Percutaneous Repair of Paravalvular Regurgitation: Characteristics and Acute Outcomes of 40 Patients
Sachin S. Goel1, Amar Krishnaswamy1, E. Murat Tuzcu1, Samir Kapadia2
1Cleveland Clinic, Beachwood, United States, 2Cleveland Clinic, Cleveland, OH, United States

Background: Percutaneous repair of paraprostatic paravalvular leak (PVL) is emerging as a potential therapy in patients that are at high surgical risk. We report our outcomes with this procedure in patients referred for catheter based repair of paraprostatic paravalvular regurgitation.

Methods: We retrospectively identified 43 percutaneous PVL closures in 40 patients performed at our institution between May 2009 and November 2012.

Results: The mean age of patients undergoing percutaneous PVL closure was 70 years (58% males) and the index procedure was median sternotomy in 80% of patients. Procedural success rate was 95% (35 patients). A total of 3 patients had surgical valve replacement following percutaneous PVL closure; of which 2 patients underwent surgery within 30 days and one patient had surgery after 1.6 years. At a mean follow up of 206 days (range 1-888 days), all cause mortality was 30%.

Conclusions: Percutaneous PVL closure is a valuable treatment option in patients with paraprothetic paravalvular regurgitation at high surgical risk, with good acute procedural success rates.

TCT-810
Long-term 25 Years Follow-up of Mitral Valvuloplasty with Single Balloon
Independent Predictors of Survival and Event Free Survival
Edison C. Peixoto1, Rodrigo T. Peixoto1, Ivana Picone Borges1, Ricardo T. Peixoto1
1Fluminense Federal University, Rio de Janeiro, Brazil, 2Military Police Centro Hospital, Rio de Janeiro, Brazil, 3State Institute of Cardiology, Rio de Janeiro, Brazil

Background: Mitral balloon valvuloplasty (MBV) with single balloon (MBVS) is the less expensive technique to perform MBV. The objectives were to evaluate long-term follow-up (FU) of MBVS Balt and to determine independent predictors of survival and event-free survival (EFS).

Methods: From 1987 to 12-31-2013, 526 procedures of MBV were performed, 404 (76.8%) with MBVS BALT, being 256 procedures with long-term FU. The balloon diameter was 25 mm in 5 procedures and 30 mm in 251, mean dilatation area 7.02 ± 0.30 cm2. The FU was 55.3 ± 33 (1 to 198) months. To determine independent predictors of survival and EFS it was used the multivariate Cox analysis.

Results: Mean age was 38.01 ± 12.6 (13 to 33) years, being 222 (86.7%) female, 215 (50%) patients had previous cardiac surgery (aortic valve replacement in 159 and mitral valve replacement in 56). The atrial rhythm, echo score (0-72.1/5 to 14) points and echo mitral valve area (MVA) pre-MBVS 0.93 ± 0.21 cm2. Mean pre and post-MBV area (Gorlin) was 0.90 ± 0.20 and 0.22 ± 0.37 cm2 (p < 0.001) and success MVA > 1.5 cm2 in 241 (94.1%) procedures and mean pulmonary artery pressure pre and post MBV were 27.10 and 20.7 mmHg. Three (1.2%) patients began the FU with severe mitral regurgitation (SMR). At the end of the FU 118 (46.1%) patients were in NYHA FC I II 71 (27.7%) in FC II, 53 (20.7%) in FC III, 3 (1.2%) in FC IV and there were 11 deaths (4.3%), 9 (3.5%) were cardiac death, being 5 during cardiac surgery. There were 17 (8.5%) patients with new SMR at the end of the FU. Twelve (4.7%) patients were submitted to new MBV, 27 (10.5%) to mitral valve surgery and 70 (26.3%) patients used no medication at the end of the FU. Independent predictors of survival and EFS it was used the multivariate Cox analysis.

Conclusions: While percutaneous repair therapies such as MitraClip are a viable option for such patients, many have unfavorable anatomy that precludes treatment. Transeptal mitral valve implantation (TMVI) is a novel treatment option. We describe the first in human implantation of the CardiAQ valve via transapical approach.

TCT-811
Transesophageal echocardiography guided trans-apical mitral implantation
Robert Moss1, Webb John1, Anson Cheung1, Stefan Verheye1, Simonu Banu1
1St Pauls Hospital, Vancouver, British Colombia

Background: Transcatheter mitral valve implantation is an emerging therapeutic option for high-risk patients with severe symptomatic mitral regurgitation and the presence of any complications was evaluated. Results: The first 2 cases of Transapical Mitral Valve Implantation (TAMI) of the Tiara were performed in a 72 year-old male and a 60 year old woman with severe functional MR. Anatomical suitability for Tiara implantation was confirmed by transthoracic echo, TEE and CT angiographic assessment prior to implantation. Implantation was guided by both TEE and fluoroscopy. TEE was critical in determining the orientation of the “D” shaped Tiara prior to deployment. In particular, the orientation of the device in the left atrium was confirmed using X-plane imaging, and rotational orientation by real time 3-D echo. Final deployment position, paravalvular mitral regurgitation and the presence of any complications was evaluated. Results: The successful immediate result [MVA 1.5 cm2 and mitral regurgitation (MR) = 1+] in 51% patients and 3 patients. A total of 3 patients had surgical valve replacement following percutaneous PVL closure; of which 2 patients underwent surgery within 30 days and one patient had surgery after 1.6 years. At a mean follow up of 206 days (range 1-888 days), all cause mortality was 30%.

