

# Four-Year Outcomes in the Navitor IDE Study

**Prof Ganesh Manoharan, MD**

Royal Victoria Hospital, Belfast, UK

*On behalf of the Navitor IDE Study Investigators*



TRANSCATHETER  
CARDIOVASCULAR  
THERAPEUTICS®



# 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

# Visit Compliance



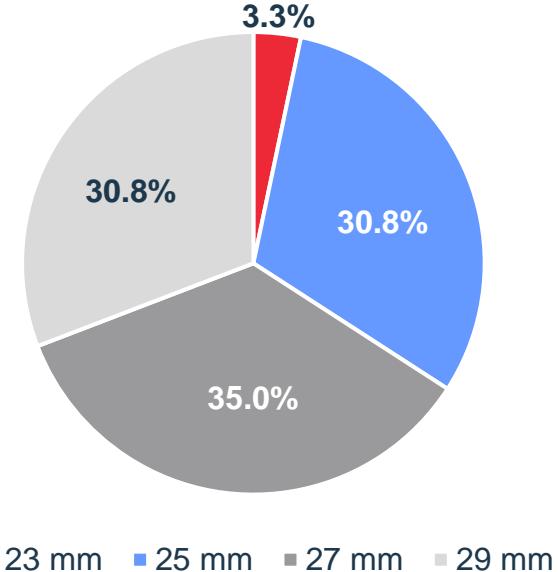
\* n=1 missed visit at 2 years

† n=2 missed visits at 3 and 4 years

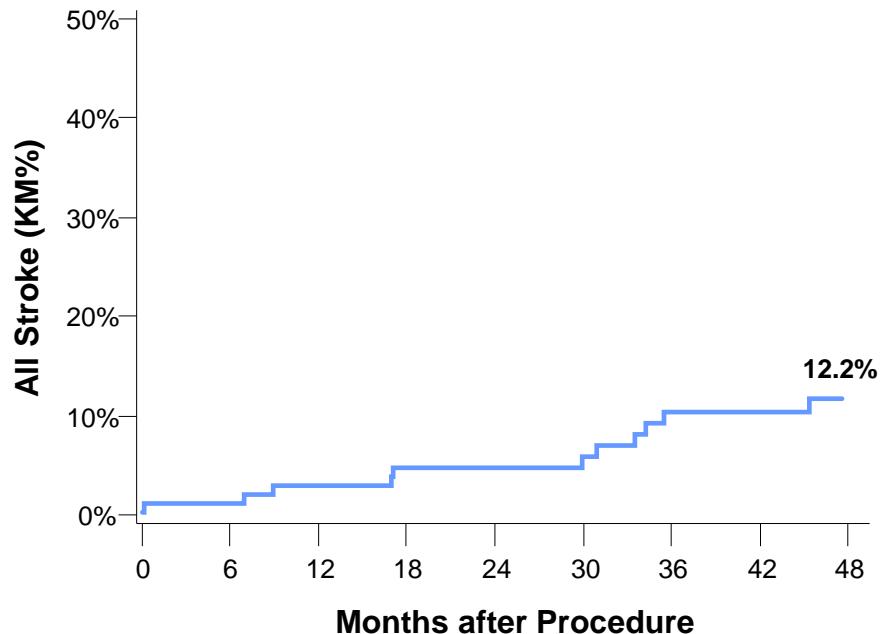
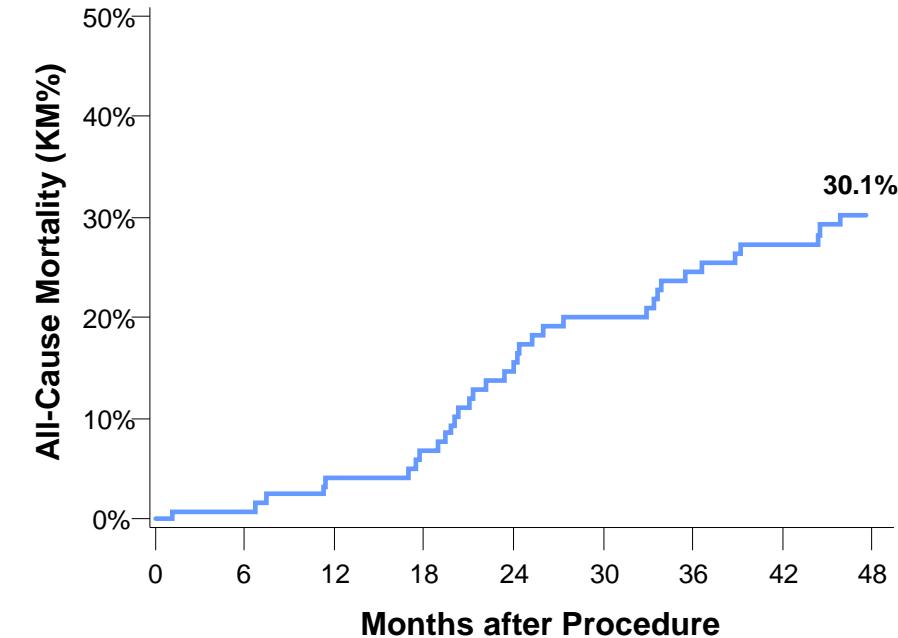
# Patient Characteristics

