TCT-79
Myocardial Recovery in Abdominal Heart Failure Patients Treated with the C-Pulse Cardiac Assist System: A Single Center Experience
Sanjeev Aggarwal1, Andrew Kao2, Mark Evertley3, Keith Allen4, Jacqueline Smith5, Michael Borkon6
1Saint Luke’s Mid America Heart Institute, Kansas City, MO
Background: The C-Pulse System is an implantable, non-blood contacting device designed to provide long-term counterpulsation therapy for patients with advanced heart failure. Results from a recently completed a 20 patient IDE prospectively study demonstrated improvements in NYHA class and quality of life with a low incidence of adverse events. We describe our single center experience in a subgroup of patients undergoing implantation of the C-Pulse system who showed signs of myocardial recovery allowing for successful discontinuation of device support.
Methods: Between July 2010 and April 2012, six patients underwent implantation of the C-Pulse device at a single institution under the feasibility study. Safety endpoints included death, aortic disruption, neurologic events, myocardial infarction, and major infection at 6 months. Quality of life was assessed using the MLWHF and the KCCQ.
Results: Mean age was 50 years (range 34-71) and 83% were male. All patients were NYHA class III at baseline, with non-ischemic etiology in 83% (5/6). Two patients were inotropic dependent. There were no deaths, no neurologic events, no aortic disruptions, myocardial infarctions, or mediastinal infections. One patient was transitioned to an implantable LVAD at 97 days post implant for worsening heart failure symptoms. Two patients remained clinically stable on device support (178 and 982 days). Three patients showed clinically significant improvement allowing for discontinuation of device support with explantation of the percutaneous lead (mean duration of support 659 days, range 534-793 days). In the patients weaned, mean ejection fraction increased from 18.3% to 29.3% with a mean reduction in LVEDD of 1.1cm. Mean follow up time post-weaning was 335 days (range 52-565 days). There have been no readmissions for recurrent heart failure.
Conclusions: Long-term counterpulsation therapy with the C-Pulse system has shown feasibility, preliminary safety and efficacy in patients with moderate to severe advanced heart failure, with the potential for sufficient myocardial recovery to allow for discontinuation of device support in a significant number of patients in our single center experience.

TCT-80
In-Vivo Long Term Evaluation of a Novel Mitral Valve Regurgitation Therapy: Experience in a Preclinical Large Animal Model
Athanasios Peppas1, Adrienne Dardenne2, Yanping Cheng3, Masahiko Shihyai4, Christopher Seguin5, Olaf Wendler6, Serge D. Roussele1, Greg L. Kalusza7, Juan Granada4
1Cardiovascular Research Foundation, Orangeburg, NY, 2Cardiovascular Research Foundation, Orangeburg, NY, 3Cardiovascular Research Foundation, Orangeburg, NY, 4Cardiovascular Research Foundation, Orangeburg, NY, 5Cardiovascular Research Foundation, Orangeburg, United States, 6CRF, Orangeburg, United States
Background: The MitraSpacer™ (Cardiosolutions, Inc.) is a novel approach to address mitral regurgitation by introducing a dynamic spacer with characteristics that constantly adjust to the instantaneous hemodynamics of the mitral apparatus and left atrium (LA). The purpose of this study was to evaluate the safety of the MitraSpacer™ within the mitral valve apparatus in the Yucatan miniature swine model.
Methods: Four (4) Yucatan miniature swine were enrolled in this study. Through a left thoracotomy, the shunt of the MitraSpacer™ was introduced into the left ventricular (LV) apex and advanced in to the LA avoiding the chordae tendineae. Once the device was in place, the balloon was partially filled to the desired volume with an iopromide/saline mix introduced by a subcutaneous access port. After implantation, all animals were survived up to 90 days.
Results: Following implantation, device performance was assessed by fluoroscopy and echocardiography. The volume within the balloon shifted during the cardiac cycle in all cases following the direction of blood flow and applied pressure. All enrolled animals survived up to 90 days for terminal imaging and tissue harvest. Echocardiographic data showed no change in LV ejection fraction from baseline to 90 days. LV end-systolic volume was decreased by 46% (34.0±10.9 ml vs. baseline 62.0±12.7 ml, p<0.001) and end-diastolic volume decreased by 32% (20.9±5.8 ml vs. baseline 29.3±9.3 ml, p<0.001) 6 weeks post TCVR. Ejection fraction was significantly increased by 14% (46.1±9.6% vs. baseline 32.7±6.6%, <p<0.01) and stroke volume was preserved (26.9±3.9 vs. baseline 27.5±4.6 ml, p=N.S.).
Conclusions: The ex-vivo simulator reliably duplicates the movement of the MV and AV. Hence it is a cost-effective, and user-centric bench top model suitable for testing TVT and training and teaching of TVT methods. Advantages are the time associated with each trial especially in comparison with animal tests and the low experimental costs while still being able to test in an intact heart.

