Navitor™ Valve in Small Aortic Annuli: Single-Digit Mean Gradients

KEY POINTS

- In patients with a small aortic annulus (SAA), transcatheter aortic valve implantation (TAVI) with either the intra-annular self-expanding Navitor™ Valve or the supra-annular self-expanding Evolut‡ Valve achieves single digit post-TAVI gradients.[1]
- Compared to balloon expandable valves in patients with SAA, both intra- and supra-annular self-expanding valves achieve larger indexed effective orifice area, lower mean gradients and lower Prosthesis-Patient Mismatch (PPM) rates.[2,3]

INTRODUCTION

A small aortic annulus (SAA) presents specific challenges to aortic valve replacement. Patients with SAA exhibit higher surgical risk and a higher risk of PPM.[4]

Several studies reported outcomes in an SAA population, with comparisons between a range of TAVI devices, including balloon expandable valves and intra- or supra-annular self-expanding valves. This document summarizes recently reported results regarding TAVI in SAA, with special focus on a comparison between two self-expandable TAVI devices.

OCEAN-TAVI REGISTRY IN SMALL AORTIC ANNULI

The OCEAN-TAVI Registry is an ongoing prospective Japanese multicenter registry recording patient data, procedural variables and clinical outcomes of TAVI procedures.

SINGLE-DIGIT MEAN GRADIENTS

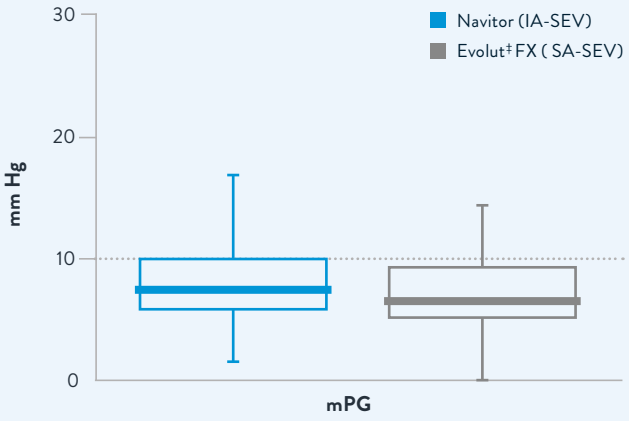

Figure 1: Mean pressure gradient in intra-annular self-expanding (IA-SEV) and supra-annular self-expanding (SA-SEV) valves. Propensity matched cohort, 306 patients each.

This retrospective analysis[1] compared the hemodynamic performance of intra- and supra-annular self-expanding TAVI devices in patients with SAA (aortic annulus area ≤ 430 mm²). The study included 518 patients with the intra-annular Navitor device (Abbott) and 401 with the supra-annular Evolut FX‡ device (Medtronic). The study found similar post-procedural outcomes for both valves regarding iEOA and mean pressure gradient. In two propensity-score matched (PMS) groups of 306 patients each, both valves showed single-digit mean gradients with SAA (Figure 1).

ADDITIONAL STUDIES ON TAVI IN SAA

(see Figure 2)

Self-expanding versus balloon expandable valves

The international, multicenter SMART trial[2] compared outcomes from TAVI with self-expanding and balloon expandable valves. This study compared supra-annular self-expanding valves (Medtronic Evolut‡ models, 355 patients) with the Sapien 3/3 Ultra balloon expandable valve (Edwards Lifesciences, 361 patients) in SAA defined as MDCT derived area < 430 mm².

The study demonstrated the mean gradient at 12 months was significantly lower in the self-expanding valve group 7.7 mm Hg vs. 15.7 mm Hg in the balloon-expandable valve group. Moderate or severe PPM was significantly less frequent with self-expanding valves than with balloon expandable valves (10.3% vs. 35.1%).

