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In Press, Corrected Proof What's this?

Performance of balloon-expandable transcatheter bioprostheses in inoperable patients with pure aortic regurgitation of a native valve: The BE-PANTHEON international project

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Highlights

- BE-PANTHEON study reveals practical implications of BE devices in NAVR management.
- TAVR with BE devices is feasible despite peri-procedural complications.
- MyVal and Sapien THVs show similar success rates in technical and device performance.
- MyVal THV accommodates larger annuli, offering an advantage over Sapien THVs.

Abstract

Background

The off-label utilization of transcatheter heart valve (THV) devices for the treatment of inoperable or high-surgical risk patients with pure native aortic valve regurgitation (NAVR) has demonstrated suboptimal outcomes, both with self- and balloon-expandable (BE) devices. The aim of this study is to compare the use of different BE scaffolds in treating pure NAVR.

Methods

Consecutive patients with pure severe NAVR who were deemed to be at high-risk and were treated with last-generation BE-THVs among seventeen Centers in Europe and US. Technical and device success rates were the primary objectives.

Results

Between February 2018 and July 2023, among 144 patients, 41 (28%) received a MyVal device and 103 (72%) were treated with a Sapien THV. Patients treated with a MyVal THV had an extra-large annulus more frequently compared to the Sapien group (49%vs.20%, $p<0.001$).

Technical and device success rates were 90% and 81%, respectively, $p>0.1$. The rate of THV migration/embolization (MyVal 4.9%vs. Sapien 11%, $p=0.4$) and second valve needed (4.9%vs.7.8%, $p=0.7$) were numerically lower in the MyVal group, whereas the rate of at least moderate paravalvular leak (15%vs.7.8%, $p=0.2$) and permanent pacemaker implantation (25%vs.18%, $p=0.16$) were numerically higher in the Myval group.

Conclusions

Off-label use of BE devices for pure NAVR represents a potential alternative in high-risk patients in the absence of dedicated devices. However, BE in NAVR is associated with suboptimal outcomes. The availability of larger THV sizes may introduce transcatheter aortic valve replacement as an effective treatment for patients traditionally deemed

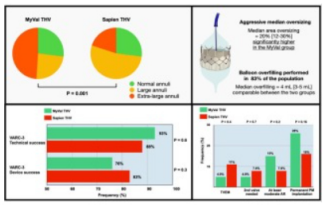
unsuitable.

Non-standard abbreviations and acronyms

AR=aortic regurgitation, BE=balloon-expandable, NAVR=native aortic valve regurgitation, PM=pacemaker, TAVR=transcatheter aortic valve replacement, THV=transcatheter heart valve, TVEM=transcatheter valve embolization and migration, VARC-3=Valve Academic Research Consortium 3.

Graphical abstract

Balloon-expandable (BE) platforms performance in the setting of pure native aortic valve regurgitation (NAVR).



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Introduction

Over the last decade, transcatheter aortic valve replacement (TAVR) has established a new paradigm for the treatment of severe aortic stenosis [1].

For many years, the Edwards Sapien valve family (Edwards Lifesciences, United States) was the unique balloon-expandable (BE) device available in the market, while a wide range of self-expanding devices have been developed [2,3]. Recently, a new BE platform, the MyVal/Octacor Transcatheter Heart Valve (THV) (Meril Life Sciences Pvt. Ltd., India), has been introduced featuring intermediate and extra-large size devices, such as 30.5 and 32mm, that cover a range of aortic areas unsuitable for other platforms [4,5].

As patients with NAVR may have a very large anatomy, this feature may be particularly beneficial considering that the only possibility to anchor a THV is more pronounced oversizing than that for aortic stenosis [6]. However, whether the availability of these extra-large sizes implies a better outcomes is not yet elucidated.

We hereby present the first real world comparison of different BE THVs in patients with pure NAVR.

Section snippets

Material and methods

The design and main results of the PANTHEON (Performance of currently Available traNscaTHEter aortic valve platforms in inoperable patients with pure aortic regurgitatiON of a native valve, NCT05319171) registry have been previously reported [6]. In brief, this international, multicentre, investigator-initiated registry was designed to collect patients' data on new generation THVs used in the treatment of pure NAVR. Twenty-three medical centers from Europe and the United States provided

Baseline characteristics

Between February 2018 and July 2023, 41 patients were treated with the MyVal THV (28%) and 103 with the Sapien THV (72%) (Fig. 1). Overall median Society of Thoracic Surgeons mortality risk score was 2.70% (IQR: 1.90–4.62%) and comparable between MyVal and Sapien groups. The two groups were comparable in their baseline clinical and imaging characteristics, except for the left ventricle impairment that was more frequently present in the Sapien group as showed by the lower ejection fraction

Discussion

The off-label utilization of THV devices for the treatment of inoperable or high-surgical risk patients with pure NAVR has been shown to be feasible with suboptimal outcomes [9]. Nevertheless, only a few reports, limited to registries [5] or small case series [10], have reported the performance of BE devices in this context. In contrast, larger registries

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have mainly reported data concerning the use of self-expanding THVs [11].

In this BE-PANTHEON study, we compared the two BE options currently

Conclusion

Off-label use of BE devices for pure NAVR represents a potential alternative in inoperable and high-surgical risk patients. Availability of THV sizes able to accommodate extremely dilated anatomies may expand TAVR to patients traditionally deemed unsuitable.

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None.

CRediT authorship contribution statement

Enrico Poletti: Writing – review & editing, Writing – original draft, Visualization, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Ignacio Amat-Santos:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Conceptualization. **Enrico Criscione:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Antonio Popolo Rubbio:** Writing – review & editing,

Declaration of competing interest

AS has served as a consultant for Edwards Lifesciences and NeoChord Inc. AL has served on the advisory board for Medtronic, Abbott Vascular, Boston Scientific, Edwards Lifesciences, Shifamed, NeoChord Inc., V-dyne, and Philips. LT is proctor/consultant for Abbot, BSCI, Medtronic, Meril. The other authors did not report any conflict of interest.

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