

Real-world Outcomes of a Self-expanding, Intra-annular TAV for Aortic Stenosis in Patients with Small Annuli

The STS/ACC TVT Registry

Raviteja Guddeti, MD

On behalf of the TAVI PAS investigators



**NEW YORK
VALVES**

THE STRUCTURAL HEART SUMMIT™

For U.S. audience, see Important Safety Information referenced within. For audiences outside of the U.S., always check the regulatory status of the device in your region.

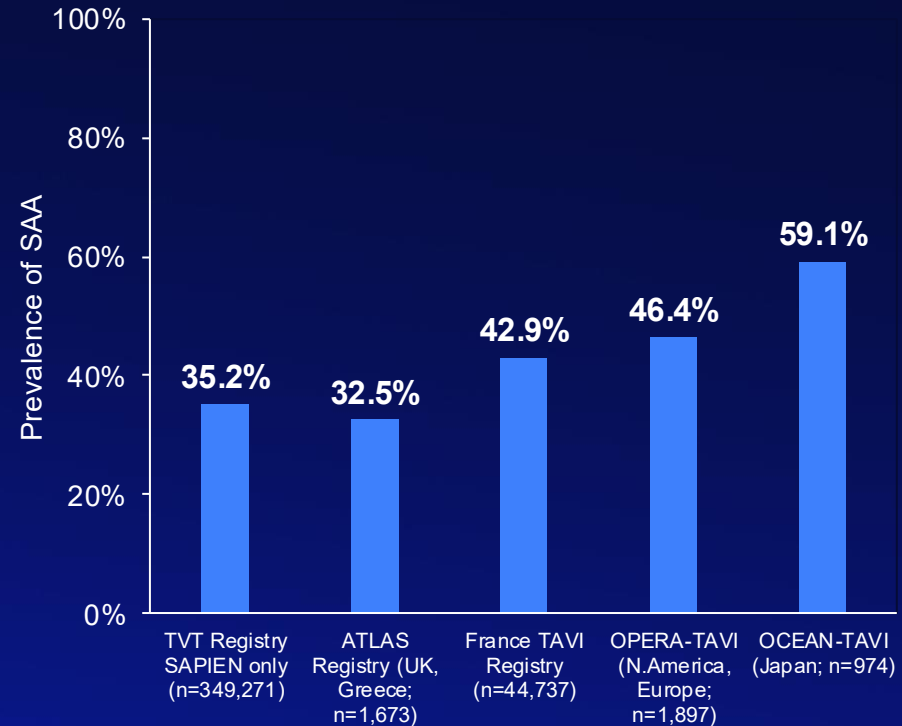
MAT-2675796 v1.0 | Item approved for Global use.

Disclosure of Relevant Financial Relationships

I, Raviteja Guddeti, DO NOT have any financial relationships to disclose.

Background

- Patients with **small aortic annuli (SAA)** treated with TAVR may be at increased risk of patient prosthesis mismatch, impaired clinical outcomes, and decreased valve durability.
- Data are limited on outcomes of TAVR with intra-annular, self-expanding transcatheter heart valves (SEV) in patients with SAA.



Definitions of SAA vary by study: TVT Registry: Makkar et al. *Lancet* 2023;402:P1529-40. ATLAS Registry: Kalogeras et al. *J Am Heart Assoc.* 2023;12:e02. France TAVI Registry: Ben Ali, Presented at TCT 2022. OPERA-TAVI: Scotti et al. *JACC Interv* 2024;17:681-92. OCEAN TAVI Registry: Hase et al. *Cath Cardiovasc Interv* 2020;97:E875-E886.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Navitor Valve: Self-expanding, Intra-annular Design