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

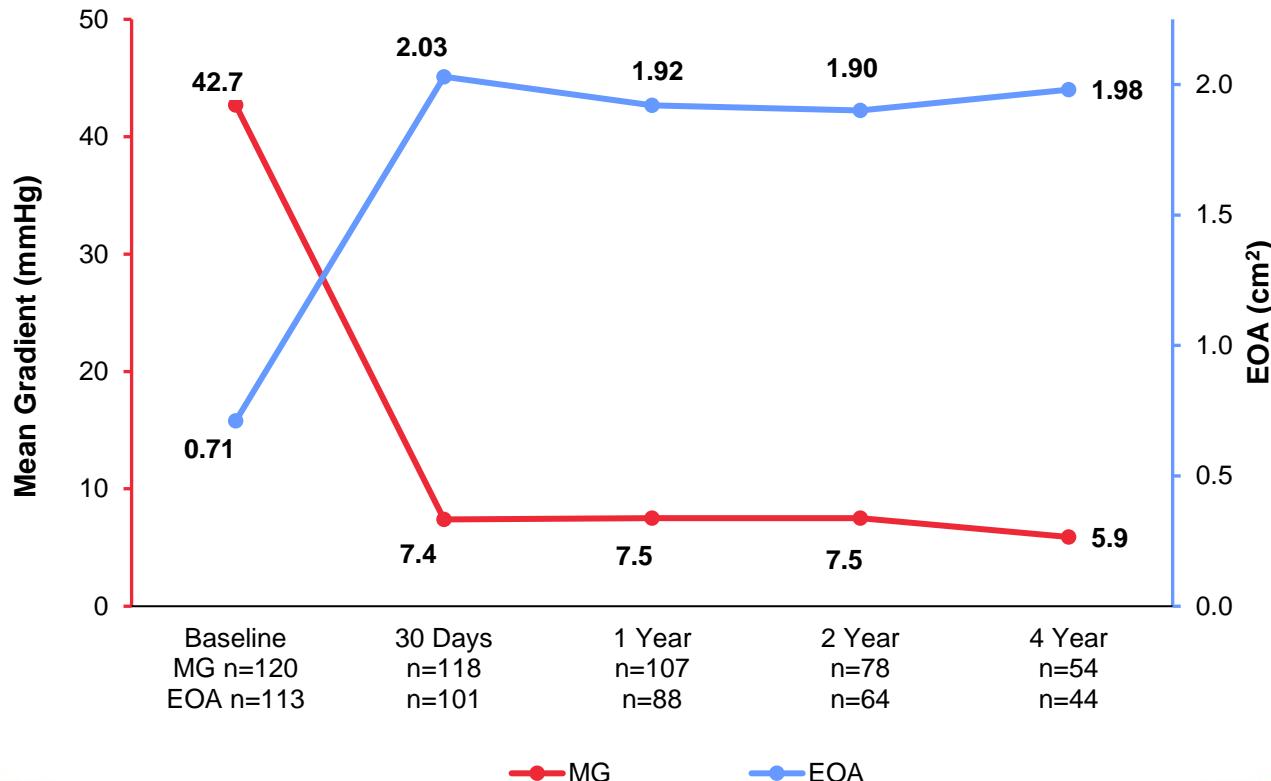


# Clinical Safety Through 4 Years



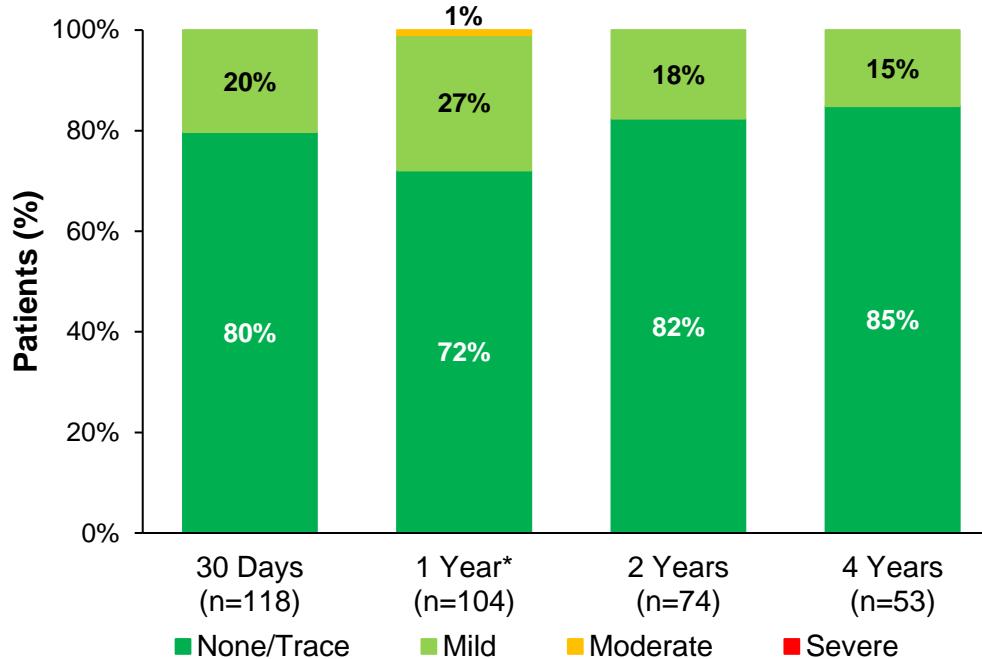
Primary safety endpoint (all-cause mortality at 30 days) was met

# Hemodynamics Through 4 Years



Echo not performed at 3-year follow up.

# Paravalvular Leak



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

# Durability Definitions



## Bioprosthetic valve dysfunction

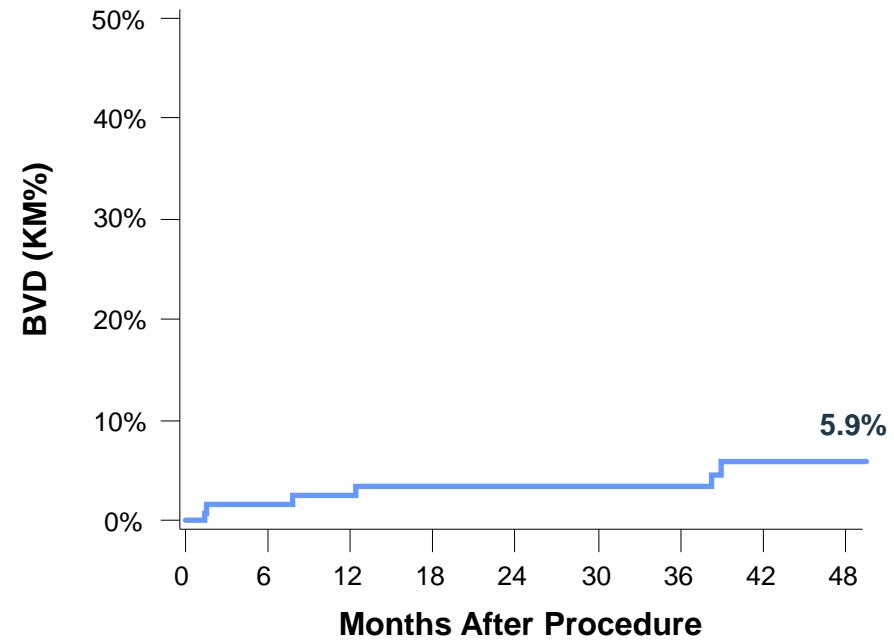
- **Moderate hemodynamic structural valve deterioration** (mean gradient  $\geq 20$  mmHg AND  $\Delta \geq 10$  mmHg from 30 days OR new or worsening moderate intra-prosthetic aortic regurgitation  $>1+/4+$ )
- **Non-structural valve deterioration** (severe prosthesis-patient mismatch or new severe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

<b>Bioprosthetic Valve Dysfunction</b>	<b>5.9%</b>
<b>Moderate HSVD</b>	<b>0%</b>
<b>Non-structural valve deterioration</b>	<b>1.7%</b>
Severe PPM	1.7%
Severe PVL	0%
<b>Infective endocarditis</b>	<b>4.2%</b>
<b>Clinical valve thrombosis</b>	<b>0%</b>
<b>Bioprosthetic Valve Failure</b>	<b>0%</b>
<b>Severe HSVD</b>	<b>0%</b>
<b>Aortic valve reintervention</b>	<b>0%</b>
<b>Valve-related death</b>	<b>0%</b>

# 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 cm<sup>2</sup>**)
- **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