TCT-81
Ex Vivo Simulator for Training, Teaching, and Testing of Transcatheter Valve Therapies Based on the Principle of a Passive Beating Heart
Matthew F. Meen2, Devesh Amaty3, Rob Fraser4, Maximilian Kaetting5, Ulrich Steinsiefer6, Gerry Wight7
1Vitro Labs Inc/C2 Institute of Applied Medical Engineering RWTH Aachen University, NRW, 2Vitro Labs, Inc., Victoria, British Columbia, 3Vitro Labs Inc, Victoria, BC, 4Institute of Applied Medical Engineering, Aachen, NRW, 5Inst. for Applied Medical Engineering, RWTH Aachen University, Aachen, NRW
Background: Commercially available in-vitro cardiac simulators offer testing opportunities for transcatheter valve therapies (TVT) as they are able to replicate the physiological flow and pressure accurately. These simulators lack the anatomical similarity needed for some transcatheter device testing as well as training and teaching physicians. The ex-vivo simulator combines the anatomical similarity with physiological flow and pressure signatures.
Methods: The left side of a porcine heart was incorporated into a circular loop and driven by a pulsatile pump. Compliance were added to achieve physiological pressure and flow signatures and native movement of the mitral (MV) and aortic (AV) heart valve. Pressure transducers acquire the aortic, ventricular, and mitral real-time pressures. A flow meter measures the cardiac output of the simulator. Access sites at aorta, atrium and apex allow the insertion of TVT devices as well as endoscopic visualization.
Results: The pressure differences over the MV and AV are comparable to physiological values. The characteristics of the valves such as orifice area as well as the duration of opening and closing comply with those in native hearts.
achieved at the expense of radius, and therefore, wall tension, in the ovine model with induced ischemic cardiomyopathy.

TCT-83
What Amount of Intravenous Fluid Produces Maximum Hemodynamic Benefit in Tamponade Patients
Vikas Singh1, Rishi Sethi2
1Paras HMRI Hospital, Patna, Bihar, 2King George’s Medical University, Lucknow, Uttar Pradesh

Background: In patients of tamponade, interim measures may occasionally be needed when facilities for pericardial fluid drainage are not immediately available. Intravascular volume expansion is the most commonly advocated measure but with limited scientific data. This study was undertaken to ascertain an optimum amount of fluid that can produce the maximum benefit in tamponade patients.

Methods: Patients ≥ 16 years of age with large circumferential pericardial effusion, and showing echocardiographic evidence of cardiac tamponade were included. Hemodynamically unstable patients; those with structural heart diseases; pregnant females and those undergoing hemodialysis were excluded. SBP and CO were measured using Edwards Life Sciences Vigilance II monitor, Swan Ganz CCO catheter and arterial access; at baseline and after each 250 ml of fluid over 5 min (totalling to 1000 ml in 20 min). The entire fluid was drained at the end of the procedure.

Results: A total of 28 patients constituted the study group; all of whom exhibited an arterial access; at baseline and after each 250 ml of fluid over 5 min (totalling to 1000 ml in 20 min). The entire fluid was drained at the end of the procedure.

Conclusions: Rapid infusion of as little as 250 ml of intravenous saline may improve the cardiac hemodynamics in a significant proportion of tamponade patients.

