

EuroValve
January 26-27, 2017



TAVI durability: similar or worse than surgical valve

Dr. T. Modine MD, PhD, MBA

Heart team

CHRU de Lille

www.eurovalvecongress.com



EuroValve

January 26-27, 2017

Speaker's name: Thomas Modine

☒ I have the following potential conflicts of interest to report:

Affiliation/Financial Relationship

Grant/Research Support
Consulting Fees / Honoraria
Major Stock Shareholder/Equity
Royalty Income
Ownership/Founder
Intellectual Property Rights
Other Financial Benefit

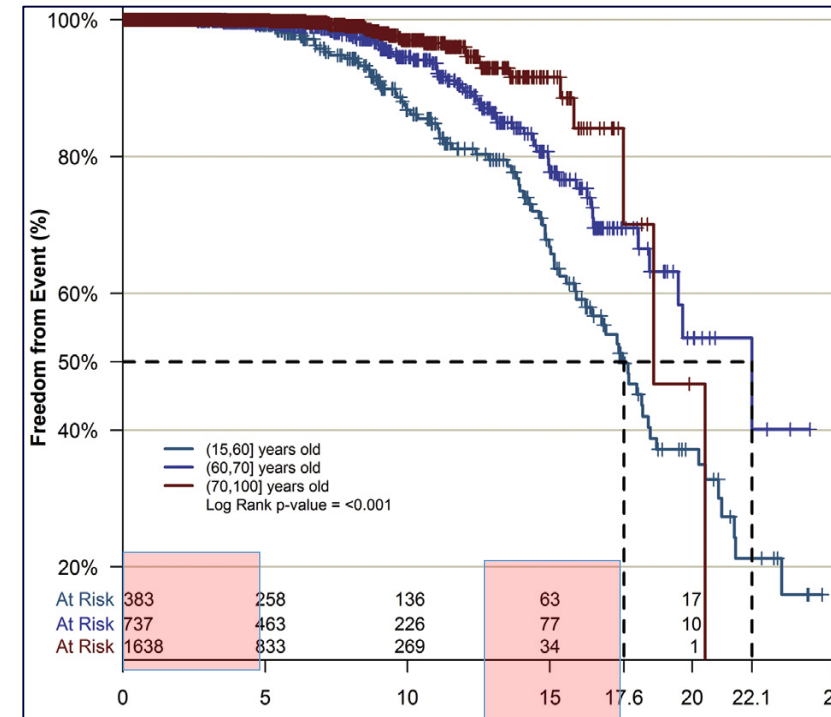
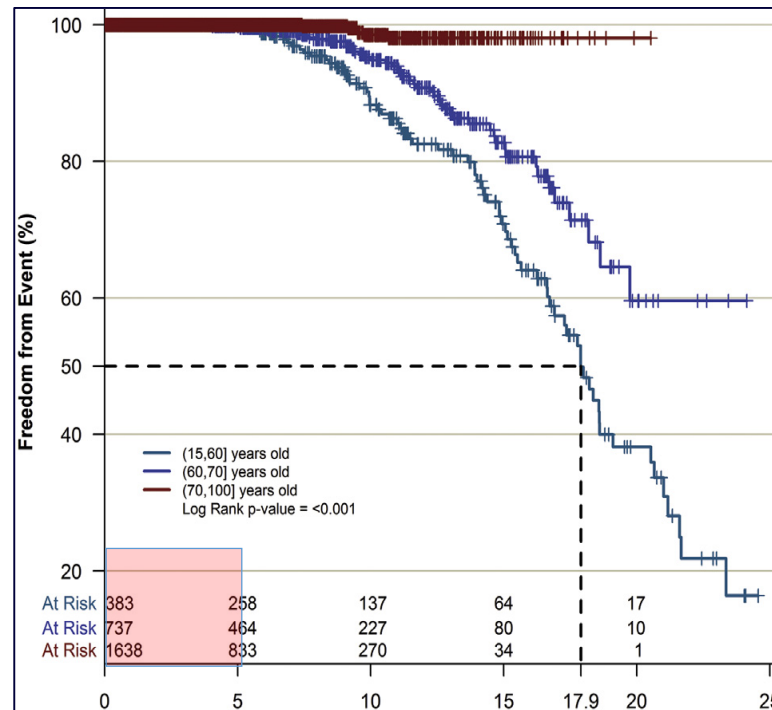
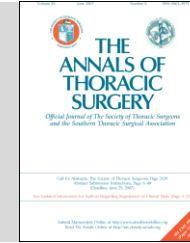
Company

