1-Year Outcomes Following TAVR with a Self-Expandable Transcatheter Aortic Valve with Intra-Annular Leaflet Position:

Real-world data from the STS/ACC TVT registry

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Nature of Financial Relationship	Ineligible Company
Consultant Fees/Honoraria	Medtronic, Abbott Vascular

All Relevant Financial Relationships have been mitigated.
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Background and Aim

- The STS/ACC TVT Registry enables assessment of contemporary TAVR practice across the United States.
- Large-scale registry analyses can characterize outcomes in broad, real-world patient populations.

Aim: To evaluate procedural, 30-day, and 1-year outcomes in patients treated with the Navitor valve between January 2023 and April 2026.

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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



Cylindrical, Non-tapered Frame
Equivalent inflow and outflow diameter

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

Valve Size	23 mm	25 mm	27 mm	29 mm	35 mm
Aortic Annulus Diameter (mm)	19-21	21-23	23-25	25-27	27-30

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STS/ACC Registry (Navitor PAS)

DESIGN	Commercial use data from the STS/ACC TVT Registry
CLINICAL SITES	274 centers within the United States
POPULATION	**6,409 patients** with native tricuspid aortic valve stenosis undergoing TAVR with the Navitor valve (Navitor Classic: 3,198 patients; Navitor Vision: 3,211 patients)
KEY ANALYSES	• **Primary outcome**: Absence of more than mild paravalvular leak (PVL) • **Secondary effectiveness outcomes**: Hemodynamic performance, improvement in quality of life • **Secondary safety outcomes:** All-cause mortality, stroke

Study sponsored by Abbott.

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Baseline Characteristics

Patient Characteristic	N=6,409
Age (years)	81.3 ± 7.5
Female (%)	57.6
BSA (m^2)	1.88 ± 0.3
STS Score (%)	6.5 ± 5.3
NYHA III or IV (%)	57.8
KCCQ-OS score	52.7 ± 25.1
Creatinine (mg/dL)	1.3 ± 1.1
LVEF (%)	58.1 ± 11.3

Medical History	N=6,409
Atrial fibrillation (%)	35.7
Conduction defect (%)	33.7
Permanent pacemaker (%)	13.3
CABG (%)	11.4
PCI (%)	29.0
Diabetes (%)	38.7
Peripheral arterial disease (%)	17.0

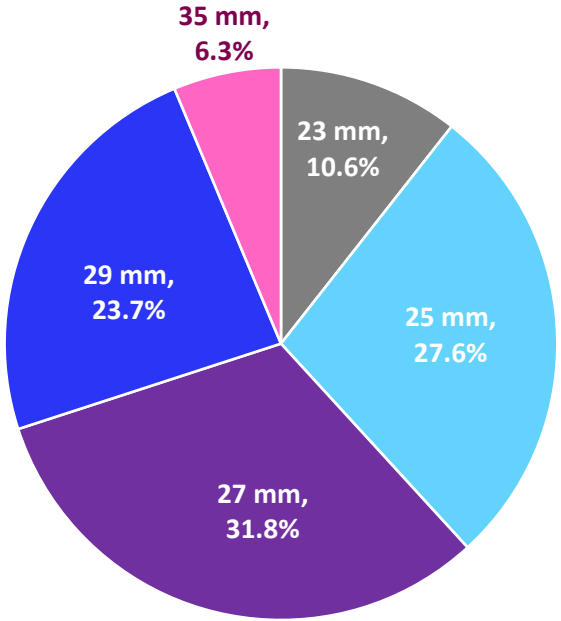
Data presented as % or mean ± SD.

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Baseline CT and Procedural Outcomes

Baseline CT Measurements	Overall N=6,409
Aortic annular diameter (mm)	21.1 ± 2.6
Aortic annular area (mm^2)	429.8± 87.9
Procedural Characteristics	**Overall N=6,409**
Conscious sedation (%)	28.4
Transfemoral access (%)	98.0
Procedure time (min)	65.6 ± 44.0
Fluoroscopy time (min)	18.1 ± 12.1
Device recapture (%)	18.6
Technical success (%)	98.6
Median hospital stay (days)	1.0 [1.0, 2.0]

