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

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Background
- Bioprosthetic surgical aortic valve replacement (SAVR) remains an important treatment option for older patients with aortic valve disease in the era of transcatheter valve interventions.
- Real-world outcomes are not well characterized due to limited prospective follow-up studies.
- Understanding long-term outcomes as well as the impact of comorbid conditions and concomitant procedures is important.

Objective
We present 10-year outcomes of Medicare beneficiaries undergoing SAVR with the Epic™ Supra bioprosthesis (Abbott, St. Paul, MN).

Methods
- This is a single-arm observational study using Medicare fee-for-service (FFS) administrative claims data.
- Patients undergoing SAVR in the U.S. 1/1/2008-12/31/2019 were selected using ICD-9/10 procedure codes then linked to a manufacturer registration database to identify valve models of interest (Figure 1).
- At least a 1-year period prior to SAVR was required to identify patient comorbidities. Patients diagnosed with endocarditis during index hospitalization were excluded.
- All-cause mortality, aortic valve reintervention (surgical replacement/ transcatheter valve-in-valve), and heart failure (HF) reintervention were evaluated at 10 years using the Kaplan-Meier (KM) method.
- Subgroup analyses were reported for baseline HF and SAVR subgroups with concomitant procedures.
- A multivariable Cox regression was used to identify predictors of mortality following SAVR.
- Western Institutional Review Board approval was received with a waiver of informed consent for utilizing a deidentified database.

Main Findings
- In >11,000 patients undergoing SAVR from 2008–2019, comorbidities were prevalent with HF in 51.6% (Table 1), and concomitant procedures were common (Table 2).
- Operative mortality through 30 days or during index hospitalization ranged from 3.1% for isolated SAVR to 24.6% for emergency SAVR with an overall average of 5.7% for the entire population (Figure 2).
- At 10 years, freedom from all-cause aortic valve reintervention was 94.6% and from HF hospitalization was 64.0% (Figure 3).
- The 10-year survival for a contemporary population of 2.3 million Medicare beneficiaries with a diagnosis of aortic valve disease was 16.7%, which is lower than the study population survival rate of 33.5% (Figure 3).
- Significant differences in survival were observed based on baseline HF and concomitant CABG or valve surgery (Figure 4).
- Top independent predictors of 10-year mortality were renal failure (HR 1.46, 95% CI 1.38-1.55) and HF (HR 1.41, 95% CI 1.33-1.49).

Conclusion
This real-world nationwide study of U.S. Medicare beneficiaries receiving the Epic™ Supra bioprosthetic valve demonstrates:
- At 10 years, >94% freedom from valve reintervention and 64% freedom from HF/rehospitalization.
- Operative mortality varies from 3.1% to 24.6% depending on concomitant procedures performed and emergency status.
- Long-term outcomes are impacted by baseline comorbidities and concomitant procedures, but is in the range of expected survival for an aged population with aortic valve disease.

Disclosures

Results (continued)

Table 1. Patient Demographics and Medical History

<table>
<thead>
<tr>
<th>Parameter</th>
<th>SAVR (N=5,699)</th>
<th>Concomitant CABG or Other Valve Surgery (N=3,969)</th>
<th>CABG (N=3,924)</th>
<th>No CABG (N=1,775)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at SAVR (years)</td>
<td>65.2 (5.6%)</td>
<td>65.6 (5.5%)</td>
<td>65.4 (5.5%)</td>
<td>64.8 (5.5%)</td>
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<tr>
<td>Gender (female)</td>
<td>46.1% (26.8%)</td>
<td>46.9% (26.7%)</td>
<td>46.4% (26.7%)</td>
<td>46.3% (26.7%)</td>
</tr>
<tr>
<td>Race (White)</td>
<td>69.9% (44.9%)</td>
<td>70.6% (44.9%)</td>
<td>69.6% (44.9%)</td>
<td>72.0% (44.9%)</td>
</tr>
<tr>
<td>Follow-up After SAVR (yrs)</td>
<td>5.2 (3.3)</td>
<td>5.2 (3.3)</td>
<td>5.2 (3.3)</td>
<td>5.2 (3.3)</td>
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</tbody>
</table>

Table 2. Operative Details

<table>
<thead>
<tr>
<th>Concomitant Procedures</th>
<th>SAVR (N=5,699)</th>
<th>Concomitant CABG or Other Valve Surgery (N=3,969)</th>
<th>CABG (N=3,924)</th>
<th>No CABG (N=1,775)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>5,243 (69.0%)</td>
<td>5,229 (69.0%)</td>
<td>5,143 (69.0%)</td>
<td>5,340 (69.0%)</td>
</tr>
<tr>
<td>Other Valve Surgery</td>
<td>1,349 (11.5%)</td>
<td>1,325 (11.5%)</td>
<td>1,325 (11.5%)</td>
<td>1,374 (11.5%)</td>
</tr>
</tbody>
</table>

Figure 1. Cohort Diagram

Figure 2. Operative Mortality (%) through 30 days or during index hospitalization

Figure 3. 10-year Kaplan-Meier Plots for (A) Survival; (B) Freedom from Reintervention [66% SAVR / 34% TAVR]; (C) Freedom from HF Rehospitalization.

Figure 4. (continued)