Ten-Year Outcomes of a Contemporary Supra-annular Porcine Aortic Bioprosthesis in a Medicare Population

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Objective: Bioprosthetic surgical aortic valve replacement (SAVR) remains an important treatment option for older patients in the era of transcatheter interventions. Real-world outcomes are not well characterized due to limited prospective follow-up studies. We present 10-year outcomes of Medicare beneficiaries undergoing SAVR with a supra-annular porcine bioprosthesis.

Methods: This is a single-arm observational study using Medicare fee-for-service (FFS) claims data. De-identified patients undergoing SAVR in the U.S. between 1/1/2008-12/31/2019 were selected by ICD-9/10 procedure codes then linked by probabilistic matching to a manufacturer device tracking database using patient implant date, date of birth, gender, and implant hospital for the supra-annular porcine bioprosthesis. All-cause mortality, aortic valve (AV) reintervention (surgical or transcatheter), and heart failure (HF) re-hospitalization were evaluated at 10-years using the Kaplan Meier (KM) method. A multivariable Cox regression was used to identify predictors of mortality, valve durability, and HF re-hospitalization following SAVR.

Results: Among 272,591 Medicare beneficiaries undergoing bioprosthetic SAVR during the study period, 11,685 were implanted with a supra-annular porcine bioprosthesis, of which 51.6% (6,029) had underlying HF. Mean age was 76±7 years with 39.5% (4,615) female and 63.9% (7,466) implanted with 21/23 mm valves. Concomitant CABG was performed in 44.9% (5,243) and concomitant other valve surgery in 11.2% (1,307). Freedom from AV reintervention was 94.6% (95% CI 93.8%- 95.3%) at 10 years (Figure). The 10-year KM freedom from all-cause mortality was 33.5% (95% CI 32.4%-34.6%) relative to 16.7% (95% CI 16.6%-16.8%) for a contemporary population of 2.3 million Medicare beneficiaries with a diagnosis of AV disease. Top two baseline characteristics independently predictive of 10-year mortality after SAVR were renal failure (HR 1.88, 95% CI 1.56- 2.27) and HF (HR 1.46, 95% CI 1.38-1.55). Survival at 10-years in patients without underlying HF at baseline was 43.5% (95% CI 41.8%-45.2%) compared to 24.1% (95% CI 22.6%-25.5%) for patients with underlying HF (p < 0.001). Older age was associated with lower risk of reintervention. The 10-year freedom from HF rehospitalization was 64.0% (95% CI 62.6%-65.3%).

Conclusions: This real-world nationwide study of U.S. Medicare beneficiaries receiving a supra-annular porcine bioprosthesis demonstrates >94% freedom from valve reintervention and a 64% freedom from HF rehospitalization at 10-years. Long-term survival and HF rehospitalization for older patients with aortic valve disease undergoing SAVR is limited and impacted by underlying HF and renal failure.
A. Kaplan-Meier