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Single-Center Evaluation of the Myval Balloon-Expandable Transcatheter Heart Valve: A Follow-Up Study: A Retrospective Cohort Study

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ABSTRACT

Background and Aims: Our objective is to report our single-center experience with the novel balloon-expandable Myval Transcatheter Heart Valve (THV) system in Transcatheter Aortic Valve Replacement (TAVR) procedures.

Methods: We conducted a retrospective study on a cohort of consecutive patients who underwent TAVR utilizing Myval THV from September 2021 to August 2023 at a tertiary care cardiac center. We collected baseline characteristics, pre- and post-procedural echocardiographic findings, procedural details, in-hospital outcomes, VARC-3 technical success, and complications. Additionally, patients were followed up for 3 months concerning their clinical outcomes.

Results: The study population comprised 92 TAVR patients with a mean age of 76.8 ± 7.3 years, 66.3% were male, and the mean STS score was 5.9 ± 3.2%. The most common valve sizes used were 24.5 mm (30.4%), 23 mm (26.1%), and 27.5 mm (17.4%). Pre-dilation was performed in 32 cases (34.8%), achieving a 93.5% technical success rate. In-hospital mortality occurred in three patients (3.3%), which included one annulus rupture. Permanent pacemaker implantation was required in six patients (6.5%). Three patients (3.3%) exhibited 3+ paravalvular leakage demonstrated by angiography. The New York Heart Association (NYHA) functional class showed significant improvement from baseline to discharge ($p < 0.0001$). At the 3-month follow-up, five patients encountered mortality (5.4), and three experienced an episode of stroke or transient ischemic attack (3.2%). Two other patients were hospitalized due to cardiovascular events during the 3-month follow-up.

Conclusion: The Myval THV shows a favorable safety and efficacy profile in TAVR, with low mortality and complications at 3 months.

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1 | Introduction

Aortic Stenosis (AS) is a prevalent valvular heart condition that primarily progresses with aging. This condition, if not addressed, can lead to severe health complications and an increased risk of death [1, 2]. Transcatheter Aortic Valve Replacement (TAVR) has emerged as a viable and less invasive alternative to the traditional Surgical Aortic Valve Replacement (SAVR) for patients facing severe AS, particularly those categorized at intermediate, high, or prohibitively high risk for surgery [3]. Recent studies demonstrating the noninferiority of TAVR in comparison to SAVR for patients with severe AS who are considered to be at low surgical risk have significantly contributed to the wider acceptance and utilization of TAVR worldwide [4, 5].

Technological advancements have focused on developing lower-profile delivery systems and improved valve designs to optimize procedural safety and outcomes [6]. Among these innovations is the Myval Transcatheter Heart Valve (THV) (Meril Life Sciences Pvt. Ltd., India), a newer-generation Balloon-Expandable (BE) valve featuring tri-leaflet bovine pericardial leaflets within a nickel–cobalt alloy stent frame that utilizes the flexible navigator balloon catheter for delivery [2, 6]. Myval received approval from India's Central Drugs Standard Control Organization (CDSCO) and Conformité Européenne (CE) mark in the European Economic Area. Currently, Myval is attaining growing acceptance worldwide [6, 7].

Although the Myval THV has shown promising safety and efficacy in initial clinical studies [7, 8], the available data on its performance are still constrained by the limited number of subjects in these studies. There is a need for more substantial real-world evidence. This study aims to present our institution's TAVR experience with the Myval THV, emphasizing procedural, post-procedural, and 3-month clinical outcomes. We will also discuss procedural complications encountered. This real-world data offers valuable insights into the application of the Myval THV system for clinical implications.

2 | Methods

In this retrospective descriptive study, we included consecutive patients subjected to TAVR for severe AS using Myval THV from September 2021 to August 2023. The first 30 cases of Myval implantation were performed with the supervision of the Meril company proctor, which was conducted before the initial date of this study and thus not included in the current study. This study was conducted at Rajaie Cardiovascular Medical and Research Center, Tehran, Iran. All patients were subjected to Computed Tomography (CT) Angiography before TAVR. Patients were excluded if Myval was implanted in any valve other than the aortic valve.

Primarily, we designed a data sheet using Microsoft Excel spreadsheet. Demographic and past medical history information of patients, their clinical manifestation, pre- and post-procedural echocardiographic findings, preprocedural Electrocardiographic (ECG) findings, laboratory test results, CT angiographic findings, and procedural information were extracted from Hospital Information System (HIS). The aortic root diameter was measured either by echocardiography or CT scan in the end-diastolic phase.

Subsequently, the Society of Thoracic Surgeons (STS) score was calculated using the appropriate findings. Additionally, STS scores were categorized as low (< 4%), medium (4%–8%), and high risk (> 8%). All findings were recorded in the Microsoft Excel data sheet. Patients or their first-degree family members were contacted by telephone and were interviewed for follow-up.

