

# Real-World Experience: 10.6% New PPI With Navitor™ Vision\* Valve After 20 Procedures

## KEY POINTS

- Increased device experience is associated with a significant reduction in permanent pacemaker implantation (PPI) at 30 days.
  - Very low 10.6% new PPI rate with Navitor™ Vision Valve in sites with ≥ 21 procedures vs. sites with ≤ 20 procedures.
- High technical success rate and low clinical event rates at 30 days.
- Excellent valve hemodynamics and low rates of paravalvular leak (PVL): Mean gradient 7.3 mm Hg, EOA 1.98 cm<sup>2</sup> in an intra-annular valve and > 98% mild or less PVL at 30 days.

## INTRODUCTION

Extensive real-world experience with the Navitor™ TAVI System from the STS/ACC TVT Registry was published in JACC: Cardiovascular Interventions.<sup>1</sup> This experience comprises data from 2,958 patients implanted with the Navitor™ Valve (n=2,237) or Navitor Vision Valve (n=721), collected by 198 U.S. clinical centers between January 2023 to December 2024.

## PATIENTS AND VALVES

Patients had a mean age of 81.4 ± 7.6 years and 62.4% were female. Their mean STS score was 6.6 ± 5.4% and 57.8% were in NYHA III or IV functional class. The average aortic annulus area was 418 mm<sup>2</sup>, and 58.3% of patients had an annular area of ≤ 430 mm<sup>2</sup> and 33.9% with ≤ 380 mm<sup>2</sup>. Sizes of implanted valve included 23 mm (11.6%), 25 mm (28.7%), 27 mm (35.0%) and 29 mm (24.8%).

## PROCEDURAL OUTCOMES

Excellent procedural outcomes were achieved with both the Navitor and Navitor Vision Valves (see Table 1).

TABLE 1: PROCEDURAL OUTCOMES

	All Navitor™ (N=2,958)	Navitor™ (n=2,237)	Navitor™ Vision (n=721)
Technical success	97.9%	97.9%	98.1%
Procedural mortality	0.1%	0.1%	0.1%
Conversion to surgery	0.1%	0.1%	0.0%
Major vascular complication	1.7%	1.8%	1.4%

\*Labeled as Navitor and Navitor Titan with Vision Technology

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

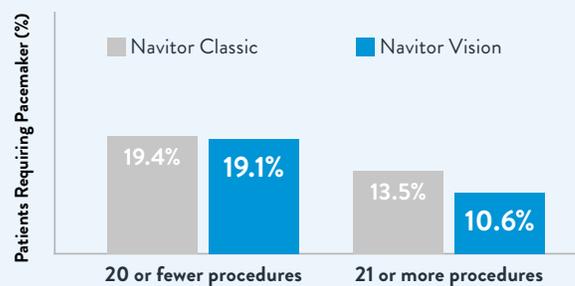
For audiences outside of the U.S., always check the regulatory status of the device in your region.

## 30-DAY SAFETY OUTCOMES

30-day safety outcomes are summarized in Table 2. The composite endpoint of 30-day all-cause mortality or all stroke was reached by 5.2% of all patients.

PPI was required in 14.1% of patients without a conduction defect at baseline. A learning curve effect for PPI was demonstrated by a significantly lower PPI rate achieved by sites performing 21 or more procedures (Figure 1).

FIGURE 1: NEW PPI RATE BY SITE EXPERIENCE AND VALVE TYPE



## ECHOCARDIOGRAPHIC OUTCOMES

Through 30 days post-TAVI, patients — predominantly with small aortic annuli — exhibited favorable hemodynamic performance characterized by single-digit mean transvalvular gradients, large effective orifice areas (Figure 3) and a low incidence (1.8%) of moderate or greater paravalvular leak (Figure 2).

TABLE 2: 30-DAY SAFETY OUTCOMES

	All Navitor™ (N=2,958)	Navitor™ (n=2,237)	Navitor™ Vision (n=721)
All-cause mortality or all stroke	5.2%	5.2%	4.9%
All-cause mortality	2.8%	2.9%	2.5%
All stroke	2.7%	2.6%	2.7%
Life-threatening / major bleeding	0.7%	0.8%	0.6%
Major vascular complications	1.8%	1.9%	1.5%
New permanent pacemaker	17.8%	17.8%	17.8%
Patients w/o baseline conduction defect	14.1%	14.5%	12.3%

FIGURE 2: PVL RATES THROUGH 30 DAYS

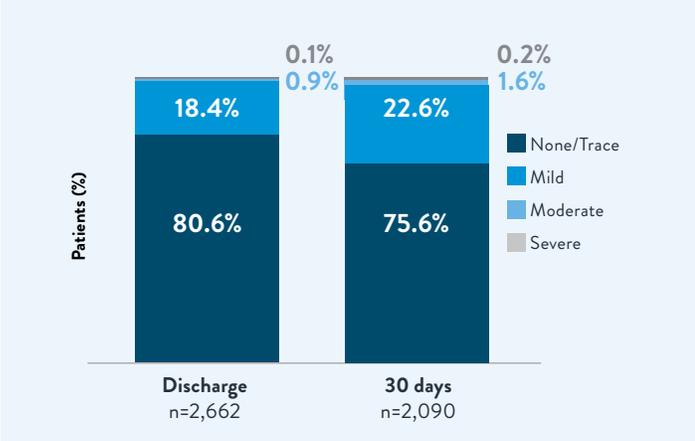
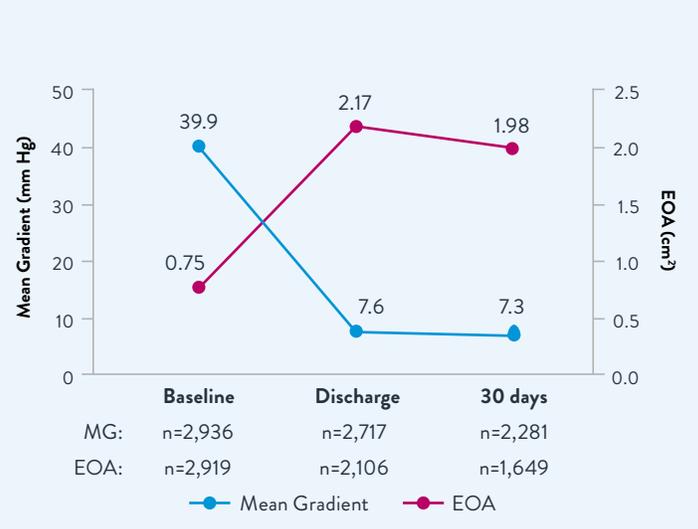


FIGURE 3: HEMODYNAMIC PERFORMANCE THROUGH 30 DAYS



CONCLUSION

As demonstrated by outcomes from this large real-world population, Navitor™ and Navitor™ Vision Valves offer a safe and effective treatment option for patients with severe symptomatic aortic stenosis.

SCAN FOR THE JACC: CI PUBLICATION



REFERENCE

- Garcia S, Sultan I, Rollefson W, et al. Early U.S. Real-World Experience With a Novel Intra-Annular Self-Expanding Valve for Transcatheter Aortic Valve Replacement. JACC Cardiovasc Interv. 2025 Dec 8;S1936-8798(25)02827-4. doi: 10.1016/j.jcin.2025.10.053. Epub ahead of print. PMID: 41518360.

Rx Only - Important Safety Information (For U.S. audience only)

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.

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