# VALVULAR DISEASE: MITRAL

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#### **TCT-701**

Mitral Transapical Transcatheter Valve-in-Valve Implantation Using The Braile Inovare Prosthesis

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**BACKGROUND** Reoperative procedure for the substitution of failed mitral bioprosthesis is a procedure that might involve considerable risk. In some special cases with selected risk factors, mortality is high and might even contraindicate the procedure. The minimally invasive valve-in-valve transcatheter transapical mitral valve implant offers an alternative, reducing morbidity and mortality. The objective of this paper is the evaluation of these implants using the Braile Inovare prosthesis.

**METHODS** The transcatheter balloon-expandable Braile Inovare prosthesis was used in 12 cases, with an average EuroSCORE of 20.1%. Procedures were performed in a hybrid operative room, under fluoroscopic and echocardiographic control. Through left minithoracotomy, the prostheses were implanted through the cardiac apex, under rapid pacing. Seriated echocardiographic and clinical controls were performed. Follow-up varied from 1 to 30 months.

**RESULTS** Correct prosthesis release took place in all cases. In one case, there was need for right lateral thoracotomy for the release of an embolized prosthesis. There was no operative mortality. 30 day mortality was of one case (8.3%). Ejection fraction showed a significant improvement after the 7th post-operative day and the aortic gradient also showed a reduction. Residual mitral regurgitation was not present. There was no peripheral vascular complication or complete atrioventricular block.



**CONCLUSIONS** The mitral valve-in-valve transcatheter implant in failed bioprosthesis is a safe procedure, with low morbidity and mortality. This possibility might alter prosthesis selection in the initial surgical prosthesis selection, favoring bioprostheses.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

**KEYWORDS** Cardiac catheterization, Cardiopulmonary Bypass, Mitral valve

## TCT-702

Association of Learning Curve with Procedural Results and Recurrence of Mitral Regurgitation After Percutaneous Mitral Valve Repair with MitraClip System

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**BACKGROUND** Percutaneous mitral valve edge-to-edge repair using the MitraClip system has been widespread for significant mitral regurgitation (MR) patients with high surgical risk. Learning curve is

an important concern for the institute which introduce the MitraClip procedure in the future. In this study, the effect of learning curve on the procedural results and recurrent MR was investigated.

**METHODS** From November 2005 to October 2013, 174 patients underwent the MitraClip procedure in our institute. These patients were classified into first 50 patients (period 1), second 50 patients (period 2), and the other 74 patients (period 3), and learning curve was evaluated by comparison of procedural results and the subsequent recurrence of MR between the 3 groups. All MitraClip procedures were performed by or under the supervision of a single operator (S. Kar).

**RESULTS** Fluoroscopic time was  $45.1 \pm 18.2$  min in period 1,  $42.7 \pm 23.1$  min in period 2, and  $34.8 \pm 13.8$  min in period 3, and significantly decreased from period 1 to period 3 (p=0.007). The number of clips was  $1.38 \pm 0.57$  in period 1,  $1.48 \pm 0.51$  in period 2, and  $1.60 \pm 0.52$  in period 3 (p=0.07). Although acute procedural success (residual MR </=2+ immediately after the procedure) was similarly achieved in the 3 groups (94.0% vs. 94.0% vs. 98.6%, p=0.31), the distribution of residual MR grade after the procedure was significantly better in period 3 than in period 1 (p=0.04). Among patients with acute procedural success, recurrent MR within 1 year was observed more frequently in period 1 (38.3%) than in period 2 (10.6%, p=0.002) and period 3 (15.3%, p=0.004).

**CONCLUSIONS** Learning curve of the MitraClip procedure was observed in terms of procedural quality and device durability. When starting the MitraClip program, these findings should be considered.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

KEYWORDS Learning curve, Mitraclip, Mitral regurgitation therapy

#### **TCT-703**

Accuracy and Procedural Characteristics of Radiofrequency Compared With Standard Needle Transseptal Puncture for Structural Heart Interventions

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**BACKGROUND** Targeted transseptal (TS) puncture is an essential technique for many structural heart interventions. Spatial accuracy of standard versus radiofrequency (RF) needles has not previously been reported.

