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The EVEREST II REALISM Continued Access study: five-year outcomes in high surgical risk patients

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS
The EVEREST II REALISM Continued Access study (REALISM) is a prospective, multi-center, continued access study to collect data on the real-world use of the MitraClip device in both high and non-high surgical risk patients. Enrollment in the high risk arm was initiated in January 2009 to provide continued access to the MitraClip therapy. We report outcomes through 5 years in the high risk arm.

METHODS AND RESULTS
REALISM high surgical risk patients had 3+ or 4+ MR and were deemed high risk for surgery predicted by STS risk calculator operative mortality of ?12%, or surgeon assessment based on pre-specified high surgical risk factors. Outcome measures included SF-36 quality of life and heart failure hospitalizations through the first year of follow-up, and NYHA functional class and echocardiographic measurements by an independent core laboratory through 5-year follow-up. A total of 628 patients (FMR 69% (n=436), DMR 31% (n=192)) were treated with the MitraClip device in the high risk arm of REALISM between January 2009 and December 2013. Patients were elderly (mean age: 76.7±10.7 years) and symptomatic with 85.2% in NYHA functional class III or IV at baseline. Mean ejection fraction was 47.6±14.1% (60.7±9.4% DMR, 41.8±11.7% FMR). The mean predicted STS surgical mortality was 11.1±7.0%.Freedom from mortality at 1, 3, and 5 years was 76.9%, 53.7%, and 34.0%, respectively. Through the first year of follow-up, SF-36 quality of life physical and mental component scores improved significantly from baseline by 4.9 ±9.8 and 6.2 ±13.1 points respectively, and annualized rate of HF hospitalizations decreased by 45.3%. In patients surviving to 5 years (n=274), discharge and last known MR severity were ?2+ in 93.2% and 85.8% respectively. In patients who died within 5 years, discharge and last known MR severity were ?2+ in 87.7% and 75.6% respectively. Median time to last available transthoracic echocardiogram was 1,464 days for survivors versus 344 days for those who died within 5 years. Congestive heart failure was present in approximately 30% of deaths. At 5 years post MitraClip procedure, 90.9% of surviving patients (n=99 paired data) had MR severity ?2+, 47.5% had MR ?1+, and 82.2% were in NYHA functional class I or II. LV end-diastolic volumes decreased numerically from 150.4±60.3 ml at baseline to 146.8±71.6 ml at 5 years in the overall cohort (p=0.39, n=89 paired), decreased significantly from 124.0 ±33.6 ml at baseline to 109.9 ±26.3 ml at 5 years in the DMR cohort (p=0.016, n=26 paired) and were unchanged from 161.3 ±65.6 ml at baseline to 162.0 ±78.6 ml at 5 years in the FMR cohort (p=0.91, n=63 paired).

CONCLUSIONS

In the REALISM registry, five-years after treatment with the MitraClip System, surviving high risk patients with severe MR achieved significant reduction in MR, and symptomatic and functional improvement. Detailed final results including outcomes stratified by etiology and predictors of survival in this highly comorbid group will be presented.