medical Center, United States, New York, NY; Yili Huang, D.O., Beth Israel Medical Center, United States, New York, NY; Michael Liou, M.D., Beth Israel Medical Center, United States, New York, NY; Muhammad Choudhry, M.D., Beth Israel Medical Center, United States, New York, NY; David James, M.D., Beth Israel Medical Center, United States, New York, NY; Ravi Diwan, M.D., Beth Israel Medical Center, United States, New York, NY; Sanjay Cherukuri, M.D., Beth Israel Medical Center, United States, New York, NY; Tak Kwan, M.D., Beth Israel Medical Center, United States, New York, NY

Background: In coronary bifurcation lesions, provisional stenting with jailed guidewire protection in the sidebranch facilitates the maintenance of TIMI 3 flow in the sidebranch. However, technical difficulties arise when using the conventional guidewire during the 5Fr transradial approach due to a size limitation of the inner lumen diameter and potential for stent loss, distal embolization of wire particles, and guiding trauma. We propose that the use of a 0.010” jailed guidewire, instead of the conventional 0.014”, will facilitate the employment of the 5Fr transradial approach in treating bifurcation lesions.

Methods: Seventeen consecutive patients undergoing elective transradial percutaneous coronary intervention (PCI) were enrolled. All of the patients had bifurcation lesions with Medina score of (1, 1, 0), (1, 0, 0), or (0, 1, 0) and underwent jailed guidewire side branch protection using either the standard 0.014”, or the 0.010”, guidewire. The rest of the interventional procedure proceeded as per usual protocol. Each of the patients had clinical follow-up post-procedure at 1 day, 7 days, and 30 days. Angiographic parameters, TIMI flow score, post-op microscopic wire examination, and major adverse cardiovascular events were assessed.

Results: In this consecutive series, we successfully treated 10 patients with the 0.010” guidewire technique, and 7 patients with the 0.014” guidewire technique. Significant microscopic 0.014” guidewire stripping of the hydrophilic coating was noted in 4/7 patients while this finding was not observed in any of the 0.010” guidewire group. Additionally, 4/7 patients in the 0.014” group were found to have significant side-branch guidewire removal difficulty with substantial deep intubation of the guiding catheter into the coronary artery. This procedural difficulty was not encountered when using the 0.010” guidewire. TIMI 3 flow was obtained in all patients post intervention. There were no cardiac events at the specified time points.

Conclusion: The use of 0.010” jailed guidewire during provisional coronary bifurcation stenting is an innovative and feasible technique that may ease the procedural difficulties commonly associated with the 5Fr transradial approach.

Disclosures: Justin Ratcliffe: This author has nothing to disclose. Yili Huang: This author has nothing to disclose. Michael Liou: This author has nothing to disclose. Muhammad Choudhry: This author has nothing to disclose. David James: This author has nothing to disclose. Ravi Diwan: This author has nothing to disclose. Sanjay Cherukuri: This author has nothing to disclose. Tak Kwan: This author has nothing to disclose.

A-023

Title: Double Kissing (DK) Crush Versus Culotte Stenting for the Treatment of Unprotected Distal Left Main Bifurcation Lesions: DKCRUSH-III, a Multicenter Randomized Study Comparing Double-Stent Techniques

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Shao-Liang Chen, M.D., Ph.D., Nanjing First Hospital, Nanjing Medical University, China, Nanjing; Bo Xu, M.B.B.S., Beijing Fuwai Hospital, China, Beijing; Yu-Jie Zhou, M.D., Beijing ANZHEN Hospital, China, Beijing; Ya-Ling Han, M.D., ShenYang Northen Hospital, China, Shenyang

Objectives: The present study aimed to investigate the differences in major adverse cardiac events (MACEs) at 12-month for unprotected left main coronary artery (ULMCA) distal bifurcation lesions after double kissing (DK) crush vs. Culotte stenting.

Background: DK crush and Culotte stenting were reported to be effective for the treatment of coronary bifurcation lesions. However, the safety and durability of these two-stent techniques for ULMCA bifurcation lesions have never been studied.

Methods: From March 2009 to October 2010, 152 patients with ULMCA bifurcation lesions from 15 centers were randomly assigned to receive either DK (n = 77) or Culotte (n = 75) treatment. The primary endpoint was the occurrence of a MACEs at 12-month, including cardiac death, myocardial infarction, and/or target-vessel revascularization. Restenosis and late loss at 6-month was a secondary endpoint, and the rate of stent thrombosis (ST) served as a safety endpoint.

Results: There were 2 (2.7%) intra-procedural ST after side branch (SB) stenting in the Culotte group. Patients in the Culotte group had higher late loss, more frequent restenosis (9.7%) at ostial SB, and MACEs (21.6%), compared to the DK group. The study protocol defined definite and probable ST rate in the Culotte group was 6.7% (all seen in bifurcation angle >90°), and it was 0% in the DK group (p = 0.027).
Distal bifurcation angle, previous MI and overlapping stent length in the left main artery were predictors of ST. A wider angle should be carefully used because it was associated with significantly increased stent thrombosis and MACEs. (ChiCTR-TRC-00000151 [http://www.chictr.org]).

Conclusion: Culotte stenting for ULMCA bifurcation lesions with a greater distal bifurcation angle was associated with lower complication rates. Mastering the retrograde approach is an essential component of developing a CTO PCI program.

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Shao-Liang Chen: This author has nothing to disclose.
Bo Xu: This author has nothing to disclose.
Yu-Jie Zhou: This author has nothing to disclose.
Ya-Ling Han: This author has nothing to disclose.

A-045

Title: Retrograde Coronary Chronic Total Occlusion: Procedural Outcomes from a Multicenter US Registry

Revascularization: Procedural Outcomes from a Multicenter US Registry

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Dimitri Karmpaliotis, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Tesfaldet Michael, M.D., VA North Texas Healthcare System and University of Texas Southwestern Medical Center, United States, Dallas, TX; Emmanouil Brilakis, M.D., Ph.D., VA North Texas Healthcare System and University of Texas Southwestern Medical Center, United States, Dallas, TX; Nicholas Lembo, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Anna Kalynych, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Harold Carlson, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Subhash Banerjee, M.D., VA North Texas Healthcare System and University of Texas Southwestern Medical Center, United States, Dallas, TX; David Kandzari, M.D., Piedmont Heart Institute, United States, Atlanta, GA; William Lombardi, M.D., Ph.D., St. Joseph Medical Center, United States, Bellingham, WA.

Background: The retrograde approach, pioneered and developed in Japan, has revolutionized the treatment of coronary chronic total occlusions (CTOs), yet limited information exists on procedural efficacy and safety in non-Japanese centers.

Methods: We examined the procedural outcomes of 401 consecutive retrograde CTO interventions performed at 3 US institutions [PeaceHealth St. Joseph Medical Center, Bellingham Washington (n = 209), Piedmont Hospital, Atlanta Georgia (n = 127) and VA North Texas Healthcare System, Dallas, Texas (n = 65)] between 2006 and 2011.

Results: Mean age was 65±10 years, 84% were men, 45% were diabetics, and 50% had prior coronary artery bypass graft surgery. The CTO target vessel was the right coronary artery (66%), circumflex (18%), left anterior descending artery (15%), and left main artery or a bypass graft (1%). The retrograde approach was used as the primary approach in 48% or after an antegrade crossing failed in 52%. The collateral vessel used was septal (71%), epicardial (19%), or bypass graft (10%).

Procedural success was achieved in 318 patients (79.3%). The techniques used for retrograde crossing were true-to-true puncture (47%), controlled antegrade and retrograde tracking and dissection (CART, 12%) and reverse CART (41%). Most patients (90%) received drug-eluting stents with a mean stent length of 71 ± 37 mm. The mean contrast volume and fluoroscopy time were 368 ± 179 mL and 65 ± 41 minutes.

A major procedural complication occurred in 16 patients (4%): 1 death (due to intracranial bleeding), 2 Q-wave myocardial infarctions, 2 donor vessel dissections (one requiring emergency coronary artery bypass graft surgery and one treated with stenting), 1 equipment entrapment requiring coil occlusion of a ventricular septal defect, and 10 perforations requiring pericardiocentesis (n = 8) or emergent surgery (n = 2).

Conclusion: In the largest collective experience reported to date in the US, retrograde CTO PCI is most commonly performed in patients with prior coronary bypass graft surgery and carries high success and low complication rates. Mastering the retrograde approach is an essential component of developing a CTO PCI program.

Disclosures:
Dimitri Karmpaliotis: This author has nothing to disclose.
Tesfaldet Michael: This author has nothing to disclose.
Emmanouil Brilakis: Abbott Vascular and Infraredx, 2. Research Grants, St Jude Medical and Terumo, 8. Speaker’s Bureau, spouse is an employee of Medtronic, Other.
Nicholas Lembo: This author has nothing to disclose.
Anna Kalynych: This author has nothing to disclose.
Harold Carlson: This author has nothing to disclose.
David Kandzari: This author has nothing to disclose.
William Lombardi: This author has nothing to disclose.

B-008

Title: Use of the CrossBoss Catheter in Coronary Chronic Total Occlusion Due to In-Stent Restenosis

Revascularization: Use of the CrossBoss Catheter in Coronary Chronic Total Occlusion Due to In-Stent Restenosis

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Aristotelis C. Papayannis, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Tesfaldet T. Michael, M.D., MPH, VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Tesfaldet Michael, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; David Kandzari, M.D., Piedmont Heart Institute, United States, Atlanta, GA; William Lombardi, M.D., Ph.D., St. Joseph Medical Center, United States, Bellingham, WA.

Background: Chronic total occlusion (CTO) of coronary arteries is a well-known condition. The retrograde approach, pioneered and developed in Japan, has revolutionized the treatment of coronary chronic total occlusions (CTOs), yet limited information exists on procedural efficacy and safety in non-Japanese centers.

Methods: We examined the procedural outcomes of 401 consecutive retrograde CTO interventions performed at 3 US institutions [PeaceHealth St. Joseph Medical Center, Bellingham Washington (n = 209), Piedmont Hospital, Atlanta Georgia (n = 127) and VA North Texas Healthcare System, Dallas, Texas (n = 65)] between 2006 and 2011.

Results: Mean age was 65±10 years, 84% were men, 45% were diabetics, and 50% had prior coronary artery bypass graft surgery. The CTO target vessel was the right coronary artery (66%), circumflex (18%), left anterior descending artery (15%), and left main artery or a bypass graft (1%). The retrograde approach was used as the primary approach in 48% or after an antegrade crossing failed in 52%. The collateral vessel used was septal (71%), epicardial (19%), or bypass graft (10%).

Procedural success was achieved in 318 patients (79.3%). The techniques used for retrograde crossing were true-to-true puncture (47%), controlled antegrade and retrograde tracking and dissection (CART, 12%) and reverse CART (41%). Most patients (90%) received drug-eluting stents with a mean stent length of 71 ± 37 mm. The mean contrast volume and fluoroscopy time were 368 ± 179 mL and 65 ± 41 minutes.

A major procedural complication occurred in 16 patients (4%): 1 death (due to intracranial bleeding), 2 Q-wave myocardial infarctions, 2 donor vessel dissections (one requiring emergency coronary artery bypass graft surgery and one treated with stenting), 1 equipment entrapment requiring coil occlusion of a ventricular septal defect, and 10 perforations requiring pericardiocentesis (n = 8) or emergent surgery (n = 2).

Conclusion: In the largest collective experience reported to date in the US, retrograde CTO PCI is most commonly performed in patients with prior coronary bypass graft surgery and carries high success and low complication rates. Mastering the retrograde approach is an essential component of developing a CTO PCI program.

Disclosures:
Aristotelis C. Papayannis: This author has nothing to disclose.
Tesfaldet T. Michael: This author has nothing to disclose.
David Kandzari: This author has nothing to disclose.
William Lombardi: This author has nothing to disclose.
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Background: Chronic total occlusions (CTO) due to in-stent restenosis represent 5-25% of total CTO intervention case volume. Failure to cross is the main reason for procedural failure. The CrossBoss catheter (BridgePoint Medical, Minneapolis, Minnesota) has been shown to improve success rates in crossing refractory CTOs, but the pivotal trial excluded CTOs due to in-stent restenosis.

Methods: We describe the outcome of using the CrossBoss catheter to cross CTOs due to in-stent restenosis. The CrossBoss catheter has a 1 mm blunt, hydrophilic-coated distal tip that can advance through the occlusion when the catheter is rotated rapidly using a proximal torque device (“fast spin” technique).

Results: The CrossBoss catheter allowed successful CTO crossing in 5 of 6 lesions (83%); in 50% the catheter entered the distal true lumen, whereas in 33% a wire was required for distal true lumen crossing (Figure). No complications were observed. The mean fluoroscopy time was 29.8 ± 20 min and the mean volume of contrast was 279 ± 59 ml.

Conclusion: Use of the CrossBoss catheter may facilitate treatment of coronary CTOs due to in-stent restenosis.

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Aristotelis C. Papayannis: This author has nothing to disclose.
Tesfaldet T. Michael: This author has nothing to disclose.
Bavana V. Rangan: This author has nothing to disclose.
Emmanouil S. Brilakis: Spouse is an employee of Medtronic, 3. Employment (full or part-time), InfraReDx, 2. Research Grants, Terumo speaker’s honoraria, Other, St. Jude Medical speaker’s honoraria, Other (please describe in Entity field), Abbott Vascular, 2. Research Grants.

B-011

Title: Does Dedicated Stent Improve the Results of Standard Therapy For Coronary Bifurcations?
Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Luis Antonio Iñigo-Garcia, M.D., Hospital Costa del Sol, Spain, Marbella; Teresa Gil-Jimenez, M.D., Hospital Costa del Sol, Spain, Marbella; Marta Pombo-Jimenez, M.D., Hospital Costa del Sol, Spain, Marbella; Miguel Angel Iñigo-Garcia, M.D., Ph.D., Hospital de La Linea, Spain, La Linea; Carmen Medina-Palomino, M.D., Hospital Costa del Sol, Spain, Marbella; Juan Francisco Muñoz-Bellido, M.D., Hospital Costa del Sol, Spain, Marbella; Leticia Fernandez-Lopez, M.D., Hospital Costa del Sol, Spain, Marbella;
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**Background:** For a long time, classic treatment for bifurcations (CTB) involved implanting a stent in the main artery, and kissing balloon inflation or a stent for the secondary branch. We evaluate the use of a dedicated Frontier stent (FS) for bifurcations vs CTB.

**Methods:** From January 2003 to August 2011 all patients admitted with a coronary bifurcation lesion treatable with percutaneous coronary intervention (PCI) were included. A mean 32-month follow-up was accomplished.

**Results:** 122 patients without significant basal differences were included. The bifurcation lesion was located in left main 10.6%, left anterior descending-diagonal in 61.5%, circumflex-posterolateral in 10.7%. The mean diameter of the stents was 3.15 mm in the Frontier group versus 3.12 mm in the other group and the average length was 18 versus 18.88 mm respectively (no significant differences). No statistically significant differences between groups in the clinical events rate were found during the follow-up. Nevertheless, in the 38 patients Frontier group, 19 of them were reevaluated by angiography due to clinical events. One case of FS restenosis was found (5.26%), the rest of them showed disease progression in other location or absence of new lesions. In the 84 patients CTB group, 32 were reevaluated, and 13 restenosis cases were found (40.62%) (p<0.05).

**Conclusions:** Our results show that dedicated stent use for coronary bifurcation treatment yields better results in relation to the treated lesion, with a similar rate of clinical events than the CTB.

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Luis Antonio Igigo-Garcia: This author has nothing to disclose.
Teresa Gil-Jimenez: This author has nothing to disclose.
Marta Pombo-Jimenez: This author has nothing to disclose.
Miguel Angel Igigo-Garcia: This author has nothing to disclose.
Carmen Medina-Palomo: This author has nothing to disclose.
Juan Francisco Muñoz-Bellido: This author has nothing to disclose.
Leticia Fernandez-Lopez: This author has nothing to disclose.
Juan Ramon Siles-Rubio: This author has nothing to disclose.
Pedro Chinchurreta-Capote: This author has nothing to disclose.
Antonio Ramirez-Moreno: This author has nothing to disclose.
Olga Sanz-Vazquez: This author has nothing to disclose.
Rafael Garcia-Peña: This author has nothing to disclose.
Francisco Ruiz-Mateas: This author has nothing to disclose.

**B-022**

**Title:** Use of the GuideLiner Catheter to Facilitate Complex Transradial Coronary Interventions

**Category:** Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

**Authors:** Moneer J. Eddin, M.D., UC Davis Medical Center, United States, Sacramento, CA\textsuperscript{1}; Ehrin J. Armstrong, M.D., UC Davis Medical Center, United States, Sacramento, CA\textsuperscript{2}; Usman Javed, M.D., UC Davis Medical Center, United States, Sacramento, CA\textsuperscript{3}; Jason H. Rogers, M.D., UC Davis Medical Center, United States, Sacramento, CA\textsuperscript{4}

**Background:** Transradial coronary intervention (TRI) is gaining popularity. However, anatomic variations and lack of guide catheter support may complicate TRI. The GuideLiner catheter (Vascular Solutions, Inc) is a guide catheter extension developed to provide more support, thereby facilitating procedural success. We describe the procedural and angiographic characteristics of cases where GuideLiner use facilitated complex TRI.

**Methods:** 75 TRIs were performed from August 2010 to November 2011. Twelve cases (16%) required GuideLiner support. Proximal vessel and target lesion angulation (Minor < 45°, Moderate 45-90°, excessive >90°) and Guideliner intubation depth was measured.

**Results:** The relevant procedural details of the 12 cases are reported in the TABLE. 6 cases were elective, 5 were UA/NSTEMI, and one was STEMI. All of the cases involved inadequate seating of the guide catheter as the primary indication for GuideLiner support. Six (50%) of the cases had GuideLiner use at the outset. The other six cases utilized the GuideLiner intraprocedurally. Eight (66%) of the cases involved a moderate or excessive tortuosity of the proximal target vessel (mean angle 79±28°), whereas the target lesion tortuosity was mild (39±16°). Nine (75%) cases involved an ACC/AHA Type B2 or C lesion. The mean GuideLiner intubation depth during TRI was 16.4 ± 13.8 mm. The procedural success was 100%.

**Conclusion:** The GuideLiner catheter has an important role in facilitating guide catheter engagement and support in a significant number of TRI cases. The main challenges include inadequate guide catheter seating and proximal vessel tortuosity.

**Key:** RRA = Right Radial Artery, LRA = Left Radial Artery, RCA = Right Coronary Artery, L Cx = Left Circumflex, Diag1 = First Diagonal Branch, LAD = Left Anterior Descending Artery, STEMI = ST elevation Myocardial Infarction, Fr = French.

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Moneer J. Eddin: This author has nothing to disclose.
Ehrin J. Armstrong: This author has nothing to disclose.
Usman Javed: This author has nothing to disclose.
Jason H. Rogers: This author has nothing to disclose.
**B-027**

**Title:** Quality of Life Improvements with Impella Hemodynamic Support Compared with Intra-Aortic Balloon Pump in High Risk Patients Receiving PCI: Results from the PROTECT II Trial  
**Category:** Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Simon Dixon, M.D., William Beaumont Hospital, United States, Royal Oak, MI; Brijshwar Maini, M.D., Pinnacle Health Systems, United States, Harrisburg, PA; Igor Palacios, M.D., MGH, United States, Boston, MA; William O’Neill, M.D., University Of Miami, United States, Miami, FL; David Gregory, None, Prescott Associates, United States, Avon, CT

**Background:** Recently released clinical and economic outcomes of hemodynamic support in patients with left ventricular dysfunction and complex anatomy translate into quality of life measurements for patients.

**Methods:** PROTECT II studied patients with 3 vessel disease and LV ejection fraction ≤ 30% or with unprotected left main/last patent conduit and LV ejection fraction ≤ 35% during PCI. Patients were randomized to either intra aortic balloon pump (IABP) or Impella (Abiomed). The primary endpoint was a composite of ten major adverse events (MAE) measured at 30 and 90 days. A parallel economic study measured episode-of-care costs, major adverse cardiac and cerebral events (MACCE), and Quality-Adjusted Life Years (QALYs) for both study arms and used a Markov model to estimate the incremental cost-effectiveness ratio (ICER).

**Results:** MAE at 90 days for Impella were 40.0% vs. IABP 51.0% (p = 0.023) including a 52% relative reduction in repeat revascularization (Impella 6.0% vs. IABP 12.4%, p = 0.024). More specifically, MACCE was reduced by 29% at 90 days in the Impella patients over the IABP patients (p = 0.03), which was associated with a gain in QALY of 2.48 for Impella patients. Additionally, median hospital days for entire episode-of-care for Impella were 7 days vs. IABP 9 days (p = 0.008), including a >40% reduction in days in Critical Care, an important marker of a patient’s quality of life. These costs and QALY measures resulted in a base case ICER of $39,367 per QALY, well below the threshold for innovative technologies.

**Conclusion:** For patients with severe LV dysfunction and complex anatomy, more than 60% of whom have no other treatment option, prophylactic use of Impella during PCI improves quality of life for patients as measured by improvement in QALY. Additional improvements in quality of life are implied for Impella patients with reduced repeat procedures and readmissions, reduced length-of-stay in the hospital, and improvement in functional status as measured by NYHA and ejection fraction.

**Disclosures:**
David Gregory: This author has nothing to disclose.

**B-036**

**Title:** Role of Embolic Protection Devices in Ostial Saphenous Vein Graft Lesions  
**Category:** Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Abdul-rahman Abdel-karim, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Aristotelis Papayannis, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Ali Mahmood, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Arif Mahmood, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Emanouil Brilakis, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX

**Background:** Although embolic protection devices (EPDs) have been shown to be beneficial in saphenous vein graft (SVG) lesions, their role in the subgroup of ostial SVG lesions has received limited study.

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Arif Mahmood: Research Grants.
Emanouil Brilakis: Research Grants.

**Figure 1. Flow chart of the patients included in the present study.**

**Figure 2. Frequency of ostial saphenous vein graft lesions treated at our institution during the study period, and frequency of embolic protection device utilization.**
Methods: The coronary angiograms and procedural outcomes of 109 patients undergoing stenting of 113 ostial SVG lesions were retrospectively reviewed to determine the frequency of EPD use and the periprocedural outcomes.

Results: Ninety-eight (87%) of the 113 lesions were suitable for EPD use, that was used in 70 lesions (71%). A Filterwire (Boston Scientific) or a Spider (ev3) filter were used in 54 (77%) and 16 (23%) of lesions, respectively. Difficulty retrieving the filter post stenting was encountered in 8 lesions (11%) and led to stent thrombosis causing cardiac arrest in one patient (1%). Angiographic success was achieved in 111 (98%) of 113 lesions.

Conclusion: EPDs can be utilized in the majority of ostial SVG lesions, but in 11% of cases filter retrieval can be challenging and may rarely (in approximately 1%) lead to a significant complication.

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Abdul-rahman Abdel-karim: This author has nothing to disclose.
Aristotelis Papayannis: This author has nothing to disclose.
Arif Mahmood: This author has nothing to disclose.
Bavana Rangan: This author has nothing to disclose.
Lorenza Makke: This author has nothing to disclose.
Emmanouil Brilakis: St Jude Medical, 8. Speaker’s Bureau, spouse is an employee of Medtronic, Other, Abbott Vascular and Infraredx, 2. Research Grants, Medicure, 5. Consulting Fees or Other Remuneration.

B-038

Title: Transradial High-speed Rotational Atherectomy for Heavily Calcified Lesions: Including the Clinical Outcomes of End-Stage Renal Disease Patients

Background: Transradial coronary intervention (TRI) has advantages as a minimally invasive procedure, including less bleeding complications and early ambulation after the procedure. High-speed rotational atherectomy (HSRA) is the most effective device to treat heavily calcified lesions but with few reports on the clinical results of HSRA by TRI.

Objective: The objective of this study is to assess the clinical outcomes of patients who were treated by the transradial approach for high-speed rotational atherectomy (TR-Rota).

Methods: Subjects were 115 consecutive patients with 195 lesions who underwent HSRA for heavily calcified lesions from March 2003 to May 2010. The early and late outcomes of TR-Rota cases were studied retrospectively.

Results: Of the 115 patients, TR-Rota was performed on 92 patients (80%) and 158 lesions. For patient characteristics, TR-Rota patients had an average age of 71±1 years, 71 (77%) were male, 50 (45%) had diabetes, and 20 (22%) were End-stage renal disease (ESRD). For lesion characteristics, 120 lesions (76%) were ACC/AHA type B2/C. The guiding catheter used was 6 Fr. in 66%, 7 Fr. in 34%, and the mean burr size was 1.59±0.13mm. Procedural success was 96.7% (86/92) and clinical success was 94.6% (84/92). For in-hospital complications, 2 patients (2.2%) had Q-wave MI, but no bleeding complications (TIMI major or minor) were recognized. There was no conversion to the femoral approach. Stent implantation following TR-Rota (n = 183) used the BMS in 30% (54/183) and DES in 70% (129/183). Restenosis rates based on follow-up angiography at a mean 7.5±2.8 months after the procedure were 33.3% (12/36) of the BMS lesions and 10.9% (10/92) of the DES lesions, with the DES group showing a significantly lower rate (p<0.05). Clinical follow-up at a mean 41.9±28.6 months revealed cardiac death in 9 patients (9.8%), myocardial infarction in 1 (1.1%), and target lesion revascularization in 12 (13%). The procedural success of TR-Rota on ESRD patients was 100% (20/20). At late follow-up, 15% (3/20) of ESRD patients had weak pulsation or occlusion in the radial artery, but no adverse effects of the TR-Rota procedure were recognized in the patients who had problems with arteriovenous shunts. Conclusion: This study demonstrates that TR-Rota using smaller bur is safe and feasible for heavily calcified lesions. It was suggested that TR-Rota would not have an adverse impact on arteriovenous shunt problems that could occur in the follow up stage.

Disclosures:
Kenji Wagatsuma: This author has nothing to disclose.

B-046

Title: In-Hospital Mortality of Obese Patients Undergoing Percutaneous Coronary Intervention has been Declining from 1989 to 2006

Background: We recently published gradual decline in the percutaneous coronary intervention (PCI) related in-hospital mortality over recent years. The goal of this study was to evaluate this trend in obese patient vs. non obese in the United States.

Method: The Nationwide Inpatient Sample (NIS) database was utilized to calculate the age-adjusted incident rate of PCI related mortality from 1989 to 2006 based the diagnosis of obesity using ICD-9 coding.
C-011

Title: Bilateral Transradial Approach for Percutaneous Coronary Intervention of Chronic Total Occlusions

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

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Background: Chronic total occlusions (CTOs) are challenging percutaneous coronary intervention (PCI) procedures. Few data is available on the use of transradial approach for PCI of CTOs.

Methods: From 2007 to 2011 consecutive patients with CTO admitted to a single tertiary cardiac center with operators skilled in trans-radial PCI were screened. CTO was defined as coronary occlusion > 3 months. Only CTOs requiring a strategy of intentional planned double guiding catheter technique, i.e. controlateral injection and/or retrograde approach, were considered for inclusion in the study. All patients with pulsating right and left radial artery were finally included. Procedural success was defined as the achievement of final artery patency after stent implantation with Thrombolysis in Myocardial Infarction (TIMI) flow of at least 2. Continuous variables were described as mean and standard deviation or median and 25th-75th percentiles, as appropriate.

Results: A total of 85 patients, (62.6±10.9) yrs-old, 76 (89.4%) males, were enrolled. The occluded vessel was left descending anterior artery in 20 (23.5%) patients, left circumflex-obtuse marginal in 16 (18.8%), right coronary artery/interventricular posterior artery in 49 (57.6%). The guiding catheter size was 7F in 2 cases; in the remainder a 6F guiding catheter was used. No switch to femoral approach for PCI occurred. Retrograde approach was performed in 22 (25.9%) patients, via septal collaterals or epicardial collaterals. Median duration of procedure was 100 minutes (71-124 minutes, 25th -75th percentiles) and median volume of contrast administered was 260 ml (177-356 ml, 25th -75th percentiles). Procedural success was achieved in 63(74.1%) patients. In all cases a final TIMI flow of 3 was achieved. There were 3 cases of coronary perforation, of which 1 requiring pericardiocentesis. No in-hospital death or major bleeding occurred.

Conclusion: Bilateral transradial approach for PCI of CTOs is an effective and safe technique. Transradial PCI training programs should be encouraged.

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Giuseppe Ferrante: This author has nothing to disclose.
Thierry Lefèvre: This author has nothing to disclose.
Thomas Hovasse: This author has nothing to disclose.
Hakim Benamer: This author has nothing to disclose.
Yves Louvard: This author has nothing to disclose.

**Background:** Updated guidelines recommend percutaneous coronary intervention (PCI) as an alternative to coronary artery bypass graft surgery (CABG) in patients with 3-vessel coronary artery disease (CAD) who have low SYNTAX scores. We sought to determine changes in the use of PCI for 3-vessel CAD since publication of the SYNTAX trial.

**Methods:** Records of patients revascularized for 3-vessel CAD from January 2009 to December 2010 at a tertiary care center were reviewed. Patients with prior CABG were excluded. Syntax scores were calculated retrospectively by reviewing angiograms. We compared the use of PCI versus CABG across different SYNTAX score categories.

**Results:** Of 1,170 patients with 3-vessel CAD, 116 (9.9%) received PCI during the 2-year period. The use of PCI in patients with 3-vessel CAD increased from 7.9% in 2009 to 15.5% in 2010 (p < 0.0001). There was no significant change in the use of PCI for the low-risk SYNTAX category (12% vs. 15.5%, p = 0.37) (figure). In the intermediate-risk SYNTAX category, PCI use doubled from 2009 to 2010 (8% vs. 16%, p = 0.014). PCI use also increased for the high-risk SYNTAX category (5% vs. 14.5%, p = 0.003). In 2010, the increased use of PCI among patients with high SYNTAX scores was driven by higher EuroSCOREs.

**Conclusion:** The use of percutaneous coronary intervention in the revascularization of SYNTAX-appropriate patients is low despite current evidence and clinical guidelines.

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- Tonga Nfor: This author has nothing to disclose.
- Wael Hassan: This author has nothing to disclose.
- Quinta Nfor: This author has nothing to disclose.
- Jayant Khitha: This author has nothing to disclose.
- Anjan Gupta: This author has nothing to disclose.
- Subhail Allaqaband: This author has nothing to disclose.
- Richard Bach: This author has nothing to disclose.
- Jasvindar Singh: This author has nothing to disclose.

**C-033**

**Title:** Use of Percutaneous Coronary Intervention for Multivessel Coronary Artery Disease Is Increasing But Still Low

**Category:** Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

**Authors:** Tonga Nfor, M.D., MSPH, ACS, Aurora Sinai/St. Luke’s Med Ctrs, Univ Wisconsin School Med & Public Health, United States,

Disclosures:
- Tonga Nfor: This author has nothing to disclose.
- Wael Hassan: This author has nothing to disclose.
- Quinta Nfor: This author has nothing to disclose.
- Jayant Khitha: This author has nothing to disclose.
- Anjan Gupta: This author has nothing to disclose.
C-044

Title: Acute and Mid-Term Outcomes After Retrograde Recanalization of Coronary Chronic Total Occlusions in a Veteran Population

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Bavana Rangan, NONE, VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Tesfaldet Michael, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Aristotelis Papayannis, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Subhash Banerjee, M.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX; Emmanouil Brilakis, M.D., Ph.D., VA North Texas Healthcare System And UT Southwestern Medical Center, United States, Dallas, TX

Background: The retrograde approach has revolutionized the treatment of chronic total occlusions (CTOs), yet limited information exists on acute procedural safety and long-term outcomes.

Methods: Between 2008 and 2011, 65 retrograde CTO interventions were performed at our institution with procedural success in 46 (71%). The medical records of the successful retrograde CTO cases were reviewed to determine the techniques utilized, the incidence of periprocedural myocardial infarction and follow-up clinical outcomes.

Results: Mean age was 63±8 years, 98% were men, 46% had diabetes mellitus, 30% had prior coronary bypass graft surgery, 61% had prior myocardial infarction, and 11% had prior stroke. The CTO target vessel was the right coronary (76%), left anterior descending (11%), or circumflex (11%) artery, or a bypass graft (2%). The retrograde was used as primary approach in 47% or after an antegrade approach failed in 53%. Lesion crossing was performed retrogradely in 27% (59%) of patients using the following techniques: controlled antegrade and retrograde tracking and dissection (CART) (1 patient), reverse CART (7 patients), retrograde true lumen puncture (13 patients), confluent balloon (1 patient) and just mark technique (5 patients). The retrograde guidewire was externalized in 17 patients: it entered the antegrade guide catheter in 9 patients and was snared in 8 patients. The guidewires most commonly externalized were the Viper (CSI Medical) and Confianza Pro 12 (Asahi Intecc). The mean number and length of wires most commonly externalized were Viper (CSI Medical) and Confianza Pro 12 (Asahi Intecc). The mean number and length of wires most commonly externalized were the Viper (CSI Medical) and Confianza Pro 12 (Asahi Intecc).

Conclusions: Retrograde CTO PCI carries high success rates, but may be associated with periprocedural myocardial infarction and subsequent cardiovascular events, that may be related to the multiple comorbidities of this high-risk veteran population.

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Bavana Rangan: This author has nothing to disclose.
Tesfaldet Michael: This author has nothing to disclose.
Aristotelis Papayannis: This author has nothing to disclose.
Subhash Banerjee: This author has nothing to disclose.
Emmanouil Brilakis: This author has nothing to disclose.

D-023

Title: Cardiac Catheterization in patients with End Stage Liver Disease: Risks and Outcomes

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Suchit Bhutani, M.B.B.S., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Jonathan Tobis, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Ruby Gevorgyan, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; William Suh, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Honda Henry, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Randolph Steadman, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA; Arjun Sinha, M.D., David Geffen School of Medicine at UCLA, United States, Los Angeles, CA

Objective: To assess the outcome of cardiac catheterization or percutaneous coronary intervention (PCI) in patients with end stage liver disease (ESLD) awaiting orthotopic liver transplant (OLT).

Background: There is little data about adverse events and bleeding complications during cardiac catheterization in ESLD patients who have an increased risk with arterial punctures. In addition, it is unclear if PCI impacts the survival rate in ESLD patients with coronary artery disease (CAD).

Methods: The records of patients with ESLD awaiting OLT who underwent cardiac catheterization from January 2006 to June 2011 were reviewed. The severity of CAD and the outcome of PCI were evaluated. The pre-operative non-invasive stress tests were compared with the coronary angiographic findings. Death rates were compared in patients segregated by presence of CAD, OLT, or PCI.

Results: Of the 328 records reviewed, 50 patients (15.2%) were diagnosed with CAD on angiography and 36 (72%) of them had PCI. 112 patients (34%) received an OLT. Of 94 (29%) deaths, the majority (82/94) were from liver disease. Peri-catheterization bleeding episodes occurred in only 4 patients (1%); classified as TIMI Minor (1) and TIMI Minimal (3). The sensitivity and specificity of Lexiscan Myoview Stress Test were 50% and 91%, and for Adenosine Stress Test: 61.5% and 94%. The prevalence of patients on dialysis-pre-catheterization was significantly higher in those with CAD compared to those ESLD patients without CAD (p = 0.04). The death rate in all patient groups was similar; the mean age at the time of death was the highest in patients who underwent PCI prior to OLT.

Conclusions: The incidence of bleeding events after cardiac catheterization using the femoral artery in ESLD patients is low. Both Lexiscan and Adenosine Stress Tests have low sensitivity for diagnosing CAD in this patient population. Aggressive diagnosis and management in patients with CAD demonstrates a post-OLT survival rate similar to ESLD patients without CAD.

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Suchit Bhutani: This author has nothing to disclose.
Jonathan Tobis: This author has nothing to disclose.
Ruby Gevorgyan: This author has nothing to disclose.
William Suh: This author has nothing to disclose.
Honda Henry: This author has nothing to disclose.
Randolph Steadman: This author has nothing to disclose.
Arjun Sinha: This author has nothing to disclose.
Title: The Glider Balloon: An Useful Device for the Treatment of Bifurcation Lesions

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Carlo Briguori, M.D., Ph.D., Clinica Mediterranea, Italy, Naples1; Gabriella Visconti, M.D., Clinica Mediterranea, Italy, Naples2; Amelia Focaccio, M.D., Clinica Mediterranea, Italy, Naples3

Background: Final kissing balloon dilatation (FKBD) is a recommended final step in case of treatment of bifurcation lesions by two stents approaches. Furthermore, dilatation of the side branch (SB) may be necessary following main vessel (MV) stenting. This requires recrossing the stent struts with a wire and a balloon. Occasionally, recrossing with a balloon is hampered because the tip hits a stent strut. The Glider (TriReme Medical, Pleasanton, CA) is a dedicated balloon designed for crossing through struts of deployed stents toward a side branch.

Methods: From October 2010 to October 2011, FKBD was attempted 191 consecutive bifurcation lesions treated in our Institution. FKBD was successfully performed by conventional balloon catheters in 178 (93%) lesions (Conventional group). In the remaining 13 (7%) lesions the Glider balloon was attempted (Glider group). The angle beta (between the axis of the MV after the branch point and the SB axis at the point of divergence) was higher in the Glider group (83 ± 17°) versus 65 ± 27°; p = 0.032). A trend toward an higher profile at one year. We plan to present the 2-year outcomes, as well the finite or probable stent thrombosis events through 1 year follow-up.

Table: Characteristics of the patients treated with the Glider balloon

<table>
<thead>
<tr>
<th>Patient</th>
<th>Bifurcation site</th>
<th>Medina group</th>
<th>a angle</th>
<th>β angle</th>
<th>Stent strategy</th>
<th>Glider balloon</th>
<th>Glider success</th>
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<tbody>
<tr>
<td>1</td>
<td>LAD-diagonal</td>
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<td>160 76</td>
<td>2 struts (misfach)</td>
<td>2.5 x 4 mm</td>
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<tr>
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<tr>
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<tr>
<td>5</td>
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<tr>
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<td>80 95</td>
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<td>80 100</td>
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<tr>
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<td>90 90</td>
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<td>150 85</td>
<td>2 struts (misfach)</td>
<td>2.5 x 4 mm</td>
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</tr>
</tbody>
</table>

Disclosures:
Carlo Briguori: This author has nothing to disclose.
Gabriella Visconti: This author has nothing to disclose.
Amelia Focaccio: This author has nothing to disclose.

Title: One-year Clinical Outcomes in Patients with Diabetes from the Pivotal RESOLUTE US Trial

Category: Complex PCI, Restenosis, Left Main & Multi-Vessel Intervention

Authors: Ash Jain, M.D., Washington Hospital Healthcare System, United States, Fremont, CA1; Thaddeus Tolleson, M.D., Tyler Cardiovascular Consultants, United States, Tyler, TX2; Douglass Spriggs, M.D., Morton Plant Hospital, United States, Clearwater, FL3; Douglas Spriggs, M.D., Morton Plant Hospital, United States, Clearwater, FL4; Martin Leon, M.D., Columbia University/NY Presbyterian Hospital, United States, New York, NY5; Laura Mauri, M.D., MSc, Brigham And Women’s Hospital, United States, Boston, MA6; Alan Yeung, M.D., Stanford University Medical Center, United States, Palo Alto, CA7

Background: RESOLUTE US is the pivotal trial designed to evaluate the Resolute zotarolimus-eluting stent (R-ZES) in the United States. The R-ZES comprises a cobalt-alloy bare metal stent and the durable BioLinx polymer that elutes 85% of the agent in the first 60 days, with full elution extended up to 180 days. Patients with diabetes mellitus (DM) are at high risk of adverse events following percutaneous coronary intervention (PCI); therefore it is important to evaluate clinical outcomes in this subgroup of patients treated with new generation drug-eluting stents. The objective of this analysis was to evaluate and report the clinical outcomes of the R-ZES in patients with DM.

Methods: RESOLUTE US is a prospective, multi-center, controlled trial comprising one large clinical cohort (n = 1242) and an angiographic cohort (n = 160). Patients were included if they had 1 or 2 de novo coronary lesions, 2.25 mm – 4.0 mm in diameter, amenable for PCI with stenting. The primary endpoint for the clinical cohort was target lesion failure (TLF; cardiac death, target vessel myocardial infarction [TVMI], and clinically-driven target lesion revascularization [TLR]) at 1 year. A patient was included in the DM cohort if they were on insulin and/or taking oral antidiabetic agents, or on a modified diet to control DM, prior to the index procedure. Patients were considered insulin treated if they were taking insulin, or both insulin and oral agents. We report here the one-year outcomes for 482 patients with DM treated with the R-ZES.

Results: Of the 1402 patients enrolled, 482 patients with DM (541 lesions), 135 (28.0%) require insulin. At baseline, this high risk patient cohort was evidenced by 37.8% women, 21.5% with prior MI, 35.3% with prior PCI, and a mean BMI of 33.2. Lesion characteristics included 27.6% with moderate/severe calcification, 23.9% with sidebranch stenosis, 12.4% with diffuse disease (> 20 mm lesion length), and 40.4% with double or triple vessel disease. The rate of TLF at 1 year was 6.3%, cardiac death was 1.3%, TVMI was 0.8% and TLR was 4.4%. There were no ARC definite or probable stent thrombosis events through 1 year follow-up.

Conclusions: In this post hoc analysis of high-risk patients with DM, the R-ZES was associated with favorable clinical outcomes and safety profile at one year. We plan to present the 2-year outcomes, as well the effect of insulin treatment at the time of the meeting.

Disclosures:
Ash Jain: Medtronic, 5. Consulting Fees or Other Remuneration.
Thaddeus Tolleson: This author has nothing to disclose.
Douglass Spriggs: This author has nothing to disclose.
Douglas Spriggs: This author has nothing to disclose.
Martin Leon: This author has nothing to disclose.
Laura Mauri: Cordis, 5. Consulting Fees or Other Remuneration.
Alan Yeung: Medtronic, 5. Consulting Fees or Other Remuneration.
A-002

Title: Beneficial Effects of Short-Term, High-Dose Statin Therapy on Prevention of Contrast-Induced Nephropathy: A Meta-Analysis of Randomized Controlled Trials

Category: Contrast Agents

Authors: Ryota Sakurai, M.D., The University of Tokyo, Japan, Tokyo

Background: Contrast-induced nephropathy (CIN) is one of the most important complications following procedures that utilize contrast agents. Although several non-randomized studies have demonstrated the beneficial effects of statin administration on prevention of CIN, the results of randomized controlled trials (RCT) still remain inconclusive. Therefore, a meta-analysis of RCT was conducted to evaluate the impact of short-term, high-dose statin therapy compared with placebo on the incidence of CIN in patients undergoing coronary angiography and/or intervention.

Methods: English RCT articles were searched using PubMed, Embase, the Cochrane Central Register of Controlled Trials, and Web of Science. Search terms included “statin”, “contrast”, “induced”, “nephropathy”, and “randomized”. The pooled odds ratio (OR) was calculated based on a fixed-effects model. If homogeneity across individual RCT was rejected by the Cochran’s Q test, a random-effects model was selected. A P value of <0.05 was considered to be statistically significant.

Results: Five RCT were included in this meta-analysis, involving 981 patients (484 patients were randomized to statin and 497 to placebo). Atorvastatin was administered in 3 RCT and simvastatin was used in 2 RCT. Statin therapy reduced the incidence of CIN compared with placebo (OR: 0.58, 95% confidence interval (CI): 0.36-0.95, P = 0.03). In a subgroup analysis, atorvastatin also showed a reduction in the occurrence of CIN (OR: 0.58, 95% CI: 0.34-0.99, P = 0.04), while a reduction induced by simvastatin was not statistically significant (OR: 0.63, 95% CI: 0.20-1.97, P = 0.42) although it may be due to a small number of patients.

Conclusion: Overall, short-term, high-dose statin therapy demonstrated beneficial effects in the prevention of CIN compared with placebo. Further studies may be warranted to investigate whether each statin possesses this favorable property.

Disclosures:
Ryota Sakurai: This author has nothing to disclose.

B-039

Title: Neutrophil Gelatinase-Associated Lipocalin and Contrast-Induced Acute Kidney Injury

Category: Contrast Agents

Authors: Carlo Briguori, M.D., Ph.D., Clinica Mediterranea, Italy, Naples; Gabriella Visconti, M.D., Clinica Mediterranea, Italy, Naples; Amelia Focaccio, M.D., Clinica Mediterranea, Italy, Naples; Gerolama Condorelli, M.D., Ph.D., Federico II University, Italy, Naples; Suddarshan Hebbar, M.D., Abbott Diagnostic, United States, Abbott Park, IL; Shaoqing DU, Ph.D., Abbott Diagnostic, United States, Abbott Park, IL.

A

B

C
Background: Neutrophil gelatinase-associated lipocalin (NGAL) has been proposed as an early marker of acute kidney injury (CI-AKI).

Methods and Results: Urine NGAL (uNGAL) and serum NGAL (sNGAL) were assessed in 218 patients enrolled in the REMEDIAL II trial. The uNGAL values were also normalized for urinary creatinine. CI-AKI was defined as a serum creatinine (sCr) increase ≥0.3 mg/dL at 48 hours following contrast media (CM) exposure. Major adverse events (MAE) at 12-month included death and dialysis. In patients who developed CI-AKI (n = 30), absolute and normalized uNGAL, and sNGAL increased significantly following CM injection. By multiple logistic regression, absolute uNGAL (p = 0.006), normalized uNGAL (p = 0.055) but not sNGAL at 6 hours (p = 0.083) resulted as an independent predictor of CI-AKI. Based on these results, uNGAL at 6 hours was tested as predictor of CI-AKI. Absolute uNGAL cutoff ≥21 ng/ml at 6 hours showed a 97% negative predictive value and a 24% positive predictive value in predicting CI-AKI. MAE at 12-month occurred in 43/218 patients (20%). According to the defined cutoffs (that is, increase in uNGAL ≥21 ng/ml and sCr ≥0.3 mg/dL) MAE occurred in 10/102 patients (9.8%) without any cutoffs satisfied (group 1), in 20/86 (23%) patients with only uNGAL increase (group 2), and in 13/30 (43%) patients with sCr alone or both cutoffs satisfied (group 3). By logistic regression analysis, the independent predictors of MAE at 12 months were group 2 (adjusted OR = 3.75; 95% CI 1.59–8.80; p = 0.002), group 3 (adjusted OR = 5.35; 95% CI 1.87–15.35; p = 0.002), and baseline glomerular filtration rate (adjusted OR = 0.91; 95% CI 0.88–0.95; p = 0.033).

Conclusions: uNGAL at 6 hours is a reliable marker for ruling out CI-AKI and predicts 12-month MAE.

ENDOVASCULAR AND PERIPHERAL INTERVENTIONS (INCLUDING NEUROVASCULAR AND CAROTID)

A-009

Title: Quantitative Image Analysis of Carotid Plaque Vasa Vasorum by Contrast Enhanced Ultrasonography. Insights into the Mechanisms of Plaque Enhancement and Correlation with Histological Findings after Carotid Endarterectomy

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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Carlo Briguori: This author has nothing to disclose.
Gabriella Visconti: This author has nothing to disclose.
Amelia Focaccio: This author has nothing to disclose.
Gerolama Condorelli: This author has nothing to disclose.
Suddarshan Hebbar: This author has nothing to disclose.
Shaqing DU: This author has nothing to disclose.

Abstracts S27

Aim of this study was to evaluate stable and unstable carotid artery plaques truly represents microvessels is a point of concern. The presence of microvessels in atherosclerotic plaques significantly affects plaque stability. A technique to analyze the neovascularization of carotid artery plaques (CAP) VV pattern on CEUS and its correlation with histological and immunochemical plaque characteristics.

Methods: Patients with CAP scheduled for plaque endarterectomy who were evaluated by CEUS were enrolled. Images obtained by CEUS were evaluated by 2 independent readers who were blinded to clinical data. CEUS images were evaluated for plaque composition and microbubbles detected in plaque were counted. Histological findings were also assessed. Results: A total of 14 patients (67.6±10.2 years, 10 males) with 86.9±11.5% degree of carotid stenosis were evaluated. Histology showed that half of the plaques were unstable. Plaque brightness enhancement on CEUS was significant for both stable and unstable plaques (p = 0.018 for both). Immunochemistry showed that microvessels,
Background: Percutaneous interventions for chronic total occlusions (CTO) in the peripheral arteries remain a technical challenge. Crossing the lesion with a guide wire is the major step for successful recanalization of CTO. The Asahi Astato peripheral guide wires (Astato 30 & Astato XS 20, Asahi Intecc, Japan) are high-penetration guide wires with a tapered tip designed to break through fibrous caps and calcium deposits. We report our experience with these guide wires in recanalization of long and complex peripheral arterial occlusions (TransAtlantic InterSociety Consensus class B, C, and D).

Methods: The Astato guide wire was used in 36 patients (70 lesions) with CTO in our facility from January 2010 to June 2011. Peripheral CTO was defined as 100% occluded vessel above or below the aortic arch (34 lower extremity arteries, 1 subclavian and 1 brachiocephalic artery) with symptoms for at least 3 months prior to the procedure. Technical success was defined as the ability of the guidewire to cross the lesion. Demographic, clinical, and angiographic data were collected retrospectively.

Results: The Astato guide wire successfully crossed 50 of the 70 lesions (technical success - 71.4%) in 36 patients who previously failed with Quick-cross catheter (Spectranetics, CO) and other stiff hydrophilic wires (~1.5 wires per lesion). Out of the 20 lesions not crossed with Astato wire, 4 lesions were crossed with Asahi Grandslam guidewire (Abbott Vascular, IL.), 1 lesion treated with bypass surgery, and the remaining lesions were not recanalized. Eight patients presented with Rutherford Class (RC) III symptoms, 21 with RC IV, and the rest with RC V symptoms. Mean age of patients was 64 years (male – 20, female – 16). Average length of the lesion was 17.6 cm. Superficial femoral artery was the most common site of lesion (69.5%). 16 patients had grade 3 calcification and 24 patients had significant inflow disease. In patients recanalized with Astato guide wires, there were no amputations at 30 days, 4 patients underwent target vessel revascularization within 30 days (percutaneous – 3, surgical – 1), 1 patient died (unrelated to target vessel intervention), 2 patients had dissection, and one patient had “no reflow” phenomena.

Conclusion: In this single center observational study, the Asahi Astato guide wire proved to have a good safety profile with a technical success rate of 71.4% in patients with peripheral arterial CTO. Randomized comparisons are needed.

Disclosures: Siddharth Wayangankar: This author has nothing to disclose.
Jigar Patel: This author has nothing to disclose.
Thomas Hennebry: This author has nothing to disclose.

A-018
Title: The Financial Burden and Clinical Outcome of Innovated Techniques Used in Renal Artery Stenting

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: Aravinda Nanjundappa, M.D., Charleston Area Medical Center/WVU, United States, Charleston, WV1; Mohammad Kaswara, M.D., Charleston Area Medical Center/WVU, United States, Charleston, WV2; Abhilasha Surampalli, M.D., Charleston Area Medical Center, United States, Charleston, WV3; Stephanie Thompson, Ph.D., Charleston Area Medical Center, United States, Charleston, WV4

Background: Technical advances in renal artery (RA) stenting maybe beneficial in certain patients, however they are coupled with increased financial costs to both patients and hospitals. Research is needed to determine which patients will maximally benefit. Thus, we wished to examine the use and economic burden of novel techniques (intravascular ultrasound [IVUS], distal protection filter, and drug eluting stents [DES]) in RA endovascular interventions and the techniques’ association with adverse patient outcomes.

A-011
Title: Use of Asahi Astato Guide Wires to Recanalize Peripheral Arterial Chronic Total Occlusions: A Single Center Experience

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: Siddharth Wayangankar, M.D., M.P.H., University of Oklahoma Health Sciences Center, United States, Oklahoma City, OK1; Jigar Patel, M.D., University of Oklahoma Health Sciences Center, United States, Oklahoma City, OK2; Thomas Hennebry, M.D., FACC, FSCAI, Oklahoma Heart Hospital, United States, Oklahoma City, OK3

Disclosures: Manolis Vavuranakis: This author has nothing to disclose.
Fragkiska Sigala: This author has nothing to disclose.
Dimitrios Vrachatis: This author has nothing to disclose.
Theodore Papaioannou: This author has nothing to disclose.
Konstantinos Kalogeras: This author has nothing to disclose.
Constantina Massoura: This author has nothing to disclose.
Maria Kariori: This author has nothing to disclose.
Levon Toufexian: This author has nothing to disclose.
Ioannis Vlasseros: This author has nothing to disclose.
Ioannis Kalikazaros: This author has nothing to disclose.
Christodoulos Stefanidis: This author has nothing to disclose.

as indicated by CD34 antibody, were more dense in unstable vs. stable plaques (36.6±17.4 vs. 13.0±7.2 respectively, p = 0.002). However, correlation between plaque brightness enhancement on CEUS and microvessel density was significant only for stable plaques (r = 0.800, p = 0.031) (Table). Moreover, semi-automated image analysis had very good intraclass correlation coefficient >0.90. Conclusion: CAP images obtained by CEUS may have a different pattern for stable and unstable plaques, while plaque brightness enhancement may not always represent a more dense microvessel network. This should be taken into account if CEUS is used for the identification of VV and microvessels within carotid atherosclerotic plaques as a screening test for plaque vulnerability.

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Manolis Vavuranakis: This author has nothing to disclose.
Fragkiska Sigala: This author has nothing to disclose.
Dimitrios Vrachatis: This author has nothing to disclose.
Theodore Papaioannou: This author has nothing to disclose.
Konstantinos Kalogeras: This author has nothing to disclose.
Konstantinos Filis: This author has nothing to disclose.
Ioannis Vlasseros: This author has nothing to disclose.
Ioannis Kalikazaros: This author has nothing to disclose.
Christodoulos Stefanidis: This author has nothing to disclose.
Methods: We retrospectively reviewed 222 RA angioplasty and stenting procedures performed in 189 individuals at our institution from 07/1/2007 to 06/30/2010. Patient outcomes of interest included all-cause mortality and re-hospitalization for congestive heart failure (CHF), renal failure (RF), hypertensive crisis (HTN), and target vessel revascularization (TVR).

Results: Forty-eight patients received IVUS during their RA stenting and 6 individuals received distal protection devices. DES were used in 5 procedures. TVR was required following 18 procedures (8.1%) while re-hospitalization for CHF, RF or HTN occurred in 17 patients (7.7%); median follow-up period: 33 months [range 11-48]. Cumulative patient survival for years 1 through 4 was 98.2%, 93.4%, 86.4% and 63.0%, respectively. Rates of TVR, readmission and all cause mortality were not affected by the use of IVUS (p>0.10 for each chi-square analyses), distal filter (p>0.60), or DES (p>0.09). These novel techniques contributed a substantial additional financial burden of $31920 for IVUS (48 x $665), $7350 for distal protection filters (6 x $1225), and $4000 for DES (5 x $800).

Conclusions: Our study demonstrates that use of novel innovated techniques including DES, distal protection devices and IVUS appeared to have no advantageous effect on re-hospitalization and mortality with an additional cost of more than $40000 to health care systems.