- Edwards
- Abbott, Boston Scientific, Medtronic, Edwards, Cephea, Microport, GE
- VALMY Ltd
- Microport
- Valmy Ltd
- Nil

Patient or device Durability?

LONGEVITY OF BIOLOGICAL PROSTHESES

Outcomes of the Carpentier-Edwards Perimount in Ao.
Bourguignon et al. Ann Thorac Surg 2015;99:831-7

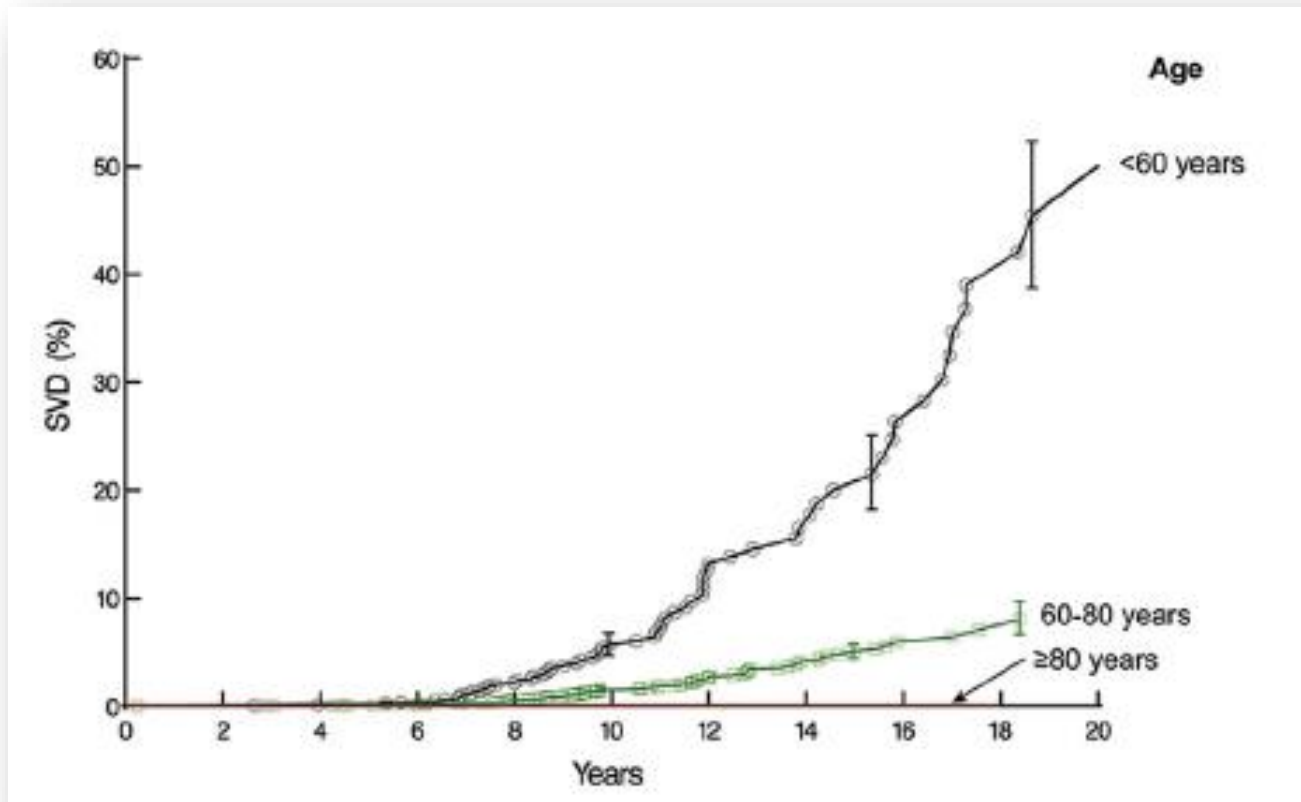


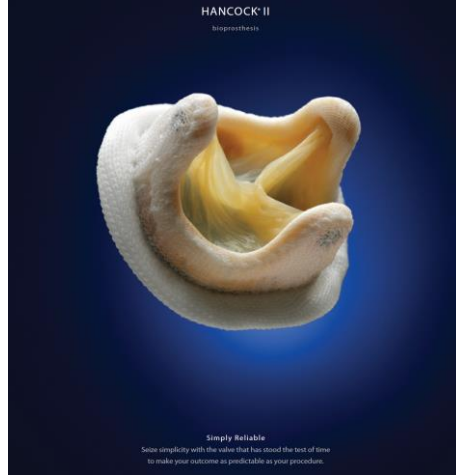
Structural valve deterioration is the **Achille's heel** of bioprostheses

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, Edward G. Soltesz, MD, Nakul Vakil, MD, Jeevanantham Rajeswaran, PhD, Eric E. Roselli, MD, Joseph F. Sabik, III, MD, Nicholas G. Smedira, MD, Lars G. Svensson, MD, PhD, Bruce W. Lytle, MD, and Eugene H. Blackstone, MD

Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio





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

Carlo Valfrè^{a,*}, Paolo Ius^a, Giuseppe Minniti^a, Loris Salvador^a, Tomaso Bottio^b,
Francesco Cesari^a, Giulio Rizzoli^b, Gino Gerosa^b

^a Cardiovascular Surgery Department, Cà Foncello Hospital, Treviso, Italy

^b Department of Cardiothoracic and Vascular Surgery, University Hospital, Padova, Italy

Received 30 September 2009; received in revised form 11 January 2010; accepted 14 January 2010

