

# Advanced Treatments for Aortic Valve Disease

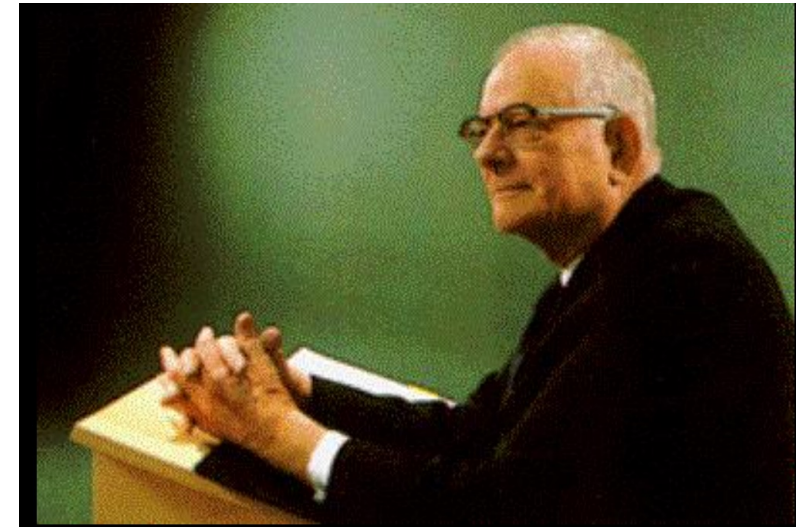
Daniel O'Hair, MD

Director of Cardiovascular Surgery,  
Boulder Heart

720-442-8775

- Design and Quality
- Durability and Performance
- Structural Valve Deterioration and Implications
- How Long is a “Lifetime”?

- Edwards Demming, PhD
- American Engineer, 20<sup>th</sup> Century Scholar
- Published 100s of articles on related topics including:
  - statistical variance, systems and systems thinking
- Father (Master) of data-driven Continuous Quality Improvement



**“Every system is perfectly designed to give the result that it does.”**



Perimount



Carpentier-Edwards  
Perimount Magna Ease



Sorin Mitroflow



CE Porcine SAV



Biocor



Medtronic Freestyle



St. Jude Toronto SPV



# Transcatheter Aortic Valve Intervention

## Competitive Device Portfolio

Commercially Available

**ABBOTT**  
Portico



**ABBOTT**  
Navitor



**BOSTON SCIENTIFIC**  
Acurate Neo2



**JENAVALVE**  
Trilogy



**MERIL**  
MyVal



**MEDTRONIC**  
Evolut R/PRO



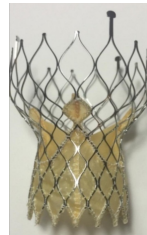
**EDWARDS**  
Sapien 3  
ULTRA



Global  
TAVR  
Devices



**Allegra**



**Venibri**



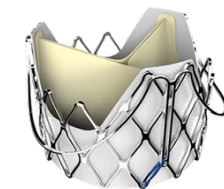
**Hydra**



**Venus**



**Vitaflow**



**J-Valve**

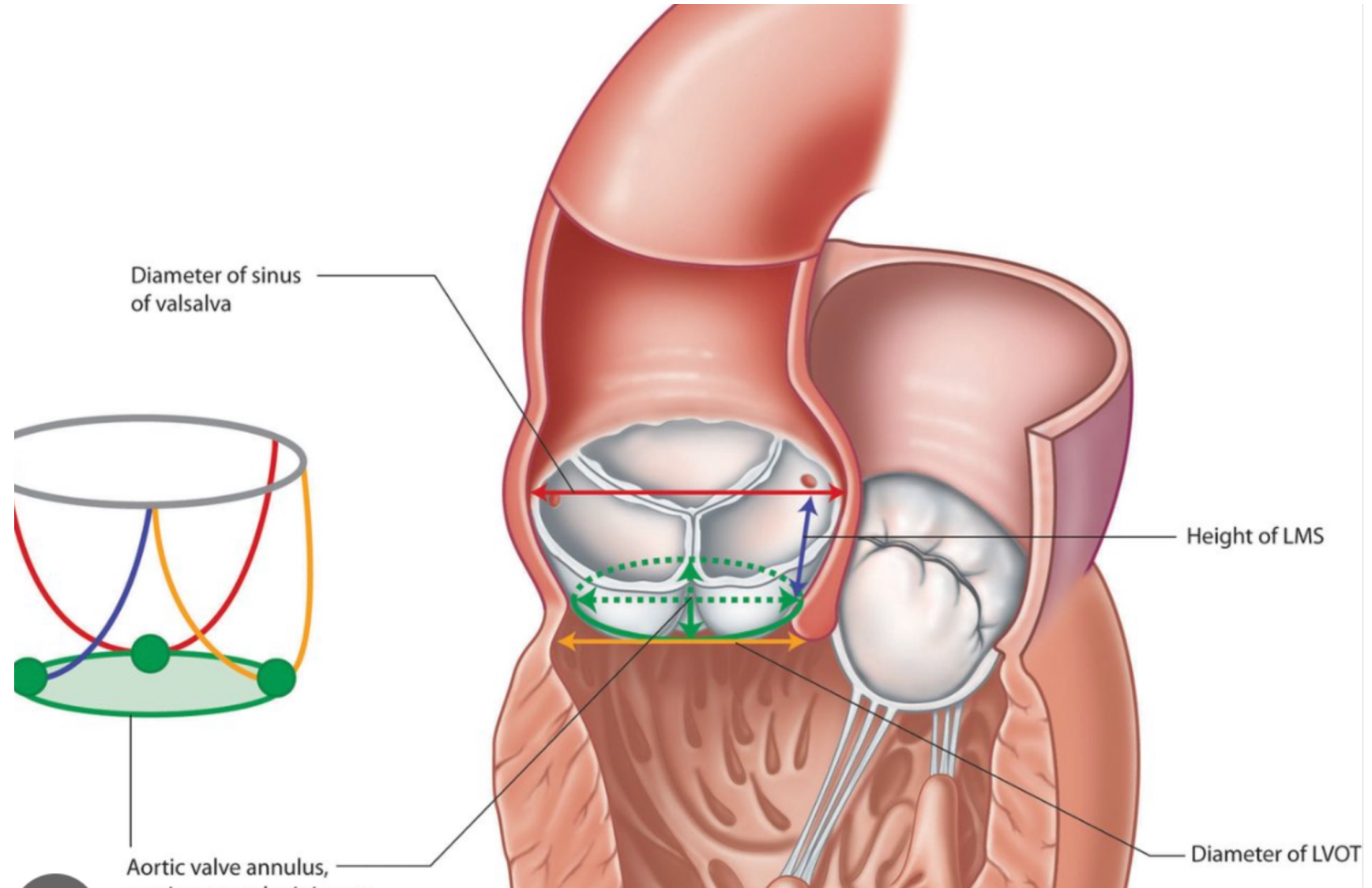


How do you make sense of all this?

“How long will my valve last?”

What is the gold standard?

