




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

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Abstract

Transcatheter aortic valve implantation (TAVI) has proved beneficial in patients with severe aortic stenosis, especially when second-generation devices are used. We aimed at reporting our experience with Navitor, a third-generation device characterized by intrannular, large cell, and cuffed design, as well as high deliverability and minimization of paravalvular leak. Between June and December 2021, a total of 39 patients underwent TAVI with Navitor, representing 20% of all TAVI cases. Mean age was 80.0 ± 6.7 years, and 14 (36.8%) women were included. Severe aortic stenosis was the most common indication to TAVI (37 [97.4%] cases), whereas 2 (5.3%) individuals were at low surgical risk. Device and procedural success was obtained in all patients, with a total hospital stay of 6.6 ± 4.5 days. One (2.9%) patient required permanent pacemaker implantation, but no other hospital events occurred. At 1-month follow-up, a cardiac death was adjudicated in an 87-year-old man who had been at high surgical risk. Echocardiographic follow-up showed no case of moderate or severe aortic regurgitation, with mild regurgitation in 18 (47%), and none or trace regurgitation in 20 (53%). The Navitor device, thanks to its unique features, is a very promising technology suitable to further expand indications and risk-benefit profile of TAVI.

KEYWORDS

aortic stenosis, Navitor, transcatheter aortic valve implantation, transcatheter aortic valve replacement

Nicola Corcione and Andrea Berni are joint first author.

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1 | INTRODUCTION

Transcatheter aortic valve implantation (TAVI), also called transcatheter aortic valve replacement (TAVR), has revolutionized the management of aortic valve disease, whose prevalence continues to be substantial given ongoing increases in life expectancy.^{1,2} Notably, improvements in devices and techniques have progressively ameliorated early and long-term results, also expanding the candidate base to patients at intermediate as well as relatively low surgical risk.^{3,4}

Device choice remains challenging, though, also in light of the remarkable improvements over several iterations, such as design, features, and miniaturization. The Portico TAVI device (Abbott Laboratories), which has a self-expandable and intra-annular design, had already shown a favorable risk-benefit profile in its early generation, but key refinements included the introduction of the FlexNav delivery system, capable of improving deliverability as well as accurate implantation.⁵⁻⁸

Most recently, the Navitor TAVI device (Abbott Laboratories) has been introduced, as a key improvement in comparison to Portico (Figure 1).^{9,10} Specifically, this device features atraumatic aortic cells, plus dedicated outer and inner fabric cuffs, as well as a landing zone without cutouts, to reduce paravalvular leak and improve sealing. Favorable results have been preliminary reported, but the actual effectiveness of Navitor for TAVI remains to be established. In particular, while residual aortic regurgitation and paravalvular leak appear uncommon with Navitor, preliminary data highlighted the potential risk of increased rates of permanent pacemaker (PM) implantation.¹¹ A pivotal multicenter trial on Navitor is ongoing, but results are not expected shortly.¹²

We hereby report our clinical experience with consecutive patients undergoing TAVI with Navitor.

2 | METHODS

This study is a prospective analysis stemming from data routinely collected in the ongoing RISPEVA registry, supplemented by anonymized data provided by S. Andrea Hospital, Rome, Italy.¹³ The RISPEVA study is registered online (NCT02713932), was approved by the competent ethics committee and all patients provided written informed consent. The only criterion for inclusion in this study was attempted TAVI with Navitor at Pineta Grande Hospital, Castel Volturno, Italy, or at S. Andrea Hospital, and no specific exclusion criterion was enforced.

