Clinical Insights from Navitor

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Speaker Name: Santiago Garcia, MD

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Institutional Grants Edwards Lifesciences, Abbott Structural Heart, Medtronic, BSCI
Consultant Fees/Honoraria	Edwards Lifesciences, Abbott Structural Heart, Medtronic, BSCI

Support of this program is provided by Abbott, and the speaker is presenting on behalf of Abbott. This program is not intended for continuing education credits for any healthcare professional. All information presented is consistent with applicable FDA requirements.

All relevant financial relationships have been mitigated.
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Navitor PAS Design

Design	The Navitor Post-Approval Study (PAS) collected commercial use data through the TVT Registry
Clinical Sites	2,958 patients in 198 centers within the United States
Population (N=2958)	Patients with tricuspid aortic valve morphology undergoing native TAVR between January 2023 - December 2024
Key analyses	• Present RWE with Navitor Classic and Navitor Vision • Technical success • Death or stroke at 30 days

Study sponsored by Abbott.

The views or opinions presented here do not represent those of the American College of Cardiology Foundation, The Society of Thoracic Surgeons, or the STS/ACC TVT Registry. The industry data file upon which the analysis was performed is a subset of the full STS/ACC TVT Registry data submissions.

Baseline Characteristics

Patient Characteristic	N=2958
Age (years)	81.4 ± 7.6
Female	62.4%
BMI (kg/m^2)	28.6 ± 6.9
STS Score	6.6 ± 5.4
NYHA III or IV	57.7%
Creatinine (mg/dL)	1.3 ± 1.2
LVEF (%)	58.5 ± 11.0

Medical History	N=2958
A fib / flutter	39.7%
Conduction defect	32.5%
CABG	11.0%
PCI	29.4%
Diabetes	38.4%
Peripheral artery disease	17.1%
Permanent pacemaker	12.1%

Data presented as % or mean ± standard deviation.

Procedural Outcomes

Outcomes	All Navitor (N=2958)	Navitor Classic (n=2237)	Navitor Vision (n=721)
Technical success*	**97.9%**	**97.9%**	**98.1%**
Second valve required	0.1%	0.1%	0.1%
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%

*Technical success (upon leaving procedure room) defined as:

1. Freedom from mortality
2. Successful access, delivery of the device, and retrieval of the delivery system
3. Correct positioning of a single Navitor valve
4. Freedom from surgery or intervention related to the device or to a major vascular or access-related, or cardiac structural complication

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See Important Safety Information referenced within.

30-Day Safety Events

Outcomes	All Navitor (N=2958)	Navitor Classic (n=2237)	Navitor Vision (n=721)
All-cause mortality or stroke	**5.2%**	**5.2%**	**4.9%**
All-cause mortality	2.8%	2.9%	2.5%
Stroke	2.7%	2.6%	2.7%
Life-threatening or major bleeding	**0.7%**	**0.8%**	**0.6%**
Major vascular complication	**1.8%**	**1.9%**	**1.5%**
Aortic valve reintervention	**0.3%**	**0.4%**	**0.1%**
New permanent pacemaker	**17.8%**	**17.8%**	**17.8%**
Patients w/o baseline conduction defect	14.1%	14.5%	12.3%

Conduction defect defined as right or left BBB, sick sinus syndrome, or first-, second-, or third-degree heart block