## Aortic annulus

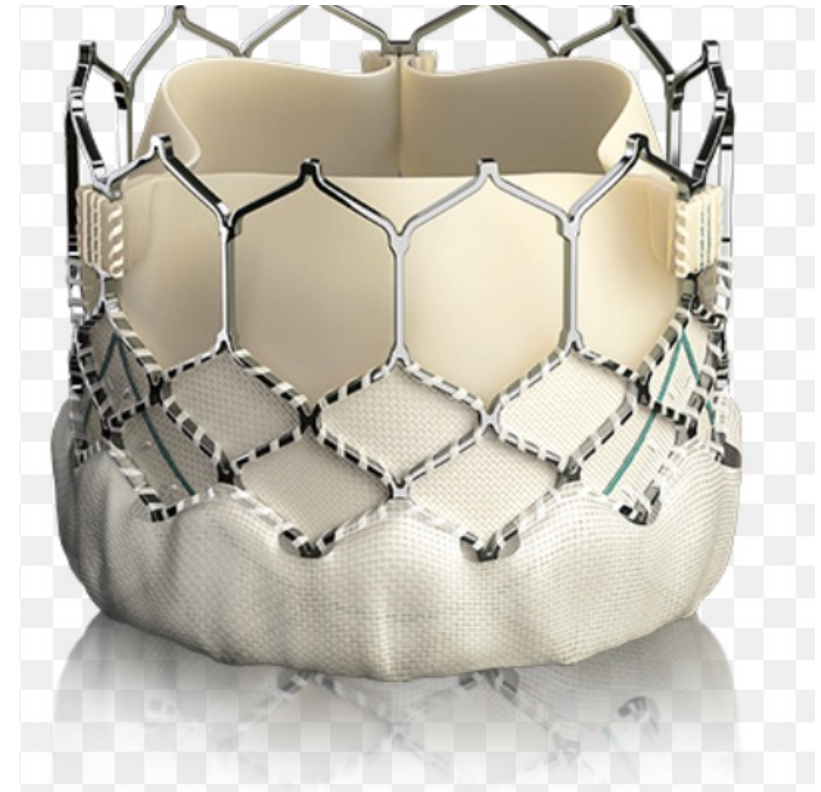




## Structural Valve Deterioration (SVD):

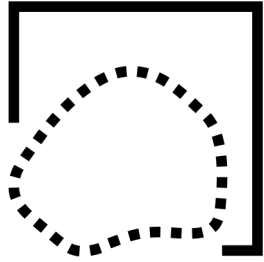
Permanent changes to the valve such as calcification, fibrosis or tear that result in degeneration or dysfunction.

- Rigid, balloon expanded Chromium frame
- Intra-annular
- Bovine pericardium

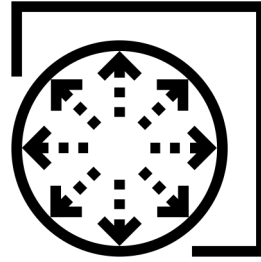


# EVOLUT SELF-EXPANDING SUPRA-ANNULAR BIOPROSTHESES

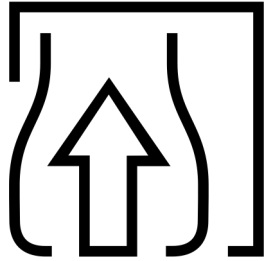
BY DESIGN - DIFFERENTIATED FROM ANNULAR BIOPROSTHESES



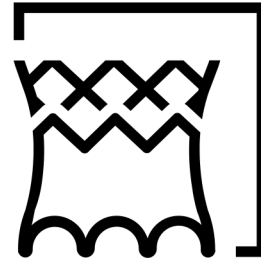
**Conformable Frame**  
Self-expanding  
nitinol frame conforms  
to annulus



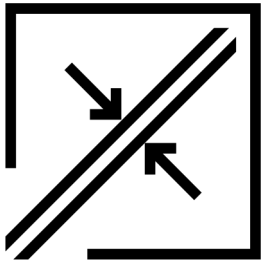
**Radial Force**  
Frame oversizing and  
cell geometry provide  
consistent radial force  
across treatable  
annulus range



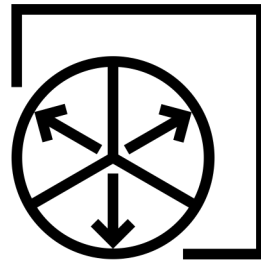
**Favorable Hemodynamics**  
Leaflet location and design  
provide large effective orifice  
area and low gradients



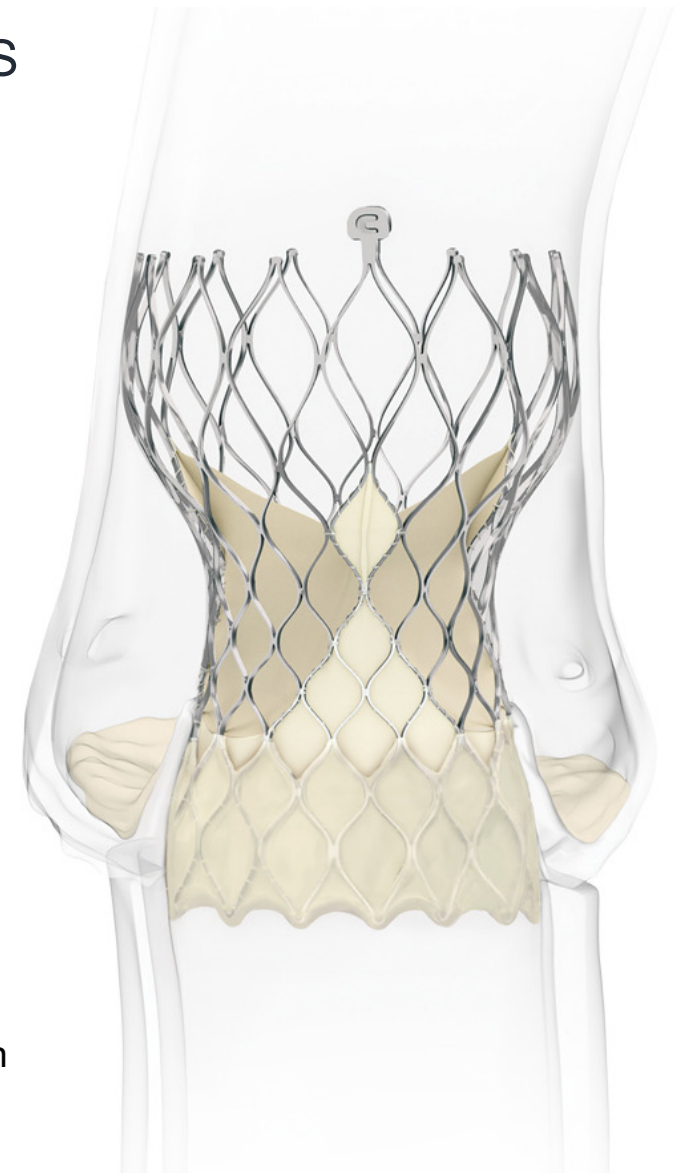
**External Wrap**  
External tissue wrap  
increases surface contact  
with native anatomy