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Mohammad Kasara: This author has nothing to disclose.
Abhilasha Surampalli: This author has nothing to disclose.
Stephanie Thompson: This author has nothing to disclose.

A-028

Title: A Risk Score to Predict In-hospital Events Following Carotid Stenting: A Report from the NCDR

Authors: Beau Hawkins, M.D., Massachusetts General Hospital, United States, Boston, MA; Kenneth Rosenfield, M.D., Massachusetts General Hospital, United States, Boston, MA; Kevin Kennedy, None, Mid-America Heart Institute, United States, Kansas City, MO; Adam Saltzman, M.D., Massachusetts General Hospital, United States, Boston, MA; Jay Giri, M.D., Massachusetts General Hospital, United States, Boston, MA; Douglas Drachman, M.D., Massachusetts General Hospital, United States, Boston, MA; Christopher White, M.D., Ochsner Heart And Vascular Institute, United States, New Orleans, LA; John Spertus, M.D., Mid-America Heart Institute, United States, Kansas City, MO; Robert Yeh, M.D., Massachusetts General Hospital, United States, Boston, MA

Background: Carotid artery stenting (CAS) represents an effective form of carotid revascularization, and is increasingly used in settings where surgical risk from endarterectomy is preclusive. Though predictors of surgical risk are well established, less is known regarding characteristics that influence CAS risk. A tool that accurately assesses CAS risk would be important to guide clinical decision-making and potentially improve outcomes. We developed and internally validated a risk score that predicts in-hospital major adverse cardiovascular events (MACE) following CAS.

Methods: Patients receiving CAS without acute evolving stroke from April 2005 through September 2011 as part of the CARE Registry were included. From >30 clinical and angiographic variables, we developed a parsimonious model to predict in-hospital MACE (myocardial infarction, stroke, or death). Internal validation was achieved with bootstrapping, and model discrimination and calibration were assessed.

Results: A total of 304 (2.73%) events occurred during 11,122 procedures. Significant predictors of MACE included age, atrial fibrillation, prior stroke, symptomatic target lesion in the previous 6 months, impending major surgery and absence of contralateral occlusion. The model was well-calibrated and had moderate discriminatory ability (c statistic 0.70). The addition of angiographic variables did not improve model performance (c statistic 0.706 vs. 0.701, p=0.671), and thus the final model used the 6 clinical variables only. A risk score for the 6
clinical variables was developed (c statistic 0.693, Table 1), and was successful in stratifying subjects into low, intermediate, and high risk categories (MACE rates 1.4% vs. 4.0% vs. 7.1%, respectively).

**Conclusion:** A simple model consisting of 6 easily obtained clinical variables can accurately predict in-hospital events following carotid stenting. This risk score should aid clinical decision-making and improve patient selection for CAS.

**Disclosures:**
Beau Hawkins: This author has nothing to disclose.
Kenneth Rosenfield: This author has nothing to disclose.
Kevin Kennedy: This author has nothing to disclose.
Adam Saltzman: This author has nothing to disclose.
Jay Giri: This author has nothing to disclose.
Adam Saltzman: This author has nothing to disclose.
Robert Yeh: This author has nothing to disclose.

**A-034**

**Title:** Patency Rates of Intraluminal Versus Device Assisted Subintimal Endovascular Revascularization of the Chronic Total Occlusion in the Superficial Femoral Artery

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: Anvar Babaev, M.D., Ph.D., NYU Medical Center, United States, New York, NY; Niju Baby Narakathu, M.B.B.S., NYU Medical Center, United States, New York, NY; Christopher White, None, NYU Medical Center, United States, New York, NY.

**Background:** Chronic total occlusions (CTO) of the superficial femoral artery are a challenging subset of lesions encountered in peripheral interventions. CTO's of the SFA are commonly crossed either with an intraluminal (IL) or re-entry device assisted subintimal (SI) approach followed by stenting. Even though both these techniques have a high immediate procedural success rate the long term outcomes of each approach are not well studied.

**Methods:** We studied 112 patients (144 limbs) with obstructive SFA disease treated with nitinol self-expanding stents; there were 77 (53.5%) limbs with CTO. We analyzed in-stent restenosis (ISR) rates as well as demographic, procedural and laboratory characteristics such as: age, sex, GFR, presence of comorbidities, lesion lengths, TASC Classification, and stent diameter in 3 subgroups of patients: without CTO; with CTO crossed IL; and with CTO crossed SI.

**Results:** Mean age of the studied patients was 73.3±3.7 years and for patients with CTO it was 74.1±6.9 years. In CTO group, 22 (28%) limbs were treated with SI approach, and 55 (72%) using IL. During mean follow up period of 27.6±17 months, ISR was diagnosed in: 21 (31.3%) patients of non-CTO group; 20 (36.4%) patients of IL CTO; and 13 (59.1%) of SI CTO group, Figure 1. The number of patients with diabetes was significantly (p<0.001) higher in CTO IL compared to CTO SI group, 73.8% versus 26% respectively. The mean lesion length was 206.4±110 mm in IL and 245.9±118 mm (p = 0.17) in SI group. There was no significant difference in the mean time to ISR, as well as other studied demographic, laboratory, and procedural parameters between studied groups.

**Conclusion:** We observed similar SFA ISR rates between patients without and with CTO but only if CTO was crossed using IL approach. However, if CTO was crossed using device assisted SI approach, there was a significantly higher ISR rates compared to non-CTO patients and trend to higher ISR compared to CTO IL group.

**Disclosures:**
Anvar Babaev: Cook, 5. Consulting Fees or Other Remuneration, CSI, 5. Consulting Fees or Other Remuneration, Cordis, 5. Consulting Fees or Other Remuneration, EV3, 5. Consulting Fees or Other Remuneration
Niju Baby Narakathu: This author has nothing to disclose.
Christopher White: This author has nothing to disclose.

**A-046**

**Title:** Role of Ultrasound-assisted Thrombolytic Therapy in Submassive Pulmonary Embolism

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: Talhat Azemi, M.D., Hartford Hospital, Hartford, CT, United States, Hartford, CT; Firas Almahasneh, M.D., Hartford Hospital, Hartford, CT, United States, Hartford, CT; Anatoliy Telis, None, NYU Medical Center, United States, New York, NY.

**Background:** Sub-massive PE (SPE) is associated with in-hospital mortality of 6-8%. Recent guidelines recommend treatment of SPE with systemic anticoagulation (class I) and fibrinolysis as a class Ib recommendation. However, data regarding the use of ultrasound-assisted catheter directed thrombolytic therapy is lacking.

**Methods:** At our tertiary care center, we used a multidisciplinary team of physicians (interventional cardiologists, vascular surgeons, and pulmonologists) to assess patients with SPE and treated all patients with catheter-directed thrombolytic therapy (CDT) if there were no contraindications. We treated 7 consecutive patients with SPE from June 2011 and December 2011. Patients had an echocardiogram, right heart catheterization, pulmonary angiogram and EKOS catheters placed followed by continuous infusion of alteplase in all patients. Follow-up included repeat echocardiogram, right heart catheterization, and pulmonary angiogram 24 hours post thrombolytic therapy. Patients also had a follow-up office visit at 30 days post hospital discharge.

**Results:** Mean age of the studied patients was 73.3±3.7 years and for patients with CTO it was 74.1±6.9 years. In CTO group, 22 (28%) limbs were treated with SI approach, and 55 (72%) using IL. During mean follow up period of 27.6±17 months, ISR was diagnosed in: 21 (31.3%) patients of non-CTO group; 20 (36.4%) patients of IL CTO; and 13 (59.1%) of SI CTO group, Figure 1. The number of patients with diabetes was significantly (p<0.001) higher in CTO IL compared to CTO SI group, 73.8% versus 26% respectively. The mean lesion length was 206.4±110 mm in IL and 245.9±118 mm (p = 0.17) in SI group. There was no significant difference in the mean time to ISR, as well as other studied demographic, laboratory, and procedural parameters between studied groups.

**Conclusion:** We observed similar SFA ISR rates between patients without and with CTO but only if CTO was crossed using IL approach. However, if CTO was crossed using device assisted SI approach, there was a significantly higher ISR rates compared to non-CTO patients and trend to higher ISR compared to CTO IL group.

**Disclosures:**
Anvar Babaev: Cook, 5. Consulting Fees or Other Remuneration, CSI, 5. Consulting Fees or Other Remuneration, Cordis, 5. Consulting Fees or Other Remuneration, EV3, 5. Consulting Fees or Other Remuneration
Niju Baby Narakathu: This author has nothing to disclose.
Anatoliy Telis: This author has nothing to disclose.
Results: Prior to CDT all patients had significant RV dysfunction on echocardiogram with elevated right sided filling pressures as well as pulmonary hypertension on right heart catheterization. Normalization of RV function and pulmonary pressures occurred within 24 hours of CDT. In-hospital mortality and 30 day mortality was 0%.

Conclusion: In patients with SPE, ultrasound-assisted CDT was associated with excellent hemodynamic and clinical outcomes. Therefore, we advocate the use of this novel therapy in patients with SPE.

Disclosures:
Talhat Azemi: This author has nothing to disclose.
Firas Elbash: This author has nothing to disclose.
Immad Sadiq: This author has nothing to disclose.

A-048

Title: Initial Development and Testing of a Tissue Engineering Scaffold for Aneurysm Repair (TESAR)

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: J. Jordan Kaufmann, None, B.S., University of Texas Health Sciences Center at San Antonio, United States, San Antonio, TX; Steven Bailey, M.D., University of Texas Health Sciences Center at San Antonio, United States, San Antonio, TX; C. Mauli Agrawal, Ph.D., University of Texas at San Antonio, United States, San Antonio, TX; G. Patricia Escobar, None, D.V.M., University of Texas Health Sciences Center at San Antonio, United States, San Antonio, TX; V. Seen Reddy, M.D., M.B.A., University of Texas Health Sciences Center at San Antonio, United States, San Antonio, TX

Background: Current commercially available EVAR grafts have questionable long term effectiveness due to endoleaks and graft migration. We have developed a bioresorbable, endovascular Tissue Engineering Scaffold for Aneurysm Repair (TESAR) which facilitates neotissue formation and vessel-graft integration at the apposition site in order to decrease these adverse events. Using tissue engineering, the neotissue should provide complete proximal and distal aneurysm apposition while creating a mechanical barrier and occluding circulation from the diseased aorta wall.

Methods: The TESAR consists of nonwoven polycaprolactone fibers approximately 6.5 µm in diameter which are more densely packed and present a curvilinear morphology on the endoluminal surface while being less densely packed and have a more linear morphology on the abluminal surface. To assess the TESAR in terms of cell infiltration and tissue formation in vivo, a surgical swine model was developed using a double peritoneal patch to form a subrenal aneurysm. Our TESAR was deployed using current endovascular techniques and compared to commercially available PTFE stent grafts over 28 days. Controls included animals which received an aneurysm but no treatment and animals that did not receive an aneurysm but underwent treatment. Ultrasound and angiography were used to monitor the aneurysm size. Immunohistochemistry, Mason’s trichrome and H&E staining were used to assess histological samples.

Results: Fluoroscopic analysis showed AAA size decreased in TESAR treated animals by an average of 22.8% over 28 days compared to PTFE controls which decreased aneurysms an average of 13.6% in the same time. Histological analysis of the TESAR revealed nearly confluent endothelium with smooth muscle cell infiltration and organization at the apposition site after 28 days. Grossly, the TESAR fully adhered to and integrated with the aorta wall at the apposition sites with no graft failure or migration noted. In contrast, one of the control PTFE grafts showed significant migration and failure to integrate or exclude the aneurysm from circulation.

Conclusions: This study suggests that a TESAR may serve as an alternative to the current bioinert EVAR grafts.

Disclosures:
J. Jordan Kaufmann: This author has nothing to disclose.
Steven Bailey: This author has nothing to disclose.
C. Mauli Agrawal: This author has nothing to disclose.
G. Patricia Escobar: This author has nothing to disclose.
V. Seen Reddy: This author has nothing to disclose.

B-003

Title: The Transradial Approach for Left Internal Carotid Artery Stenting

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: Nicholena Etxegoien, None, B.S., Wake Heart And Vascular Associates, United States, Raleigh, NC; Diana Rhyne, None, B.S., Wake Heart And Vascular Associates, United States, Raleigh, NC; Kimberly Livingston, M.D., Wake Heart And Vascular Associates, United States, Raleigh, NC; Ravish Sachar, M.D., Wake Heart And Vascular Associates, United States, Raleigh, NC; Tift Mann, M.D., Wake Heart And Vascular Associates, United States, Raleigh, NC

Background: Carotid artery stenting (CAS) is an approved strategy for revascularization of the internal carotid artery (ICA) in patients (pts) with increased surgical risk. Previous studies have demonstrated that the right radial approach (RRA) is an alternative strategy for CAS in pts with right(R)ICA or bovine left (L) ICA disease when factors that increase the risk or difficulty of femoral access are present. However, a consistent technique for nonbovine LICAS using the RRA has been thwarted by the acute angle that must be traversed for deployment of a shuttle sheath (SS) in the LCA. The purpose of the present study is to evaluate a new technique using the RRA for CAS in these pts.

Methods: CAS via the RRA was performed between 6/11-12/11 in 16 consecutive pts with significant (>80%) nonbovine LICAS lesions and comorbid or anatomical conditions increasing the risk of carotid endarterectomy. The left common CA was cannulated using a 5F wire-braided Simmons 2 catheter. A .035” tapered guidewire (TAD II,
Covidien) was advanced directly into the external CA (81%) or positioned beneath the bifurcation (19%). A 5 or 6F shuttle sheath was then exchanged for the diagnostic catheter directly (81%) or telescoped over the Simmons 2 (19%). The telescoping technique was generally utilized in pts with type II arches and a 5F shuttle sheath was used in pts with small RRA. CAS was performed through the shuttle sheath using standard techniques.

**Results:** CAS from the RRA was successful in 16/16 patients (mean age 69±2, 50% male). Type I aortic arch was present in 54%, type II in 46%. The majority (81%) were asymptomatic. Three different carotid artery stents (50% Carotid Wallstent) and 5 different embolic protection devices were successfully deployed via the RRA. Eight (50%) procedures were performed using a 5Fr shuttle sheath. No cerebrovascular accident, myocardial infarction, or death occurred at 30 days. No post-procedure RA occlusion or other access site complication occurred.

**Conclusion:** The present study describes a technique that addresses the technical challenges of transradial LICA stenting posed by non-bovine aortic arch anatomy. The longer distal limb and wire-braiding of the Simmons 2 provided adequate support for the TAD II guidewire, over which the SS could be deployed. The success in this small study warrants further evaluation in a larger series that includes pts with type III arch anatomy.

**Disclosures:**
- Nicholena Etxegoien: This author has nothing to disclose.
- Diana Rhyne: This author has nothing to disclose.
- Kimberly Livingston: This author has nothing to disclose.
- Ravish Sachar: This author has nothing to disclose.
- Tiff Mann: This author has nothing to disclose.

**B-017**

**Title:** Long Term Follow up Results: Superficial Femoral Artery (SFA) Recanalization with Self-Expanding Nitinol Stent (S.M.A.R.T.)

**Does the Definition of PSVR Influence Patency Rate?**

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

**Authors:** akihiro higashimori, M.D., The Japanese Circulation Society, Japan, osaka¹; yoshiaki yokoi, M.D., Ph.D., The Japanese Circulation Society, Japan, osaka²

**Purpose:** Prospective trials to evaluate newer Nitinol self-expanding stents in the superficial femoropopliteal artery (SFA) disease are currently underway. Mostly patency is checked by Doppler technique by using peak systolic velocity ratio (PSVR). But the definition of PSVR to evaluate primary patency is different in each trials. We investigate how the patency rate is influenced by the definition of PSVR.

**Methods** Single center retrospective study was conducted. Between 2003 and 2006, 76 consecutive patients (83 limbs) were treated with the Nitinol self-expandable stent (S.M.A.R.T., Cordis Corp, Miami Lakes, FL, USA ) for SFA disease. Primary patency was defined to 3 categories. Category 1 was defined <2.00 of PSVR, category 2 was defined <2.40 of PSVR and category 3 was defined <2.85 of PSVR. Primary endpoint was examined by the Kaplan-Meier method and the groups were compared with the log rank test.

**Results:** Mean follow up time was 51 ± 27 months. In category 1 (PSVR = 2.00) Kaplan-Mayer estimates for primary patency rates were 62.6%, 36.8%, 27.6%, in category 2 (PSVR = 2.40) 75.2%, 46.5%, 37.1% and in category 3 (PSVR = 2.85) 75.2%, 46.1%, 46.1% at 1.5, and 7 years, respectively.

Significant difference in primary patency was found between category 1 (PSVR = 2.00) and category 3 (PSVR = 2.85) (P = 0.038 by log rank test). There were not differences in primary patency between category 2 (PSVR = 2.40) and category 3 (PSVR = 2.85) (P = 0.786 by log rank test). There tended to be differences between category 1 (PSVR = 2.0) and category 2 (PSVR = 2.4) (P = 0.069 by log rank test).

**Conclusion:** The definition of PSVR may influences the long time patency rate for SFA stent. We should consider the definition of restenosis in each trials.

**Disclosures:**
- Akihiro Higashimori: This author has nothing to disclose.
- Yoshiaki Yokoi: This author has nothing to disclose.

**B-025**

**Title:** Comparison Between Ante-grade Approach and Bidirectional Approach for Long Segment Femoral Artery CTO Intervention -Using Only 0.014 Wires-

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

**Authors:** Yasuhiro Akazawa, M.D., Osaka Police Hospital, Japan, Osaka¹; Koshi Matsuo, M.D., Osaka Police Hospital, Japan, Osaka²; Yasunori Ueda, M.D., Osaka Police Hospital, Japan, Osaka³

**Background:** The intervention of long chronic total occlusion (CTO) lesion in the superficial femoral artery (SFA) is very difficult and has low success rate.

**Objectives:** To evaluate the effectiveness of bidirectional approach for the long SFA CTO lesion intervention concerning the amount of contrast medium, procedure time, and success rate.

**Methods:** In 20 consecutive patients who received intervention of long (>200mm) SFA CTO lesion, we compared the amount of contrast medium, procedure time, and success rate between the cases treated by ante-grade approach and those treated by bidirectional approach.

**Results:** The amount of contrast medium used was less (87±35mL vs. 125±44mL, p = 0.05) and success rate was higher (100% vs. 58%, p = 0.03) in bidirectional approach group than in ante-grade approach group, although the procedure time was not different (228±60min vs. 252±84min, p = 0.5) between the groups. No procedural complications were detected in either group.

**Conclusion:** Bidirectional approach for long-lesion SFA CTO intervention was superior to ante-grade approach in terms of success rate and the amount of contrast medium.

**Disclosures:**
- Yasuhiro Akazawa: This author has nothing to disclose.
- Koshi Matsuo: This author has nothing to disclose.
- Yasunori Ueda: This author has nothing to disclose.
B-033
Title: Predictors of In-Stent Restenosis and Two-Year Patency Rates of Nitinol Self Expanding Stents in the Superficial Femoral Artery
Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)
Authors: Niju Baby Narakathu, M.B.B.S., NYU Medical Center, United States, New York, NY; Anatoly Telis, None, NYU Medical Center, United States, New York, NY; Anvar Babaev, M.D., Ph.D., NYU Medical Center, United States, New York, NY

Introduction: The superficial femoral artery (SFA) is prone to frequent restenosis after stenting. A number of factors have been recognized as potential risk factors for the development of in-stent restenosis (ISR) in the SFA. However, there is a lack of sufficient confirmatory data.

Methods: We studied 112 patients (144 limbs) with obstructive SFA disease treated with nitinol self-expanding stents. We analyzed ISR rates as well as demographic, procedural and laboratory characteristics that could potentially be predictors of ISR: age, sex, blood pressure, GFR, WBC, monocyte count, blood glucose, lipids, presence of diabetes and coronary artery disease, lesion lengths, TASC Classification, and stent diameter.

Results: Among patients treated 74% had severe claudication and 26% critical limb ischemia. Mean age was 73.3 ± 7.3, mean treated lesion length was 168.1 ± 113.2 mm, 42.4% were TASC C/D lesions. During mean follow up period of 25.4 ± 16 months, 54 patients (37.5%) developed ISR. The mean total cholesterol in the group with ISR was 188.2 ± 98.4 mg/dl and 170.2 ± 44 mg/dl with no ISR (p = 0.02); mean LDL was 109.7 ± 39.8 mg/dl and 90.8 ± 36.7 mg/dl (p = 0.004), mean non-HDL cholesterol 143.2 ± 49.1 mg/dl and 125.6 ± 40.8 mg/dl (p = 0.022), respectively. The mean lesion length in the group with ISR was 190.1 ± 115.7 mm and 154.7 ± 109.8 mm with no ISR (p = 0.06). The mean time to restenosis was 11.8 ± 7.2 months. There was no significant difference between the patients with and without ISR in the rest of demographic, procedural and laboratory parameters.

Conclusion: In our single center registry, the patency rate of nitinol stents in the SFA was 62.5% in up to 2 years of follow up. In our study, among all potential risk factors for the development of ISR, only elevated levels of total cholesterol, LDL and non-HDL cholesterol were associated with higher rates of ISR.

Disclosures:
Niju Baby Narakathu: This author has nothing to disclose.
Anatoly Telis: This author has nothing to disclose.

B-043
Title: Safety and Efficacy of Same Day Discharge of Patients Following Lower Extremity Percutaneous Intervention with the Use of Dual Anti-Coagulation Clopidogrel & Acetylsalicylic Acid (ASA) with a Vascular Closure Device
Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)
Authors: Radoslaw Kiesz, M.D., San Antonio Endovascular And Heart Institute, United States, San Antonio, TX; Michael Cavazos, M.D., San Antonio Endovascular And Heart Institute, United States, San Antonio, TX; Adam Janas, M.D., San Antonio Endovascular And Heart Institute, United States, San Antonio, TX; Magda Konkolewska, M.D., San Antonio Endovascular And Heart Institute, Poland, Katowice

Methods: We studied 110 patients (mean age 68.7 ± 10 years, 63.7% had severe claudication and 36.3% critical limb ischemia). The mean treated lesion length was 168 ± 113.2 mm, 42.4% were TASC C/D lesions. During mean follow up period of 25.4 ± 16 months, 54 patients (37.5%) developed ISR. The mean total cholesterol in the group with ISR was 188.2 ± 98.4 mg/dl and 170.2 ± 44 mg/dl with no ISR (p = 0.02); mean LDL was 109.7 ± 39.8 mg/dl and 90.8 ± 36.7 mg/dl (p = 0.004), mean non-HDL cholesterol 143.2 ± 49.1 mg/dl and 125.6 ± 40.8 mg/dl (p = 0.022), respectively. The mean lesion length in the group with ISR was 190.1 ± 115.7 mm and 154.7 ± 109.8 mm with no ISR (p = 0.06). The mean time to restenosis was 11.8 ± 7.2 months. There was no significant difference between the patients with and without ISR in the rest of demographic, procedural and laboratory parameters.

Conclusion: In our single center registry, the patency rate of nitinol stents in the SFA was 62.5% in up to 2 years of follow up. In our study, among all potential risk factors for the development of ISR, only elevated levels of total cholesterol, LDL and non-HDL cholesterol were associated with higher rates of ISR.

Disclosures:
Radoslaw Kiesz: This author has nothing to disclose.
Michael Cavazos: This author has nothing to disclose.
Adam Janas: This author has nothing to disclose.
Magda Konkolewska: This author has nothing to disclose.
Radoslaw Szymanski: This author has nothing to disclose.
Szymon Wiernek: This author has nothing to disclose.
Pawel Buszman: This author has nothing to disclose.

C-007
Title: Endovascular Embolization Therapy
Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)
Authors: Ramesh Adiraju, M.D., facc, Renu-CA Research Institute, United States, bristol, PA

Background: Occluding an artery can be therapeutic in situations such as uncontrolled bleeding, vascular steal, aneurysmal dilation and some tumors. GI bleeding is the most common bleeding complication among elderly and anticoagulated patients which drains significant health care dollars and presents a treatment decision dilemma. Surgical approach is high risk in most cases. Identifying the bleeder can be challenging as
bleeding scans are negative >40% of the time due to vascular clamping that causes intermittent bursts of bleeding.

**Methods:** Endovascular selective coil embolization was successfully utilized in varied clinical situations to achieve hemostasis or prevent vascular steal. VortX-18 vascular coils(boston scientific) were delivered through renegade-18 microcatheters(boston scientific) after selective cannulation of the feeder vessel. Percutaneous 5fr/6fr sheath access was obtained and angiography was carried out. 3000 units of heparin were administered during the case. After identifying the culprit vessel .014 guide wire was used to selectively access the vessel. A Renegade-18 catheter was then advanced into the culprit vessel over the guide wire. 3 to 9 coils were then delivered until complete occlusion of the vessel. Complete occlusion of the vessel is important to avoid recanalization and re-bleeding.

**Tips to identify the bleeder:** String sign-reflex clamping of the vessel,swirl sign-Slow extravasation of dye with persistent staining during angiography.

**Results:** 45 cases were done between 2003 and 2011. 9 cases of LIMA branch embolization for coronary steal. 3 cases of uterine bleeding immediate post partum hysterectomy for life threatening bleeding. 33 were GI bleeder of which majority were on coumadin. 9/33 GI cases were diverticular bleeds uncontrolled through endoscopic measures. There were 2 cases of a-v malformation bleeds that had re-bled. These were successfully managed by selective re-embolization of another feeder vessel. There were no failures, no major complications. One patient had multiple polyposis with recurrent bleeds that required colectomy.

**Conclusion:** Embolization therapy has varied clinical applications. It is minimally invasive and can be attempted in any patient. It requires careful and patient approach to avoid complications such as embolization of the coils,vascular perforation. It is very cost affective as is less expensive than vascular surgery, patient friendly, early amputation and discharge are possible. This approach also minimizes blood transfusions.

**Disclosures:**
Ramesh Adiraju: This author has nothing to disclose.

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**C-023**

**Title:** Utility and Feasibility of Ultrasound Guided Access in Patients with Critical Limb Ischemia

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: J A Mustapha, M.D., Metro Health Hospital, United States, Wyoming, MI\(^1\); Tony Das, M.D., Texas Health Presbyterian Heart and Vascular Group, United States, Dallas, TX\(^2\); Lary Diaz, M.D., Metro Health Hospital, United States, Wyoming, MI\(^3\); Barbara Karenko, D.O., Metro Health Hospital, United States, Wyoming, MI\(^4\); lance Richards, D.O., Metro Health Hospital, United States, Wyoming, MI\(^5\); Theresa Laeder, R.N., Metro Health Hospital, United States, Wyoming, MI\(^6\); Carmen Heaney, R.N., Metro Health Hospital, United States, Wyoming, MI\(^7\); Fadi Saab, M.D., Metro Health Hospital, United States, Wyoming, MI\(^8\)

**Background:** Patients with advanced peripheral vascular disease (PVD) and critical limb ischemia (CLI) require immediate revascularization to improve blood flow and prevent amputation. Vascular and especially tibial access is arguably a very important part of the procedure. We hypothesized that the routine use of ultrasound (US) guidance should maximize success while minimizing complications related to arterial access.

**Methods:** This is a retrospective analysis of patients admitted to our institution between calendar years 2010 and 2011. 86 patients with 191 lesions underwent revascularization for CLI. 70.5% patients were classified at Rutherford IV-VI. Foot ulcers were documented in 41% of patients. US guidance was utilized to access the vascular bed in an antegrade or retrograde fashion in 100% of these patients.

**Results:** The average age was 70 and 69.7% of patients were males. All tibial access (33.7%) were obtained under US guidance. Antegrade access was obtained in 45 (52%) of patients. A closure device was utilized in 52 (60.4%) of patients; manual compression was used in the rest. At discharge, access site complications were limited to one patient (1.1%) related to non healing infection. No access complication related to the tibial vessels. At 30 days, there was one below the knee amputation (1.1%) related to non healing infection.

**Conclusion:** US guided access is a feasible and safe procedure that facilitates arterial access in patients with severe PVD. Applying this technique across the board in CLI patients decrease the risk of immediate complications and facilitates accessing tibial arteries.

**Disclosures:**
J A Mustapha: This author has nothing to disclose.
Tony Das: This author has nothing to disclose.
Lary Diaz: This author has nothing to disclose.
Barbara Karenko: This author has nothing to disclose.
lance Richards: This author has nothing to disclose.
Theresa Laeder: This author has nothing to disclose.
Carmen Heaney: This author has nothing to disclose.
Fadi Saab: This author has nothing to disclose.

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**C-045**

**Title:** Outcomes of Revascularization for Chronic Mesenteric Ischemia

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

Authors: William Hood, D.O., Charleston Area Medical Center, United States, Charleston, WV\(^1\); Aravinda Nanjundappa, M.D., Charleston Area Medical Center/WVU, United States, Charleston, WV\(^2\); Stephanie Thompson, Ph.D., Charleston Area Medical Center/WVU, United States, Charleston, WV\(^3\); Akram Kawsara, M.D., Charleston Area Medical Center/WVU, United States, Charleston, WV\(^4\)

**Background:** Chronic mesenteric ischemia (CMI) manifests as post-prandial abdominal discomfort and sitophobia resulting in significant weight loss, with atherosclerosis of the superior mesenteric artery (SMA) the most common etiology. Treatment for CMI requires open surgical repair or percutaneous angioplasty and stent placement. Our aims are to examine the differences in cardiovascular outcomes between open versus endovascular revascularization of CMI.

**Methods:** We retrospectively studied patients presenting with CMI between 2000 through 2011. Patient data was obtained from electronic and clinic records. Data analyzed included demographics, comorbidities, type and date of revascularization, body mass index, medications, location and severity of stenosis, symptoms at presentation and follow-up, periprobe complications, readmission and reintervention dates, and deaths. Differences among the cohorts will be determined using a t-test for continuous variables and a chi-square for categorical variables. A p value of <0.05 will be considered significant.

**Results:** We reviewed 15 patients that received intervention for CMI between 2000 and 2011. Four received initial open surgical revascularization while 11 had endovascular repair. The majority were female (80.0%). The most common symptom prior to intervention was abdominal pain (93.3%) followed by weight loss (66.7%) and post-prandial pain (66.7%). The mean age of patients receiving endovascular repair was 65.8± 11 years and significantly older than those receiving open repair (50.5 ± 9.4, t-test, p = 0.03).

In those receiving open repair, all had revascularization of their SMA with 1 also receiving celiac artery intervention. One patient receiving...
open intervention occluded of 1 of 2 bypasses 9 months following procedure and had no further intervention. Two receiving open and 1 receiving endovascular intervention required blood transfusion. Renal failure developed in 1 patient receiving endovascular repair. Five of the 11 patients undergoing endovascular repair required revascularization within 1 year of procedure. One patient underwent open repair 4 days after celiac stenting and died within the perioperative period.

**Conclusion:** Endovascular repair of mesenteric arteries had a high rate of restenosis and need for target vessel revascularization within 1 year. However, this approach remains a valid option especially for those patients who are poor candidates for open surgical intervention.

**Disclosures:**
William Hood: This author has nothing to disclose.
Aravinda Nanjundappa: This author has nothing to disclose.
Stephanie Thompson: This author has nothing to disclose.
Akram Kawsara: This author has nothing to disclose.

**C-046**

**Title:** Analysis of retrieved particulate debris after superficial femoral atherectomy using the Spectranetics Excimer Laser Turbo Elite® device

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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**Background:** Endovascular therapy for PAD can be associated with clinically-significant distal embolization. Our previously published data showed the incidence and histology of embolized debris during directional SFA (D-SFA) atherectomy. We investigate the incidence and composition of debris retrieved with a distal embolic protection (DEP) device during SFA atherectomy using the Spectranetics Excimer Laser device.

**Methods:** Between Aug. 2009 – Feb. 2011, we enrolled 14 consecutive eligible (≥ 18 y/o and ≥ 70% SFA stenosis) patients with non-occlusive SFA stenoses. In all patients DEP and debris retrieval were achieved using the Emboshield NAV™ system (Abbott). All patients underwent atherectomy with the Spectranetics Excimer Laser Turbo Elite® device. All filter baskets were retrieved and their content analyzed by a pathologist for number, size and composition of embolized debris.

**Results:** Mean age of patients was 70.7 years and 57.1% were males. 71.4% had multiple risk factors for PAD. The average lesion length was 148.6 mm. Procedural success (<20% residual stenosis) was achieved in 92.8% of cases. Macroscopic debris was retrieved in 12 of the 14 patients (85.7%). Clinically-significant emboli (capable of causing no-reflow and ischemia) were found in 28.6% of patients (4/14). The histologic analysis of the debris demonstrated collagen/fibrosis in 83.3% of samples (10/12), fibrin in 91.7% (11/12), macrophages in 33.3% (4/12), calcification in 50% (6/12), and cholesterol-rich material in 8.3% (1/12) (Fig.1).

**Conclusion:** In this study we demonstrate that, similar to other devices, atherectomy with Spectranetics Excimer Laser device almost always generates embolizing debris. Clinically-significant emboli were found less often than with D-SFA atherectomy (28.6% vs 33.3% of patients - comparison with data from our previously published registry). Moreover, their composition seems different than of those retrieved during D-SFA atherectomy (Fig. 1).

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Zsolt Jobbagy: This author has nothing to disclose.
Marc Cohen: This author has nothing to disclose.
Najam Wasty: This author has nothing to disclose.

**D-006**

**Title:** Endovascular Repair of Traumatic Aortic Injury: A Novel Arena in Interventional Cardiology

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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**Objective:** To assess the feasibility and outcomes following endovascular repair of traumatic aortic injuries performed by interventional cardiologists in collaboration with cardiothoracic surgeons at our level one trauma institution.

**Background:** Traumatic aortic injury (TAI) represents a significant cause for mortality in trauma patients. Endovascular techniques have recently come into play for the management of TAI and are usually performed by a multidisciplinary team consisting of a thoracic or vascular surgeon and/or interventional radiology. With extensive expertise in catheter based interventions, interventional cardiologists may have a pivotal role in this important procedure.

**Methods:** From January 2009 to July 2011, we reviewed the repair of TAI performed by endovascular techniques by a team of interventional cardiologists in collaboration with cardiothoracic surgery at our institution. The charts of these patients were reviewed to collect desired data which included preoperative, procedural, and follow-up details.
Results: Twenty patients were identified in our series (Table 1). Most of these patients developed TAI from motor vehicle accidents. Technical success for endovascular repair of TAI was achieved in all patients. Two patients developed endoleak, of which one patient required subsequent open repair. Two patients expired in the hospital from coexistent injuries.

Conclusion: Our series of endovascular repair for TAI performed by interventional cardiologists with the collaboration of cardiothoracic surgeons showed excellent outcomes. Our experience should help shed some light into the role of endovascular repair of TAI and the collaboration of interventional cardiology and cardiothoracic surgery for its management.

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Soni Zacharias: This author has nothing to disclose.
Donald Stowell: This author has nothing to disclose.
Jorge Saucedo: This author has nothing to disclose.

D-010

Title: Limb Salvage in Patients with Chronic Kidney Disease and Critical Limb Ischemia Using an Endovascular Approach

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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Background: Patients with chronic critical limb ischemia (CCLI) and chronic kidney disease (CKD) represent a difficult population due to multiple comorbidities, complex anatomy and a high-risk of contrast-induced nephropathy (CIN). Information regarding the feasibility of limb-salvage in this population using an endovascular approach is limited. The aim of this study was to evaluate the rate of limb salvage, outcomes and incidence of CIN in a group of patients with CCLI and CKD using a comprehensive endovascular approach focused in the prevention of CIN.

Methods: Patients with Rutherford-Baker class IV and above, with CKD III/IV were prospectively included in the study. Demographics, kidney function, incidence of CIN, limb salvage and survival were evaluated after a mean follow up of three years. Pre-operative Duplex ultrasound, pre- and post- revascularization ankle brachial index (ABI) and transcutaneous oxymetry (TCO2) were completed in all patients. A CIN prevention protocol was followed to minimize the contrast load and maximize peri-procedural hydration.

Results: 40 patients (65% males, 68±10 Years) were included in the study. 34 (87%) were diabetic, 28 (72%) hypertensive, 27(68%) had history of CAD, 9(23%) prior stroke, 27(67%) dyslipidemia, 17(42%) active smoking, 15(38%) patients had a prior endovascular and 10(25%) a prior surgical revascularization procedure. Aorto-iliac interventions were undertaken in 7(17%) patients, 34(85%) underwent femoro-popliteal revascularization and 24(60%) bellow the knee interventions. Overall survival was 72% after a mean follow-up of three years, with 14(35%) amputations (5 major and 9 minor). Revision for secondary
patency was necessary in 15 patients (37%) and subsequent surgical revascularization in 5 patients (12%). Pre- and post- intervention mean creatinine and GFR were respectively: 2.8±0.6 & 3.1±0.8 mg.dl and 32±10 & 38±8, mL/min/1.73 m² with an incidence of CIN of 27% and need of hemodialysis in 3 patients (5%). The mean contrast volume used for the index intervention was 151±50 cc. Pre and post intervention mean ABI and TCO₂ values increased from: 0.4±0.18 to 0.7±0.17 and 26.7±15 to 70±17 mmHg respectively.

Conclusion: Treatment of patients with CKD and CCLI with a primary endovascular approach with a focus in preventing CIN is a feasible and effective mean of limb-salvage, providing a good short-term survival and with an acceptable incidence of CIN and renal replacement therapy.

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Eduardo Salcedo: This author has nothing to disclose.

D-016

Title: Reduction in the Duration of Parenteral Anticoagulation for Deep Venous Thrombosis in Patients Undergoing Percutaneous Endovenous Intervention and Receiving Dabigatran

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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Background: The accepted approach in the treatment of deep venous thrombosis (DVT) is a minimum of 5 days of parenteral anticoagulation with at least 24 hours of overlap with warfarin at a therapeutic state. Recently it has been demonstrated that percutaneous endovenous intervention (PEVI) reduces the sequelae of DVT by early removal of thrombus. Since thrombus begets thrombus, it is interesting to postulate that early removal of thrombus may reduce the need for parenteral anticoagulation.

Methods: 34 patients with femoropopliteal or iliac DVT who had undergone PEVI for DVT underwent initiation of dabigatran within 6 hours after their procedure. No parenteral anticoagulation was given when dabigatran was started. The mean follow up was 8±2 months. Aspirin at 81mg daily was given to 15 patients who had received an endovenous stent. The patients were evaluated for recurrent venous thromboembolic (VTE) disease and bleeding during the follow-up period.

Results: There was no bleeding or recurrent VTE in any patient. One patient could not tolerate dabigatran due to gastrointestinal side effects. The mean duration of parenteral treatment was 22±5 hours. Enoxaparin was the parenteral anticoagulant in 24 patients and unfractionated heparin in 14 patients. The mean duration of hospitalization was 34±6 hours.

Conclusion: In patients undergoing PEVI, the duration of safe and effective parenteral anticoagulation may be less than the traditionally accepted minimum of 5 days. Initiation of dabigatran soon after PEVI allows for early discharge and obviates the inconveniences associated with regulation of warfarin.

Disclosures:
Mohsen Sharifi: Covidien, 5. Consulting Fees or Other Remuneration Laura Skrocki: This author has nothing to disclose.
Curt Bay: This author has nothing to disclose.
David Lawson: This author has nothing to disclose.
Kyle Spagnolo: This author has nothing to disclose.
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grouped into long and short categories. Baseline demographics and lesion angiographic characteristics were compared between groups. Re-stenosis, as assessed by duplex ultrasound (peak systolic velocity ratio ≥ 2.0), was determined at 1, 6, and 12 months post-intervention. Major amputation was defined as any amputation performed above the level of the ankle joint.

**Results:** Among 84 consecutive patients, 51 had long FP lesions (mean length 255 ± 48 mm) and 33 had short FP lesions (mean length 81 ± 44 mm). The majority of cases (70% in each group) were performed for critical limb ischemia. Baseline characteristics, including diabetes, smoking history, and statin use were similar between groups (Table). Long FP lesions were more frequently total occlusions (49% vs. 24%, p = 0.02), and were on average more heavily calcified (57 vs. 37%, p = 0.07) but had similar rates of 1 vessel infrapopliteal runoff (41% vs. 44%, p = 0.8). There was a trend toward more frequent stent placement among patients with long FP lesions (69% vs. 51%, p = 0.1). Primary patency was lower at 12 months for long FP lesions (32% vs. 48%, p = 0.2), but 12-month target vessel revascularization rates (29% vs. 24%) and limb salvage rates (82% for both groups) were similar for both short and long FP lesions.

**Conclusion:** In this high-risk cohort of patients with primarily critical limb ischemia, treatment of long FP lesions was associated with a trend toward lower 12-month patency rates, but identical rates of limb salvage.

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John Laird: This author has nothing to disclose.

**D-045**

**Title:** Procedural and Clinical Outcomes After Endovascular Intervention for Femoral-Infrapopliteal Graft Stenosis

**Category:** Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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**Background:** The value of femoral-infrapopliteal (FIP) bypass for limb salvage in critical limb ischemia is well documented. Intragraft or anastomotic graft stenosis (GS) can occur and result in graft failure. The procedural and clinical outcomes after endovascular treatment for FIP GS have not been adequately assessed.

**Methods:** A retrospective chart review was performed on 13 patients (19 limbs) who underwent endovascular treatment for FIP GS between 2006 and 2010. Clinical and procedural outcomes were evaluated against 14 control patients who did not undergo endovascular treatment.

**Results:** The procedural and clinical outcomes were comparable between the treatment and control groups. The rate of primary patency at 12 months was 48% for the treatment group and 50% for the control group (p = 0.7). The rate of target vessel revascularization at 12 months was 20% for both groups (p = 0.7). The rate of major amputation at 12 months was 10% for both groups (p = 0.1). The rate of minor amputation at 12 months was 5% for both groups (p = 0.1). The rate of wound healing at 12 months was 90% for both groups (p = 0.1). The rate of limb salvage at 12 months was 90% for both groups (p = 0.1).

**Conclusion:** The procedural and clinical outcomes after endovascular treatment for FIP GS were comparable to those of the control group. Further studies are needed to validate these findings.
including 6 and 12-month primary patency (<50% stenosis by duplex ultrasonography without the need for reintervention).

Results: Patient indices and procedural outcomes are summarized in table 1. Among 19 limbs treated, 16 (84.2%) had vein grafts. 52% of the procedures were performed by surveillance duplex while 37% were performed for critical limb ischemia. Acute procedural success was achieved in 18 (94.7%) limbs. The median length of GS was 15 mm (IQR, 10, 50 mm). Cutting balloon angioplasty was employed in 15 (78.9%) cases. Two patients (10.6%) required additional angioplasty beyond the distal anastomosis. Only one patient presented with acute graft occlusion. The 6 and 12-month PP rates were 57.9% and 36.8% while primary assisted patency rates were 71.5% and 53.6% respectively. There was a marginal increase in toe brachial index after revascularization (0.40 vs. 0.48, p = 0.09). Patency was not affected by patient characteristics, graft type/diameter or below the knee run-off. Lesion length of < 50 mm was associated with higher patency (r = 0.72, p = 0.019). Target lesion revascularization (TLR) rate was 20% and 22.2% at 6 and 12 months. Only one patient required an ipsilateral amputation.

Conclusion: Restenosis of FIP grafts after endovascular intervention is relatively high. However, graft occlusion rate and need for amputation is low.

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Caroline McCouch: This author has nothing to disclose.
Greg Westin: This author has nothing to disclose.
John Laird: This author has nothing to disclose.

D-047

Title: The Emerging Role of Interventional Cardiologists in the Management of Sub-massive Pulmonary Embolism

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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Background: Patients (pts) with sub-massive pulmonary embolism (SPE) have a high in-hospital mortality rate. Mainstay therapy for these pts is usually systemic anticoagulation. However, this fails to improve the short and long-term outcomes in many pts. American Heart Association guidelines (GL) recommend the use of catheter-directed thrombolysis therapy (CDT) in select SPE pts (class IIb recommendation).

We highlight the emerging role of interventional cardiologists (IC) as a specialty in the management of these sick pts as a direct result of incorporation of these GL into clinical practice.

Methods: At a large tertiary care hospital a multi-disciplinary team of doctors led by IC was formed following the publication of AHA GL. This team assessed SPE pts which were offered CDT if no contraindications to thrombolytic therapy existed. This CDT consisted of bilateral pulmonary artery ultrasound-assisted rt-PA administration for 12-15 hours. Infusion rate of rt-PA was 1-3 mg/hour via each catheter. All procedures were performed in the cath lab after obtaining informed consent. All these patients also underwent imaging confirmation of SPE (including CT, echocardiogram, V/Q scan and pulmonary angiography), Troponin I (Tnl) evaluation, and right heart hemodynamics.

We assessed pre-CDT and post-CDT cardiac hemodynamics, right ventricular (RV) diameter, RV to left ventricular (LV) diameter ratio, in-hospital and 30-day mortality.

Results: A total of seven consecutive pts were treated between April and December 2011.

All patients were found to have SPE with high-risk features of significant RV dysfunction, RV/LV ratio of > 1.0, PA systolic pressure > 50 mm Hg and Tnl elevation.

All pts underwent CDT within 12 hours of diagnosis. Invasive and echocardiographic parameters normalized in all patients within 24 hours of CDT. All patients were alive at the time of hospital discharge and at 30-d follow-up.

Conclusion: IC, based on their experience with prompt STEMI management have a new leadership role to offer life-saving therapy to SPE pts.

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Immad Sadiq: This author has nothing to disclose.

AO-010

Title: Long term patency of failed hemodialysis AV access after endovascular revascularization

Category: Endovascular and Peripheral Interventions (Including Neurovascular and Carotid)

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Introduction: Renal replacement therapy in hemodialysis-dependent patients depends on reliable arteriovenous access. However, AV access dysfunction and failure is a frequent and recurrent problem. Endovascular interventions aim to preserve AV access longevity. This study compares the efficacy of several percutaneous techniques in maintaining AV access patency.

Methods: We performed a retrospective analysis of 464 consecutive endovascular procedures for patency restoration in failed AV access sites between June 1, 2008 and January 31, 2011. Demographics, type of AV access, cause of malfunction, method of revascularization, and patency duration were recorded. Statistical analysis was performed using Student’s t test.

Results: A total of 464 procedures were performed in 200 patients; 85.3% were recurrent failures. Mean age was 65.8 years, 47.4% female, 49.5% were AV fistulas and 46.5% prosthetic AV grafts. Comorbid conditions included diabetes (62.8%), hypertension (91.2%), CAD (32.1%), PAD (18.5%) and smoking (18.1%). Patients with recurrent AV access failures had an average of 2.99 procedures during study period with mean patency duration of 89.9 days. The most common cause of first time AV access failure was venous stenosis (66.8%) vs. fistula/graft thrombosis (77.2%) for recurrent failure. Technical success was achieved in 93.2% of cases; 11.9% had complications including perforation, dissection, arterial embolization, hemodynamic compromise, major bleeding and severe contrast reaction. Modes of revascularization included PTA...
(94.9%), thrombectomy (63.9%), and stenting (17.3%). The method of revascularization did not affect procedural outcome. The need to use both Trerotola and Angiojet thrombectomy predicted worse long term patency than PTA alone, 53.9 days vs. 103.1 days (p = 0.05).

Conclusions: Endovascular revascularization of failed AV dialysis access aims to prevent the need for new access. The main causes of failure include venous stenosis and thrombosis. Individual revascularization techniques are not superior in preserving patency. Thrombosis requiring use of multiple thrombectomy devices predicts poor long term prognosis. Rates of technical success are excellent, but the rate of procedural complications is substantial. Endovascular techniques have a primary role as temporary means for continued hemodialysis while new AV access is obtained.

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Katrine Zhiroff: This author has nothing to disclose.
Edwin Perez Marrero: This author has nothing to disclose.
Robert Kloner: This author has nothing to disclose.

Methods: A balloon occlusion followed by reperfusion in the coronary artery was used to study acute myocardial infarction (AMI) in 6 swine. C-arm CT images were acquired 90 min after infarct creation during a peripheral iodine (Omnipaque 350) contrast injection (first-pass image), at 1 min, and then every 5 min for up to 30 min, with no additional contrast. Infarct morphology was assessed by hand-tracing regions of hyper- and hypoenhancement on short-axis slices in the first-pass through 15 min images. Total infarct volume and MO volume measured on C-arm CT were compared to the volumes measured on pathologic specimens stained with 2,3,5-triphenyltetrazolium chloride and thioflavin S, respectively. Agreement between volume measurements was assessed using concordance correlations (CC) and mean difference ± standard deviation.

Results: The total volume of the infarct was best visualized 1 min after contrast injection as a combined region of hyper- and hypoenhanced tissue (CC = 0.98, mean difference = 0.52±1.31 cm³). MO was seen as a hypointense region on 4 of 6 animals beginning on the first-pass image and decreasing in size in subsequent images as contrast diffused throughout the affected territory. The volume of MO measured on C-arm CT best correlated with thioflavin S-stained tissue at 5 min after contrast injection (CC = 0.87, mean difference = 0.75±3.47 cm³).

Conclusions: Total volume of AMI and MO can be accurately assessed using C-arm CT. In addition to providing early prognostic information, C-arm CT images of AMI could be used for the investigation and delivery of cellular or molecular therapies for AMI.
Background: The incidence of false positive myocardial perfusion imaging (MPI) results in patients with normal variants of coronary anatomy is unknown. We examined the influence of coronary arterial dominance and the anatomical types of the left anterior descending coronary artery (LAD) on MPI results.

Methods: All patients who underwent both MPI and coronary angiography between June 2002 and December 2010 at our institution were screened for inclusion. Patients with abnormal MPI results and normal coronary angiograms were defined as cases. Patients with normal MPI results and normal coronary angiograms, performed due to persistent symptoms, were defined as controls. LAD types were classified based on coronary angiography: LAD that does not reach the left ventricular apex (type 1), LAD that reaches the apex (type 2), and LAD that wraps around the apex (type 3). Coronary angiograms and MPI studies were interpreted by two experienced readers. Patients with co-dominant coronary systems were excluded.

Results: A total of 367 patients were included (184 cases and 183 controls). False positive MPI rates were significantly higher in patients with LAD type 1 and type 3 when compared with patients with LAD type 2 (73% vs. 58% vs. 37% respectively, p < 0.001). Compared with LAD type 1, LAD type 3 was associated with more perfusion defects in the anterolateral segments (31% vs. 38%) and anteroseptal segments (23% vs. 32%), although not statistically significant. Coronary artery dominance did not correlate significantly with the false positivity rate of MPI studies (right dominance 90% in controls vs. 88% in cases). Regression analysis showed that LAD types 1 and 3 significantly predicted false positive MPI (OR 3.9, 95% CI: 2.4 to 6.5; P = 0.001) after adjusting for factors such as age, gender, body mass index, smoking status, chronic kidney disease and coronary dominance.

Conclusion: Our results show that the likelihood of false positive results from MPI studies is significantly higher in patients with LAD types 1 and 3, irrespective of the coronary arterial dominance. Thus, knowing the patient’s LAD anatomical type would help the interpretation of future MPI studies, and may reduce unnecessary coronary angiograms.

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Peter Tadros: This author has nothing to disclose.
Mark Wiley: This author has nothing to disclose.

INTRAVASCULAR IMAGING (IVUS)/PHYSIOLOGY

A-014

Title: Differential Coronary Remodeling and Plaque Composition Patterns Manifest in Diabetic vs. Non Diabetic Coronary Artery Disease: Insights From Pre-PCI in vivo Compositional Analysis

Using Intravascular Ultrasound Virtual Histology

Category: Intravascular Imaging (IVUS)/Physiology

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Figure 1. Coronary Remodeling in DM vs non-DM Patients.
Background: Prior reports note patients (pts) with diabetes mellitus (DM) and coronary artery disease (CAD) undergo negative vascular remodeling with vessel shrinkage and low-volume plaque in angiographically stenosed segments. We assessed coronary remodeling and correlated findings with in vivo Intravascular Ultrasound - Virtual Histology (IVUS-VH) compositional analyses.

Methods: 2,579 IVUS-VH frames acquired in DM (n = 15) and non-DM (n = 21) pts, pre-PCI via Volcano Eagle-Eye Platinum 20 MHz IVUS and automated pullback were traced, blindly adjudicated and analyzed for remodeling parameters and VH plaque composition. Statistical analyses were performed using SPSS 20.0.

Results: DM pts had significantly greater coronary remodeling, plaque area and burden but smaller luminal cross-sectional area (CSA) as compared with non-DM pts despite nearly identical reference segment IVUS dimensions and angiographic lesion appearance (Figure 1). By IVUS-VH, DM plaque contained greater necrotic core (1.87 vs 1.66 mm²/frame, p = 0.002) and fibrous content (4.94 vs 4.44 mm²/frame, p < 0.001).

Conclusion: Contrary to prior reports, we demonstrate DM pts have positive coronary remodeling in response to CAD and to a greater extent than non-DM pts. Observed plaque burden in DM pts was a result of both increased plaque area/frame and decreased luminal CSA. The differential VH plaque composition in DM pts may be linked with the differential remodeling pattern observed. These data have significant implications on pathogenesis and treatment of DM CAD.

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Title: Coronary Plaque Component Changes Before and After Rotational Atherectomy: Assessment by Intravascular Ultrasound and Virtual Histology

Category: Intravascular Imaging (IVUS)/Physiology

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Background: Rotational atherectomy (RA) is currently the preferred strategy for treating heavily calcified atherosclerotic lesions. In vitro studies have suggested that this technique selectively abrades calcified plaques. However, there are few studies on the effects of RA on plaque compositional changes in vivo. Intravascular ultrasound with virtual histology (VH-IVUS) can provide detailed transmural imaging of coronary arteries and delineate coronary plaque composition in vivo. Therefore, we used VH-IVUS imaging before and after RA to characterize its mechanisms and effects on human atherosclerotic coronary arteries in vivo.

Methods: Between February 2009 and November 2011, 120 consecutive patients underwent percutaneous coronary intervention with RA at our center. Pre- and post-RA VH-IVUS images were successfully obtained at the minimum lumen sites in 66 lesions in 60 patients. VH-IVUS analysis classified plaques into the following 4 major components: fibrotic (FI), fibrofatty (FF), dense calcium (DC), and necrotic core (NC). We defined calcified lesions as those with superficial calcification >90% of the arc.