Conclusions: Percutaneous PVL closure is a valuable treatment option in patients with paraprothetic paravalvular regurgitation at high surgical risk, with good acute procedural success rates.

TCT-812
Immediate and 18-Month Outcome of Balloon Mitral Valvuloplasty: Comparison of Inoue and Multi-Track System
Ali Youssaf1, Mohamed Oraby2
1Suez Canal University, Ismailia, Egypt, 2Suez Canal University, Ismailia, Egypt

Background: To compare the immediate and 18-month clinical and echocardiographic outcomes of Inoue and multi-track system for balloon mitral valvuloplasty (BMV).

Methods: We included 78 consecutive patients with moderate to severe rheumatic mitral stenosis (MS) [mitral valve area (MVA)< 1.5 cm2] and clinically indicated BMV. The first 42 consecutive patients were assigned to Inoue BMV and the following 36 consecutive patients were assigned to multi-track system (group M). Clinical and echocardiographic assessment was performed before, immediately after, 3 months after, and 18 months after the procedure.

Results: The successful immediate result [MVA > 1.5 cm2 and mitral regurgitation (MR) 2+] was achieved in 75 (95.2%) patients. The MVA was significantly higher in group I and group M patients of group M (P = 0.12). Immediately after BMV,MVA increased from 0.9 ± 0.4 to 1.7 ± 0.5 cm2 in group I and from 0.8 ± 0.2 to 1.9 ± 0.3 cm2 in group M (P < 0.01). Bilateral commissural splitting was significantly higher in group M (P < 0.01). This was associated with higher incidence of mild commissural mitral regurgitation. There were no significant differences of moderate to severe MR. Both procedure and fluoroscopy time were significantly shorter in group I (P < 0.001). Eighteen month clinical and echocardiographic evaluation was available for
TCT-814
Mitral Annular Evaluation with Computed Tomography in the Context of Transcatheter Mitral Valve Implantation: A New Paradigm
Philipp Blankenburg, Danny Deir, Anson Cheung, Jan James Ye, Bruce Precioso, Adam J. Berger, Robert Moss, David A. Wood, John Webb, Jonathan A. Leipsic, St. Paul’s Hospital, University of British Columbia, Vancouver, BC, 2St Paul’s Hospital, Vancouver, Canada, 3St Pauls Hospital, Vancouver, British Columbia, 4University of British Columbia, Vancouver, Canada, 5St. Paul’s Hospital, Vancouver, Canada

Background: The non-planar, saddle-shaped structure of the mitral annulus has been well established through decades of anatomical and echocardiographic study. Its non-planar, saddle-shaped structure of the mitral annulus has been well established through decades of anatomical and echocardiographic study. Its non-planar, saddle-shaped structure of the mitral annulus has been well established through decades of anatomical and echocardiographic study. Its non-planar, saddle-shaped structure of the mitral annulus has been well established through decades of anatomical and echocardiographic study.

Methods: ECG-gated, end-diastolic CT data of 28 patients with severe functional mitral regurgitation was analyzed. The annular contour was segmented and fibrous trigones were identified yielding annular perimeter, projected area, inter-trigone (TT) and septal-lateral (SL) distances and annular height. The traditional saddle shaped annulus was defined including the aortomitril continuity. The D-shaped annulus was defined as being limited anteriorly by the TT line, excluding the aortomitril continuity. Hypothetical left ventricular outflow tract (LVOT) clearance and orthogonal projection angles were assessed.

Results: Projected area, perimeter and SL distance were found to be significantly smaller for the D-shaped annulus than for the saddle-shaped annulus (11.2±2.7cm2 vs. 13.0±3.0cm2, 124.1±15.1mm vs. 136.0±15.5mm, 32.1±4.0mm vs. 40.1±4.9mm respectively, p<0.001). TT distances were identical (32.7±4.1mm). The D-shaped annulus was more planar demonstrating a reduced annular height (2.11±0.7mm vs. 10.6±1.5mm, p<0.001). LVOT clearance was significantly reduced for the saddle-shaped annulus, but preserved for the D-shaped annulus (10.7±2.2mm vs. 17.5±3.0mm, p<0.001). A line of perpendicularity for orthogonal views was identified. SL views were on average found at 25.5±7.7° RAO, 22.5±10.2° cranial, whereas TT views were found at 74.7±20.5° RAO, 57.0±8.4° cranial.

Conclusions: The historically established methodology for mitral annulus sizing appears inappropriate for TMVI, yielding significantly larger dimensions compared to the D-shaped annulus approach with resultant significantly reduced LVOT clearance. CT-based mitral annulus assessment may be preferable to echocardiography in guiding per-procedural sizing, ensuring appropriate patient and device selection and guide device deployment.