Large Cell Design

Minimizes coronary obstruction

Consistent Radial Force

Expands, anchors, stabilizes, and seals

Active-sealing Cuff

Synchronizes to the cardiac cycle to seal and mitigate PVL^a

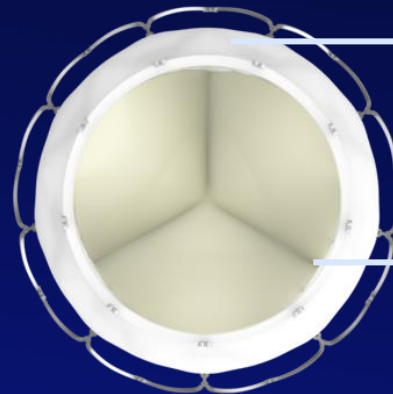


Cylindrical, Non-tapered Frame

Equivalent inflow and outflow diameter

Intra-annular Leaflets

Open fully to maximize orifice area and achieve single-digit gradients



Three Radiopaque Markers

Provide clear visualization of implant depth

Valve Size	23 mm	25 mm	27 mm	29 mm	35 mm
Patient Annular Diameter (mm)	19-21	21-23	23-25	25-27	27-30

^aSondergaard, L. 30-day outcomes from a next generation TAVI device with an active sealing cuff. Presented at: EuroPCR conference; May 18-20, 2021.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

STS/ACC Registry (Navitor PAS)

DESIGN	Commercial use data from the STS/ACC TVT Registry
CLINICAL SITES	141 centers within the United States
POPULATION	• 2496 small aortic annuli (SAA) patients with native tricuspid aortic valve stenosis undergoing TAVR with the Navitor valve (Navitor Classic: 1356 patients; Navitor Vision: 1140 patients) • SAA defined as annular area $\leq 430 \text{ mm}^2$
KEY ANALYSES	• Primary outcome: Prosthesis-patient mismatch • Secondary outcome: Bioprosthetic valve dysfunction (BVD)^a • Additional safety and effectiveness outcomes were defined by the registry

Study sponsored by Abbott.

^a Composite of hemodynamic structural valve dysfunction, defined as an aortic valve mean gradient $\geq 20 \text{ mm Hg}$; nonstructural valve dysfunction, (severe prosthesis patient mismatch or moderate or greater total aortic regurgitation); clinical valve thrombosis; endocarditis; or aortic-valve reintervention.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Baseline Characteristics

Patient Characteristic	Overall N=2496	Medical History	Overall N=2496
Age (years)	81.7 ± 7.3	Atrial fibrillation (%)	30.8
Female (%)	85.5	Conduction defect (%)	30.2
BSA (m ²)	1.78 ± 0.2	CABG (%)	6.0
STS Score (%)	7.0 ± 5.5	PCI (%)	24.2
NYHA III or IV (%)	55.1	Diabetes (%)	36.5
KCCQ-OS score	52.9 ± 24.8	Peripheral arterial disease (%)	16.1
Creatinine (mg/dL)	1.2 ± 0.9	Permanent pacemaker (%)	10.6
LVEF (%)	60.6 ± 10.0		

Data presented as % or mean ± standard deviation.

For U.S. audience, see Important Safety Information referenced within.

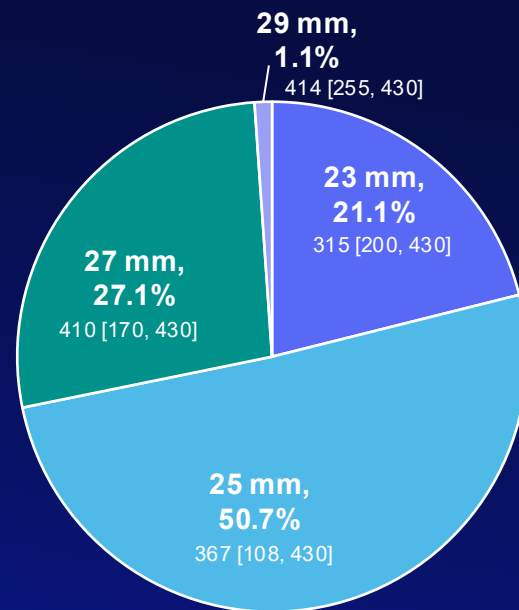
For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Baseline CT and Procedural Outcomes

Baseline CT Measurements	Overall N=2496
Annular diameter (mm)	19.5 ± 1.8
Annular area (mm ²)	365.8 ± 42.4
Procedural Characteristics	Overall N=2246
Conscious sedation (%)	23.5
Transfemoral access (%)	98.4
Procedure time (min)	67.7 ± 56.1
Fluoroscopy time (min)	17.5 ± 10.1
Device recapture (%)	16.3
Technical success (%)	98.0
Median hospital stay (days)	1.0 [1.0, 2.0]

Implanted Valve Sizes^a



Median [IQR] for aortic valve area shown by valve size.

