Device design and favorable 5-year durability reinforce Navitor™ TAVI long-term outlook

KEY FINDINGS:

The Abbott TAVI platform is proven durable through 5-years:

- Over 97% freedom from Bioprosthetic Valve Failure (BVF) – BVF (2.7%), primarily driven by an aortic reintervention rate (2.0%) due to paravalvular leak (PVL) with a first generation THV that did not have a PVL mitigation feature[1]
- 100% freedom from severe Hemodynamic Structural Valve Deterioration (HSVD)[1]
- Low rate of moderate HSVD (0.9%) and clinical valve thrombosis (0.7%)[1]
- Low reintervention rate (2.0%) or valve-related death (0.7%)[1]

INTRODUCTION

Pooled data from three prospective international multicenter studies using the first generation Abbott transcatheter heart valve (THV) were analyzed with respect to 5-year outcomes and valve durability.[1] The studies had similar design with regard to inclusion/exclusion criteria, follow-up schedule, independent core laboratory echocardiographic analysis and clinical events committee adjudication. The pooled analysis comprised of nearly 1,500 subjects with severe, symptomatic AS at high/extreme surgical risk from:

- First-generation Abbott TAVI RCT (N=375)
- First-generation Abbott TAVI Adjudicated Registry (N=941)
- First-generation Abbott TAVI Continued Access Protocol (N=148)

PATIENTS

A total of 1464 patients at high or extreme surgical risk underwent an implant attempt were included in this analysis (Table 1). This pooled cohort was followed for a median of 4.2 years [IQR: 1.6, 5.0].

TABLE 1: DEMOGRAPHICS AND BASELINE CHARACTERISTICS OF THE POOLED COHORT (N=1464)

Age (years)	83.0 (79.0, 87.0)
Female (%)	61.7
Body surface area (m^2)	1.8 (1.6, 2.0)
BMI (kg/m^2)	27.0 (23.7, 31.1)
STS score (%)	4.9 (3.3, 7.6)
NYHA III/IV (%)	65.8
Mean transvalvular gradient (mmHg)	45.0 (39.0, 55.0)
Aortic valve area (cm^2)	0.70 (0.57, 0.80)
LVEF (%)	60 (53, 65)

Data presented as % or median (IQR).

5-YEAR CLINICAL OUTCOMES

Clinical outcomes at 5-years after TAVI are summarized in Table 2.

TABLE 2: 5-YEAR CLINICAL OUTCOMES

All-cause mortality	49.4%
Cardiovascular mortality†	28.6%
Myocardial infarction	7.9%
Heart failure hospitalization	23.3%
Clinical valve thrombosis	0.7%
Endocarditis	1.6%
Aortic valve reintervention	2.2%
All Strokes	12.3%

Data are pooled Kaplan-Meier rates from meta-analysis with random effects model
† Reported in two studies with 1316 enrolled patients

The overall 5-year stroke rate was consistent with high and extreme risk population. At 2 years post-TAVI, most strokes were ischemic (6.3%, versus 0.4% hemorrhagic strokes) and half of the events were non-disabling (3.2% versus 3.2% disabling strokes, as reported by two studies).

VALVE PERFORMANCE

Through 5-year follow up, single-digit aortic valve gradients and a large effective orifice area were observed (Figure 1) despite available valve sizes being limited to 23 mm through 29 mm. Notably, 27 and 29 mm valves were not initially available in the First-generation Abbott TAVI Postmarket Registry (N=941). A low rate of ≥moderate PVL was achieved, which improved over time through 5-year follow-up (Figure 2). This trend was observed in the total cohort and in a paired analysis including only patients with data at 30 days and 5 years. Subgroup analysis demonstrated favorable outcomes irrespective of annular size.

FIGURE 1: SINGLE DIGIT AORTIC VALVE GRADIENTS AND EFFECTIVE ORIFICE AREA REMAINING STABLE THROUGHOUT 5 YEARS POST-TAVI

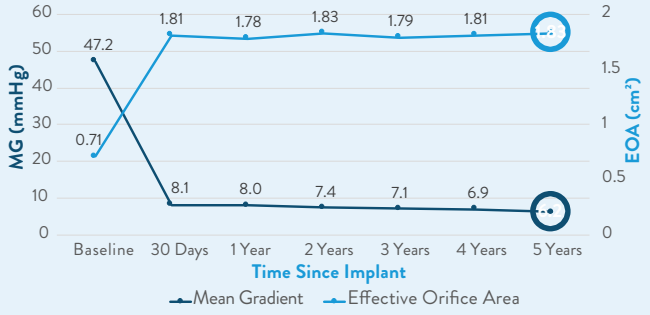
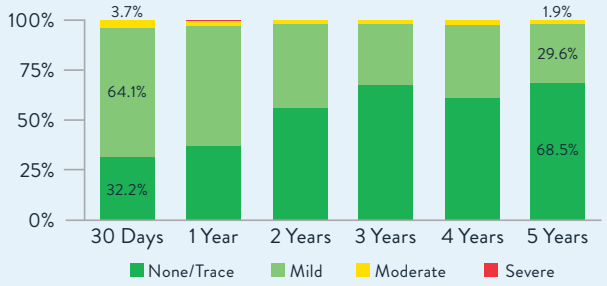