Abstract

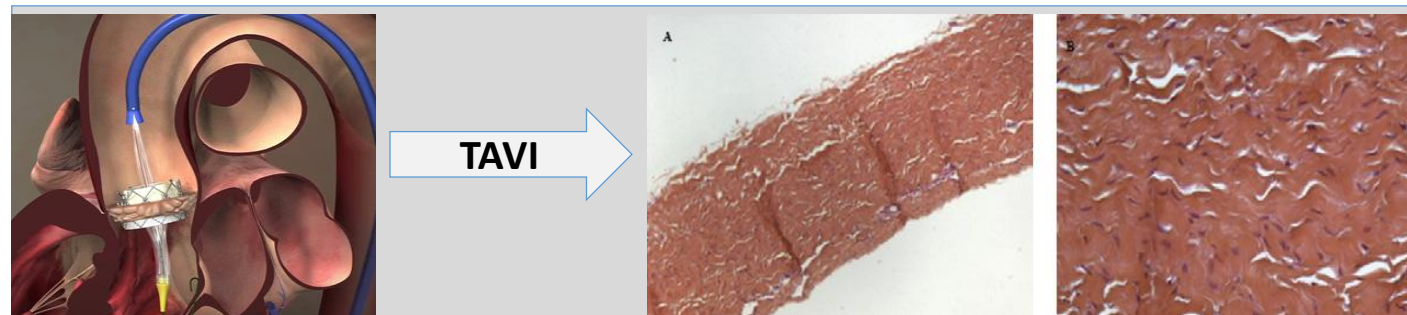
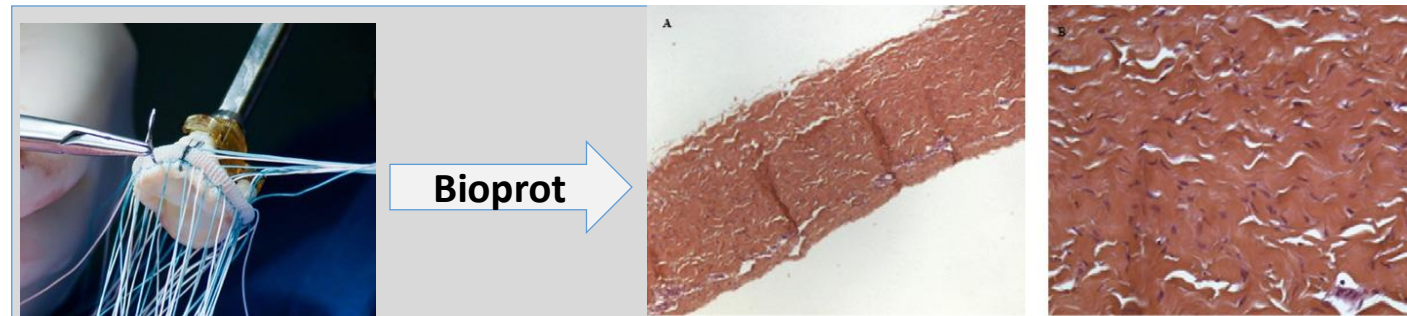
Objective: The Hancock II (HII) is a second-generation porcine bioprosthesis introduced into clinical use in 1982. This study aimed to evaluate very long-term outcomes for the HII valve in a large patient population. **Methods:** Between May 1983 and November 1993, 517 consecutive patients (pts) (309 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 23.3% in AVR pts and 39.0% and 15.8% in MVR pts. At 25 years the survival of MVR pts was 13.7% (four 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 ($p < 0.0001$), while in the MVR population it was 41.4% in G1 pts and 61.7% in G2 pts ($p = 0.201$), respectively. **Conclusions:** These results confirm the excellent long-term performance of the HII bioprosthesis.

© 2010 Published by Elsevier B.V. on behalf of European Association for Cardio-Thoracic Surgery.

Keywords: Bioprosthesis; Hancock valve; Long-term outcome

LONGEVITY OF BIOLOGICAL PROSTHESES

Evidence of leaflet injury during TAVI deployment
Zegdi et al. Eur J Cardiothorac Surg 2011;40:257-9



