

transcatheter aortic valves into the mitral position in patients with mitral valve disease.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

KEYWORDS Mitral valve replacement, Transapical Access, Transcatheter intervention

TCT-710

Learning Curve Experience in the MitraClip® REALISM Trial: An Analysis of 899 High Risk and Non-High Risk Subjects

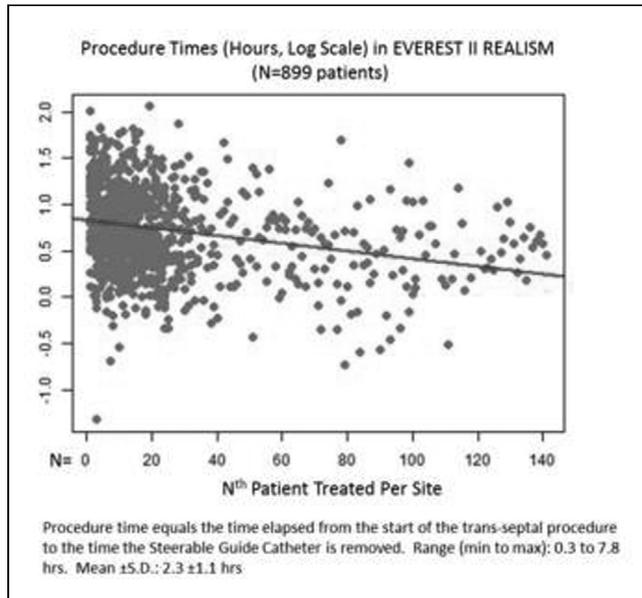
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BACKGROUND The REALISM study, the largest US-based study of the MitraClip Device, is a continued access registry designed for long-term data collection on the use of MitraClip Device in a “real world” setting. Retrospective analyses are being performed to determine the procedural learning curve related to the MitraClip procedure.

METHODS A total of 628 high risk and 271 non-high risk patients, with symptomatic chronic moderate-to-severe (3+) or severe (4+) mitral regurgitation (MR), were enrolled at 38 centers with varying degrees of experience. Learning curve effects on procedural, safety, and efficacy parameters are of particular interest will be investigated.

RESULTS Initial analyses indicate significant reduction in procedure and device time as sites gain experience with the MitraClip device. Following initial experience, reduction in procedure, device, and fluoroscopy time was observed, with continuing trend of further gradual reduction in time. The effect of learning curve on safety and efficacy is being analyzed.



CONCLUSIONS Initial analysis demonstrates reduction in procedure time is achieved as each site gains experience. Further analysis will determine any changes in efficacy and/or safety outcomes associated with further experience in this large study cohort.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

KEYWORDS Learning curve, Mitraclip, Mitral regurgitation

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Moderately Elevated Mean Mitral Gradient after MitraClip Repair of Mitral Regurgitation Is Not Associated with Increased Mortality

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BACKGROUND Mean mitral gradient (MMG) increases after percutaneous edge-to-edge repair of mitral regurgitation (MR). Near complete reduction of MR has been associated with improved outcomes but may result in an elevated MMG. However, it is not known whether an elevated post-procedural MMG is associated with all-cause mortality.

METHODS Patients (pts) who underwent percutaneous repair of MR between April 2009 and May 2014 with the MitraClip device (Abbott Vascular, Santa Clara, CA) were included. An elevated gradient was defined as a MMG ≥ 5 mmHg on transthoracic echocardiogram prior to discharge. Survival was compared between pts with and without an elevated post-procedural MMG by Log Rank test. Univariate Cox regression analysis of all-cause mortality was performed for the predictor variables of post-procedural MMG and change in MMG. Multivariate logistic regression analysis of predictors for an elevated post-procedural MMG was performed for normal ejection fraction $\geq 60\%$, reduction of MR \leq mild-or-moderate, number of clips placed, and age.

RESULTS 174 pts were included in the analysis. Mean age at percutaneous repair was 76.9 ± 12.6 yrs and 40.8% were females. Post-procedural MMG ranged from 1 to 10 mmHg. An elevated post-procedural MMG ≥ 5 mmHg occurred in 52/174 (29.9%) of pts with an average MMG of 5.9 ± 1.2 mmHg in this group. MMG was significantly lower in the remaining pts (2.7 ± 0.9 mmHg) $p < 0.001$. Baseline MR was moderate-to-severe in 36/174 (20.7%) of pts and severe in 138/174 (79.3%) of pts and not different between the groups ($p=1.000$). Number of clips used was 1.5 ± 0.5 (median 2) and not different between the groups ($p=0.144$). Procedural success of reducing MR by 2 or more grades (95.4% of pts) or to less than or equal to mild-or-moderate (82.8% of pts) was not different between groups $p=0.242$ and $p=0.665$, respectively. Pts with an elevated post-procedural MMG had a higher increase in MMG 3.6 ± 1.5 vs. 0.9 ± 1.0 mmHg ($p < 0.001$) after clipping. Pts with an elevated post-procedural MMG had improved survival (Log rank $p=0.036$). In univariate Cox regression analysis both post-procedural MMG and change in MMG were associated with decreased all-cause mortality hazard ratio 0.839 (95% CI 0.721 - 0.977) $p=0.024$ and 0.830 (95% CI 0.711 - 0.969) $p=0.019$, respectively. On multivariate logistic regression analysis pts with normal ejection fraction $\geq 60\%$ had an odds ratio of 2.241 (95% CI 1.125 - 4.461) $p=0.022$ for developing an elevated post-procedural MMG. Reduction of MR to \leq mild-or-moderate, number of clips, and age were not significantly associated with an elevated post-procedural MMG.

CONCLUSIONS Moderate elevation of post-procedural MMG is not associated with increased mortality and may be the expression of improved hemodynamics. An increase of MMG ≥ 3 mmHg to a post-procedural MMG of 5-10 mmHg might be expected for optimal outcomes.

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KEYWORDS Mitraclip, Mitral valve disease, Percutaneous mitral valve repair

TCT-712

Immediate and mid-term impact of successful percutaneous transvenous mitral commissurotomy on right ventricular systolic function

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BACKGROUND Right ventricular function is an important determinant of clinical symptoms, exercise capacity, and survival in patients with Mitral Stenosis. The aim of this study is to evaluate immediate and mid-term impact of successful percutaneous transvenous mitral commissurotomy (PTMC) on systolic right ventricular function.

METHODS Twelve patients with severe symptomatic mitral stenosis who underwent PTMC were included, all patients were subjected to transthoracic echocardiography assessment of severity of mitral stenosis and right ventricular systolic function before and 24h post-PTMC then at one and three months.