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OUTCOMES OF THE RANDOMIZED EVALUATION OF A SURGICAL TREATMENT FOR OFF-PUMP REPAIR OF THE MITRAL VALVE (RESTOR-MV) TRIAL

ACC Oral Contributions
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Background: Functional mitral regurgitation (FMR) occurs when ventricular remodeling impairs valve function. Coapsys is a ventricular shape change device placed without cardiopulmonary bypass to reduce FMR. The device compresses the mitral annulus and positively reshapes the ventricle. We hypothesized Coapsys therapy for FMR would improve clinical outcomes when compared to standard therapies.

Methods: The RESTOR-MV Trial was a randomized, prospective, multicenter study of patients with FMR undergoing coronary artery bypass surgery (CABG). 90.3%of the patients were stratified to CABG with mitral valve (MV) repair and were then randomized to either Control (MVrepair+CABG) or Coapsys+CABG. In a secondary stratum, randomization was between Control (CABG_Alone) and Coapsys+CABG.

Results: The study terminated when the sponsor failed to secure ongoing funding; 165 patients had been randomized. Both mitral repair and Coapsys were associated with reductions in ventricular end-diastolic dimension (LVEDD) and long-term MR reduction ($p<0.001$), but Coapsys produced a significantly greater reduction in LVEDD ($p=0.021$). MVrepair had lower MR grades during follow-up ($p=0.01$). Coapsys showed a survival advantage compared to Control at 2 years (87% versus 77%) [HazardRatio=0.421, 95% CI(0.200 - 0.886), stratified log-rank test, $p=0.038$]. Complication-free survival (including death, stroke, myocardial infarction, and valve reoperation) was significantly better with Coapsys than Control at 2 years (85% versus 71%) [HR=0.372, 95% CI(0.185-0.749), adjusted log-rank test $p=0.019$].

Conclusions: Analysis of all patients randomized in the two strata of the RESTOR-MV Trial indicates that patients with FMR requiring revascularization who were treated with ventricular reshaping rather than standard surgery had improved survival and a significant reduction of major adverse outcomes. These analyses correspond to the timing of the first planned interim analysis described in the study protocol. This trial demonstrates the proof-of-concept that ventricular reshaping is a potentially useful strategy in a subset of patients with heart failure.