Angiography and QCA
Washington Convention Center, Lower Level, Hall A
Saturday, September 13, 2014, 5:00 PM–7:00 PM
Abstract nos: 84-93

TCT-84
Prospective, Online, Interactive Survey Comparing Visual Lesion Estimation To Quantitative Coronary Angiography
Paul T. Campbell1, Elihtishum Mahmud2
1Sanger Heart & Vascular Institute, Concord, NC, 2University of California, San Diego, San Diego, United States

Background: Inaccurate lesion measurement and inappropriate stent length selection can negatively affect clinical outcomes following coronary stent deployment. Measurement errors resulting in longitudinal geometric miss or the use of inappropriately long stents have been associated with restenosis and the need for target lesion revascularization. This study evaluated interventional cardiologists’ (IC) ability to measure lesions and select stent lengths.

Methods: This evaluation was conducted as a prospective, online, interactive survey of 25 matched orthogonal angiographic images that were pre-scored using quantitative coronary angiography (QCA). Participants provided estimates of lesion length and stent length selection. These estimates were compared to the maximum QCA value. A 2-4 mm stent overlap of both the proximal and distal lesion edges was considered to be optimal. Based on this, lesion lengths measurements >1 mm below and >4 mm above and stent lengths that were less than 4 mm and >8 mm from the QCA value were considered to be short and long, respectively. Five of the 25 images were repeated to assess intra-rater variability.

Results: Forty ICs participated. The results are summarized in Table 1. Accurate lesion length measurement and stent length selection occurred in only 30.4% and 22.3% of the cases, respectively. Stent length misses that would fail to cover the entire lesion comprised 23.8% of the cases. Analysis of repeated images showed a >3mm difference in 38.5% and 37.5% of length measurements and stent length selections, respectively.

Table 1. Evaluator Lesion Length Measurement and Stent Length Selection Relative to QCA

<table>
<thead>
<tr>
<th>Lesion Length Measurement</th>
<th>Short</th>
<th>Accurate</th>
<th>Long</th>
</tr>
</thead>
<tbody>
<tr>
<td>409 (51.1%)</td>
<td>243 (30.4%)</td>
<td>152 (19.0%)</td>
<td></td>
</tr>
<tr>
<td>47.6%, 64.6%</td>
<td>27.2%, 33.7%</td>
<td>16.3%, 21.9%</td>
<td></td>
</tr>
<tr>
<td>Stent Length Selection</td>
<td>440 (55.0%)</td>
<td>178 (22.3%)</td>
<td>182 (22.8%)</td>
</tr>
<tr>
<td>51.5%, 58.5%</td>
<td>19.4%, 25.3%</td>
<td>19.9%, 25.8%</td>
<td></td>
</tr>
</tbody>
</table>

N (percent of total) 95% confidence interval

Conclusions: Manual assessment of the coronary lesion length has a high degree of inter- and intra-rater variability, which may lead to inadequate stent selection and lesion treatment. Employing methodology to improve the accuracy of lesion measurement may improve patient outcomes.

TCT-85
Factors Influencing Stent Recoil and Underexpansion In Vivo Independent of Atherosclerosis: A Multimodality Imaging Study in Normal Porcine Coronary Arteries
Masahiko Shibuya1, Carlos A. Gongora2, Yangping Cheng3, Gerard B. Condit4, Jenn McGregor1, Juan Granade1, Greg L. Kaluza1
1Cardiovascular Research Foundation, Orangeburg, NY

Background: Stent underexpansion and malapposition continue to be important factors in suboptimal outcomes of stent treatment of obstructive coronary disease. It is well established that stents rarely achieve intended post-implant diameters that would be expected from the maximum applied pressure and the stent pressure-diameter characteristics provided by the manufacturer. In human arteries, the restrictive forces preventing the stent from fully expanding are attributed to the rigidity and heterogeneous composition of atheroscleroticly damaged wall, calcifications in particular. We sought to examine the true in-vivo stent recoil in response to elastic forces posed by healthy porcine arteries.