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

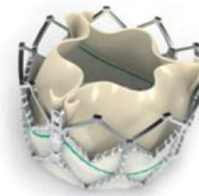
Edwards SAPIEN



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

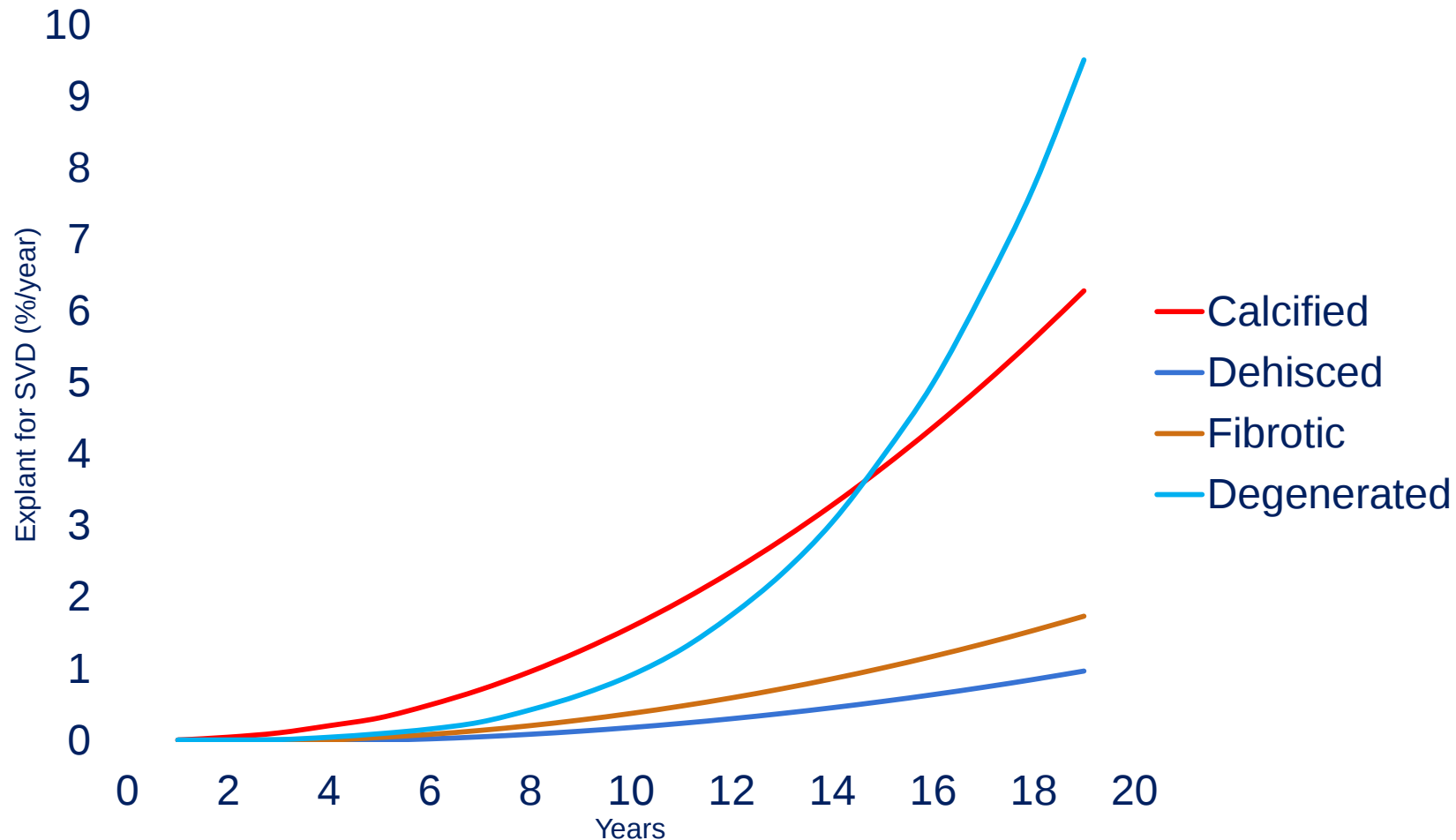
22F, 24F

18F, 19F

