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Safety and performance parameters of the Myval transcatheter aortic valve bioprosthesis: The SAPPHIRE prospective registry

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Highlights

- A new generation of TAVR platforms is currently under evaluation aiming at improving the results of previous generation
- The Myval™ THV is a balloon-expandable TAVR system made by a nickel-cobalt alloy frame composed of hexagons cells.
- The present manuscript reports a high success rate as well as a very low rate of vascular complication and PM implantation
- The 2 year follow up showed no cases of structural valve deterioration
- Large RCTs against the current generation are needed to place this new platform into the cardiovascular arena

Abstract

Background

TAVR is an established treatment for patients with severe symptomatic aortic stenosis. Different THV platforms are nowadays available, each of them with its inherent limitations and others are under development aiming at overcoming such limitations.

We thus sought to investigate the performance and 1-year clinical outcome of a new generation, balloon expandable, THV: the Myval™ (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India).

Methods

This registry included the first 100 consecutive patients (mean age 80.7±7.7; STS 4.3±3.3%), who underwent transcatheter aortic valve implantation for severe stenosis of the native aortic valve from May 2020 to December 2020, in two Italian Centers. Clinical and procedural outcomes were defined according to VARC-3 criteria.

Results

Transfemoral Myval THV was successfully implanted in all patients, with no intra-hospital mortality (technical success 100%): vascular access complications were all "minor" (16%), and managed by compression/balloon inflation; no cases of annular rupture or coronary obstruction occurred; 5% of patients required an in-hospital pacemaker implantation (PM). Device success was 99%.

Overall and cardiovascular mortality were 6% (CI 5%–7%) and 4% (CI 2%–5%) at 1- year, while 12% (CI 9%–14%) and 7% (6–9%) at 2years. A total of 9% of the patients required a PM within 12months, and no further PM implantation occurred afterwards. No cerebrovascular events, renal failure and myocardial infarction occurred between discharge and 2-year follow-up. No events of structural valve deterioration but a sustained improvement of echocardiographic parameters were observed.

Conclusion

The Myval THV has a promising safety/efficacy profile at 2year follow up. This

performance should be further evaluated in the context of randomized trials to better elucidate its potential.

Introduction

Transcatheter aortic valve replacement (TAVR) is an established technique for the treatment of patients with severe symptomatic aortic stenosis (AS). Different randomized controlled trials established superiority of TAVR over surgical aortic valve replacement (SAVR) in patients at prohibitive and high risk for surgery, as well as noninferiority of TAVR over SAVR in patients with AS at intermediate surgical risk [1], [2], [3], [4], [5], [6], [7]. Additionally, TAVR has been reported to be noninferior and/or superior to SAVR in patients at low surgical risk [8], [9], [10], [11].

Nevertheless, the available platforms used for TAVR still face the issues of paravalvular leakage (PVL), vascular complications, stroke, coronary access and conduction disturbances leading to new permanent pacemaker implantation (PPI).

New platforms are under development with the ambition of improving current results of the TAVR procedure. The Myval™ Transcatheter Heart Valve (THV) (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India) is a new-generation, balloon-expandable TAVR system featuring new technological solutions with the aim of overcoming the issues of current-generation THVs.

We hereby evaluate the safety/efficacy profile of the Myval in a single arm prospective registry concerning the first 100 cases performed in Italy, in patients with severe symptomatic aortic stenosis.

Section snippets

Methods

This is a single arm prospective registry that included cases of patients with severe symptomatic aortic stenosis performed in 2 centers from May 2020 to December 2020. Pre-procedural computed tomography scan was performed in all patients to plan the procedure. All subjects were evaluated by the local Heart team and provided written informed consent for the procedure. A total of 100 patients were included. During the same period, a total of 250 TAVR have been performed in the two centers.

Baseline and procedural characteristics

Demographic characteristics are summarized in Table 1. The majority of patients were male (62/100, 62%) and had a mean age of 80.7±7.7years. The STS Mortality score was 4.3±3.3%. 78% of patients had arterial hypertension and 25% were diabetic. Atrial fibrillation was present in 30 patients (33%). Chronic heart failure was diagnosed in the 22% of patients, while syncope and angina were present only in the 8% and 9% of patients, respectively.

Overall, the enrolled population mirrors

Discussion

The TAVR procedure is nowadays an established therapy for patients with severe aortic stenosis, at any level of surgical risk. Multiple platforms are available but still there is a significant proportion of patients experiencing complications related to vascular access, conduction disturbance, PVL and stroke.

In this scenario, new technologies are reaching the clinical implementation aiming at improving the results obtained so far. The Myval™ THV is a new balloon-expandable TAVR system

Limitations

The present report has some intrinsic limitations. In particular, the small sample size that doesn't allow definite conclusions, and the FU, although the longest to the best of our knowledge, is not long enough to evaluate the rate of SVD.

There is no clinical event committee and Core Lab to evaluate the echo parameters, however, the participating centers have large experience in the field of TAVR and all the patients suitable for the MyVal according to the IFU have been enrolled.

Conclusions

The Myval THV technology showed an encouraging safety/efficacy profile within 2 years post procedure. Larger data set with longer follow up are needed to clarify the role of this new technology within the TAVR armamentarium.

Source of funding

None.

Subject terms

TAVR, balloon expandable THV.

CRediT authorship contribution statement

LT and EC: conceptualization and proofing.

APR, MS, AI: data acquisition and management.

MT, NB, FB: reviewing and editing.

Declaration of competing interest

None inherent to the present manuscript.

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