Methods: One hundred fifty eight stents were implanted in coronary arteries in a swine model aiming at an 120% overstretch ratio. Final minimum stent diameter (MSD) immediately post-deployment was measured by QCA (XIENCE=39, RESOLUTE=41, OMEGA=42), intravascular ultrasound (IVUS) (LIBERTE =23, PROMUS =16) and optical coherence tomography (OCT) (XIENCE=12). In 122 stents examined by QCA, minimum balloon diameter (MBD) during stent deployment was also measured. For each stent, MBD was compared to the projected diameter (PD) that the stent was to achieve per compliance chart at the pressure used.

Results: The average MBD by QCA was 7.9±0.4% lower than the PD expected from the compliance chart at the pressure used. IVUS and OCT demonstrated similar deficit of MBD in comparison to PD (7.1±5.7% by IVUS and 9.4±4.8% by OCT). MBD was only 2.5±6.4% lower than PD, thus accounting for ~1/3 of the deficit, while ~2/3 was due to true recoil. Stent type, coronary branch location (RCA, LAD or LCX), baseline artery size (reference diameter), tapering of the stented segment and the actual overstretch ratio had no evident impact on the magnitude of deficit/recoil.

Conclusions: Elastic resistance of normal porcine coronary arteries is sufficient to minimize stent recoil significantly beyond the typical manufacturer’s claim of less than 3% based on bench testing in air with no external resistance. As a consequence, stents consistently achieve 7-10 % less than the predicted diameter, even in complete absence of atherosclerosis.

TCT-86
Quantification and Impact of the Proportion of Coronary Disease Burden Treated by Percutaneous Coronary Intervention: The SYNTAX Revascularization Index
Philippe Genereux1, Mazynk Yadav2, Adriano Caixeta1, Ke Xu1, Ajay J. Kirtane1, George Dangas3, Roxana Mehran1, Martin Leon1, Patrick W. Serruys4, Gregg W. Stone10
1Columbia University Medical Center, New York, 2Cardiovascular Research Foundation, New York, NY, 3Hospital Israelita Albert Einstein, São Paulo, Brazil, 4Cardiovascular Research Foundation, New York, NY, 5University / Cardiovascular Research Foundation, New York, United States, 6Mount Sinai, New York, New York, United States, 7Mount Sinai Hospital, New York, United States, 8Cardiovascular Research Foundation, New York, United States, 9Imperial College London, London, Netherlands, 10Cardiovascular Research Foundation, NY, NY

Background: The extent of coronary artery disease (CAD), as quantified by the baseline SYNTAX Score (bSS) and the residual SS (rSS) after PCI, have been shown to be associated with adverse ischemic outcomes in various studies. We sought to quantify the proportion of CAD burden treated by PCI and to evaluate its impact on 1-year adverse ischemic events, using a newly developed index (the SYNTAX Revascularization Index; SRI).

Methods: The bSS and rSS from 2,681 angiograms from patients enrolled in the prospective ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) trial were determined. The SRI was then calculated for each patient by the following formula [1-(rSS/bSS)] x 100. Patients were then stratified and outcomes examined according to the proportion of revascularized myocardium (SRI=100% (complete revascularization), 50-99% and < 50%).

Results: The mean bSS was 12.8 ± 6.7, and after PCI the mean rSS was 5.6 ± 2.2. The SRI was 100% in 1079 patients (40.2%) 50-99% in 908 patients (33.9%), and < 50% in 694 patients (25.9%). One-year adverse outcomes, including death, were inversely proportional to the SRI (Table). By multivariable analysis, SRI was found to be an independent predictor of 1-year mortality (hazard ratio [HR] = 0.48 [95%CI 0.24, 0.95], P=0.03). An SRI cutoff of < 80% (present in 1287 (48.0%) of patients after PCI) had the best prognostic accuracy for risk prediction of death (AUC 0.60, 95% CI 0.53, 0.67, p=0.004).

JACC Vol 64/11/Suppl B | September 13–17, 2014 | TCT Abstracts/Angiography and QCA | B25