**Low Profile In-Line Sheath**  
The in-line sheath provides  
vascular access diameter  
down to 5.0 mm with 23/26/29  
Evolut PRO+ and 6.0 mm for  
34 mm Evolut PRO+



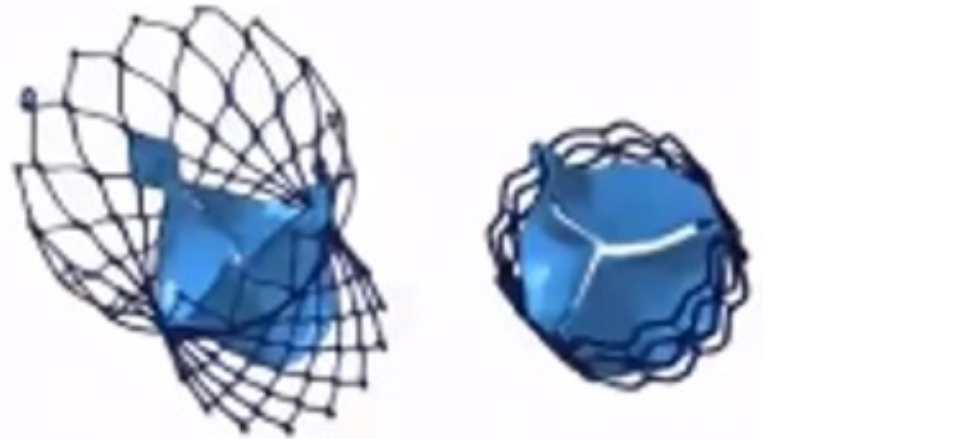
**Controlled Expansion**  
Avoids barotrauma to the  
LVOT outflow track in the  
setting of severe calcification