Results: The largest RA burr tips used ranged from 1.5 to 2.25 mm (mean: 1.9 ± 0.2 mm). RA achieved significant increase in lumen areas (1.87 ± 0.51 vs. 3.35 ± 1.20 mm² before and after RA, respectively; p < 0.0001) by significant reduction in plaque areas (9.37 ± 3.96 vs. 8.11 ± 3.75 mm², p < 0.0001) with no significant change in vessel areas (11.30 ± 4.07 vs. 11.46 ± 4.01 mm², p = ns). Plaque area reduction after RA was mainly caused by decrease in FI or FF (FI, 3.81 ± 2.51 vs. 3.08 ± 2.04 mm², p < 0.0001; FF, 1.34 ± 0.92 vs. 0.79 ± 0.85 mm², p < 0.001, respectively). DC and NC were less responsive to RA (DC, 0.67 ± 0.56 vs. 0.73 ± 0.68 mm², p = ns; NC, 1.47 ± 1.06 vs. 1.34 ± 1.07 mm², p = ns, respectively). In addition, DC ablation was minimal in calcified lesions (1.00 ± 0.52 vs. 1.04 ± 0.68 mm², p = ns). There was a weak but significant positive correlation between plaque area reduction and final lumen area following adjunctive balloon angioplasty and/or additional stent implantation (r = 0.26, p = 0.03).

Conclusion: Contrary to common perceptions, the atheroablative effect of RA was mainly attributable to the removal of fibrotic and fibrofatty plaques, regardless of the presence of superficial calcification. Nevertheless, the potential to abrade atherosclerotic plaque with minimal arterial barotrauma may merit the use of RA.

Disclosures: Yoshihisa Shimada: This author has nothing to disclose. Naoto Kino: This author has nothing to disclose. Kentaro Yano: This author has nothing to disclose. Daisuke Tonomura: This author has nothing to disclose. Kosuke Takehara: This author has nothing to disclose. Keiichi Furubayashi: This author has nothing to disclose. Toshiya Kurotobi: This author has nothing to disclose. Takao Tsuchida: This author has nothing to disclose.

Title: Legitimacy of Current Anatomical Criteria for Guidance of PCI: Investigation Using a Novel Percutaneous Model of Coronary Artery Stenosis

Category: Intravascular Imaging (IVUS)/Physiology

Authors: Nicolas Foin, Ph.D., Imperial College, United Kingdom, London1; Sayan Sen, M.D., Imperial College, United Kingdom, London2; Ricardo Petracco, M.D., Imperial College Healthcare, United Kingdom, London3; Ryo Torii, Ph.D., Imperial College, United Kingdom, London4; Yun Xu, Ph.D., Imperial College, United Kingdom, London5; Carlo Di Mario, M.D., Ph.D., Imperial College, United Kingdom, London6; Rob Krams, M.D., Ph.D., Imperial College, United Kingdom, London7; Justin Davies, M.D., Ph.D., Imperial College, United Kingdom, London8

Background: Minimum Lumen Area (MLA) is generally considered a critical parameter for guidance of PCI treatment. Recently the validity of such anatomical based criteria has been questioned as the correlation with functional measures such as FFR remains modest.

Methods: To study this interaction, we developed a series of percutaneous stenotic stent models, mimicking intermediate to severe stenosis, and implanted them in coronary arteries of 8 healthy hybrid landrace pigs. OCT pullbacks and FFR were acquired along the artery after implantation of the stenotic stent.

Results: Average MLA was 1.7 ± 0.5 mm² ranging from 1.0 to 2.7 mm² (95% C.I.: 1.3-1.9) suggesting a need for intervention in all the lesions based on current IVUS-based criteria of lesion severity. Average
FFR value was 0.83 ± 0.13. A poor correlation was observed between FFR and MLA or percentage area stenosis evaluated by OCT (respectively $r = 0.02$, $p = 0.94$ and $r = -0.55$, $p = 0.12$). On the other hand, a severity OCT evaluation based on a volumetric percentage stenosis resulted in significant better correlation with FFR ($r = -0.78$, $p = 0.01$).

**Conclusion:** Results suggest that MLA based criteria alone cannot reliably be used to determine PCI treatment. We suggest here that a lesion assessment based on an OCT derived % volume stenosis may provide a better anatomical parameter for assessment of lesion severity by intravascular imaging than simple MLA.

**Disclosures:**
Nicolas Foin: This author has nothing to disclose.
Sayan Sen: This author has nothing to disclose.
Ricardo Petraco: This author has nothing to disclose.
Ryo Torii: This author has nothing to disclose.
Yun Xu: This author has nothing to disclose.
Carlo Di Mario: This author has nothing to disclose.
Rob Krams: This author has nothing to disclose.
Justin Davies: This author has nothing to disclose.

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**Table A-043**

**Title:** Using Optical Coherence Tomography to Evaluate Atherosclerotic Lesion Formation in the Watanabe Heritable Hyperlipidemic (WHHL) Rabbit Model  
**Category:** Intravascular Imaging (IVUS)/Physiology  
**Authors:** Michael Frie, None, B.A., American Preclinical Services, United States, Minneapolis, MN; Mark Smith, Ph.D., American Preclinical Services, United States, Minneapolis, MN

**Background:** A reproducible animal model of calcified atherosclerotic plaque exhibiting similar properties to those observed in the human population has proven difficult to develop. One of the more promising models is the Watanabe Heritable Hyperlipidemic (WHHL) rabbit. The WHHL rabbit is a well studied and characterized model for hypercholesterolemia in which atherosclerotic lesions develop naturally. Lipid-dense atheromas, similar to those found in human cases of atherosclerosis, can be found throughout the aorta and iliac arteries, at varying levels of severity. Since the extent of these lesions are not always apparent when viewed under fluoroscopy, we evaluated the use of optical coherence tomography (OCT) imaging as a guide for identifying animals with adequate plaque burden and then targeting optimum lesion sites for treatment within a region of vessel. OCT imaging can also allow interim evaluation of the disease progression without sacrificing the animal.

**Methods:** Six WHHL rabbits were sedated and prepped steriley for the implant procedure. An introducer sheath was placed in the carotid artery for vascular access. OCT images of the external iliac arteries and infra-renal aorta were acquired and the overall plaque burden was evaluated. Target implant sites were selected based on vessel size and the severity of plaque burden and treated with a balloon expandable stent. OCT images of the implanted stents were acquired after stent placement and stent to vessel wall apposition was evaluated. The animals were then recovered and transferred to long-term animal housing.

**Results:** Using the OCT in conjunction with the fluoroscopic images, eight stents were successfully implanted in a portion of vessel that displayed moderate to marked plaque burden. The atherosclerotic lesions observed in WHHL rabbit arteries were not easily identifiable via fluoroscopy and were overall diffuse in nature; with moderate atheroma formation observed in the infra-renal aorta and marked atheroma formation observed in the iliac arteries.

**Conclusion:** OCT is a necessary tool to ensure that a subject animal has suitable overall atheroma formation and also that an experimental therapeutic device will be delivered to and evaluated within a lesion rich portion of test vessel. The plaques observed were variable in location and severity, and could not reliably be visualized or accessed via fluoroscopy, but OCT imaging was able to identify target lesions reliably.
C-005

Title: Aortic Stiffness Invasive Assessment With a New Angiographic Bilumen Catheter

Category: Intravascular Imaging (IVUS)/Physiology

Authors: Filippo Scalise, M.D., FSCAI FACC FESC, Catheterization Laboratory - Policlinico di Monza, Italy, Monza1; Paolo Villa, M.D., Università degli Studi Milano Bicocca, Italy, Milano2; Alberto Cereda, M.D., Università degli Studi Milano Bicocca, Italy, Milano3; Carla Auguadro, M.D., Ph,D., Catheterization Laboratory - Policlinico di Monza, Italy, Monza4; Luca Mainardi, Ph,D., Dipartimento Bioingegneria Politecnico di Milano, Italy, Milano5; Marta Alioni, M.D., Università degli Studi Milano Bicocca, Italy, Milano6; Cristina Giannattasio, M.D., Ph,D., Università degli Studi Milano Bicocca, Italy, Monza7

Objective: Pulse wave velocity (PWV) is an important marker of aortic stiffness. PWV is usually assessed by the foot-to-foot velocity method from carotid and femoral waveforms and it is calculated as PWV = D/T, where D is the distance between the two reference points (meters) and T is the time to cover D (seconds). The present study was aimed at comparing PWV non-invasive measurements (niPWV), performed via the validated Complior device, versus invasive PWV (iPWV), as assessed by a new catheter capable to detect the same pressure wave at two reference points (FS-StiffCath, Flag Vascular, Monza, Italy) to verify the impact of the measured superficial distance between the two references on the real PWV value.

Methods: We enrolled 20 consecutive patients undergoing cardiac catheterization due to coronary artery disease. Prior to the angiographic evaluation we measured blood pressure (BP) and niPWV as well as FS-StiffCath. Invasive D was individualized with three possible lengths (60, 70 and 80 cm), while niD was measured with a rigid caliper following the European Expert Consensus Recommendations. Data collected from FS-StiffCath were analyzed offline via a dedicated software (StiffCalc, Flag Vascular, Monza, Italy) to verify the impact of the measured superficial distance between the two references on the real PWV value.

Results: Patients were aged 67±10 yrs with an echocardiographic ejection fraction amounting to 56±11%. NiPWV was significantly greater than iPWV (12.6±2.6 m/sec vs 10.3±2.3 m/sec, P<0.0001). Although they were significantly related each other (r = 0.90, P<0.001), the concordance correlation coefficient between niPWV and iPWV amounted to 0.56 (CI 0.33 - 0.72) and Bland-Altman plot failed to show a good relation between the two sets of data, the mean difference in PWV values being quite consistent. Carotid-femoral distance measured by Complior method on patients’ body surface didn’t differ from the values used for the invasive method. Individual differences between niPWV and iPWV were however inversely and significantly correlated with body mass indexes (r = -0.50, P = 0.02). Finally, niT was lower than iT (0.048±0.010 sec vs. 0.062±0.015 sec, P < 0.001).

Conclusion: The present data provide evidence that 1) PWV is greater when measured non-invasively, particularly in lean individuals 2) BMI (more than absolute distance) represents a significant predictor of the difference between the two measurements and 3) the non-invasive Complior method estimates shorter transit time values than the invasive one.

Disclosures:
Filippo Scalise: Flag Vascular, 4. Ownership or Partnership
Paolo Villa: This author has nothing to disclose.
Alberto Cereda: This author has nothing to disclose.
Carla Auguadro: This author has nothing to disclose.
Luca Mainardi: This author has nothing to disclose.
Marta Alioni: This author has nothing to disclose.
Cristina Giannattasio: This author has nothing to disclose.

AO-007

Title: Use of Regadenoson for Fractional Flow Reserve (FFR) Measurement

Category: Intravascular Imaging (IVUS)/Physiology

Authors: Aditya Prasad, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA1; Reece Dougherty, None, B.S., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA2; Arnold Seto, M.D., UC Irvine Medical Center, United States, Irvine, CA3; Anikumar Mehta, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA4; Leonardo Clavijo, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA5; Ray V Mathews, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA6; David Shavelle, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA7

Background: Fractional flow reserve (FFR) is commonly used to assess the functional significance of intermediate coronary artery stenosis. Regadenoson is currently approved for pharmacologic myocardial perfusion imaging, requires single bolus administration, has a fixed dose regardless of body weight, and is a selective A2a receptor agonist with an improved side effect profile compared to Adenosine. There have been few reports describing the use of Regadenoson for assessment of FFR. The goal of this study was to compare the efficacy of Adenosine and Regadenoson for measurement of FFR.

Methods: Twenty-one patients undergoing FFR for the assessment of 22 intermediate coronary artery lesions were included. For the initial assessment of FFR, hyperemia was achieved by a standard intravenous (IV) Adenosine infusion (140mcg/kg/min) for 3 minutes. After a washout period of 10 minutes, FFR was reassessed using Regadenoson as a single 0.4mg IV bolus. FFR measurements were recorded at baseline and following maximal hyperemia with both agents.

Results: Mean (+SD) age was 58 (+9) years and 17 were male. No patients experienced any side effects related to Regadenoson. The coronary lesion for FFR assessment was located in the left anterior descending in 14 patients, the left circumflex in 2 patients and the right coronary artery in 6 patients. The mean (+SD) FFR following Adenosine and Regadenoson was 0.77 (+0.09) and 0.77 (+0.09), respectively, p NS (Figure).

Conclusion: Regadenoson appears to be a viable alternative to IV Adenosine for achieving maximal hyperemia during FFR assessment. In addition to offering comparable hemodynamic results, Regadenoson is easier to use and may have an improved side effect profile.

Disclosures:
Aditya Prasad: This author has nothing to disclose.
Reece Doughty: This author has nothing to disclose.
Arnold Seto: This author has nothing to disclose.
Anilkumar Mehra: This author has nothing to disclose.
Leonardo Clavijo: This author has nothing to disclose.
Ray V Matthews: St Jude Medical, 2. Research Grants.
David Shavelle: St Jude Medical, 2. Research Grants.

A-006
Title: Frequency of Patients with Undiagnosed Left Main Coronary Artery Vasospasm Undergoing Coronary Artery Bypass Grafting Surgery

Category: Left Main & Multi-Vessel Intervention
Authors: Asim Mohammed, M.B.B.S., Christiana Care Health System, United States, Newark, DE1; Asim Mohammed, M.B.B.S., Christiana Care Health System, United States, Newark, DE2; Andrew Yang, None, Christianacare Health System, United States, Newark, DE3; Kimberly Shao, None, Christianacare Health System, United States, Newark, DE4; Angela DiSabatino, R.N., Christianacare Health System, United States, Newark, DE5; Angela DiSabatino, R.N., Christianacare Health System, United States, Newark, DE6; Ray Blackwell, M.D., Christianacare Health System, United States, Newark, DE7; Michael Banbury, M.D., Christianacare Health System, United States, Newark, DE8; William Weintraub, M.D., Christianacare Health System, United States, Newark, DE9; Andrew Doorey, M.B.B.S., Christianacare Health System, United States, Newark, DE10

Background: Left main coronary artery (LMCA) vasospasm induced by a coronary catheter during the angiography can be falsely diagnosed as LMCA atherothrombotic disease and the patient may be referred for coronary artery bypass graft (CABG) surgery. However, the frequency of CABG in the number of patients with LMCA vasospasm without significant atherothrombotic disease is unknown. The aim of this study is to identify the frequency of possible LMCA vasospasm in patients who underwent CABG at our academic medical center.

Methods: In a retrospective analysis, we identified cases in the last 10 years, using the STS (Society for Thoracic Surgery) database, in which CABG was performed in the presence of significant (>50%) LMCA stenosis. We then identified those patients who had a subsequent catheterization done using the cardiac catheterization laboratory database. If the repeat catheterization following CABG showed normal or minimal luminal irregularities in LMCA the findings on the pre-CABG angiogram was defined as LMCA vasospasm.

Results: In this 10 year period, 2313 patients went for CABG with a significant LMCA stenosis. Of these, 385 had a subsequent catheterization at our facility. Sixteen out of the 385 (4.1%) had no LMCA stenosis identified on repeat study. A sizeable minority of patients, 6/16 (37.5%) underwent CABG primarily for LMCA stenosis, with minimal disease in other coronaries. In the repeat study, 6/15 (40%) internal mammary conduits to the left anterior descending coronary artery were arteric or occluded.

Conclusion: LMCA vasospasm among patients undergoing catheterization pre-CABG is not uncommon, and may even be the primary reason for the surgery. This exposes patients to unnecessary high-risk surgical intervention, and possible occlusion of grafts due to competitive flow. Exclusion of spasm in the cardiac catheterization laboratory should be considered as it may profoundly affect revascularization decisions.

Disclosures:
Asim Mohammed: This author has nothing to disclose.
Asim Mohammed: This author has nothing to disclose.

B-048
Title: Mandatory IVUS Guidance and Outcomes in Percutaneous Revascularization Among High Risk Patients With Unprotected Left Main Disease

Category: Left Main & Multi-Vessel Intervention
Authors: Hoang Thai, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ1; Madhan Shanmugasundaram, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ2; Vinny Ram, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ3; Sasanka Jayasuria, M.D., University of Arizona, United States, Tucson, AZ4; Steven Goldman, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ5

Background: Percutaneous coronary intervention (PCI) in patients with unprotected left main (UPLM) disease continues to evolve following clinical studies demonstrating effective and safe outcomes among intermediate risk patients. However there is limited data on PCI of UPLM among high risk patients. In particular when a strategy of mandatory intravascular ultrasound (IVUS) is employed.

Methods: We retrospectively reviewed 119 high risk patients with UPLM who underwent PCI with drug eluting stents and IVUS guidance. We compared their outcomes against 50 patients with UPLM who underwent coronary artery bypass graft (CABG) surgery during a 3 year period and followed their outcomes up to 12 months. The patients were age and gender matched. It was not possible to perform a propensity risk evaluation since the CABG patients were all low to moderate risk. The primary endpoints were major adverse cardiac events (MACE), which included myocardial infarction (MI), death and target vessel revascularization (TVR). The secondary endpoints were: TVR and graft occlusion and/or ARC probable stent thrombosis (ST). Logistic regression analysis was used to model predictors of MACE.

Results: There was a difference in the Euroscore in the PCI versus CABG cohort (8.4 + 2.2 vs 3.7 + 1.2, p<0.005). This highlights the selection bias seen favoring patients with UPLM undergoing CABG. Despite this bias there was no difference in the MACE rate between PCI and CABG patients (11.8 vs 12.6%, p = ns), similarly there was no difference in the TVR rate at 12 months between PCI and CABG patients (3.3 vs 4.2%, p = ns). There was no graft occlusion or stent thrombosis by either group. A Euroscore > 6 was associated with a MACE odds ratio of 7.9 (p<0.0005).

Conclusion: High risk patients with UPLM disease undergoing PCI had similar clinical outcomes compared with intermediate risk patients undergoing CABG at 12 months. The use of routine IVUS guidance appears to be beneficial.

Disclosures:
Hoang Thai: This author has nothing to disclose.
Madhan Shanmugasundaram: This author has nothing to disclose.
Vinny Ram: This author has nothing to disclose.
Sasanka Jayasuria: This author has nothing to disclose.
Steven Goldman: This author has nothing to disclose.
C-009

Title: Outcomes Based on Revascularization Sequence in Patients Undergoing Robotically-Assisted Hybrid Coronary Revascularization

Category: Left Main & Multi-Vessel Intervention

Authors: Mukta Srivastava, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Mark Vesely, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Jeffrey Lee, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Eric Lehr, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Brody Wehman, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Nikolaos Bonaros, M.D., Innsbruck Medical University, Austria, Innsbruck; Thomas Schachner, M.D., Innsbruck Medical University, Austria, Innsbruck; Guy Friedrich, M.D., Innsbruck Medical University, Austria, Innsbruck; David Zimrin, M.D., University of Maryland Medical Center, United States, Baltimore, MD; Johannes Bonatti, M.D., University of Maryland Medical Center, United States, Baltimore, MD.

Background: Hybrid coronary revascularization (HCR) is a coronary revascularization strategy that combines the advantages of minimally-invasive surgical therapy and percutaneous coronary intervention (PCI) to treat a given set of cardiac lesions. However, the optimal sequence by which revascularization should be accomplished has not been determined. Our aim was to compare clinical outcomes based on revascularization sequence in a series of patients who were planned for HCR via robotically-assisted totally endoscopic coronary artery bypass (TECAB) and standard PCI.

Methods: 238 patients planned for HCR between 2001 and 2011 were reviewed on an intention-to-treat basis in 3 groups: patients undergoing PCI prior to TECAB vs PCI post-TECAB vs during a simultaneous procedure. Outcomes evaluated included incidence of surgical revision for bleeding, intra-aortic balloon counter-pulsation device (IABP) placement, atrial fibrillation, cerebrovascular accident (CVA), need for dialysis, ventilation time, intensive care unit (ICU) length of stay (LOS), hospital LOS and 1-year freedom from major adverse cardiovascular and cerebrovascular events (MACCE). Demographic features were reviewed to determine baseline differences between each group.

Results: Of the 238 patients, 175 (74%) underwent TECAB prior to PCI, 38 patients (16%) underwent PCI prior to TECAB and 25 (11%) underwent a simultaneous revascularization procedure. At baseline, patients undergoing TECAB prior to PCI were significantly older (p = 0.045) but were matched for baseline demographic features of EuroSCORE, body mass index (BMI), ejection fraction (EF) and gender. No significant differences were noted in the incidence of surgical revision for bleeding, IABP placement, atrial fibrillation, CVA, need for dialysis and 1-year freedom from MACCE between the three groups. There was a significant difference in ICU LOS with a trend towards shorter ICU stays in the simultaneous revascularization group (p = 0.031) and a significant difference was noted in hospital LOS with a trend towards shorter hospital stays in the PCI prior to TECAB group (p = 0.021).

Conclusion: Surgical revascularization sequence did not dramatically impact evaluated clinical outcomes. Patients undergoing PCI first and simultaneous interventions had shorter hospital LOS and ICU lengths of stay. These differences may be explained by a different demographic risk profile in the TECAB prior to PCI group.

Disclosures: Mukta Srivastava: This author has nothing to disclose.
Mark Vesely: This author has nothing to disclose.
Jeffrey Lee: This author has nothing to disclose.
Eric Lehr: This author has nothing to disclose.
Brody Wehman: This author has nothing to disclose.
Nikolaos Bonaros: This author has nothing to disclose.
Thomas Schachner: This author has nothing to disclose.
Guy Friedrich: This author has nothing to disclose.

David Zimrin: This author has nothing to disclose.
Johannes Bonatti: This author has nothing to disclose.

C-014

Title: Is Routine Use of the SYNTAX Score Necessary in the Evaluation of Coronary Revascularization in Patients With Severe Coronary Artery Disease?

Category: Left Main & Multi-Vessel Intervention

Authors: Yumiko Kanei, M.D., Albert Einstein College of Medicine at Beth Israel Medical Center Program, United States, New York, NY; Justin Ratcliffe, M.D., Albert Einstein College of Medicine at Beth Israel Medical Center Program, United States, New York, NY; David Fishman, M.D., Albert Einstein College of Medicine at Beth Israel Medical Center Program, United States, New York, NY; Rahul Patri, M.D., Albert Einstein College of Medicine at Beth Israel Medical Center Program, United States, New York, NY; John Fox, M.D., Albert Einstein College of Medicine at Beth Israel Medical Center Program, United States, New York, NY.

Background: In the SYNTAX trial, a high SYNTAX score was associated with better clinical outcomes with coronary artery bypass graft (CABG) surgery at 3 years compared to percutaneous coronary intervention (PCI). The aim of this study is to evaluate the utility of adding SYNTAX scores in the evaluation of coronary revascularization.

Methods: 203 consecutive patients with three vessel coronary artery disease on diagnostic coronary angiogram were reviewed. The revascularization methods were decided at the discretion of the treating physician, and SYNTAX score was not routinely calculated. Patients with concomitant valvular disease requiring cardiac surgery were excluded, but patients with previous PCI and acute myocardial infarction (AMI) were included to reflect real world practice. The diagnostic coronary angiogram was reviewed by an experienced angiographer to calculate the SYNTAX score. Clinical and procedural characteristics were compared in patients who underwent CABG and PCI.

Results: After excluding 12 patients with valvular disease, and 9 patients with missing information, 182 patients were included in the study. Indication of acute myocardial infarction (AMI) was seen in 57 patients, and 41 patients had previous PCI. 74 patients underwent PCI, 84 patients underwent CABG, and 24 patients were treated medically. Among patients with high (n = 64), intermediate (n = 68), low (n = 50) SYNTAX score, 37 (58%), 32 (47%), 15 (30%) underwent CABG and 18 (28%), 29 (43%), 27 (54%) underwent PCI, respectively. Clinical characteristics were similar in patients who underwent CABG and PCI with a trend of younger population undergoing CABG (66+ 10 vs 69 + 12, p = 0.089). SYNTAX score was statistically higher in patients undergoing CABG (33 + 12 vs 27 +9, p<0.001), but there were no difference in left ventricular function.

Conclusion: In daily practice, the treating physicians appear to make a decision regarding revascularization methods based on disease burden without calculating the SYNTAX score. Diabetes mellitus and decreased left ventricular function was not associated with the choice of revascularization.

Disclosures: Yumiko Kanei: This author has nothing to disclose.
Justin Ratcliffe: This author has nothing to disclose.
David Fishman: This author has nothing to disclose.
Rahul Patri: This author has nothing to disclose.
Navin Nakra: This author has nothing to disclose.
John Fox: This author has nothing to disclose.
C-047

**Title:** Hybrid Robotic Coronary Revascularization Shortens the Recovery Time Required for the Treatment of Multi-vessel Coronary Disease

**Category:** Left Main & Multi-Vessel Intervention

Authors: Sugam Bhatnagar, M.B.B.S., MPH, University of Arizona, United States, Tucson, AZ; Michael Simmons, None, BS, University of Arizona, United States, Tucson, AZ; Ellen Pearson, R.N., University of Arizona, United States, Tucson, AZ; Heather Brack, R.N., University of Arizona, United States, Tucson, AZ; Adam Ratesic, None, BS, University of Arizona, United States, Tucson, AZ; Molly Szerlip, M.D., University of Arizona, United States, Tucson, AZ; Robert Poston, M.D., University of Arizona, United States, Tucson, AZ

**Background:** Hybrid techniques integrate the beneficial features of both PCI and robotic assisted CABG (rCABG) for the revascularization of patients with multi-vessel disease. It has been suggested that avoiding the sternotomy reduces surgical morbidity and shortens postoperative recovery. In order to confirm this assertion, we prospectively investigated the postoperative outcomes and functional recovery in patients during the first month after rCABG.

**Methods:** We prospectively monitored the outcomes of consecutive patients undergoing hybrid coronary revascularization during a one year period (n = 32). The observed risk was adjusted according to the expected risk of major complications as defined by the STS database (O/E ratio). Functional recovery was defined by a standardized survey, the Duke Activity Status Index (DASI), acquired at 1 month and converted to metabolic equivalents (METs). The analysis was performed in SPSS 20.0 statistical software.

**Results:** The overall O/E ratio for the composite risk of major morbidity and mortality for the cohort was 0.84. The patient characteristics include mean age = 65 ± 8.68, BMI = 26.6 ± 3.4, mean hospital stay = 4.3 ± 1.5, mean functional capacity (1 month) = 8.3 ± 1.0. At one month, 85% of the patients reported of being capable to perform yard work (4.5 METS) and run a short distance (8.0 METS) on the DASI survey.

**Conclusion:** Our experience with hybrid robotic revascularization demonstrated a lower than expected risk of postoperative complications and return to close-to-normal activity by one month after surgery. These improvements in early quality of life suggest that the benefits of less invasive surgical techniques expand beyond cosmetic and may provide important societal benefits.

**Disclosures:** Sugam Bhatnagar: This author has nothing to disclose. Michael Simmons: This author has nothing to disclose.

AO-004

**Title:** Impact of Appropriate Revascularization Strategy on Clinical Outcomes in Patients With Multivessel Coronary Artery Disease: The ARM Study (Appropriate Revascularization for Multivessel Coronary Artery Disease)

**Category:** Left Main & Multi-Vessel Intervention


**Background:** SYNTAX score is a valid tool to guide revascularization strategy in patients with 3-vessel or left-main coronary artery disease (CAD), but it is not routinely used. We hypothesized that appropriate SYNTAX-based revascularization strategy (percutaneous coronary intervention [PCI] vs. coronary artery bypass graft [CABG]) improves clinical outcomes.

**Methods:** Nonrandomized study of patients with 3-vessel or left-main (plus 1-, 2- or 3-vessel) CAD undergoing PCI or CABG at a tertiary care center from 2008 to 2009, when choice of method was based on clinical and angiographic assessment without SYNTAX scoring.

**Disclosures:**

Sugam Bhatnagar: This author has nothing to disclose. Ellen Pearson: This author has nothing to disclose. Michael Simmons: This author has nothing to disclose. Adam Ratesic: This author has nothing to disclose. Molly Szerlip: This author has nothing to disclose. Robert Poston: This author has nothing to disclose.

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**Table: Comparison of Primary End Point* Between Appropriate and Inappropriate Revascularization Method.**

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Choice of revascularization method</th>
<th>Primary end point (%)</th>
<th>HR(95% CI) p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYNTAX score</td>
<td>Appropriate n=158</td>
<td>8.9</td>
<td>n/a</td>
</tr>
<tr>
<td>&lt;22</td>
<td>Inappropriate* n=0</td>
<td>-</td>
<td>-</td>
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<td>23-32</td>
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<td>0.35 (0.14-0.87)</td>
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<td>19.4</td>
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<td>&gt;32</td>
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<td>0.18 (0.09-0.39)</td>
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<td>Inappropriate n=26</td>
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<td>Appropriate n=252</td>
<td>2.4</td>
<td>0.18 (0.05-0.64)</td>
</tr>
<tr>
<td>0-5</td>
<td>Inappropriate n=32</td>
<td>12.5</td>
<td>-</td>
</tr>
<tr>
<td>6-10</td>
<td>Appropriate n=62</td>
<td>12.9</td>
<td>0.39 (0.14-0.98)</td>
</tr>
<tr>
<td>Inappropriate n=20</td>
<td>30.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>&gt;11</td>
<td>Appropriate n=58</td>
<td>41.4</td>
<td>0.78 (0.41-1.48)</td>
</tr>
<tr>
<td>Inappropriate n=36</td>
<td>44.4</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*death, stroke or myocardial infarction

*Among patients with SYNTAX scores &lt;22, 1 patient with SYNTAX score was inappropriate.*
Angiograms were retrospectively reviewed and SYNTAX scores calculated. Revascularization strategy was deemed appropriate if PCI was done in a patient with SYNTAX score <22 or CABG in patients with score >22. Primary end point was combined death, stroke or myocardial infarction (MI). Analysis was adjusted for demographics, baseline comorbidities and euroSCORE.

**Results:** Of 464 patients, 376 (81%) had appropriate revascularization strategy and 88 (19%) had inappropriate. After 3 years, primary end point was significantly lower in the appropriate group (10.1% vs. 29.5%; HR 0.61 [95% CI 0.34-0.88], p = 0.001). The appropriate group had lower incidence of primary end point across different SYNTAX and euroSCORE categories, except when euroSCORE was >10 (table). Incidence of death was lower with the appropriate group (6.9% vs. 25%, HR 0.62 [95% CI 0.31-0.98], p = 0.03). There was no significant difference in stroke or MI. Repeat revascularization was lower in the appropriate group (10.6% vs. 38.6%; HR 0.13 [95% CI 0.08-0.21] p<0.001), as was combined death, stroke, MI or repeat revascularization (19.1% vs. 61.4%; HR 0.27 [95% CI 0.18-0.40] p<0.001).

**Conclusion:** SYNTAX score-based revascularization strategy for 3-vessel or left-main CAD is associated with lower incidence of combined death, stroke or MI.

**Disclosures:**
- Tonga Nfor: This author has nothing to disclose.
- Babak Haddadian: This author has nothing to disclose.
- Kambiz Shetabi: This author has nothing to disclose.
- Fengyi Shen: This author has nothing to disclose.
- Wael Hassan: This author has nothing to disclose.
- Molla Teshome: This author has nothing to disclose.
- Jayant Khitha: This author has nothing to disclose.
- Anjan Gupta: This author has nothing to disclose.
- Tanvir Bajwa: This author has nothing to disclose.
- Suhail Allaqaband: This author has nothing to disclose.

**Results:** A total of 179 patients: mean age 66.5±12.7 years and 83.2% were male with mean left ventricular ejection fraction 54.6±8.4% and SYNTAX score 23.3±31.2. The median follow-up was 705.5 days (interquartile range 339.8-1168.0). First-generation DES were used in 53.1% (of which 51.6% were sirolimus and paclitaxel 48.4%) and 46.9% had second-generation DES (85.7% everolimus; 11.9% zotarolimus; 2.4% biolimus). Interestingly, there were more patients with diabetes treated with first-generation (30.5% vs. 14.3%; p = 0.023). Regarding the procedure, intravascular ultrasound guidance was similar between first and second-generation (respectively 47.4% vs. 59.5%; p = 0.130). There were more patients in the first-generation group with distal ULMCA disease (82.1% vs. 67.9%; p = 0.064). At follow-up, there was a significant difference in MACE favouring second-generation (30.5% vs. 19.0%; p = 0.047), most related to a reduction in the TLR (13.7% vs. 4.8%; p = 0.026) and TVR (24.2% vs. 14.3%; p = 0.031). However, there was no difference in all-cause mortality (10.5% vs. 7.1%; p = 0.138) with a trend for increased cardiovascular mortality in those treated by first-generation (8.4% vs. 2.4%; p = 0.082). Moreover, there were 5 definite/probable stent thromboses amongst first-generation (5.3% vs. 0%; p = 0.020).

**Conclusion:** Second-generation DES have improved results with regards to MACE and ST at mid-term follow-up, perhaps secondary to patient selection. This needs to be confirmed at longer term follow-up.

**Disclosures:**
- Gill Louise Buchanan: This author has nothing to disclose.
- Chiara Bernelli: This author has nothing to disclose.
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- Azeem Latib: This author has nothing to disclose.
- Filippo Figini: This author has nothing to disclose.
- Cosmo Godino: This author has nothing to disclose.
- Santo Ferrarello: This author has nothing to disclose.
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- Irene Franzoni: This author has nothing to disclose.
- Mauro Carlini: This author has nothing to disclose.
- Antonio Colombo: This author has nothing to disclose.
coronary artery disease (ULMCA). Long-term outcomes data of PCI vs. CABG in ULMCA disease are largely lacking.

**Methods:** We performed meta-analyses of all studies reporting at least 36 months follow-up of PCI (DES) compared to CABG in patients with ULMCA disease. A search of Medline & conference proceedings from 01/01/2003 - 12/31/2011 identified 11 studies enrolling 4,936 patients (PCI = 2,151 & CABG = 2,785). These studies reported the longest follow-up periods up to 48 and 60 months from randomized clinical trials and registries, respectively. Clinical endpoints of interest include all cause death, MACCE, non-fatal MI, repeat revascularization, stroke and the composite safety endpoint (death, MI & stroke). Meta-analyses were performed using Review Manager 5.1 (Cochrane Collaboration) & summary odds ratios & 95% confidence intervals were calculated (random-effects model).

**Results:** Patients in the PCI and CABG arm had similar baseline characteristics. Compared with CABG, the PCI group had shorter hospital stay (6.2 ± 1.2 vs. 15.2 ± 2.4 days, p < 0.001). At a maximum follow-up of 60 months, patients in PCI group had lower rates of stroke (OR = 0.35, 95% CI 0.20-0.63), lower composite safety endpoint (OR = 0.73, 95% CI 0.57-0.93), & similar rates of death (OR = 0.82, 95% CI 0.68-1.00) and non-fatal MI (OR = 1.42, 95% CI 0.76-2.67) compared with CABG. PCI group experienced an increased risk of MACCE (OR 1.38, 95% CI 1.15-1.66) driven primarily by higher rates of repeat revascularization (OR 3.47; 95% CI 1.15-1.66) & summary odds ratios & 95% confidence intervals were calculated (random-effects model).

**Conclusion:** At a maximum follow-up of 60 months, PCI with DES for ULMCA disease was associated with lower rates of stroke & composite of death, MI and stroke, but higher rates of MACCE and repeat revascularization. Patients undergoing PCI and CABG sustained comparable rates of all-cause death and non-fatal MI.

**Disclosures:**
Mahboob Alam: This author has nothing to disclose.
Mahboob Alam: This author has nothing to disclose.
Henry Huang: This author has nothing to disclose.
Paul Rogers: This author has nothing to disclose.
David Paniagua: This author has nothing to disclose.
Biswajit Kar: This author has nothing to disclose.
Kodangudi Ramanathan: This author has nothing to disclose.
Neal Kleiman: This author has nothing to disclose.
Hani Jneid: This author has nothing to disclose.

**A-012**

**Title:** Operator vs. Independent Adjudication of Angiographic Reperfusion Markers in Patients Undergoing Primary Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction

**Category:** Miscellaneous

**Authors:** Sorin Brener, M.D., NY Methodist Hospital, United States, Brooklyn, NY 1; Ecaterina Cristea, M.D., Cardiovascular Research Foundation, United States, New York, NY 2; Martin Fahy, None, MS, Cardiovascular Research Foundation, United States, New York, NY 3; Roxana Mehran, M.D., Mount Sinai Medical Center, United States, New York, NY 4; Gregg Stone, M.D., Columbia University Medical Center, United States, New York, NY 5

**Abstract:**

**Objective:** To determine the agreement level between Op and ACL for TIMI flow and TIMI Myocardial Perfusion Grade (TMPG) when compared with an Angiography Core Laboratory (ACL).

**Methods:** Op and ACL estimation of TIMI flow and TMPG were compared using the Cohen’s Kappa coefficient. A multivariable model for long-term survival derived from HORIZONS AMI trial and to evaluate the prognostic impact of Op TMPG on 3-year death.

**Results:** After excluding patients treated medically (N = 193) and those treated with delayed PCI or surgery (N = 64), 3,345 subjects were eligible for this study. K was highest for pre-PCI TIMI flow (0.56-0.62) and lowest for post-PCI TMPG (0.11-0.22). Of the 593 patients with final TMPG 0 or 1 by ACL, 456 (76.8%) were classified as TMPG 2 or 3 by Op. Similarly, among 415 patients with TIMI flow <3 by ACL, the Op scoring was TIMI flow 3 in 267 (64.3%). Op TMPG was highly predictive of 3-year survival: HR = 0.42 [0.28, 0.62], P < 0.0001.

**Conclusion:** Op assessment of angiographic markers of reperfusion in STEMI demonstrates only modest agreement with ACL findings and there is directionality in these disagreements with overestimation of unfavorable results. Further education of operators may improve quality of PCI in STEMI and reliability of site reported findings in clinical investigation.

**Disclosures:**
Sorin Brener: This author has nothing to disclose.
Ecaterina Cristea: This author has nothing to disclose.
Martin Fahy: This author has nothing to disclose.

**A-030**

**Title:** Repeat- Enhanced External Counterpulsation (EECP) and Long Term Major Adverse Cardiac Event Rates in Patients with Refractory Angina Pectoris and Systolic Heart Failure

**Category:** Miscellaneous

**Authors:** Ozlem Soran, M.D., MPH, University of Pittsburgh, Cardiovascular Institute, United States, Pittsburgh, PA 1; Elizabeth Kennard, Ph.D., University Of Pittsburgh, United States, Pittsburgh, PA 2; Sherly Kelsey, Ph.D., University Of Pittsburgh, United States, Pittsburgh, PA 3

**Objectives:** Enhanced external counterpulsation (EECP) is a non-invasive circulatory assist device that has recently emerged as a treatment option for refractory angina in patients with left ventricular dysfunction.
A-032

Title: Adverse events in patients undergoing percutaneous coronary intervention utilizing Optical Coherence Tomography

Category: Miscellaneous

Authors: Juan Diego Martinez, M.D., UTMB Division Of Cardiology, United States, Galveston, TX; Milagros Anahi Martinez, M.D., UTMB Division Of Cardiology, United States, Galveston, TX; Kenichi Fujise, M.D., UTMB Division Of Cardiology, United States, Galveston, TX

Background: Optical coherence tomography (OCT) is a useful invasive tool to assess coronary artery disease and guide stent width and diameters. No data has been described on clinical events in patients undergoing percutaneous coronary interventions (PCI) with use of OCT. We evaluated adverse events in patients undergoing coronary stent implantation with use of OCT.

Methods: Patients who underwent stent implantation with angiography and OCT from July 2011 to November 2011 were included for data analysis. Randomly selected patients having undergone stent implantation using angiography alone within the same time period were included for comparative analysis. Data recorded included baseline demographics, lesion complexity, amount of radiocontrast media (RCM) used, presence of significant blood loss (>3 gm/dL drop in hemoglobin post procedure), peri-procedural myocardial necrosis (rise in CKMB 3x the upper limit of normal), development of contrast induced nephropathy (rise in peri-procedure creatinine >25% above baseline), number of stents deployed, and complexity of atherosclerotic lesion. Data was analyzed by Student’s t-test and Pearson’s chi-square with significant p value of <0.05.

Results: Baseline characteristics were similar among the groups. No difference was detected in the coronary artery disease complexity. Seventeen patients underwent OCT with stent implant without other invasive coronary evaluation and compared to 10 patients who underwent stent implantation without any invasive coronary evaluation other than angiography. OCT patients had significantly higher RCM use (71% vs. 33%, p < 0.0001) than stent alone, although stent without OCT had longer durations of fluoroscopy (29% vs. 44%, p = 0.0276). No difference in blood loss (41% vs. 33%, p = 0.2413) between the groups was noted. However, peri-procedural note of myocardial necrosis (23% vs. 11%, p = 0.0239) and development of contrast induced nephropathy (6% vs. 0%, p < 0.0129) was more likely to occur in the OCT group. The stent alone group had significantly higher deployment of multiple stents (18% vs. 50%, p < 0.0001).

Conclusion: Use of OCT is associated with higher RCM loads, more CIN, and higher degree of peri-procedural myocardial necrosis compared to stenting alone. OCT utilization was associated with reduced use of multiple stents. Use of less stents when combining OCT with angiography may translate to reduction of long term events, however further study is needed.

Disclosures: Juan Diego Martinez: This author has nothing to disclose.
Milagros Anahi Martinez: This author has nothing to disclose.
Kenichi Fujise: This author has nothing to disclose.

A-033

Title: Pre-Procedure Risk Score Predicts Total Costs, Length of Stay, and Transfusion Rates

Category: Miscellaneous

Authors: Craig Strauss, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Ivan Chavez, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Ross Garberich, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Jeffrey Chambers, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Anthony Baran, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Timothy Henry, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN; Ross Garberich, M.D., Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, United States, Minneapolis, MN

Background: Over 1.3 million percutaneous coronary interventions (PCI) are performed annually in the United States. Peri-procedure bleeding complications are common (3-6%), increasing length of stay, hospital costs and mortality. Recently, a pre-PCI bleeding risk score (Circ Cardiovasc Interv 2009;2:222) was proposed.

Methods: We applied the pre-PCI bleeding risk score to all PCI patients at 3 high volume hospitals within the Allina CV Service Line between January 2009 and September 2011. Bleeding risk scores were calculated and cases were grouped by low risk (0-7), intermediate risk (8-17), and high risk (18+). All data was based on NCIDR definitions.

Results: Among 8,309 PCI patients, high (1,268 15%), intermediate (4,010 48%), and low risk patients (3,031 37%) had statistically significantly different rates of any complication (24.5% vs. 7.5% vs. 2.4%; p<0.001), need for RBC transfusion (12.3% vs. 3.1% vs. 0.5%; p<0.001), length of stay (days) (5.2 vs. 2.9 vs. 1.9; p<0.001), total costs ($22,821 vs. $14,500 vs. $11,539; p<0.001), total drug costs ($1,060 vs. $442; p<0.001), and mortality (6.7% vs. 1.2% vs. 0.7%; p<0.001) (Figure).
Conclusion: A pre-procedure bleeding risk assessment score can accurately identify high risk, high cost patients and may provide an opportunity to employ bleeding avoidance strategies to improve patient outcomes and reduce total costs.

Disclosures:
Craig Strauss: This author has nothing to disclose.
Ivan Chavez: This author has nothing to disclose.
Ross Garberich: This author has nothing to disclose.
Jeffrey Chambers: This author has nothing to disclose.
Kenneth Baran: This author has nothing to disclose.
Timothy Henry: This author has nothing to disclose.

A-036
Title: Impact of Chronic Thrombocytopenia in Patients with Coronary Artery Disease and Cancer

Authors: Siddharth Mukerji, M.D., UTHSC-Houston Medical School, United States, Houston, TX
Wamique Yusuf, M.D., MD Anderson Cancer Center, Cardiology, United States, Houston, TX
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Gerryross Tomakin, R.N., MD Anderson Cancer Center, Cardiology, United States, Houston, TX
Gloria Iliescu, M.D., MD Anderson Cancer Center, Cardiology, United States, Houston, TX
Jean Bernard Durand, M.D., MD Anderson Cancer Center, Cardiology, United States, Houston, TX
Cezar Iliescu, M.D., MD Anderson Cancer Center, Cardiology, United States, Houston, TX

Background: Thrombocytopenia is a common occurrence in cancer patients. Although platelets play an important role in the development of acute coronary syndrome, thrombocytopenia does not protect cancer patients from ischemic events. The purpose of this study was to identify thrombocytopenia as a predictor of inhospital major adverse cardiovascular events (MACE) in patients treated invasively.

Methods: Between 11/2009 and 8/2011 a total of 380 consecutive cancer patients underwent endovascular procedures. Patients with active bleeding, sepsis and acute thrombocytopenia were excluded. Adverse outcomes defined as death, myocardial infarction, stroke and interventional complications including bleeding, were evaluated.

Results: Out of the 380 cancer patients treated, 78 (20.5%) had thrombocytopenia (platelets<100K/mm^3). Mean platelet count was 49K/mm^3 with the lowest being 8K/mm^3. Procedures were performed successfully in all patients (100%) utilizing both femoral (60%) and radial (40%) access. Out of 78 invasive procedures, 38 (48.7%) were interventional procedures requiring higher ACT and dual antiplatelet therapy. The quartile distribution invasive/interventional procedures was: 9/18 platelet count < 25K/mm^3, 10/17 platelets 26-50K/mm^3, 10/17 with a count of 51-75K/mm^3 and 9/26 with a platelet count 76-99K/mm^3. No significant bleeding complications were identified; one patient had a clinically non-significant femoral hematoma. No cardiovascular related deaths occurred.

Conclusion: Chronic thrombocytopenia was not associated with increased major bleeding or major adverse cardiovascular events in a tertiary center with expertise in high-risk interventions. Therefore, severe thrombocytopenia should not be the main decision factor for conservative versus invasive treatment in cancer patients. An invasive strategy should be also offered to patients with chronic thrombocytopenia.

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Siddharth Mukerji: This author has nothing to disclose.
Wamique Yusuf: This author has nothing to disclose.
Jose Banchs: This author has nothing to disclose.
Elie Mouhayar: This author has nothing to disclose.
Gerryross Tomakin: This author has nothing to disclose.
Gloria Iliescu: This author has nothing to disclose.
Cezar Iliescu: This author has nothing to disclose.

A-039
Title: Rising Health Care Cost In United States: Is Defensive Medicine The Cause? Analysis In A Chest Pain Rule Out Cohort

Category: Miscellaneous

Authors: Rojina Pant, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL
Jeffrey Cook, M.D., Advocate Illinois Masonic Medical Center, United States, Chicago, IL
Mukesh Gopalakrishnan, M.D., Advocate Illinois Masonic Medical Center, United States,
TABLE 1.

<table>
<thead>
<tr>
<th>Group</th>
<th>DFS&lt;40% (A)</th>
<th>DFS≥40% (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean DFS (SD)</td>
<td>13.67 (7.32)</td>
<td>12 (12.6%)</td>
</tr>
<tr>
<td>Positive MPI (%)</td>
<td>22 (10%)</td>
<td>13 (28%)</td>
</tr>
<tr>
<td>Cardiac Catheterization (%)</td>
<td>5.2%</td>
<td>10 (21.7%)</td>
</tr>
<tr>
<td>CAD (%)</td>
<td>3 (1.3%)</td>
<td>6 (1.3%)</td>
</tr>
<tr>
<td>Revascularization (%)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>PPV of MPI</td>
<td>22.7%</td>
<td>83.3%</td>
</tr>
</tbody>
</table>

Physician (MD) Survey: Response to role of defensive medicine (defined as the practice of ordering medical tests or procedures of limited clinical value with the partial goal of protecting the medical community from lawsuits) in ordering MPI for group A subjects (DFS<40%).

1. Significant (70-100%) role: 17%.
2. Some (40-69%) role: 28%.
3. No (0%) role: 55%.

Background: The cost of medical care in the U.S. is rising, and whether “defensive medicine” plays a role is under debate. We aim to quantify the economic burden caused by inappropriate resource use in a chest pain cohort and seek the role of defensive medicine therein.

Methods: A 1-year cohort of 265 patients admitted with chest pain who underwent Myocardial Perfusion Imaging (MPI) was studied. Pretest probability was calculated using the Diamond and Forrester Score (DFS). Pretest probability at which a negative test would reduce the post-test probability to <10% was taken as <40% (based on sensitivity and specificity of 85% for MPI), and subjects were divided into two groups: DFS<40% (A) and DFS≥40% (B). Accuracy of MPI was studied in each group. Physicians ordering MPI for group A subjects were surveyed about role of defensive medicine in ordering the MPI. Cost of MPI, inpatient workup was analyzed.

Results: Only 10% of group A subjects had positive MPI, 2.2% had coronary artery disease (CAD); none were ruled in for Myocardial Infarction. Positive MPI was 3.6 times more likely to predict CAD in group B than group A. Physician survey revealed that in 45% of group A subjects, there was a considerable role of defensive medicine in ordering the MPI. About $600,000/year could have been saved at our hospital if MPI was not ordered in group A subjects (DFS<40%).

Conclusion: Accurate risk stratification in chest pain patients can reduce cost without compromising safety. Defensive medicine increases resource utilization.

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Rojina Pant: This author has nothing to disclose.
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Mukesh Gopalakrishnan: This author has nothing to disclose.
Carlos Urudninea: This author has nothing to disclose.
Toyiba Syed: This author has nothing to disclose.
German Rossell: This author has nothing to disclose.
Kiran Regmi: This author has nothing to disclose.
Dana Villines: This author has nothing to disclose.
Lloyd Klein: This author has nothing to disclose.

B-012

Title: The Level of Blood Pressure Does Not Identify the Presence or Severity of RAS in Hypertensive Patients Undergoing Cardiac Catheterization

Category: Miscellaneous

Authors: Taylor Bazemore, None, University of North Carolina at Chapel Hill, United States, Chapel Hill, NC; Joseph Bumgarner, M.D., University of North Carolina at Chapel Hill, United States, Chapel Hill, NC; George Stouffer, M.D., University of North Carolina at Chapel Hill, United States, Chapel Hill, NC.

Background: Hemodynamically severe renal artery stenosis (RAS) is thought to cause severe hypertension. It is unknown however whether blood pressure is higher in patients with RAS compared to patients with essential hypertension.

Methods: Patients from the UNC Cardiac Catheterization Laboratory database who had renal angiography between 2004 and 2011 were divided into three groups: severe RAS (stenosis ≥70%), moderate RAS (10-69%) and minimal RAS (<10%). In addition, patients with severe RAS were divided into two groups, uncontrolled and controlled hypertension, based on mean aortic blood pressure (MAP) determined at the time of angiography. Hypertension was defined as using JNC7 guidelines as MAP ≥ 96 mmHg. Comparison was done using one-way ANOVA on ranks or Mann-Whitney Rank Sum test.

Results: 762 patients had renal angiography with minimal, moderate and severe RAS being found in 62%, 25% and 14%, respectively. The mean (SD) RAS was 1±0.2%, 35±16% and 81±10%. There was no difference between the three groups in MAP or number of antihypertensive medications. Patients with minimal RAS were younger and heavier than patients with moderate or severe RAS, and there was a progressive increase in significant coronary artery disease, prior myocardial infarction, and history of coronary revascularization with the progression of minimal to moderate to severe RAS. Creatinine levels were higher in severe RAS than minimal or moderate RAS. In patients with severe RAS, there was no difference in gender, age, weight, diabetes, number of hypertensive medications, degree of RAS, or amount of coronary artery disease between groups with uncontrolled (n = 62) or controlled (n = 44) hypertension.

Conclusion: The level of blood pressure did not identify the presence or severity of RAS in hypertensive patients undergoing cardiac catheterization. In patients with severe RAS, the degree of stenosis did not identify patients with uncontrolled blood pressure.

Disclosures:
Taylor Bazemore: This author has nothing to disclose.
Joseph Bumgarner: This author has nothing to disclose.
George Stouffer: This author has nothing to disclose.
B-015

Title: Accreditation for Cardiovascular Excellence (ACE): The First Experience with Process Reviews

Category: Miscellaneous

Authors: Bonnie H. Weiner, M.D., MSEC MBA, St Vincent Hospital, United States, Worcester, MA; Ralph G. Brindis, M.D., MPH, Kaiser Permanente Medical Centers, Oakland and San Francisco, CA, United States, Oakland, CA; Charles E. Chambers, M.D., Penn State Hershey Heart and Vascular Institute, United States, Hershey, PA; Gregory J. Dehmer, M.D., Scott & White Texas A&M University System College of Medicine, United States, Temple, TX; Christopher J. White, M.D., Ochsner Medical Center, United States, New Orleans, LA; April W. Simon, R.N., MSN, Cardiac Data Solutions, Inc, United States, Atlanta, GA; Kimberly Wright, R.N., Cardiac Data Solutions, Inc, United States, Glen Allen, VA; Mary E. Heisler, R.N., BA, Accreditation for Cardiovascular Excellence, United States, Washington, DC

Accreditation for Cardiovascular Excellence (ACE) accredits facilities performing invasive cardiovascular procedures. This report summarizes lessons learned from the initial 7 facilities reviewed.

On-site reviews are performed by trained nurse reviewers. Policy and procedures, medical records, and cath reports are reviewed for completeness and compliance with ACE standards. Each item was recorded as meeting, partially meeting, or not meeting the standard. Variables used by NCDR CathPCI Registry for risk adjustment or appropriate use determination were also assessed.

147 records were reviewed: 50% cath/PCI, 45% catheterizations, and 5% PCI only. Of the PCIs, 51% were elective, 32.1% urgent and 15.5% emergent.

More than 95% of charts met the reporting requirements of The Joint Commission except for documentation of complications (88% 3%, 87%), radiation (81.5% 17.9%) and reporting of both fluoroscopy time and air kerma (56.3%, 40.4%, 0.7%) (met, partially met, did not meet respectively). The completeness of data used for NCDR risk stratification for the 83 PCI procedures is shown in Table 1.

Biomarker status was recorded in 61.7%. Attributable readmission was documented in 5 (6%) patients. Readmission, mortality post discharge or the development of contrast induced nephropathy was not available in approximately 72% of records. NYHA classification was not recorded in 41.6%

Angina class, NYHA class and risk/extent of ischemia were missing in 12.1%, 8.5% and 13.4% respectively. For elective cases 63.2% had not been on anti angina therapy for a week or more prior to the procedure.

During ACE reviews, inadequate clinical documentation was frequently observed. Difficulties in validating data submitted to NCDR from the medical record was common due to absent documentation. Attention to the process and documentation as well as training data abstractors is necessary. Increased physician involvement in data review before and after case submissions is required.