A Transthoracic Echocardiogram (TTE) was performed before and within 4–6 h of the TAVR in line with American Society of Echocardiography guidelines [9]. The vascular access and aortic valve were assessed through a CT angiogram before TAVR. CT angiogram was analyzed using 3mensio software and performed by Emeril core lab. TAVR was performed through trans-femoral access in all patients. Additionally, patients were prescribed 75 mg/day of Clopidogrel for 3 months and 80 mg/day of Aspirin for 12 months.

The primary endpoint of this study was the occurrence of a Major Adverse Cardiovascular Event (MACE) during hospital admission. MACE was defined as either of the following: Paravalvular Leakage (PVL), Transient Ischemic Attack (TIA), stroke, bleeding, arrhythmia, the need for a permanent pacemaker, endocarditis, Myocardial Infarction (MI), the need for subsequent surgical intervention, THV migration or embolization, coronary artery compression, valve dysfunction or thrombosis, major vascular complication, or death. Major vascular complications are composed of vascular perforation, dissection, limb ischemia, access site hematoma, pseudoaneurysm annulus rupture leading to mortality, life-threatening or major bleeding, or neurological impairment, alongside patients exhibiting retroperitoneal hemorrhage, irreversible nerve injury, or visceral ischemia [10]. Vascular complications not fulfilling the major vascular complication criteria were considered minor vascular complications. These were self-limiting and did not require any additional interventions or blood transfusions [10]. VARC-3 technical success was assessed and recorded [11].

Secondary endpoints of the study composed of reversible access site nerve injury, Acute Renal Failure (ARF) during hospital stay, defined as contrast-induced nephropathy stage two or three, and occurrence of stroke, cardiovascular hospitalization, major vascular complications, or mortality within the 3-month period beginning from the time of the index procedure.

2.1 | Ethical Approval

We conducted this study in accordance with the Declaration of Helsinki guidelines. The institutional ethics committee approved it with approval ID IR. RHC.REC.1402.100. All data was deidentified, and a unique identifier number was assigned to each participant to ensure that the participants' identities remained confidential. Informed consent was obtained from all participants.

2.2 | Device Description

Myval is a next-generation balloon-expandable THV system. The device is structured on a nickel–cobalt alloy (MP35N) frame, which allows for optimal radial strength and radiopacity. The valve design is characterized by a unique honeycomb hybrid design cell structure comprising only one design element—a hexagon (large and small). The upper half of the frame (53% of expanded frame height) is composed of a large open-cell hexagonal configuration (clinical propensity to un-jail coronary ostia which preserves coronary flow); while the lower half of the frame (47% of expanded frame height) is composed of two short rows of close-cell hexagonal configuration providing high radial strength required at the annular base to ensure orthotopic valve fixation. The valve construction material is decellularized bovine pericardium tissue, crafted into a tri-leaflet valve, fixed towards the valve outflow zone at three equipoised (separated at 120°) vertical commissural posts on the metal frame. The lower closed-cell part of the valve frame has an internal skirt made of Polyethylene Terephthalate (PET). Additionally, the external skirt sits on the outer frame. Myval THV is delivered using a specially designed hi-flex, over-the-wire balloon catheter system—Navigator THV delivery system (Meril Life Sciences Pvt. Ltd., India). Myval is available in unique dimensional matrices ranging from conventional (20, 23, 26, and 29 mm), intermediate (21.5, 24.5, and 27.5 mm), and extra–large (30.5 and 32 mm) sizes. The availability of the wide diameter range ensures optimal sizing of bioprosthetic valve to the patient's computed tomography (CT)-derived annulus diameter, thus preserving the bioprosthetic valve geometry and respecting the patient's aortic root complex. All diameters of Myval THV are compatible with 14 Fr Python introducer sheath (Meril Life Sciences Pvt. Ltd., India). Additionally, in case of a challenging anatomy where the operator is unable to cross the annulus, undeployed Myval THV can be fully retrieved through the Python sheath out of the patient. During fluoroscopy, the crimped hexagonal cells of Myval THV over the Navigator delivery system appear as an alternative dark-light band-like pattern that facilitates the valve implantation procedure. The delivery system allows the flexion of the distal part, which lowers the risk of periprocedural strokes during arch navigation. The sub-annular depth of Myval THV across the diameter range is normally 3–3.5 mm. This shallow deployment of the valve does not affect the membranous septum, thus preventing a new conduction system disorder [6, 8, 12] (Figure 1).

We used the BAVARD method and ICD (inter-commissural diameter) measurement for BAV patients, and if needed, we used the circular method using a virtual valve. For severely calcified patients with features indicating a high risk of complications like annular rupture or risk of severe paravalvular regurgitation, we tend to deploy self-expandable THV, while for the ones without these characteristics, we inflated once with full expansion of THV and assessed the gradient and paravalvular leakage with hemodynamic and echocardiographic parameters after the procedure. If these assessments showed a high mean gradient or more than moderate paravalvular leakage, we inflated one more time with the same balloon, increasing the prior volume by 1 cc.

