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Original Article

Early outcomes of balloon-expandable Myval, Sapien-3, and self-expandable valves in aortic stenosis: Propensity score-matched analysis

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ABSTRACT

Objective: Balloon-expandable (BE) Myval transcatheter heart valve (THV) series demonstrated safety and efficacy in aortic stenosis (AS) in low, intermediate/high surgical risk patients. However, there is a limited comparative data with other contemporary valves. The study aimed to compare the early clinical outcomes of next-generation BE Myval THV series with Sapien-3 THV and self-expandable (SE) valves in severe AS patients.
Methods: This retrospective study included 315 AS patients who underwent transcatheter aortic valve implantation (TAVI) with BE Myval THV series (n = 108), or BE Sapien-3 THV (n = 99) or SE valves (n = 108). Propensity-matching data (86 pairs) compared the clinical and hemodynamic outcomes at 30 days.
Results: No intraprocedural death/complications were reported post-TAVI. Aortic valve area was significantly improved in BE Myval THV series (0.57 ± 0.18 cm^2 to 2.93 ± 0.49 cm^2) and SE valves (0.60 ± 0.23 cm^2 to 2.66 ± 0.92 cm^2) cohorts from baseline to 30 days, and peak and mean aortic gradients were significantly (p < 0.0001) reduced. Permanent pacemaker implantations (PPI) requirement was 1.16% in BE Myval THV series, 4.65% in Sapien-3 THV and 10.47% in SE valves, whereas 3.49% death observed in SE valves, 2.33 % in Myval THV series and 1.19% in Sapien-3 THV at 30 days. SE valves had 13.04% moderate and severe paravalvular regurgitation (PVR), while Myval THV series and Sapien-3 THV cohort had none.
Conclusion: Safety and efficacy outcomes were comparable among three cohorts, except for higher PPI rate in SE valves cohort. At 30 days, clinical outcomes showed acceptable rates of stroke and death. Valve hemodynamics were excellent, with low rate of PVR in Myval THV series cohort.

1. Introduction

In the present years, transcatheter therapies have emerged as the primary therapeutic option for most patients with aortic stenosis (AS).[1–4] The development of novel transcatheter heart valve (THV) systems for transcatheter aortic valve implantation (TAVI) has significantly enhanced clinical outcomes, reduced the risk for procedure-related adverse events, and lowered treatment costs.[5–7].

The Balloon-expandable (BE) Sapien-3 THV system (Edwards Lifesciences, California, USA) has demonstrated good clinical outcomes and hemodynamic valve performance, with very low rates of early mortality, stroke, and major vascular complications (all <2%) in low-risk patients with native severe AS.[6] In comparison to several self-expandable (SE) valves, it has demonstrated comparable outcomes in terms of residual aortic regurgitation (AR), positively impacting major outcomes.[4,7,8]

The BE Myval THV series (Meril Life Sciences Pvt Ltd, India) is a new-generation THV system that has demonstrated safety and short-term clinical efficacy.[9] In comparison to other BE valves, Myval THV series offers a broader and more comprehensive range of device sizes, including intermediate and extra-large (XL) sizes. This tailored device sizing minimizes the risk of under- or oversizing, potentially reducing procedural adverse events and improving clinical outcomes.[10–12] The Myval THV series has been associated with high device success rates exceeding 97%, low incidences of stroke, vascular complications, and pacemaker implantation, and excellent post-procedural hemodynamics in multicenter, real-world and early clinical experiences.[13–15]

The ongoing prospective, randomized, controlled, non-inferiority LANDMARK trial (NCT04275726) is designed to compare the safety and effectiveness of the Myval THV series with contemporary THV series (BE Sapien THV and SE Evolut THV series) in patients with severe

Abbreviations: A-FIB, atrial fibrillation; AS, aortic stenosis; BE, balloon expandable; CAD, coronary artery disease; CAG, coronary angiography; PPI, permanent pacemaker implantation; PTCA, percutaneous transluminal coronary angioplasty; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve.