Disclosures:
Bonnie H. Weiner: Accreditation for Cardiovascular Excellence, Inc,
Ralph G. Brindis: Accreditation for Cardiovascular Excellence, Inc,
Charles E. Chambers: Accreditation for Cardiovascular Excellence, Inc,
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April W. Simon: Accreditation for Cardiovascular Excellence, Inc,
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Table 1 Used for Risk adjustment in NCDR

<table>
<thead>
<tr>
<th>Variables coded on admission</th>
<th>Included</th>
<th>Recorded</th>
<th>Not Recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Age (&lt; or &gt;70)</td>
<td>100.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>2. EMI</td>
<td>95.2%</td>
<td>4.8%</td>
<td></td>
</tr>
<tr>
<td>3. Cardiogenic shock on admission</td>
<td>16.9%</td>
<td>83.1%</td>
<td></td>
</tr>
<tr>
<td>4. Prior CHF</td>
<td>20.5%</td>
<td>79.5%</td>
<td></td>
</tr>
<tr>
<td>5. Prior valvular surgery</td>
<td>10.6%</td>
<td>89.4%</td>
<td></td>
</tr>
<tr>
<td>6. Cerebrovascular disease</td>
<td>14.5%</td>
<td>85.5%</td>
<td></td>
</tr>
<tr>
<td>7. PVD</td>
<td>16.9%</td>
<td>83.1%</td>
<td></td>
</tr>
<tr>
<td>8. Diabetes (and type of control)</td>
<td>43.4%</td>
<td>56.6%</td>
<td></td>
</tr>
<tr>
<td>9. Chronic lung disease</td>
<td>13.3%</td>
<td>86.7%</td>
<td></td>
</tr>
<tr>
<td>10. Previous PCI</td>
<td>43.4%</td>
<td>56.6%</td>
<td></td>
</tr>
<tr>
<td>11. GFR</td>
<td>86.7%</td>
<td>13.3%</td>
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</tr>
<tr>
<td>12. Diabetes</td>
<td>2.4%</td>
<td>97.6%</td>
<td></td>
</tr>
</tbody>
</table>

B-019

Title: What is the Best Approach for Angiography of Double in Situ Mammary Grafts?

Category: Miscellaneous

Authors: Yves Louvard, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Yves Louvard, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Hakim Benamer, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Hakim Benamer, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Philippe Garot, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Thierry Unterseeh, M.D., Institut Cardiovasculaire Paris Sud, France, Massy; Cedric Gaultier, M.D., LA Roseraie, France, Aubervilliers; Thierry Lefevre, M.D., Institut Cardiovasculaire Paris Sud, France, Massy

Purpose: To compare different vascular access for angiographic assessment of double in situ mammary grafts.

Methods: From a prospective database of 557 coronary angiographies in patients with at least one mammary graft between Jan 2009 and Oct 2011, we extracted 166 procedures in 153 patients with 2 in situ mammary grafts, in order to compare different approaches (14 operators). Quality of mammary graft angio was attested by an independent reviewer: 1 or 2 respectively for selective or subselective completely diagnostic angio (graft, anastomosis and all distal vessels), 3 for non selective good visualization of graft and partial analysis of distal bed, 4 for graft patency or not diagnosis only.

Results: We identified 4 approaches: systematic double radial approach (n = 4), left radial approach (LR) (n = 12), femoral (F) (n = 105) and right radial (n = 39) approaches. As the quality of right mammary angio was very poor from left radial (11.1% diagnostic), we compared femoral and right radial approaches.

Conclusions: Regardless of the potential advantages of right radial approach, right radial approach is an acceptable alternative to femoral approach for coronary angiography in patients with 2 in situ mammary grafts.
TABLE 1.

<table>
<thead>
<tr>
<th></th>
<th>Femoral n=105</th>
<th>Right radial n=39</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>105</td>
<td>39</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>64.8±10.6</td>
<td>65.4±8.4</td>
<td>0.75</td>
</tr>
<tr>
<td>Male (%)</td>
<td>90.5</td>
<td>97.4</td>
<td>0.29</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>169±13</td>
<td>172±7</td>
<td>0.17</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>78±15</td>
<td>83±12</td>
<td>0.06</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>31.4</td>
<td>35.9</td>
<td>0.69</td>
</tr>
<tr>
<td>High blood pressure (%)</td>
<td>60.0</td>
<td>66.7</td>
<td>0.56</td>
</tr>
<tr>
<td>Total N of grafts (n)</td>
<td>2.6±0.7</td>
<td>2.5±0.6</td>
<td>0.43</td>
</tr>
<tr>
<td>Total N of anastomosis (n)</td>
<td>2.8±0.9</td>
<td>2.8±0.7</td>
<td>1</td>
</tr>
<tr>
<td>Crossover to femoral (failure)(n)</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cross over to femoral (for angio)(n)</td>
<td>-</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cross over to radial (for angio) (n)</td>
<td>1</td>
<td>2 (left)</td>
<td></td>
</tr>
<tr>
<td>Quality left mammary</td>
<td>1.5±0.7</td>
<td>1.8±0.9</td>
<td>0.04</td>
</tr>
<tr>
<td>Quality right mammary</td>
<td>1.9±1.1</td>
<td>1.8±0.9</td>
<td>0.61</td>
</tr>
<tr>
<td>Good quality (1/2) both mam.</td>
<td>60.0</td>
<td>69.0</td>
<td>0.34</td>
</tr>
<tr>
<td>Procedural time (Min.)</td>
<td>29.5±12.7</td>
<td>31.5±15.8</td>
<td>0.43</td>
</tr>
<tr>
<td>Time/graft (Min.)</td>
<td>11.6±6.0</td>
<td>13.0±7.7</td>
<td>0.25</td>
</tr>
<tr>
<td>Time/anastomosis (Min.)</td>
<td>10.6±5.8</td>
<td>11.2±5.5</td>
<td>0.57</td>
</tr>
<tr>
<td>Contrast volume (cc)</td>
<td>144±63</td>
<td>145±59</td>
<td>0.93</td>
</tr>
</tbody>
</table>

Disclosures:
Yves Louvard: This author has nothing to disclose.
Hakim Benamer: This author has nothing to disclose.
Philippe Garot: This author has nothing to disclose.
Thierry Unterseeh: This author has nothing to disclose.
Cédric Gautier: This author has nothing to disclose.
Thierry Lefe`vre: This author has nothing to disclose.

B-028

Title: Improved Diagnosis of Coronary Artery Stenoses Using Pressure Drop Coefficient and Lesion Flow Coefficient: A Pilot Study in Humans

Category: Miscellaneous

Authors: Kranthi Kumar Kolli, None, MS, University of Cincinnati, United States, Cincinnati, OH; Mohamed A Effat, M.D., University of Cincinnati College of Medicine, United States, Cincinnati, OH; Tarek A Helmy, M.D., University of Cincinnati College of Medicine, United States, Cincinnati, OH; Imran Arif, M.D., University of Cincinnati College of Medicine, United States, Cincinnati, OH; Massoud A Leesar, M.D., University of Cincinnati College of Medicine, United States, Cincinnati, OH; Lloyd Back, Ph.D., Jet Propulsion Laboratory, United States, Irvine, CA; Srikara Viswanath Peelukhana, None, MS, University of Cincinnati, United States, Cincinnati, OH; Rupak K Banerjee, Ph.D., University of Cincinnati, United States, Cincinnati, OH

Background: Myocardial fractional flow reserve (FFR) in conjunction with coronary flow reserve (CFR) is used to evaluate the hemodynamic severity of coronary lesions. However, discordant results between FFR and CFR have been observed in intermediate coronary lesions. A functional parameter, pressure drop coefficient (CDP) was assessed using intracoronary pressure drop (dp) and average peak velocity (APV). Also, lesion flow coefficient (LFC), a combined functional and anatomical parameter, was evaluated from dp, APV and area stenosis (%AS) data. Both the CDP and LFC are non-dimensional ratios, derived from fundamental fluid dynamic principles.

Methods: Eighteen patients with reversible perfusion defects based on SPECT were consented for the study before cardiac catheterization. Distal coronary pressure and APV were measured simultaneously for each coronary lesion using a Combowire during cardiac catheterization. Reference diameter, minimal lumen diameter and %AS were obtained by quantitative coronary angiography. Maximum hyperemia was induced by 140 μg IV adenosine. CDP was calculated as, (dp)/(0.5xAPV^2). LFC was calculated as the ratio of %AS to CDP at throat region. The density of blood (ρ) was 1.05 gm/cm^3.
Results: Mean FFR, CFR, CDP and LFC values were: 0.80±0.02, 1.79±0.07, 37.17±5.11 and 0.48±0.06, respectively (p<0.05). The mean %AS was 68% (range: 44% to 89%). A linear correlation was observed for CDP (r = 0.56, p<0.05) and LFC (r = 0.36, p = 0.14) with FFR. When CDP was correlated simultaneously with FFR and CFR, r improved to 0.61 (p<0.05). Similarly when LFC was correlated simultaneously with FFR, CFR and %AS, r improved to 0.86 (p<0.05).

Conclusion: In conclusion, CDP (functional parameter) assessed in this human study, correlated linearly and significantly with FFR and CFR. LFC (combined functional and anatomic parameter) correlated with FFR, CFR (both hemodynamic endpoints) and %AS (anatomic endpoint).

Disclosures: Kranthi Kumar Kolli: This author has nothing to disclose. Mohamed A Effat: This author has nothing to disclose. Tarek A Helmy: This author has nothing to disclose. Imran Arif: This author has nothing to disclose. Massoud A Leesar: This author has nothing to disclose. Lloyd Back: This author has nothing to disclose. Srikara Viswanath Peelukhana: This author has nothing to disclose. Rupak K Banerjee: This author has nothing to disclose.

B-029

Title: Women Heart Health Initiative: Collaborative Effort is The Key

Category: Miscellaneous

Authors: Sudhir Mungee, M.D., FACC, FSCAI, University of Illinois College of Medicine at Peoria, United States, Peoria, IL; Matilde Elvira Marrero, MD, University of Illinois College of Medicine at Peoria, United States, Peoria, IL; Nikhil Martis, M.D., University of Illinois College of Medicine at Chicago, Program, United States, Chicago, IL; Auroa Badin, M.D., University of Illinois College of Medicine at Peoria, United States, Peoria, IL; Hauping Wang, Ph.D., University of Illinois College of Medicine at Peoria, United States, Peoria, IL; Michelle Couri, M.D., FACOG, University of Illinois College of Medicine at Peoria, United States, Peoria, IL

Background: Every minute a woman dies of cardiovascular disease in the United States[1]. And despite a decade of efforts to raise awareness to women’s heart health, fifty percent of women refuse to acknowledge coronary heart disease as the leading cause of death amongst women [2]. Gynecologists remain the sole physicians for many women in the United States[3].

Methods: This is a cross-sectional heart disease screening and awareness survey of 500 women over the age of 40 years during their gynecologist’s office visits. Information pertaining to demographics, CVD awareness, CVD symptoms, OB-GYN history, and presence of a primary care provider (PCP) were collected. Univariate analysis using SAS 9.2 (SAS institute Inc.Cary,NC) was used to compare differences in variables. Two tailed P values were calculated and a P <0.05 was considered significant.

Results: 13% of women had 3 or above CVD risk factors. 80% of women with a cholesterol >200 mg/dl knew they have hypercholesterolemia; 6.5% of women with BP >120/80 mmHg knew they have an “abnormal” blood pressure; and 68% of women with BMI >25 knew they were overweight. Univariate analysis revealed that menopausal women (P<0.0001), women with oophorectomy (P = 0.002), and women with hysterectomy (P = 0.0002) were likely to have more CVD risk factors. 20% of women had their gynecologist as their only PCP. There was no difference in women reporting of cardiac disease symptoms whether women had a PCP other than their gynecologist or not.

Conclusion: Lack of perception in women of CVD risks remains significant. Post menopausal women and those with oophorectomy or hysterectomy had more CVD risk factors. Significant number of women over age of 40 years had no PCP other than their gynecologists. Gynecologists hold a unique position to further close the gaps in women heart health awareness. Collaborative efforts involving gynecologists, cardiologists and PCPs could play a significant role in the epidemic of heart disease in women.

References:

Disclosures: Sudhir Mungee: Abbott vascular, 8. Speaker’s Bureau. Matilde Elvira Marrero: This author has nothing to disclose. Nikhil Martis: This author has nothing to disclose. Auroa Badin: This author has nothing to disclose. Hauping Wang: This author has nothing to disclose. Michelle Couri: This author has nothing to disclose.

C-001

Title: Use of a Monorail Coronary Balloon Catheter for Intracoronary Drug Administration: from Necessity to Routine

Category: Miscellaneous

Authors: Gustavo Samaja, M.D., FSCAI, Sanatorio Colegiales, Argentina, CABA; Aldo Rodríguez Saavedra, M.D., Hospital de Alta Complejidad de Formosa, Argentina, CABA; Ramiro Costello, M.D., Hospital de Alta Complejidad de Formosa, Argentina, Formosa

Figure 1. Linear correlation of CDP and LFC with FFR.
Background: No Reflow (NR) is a serious and potentially grave complication. NR requires prompt identification and treatment: intracoronary drug administration (ICDA) of agents so that it ensures drug delivery to the distal vascular bed. Current alternatives are: infusion catheters, the central lumen of an over the wire balloon, thrombectomy catheters. The use of these devices can be cumbersome and increase costs. We describe a technique for ICDA through the central lumen of a monorail coronary balloon catheter (MCBC) after a simple and quick maneuver and we report our results in 100 consecutive patients. We used the maneuver in the first two cases because specific catheters for ICDA were not available and after that the technique became our routine practice.

Methods: In order to allow ICDA into the distal vascular bed we performed a longitudinal excision on the balloon component of the MCBC with a surgical blade: the drug injected through the balloon port of the MCBC exits out the shaft at the site of excision (Figure 1). We analyzed the first 100 consecutive cases of NR in PCI treated with this maneuver. We evaluated clinical characteristics, intervention done, feasibility of the maneuver (success in reaching the distal vessel and performing ICDA), time consumed (from NR diagnosis to ICDA) and complications derived from de maneuver (catheter entrapment, stent dislodgement, vessel injury).

Results: We use our maneuver in 100 consecutive PCI complicated with NR: 91 AMI and 9 ACSNSTE. Vessels treated: 78 LAD, 12 RCA.

Conclusion: The use of a MCBC for ICDA is feasible and it is a low cost alternative to be considered for simplicity and quickness. It was safe in this cohort of patients but there is a risk of complications that must be evaluated.

Disclosures:
Gustavo Samaja: This author has nothing to disclose.
Aldo Rodriguez Saavedra: This author has nothing to disclose.
Ramiro Costello: This author has nothing to disclose.

C-008

Title: Relationship Between the Levels of Circulating Microparticles and Plaque Composition Identified by Virtual Histology Intravascular Ultrasound in Stable Angina Patients

Category: Miscellaneous

Authors: Pil-Ki Min, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Eui-Young Choi, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Jong-Youn Kim, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Young-Won Yoon, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Byoun Kwon Lee, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Bum-Kee Hong, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Se-Joong Rim, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul; Hyuck Moon Kwon, M.D., Ph.D., Gangnam Severance Hospital, Yonsei University College of Medicine, Korea, South, Seoul

Backgrounds: High levels of microparticles (MPs) circulate in the blood of patients with atherosclerotic diseases, where they could serve as a useful biomarker of vascular injury and a potential predictor of cardiovascular outcome. We used virtual histology intravascular ultrasound (VH-IVUS) to evaluate the relationship between the levels of circulating MPs and coronary plaque composition in patients with stable angina.

Methods: In this study, we studied 23 patients with stable angina (12 men, age 67 ± 9) who had a de-novo target lesion. Preintervention grayscale and VH-IVUS analysis was done across the target lesion. Using VH-IVUS, plaque was characterized as fibrotic (FT), fibrofatty (FF), dense calcium (DC), and necrotic core (NC). Planar VH-IVUS analysis at the minimum luminal site and at the largest necrotic core site and volumetric analysis over a 10-mm-long segment centered at the minimum luminal site were performed. Blood samples for analysis of MPs were obtained from the femoral artery before coronary angioplasty. MPs were isolated by capture with annexin A5 and determined their procoagulant potential with a prothrombinase assay using commercial kit. The cell origins of MPs were determined by antigenic capture with specific antibodies.

Results: Of 23 patients studied, 15 had type 2 diabetes. There was no significant difference in serum hs-CRP, procoagulant MPs levels, and plaque composition by VH-IVUS between the diabetic and non-diabetic patients. Serum hs-CRP level showed no significant correlation with the plaque composition in VH-IVUS analysis. However, total procoagulant MPs were positively correlated to the percentage of NC (r = 0.737, p = 0.004) and negatively correlated to the percentage of FF (r = -0.830, p<0.001). Circulating MPs captured with anti-CD31 antibody also showed positive correlation with the percentage of NC (r = 0.786, p = 0.001) and negative correlation with the percentage of FF (r = -0.802, p = 0.001), whereas those captured with anti-CD146 or anti-CD42b did not.

Conclusion: Elevated levels of circulating MPs were related to the amount of necrotic core in the target lesion of stable angina.

Disclosures:
Pil-Ki Min: This author has nothing to disclose.
Eui-Young Choi: This author has nothing to disclose.
Jong-Youn Kim: This author has nothing to disclose.
Young-Won Yoon: This author has nothing to disclose.
Byoun Kwon Lee: This author has nothing to disclose.
Bum-Kee Hong: This author has nothing to disclose.
Se-Joong Rim: This author has nothing to disclose.
Hyuck Moon Kwon: This author has nothing to disclose.

C-013

Title: Comparison of Cardiac Output Using Oxygen Consumption Measured with a Portable Device to Assumed Oxygen Consumption

Category: Miscellaneous

Authors: Matthew Grove, D.O., Christiana Care Health System, United States, Newark, DE; Mitchell Saltzberg, M.D., Christiana Care Health System, United States, Newark, DE; Gerald O’Brien, M.D., Christiana Care Health System, United States, Newark, DE; Chia-Shing Yang, M.D., Christiana Care Health System, United States, Newark, DE; Cassie Walls, R.T., Christiana Care Health System, United States, Newark, DE; Donald Cobourn, None, BS, RRT, RPFT, Christiana Care
Background: Accurate assessment of cardiac output (CO) is essential in the evaluation and management of patients with heart disease. The Fick oxygen technique using an estimation of oxygen consumption (VO₂) is employed in many cardiac catheterization laboratories given the historically cumbersome nature of direct VO₂ measurement. Assumed VO₂ is the default measurement in our lab (Philips Xper Connect, Melbourne, FL) and many others. New portable devices have simplified the actual measurement of VO₂, allowing the relatively rapid assessment using a facemask device.

Methods: 22 consecutive patients undergoing right heart catheterization had determination of CO by both measured and assumed Fick techniques, as well, as thermodilution. For measured VO₂, a fitted full-face mask was connected to an analyzer (MedGraphics, St. Paul, MN). All measurements including the femoral and pulmonary artery saturations used in the calculation of cardiac output, as well as, thermodilution cardiac outputs were obtained in triplicate. One patient had unreliable tracings due to Cheyne-Stokes respiration.

Results: Measured VO₂ CO and assumed VO₂ CO measurements correlated poorly (Figure, R = 0.65). Measured VO₂ CO and thermodilution CO correlated poorly (R = 0.74). Calculated aortic valve areas derived from measured and assumed oxygen consumption values correlated poorly as well (R = 0.80). Cardiac output often changed during the course of a procedure, but measured valve areas were very nearly identical, illustrating reproducibility of the directly measured technique with this device.

Conclusion: Cardiac output calculated from measured VO₂ varies substantially from assumed VO₂ values, which is often the default method in the software in computerized lab systems. These differences can have important clinical sequelae, guiding therapeutic decisions for patients and for calculating valve areas.

Disclosures:
Matthew Grove: This author has nothing to disclose.
Mitchell Saltzberg: This author has nothing to disclose.

C-015

Title: Accreditation for Cardiovascular Excellence (ACE): The First Experience with Angiographic Reviews

Category: Miscellaneous

Authors: Bonnie H. Weiner, M.D., MSEC MBA, St Vincent Hospital, United States, Worcester, MA; Ralph G. Brindis, M.D., MPH, Kaiser Permanente Medical Centers, Oakland and San Francisco, CA, United States, Oakland, CA; Charles E. Chambers, M.D., Penn State Hershey Heart and Vascular Institute, United States, Hershey, PA; Gregory J. Dehner, M.D., Scott & White Texas A&M University System College of Medicine, United States, Temple, TX; Christopher J. White, M.D., Oschner Medical Center, United States, New Orleans, LA; Mary E. Heisler, R.N., BA, Accreditation for Cardiovascular Excellence, United States, Washington, DC

ACE accredits facilities performing invasive cardiovascular procedures. We describe the findings from the first 5 facilities completing angiographic reviews. Randomly selected angiograms are review by ACE physician reviewers. Each operator has a minimum of 3 studies reviewed. Table 1 shows the indications for angiography in the 122 studies reviewed.

Ischemia was documented prior to the procedure in 51%, 17.4% had no ischemia, 11% were indeterminant, 20.6% were unknown. Lesion characterization was excellent. Only 7.3% had excessive number of views and 5% too few. The extent of disease is in Table 2.

<table>
<thead>
<tr>
<th>Table 2 Extent of Disease</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>LM</td>
<td>8</td>
<td>3.4%</td>
</tr>
<tr>
<td>Single Vessel</td>
<td>66</td>
<td>27.8%</td>
</tr>
<tr>
<td>Two Vessel</td>
<td>41</td>
<td>17.3%</td>
</tr>
<tr>
<td>Three Vessel</td>
<td>51</td>
<td>21.5%</td>
</tr>
<tr>
<td>Graft Disease</td>
<td>13</td>
<td>5.5%</td>
</tr>
<tr>
<td>Normal</td>
<td>58</td>
<td>24.5%</td>
</tr>
</tbody>
</table>
For the primary (first) lesion treated, 93.7% were $\geq 50\%$. Two lesions were $<30\%$ and 7 were $30-50\%$ stenosed. Eleven lesions (10.5%) had in lab assessment. Half of these were inadequate or indeterminate. Documentation of these studies, particularly IVUS, was poor. The results of PCI were adequate in 87.2% and inadequate or indeterminate in 6.3% each. In non-ACS cases care was appropriate in 61.4%, inappropriate in 7.9% and uncertain in 30.7%. Common findings were inadequate documentation of variables required for risk adjustment and appropriate use.

Insufficient or unclear risk and appropriateness information are in the cath reports. Reports should be standalone documents with the pertinent clinical and technical information included. Random case reviews for appropriateness and quality were not uniformly performed and should be routine.

Disclosures:
Mary E. Heisler: Accreditation for Cardiovascular Excellence, Inc., 5. Consulting Fees or Other Remuneration.

C-035

Title: Gradual Decline in In-Hospital Mortality of Patients Undergoing Percutaneous Coronary Intervention in Diabetes and Non-Diabetes Patients.

Category: Miscellaneous

Authors: Mohammad Reza Movahed, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 1; Marcelo Cantarelli, M.D., Ph.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 2; Hélio Castello, M.D., M.B.A., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 3; Rosaly Gonçalves, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 4; Evandro Ribeiro, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 5; João Batista Guimarães, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 6; Silvio Gioppato, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 7; Rodrigo Barreto, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 8; Julio Cesar Vardi, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 9; Roberto Almeida, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 10; Ricardo De Gasperi, M.D., Bandeirantes Hospital, Brazil, São Paulo, São Paulo 11; Muhammad Khan, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ 1; Mehrnoosh Hashemzadeh, Ph.D., University of Arizona, United States, Tucson, AZ 2; Muhammad Reza Habibzadeh, M.D., University Of Arizona/SAVAHCS Medical Center, United States, Tucson, AZ 3; Mehrnoosh Hashemzadeh, None, MS, Long Beach VA Health Care System, United States, Long Beach, CA 4

Background: We recently published gradual decline in the percutaneous coronary intervention (PCI) related in-hospital mortality over recent years. The goal of this study was to evaluate this trend in diabetes vs. non-diabetes patients in of PCI related mortality declined gradually in diabetes or non-diabetes patients over the year studied with lowest level seen in 2006. PCI related mortality in DM was 94 per 100,000 in 1988 with gradual decline to the lowest incidence of 24 per 100,000 in 2006 ($p<0.01$). Similar decline was seen in non-diabetes population (73 per 100,000 in 1988 vs. 36 per 100,000 in 2006).

Conclusion: PCI related mortality has been declining over the last few decades in DM and non-DM patients. This suggests that improvement in the care of patients undergoing PCI has translated in a better outcome regardless of important comorbidities.

Disclosures:
Mohammad Reza Movahed: This author has nothing to disclose.
Mehroon Hashemzadeh: This author has nothing to disclose.
Muhammad Khan: This author has nothing to disclose.
Mohammad Reza Habibzadeh: This author has nothing to disclose.
Mehrtash Hashemzadeh: This author has nothing to disclose.

C-039

Title: Impact of Obesity on In-Hospital Outcomes of Percutaneous Coronary Intervention: Results of Hospital Bandeirantes Registry

Background: Obese patients may have better outcomes after percutaneous coronary intervention (PCI) compared to those with normal body mass index (BMI), the so-called “obesity paradox”. This study was aimed at evaluating whether this paradox is observed in our country.

Methods: This study included 4,957 consecutive patients submitted to PCI. Patients were classified as non-obese (BMI < 30 kg/m²) and obese (BMI $\geq 30$ kg/m²). Major adverse cardiac and cerebrovascular events (MACCE) were recorded at hospital discharge.

Results: The obese group was three years younger, with a higher prevalence of risk factors for coronary artery disease, except for smoking. Clinical presentation was similar, with a predominance of stable coronary patients. Single vessel disease was the most frequent finding and the complexity of the lesions was not different between groups, except for calcified lesions, and left ventricular dysfunction was less frequent in the obese group. Stent diameter and length were similar between groups. Procedure success rate was high and similar for obese and non-obese patients. At hospital discharge, the incidence of MACCE (2.5% vs. 2.7%; $P = \text{0.76}$), in-hospital death (1% vs. 1.1%; $P = 0.88$), stroke (0.1% vs. 0.1%; $P = 0.79$), acute myocardial infarction (1.6% vs. 1.8%; $P = 0.74$) and emergency CABG (0 vs. 0.1%; $P = 0.35$) was not different between groups. Age, diabetes, hypertension and type B2/C lesions were the variables that best explained MACCE.

Conclusion: In patients with coronary artery disease undergoing PCI, BMI $\geq 30$ kg/m² did not increase the risk of procedure-related in-hospital clinical events.

Disclosures:
Leonardo Coelho: This author has nothing to disclose.
Marcelo Cantarelli: This author has nothing to disclose.
Hélio Castello: This author has nothing to disclose.
Rosaly Gonçalves: This author has nothing to disclose.
Evandro Ribeiro: This author has nothing to disclose.
João Batista Guimarães: This author has nothing to disclose.
Silvio Gioppato: This author has nothing to disclose.
Patricia Silva: This author has nothing to disclose.
Rodrigo Barreto: This author has nothing to disclose.
Julio Cesar Vardi: This author has nothing to disclose.
Roberto Almeida: This author has nothing to disclose.
Ricardo De Gasperi: This author has nothing to disclose.

C-040

Title: Using a Cylinder of Bone Marrow as a Novel, Reproducible Animal Model of Calcified Atherosclerotic Plaque in the Porcine Coronary Vasculature

Category: Miscellaneous

Authors: Michael Frie, None, B.A., American Preclinical Services, United States, Minneapolis, MN1; Mark Smith, Ph.D., American Preclinical Services, United States, Minneapolis, MN2

Background: A reproducible animal model of calcified atherosclerotic plaque exhibiting similar properties to those observed in the human population has proven difficult to develop. We intended to simulate the properties of a calcific chronic partial occlusion (CPO), to be used for the evaluation of percutaneously delivered technologies, through the implantation of a bone marrow plug in porcine coronary arteries.

Methods: Twenty-four pigs were sedated and prepped sterilely for creation of the CPO. Angiograms of the left anterior descending (LAD) coronary artery were obtained and the lumen diameter was measured. A section of vessel measuring 2.8 – 3.0mm in diameter was identified for implantation with the plug. A cylinder of bone marrow measuring 3mm in diameter by 8mm in length was obtained from the rib of a donor animal and a lumen measuring approximately 1.6mm in diameter was cored out. The bone plug was loaded into a 9Fr guide catheter and tracked to the targeted location within the LAD and deployed. Post deployment angiograms were obtained and the animals were recovered from the implant procedure. The animals were re-evaluated between 4 and 14 days post bone plug implant for patency, lesion lumen diameter and overall vessel integrity.

Results: Angiography immediately post deployment demonstrated an average lesion lumen diameter of 1.32mm (1.08 – 2.35mm). Overall, seventeen of twenty-four (71%) pigs survived to the scheduled follow-up procedure. Three of the seventeen implanted bone plugs resulted in a total occlusion, with the remainder showing patency. Follow-up angiography demonstrating reduced blood flow through the lesion sites (TIMI 1 – 2) with an average lesion lumen diameter of 1.46mm (0.93 – 2.59mm).

Conclusion: We can reliably create a porcine coronary model simulating a calcific partial occlusion, which has successfully been used for the evaluation of interventional technologies used to treat coronary artery disease including chronic total occlusion (CTO) crossing systems and PTCA devices. The results of previous studies have shown successful deployment of a CTO version of the bone plug in the coronary vasculature and the successful deployment of the bone plug (both CTO and CPO versions) in the peripheral vasculature. Additionally, we have demonstrated the ability to reduce the calcium content of the bone marrow core prior to deployment in the coronary or peripheral vasculature, thereby decreasing the hardness, or resistivity, of the lesion.

Disclosures:
Michael Frie: This author has nothing to disclose.
Mark Smith: This author has nothing to disclose.

C-043

Title: Percutaneous Coronary Intervention in Hispanic Patients: Characteristics and Hospital Outcomes

Category: Miscellaneous

Authors: Ambarish Gopal, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA1; David M. Shavelle, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA2; Han Tun, M.D., MPH, University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA3; Anilkumar Mehra, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA4; Ray V. Matthews, M.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA5; Leonardo C. Clavijo, M.D., Ph.D., University of Southern California/LAC+USC Medical Center Program, United States, Los Angeles, CA6

Background: Previous studies suggest that ethnicity/race correlates with differences in clinical presentation and outcomes after percutaneous coronary intervention (PCI). There is limited information about the effect of Hispanic ethnicity on baseline angiographic/procedural characteristics and hospital outcomes after PCI.

Table 1. Comparison of in-hospital outcomes between Ethnic Groups

<table>
<thead>
<tr>
<th>Hospital Outcomes</th>
<th>White (n=256)</th>
<th>Black (n=118)</th>
<th>Asian (n=228)</th>
<th>Hispanic (n=409)</th>
<th>Others (n=216)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days int invasive care, (mean±SD)</td>
<td>2.7±2.3</td>
<td>3.6±3.32</td>
<td>3.9±3.15</td>
<td>2.9±3.43</td>
<td>2.7±3.30</td>
<td>0.29</td>
</tr>
<tr>
<td>Length of Hospital stay, (mean±SD)</td>
<td>4.89±7.63</td>
<td>5.7±9.86</td>
<td>4.4±6.54</td>
<td>5.0±7.31</td>
<td>3.6±4.89</td>
<td>0.04</td>
</tr>
<tr>
<td>In-hospital mortality, n(%)</td>
<td>16(6.3)</td>
<td>10(8.1)</td>
<td>8(3.6)</td>
<td>28(7.0)</td>
<td>20(9.1)</td>
<td>0.16</td>
</tr>
<tr>
<td>Ventricular tachycardia, n(%)</td>
<td>20(7.0)</td>
<td>0(0)</td>
<td>0(0)</td>
<td>20(4.9)</td>
<td>0(0)</td>
<td>0.48</td>
</tr>
<tr>
<td>Atrial fibrillation, n(%)</td>
<td>10(4.0)</td>
<td>8(6.8)</td>
<td>0(0)</td>
<td>10(2.5)</td>
<td>0(0)</td>
<td>0.003</td>
</tr>
<tr>
<td>Hospital Readmissions, n(%)</td>
<td>10(4.0)</td>
<td>0(0)</td>
<td>0(0)</td>
<td>10(2.5)</td>
<td>0(0)</td>
<td>0.09</td>
</tr>
<tr>
<td>Bleeding complications, n(%)</td>
<td>4(1.6)</td>
<td>5(4.3)</td>
<td>4(1.8)</td>
<td>14(3.5)</td>
<td>4(1.8)</td>
<td>0.29</td>
</tr>
<tr>
<td>Reocclusion, n(%)</td>
<td>20(7.9)</td>
<td>1(0.8)</td>
<td>10(4.4)</td>
<td>20(5.0)</td>
<td>6(2.8)</td>
<td>0.02</td>
</tr>
<tr>
<td>Vascular complications, n(%)</td>
<td>8(2.5)</td>
<td>5(4.3)</td>
<td>4(1.8)</td>
<td>15(3.7)</td>
<td>2(0.9)</td>
<td>0.48</td>
</tr>
<tr>
<td>Electrocardiogram Changes, n(%)</td>
<td>10(4.0)</td>
<td>2(1.7)</td>
<td>0(0)</td>
<td>10(2.5)</td>
<td>0(0)</td>
<td>0.05</td>
</tr>
</tbody>
</table>
CABG (p < 0.0001) of left main coronary artery disease (p < 0.0001), had higher CΡK-MB (p = 0.001), fasting glucose (P < 0.0001) and hemoglobin A1C (p = 0.005) levels at presentation; but were less likely to have a family history of coronary artery disease (p = 0.001), had lower rates of dyslipidemia (p = 0.001) and chronic renal insufficiency (p = 0.0004) including dialysis requirement (P = 0.0004) or to meet criteria for metabolic syndrome (P = 0.0002). Additionally, Hispanics more frequently had a history of myocardial infarction (p = 0.001), but less often a history of CABG (p = 0.002). In the Hispanic group, there was a lower occurrence of left main coronary artery disease (p < 0.0001). The use of drug-eluting stents and bare-metal stents in Hispanic patients were 61% and 31%, respectively. During hospitalization, Hispanic patients had a higher history of myocardial infarction (p = 0.001), but less often a history of CABG (p = 0.002). In the Hispanic group, there was a lower occurrence of left main coronary artery disease (p < 0.0001). The use of drug-eluting stents and bare-metal stents in Hispanic patients were 61% and 31%, respectively. During hospitalization, Hispanic patients had a higher history of myocardial infarction (p = 0.001), but less often a history of CABG (p = 0.002). In the Hispanic group, there was a lower occurrence of left main coronary artery disease (p < 0.0001). The use of drug-eluting stents and bare-metal stents in Hispanic patients were 61% and 31%, respectively. During hospitalization, Hispanic patients had a higher history of myocardial infarction (p = 0.001), but less often a history of CABG (p = 0.002). In the Hispanic group, there was a lower occurrence of left main coronary artery disease (p < 0.0001). While the transradial approach is currently in vogue, this small study suggests that the patient convenience might be replaced with danger to the operator. Based on these findings, the use of the transradial approach should be carefully considered. Findings showed that the operator received over 14 times as much radiation-when standing in the transradial position. These results show a clear distinction in operator exposure. Further evaluation is ongoing at our site. Long term exposure risk has not been evaluated in this small sample of patients.

Disclosures:
Robert Siegel: This author has nothing to disclose.
Gilbert Ortega: This author has nothing to disclose.
Shantha Kumar: This author has nothing to disclose.
Pooja Raghani: This author has nothing to disclose.

D-007
Title: Teaching in the Cardiac Catheterization Laboratory:
Perceptions of Attendings and Trainees
Category: Miscellaneous
Authors: Sandy Green, M.D., University of Pittsburgh, Cardiovascular Institute, United States, Pittsburgh, PA; Kathryn Berlacher, M.D., University of Pittsburgh, Cardiovascular Institute, United States, Pittsburgh, PA; Jamie Green, M.D., Univ Of Pittsburgh Med Center, United States, Pittsburgh, PA; Firas Zahr, M.D., University Of Pittsburgh Medical Center, United States, Pittsburgh, PA; Suresh Mulukutla, M.D., University of Pittsburgh, Cardiovascular Institute, United States, Pittsburgh, PA; Michael Elnicki, M.D., Univ Of Pittsburgh Med Center, United States, Pittsburgh, PA

Background: The current paradigm of training cardiology fellows to perform cardiac catheterization is based on the apprenticeship model of learning, which utilizes direct patient experience with little formal instruction or adult centric learning opportunities. It is unclear how fellows and attendings perceive the efficacy of this traditional type of learning.

We sought to examine cardiology fellow and attending attitudes regarding current teaching methods.

Methods: We performed a targeted attitudinal assessment of 3rd year graduating cardiology fellows (N = 11) and interventional cardiology attendings (N = 9) at a major academic center. A 30-question investigator designed survey was administered to evaluate the importance cardiology attendings and fellows place on various skills and teaching activities performed in the cardiac catheterization lab, satisfaction with current teaching methods, and confidence in procedural skills. Questions where scored on a 1-5 point Likert scale, with 1 = Not Important/Satisfied/Confident and 5 = Very Important/Satisfied/Confident.
Results: The survey showed good correlation between cardiology attending confidence in fellows’ procedural skills and fellow confidence in performing the basic procedures of an invasive cardiologist. The importance placed on teaching and the use of simulation as a teaching modality were similar between groups (rated at 4.6 and 4.0 by attendings and 4.5 and 4.0 by fellows, respectively). Larger discrepancies existed in satisfaction with current teaching methods, with fellows ranking journal club, overall educational experience, and teaching provided at 2.6, 2.2 and 2.2, respectively, vs. attendings who ranked fellow satisfaction with these areas at 3.9, 3.4 and 3.2, respectively.

Conclusion: Despite similar opinions on fellow confidence and the importance of procedural skills and teaching in the cardiac catheterization lab, large gaps exist between cardiology fellow satisfaction and attending perception of fellow satisfaction when it comes to the current apprenticeship model of learning in the cardiac catheterization lab. Attending interventional cardiologists are largely unaware of trainee dissatisfaction with the current apprenticeship model of teaching. Alternative teaching methods, such as simulation training, may improve fellow satisfaction with teaching.

Disclosures:
Sandy Green: This author has nothing to disclose.
Kathryn Bezler: This author has nothing to disclose.
Jamie Green: This author has nothing to disclose.
Firas Zahr: This author has nothing to disclose.
Suresh Mulukutla: This author has nothing to disclose.
Michael Elnicki: This author has nothing to disclose.

D-019

Title: What is the Best Access for Angiography in Patients with a Single in Situ Left Mammary Artery Graft?

Category: Miscellaneous

Authors: Yves Louvard, M.D., Institut Cardiovasculaire Paris Sud, France, Massy1; Giuseppe Ferrante, M.D., Institut Cardiovasculaire Paris Sud, France, Massy2; Thomas Hovasse, M.D., Institut Cardiovasculaire Paris Sud, France, Massy3; Thierry Unterseeh, M.D., Institut Cardiovasculaire Paris Sud, France, Massy4; Philippe Garot, M.D., Institut Cardiovasculaire Paris Sud, France, Massy5; Oscar Tavolaro, M.D., Institut Cardiovasculaire Paris Sud, France, Massy6; Hakim Benamer, M.D., Institut Cardiovasculaire Paris Sud, France, Massy7; Thierry Lefèvre, M.D., Institut Cardiovasculaire Paris Sud, France, Massy8

Purpose: To compare different vascular access for coronary angiography in patients with a single in situ Left Mammary graft.

Methods: From a prospective database between Jan 2009 and Oct 2011 of 557 coronary angiography in patients treated with at least one mammary graft, we extracted 341 angiography in patients with one Left Mammary graft (14 operators). Quality of left mammary angiography was assessed by one independent reviewer: 1 or 2 respectively for selective or subselective truly diagnostic angio (graft, anastomosis and distal bed), 3 for non selective good visualization of graft and partial analysis of distal vessels, 4 for graft patency or not diagnosis only. Continuous variables are described as median and interquartile ranges (25th/75th), comparisons are done using non parametric statistics.

Results: We compared Femoral (F)(n = 85), Right (n = 35) and Left Radial (LR)(n = 223) approaches.

Conclusion: Left radial access is the best approach to coronary angiography in patients with a single in situ Left Mammary graft for angiography quality and potential reduction of vascular complications, with the same procedural time and contraste volume as Femoral approach. Right radial approach seems a poor access in this multi operator registry.

Disclosures:
Yves Louvard: This author has nothing to disclose.
Giuseppe Ferrante: This author has nothing to disclose.
Thomas Hovasse: This author has nothing to disclose.
Thierry Unterseeh: This author has nothing to disclose.
Philippe Garot: This author has nothing to disclose.
Oscar Tavolaro: This author has nothing to disclose.
Hakim Benamer: This author has nothing to disclose.
Thierry Lefèvre: This author has nothing to disclose.

D-030

Title: Analyzing Hospitalization Pattern in Elderly (> 75 years) after Percutaneous Coronary Interventions (PCI), with and Without Major Bleeding Complications: Experience from a Single System with 2187 Patients from 2007-2010

Category: Miscellaneous

Authors: Rahul Wadke, M.B.B.S., University of Chicago/Northshore University, United States, Evanston, IL1

Background: Improvements in the techniques, evidence based practice, improved pharmacotherapy lead to reduction of post PCI bleeding complications. The rate of bleeding complications even when low has been identified as important predictor of morbidity and mortality. The purpose of this study is to evaluate duration of hospitalization post PCI in elderly (> 75 years) population with and without bleeding complications.

TABLE 1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Femoral n=85</th>
<th>Right radial n=35</th>
<th>Left radial n=223</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>72 (63-79)</td>
<td>73 (64-79)</td>
<td>73 (65-79)</td>
<td>0.73</td>
</tr>
<tr>
<td>Male (%)</td>
<td>83.9</td>
<td>87.2</td>
<td>88.6</td>
<td>0.72</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>168 (163-179)</td>
<td>170 (162-176)</td>
<td>165 (165-175)</td>
<td>0.43</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>82 (72-89)</td>
<td>83 (69-90)</td>
<td>80 (70-88)</td>
<td>0.643</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>46.9</td>
<td>33.3</td>
<td>30.7</td>
<td>0.03</td>
</tr>
<tr>
<td>Total N° of grafts (n)</td>
<td>2.2±0.78</td>
<td>2.1±1</td>
<td>2.1±0.9</td>
<td>0.33</td>
</tr>
<tr>
<td>Total N° of anastomosis (n)</td>
<td>2.5±0.8</td>
<td>2.56±1</td>
<td>2.3±0.97</td>
<td>0.12</td>
</tr>
<tr>
<td>Crossover to femoral (failure) (n)</td>
<td>1 contro</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Approach crossover (for graft) (n)</td>
<td>1 LR for left mam.</td>
<td>6 LR for left mam.</td>
<td>1 F for native</td>
<td></td>
</tr>
<tr>
<td>Quality left mammary (%)</td>
<td>1.6±0.86</td>
<td>2.1±1</td>
<td>1.4±0.6</td>
<td>0.008</td>
</tr>
<tr>
<td>Good quality left mammary (%)</td>
<td>80.25</td>
<td>64.1</td>
<td>92.44</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedural time (min.)</td>
<td>23 (18-32)</td>
<td>29 (19-45)</td>
<td>21 (15.5-29)</td>
<td>0.004</td>
</tr>
<tr>
<td>Contrast volume (cc)</td>
<td>120 (90-160)</td>
<td>124 (100-150)</td>
<td>115 (86-151.5)</td>
<td>0.77</td>
</tr>
</tbody>
</table>
Methods: Clinical data was collected from National cardiovascular data registry (NCDR). A total of 6028 consecutive diagnostic cardiac catheterizations (total 2187 PCI) performed at 3 centers of Northshore University Health System, Evanston, Illinois during 2007, 2008, and 2010. All patients undergoing emergent, urgent, and elective PCI at the center were included in analysis. Patients were divided into three groups (< 6, 65-74, >75 years) according to their age.

Results: Overall rate of Post PCI bleeding complications incidence dropped from 2.4% to 1.1% among entire study population, on the contrary incidence increased from 0.44% to 0.88% among elderly patients. Elderly patient’s hospitalization duration decreased from mean of 3.02 days (SD +/- 3.5) in 2007 to mean of 2.17 days (SD +/-2.55) in 2010. Hospitalization stay for elderly patients was one day longer than patients less that 75 year old irrespective of bleeding complications. Elderly patients remained hospitalized for mean of 5.53 days for major bleeding complications as compared to 2.84 days without complications.

Conclusion: Post PCI bleeding complications rate (1.1%) remained low but was associated with longer hospitalization, increase resource utilization, and overall higher treatment cost. Length of stay was significantly higher in elderly with and without bleeding complications compared to younger patients (< 75 years). Elderly patients with bleeding complications stayed longer compared to elderly without bleeding complications. Patients with complications were older, predominantly male, and femoral access site was accessed for PCI. In economically constraint environment, we need more efforts in better understanding of risk factors for longer hospitalizations, bleeding complications to minimize the clinical and economic impact.

Disclosures:
Rahul Wadke: This author has nothing to disclose.

D-042

Title: Repeat Radiological Procedures in Patients with Prior Radiation-Induced Skin Injury: A Novel Method to Reduce Site-Specific Direct Beam Exposure

Category: Miscellaneous

Authors: Nicholas Lembo, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Dimitri Karmpaliotis, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Anna Kalynych, M.D., Piedmont Heart Institute, United States, Atlanta, GA; Harold Carlson, M.D., Piedmont Heart Institute, United States, Atlanta, GA; David Kandzari, M.D., Piedmont Heart Institute, United States, Atlanta, GA

Percutaneous revascularization of complex coronary disease is associated with increased risk of radiation skin injury related to prolonged ionizing radiation exposure. Particularly among patients with prior radiation-induced dermatitis, avoidance of repeat exposure is preferred although unavoidable in selected clinical circumstances. In such instances, methods to avoid and/or limit focal radiation exposure to the injured site is essential.

As a technique to nearly completely limit direct beam radiation to the affected area, a radiation shield may be constructed from a commercially available shielding product (RADPAD, Kansas City, KS). Specifically, the shield is tailored to the area of skin injury by cutting the shield and placing it over the skin at the site of previous injury (Inserts A, B). The shield will attenuate approximately 90% of direct beam radiation and permits a visible 'shade' to the operator under fluoroscopic guidance that obscures visualization and requires alteration of beam angle.

This method represents a novel approach with a commonly available product to selectively shield areas of prior radiation skin injury when repeat X-ray imaging is unavoidable.

Disclosures:
Nicholas Lembo: Bridgepoint Medical, Institutional educational grant support, Other.

D-046

Title: NILE Registry (National Heart Institute Large Egyptian): Registry of Cardiac Catheterization and Angioplasty Before the 2011 Revoltion

Category: Miscellaneous

Authors: Hamdy Soliman, M.D., Cardiology National Heart institute, Egypt, Cairo; N. El-shehaby, M.D., Cardiology Department - Ain shams University - Cairo - Egypt, Egypt, Cairo; S.M. Shaheen, M.D., Cardiology Department - Ain shams University - Cairo - Egypt, Egypt, Cairo

Introduction: A cardiac cath registry started since 2007 in the two largest cardiac centers in Egypt till January 2011, one in the National Heart Institute (the largest cardiac center in Egypt) and the other in Ain Shams university hospital. The data collected in both centers utilize the same data base system.

Objectives: The aim of this report is to describe the practice and outcomes of cardiac catheterization in both centers. This report also is meant to document the type of service provided to Egyptian cardiac patients before the January 2011 revolution in Egypt.

Methods: This registry included all patients admitted to the cath lab in both ain shams university hospital ASUH (from 3/2007 till 1/2011) and the National Heart Institute NHI (from 6/2009 till 1/2011). The total number of patients in this report is 33288 patients (11692 in ASUH and 21596 in NHI).

Results: The patients’ mean age 54.1 years (only 14% were 65 years old) and 73.6% were males. The majority of patients (72.5% ASUH and 78% in NHI) had just coronary angiography while the remaining had percutaneous coronary intervention (PCI). Among the PCI patients, the mean BMI was 29.1, 15% had history of myocardial infarction, 3.9% had history of PCI, 0.9% had history of CABG and 0.5%, 0.9%, 0.2% had history of stroke, congestive heart failure and chronic renal failure, respectively. The prevalence of smoking, diabetes and hypertension was 32.2%, 16.4% and 20.1%, respectively. Only 7.2% of PCI procedures were for urgent non-elective patients, 69% was a one vessel intervention, 0.2% was PCI to to a graft, and 5.9% was PCI to left main. The arterial access was femoral in 99.9% of cases and there was no usage of IVUS.
pressure wires, rotablaters, atherectomy or brachytherapy. The total number of implanted stents was 7128; a single stent was implanted in 69% and 2 stents were implanted in 26% of patients. The penetration rate of drug eluting stents was only 3.9%. The success rate (freedom from death or life threatening complications was 99.8% among the PCI procedures, while hospital mortality was 0.1%. 

**Conclusion:** The lack of modern cardiac cath lab procedures and equipment in the largest two public hospitals in Egypt, characterize the type of service to the Egyptian patients prior to the January 2011 revolution.

**Disclosures:**
Hamdy Soliman: This author has nothing to disclose.
N. El-shehaby: This author has nothing to disclose.
S.M. Shaheen: This author has nothing to disclose.

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**PEDIATRIC**

**A-003**

**Title:** Use of a Pressure Guidewire to Assess Pulmonary Artery Band Adequacy in the Hybrid Stage I Procedure for High-Risk Neonates with Hypoplastic Left Heart Syndrome and Variants

**Category:** Pediatric

Authors: Jeffrey D. Zampi, M.D., University of Michigan Health System, United States, Ann Arbor, MI; Bryan H. Goldstein, M.D., Cincinnati Children’s Hospital Medical Center, United States, Cincinnati, OH; Jennifer C. Hirsch, M.D., M.S., University of Michigan Health System, United States, Ann Arbor, MI; Aimee K. Armstrong, M.D., University of Michigan Health System, United States, Ann Arbor, MI

**Background:** The hybrid stage I procedure is an alternative palliative strategy for patients with hypoplastic left heart syndrome (HLHS) and HLHS variants who traditionally have undergone the Norwood operation. At our institution, the hybrid stage I procedure is employed only for patients with high operative risk. We describe our use of a pressure guidewire during the hybrid stage I procedure and subsequent catheterizations to assess quantitatively pulmonary artery (PA) band adequacy.

**Methods:** Chart review was completed on all HLHS and HLHS-variant patients who underwent a hybrid stage I procedure at our institution; all met two or more high-risk criteria for the Norwood operation. We identified two groups of patients; those who underwent the standard hybrid stage I palliation (standard cohort) and those who underwent the procedure with pressure wire facilitated assessment of distal branch PA pressure (pressure wire cohort). Comparison between the two groups was performed to evaluate the impact of pressure guidewire use on procedural risk, radiation time, patient outcomes, and need for re-operation for PA band adjustment. Changes in PA pressures over time were also assessed.

**Results:** The pressure guidewire was used in 8 of 14 (57%) patients at the time of hybrid stage I procedure and was successful in all attempts. In the standard cohort, 67% of patients needed re-operation for PA band adjustment, compared to 12.5% of patients in the pressure wire cohort (p = 0.09). Procedure time, radiation exposure, and survival to hospital discharge (67% in the standard cohort and 88% in the pressure wire cohort) were not significantly different between groups. There were no complications related to pressure guidewire use. Unless restriction at the atrial septum developed, PA pressures did not change significantly over time after PA band placement (mean follow-up time 97.4 days, range 32 to 135 days) in either cohort.

**Conclusion:** This novel use of a pressure guidewire to assess quantitatively PA band adequacy at the time of placement in high-risk HLHS patients is feasible, safe and may decrease the need for re-operation for PA band adjustment. More data are needed to determine the optimal mean PA pressure at the time of PA band placement.

**Disclosures:**
Jeffrey D. Zampi: This author has nothing to disclose.
Bryan H. Goldstein: This author has nothing to disclose.
Jennifer C. Hirsch: This author has nothing to disclose.
Aimee K. Armstrong: AGA Medical Corporation Consultant and Proctor, Other.

**A-049**

**Title:** Comparison of Geometric Changes in Bare Metal Stents Used for Coarctation of the Aorta

**Category:** Pediatric

Authors: Asra Khan, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX; Yoshiyuki Kado, M.D., Kurume University School of Medicine, Japan, Kurume City; Charles Mullins, M.D., Baylor College of Medicine/Texas Children’s Hospital, United States, Houston, TX; Christopher Petit, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX; Henri Justino, M.D., Baylor College of Medicine/Texas Children’s Hospital, United States, Houston, TX; Frank Ing, M.D., Baylor College of Medicine/Texas Children’s Hospital, United States, Houston, TX

**Objectives:** The purpose of our study was to compare the change in stent (S) geometry following implantation of large and extra-large size bare metal stents in coarctation of aorta (CoA).

**Background:** Over the past decade, emergence of new Ss deemed more suitable for congenital heart disease has led to more options for treating CoA. However, there is a paucity of data to determine which is the best S to use in this lesion. Post-inflation changes in S geometry may be important when choosing the type & size of S. We analyzed & compared S foreshortening & recoil as well as complications resulting from 5 most commonly used Ss for CoA.

**Methods:** All pts who received Ss for CoA at our institution between 1/2000 & 12/2009 were included. A retrospective review of demographic & hemodynamic data, stent geometry pre & post inflation and complications was performed.

**TABLE 1**

<table>
<thead>
<tr>
<th></th>
<th>Palmez 8 series</th>
<th>Palmez XL</th>
<th>Maxi LD</th>
<th>Genesis XD</th>
<th>CP</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>12</td>
<td>13</td>
<td>25</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Minimum Diameter (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>9.5 (2.5-13.3)</td>
<td>8.9 (1.9-12.1)</td>
<td>7.8 (2.1-12.7)</td>
<td>6.5 (1.1-10.8)</td>
<td>4.3 (1.7-15)</td>
</tr>
<tr>
<td>Post</td>
<td>13.1 (9.2-16.2)</td>
<td>15.5 (9.2-23.0)</td>
<td>12.6 (9-17.6)</td>
<td>11.2 (5.3-15.3)</td>
<td>12.3 (9-20.4)</td>
</tr>
<tr>
<td>Gradient (mmHg)</td>
<td></td>
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<td></td>
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<tr>
<td>Pre</td>
<td>31.5 (11-82)</td>
<td>25.5(10-42)</td>
<td>31 (10-73)</td>
<td>10 (2-57)</td>
<td>26 (17-47)</td>
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<tr>
<td>Post</td>
<td>1.5 (0-28)</td>
<td>0 (0-14)</td>
<td>3 (0-11)</td>
<td>0 (0-5)</td>
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<td>Foreshorting (%)</td>
<td>78 (57.2-94)</td>
<td>93.9 (79.7-98.3)</td>
<td>98.7 (77.8-109)</td>
<td>84.7 (74.8-100)</td>
<td>95.3 (91-100.4)</td>
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<tr>
<td>Recoil (%)</td>
<td>6.7 (0-13.3)</td>
<td>6.3 (0-11.5)</td>
<td>4.2 (0-13.7)</td>
<td>7 (2.4-11)</td>
<td>6 (0-13.3)</td>
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S64 Abstracts

Results: (Table 1) 69 pts underwent S implantation using Palmaz 8-series, Palmaz XL, Maxi LD, Genesis XD and CP Ss. There was significant improvement in vascular diameter & gradient across the CoA in all groups. Pre & post-implant S diameter were comparable in all groups. Maxi LD Ss had the least foreshortening & least radial recoil compared to the others (p <0.05). Furthermore, 39% of Maxi LD Ss increased in length after expansion due to its “open-cell” design. The % recoil was not related to the maximum balloon diameter or the balloon diameter:-minimum CoA diameter ratio. There was one minor complication (hematoma). Despite jailing off brachiocephalic vessels in 5 pts, there was no evidence of obstruction to flow.