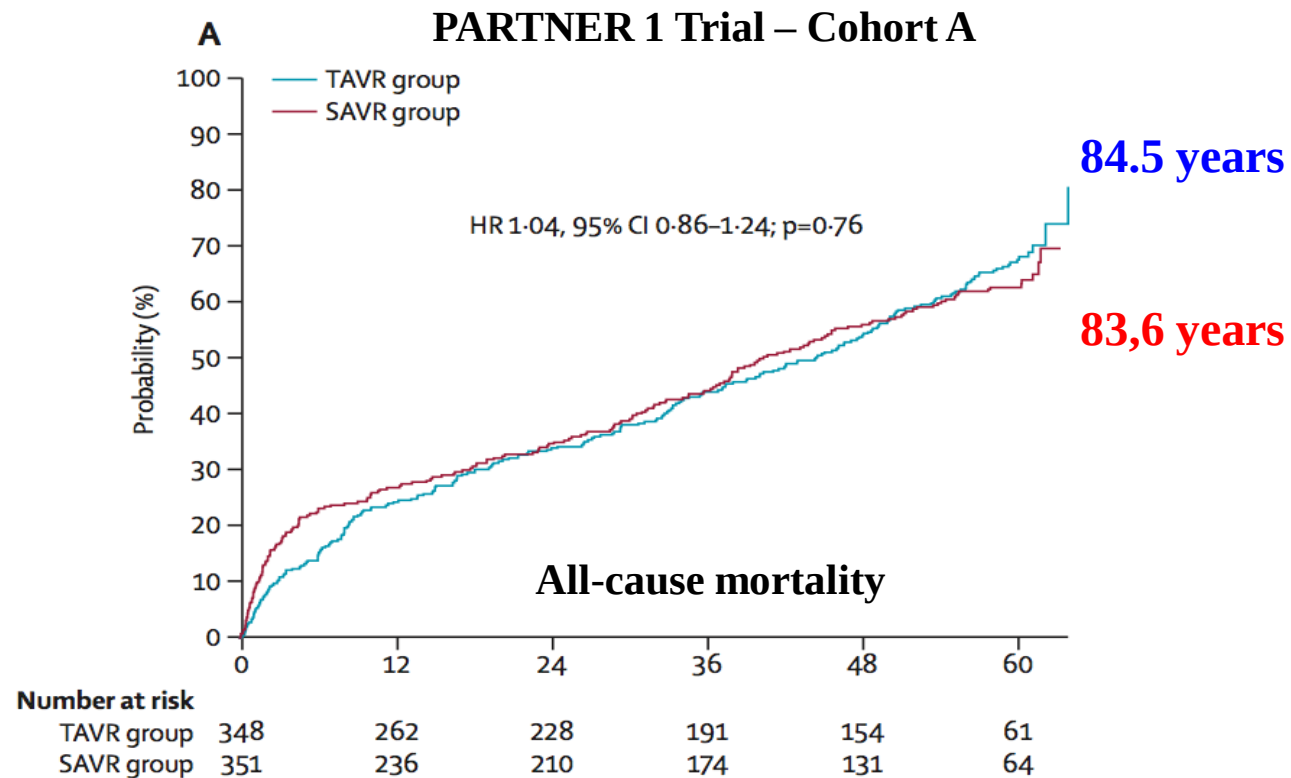
14F, 16F

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

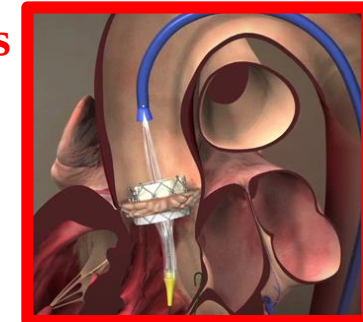


TAVI is a safe and effective treatment option for high-risk patients with symptomatic severe Aortic Stenosis