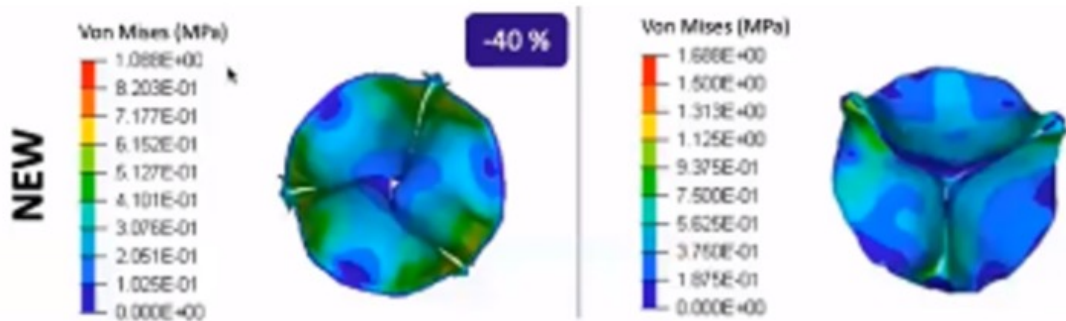
# PRECLINICAL STUDIES EVALUATING LEAFLET STRESS

## 40% LOWER LEAFLET STRESS WITH COREVALVE/EVOLUT V SAPIEN/SAPIEN 3

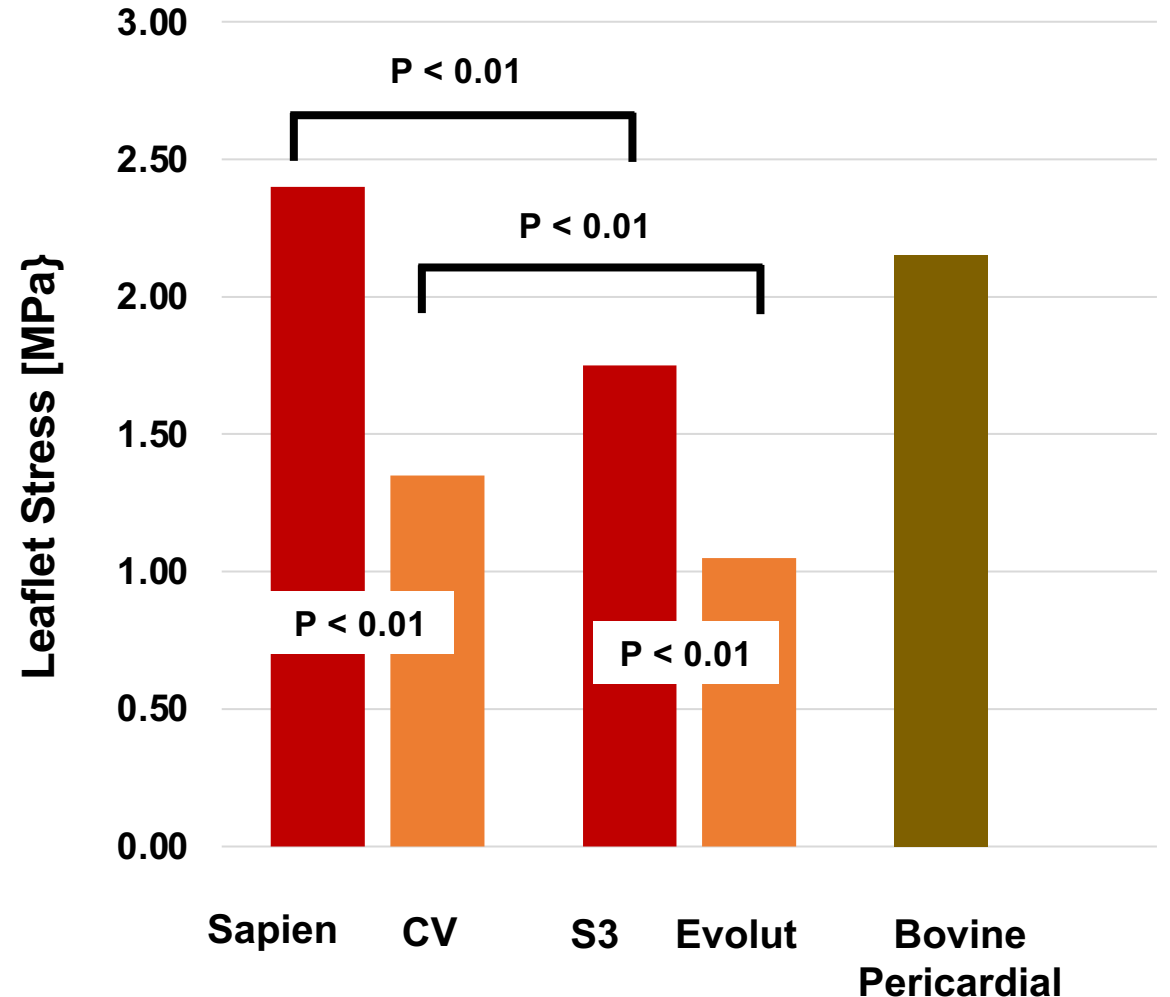
### Supra-annular v. Annular



### Leaflet Stress

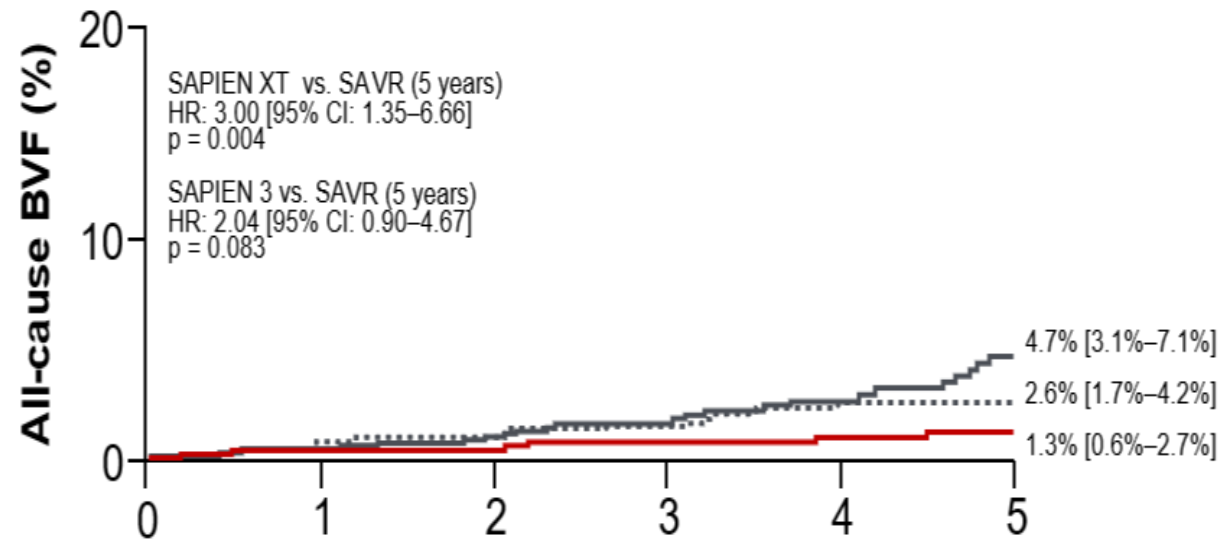
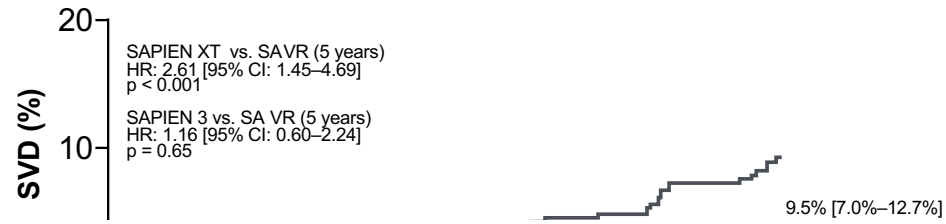


### Leaflet Stress by FEA



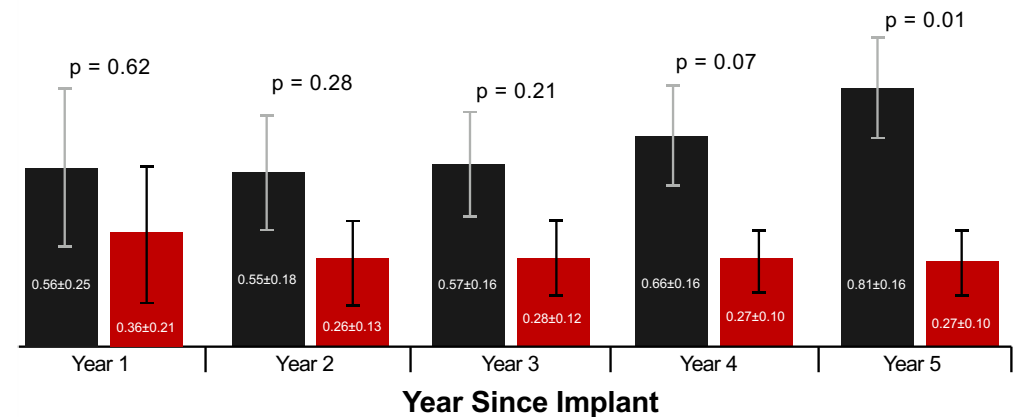
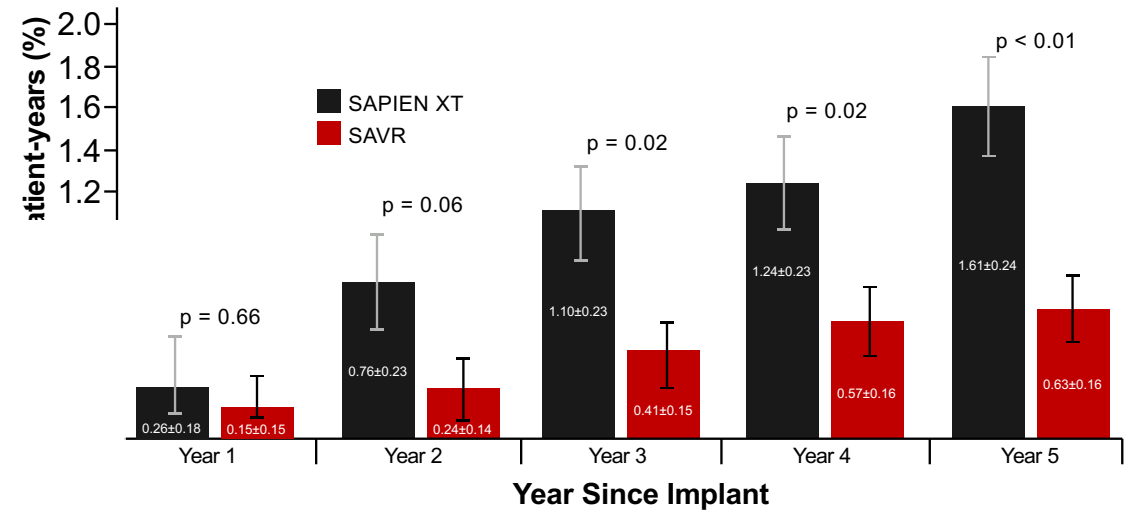
# PARTNER 2: 5-YEAR FOLLOW-UP FOR SVD