Patients were considered for TAVI with Navitor if presenting moderate, high, or prohibitive surgical risk, or other contraindications to cardiac surgery, and severe aortic valve disease (stenosis, as well as regurgitation but provided there was no annulus dilation). At both institutions, Navitor was chosen as primary option, reserving Evolut (Medtronic) mainly to patients with very large annuli. This preference was based on Navitor flexibility and intra-annular design, which make it perfectly suitable for patients candidate to Portico (e.g., those with

NAVITOR 3rd generation TAVI device

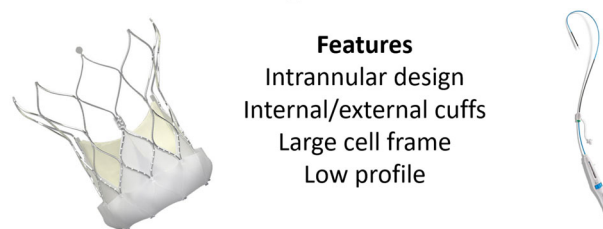


FIGURE 1 Main features of the Navitor transcatheter aortic valve implantation (TAVI) device [Color figure can be viewed at wileyonlinelibrary.com]

severe vascular tortuosity or horizontal aorta, as well as those with low ejection fraction), as well as its dedicated skirt, which supports its use in subjects of relatively younger age or at low or moderate surgical risk, given its capability to minimize paravalvular leak and prosthetic aortic regurgitation.

Preprocedural planning was based on computed tomography angiography, with device sizing criteria applicable to the Navitor device being basically the same established criteria already used for other TAVI devices. Indeed, we routinely measured perimeter, area, and derived diameter at the annular level, as well as at the sinuses of Valsava, sinotubular junction, and ascending aorta, with all these parameters considered relevant, even if the combination of perimeter, area, and derived diameter at the annular level are the most important. Default access was percutaneous transfemoral with preclosure with two Perclose Proglides (Abbott Vascular), but percutaneous axillary access was also considered as bail-out. All procedures, including heart team evaluation and ancillary pharmacologic therapy, were based on current European Society of Cardiology (ESC) guidelines for valvular heart disease and expert recommendations.^{14,15}

Transthoracic echocardiogram was performed at discharge and 1-month follow-up, and the same applied to clinical status assessment, without routine computed tomographic surveillance for leaflet thrombosis. Specifically, clinical follow-up was based on review of hospital charts, in-person visit, and phone contact performed by a dedicated research nurse. Notably, definitions of clinical and imaging endpoints were in agreement with current Valve Academic Research Consortium (VARC)-3 recommendations, using a dedicated grading scheme for prosthetic aortic valve regurgitation, distinguishing the following grades: none/trace, mild, moderate, and severe.¹⁶ Specifically, we collected data on death, cardiovascular death, stroke, myocardial infarction, bleeding (distinguishing type 1, 2, 3, and 4), access-site complication (distinguishing minor vascular, major vascular, minor nonvascular, and major nonvascular), permanent PM implantation, and New York Heart Association class. Major adverse events were defined as the composite of death, myocardial infarction, stroke, bleeding (any type), and vascular complication (any type), according to VARC-3 recommendations.

Descriptive analysis was based on reporting mean \pm standard deviation for continuous variables and count (%) for categorical variables. Inferential analysis was based on point estimate of incidence, as well as two-tailed 95% confidence intervals generated according to the Wilson method, without multiplicity adjustment, using the EpiTools online package.^{17,18}

3 | RESULTS

Between June and December 2021, a total of 39 patients underwent TAVI using the Navitor device (Table 1). Notably, age was 80 ± 7 years, and there were 14 (37%) women, while pure aortic regurgitation was present in 1 (3%). Aortic valve area was 0.6 ± 0.1 , whereas mean aortic valve gradient was 46 ± 15 . Surgical risk was 12 ± 9 according to the Logistic EuroSCORE and 2 ± 2 according to EuroSCORE II, with low surgical risk evident in two patients (5%). Finally, 6 (16%) individuals were in New York Heart Association Class III or IV.