84.5 years

83,6 years



5-year outcomes of...PARTNER 1. Mack M et al. Lancet 2015;385:2477-84

Years of Follow-up on Commercially Available Valves

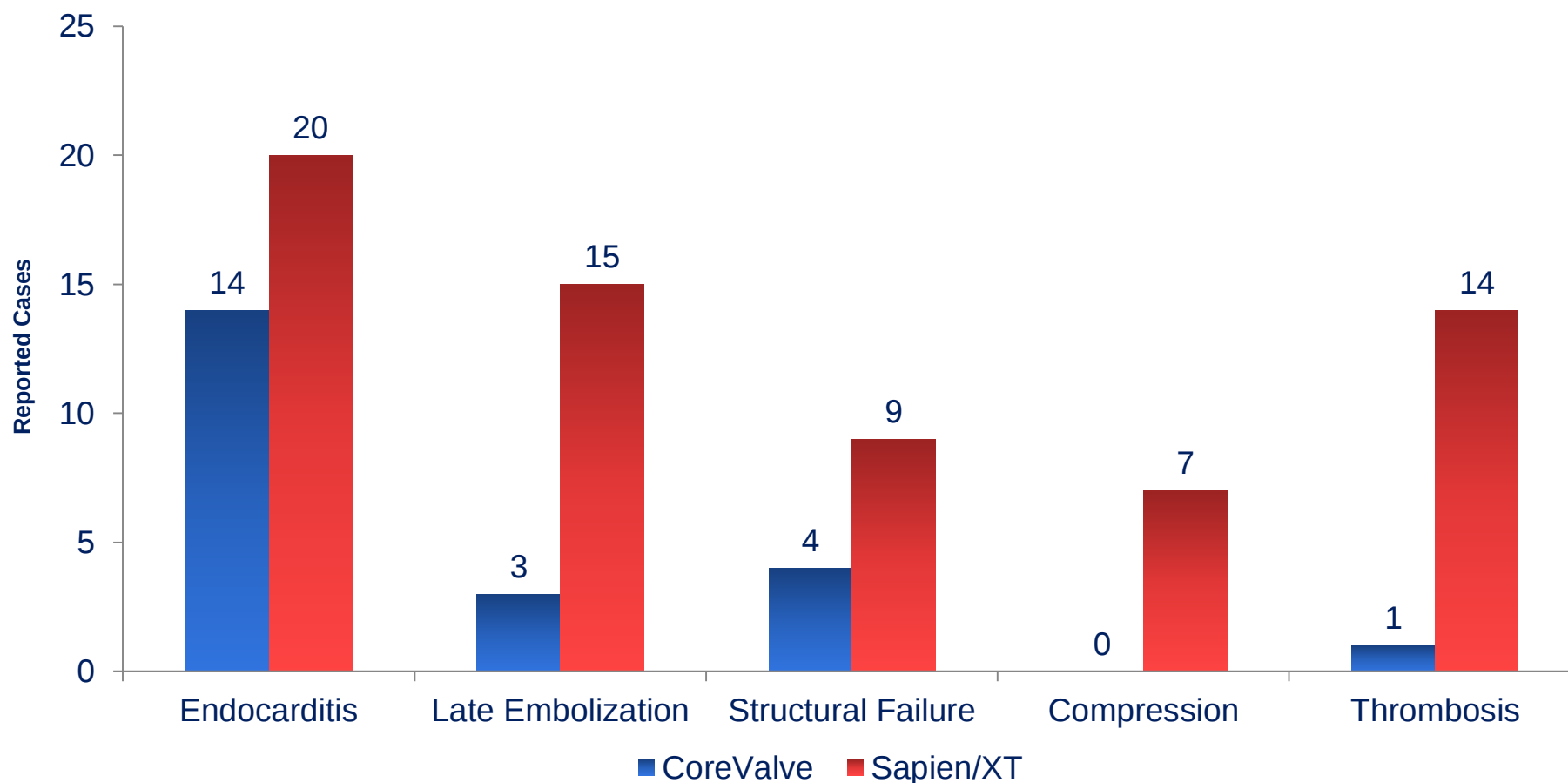
Device follow-up data published or presented in major meetings.



Sources: 1. El-Mawardy, Presented at London Valves 2014; 2. Windecker, Presented at EuroPCR 2014; 3. Webb, et. al. Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve, JACC 2014; 4. Meredith, Presented at TCT 2014; 5. Manahoran, Presented at TCT 2014