Conclusion: The Maxi LD S showed the least foreshortening & least recoil post stenting while Palmaz 8-series Ss showed the most foreshortening, & the Genesis XD showed the most recoil. S geometry was best preserved with the Maxi LD S after implantation in CoA.

Disclosures:
Asra Khan; This author has nothing to disclose.
Yoshiyuki Kudo: This author has nothing to disclose.
Charles Mullins: This author has nothing to disclose.
Christopher Petit: This author has nothing to disclose.
Henri Justino: This author has nothing to disclose.
Frank Ing: This author has nothing to disclose.

B-005

Title: Single Center Experience of PDA Stent In Saudi Arabia
Category: Pediatric
Authors: Mashail Bin obaidan, M.D., Prince Sultan Cardiac Center, Riyadh Armed Forces Hospital, Saudi Arabia, Riyadh, Riyadh 1

Background: Transcatheter PDA stenting is considered now as an alternative to surgical aortopulmonary shunt in a selected patients who are suitable for the procedure.

Method: Between Jan 2005 to May 2011, 87 patients underwent PDA stenting in PSCC after full assessment by echocardiogram and angiogram 41 patients (47%) patient have PA & VSD 25 of them with 2 ventricles and the remaining 16 with single ventricle morphology, 22 (25%) patients have TOF, 24 patients (28%) have PA & IVS, 11 patients have Laser wire/RF perforation of the pulmonary valve same time. Median age is 8 days, median weight is 3.2 kg, procedure is prograde or retrograde.

Result: Mean ventilatory support is 2 days, median hospital stay is 4 days, median saturation is 79%, median follow up is 45 mo, median floroscopy time is 17.6 minutes (7.7-43 min), 6 (6.8%) of them has NEC first few days post stenting, 3 (3.4%) has stent migration, 4 (4.6%) lost follow up, 2 (2.2%) deaths.

Conclusion: We conclude that PDA stenting is a safe and alternative procedure Surgical aortopulmonary shunt.

Disclosures:
Mashail Bin obaidan: This author has nothing to disclose.

B-014

Title: Versatility of the Amplatzer Vascular Plug II in Closing Cardiovascular Lesions in Patients with Congenital Heart Disease
Category: Pediatric
Authors: Abraham Rothman, M.D., Children’s Heart Center Nevada and University of Nevada, School of Medicine, United States, Las Vegas, NV; Alvaro Galindo, M.D., Children’s Heart Center Nevada and University of Nevada, School of Medicine, United States, Las Vegas, NV; William Evans, M.D., Children’s Heart Center Nevada and University of Nevada, School of Medicine, United States, Las Vegas, NV; Humberto Restrepo, M.D., MPh, Children’s Heart Center Nevada and University of Nevada, School of Medicine, United States, Las Vegas, NV

Background: Percutaneous closure of a variety of cardiovascular lesions in patients with congenital heart disease has become routine. Several devices have been utilized. The Amplatzer Vascular Plug II (AVP II) is a recent introduction with ostensible improved occlusion properties.

Methods: We describe our experience using this device to close 36 redundant cardiovascular structures. From August 2009 to November 2011 we used the AVP II to close 30 patent ductus arteriosus (PDAs), 2 perimembranous ventricular septal defects (VSDs), 2 left superior vena cavae (LSVCs) to coronary sinus and 1 large decompressing azygous vein in 3 patients with cavopulmonary connections, and 1 obsolete Sano shunt in a patient with hypoplastic left heart.

Results: There were 24 females and 12 males. The median age at intervention was 16 months and the median weight was 9.6 kg. Among the PDA patients, 3 weighed about 4.0 kg at the time of the procedure. Closure was performed easily from either the pulmonary or the aortic end. Minimum PDA diameters ranged from 1.2 to 4.7 mm. Device sizes were: 4 mm (n = 13), 6 mm (n = 13), 8 mm (n = 2), and 10 mm (n = 2). In the 2 VSD patients, the device was delivered with the distal disc and midportion of the device inside the aneurysm and the proximal disc on the right ventricular side of the aneurysm. The Sano shunt (5 mm diameter) was closed with a 6 mm AVP II device. All of the PDAs, the decompressing veins and the Sano shunt were completely occluded. In one patient with a large PDA, the AVP II was used successfully, after a previously-placed Amplatzer Duct Occluder device embolized and was retrieved. The 2 VSD patients had small residual shunts after the procedure and at follow up echocardiography (1 and 2 months later, respectively). There were no complications during the procedure or at follow-up in any of the patients. The device was particularly well-suited to close PDAs with a fingerlike diverticulum and a stenosis towards the pulmonary end.

Conclusion: The AVP II was very safe and effective in closing a variety of cardiovascular lesions in patients with congenital heart disease. The ease of delivery and retrievability make it an important component in the toolbox of the interventionalist.

Disclosures:
Abraham Rothman: AGA-St Jude, Other.
Alvaro Galindo: This author has nothing to disclose.
William Evans: This author has nothing to disclose.
Humberto Restrepo: This author has nothing to disclose.

B-030

Title: Pre- and Intra-Procedural Predictors of Outcome in Pulmonary Atresia-Intact Ventricular Septum Following Radiofrequency Perforation and Balloon Valvuloplasty
Category: Pediatric
Authors: Jon Wagner, D.O., Children’s Mercy Hospital, United States, Kansas City, MO; Karina Carlson, M.D., Children’s Mercy Hospital, United States, Kansas City, MO; Michael Bingler, M.D., Children’s Mercy Hospital, United States, Kansas City, MO; Marius Hubbell, M.D., Children’s Mercy Hospital, United States, Kansas City, MO; Michael Bingler, M.D., Michael Bingler, M.D.; children’s Mercy Hospital, United States, Kansas City, MO; Stephen Kaine, M.D., Children’s Mercy Hospital, United States, Kansas City, MO; Jon Wagner, D.O., Children’s Mercy Hospital, United States, Kansas City, Missouri, MO

Background: For patients with pulmonary atresia-intact ventricular septum (PA-IVS) undergoing radiofrequency perforation (RFP) and
balloon valvuloplasty (BV) as an initial palliation, it is variable whether additional catheter based and/or surgical interventions will be required. Predicting the necessity for further intervention at the time of initial palliation remains difficult.

Objective: In neonates with PA-IVS undergoing RFP and BV, pre- and intra-procedural echocardiographic and hemodynamic measures were assessed to determine predictors of additional surgical/catheter intervention.

Methods: Between 1999 and 2011, 20 neonates with PA-IVS underwent RFP and BV as an initial palliation at our institution. Data collection included pre-procedural echocardiographic tricuspid and pulmonary valve annuli, intra-procedural right ventricular pressure (RVP) (pre and post), right ventricular to pulmonary artery gradient (pre and post), balloon diameter, need for further surgical/catheter interventions and clinical status on recent follow-up. Differences between groups were assessed by unpaired t-test.

Results: Overall survival was 95%. One patient died 5 days following intervention. In survivors, augmented pulmonary blood flow (APBF) with a Blalock-Taussig Shunt or ductal stent was required in 68% (13 patients). Further balloon dilation was performed in 47% (9 patients) and subsequent surgical outflow tract reconstruction in 47% (9 patients). On follow-up, 79% achieved 2-ventricle (15 patients) and 21% 1.5-ventricle repair (4 patients). In patients requiring APBF, tricuspid valve Z-score was -1.26 +/- 0.98 versus 0.40 +/- 0.57 without APBF (p = 0.001). Procedural ΔRVP was 58.38 +/- 29.88 mmHg in patients with APBF versus 29.67 +/- 18.82 without APBF (p = 0.047). No parameter predicted subsequent need for balloon valvuloplasty, right ventricular outflow tract reconstruction, or 1.5-ventricle repair.

Conclusion: PA-IVS newborns with smaller tricuspid valve Z-score and higher ARVP after RFP and BV are more likely to require APBF, but need for further interventions could not be predicted at initial intervention.

Disclosures:
Jon Wagner: This author has nothing to disclose.
Karina Carlson: This author has nothing to disclose.
Michael Bingler: This author has nothing to disclose.
Marius Hubbell: This author has nothing to disclose.
Stephen Kaine: This author has nothing to disclose.
Jon Wagner: This author has nothing to disclose.

B-031

Title: Enhanced Ventricular Interdependence is Commonly Observed in Pediatric Patients with Right Ventricular Hypertension

Category: Pediatric

Authors: Olawale Olabiyi, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX 1; Matthew Crystal, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX 2; Henri Justino, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TN 3

Background: Enhanced ventricular interdependence (EVI) has become an important diagnostic feature of constrictive pericarditis. However, EVI may be encountered in other cardiac conditions where dissociation of intrathoracic and intracardiac pressures occurs, possibly secondary to either ventricular septal shift and/or pericardial constraint. EVI has not been previously described in the pediatric population, or in congenital heart disease. We sought to describe findings of EVI in pediatric patients (pts) with right ventricular (RV) hypertension due to pulmonary hypertension (PH) of various etiologies or pulmonary stenosis (PS).

Methods: We performed a retrospective review of pts with PH or PS that underwent catheterization (cath) from 1/03 - 12/05. Inclusion criteria included the availability of simultaneous pressure tracings of right ventricle (RV) and either aorta or left ventricle during at least 2 respiratory cycles. EVI was defined as out-of-phase occurrence of peak RV vs peak aortic or LV pressure during the respiratory cycle. Pressure tracings were analyzed pre- and post-ballooning pulmonary valvuloplasty (BPV) for PS group.

Results: Of 104 pts, 59 (13 PH, 46 PS) met inclusion criteria. Overall, 26/59 pts (44%) had EVI at baseline. For PH group, 7/13 had EVI, with no statistically significant differences between pts with EVI vs. without EVI in age (mean = 10.5 vs 8 yrs), absolute RV pressure (mean = 79 vs 68 mmHg), or RV/ systemic pressure ratio (mean 0.9 vs 0.8). For PS group, 19/46 pts (41%) had EVI pre-BPV. There were no differences between pts with EVI vs without EVI in age (mean = 2.8 vs 2.5 yrs), absolute RV pressure (mean = 72 vs 71 mmHg) or RV/systemic pressure ratio (1.0 vs 0.9). 18/19 pts (95%) with EVI at baseline had no EVI post BPV; 1 pt with EVI post BPV had ineffective BPV due to residual supravalvar PS.

Conclusion: This is the first study to systematically evaluate the occurrence of EVI in RV hypertension. EVI, a form of adverse ventricular-ventricular interaction, is not exclusively encountered in constrictive pericarditis, occurring in almost half of pediatric pts with RV hypertension referred for cath with PS or PH, with no clear association with age, absolute RV pressure, or RV to systemic pressure ratio. However, relief of RV hypertension, such as with BPV, results in resolution EVI. The clinical implications of EVI are unknown, more studies are required to determine if EVI correlates with symptoms or mortality, particularly in PH.

Disclosures:
Olawale Olabiyi: This author has nothing to disclose.
Matthew Crystal: This author has nothing to disclose.
Henri Justino: This author has nothing to disclose.

B-032

Title: Left Atrial Decompression During Extra Corporeal Membrane Oxygenation in Children with Failing Heart - A 10 Year Retrospective Study

Category: Pediatric

Authors: Lakshmi Nagaraju, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 1; Daniel Turner, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 2; Harinder Singh, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 3; Wei Du, Ph.D., Children’s Hospital Of Michigan, United States, Detroit, MI 4; Daisuke Kobayashi, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 5; Raphael Delius, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 6; Thomas Forbes, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 7; Srinath Gowda, M.D., Children’s Hospital Of Michigan, United States, Detroit, MI 8

Background: Extracorporeal membrane oxygenation (ECMO) has been used in children for severe end stage heart failure. Acute pulmonary edema following ECMO is a relatively common complication due to left atrial hypertension. Early left atrial decompression (LAD) promotes recovery of left ventricular function. We sought to evaluate risk factors for left atrial hypertension in patients placed on ECMO and describe methods of LAD and their outcome from our center.

Methods: Retrospective review of all patients with normal cardiac septal anatomy who underwent ECMO from January 2001 to January 2011 was performed. Patients were grouped into two groups, with and without LAD. To analyze the factors predicting the need for LAD; shortening fraction, aortic pulsatility, ECMO flow rate and X ray findings were compared among the two groups using T tests and Fischer’s extract. Aortic pulsatility was calculated by dividing pulse pressure by mean pressure based on pre ECMO arterial blood pressure reading. On chest X ray pulmonary interstitial edema was considered as mild and bilateral opacities as severe pulmonary edema.
A total of 31 patients were included. The median age was 5 years (0.1-34) with 14 female (45%). The median ECMO duration was 167 hours (1-325). LAD was performed in 9/31 (29%), in whom transeptal needle puncture was performed followed by atrial septal serial balloon dilatation. The median final balloon dilatation size was 12 (10-20). None of the patients required re-interventions. Left atrial mean pressure gradient improved from 21.7±8.4 to 5.3±5.7 mmHg. There were no procedure related deaths or complications. On follow-up, LAD group had 4 deaths and 5 survived post transplant. Non-LAD group had 8 deaths, 8 survived post transplant and 6 improved with good ventricular function. Comparing the two groups, patients requiring LAD had shortening fraction 12.0 vs. 7.2 (P = 0.01) indicating severe left ventricular dysfunction, more patients had severe pulmonary edema (P = 0.05), higher ECMO flow rate 97.9±27.0 vs. 80.8±31.9 (NS) and lower aortic pulsatility 0.48±0.37 vs. 0.70+/-.28 (NS).

Conclusions: Atrial septal serial balloon dilatation is an effective method of LAD decompression with excellent acute results. Severe left ventricular dysfunction and severe pulmonary edema is a strong predictor for left atrial hypertension requiring LAD as a bridge to transplant and possible recovery.

B-040

Title: Dual Wire Stenting Technique in Congenital Heart Disease: Exploring New Frontiers

Background and Aims: Placement of a stent is problematic close to bifurcations, the origin of side branches or for external compression without anatomical obstruction (insufficient anchorage and risk of embolisation). Patients and Methods: prospective study tertiary interventional centre. Stents were implanted in 9 patients. Indications were: anatomic obstruction in 6, external compression of pulmonary veins in 2 and exclusion of an aortic aneurysm in close proximity to the subclavian artery in 1 patient.

Results: Median age of the group was 10.0 years (range 1.5 – 19.6) with body weight 34.4 kg (range: 10.6 – 78.0). A variety of stents (Genesis, CP & CCP), balloons (Opta, Z-Med, Tyshak) and sheaths was used to keep vascular trauma minimal. Stents were safely implanted in all patients with patency of all side vessels. Median diameter of the stenosis increased from 5.9mm (range: 1.1 – 13.2) to 9.8 mm (range: 8.0 – 17.6) (p < 0.01, 95% CI: 2.0 – 7.2 ). The distal aspect of the stent was larger than the proximal with a median ratio of 1.4 (range: 1.2 – 1.8) illustrating the eccentric opening of the stents.

Disclosures: Makram Ebeid: travel grant, Other. Mary Anne Kosek: This author has nothing to disclose. Mary Anne Kosek: This author has nothing to disclose. Cauveh Erami: This author has nothing to disclose. Charles Gaymes: This author has nothing to disclose.
Disclosures:
Marc Gewillig: Numed, 8. Speaker’s Bureau
Stephen Brown: This author has nothing to disclose.
Derize Boshoff: This author has nothing to disclose.
Nazan Ozbarlas: This author has nothing to disclose.
Ruth Heying: This author has nothing to disclose.
Bjorn Cools: This author has nothing to disclose.
Ruth Heying: This author has nothing to disclose.
Marc Gewillig: This author has nothing to disclose.

B-049

Title: Eliminating Stent Slippage Using a Combined Sheath-Balloon Catheter

Category: Pediatric

Authors: Yashu Coe, M.B.B.S., MD FRCP(C) FACC FAHA, University of Alberta, United States, Edmonton, AB; Dylan Taylor, M.D., FRCP(C), University Of Alberta Hospital, Canada, Edmonton, AB

Background: Percutaneous stent placement has become a mainstay of transcatheter treatment of vascular stenosis & coarctation. Pre-mounted stents may not be available in the sizes needed. The stents are usually hand cramped onto the balloon in vitro, and advanced into the stenosis through long sheaths previously placed. Stents can rarely slip off the balloon during its introduction through the hemostatic valve of the sheath, but more likely through the heart or vessels that have tight corners that distort or kink the sheath. The stent has to be retrieved, repositioned or remounted prolonging the procedure. Surgical removal may be necessary if the stent slips distally. Despite advances in balloon and catheter technology and delivery techniques, this complication persists. We describe a novel method of stent delivery that eliminates stent slippage using a front loaded stent-in-balloon delivery system.

Methods: The stents (n = 7) were delivered under GA to relieve pulmonary artery stenoses or prior to pulmonary valve replacements (n = 4). Initially, using a conventional balloon-in-balloon catheter, a Palmaz P4010 stent slipped off the balloon completely as it was advanced through the sheath in the right ventricular. The stent was retrieved and remounted on the balloon of a custom made all-in-one balloon sheath catheter (NuMed Inc., Hopkinton, NY). The stent, front loaded on the balloon (10-18 mm), covered by the sheath, permitted movement of the stent-in-sheath as one system. The procedure was repeated in others with pulmonary artery stenosis.

Results: Multiple arrhythmias occurred during the passage of the stent-in-sheath through the RV, but there was no myocardial or vascular injury. Significant friction was encountered during the stent’s passage through the RV and stenotic pulmonary valve. Despite significant force used to advance the stent-in-sheath through the RV and into the pulmonary artery, the stent remained on the balloon, and was deployed uneventfully.

Conclusion: Using the front-loaded all-in-one balloon sheath catheter, stent slippage off the balloon is eliminated. The procedural time is shortened, and morbidity reduced. This should be the device of choice in stenting stenoses.

Disclosures:
Yashu Coe: This author has nothing to disclose.
Dylan Taylor: This author has nothing to disclose.
C-003

Title: Right Ventricular Outflow Tract Stenting in the Symptomatic Infant with Tetralogy of Fallot

Category: Pediatric

Authors: Mashail Bin obaidan, M.D., Prince Sultan Cardiac Center, Riyadh Armed Forces Hospital, Saudi Arabia, Riyadh, Riyadh

Background: The Debate continues regarding the initial management of cyanotic or duct-dependent infants with TOF especially those patients with pulmonary artery hypoplasia. While repair can and has been performed in these patients, it is associated with increased morbidity.

Objective: We review the effectiveness of right ventricular outflow tract (RVOT) stenting in the symptomatic young infant with TOF.

Methods: Clinical, echocardiographic, angiographic and hemodynamic data were reviewed for 11 patients who underwent 14 RVOT stenting procedures from June 2007 to March 2010.

Results: There were 7 girls and 4 boys with median age 3 month and weight 3.5 kg. The pulmonary valve was hypoplastic in all patients. Median pulmonary valve diameter 3.1 mm (range 2.7–5.2), Z-score -5.5 (range -8.0 to -4.4). RVOT stenting improved arterial oxygen saturation from a median of 60% (55–66%) to 91% (82–94%). Median Z-score for proximal stenosis was 1.8 (-0.3 to -2.9) before stent implantation to 1.1 (-0.4 to -0.8) at time of surgery. Median Z-score for the right pulmonary artery increased from -3.1 (-0.2 to -2.1) to -1.1 (-0.2 to 0.1). There were no complications. 7 patients have undergone successful repair. There were no immediate or early deaths.

Conclusion: In the symptomatic young infant with TOF, who abandoned surgery for any reason or at high risk stenting of the RVOT provides a safe and effective management strategy, improving arterial oxygen saturation and encouraging pulmonary artery growth.

Disclosures:
Mashail Bin obaidan: This author has nothing to disclose.

C-006

Title: Transcatheter Treatment of Pulmonary Artery Stenosis in Children with Alagille Syndrome

Category: Pediatric

Authors: Matthew Zussman, M.D., Cincinnati Children’s Hospital Medical Center, United States, Cincinnati, OH1; Robert H. Beekman III, M.D., Cincinnati Children’s Hospital Medical Center, United States, Cincinnati, OH2; Russel Hirsch, M.D., Cincinnati Children’s Hospital Medical Center, United States, Cincinnati, OH3

Background: Pulmonary artery stenosis (PAS) is common in Alagille Syndrome (ALS). The nature of this association may differ significantly from PAS in other forms of congenital heart disease (CHD). Therefore, responsiveness of PAS lesions to transcatheter therapies may also differ.

Methods: In this single-center series, we reviewed procedural, hemodynamic and angiographic data from all patients with ALS and PAS who underwent cardiac catheterization from 2003-2011. Minimal luminal diameter (MLD) was defined as the narrowest portion of the vessel. Proximal vessel diameter was defined as the vessel diameter immediately prior to the stenosis. Vascular stenosis was calculated as (1 – Proximal vessel diameter/MLD) x 100.

Results: Eight patients with ALS and PAS underwent interventions on 31 vessels during 21 catheterizations. Interventions included balloon angioplasty (BA), cutting balloon angioplasty (CBA) and pulmonary artery stent (ST) placement. Median age was 9.1 years (range 0.9-14.3) and weight was 21.3 kg (48.5-52.5). All patients had associated CHD (5 TOF, 1 PAIVS and 1 ASD). Angiographic data from subsequent catheterizations were available for 19 treated lesions (BA n = 12, ST n = 6, CBA n = 1) at a median follow-up time of 11 months. Mean data are shown in table 1. The development of in-stent stenosis was identified in all ST-treated lesions. Three minor complications (2 small contained vascular tears and 1 stent embolization) and 1 major complication occurred (in lab mortality due to hemorrhage from esophageal varices).

Conclusions: Transcatheter intervention for PAS in ALS is generally safe and acutely effective, across all treatment modalities. Although stent implantation was associated with the greatest immediate improvement in MLD, in-stent stenosis was universal at follow-up. Balloon angioplasty alone was associated with continued PA growth at mid-term follow-up, and therefore may be the preferred initial therapy.

Disclosures:
Matthew Zussman: This author has nothing to disclose.
Robert H. Beekman III: This author has nothing to disclose.
Russel Hirsch: This author has nothing to disclose.
Bryan H. Goldstein: This author has nothing to disclose.

Table 1

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C-030

Title: Use of Covered Cheatham-Platinum (CCP) Stents in Congenital Heart Disease

Category: Pediatric

Authors: Marc Gewillig, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven1; Ward Vanagt, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven2; Derize Boshoff, M.D., University of Leuven, Belgium, Belgium, Leuven3; Bjorn Cools, M.D., University of Leuven, Belgium, Belgium, Leuven4; Ruth Heying, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven5; Els Troost, M.D., University of Leuven, Belgium, Belgium, Leuven6; Werner Budts, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven7

Objective: Evaluation of possibilities and safety of covered Cheatham-Platinum (CCP) stents in congenital heart disease (CHD) patients.

Methods: Single-center retrospective CHD-database study of all CCP stents, 2003-2011. Three study groups: aortic coarctation (CoA), RVOT pre-stenting for percutaneous revaluation, and miscellaneous. Indication, effectiveness and safety were assessed. Narrowed segments were expanded at moderate pressures 4-6 atm, apposing the CCP stent against the wall. When this resulted in suboptimal relief of the obstruction and if a tear was expected, time was allowed for “ingrowth” of the stent until full expansion at a 2nd procedure.

Results: Overall 78 CCP stents in 80 patients.

Coarctation group: CoA group, 45 CCP stents in 44 patients: 2/44 for aneurysm exclusion, 42/44 prophylactically (atresia requiring puncture in 1, filiform in 4, pinpoint in 17 pts). CCP stent dilated to desired dimension at implantation in 35/44 patients, stent re-dilation after 6.7±7.5 months in 9/44 patients. Final CCP stenting resulted in significant increase in CoA diameter from 6±4 (range 0 – 12) to 15±2 (range 12 – 20 mm, PTP gradient decrease from 28±18 to 3±5mmHg).

RVOT group, 27 CCP stents in 25 patients with stenosed conduit. In 6 pts CCP was used to protect the delivery balloon after rupture of predilation balloon; dilation up to “nominal” in 24/25 patients, further dilation 2 – 6mm beyond “nominal” diameter in 13/25 (52%) patients.
Miscellaneous group, 15 CCP stents in 11 patients: closure of a Fontan-circuit fenestration (n = 3), restoration of caval vein (n = 2), cavo-pulmonary connection (n = 2), or pulmonary artery (n = 2) patency, relief of supra-pulmonary stenosis (n = 2). Hybrid procedure in 2 patients to connect suturelessly a conduit to excluded, minute intrapulmonary arteries. CCP stent as rescue treatment in 2 patients.

The desired result was obtained in every patient; no extravasation was encountered despite significant expansion and presumed tears of narrow segments.

**Conclusion:** Where vessel tear and extravasation can be expected, the use of covered stents is safe and opens new opportunities with more complete dilation. Therapeutic use includes aneurysm exclusion and control of bleeding.

**Disclosures:**
- Marc Gewillig: NUMED, 8. Speaker’s Bureau
- Ward Vanagt: This author has nothing to disclose.
- Derize Boshoff: This author has nothing to disclose.
- Ruth Heying: This author has nothing to disclose.
- Els Troost: This author has nothing to disclose.
- Werner Budts: This author has nothing to disclose.

C-038

**Title:** Stretch a Little: Compliant Sizing Balloon Technique to Assess Distensibility of Stenotic Vascular Segments

**Category:** Pediatric

**Authors:**
- Matthew Williams, M.D., UCSD, United States, San Diego, CA
- Howaida El-Said, M.D., UCSD, United States, San Diego, CA
- Andras Bratincsak, M.D., UCSD, United States, San Diego, CA
- Sanjeeet Hegde, M.D., UCSD, United States, San Diego, CA
- John Moore, M.D., MPH, UCSD, United States, San Diego, CA

**Background:** Angiography is the standard method of assessing vascular stenosis for both diagnosis & intervention. However, angiography is limited in its ability to accurately assess low-pressure vessel distensibility, which may potentially lead to stent embolization or other complications. Angiography also frequently requires administration of relatively large doses of both contrast and radiation.

**Methods:** Amplatzer sizing balloon catheters (18-24mm) were used to assess vessel anatomy and distensibility. This Compliant Sizing Balloon Technique (CSBT) was compared with angiography in nine consecutive cases: 4 CoA, 2 TOF/d-TGA, 3 Fontan. We performed balloon sizing of the aortic arch, pulmonary arteries, RV-to-PA conduit, SVC, Fontan, and pulmonary veins respectively.

**Results:** The degree of low-pressure vessel distensibility was underestimated by angiography & assessment of dynamic vessel curvature was also limited. CSBT was helpful in accurately assessing these characteristics, and was crucial in modifying planned intervention and stent sizing in all cases. CSBT led to lower doses of contrast and radiation. Representative cases below.

**Conclusion:** Compliant sizing balloons can be helpful in evaluating vascular stenosis, and may be superior to angiography in the context of distensible stenotic segments or dynamic vessel curvature. This method is also beneficial in reducing the dose of contrast administered and radiation exposure compared to angiography.

**Disclosures:**
- Matthew Williams: This author has nothing to disclose.
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- Sanjeeet Hegde: This author has nothing to disclose.
- John Moore: This author has nothing to disclose.
C-042
Title: Off-Label Use of Percutaneous Pulmonary Valved Stents in the RVOT.
Category: Pediatric
Authors: Derize Boshoff, M.D., University of Leuven, Belgium; Bjorn Cools, M.D., University of Leuven, Belgium; Ruth Heying, M.D., Ph.D., University of Leuven, Belgium; Werner Budts, M.D., Ph.D., University of Leuven, Belgium; Marc Gewillig, M.D., Ph.D., University of Leuven, Belgium

Introduction: Percutaneous pulmonary valve implantation is now considered feasible and safe in selected patients with dysfunctional RVOT conduits. The “native” RVOT, smaller conduits (less than 16mm) and the relatively large RVOT with dynamic outflow aneurysms, as commonly seen with trans-annular patch repair of the RVOT, are considered off-label use for percutaneous valve implantation. Modification of the device design to make it suitable for patients with aneurysmal RVOT is being explored but clinical reports are so far limited.

 Aim of study: To report the safety and feasibility of extended (off-label) application of percutaneous pulmonary valve implantation in patients with RVOT dysfunction.

 Design: Retrospective analysis of prospectively collected data.

 Setting: Tertiary pediatric and adult congenital heart cardiac centre.

 Patients and Methods: Off-label use was defined as valve implantation in patients with a native RVOT (pulmonary valve or patch). RVOT conduits smaller than 16mm or larger than 24mm or the final valve diameter ≥110% of the nominal conduit diameter. Successful valve implantation was defined as sufficient relief of RVOT obstruction (if present) and valve competence.

 Results: Twenty Melody® valves and 2 Sapien® valves were successfully implanted in 22 patients at a mean age of 17 years (range 6.1 – 80.4years). Pre-stenting was performed in 21 patients 4.8 months (range 0 – 69.2) before valve implantation (14 covered stents; 12 bare stents). In 10 patients valves were implanted in the native RVOT after transannular/infundibular patch (n = 8, age 6-11 years) or pulmonary valvoplasty (n = 2). Mean diameter of the native RVOT was 18.8mm (range 14 – 24) and mean final valve diameter was 22mm (range 16 – 26). Twelve patients had their valves implanted in existing conduits ranging from 10 to 20mm in size (mean 16mm) with a mean final valve diameter of 20mm (range final size 18 – 22); increase of size was safe without extravasation by using covered CP stents, diameter increased from nominal 4mm (range 2-6 mm)). The implantations were uneventful.

 Conclusion: Percutaneous pulmonary valve implantation is safe and feasible even in patients with unfavourable anatomy according to traditional protocol. Creating an adequate “landing zone” by pre-stenting is recommended. The “ideal timing” for pre-stenting of the native RVOT needs to be determined. Covered stents appear safe when augmentation of the conduit is anticipated.

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Ruth Heying: This author has nothing to disclose.
Werner Budts: This author has nothing to disclose.
Marc Gewillig: Numed, 8. Speaker’s Bureau.

D-004
Title: Impact of Fenestration Creation on Managing Patients with Protein Loosing Enteropathy Complicating Fontan Procedure
Category: Pediatric
Authors: Mashail Bin obaidan, M.D., Prince Sultan Cardiac Center, Riyadh; Ahmed bin Shady, M.D., Riyadh Armed Forces Hospital, Saudi Arabia; Riyadh, Riyadh

Introduction: Protein loosing enteropathy (PLE) is well known complication following Fontan procedure and one way of managing such complication is to create fenestration if it is not present or enlarging it if it is small to reduce the Fontan pressure and reduce venous congestion which end up by intestinal protein loss.

 Aim: To evaluate the effect of such procedure in our population

Method: From February 2006 through October 2011 9 patients who underwent fenestration creation due to development of PLE were assessed in regard to clinical, laboratory result and hemodynamic effect prior and post procedure.

Result: Median age is 7 years(4-21) , median weight is 23 kg (15-52) , male: female ratio is 3:5:1 (male & 2 female), median saturation pre and post procedure was 93% and 82% respectively, median albumin pre and post procedure was 18 gm/dl and 31 gm/dl during the first 2 wks and 36gm/dl thereafter, median pulmonary artery pressure before and after was 25 mmhg (17-32mmhg) and 16 mmhg. (14-19 mmhg), transpulmonary pressure gradient reduced from a median of 11 mmhg, to 5 mmhg, No immediate deaths , 2 patients need re-dilatation, there was 2 (22%) late deaths (one t has stent thrombosis one month after followed by fulminant pulmonary embolism, though all patients were on anticoagulant other one with sudden arrest came to the emergency could not be resuscitated) 3 (33%) patients have persistent low albumin though the fenestration is patent.

Conclusion: Transcatheterfenestration creation as a management of PLE following Fontan procedure is feasible procedure , can be done in the cath. lab with little morbidity and mortality and with beneficial effect however late complication and complete resolving of PLE is of concern especially if done late.

Disclosures:
Mashail Bin obaidan: This author has nothing to disclose.

D-012
Title: Ductal Stenting in Pulmonary Atresia with Intact Interventricular Septum: Single Centre Experience
Category: Pediatric
Authors: Sujit Sawadatkar, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Chandrashekhar Mahale, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Manuel Durairaj, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Jagdish Hiremath, M.D., D.M., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Akash Motgi, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Vivek Gaikwad, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Shirish Hiremath, M.D., D.M., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra; Purvez Grant, M.D., Ruby Hall Clinic, Grant Medical Foundation, India, Pune, Maharashtra

Introduction: Patency Of Ductus is Very Important for the Survival of Neonates in Pulmonary Atresia with Intact Ventricular Septum. Early Patency is Maintained by use of Prostaglandin Infusion but Lateron Patency can be Maintained Using a stent as an Immediate Palliative Measure. Herewith we Present our experience of 5 Patients Of Ductal Stenting.

Methods and Material: 5 Patients With Pulmonary Atresia With Intact Ventricular Septum Having RV Dependent Circulation Underwent Stenting of PDA as they were Requiring High Dose of Prostaglandin
Infusion to Maintain Patency of Ductus. One Neonate Required Axillary Artery Cut Down While in Remaining 4 Neonates Procedure Was Done Through Femoral Access. 0.014” Guide Wirw Was Used To Cross The Duct. 4 Neonates Were Less Than 3 Kg, So A Premounted Stent Prolink Was Used Of 3 mm Diameter With Length Varying From 13 To 18 mm. In 1 Neonate Stent Of 4 To 16 mm Titan was Used.

Results: All Stents Could Be Safely Deployed With Adequate Pumonary Blood Flow. Interim Results Were Good.

Complications: There Was No Procedure Related Complication. In One Patient Ductal Stent Got Dislodged For Which Emergency bt Shunt Was Done.

Follow Up: Acute Stent Thrombosis Was Not Seen In any of the Patients. All Patients Were Followed Up and had Satisfactory Symptomatic Relief.

Conclusion: With Available Technology, Stenting of Duct can be Done Effectively Allowing Good Palliative and Adequate Growth of Pulmonary Arteries.

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Sujit Sawadatkar: This author has nothing to disclose.
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Jagdish Hiremath: This author has nothing to disclose.
Akash Motgi: This author has nothing to disclose.
Vivek Gaikwad: This author has nothing to disclose.
Shirish Hiremath: This author has nothing to disclose.
Purvez Grant: This author has nothing to disclose.

D-013

Title: Balloon Angioplasty of Native Coarctation in Infants

Category: Pediatric

Authors: Makram Ebeid, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Charles Gaymes, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Mary Anne Kosek, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Avichal Aggarwal, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Cauveh Erami, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Jennifer Shores, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Daniel Dibardino, M.D., University of Mississippi Medical Center, United States, Jackson, MS; Jorge Salazar, M.D., University of Mississippi Medical Center, United States, Jackson, MS

Background: Catheter intervention for patients with recurrent/residual coarctation (Coa) has been accepted as an alternative to repeat surgical intervention. Additionally, interventions for native Coa by placing stents has been gaining more enthusiasm as an alternative to surgery in selected patients. The role of balloon angioplasty in native coa in infants has not been established. In our institution balloon angioplasty for native coa was initially considered in cases with added surgical risk factors. As more and more experience and confidence in the procedure was gained it has been offered for some patients who were felt to have favorable anatomy.

Objectives: The aim of this report is to assess the acute results of balloon angioplasty in infants with native coa.

Methods: Retrospective review was performed to evaluate the results of balloon angioplasty in this subgroup of patients. Inclusion criteria included patients ≤ 1 year of age with native coa.

Results: Out of 121 patients who underwent balloon angioplasty for coa 6 met the inclusion criteria and are the focus of this report. Their median age was 3 months (± 2.7); weight was 5.9 (± 1.7) Kg. No sheath larger than 4 French was used in the artery. Pre intervention, the median gradient in the cath lab was 45 (± 15.6) mmhg (range 18-52 mmhg). Post balloon angioplasty the gradient decreased to 0 ( + 5.4) mmhg (range 17-0 mmhg). The fluoroscopy time was 7.75 min (± 8.1) minutes (range 5.2 -14 minutes). In 1 patient the angioplasty was performed using the venous approach only. The pre balloon gradient was not measured in that patient and the post balloon gradient is not included in this report. Five of the 6 patients were done under conscious/deep sedation protocol. All the patients except 1 had the procedure done as an outpatient. One patient who failed extubation post repair of truncus arteriosus was found post operatively to have severe coa. He underwent successful balloon angioplasty and was successfully extubated and discharged home few days later. Conclusion: In selected patients, balloon angioplasty can be safely and effectively performed in infants less than 1 year old with native coa. Long term follow-up for safety and efficacy are needed.

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Jennifer Shores: This author has nothing to disclose.
Daniel Dibardino: This author has nothing to disclose.
Jorge Salazar: This author has nothing to disclose.

D-017

Title: A New "Ultra-ALARA" Radiation Reduction Protocol for Right Heart Catheterization with Surveillance Biopsy in the Pediatric Transplant Patient

Category: Pediatric

Authors: Robert Pass, M.D., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY; Laura Gellis, None, B.A., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY; Nicole Sutton, M.D., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY; Daphne Hsu, M.D., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY; Alan Schoenfeld, None, M.S., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY; Jacqueline Lamour, M.D., Children’s Hospital at Montefiore - Albert Einstein College of Medicine, United States, Bronx, NY

Background: Surveillance endomyocardial biopsy (EMB) with right heart catheterization (RHC) are the standard of care for the assessment of post cardiac transplantation rejection. This procedure has traditionally relied upon fluoroscopy, which exposes both patient and staff to the risks of ionizing radiation. These risks may be of particular concern in the transplant patient who must undergo many such procedures lifelong. We present data on a new “Ultra-ALARA – As Low As Reasonably Achievable” protocol to reduce radiation exposure during the performance of RHC with EMB.

Methods: All cardiac transplantation patients < 21 years of age who underwent RHC with EMB at The Children's Hospital at Montefiore from 6/11-12/11 were included. EMB was performed after all right heart pressures including wedge pressure and thermodilution cardiac output were measured. A novel ALARA protocol consisting of multiple features including ultra-low frame rates (2-3fps), low fluoro dose/frame (10-18 nGy/frame), use of the “air-gap” technique for patients<20 kg, and other techniques aimed at minimizing use of fluoroscopy were employed in all cases. Demographics, procedural data and patient radiation exposure levels were collected and analyzed.

Results: 18 patients underwent 45 surveillance RHC with EMB in the study period and were the subject of this analysis. The median age was 3.0 yrs (range 0.6 -20.0), weight was 12.7 kg (range 5-66) and BSA was 0.55 m² (range 0.28-1.67). PA fluoroscopy was used exclusively in 45/45. Vascular access was RFV (21/45; 47%), RDJ (17/45; 38%),
LFV (4/45; 9%) and LIJV (3/45; 7%). The median number of EMB specimens obtained was 5 (range 4–7). The median fluoroscopy time 3.7 minutes (range 1.2–9.0) and dose area product (DAP) was 15.8 mGy² (range 3.50–144.5). The K and DAP are substantially lower than any prior recent published data for RHC/EMB in this patient group. There were no procedural complications.

**Conclusion:** The use of a novel Ultra–ALARA protocol for RHC and EMB in pediatric cardiac transplantation patients markedly reduced radiation exposure to levels far below recently reported values without negatively affecting the safety or efficacy of these procedures.

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Alan Schoenfeld: This author has nothing to disclose.
Jacqueline Lamour: This author has nothing to disclose.

**D-021**

**Title:** Utility of 3-Dimensional Rotational Angiography in Assessing Airways During Catheterization-Based Intervention in Congenital Heart Disease

**Category:** Pediatric

**Authors:** Uyen Truong, M.D., University Of Colorado Denver, United States, Aurora, CO¹; Tom Fagan, M.D., University Of Colorado Denver, United States, Aurora, CO²; Brian Fonseca, M.D., University Of Colorado Denver, United States, Aurora, CO³; Jeffery Darst, M.D., University Of Colorado Denver, United States, Denver, CO⁴

**Introduction:** 3-dimensional rotational angiography (3DRA) has emerged as a promising tool for improved visualization of cardiac and vascular structures in congenital heart disease. This technique also allows multiplanar reconstruction (MPR) and volume rendering of airways.

**Methods and Materials:** In four cases, a 3DRA acquisition was obtained for airway anatomy.

**Results:** Two cases involved children with repaired truncus arteriosus and criss-cross pulmonary arteries who were scheduled to undergo surgical posterior pulmonary artery bifurcation side to side arterioplasty. This repair depends on an airway location which is posterior to the point at which the pulmonary arteries lose their close approximation. This anatomy was demonstrated on both the MPR and volume rendering of the 3DRA (Fig. A.)

The third case involved a child with bilateral proximal pulmonary artery stenoses referred for balloon angioplasty and possible stent placement. A baseline 3DRA showed close proximity to both branch pulmonary arteries to their respective bronchi. A 3DRA during balloon dilation of the proximal right pulmonary artery showed no airway compression and a stent was successfully placed. A 3DRA was obtained during balloon dilation of the proximal left pulmonary artery and the MPR showed significant superior compression of the left bronchus (Fig. B.) Bronchoscopy confirmed this finding and stent placement was not performed.

The fourth case involved a child with repaired double outlet right ventricle referred for diagnostic catheterization. During anesthesia induction, decreased aeration of the left lung was noted. Bronchoscopy demonstrated occlusion of the left bronchus due to pulsatile posterior compression. 3DRA demonstrated posterior extrinsic compression of left bronchus by the descending aorta which was confirmed by CT scan.

**Conclusion:** 3DRA can visualize airway anatomy and its relationship to vasculature accurately and in real time during interventional catheterization.

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Uyen Truong: This author has nothing to disclose.
Brian Fonseca: This author has nothing to disclose.
Jeffery Darst: This author has nothing to disclose.

**D-025**

**Title:** Self-Expanding Stent Implantation with Subsequent Overdilation; A Strategy to Treat Vascular Stenoses in Small Children Demonstrated in a Goat Model

**Category:** Pediatric

**Authors:** Thomas Fagan, M.D., University Of Colorado Denver, United States, Aurora, CO¹; Lisa Mangin, None, CVT, Colorado State University School of Veterinary Medicine, United States, Fort Collins, CO²; Mark Lovell, M.D., University Of Colorado Denver, United States, Denver, CO³; Janice Bright, None, DVM, Colorado State University School of Veterinary Medicine, United States, Fort Collins, CO⁴

**Background:** Strategies for stent placement in stenotic vessels of small children remain limited and suboptimal. Properties of certain self-expanding stents (SES) allow marked over-dilation (OD) and eventual fracture at low ATM (<2 in-vitro). We tested the feasibility of implantation and subsequent OD of SES in a goat model.

**Methods:** SES stents were implanted in native vessels of 2 infant goats (4.5 kg, 8.0 kg). At 7 mos and 8 mos (35 kgs, 31 kgs respectively) balloon expandable stents (BES) were placed within the SES and OD to
2X nominal SES diameter or size felt safe based on adjacent vessel diameter (AVD). Pre-OD and post-OD diameters were compared (paired-t). Gross pathologic and limited histologic evaluation was performed.

**Results:** 11 SES implants included: segmental pulmonary arteries (PA)-5mm (4) and 6mm Precise (2); central PAs-8mm Smart (1), 10mm Precise (1); SVC and IVC-8mm Smart (2); abdominal aorta-8mm Precise (1). 6 Fr sheaths were used for all SES. A 5mm and 10mm SES were shortened prior to implant secondary to anatomic constraints. At the OD procedures, 9 SES had OD. BES included PG 2510 (2), P308 (7), P188 (1). Median ATM required for OD was 14 (11-15). Mean vessel diameter increased from 6.3mm (4.4-8.9) (Fig. a) to 11.7mm (7.7-18.1) (Fig. b); median percentage increase of 175% (134-253); (paired-t:<0.001). Minimal growth of AVD occurred in both goats; median AVD/pre-OD stent diameter ratio of 136% (90-154). PA rupture occurred post OD of an 8mm SES; injury occurred at distal end of BES. Angiography and gross exam revealed no thrombus or excess intimal proliferation (Fig. c-e). Evidence of fracture was noted in 8/9 OD SES. With the exception of the PA rupture felt unrelated to SES, no injury extended deeper than the intima (Fig. c,e).

**Conclusion:** Self-expanding stent implantation with subsequent over-dilation at modest ATM is feasible allowing significant increase in vessel diameter. Stent fracture occurred with minimal injury to vessel wall.

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- Thomas Fagan: This author has nothing to disclose.
- Lisa Mangin: This author has nothing to disclose.
- Mark Lovell: This author has nothing to disclose.
- Janice Bright: This author has nothing to disclose.

**D-027**

**Title:** Utility of Pre-Procedural Checklists in the Cardiac Catheterization Laboratory

**Category:** Pediatric

**Authors:** Brent M. Gordon, M.D., Loma Linda University Medical Center, United States, Loma Linda, CA; Teresa Lam, M.D., Loma Linda University Medical Center, United States, Loma Linda, CA; Khaled Bahjri, M.D., MPH, Loma Linda University School of Public Health, United States, Loma Linda, CA; Aijaz Hashmi, M.D., Loma Linda University Medical Center, United States, Loma Linda, CA; Micheal A. Kuhn, M.D., Loma Linda University Medical Center, United States, Loma Linda, CA.

**Background:** Pre-procedure meetings have become more commonplace in medicine, but are not routinely performed in the cardiac catheterization laboratory. We sought to create, implement, and evaluate a pre-procedural meeting in the form of a checklist for the cardiac catheterization laboratory. Staff attitudes and perceptions toward safety and sense of team were also analyzed.

**Methods:** Cardiac catheterization laboratory (CCL) staff and anesthesiologists were surveyed at the beginning and end of the study period. Participants were asked scaled questions about safety, team climate, and the impact of errors. All procedures performed in the cardiac catheterization laboratory on patients with structural heart disease from July 2010 through August 2011 were retrospectively reviewed for patient demographics, types of procedure, and reported complications. A checklist was introduced to the pre-procedure protocol at the halfway point of the study period and groups were divided into a pre-checklist cohort (Group A) and post-checklist cohort (Group B). Data was analyzed with SPSS and all variables are reported as median with range unless otherwise noted. Significance was set at p <0.05.

**Results:** The total number of procedures (Group A = 217, Group B = 215), patient demographics, and inpatient vs. outpatient status did not differ significantly among groups. Proportion of diagnostic, interventional, and heart transplant patients undergoing annual evaluation were equivalent as were the total procedure and fluoroscopy time. Types of intervention did not differ significantly between groups with the exception of coarctation of the aorta (1.4% vs. 4.7%, p < 0.05). The number of complications (Group A = 8 vs. Group B = 7) and severity of complication (2, range 1-3 vs. 3, range 1-4) were equivalent among groups. There were no deaths in either group. CCL staff differed from anesthesiologists in perception of team climate, patient-related errors, and communication. CCL staff reported an increased awareness by being briefed before the procedure.
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Conclusion: A pre-procedure checklist for cardiac catheterization cases is easy to perform and improves staff awareness of patient condition. Further studies will be required to determine if this briefing could lead to better communication among services and reduce the number and severity of complications.

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Micheal A. Kuhn: This author has nothing to disclose.

D-031
Title: Pulmonary Artery Stents in Children <13 Years Old with Immediate and Long-term Outcome and Their Ability to Re-dilate with Growth
Category: Pediatric
Authors: Daisuke Kobayashi, M.D., Children’s Hospital of Michigan-Cardiology, United States, Detroit, MI; Daniel Turner, M.D., FACC, Children’s Hospital of Michigan-Cardiology, United States, Detroit, MI; Paul Knapp, None, Children’s Hospital of Michigan-Cardiology, United States, Detroit, MI; Thomas Forbes, M.D., FACC, Children’s Hospital of Michigan-Cardiology, United States, Detroit, MI; Srinath Gowda, M.D., Children’s Hospital of Michigan-Cardiology, United States, Detroit, MI.

Background: Pulmonary artery (PA) stents effectively relieve the stenosis in older children. However, long-term outcome of PA stents in young children remains unknown. We sought to evaluate immediate and long-term outcome of PA stents in children and the ability to re-dilate with somatic growth.

Methods: We retrospectively reviewed patients aged < 13 years old, who underwent pulmonary artery stents placement between Jan 1997-Nov 2011. Procedure and follow-up catheterization data, angiographic PA size measurements were manually measured and evaluated. The stents in children were grouped as dilatable and non-dilatable based on their ability to re-dilate to adult size with growth.

Results: A total of 84 patients (140 stents) underwent PA stents placement at the median age of 3.3 yr (22d-13y), female 49%, weight of mean 7.1 kg with growth. No patients had residual LV dilation (mean LVEDD z-score not noted to have elevated pulmonary vascular resistance (> 3 Wood Units per meter squared body surface area). The average PA diameter was 3.9±0.7mm. AVPII device size was chosen to be approximately 50% greater than the PDA diameter, with a mean AVPII to PDA diameter ratio of 1.54±0.07. Complete occlusion was documented angiographically in all patients. There was no evidence of aortic arch or branch pulmonary artery obstruction. There were no complications. All patients had an echocardiogram 24 hours post-catheterization. 5 patients had complete PDA occlusion, with 1 having a trivial residual shunt seen by color Doppler. The median duration of follow up was 7 97 (range 1-15). At most recent follow up, all patients had complete PDA occlusion with no residual shunt seen by echocardiogram.

Conclusion: Transcatheter occlusion of a PDA with the AVPII is safe and effective in smaller patients and should be considered for tubular PDA morphology where other approved devices may not be suitable.

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Daisuke Kobayashi: This author has nothing to disclose.
Daniel Turner: This author has nothing to disclose.
Paul Knapp: This author has nothing to disclose.
Thomas Forbes: This author has nothing to disclose.
Srinath Gowda: This author has nothing to disclose.

D-038
Title: Percutaneous Closure of a Patent Ductus Arteriosus in Infants and Small Children Using the Amplatzer Vascular Plug II
Category: Pediatric
Authors: Gary Stapleton, M.D., All Children’s Hospital, United States, St Petersburg, FL.

Introduction: Transcatheter occlusion of a patent ductus arteriosus (PDA) is the preferred method of closure in most patients. However, occlusion of the tubular shaped (Type C) PDA can be challenging, particularly in smaller patients. The Amplatzer Vascular Plug II (AVPII) is indicated for closure of various peripheral vascular malformations and may be used as an alternative device for transcatheter PDA closure.

Methods: We retrospectively analyzed data from patients who underwent transcatheter closure of a PDA with the AVPII at All Children’s Hospital from 2010-11.

Results: 6 patients (4 female) underwent transcatheter PDA closure with an AVPII. The median age was 7.5 months (range 1-26), with a mean weight 7.1±2.5kg (range 3.4-10.4). 4 patients had left ventricular (LV) dilation (LV end-diastolic dimension (LVEDD) z-score > 2) by echocardiogram. All 6 patients had tubular PDA morphology demonstrated by angiography. The mean Qp:Qs was 2.6±0.9. The average estimated pulmonary artery pressure had decreased by 50% compared to initial result (initial vs. final cath), median follow-up duration of 2.7yrs (6d-12.2yr).

Conclusion: Transcatheter occlusion of a PDA with the AVPII is safe and effective in smaller patients and should be considered for tubular PDA morphology where other approved devices may not be suitable.

Disclosures:
Gary Stapleton: This author has nothing to disclose.
D-039

Title: Sternotomy as a Safe Alternative ‘Access’ for Transluminal Interventions in Low Birth Weight infants

Category: Pediatric

Authors: Marc Gewillig, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven1; Bjorn Cools, M.D., University of Leuven, Belgium, Belgium, Leuven2; Derize Boschoff, M.D., University of Leuven, Belgium, Belgium, Leuven3; Ruth Heying, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven4; Filip Rega, M.D., Ph.D., University of Leuven, Belgium, Belgium, Leuven5; Bart Meys, M.D., Ph.D., University of Leuven, Belgium, Belgium, leuven6

Background: Low birth weight infants with congenital heart defect remain a therapeutic challenge. Prolonged administration of prostaglandin and surgical options yield high morbidity and mortality; vascular access for percutaneous interventions may seriously damage vessels required for later procedures.

Patients and Methods: 4 patients: hybrid suite; sternotomy.

A/3 patients (weight 1620, 2190 & 2630 g) extreme Fallot – pulmonary atresia with hypoplasia pulmonary trunk (2-3 mm); purse string on the right ventricle; 2 vascular clips as radio-opaque markers; one at the pulmonary valve annulus, one at the puncture site. Double needle technique: 2 identical 21G needles: 1 needle as a reference adjacent on the surface of the RVOT; the other needle was used to perform the puncture. Puncture under direct vision in two motions: first access perpendicular to the surface for 10-15 mm into RV, second angulation of the needle towards and through the atretic outflow tract into the pulmonary trunk. 0.014” coronary wire into the pulmonary arterial branch; needle exchanged for a 4 Fr short sheath; angiography by mini lcc injections through side-arm; premounted coronary stent deployed in RVOT 5/16 mm to obtain an “intracardiac Sano shunt”; sheath and clips removed.

B: 1 patient (900g) with critical aortic coarctation and open duct under PG; purse-string on the ascending aorta with radiomarker clip; puncture with 21G needle; 0.014” wire into the descending aorta; needle exchanged for a 4 Fr short sheath with the tip at the aortic cross. A 3/8 mm coronary stent deployed into the aortic isthmus (from LSA until beyond coarctation); arterial duct clipped.

Results: Fallot: adequate palliation with good anterograde flow to pulmonary arteries (sat> 92%). After a median of 3 months additional transvenous stenting required in all patients because of progressive muscular infundibular stenosis. Two patients evolved to full repair at 5 months; one patient with multiple hilar stenoses requires additional percutaneous procedures through the stented RV outflow tract. Coarctation: good aortic flow, stent resected at 4 months. No associated morbidity as frequently seen in premature infants with CHD.

Conclusion: Medial sternotomy can be a safe alternative access for bail out transluminal cardiac interventions in low birth weight infants allowing conventional repair at bigger weight. The technique with 2 identical needles and radio-opaque markers markedly simplifies the hybrid procedures.

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Derize Boschoff: This author has nothing to disclose.
Ruth Heying: This author has nothing to disclose.
Filip Rega: This author has nothing to disclose.
Bart Meys: This author has nothing to disclose.

D-040

Title: Transcatheter Management of Failed Melody Valve After Successful Placement

Category: Pediatric

Authors: Yashu Coe, M.B.B.S., MD FRCP(C) FACC FAHA, University of Alberta, Canada, Edmonton, AB1; Dylan Taylor, M.D., FRCP(C), University of Alberta Hospital, Canada, Edmonton, AB2

Background: Transcatheter replacement of pulmonary valves with Melody valve is an accepted therapy in select patients with failed right ventricular – pulmonary artery (RV-PA) homograft or pulmonary prosthetic valve. Short term result is excellent but mid & late outcome is unknown. Evaluation of the durability and longevity of the Melody valve is ongoing. This study examined the Melody valve failure after successful placement. Failure is defined as symptomatic recurrence of significant stenosis ± regurgitation.