FIGURE 2: PARAVALVULAR LEAK, WITH LOW INCIDENCE OF ≥MODERATE PVL AND GRADUAL IMPROVEMENT OVER TIME



DURABILITY

A low 5-year rate of bioprosthetic valve failure (BVF) was observed, with valve related death in 0.7% and aortic valve reintervention in 2.0%. The majority of reinterventions were for PVL. Unlike the first generation THV, the Navitor platform incorporates an active-sealing cuff that has shown to eliminate moderate/severe PVL.[2,3,4]
No cases of severe hemodynamic structural valve deterioration (HSVD) occured and only 0.9% of the patients had moderate HSVD (Table 3).

TABLE 3: 5-YEAR VALVE DURABILITY OUTCOMES

Bioprosthetic Valve Failure (BVF) Valve related death Aortic valve reintervention Severe hemodynamic structural deterioration (HSVD)	2.7% 0.7% 2.0% 0.0%
Moderate structural valve deteriorationv (HSVD)	0.9%
Endocarditis	1.3%
Clinical valve thrombosis	0.7%

Data are pooled KM event rates. Death treated as competing risk in the estimation of cumulative incidence.

SUMMARY AND CONCLUSIONS

The low rates of BVF and HSVD at 5-years in the pooled cohort are notable. These data compare favorably with intra-annular balloon-expandable valves as well as supra-annular self-expanding valves out to 5-years in patients at intermediate or high surgical risk.[5-8]

These results come from the first-generation device, which established the intra-annular leaflet and stent architecture carried forward into Navitor™ TAVI platform. Design enhancements—such as the active-sealing cuff and consistent radial force—further aim to reduce PVL and maintain performance over time. These improvements, combined with IDE study results—demonstrating 0% moderate/severe HSVD, 0% BVF, and 0% moderate/severe PVL in patients at high/extreme surgical risk at 4-years—reinforce confidence in the long-term durability and performance of the Navitor TAVI platform today and for future generations.

Rx Only
Important Safety Information

NAVITOR™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

INDICATIONS
The Navitor™ Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

CONTRAINDICATIONS
The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant therapy or nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with the use of transcatheter bioprosthetic heart valves include but are not limited to: access site complications (e.g., pain, bleeding, infection, hematoma, pseudoaneurysm, etc.); acute coronary obstruction; acute myocardial infarction; allergic reaction to antiplatelet agents, contrast medium, or valve components; aortic rupture; ascending aorta trauma; atrio-ventricular node block; cardiac arrhythmias; conduction system injury; conversion to open surgical procedure; death; dissection; embolism; emergent balloon valvuloplasty; emergent percutaneous coronary intervention (PCI); emergent surgery (i.e., coronary artery bypass, heart valve replacement); endocarditis; explantation; heart failure; hemodynamic compromise; hemolysis; hemolytic anemia; hemorrhage; hypotension or hypertension; infection; myocardial ischemia; mitral valve insufficiency; multi-organ failure; non-structural dysfunction (i.e., entrapment by pannus, paravalvular leak, inappropriate sizing or positioning); pannus; pericardial effusion; perforation of the myocardium, ventricle, or a blood vessel; permanent disability; permanent pacemaker; regurgitation; renal insufficiency or renal failure; reoperation; respiratory failure; sepsis; stroke; structural deterioration (i.e., calcification, leaflet tear); thrombosis; tamponade; transfusion; valve embolization or migration; vessel dissection or spasm.

REFERENCES
1. Puri R, Thiele H, Fichtlscherer S, et al. Five-Year Clinical Outcomes and Durability of a Self-Expanding Transcatheter Heart Valve With Intra-Annular Leaflets. Circ Cardiovasc Interv. 2025 Oct 24:e015430. doi: 10.1161/CIRCINTERVENTIONS.125.015430. Epub ahead of print. PMID: 41133305. 2. Worthley SG, Giordano A, Corcione N, et al. 30-Day and 1-Year Outcomes of Navitor Transcatheter Aortic Valve in Low- or Intermediate-Risk Patients. JACC Cardiovasc Interv. 2025 Oct 27;18(20):2517-2527. 3. Reardon MJ, Chehab B, Smith D, 30-Day Clinical Outcomes of a Self-Expanding Transcatheter Aortic Valve: The International PORTICO NG Study. JACC Cardiovasc Interv. 2023 Mar 27;16(6):681-689. 4. Four-Year Outcomes in the Navitor IDE Study. Presented by Ganesh Manoharan at TCT 2025 on October 28 in San Francisco; USA 5. Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. J Am Coll Cardiol 2018;72:2687-2696. 6. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet 2015;385:2477-2484. 7. O'Hair D, Yakubov SJ, Grubb KJ, et al. Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk. JAMA Cardiol 2023;8:111-119. 8. Pibarot P, Ternacle J, Jaber WA, et al. Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial. J Am Coll Cardiol 2020;76:1830-1843.

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