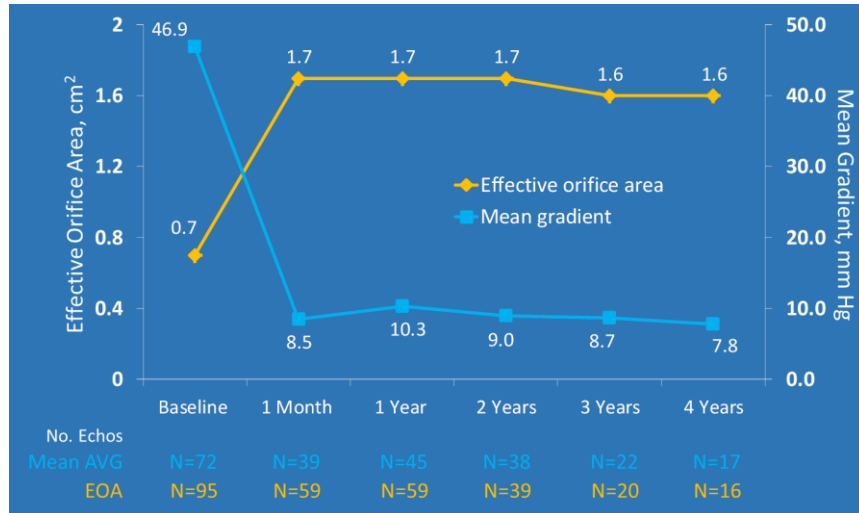
Meta-Analysis of Transcatheter Valve Failure

A recent meta-analysis included 70 publications from a total of 2,400 reviewed, identifying 87 individual cases of transcatheter valve device failure. Results were categorized by device type across 5 primary failure modes.

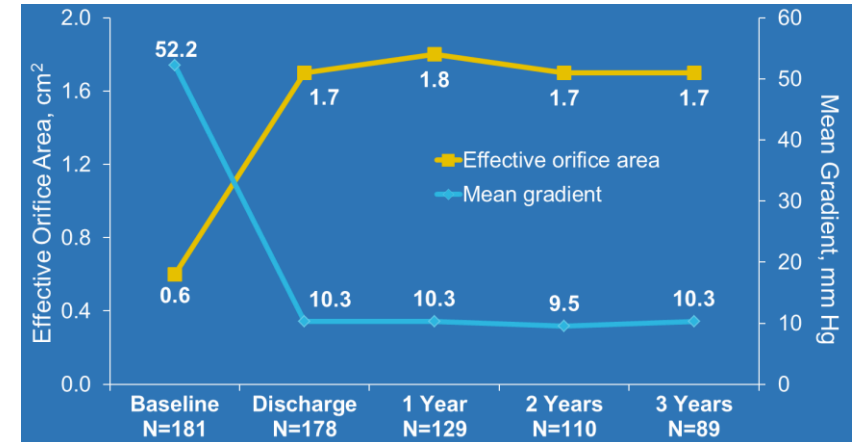


CoreValve shows stable hemodynamic performance through 5 years

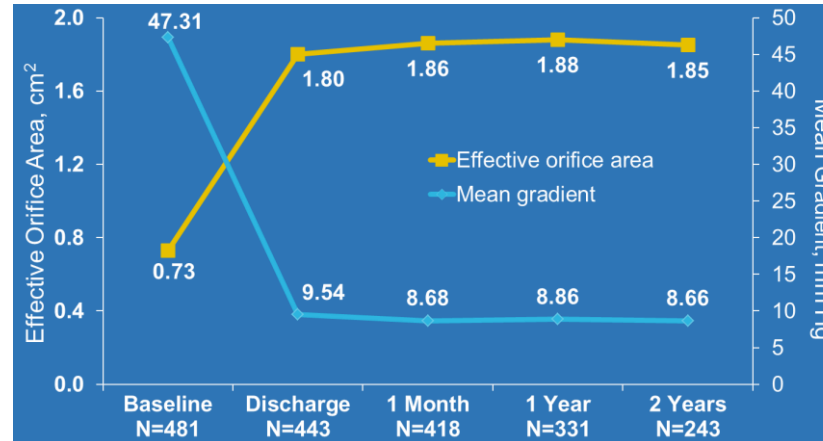
CoreValve CE Pivotal Trial¹



Italian CoreValve Registry²



US Pivotal Trial Extreme Risk Study³



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:
 - TAVI and AVR
 - What is deterioration
 - How to assess it
 - Consequences for the patient: redo surgery vs TAVI
- Follow-up: Natural history