2022 euro PCR

One-year outcomes from a next generation TAVI device with an active sealing cuff

EAPCI
European Society of Cardiology

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on behalf of the PORTICO NG Study Investigators and Coordinators

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Purpose

The PORTICO NG study is a prospective, multi-center, global, investigational study evaluating the safety and effectiveness of the Navitor™ transcatheter aortic valve in patients with symptomatic severe aortic stenosis and high or extreme surgical risk.

This study is funded by Abbott.

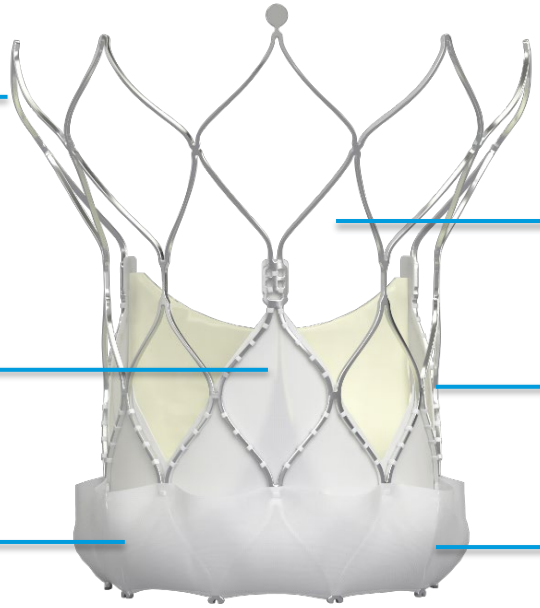
Navitor™ Valve

Unique System Features State of the Art Valve Design

Curved Aortic Cells
Reduces risk of injury to native structures[1]

Inner NaviSeal™ Cuff
Fabric material maintains low profile and improved durability

Outer NaviSeal™ Cuff
Actively synchronizes to the cardiac cycle to seal and mitigate PVL[2]



Large Cell Design
Minimizes coronary obstruction and improves coronary access and flow

Optimized Radial Force
For improved opening, expansion, anchoring, stability and sealing

Increased Sealing Zone
Mitigates PVL

Annulus Treatment Range
Treats 19 mm to 27 mm Annulus Diameters

1. Abbott data on file CL1007744. 2. Sondergaard, L. 30-day outcomes from a next generation TAVI device with an active sealing cuff. Presented at: EuroPCR conference; May 18-20, 2021.

Study Design

- Subjects with symptomatic severe AS were enrolled at 19 sites in Europe, Australia, and the United States
- Follow-up visits were conducted at discharge and 30 days, and annual follow-up is ongoing to 5 years
- *Primary endpoints:*
  - All-cause mortality at 30 days
  - Moderate or greater PVL at 30 days
- *Descriptive endpoints:*
  - VARC-2 clinical events at 30 days
  - Valve hemodynamics and PVL at discharge and 30 days
  - Changes in NYHA and six-minute walk distance (6MWD) from baseline to 30 days

Baseline Demographics

Baseline Characteristics	N=120
Age (Years)	83.5
Gender (Female)	58.3%
NYHA class III and IV	56.7%
STS score	4.0%
Extreme Risk	18.3%
Pulmonary Hypertension	15.0%
Coronary Artery Disease	61.7%
Arrhythmias	55.8%
Diabetes	27.5%
Chronic Lung Disease	27.5%
Kidney disease	25.8%
Prior pacemaker	10.8%
≥1 Frailty Factor	83.3%

Procedural Characteristics

Procedural Characteristics	N=120
Total Procedure Time (min)	72.8
Total Fluoroscopy Time (min)	20.7
Transfemoral access	99.2%
Pre-implant BAV	92.5%
Post-implant BAV	32.5%
Valve Size	
23 mm	3.3%
25 mm	30.8%
27 mm	35.0%
29 mm	30.8%

Procedural Outcomes

- No procedural deaths or conversion to SAVR
- 3 subjects required an additional Navitor™ valve due to malposition of the first device or movement upon post-dilatation

Outcomes	N=120
Procedural Success[1]	97.5%
Procedural Mortality	0.0%
Second valve required	2.5%
Conversion to SAVR	0.0%
No valve implanted	0.0%

