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Safety and effectiveness of the novel Myval Octacor transcatheter heart valve in severe, symptomatic aortic valve stenosis — A real-world Indian experience (The OCTACOR India Study)

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Highlights

- Transcatheter aortic valve implantation (TAVI) has become an established intervention for treating severe aortic stenosis.
- Cardiac complications can occur after TAVI due to improper size or fit of the valve.
- The commonest complications are left bundle branch block and paravalvular leak.
- The design of the new Myval Octacor transcatheter heart valve (THV) aims at minimizing these complications.
- In this study, the rate of these complications after Myval Octacor THV implantation was low.

Abstract

Purpose

To evaluate the safety and effectiveness of the novel, next-generation Myval Octacor — Transcatheter Heart Valve (THV) in patients with severe, symptomatic, native aortic stenosis (AS).

Methods

This multicenter, real-world observational registry included 123 patients with severe symptomatic AS, across 16 Indian centers who underwent treatment with the novel Myval Octacor THV. Study endpoints included all-cause mortality, all stroke, acute kidney injury (AKI), major vascular complications, moderate or severe paravalvular leakage (PVL) and new permanent pacemaker implantation (PPI) until 30days follow-up.

Results

Of the 123 patients (average age 70.07±8.33years), 37.4% (n=46) were female and 39.84% presented with bicuspid valves. The technical success rate of the procedure was 100% and the device success rate at 30days was 98.4%. At 30days (n=123) after the procedure, the overall mortality was 1.6%. AKI occurred in 1.6% of patients and there was no incidence of stroke, bleeding (types 3 and 4), and major vascular complications. In an analysis of 31 patients whose echocardiographic parameters were available across all timepoints, there were significant improvements in the mean pressure gradient (54.31±18.19mmHg vs. 10.42±4.24mmHg; $p<0.0001$) and effective orifice area (0.66±0.21 cm^2 vs. 1.80±0.44 cm^2; $p<0.0001$) from baseline to the 30-day follow-up. None of the patients experienced severe PVL, while moderate PVL was observed in two patients (1.6%).

Conclusions

Conclusions

Early outcomes of the next-generation, novel Myval Octacor THV proved its safety and effectiveness in the treatment of severe AS.

Introduction

Aortic stenosis (AS) is the most common valvular heart disease globally [1], and its prevalence increases exponentially with age [2,3]. Transcatheter aortic valve implantation (TAVI) has become an established intervention strategy for patients with severe AS [3]. Meanwhile, TAVI has shown an increasing survival benefit and is considered a Class I/Level A recommendation as per ACC/AHA and ESC/EACTS guidelines for treating severe, symptomatic AS, regardless of surgical risk [3,4]. With advancements in the procedure, TAVI is now more widely accepted for younger and lower-risk patients [[5], [6], [7]]. Nevertheless, there are cardiac complications associated with TAVI, especially if the valve size is inappropriate or if the valve is not positioned accurately [7].

Myval Octacor transcatheter heart valve (THV) is the newly designed version of the balloon-expandable (BE) Myval THV. The new design has the same frame height as the previous Myval version (17.35–21.14 mm) but with only two rows of identical octagonal cells. This reduces the foreshortening of the Myval Octacor THV during expansion and facilitates accurate deployment. Moreover, Myval is directly mounted on its balloon delivery system, which reduces the need for in situ maneuvering. This minimizes the procedural steps and ensures procedural success with less effort. Complementing the TAVI effort, a low-profile 14Fr Python introducer sheath was developed which is compliant with all Myval THV diameters (from 20 to 32 mm) with a unique feature of full retrievability in case the operator is not able to cross the annulus. The distinct features of Myval Octacor THV have been designed with an aim to facilitate precise positioning and deployment. This has been demonstrated earlier in a small patient pool [8]. The external skirt in Myval Octacor THV is up to 50% of the frame height which minimizes the propensity for paravalvular leak (PVL). A landing zone marker towards the ventricular end of the Navigator Inception THV delivery system facilitates precise positioning of Myval Octacor THV at the annulus [9].

Previous clinical studies with Myval THV showed satisfactory safety and efficacy outcomes in patients with AS [[10], [11], [12], [13], [14], [15], [16]]. In these studies, the patient population was selected using specific eligibility criteria. Real-world evidence is critical in assessing the safety and efficacy of medical devices as it provides insight into their actual use in clinical practice and can help identify emerging risks. Therefore, real-world data is warranted for establishing the safety and efficacy of Myval Octacor THV in real-world settings. This paper presents the short-term outcomes of a real-world, multicenter observational registry to evaluate the safety and effectiveness of Myval Octacor THV in patients with symptomatic severe native AS (CTRI/2023/07/055010).

Section snippets

Study design

This multicenter, real-world retrospective registry collected the data of 123 severe symptomatic AS patients across 16 Indian centers who underwent TAVI with Myval Octacor THV. All patients with severe symptomatic AS were treated with the study device at the discretion of the investigator in real-world settings. There were no formal exclusion criteria for the study and all data available from the medical records were analyzed. The endpoints were defined according to the Valve Academic Research

Patient demographics and medical history

The study included 123 patients from 16 centers in India; of these, 37.4% (n=46) were female. The mean age was 70.07±8.33 years. Baseline data and demographic data of the study subjects are summarized in Table 1. The median Society of Transthoracic Surgeons (STS) risk score was 3.20% (1.80–5.05). 74 patients (60.16%) had a native tricuspid aortic valve and 49 (39.84%) had a native bicuspid aortic valve (BAV) anatomy.

The minimum and maximum aortic annulus diameters were 20.71±2.49 mm

Discussion

This study demonstrated early safety and effectiveness of Myval Octacor THV in patients with severe AS. Among the major outcomes, the all-cause 30-day mortality was 1.6%, technical success 100%, device success 98.4%, and the rate of moderate/severe PVL was 1.6%. Hemodynamic parameters, mean pressure gradient and EOA were significantly improved from baseline to 30-day follow-up.

Previous studies have demonstrated the safety and efficacy of the earlier versions of Myval THV. In the MyVal-1

Conclusions

The novel, next-generation, Myval Octacor THV has demonstrated early safety and effectiveness in treating severe symptomatic aortic stenosis. Both procedural and early clinical outcomes have been favorable. Further randomized studies are necessary to validate the long-term safety and efficacy of this device in comparison to other contemporary THVs.

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CRediT authorship contribution statement

John Jose: Writing – review & editing, Methodology, Investigation, Conceptualization. **Asishkumar Mandalay:** Writing – review & editing, Investigation. **Manjunath N. Cholenahally:** Writing – review & editing, Supervision, Investigation. **Ravindranath S. Khandenahally:** Writing – review & editing, Investigation. **Srinivas C. Budnur:** Writing – review & editing, Investigation. **Maulik Parekh:** Writing – review & editing, Investigation. **Ravinder S. Rao:** Writing – review & editing, Investigation. **Ashok Seth:**

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Sengottuvelu Gunasekaran reports a relationship with Meril Life Sciences Pvt. Ltd. that includes: consulting or advisory. John Jose, Ashok Seth, Ravinder S. Rao & Haresh Mehta reports a relationship with Meril Life Sciences Pvt. Ltd. that includes: consulting or advisory. Other authors declare that they have no known competing financial interests or personal

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