Methods: Since July 2006, 62 of 63 Melody valves had been successfully implanted in 55 patients. The valves have failed in 6 patients 0.4-4.5 (mean 2.6, median 2.3) years after successful implant. Three of the six were pre-stented before valve replacement. One failed Melody valve was replaced surgically and one await cardiac catheterization. The remaining 4 patients underwent transcatheter placement of another Melody valve after evaluation by CT-angiography. All were pre-stented before replacing successfully with another Melody valve.

Results: There was no mortality, vascular or myocardial injury. The valves narrowed from a mean diameter of 19.7 (range 18-22, median 19.0) mm in diameter after the first Melody valve, to a mean of 11.4 (range 9-15, median 10.8) mm. All valve stents were fractured, spontaneous in two, and after high impact chest contact activity in the others. One was inadequately expanded at first Melody valve implant, and two were pre-stented. The ensuing significant stenosis was reduced from 46-64 (mean 56, median 57) mmHg to 15-34 (mean 22, median 17) mmHg after the second Melody valve implant. All new Melody valves were competent.

Conclusion: We conclude that it is feasible to manage failed Melody valves by transcatheter placement of a second Melody valve, thereby prolonging the lifespan of the original RV-PA conduit and avoiding another open heart procedure.

Disclosures:
Yashu Coe: This author has nothing to disclose.
Dylan Taylor: This author has nothing to disclose.

D-043

Title: Morphology of Inter Atrial Defects Created by Different Interventionsal Techniques in an Animal Model.

Category: Pediatric

Authors: Holly DeSena, M.D., UTSW Medical Center, United States, Dallas, TX1; Surendranath Reddy Veeram Reddy, M.D., UTSW Medical Center, United States, Dallas, TX; Jian Wang, M.D., Ph.D., UTSW Medical Center, United States, Dallas, TX; Te’ Welch, Ph.D., UTSW Medical Center, United States, Dallas, TX1; Joseph Forbess, M.D., UTSW Medical Center, United States, Dallas, TX1; Alan Nugent, M.B.B.S., UTSW Medical Center, United States, Dallas, TX

Background: Patients with certain forms of congenital heart disease require an inter atrial defect (IAD) to provide adequate mixing of blood and/or prevent left atrial hypertension. Several interventional methods for creation or enlargement of an IAD are described; however, no formal evaluation as to the size of defect created by each method has been previously performed.
Methods: The atrial septum of five neonatal piglets (age 1-3 days, weight 1-1.5 kg) was exposed following euthanasia. An IAD was created with a needle puncture and dilated using a 3mm standard angioplasty balloon (Maverick(R) Boston Scientific), 3mm cutting balloon (Flextome Cutting Balloon(TM) Boston Scientific) and 3mm cryoplasty balloon (PolarCath(TM) Boston Scientific). This technology is designed to induce apoptosis by freezing intracellular fluid. A 3mm coronary stent (Multi-Link Vision(R) Abbott Vascular) was inflated across a patent foramen ovale (PFO). All balloons were inflated to rated burst pressure. Finally a balloon atrial septostomy was performed with 2cc volume (Miller Edwards(R), Edwards Lifescience) via a PFO. Direct measurements of the size of the IAD and photographs were obtained.

Results: In the created IAD, the angioplasty balloon created a 3mm circular IAD (Figure A), the cutting balloon produced a 2mm triangular IAD corresponding to the 3 atherotomes (Figure B) and the cryoplasty balloon created an oval 4 x 5 mm IAD (Figure C). Both the 3mm stent in a PFO and the septostomy created a 3mm circular IAD (Figures D,E).

Conclusion: The cryoplasty balloon created the largest IAD of all interventional techniques and potentially could be an option for creating an IAD in humans. The surprising finding was the defect was larger than the balloon diameter.

Disclosures: Holly DeSena: This author has nothing to disclose. Surendranath Reddy Veeram Reddy: This author has nothing to disclose. Jian Wang: This author has nothing to disclose. Tre’ Welch: This author has nothing to disclose. Alan Nugent: This author has nothing to disclose.

CO-004

Title: A 15-year Experience of Stent Implantation for Coarctation of the Aorta
Category: Pediatric

Authors: Matthew Crystal, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX; William Payne, None, Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX; Henri Justinio, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX; Frank Ing, M.D., Baylor College of Medicine, Texas Children’s Hospital, United States, Houston, TX

Background: Percutaneous therapeutic options for discrete coarctation of the aorta include balloon angioplasty or stent implantation.

Methods: Retrospective review of all patients with CoA of the aorta who were treated by percutaneous stent implantation from March 1997 to February 2011 in our institution. Data obtained by chart review included demographics, clinical data including catheterization (cath) and surgery.

Results: A total of 69 patients (41 males) received a stent. Median weight 49.3kg (range 10.5-100kg). A genetic syndrome was present in 7 patients (Noonan 1, Williams 4, Turner 1, DiGeorge 1). All patients had a left aortic arch, 4 aberrant right subclavian arteries. 27 patients had prior CoA surgery (subclavian flap 6, end-to-end anastamosis 11, interposition graft 2, patch aortoplasty 4, unspecified 4). Prior cath including balloon angioplasty in 18 patients. CoA gradient decreased from 30.1/C6 16.3 mmHg to 1.3/C6 14.2 mmHg (p < 0.001) and minimum CoA diameter increased from 6.8/C6 3.6 mm to 12.7/C6 3.4 (p < 0.001). Stents were implanted on a median maximal balloon diameter 14 mm (range 8-22), with a balloon:CoA diameter ratio 2.7/C6 1.7, (range 1.1-10). Complications (12) were experienced in 11 patients with 1 major (stroke), 11 minor (5 stent malpositions, 4 groin hematomas, 1 pericardial effusion and 1 SVT during transseptal puncture). T-test showed patients with prior CoA surgery (subclavian flap 6, end-to-end anastamosis 11, interposition graft 2, patch aortoplasty 4, unspecified 4). Prior cath including balloon angioplasty in 18 patients. CoA gradient decreased from 30.1 ± 16.3 mmHg to 1.3 ± 14.2 mmHg (p < 0.001) and minimum CoA diameter increased from 6.8 ± 3.6 mm to 12.7 ± 3.4 (p < 0.001). Stents were implanted on a median maximal balloon diameter 14 mm (range 8-22), with a balloon:CoA diameter ratio 2.7 ± 1.7, (range 1.1-10). Complications (12) were experienced in 11 patients with 1 major (stroke), 11 minor (5 stent malpositions, 4 groin hematomas, 1 pericardial effusion and 1 SVT during transseptal puncture). T-test showed patients with prior surgery had a smaller CoA minimum diameter (p = 0.01) and a higher pre-stent gradient (p = 0.04). At mean follow-up of 3.4 ± 2.7 years balloon:CoA diameter ratio, age, complications and any antihypertensive medications were not statistically correlated with outcomes. Baseline right arm systolic blood pressure was noted to decrease from 134.4 ± 17.9 mmHg to 126.1 ± 18.9 mmHg at most recent clinic visit (p = 0.015). Univariate analysis demonstrated increased age at time of intervention to be highly associated with higher right arm BP at most recent follow-up (p = 0.001). Overall, one patient died of non-cardiac related causes. One patient developed significant aneurysm formation.
Title: Atrial Septal Shortening – Expected Values and Effect of Septal Defect Closure Devices

Category: Pediatric

Authors: Christopher Bellotti, M.D., Cleveland Clinic, United States, Cleveland, OH; Larry Latson, M.D., Joe DiMaggio Children’s Hospital, United States, Hollywood, FL.

Abstract: The extent of atrial septal shortening throughout the cardiac cycle has not been previously systematically measured. Intuitively any intrinsic shortening may affect atrial septal defect (ASD) devices and the devices may affect atrial septal shortening. The purpose of this study was to investigate septal shortening in patients with an ASD before and after device closure using two different devices.

Methods: The study population consisted of 94 consecutive patients, ages 5-77 with a sole diagnosis of secundum type ASD who had device closure between November 1998 and September 2009 with either an Amplatzer Septal Occluder or HELEX Septal Occluder. Two-dimensional echocardiography was used to evaluate the pre- and post-device shortening of the atrial septum. The atrial septal length was measured in two standard views, at end atrial systole and end atrial diastole. The pre-closure measurements were compared to post device closure measurements.

Results: Our data demonstrates that the atrial septum shortens by an average of 30% (31.7% +/- 14.7%) during atrial systole, and the placement of a device in the septum reduces the atrial septal shortening fraction significantly to 18.8% (+/-9.9%, p<0.001).

Conclusion: The echocardiographic measurement of atrial length changes significantly during the cardiac cycle. Placement of an ASD septal occlusion device alters the measured atrial septal shortening. Further investigation of this phenomenon may be helpful to evaluate the long term effects of atrial septal shortening on an ASD closure device, and whether alterations in shortening by a device may be associated with any long term deleterious effects.

Disclosures:

Christopher Bellotti: This author has nothing to disclose.
Larry Latson: W.L. Gore, 2. Research Grants

CO-005

Title: Magnetically Assisted Fetal Cardiac Interventions: Antegrade Aortic Valve Dilation in a Fetal Lamb

Category: Pediatric

Authors: Alan Nugent, M.B.B.S., Children’s Medical Center of Dallas, United States, Dallas, TX; Adrian Dyer, M.D., Children’s Medical Center of Dallas, United States, Dallas, TX; Reenu Eapen, M.D., Baylor university medical center dallas, United States, Dallas, TX; Catherine Ikemba, M.D., Children’s Medical Center of Dallas, United States, Dallas, TX; Robert Kowal, M.D., Baylor Heart and Vascular Hospital, Dallas, TX, United States, Dallas, TX; Michael Talcott, None, DVM, DAACLAM, Washington University St Louis, United States, St Louis, MO; Kevin Magee, M.D., Baylor university medical center dallas, United States, Dallas, TX.

Abstract: Fetal cardiac interventions via direct transthoracic approach are reported. Despite refinements there are major limitations: fetal lie, hemopericardium, bradycardia and resuscitation. In many cases reversion to maternal laparotomy is necessary. The transhepatic route has been reported in animal models with laparotomy, but not antegrade aortic valve access. The aim is to develop a technique for antegrade aortic valve dilation in a fetal lamb model without maternal laparotomy or fetal perventricular puncture.

Methods: 4 pregnant ewes 110-120 days gestation were placed under general anesthesia. Using percutaneous ultrasound guidance various access sites were tested: umbilical vein, hepatic vein and right atrium. Via the introducer a magnetically steerable 0.014 wire was manipulated to the right atrium, left atrium, left ventricle and into the descending aorta.

Results: The initial 2 fetuses had access in all 3 sites with a 20G needle. The umbilical vein course was tortuous and while magnetic navigation made access to the heart possible, the technical difficulty and time spent were major disadvantages. Direct right atrial puncture caused immediate hemopericardium as expected. The transhepatic route was clearly superior and enabled direct passage of the wire. With magnetic navigation, manipulation of the 0.014 wire was successful across the aortic valve in both. The next fetus a 4Fr sheath was used for passage of both wire and balloon across maternal skin/uterus and fetal skin. After obtaining transhepatic access with an 18G needle, the sheath was advanced over a wire. Balloon delivery and inflation across the aortic valve was achieved. The final lamb had an unknown venous anomaly, ventricular hypertrophy and tachycardia and expired.

Conclusion: Fetal antegrade aortic valve dilation is feasible via transhepatic route. The potential advantages applicable to humans are less maternal morbidity and avoidance of the complications of direct cardiac puncture.

Disclosures:

Alan Nugent: This author has nothing to disclose.
Adrian Dyer: This author has nothing to disclose.
Reenu Eapen: This author has nothing to disclose.
Catherine Ikemba: This author has nothing to disclose.
Robert Kowal: This author has nothing to disclose.
Michael Talcott: Stereotaxis, 5. Consulting Fees or Other Remuneration
Kevin Magee: This author has nothing to disclose.
CO-001
Title: Outcome of Endovascular Stent Implantation in Infants with Congenital Heart Disease
Category: Pediatric

Introduction: Endovascular stents are useful to relieve vessel stenoses, however there are challenges to the use of small stents in infants. We sought to describe outcomes of stents implanted in infants with congenital heart disease.

Methods: Pts <2y who had stents <6mm in diameter implanted over a 10y period were included. Stents placed in shunts, conduits, outflow tracts, atrial septae and arterial ducts were excluded. Outcomes were analyzed based on stent type: coronary stent (CS) vs non-coronary stent (NCS); and type of vessel stented: pulmonary artery (PA), pulmonary vein (PV), systemic artery (SA) and systemic vein (SV). Re-interventions (RI) included balloon angioplasty (BA), cutting balloon (CB), and implantation of a larger stent with or without unzipping. Unzipping is done by high-pressure BA to cause a longitudinal fracture. Primary outcomes were refractory re-stenosis (RRS) (ratio of minimal stent luminal diameter compared to distal vessel diameter after last intervention) and in-stent stenosis (ISS) (ratio of minimal luminal diameter to outer stent diameter at any follow-up). Significant stenoses were defined as >30%.

Results: 44 (40%) CS and 66 (60%) NCS were implanted in 87 pts; 64 in PA, 13 in PV, 9 in SA and 24 in SV. Median age at initial intervention was 18.3 months (3.5 months – 19.5 years) and median weight was 8.5 kg (2.8 – 47.7 kg). Follow-up data was available for 56 of these interventions with a median follow-up of 3.8 months (0.6 months – 3.3 years). There was a significant increase in pulmonary vein diameters from 2.3 ± 1.0 mm to 4.1 ± 1.4 mm (p < 0.0001) and a decrease in pulmonary vein gradient by 14.1 ± 9.0 mmHg to 4.5 ± 3.2 mmHg (p < 0.0001) immediately following CB. Stroke occurred within 24 hours of CB in one patient. Thirty-five reinterventions for PVS were required at follow-up, including further cryoplasty (18), standard balloon angioplasty (3), stent angioplasty (4), sutureless surgical repair (5), and lung transplantation (5). Two veins were found to be completely atretic at follow-up. Freedom from reintervention was 57.4% at 6 months and 33.1% at 12 months. Multivariate analysis demonstrated that reintervention was less likely to be required in patients with previous history of CB.

Conclusion: CB is safe and effective for the immediate relief of PVS, but carries a high rate of restenosis at follow-up requiring reintervention. Subsequent applications of this therapy are less likely to require reintervention than are initial interventions.

Disclosures:
Michael J. Angtuaco: This author has nothing to disclose.
Jeffrey R. Darst: This author has nothing to disclose.
Thomas E. Fagan: This author has nothing to disclose.

CO-003
Title: Outcomes of Cryo-balloon Angioplasty for the Treatment of Pulmonary Vein Stenosis
Category: Pediatric
Authors: Michael J. Angtuaco, M.D., University Of Colorado Denver, United States, Denver, CO; Jeffrey R. Darst, M.D., University Of Colorado Denver, United States, Denver, CO; Thomas E. Fagan, M.D., University Of Colorado Denver, United States, Denver, CO

Background: Current treatment options for pulmonary vein stenosis (PVS) are limited by a high rate of restenosis after intervention. Cryo-balloon angioplasty (CBa) delivers cold therapy in addition to mechanical dilation, theoretically interrupting the cellular processes leading to neo-intimal hyperplasia and restenosis. We sought to determine whether the serial application of this therapy to patients with PVS is effective in preventing restenosis.

Methods: We performed a retrospective review of medical records of children and young adults undergoing CBa for PVS, collecting demographic data, clinical history, angiographic measurements, and hemodynamics from catheterization, including both information from the original intervention, repeat intervention, and follow-up evaluation.

Results: Fifty-nine separate CBa procedures were performed for PVS between August 2005 and November 2011. Thirty-eight veins were intervened upon in 24 patients (17 with primary PVS, 7 with post-surgical PVS), with 17 patients requiring intervention on more than one pulmonary vein. Also, of these 38 pulmonary veins, 13 underwent multiple CBa interventions. Median age at initial intervention was 18.3 months (3.5 months – 19.5 years) and median weight was 8.5 kg (2.8 – 47.7 kg). Follow-up data was available for 56 of these interventions with a median follow-up of 3.8 months (0.6 months – 3.3 years). There was a significant increase in pulmonary vein diameters from 2.3 ± 1.0 mm to 4.1 ± 1.4 mm (p < 0.0001) and a decrease in pulmonary vein gradient by 14.1 ± 9.0 mmHg to 4.5 ± 3.2 mmHg (p < 0.0001) immediately following CBa. Stroke occurred within 24 hours of CBa in one patient. Thirty-five reinterventions for PVS were required at follow-up, including further cryoplasty (18), standard balloon angioplasty (3), stent angioplasty (4), sutureless surgical repair (5), and lung transplantation (5). Two veins were found to be completely atretic at follow-up. Freedom from reintervention was 57.4% at 6 months and 33.1% at 12 months. Multivariate analysis demonstrated that reintervention was less likely to be required in patients with previous history of CBa.

Conclusion: CBa is safe and effective for the immediate relief of PVS, but carries a high rate of restenosis at follow-up requiring reintervention. Subsequent applications of this therapy are less likely to require reintervention than are initial interventions.

Disclosures:
Sharna Basu: This author has nothing to disclose.
Yoav Dori: This author has nothing to disclose.
Jonathan Rome: This author has nothing to disclose.
Methods: Single center retrospective review of all pts who under-went catheterization with the use of 3DRA to image complex dysfunc-tional RVOTs. 3DRA acquisition entailed a 5 second injection of non-dilute or dilute contrast while sequential images were acquired during a 200° rotation of the AP camera. Images were retrospectively assessed for diagnostic quality and compared with corresponding 2DA.

Results: Between 1/2010 – 9/2011, 98 3DRA’s were performed in 88 pts undergoing evaluation of dysfunctional RVOTs. Median age was 9.5yrs (20days–44.3yrs) and median weight was 28.5kg (2.7–108.6). Sixty-two pts had prior conduit surgery and 26 pts had prior RVOT patch reconstruction. 3DRA was performed in the RV apex (46), conduit (30), or RVOT (22). Heart rate was manipulated during acquisition in 76 (78%) cases: rapid RV pacing (64), bolus IV adenosine (12). Median contrast dose for 3DRA and total case was 1.5 ml/kg (0.4–2.8) and 6.8 ml/kg (1.7–16.5), respectively. 3DRA’s were diagnostic in 78 (80%), partially diagnostic in 11 (11%) and non-diagnostic in 9 (9%). Charac-terization of the variable RVOT morphologies into one of five previ-ously defined categories was reproducible in 77 of the diagnostic studies. Seventy-one pts underwent catheter-based interventions: pulmonary valve implantation (30), stent implantation (16), balloon angioplasty (25). When compared to 2DA, 3DRA provided additional diagnostic in-formation in 62 of these pts; including optimal gantry angles to profile area of interest, more precise relationship of proximal BPA’s to the RVOT, and the relationship of the RVOT to surrounding extracardiac structures. One pt experienced ventricular fibrillation with cessation of RV pacing requiring cardioversion. No other complications occurred.

Conclusion: 3DRA is safe and can be used to accurately assess and characterize complex RVOTs and its adjoining structures. 3DRA has the potential to play a critical role in the real-time assessment of pt candi-dacy for catheter-based RVOT rehabilitation.

Disclosures:
Federica Sidoti: This author has nothing to disclose.
Darren Berman: This author has nothing to disclose.
Jonathon Steinman: This author has nothing to disclose.
Yunin Gutierrez: This author has nothing to disclose.
Evan Zahn: This author has nothing to disclose.

CO-007

Title: The Use of the Immediate Release Patch Plug in Left and Right Ventricular Perventricular Interventions in Piglets

Category: Pediatric

Authors: Basilios Sideris, B.S.N., Athenian Institute of Pediatric Cardiology, Greece, Athens; Eleftherios Sideris, M.D., Athenian Institute of Pediatric Cardiology, Greece, Athens; Keyhan Sayadpour Zanzani, M.D., Tehran University of Medical Sciences, Iran; Demetrios Bramos, M.D., Athenian Institute of Pediatric Cardiology, Greece, Athens; Savvas Toumanides, M.D., Department Clinical Therapeutics University of Athens, Greece, Athens; Spyridon Moulopoulos, M.D., Department Clinical Therapeutics University of Athens, Greece, Athens

Background: Perventricular (PV) interventions are usually performed through a surgical thoracotomy, A modified immediate release patch (IRP) could be conceivably applied as a myocardial plug (MP) after PV interven-tions, avoiding surgical morbidity. The purpose of this study was to assess the safety and efficacy of the IRP as a MP in 20 PV interventions in piglets.

Method: The IRP MP consists of a polyurethane patch placed as a sleeve over a Latex detachable balloon, a floppy wire attached on the tail of the patch, and a bio-absorbable thread. The IRP is inserted through the same sheath following the PV procedure, inflated to 10mm in diameter, detached and then pulled against the residual myocardial opening. It is immobilized by the floppy wire on the epicardium as well as by the bio-absorbable thread, which is sutured sub-cutaneously on the chest. Fifteen MP’s were used after left ventricular PV procedures, including transcatheter aortic valves and aortic covered stents. Five right ventricular PV interven-tions were performed, including application of flow restrictors and pul-monic valves. The procedures were performed through 11-14F sheaths in 11-15kg piglets. The animals were followed for periods ranging from 24hrs to two months. Autopsies were performed in all animals.

Results: All animals survived the procedure with full occlusion of the residual myocardial opening. A leaking device was retrieved and replaced immediately after detachment (prior to sheath withdrawal). Two cases with chest infection were noticed. Minor bleeding and transient EKG changes during pericardial puncture were noticed in most cases. The device was well endothelialized after two weeks, as seen in autopsy, with smooth reconstruction of the opening.

Conclusion: Non-surgically applied IRP MP’s appear to be effective and safe after left and right PV experimental procedures. The bio-absorbable IRP is easy to use and has a good anatomic result. Carefully designed clinical trials should assess the safety of perventricular procedures using myocardial plugs as an alternative to surgery.

Disclosures:
Basilios Sideris: This author has nothing to disclose.
Eleftherios Sideris: patent holder, Others.
Keyhan Sayadpour Zanzani: This author has nothing to disclose.
Demetrios Bramos: This author has nothing to disclose.
Savvas Toumanides: This author has nothing to disclose.
Spyridon Moulopoulos: This author has nothing to disclose.

PHARMACOTHERAPY

A-017

Title: Telephone Contacts to Improve Adherence to Dual Anti-Platelet Therapy Following Drug-Eluting Stent Implantation; A Randomized Controlled-Trial

Category: Pharmacotherapy

Authors: Ste´phane Rinfret, M.D., S.M., Quebec Heart and Lung Institu-tute, Canada, Quebec, QC1; Rodrigo Bagur, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC2; Josep Rodés-Cabau, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC3; Jean-Pierre Déry, M.D., M. Sc., Quebec Heart and Lung Institute, Canada, Quebec, QC4; Eric Lar-ose, M.D., D.M.V., Quebec Heart and Lung Institute, Canada, Quebec, QC5; Marc Dorais, None, M.Sc., StatSciences, Canada, Montreal, QC6; Gerald Barbeau, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC7; Onil Gleenon, M.D., Quebec Heart and Lung Institu-tute, Canada, Quebec, QC8; Can Manh Nguyen, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC9; Bernard Noël, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC10; Guy Proulx, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC11; Rodrigo Bagur, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC12; Louis Roy, M.D., Quebec Heart and Lung Institute, Canada, Quebec, QC13; Marc Dorais, None, M.Sc., StatSciences, Canada, Montreal, QC14; Isabelle Taillon, None, M.Sc., Quebec Heart and Lung Institute, Canada, Quebec, QC15; Olivier Bertrand, M.D., Ph.D., Quebec Heart and Lung Institute, Canada, Quebec, QC16.

Background: Previous studies have shown that many patients either delay or interrupt dual antiplatelet therapy (DAT) following drug-eluting stent (DES) implantation. We tested the hypothesis that a simple approach consisting of telephone contacts would improve DAT adherence.
Methods: The Early discharge After transradial Stenting of Coronary Artery-Y-IMPoving Adherence to Clopidogrel Trial (EASY-IMPACT) (NCT01134679) was an open-label, single center, randomized controlled trial that recruited patients immediately after DES implantation and who had no contraindication for 12-month DAT. Patients were randomized to one of the 2 groups: intervention, with telephone follow-up vs. control. In the intervention group, phone calls were made within 7 days of implantation, and at 1, 6 and 9 months to assess drug adherence, reminding the importance of DAT. Control patient were followed as per usual clinical practice. Both groups were briefed on the importance of DAT adherence prior to discharge. Individual pharmacy data were collected to assess drug filling and refill. Primary endpoint was the proportion of days covered with aspirin and clopidogrel over the 12 month period following discharge.

Results: A total of 300 patients were randomized. Mean age was 63 years, 73% were male, and 35% diabetics. They received a median of 2 DES. Most patients (73%) underwent DES implant in the context of an acute coronary syndrome. All patients had drug insurance coverage, either from the public plan (59%) or through private plans (41%). Complete pharmacy follow-up data was available in 98%. At 12 months, median adherence to aspirin and clopidogrel were 99.2% (IQR 97.5%-100%) and 99.2% (IQR 97.5%-100%) in the intervention group compared to 90.2% (IQR 84.2%-95.4%) and 91.5% (IQR 85.1%-96.0%) in the control group (Wilcoxon-Mann-Whitney two-sided p-value <0.0001 for ASA and clopidogrel).

Conclusion: A simple and low-cost approach of 4 telephone contacts with patients following DES implantation significantly improves one-year drug adherence to near perfect scores.

Disclosures:
Stéphane Rin fret: BMS-sanofi, 5. Consulting Fees or Other Remuneration, BMS-sanofi, 2. Research Grants
Rodrigo Bagur: This author has nothing to disclose.
Josep Rodés-Cabau: This author has nothing to disclose.
Jean-Pierre Dixy: This author has nothing to disclose.
Eric Larose: This author has nothing to disclose.
Jessie Michouluk: This author has nothing to disclose.
Marc Dorais: This author has nothing to disclose.
Gerald Barbeau: This author has nothing to disclose.
Onil Gleeton: This author has nothing to disclose.
Can Manh Nguyen: This author has nothing to disclose.
Bernard Noël: This author has nothing to disclose.
Guy Proulx: This author has nothing to disclose.
Rodrigo Bagur: This author has nothing to disclose.
Louis Roy: This author has nothing to disclose.
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Marc Dorais: This author has nothing to disclose.
Isabelle Taillon: This author has nothing to disclose.
Robert De Larochellière: This author has nothing to disclose.
Robert De Larochellière: This author has nothing to disclose.
Olivier Bertrand: This author has nothing to disclose.

A-029

Title: Comparison of Bivalirudin to Heparin and Glycoprotein IIB/IIIa Inhibitors in Patients Undergoing PCI: In-Hospital Results from the TAXUS Liberte Post-Approval Study

Category: Pharmacotherapy

Authors: Robert Kumar, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Aditya Mangla, D.O., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Joseph Puma, D.O., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; David Lee, M.D., Stanford University Medical Center, United States, Stanford, CA; Kenneth Winters, M.D., Eli Lilly and Company, United States, Indianapolis, IN; Thomas Bowman, M.D., MPH, Boston Scientific Corp, United States, Marlborough, MA; Kirk Garratt, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY

Background: Bivalirudin, when compared to heparin and glycoprotein Iib/IIIa inhibitors (GPIs) in patients undergoing PCI, is associated with a reduction in bleeding events and similar overall efficacy, but with a higher rate of acute stent thrombosis in patients undergoing primary PCI for STEMI. These studies were performed in patients predominantly receiving antiplatelet therapy with aspirin and clopidogrel. The performance of bivalirudin compared to heparin and GPIs in a broader patient population, including those who receive therapy with the newer thienopyridine agent prasugrel, is unknown.

Methods: The TAXUS Liberte Post-Approval Study is a prospective, multicenter registry examining 5-year clinical outcomes in patients with implanted TAXUS Liberte® stents and concomitant prasugrel therapy. The initial cohort enrolled into this registry reflects a “real-world” population of patients undergoing PCI with current DES usage patterns and modern stent technology. For this analysis, 1933 patients who received bivalirudin and 354 patients who received heparin and a GPI were studied, and in-hospital outcomes in these groups were compared.

Results: Baseline demographics were similar between the two groups (Bivalirudin vs. GPI: age 59.4y vs. 58.2y, male 71.8% vs. 73.4%, weight 93.0kg vs. 91.1kg). Patients in the GPI group had higher rates of MI as the clinical presentation (54.0% vs. 20.5% bivalirudin), intracoronary thrombus (23.3% vs. 5.9% bivalirudin), and cardiogenic shock (2.0% vs. 0.1% bivalirudin). At the time of PCI, 70.9% of patients in the GPI group and 67.4% of patients in the bivalirudin group received a loading dose of prasugrel. All patients were discharged on prasugrel. In-hospital event rates were low, and similar between groups (Death 0% in both groups; ARC-defined MI 2.5% GPI vs. 0.4% bivalirudin, p = 0.62; ARC-defined stent thrombosis 0.3% GPI vs. 0.5% bivalirudin, p = 1.0). Rates of major bleeding (GUSTO moderate or severe) were also low and similar between groups (0.6% GPI vs. 0.4% bivalirudin, p = 0.66).

Conclusion: In real-world patients undergoing PCI with DES who predominantly receive antiplatelet therapy with prasugrel, the use of bivalirudin is associated with low and similar in-hospital event rates when compared to the use of heparin and glycoprotein Iib/IIIa inhibitors. These patients will continue to be followed to assess longer-term outcomes.

Disclosures:
Robert Kumar: This author has nothing to disclose.
Aditya Mangla: This author has nothing to disclose.
Joseph Puma: This author has nothing to disclose.

B-006

Title: Point-of-Care Platelet Reactivity Determination with VerifyNow-P2Y12® Following Administration of Clopidogrel or Prasugrel: Data From a Real-World Clinical Care Setting

Category: Pharmacotherapy

Authors: Sean Cannistrilli, Ph.D., RTI Health Solutions, United States, Research Triangle Park, NC; Jay Bae, Ph.D., Eli Lilly and Company,
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**Background:** VerifyNow-P2Y12® (VN-P2Y12) is a point-of-care device that measures platelet reactivity. Past assessments of thienopyridine therapy utilizing VN-P2Y12 have largely come from well-controlled, clinical trial settings. Consequently, limited data are available describing the use of this technology in a “real-world” setting. This study sought to describe VN-P2Y12 results from patients treated with either clopidogrel or prasugrel who were seeking care in a hospital setting.

**Methods:** Clinical and administrative data were collected and analyzed for patients admitted to Huntsville Hospital (Huntsville, Alabama, USA) and who underwent VN-P2Y12 testing between 1/1/2009, and 10/31/2010. VN-P2Y12 data included P2Y12 reaction units (PRU) and device-reported % inhibition. Other data assessed included patient demographics, co-morbidities, clinical history, and use of antiplatelet and other concomitant medications. Descriptive analyses were conducted with t-tests.

**Results:** 2,882 tests were analyzed of which 2,476 were following clopidogrel dosing and 406 were following prasugrel dosing. Among tests for patients who had received clopidogrel, 64.2% were for males, the mean (SD) age was 64.9 (12.5) years, and 90.8% were Caucasian; for patients who received prasugrel, 67.2% were for males, the mean age was 60.7 (11.1) years, and 90.4% were Caucasian. For clopidogrel and prasugrel patients, respectively, mean PRU (SD) was 206 (90) and 107 (93) (P<0.001) and mean % inhibition (SD) was 31% (26%) and 63% (31%) (P<0.001). Real-world data suggest that prasugrel is associated with significantly lower PRU and greater % inhibition than clopidogrel, regardless of age, race, gender, diabetes, obesity, or PPI use.

**Conclusion:** In this relatively large cohort of patients in a hospital setting, we found that compared with clopidogrel, treatment with prasugrel was associated with greater platelet inhibition overall and across relevant patient subgroups, including those with co-morbidities previously shown to be associated with high platelet reactivity on clopidogrel.

**Disclosures:**
- Jamie Fortenberry: This author has nothing to disclose.
- David Drenning: This author has nothing to disclose.

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**B-016**

**Title:** Successful Rapid Aspirin Desensitization in Eighteen Aspirin-Allergic Patients with Coronary Artery Disease Undergoing Percutaneous Coronary Interventions

**Category:** Pharmacotherapy

**Authors:** Wai Ling Chan, M.B.B.S., Grantham Hospital, Hong Kong, Hong Kong; WH Chow, M.B.B.S., Grantham Hospital, Hong Kong, Hong Kong; YY Fan, M.B.B.S., Grantham Hospital, Hong Kong, Hong Kong

**Background:** Combined therapy with aspirin and clopidogrel is the current standard of care for patients who suffered from acute coronary syndrome, especially when they proceed to have coronary intervention and coronary artery stenting. Aspirin desensitization protocols that can be completed in a rapid manner in aspirin-allergic patient will benefit patient’s care.

**Purpose:** The aim of this study was to test the safety and efficacy of two rapid aspirin desensitization protocols in patient with coronary artery disease undergoing percutaneous coronary interventions.

**Methods:** Eighteen consecutive aspirin-allergic patients were desensitized by two oral protocols based on incremental dose of aspirin. The starting dose was 1mg and the target dose was 80mg. The dosing intervals were 15 and 30 minutes respectively. No pretreatment with anti-histamine was used. Steroid was prescribed if contrast injection was scheduled within 24 hours of the aspirin desensitization procedure.

**Results:** From August 2008 to November 2011, eighteen patients (mean age 61.7 ± 12.35, male 72%) with history of aspirin allergy who scheduled to have coronary intervention underwent aspirin desensitization. One patient has history of aspirin-induced allergy and two patients have history of angioedema. No patients have history of anaphylaxis. 5 patients have concomitant allergic history to NSAID. Two patients have acute coronary syndrome within one month. Two patient received 80mg prednisolone before the desensitization procedure in each group. The first thirteen patients were desensitized by a protocol using dosing interval of 30 minutes. One patient who developed hypotension and bradycardia when the dose reached 20mg. He tolerated a repeated desensitization protocol two days later after receiving 80mg oral prednisolone. Another patient developed significant gastrointestinal bleeding two days after desensitization and aspirin was discontinued. Patient fourteen to patient eighteen were desensitized by a protocol with dosing interval of 15 minute. No patient reported adverse event. The mean duration of follow-up was 12.3±10.7 months. The mean daily dose was 100mg. Two patients discontinued aspirin because of gastrointestinal bleeding and dyspepsia respectively.

**Conclusion:** Rapid aspirin desensitization is safe and effective in aspirin-allergic patient with coronary artery disease that requires dual anti-platelet therapy.

**Disclosures:**
- Wai Ling Chan: This author has nothing to disclose.
- WH Chow: This author has nothing to disclose.
- YY Fan: This author has nothing to disclose.

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**B-037**

**Title:** Intra-Graft Abciximab and Verapamil Combined with Direct Stenting can be Used as an Alternative to Distal Embolic Protection Devices in Saphenous Vein Graft Lesions not Associated with Thrombus to Prevent Slow-Flow and No-Reflow Phenomenon

**Category:** Pharmacotherapy

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**Background:** Slow flow and no-reflow phenomenon (SF-NR) in saphenous vein grafts (SVG) stenting is related to the occurrence of distal plaque embolization, platelet activation and microvascular vasospasm.

**Methods:** Data from 163 consecutive patients who underwent PCI of SVG lesions without visible macro-thrombus without use of distal embolic protection device over a 10-year period were reviewed. Patients
with visible macro-thrombus in the vein graft were excluded from the study, since these patients underwent PCI with use of the distal embolic protection (filter). Patients in the novel strategy group received prophylactic intra-graft administration of abciximab and verapamil followed by direct stenting (n = 91). Patients who had undergone conventional PCI technique before the routine availability of distal embolic protection devices, with balloon pre-dilatation of the target lesion followed by stent deployment; optional use of intragraft verapamil or intravenous abciximab comprised the control group (n = 72).

**Results:** SF-NR occurred more frequently in the control group compared to the novel strategy group (18% vs. 1%, P = 0.0001). One patient in the control group died after developing persistent SF-NR and acute MI post-PCI. No death was reported in the novel strategy group. In the control group, 13% patients developed cardiac enzyme elevation 3 times more than normal after the PCI as compared to 1% in the novel strategy group (P<0.05). The 180-day MI and MACE incidence was significantly higher in control group.

**Conclusion:** In carefully selected subgroup of SVG lesions without visible macro-thrombus, a strategy of prophylactic intra-graft administration of abciximab and verapamil, combined with direct stenting of the graft lesion without pre-dilatation, can be accomplished without use of a distal embolic protection device and is not associated with any significant risk of slow-flow/no-reflow phenomenon.

**Disclosures:**
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Sarabjeet Singh: This author has nothing to disclose.
Rasham Sandhu: This author has nothing to disclose.
Joel Lardizabal: This author has nothing to disclose.
Kirit Desai: This author has nothing to disclose.
William Nyitray: This author has nothing to disclose.
Brijesh Bhambi: Boston Scientific, 2. Research Grants
Tetsuo Ishimori: This author has nothing to disclose.

**B-042**

**Title:** High Prevalence of Aspirin Resistance in Patients with Peripheral Artery Disease is Associated with Adverse Cardiovascular Outcomes

**Category:** Pharmacotherapy

**Authors:** Jennifer Soo Hoo, None, Case Western Reserve University/Metrohealth Campus, United States, Cleveland, OH; Jeffery Alexander, M.D., Case Western Reserve University/Metrohealth Campus, United States, Cleveland, OH; Sanjay Gandhi, M.D., Case Western Reserve University/Metrohealth Campus, United States, Cleveland, OH

**Background:** Aspirin (ASA) therapy reduces the risk of major adverse cardiovascular events by 25% in patients with coronary and peripheral arterial disease (PAD). However, a subset of patients on ASA continues to have recurrent vascular events. There is no current data on long term outcomes of patients with PAD who are ASA resistant.

We propose that patients with PAD who are aspirin resistant, as defined by aspirin resistance units (ARU) >550 by Verify Now assay, will have a higher incidence of adverse cardiovascular outcomes compared with patients who are aspirin responsive.

**Methods:** We prospectively enrolled patients with PAD on long term aspirin (>1/4 weeks) therapy at our institution. Patients on dual anti-platelet therapy including clopidogrel or cilostazol or non-steroidal anti-inflammatory medications were excluded. Eligible patients had a baseline assessment of atherosclerotic risk factors and were tested for ASA responsiveness using the Verify Now-ASA system. Patients were followed for up to two years with phone calls and review of medical records every 6 months. Primary endpoint was a composite of death, MI, and ischemic stroke at 2 years. Secondary endpoints included rate of vascular intervention (surgical or percutaneous) and amputation/gangrene due to vascular disease.

**Results:** 131 patients (80 men and 51 women, mean age 64.7 years) were enrolled in our study. There were no significant differences in both groups in baseline characteristics. History of hypertension, diabetes mellitus, hyperlipidemia and smoking was present in 92.4%, 48.9%, 81% and 90% of patients respectively. 33 out of 131 patients (25.2%) were found to have ARU value > 550 and were deemed to be ASA resistant. The primary end point occurred in 18 of 98 (18.4%) patients in ASA sensitive group and 10 of 33 patients (30.3%) in ASA resistant group (p value = 0.074) at 2 years. The incidence of lower extremity revascularization or amputation was 44.8% (44/98) in the ASA sensitive group and 63.6% (21/33) in the ASA resistance group (p value = 0.032).

**Conclusion:** Our results demonstrate that there is a high prevalence of ASA resistance in patients with PAD associated with a trend for higher rate of adverse cardiovascular outcomes. There is a need for further evaluation of additional or alternative pharmacotherapy in PAD patients with ASA resistance.

**Disclosures:**
Jennifer Soo Hoo: This author has nothing to disclose.
Jeffery Alexander: This author has nothing to disclose.
Sanjay Gandhi: This author has nothing to disclose.

**B-044**

**Title:** Outpatient Screening for 2C19 Alleles and Clopidogrel Dose Escalation: a Pilot Study

**Category:** Pharmacotherapy

**Authors:** Joseph Rossi, M.D., University of North Carolina, Cardiology, United States, Chapel Hill, NC; Michael Cammarata, M.D., University of North Carolina, Cardiology, United States, Chapel Hill, NC; Jayalalitha Dharmavaram, M.D., University of North Carolina, Cardiology, United States, Chapel Hill, NC; Karen Weck, M.D., Ph.D., University of North Carolina at Chapel Hill, United States, Chapel Hill, NC; Waldo Christine, None, PharmD, University of North Carolina at Chapel Hill, United States, Chapel Hill, NC; Don Gabriel, M.D., Ph.D., University of North Carolina at Chapel Hill, United States, Chapel Hill, NC; George Stouffer, M.D., University of North Carolina, Cardiology, United States, Chapel Hill, NC

**Background:** Screening of stable outpatients who are on chronic clopidogrel therapy for CYP2C19*2 is not recommended, in part because the best treatment strategy in these patients is unknown. The 2C19*17 allele is associated with increased clopidogrel metabolism and possibly increased bleeding risk.

**Methods:** We identified 211 stable outpatients with a history of PCI who were receiving chronic aspirin and clopidogrel therapy and assayed CYP2C19 alleles and platelet function (using VerifyNow P2Y12 platelet reactivity units (PRU)). Patients with at least one CYP2C19*2 allele were enrolled in a cross-over study comparing 30 days of standard dose clopidogrel (75 mg) to 30 days of high dose clopidogrel (150 mg). In these patients, platelet function was further assessed using light transmission aggregometry (LTA) and active clopidogrel metabolites were measured.

**Results:** Baseline PRU values while patients were receiving chronic therapy with 75 mg daily of clopidogrel were elevated among CYP2C19*2 carriers (n = 52, 25%) compared to *1*1 wild-type (237.5 vs. 172.0 PRU, p<0.001). Carriers of the 2C19*17 allele (n = 51, 24%) displayed similar levels of platelet inhibition compared to wild-type patients (166.7 vs. 172.0 PRU, p>0.5). 50 patients with at least one CYP2C19*2 allele completed the cross-over study. Treatment with 150 mg daily of clopidogrel was associated with improved ADP-specific platelet inhibition measured by VerifyNow (217 vs. 258 PRU, p = 0.01) and LTA assessment (51.5% vs. 66.2% of maximal aggregation, p =...
0.02) compared to 75 mg daily. Both VerifyNow and LTA correlated poorly with measured clopidogrel metabolite levels (adjusted r-squared values of 0.27 and 0.23).

**Conclusion:** Carriers of CYP 2C19*2 displayed increased platelet reactivity compared to non-carriers as measured by VerifyNow. 2C19*17 carrier status did not effect platelet function. Treatment with 150 mg daily of clopidogrel reduced, but did not eliminate, the increased platelet reactivity seen in 2C19*2 carriers. Both LTA and VerifyNow P2Y12 correlated poorly with measured active metabolite levels.

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Michael Cammarata: This author has nothing to disclose.
Jayalalitha Dharmavaram: This author has nothing to disclose.
Karen Weck: This author has nothing to disclose.
Walko Christine: This author has nothing to disclose.
Don Gabriel: This author has nothing to disclose.
George Stouffer: This author has nothing to disclose.

**C-017**

**Title:** Comparison of Switching from Clopidogrel to Prasugrel vs. Prasugrel Alone in Patients Undergoing PCI with Drug-Eluting Stents in a “Real-World” Population: In-Hospital Results from the TAXUS Liberte Post-Approval Study

**Category:** Pharmacotherapy

**Authors:** Kumar Robert, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY1; Robert Kumar, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY2; Alrich Gray, M.D., Ph.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY3; Arun Patil, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY4; David Lee, M.D., Stanford Medical Center, United States, Stanford, CA5; Kenneth Winters, M.D., Eli Lilly and Company, United States, Indianapolis, IN6; Thomas Bowman, M.D., MPH, Boston Scientific Corp, United States, Marlborough, MA7; Kirk Garratt, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY8

**Background:** Recent data from clinical trials have demonstrated superiority of prasugrel over clopidogrel in patients with acute ST-elevation myocardial infarction (STEMI) undergoing PCI. In the short-term period following PCI (0-30 days) for STEMI, the benefit of prasugrel over clopidogrel was present without an associated increase in bleeding risk. However, in clinical practice, many patients have received clopidogrel prior to undergoing PCI, and there is little data regarding the safety and efficacy of a strategy of switching from clopidogrel to prasugrel at the time of PCI.

**Methods:** The TAXUS Liberte Post-Approval Study is a prospective, multicenter registry examining 5-year clinical outcomes in patients with implanted TAXUS Liberte stents and concomitant prasugrel therapy. For patients undergoing PCI with TAXUS Liberte stents and concomitant prasugrel therapy. For patients undergoing PCI with TAXUS Liberte stents at the time of PCI.

**Results:** Baseline demographics were similar between groups (Group 1 vs. Group 2: age 59.1y vs. 59.4y; male 71.9% vs. 74.7%; weight 93.2kg vs. 91.7kg). More patients in Group 2 had multivessel disease (40.6% vs. 33%) and were undergoing PCI for restenosis (8.0% vs. 5.3%) or CTO (2.2% vs. 1.3%). The in-hospital event rates for death (0.0% Group 1 vs. 0.1% Group 2; P = 0.27), ARC-defined MI (2.0% Group 1 vs. 2.6% Group 2; P = 0.29), and ARC-defined stent thrombosis (0.2% Group 1 vs. 0.4% Group 2; P = 0.48) were similar between groups. Major bleeding (GUSTO moderate or severe) was also similar between groups (0.5% Group 1 vs. 0.6% Group 2; P = 0.67).

**Conclusion:** In real-world patients undergoing PCI with DES, switching from clopidogrel to prasugrel at the time of PCI or during the index hospitalization was associated with low and similar in-hospital event rates, and no increase in major bleeding complications when compared to the use of prasugrel without antecedent clopidogrel. These patients will continue to be followed to assess long-term comparative outcomes between the two groups.

**Disclosures:**
Kumar Robert: This author has nothing to disclose.
Robert Kumar: This author has nothing to disclose.
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Arun Patil: This author has nothing to disclose.

Thomas Bowman: Boston Scientific, 3. Employment (full or part-time), Boston Scientific, 1. Stock Options or Bond Holdings.

**C-028**

**Title:** Three-Year Cardiovascular Event Rates Were Lower in Type 2 Diabetic Patients with Pioglitazone Treatment after Zotarolimus-Eluting Stent Implantation

**Category:** Pharmacotherapy

**Authors:** Soon Jun Hong, M.D., Ph.D., Korea University Anam Hospital, Korea, South, Seoul1; Jae Hyoung Park, M.D., Korea University Anam Hospital, Korea, South, Seoul2; Chul-Min Ahn, M.D., Korea University Anam Hospital, Korea, South, Seoul3; Do Sun Lim, M.D., Ph.D., Korea University Anam Hospital, Korea, South, Seoul4

**Background:** Recent studies highlight the beneficial effect of pioglitazone in reducing major adverse cardiovascular events (MACEs) in type 2 diabetic patients. We prospectively investigated the effects of pioglitazone in reducing MACEs after zotarolimus-eluting stent (ZES) implantation in type 2 diabetic patients with significant coronary artery narrowing during the 3-year follow-up.

**Methods:** Type 2 diabetic patients with coronary artery diseases were randomly assigned to pioglitazone (n = 91) or placebo (n = 114) after ZES implantation. Baseline and 8-month coronary intravascular ultrasound (IVUS) were compared for neointimal growth. Primary endpoint was to compare MACEs such as non-fatal myocardial infarction, death, stroke, and target lesion revascularization (TLR) between the 2 groups during the 3-year follow-up. Secondary endpoints were to compare rates of new-onset heart failure, fracture, and non- TLR target vessel revascularization (TVR) between the 2 groups.

**Results:** MACEs were significantly higher in the placebo group than the pioglitazone group during the follow-up [hazard ratio 2.326 (95% CI 1.167-4.638), p = 0.016] (Figure 1). Rates of non-fatal myocardial infarction [odds ratio (OR) 1.011 (95% CI 0.989-1.033)], death [OR 0.974 (95% CI 0.945-1.004)], and stroke [OR 2.537 (95% CI 0.227-28.450)] showed no significant differences between the 2 groups; however, TLR [OR 0.322 (95% CI 0.144-0.721)] was significantly lower in the pioglitazone group than the placebo group. Rates of new-onset heart failure [OR 2.222 (95% CI 0.776-6.365)], fracture [OR 1.636 (95% CI
Title: Short Term Follow up of Prediabetics Undergoing Elective Percutaneous Coronary Intervention

Category: Pharmacotherapy

Authors: Ahmed Shawky, M.D., Cardiology department - Ain shams University, Egypt, Cairo, Cairo

Introduction and Objectives: Epidemiologic evidence suggests that the complications of diabetes begin early in the progression from normal glucose tolerance to frank diabetes. Prediabetes, defined as people with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), some of whom in fact already have the characteristic microvascular changes resulting from diabetes itself. This study was aimed to determine the short term outcomes as regards major adverse cardiac & cerebral events (MACCE) in prediabetic patients as compared to diabetic and non diabetic patients undergoing elective percutaneous coronary intervention (PCI).

Methods: This study was conducted on 108 patients presenting to Ain-Shams university catheterization laboratory for elective percutaneous coronary intervention by bare metal stents in the period from September 2009 to June 2010 (48 diabetic patient, 30 pre diabetic patient and 30 non diabetic level patient). Each patient was subjected to the following: full history, examination, laboratory investigations including serum creatinine, fasting and 2 hours post prandial glucose levels and echocardiography. All patients underwent bare metal stents deployment. Follow up was done at 3 and 6 months for major adverse cardiac & cerebral events (cardiovascular death, acute coronary syndrome, cerebrovascular stroke, target vessel revascularization).

Results: Our findings demonstrate that there was no statistically significant difference between patients of the 3 different study groups (diabetics = 18.8%, pre diabetics = 13.3%, non diabetics = 3.3%, p-value = 0.1) regarding composite end point of death, stroke, acute coronary syndrome and target vessel revascularization at 3 months follow up, but there was high statistical difference between them regarding acute coronary syndrome (diabetics = 43%, pre diabetics = 26%, non diabetics = 10%, p-value = 0.006) at 6 months follow up.

Conclusion: Prediabetes, though not a disease entity by itself, is associated with of risk for both macrovascular and increasingly, microvascular pathology. It is important to identify these conditions to prevent incident diabetes and to take measures to stop the vascular complications. Our study findings revealed that complications of diabetes may begin as early as patients are suffering impaired glucose homeostasis, which warrants further evaluation in larger studies.

Disclosures:
Ahmed Shawky: This author has nothing to disclose.

D-015

Title: High On-Treatment Residual Platelet Reactivity Post-Percutaneous Coronary Intervention in Patients Loaded With High-Dose Clopidogrel: Impact of Diabetes, Age, African American Race and Presentation Acuity on Antiplatelet Hyporeactivity

Category: Pharmacotherapy

Authors: Sandeep Nathan, M.D., M.Sc., University of Chicago Medical Center, United States, Chicago, IL; Janet Karol, None, APN, NP-C, University of Chicago Medical Center, United States, Chicago, IL; Auddie Sweis, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Vikrant Jagadeesan, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Narayan Saha, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Mark Gajjar, M.D., University of Chicago Medical Center, United States, Chicago, IL; Linda Lee, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Sandra Weiss, M.D., University of Chicago Medical Center, United States, Chicago, IL

Background: High residual platelet reactivity (HRPR) on clopidogrel is variably defined and linked with factors such as age, race, genetics and diabetes (DM). We investigated the prevalence of HRPR and validated its link to reported risk factors in a high-risk PCI population using published definitions.

Methods: 127 PCI pts had prospective platelet inhibition testing via the Accume TRacks VerifyNow P2Y12 platform, 24 hrs post-600 mg
clopidogrel po. Inhibition of platelet aggregation (IPA) and residual platelet reactivity (P2Y12-reactivity units, PRU) were analyzed on continuous and dichotomous scales with varying data-supported cutoff values: PRU<230, IPA<10%. Predictors of HRPR were analyzed.

Results: In 127 pts (age 64±11, DM 50.4%, male 63.7%) mean PRU was 198.0±107 (39.3% ± 30.2% IPA). Using cutoffs of PRU>230, PRU>208 and IPA <10%, HRPR was seen in 42.5%, 48.0% and 24.4% of pts, respectively (Fig 1). DM (220<114.3 vs 177±97, P=0.022) and age>65 yrs (177±107 vs 219±106, P=0.026) were predictive of high residual platelet reactivity (HRPR) and increasing age was continuously correlated with HRPR (r=0.184, p=0.038). 70.1% of pts were African American (AA) and 34.6% presented with STEMI/ACS but neither factor correlated with HRPR.

Conclusion: HRPR on clopidogrel was highly prevalent post-PCI but with great variability based on definition. DM and older age were linked with HRPR but several other risk factors. These data suggest limited predictability of HRPR based on published metrics of risk.

Disclosures:
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**STENTS (INCLUDING DES)**

**A-001**

**Title:** Steroids for the Prevention of Restenosis in Bare Metal Stent: A Systematic Review and Meta-analysis

**Category:** Stents (including DES)

**Authors:** Saurav Chatterjee, M.D., Maimonides Medical Center, Brooklyn, United States, Brooklyn, NY; Partha Sardar, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Kirk Garratt, M.D., University of Chicago Medical Center, United States, Chicago, IL; Patrick Dillon, M.D., University of Chicago Medical Center, United States, Chicago, IL; Debbabata Mukherjee, M.D., FACC, Texas Tech Health Sciences Center, United States, El Paso, NY; Kirk Garratt, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY

**Introduction:** Stent restenosis remains a common complication of bare metal stent (BMS) implantation. Even in the drug eluting stent (DES) era, there remains a significant proportion of patients who may not be eligible for DES due to inability to comply with prolonged dual antiplatelet therapy. We reviewed validity of empirical evidence that peri-procedural treatment with steroids at the time of insertion of a bare metal stent may delay restenosis, and provide benefit through reductions in adverse clinical events.

**Methods:** We searched PubMed, EMBASE and Cochrane Central Register of Controlled Trials’ databases for randomized controlled trials conducted between 1990 and 2011 that assessed the impact of systemic steroid administration within 72 hours to 7 days of angioplasty alone and BMS placement. The comparator included standard medical therapy and/or placebo. Outcomes assessed were (1) rates of restenosis at the end of at least 6 months of follow up; (2) rates of target vessel revascularization; (3) risk of all-cause mortality. Relative risk of restenosis, revascularization and rates in-hospital mortality for treatment and control groups were compared using a random effects model (Mantel-Haenszel).

**Results:** We identified 5 studies that met inclusion criteria. No significant reduction in restenosis rates were observed after angioplasty alone with steroids. However with BMS, significant reductions in restenosis rates (RR 0.60, 95% CI 0.37-0.97; p=0.04), and target vessel revascularization rates (RR = 0.56, 95% CI 0.34-0.92; p=0.02) were observed in the steroid-treated group. A 28% mortality reduction was observed with steroid treatment with BMS placement, but was not statistically significant.