All but 1 (3%) procedure were performed under local anesthesia, and percutaneous axillary access was used in 2 (5%) of cases (Table 2). All device sizes were used, despite some preference for 27 and 29 mm devices, with 3–6 mm as the most common implant height. Total contrast volume was 76 ± 15 ml, with fluoroscopy and procedural times of, respectively, 16 ± 3 and 61 ± 12 min. Notably, device success and procedural success were obtained in all 39 patients (100%), and only 1 patient (3%) required permanent PM implantation. No other clinical events occurred during hospitalization, leading to a total hospital stay of 7 ± 5 days.

Clinical and imaging follow-up was collected in all patients 1 month after the procedure (Table 3) (Figure 2). Notably, major adverse events occurred in 1 (3%) patient, specifically cardiac death occurring after discharge in an 87-year-old man who had been at high surgical risk. No stroke, myocardial infarction, bleeding or access-site complication occurred. No other patient required permanent PM implantation, and no rehospitalizations occurred. All patients were in New York Heart Association Class I or II. Echocardiographic follow-up showed mean aortic valve gradient of 8 ± 5 mmHg, with no or trace aortic regurgitation in 20 (53%), mild regurgitation in 18 (47%), and no subjects with moderate or severe regurgitation.

4 | DISCUSSION

This study, originally reporting on procedural and early clinical outcomes of patients undergoing TAVI with the novel Navitor device, despite being limited by the small sample size, nonsystematic patient selection and lack of external event adjudication or computed tomography follow-up, has the following implications: first, Navitor is a user-friendly self-expandable intra-annular TAVI device which can be used in most patients considered eligible for TAVI; second, device and procedural success rates are very high with this device in

TABLE 1 Baseline features

Feature	Mean or count	Standard deviation or proportion
Patients	39	-
Age (years)	80.0	6.7
Women	14	36.8%
Height (cm)	164.2	4.0
Weight (kg)	82.5	14.2
Body surface area (m ²)	1.94	0.17
Body mass index (kg/m ²)	30.4	5.6
Diabetes mellitus	8	21.1%
Dyslipidemia	20	52.6%
Hypertension	23	60.5%
Chronic obstructive pulmonary disease	3	7.9%
Smoking	1	2.6%
Prior cancer	3	7.9%
Prior myocardial infarction	7	18.4%
Prior stroke	3	7.9%
Prior pacemaker implantation	4	16.7%
Chronic renal failure	4	16.7%
Prior aortic valvuloplasty	1	2.6%
Glomerular filtration rate (mL/min/1.73 m ²)	70.2	23.7
Left ventricular ejection fraction (%)	53.4	8.6
Peak aortic valve gradient (mmHg)	94.3	20.3
Mean aortic valve gradient (mmHg)	46.4	15.4
Aortic valve area (cm ²)	0.63	0.13
Bicuspid aortic valve disease	0	0%
Aortic regurgitation as indication to transcatheter aortic valve implantation	1	2.6%
Moderate or severe mitral regurgitation	1	2.6%
Systolic pulmonary artery pressure (mmHg)	46.8	12.5
Ilio-femoral tortuosity	2	5.3%
New York Heart Association		
I	2	5.3%
II	30	78.9%
III	6	15.8%
IV	0	0%
Logistic EuroSCORE (%)	12.2	8.6
EuroSCORE II	2.4	1.9
Low surgical risk	2	5.3%

TABLE 2 Procedural features

Feature	Mean or count	Standard deviation or proportion
Patients	39	-
General anesthesia	1	2.6%
Access		
Femoral	36	94.7%
Axillary	2	5.3%
Temporary pacing	33	86.8%
Predilation	27	71.1%
Predilation balloon diameter (mm)	20.1	1.4
Device size (mm)		
23	3	7.9%
25	9	23.7%
27	13	34.2%
29	13	34.2%
Implant height (mm)		
<3	15	39.5%
3–6	19	50.0%
>6	4	10.5%
Postdilation	15	39.5%
Postdilation balloon diameter (mm)	23.1	2.1
Left ventricular ejection fraction (%)	51.9	10.1
Moderate or severe aortic regurgitation	1	2.6%
Systolic pulmonary artery pressure (mmHg)	40.6	9.4
Contrast volume (ml)	75.6	14.7
Fluoroscopy time (min)	16.3	2.7
Procedural time (min)	61.4	12.3
Hemostasis with 2 ProGlide	38	100%
Postimplant ECG changes	8	21.1%
Postimplant left bundle branch block	7	18.4%
Postimplant pacemaker dependency	2	5.7%
Device success	38	100%
Procedural success	38	100%
Hospital stay (days)	6.6	4.5