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symptomatic native aortic valve stenosis. The LANDMARK trial demonstrated that the Myval THV series is non-inferior to contemporary THV series in real-world patients with AS.[16] It also reported comparable hemodynamic outcomes and lower rates of moderate prosthesis–patient mismatch (PPM) with Myval THV series compared to Sapien THV series, while maintaining comparable outcomes to Evolut THV series.[17] The COMPARE-TAVI 1 trial (NCT04443023), another large multicenter randomized study, demonstrated the non-inferiority of Myval THV series to Sapien-3 THVs for the composite endpoint of death, stroke, moderate or severe aortic regurgitation, or moderate or severe haemodynamic THV deterioration at 1 year.[18]

The MYLAND registry and other European multicenter studies further confirmed favorable procedural success (≈98–99%), low rates of ≥moderate paravalvular leak (≤1%), and acceptable 30-day mortality (≤2%), establishing Myval THV series as a safe and efficient option in routine TAVI practice.[13,14,19]

Although large randomized trials such as the COMPARE-TAVI trial and LANDMARK trial have established the safety and non-inferiority of Myval THV series versus contemporary transcatheter heart valves, these studies are conducted in controlled settings with selected patient populations. In contrast, real-world TAVI practice often involves heterogeneous anatomies, variable procedural strategies, and diverse valve platforms. Furthermore, data from Indian populations for bicuspid anatomy and smaller annular dimensions remain limited. Therefore, we aimed to investigate the early safety and hemodynamic outcomes of balloon-expandable Myval THV series, Sapien-3 THV, and self-expandable valves in Indian patients with AS undergoing TAVI in real-world procedural conditions, providing complementary evidence to randomized trials which addresses the critical evidence gap in contemporary TAVI practice.

2. Methods

2.1. Study design

This observational registry study was conducted between April 2016 and January 2024. A total of 315 patients with AS underwent TAVI, of which 108 patients were implanted with Myval THV series, 99 patients with Sapien-3 THV, and 108 patients with SE valves (Evolut, Evolut R, Evolut Pro, Evolut Pro+, Evolut Fx, Hydra, ACURATE neo, ACURATE neo2, Portico, and Navitor), respectively. The propensity score-matched cohort included 258 patients, with 86 patients in each group. The study protocol conformed to ethical guidelines as per the 1975 Declaration of Helsinki. All patients gave written informed consent for the procedure and data collection.

2.2. Baseline characteristics

Before TAVI, a comprehensive pre-procedural assessment was performed. This included demographic, clinical, and laboratory assessments (medical, surgical, and interventional history, symptoms, laboratory tests, risk evaluation, New York Heart Association [NYHA] class, EuroSCORE, Society of Thoracic Surgeons [STS] score, and FRAILTY risk assessment).

2.3. Cardiac assessments

Cardiac assessments were performed using electrocardiography, echocardiography, coronary angiography, and multi-slice computed tomography (MSCT). Echocardiographic examinations were performed according to the guidelines of the American Society of Echocardiography. The following measurements were obtained: left ventricular ejection fraction (LVEF), aortic valve morphology, aortic valve area, aortic valve mean gradients, mitral regurgitation (MR) and its severity, mean/peak transvalvular gradients and the degree and type of AR. The severity of AR was evaluated using a multiparametric approach and classified according to the Valve Academic Research Consortium-3 (VARC-3) recommendations.[20] Multidetector computed tomography (CT) examinations were performed in accordance with the guidelines of the Society of Cardiovascular Computed Tomography.[21,22]

2.4. Procedural details

The TAVI procedure was performed by an experienced team in the same catheterization laboratory, following guideline-driven protocols at both centers. Patients with bicuspid, tricuspid, and bioprosthetic valves were included in the study analysis.

Device size selection and suitability of each valve system were determined by the experienced TAVI team, aided by MSCT assessments. The TAVI procedure was conducted under general anaesthesia. The decision to perform pre- and post-dilatation was left to the discretion of the operating team, based on the anatomical and clinical characteristics of the patient.[23]

The procedural findings included the TAVI approach, fluoroscopy, procedural time, and contrast volume. Following TAVI, clinical evaluations were conducted in-hospital and at 30 days post-procedure.