**Conclusion:** Peri-procedural steroid administration during BMS implantation may reduce rates of restenosis and target vessel revascularization, without adverse clinical effects attributable to steroid use.

**Disclosures:**
Saurav Chatterjee: This author has nothing to disclose.
Partha Sardar: This author has nothing to disclose.
Kirk Garratt: This author has nothing to disclose.

**A-013**

**Title:** Correlation Between Predicted to Observed Coronary Stent Expansion as Determined by Intravascular Ultrasound following High-Pressure Drug-Eluting Stent Deployment: Impact of Lesion Location, Plaque Burden and Variance Between Stent Platforms

**Category:** Stents (including DES)

**Authors:** Sandeep Nathan, M.D., M.Sc., University of Chicago Medical Center, United States, Chicago, IL; Vikrant Jagadeesan, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Asrar Khan, None, B.S., University of Chicago Medical Center, United States, Chicago, IL; Patrick Dillon, M.D., University of Chicago Medical Center, United States, Chicago, IL; Mark Gajjar, M.D., University of Chicago Medical Center, United States, Chicago, IL; Sandra Weiss, M.D., University of Chicago Medical Center, United States, Chicago, IL

**Background:** Manufacturer-predicted stent expansion is based on in-vitro testing. Actual expansion is related to stent architecture, lesion characteristics, etc. We evaluated the relationships between these variables on coronary drug-eluting stent (DES) expansion during PCI via intravascular ultrasound (IVUS).
Methods: 1,334 IVUS frames were acquired and analyzed in 44 lesions post-DES via Volcano EagleEye Platinum 20 MHz IVUS. DES studied were Medtronic Endeavor (n = 32, 624 mm) and Abbott Xience (n = 12, 215 mm), deployed at 16-22 ATM after predilatation. Expansion deficit (ED, %) was the ratio of observed to predicted stented cross-sectional area.

Results: Both DES were less expanded than predicted (ED = -10.2%, p < 0.001) but neither evidenced malapposition. Mean ED was higher in Endeavor vs. Xience (-11.5% vs. -6.0%, p < 0.001, Fig 1A), 93.5% of Endeavor frames under-expanded vs. 80.4% Xience (p < .001) however Endeavor had less overexpansion than Xience (6.5% vs. 19.6%, p < .001). ED was greater in ACS vs. non-ACS (-11.26% vs. -9.76%, p < .002) and LAD vs. non-LAD lesions (-12.22% vs. -6.52%, p < .001). The highest ED (-11.86%, p < .001) was in 3.0 mm DES. ED correlated with plaque burden (Fig 1B).

Conclusion: Actual DES expansion is less than predicted despite high-pressure deployment. Inter-stent differences and lesion/vessel-specific variables impact stent performance in vivo. These data have implications on stent selection/deployment and underscore the value of post-DES intravascular imaging.

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Sandeep Nathan: Volcano, 5. Consulting Fees or Other Remuneration, Medtronic, Inc, 5. Consulting Fees or Other Remuneration.
Vikrant Jagadeesan: This author has nothing to disclose.
Asrar Khan: This author has nothing to disclose.
Patrick Dillon: This author has nothing to disclose.
Mark Gajjar: This author has nothing to disclose.
Sandra Weiss: This author has nothing to disclose.

A-020

Title: Clinical Outcomes with 6 Months versus 12 Months versus 24 Months Dual Antiplatelet Therapy in Patients Treated With the Resolute Zotarolimus Eluting Stent: Insights from the RESOLUTE US Trial

Category: Stents (including DES)

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Background: Dual antiplatelet treatment (DAPT) for at least 12 months is recommended following PCI using drug-eluting stents in patients with coronary artery lesions. However, there is lack of published data on optimal duration of treatment, with significant variations in practices seen. We evaluated patients treated with Resolute zotarolimus eluting stents (R-ZES) enrolled in the RESOLUTE US (R-US) Trial.

Methods: R-US is a prospective, multi-center, non-randomized, observational study comprising a clinical (n = 1242) and angiographic (n = 160) cohort. The R-US trial recruited patients with de novo native coronary lesions suitable for 1- or 2-vessel treatment with stents ranging
from 2.25 to 4.0 mm in diameter. The primary endpoint for the clinical cohort was target lesion failure (TLF; cardiac death, target vessel myocardial infarction [TVMI] and clinically-driven TLR) at 1 year. Planned comparisons include patients on DAPT at 6 months but not at 12 months versus patients on DAPT at 6 and 12 months. Additional data on DAPT treatment outcomes through 24 months follow-up will also be provided. The primary objective of the analysis is to evaluate late-term safety outcomes (death, MI, ARC ST) relative to the duration of DAPT adherence. Patients will be analyzed for all safety endpoints based on an intent-to-treat analysis.

Results: A total of 1402 patients were enrolled. At baseline, the mean reference vessel diameter was 2.59 ±0.47 mm and diabetes prevalence was 34.4%. At 1 year, the overall TLF rate was 4.7% and rates of cardiac death, MI, TLR, and ST were 0.7%, 1.4%, 2.8%, and 0.1% respectively. Data on DAPT use is shown in the Table.

Conclusion: Among patients treated with R-ZES on DAPT at 6 months, late-term event rates of death, MI, stroke, and ST will be compared between patients off DAPT vs patients on DAPT at 12 and 24 months. These findings may help identify the appropriate duration of DAPT treatment following R-ZES implantation.

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Laura Mauri: Abbott Vascular, 5. Consulting Fees or Other Remuneration, Cordis, 8. Speaker’s Bureau, Medtronic, 8. Speaker’s Bureau, Cordis, 5. Consulting Fees or Other Remuneration, Medtronic, 5. Consulting Fees or Other Remuneration, Abbott Vascular, 8. Speaker’s Bureau
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Martin Leon: This author has nothing to disclose.

A-031

Title: Clinical Outcomes in Patients with Coronary Artery Disease Undergoing Two Vessel Treatment with the Resolute Zotarolimus-eluting Stent: A Prespecified Subset Analysis of the RESOLUTE US Trial

Category: Stents (including DES)

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Background: The RESOLUTE US Trial was designed to evaluate the Resolute zotarolimus-eluting stent (R-ZES) in patients with de novo native coronary artery lesions. At 1 year this prospective, observational, multicenter trial showed that the R-ZES was safe and effective with an overall target lesion failure (TLF) rate of 4.7% and low rate of stent thrombosis (0.1%).

Methods: The RESOLUTE US Trial enrolled 1402 patients treated with 2.5-4.0 mm stents with 1242 patients in the main clinical cohort (2.5-3.5 mm stents) and 3 smaller substudies. Evaluation of clinical outcomes for dual vessel treatment was a prespecified subset analysis of the main clinical cohort for key safety and efficacy endpoints TLF, cardiac death and myocardial infarction (CD/MI), clinically-driven target lesion revascularization (TLR), and stent thrombosis at 1 year.

Results: Of the 1242 patients enrolled in the main clinical cohort, 108 were treated in 2 vessels and 3 patients were treated in 3 vessels. Baseline characteristics of this patient subgroup included 20.7% women, 23.4% with prior MI, 24.3% with prior PCI, and 39.6% with diabetes mellitus. Lesion characteristics included 22.9% with moderate/severe calcification, 40.7% with branch vessel disease, and 76.2% Class B2/C lesions. The rate of TLF at 1 year was 5.4%, target vessel MI was 1.8% and TLR was 3.6%. There were no cardiac deaths and no ARC definite or probable stent thrombosis events through 1 year follow-up.

Conclusion: One year clinical outcomes following implantation of the R-ZES in patients with dual vessel disease demonstrate safety and efficacy consistent with the results in the overall population. Further follow-up of clinical outcomes to 2 years for all patients receiving 2-vessel treatment with the R-ZES will be reported.

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Alan Yeung: Medtronic, 5. Consulting Fees or Other Remuneration.

A-037

Title: Long-term Survival of Patients With and Without Peripheral Vascular Disease Following Percutaneous Coronary Interventions in the Drug-Eluting Stent Era

Category: Stents (including DES)

Authors: Konstantinos Charitakis, M.D., New York Presbyterian/Weill Cornell Medical College, United States, New York, NY; Scott...
Background: Patients with peripheral vascular disease (PVD) undergoing coronary revascularization have high rates of adverse short-term outcomes. However, the long-term clinical outcomes of patients with PVD undergoing PCI in the contemporary drug-eluting stent era have not been well characterized. The objective of this study was to compare in-hospital and long-term (4-year) outcomes in patients with versus without PVD after undergoing PCI.

Methods: The 2004/2005 Cornell Angioplasty Registry database was used to evaluate the in-hospital and long-term clinical outcomes in patients undergoing urgent or elective PCI. A total of 2,455 study patients were examined. We excluded patients presenting with an ST-elevation MI >24 hours, hemodynamic instability/shock, thrombolytic therapy ≤7 days, or renal insufficiency (creatinine ≥4mg/dl). Mean follow-up was 4.4 ± 1.1 years.

Results: Of the 2,455 patients, 173 (7%) had PVD and 2,282 (93%) had no reported history of PVD. Drug-eluting stents were used in 87% of the PCI and glycoprotein IIb/IIIa inhibitors were used in 53% of the patients. The incidence of in-hospital death (1.7% vs. 0.1%, p = 0.006) was greater in the PCI group, whereas post-procedural MI (6.4% vs. 4.5%, p = 0.006) and MACE rates including death, stroke, emergent CABG/PCI, and MI (8.7% vs. 7.0%, p = 0.360) were similar in the PVD vs. no PVD groups. Long-term Kaplan-Meyer survival (89.2% vs. 84.1%, p = 0.001) was significantly higher in the patients without PVD vs. with PVD, respectively (Figure). After adjustment with a multivariate Cox regression analysis, long-term all-cause survival was similar in patients with vs. without PVD (HR 1.27, 95% CI 0.89-1.82, p = 0.183).

Conclusion: In contemporary PCI utilizing DES, glycoprotein IIb/IIIa inhibitors and clopidogrel, PVD is associated with a higher in-hospital and 4-year all-cause mortality. In our study this difference in long-term survival was mainly driven by a higher rate of comorbidities in the PVD population that underwent PCI.

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Olga Sanz-Vazquez: This author has nothing to disclose.
Pedro Chinchurreta-Capote: This author has nothing to disclose.
Francisco Ruiz-Mateas: This author has nothing to disclose.

B-021
Title: Long-Term Follow-Up of Frontier Stent Therapy for Coronary Bifurcations

Category: Stents (including DES)

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Background: Frontier stent (FS) was designed for treatment of coronary bifurcation by means of a trousers-like asymmetric structure which was implanted with 2 guides, one for each branch, to fill the bifurcation with stent, and so to prevent plaque to move from one branch to the other, a frequent complication when a conventional stent is used. We evaluate the results of long-term use of FS.

Methods: From June 2004 to April 2009 all patients admitted with a coronary bifurcation lesion treated with a FS were included. A mean 30-month follow-up was accomplished (minimum 2 weeks to 7 years maximum).

Results: 38 patients were included during the study. The bifurcation lesion was located in left main 2.63%, LAD-diagonal in 57.89%, CX-marginal in 26.31%, and RCA-posterolateral in 13.15%. The stent diameter was from 2.5 to 4 mm (average 3.15) and length 18 mm. 19 patients were reevaluated by angiography due to clinical events; 10 for new beginning of angina: 6 for NSTEMI, 2 for STEMI, and 1 due to heart failure. Only one case of FS restenosis was found (5.26%), the rest of them progressed to another location illness or didn't show new lesions. During the follow-up, one case of FS thrombosis was found, and one patient died following a cardiac event.

Conclusion: Our results show that dedicated stent use for Frontier bifurcations treatment has demonstrated safety and a low rate of events at the lesion treated in the long term.

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Antonio Ramirez-Moreno: This author has nothing to disclose.
Pedro Chinchurreta-Capote: This author has nothing to disclose.
Francisco Ruiz-Mateas: This author has nothing to disclose.
Title: Comparison of Neointimal Coverage between Zotarolimus-Eluting Stents and Everolimus-eluting Stent

Authors: Koshi Matsuo, M.D., Oska Police Hospital, Japan, Osaka; Yasunori Ueda, M.D., Osaka Police Hospital, Japan, Osaka; Yasuhiro Akazawa, M.D., Osaka Police Hospital, Japan, Osaka

Background: Drug-eluting stents (DES) have demonstrated to reduce late loss and target lesion revascularization through an inhibitory effect on neointimal hyperplasia but increased the risk of late or very late stent thrombosis due to incomplete neointimal coverage. However, the difference in neointimal coverage between zotarolimus-eluting stent (ZES) and everolimus-eluting stent (EES) has not been reported.

Methods: Patients who received an implantation of ZES (n = 42) or EES (n = 42) were included in this study. Follow-up angiographic and angioscopic examinations were performed at 371±61 days later in ZES group and at 366±33 days later in EES group. Yellow color grade (grade 0-3), neointima coverage grade (grade 0-2), and thrombus (presence or absence) at stented lesion were evaluated by angiography.

Results: Yellow color grade was higher in EES than in ZES (0.38±0.76 vs. 1.29±0.92, p<0.0001). Stent coverage was better in ZES than in EES (1.98±0.15 vs. 1.17±0.49, p<0.0001). Prevalence of thrombus was not different between ZES and EES. ZES had higher prevalence of white good (grade-2) neointima coverage, which is common in bare metal stents, than EES (97.6% vs. 16.7%, p<0.0001). Neointima coverage was generally homogenous in both stents.

Conclusion: Although ZES had higher prevalence of white and good neointima coverage than EES, both stents commonly had low incidence of in-stent thrombus formation.

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Title: Real World Outcomes in Small Vessel Interventions with Everolimus-Eluting Stent

Authors: Aniket Puri, M.D., CSM Medical University, India, Lucknow; Micheal Liang, M.D., Waikato hospital, New Zealand, Hamilton; Gerard Devlin, M.D., Waikato hospital, New Zealand, Hamilton

Background: Intervention in small vessels with small stents is thought to be associated with an increased incidence of stent related complications and poorer outcomes. Previous studies with drug-eluting stents have shown a reduction in in-stent restenosis compared to bare-metal stents and overall favourable clinical outcomes. However, limited data exists on outcomes with drug eluting stents in small vessels in the real world setting.

Methods: All consecutive patients who had single EES(PROMUS™, Boston Scientific, Natick USA; XIENCE V™, Abbott Vascular, Santa Clara USA) implanted between Mar 2007 to Sep 2009 were identified. Patients were divided into group having vessel size ≤2.75mm and group 2 having vessel size >3.0mm. The incidence of major adverse cardiac events (MACE) including all-cause mortality, myocardial infarction (MI), target vessel revascularization(TVR) and definite stent thrombosis(ST), was assessed.

Results: 209 patients were identified; 91 patients having vessel size ≤2.75mm (mean age 61yrs, 60% males) and 118 patients having vessel size >3.0mm (mean age 65yrs, 70% males). During a mean follow up of 24 months the MACE rates in small vessel group was 12% versus 9% in the larger vessel group (p = 0.34). All cause mortality was 6% versus 5% (p = 1.0); MI was 2% versus 1% (p = 0.58);TVR was 3% in each group (p = 1.0); and definite ST was seen only in 1 patient in the small vessel group.

Conclusion: Everolimus-eluting stent use in smaller vessels in the real world setting is associated with good clinical outcomes and very low adverse event rates and compares favourably with outcomes in larger vessels.

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Title: Prolonged Dual Anti-Platelet Therapy Beyond Three Years is Crucial to Prevent Very Late Stent Thrombosis After Stenting of Bifurcations with the “Crush” Technique Using Drug-Eluting Stents

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Background: Very late thrombosis (VLST) can occur after bifurcation stenting with “crush” technique due to delayed endothelialization of the stents. It is likely related to the the slower coverage of the stent struts in the acute angle segment at the “elbow” region of the bifurcation and the “crushed” segment of the stent in the main branch where there are three layers of stent struts. We have employed uninterrupted dual-anti-platelet therapy beyond 3 years in the belief that stent endothelialization of the bifurcation may not be complete even beyond 3 years.

Methods: We followed 84 patients who had undergone stenting of bifurcations using the “crush” technique for occurrence of death, myocardial infarction (MI), target vessel revascularization or VLST. All patients were prescribed dual anti-platelet therapy (DAPT) with daily aspirin 325 mg and clopidogrel 75 mg or prasugrel 10 mg.

Results: Stenting of the LAD-diagonal was carried out in 48 patients, LCx-OM in 20 patients and RPDA-PL branch in 16 patients. Only DES were used- Cypher in 6 patients, Taxus in 38 patients and Promus in 40 patients. Follow-up data are available for a period of 58+/15 months (mean+/-SD). Two patients developed VLST after DAPT was discontinued. One patient developed VLST 3 days after DAPT was stopped for head injury-subdural hematoma necessitating repeat PCI. Another patient developed VLST 4 weeks after discontinuing DAPT.

There was no occurrence of VLST or MI in all the other 82 patients who were compliant with DAPT. There was no death in the cohort. Two patients developed restenosis of the bifurcation lesion treated with CABG. There were no other life-threatening bleeding events in the other patients.

Conclusion: VLST can occur even five years after “crush” technique stenting, suggesting that endothelialization of the stent struts may not be
complete even after 5 years. DAPT possibly indefinitely, with daily aspirin and clopidogrel or prasugrel may be required to ensure stent patency. Benefits of DAPT seem to outweigh the risks for bifurcation “crush” technique stenting.

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Tetsuo Ishimori: This author has nothing to disclose.
Sanjiv Sharma: This author has nothing to disclose.
Sanjiv Sharma: This author has nothing to disclose.

C-034

Title: Optical Coherence Tomography Analysis of the SOS Xience V Study: the Use of the Everolimus-Eluting Stent in Saphenous Vein Graft Lesions

Category: Stents (including DES)

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Background: The use of drug-eluting stents (DES) in saphenous vein graft (SVG) lesions is not well-studied. The Stenting of Saphenous Grafts - Xience V (SOS-Xience V) trial prospectively examined the frequency of angiographic in-stent restenosis in SVG lesions 12 months after implantation of a Xience V everolimus-eluting stent (EES, Abbott Vascular, Santa Clara, California). We present the first EES optical coherence tomography (OCT) analysis of EES in SVGs.

Methods: Forty patients with 40 lesions (one stent per lesion) were enrolled in the study. Twelve-month follow-up angiography and OCT evaluation was performed at 27 and 12 patients respectively. OCT strut-level analysis was performed to determine the percentage of strut coverage, malapposition, strut protrusion, neointimal thickness and the existence of thrombus.

Results: A total of 2,584 struts were evaluated. The percentages of uncovered, malapposed and protruding struts were 4%, 9% and 15% respectively. The mean strut neointimal thickness was 94 ± 94 μm (interquartile range 30, 130). Four stents (33%) showed full neointimal coverage. The mean difference between the stent area and the lumen area was 0.36 ± 1.6 mm2. No thrombus was detected in the stented areas.

Conclusion: Use of EES in SVGs effectively suppresses neointima formation. The percentage of malapposed struts is high, when compared to native arteries, possibly due to the large caliber of SVGs.

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VALVULAR INTERVENTIONS AND STRUCTURAL HEART DISEASE

A-004

Title: Transcatheter Aortic Valve Implantation (TAVI) in nonagenarian patients

Category: Valvular Interventions and Structural Heart Disease

Authors: Keita Yamasaki, M.D., Ph.D., Karolinska University hospital, Sweden, Stockholm; Andreas Rück, M.D., Ph.D., Karolinska University Hospital, Sweden, Stockholm; Anders Jönsson, M.D., Ph.D., Karolinska University hospital, Sweden, Stockholm; Magnus Settergren, M.D., Ph.D., Karolinska University hospital, Sweden, Stockholm

Background: The prevalence of calcified aortic stenosis is increasing with age. Despite the high mortality and morbidity associated with symptomatic untreated aortic valve stenosis, many elderly patients do not receive surgical treatment. Older age is the most common cause for denying surgery. It has recently been shown that in patients with severe aortic stenosis who are not candidates for surgery, TAVI significantly reduced the mortality compared to standard treatment. However, the effect of TAVI in the very old is still largely unknown.

Aims: To retrospectively evaluate the procedural and mid-term outcomes of TAVI in patients ≥90yrs of age.

Methods and Results: Twenty-two consecutive patients, aged 91.8±1.9yrs (90-96.8yrs) with severe aortic stenosis who were not candidates for surgery and underwent TAVI between 2008/5/26 and 2011/10/5 were analysed for demographics, acute procedural outcomes, length of hospital stay, morbidity and mortality. In base line characteristics, Logistic Euroscore was 23.5±12.7% (10.8-68.9%), 3pts(14%) underwent previous heart operation, 4pts(18%) underwent previous PCI, and 4pts(18%) had good LV function (LVEF>51%), 7pts(32%) had moderate LV function (LVEF 21-30%). All patients successfully underwent TAVI(CoreValve). All procedures were done under light sedation without intubation, femoral access was used with percutaneous closure of the access site. There was no access site complication. Mean aortic valve gradient was reduced from 4.3±1.2 to 1.9±0.5m/sec. Total follow up duration was 570±378days (30-1291days). 30-days (0/22pts) and one-year mortality (0/15pts) was 0%. Two patients died 398 and 868 days following the procedure, respectively. One patient suffered from stroke during the procedure. 5pts had a permanent pacemaker implanted due to AV-block following the procedure. Total hospitalized days after TAVI was 7.3±2.8days (3-15days). 5pts (23%) were directly discharged to their homes, 15pts (68%) to rehab and 2pts (9%) to another hospital. Finally, all patients were discharged to their homes.

Conclusion: The TAVI procedure seems to be a safe and effective treatment for aortic stenosis in nonagenarian patients. We now have a treatment option for a patient category that previously have been largely untreated and as a consequence of this have faced high morbidity and mortality.

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Magnus Settergren: This author has nothing to disclose.

A-008

Title: Combined Balloon Mitral Valvuloplasty and Balloon Tricuspid Valvuloplasty in Rheumatic Valvular Heart Disease - Single Centre Experience

Category: Valvular Interventions and Structural Heart Disease

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A-024

Title: Clinical Course in Patients With Touching of Left Atrial Disk of Device to the Mitral Valve After the Transcatheter Closure of ASD

Category: Valvular Interventions and Structural Heart Disease

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Su-Jin Park: This author has nothing to disclose.
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Jae Young Choi: This author has nothing to disclose.

Background: Transcatheter closure of atrial septal defect (ASD) is a standard treatment in the feasible patient. One of the most important factors in successful transcatheter closure of ASD is the presence of sufficient mitral valve rim of the atrial septum. In many cases of ASD with deficient mitral rim, mitral valve encroachment by device can be a cause of failure in the procedure. However, when the device only slightly touches the mitral valve, it is not considered an absolute contraindication of procedure. Therefore, the purpose of this study was to investigate the clinical course of patients with LA disk of the device that slightly touches the mitral valve after the transcatheter closure of ASD.

Methods: From May 2003 to June 2011, 723 patients underwent transcatheter closure of ASD in our institute. Among them, 102 patients (14%) showed touch of mitral valve with left atrial disk of the device after the procedure. In these patients, 39 (38%) no longer showed touch of device to mitral valve during follow-up period. These patients were categorized as group 1 (normalized group), and the remaining patients were categorized as group 2 (persistent mitral valve touch group). We retrospectively reviewed the clinical course of these patients and analyzed the difference between the two groups.

Results: Mild touch of mitral valve with left atrial disk of device did not result in any kind of erosions nor perforation during the follow-up period in all patients. The Qp/Qs ratio and the device size were not different between group 1 and group 2 (Qp/Qs = 2.7±0.6 vs 2.5±0.6, Device size = 24.8±9.9 vs 22.0±7.4). The mean follow-up period of all patients was 2.5 years. Group 2 patients with persistent touch to mitral valve were older than group 1 (15.6±15.8 vs 11.0±14.4). But, the difference was not significant statistically. (P = 0.146). Total follow-up duration was longer in group 1 than group 2 (3.4 years vs. 1.8 years, P < 0.001).

Conclusions: As long as the device did not encroach upon the mitral valve, critical complications such as erosion or perforation was not present. In the patients who were followed-up for a longer period of time, showed a higher chance of normalization, meaning that the device no longer touched the mitral valve. Therefore, mild touching of the device to the mitral valve may not be an absolute contraindication of the procedure in carefully selected cases. Long term follow-up and close observation will be needed in this group of patients.

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Jae Young Choi: This author has nothing to disclose.

A-025

Title: Beyond STS: Clinical Risk Factors Perceived to Increase 30-Day Mortality Risk in Elderly Patients with Aortic Stenosis: Results of a MultiCenter Clinical Survey of High-Volume Cardiac Surgeons

Category: Valvular Interventions and Structural Heart Disease

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Background: Risk factors for the Society for Thoracic Surgery (STS) predicted risk of mortality (PROM) algorithm were derived from patients undergoing isolated surgical aortic valve replacement (sAVR). Despite its overall value for clinical studies, there are a number of potentially significant risk factors that markedly enhance the risk of sAVR. The impact of these factors on outcome after sAVR is not known.

Methods: To evaluate cardiac thoracic surgeons perceived incremental risk to STS score of variables not accounted for in the STS models, clinical surveys were sent to 36 high-volume cardiothoracic surgeons to provide estimates of incremental 30-day surgical mortality for factors not included in the current STS PROM algorithm. Porcelain aorta was defined as an unclampable aorta.

Results: See Table 1A. Frailty risk was assigned according to four factors and stratified by age (Table 1B). These results suggest that liver disease (Child’s Class C), extreme frailty, porcelain aorta, FEV1 < 750 cc, hostile mediastinum, and a pulmonary artery systolic pressure (PASP) >80mmHg are perceived to yield substantial mortality risk with sAVR. The incremental risk associated with frailty varies by age.

Conclusion: This survey of high-volume cardiac surgeons suggests that a number of factors beyond the STS PROM may contribute to 30-day mortality after sAVR. As these patients are often not offered sAVR, they may not be fully represented in the current STS PROM. Validation of these factors in the U.S. CoreValve percutaneous aortic valve replacement is needed.

Disclosures:
Christopher Meduri: This author has nothing to disclose.
Christopher Meduri: This author has nothing to disclose.
Title: Is the MitraClip System Feasible for Mitral Valve Prolapse Outside the A2-P2 region?

Category: Valvular Interventions and Structural Heart Disease

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Background: The Everest ll study showed that the MitraClip system is effective in reducing mitral regurgitation and improving symptoms in patients with prolapse in the A2-P2 region. This is also the most suitable pathology for surgical mitral valve repair. However, the surgical repair results in patients with mitral valve prolapse outside the A2-P2 region are not equivalent successful.

Our aim was to investigate if the MitraClip system is safe and with clinical benefit in patients with mitral valve prolapse outside the A2-P2 region and who are denied conventional surgery due to high age and co-morbidity.

Method: Seven consecutive patients with prolapse in the non A2-P2 region were included in the analysis of safety and effectiveness.

Results: The group consisted of five men and two women with an average age of 80±6 years. The mean Euroscore and NYHA-class was 10%±5 and 3±0, respectively. All patients were diagnosed with mitral regurgitation caused by mitral valve prolapse outside the A2-P2 region. We were able to implant a MitraClip in all patients. One patient received two clips. All patients had a reduction of mitral regurgitation. The mean decrease of mitral regurgitation was 2±0.8 steps on a four graded scale.

There was no procedural or 30 day mortality. There were no complications. In two patients we were caught in a chordae tendinae during the procedure, but were successful in retracting the MitraClip to the atrium without complication. The patients were discharged from the hospital directly to their homes. At follow up all patients, but one, had improved one or two steps in the NYHA classification.

Conclusions: This study indicates that the MitraClip procedure is safe and clinically effective in patients with mitral valve prolapse in the non A2-P2 region. However, the procedure can be technically challenging and requires live 3D trans esophageal echocardiography and should therefore only be performed in centers with extensive experience from the MitraClip system.

Disclosures:
Per Jacobsen: This author has nothing to disclose.
Anders Jönsson: This author has nothing to disclose.
Magnus Bäck: This author has nothing to disclose.

Title: Outcome of Percutaneous Closure of Post-Myocardial Infarction Ventricular Septal Defect

Category: Valvular Interventions and Structural Heart Disease

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Background: Post-myocardial infarction ventricular septal defect (post-MI VSD) is a rare but serious complication. Although surgical repair is the treatment option for this serious complication, mortality rate after the procedure is still high. In addition, surgical closure is difficult in acute phase due to necrotic tissue surrounding VSD. In the recent decade, percutaneous closure of VSD has become safe and less invasive with development of device. Percutaneous closure may be an alternative treatment choice for post-MI VSD.

Methods: In this study, 9 patients who underwent percutaneous post-MI VSD closure in our institution were retrospectively reviewed. Clinical course and outcome of those patients were reported.

Results: Patients’ mean age was 66.4 years old, and 7 of 9 patients (77.8%) were male. The mean time between MI occurrence and VSD closure was 22.6 days. Of the 9 patients, 2 patients needed second percutaneous closure because of significant residual shunt (6 and 57 days after first procedure, respectively). At the time of procedures, cardiogenic shock was present in 9 of 11 (81.8%) procedures. Of 11 procedures, 12 devices were deployed (1 CardioSEAL septal occluder, 4 Amplatzer atrial septal defect occluders, 5 Amplatzer muscular VSD occluders, 2 Amplatzer post-MI muscular VSD occluders). Successful device deployment was performed in 10/11 (90.9%) procedures. In 1 procedure, patient died before device deployment. In 1 patient, device deployment was successful, but patient needed coronary artery bypass graft and surgical repair because of unsuccessful percutaneous coronary intervention and severe tricuspid valve regurgitation. In-hospital death occurred in 4/9 (44.4%) patients. In the remaining 5 patients, one additional patient died because of sepsis (7 days after procedure).

Conclusions: Percutaneous closure may be considered as the treatment option for most cases of high risk post MI VSD cases.

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Asma Hussaini: This author has nothing to disclose.
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Robert Siegel: This author has nothing to disclose.
Saibai Kar: St Jude Medical, 2. Research Grants
Background: Pulmonary vein stenosis (PVS) is an infrequent but well-known complication of pulmonary vein isolation (PVI), and can sometimes progress to total pulmonary vein occlusion (PVO). We have previously published our diagnostic strategies and procedural techniques to treat PVO, and now review our intermediate results.

Methods: Patients with angiographic evidence of PVO in whom recanalization was attempted were retrospectively identified from our catheterization database. We reviewed medical records including diagnostic evaluation pre-intervention for PVS, catheterization reports, and patient follow-up including symptoms, pulmonary vein patency, and lung perfusion scans.

Results: Sixteen patients who underwent attempted recanalization between 6/2005 and 12/2011 were identified, with median age of 56.6 (0.2-67.3) years and median weight of 88 (5.0-111.4) kg. Median NYHA Class was 2.6 ± 0.6 and symptoms included dyspnea in 13/16 (81%), cough in 8/16 (50%), and hemoptysis in 6/16 (46%). Procedural success, defined as recanalization of occluded vein, was accomplished in 14/16 patients (88%), with 11 patients undergoing primary balloon dilation and 3 primary stenting. Median follow-up was 14 (0-42) months, with one patient still awaiting follow-up. Of the remaining 13 patients, 7/13 (54%) had reocclusion of affected vein at a median follow-up of 3 (0.6-7) months: 6/10 (60%) post primary balloon dilation and 1/3 (33%) post primary stenting. Despite reocclusion in many, the reference vessel diameter still increased from 4.8 ± 2.4 mm to 8.5 ± 4.2 mm (p<0.001) between the first and second catheterizations, allowing for a more lasting secondary intervention. Successful repeat recanalization and stent placement were accomplished in 5/7 (71%). At latest follow-up, 11/13 (85%) vessels remain patent and % flow to affected lung segment increased from 6.3 ± 3.7% pre-intervention to 12.1 ± 6.7% post-intervention (p<0.001). Mean NYHA Class symptoms improved from 2.6 ± 0.6 to 1.4 ± 0.4 (p<0.001), and no patient had residual hemoptysis.

Conclusion: Recanalization of total PVO can be accomplished with good mid-term vessel patency with improvement in symptoms and flow to affected lung quadrants. Reocclusion following balloon angioplasty is common, but vessel growth is often observed allowing placement of a residual hemoptysis.

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A-041

Title: VARC Outcomes Following Transcatheter Aortic Valve Implantation With Both Edwards SAPIEN™ and Medtronic CoreValve ReValving System® Devices: 30-Days and One-Year Results from the Milan Registry

Category: Valvular Interventions and Structural Heart Disease

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Background: To assess clinical outcomes following transcatheter aortic valve implantation (TAVI) according to the Valve Academic Research Consortium (VARC) definitions.

Methods: All consecutive patients with severe native valve aortic stenosis treated with TAVI from November 2007 to November 2011 in our center utilizing either Edwards SAPIENTM (ESV) or Medtronic CoreValve ReValving System® (MCV) were analyzed. The analyses for valve types and experience (2007-2009 vs.2010-2011) were performed in the transfemoral (TF) group.

Results: In total, 359 patients treated with TAVI were included. In most cases, the TF access site (n = 296; 82.5%) was used. The overall mean age was 79.6±7.0 years, logistic EuroSCORE 23.6±16.5% and STS score 8.8±8.6%. The median clinical follow-up length was 373.5 (IQR 101.8-544.8) days. Thirty-day mortality was 5.2% in the overall population with myocardial infarction rate 1.4% and stroke 0.8%. Life-threatening bleeding occurred in 24.2% and 14.5% had a major vascular complication. At one-year, all-cause mortality was 17.9%. According to valve type, there were no differences in device success, combined safety or efficacy endpoints. However, there was a significantly higher rate of conduction disturbances or arrhythmia (29.6% vs. 13.8%; p = 0.001) as well as pacemaker implantation (28.7% vs. 6.1%; p<0.001) with MCV. According to experience, there were reductions in life-threatening bleeding (36.0% vs. 15.3%; p<0.001) and major vascular complications (24.0% vs. 12.2%; p = 0.009) resulting in a trend for improvement in the combined safety endpoint (55.0% vs. 65.3%; p = 0.084).

Conclusion: In our single-center experience, TAVI was a safe and effective procedure in patients with severe AS considered high-risk for SAVR, with a low mortality rate at 30-days and one-year follow-up and acceptable outcomes according to VARC definitions.

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B-004

Title: Outcome of Aortic Valve Replacement in a Single in Centre in the UK and the Future of TAVI

Category: Valvular Interventions and Structural Heart Disease

Authors: Tarq Husein, M.B.B.S., ABMU Health Board, United Kingdom, Swansea, Wales1; Omar Aldalati, M.D., MRCP, ABMU Health Board, United Kingdom, Swansea, Wales2; Hussain Hussain, M.B.B.S., ABMU Health Board, United Kingdom, Swansea, Wales3;
Introduction: TAVI is being increasingly adopted worldwide. A EUROSCORE of 10 (peri-operative mortality of approximately 20%) is a commonly used indication, however it is not globally agreed on, and the selection process for TAVI is case-based.

Objectives: To compare the outcome of the conventional AVRs in our centre, based on their EUROSCORE, low risk versus high risk (cutoff 10, potential TAVI candidates, EUROSCORE >9).

Methods: We data-mined our cardio-thoracic and Welsh demographic databases for all the AVRs done between 1996 and 2009. SPSS 17 was used to carry out the analysis.

Results: 1905 AVRs were done in our centre during the study period. Out of which, 884 cases had a valid EUROSCORE, unsurprisingly all after 2006 (male 62.7%, mean age [SD] 71.05 [10.19] years, range 18-94y). Patients with a EUROSCORE more than 9 were three times more likely to succumb within one year of the operation (relative risk 2.875). The mean survival for those with a high score of more than 9 was 912.15 days where as the mean was 1023.54 days for those with a low score (p value <0.02). Using Kaplan-Meier survival curve shows a difference in survival between the two groups. The Mean bypass operation time was 170.38 minutes for high score versus 144.03 for low score (p <0.02). Patient mean total hospital stay in days was 31.21 for the group with a EUROSCORE > 9 versus 17.01 for those with a lower score (p<0.02).

Conclusion: Patients with perioperative mortality for conventional AVR of 20% (EUROSCORE >9 ) have a worse outcome than patients with a lower EUROSCORE, though the survival of both groups is still comparable. Further studies are required to determine a better scoring system to aid us in deciding on suitable candidates for TAVI.

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Tareq Husein: This author has nothing to disclose.
Omar Aldalati: This author has nothing to disclose.
Hussain Hussain: This author has nothing to disclose.
Rushda Rajak: This author has nothing to disclose.
Adrian Ionescu: This author has nothing to disclose.

Title: What is the Optimal Attachment Method for the Transcatheter Patch in Left Atrial Appendage Occlusion: Surgical Adhesive or Direct Stretching?

Category: Valvular Interventions and Structural Heart Disease

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Background: The Transcatheter Patch (TP) is a wireless bio-absorbable device which can be attached to the left atrial appendage (LAA) using a surgical adhesive (SA) or through direct stretching of the appendage walls with the immediate release patch (IRP) model. The purpose of this observational study was to compare the efficacy of attachment between the two methods. Results from our early experience with the IRP were compared with results from our experience with the SA method. All procedures were performed in high risk for stroke patients with atrial fibrillation (AF).

Method: LAA occlusions were performed in 20 patients with the SA method and in five patients with the IRP. In the SA group, the two stage adhesive (polyethylene glycol) was applied on the distal half of the patch in an inactive form; activation occurred after placement and the patch was released in 45 minutes. In the IRP group, the device was inflated in the appendage, stretching the walls, and was immediately released in its inflated form. Occlusion was performed under TEE and Fluoroscopy. Angiography was performed in three SA patients and in all IRP patients.

Results: The TP was well attached in 17/20 patients of the SA group. In three patients with prior angiography, the patch was not attached after 45 minutes and required retrieval. In a fourth case there was thrombus formation after the long sheath was withdrawn (45 minutes) requiring treatment. All patients in the IRP group had full occlusion and immediate release of the device without complications. All implanted patients in both groups had no long term complications or recurrence of the strokes.

Conclusion: TP occlusion of the LAA is safe in most high risk for stroke patients. Angiography seems to be contraindicated in patients where SA is used. Attachment of the IRP by direct stretching of the LAA appears more convenient since the device is immediately released and is not dependent on factors affecting SA attachment.

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Title: Inferior Epigastric Artery as a Landmark for Transfemoral Transcatheter Aortic Valve Implantation with CoreValve

Category: Valvular Interventions and Structural Heart Disease

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Method: During the study period, 35 consecutive patients (men 21, mean age 71 years) were included, 24 of whom had a simple transfemoral approach with ilio-femoral access and trans-septal orientation. In these patients, a single 7 French wire with a 9 French sheath (since February 2006) was used. The 11 patients that underwent trans-septal approach were younger (62 years) and had a higher logistic EuroSCORE (17.1% vs 7.1%). The duration of hospitalization was significantly lower in the transfemoral approach group (1.3±1.1 days vs 7±1 days, p=0.006) and the mean percutaneous time was 4.3±1.4 minutes vs 6.3±2.5 minutes (p<0.001). In the trans-septal approach group, the time required for access to the sheath was longer, while the mean time to the trans-septal puncture was shorter (33±5 vs 48.6±5.2 minutes, p<0.001).

Conclusion: The inferior epigastric artery (IEA) is a reliable landmark for guiding the transfemoral approach in transcatheter aortic valve implantation (TAVI) with CoreValve. The trans-septal approach does not appear to significantly impact the operative results, but requires additional time for trans-septal puncture. The use of a single 7 French wire and 9 French sheath may contribute to reducing the time required for the procedure and hospitalization.
Background: Vascular access complications are a main issue during Transfemoral Aortic Valve Implantation (TAVI). The need for establishment of reliable predictors for these serious events remains important. This study sought to investigate whether the site of common Femoral Artery (FA) cannulation in regard to the inferior epigastric artery, is associated with the incidence of vascular complications in patients undergoing TAVI.

Methods: A total of 90 patients, who had undergone TAVI, were retrospectively studied. Vascular complications were defined as major and minor according to the Valve Academic Research Consortium (VARC) criteria. Patients were divided into High Cannulation Site (CS) group and Low CS group depending on the common FA puncture site position, in regards to the most inferior border of the inferior epigastric artery.

Results: Vascular complications were significantly more frequent in the high CS group versus the low CS group (32.3% vs 11.9%, p = 1.441-16.168; p = 0.011). High cannulation remained an independent predictor of vascular complications after adjustment for known risk factors (OR: 4.827, CI: 1.441-16.168; p = 0.011).

Conclusion: In patients undergoing transfemoral TAVI, arterial puncture above the most inferior border of the inferior epigastric artery is associated with vascular complications.

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Christodoulos Stefanadis: This author has nothing to disclose.

B-026

Title: Discrepancies Between Direct Catheter and Echocardiography Based Values in Aortic Stenosis

Category: Valvular Interventions and Structural Heart Disease

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Background: Current guidelines discourage aortic stenosis (AS) evaluation by direct pressure measurement if echocardiography (echo) is adequate. Several studies show sizable differences between echo and catheterization (cath) lab measurements; using high quality techniques, we examine this correlation.

Methods: We performed sequential retrospective review of patients aged 40-90 years with suspected AS by echo (n = 42) who underwent right and left heart catheterization during 2008 to 2011. Catheterizations were conducted by two interventional cardiologists in an academic community hospital. Valve measurements were derived from directly measured pressure gradients via left ventricular pressure wire (St. Jude) and ascending aorta catheter; this is in contrast to previous studies which have utilized variations of the “pull-back” method with diagnostic catheters.

Pre-catheterization 2D trans-thoracic echocardiograms were from various institutions, obtained by a wide variety of echocardiography technicians, and read by 15 certified cardiologists. Original echocardiogram films were independently reviewed by the investigators to assess the quality of community-based readings.

Results: Cath changed assessment of severity of aortic valve area (AVA) by more than 0.3cm² in 33% and 0.5cm² in 12%. Values changed to over or under the surgical threshold of AVA <1cm² in 25% of the patients. Pearson correlation of 0.45 between measurements of AVA is lower than prior studies indicate. Echo reviews provided minimal improvement in discrepancies, suggesting quality of initial interpretation was not the issue.

Conclusion: Cath-echo correlation of AS severity is lower in contemporaneous practice than previously assumed. This can alter the decision for aortic valve replacement. Sole reliance on echo-derived assessment of AS may need to be reconsidered.

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Chia-Shing Yang: This author has nothing to disclose.
Erik Marshall: This author has nothing to disclose.
Michael Kostal: This author has nothing to disclose.
Joseph West: This author has nothing to disclose.
Andrew Doorey: This author has nothing to disclose.
Title: Predictive Factors of Access Site Vascular Complications After TAVI in Patients Treated with a Default Percutaneous Strategy. Experience with the Prostar Closure Device

Category: Valvular Interventions and Structural Heart Disease

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Background: Access site vascular complications, despite the use of percutaneous approach techniques with closure devices such as Prostar, still occur. In this retrospective study we will report, incidence and factors predisposing to access site vascular complications from two centres.

Methods: Consecutive patients who underwent TAVI through femoral access during the last three years were included. The incidence of access site vascular complications was evaluated both by VASC criteria and Prostar-access site bleeding criteria as defined by the protocol. The impact of the ratio of total arterial tortuosity divided to access vessel diameter was assessed during the last three years. The incidence of access site vascular complications was 8.7%.

Results: Overall, data from 84 patients (42 males (48.8%), 38 females (51.2%)) were analyzed. Vascular complications reported with an incidence of 21.43%. Patients with greater TT/AD, not ideal puncture and those with combination of atheromatosis and angulation at the puncture site had a greater incidence of vascular complications as defined by both classifications. Additionally, TT/AD predicted with 66.7% sensitivity and 74.2% specificity vascular complications. Furthermore, the ratio TT/AD (p = 0.016) remained an independent predictor after adjustment for covariants. Finally, overall morality observed at 30 days was low (4.76%).

Conclusion: Access site complications after TAVI with the use of Prostar closure device can be predicted by TT/AD ratio, not ideal puncture and combination of atheromatosis and angulation at the puncture site. Further validation for our findings will enforce the use of the above criteria into clinical practice.

Disclosures: Manolis Vavuranakis: This author has nothing to disclose. Maria Kariori: This author has nothing to disclose. Vassilios Voudris: This author has nothing to disclose. Dimitrios Vrachatis: This author has nothing to disclose. Konstantinos Kalogeris: This author has nothing to disclose. Carmen Moldovan: This author has nothing to disclose. Sophia Thomopoulou: This author has nothing to disclose. Konstantinos Assaadou: This author has nothing to disclose. Konstantinos Athis: This author has nothing to disclose.

C-029

Title: Interventional Closure of the Left Atrial Appendage for Stroke Prevention in Clinical Routine is Safe- Experience From a High Volume Center

Category: Valvular Interventions and Structural Heart Disease

Authors: Sven Möbius-Winkler, M.D., Heart Center, University of Leipzig, Germany, Leipzig; Marcus Sandri, M.D., Heart Center, University of Leipzig, Germany, Leipzig; Ingo Dähnert, M.D., Heart Center, University of Leipzig, Germany, Leipzig; Nicolas Majunke, M.D., Heart Center, University of Leipzig, Germany, Leipzig; Christodoulos Stefanadis: This author has nothing to disclose.

Background: Since the PROTECT AF study was published, left atrial appendage (LAA) closure with the Watchman Device is an alternative therapy to oral anticoagulation for patients suffering from atrial fibrillation at risk for stroke. Recently published data showed a remarkable learning curve for the implantation procedure of the Watchman device. However, data from clinical routine are rare.

Aim of the current study was to assess implantation success and rate on serious pericardial effusion as well as overall complication rates in clinical routine at a high volume center.

Methods: Since implementation of the LAA closure program implantation of a LAA occluder (Watchman or ACP device) was performed in 155 patients. 146 patients underwent Watchman device implantation whereas 9 patients underwent ACP device implantation under mild analgesia with midazolam and propofol since late 2009.

Results: The patients were in mean 73.4 years old with a moderate to high risk for stroke (CHADS2 Score 2.85). Over all 150 patients were successfully implanted (96.9%), whereas 4 patients were not implanted due to anatomical reasons, and in 1 patient device embolisation occurred (3.1%). From the successfully implanted 150 patients 3 patients (2%) had a second implantation procedure due to unsuccessful first implantation.

The following complications occurred:

<table>
<thead>
<tr>
<th>All complications</th>
<th>155 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>death</td>
<td>0</td>
</tr>
<tr>
<td>stroke/TIA</td>
<td>0</td>
</tr>
<tr>
<td>pericardial tamponade</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td>pericardial effusion without therapy</td>
<td>5 (3.2%)</td>
</tr>
<tr>
<td>transient ST segment elevation due to air embolisation</td>
<td>3 (2%)</td>
</tr>
</tbody>
</table>

Conclusion: Implantation of an LAA Occluder in a high volume center is safe and feasible. There are only rare cases where an LAA Occluder is not implantable for anatomical reasons. Despite an over all complication rate of 5.8% life threatening complications are rare.

Disclosures: Sven Möbius-Winkler: Procter Fee, 5. Consulting Fees or Other Remuneration, Honorary, 8. Speaker’s Bureau. Nicolas Majunke: This author has nothing to disclose.
C-037

Title: Outcomes Following Transcatheter Aortic Valve Implantation Comparing Edwards SAPIENTM With Medtronic CoreValve ReValving System® Devices: Results from the Milan Registry

Category: Valvar Interventions and Structural Heart Disease

Authors: Gill Louise Buchanan, M.D., San Raffaele Scientific Institute, Italy, Milan; Alaide Chieffo, M.D., San Raffaele Scientific Institute, Italy, Milan; Matteo Montorfano, M.D., San Raffaele Scientific Institute, Italy, Milan; Francesco Miasano, M.D., San Raffaele Scientific Institute, Italy, Milan; Filippo Fignon, M.D., San Raffaele Scientific Institute, Italy, Milan; Micaela Cioni, M.D., San Raffaele Scientific Institute, Italy, Milan; Remo Daniel Covello, M.D., San Raffaele Scientific Institute, Italy, Milan; Annalisa Franco, M.D., San Raffaele Scientific Institute, Italy, Milan; Chiara Gerli, M.D., San Raffaele Scientific Institute, Italy, Milan; Antonio Colombo, M.D., San Raffaele Scientific Institute, Italy, Milan; Ottavio Alfieri, M.D., San Raffaele Scientific Institute, Italy, Milan.

Background: To assess clinical outcomes of transcatheter aortic valve implantation (TAVI) comparing Medtronic CoreValve ReValving System® with Edwards SAPIEN XT™.

Methods: All consecutive patients in our center with aortic stenosis treated with transfemoral Medtronic CoreValve ReValving System® (MCV) from November 2009 to September 2011 (learning curve patients excluded) or Edwards SAPIENT™ (ESV) from April 2010 to September 2011 when the device became available were included.

Results: In total, there were 192 patients in this analysis. The overall mean age was 79.4 ± 8.1 years, logistic EuroSCORE 21.1 ± 15.9% and STS-PROM score 8.8 ± 8.6%. The MCV group consisted of a greater proportion of males (60.3% vs. 43.7%; p = 0.012) with an additionally higher rate of prior surgery (56.7% vs. 37.5%; p = 0.002). The median clinical follow-up length was 171 (IQR 54-357) days. Thirty-day all-cause mortality was 4.0%, myocardial infarction rate 1.0% and stroke 0.5%, with no differences between valve types. Life-threatening bleeding occurred in 14.7% and 11.5% had a major vascular complication. There were no differences in the combined safety endpoint at 30 days (ESV 72.2% vs. MCV 71.9%; p = 0.936). However, there was a significantly higher rate of device success amongst the ESV group (98.5% vs. 90.4%; p = 0.012) with additionally a significantly higher rate of conduction disturbances/arrhythmia (31.5% vs. 16.0%; p = 0.011) as well as pacemaker implantation (28.6% vs. 5.0%; p < 0.001) with MCV compared with ESV.

Conclusion: In our single center experience, TAVI was a relatively safe and effective procedure utilizing both commercially available devices. However, there was an increased incidence of arrhythmia and pacemaker implantation in the MCV group.

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Gill Louise Buchanan: This author has nothing to disclose.
Alaide Chieffo: This author has nothing to disclose.
Matteo Montorfano: This author has nothing to disclose.
Francesco Miasano: This author has nothing to disclose.

C-041

Title: Long-term Safety and Efficacy of Percutaneous Left Ventricular Transapical Access and Closure for Structural Heart Disease Interventions

Category: Valvar Interventions and Structural Heart Disease

Authors: Chad Kliger, M.D., M.S., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Bryce Einhorn, None, Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Vladimir Jelnin, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Leon-dro Maranan, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Izhak Kronzon, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Howard Cohen, M.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY; Carlos E. Ruiz, M.D., Ph.D., Lenox Hill Heart and Vascular Institute of New York, United States, New York, NY.

Background: Percutaneous transapical left ventricular (LV) access has been used for many years in the diagnostic and hemodynamic assessment of heart disease and more recently, for a multitude of interventional procedures. Common structural heart disease procedures that have benefitted from this approach include the closure of prosthetic paravalvular leaks (PVL), ventricular septal defects (VSD), and LV pseudoaneurysms. Direct transapical puncture and device closure of the LV access site have demonstrated acute feasibility and safety with low complication rates. However, the long-term safety and efficacy of transapical access and closure have not been evaluated.

Methods: We evaluated patients at our center, from March 2008 to June 2011, who underwent structural heart disease interventions via a percutaneous transapical approach, were at least 6 months from their procedure and received a 6-mm Amplatz Ductal Occluder for transapical closure. Post-procedural aspirin and clopidogrel therapy were not required. Follow-up 2-D and 3-D transthoracic echocardiography (TTE) was performed in all patients. Cardiac computed tomographic angiography (CTA) with retrospective electrocardiogram-gated multiphase reconstruction was performed if TTE views were limited.

Results: A total of 6 patients were included (4 PVLs, 1 VSD, and 1 LV pseudoaneurysm). Mean time of procedure to follow-up imaging study was 11.2 ± 2.6 months. In all 6 patients, there were no changes to the LV myocardium, to the device, or to the lungs and no pericardial or pleural effusions were noted. There were no LV pseudoaneurysms at the puncture site or new wall motion abnormalities. In 2 patients, an apical wall motion abnormality was observed around the closure device. However, this was unchanged from the pre-procedural TTE and occurred in the setting of ventricular pacing. The devices were stable in location and exhibited no evidence of erosion, calcification, or thrombus formation. In the four patients in whom a CTA was performed, there was no evidence of left lung scarring or other pathology.
Conclusion: Early experience of long-term follow-up of left ventricular transapical access and closure demonstrates that using an Amplatzer Ductal Occluder can be safe and reliable, without evidence of structural abnormalities. Further evaluation of the long-term safety and efficacy of transapical closure is necessary given the increased utilization of this technique.

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Bryce Einhorn: This author has nothing to disclose.
Vladimir Jelnin: This author has nothing to disclose.
Leandro Maranan: This author has nothing to disclose.
Gila Perk: This author has nothing to disclose.
Howard Cohen: This author has nothing to disclose.
Itzhak Kronzon: This author has nothing to disclose.
Carlos E. Ruiz: This author has nothing to disclose.

D-008
Title: Left Ventricular Pseudoaneurysm Exclusion by Trans-Apical Placement of an Amplatzer VSD Occluder: A Hybrid Procedure
Category: Valvular Interventions and Structural Heart Disease
Authors: Peter Pelikan, M.D., Pacific Heart Institute, United States, Santa Monica, CA 1; John Robertson, M.D., Saint John’s Health Center, United States, Santa Monica, CA 2; Curtis Hunter, M.D., Saint John’s Health Center, United States, 2121 Santa Monica Boulevard, CA 3; Richard Wright, M.D., Pacific Heart Institute, United States, Santa Monica, CA 4

Background: Left ventricular (LV) pseudoaneurysm can occur as a complication of myocardial infarction, trauma, endocarditis, operative LV vent placement, and cardiac surgery including valve replacement. This 70 year old female with a strong family history of thoracic aortic dissection underwent Bentall aortic root replacement in 1999 with a 25 mm St. Jude valved conduit. During serial echocardiographic follow-up, a “mass” was noted near the right coronary artery (RCA) re-implant site. Coronary angiography showed no evidence of RCA pseudoaneurysm. Trans-septal catheterization and LV-angiography revealed a high-septal, multi-lobed LV pseudoaneurysm with systolic expansion (Fig. 1). Serial follow-up with CT angiography documented progressive enlargement over three years.

Methods: The patient was fully consented for off-label use of an Amplatzer muscular VSD occluder. A trans-apical approach was chosen as the best option to deliver the device to the high LV septum. Trans-septal delivery was considered, but it was thought that the delivery catheter would kink during retroflexion to the LV outflow tract. A 9F sheath was trans-apically placed during left thoracotomy, with direct surgical closure of the apical puncture site at the end of the procedure. A 6F Terumo destination sheath was advanced through the 9F sheath and into the pseudoaneurysm cavity, after which a 6 mm Amplatzer VSD device was deployed under fluoroscopic and trans-esophageal guidance.