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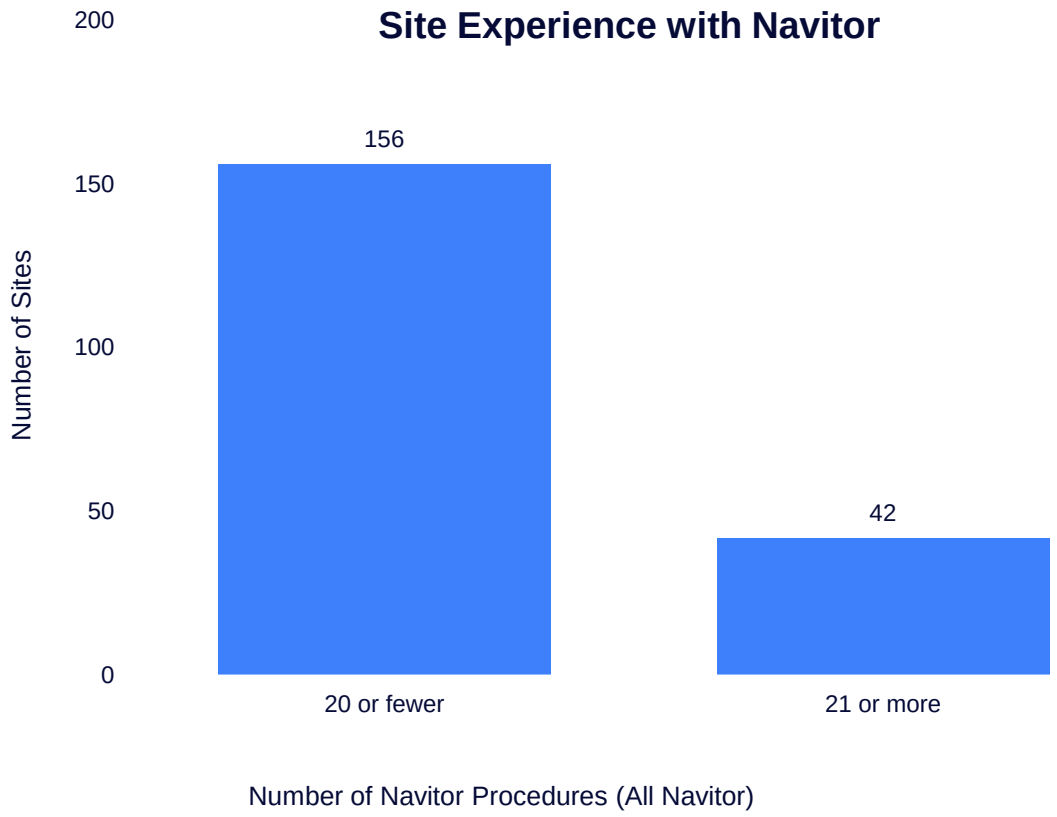
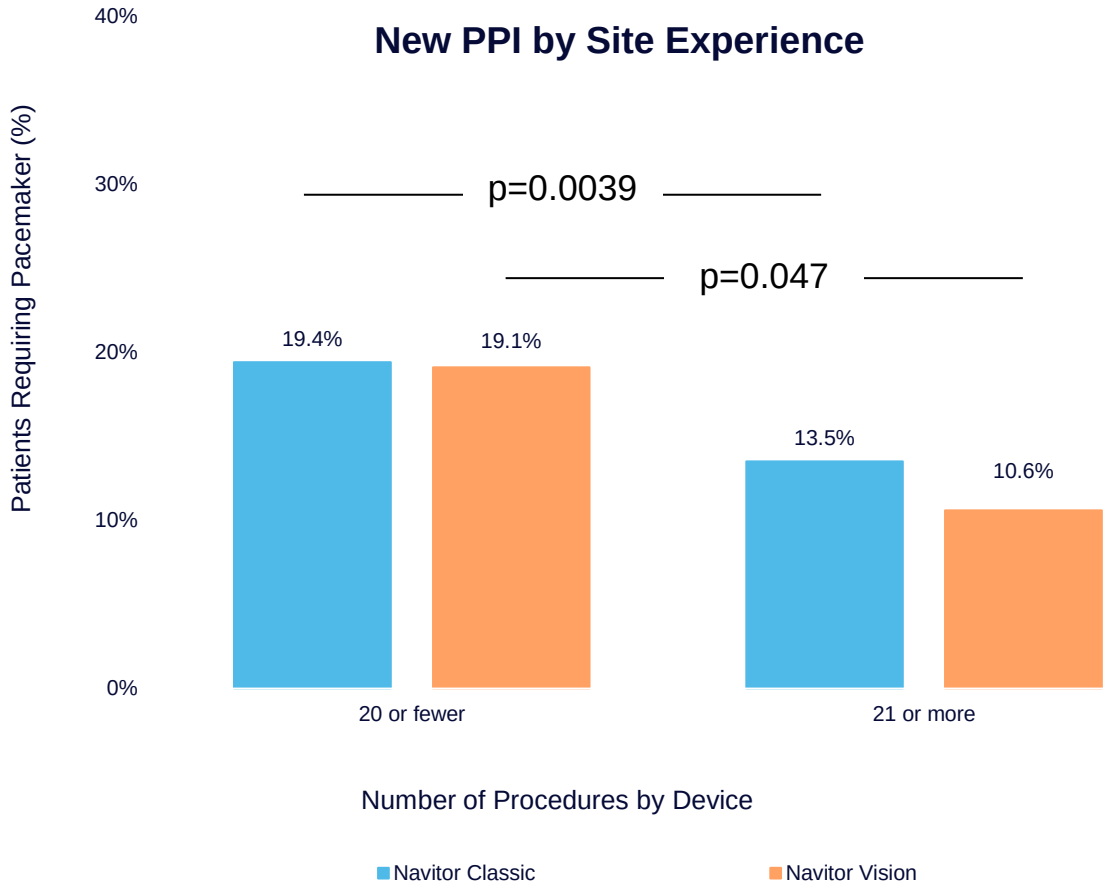
PPI by Site Experience

