Valvular disease - Aortic: Balloon Aortic Valvuloplasty

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Saturday, September 13, 2014, 4:00 PM–7:00 PM

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TCT-786
In-Hospital Outcomes of balloon aortic valvuloplasty and percutaneous coronary intervention during the same hospitalization in the US

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Background: There has been resurgence in the use of Percutaneous Aortic Balloon Valvotomy (PABV) in patients at high surgical risk due to development of less invasive endovascular therapies. We determined the outcomes of concomitant PABV and percutaneous coronary intervention (PCI) during same hospitalization and compared them to PABV alone using the nation’s largest hospitalization database.

Methods: This is a cross-sectional study with time trends using the Nationwide Inpatient Sample database between the years 1998-2010. We identified patients using the International Classification of Diseases, 9th Revision, Clinical Modification procedure code for valvotomy. Only patients >80 years of age with aortic stenosis were included. Primary outcome included in-hospital mortality and secondary outcomes included procedural complications and length of hospital stay.

Results: A total of 2,127 PABV procedures were identified of which 247 were PABV + PCI (PABV + PCI group) and 1,880 (weighted N = 9411) were PABV's alone (PABV group). Majority (69%) of the patients in PABV + PCI group were >80 years old with equal representation from both genders. The utilization rate of concomitant PABV + PCI during the same hospitalization has significantly increased by 225% from 5.1% in 1998-1999 to 16.6% in 2009-2010 in US (p < 0.001). Overall in-hospital mortality rate in the PABV + PCI group was identical to that of the PABV group (10.3% vs 10.5%). The overall complications rates were also similar in PABV + PCI vs PABV group (28% vs 29.1%). Patients in the PABV + PCI group had significantly longer stay [median (interquartile range)] in the hospital (75(14) vs 52(11) days, p < 0.001) and increased cost of hospitalization ($30,880(29,195 - $48,267) vs $18,421(11,482 - $32,215), p < 0.001) when compared to those of PABV group. The significant predictors of increased LOS and cost of hospital admission were unstable condition, occurrence of any complication, weekend admission and low operator volume.

Conclusions: Concomitant PCI and PABV during the same hospitalization does not increase in-hospital mortality or complications rate when compared to PABV however it increases length of hospital stay and cost of hospitalization.

TCT-787
A Prospective Study of the Contemporary Role of Balloon Aortic Valvuloplasty in the Management of Patients with Severe Aortic Stenosis

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Background: The increased prevalence of transcatheter aortic valve replacement (TAVR) has brought a renewed interest in the role for balloon aortic valvuloplasty (BAV) in the management of patients with severe aortic stenosis (AS). The current study is a prospective study of BAV analyzed by intent-to-treat.

Methods: This is a study of 100 patients undergoing BAV for management of severe AS. Before the procedure, physicians assigned intent of BAV as 1) bridge to decision for treatment (BTD); 2) therapeutic bridge to planned therapy (BTX); or 3) palliation (PAL). Patients were followed up to 1 year, with outcomes including quality of life as measured by the Kansas City Cardiomyopathy Questionnaires (KCCQ).

Results: Intent in 84 of the planned 100 patients currently enrolled is shown in the figure: 62 BTD; 18 BTX; and 4 PAL. 30-day mortality for all patients was 5.8% (6.0%). Two of these patients were in the palliative cohort. Other complications included cerebrovascular accident 2/84 (2.4%) and acute kidney injury 5/84 (6.0%). Mean follow-up was 124.0±91.9 days. Treatment outcomes after BAV are shown in the figure. Of all patients surviving to 30 days without having received a valve (n=41), summary KCCQ score increased from 40.0±22.05 at baseline to 49.49±24.04 at 30 days (p=0.67).

Conclusions: Prior to definitive treatment, patients saw a non-significant improvement in quality of life at 30 days. 61.1% (11/18) BTX patients and 30.6% (19/62) BTD patients went on to undergo aortic valve replacement. BAV has evolved as a diagnostic tool to aid in decision-making for TAVR candidacy.

Valvular disease - Mitraclip

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TCT-788
Outcomes Following Percutaneous Reduction of Significant Mitral Regurgitation in EVEREST II High Risk Patients Who Were Symptomatic Despite Cardiac Resynchronization Therapy

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Background: Among patients with significant functional mitral regurgitation (FMR), surgery is not always indicated and medical therapy may provide limited relief. Cardiac resynchronization therapy (CRT) reduces FMR in some but not all patients. This analysis describes improvements observed following treatment with MitraClip in high risk FMR patients who were symptomatic despite CRT.

Methods: EVEREST II high risk patients with MR≥3+ who were NYHA Class III/IV at study entry despite CRT-D or CRT-P implantation were analyzed. Patients eligible for MitraClip had left ventricular (LV) dysfunction with LVEDD ≥60 mm and LVEF <20%. One-year outcomes included NYHA Class, Quality of Life (Qol), heart failure (HF) hospitalizations and echocardiographic measures analyzed by an independent core lab.

