Navitor™ TAVI System: Sustained performance in patients at low or intermediate surgical risk from the large, international, VANTAGE study.[1,2]

KEY FINDINGS

- Navitor™ TAVI System met all safety and effectiveness endpoints in the VANTAGE study (N=434) — an international study supporting the CE-mark approval of the Navitor TAVI System for the treatment of low or intermediate risk patients with aortic stenosis.
- Thirty-day outcomes were favorable: low rates of all-cause mortality (LR: 0%, IR: 0.9%), CV mortality[1] (LR: 0%, IR: 0.9%), fatal stroke/stroke with disability (LR: 0.5%, IR: 1.3%), major vascular complications (LR: 3.0%, IR: 5.6%), aortic valve reintervention (LR: 0.5%, IR: 0.4%), moderate or greater PVL (LR: 0%, IR: 0%), and mean gradient of 7.7 mm Hg.[1]
- One-year outcomes continue to support excellent results: low rates of all cause mortality (LR: 0%. IR: 1.7%), CV mortality (LR: 0%, IR: 1.7%), fatal stroke/stroke with disability (LR: 0.5%, IR: 1.7), aortic valve reintervention (LR: 0.5%, IR: 0.4%), moderate or greater PVL (LR: 0%, IR: 0%), and mean gradient of 8.0 mm Hg.[2]

INTRODUCTION

The VANTAGE study is a prospective, single-arm, multi-center trial assessing the safety and performance of the Navitor TAVI system in patients with symptomatic, severe AS at low or intermediate surgical risk. It evaluates key safety and effectiveness endpoints, including 12-month all-cause mortality or fatal stroke/stroke with disability and 30-day moderate or greater paravalvular leak (PVL). Its primary aim is to support expanding Navitor TAVI indications to these patients.

VANTAGE STUDY AT A GLANCE

- 36 centers in 11 countries, 434 patients — 203 at LR; 231 at IR
- Risk classification per local heart team, confirmed by the Subject Screening Committe (SSC)
- Evaluation against performance goals derived from pivotal trials of competitive TAVI devices
- Powered for both the primary safety and effectiveness endpoints
- Independent clinical events committee and echocardiography core laboratory

PATIENT & PROCEDURAL CHARACTERISTICS

Table 1 outlines patient characteristics. Most procedures were transfemoral using the Navitor™ valve (no Navitor™ Vision* valves). Valve sizes of 23–29 mm were used in 95% of cases; 35 mm valves in 5%. Pre-dilation occurred in 91% of cases, post-dilation in 33%. There were no procedural mortalities and technical success rate was 97%.

PRIMARY AND SECONDARY ENDPOINTS

The VANTAGE study previously met all primary and secondary endpoints, with an all-cause mortality or fatal stroke/stroke with disability rate of 2.3% at 12 months (N=262) and 0% moderate or greater PVL at 30 days (N=434).[1] Moreover, the full cohort primary safety endpoint was met with an all-cause mortality or fatal stroke/stroke with disability rate of 1.9% at 12 months (N=434).

TABLE 1: PATIENT BASELINE CHARACTERISTICS

	Intermediate risk (n=231)	Low risk (n=203)	Total (N=434)
Age (years)	79.1 ± 3.7	75.1 ± 3.2	77.2 ± 4.0
Female	52.8%	46.8%	50.0%
NYHA III/IV	27.7%	20.2%	24.2%
STS-PROM	2.6 ± 1.2%	1.5 ± 0.5%	2.1 ± 1.1%
Cerebrovascular accident	5.2%	3.0%	4.1%
Myocardial infarction	4.8%	4.4%	4.6%
Diabetes	30.3%	31.0%	30.6%
Permanent pacemaker	6.5%	3.9%	5.3%
Cardiac arrhythmias and conduction disorders	47.6%	28.6%	38.7%

ECHOCARDIOGRAPHIC OUTCOMES

Patients treated with the intra-annular Navitor valve showed remarkable, sustained hemodynamic performance through 30 days and 1 year with single-digit mean gradients and large effective orifice areas (see Figure 1). PVL incidence was low, with 0% moderate or greater PVL and only 13.6% mild PVL at 30 days (see Figure 2).

