Outcomes of Sutureless/Rapid Deployment Valves Compared to Traditional Bioprosthetic Aortic Valves

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Background

Sutureless/rapid-deployment (SRD) valves for aortic valve replacement (AVR) are a new class of surgical bioprosthetic valve meant for simplified insertion. Two valves were approved in the United States for commercial use in 2016. The Perceval S (Ussana, Houston TX), made from nitinol “memory” frames, is deployed with three guiding sutures that are removed after valve seating. The Intuity valve (Edwards Lifesciences, Irvine CA) uses a balloon-expandable frame made of stainless steel and cloth and requires three sutures.

Pre-commercial data on SRD valves have shown reductions in cross-clamp times and fewer minimally-invasive AVR (MIAVR) [1]. However, concerns about perivalvular leak (PVL) and post-operative pacemaker implants remain based on the TRANSFORM and CAVALIER trial data [2, 3].

Research Objectives

We sought to compare outcomes of SRD and stented bioprosthetic (SBP) valves in AVR using the Society of Thoracic Surgeons (STS) national database. We hypothesized morbidity and mortality for SRD valves are equivalent or superior to SBP valves for AVR at 30 days.

Methods

Although SRD valves were commercially available in 2016, data was not entered in the STS database until version 2.9 in July 2017. Data extraction was limited to adults (at least 18 years of age) who were operated on between July 1, 2017 and June 30, 2018. Patients of interest received isolated AVR or AVR with any concomitant procedure using an SRD or SBP valve.

Study Outcomes

The primary outcome was 30-day mortality. Secondary outcomes related to surgical times, post-operative complications, hospital stay or 30-day readmissions for stroke, renal failure, new onset arrhythmia, moderate or greater PVL, infection, and permanent pacemaker (PPM) implantation were analyzed. Subset analyses were performed on 1) isolated AVR procedures; and 2) SRD valve type.

Statistical Analysis

Summary statistics were reported using standard methods and statistical tests for categorical and continuous variables. Propensity score matching (PSM) was performed on a logistic regression model. Adjustment variables were selected based on expert considerations and observed baseline imbalances in the unmatched groups. Each suitable SRD case was matched with 1:up-to-3 SBP controls, if their propensity scores were within 0.5 logit-SP standard deviation units.

Results

The STS database query resulted in 76,627 devices implanted in the aortic position. After excluding non-study devices, 55,591 SRD and SBP remained and were divided as in Figure 3.

Unmatched Data

Compared to SBP patients, the SRD patients were older (70.4±8.5 vs. 68.3±10 years, p<0.002), more likely to be female (38% vs. 31%, p<0.001), and had greater BMI (30.3 vs. 30.0, p<0.001). SRD patients had greater diastolic dysplasia (83% vs. 80%, p<0.001), hypertension (86% vs. 84%, p<0.001), and chronic lung disease (29% vs. 26%, p<0.001).

Matched Data

After PSM, baseline covariates in the SRD and SBP groups were adequately balanced except for bicuspid aortic valve (BAV). BAV was expected to be different because SRD and SBP valve because of manufacturer contraindications to placement of SRDs in BAV patients. In the PSM, procedure duration was 17 minutes less, median CPB time was 18 minutes less, and median X-clamp time 19 minutes less (Figure 4). Placement of an SRD valve using sternotomy was less frequent compared to SBP (75% vs. 88%, p<0.001). There were no differences in 30-day mortality or major co-morbidities. However, SRD patients were slightly more likely to be readmitted to the ICU or to experience unspecified in-hospital adverse events.

Post-implant intraoperative TEE showed SRD and SBP patients were similar in degree of moderate or greater PVL (0.2% vs. 0.2%, p=0.39). Few patients underwent ICD placement. New pacemaker implants were higher in SRD patients compared to SBP patients (11.4% vs. 4.9%, p<0.001). Odds of a new pacemaker implant for SRD were 2.44 (95% CI [2.17, 2.76], p<0.001).

Conclusions

Compared to SBP valves, AVR with SRD valves is safe and is associated with reduced operative times and greater MIAVR. While PUL was not elevated in the SRD group, conduction disturbances requiring PPM implantation were higher. Outcomes were not affected by concomitant procedures. Mortality and morbidity were similar between Intuity and Perceval valves. Additional studies are needed to determine late outcomes.

References