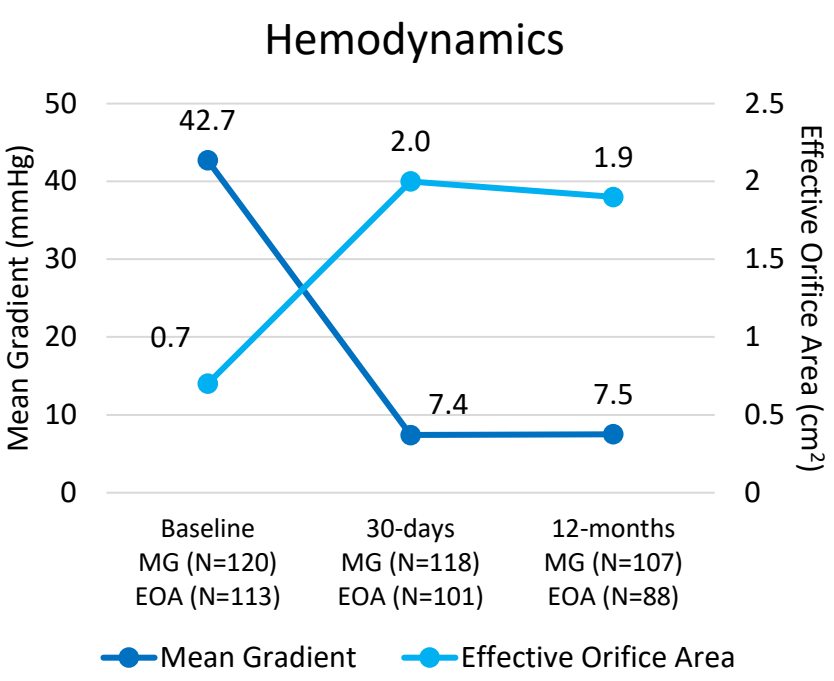
[1] Defined as absence of procedural mortality and correct positioning of a single Navitor™ valve in the annulus

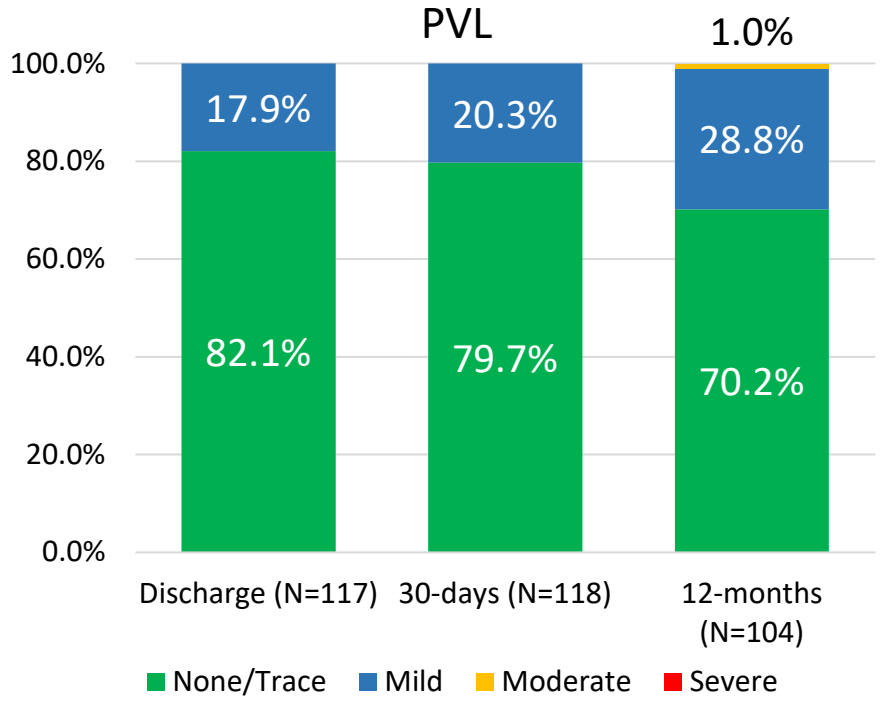
Safety Outcomes

Clinical Outcome (VARC-2)	30-days N=120 (%)	1-year N=120 (%)
All-cause mortality	0.0%[1]	4.2%
Disabling stroke	0.8%	0.8%
Acute kidney injury (stage 2/3)	1.7%	1.7%
Life-threatening bleeding	2.5%	5.0%
Major vascular complication	0.8%[2]	0.8%
Naïve Pacemaker Implantation	15.0%	16.8%[3]

[1]Primary safety endpoint
[2]CEC adjudicated as related to procedure but not to device
[3]Of the 18 subjects who required new PPI through 1 year, 13 had pre-existing conduction abnormalities