## SAPIEN XT VERSUS SURGERY

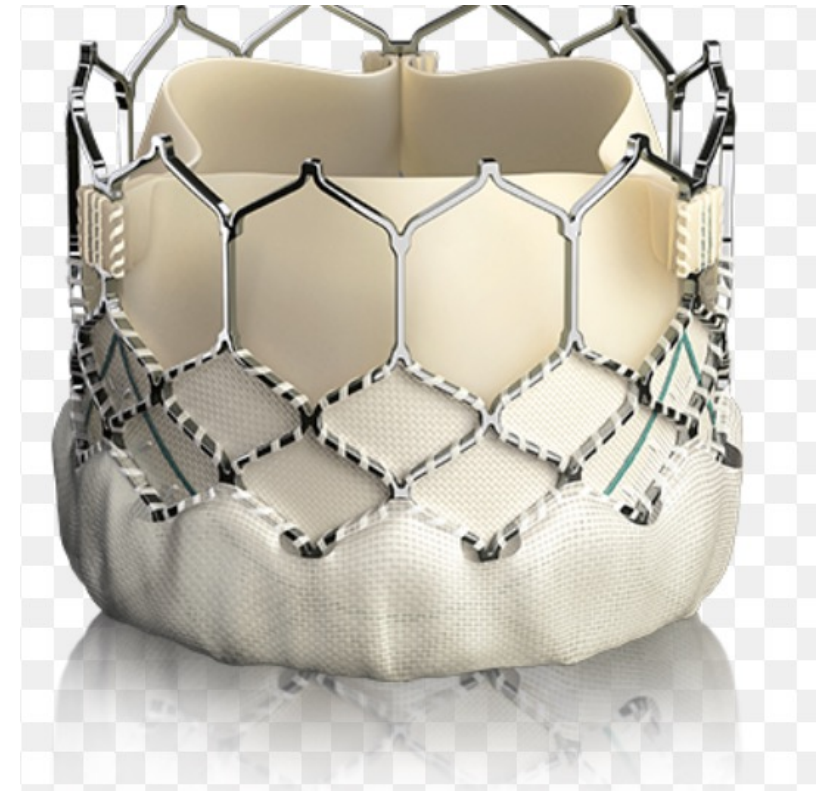


No. at risk:

	0	1	2	3	4	5
SAVR	936	762	643	536	423	321
SAPIEN XT	974	813	689	556	406	326
SAPIEN 3	1,069	909	764	628	451	312



- Rigid, balloon expanded Chromium frame
- Intra-annular
- Bovine pericardium



JAMA Cardiology | **Original Investigation**

## Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk

Daniel O'Hair, MD; Steven J. Yakubov, MD; Kendra J. Grubb, MD; Jae K. Oh, MD; Saki Ito, MD; G. Michael Deeb, MD; Nicolas M. Van Mieghem, MD, PhD; David H. Adams, MD; Tanvir Bajwa, MD; Neal S. Kleiman, MD; Stanley Chetcuti, MD; Lars Søndergaard, MD; Hemal Gada, MD; Mubashir Mumtaz, MD; John Heiser, MD; William M. Merhi, DO; George Petrossian, MD; Newell Robinson, MD; Gilbert H. L. Tang, MD, MSc, MBA; Joshua D. Rovin, MD; Stephen H. Little, MD; Renuka Jain, MD; Sarah Verdoliva, MSc; Tim Hanson, PhD; Shuzhen Li, PhD; Jeffrey J. Popma, MD; Michael J. Reardon, MD

Table. Baseline Clinical Characteristics

Characteristic	Patients, No. (%) <sup>a</sup>		
	Surgery RCT (n = 971)	TAVI RCT (n = 1128)	TAVI non-RCT (n = 2663) <sup>b</sup>
Age, mean (SD), y	80.6 (6.3)	80.9 (6.5)	83.1 (8.0) <sup>c</sup>
Sex			
Female	444 (45.7)	496 (44.0)	1217 (45.7)
Male	527 (54.3)	632 (56.0)	1446 (54.3)
Body surface area, mean (SD), m <sup>2</sup>	1.9 (0.2)	1.9 (0.2)	1.9 (0.3) <sup>c</sup>
STS-PROM, mean (SD) <sup>d</sup>	5.3 (2.5)	5.2 (2.4)	8.7 (4.6) <sup>c</sup>
NYHA HF class III/IV	639 (65.8)	757 (67.1)	2288 (85.9) <sup>c</sup>
Prior percutaneous coronary intervention	253 (26.1)	280 (24.8)	1052 (39.5) <sup>c</sup>
Prior coronary artery bypass surgery	213 (21.9)	229 (20.3)	973 (36.5) <sup>c</sup>
Hypertension	889 (91.6)	1056 (93.6)	2458 (92.3)
Creatinine >2.0 mg/dL	24 (2.5)	24 (2.1)	121 (4.5) <sup>c</sup>
Prior atrial fibrillation/flutter	305 (31.4)	348 (30.9)	1132 (42.6) <sup>c</sup>
Baseline anticoagulation therapy	236 (24.3)	236 (20.9)	558 (21.0)

Abbreviations: HF, heart failure; NYHA, New York Heart Association; RCT, randomized clinical trial; STS-PROM, Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI, transcatheter aortic valve implantation.

SI conversion factor: To convert creatinine to  $\mu\text{mol/L}$ , multiply by 88.4.

<sup>a</sup> There were no significant differences between the surgery and TAVI RCT populations.

<sup>b</sup> The non-RCT TAVI cohort comprises the pooled CoreValve US Extreme Risk and the CoreValve CAS populations.

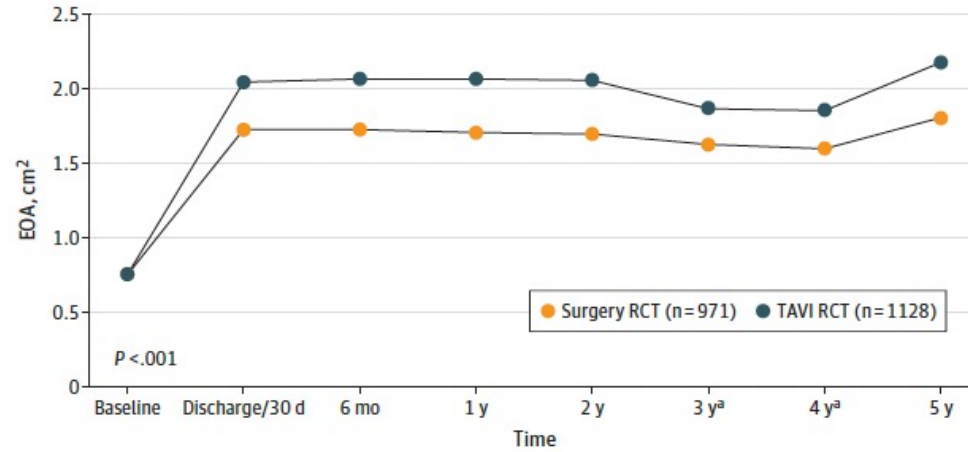
<sup>c</sup>  $P < .001$  vs TAVI RCT.

<sup>d</sup> STS-PROM provides an estimate of the risk of death at 30 days among patients undergoing surgical aortic valve replacement based on several demographic and procedural variables.



