THE EVEREST II HIGH SURGICAL RISK COHORT: EFFECTIVENESS OF TRANSCATHETER REDUCTION OF SIGNIFICANT MITRAL REGURGITATION IN HIGH SURGICAL RISK PATIENTS

Oral Contributions
West, Room 2010
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Session Title: Valvular Heart Disease: Year in Review, Functional MR, E-Clip Updates and MR in the Context of AS
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Authors: Scott Lim, Saibal Kar, Peter Fail, Brian Whisenant, William Gray, Tanvir Bajwa, Michael Rinaldi, Robert Kipperman, John Williams, Richard Smalling, James Hermiller, Paul Grayburn, Gorav Ailawadi, Neil Weissman, Elyse Foster, Donald Glower, Ted Feldman, EVEREST II Investigators, University of Virginia Health System, Charlottesville, VA, USA

Background: The EVEREST II high surgical risk cohort included 351 high risk patients pooled from the EVEREST II High Risk Study and the EVEREST II REALISM Continued Access Study. As of July 2012, all patients completed 1 year follow-up and a subset of 211 patients completed 2 year follow-up. One year outcomes on all 351 patients and two year results on the subset of 211 patients are reported.

Methods: EVEREST II high surgical risk patients had 3+ or 4+ mitral regurgitation (MR) and were deemed high risk for surgery as predicted by a STS risk calculator operative mortality of ≥12%, or surgeon assessment based on pre-specified high surgical risk factors. Outcome measures included NYHA class, quality of life measures, hospitalizations for CHF, and echocardiographic measurements by an independent core lab.

Results: Mean age of the patients was 76 ±11 years; baseline LVEF was 48%. Functional MR (FMR) was present in 70% and degenerative MR (DMR) in 30%. Baseline comorbidities included CHF (98%), CAD (82%), cardiomyopathy (58%), and previous cardiac surgery (60%). At baseline 85% of patients were in NYHA Class III/IV. Mean predicted surgical mortality by STS calculator was 11 ±8%. Freedom from mortality at 30 days and 12 months was 95% and 77%, respectively. At 12 months, 83% of surviving patients experienced MR reduction to ≤2+ with significant reductions in LV volumes. In the subset of 211 patients through two-year follow-up, freedom from mortality was 64% and MR reduction was durable. A majority of patients had reduced symptoms, with 83% of patients in NYHA Class I/II at 12 months. Scores for the physical and mental components of the SF-36 improved between baseline and 12 months. The annual rate of hospitalizations for CHF 12 months pre and post the MitraClip procedure was 0.79 and 0.41, respectively (p<0.001). Safety and effectiveness of the MitraClip device in the subgroups of FMR and DMR etiologies were comparable.

Conclusion: In high risk surgical patients, the MitraClip procedure resulted in significant and durable improvements in MR severity, significant improvements in LV remodeling, clinical relevant improvements in quality of life measures, and a significant reduction in re-hospitalization for CHF.