TAVI durability: similar or worse than surgical valve

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I have the following potential conflicts of interest to report:

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>Edwards</td>
</tr>
<tr>
<td>Consulting Fees / Honoraria</td>
<td>Abbott, Boston Scientific, Medtronic, Edwards, Cephea, Microport, GE</td>
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<tr>
<td>Major Stock Shareholder/Equity</td>
<td>VALMY ltd</td>
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<td>Royalty Income</td>
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<td>Ownership/Founder</td>
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<tr>
<td>Intellectual Property Rights</td>
<td>Nil</td>
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<td>Other Financial Benefit</td>
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Patient or device Durability?
Structural valve deterioration is the Achille’s heel of bioprostheses.
Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

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The fate of Hancock II porcine valve recipients 25 years after implant

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Abstract

Objective: The Hancock II (HII) is a second-generation porcine bioprosthesis introduced into clinical use in 1982. This study aimed to evaluate very long-term outcomes for the HII valve in a large patient population. Methods: Between May 1983 and November 1993, 517 consecutive patients (pts) (309 male, mean age: 64 ± 9 years) underwent valve replacement (VR) surgery with HII, with 302 (58.4%) in the aortic VR (AVR) and 215 (41.6%) in the mitral VR (MVR) position, respectively. At implant, 106 pts (20.5%) were <60 years of age (G1), while 411 (79.5%) were ≥60 years of age (G2). The 25-year follow-up was complete for all pts at a median of 12 years (range: 0–25). Results: Long-term death occurred in 208 AVR and in 165 MVR pts. Survival at 15 and 20 years was 39.5% and 22.3% in AVR pts and 39.0% and 15.8% in MVR pts. At 25 years, the survival of MVR pts was 13.7% (377 pts at risk). Late freedom from re-operation was 85.5% and 79.3% at 15 and 20 years in the AVR pts and 73.3% and 52.8% in the MVR pts, respectively. In the AVR population, 20-year freedom from re-operation was 52.2% in G1 pts and 86.8% in G2 pts (p < 0.0001), respectively. Conclusions: These results confirm the excellent long-term performance of the HII bioprosthesis.

Keywords: Bioprosthesis; Hancock valve; Long-term outcome
LONGEVITY OF BIOLOGICAL PROSTHESES

Evidence of leaflet injury during TAVI deployment

Collagen fiber fragmentation and disruption
**SAPIEN 3 Characteristics – Edwards Lifesciences**

- **2000 (FIM 2002)**: Percutaneous Heart Valve
  - Péricarde bovin Stent en acier Ø 23 mm

- **2003**: Cribier Edwards
  - Péricarde équin Stent en acier Ø 23 mm

- **2006**: Edwards SAPIEN
  - Péricarde bovin Stent en acier Ø 23 et 26 mm

- **2009**: SAPIEN XT
  - Péricarde bovin Stent cobalt/chrome Ø 23, 26, 29 mm Ø 20 mm en évaluation

- **2013**: SAPIEN 3
  - Péricarde bovin Stent cobalt/chrome Ø 20, 23, 26, 29 mm

**Calibre des introducteurs**
- 24F → 22F → 22F, 24F → 18F, 19F → 14F, 16F
Despite Durability of Bioprosthetic Valves, Early Failure in Isolated Cases is Known to Occur

Current generation surgical pericardial bioprostheses reveal that while durable, these devices can exhibit structural valve deterioration (SVD) leading to explant as early as two to four years with continued risk of failure over time.

TAVI is a safe and effective treatment option for high-risk patients with symptomatic severe Aortic Stenosis.

Years of Follow-up on Commercially Available Valves

Device follow-up data published or presented in major meetings.

<table>
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<th>Device</th>
<th>30-Day</th>
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<th>2 Year</th>
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A recent meta-analysis included 70 publications from a total of 2,400 reviewed, identifying 87 individual cases of transcathether valve device failure. Results were categorized by device type across 5 primary failure modes.

CoreValve shows stable hemodynamic performance through 5 years

CoreValve CE Pivotal Trial

Italian CoreValve Registry

US Pivotal Trial Extreme Risk Study

TAVI durability: similar or worse than surgical valve?

• Today: surgery has longer follow-up

• Tomorrow: be patient and enjoy the present
Conclusion

• Definition of durability:
  o TAVI and AVR
  o What is deterioration
  o How to assess it
  o Consequences for the patient: redo surgery vs TAVI

• Follow-up: Natural history