2.5. Study devices

A detailed description of the Myval THV (Meril Life Sciences Pvt Ltd, India) was provided in earlier publications.[9] The Myval THV series received the Conformité Européenne, is made from bovine pericardium tissue with three leaflets and features an anti-calcification treatment known as AntiCa. The Myval THV series is available in conventional sizes (20 mm, 23 mm, 26 mm, and 29 mm), intermediate sizes (21.5 mm, 24.5 mm, and 27.5 mm), and extra-large sizes (30.5 mm and 32 mm). Importantly, the diameters can be further modified by adding or subtracting 1–2 mL of saline/contrast to the balloon, allowing for optimal device sizing which can be achieved with 0.5 mm increments. All diameters of the Myval THV series are compatible with a 14Fr Python introducer sheath.[24]

The Sapien-3 THV, trileaflet valve held on a chromium-cobalt frame, is made from bovine pericardium tissue, with a skirting of polyethylene terephthalate to reduce paravalvular leakage. It is available in 20 mm, 23 mm, and 26 mm sizes, compatible with a 14Fr expandable sheath (minimal vessel diameter 5.5 mm) and 29 mm compatible with a 16Fr expandable sheath (minimal vessel diameter 6 mm).[5]

The SE valves implanted in this registry included Evolut, Evolut R, Evolut Pro, Evolut Pro+, Evolut Fx, Hydra, ACURATE neo, ACURATE neo2, Portico, and Navitor. These valves were repositionable, partially recapturable, and deliverable using a dedicated delivery system compatible with 14/16-Fr sheaths, depending on the valve size. These valves are available in a range of sizes, including 23 mm, 26 mm, 29 mm, and 34 mm.[25] This cohort included multiple valve platforms and generations, which may differ in design characteristics and performance.

2.6. Study endpoints

The primary study endpoints included the degree of AR, mean and peak aortic gradients, and aortic valve area after matching baseline characteristics. Additional endpoints were procedural complications and clinical outcomes at 30 days, summarised as early safety and clinical efficacy according to VARC-3 criteria.[14]

Procedural complications consisted of valve embolization, annular rupture, coronary obstruction, and procedural death. Clinical outcomes at 30 days were all-cause mortality, all stroke, stage 2-4 acute kidney injury (AKI), new permanent pacemaker implantation (PPI), and major vascular complications.

2.7. Statistical analysis

Categorical variables were presented as frequencies (with

percentages), and comparisons between groups were performed using the Chi-square test or Fisher's exact test when necessary. Continuous variables were presented as mean ± SD or median (Q1–Q3). The normal distribution of continuous variables was tested using Shapiro–Wilk's test. Comparisons between groups were performed using ANOVA or the Kruskal–Wallis test, according to variable distribution. Tukey's or Bonferroni's post-hoc test was used for multiple comparisons. All tests were 2-sided with a significance level of 0.05.

Data from 86 matched cases in each group were compared after propensity score-matching. Propensity scores were calculated using binary logistic for the primary composite outcome and secondary outcomes, adjusted for the following baseline characteristics: age, body mass index, body surface area, EuroSCORE II, STS risk score, and LVEF at baseline. Pairs of patients were derived using the Greedy nearest neighbour method. Statistical analysis was performed using the R program (version 4.3.2).

3. Results

3.1. Baseline characteristics

Table 1 presents the baseline characteristics of the 315 patients who underwent TAVI at the study centers. Data from 258 patients who underwent TAVI with either the Myval THV series or the Sapien-3 THV or any SE valves were analysed, with 86 pairs included in the propensity score-matched analysis. The baseline data of the matched cohort comprising of 258 patients included in this propensity matched analysis with 86 patients in each arm is presented in Table 2.

The baseline characteristics of the matched cohort were well balanced across the Myval THV series, Sapien-3 THV, and SE valves cohort, with a few exceptions. The SE valves cohort had a lower percentage of males (51.16%; $p = 0.009$) compared to the Myval THV series (72.09%) and Sapien-3 THV (68.6%) cohort. The Sapien-3 THV cohort had a higher eGFR (69.68 ± 26.11 ml/min/1.73 m^2; $p = 0.033$) compared to Myval THV series (60.92 ± 21.54 ml/min/1.73 m^2) and SE valves (61.45 ± 25.54 ml/min/1.73 m^2) cohort. Pre-operative creatinine values were higher in the Myval THV series cohort (1.2 mg/dl; $p = 0.0237$) compared to the Sapien-3 (1.0 mg/dl) and SE valves (0.9 mg/dl) cohort. Additionally, the Myval THV series had a higher incidence of syncope (27.91%; ($p = 0.0005$) compared to Sapien-3 THV (10.47%) and SE valves (8.14%) cohort. More patients in the SE valves cohort had undergone previous aortic valve replacement before TAVI (12.79 %, $p = 0.0005$) compared to the Sapien-3 THV (3.49%) and Myval THV series (0%) cohort. Regardless of the aortic valve type implantation, most patients had NYHA class either 3 (76.36 %) or 4 (16.28%). Despite propensity matching, some baseline imbalances persisted, including differences in prior valve replacement and renal function.