Results: A total of 48 symptomatic high risk FMR patients (mean age 74 yrs) with CRT underwent the MitraClip procedure. Baseline co-morbidities included CAD (88%), prior CV surgery (67%) and moderate-severe renal disease (35%). LVEF pre-MitraClip was 38±9%. Predicted mortality by STS risk score was 11.5±7.5%. Observed 30-day mortality was 6%. MR reduction to ≤2+ was observed in 78% of CRT patients within 30 days of MitraClip procedure. Despite advanced disease and co-morbidities, 94% were
Background: MitraClip reduced MR and improved symptoms in EVEREST II high risk FMR patients who had persistent symptomatic MR after CRT. These results are consistent with the broader experience of MitraClip in high risk patients. The ongoing COAPT trial will provide insight into the effectiveness of MitraClip in FMR patients with HF who are refractory to optimal standard of care including CRT. Study funded by Abbott Vascular.

TCT-789
Symptomatic Improvement with MitraClip Therapy for Prohibitive High-Risk DMR Patients
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Background: Percutaneous mitral valve repair using the transcatheter MitraClip device is a novel therapy recently FDA approved for patients with severe degenerative mitral regurgitation (DMR) who are at prohibitive risk for surgery. We herein report the results of an ongoing single-center post-market series in the United States.

Methods: Patients were screened with transthoracic (TTE) and transesophageal (TEE) echocardiography to identify patients with ischemic or non-ischemic functional mitral regurgitation (FMR). We herein report the results of 21 patients with severe (4+) DMR who were eligible for MitraClip therapy. MitraClip therapy was performed in 20 (95%) of these patients. A multi-disciplinary heart team deemed 21 (21.6%) patients to be prohibitive risk for surgery. The MitraClip was deployed under 2- and 3-dimensional (TTE) and transesophageal (TEE) guidance.

Results: Freedom from MR grade 2+ or less was similar (60 (92%) ischemic vs 60 (93%) non-ischemic FMR, p=0.90). NYHA class, however, improved significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (p<0.0002). Mean BNP levels decreased significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (p<0.0002). Mean BNP levels decreased significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (p<0.0002). Mean BNP levels decreased significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (p<0.0002). Mean BNP levels decreased significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (p<0.0002).

Conclusions: In patients with severe MR, PMVR using the MitraClip device improves TR. Reduction of TR is associated with the improvement of symptomatic status after PMVR. A transcatheter TR solution is required for those patients who experience worsening of TR despite improvement of MR.

TCT-791
The MitraClip Procedure For Functional Mitral Regurgitation: Improved Outcomes For Both Ischemic and Non-Ischemic Types
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Background: Outcomes of transcatheter mitral valve repair with the MitraClip in patients with ischemic or non-ischemic functional mitral regurgitation (FMR) have not been analyzed separately. Representing the largest single center experience of the MitraClip procedure in the US, we sought to determine if the outcomes differ between the two types.

Methods: One hundred and eleven consecutive patients treated with the MitraClip procedure were analyzed and their outcomes were compared according to the type of FMR.

Results: Baseline characteristic between the two types were similar except a preponderance of males and a higher STS score in the ischemic FMR group (Table 1). Post-procedural reduction of FMR to grade 2+ or less was similar (60 (92%) ischemic vs 42 (91%) non-ischemic FMR, p=0.56). Over a median follow-up of 23 months (IQR 11 to 40months), Kaplan-Meier estimates freedom from all cause death (77% vs 79% at 60-months, p=0.16), heart failure hospitalization (77% vs 79% at 60-months, p=0.77), conduction system disease (90% vs 97% at 60-months, p=0.24), and FMR grade 3+ or greater (97% vs 89% at 60-months, p=0.17) were similar between ischemic and non-ischemic FMR respectively.

Conclusions: MitraClip reduced MR and improved symptoms in EVEREST II high risk FMR patients who had persistent symptomatic MR after CRT. These results are consistent with the broader experience of MitraClip in high risk patients. The ongoing COAPT trial will provide insight into the effectiveness of MitraClip in FMR patients with HF who are refractory to optimal standard of care including CRT. Study funded by Abbott Vascular.

TCT-789
Symptomatic Improvement with MitraClip Therapy for Prohibitive High-Risk DMR Patients
Brij Mami,1 O’Hara Hailey,2 Mubashir Mumtaz,2 Gregg W. Stone3
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Background: Percutaneous mitral valve repair using the transcatheter MitraClip device is a novel therapy recently FDA approved for patients with severe degenerative mitral regurgitation (DMR) who are at prohibitive risk for surgery. We herein report the results of an ongoing single-center post-market series in the United States.