METHODS Consecutive patients undergoing left-sided structural heart interventions requiring TS puncture were included in an ongoing registry. The BRK needle (St Jude Med) paired with Mullins sheath (Medtronic) was used alternately with RF needle (Baylis Med) paired with SL1 Sheath (St Jude Med). Procedural times were: (1) withdrawing the TS system from the SVC and positioning at the intended TS site; (2) time to cross septum once site was selected; (3) time to advance the sheath across the septum. Transesophageal echocardiographic (TEE) measurements of intended versus final TS crossing site on the septum were obtained. These measurements were made from reproducible edges of the visible portions of the fossa ovalis and/or interatrial septum to the TS site in bicaval and short axis (SAX) TEE views both pre and post TS puncture. Pre puncture and maximal tenting of the septum were also quantified.

**RESULTS** 25 patients underwent standard needle and 27 RF needle TS access. 2 patients crossed over from the standard needle group to the RF group due to inability to puncture. Data is reported in an "as treated" analysis. Left-sided heart interventions included the Mitra-Clip (N=35), Watchman (N=9), and Lariat (N=7) procedures and percutaneous balloon mitral valvuloplasty (N=1). The principal findings are shown in the Table. TS procedural times significantly favored the RF needle for time from septum to puncture. Both standard and RF access yielded accurate crossing technique with no statistical differences between the intended and actual crossing site. Maximal tenting was significantly less with the RF needle. Few patients had challenging atrial anatomy such as atrial septal aneurysm, thickened septum primum or prior TS attempts. 2 patients in the standard arm required the mandril wire for assistance to cross. There were no major complications.

Parameter	Needle	RF N=27	p value
Septum to puncture (sec)	43 ± 40	22 ± 22	0.02
Puncture to cross (sec)	22 ± 9	22 ± 11	1
Absolute  Pre-Post  Difference			
Superior Rim to TS site (mm)	0.8 ± 0.9	1.0 ± 1.2	0.24
Inferior Rim to TS site (mm)	0.7 ± 0.6	1.1 ± 1.2	0.12
Anterior Rim to TS site (mm)	1.8 ± 2.0	1.4 ± 1.6	0.45
Posterior Rim to TS site (mm)	1.3 ± 1.8	1.3 ± 1.5	0.97
Pre-to-max Tent TS site (mm)	4.7 ± 3.0	2.8 ± 2.8	0.02

**CONCLUSIONS** Procedural times and degree of septum tenting favored the RF over standard needle; however, accuracy was similar with both approaches. RF was a successful strategy when standard needle failed. There were no major complications with either TS puncture strategy.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral KEYWORDS Structural heart, Transseptal puncture

#### **TCT-704**

# Mitral Annular Calcification Does Not Impact MitraClip Procedural Success and Is Not Associated with Durability of Repair

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**BACKGROUND** Mitral annular calcification (MAC) has been associated with coronary atherosclerosis and increased mortality. While patients (pts) undergoing percutaneous edge-to-edge repair of mitral regurgitation (MR) often have significant MAC, the impact of MAC on procedural success and durability of repair is not known.

METHODS Pts who underwent percutaneous repair of MR between April 2009 and May 2014 with the MitraClip device (Abbott Vascular, Santa Clara, CA) were included in the analysis. Procedural success was defined as a reduction of MR of 2 grades or more on transthoracic echocardiogram done prior to discharge. A second metric of procedural success was a reduction of MR to less than or equal to mild-to-moderate. Durability of repair was defined as successful retention of procedural success at 1-yr transthoracic echocardiogram. Pts were graded as having mild MAC if annular calcification involved one-third or less of the posterior annulus, or moderate or severe if it involved more. Procedural success was compared across severities of MAC, and durability of repair was compared between pts with no or mild MAC and those with moderate or severe MAC.