2.3 | Statistical Analysis

We employed SPSS V.26 (IBM Inc., Chicago, IL, USA) and GraphPad Prism (V9.0, GraphPad Software Inc., San Diego, CA, USA) for data visualization, summarization, and statistical analysis. All categorical variables are presented as frequency (percentage), and all continuous variables are summarized as mean±Standard Deviation (SD). A paired Wilcoxon signed-rank test was employed for comparison of ordinal variables, that is, pre- and post-procedural NYHA class and Mitral Regurgitation (MR) severity. This test was prespecified and conducted in a two-tailed manner, with p-value < 0.05 being considered statistically significant.

3 | Results

3.1 | Baseline Patients' Characteristics

From September 2021 to August 2023, a total of 92 consecutive patients who underwent TAVR with the Myval THV were included in the study. Of these, 61 (66.3%) were male, with an average age of 76.8 ± 7.3 years. Bicuspid Aortic Valve (BAV) was present in 6 (6.5%) patients. While moderate to severe Aortic Regurgitation (AR) was observed in 45 (48.9%) patients. Moderate to severe aortic valve calcification was identified in 70 (76.1%) patients. The mean STS score was 5.9 ± 3.2%. Detailed baseline clinical, ECG, echocardiographic, and imaging parameters are summarized in Table 1. Two patients were lost to follow-up (2.2%).

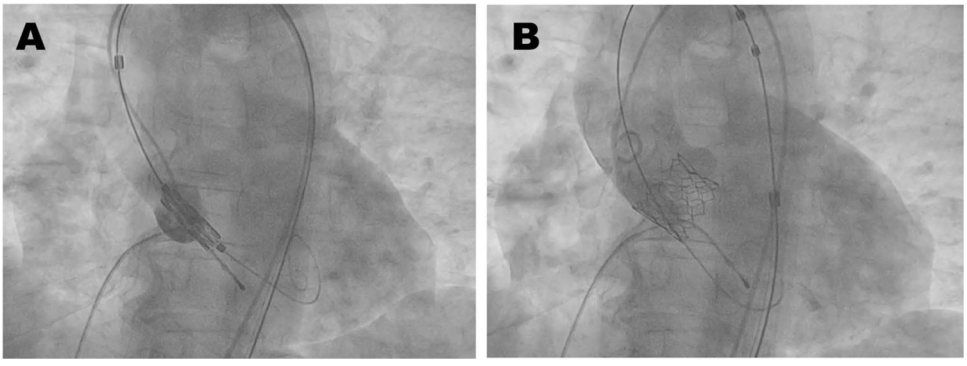

FIGURE 1 | Deployment of the Myval valve in a patient with aortic stenosis. Positioning of the Myval Valve. The central dense marker band of the crimped prosthesis is aligned with the plane of the aortic valve annulus to ensure accurate placement. (A) Postimplantation result. (B) Successful deployment of the Myval THV within the aortic annulus, with no evidence of PVL or malposition.

TABLE 1 | Baseline characteristics and clinical parameters of the study population.

Baseline characteristics			Myval ($n = 92$)
Age (years)			76.8 ± 7.3
Male (%)			61 (66.3)
Body surface area (m^2)			1.7 ± 0.1
History of chronic conditions		Smoking	24 (26.1)
		Diabetes	22 (23.9)
		Hypertension	49 (53.3)
		Chronic kidney disease	16 (17.4)
		Chronic heart failure	20 (21.7)
Previous history and interventions		Coronary artery bypass grafting	15 (16.3)
		Percutaneous coronary interventions	7 (7.6)
		Previous myocardial infarction	2 (2.2)
		Cerebral vascular disease	3 (3.3)
		Aortic valve repair	1 (1.1)
		Transcatheter aortic valve implantation	0 (0)
NYHA function class		I	1 (1.1)
		II	15 (16.3)
		III	68 (73.9)
		IV	8 (8.7)
ECG characteristics		Atrial fibrillation	10 (10.9)
		Wide QRS complex	16 (17.4)
		Atrioventricular block	1 (1.1)
Echocardiographic findings		LVEF (%)	45.8 ± 13.5
		LVEDVI (mL/m^2)	64.1 ± 24.4
		Aortic regurgitation (moderate/severe)	45 (48.9)
		Aortic calcification (moderate/severe)	70 (76.1)
		Mitral regurgitation (moderate/severe)	39 (42.4)
		Mean aortic valve gradient (mmHg)	44.3 ± 14.8
		Peak aortic valve gradient (mmHg)	74.5 ± 20.9
		Peak aortic valve velocity (m/s)	4.1 ± 0.6
		Aortic valve area (cm^2)	0.8 ± 0.2
		Ascending aorta diameter (cm)	3.7 ± 0.5
		Bicuspid aortic valve	6 (6.5)
Computed tomography findings	Aortic root diameter (mm)		35.2 ± 6.6
	Annulus diameter (mm*mm)		27.5 ± 2.8*23.1 ± 2.7
	Annulus area (mm^2)		496.3 ± 90.6
	Annulus perimeter (mm)		80.2 ± 7.3
	Sinus of Valsalva width (mm)	Right	30.8 ± 3.2
		Left	31.7 ± 3.1
		Non coronary	32.29 ± 3.5
	Right ostial coronary height (mm)		14.5 ± 3.2
	Left ostial coronary height (mm)		13.0 ± 3.2
	Calcium score (AU)		2726 ± 1808
Society of thoracic surgeons score (%)			5.9 ± 3.2

Note: Values are *n* (%) or mean ± SD.
Abbreviations: AU, Agatston unit; ECG, electrocardiogram; LVEDVI, left ventricular end-diastolic volume index; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association functional classification.