Results: After device deployment, minimal contrast entry into the pseudoaneurysm was immediately noted (Fig. 2). CT angiographic follow-up showed complete involution of the pseudoaneurysm.

Conclusion: Because of the mortality associated with LV pseudoaneurysm, and with progressive enlargement over three years, closure was indicated. Open surgical closure would have required a complete re-do of the Bentall, which could have again left this patient at risk for recurrent pseudoaneurysm formation. This hybrid approach allowed direct closure with a VSD closure device with a much less invasive, and a lower risk procedure. This method should be considered for LV pseudoaneurysms not accessible via trans-septal approach. The relative benefits of percutaneous vs. open/hybrid procedures will be presented.

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Peter Pelikan: This author has nothing to disclose.
John Robertson: This author has nothing to disclose.
Curtis Hunter: This author has nothing to disclose.
Richard Wright: This author has nothing to disclose.

D-018
Title: Patients with Increased Troponin I Levels After TAVI Manifested Distinct Electrocardiographic Changes
Category: Valvular Interventions and Structural Heart Disease
Authors: Manolis Vavuranakis, M.D., Ph.D., Hippokration Hospital, National and Kapodistrian University of Athens, Greece, Athens 1; Maria Kariotiri, M.D., Hippokration Hospital, National and Kapodistrian University of Athens, Greece, Athens 2; Carmen Moldovan, M.D., Hippokration...
Background: Uncomplicated transcatheter aortic valve implantation (TAVI) procedures could be associated with a rise in cardiac markers of myocardial injury. The reason for that is multifactorial. It has not been evaluated whether this elevation is associated with new electrocardiographic (ECG) findings after TAVI. We determined the incidence and evaluated whether this elevation is associated with new electrocardiographic findings after TAVI. We determined the incidence and agreement with the respective findings after TAVI for every patient with elevated troponin levels, baseline and post-procedural ECG recordings were compared.

Methods: Consecutive patients, without significant coronary artery disease, who underwent uncomplicated transcatheter aortic valve implantation (TAVI) were evaluated. Troponin I levels and electrocardiograms were recorded daily, before and for 5 days after the procedure. In patients with elevated troponin levels, baseline and post-procedural ECG recordings were compared.

Results: Out of 115 consecutive patients (pts), 47 pts (20 males, mean age 80.55±5.07 yrs) manifested elevated troponin I levels (mean troponin I = 1.38 ±1.05). The ECG findings before TAVI showed a significant agreement with the respective findings after TAVI for every ECG feature except for QTc prolongation. Before TAVI, QTc prolongation (470.13±7.67) was detected in 8 pts (18.2%) while after TAVI, prolonged QTc (481.8±20.2) was observed in 73.3% (p<0.001). Moreover after TAVI, we recorded significant increase in 1st degree atrioventricular block (15.9% vs. 31.8%, p<0.01) and left bundle branch block (LBBB) frequency (4.5% vs. 45.5%, p<0.01).

Conclusion: In patients with increased Troponin I elevation after TAVI the incidence of prolonged QTc is increased. This may reflect ischemia as a result of microembolization or the mechanical effect of the prosthesis itself on the conduction system.

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Manolis Vavuranakis: This author has nothing to disclose.
Maria Kariori: This author has nothing to disclose.
Carmen Moldovan: This author has nothing to disclose.
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Konstantinos Kalogeras: This author has nothing to disclose.
Theodore Papaoannou: This author has nothing to disclose.
Sofia Thomopoulou: This author has nothing to disclose.

Konstantinos Tzannos: This author has nothing to disclose.
George Lazaros: This author has nothing to disclose.
Dimitrios Vrachatis: This author has nothing to disclose.
Konstantinos Kalogeras: This author has nothing to disclose.
Theodore Papaoannou: This author has nothing to disclose.
Sofia Thomopoulou: This author has nothing to disclose.

Vascular Complications Following Percutaneous Aortic Valve Balloon Valvuloplasty

Figure 1. Vascular Complications Following Percutaneous Aortic Valve Balloon Valvuloplasty.
underwent standard sheath removal technique (waiting for ACT to be lower than 180) following PABV.

**Results:** Twenty eight patients underwent PABV between 2009 and 2011. Thirteen patients (46%) underwent standard sheath removal after ACT decreased to <180, and 15 patients (54%) received protamine followed by immediate sheath removal. Among the 13 patients who underwent standard sheath removal technique following PABV, 2 patients (15.4%) developed pseudoaneurysms, 3 patients (23.1%) developed hematomas, and 2 patients (15.4%) required blood transfusions. In comparison, among the 15 patients who were given protamine and followed by early sheath removal, there were no vascular complications reported.

**Conclusion:** According to our experience, protamine administration followed by early sheath removal was associated with a reduction of vascular complications compared to standard sheath removal technique. This approach might be beneficial when vascular closure devices need to be avoided to allow future femoral arterial access for TAVR.

**Disclosures:**

Amrish Malhi: This author has nothing to disclose.
Steve Simpson: This author has nothing to disclose.
Fadi Alqaisi: This author has nothing to disclose.
Janet Wyman: This author has nothing to disclose.
Surbhi Chamarian: This author has nothing to disclose.
Jimmy Zeng: This author has nothing to disclose.
Eric Yang: This author has nothing to disclose.
Adam Greenbaum: This author has nothing to disclose.
Mayra Guerrero: This author has nothing to disclose.

**AO-008**

**Title:** Echocardiographic Predictors of Single Versus Dual MitraClip Implantation and Long-Term Reduction of Mitral Regurgitation After Percutaneous Repair

**Category:** Valvular Interventions and Structural Heart Disease

**Authors:** Ehrin Armstrong, M.D., UC Davis Medical Center, United States, Sacramento, CA; Jason Rogers, M.D., UC Davis Medical Center, United States, Sacramento, CA; Christo Swan, M.D., Duke Medical Center, United States, Durham, NC; Deepa Upadhyaya, M.D., UCSF Medical Center, United States, San Francisco, CA; Ravi Garg, M.D., UCSF Medical Center, United States, San Francisco, CA; Ravi Garg, M.D., UCSF Medical Center, United States, San Francisco, CA; Esperanza Viloria, None, UCSF Medical Center, United States, San Francisco, CA; Christo Swan, None, UCSF Medical Center, United States, San Francisco, CA; Charles McCulloch, Ph.D., UCSF Medical Center, United States, San Francisco, CA; Ted Feldman, M.D., Evanston Hospital, Chicago, IL, United States, Evanston, IL; Elyse Foster, M.D., UCSF Medical Center, United States, San Francisco, CA.

**Background:** Percutaneous mitral valve repair is an emerging treatment option for patients with significant mitral regurgitation (MR). In the EVEREST trials, one or two MitraClip devices were implanted to reduce MR, as needed. We analyzed the association between baseline echocardiographic characteristics, the number of devices implanted, and long-term reduction in MR.

**Methods:** Pre-procedural transthoracic (TTE) and transesophageal echocardiograms (TEE) of 233 subjects who received one or two MitraClip devices in the EVEREST II Randomized Trial and High-Risk Registry were analyzed. Follow-up MR was assessed by interval TTE post-procedure and at 12 months. A multivariate model was developed to explore the relationship between echocardiographic characteristics and the number of devices implanted.

**Results:** 97/233 subjects (42%) had two MitraClip devices implanted. On univariate analysis, subjects with more severe MR were more likely to receive two devices (mean regurgitant volume 45.9±21.9 mL vs. 36.3±18.5 mL for two vs. one device, p < 0.001). On multivariate analysis, increased anterior leaflet thickness (p = 0.007) and greater baseline regurgitant volume (p = 0.01) were associated with increased odds of implanting two MitraClip devices. The frequency of 2+ MR or less at hospital discharge was similar regardless of the number of devices implanted (83% for one device and 79% for two devices, p = 0.4). At 12 months, MR was also significantly reduced regardless of the number of devices implanted (Figure).

**Conclusion:** Subjects with thicker anterior mitral leaflets and quantitatively more severe MR were more likely to receive two MitraClip devices. Immediate and long-term reduction in MR was similar with 1 or 2 devices.

**Disclosures:**

Ehrin Armstrong: This author has nothing to disclose.
Jason Rogers: Medtronic, 5. Consulting Fees or Other Remuneration, Boston Scientific, 5. Consulting Fees or Other Remuneration, Volcano, 5. Consulting Fees or Other Remuneration.
Christo Swan: This author has nothing to disclose.
Deepa Upadhyaya: This author has nothing to disclose.
Ravi Garg: This author has nothing to disclose.
Ravi Garg: This author has nothing to disclose.
Charles McCulloch: This author has nothing to disclose.

**AO-002**

**Title:** Final Results of the EVEREST I Feasibility Study of MitraClip Therapy

**Category:** Valvular Interventions and Structural Heart Disease

**Authors:** Ted Feldman, M.D., Evanston Hospital, Northshore University Healthsystems, United States, Evanston, IL; Elyse Foster, M.D., University of California (San Francisco), United States, San Francisco, CA; Howard Herrmann, M.D., Hospital of the University of Pennsylvania, United States, Philadelphia, PA; Patrick Whitlow, M.D., Cleveland Clinic Foundation, United States, Cleveland, OH; William Gray, M.D., New York Presbyterian Hospital, Columbia Campus, United States, New York, NY; Laura Mauri, M.D., Brigham & Women’s Hospital, United States, Boston, MA.

**Background:** EVEREST I was a prospective, non-randomized, first-in-man evaluation of the preliminary safety and effectiveness of MitraClip therapy for the percutaneous reduction of significant mitral regurgitation (MR). Five-year follow-up is complete, and the study is closed. We report 5 year outcomes.

**Methods:** Patients with 3+ or 4+ MR with symptoms, or if asymptomatic, with LV dysfunction, and who were candidates for mitral valve (MV) surgery were considered for enrollment. Echocardiographic eligibility criteria were used; each patient had core lab assessed transthoracic and transesophageal echocardiograms. As stipulated in the EVEREST I protocol, patients who did not receive a MitraClip during the procedure
or who underwent MV surgery were withdrawn from the study. Clinical outcomes are reported for patients who achieved procedural success.

**Results:** Fifty-five patients were enrolled at 11 sites. The mean age of the patients was 68 years; baseline LVEF was 62%. Functional MR was present in 16%, Six (11%) of the 55 patients did not receive a MitraClip and were withdrawn from the study. The remaining 49 (89%) patients were implanted with 1 MitraClip (n = 34) or 2 MitraClips (n = 15); of these 49 patients, 82% were discharged with MR < = 2+. There were no deaths within 30 days of the procedure and no device embolizations during the 5-years. By 5 years, 16 (29%) patients underwent MV surgery and were withdrawn. Of these 16 patients, 8/16 underwent MV surgery by 1 year; all 8 of these patients had degenerative MR and the majority (6/8 = 75%) had a successful surgical MV repair. Reasons for the 16 MV surgeries include single leaflet device attachment (5/16), recurrent MR (5/16), residual MR (3/16) and clinical symptoms (3/16). An additional 14 (25%) patients withdrew consent to participate during the 5-year follow-up. Of the remaining 19 patients, 4 deaths occurred during the 5-year follow-up. Patients who completed 5-year follow-up showed sustained MR < = 2+ in 73%, and improvements in LV volumes (mean decrease LVEDV 58 +/- 14 ml) and NYHA Functional Class (95% Class I/II).

**Conclusion:** While representative of early learning curve results, these data from the initial safety and feasibility cohort of patients treated with MitraClip demonstrate that when successful, MR reduction with MitraClip is accompanied by reverse LV remodeling and improvements in NYHA Functional Class, consistent with the results from more contemporary MitraClip studies.

**Disclosures:**
Elyse Foster: Abbott Vascular - modest research support, Other.
Howard Hermann: Micro Interventional Devices, 5. Consulting Fees or Other Remuneration, Edwards Lifesciences - speaker fees, Other (please describe in Entity field), St. Jude Medical, 5. Consulting Fees or Other Remuneration.
Patrick Whitlow: Abbott Vascular - modest research support, Other (please describe in Entity field).
William Gray: Abbott Vascular - modest research support, Other (please describe in Entity field).
Laura Mauri: Abbott Vascular - modest research support, Other (please describe in Entity field), Boston Scientific, Cordis, Medtronic, Bristol-Myers Squibb, Sanoﬁ-Aventis, Eli Lilly, Daiichi-Sankyo, 2. Research Grants.

**AO-001**

**Title:** Impact of Experience of Percutaneous Reduction of Mitral Regurgitation With the MitraClip Device on Procedural Results

**Category:** Valvular Interventions and Structural Heart Disease

**Authors:** Saibal Kar, M.D., Cedars-Sinai Medical Center, United States, Los Angeles, CA; D. Scott Lim, M.D., University of Virginia Health System, United States, Charlottesville, VA; Michael Rinaldi, M.D., Carolinas Heart and Vascular Institute, United States, Charlotte, NC; Elyse Foster, M.D., University of California, San Francisco, United States, San Francisco, CA; Laura Mauri, M.D., Brigham And Women’s Hospital, United States, Boston, MA; Donald Glower, M.D., Duke University Medical Center, United States, Durham, NC; Ted Feldman, M.D., Evanston Hospital, Northshore University Healthsystems, United States, Evanston, IL.

**Background:** The effects of clinical experience, improved patient selection, and physician training contribute to improvement of procedural results of new medical devices over time. The purpose of this analysis is to assess learning over time in the use of the MitraClip device. We report on the following measures of experience in the 7-year duration of the EVEREST trials: procedure and device time, fluoroscopy duration, incidence of zero devices implanted, incidence of acute procedural success (APS), and incidence of single leaflet device attachment (SLDA).

**Methods:** Data from the EVEREST I, EVEREST II Randomized Clinical Trial, EVEREST II High Risk trial and REALISM Continued Access trial were aggregated (n = 710). For continuous outcomes, linear models and, for dichotomous outcomes, logistic regression models were developed to estimate the effect of time since the first device treatment. In addition, the model fit for APS accounted for surgical risk status of patients and the interaction effect for time and surgical risk status.

**Results:** Mean procedure time decreased by 151 minutes (p<0.001) in the 7-year duration of the EVEREST trials between the first and last patients implanted with the Device. A reduction in the mean Device time of 118 minutes (p<0.001) and mean fluoroscopy duration of 35 minutes (p<0.001) were also observed. During the same period, the odds of implanting a MitraClip device improved 4-fold (p = 0.01) and was accompanied by a significant 3-fold improvement in the odds of achieving APS (p = 0.03). Surgical risk status and the interaction effect for month and surgical risk status had no significant impact on the rate of APS (p = 0.74 and 0.24, respectively). The odds of achieving no SLDA improved 15-fold (p<0.001) between the first and last MitraClip device implanted across the EVEREST trials.

**Conclusion:** Measures of MitraClip procedural technique have improved over the last 7 years as evidenced by the significant reductions in procedure time, Device implantation time, fluoroscopy time, and significant improvement in the rate of APS achieved. In addition, there is evidence of a significant decrease in the odds of patients not being implanted with a Device and a decrease in the odds of patients experiencing a SLDA, likely due to improvements in training, technique and patient selection. These outcomes from the controlled EVEREST trials provide evidence that experience with the MitraClip device resulted in important procedural learning.

**Disclosures:**
**VAScular ACCESS and ARTERIAL CLOSURE DEVICES**

**A-044**

**Title:** Radial Artery Occlusion After Transradial Catheterization in Patients Receiving Warfarin Anticoagulation

**Category:** Vascular Access and Arterial Closure Devices

**Authors:** Imdad Ahmed, M.D., Wright Center for Graduate Medical Education, Scranton, PA., United States, Scranton, PA 1; Pranjal Boruah, M.D., Wright Center for Graduate Medical Education, Scranton, PA., United States, Scranton, PA 4; Samir Pancholy, M.D., Wright Center for Graduate Medical Education, Scranton, PA., United States, Scranton, PA 4

**Background:** Transradial catheterization (TRC) has been shown to be safe in systemically anticoagulated patients on warfarin. There is no data on the incidence of radial artery occlusion (RAO) in this population.

**Methods:** 86 patients with INR greater than 2.0 on warfarin referred for TRC (Group I) were compared to 250 age, gender, size and co-morbidity matched control patients undergoing TRC (Group II), not on warfarin, receiving 50 units/kg unfractionated heparin during the procedure. TRC was performed using 5 french hydrophilic sheath and catheters and hemostasis was achieved using patent hemostasis technique. Age, gender, history of hypertension, diabetes mellitus, body mass index, and serum creatinine were recorded. RAO was assessed using plethysmography at 24 hours and 30 days after the procedure.

**Results:** Demographic, morphologic and comorbidity data are shown in Table 1, with no statistically significant differences noted between the two groups. Early RAO occurred in 18.6% patients in Group I compared to 9.6% of patients in Group II, (P = 0.024), and chronic RAO occurred in 13.9% of patients in Group I and 5.2% of patients in Group II, (P < 0.01) (Figure 1).

**Disclosures:**
- Imdad Ahmed: This author has nothing to disclose.
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- Samir Pancholy: Terumo, 8. Speaker’s Bureau

**B-001**

**Title:** Transradial Access for Coronary Intervention in the Very Elderly: Comparison Between Men and Women Regarding Feasibility, Efficacy and Safety

**Category:** Vascular Access and Arterial Closure Devices

**Authors:** Gustavo Samaja, M.D., FSCAI, Sanatorio Colegiales, Argentina, CABA 1; Aldo Rodriguez Saavedra, M.D., Hospital de Alta Complejidad de Formosa, Argentina, CABA 2; Roberto Sapino, M.D., Sanatorio Colegiales, Argentina, CABA 3; Ramiro Costello, M.D., Hospital de Alta Complejidad de Formosa, Argentina, Formosa 4

**Background:** Bleeding is a known predictor of mortality in Percutaneous Coronary Interventions (PCI). PCI through Transradial Access (TA) is accepted as an effective alternative to femoral approach in patients (p > 80 years old (Very Elderly) due to fewer vascular complications and improved comfort. Very Elderly (VE) women are high-risk population for bleeding but TA is more difficult in female patients because they have smaller mean radial diameter, more vascular tortuosity and present more arterial spasm. We aim to assess the feasibility, efficacy and safety of the TA for PCI in VE women and to evaluate the results as compared with VE men.

**Methods:** We analyzed 50 consecutive VE women treated with PCI through TA (Group A) and we compared them with 50 consecutive VE male TA PCI (Group B). We excluded p with mild or absent radial pulse, abnormal Allen test, primary PCI or in shock. We analyzed Clinical Characteristics, Severe Vascular Tortuosity (360° loop or ≥90° curve); Arterial Spasm (significant limitation of catheter movement), feasibility of TA (PCI completed through the TA), major adverse cardiovascular events (MACE) including death, AMI, emergency PCI or CABG and stroke; TA PCI success (residual stenosis <20% without MACE in TA performed PCI), major vascular complications (bleeding requiring prolonged hospitalization, surgical intervention or blood transfusion; pseudoneuromy; arteriovenous fistula; limb ischemia and nerve damage); and minor vascular complications (hematoma, neuritis).

**Results:**
- Major adverse cardiovascular events (MACE) including death, AMI, emergency PCI or CABG and stroke: TA PCI success (residual stenosis <20% without MACE in TA performed PCI)
- Major vascular complications (bleeding requiring prolonged hospitalization, surgical intervention or blood transfusion; pseudoneuromy; arteriovenous fistula; limb ischemia and nerve damage)
- Minor vascular complications (hematoma, neuritis)

<table>
<thead>
<tr>
<th>Group A n:50</th>
<th>Group B n:50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>82 (80-95)</td>
</tr>
<tr>
<td>Height (cm)/Weight (kg)</td>
<td>152/61.5</td>
</tr>
<tr>
<td>Severe tortuosity*</td>
<td>17 (34%)</td>
</tr>
<tr>
<td>Use of Wholey* or</td>
<td>19 (38%)</td>
</tr>
<tr>
<td>Hydrophilic 0.035 Wires*</td>
<td>15 (30%)</td>
</tr>
<tr>
<td>Arterial Spasm*</td>
<td>45 (90%)</td>
</tr>
<tr>
<td>TA Success: Feasibility*</td>
<td>43/45 (95.5%)</td>
</tr>
<tr>
<td>TA PCI Success: Effectiveness</td>
<td>43/45 (95.5%)</td>
</tr>
<tr>
<td>Major Vascular Complications</td>
<td>0</td>
</tr>
<tr>
<td>Minor Vascular Complications</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>In Hospital MACE</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

*p<0.05 Fishers exact test; **STEMI, Non Cardiac Death; **NSTEMI.

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<table>
<thead>
<tr>
<th>Table 1: Demographic, morphologic and comorbidity variables</th>
</tr>
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<tbody>
<tr>
<td><strong>Group I</strong></td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Gender (%) Female</td>
</tr>
<tr>
<td>Hypertension (%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Body mass index</td>
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<tr>
<td>Serum Creatinine</td>
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Conclusion: Among women >80 years old, TA PCI is feasible, effective and safe. The VE women are smaller and have more vascular tortuosity than VE men. We found more vascular spasm in women and TA results technically more challenging, with less feasibility. Effectiveness or safeness was not affected by gender differences.

Disclosures:
Gustavo Samaja: This author has nothing to disclose.
Aldo Rodriguez Saavedra: This author has nothing to disclose.
Roberto Sapino: This author has nothing to disclose.
Ramiro Costello: This author has nothing to disclose.

B-007

Title: Implementation of Radial and Assisted-Femoral Access: A QIT-Parallel Initiative

Category: Vascular Access and Arterial Closure Devices

Authors: Heidar Arjomand, M.D., FSCAI, York Hospital, United States, York, ME; Karen Monahan, R.T., York Hospital, United States, York, ME; Lisa Sprague, R.T., York Hospital, United States, York, ME; Tammy Trepanier, R.T., York Hospital, United States, York, ME; Patty LeBlanc, R.N., York Hospital, United States, York, ME; Tammy Trepanier, R.T., York Hospital, United States, York, ME; Patty LeBlanc, R.N., York Hospital, United States, York, ME; Karen Monahan, R.T., York Hospital, United States, York, ME; Alan Hymanson, M.D., York Hospital, United States, York, ME; Lawrence Petrovich, M.D., York Hospital, United States, York, ME; Patty LeBlanc, R.N., York Hospital, United States, York, ME; Tammy Trepanier, R.T., York Hospital, United States, York, ME; Alan Hymanson, M.D., York Hospital, United States, York, ME; Patty LeBlanc, R.N., York Hospital, United States, York, ME; Tammy Trepanier, R.T., York Hospital, United States, York, ME; Alan Hymanson, M.D., York Hospital, United States, York, ME; Patty LeBlanc, R.N., York Hospital, United States, York, ME; Tammy Trepanier, R.T., York Hospital, United States, York, ME; Alan Hymanson, M.D., York Hospital, United States, York, ME.

Background: In patients undergoing interventional cardiovascular procedures, access site bleeding complications result in significant morbidity and mortality. Radial artery access reduces access site bleeding. Recent data also suggest reduced vascular complications with ultrasound-assisted femoral arterial access.

Methods: We have recently enrolled in SCAI-supported Quality Improvement Toolkit (QIT) project. In parallel with QIT project, we prospectively started an initiative of monitoring physician adoption of radial or assisted-femoral access (AFA). We devised a scoring system for AFA, which allocated points for the following: pre-procedure fluoroscopy, Ultrasound or Doppler needle, and pre-procedure femoral angiogram. Utilization of each of these modalities would have score of +1, while lack of use of each modality would get a score of -1. As such, each femoral access procedure could have score ranging from -3 to +3; radial access would have score of +3.

Results: The study cohort includes 4 cardiologists (3 interventional and 1 invasive). All operators and supporting Cath Lab staff attended educational seminars on access site bleeding and outcome. Operator efficiency was assessed with operator Efficiency Rate (OER), defined as the percentage of adoption of radial access or adherence with three steps for AFA (table). Two junior operators (A & B) preferentially used radial access for most cardiac procedures, while two senior operators (C & D) continued with their routine use of femoral access. Adoption of steps of AFA varied significantly among operators; two operators (A & D) had OER of 100%, while two operators (B & C) had significant variations in their OER.

Conclusion: Our QIT-parallel initiative suggests that adoption of radial arterial access appears to be dependent, while operator willingness to adopt steps of AFA appears independent of senior/junior status. Continued education has potential to improve safety of arterial access.

Disclosures:
Heidar Arjomand: This author has nothing to disclose.
Karen Monahan: This author has nothing to disclose.
Lisa Sprague: This author has nothing to disclose.
Ramiro Costello: This author has nothing to disclose.

B-034

Title: The Significance of the Right Innominate Artery Tortuosity “M sign” in Radial Approach

Category: Vascular Access and Arterial Closure Devices

Authors: Wissam Khalife, M.D., FACC, UTMB Division Of Cardiology, United States, Galveston, TX; Mohamed Morsy, M.D., facc, UTMB Division Of Cardiology, United States, Galveston, TX; Alya Mubshat, M.D., UTMB Division Of Cardiology, United States, Galveston, TX.

Background: In the last decade the radial artery access use in the catheterization laboratory has noticeably increased worldwide. From an initial sporadic use as alternative but challenging vascular approach, radial artery is today utilized by default for percutaneous procedures in many centers. The interest in the radial artery approach is evidenced by increasing presence of specific sessions in the main interventional meetings and by continuous development of dedicated catheters and ancillary devices by manufacturers. There are several anatomical challenges facing the operator during the radial artery approach.

Methods: In our retrospective study in an academic medical center we identified the presence of a tortuous innominate artery, during right radial access, in the shape of the letter “M” as a causal factor for longer
procedure time, longer fluoroscopy time, and more use of contrast. We documented 17 patients with the “M” sign and 34 patients without the sign (2:1 for comparison). We included patients only who had diagnostic coronary angiogram. We excluded patients who had PCI or history of CABG.

Results: The average procedure time was 69 minutes for those with the “M” sign versus “44” in those without the “M” sign, with a P<0.005. The average fluoroscopy time was 21 minutes for those with the “M” sign versus 9 minutes for those without the sign with a P<0.005. The average contrast was 107 ml in those with the “M” sign versus 73 ml in those without the sign with a P<0.005.

Conclusion: Our observations support that tortuous innominate artery, the “M” sign, is highly predictive of longer procedure time, more fluoroscopy time, and more contrast use in right radial artery access for coronary catheterization. Based on our observation it might be reasonable to switch to femoral access when the “M” sign is identified.

Disclosures:
Wissam Khalife: This author has nothing to disclose.
Mohamed Morsy: This author has nothing to disclose.
Alya Mushtaq: This author has nothing to disclose.

C-002
Title: Improved Radial Artery Access Using Ultrasound Guidance
Category: Vascular Access and Arterial Closure Devices
Authors: Peter Higgins, M.D., Meadows Regional Medical Center, United States, Vidalia, GA; Travis Roose, R.T., Meadows Regional Medical Center, United States, Vidalia, GA; Heather Walters, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; Walter Hodge, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; Brandi McGowan, None, RCIS, Meadows Regional Medical Center, United States, Vidalia, GA; Kyle Gay, R.T., Meadows Regional Medical Center, United States, Vidalia, GA; Tricia Grannemann, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; John Chalker, R.N., Meadows Regional Medical Center, United States, Vidalia, GA

Background: Failure to achieve radial arterial access has been reported in 4-10% of radial catheterization procedures. As a mode of failure, unsuccessful arterial entry has been reported as the third most common mechanism. The need for right heart catheterization has been reported as a relative contraindication to radial approach. In addition, the intention of using radial access creates an expectation for the patient that the procedure will be done via the radial route. Ultrasound guidance has been shown to improve access and reduce complications in femoral catheterization. To our knowledge ultrasound guidance has not been evaluated in radial artery catheterization.

Methods: Patients referred for radial artery catheterization from Jan 2011 through Nov 2011 were included for analysis. All patients had a modified Allen’s test performed. Right heart catheterization, was performed from the same arm as the arterial access. The patient’s arms were prepped from mid humerus to the fingers and placed on an arm board in an abducted position at 90 degrees. With the operator seated, under ultrasound guidance first venous access, if required, then arterial access was obtained using a micro-puncture needle and .018 wire. The needle was visualized entering the vessel using a through and through technique at an 80-90 degree angle. The needle was flattened to 15-30 degrees and withdrawn. With flashback of blood the .018 wire was advanced. If resistance was met the needle was withdrawn slightly and the wire re-advanced. The needle was removed and 4.5 or 6F glide sheath (Terumo) was then advanced over the wire. The arm was then adducted and catheterization performed in standard fashion. If the wire could not be advanced ultrasound guidance allowed visualization of the artery as well as any intraluminal thrombus or dissection. With ultrasound guidance a patent section of artery could be identified, either more proximal or distal and the access procedure repeated.

Results: A total of 94 patients underwent radial arterial catheterization. The success rate for obtaining artery access was 100%. The artery and needle entry were easily visualized with ultrasound as well as any vascular issues that may be impeding wire passage.

Conclusion: Ultrasound guidance for radial artery catheterization allows artery access success rates of 100%. This is improved compared to published series without ultrasound guidance. Ultrasound guidance also allows successful venous access in the same arm.

Disclosures:
Peter Higgins: This author has nothing to disclose.
Travis Roose: This author has nothing to disclose.
Heather Walters: This author has nothing to disclose.
Walter Hodge: This author has nothing to disclose.
Brandi McGowan: This author has nothing to disclose.
Kyle Gay: This author has nothing to disclose.

C-004
Title: Learning Curve in Trans-Radial Cardiac Catheterization: Procedural Related Parameters Stratified by Operators’
Category: Vascular Access and Arterial Closure Devices
Authors: Peter Higgins, M.D., Meadows Regional Medical Center, United States, Vidalia, GA; Travis Roose, R.T., Meadows Regional Medical Center, United States, Vidalia, GA; Heather Walters, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; Walter Hodge, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; Brandi McGowan, None, RCIS, Meadows Regional Medical Center, United States, Vidalia, GA; Kyle Gay, R.T., Meadows Regional Medical Center, United States, Vidalia, GA; Tricia Grannemann, R.N., Meadows Regional Medical Center, United States, Vidalia, GA; John Chalker, R.N., Meadows Regional Medical Center, United States, Vidalia, GA

Background: Although previous studies have demonstrated a relationship between increased volume and decreased procedural time, no studies have looked at the integration of radial access over time.

Methods: Data was collected from patients who presented to the Vanderbilt University Medical Center cardiac catheterization laboratory from Jan 2009 to April 1 2011. Patients who underwent radial access diagnostic catheterization with and without percutaneous coronary intervention were included in this study. In total, 1,112 diagnostic cardiac catheterizations through the radial access site were analyzed. High volume, intermediate volume, and low volume operators were grouped based on the percentage of procedures performed through a radial approach.

Results: From 2009 to 2011, there was a significant decrease in fluoroscopy time in all operator groups for diagnostic catheterization (p = 0.035). The high volume operator group had 1.88 and 3.66 minute reductions in fluoroscopy time compared to the intermediate and low volume operator groups, respectively (both p values <0.001). Likewise, the intermediate volume operator group had a 1.77 minute improvement compared to the low volume operator group but this did not reach
statistical significance ($p = 0.102$). The improvement in fluoroscopy time and other procedure-related parameters was seen after approximately 25 cases with further improvement after 75 cases.

**Conclusion:** The incorporation of the radial access approach in cardiac catheterization laboratory led to a decrease in fluoroscopy time for each operator and operator group over the last three years. Our data demonstrated that higher volume radial operators have better procedure, room and fluoroscopy times when compared to intermediate and low volume operators. However, lower volume operators have a reduction in procedure-related parameters with increased radial cases. Number of procedures needed to become sufficient was demonstrated in current study.

**Disclosures:**
Ehab Kasasbeh: This author has nothing to disclose.
Babar Parvez: This author has nothing to disclose.
Robert Huang: This author has nothing to disclose.
Michele Hasselblad: This author has nothing to disclose.
Mark Glazer: This author has nothing to disclose.
Joseph Salloum: This author has nothing to disclose.
John Cleator: This author has nothing to disclose.
David Zhao: This author has nothing to disclose.

**C-006**

**Title:** Single Angio-Seal Vascular Closure of 12F Arteriotomy

**Category:** Vascular Access and Arterial Closure Devices

**Authors:** Michael Kleyan, M.D., Maimonides Medical Center, United States, Brooklyn, NY, Sergey Ayzenberg, M.D., Maimonides Medical Center, United States, Brooklyn, NY, Robert Frankel, M.D., Maimonides Medical Center, United States, Brooklyn, NY, Jacob Shani, M.D., Maimonides Medical Center, United States, Brooklyn, NY

**Objectives:** The study assessed clinical safety and efficacy of Angio-Seal for closure of 12 French arteriotomy sites in patients undergoing balloon aortic valvuloplasty (BAV).

**Background:** Procedures such as balloon aortic valvuloplasty represent challenges in management in arteriotomy closure. These patients require larger bore access and therefore carry an increased risk of vascular morbidity. Angio-Seal (St Jude Medical, St Paul, Minnesota) is among the most widely used access closure devices and its use for closure of large diameter sheath may reduce bleeding complications.

**Methods:** In this single center case series, we have evaluated 10 patients who underwent successful percutaneous aortic balloon valvuloplasty followed by use of Angio-Seal device to achieve hemostasis after removal of 12 French (4 mm) sheath in femoral artery. The device deploys a poly lactide/poly glycolide anchor inside the vessel, and collagen plug is deployed outside the vessel wall. The anchor measures 10mm in length and 2mm in width. The collagen plug measures approximately 5mm in width when deployed and layers on top of the perforation in the vessel made for access.

**Results:** Between 2008 and 2011, 10 procedures were performed. Patients ranged between the ages of 65 and 95 and had significant comorbidities that were not surgical candidates. To close the arteriotomy site we utilized single 8 French Angio-Seal closure device.

We did not experience any complications during the deployment of Angio-Seal. The device deployments were successful in all cases, and none of the anchors dislodged during the deployment of the device. No significant bleeding requiring transfusion, or thromboembolic event were noted. None of the patients developed hematoma or pseudoaneurism.

**Conclusion:** Use of single 8 French Angio-Seal devices for closure of 12 French (BAV) access sites is feasible. The diameter of arteriotomy is 4mm and 8 F Angio-Seal device provides adequate closure to achieve hemostasis. We did not experience any post-procedural complications in our group of patients.

**Disclosures:**
Michael Kleyan: This author has nothing to disclose.
Sergey Ayzenberg: This author has nothing to disclose.
Robert Frankel: This author has nothing to disclose.
Jacob Shani: This author has nothing to disclose.

**C-010**

**Title:** A Randomized, Placebo-Controlled, Double-Blind Trial of Topical Nitroglycerin and Lidocaine to Dilate the Radial Artery Prior to Transradial Cardiac Catheterization: The PRE-DILATE Study

**Category:** Vascular Access and Arterial Closure Devices

**Authors:** Anna Beyer, M.D., UCSF-Interventional Cardiology, United States, San Francisco, CA; Ramford Ng, M.D., Ucsf Department Of Cardiology, United States, Pleasanton, CA; Amardeep Singh, M.D., UCSF- Interventional Cardiology, United States, Stockton, CA; Thomas Ports, M.D., FACC, UCSF- Interventional Cardiology, United States, San Francisco, CA; Yerem Yeghiazarians, M.D., UCSF- Interventional Cardiology, United States, San Francisco, CA; Andrew Boyle, M.B.B.S., UCSF- Interventional Cardiology, United States, San Francisco, CA

**Objective:** Transradial access (TRA) is being increasingly used for both diagnostic and interventional cardiac procedures. Use of TRA offers many advantages including decreased bleeding and vascular complications, reduced length of hospital stay and reduced cost. However, the small size of the radial artery limits the size of the equipment that can be used via this approach. We sought to determine whether pre-procedural administration of topical nitroglycerin and lidocaine increases the size of the radial artery.

**Methods and Results:** Patients undergoing transradial cardiac catheterization were randomized in a double-blind fashion to a topical combination of nitroglycerin and lidocaine or placebo ointment. The primary endpoint was change in radial artery size. Secondary endpoints included radial artery spasm and radial artery patency. A total of 86 patients were enrolled (43 allocated to treatment group and 43 to placebo group). Patients underwent ultrasound of the radial artery at baseline, after the administration of the topical treatment (before the catheterization) and again before discharge. Complications were rare: one hematoma (placebo group) and one radial artery occlusion (placebo group). Baseline demographic and clinical characteristics were similar between the groups. PCI was performed in 13 (33%) patients in the treatment group 15 (36%) patients in placebo group. The baseline radial artery cross-sectional area (CSA) was similar in both groups (4.95±0.24 mm² in placebo group and 5.14±0.34 mm² in the treatment group). However, the final CSA decreased to 4.66±0.25mm² in the placebo group and increased to 5.78±0.38mm² in the treatment group ($p = 0.02$), which corresponded to a decrease in CSA by $5.6±2.1\%$ and an increase in CSA by $16.5±4.2\%$ ($p<0.0001$), respectively. Patients in the placebo group had radial arteries smaller than the outer circumference of a 6 French sheath (4.98 mm²), yet all the patients in the treatment group had arteries larger than this. Most patients in the treatment group would even be able to accommodate a sheathless 8 French guide (5.47 mm²). This has significant implications for minimizing trauma to the artery during sheath/guide insertion.

**Conclusion:** Pre-procedural administration of topical mixture of lidocaine and nitroglycerin increases pre-procedural radial artery diameter in patients undergoing cardiac catheterization via the radial artery.
C-024

Title: A Novel Method to Improve the Safety of Common Femoral Artery Puncture for Femoral Arterial Access

Category: Vascular Access and Arterial Closure Devices

Authors: Peter Pollak, M.D., UVA, United States, Charlottesville, VA; George Gillies, Ph.D., UVA, United States, Charlottesville, VA; Michael Ragosta, M.D., UVA, United States, Charlottesville, VA

Vascular complications from femoral arterial access (FA) are often caused by puncture at sites other than the common femoral artery (CFA). Current techniques for obtaining FA are guided by palpable and bony landmarks; however, the location of the puncture site is not known until after sheath insertion. We explored the feasibility of a novel method of gaining FA using a small caliber needle to identify relevant vascular landmarks angiographically.

18 patients undergoing elective FA were enrolled. Fluoroscopy was used to locate the center of the femoral head. The femoral artery pulse was palpated and a 21-gauge needle advanced until pulsatile blood returned. Contrast was injected using a 5 cc syringe during fluoroscopy, and puncture was repeated if the needle was not in the CFA. Once the operator was satisfied with the location, a 0.018” guide wire was advanced and a 6 Fr sheath inserted. Angiography was also performed through the femoral artery sheath. Both the needle angiogram (NA) and the sheath angiogram (SA) were analyzed to determine: 1) visualization of the inferior epigastric artery, 2) visualization of the bifurcation of the CFA and 3) if the puncture was in the CFA.

Both the NA and SA visualized the bifurcation of the CFA in all 18 patients. The inferior epigastric artery was visualized in 14/18 patients by NA and 17/18 patients by SA. In 3 patients, the initial puncture was not in the CFA; the needle was repositioned and ultimately all 18 patients had correct placement in the CFA. In another 3 patients, staining of the arterial wall was noted after the NA likely from streaming of contrast into a subintimal location. No vascular complications were observed in this pilot study.

Angiography through an 18-gauge needle provides adequate visualization of the important arterial landmarks for certain access to the CFA. This seminal data is proof of concept for a novel device allowing consistent definite puncture of the CFA.

Disclosures:
Peter Pollak: This author has nothing to disclose.
George Gillies: This author has nothing to disclose.
Michael Ragosta: This author has nothing to disclose.

C-032

Title: Algorithm for Heparin Dosing In Orally Anticoagulated Patients Undergoing Transradial Catheterization: Results of a Pilot Study

Category: Vascular Access and Arterial Closure Devices

Authors: Gautam K. Visweswaran, M.D., Milton S. Hershey Medical Center/Penn State University, United States, Hershey, PA; Gurpal Singh, M.D., Penn State Hershey Heart and Vascular Institute, United States, Hershey, PA; Pradeep K. Yadav, M.D., Penn State Hershey Heart and Vascular Institute, United States, Hershey, PA; Ian C. Gilchrist, M.D., Penn State Hershey Heart and Vascular Institute, United States, Hershey, PA

Abstracts S107
Background: Radial artery occlusion (RAO) can be minimized with adequate anticoagulation during radial catheterization. What to do with orally anticoagulated patients undergoing radial procedures is unclear. Oral anticoagulation is not protective against RAO but the effect of additional heparin in these patients is poorly defined. We report the results of a prospective pilot project of INR-adjusted, heparin-dosing regimen for achievement of a target activated clotting time (ACT) of 200s.

Methods: Standard NCDB baseline demographics and medications were recorded. ACT measurements immediately before and 10 mins after administration of an INR-adjusted heparin dosing regimen (if INR <2, then 50 IU/kg; INR 2-3, then 34 IU/kg; and INR >3, then 17 IU/kg) were recorded as part of a quality initiative in patients presenting with chronic warfarin anticoagulation. Correlation of ACT with baseline INR and after heparin was assessed with a goal of ACT >200s.

Results: Patients (N = 27) were on chronic anticoagulation, with no interruption or dosing change as per local practice, during transradial catheterization with planned heparin therapy. A strong positive correlation was noted between index INR and the index ACT (r = 0.53, p = 0.004). 20 (74%) patients received correct heparin dosing per protocol with 7 patients (26%) receiving dose as per the discretion of the attending physician. Of the 20 patients who received heparin dosing per protocol the final ACT was 220 ± 32s, p = 0.011, (95% CI 5.12-35.17). There were no instances of hyper-anticoagulation by ACT, prolonged hemostasis, and clinical thrombus formation in the test subjects. There were also no access related complications.

Conclusion: An INR-adjusted heparin dosing regimen may be a safe and reasonable method to achieve optimal IV anticoagulation as assessed by ACT in the chronically anticoagulated patients presenting for transradial cardiac catheterization. Further work is needed to assess such INR-driven, heparin-dosing algorithms on outcomes such as radial artery occlusion that has been reported to be relatively high on warfarin alone. Safety of heparin on top of warfarin therapy needs further definition especially in light of the variety of anti-platelet and anti-thrombin agents that may be adjunctively used in this patient population.

Disclosures: Gautam K. Visweswaran: This author has nothing to disclose. Gupral Singh: This author has nothing to disclose. Pradeep K. Yadav: This author has nothing to disclose. Ian C. Gilchrist: This author has nothing to disclose.

D-005

Title: Novel Femoral Artery Bioabsorbable Closure Device After Percutaneous Femoral Procedures: a Single-Center Preliminary Experience

Category: Vascular Access and Arterial Closure Devices

Authors: Radoslaw Kiesz, M.D., San Antonio Endovascular & Heart Institute, United States, San Antonio, TX; Brandao Carreira Virginie, M.D., Lagney Sur Marne, France, Lagney Sur Marne; Elhadad Simon, M.D., Lagney Sur Marne; Hattab Madjid: This author has nothing to disclose.

Background: Obtaining safe and effective closure of the femoral access site following percutaneous coronary interventions (PCI) can sometimes be challenging, especially in patients on anti-coagulation or anti-platelet therapy. Vascular closure devices (VSC) have been shown to shorten hemostasis time, reduce the discomfort of manual or mechanical compression, and allow for earlier ambulation after percutaneous invasive procedures without increasing vascular complications compared with conventional compression techniques.

Methods: The objective of the study was to assess the efficacy and safety of the 6 French EXOSEAL (Cordis), a novel bioabsorbable VSC that employs an extravascular closure strategy, in patients undergoing PCI and endovascular peripheral procedures via a retrograde femoral artery access. The EXOSEAL closure device is composed of a bioabsorbable plug and a Plug Delivery System which positions and releases the bioabsorbable plug to the extravascular surface of the femoral artery. Consecutive patients with a retrograde femoral arterial approach for 6 French PCI or peripheral interventions received the Exoseal VSC immediately after the procedure. Patients were ambulated 3-6 hours later, and the presence of vascular complications was determined clinically before hospital discharge.

Results: From October 2010 to February 2011, 79 patients received an 6 French Exoseal VSC after PCI(n=71) or endovascular peripheral intervention (n=8). The device could be successfully deployed in all the patients. Immediate total hemostasis was achieved with the device in 74 of 79 patients (93.7%), 5 patients needed additional manual compression and 2 experienced a minor complication (hematoma<5cm) without clinical sequelae. No other vascular complications occurred.

Conclusion: Closure of retrograde femoral artery access sites with the 6 Fr Exoseal device resulted in excellent efficacy and safety after cardiac PCI and peripheral interventions.

Disclosures: Hattab Madjid: This author has nothing to disclose. Brandao Carreira Virginie: This author has nothing to disclose. Elhadad Simon: This author has nothing to disclose.

D-020

Title: Comparison Between Antegrade vs. Retrograde Approach to Common Femoral Artery in one Day Discharge Peripheral Procedures. The CAR Trial

Category: Vascular Access and Arterial Closure Devices

Authors: Radoslaw Kiesz, M.D., San Antonio Endovascular & Heart Institute, United States, San Antonio, TX; Adam Janas, M.D., San Antonio Endovascular & Heart Institute, United States, San Antonio, TX; Magda Konkolewska, M.D., American Heart Of Poland, Poland, Katowice; Radoslaw Szymanski, M.D., American Heart Of Poland, Poland, Katowice; Szymon Wierniek, M.D., San Antonio Endovascular & Heart Institute, United States, San Antonio, TX; Micheal Cavazos, M.D., San Antonio Endovascular & Heart Institute, United States, San Antonio, TX; Pawel Buszman, M.D., Ph.D., American Heart Of Poland, Poland, Katowice.

Background: The catheter introduction site complications are the most common problem in the endovascular procedures. There are two modes of the common femoral artery access: the antegrade and the retrograde approaches. The first stick is considered as a more challenging approach to achieve, but afterwards more convenient for an operator especially during complex below the knee or distal heavily calcified arteries. Nevertheless the retrograde approach is preferred strategy in endovascular interventions. In this study we sought to evaluate differences in safety and utility between the two types of arterial access combined with Bivalirudin and Vascular Closure Device (VCD).

Methods: Between 2007 and 2012 we assigned 169 patients which undergo 335 peripheral interventions. Patients received Bivalirudine according to standard protocol. The VCD was used to achieve homeostasis in every procedure. Primary end points (Major Vascular Complications) are: retroperitoneal bleeding, urgent hospitalizations, hematoma >5cm and pseudoaneurysm. Secondary end points (Minor Vascular Complications) are: ecchymosis, hematoma <5cm and adjunctive manual compression. The follow up was proceeded before, 3 days (<2) and 30 days (<5) after discharge respectively.

Results: Average patient’s age was 68.3. 225 (67%) interventions were done with antegrade access. Homeostasis was achieved in 335
(100%) cases. Mean time to ambulation was 3.4±(2.4) hours. In the antegrade group the primary end points noted in 11 (5%) cases included 5 hematomas>5cm, 2 retroperitoneal bleedings, 0 pseudoaneurysms and 4 hospitalizations. Secondary end point was observed after 38 (17%) procedures included 11 hematomas<5cm, 8 adjunctive manual compressions, 19 ecchymosis<20cm. In the retrograde group the primary end points noted in 2 (2%) cases included 1 hematoma>5cm, 0 retroperitoneal bleedings, 1 pseudoaneurysms and 0 hospitalizations. Secondary end point was observed after 9 (8%) procedures included 11 hematomas<5cm, 8 adjunctive manual compressions, 19 ecchymosis<20cm. There were no significant differences in the primary and secondary end points between both groups.

Conclusion: It appears that there are no significant differences in the complications rate between the antegrade and the retrograde approach. Thus in patients with complex, calcified arteries the antegrade stick should be preferred.

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D-022
Title: Ambulation Three Versus Six Hours Post Femoral Artery Hemostasis in the Percutaneous Coronary Intervention Patient Category: Vascular Access and Arterial Closure Devices Authors: Warfield Karen, R.N., C.N.S, M.S.N., Mayo Clinic, United States, Rochester, MN1; Tilbury R. Thomas, M.D., Mayo Clinic, United States, Rochester, MN2; John Bresnahan, M.D., Mayo Clinic, United States, Rochester, MN2; Abhiram Prasad, M.D., Mayo Clinic, United States, Rochester, MN3; Ryan Lennon, None, Mayo Clinic, United States, Rochester, MN3

Background: Prolonged bed rest after femoral artery sheath removal following percutaneous coronary intervention (PCI) is associated with discomfort. The aim of this study was to investigate patient perceived back pain, overall discomfort, and the safety and efficacy of reducing the duration of post PCI bed rest from six to three hours.

Methods: 249 patients, including those receiving GP IIb/IIIa inhibitors, undergoing PCI utilizing 5 or 6 French sheaths from the femoral access site were randomized to either three (n = 127) or six hours (n = 122) of bed rest. Perceptions of back pain and over-all discomfort were measured by the McGill Pain Questionnaire – short form (SF-MPQ) and the Visual Analog Scale (VAS).

Results: At 3 hours post-hemostasis, 30% of all patients had at least one verbalization of pain since sheath removal and 28% required analgesics, with similar proportions in both treatment groups. Six patients developed a hematoma > 5 cm. From 3 to 6 hours post-hemostasis, 21% of patients verbalized experiencing pain on one or more occasion, and 16% required analgesia. Patient randomized to 6 hours of bed rest experienced significantly more pain: visual analog scale (p = 0.005), the Pain Rating Index (PRI) (p = 0.003) and the Present Pain Index (PPI) (p = 0.015). One patient (randomized to 3 hrs bed rest) had a hematoma at this point. After ambulation a hematoma >5 cm was observed in one patient in each of the two treatment groups (p>0.99). Re-bleeding occurred in 2 (1.6%) of the patients who had 3 hours of bed rest, compared to 1 (0.8%) of the patients with 6 hours bed rest (p>0.99).

Conclusion: Bed rest time following PCI via femoral access using 5 or 6 French sheaths can be safely reduced from six to three hours with improvement in patient comfort.

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D-044
Title: Facilitated Compression of the Radial Artery with the Syvek Patch Allows Early Hemostasis and Preservation of Radial Artery Patency: Preliminary Results of the RAPID Trial Category: Vascular Access and Arterial Closure Devices Authors: Zoltan Turi, M.D., Cooper University Hospital, United States, Camden, NJ1; Brian McEniry, None, M.S., Cooper University Hospital, United States, Camden, NJ2; Janah Aji, M.D., Cooper University Hospital, United States, Camden, NJ3; iliadis Elias, M.D., Cooper University Hospital, United States, Camden, NJ4; Simon Topalian, M.D., Cooper University Hospital, United States, Camden, NJ5; Steven Werns, M.D., Cooper University Hospital, United States, Camden, NJ6; Hasana O’Neal, P.A., Cooper University Hospital, United States, Camden, NJ7

Background: With increasing use of the radial approach for diagnostic and interventional cardiac catheterization, the standard of post procedure care has been prolonged compression, typically 2 to 6 hours, using a variety of compression techniques. The literature to date has demonstrated early loss of radial artery patency at 24 hrs in > 10% of patients, and at 30 days in approximately 5%. We hypothesized that facilitated compression using a hemostatic agent, poly-n-acetyl glucosamine (Syvek Patch, Marine Polymer Technologies, Danvers, MA) would allow shorter compression times and in turn better radial artery patency rates.

Methods: 50 patients undergoing cardiac catheterization were included in the study. The first 15 patients acted as a roll-in group for device and procedure standardization. The remaining 35 (26 diagnostic and 9 interventional) were randomized to either 10, 30, or 60 minute compression with a compression device plus a Syvek patch (n = 11,11, and 13 pts respectively). All 50 patients were included in the safety analysis. Phlebography and oximetry were recorded and a Barbeau classification was determined for both radial and ulnar artery flow at baseline, during compression, immediately after compression release, and 1hr, 4hr, and 1 day post hemostasis depending on the length of patient hospital stay. A 30 day follow-up telephone call was made to assess for any late complications.

Results: Hemostasis was successful immediately after the assigned time of compression in 34 of the 35 patients. Immediately after compression release, 31 patients had Barbeau Class A phlebography, 3 had Class B. Only 1 radial artery was occluded; that patient had a patent radial by 1 hour. The majority of patients (n = 24) were discharged after their 1 hr assessment; at the time of last in hospital assessment, the radial artery was occluded in 3 patients. There were no hematomas or other complications in any of the 50 patients, and 30 day follow-up telephone calls revealed no complaints relegatable to the radial catheterization.

Conclusion: Accelerated hemostasis with a poly-n-acetyl glucosamine containing patch allows for very short compression times and high early radial artery patency. A larger randomized trial will be performed to confirm the benefit of ultra-short compression on preservation of radial artery flow.

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Title: Trends in Major Entry Site Complications from Percutaneous Intervention from 1997 to 2006: Data From the Dynamic Registry

Category: Vascular Access and Arterial Closure Devices

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Background: Patient demographics, arterial access, and anticoagulation protocols are known to influence the risk of percutaneous coronary intervention (PCI) related major entry site complications (MES). Since the characteristics of PCI patients and adjunctive therapies have evolved over time we sought to examine the trends in MES in unselected patients in clinical practice during the stent era.

Methods: Data from the multicenter National Heart, Lung, and Blood Institute Dynamic Registry including five distinct recruitment waves from 1997 to 2006 (N = 10,952) were used to assess baseline characteristics and MES among consecutive patients undergoing PCI. MES was defined as bleeding requiring transfusion, pseudoaneurysm, thrombus, surgery, or other. Uncomplicated hematomas were not included.

Results: Several trends were observed in the prevalence of clinically important demographic data including an increase from wave 1 to wave 5 for BMI >30 kg/m² (30.2% to 40.4%), renal disease (3.5% to 9.1%), diabetes (28.0% to 34.1%), hypertension (59.4% to 78%), and hyperlipidemia (61% to 79.1%) (p < .0001 for all). Procedural anticoagulation varied with time. Use of a thienopyridine increased significantly from wave 1 (49.7%) to wave 5 (84%) whereas application of IIb/IIIa receptor antagonist peaked in wave 3 (53.1%) and then decreased (p < .0001). Use of postprocedure heparin also consistently decreased from waves 1 to 5 (38.6% to 10.6%, p < .0001). Bivalirudin use was reported in waves 4 and 5 and was 31.9% and 32% respectively. Access site was predominately femoral (99.4% wave 1, 93.2% wave 5) but radial access increased over time (0.3% wave 1, 6.6% wave 5) (p = <.0001). The rates of MES (2.8% to 2.2%, p < .0001) and MES requiring transfusion (2.0% to 0.74%, p < .0001) decreased slightly with time (Figure); whereas rates of pseudoaneurysm were similar over time (0.75% overall). Among patients that experienced bleeding (n = 426), the access site was the cause in 74.4%, 72.0%, 60.0%, 49.4% and 71.4% of cases in waves 1 to 5.

Conclusion: Despite significant shifts in patient and procedural variables MES is still the major cause of bleeding with PCI and rates have only decreased slightly suggesting that there is still room for improvement. Attention to non-access site bleeding risk and benefits of hemostasis techniques and radial access deserve further study.

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