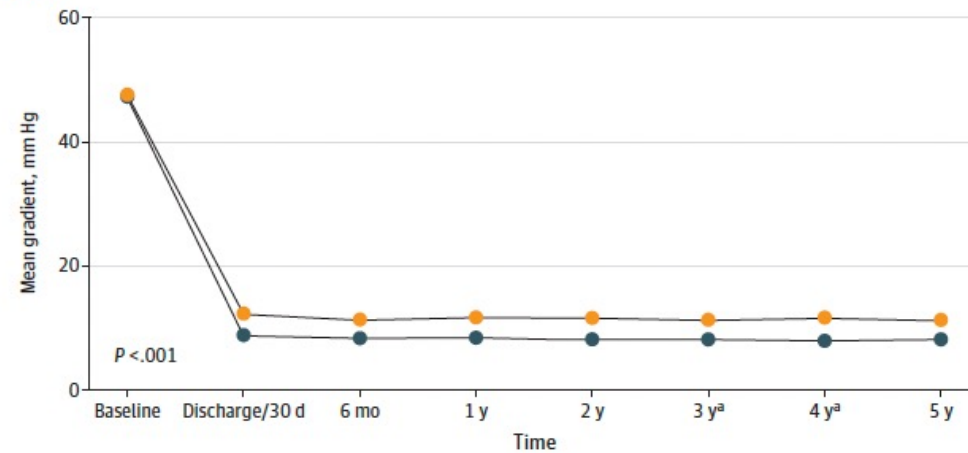
Figure 1. Hemodynamics in Patients Randomized to Surgery or Transcatheter Aortic Valve Implantation (TAVI)

**A** EOA



No. at risk	Baseline	Discharge/30 d	6 mo	1 y	2 y	3 y <sup>a</sup>	4 y <sup>a</sup>	5 y
Surgery EOA	919	705	821	752	649	558	456	266
TAVI EOA	1061	951	989	930	788	702	579	434

**B** Mean gradient



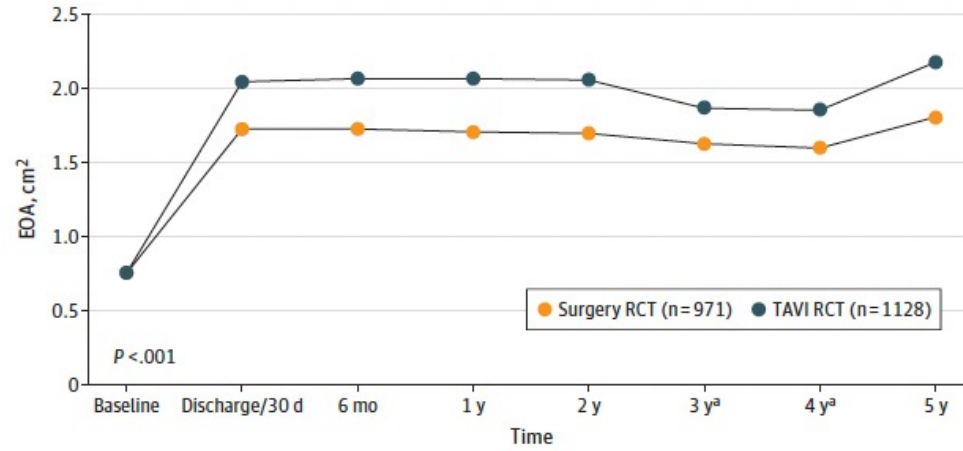
No. at risk	Baseline	Discharge/30 d	6 mo	1 y	2 y	3 y <sup>a</sup>	4 y <sup>a</sup>	5 y
Surgery gradient	966	872	898	829	725	620	512	405
TAVI gradient	1122	1026	1071	1007	882	769	644	499

Effective orifice area (EOA) and mean gradient hemodynamic trends through 5 years. Patients in the TAVI group had significantly larger EOA and significantly lower mean gradient than patients in the surgery group at all time points after the procedure. RCT indicates randomized clinical trial.

<sup>a</sup> Change from Core Laboratory to site-reported echocardiographic readings.

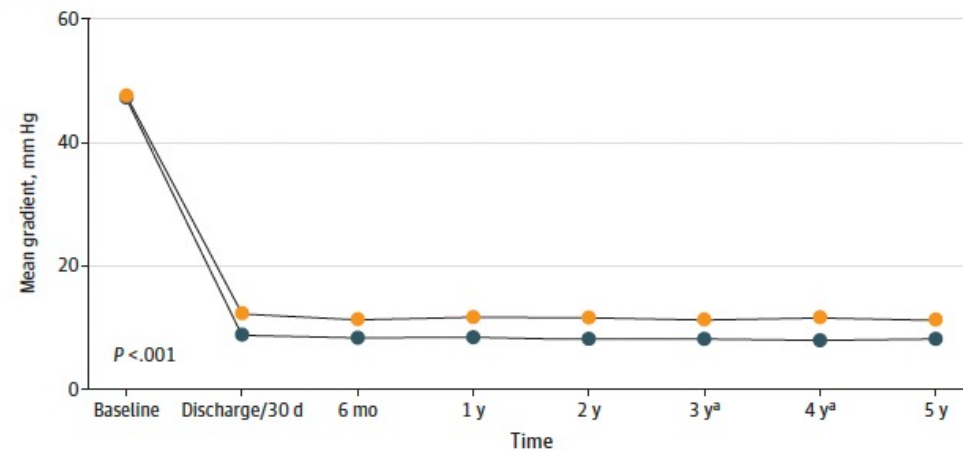
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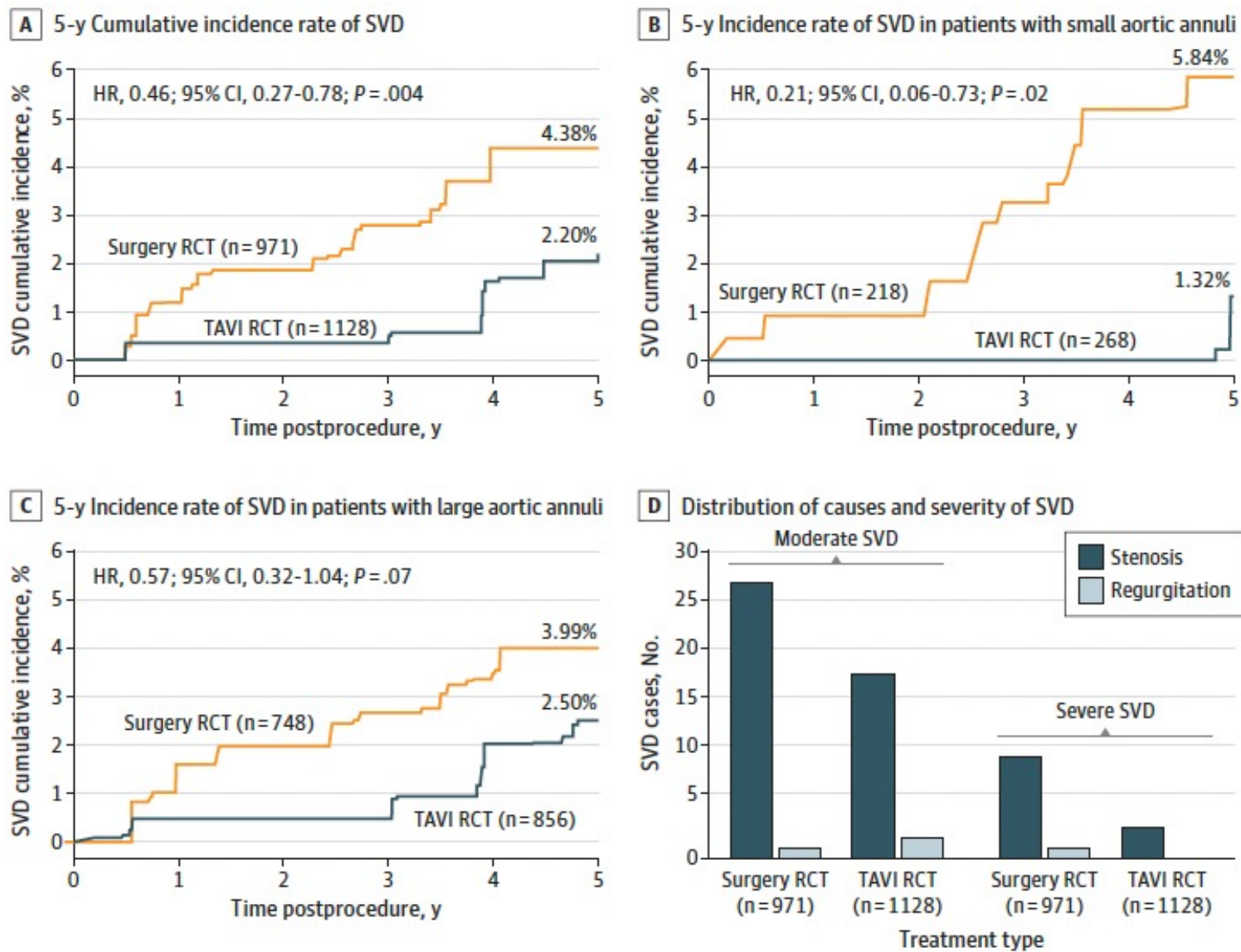