3.2 | Procedural Characteristics

Table 2 describes the procedural details. The most commonly used Myval THV sizes in this study were 24.5, 23, and 27.5 mm, with 30.4%, 26.1%, and 17.4%, respectively. The 24.5 mm was also the most frequent Myval THV size in BAV patients, used in half of BAV patients. The 26 mm was used for two of the remaining three BAV patients and 29 mm for the last. Pre-dilation was performed in 32 (34.8%) patients. The technical success was achieved in 86 (93.5%) patients. The average length of hospital and ICU stays was 6.2 ± 6.8 days and 1.9 ± 4.7 days, respectively.

3.3 | Procedural Outcomes and Complications

In this study, there were three (3.3%) in-hospital deaths. Coronary compression occurred in two (2.2%) patients, whereas no cases of MI were reported. TIA was experienced by one (1.1%) patient, and six (6.5%) patients developed ARF. Major bleeding and annulus rupture were observed in two (2.2%) and one (1.1%) patients, respectively. Permanent pacemaker implantation was required for six patients (6.5%). Of these, before TAVR, two had atrial fibrillation (AF), and two presented with a wide QRS complex, but none had an atrioventricular (AV) block, and none exhibited complete right bundle branch block. Angiography footage demonstrated 2+ PVL in three (3.3%) and 3+ in seven (7.7%) patients. Major vascular complications were observed in six (6.6%) patients, including two (2.2%) with visceral ischemia and one each (1.1%) with retroperitoneal hemorrhage, annular rupture, access site hematoma causing neurological impairment and vascular perforation leading to major bleeding. The one patient experiencing annular rupture did not have any risk factors except for smoking, had an ascending aorta diameter of 3.7 cm, aortic valve area of 0.6 cm^2, peak gradient of 71 mmHg, and severe calcification on the annulus, and one nodular calcification on the left coronary cusp. The patient died during hospitalization. Minor vascular complications occurred in 13 (14.3%) patients, with 11 (12.4%) experiencing access site hematomas, two (2.2%) with pseudoaneurysms, and 1 (1.1%) with vascular dissection.

A total of 7 patients (7.69%) had ostial heights less than 10 mm; for patients with ostial heights less than 10 mm or leaflet heights of more than 10 mm, a guidewire with a stent was parked in the left system. Coronary obstruction complicated the procedure in two

TABLE 2 | Procedural characteristics of study population.

Parameters		Myval ($n = 92$)
Myval size (mm)	20	1 (1.1)
	21.5	1 (1.1)
	23	24 (26.1)
	24.5	28 (30.4)
	26	11 (12.0)
	27.5	16 (17.4)
	29	7 (7.6)
	30.5	4 (4.3)
Pre-dilation		32 (34.8)
Post-dilation		0 (0.0)
Access site closure	Arteriotomy	39 (42.4)
	Proglide	53 (57.6)
Technical success		86 (93.5)
Length of hospital stay (day)		6.2 ± 6.8
Length of ICU stay (day)		1.9 ± 4.7

Note: Values are summarized as *n* (%) or mean ± SD.
Abbreviation: ICU, intensive care unit.

TABLE 3 | Post-procedural outcomes.

Outcomes	Myval ($n = 92$)
In-hospital mortality	3 (3.3)
Myocardial infarction	0 (0.0)
Coronary compression	2 (2.2)
Stroke or TIA	1 (1.1)
Acute renal failure	6 (6.5)
Major bleeding	2 (2.2)
New permanent pacemaker implantation	6 (6.5)
Valve-related dysfunction requiring a repeat procedure	0 (0.0)
Conversion to surgery	0 (0.0)
Paravalvular leak	
1+	16 (17.6)
2+	7 (7.7)
3+	3 (3.3)
4+	0 (0.0)
Major vascular complication	6 (6.6)
Perforation	1 (1.1)
Dissection	0 (0.0)
Limb ischemia	0 (0.0)
Access site hematoma	1 (1.1)
Retroperitoneal hemorrhage	1 (1.1)
Pseudoaneurysm	0 (0.0)
Visceral ischemia	2 (2.2)
Annulus rupture	1 (1.1)
Irreversible nerve injuries related to vascular access	0 (0.0)
Minor vascular complication	13 (14.3)
Perforation	0 (0.0)
Dissection	1 (1.1)
Limb ischemia	0 (0.0)
Access site hematoma	11 (12.4)
Pseudoaneurysm	2 (2.2)
Device migration or embolization	0 (0.0)
Endocarditis	0 (0.0)

Note: Values are summarized as *n* (%).
Abbreviation: TIA, transient ischemic attack.