RESULTS 173 pts were included in the analysis. Mean age at percutaneous repair was 76.9  $\pm$  12.6 yrs and 40.8% were females. Hemodialysis and coronary artery disease was present in 10/173 (5.8%) and 94/173 (54.3%) of pts, respectively. Pts with MAC were older 79.9  $\pm$ 10.1 vs. 74.3  $\pm$  14.0 yrs (p=0.003). MR was moderate-to-severe in 35/ 173 (20.2%) of pts and severe in 138/173 (79.8%) of pts. Procedural success of reduction of MR of 2 grades or more was obtained in 81/87 (93.1%) pts with no MAC, 60/61 (98.4%) pts with mild MAC, and 24/25 (96.0%) pts with moderate or severe MAC (p=0.321). At 1-yr follow-up for those who obtained initial reduction of MR of 2 grades or more, pts with no or mild MAC retained the reduction in 86/99 (86.9%) instances, while pts with moderate or severe MAC retained the reduction in 14/15 (93.3%) instances (p=0.690). Procedural success of reduction of MR  $\leq$  mild-to-moderate was obtained in 69/87 (79.3%) pts with no MAC, 52/61 (85.2%) pts with mild MAC, and 22/25 (88.0%) pts with moderate-to-severe MAC (p=0.481). At 1-yr follow up for those who obtained initial reduction of MR < mild-to-moderate, pts with no or mild MAC retained the reduction in 67/86 (77.9%) instances, while pts with moderate or severe MAC retained the reduction in 11/14 (78.6%) instances (p=1.000).

**CONCLUSIONS** MAC does not impact MitraClip procedural success in percutaneous edge-to-edge MR repair despite increased age in pts

with MAC. Procedural success is high across MAC severities and MAC alone should not preclude percutaneous edge-to-edge repair of MR. Moreover, moderate or severe MAC, which may make surgical repair of MR challenging, is not associated with decreased durability of percutaneous repair. Further investigations are warranted to explore this relationship.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

KEYWORDS Calcification, Mitraclip, Percutaneous mitral valve repair

#### TCT-705

Immediate and long term outcomes after repeat percutaneous mitral valvuloplasty for patients with mitral valve restenosis

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**BACKGROUND** Only rare reports have been published about redo PMV and data regarding its long term safety and efficacy are scarce. So we decided to explore the immediate and long-term outcomes of repeat (redo) percutaneous mitral valvuloplasty (PMV) in a series of patients with mitral restenosis in comparison with initial PMV in the same series and to determine prognostic factors of outcomes.

METHODS A retrospective study enrolling a population of 170 patients treated by PMV in the university hospital Habib Thameur, Tunisia, between January 1997 and January 2011. The study group consisted of 50 patients (mean age 47±10 years) who underwent a redo PMV. All redo PMV procedures were performed using the Inoue balloon system. Procedural success was defined as 50% or more increase of mitral valve area (MVA) with a final MVA ≥1.5 cm2, without major complications. Restenosis was defined as loss of >50% of the initial gain of MVA by the preceding PMV with a final MVA <1.5 cm2.

RESULTS Successful procedural result was achieved in 81.1% of patients. There were no in-hospital complications. Both the initial and redo procedures were similar concerning the final increase of mitral valve area, the decrease of mean transmitral pressure gradient and the mean pulmonary artery pressure (P<0.001 for all). The Procedural success and the gain of MVA were higher in the initial as compared to the redo procedure (P<0.05). The only independent predictor of redo PMV success was an echocardiographic score <8. Early symptomatic improvement after redo PMV of  $\geq 1$  NYHA functional class was obtained in 95% of the patients. The mean follow-up was 80, 85±35 months. There were no deaths and restenosis was noted in 40%. Eight (16%) patients required mitral valve replacement (34.21 months after redo PMV) due to recurrent symptoms. The predictive factors of restenosis identified by the univariate analysis in our study were: previous surgical commissurotomy (p=0.01) and a high echocardiographic score (p=0.028).

**CONCLUSIONS** Repeat PMV is safe and provides good immediate results in patients with restenosis after successful first procedure. Longterm results of redo PMV are satisfactory and related mainly to the echo score.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

## TCT-706

Sustained improvement of mitral regurgitation and symptoms after MitraClip $^{\otimes}$  – The results of the Swiss nationwide investigator-initiated prospective registry MitraSwiss

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**BACKGROUND** Percutaneous mitral valve repair (PMVR) using the MitraClip®-system has become a valid alternative for patients with severe mitral regurgitation (MR) and high surgical risk. For a lack of evidence deriving from randomized trials, data from high volume registries is therefore of interest. Herein, we report the results of the