Data presented as %, mean ± standard deviation, or median [interquartile range].

^a21.5% oversized, including 100% of patients treated with 29 mm valves and 45.2% of patients treated with 27 mm valves.

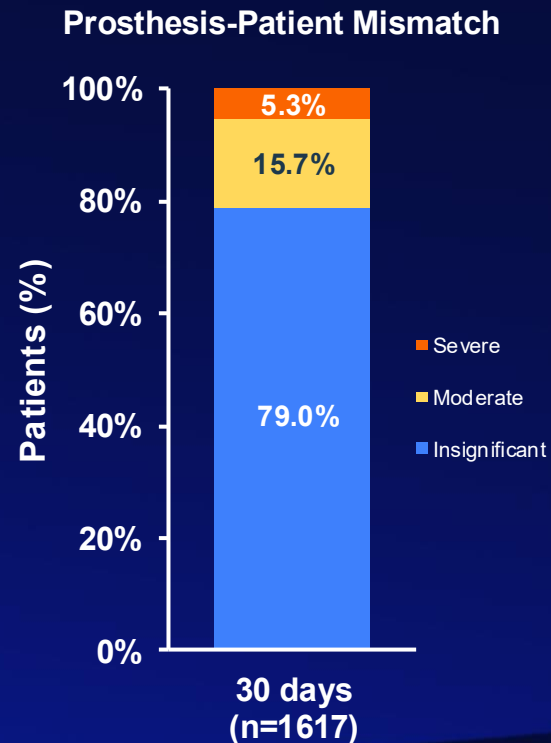
For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Clinical Outcomes and 30-day PPM

Outcomes	30 Days	1 Year
All-cause mortality or stroke	5.6%	14.5%
All-cause mortality	2.2%	10.0%
All stroke	3.6%	5.6%
Life-threatening or major bleeding	0.8%	2.9%
Major vascular complication	1.7%	NA
Aortic valve reintervention	0.2%	0.2%
New permanent pacemaker	15.8%	17.3%