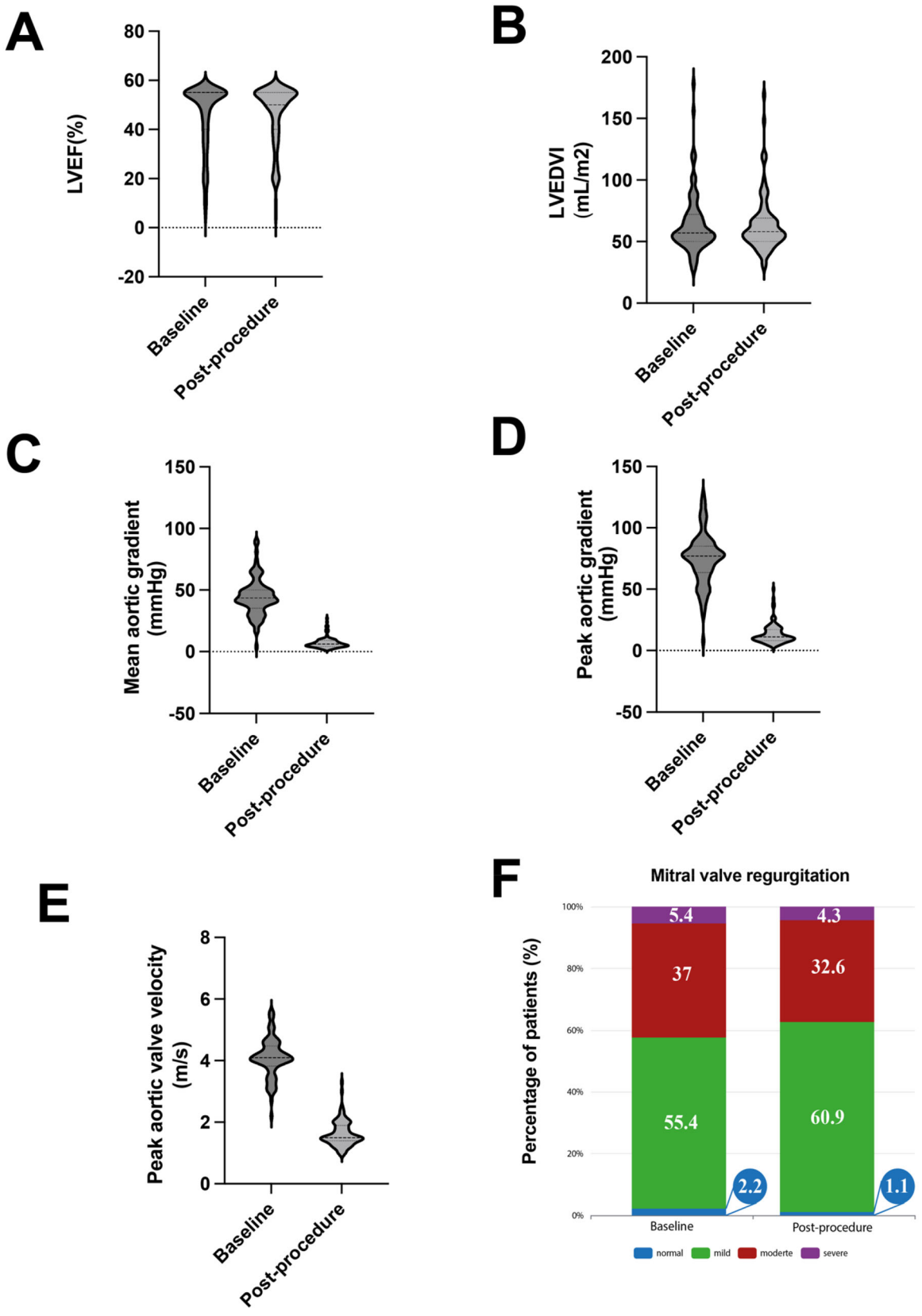

FIGURE 2 | The violin plot compares the impact of transcatheter aortic valve replacement using Myval on various echocardiographic parameters: ejection fraction, left ventricular end-diastolic volume index, mean aortic valve gradient, peak aortic valve gradient, and peak aortic valve velocity. The plots (A–E) display the medians as well as the 25th and 75th percentiles. Additionally, improvements in mitral valve regurgitation, assessed echocardiographically before and after the procedure, are shown in plot (F).

patients (2.2%), with ostial heights of 10.2 and 10 mm, and in these two cases, we parked a guidewire and a stent in the left system, considering the leaflet height of more than 10 mm. Inflation of the parked stent within the coronary artery resulted in the resolution of coronary obstruction in both cases. None of the coronary obstruction cases experienced in-hospital mortality.

There were no instances of valve-related dysfunction leading to repeat procedures or surgeries. Additionally, device migration, embolization, and endocarditis were not observed during hospitalization. Vascular access-related nerve injuries occurred in five (5.4%) patients, all of which resolved before discharge. Details of the procedural outcomes and complications are provided in Table 3.

