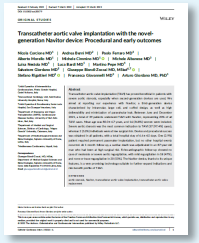
Clinical Insights

NAVITOR™ TAVI SYSTEM

PROCEDURAL AND EARLY OUTCOMES FROM A DUAL-CENTER OBSERVATIONAL STUDY

Publication Background[1]



TITLE

Transcatheter aortic valve implantation with the novel generation Navitor device: Procedural and early outcomes

JOURNAL

Catheterization and Cardiovascular Interventions

AUTHORS

Nicola Corcione et al.

BACKGROUND

- The Navitor TAVI system was recently introduced as a key improvement in comparison to Portico.
- This publication reports on first clinical experience from two centers.

METHODS

- Prospective, dual-center observational study using data routinely collected in the ongoing RISPEVA registry.
- 39 consecutive patients undergoing TAVI with Navitor (June – December 2021).
- CT angiography for preprocedural planning. Device sizing consistent with established criteria for other TAVI devices.
- Guideline-directed patient evaluation, procedures and pharmacological therapy.
- TTE and clinical status assessment at discharge and 1-month follow-up.
- Clinical and imaging endpoints according to VARC-3 recommendations

1. Corcione N et al. Transcatheter aortic valve implantation with the novel generation Navitor device: Procedural and early outcomes. Catheter Cardiovasc Interv 2022 May 12. doi: 10.1002/ccd.30179. Online ahead of print.

Patients

- 39 consecutive patients with attempted TAVI using Navitor.
- Moderate*, high, or prohibitive surgical risk.
- Severe aortic valve disease (stenosis or regurgitation).
- Navitor was primary option, reserving Evolut to patients with very large annuli.

PATIENT BASELINE DATA (N=39)	
Age	80.0 ± 6.7 years
Women	14 (36.8%)
Prior stroke	3 (7.9%)
Prior pacemaker implantation	4 (16.7%)
Chronic renal failure	4 (16.7%)
Prior aortic valvuloplasty	1 (2.6%)
LVEF	53.4 ± 8.6%
Peak aortic valve gradient	94.3 ± 20.3 mmHg
Mean aortic valve gradient	46.4 ± 15.4 mmHg
TAVI indicated by aortic regurgitation	1 (2.6%)
NYHA class	
I	2 (5.3%)
II	30 (78.9%)
III	6 (15.8%)
IV	0
Logistic EuroSCORE	12.2 ± 8.6%
EuroSCORE II	2.4 ± 1.9
Low surgical risk	2 (5.3%)

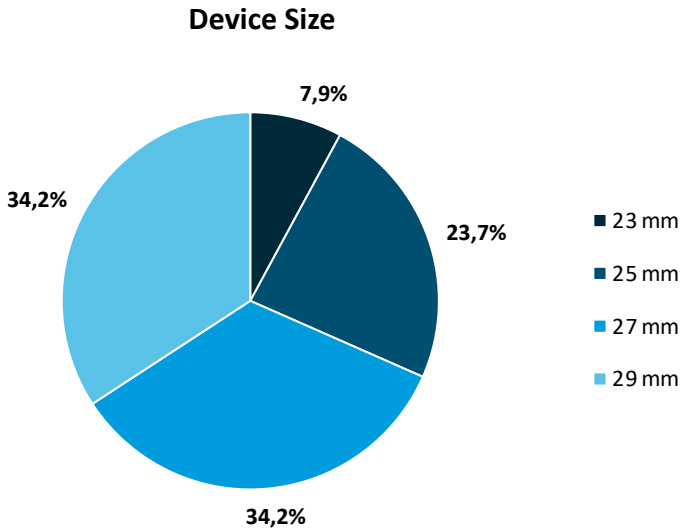
Mean ± standard deviation / Numbers (percentage)

*The Navitor™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.