Methods: Patients were screened with transthoracic (TTE) and transesophageal (TEE) echocardiography (TEE) between November of 2013 and April of 2014, 97 patients presented with severe (4+) DMR. Mitral valve surgery was performed in 76 (78.4%) of these patients. A multi-disciplinary heart team deemed 21 (21.6%) patients to be at prohibitive risk for surgery. The MitraClip was deployed under 2- and 3-dimensional TEE, 3D real-time intracardiac echocardiography, and fluoroscopic guidance.

Results: Mean age was 78.2±9 years and the average STS score was 12.2%. MitraClip deployment was successful in 20/21 patients (95.3%); 1 case was unsuccessful due to a very small left atrium. Two clips were deployed in 3 patients (14.3%). There were no vascular complications, strokes or procedural deaths. At 30 days there were 2 patients who had died (9.5%), 1 due to respiratory failure at 48 hours and 1 due to a stroke at 3 weeks. At 1-month follow-up, 17 patients (81.0%) had Grade 1-2+ MR. Left ventricular ejection fraction was unchanged from baseline to 1 month (mean 40% to 39.5% respectively, P=0.80). NYHA class, however, improved significantly following intervention with 63.2% of patients being NYHA class III at 1 month compared to 12.5% at baseline (P=0.0002). Mean BNP levels decreased significantly following MitraClip from 1739 pg/ml at baseline to 377.84 pg/ml at 1 month (P=0.02).

Conclusions: In our experience approximately 1 in 5 patients with severe DMR may not be eligible for mitral valve surgery. MitraClip edge-to-edge repair is feasible in such patients, and successfully reduces the severity of MR while improving NYHA class in the majority. Further studies are needed to examine whether these results are durable and associated with improved outcomes.

TCT-790
Impact of Percutaneous Mitral Valve Repair on Tricuspid Regurgitation
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Background: Tricuspid regurgitation (TR) and right ventricular (RV) dysfunction have been identified as significant predictors of outcome after mitral valve surgery. Notably, mitral valve surgery tends to worsen TR and RV parameters. However, the impact of percutaneous mitral valve repair (PMVR) with the MitraClip system in TR and RV parameters has not been investigated yet.

Methods: We retrospectively assessed TR and RV function parameters on baseline and follow-up (3-12 months after PMVR) transthoracic echocardiography of 60 consecutive patients (mean age 72±11 years, male gender 65.6%) with functional (57.4%), degenerative (32.8%), or mixed (9.8%) mitral regurgitation (MR), who underwent PMVR using the MitraClip system. TR was graded on a scale from 1 to 3 according to recommendations of the American Society of Echocardiography. RV function was analyzed using the fractional area change (FAC) and tricuspid annular plane systolic excursion (TAPSE).

Results: Acute procedural success of PMVR was achieved in 56 (93%) patients. Baseline TR was grade 1 in 23 (38%), grade 2 in 18 (30%), and grade 3 in 19 (32%) patients. TR change (by at least one grade) after PMVR was as follows: decrease in 20 (33%) and increase in 7 (12%) patients (p=0.039). Systolic RV function (prepost FAC and TAPSE) did not change significantly. The tricuspid annular diameter also remained unchanged. There was a trend toward a decrease in maximum pressure gradient across the tricuspid valve (36 mmHg versus 33 mmHg, p=0.14) which was poorly correlated with improvement in TR severity (OR 1.07; p=0.18). These findings were accompanied by a significant improvement of NYHA functional class (p<0.01).

Conclusions: In patients with severe MR, PMVR using the MitraClip device improves TR. Reduction of TR is associated with the improvement of symptomatic status after PMVR. A transcatheter TR solution is required for those patients who experience worsening of TR despite improvement of MR.

Table 1. Baseline characteristics.

<table>
<thead>
<tr>
<th>Functional Mitral Regurgitation</th>
<th>Ischemic</th>
<th>Non-Ischemic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>n=65</td>
<td>n=46</td>
</tr>
<tr>
<td>Male</td>
<td>77±9</td>
<td>73±14</td>
</tr>
<tr>
<td>NYHA functional class III or IV</td>
<td>63 (97)</td>
<td>41 (89)</td>
</tr>
<tr>
<td>Society of Thoracic Surgeons Score, %</td>
<td>12±3:7:4</td>
<td>10±1:8:2</td>
</tr>
<tr>
<td>Left Ventricular Ejection Fraction, %</td>
<td>42±15</td>
<td>41±19</td>
</tr>
<tr>
<td>Left Ventricular End Diastolic Dimension, mm</td>
<td>43±9</td>
<td>45±12</td>
</tr>
</tbody>
</table>

Conclusions: In this first-of-a-kind study from the largest single center experience of the MitraClip procedure in the US for ischemic and non-ischemic FMR, significant and sustained improvements in outcomes were similar for both types. Consequently, suitable patients with either subtype can be treated effectively.