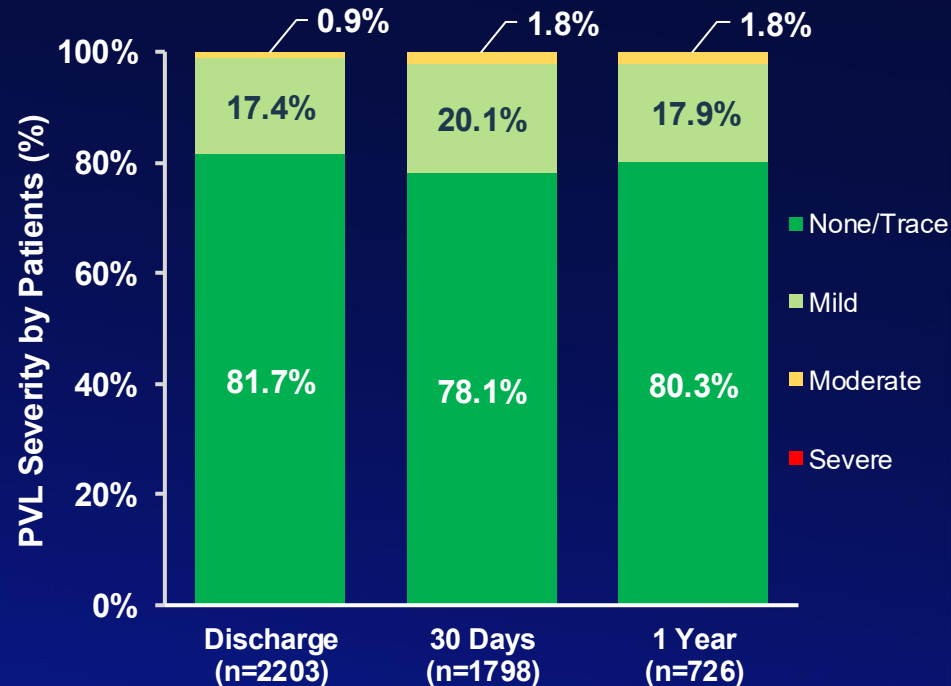
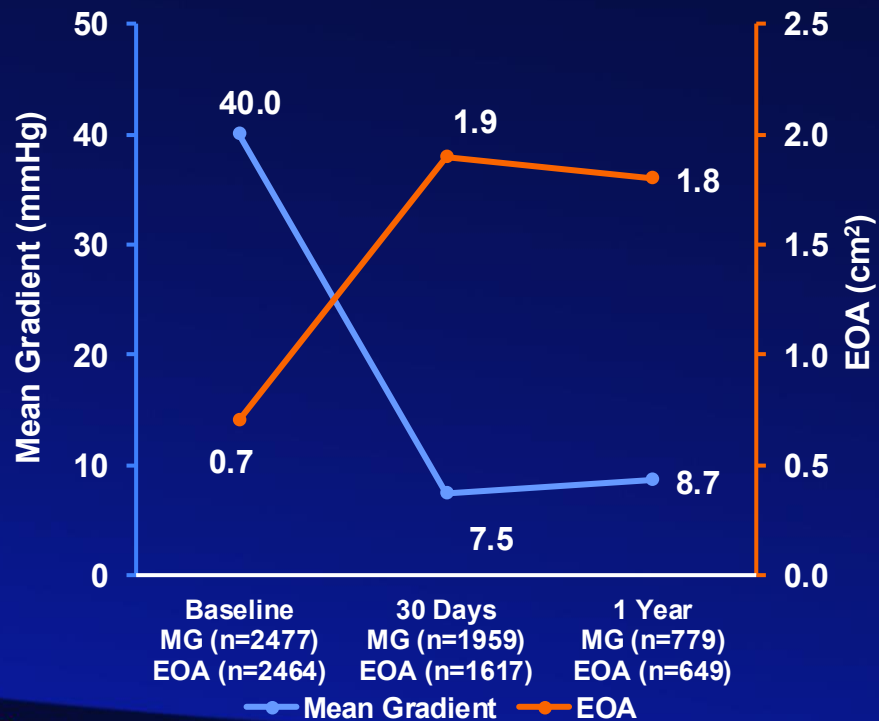
Note: The event rates are estimated by Kaplan-Meier analysis. New permanent pacemaker reported for pacemaker-naïve patients. Components of vascular complications not assessed beyond 30 days. For PPM, binary rate at 30 days shown.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

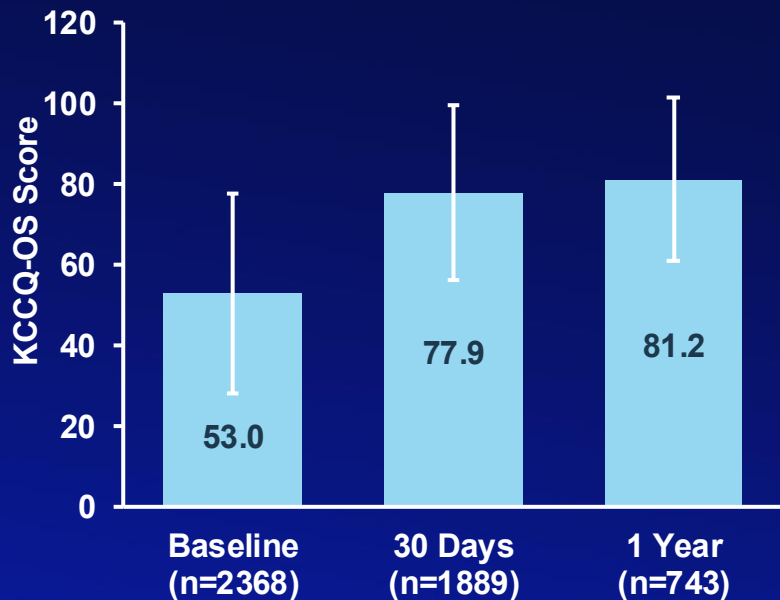
MAT-2675796 v1.0 | Item approved for Global use.