experienced hands; third, short-term clinical outcomes are clearly favorable, despite the advanced patient population typically undergoing TAVI, with very low rates of composite outcomes, as well as permanent PM implantation, on top of no case of moderate or severe prosthetic aortic valve regurgitation.

The introduction of TAVI has clearly changed the way severe aortic valve disease is managed.⁴ Indeed, surgical aortic valve

TABLE 3 One-month outcomes

Feature	Mean or count	Standard deviation or proportion ^a
Patients	39	-
Major adverse events ^b	1	2.6%
Death or stroke	1	2.6%
Death	1	2.6%
Myocardial infarction	0	0%
Stroke	0	0%
Bleeding		
Any	0	0%
Type 1 bleeding	0	0%
Type 2 bleeding	0	0%
Type 3 bleeding	0	0%
Type 4 bleeding	0	0%
Access-site complication		
Any	0	0%
Major access-site vascular complication	0	0%
Minor access-site vascular complication	0	0%
Major access-site nonvascular complication	0	0%
Minor access-site nonvascular complication	0	0%
Permanent pacemaker implantation	1	2.9%
Rehospitalization	0	0%
New York Heart Association Class		
I	16	42.1%
II	22	57.9%
III	0	0%
IV	0	0%
Left ventricular ejection fraction (%)	56.1	6.8
Peak aortic valve gradient (mmHg)	16.3	9.2
Mean aortic valve gradient (mmHg)	8.2	4.9
Aortic regurgitation		
None/trace	20	52.6%
Mild	18	47.3%
Moderate	0	0%
Severe	0	0%
Mitral regurgitation		
None	17	44.7%
Mild	21	55.3%
Moderate	0	0%
Severe	0	0%
Systolic pulmonary artery pressure (mmHg)	33.1	10.9

^aDenominators are 39 for all outcomes except for pacemaker (PM) implantation, where denominator is 35.

^bComposite of death, myocardial infarction, stroke, bleeding, or access-site complication.

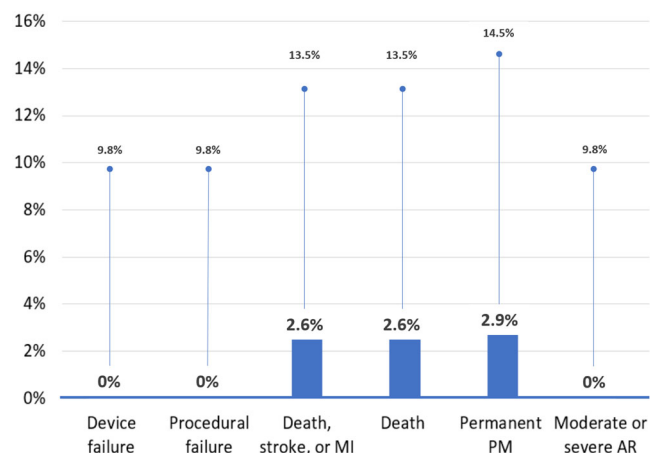


FIGURE 2 Barplot highlighting key procedural and clinical events up to 1 month of follow-up, reported as point estimates of effect, and 95% confidence intervals computed with the Wilson method (denominators are 39 for all outcomes except for pacemaker [PM] implantation, where denominator is 35). AR, aortic regurgitation; MI, myocardial infarction [Color figure can be viewed at wileyonlinelibrary.com]