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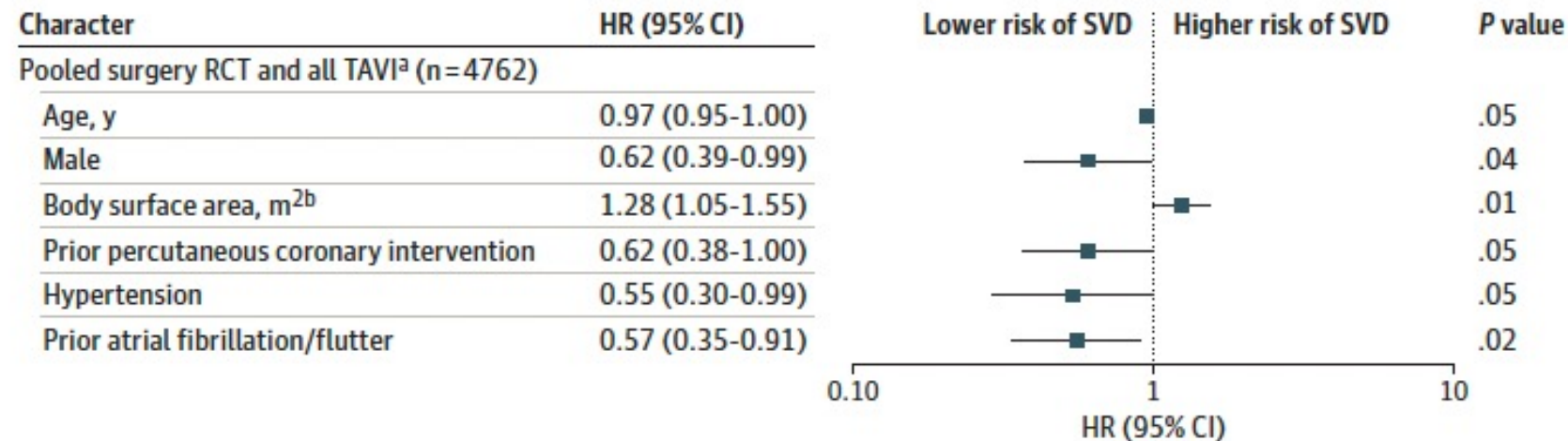
**Figure 2. Comparison of Structural Valve Deterioration (SVD) in Patients Randomized to Surgery or Transcatheter Aortic Valve Implantation (TAVI)**



Small aortic annuli was defined as computer tomography perimeter-derived diameter of 23 mm or smaller and large aortic annuli as greater than 23 mm. Severe SVD cases were based on status at any follow-up echocardiography, not just at last-available echocardiography. For hazard ratios (HRs), Fine-Gray *P* values are reported. AR indicates aortic regurgitation; AS, aortic stenosis; RCT, randomized clinical trial.

## ■ Predictors

Figure 4. Multivariate Predictors of Structural Valve Deterioration (SVD)

