

Midterm Outcomes of the Self-Expanding Navitor Transcatheter Heart Valve: A Systematic Review and Meta-Analysis

Sahar Samimi, MD

Department of Internal Medicine, Baylor College of Medicine

Houston Methodist DeBakey Heart and Vascular Center,

Houston, Texas, USA



TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS®

Disclosure of Relevant Financial Relationships

I, Sahar Samimi DO NOT have any financial relationships to disclose.

INTRODUCTION

- The Navitor™ valve (Abbott Structural Heart) is an intra-annular, self-expanding transcatheter heart valve (THV).
- The device builds on the Portico valve, with an active outer fabric cuff to reduce paravalvular leak (PVL).
- Third commercially approved THV in the USA for symptomatic, severe aortic stenosis who are at high or extreme surgical risk.¹

Large cell design

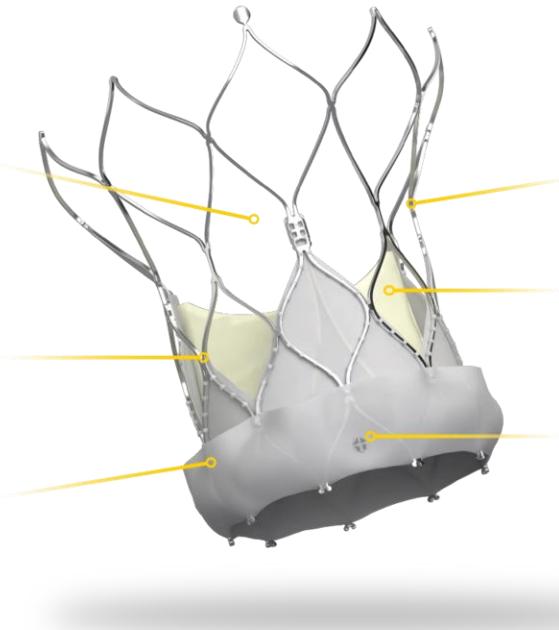
Minimizes coronary obstruction
and improves coronary
access and flow

Annulus treatment range

19 mm to 30 mm diameters

Active-sealing cuff

Synchronizes to the cardiac cycle
to seal and mitigate PVL²



Consistent radial force

Expands, anchors, stabilizes and seals

Intra-annular leaflets

Function immediately for continuous
hemodynamic stability during deployment

Three radiopaque markers

Provide clear visualization of 3 mm
implant depth

METHODS

- Systematic literature review through September 30th, 2025
 - Included: Studies reporting 30-day/1-year clinical outcomes of the Navitor among patients undergoing TAVR indicated for native aortic stenosis.
 - Excluded: Case reports/series <10, Redo-TAVR
- Random-effects study-level meta-analysis with inverse-variance weighting
 - Outcomes with < 5% incidence rate: Freeman-Tukey transformation
 - Outcomes with $\geq 5\%$ incidence rate: Logit transformation