replacement is now considered mainly for fit and young patients, and balloon aortic valvuloplasty used only in subjects with very limited life expectancy. Conversely, the role of TAVI is expanding thanks to improvements in access to devices, technological improvements, and procedural refinements.^{3,18} Several TAVI devices are currently available, including balloon-expandable ones such as Sapien (Edwards Lifesciences), and Myval (Meril Life Sciences), and self-expandable ones such as Evolut (Medtronic), Acurate and Lotus (Boston Scientific), Portico and Navitor (Abbott Laboratories), and Allegra (NVT).¹⁹ Clearly, the multiplicity of designs and devices puts clear emphasis on patient selection and operator skill, but new-generation devices are clearly associated with more favorable results than early-generation ones.¹³

Notably, Portico has been recently introduced with favorable procedural and clinical results, despite some issues with valve functionality (given the anecdotal reports of subclinical leaflet thrombosis).¹⁹ Subsequent reports were however more favorable, and further improvements in this TAVI device were provided by a dedicated delivery system, FlexNav.^{5,8}

Most recently, a new device from the same manufacturer has complemented Portico: Navitor. This device maintains the self-expandable, intra-annular specifications, and ease of use of the FlexNav delivery system of Portico. However, it boasts a dedicated large-cell metallic frame, inner and outer fabric skirts, and a refined landing zone cutouts generating a veritable sealing border to further limit regurgitation. Despite favorable early data on Navitor, the evidence base on this device is very limited to date.^{9,10} In this article, we originally report on our two-center experience with Navitor in unselected patients considered for TAVI. We found indeed that the device was capable of treating most patients with indication for TAVI, as well as being user-friendly and suitable for percutaneous femoral as well as axillary delivery. Accordingly,

device and procedural success were 100%, and only 1 patient out of 35 required permanent PM implantation. Most notably, no stroke, myocardial infarction, bleeding, or access-site complication occurred up to 1 month of follow-up. The only major adverse event was a cardiac death occurring after discharge in an elderly and frail patient. The favorable impact of the skirt 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.

In light of prior data on Portico, as well as most recent reports supporting the use of FlexNav and Navitor, we can envision a broader use of this third-generation TAVI device. It is true though that device choice for TAVI remains a challenging step, given the plethora of available devices, each one with its peculiar features, ranging from expansion mechanism to annular position.¹⁵ Evidently, self-expandable devices such as Navitor may prove particularly appealing for operators with limited experience or patients with challenging anatomy, given the advantages of the FlexNav delivery system. Nonetheless, further studies of larger size and exploiting controlled comparisons (e.g., randomized trials or propensity score-matched analyses) are eagerly awaited to further confirm or disprove the favorable early results hereby reported for Navitor.

These premises seem to be confirmed by an informal comparison of the present series to others stemming from our institutional experience.²⁰ Indeed, in comparison to the majority of TAVI patients treated in our centers in the recent past, subjects hereby described had a relatively younger age, were more commonly men, had lower surgical risk scores, fewer comorbidities, and more commonly underwent TAVI under local anesthesia using a fully percutaneous approach.

As also previously highlighted, this study has several limitations, including the observational design, two-center setting, informal patient selection, small sample size, and short-term follow-up. Furthermore, no routine program of computed tomography surveillance for leaflet thrombosis was adopted.²¹ Accordingly, larger studies with longer follow-up, and including several other device types should be conducted to expand the present hypothesis-generating results.²²

5 | CONCLUSION

The take-home message of the present pilot two-center registry is that 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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CONFLICTS OF INTEREST

Giuseppe Biondi-Zoccai has consulted for Cardionovum, Cranmedical, Innovheart, Meditrial, Opsens Medical, Replycare, and Terumo. The remaining authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data set and analysis codes are available from the corresponding author with motivated requests.

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