3.4 | Echocardiographic Findings

Figure 2 demonstrates significant post-procedural reductions in mean aortic gradient (from 44.3 ± 14.8 to 7.159 ± 4.6 mmHg) and peak aortic valve velocity (from 74.5 ± 20.9 to 13.42 ± 8.1 cm/s, and from 4.1 ± 0.6 to 1.6 ± 0.4 m/s). Conversely, the Left Ventricular Ejection Fraction (LVEF) and End-Diastolic Volume (LVEDV) experienced minimal changes, with LVEF altering from $45.8 \pm 13\%$ to $46.10 \pm 12.5\%$ and LVEDV from 64.1 ± 24.4 to 63.75 ± 22.6 mL/m^2. The proportion of patients with moderate to severe Mitral Valve Regurgitation (MR) decreased after the procedure, from 39 (42.4%) pre-procedure to 34 (36.9%) postprocedure (p value: 0.45).

3.5 | NYHA Functional Outcomes

The NYHA functional class showed significant improvement (p value < 0.001) from baseline to discharge, as depicted in Figure 3.

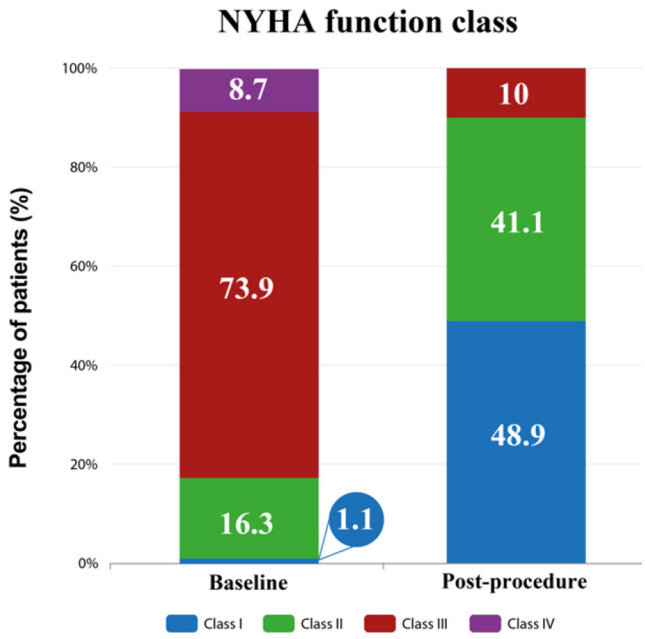

FIGURE 3 | Clinical status of patients before and following the procedure, categorized according to the New York Heart Association Functional Classification.

3.6 | Clinical Follow-Up at 3 Months

Table 4 provides a detailed summary of the clinical outcomes, including MACE, at the 3-month follow-up. The overall mortality rate at 3 months was 5.4%, with five deaths reported—three occurring in-hospital and two post-discharge. Additionally, 2.2% of patients (two individuals) experienced a stroke or TIA after discharge. One patient (1.1%) suffered a TIA during hospitalization without any stroke, resulting in an overall 3-month stroke or TIA rate of 3.2% (three patients). Another 2.2% of patients required hospital readmission due to cardiac issues within the 3-month period. Although no major vascular complications were reported after discharge, two patients (2.2%) experienced major vascular complications during their hospitalization, resulting in an overall rate of 2.2% within the 3-month period.

4 | Discussion

The technical success rate in this study was 93.5%, which is consistent with previous research ranging from 93.2% to 100% [3, 7, 8, 13–19]. We observed 3+ PVL in 3.3% of our patients, evaluated by angiography, which was in line with other studies suggesting that moderate–severe PVL ranges from 0% to 25.9% following Myval TAVR [3, 7, 8, 13–22].

We summarized the prior publication in Table 5. Only 8.7% of our patients required Permanent Pacemaker Implantation (PPI) after the procedure, similar to other Myval studies that range from 0% to 31% [3, 7, 8, 13–24]. In this regard, the study by Magyari et al. reported that a new PPI was necessary in 34% of Bicuspid Aortic Valve (BAV) cases and 30.4% of Tricuspid Aortic Valve (TAV) cases [8]. A comparison of Myval with the other five THVs demonstrated that patients for whom Myval was implanted had the lowest rate of new PPI. Although this difference did not reach a statistically significant difference between Myval and Sapien 3 and Acurate, it was significantly lower for Myval compared to Evolut, Portico, and Allegra [23].

We believe Myval THV precise implantation has some technical differences from other balloon expandable platforms. Its foreshortening and precise positioning to achieve proper depth could impact conduction disturbances. As operators get used to its implantation, the need for a permanent pacemaker will potentially decrease.

TABLE 4 | Outcomes at 3-month follow-up.

Outcome	3-months follow-up ($n = 92$)
Mortality	5 (5.4)
Stroke or TIA	3 (3.2)
Cardiovascular hospitalization	2 (2.2)
Major vascular complication	2 (2.2)

Note: Values are n (%).
Abbreviation: TIA, transient ischemic attack.

TABLE 5 | Comprehensive review of clinical outcomes of previous studies evaluating the Myval transcatheter heart valve.

