

Four-Year Outcomes in the Navitor IDE Study

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On behalf of the Navitor IDE Study Investigators



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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:

Nature of Financial Relationship

Consultant/Proctor:

Company

Abbott, Medtronic, PiCardia

Navitor IDE Study Design

Navitor IDE (Portico NG) Study

Prospective, multicenter, international study
26 sites in Australia, Europe, and United States



Patients with severe, symptomatic aortic stenosis at high or extreme surgical risk

N=260 total (120 in CE-mark cohort)

Follow-up

Discharge, 30 days, 1 year, and annually through 5 years

Study oversight

- Clinical Events Committee
- Echocardiography Core Lab
- CT Core Lab



Navitor Transcatheter Aortic Valve

Aim: To report the 4-year outcomes of the CE-mark cohort (N=120)

Key Analyses Through 4 Years



1

Safety

Mortality, stroke

2

Device performance

Hemodynamics and paravalvular leak

3

Device durability

Bioprosthetic valve dysfunction and bioprosthetic valve failure

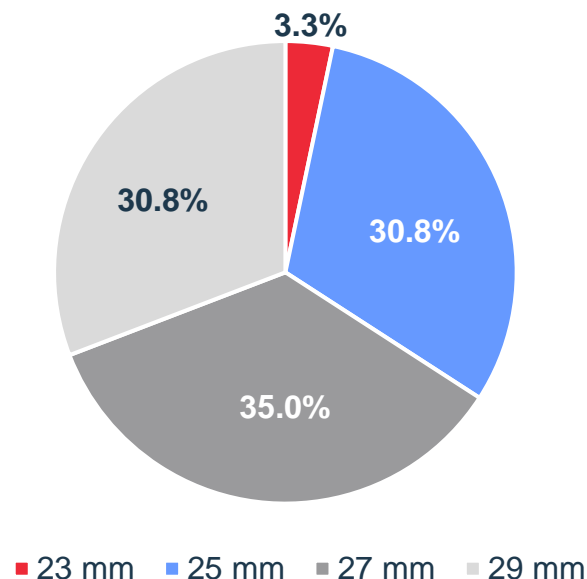
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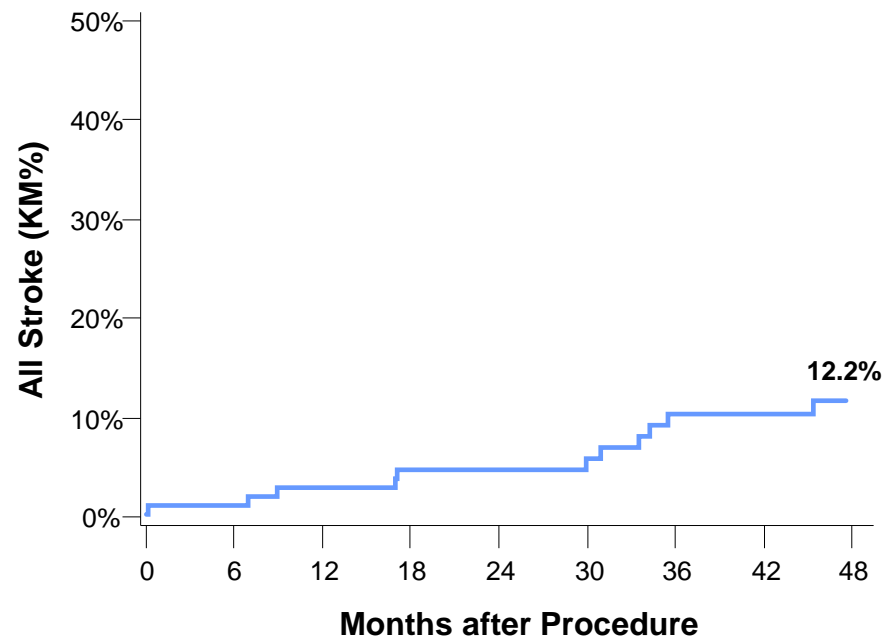
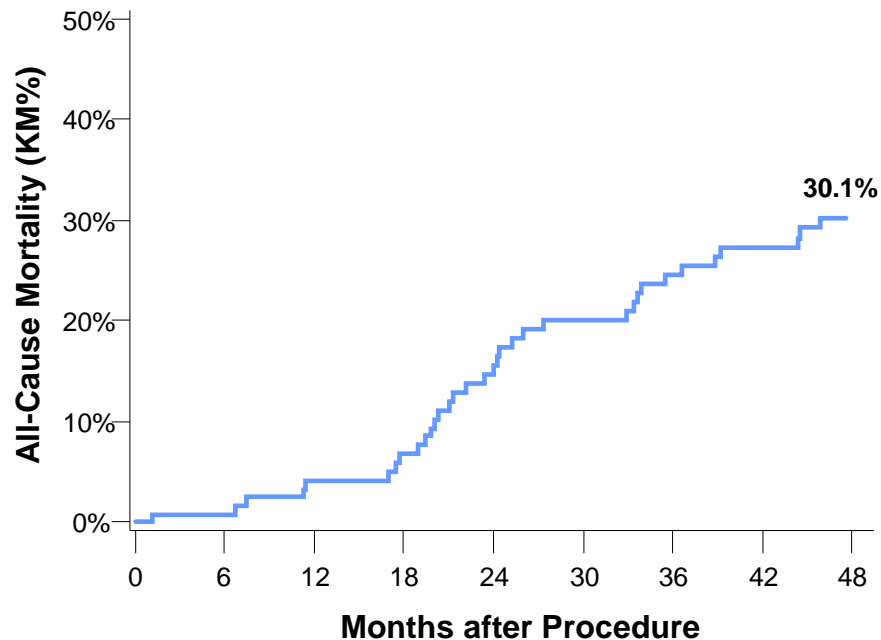
Patient Characteristics