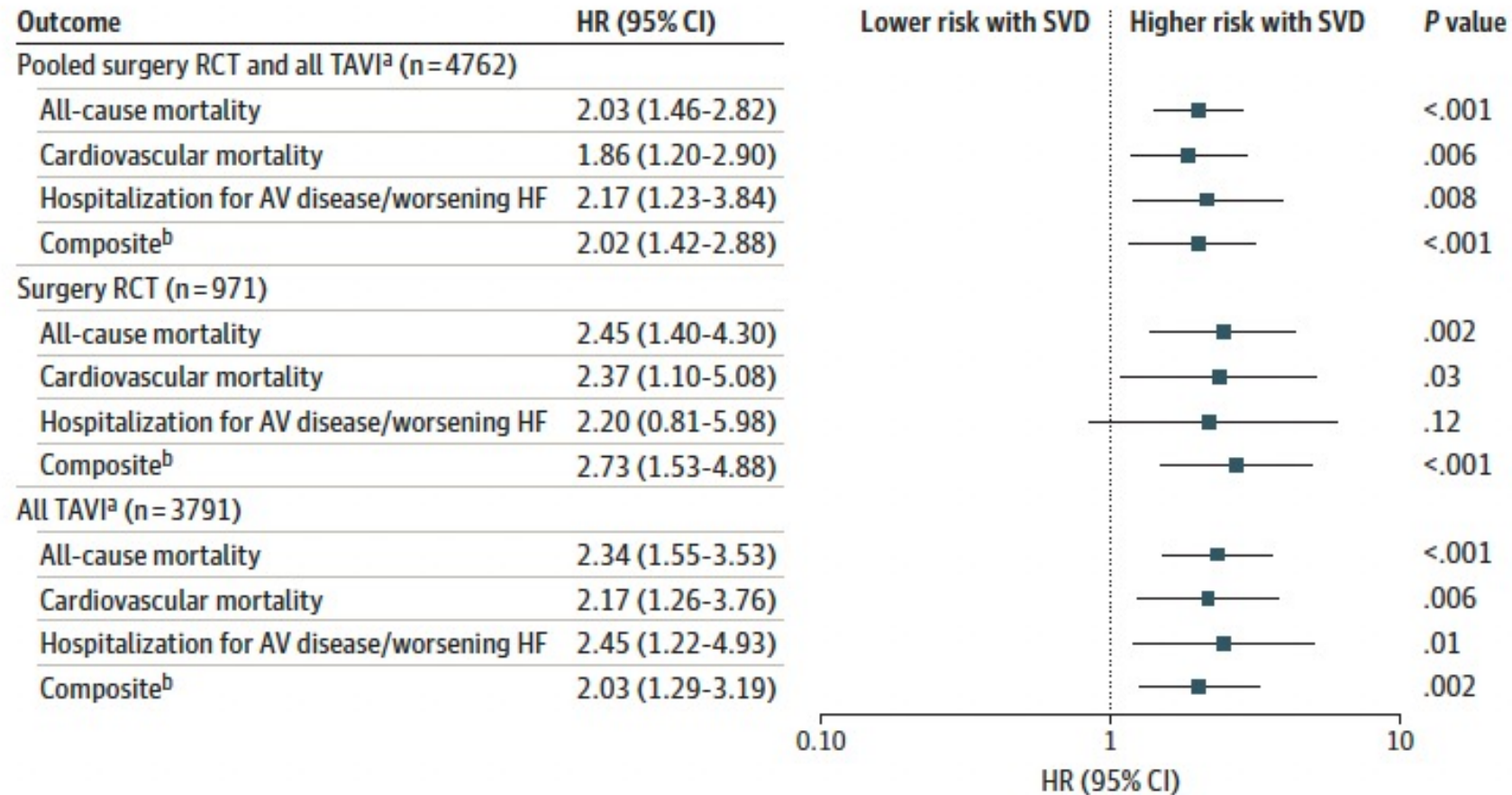


HR indicates hazard ratio; RCT, randomized clinical trial; TAVI, transcatheter aortic valve implantation.

<sup>a</sup> The all TAVI cohort comprises the pooled RCT and non-RCT populations.

<sup>b</sup> HR per 0.2-m<sup>2</sup> increase in body surface area.

Figure 3. Association Between Clinical Outcomes and Structural Valve Deterioration (SVD)

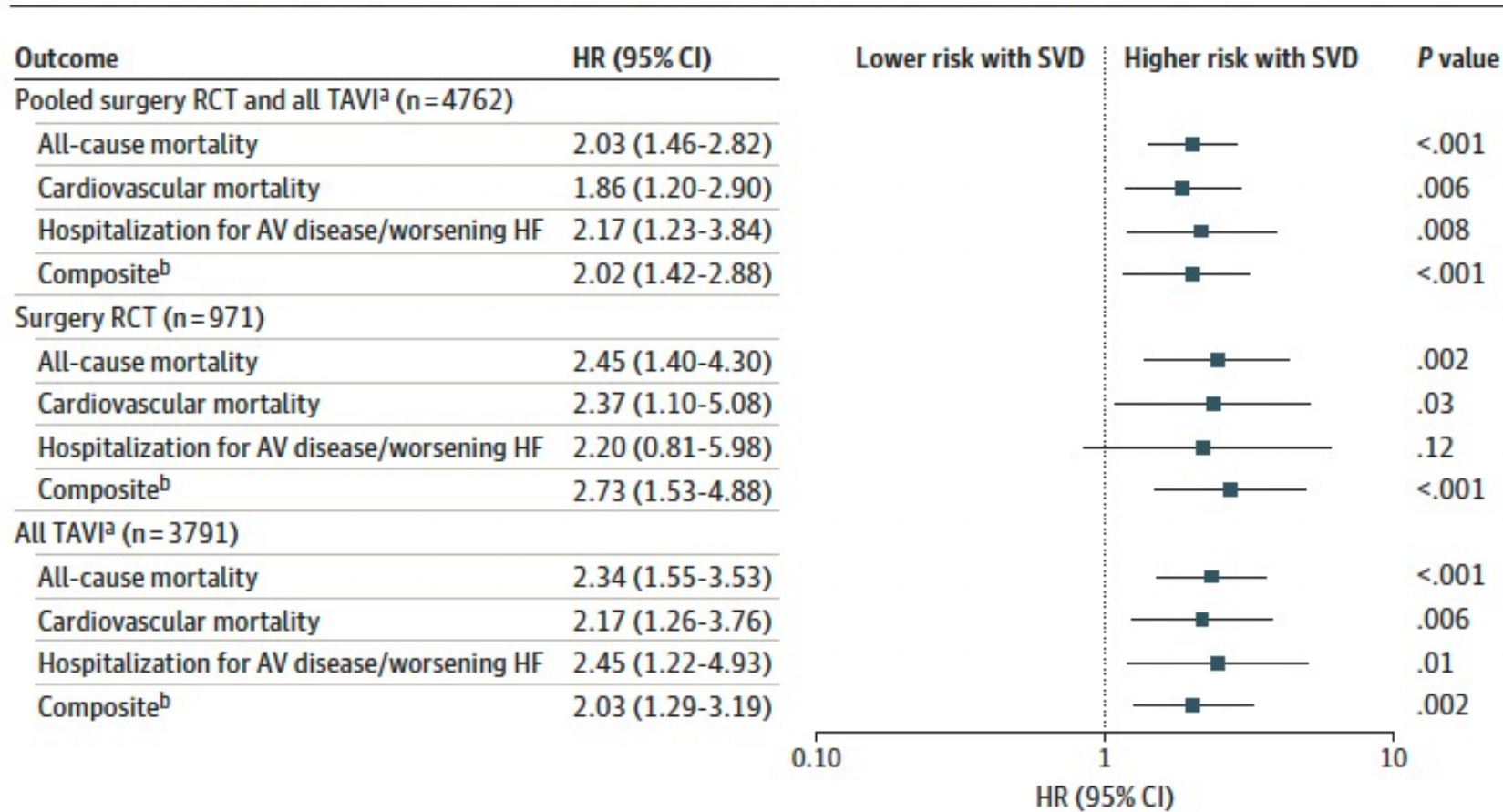


AV indicates aortic valve; HF, heart failure; HR, hazard ratio; RCT, randomized clinical trial; TAVI, transcatheter aortic valve implantation.

<sup>a</sup> The all TAVI cohort comprises the pooled RCT and non-RCT populations.

<sup>b</sup> Composite of all-cause mortality or hospitalization for AV disease or worsening HF.

Figure 3. Association Between Clinical Outcomes and Structural Valve Deterioration (SVD)



AV indicates aortic valve; HF, heart failure; HR, hazard ratio; RCT, randomized clinical trial; TAVI, transcatheter aortic valve implantation.

<sup>a</sup> The all TAVI cohort comprises the pooled RCT and non-RCT populations.

<sup>b</sup> Composite of all-cause mortality or hospitalization for AV disease or worsening HF.

- Cumulative incidence of SVD was lower in patients undergoing TAVI than surgery.
- This difference was magnified in patients with small annuli (23 or smaller).
- SVD was associated with increased all-cause mortality, CV mortality and heart failure admission.
- Younger age and female gender predicted higher risk of SVD.

- Implant the best valve first.
- We are constantly reading and writing the research that keeps our patients on the cutting edge of heart valve care.



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