Significant improvement in PPI rate after 20 implants





Number of procedures reflects procedures documented in TVT Registry from January 2023 to December 2024

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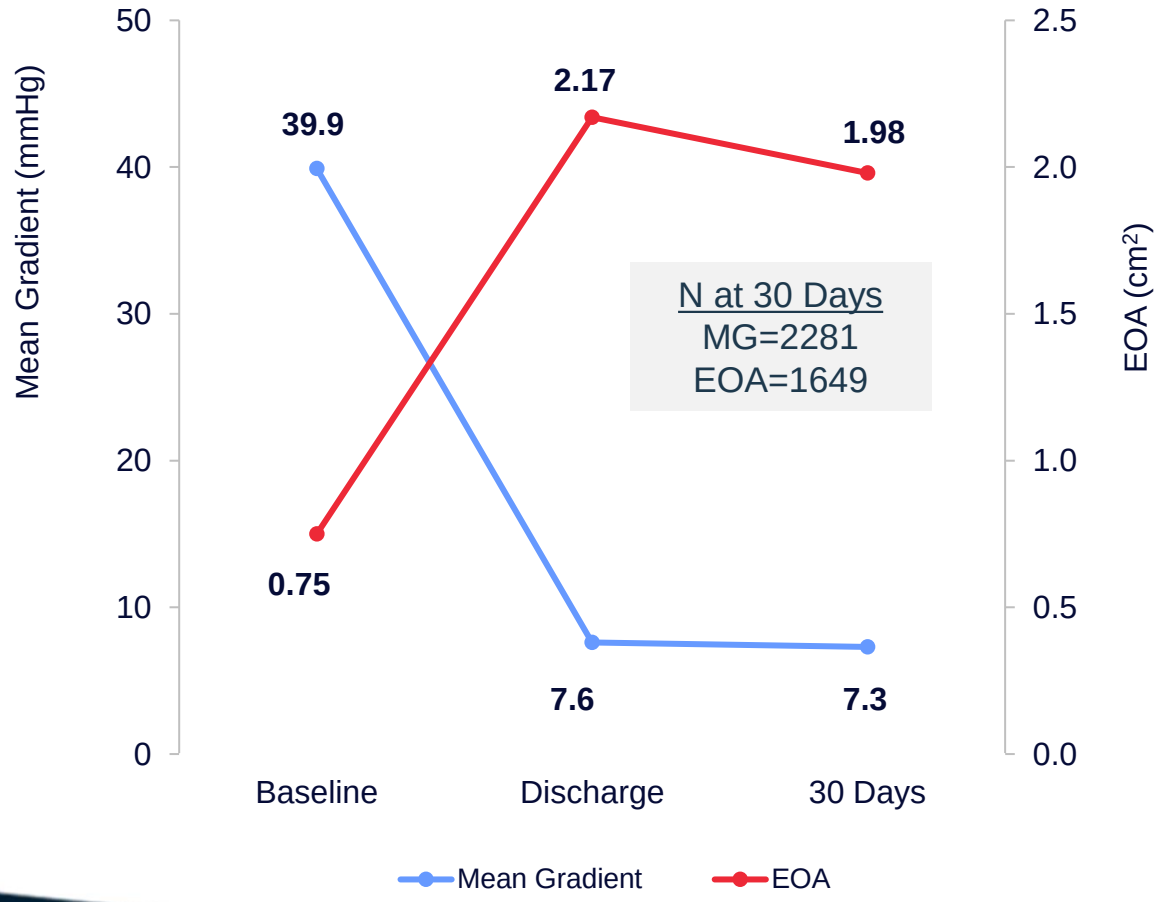
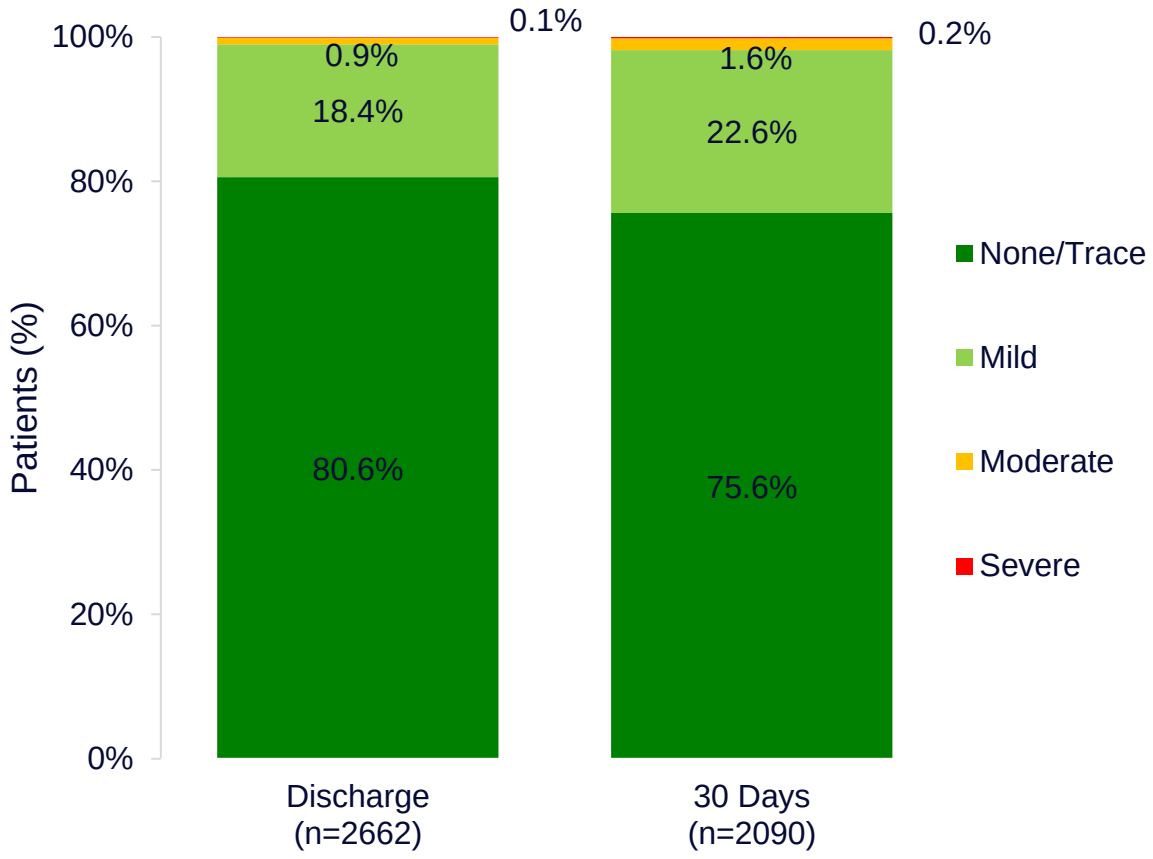
Echocardiographic Outcomes

Hemodynamics



Paravalvular Leak



Site-assessed.