Baseline Characteristic	N=120
Age (years)	83.5 ± 5.4
Female	58.3%
STS-PROM Score (%)	4.0 ± 2.0
≥1 Frailty Criteria	44.2%
NYHA Class III/IV	56.7%
Risk Class	
High	81.7%
Extreme	18.3%

Implanted Navitor Size

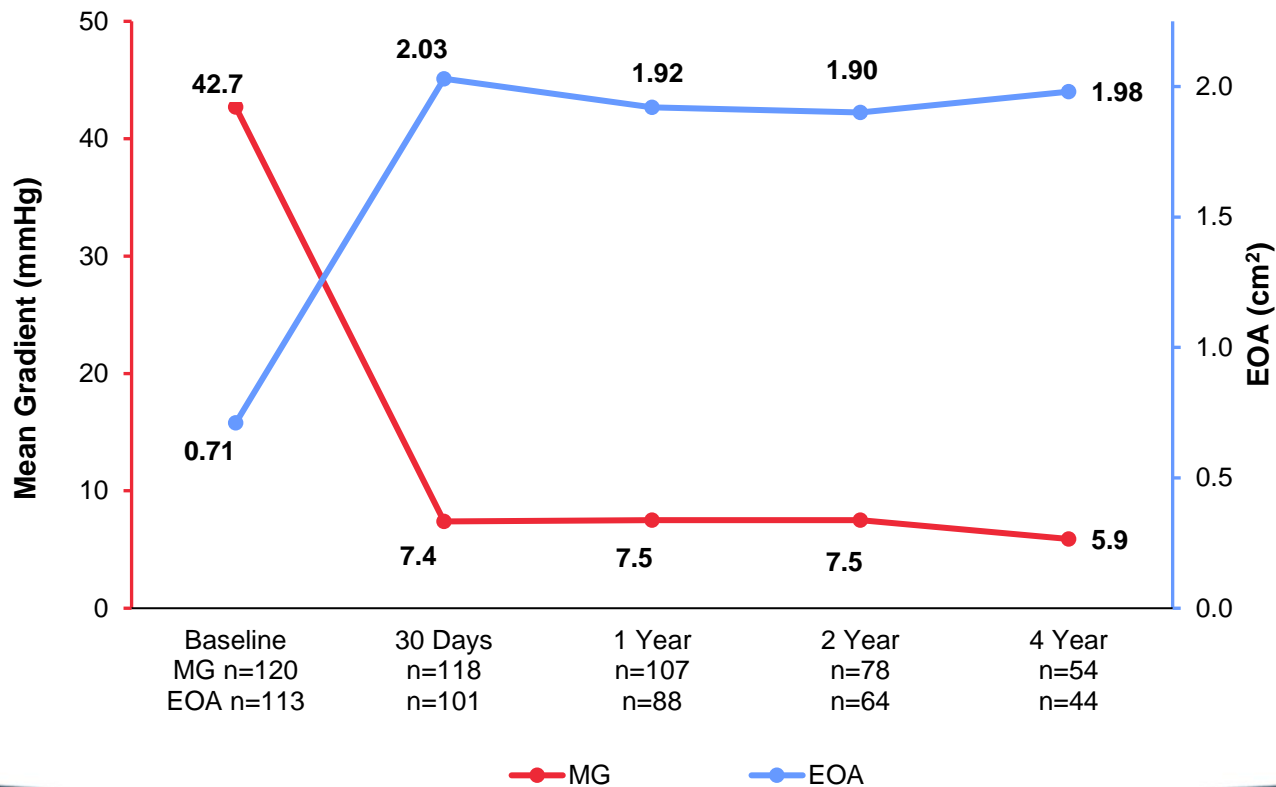


Clinical Safety Through 4 Years

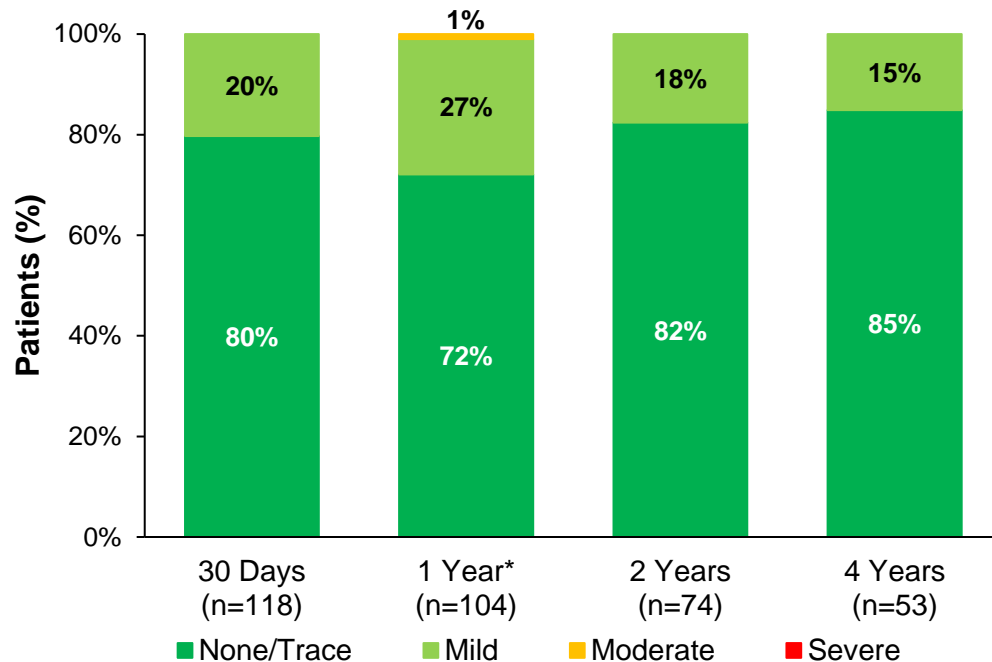


Primary safety endpoint (all-cause mortality at 30 days) was met

Hemodynamics Through 4 Years



Paravalvular Leak



Primary effectiveness endpoint
(moderate or greater paravalvular leak at 30 days) **was met**

Durability Definitions



Bioprosthetic valve dysfunction

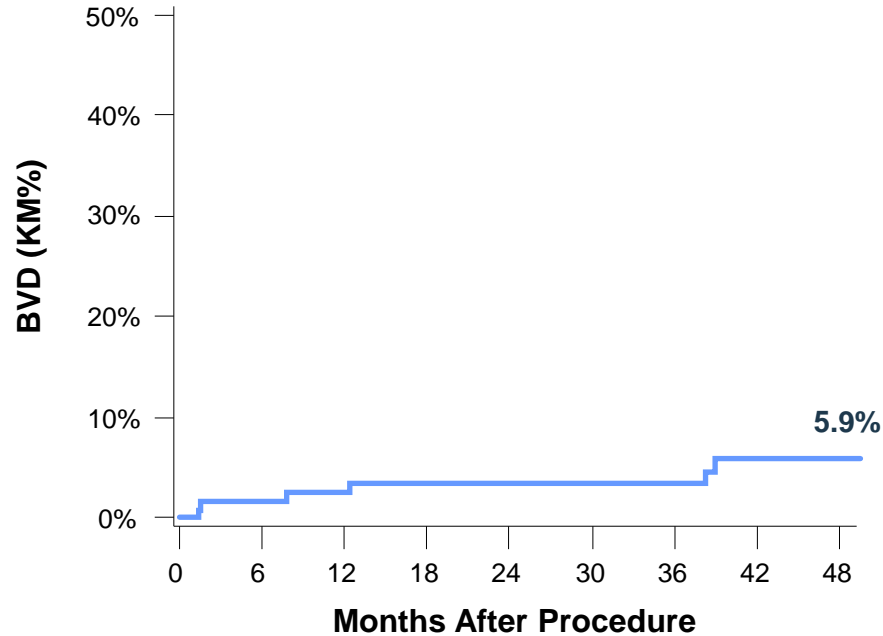
- **Moderate hemodynamic structural valve deterioration** (mean gradient ≥ 20 mmHg AND $\Delta \geq 10$ mmHg from 30 days OR new or worsening moderate intra-prosthetic aortic regurgitation $>1+/4+$)
- **Non-structural valve deterioration** (severe prosthesis-patient mismatch or new severe paravalvular leak)
- **Infective endocarditis**
- **Clinical valve thrombosis**

Bioprosthetic valve failure

- **Severe hemodynamic structural valve deterioration** (mean gradient ≥ 30 mmHg AND $\Delta \geq 20$ mmHg from 30 days OR new or worsening severe intra-prosthetic aortic regurgitation $>2+/4+$)
- **Aortic valve reintervention**
- **Valve-related death**

Device Durability

Bioprosthetic Valve Dysfunction



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%

Conclusions

Four-year outcomes of the CE-mark cohort demonstrate the safety, effectiveness, and durability of the Navitor valve

Favorable device performance sustained through 4 years

- Single-digit mean gradients (**5.9 mmHg**) and large EOA (**1.98 cm²**)
- **100%** of patients with mild or less paravalvular leak at 4 years
- **Low rates of clinical events**
- Death (**30.1%**) and stroke (**12.2%**) rates consistent with high and extreme risk population
- **Durable platform with low rates of BVD and no BVF**
- No hemodynamic SVD (**0%**) or valve thrombosis (**0%**), low rates of non-SVD (**1.7%**)
- No reintervention or valve-related death