Echocardiographic Outcomes

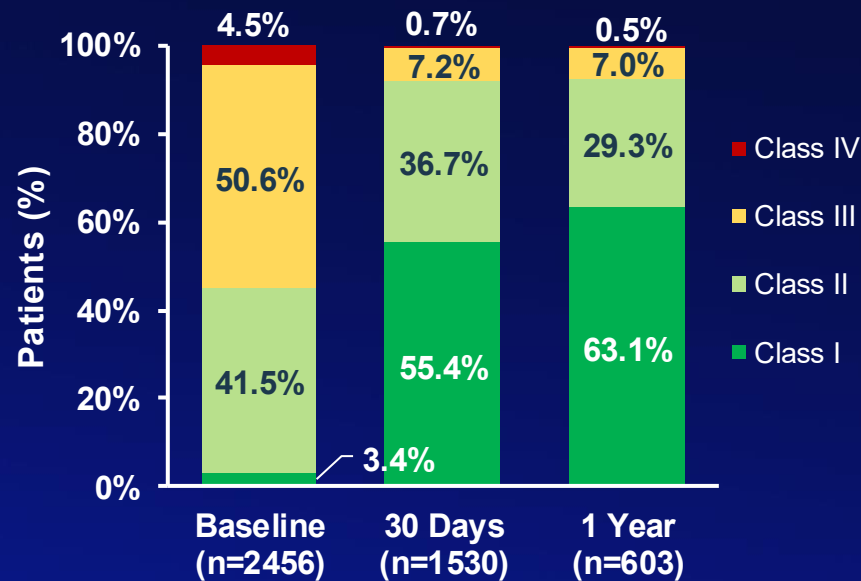


Quality of Life and Functional Capacity

KCCQ-OS



NYHA Class



KCCQ-OS plotted as mean $\pm$ standard deviation.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Bioprosthetic Valve Dysfunction Through One Year

Valve Dysfunction	30 Days	1 Year
BVD composite	5.5%	9.7%
Hemodynamic SVD	0.5%	2.2%
NSVD	4.8%	6.7%
Severe PPM	3.6%	NA
Moderate or greater PVL	1.3%	3.0%
Clinical valve thrombosis	0.0%	0.3%
Endocarditis	0.1%	0.5%
Aortic reintervention	0.2%	0.2%

Note: The event rates are estimated by Kaplan-Meier analysis. PPM only assessed at 30 days; shown here as Kaplan-Meier rate for calculation of BVD composite. Composite of hemodynamic structural valve dysfunction, defined as an aortic valve mean gradient ≥ 20 mm Hg; nonstructural valve dysfunction, (severe prosthesis patient mismatch or moderate or greater total aortic regurgitation); clinical valve thrombosis; endocarditis; or aortic-valve reintervention (Hermann et al., *N Engl J Med.* 2024;390(21):1959-1971.)

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

MAT-2675796 v1.0 | Item approved for Global use.

Limitations

- All procedures, assessments, and events were performed or reported per site standard of care, without independent core laboratory adjudication and review.
- The STS/ACC TVT Registry is an observational single-arm registry of site-reported data subject to incomplete reporting.

Conclusions

In the STS/ACC TVT Registry, patients with SAA treated with the intra-annular, self-expanding Navitor valve demonstrated favorable outcomes through 1 year.

- Technical success in **98%** of patients
- 30-day severe PPM rate of **5.3%**
- Favorable clinical and echocardiographic outcomes:
 - **98.2%** of patients with mild or less PVL
 - **8.7 mmHg**: Mean gradient at 1 year
 - **0.2%**: 30-day and 1-year rate of aortic-valve reintervention

For U.S. audience only

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 $\geq 8\%$ 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.

Source: Guddeti R. Real-world Outcomes of a Self-expanding, Intra-annular TAV for Aortic Stenosis in Patients with Small Annuli: The STS/ACC TVT Registry Presented at New York Valves: The Structural Heart Summit, June 24-26, 2026. New York.

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.
Photo(s) on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA

[™] indicates a trademark of the Abbott group of companies.
‡ Indicates a third-party trademark, which is property of its respective owner.

www.structuralheart.abbott

© 2026 Abbott. All rights reserved.
MAT-2675796 v1.0 | Item approved for Global use.

ABBOTT