Implanted Valve Sizes

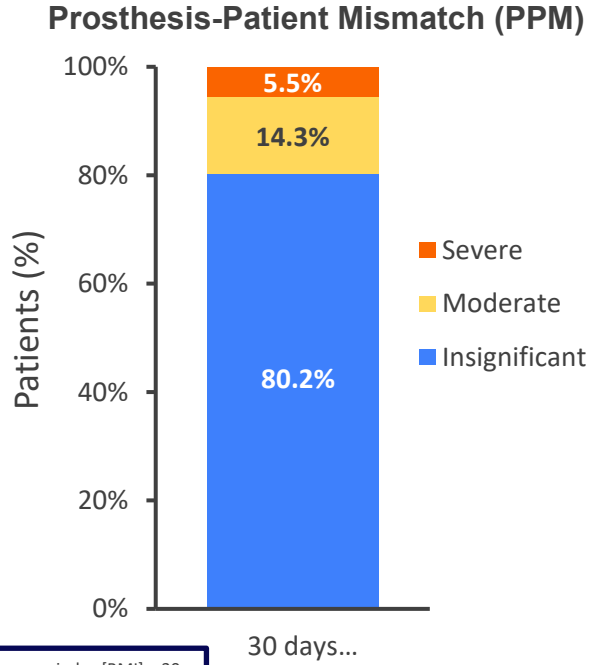


Data presented as %, mean ± SD, or median [interquartile range].

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One-year Clinical Outcomes and 30-day PPM

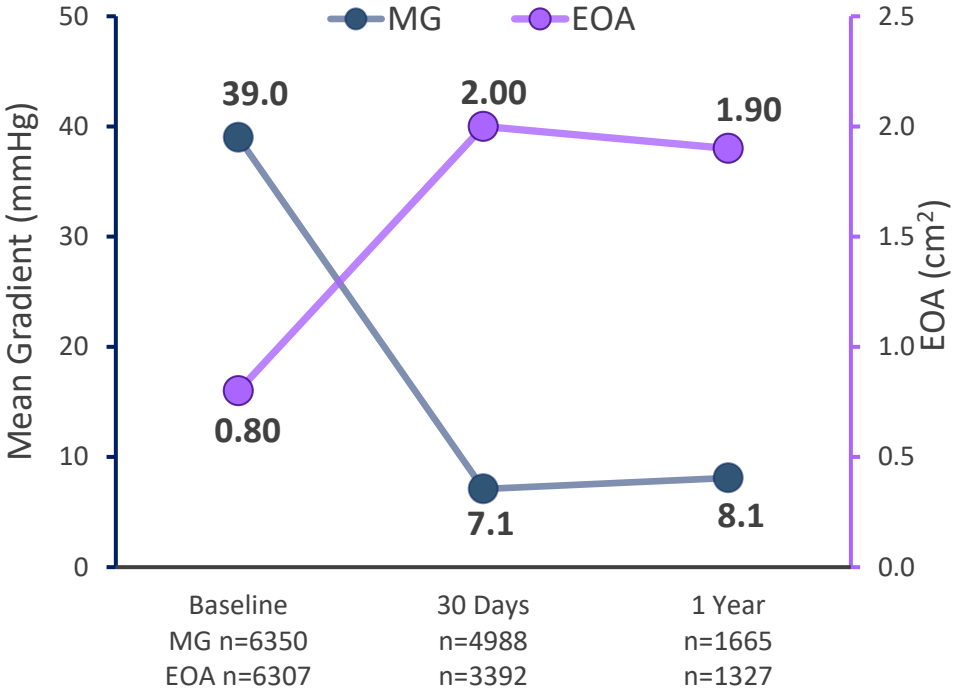
Outcomes	30 Days	1 Year
All-cause mortality or stroke	5.3%	16.2%
All-cause mortality	2.6%	12.4%
All stroke	3.0%	5.1%
Life-threatening or major bleeding	0.8%	3.1%
Major vascular complication	1.4%	NA
Aortic valve reintervention	0.3%	0.6%
New permanent pacemaker	18.7%	20.7%