Author, year, country	Study design	Population	STS score (%)	Technical success (%)	Device success (%)	Early Safety (%)	Longest follow-up	Mortality (%)	Stroke (%)	Kidney dysfunction (stage 2,3) (%)	Major vascular complications (%)	Moderate to severe PVL (%)	New permanent pacemaker (%)	NYHA function class I/II baseline→ follow up	Ref
Akyüz, 2021, Turkey	Retrospective single-center single arm	25 severe AS patients	5.4 ± 3.5	NM	23 (92)	NM	3 months	2 (8.0)	0 (0.0)	4 (16.0)	1 (4.0)	2 (8.0)	2 (8.0)	12% → 72%	[22]
Barki, 2022, Italy	Retrospective single-center study	166 severe AS Patients (58 Myval)	NM	57 (98.3)	55 (94.8)	47 (81.0)	6 months	3 (5.2)	2 (3.4)	1 (1.7)[a]	1 (1.7)[a]	15 (25.9)	6 (10.3)	32.8% → 96.6%	[13]
Baumbach, 2024, Multinational	Non-inferiority randomized controlled trial	768 severe AS Patients (384 Myval)	2.6 [1.7–4.0]	365 (96.3)	345 (91.0)	339 (89.4)	30 days	9 (2.3)	12 (3.1)	4 (1.0)	6 (1.6)	8 (2.1)	57 (15.0)	22.7% → 93.5%	[14]
Delgado-Arana, 2022, four European countries	Propensity match of a prospective multicenter study	416 severe AS Patients (103 Myval)	3.3 [2.2–5.4]	96 (93.2)	NM	5 (4.9)	30 days	1 (1.0)	0 (0.0)	3 (2.9)	0 (0.0)	1 (1.0)	6 (5.8)	NM	[15]
Garcìa-Gòmez, 2021, five European countries	Retrospective multi-center single-arm	100 severe AS patients	2.4 ± 0.8	99 (99.0)	NM	3 (3.0)	30 days	0 (0.0)	1 (1.0)	0 (0.0)	3 (3.0)	4 (4.0)	8 (8.0)	NM	[16]
Halim, 2023, Netherlands	Retrospective single-center propensity-matched study	223 severe AS Patients (91 Myval)	NM	NM	NM	NM	12 months	8 (8.8)	6 (6.6)	5 (5.5)[a]	0 (0.0)[a]	1(1.1)[a]	4 (4.4)[a]	NM	[20]
Halim, 2023, Netherlands	Prospective single-center single-arm study	120 severe AS patients	4.0 ± 2.8	118 (98.3)	NM	NM	6 months	2 (1.7)	7 (5.8)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	23.3% → 100%	[17]
Holzamer, 2023, Multinational	Retrospective multicenter single-arm study	10 severe AS Patients with extremely large aortic annuli	2.66 ± 1.37	10 (100)	10 (100)	NM	30 days	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	2 (20.0)	0% → 100%	[3]
Kilic, 2024, three European countries	Retrospective multicenter single-arm study	207 severe AS patients	4.0 ± 1.9	204 (98.5)	189 (91.3)	161 (77.8)	24 months	36 (17.4)	20 (9.7)	8 (3.9)	3 (1.4)	10 (4.8)	23 (11.1)	26% → 98%	[18]
Magyari, 2023, Hungary	Retrospective Single-center single arm	100 severe AS patients	5.6 ± 3.9	99 (99.0)	99 (99.0)	NM	12 months	8 (8.0)	5 (5.0)	3(3.0)	6(6.0)	0(0.0)	31 (31.0)	15% → 100%	[8]
Moscarella, 2024, Italy	Retrospective single-center cohort study	166 severe AS Patients (58 Myval)	NM	NM	NM	NM	24 months	6 (10.3)	1 (1.7)	8 (13.8)	1 (1.7)	2 (4.3)	6 (10.3)	NM	[21]
Santoz Martinez, 2022, four European countries	Retrospective multicenter study	1131 severe AS Patients (135 Myval)	NM	NM	NM	NM	Post operation	0 (0.0)	0 (0.0)	NM	0 (0.0)	NM	10 (7.4)	NM	[23]

(Continues)

TABLE 5 | (Continued)

Author, year, country	Study design	Population	STS score (%)	Technical success (%)	Device success (%)	Early Safety (%)	Longest follow-up	Mortality (%)	Stroke (%)	Kidney dysfunction (stage 2,3) (%)	Major vascular complications (%)	Moderate to severe PVL (%)	New permanent pacemaker (%)	NYHA function class I/II baseline→ follow up	Ref
Sharma, 2020, India	Prospective multi-center single-arm	30 severe AS patients	6.4 ± 1.8	29 (96.7)	30 (100.0)	3 (10.0)	12 months	4 (13.3)	0 (0.0)	1 (3.3)	2 (6.7)	0 (0.0)	0 (0.0)	30% → 100%	[7]
Testa, 2023, Italy	Prospective multi-center single-arm registry	100 severe AS patients	4.3 ± 3.3	100 (100)	99 (99.0)	NM	24 months	7 (7.0)	3 (3.0)	3 (3.0)	0 (0.0)	5 (5.0)	9 (9.0)	15% → 74%	[19]
Özderya, 2024, Turkey	Retrospective single-center single-arm	110 severe AS patients	Pacemaker required group: 3.63 [1–9] No pacemaker required group: 3.1 [1.3–15.05]	NM	NM	NM	Post operation	4 (3.6)	0 (0.0)	NM	NM	NM	17 (15.4)	NM	[24]

Note: Data are presented as frequency (%), mean ± standard deviation, or median [IQR].
Abbreviations: AS, aortic stenosis; NM, not mentioned; NYHA, New York Heart Association; PVL, paravalvular leakage; STS, Society of Thoracic Surgeons.
[a]Indicates data presented at 30 days, regardless of the latest follow-up period.