RESULTS

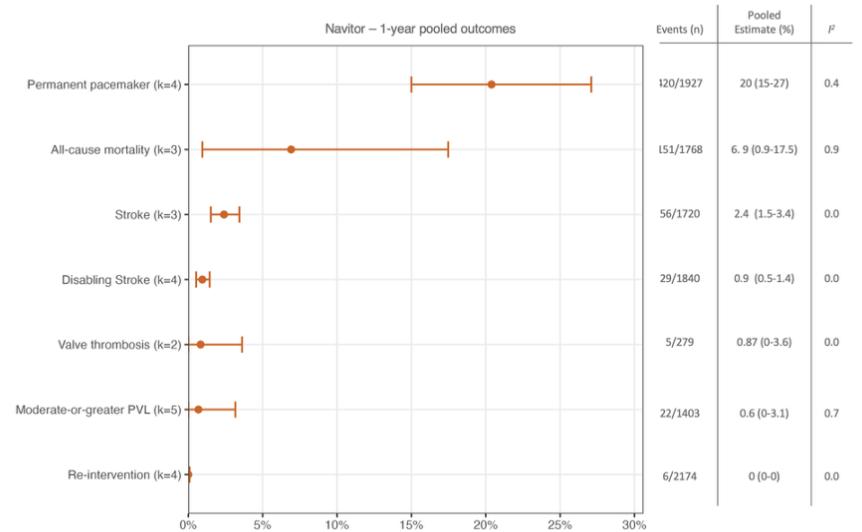
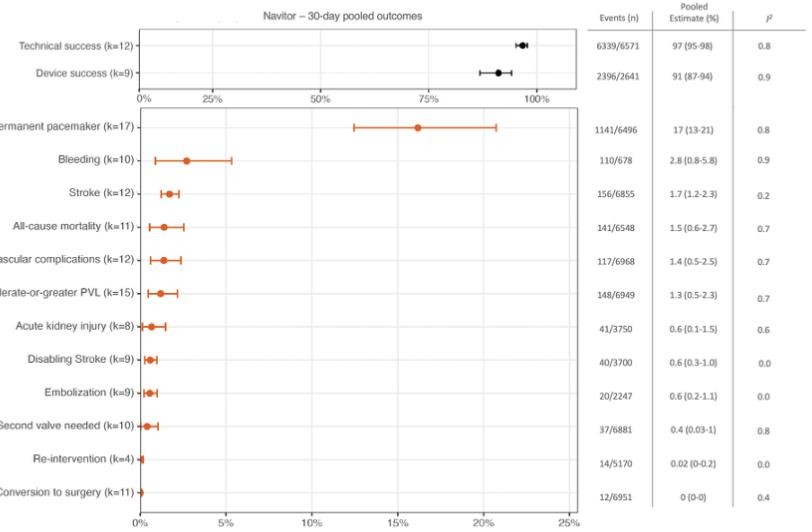
- A total of 19 studies comprising 7743 patients were included.
 - Pooled mean age: 81.8 years (95% CI: 80.6–83.1)
 - Pooled mean STS score: 4.3% (95% CI: 2.7–6.7).
 - Pooled proportion of Females: 63.2%

RESULTS (30-day Outcomes)

- Technical success: 96.7% (95% CI: 95.2 - 97.8; k = 12; $I^2 = 0.9$)
- Device success: 91.1% (86.8 - 94.1; k = 9; $I^2 = 0.7$)
- New PPI: 16.7% (12.9 - 21.4; k = 17; $I^2 = 0.8$)
- \geq Moderate PVL: 1.3% (0.5–2.3; k = 15; $I^2 = 0.7$)
- All remaining pooled 30-day event rates were $\leq 3\%$.

RESULTS (One-year Outcomes)

- New PPI: 20.4% (15.0 - 27.1; $k = 4$; $I^2 = 0.4$).
- \geq Moderate PVL: 0.6% (0.00–3.16; $k = 5$; $I^2 = 0.7$).
- All-cause mortality: 6.9% (0.9 - 17.5; $k = 3$; $I^2 = 0.9$).
- All remaining pooled 1-year event rates remained low at $\leq 3\%$



RESULTS

(BAV Sensitivity Analysis)

- Two studies ([n=107](#)) exclusively enrolled patients with BAV.
- 30-day sensitivity analysis comparing BAV vs. TAV:
 - New PPI: 15.5% (17) vs 16.8% (1124).
 - \geq Moderate PVL: 1.2% (2) vs 1.2% (146).
 - No evidence of effect modification by valve morphology (p -interaction >0.05)
 - Limited by the small number of patients with BAV.

LIMITATIONS

- Non-randomized, observational studies
- Absence of patient-level data.
- Variability in procedural protocols and lack of granular procedural characteristics (e.g., implantation depth).
- One-year results were derived from few studies
 - (k=5 for \geq moderate PVL and k=4 for other outcomes).

SUMMARY

- The Navitor system demonstrates strong early performance with:
 - High technical and device success
 - Consistently low rates of \geq moderate PVL at 30 days and 1 year.
- PPI remains frequent.
 - Need for further evaluation of strategies to mitigate conduction injury (e.g., implant depth optimization, cusp-overlap technique, and selective pre-/post-dilation).

Thank you to my mentors,
Dr. Sachin S. Goel and Dr. Michael Reardon for their guidance.