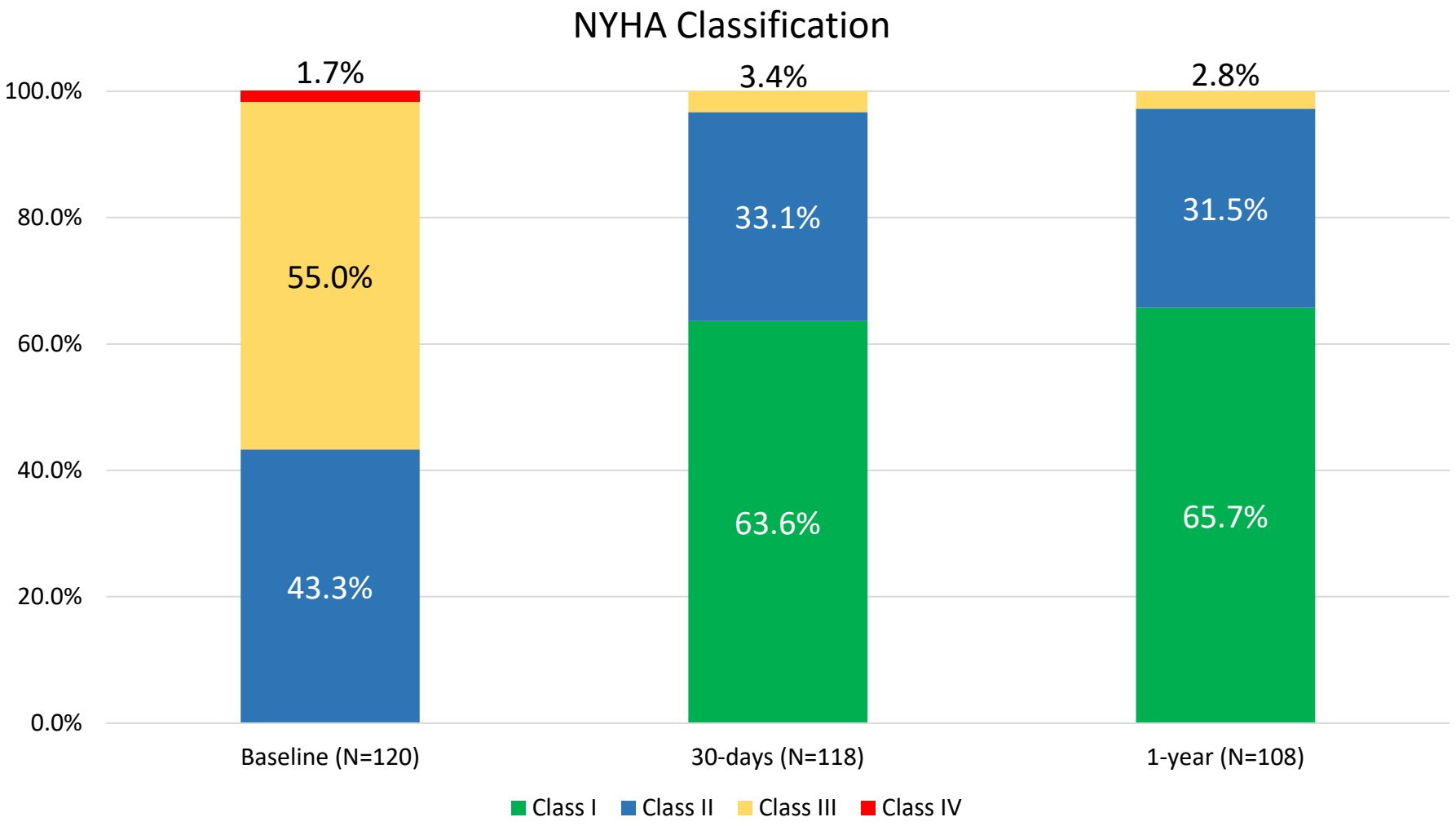
Hemodynamics and PVL





*At 12 months, 4 echoes were not evaluable for PVL and 5 echoes were not performed at the visit

Functional Class



Conclusions

- Low VARC-2 event rates at 1 year
  - All-cause mortality: 4.2%
  - Disabling Stroke: 0.8%

- Excellent hemodynamics through 1-year
  - Large EOA (1.9 cm^2) and single-digit mean gradients (7.5 mmHg)
  - Low rates of PVL

- The Navitor™ transcatheter aortic heart valve offers a safe and effective option for patients with symptomatic, severe aortic stenosis at high and extreme surgical risk.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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