TCT-815
Treatment of Functional Mitral Regurgitation by Percutaneous Annuloplasty Using the Carillon Mitral Contour System Results in Improved Clinical Efficacy – The TITAN II Study
Michael Haude, Hubertus Degen, Tomasz Sminiai, Piotr Kaluski, Horst Sievert, Jochen Müller-Elmsen, Benjamin Krausgrill, Janusz Lipiński, Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany, 2Städtische Kliniken-Neuss, Lukaskrankenhaus GmbH, Neuss, Germany, 3Poznan University of Medical Sciences Interventional Cardiology, Poznan, Poland, 4CardioVascular Center Frankfurt, Frankfurt, Germany, 5Universität zu Köln, Köln, Germany, 6Pôle Santé République, Clermont Ferrand, France

Background: Functional mitral regurgitation (FMR) contributes to both morbidity and mortality of patients with systolic heart failure. Percutaneous mitral annuloplasty (PMA), using the Carillon Mitral Contour System, to reduce FMR is feasible in these patients. The aim of the study was to assess whether the reduction of FMR associated with PMA will result in clinical benefit as measured by exercise capacity.

Methods: Patients with NYHA II-IV heart failure and stable medical therapy, moderate to severe FMR, and LVEF< 40% underwent PMA. Clinical measures of efficacy including NYHA and six minute walk distance (6MWD) were collected through 12 months.

Results: At baseline, dilated cardiomyopathy was of ischemic origin in 60% of patients, mean EF was 32.3%, and mean LV end diastolic dimension was 6.4 cm. Carillon device placement was achieved in 30/36 patients (83%). The major adverse event rate at 30-days for all 36 attempted patients was 2.8% (one death unrelated to the procedure or the device). There were no device related major adverse events through 12 months. The 12-month mortality was 23%. The changes in mean MR Grade, 6MWD and NYHA classification through 12 months are detailed in the table below.

Table. Mean MR Grade, 6MWD and NYHA through 12 months (p value compared to baseline)

<table>
<thead>
<tr>
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<th>Baseline</th>
<th>1 month</th>
<th>6 months*</th>
<th>12 months*</th>
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<tr>
<td><strong>Mean MR Grade</strong></td>
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<tr>
<td>(N=26)</td>
<td>2.73 ± 0.6</td>
<td>1.57 ± 0.95</td>
<td>1.35 ± 0.79</td>
<td>1.13 ± 0.89</td>
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<td>(p=0.001)</td>
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<td><strong>Mean 6MWD</strong></td>
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<tr>
<td>(m)</td>
<td>291.2 ± 82.6</td>
<td>376.2 ± 100.8</td>
<td>419.9 ± 116.3</td>
<td>363.8 ± 142.1</td>
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<td>(N=28)</td>
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<td>(p=0.001)</td>
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<tr>
<td><strong>Mean NYHA Class</strong></td>
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<tr>
<td>(N=29)</td>
<td>3.03 ± 0.42</td>
<td>2.11 ± 0.57</td>
<td>2.05 ± 0.71</td>
<td>2.06 ± 0.66</td>
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<td>(p=0.001)</td>
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Conclusions: Implantation of the modified Carillon device using refined procedural techniques was safe, resulted in an improved implant rate and reduction in FMR and was associated with marked symptomatic and functional improvement.

TCT-816
Comparison between of Mitral Balloon Valvuloplasty and Surgical Commisurotomy for Mitral Valve Stenosis: Meta-Analysis of the Randomized Clinical Trials
Daniel Garcia, Mohammad M. Ansari, Claudia A. Martinez, Alexandre Ferreira, Eduardo de Marchena
1University of Miami, Miami, FL, 2University of Miami-Jackson Memorial Hospital, Miami, FL, 3University of Miami, Miller School of Medicine, Miami, FL, 4University of Miami Miller School of Medicine, Miami, FL

Background: Percutaneous mitral balloon valvuloplasty (PMB) has been described as a feasible alternative option for surgical commisurotomy among patients with mitral valve stenosis. We aimed to evaluate the post procedures outcomes and its clinical significance on long term follow up between these two treatment modalities.

Methods: Pub Med, Cochrane and Scopus were systematically searched up to May 2014. Subjects of analysis were post procedure hemodynamic analysis of mitral valve area by Gorlin formula and transmirtal gradient. Post procedure long term follow-up outcomes were analyzed by MVA, mitral valve re-stenosis, new or increase of mitral regurgitation, and poor clinical status as NYHA class III/IV. We used Fixed or Random Effect analysis using the Cochrane Handbook of Systematic Reviews.

Results: A total of 9 RCTs were selected and provided a total of 1200 patients on the PMB group and 1020 patients on the surgical group. The PMB presented with a trend towards higher MVA with significant decrease of the transmirtal gradient (Figure 1). Clinical follow up disclosed no difference among groups (Figure 2).