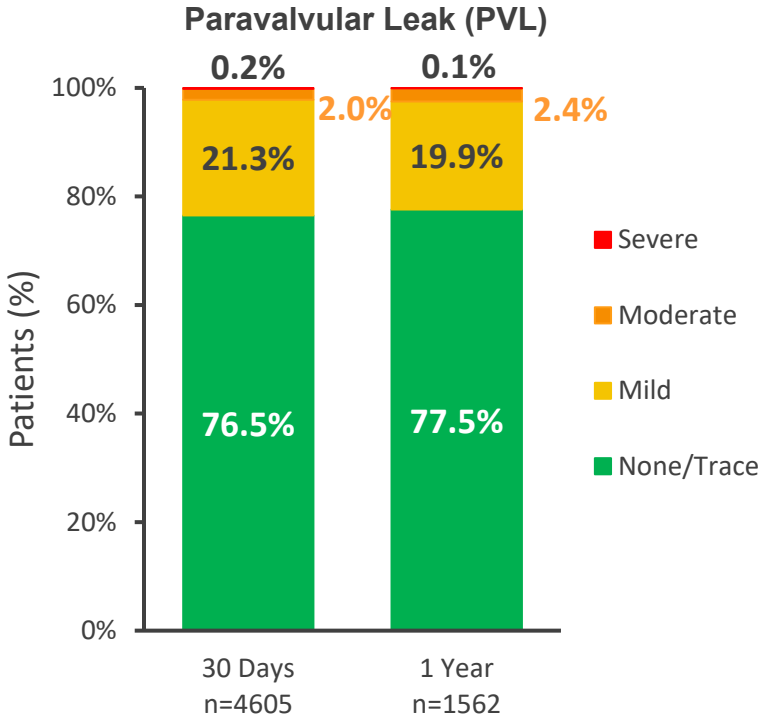


Note: The event rates are estimated by Kaplan-Meier analysis. PPM defined as: insignificant (aortic valve area index [AVAI] > 0.85 cm²/m² [body-mass index [BMI] < 30 kg/m²] > 0.70 cm²/m² [BMI ≥ 30 kg/m²]; moderate (AVAI 0.66 - 0.85 cm²/m² [BMI < 30 kg/m²] or 0.56 - 0.70 cm²/m² [BMI ≥ 30 kg/m²]; or severe PPM (≤ 0.65 cm²/m² [BMI < 30 kg/m²] or ≤ 0.55 cm²/m² [BMI ≥ 30 kg/m²]). 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.

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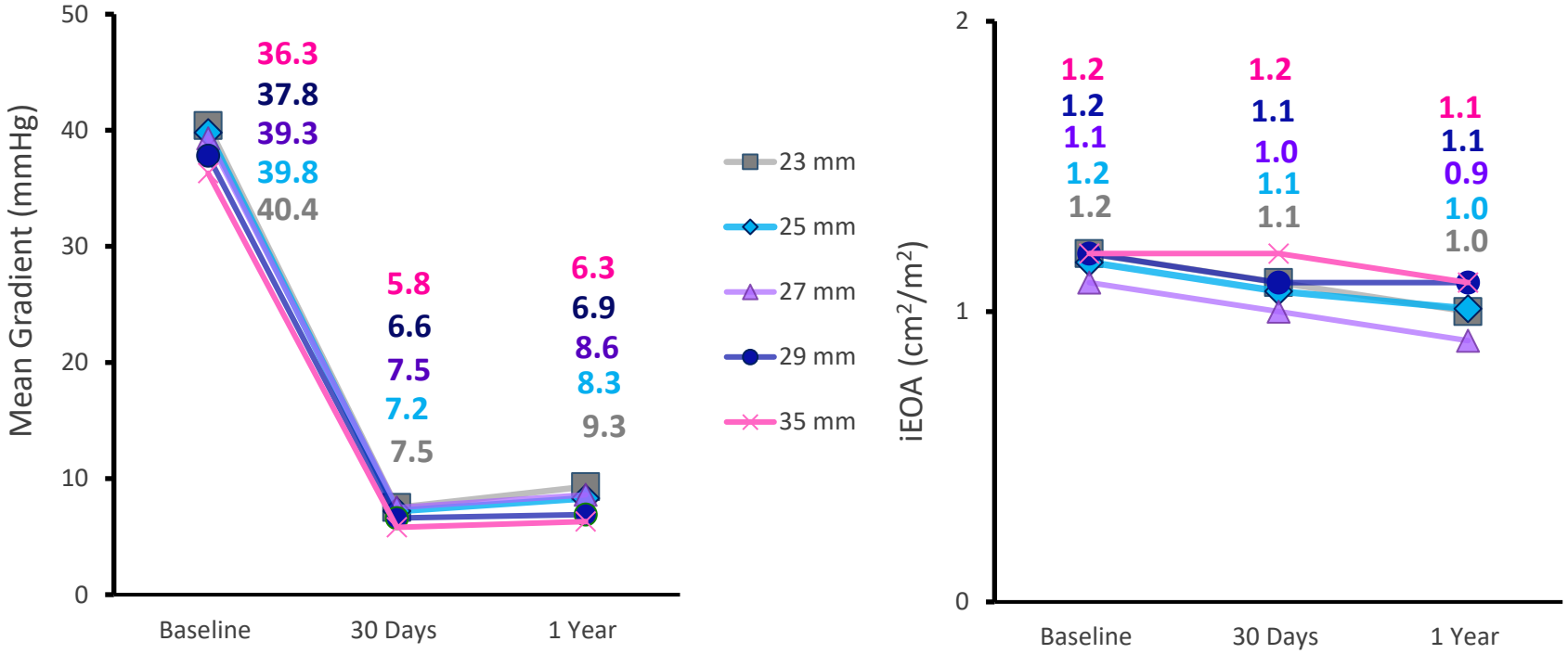
Hemodynamic Outcomes