Procedures

PROCEDURAL DATA (n=39)	
General anesthesia	2.6%
Femoral access	94.7%
Axillary access	5.3%
Predilation	71.1%
Postdilation	39.5%
Moderate/severe aortic regurgitation	2.6%
Contrast volume	75.6 ± 14.7 mL
Fluoroscopy time	16.3 ± 2.7 min
Procedural time	61.4 ± 12.3 min
Post-implant ECG changes	21.1%
Post-implant LBBB	18.4%
Post-implant pacemaker dependency	5.7%
Device success	100%
Procedural success	100%
Hospital stay	6.6 ± 4.5 days

Mean ± standard deviation / Percentage



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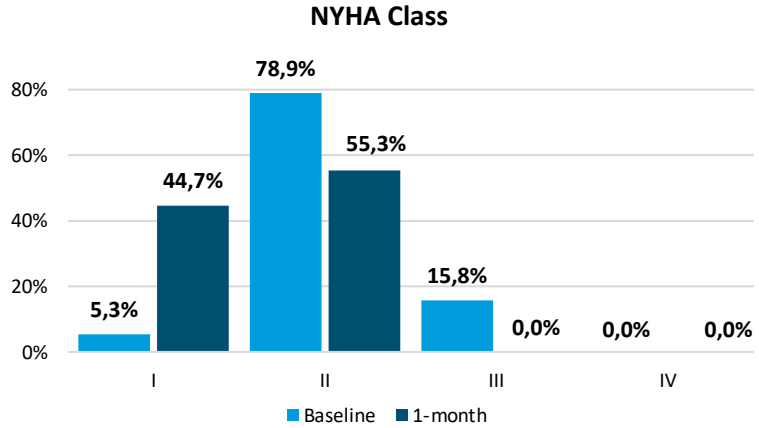
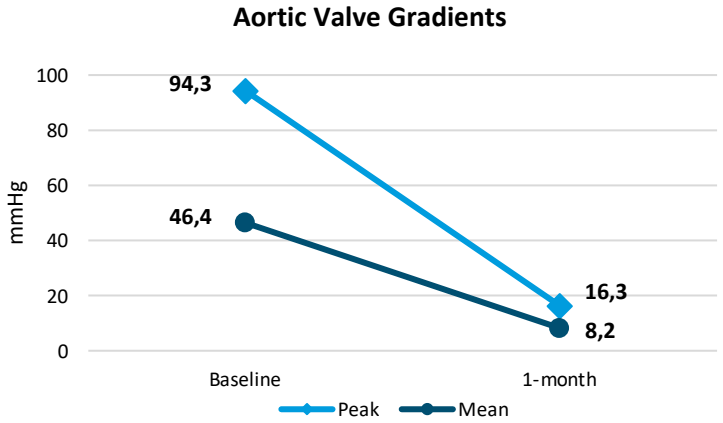
One-month Outcomes

- No moderate/severe aortic or mitral regurgitation.
- Permanent pacemaker implantation in 1 patient (2.9%).
- No stroke, myocardial infarction, bleeding, access-site complication, rehospitalization occurred up to 1 month of follow-up.
- 1 major adverse event (2.6%): cardiac death* at 1-month follow-up.

The favorable impact of the skirt [NaviSeal™ cuff] adjunct seems to be confirmed in this series, with most patients exhibiting no or trace prosthetic aortic valve regurgitation, and no case of moderate or severe regurgitation.





*Cardiac death in an 87-year-old, frail patient who had been at high surgical risk.

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Key Takeaway

NAVITOR IS A USER-FRIENDLY TAVI DEVICE WHICH CAN BE USED IN MOST PATIENTS CONSIDERED ELIGIBLE FOR TAVI

VERY HIGH DEVICE AND PROCEDURAL SUCCESS RATES IN EXPERIENCED HANDS

FAVORABLE SHORT-TERM CLINICAL OUTCOMES

- Very low rate of major adverse events
- Low permanent pacemaker implantation rate
- No case of moderate or severe prosthetic aortic valve regurgitation

CONCLUSION

The Navitor device, thanks to its unique features, appears a promising technology suitable to further expand indications and risk-benefit profile of TAVI, especially in patients with challenging anatomies, including those at low or moderate surgical risk, given the minimal risk of paravalvular leak.

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