*Labeled as Navitor and Navitor Titan with Vision Technology

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FIGURE 1: HEMODYNAMIC PERFORMANCE[2]

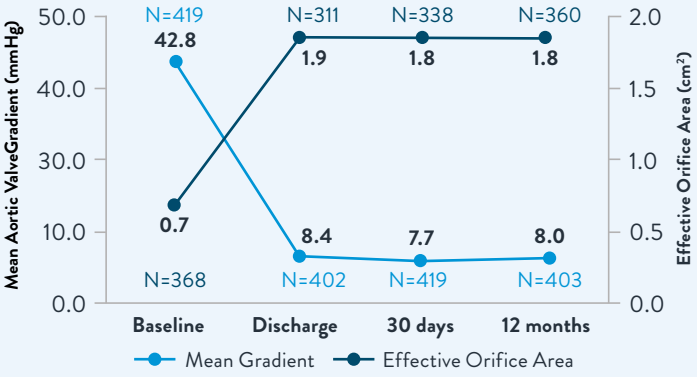
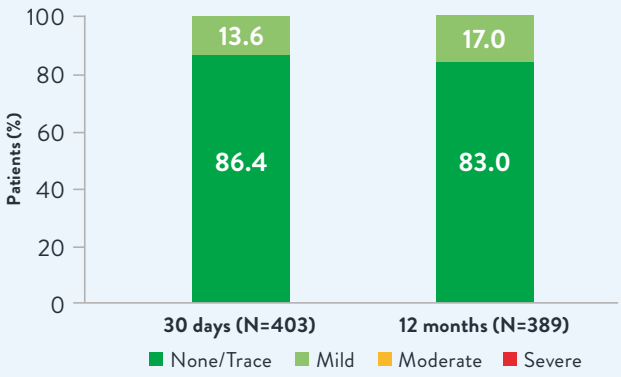


FIGURE 2: PARAVALVULAR LEAK[2]



30-DAY AND 1-YEAR OUTCOMES

Table 3 summarizes the favorable 30-day and 1-year outcomes (full cohort) from the VANTAGE study. New permanent pacemaker rate (PPI) at 30 days for low and intermediate risk patients was 15.9% and 21.3%, respectively. These PPI rates are comparable to other self-expanding valve pivotal trials–notably 17.4% in Evolut‡ Low Risk and 25.9% in SURTAVI intermediate risk trials respectively.[3,4]

These results were achieved using the Navitor™ valve (no Navitor™ Vision valves) and without full utilization of optimal implant technique. Contemporary data indicate that experienced operators utilizing optimal techniques may achieve substantially lower PPI rates.[5] In addition, US STS/ACC TVT Registry published data showed that the combination of the Navitor Vision valve and site experience (after 20 procedures), achieved a low PPI rate of 10.6% at 30-days, indicating proficiency matters in PPI outcomes.[6]

TABLE 3: EVENT RATES

	30 days (Events / Patients)			12 months (Kaplan-Meier estimates)		
	Intermediate Risk (N=231)	Low Risk (N=203)	Total (N=434)	Intermediate Risk (N=231)	Low Risk (N=203)	Total (N=434)
All-cause Mortality	0.9%	0.0%	0.5%	1.7%	0.0%	0.9%
Cardiovascular Mortality	0.9%	0.0%	0.5%	1.7%	0.0%	0.9%
All Stroke	2.2%	1.0%	1.6%	2.6%	1.0%	1.8%
Fatal Stroke/Stroke with Disability	1.3%	0.5%	0.9%	1.7%	0.5%	1.2%
Type 3/4 Bleeding	4.8%	2.5%	3.7%	-	-	-
Stage 3/4 Acute Kidney Injury	0.9%	0.0%	0.5%	-	-	-
Major Vascular Complication	5.6%	3.0%	4.4%	-	-	-
Coronary Obstruction Requiring Intervention	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Aortic Valve Reintervention	0.4%	0.5%	0.5%	0.4%	0.5%	0.5%
Prosthetic Valve Endocarditis	-	-	-	0.9%	1.5%	1.2%
PPI in Pacemaker-Naive Patients	21.3%	15.9%	18.7%	-	-	-
Rehospitalization*	7.8%	6.4%	7.1%	16.6%	13.9%	15.3%

*Valve-related or procedure-related hospitalization, or other cardiovascular hospitalization.
All events were adjudicated by an independent Clinical Events Committee (CEC) according to VARC-3 definitions.

CONCLUSION: **Findings from the VANTAGE supported the CE mark approval of the expanded indication of the Navitor™ TAVI System to include patients at low and intermediate surgical risk.**

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6. Garcia S, et al. Early U.S. Real-World Experience With a Novel Intra-Annular Self-Expanding Valve for Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv*. 2026 Apr 13;19(7):801-809.

CE Mark Reference: 2797

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