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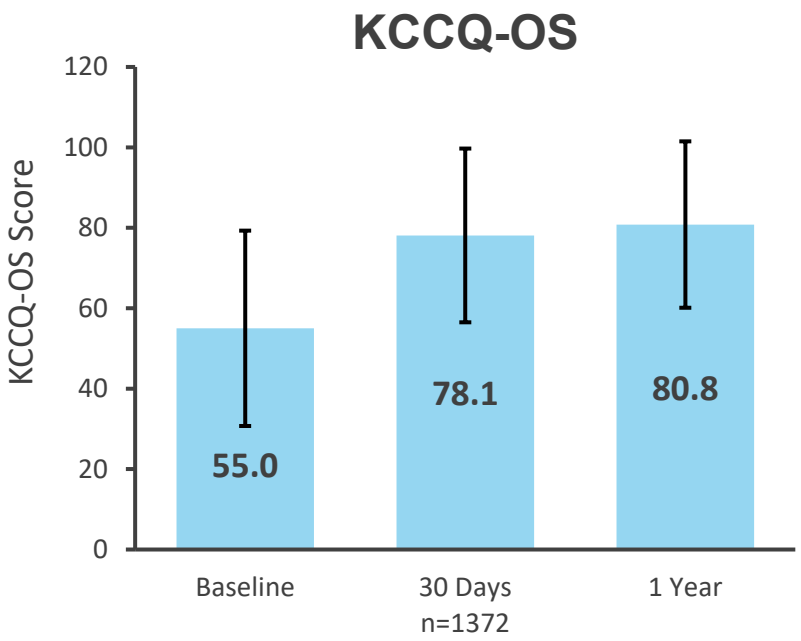
Hemodynamics by Valve Size

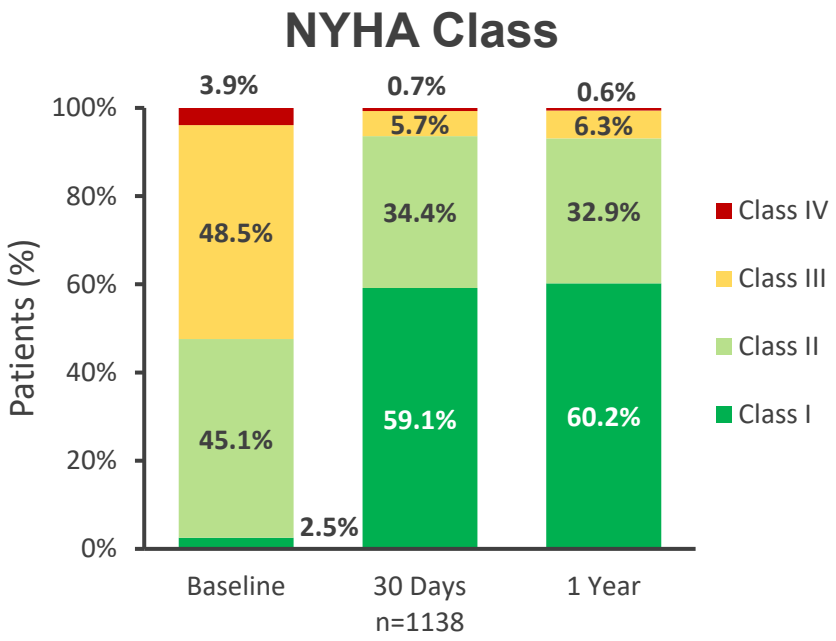


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Quality of Life and Functional Capacity





Paired data. KCCQ-OS plotted as mean± SD.

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Bioprosthetic Valve Dysfunction Through One Year

Valve Dysfunction	30 Days	1 Year
BVD composite	**5.4%**	**10.3%**
Hemodynamic Structural Valve Dysfunction	0.6%	2.2%
Non-Structural Valve Deterioration	4.6%	7.4%
Severe PPM	3.0%	NA
Moderate or greater PVL	1.7%	4.2%
Clinical valve thrombosis	0.0%	0.2%
Endocarditis	0.1%	0.6%
Aortic reintervention	0.3%	0.6%

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 (Herrmann et al., *N Engl J Med.* 2024;390(21):1959-1971.)

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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.

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Conclusions

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

- Patients were predominantly elderly and at higher surgical risk; aligned with the current indication for Navitor in the U.S.
- Technical success in 98.6% of patients
- Favorable clinical and echocardiographic outcomes at 1 year:
  - 97.4% of patients with mild or less PVL
  - Mean gradient 8.1 mmHg
  - Aortic-valve reintervention rate 0.6%
- Severe PPM occurred in 5.5% of patients at 30 days

For PPM, binary rate at 30 days shown.

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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.

Source, original presentation: Kliner D. 1-Year Outcomes Following TAVR with a Self-Expandable Transcatheter Aortic Valve with Intra-Annular Leaflet Position: Real-world data from the STS/ACC TVT registry. Presented at TCT 2026 on November 2, 2026. San Diego, USA.

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