Only 6.5% of our patients developed ARF (stage 2 or 3), similar to other studies ranging from 0% to 16% [3, 7, 8, 13–23]. We encountered lower EF compared to prior studies, which might explain the slightly higher rate of ARF due to cardio-renal syndrome [8, 22]. Despite the design of Myval to prevent coronary obstruction, Myval implantation brought about coronary compression in two patients (2.2%). The majority of studies on Myval did not have any cases of coronary obstruction; however, it has been reported up to 4% in some studies [3, 7, 16, 22, 25]. Nearly 7% of our patients developed major vascular complications. The rate of major vascular complications ranges from 0% in many studies to 6.7% pursuant to Myval implantation, according to prior studies [3, 7, 8, 13–23].

We encountered 3.3% in-hospital mortalities following Myval implantation. In-hospital mortality ranged from 1% to 8% following Myval implantation, as found in preceding publications [8, 22, 24]. Three-month follow-up of patients revealed a 2.2% all-cause mortality rate in the current study. The rate of 1-month and 1-year all-cause mortality of Myval ranges from 1% to 3.3% and 7% to 13%, respectively, according to preceding studies [7, 8, 25, 26].

In the current study, one patient (1.1%) exhibited TIA during hospitalization without any stroke, and two others (2.2%) experienced an episode of TIA or stroke within the 3-month follow-up period. Consistent with our study, most studies did not encounter in-hospital stroke following Myval implantation [3, 22, 25, 27]. The rate of post-Myval implantation stroke was reported 2% during the first month and 7% during the first year which was similar to self-expanding Evolut [26]. Other studies reported strokes within the first year of Myval implantation in the range of 0% to 6.6% of patients [7, 8, 17].

4.1 | Limitation

A limitation of this study is the small sample size and its retrospective, single-center design. Another limitation includes the assessment of safety and efficacy over a relatively short follow-up period. Additionally, our study has limitations in evaluating device success and early safety, as this requires patient assessments 30 days postoperation. However, the study endpoints were confined to post-procedural outcomes and 3-month follow-up data. Furthermore, the lack of comparison with other THV systems underscores the need for future trials with larger, more diverse populations.

5 | Conclusion

In conclusion, this study highlights the safety and efficacy of Myval THV in the treatment of patients with severe AS who are at intermediate to high surgical risk. The findings demonstrate a satisfactory technical success rate accompanied by low incidences of complications and mortality. Furthermore, the occurrence of severe PVL and the need for a permanent pacemaker was infrequent, underscoring the potential of the Myval THV as a favorable option for this patient population. These results provide a promising outlook for the application of Myval

THV in clinical settings and warrant further investigation to validate these outcomes in broader patient cohorts.

Author Contributions

Mohammadreza Baay: methodology, resources, writing – original draft, writing – review and editing. **Ata Firouzi:** conceptualization, methodology, resources, writing – original draft, writing – review and editing. **MohammadHossein MozafaryBazargany:** data curation, formal analysis, writing – original draft, writing – review and editing. **Amir Azimi:** formal analysis, visualization, writing – original draft, writing – review and editing. **Armin Elahifar:** resources, writing – review and editing. **Mohammad Javad Alemzadeh-Ansari:** resources, writing – review and editing. **Zahra Hosseini:** resources, writing – review and editing. **Seifollah Abdi:** resources, writing – review and editing. **Amineh Safairad:** investigation, writing – review and editing. **Peyman Bashghareh:** data curation, investigation, writing – original draft, writing – review and editing. **Ehsan Khalilipur:** conceptualization, investigation, methodology, resources, writing – review and editing.

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The authors have nothing to report.

Ethics Statement

We conducted this study in accordance with the Declaration of Helsinki guidelines. The institutional ethics committee approved it with approval ID, IR. RHC.REC.1402.100. All data was deidentified, and a unique identifier number was assigned to each participant to ensure that the participants' identities remained confidential.

Conflicts of Interest

S. Abdi has a role as a clinical proctor for the Sapien 3 valve by Edwards Lifesciences. E. Khalilipur is certified as an independent operator in transcatheter heart valve replacements with the Myval THV system. A. Firouzi is an international proctor for Myval THV. The remaining authors declare no conflicts of interest. Supporting sources were not involved in study design, data collection, analysis, interpretation, writing the report, or deciding to submit the report for publication.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Transparency Statement

The corresponding authors Peyman Bashghareh, Ehsan Khalilipur affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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