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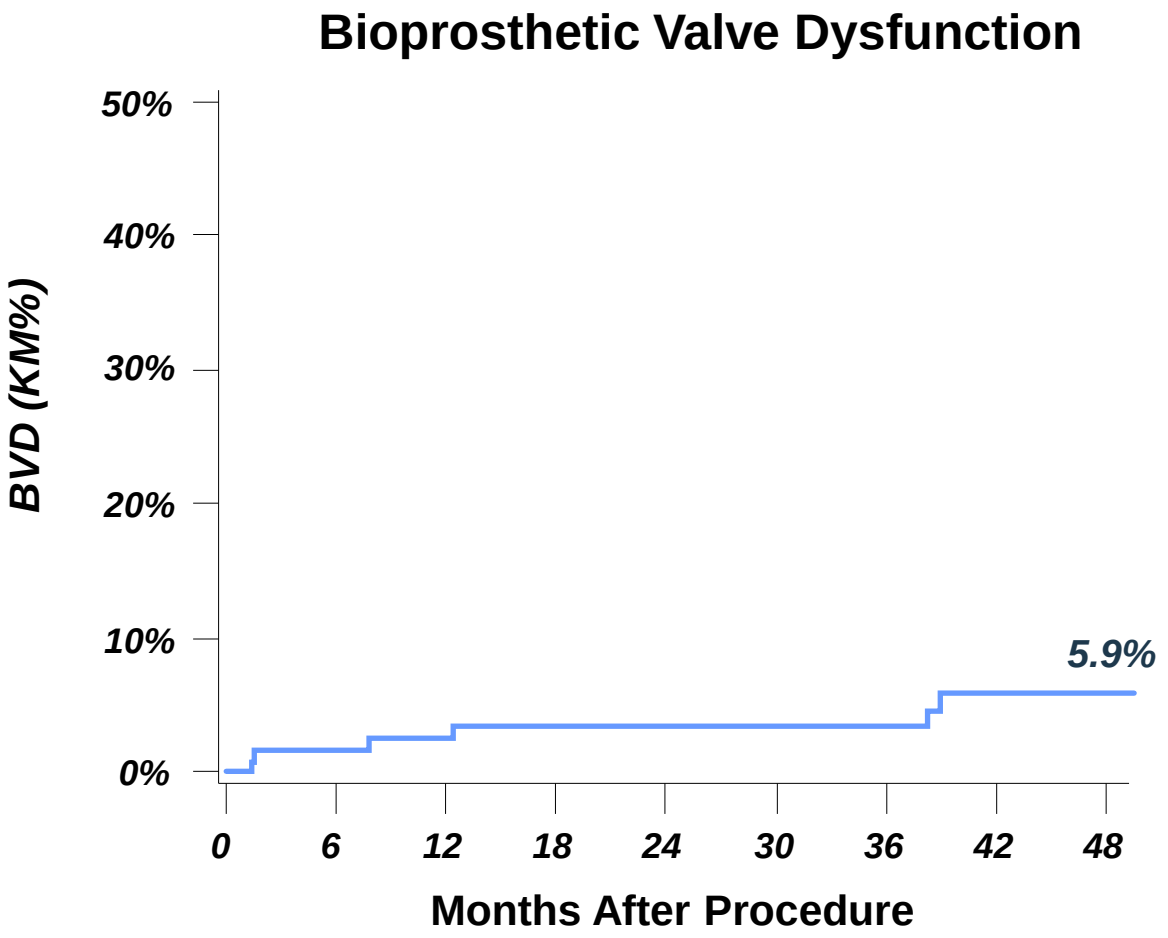
Four-Year Outcomes in the Navitor IDE Study
Device Durability



Component Rates at 4 Years	
Bioprosthetic Valve Dysfunction	**5.9%**
Moderate HSVD	0%
Non-structural valve deterioration	1.7%
➢ Severe PPM	1.7%
➢ Severe PVL	0%
Infective endocarditis	4.2%
Clinical valve thrombosis	0%
Bioprosthetic Valve Failure	**0%**
Severe HSVD	0%
Aortic valve reintervention	0%
Valve-related death	0%

Kaplan-Meier rates shown.

Conclusions

- First report of commercial experience with Navitor Vision Valve
- Largest reported cohort of Navitor patients (N=2958)
- High technical success rate and low clinical event rates at 30 days
- Excellent valve hemodynamics and low rates of PVL
- Significant decrease in rates of PPI with increased device experience

Navitor and Navitor Vision offer a safe and effective treatment option for patients with severe symptomatic AS

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