Comparison of multiple TAVI systems

A German multicenter study[3] compared outcomes in 1,069 patients with SAA, defined as a CT-derived aortic annulus area < 400 mm². Among the various TAVI systems used in this study, the Abbott first generation TAVI valve achieved the lowest prevalence of severe and moderate PPM (4.4% and 21.1%, respectively vs. a mean prevalence for all valves of 10.2% and 28.1%).

Self-expanding valves showed superior hemodynamics compared to balloon expandable valves (iEOA: 0.9–1.0 cm²/m² vs. 0.8 cm²/m²), with similar performance for intra-annular and supra-annular valves. However, self-expanding valves were associated with a higher incidence of PVL compared to balloon expandable valves (PVL > mild: 3.9%–7.0% vs. 2.4%).

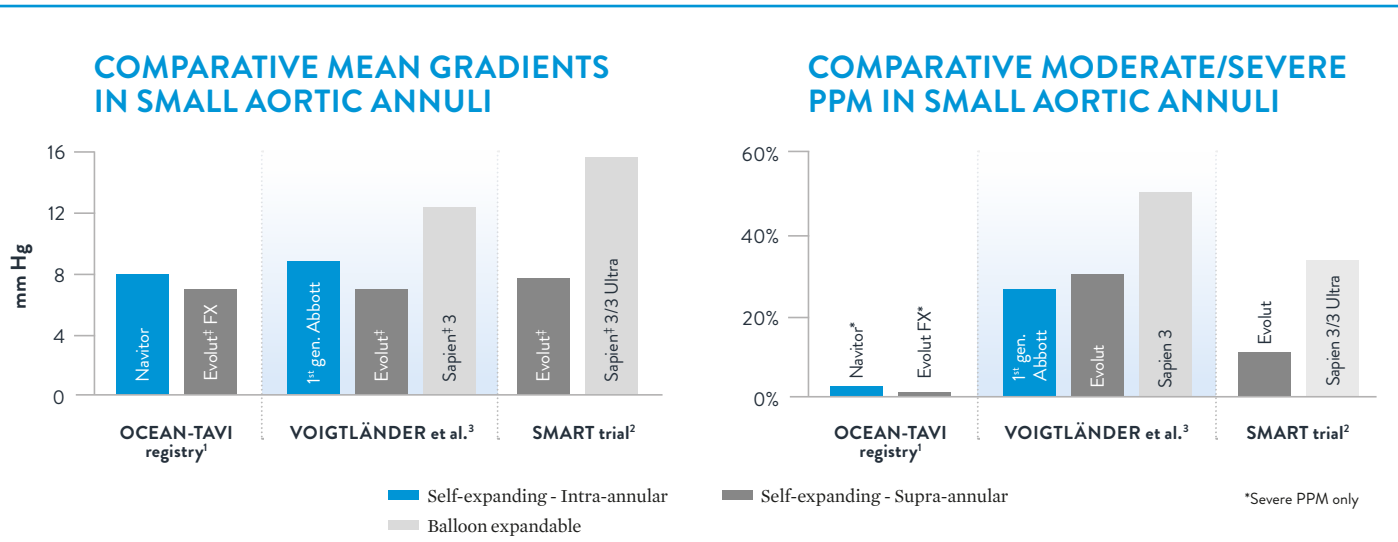

Figure 2
Comparison of outcomes from intra- and supra-annular self-expanding valves and balloon expandable valves in patients with SAA. While intra- and supra-annular self-expanding valves achieve similar hemodynamic outcomes, outcomes between self-expanding and balloon expandable valves are different.

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

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2. Herrmann HC, Mehran R, Blackman DJ, et al. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med*. 2024;390(21):1959-1971.
3. Voigtländer L, Kim WK, Mauri V, et al. Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves. *Clin Res Cardiol*. 2021;110(12):1957-1966.
4. Freitas-Ferraz AB, Tirado-Conte G, Dagenais F, et al. Aortic Stenosis and Small Aortic Annulus. *Circulation*. 2019;139(23):2685-2702.

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