Table 1
Baseline characteristics of overall patients.

Parameter	Overall ($n = 315$)	Myval THV series ($n = 108$)	Sapien-3 THV ($n = 99$)	SE valves ($n = 108$)	*p*-value
Age (in years)	72 (66-78)	73 (68-79)	72 (65-78)	71 (66-76)	0.077
Gender, n (%)					
Male	200 (63.49)	74 (68.52)	69 (69.70)	57 (52.78)	0.017
Female	115 (36.51)	34 (31.48)	30 (30.30)	51 (47.22)	
BMI (kg/m^2)	25.34 (22.74-29.04) ($n = 313$)	24.34 (21.59-28.13) ($n = 107$)	25.46 (23.72-29.91) ($n = 99$)	25.89 (22.93-29.24) ($n = 107$)	0.018
BSA (m^2), mean ± SD	1.75 ± 0.22 ($n = 313$)	1.72 ± 0.22 ($n = 107$)	1.80 ± 0.20 ($n = 99$)	1.74 ± 0.23 ($n = 107$)	0.029
Syncope, n (%)	55 (17.46)	28 (25.93)	12 (12.12)	15 (13.89)	0.016
Previous bioprosthesis AVR, n (%)	19 (6.03)	0 (0.00)	3 (3.03)	16 (14.81)	0.000
COPD, n (%)	57 (18.1)	19 (17.59)	17 (17.17)	21 (19.44)	0.901
eGFR (mL/min/1.73m^2), mean ± SD	63.64 ± 24.55 ($n = 315$)	60.55 ± 21.56 ($n = 108$)	69.29 ± 25.62 ($n = 99$)	61.55 ± 25.67 ($n = 108$)	0.020
Mean aortic gradient (mmHg), median (Q1-Q3)	47 (40-58) ($n = 314$)	48 (39-61) ($n = 108$)	44.5 (40-56.75) ($n = 98$)	47.5 (40-58) ($n = 108$)	0.784
Mean gradient <40 mmHg, n (%)	70 (22.29)	27 (25.00)	21 (21.43)	22 (20.37)	<0.0001
Aortic valve area (cm^2), median (Q1-Q3)	0.56 (0.44-0.7) ($n = 307$)	0.59 (0.44-0.7) ($n = 108$)	0.53 (0.44-0.7) ($n = 97$)	0.57 (0.45-0.71) ($n = 102$)	0.613
Annulus Perimeter (mm), median (Q1-Q3)	75.75 (69.53-81.35) ($n = 210$)	76.8 (70.1-83.3) ($n = 77$)	78.25 (72.15-83.15) ($n = 70$)	69.9 (61.35-76.3) ($n = 63$)	0.000
Annulus Area (mm^2), mean ± SD	445.21 ± 111.85 ($n = 210$)	467.29 ± 109.34 ($n = 77$)	483.93 ± 99.25 ($n = 70$)	375.19 ± 96.31 ($n = 63$)	0.000

Data was presented as median (IQR) unless specified. p-value was calculated using ANOVA test. AVR, aortic valve replacement; BMI, body mass index; BSA, body surface area; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; IQR, interquartile ranges; SE, self-expandable; SD, standard deviation.

3.2. Electrocardiogram, echocardiographic and multi-sliced computed tomography (MSCT) findings at baseline

The baseline cardiac assessment findings are summarised in Supplementary Table S1. At baseline, atrial fibrillation was present in 2.33% of the total patients, and one patient with left bundle branch block (LBBB) was implanted with the SE valves. Most patients in each cohort had tricuspid aortic valve morphology (60.08%), while 34.88% had bicuspid aortic valve morphology. The Myval THV series cohort had the highest percentage of tricuspid valve morphology (67.44 %), which was significantly different from the SE valves cohort. The distribution of bicuspid aortic valve was similar across all three, with the highest (38.37%) in the Sapien-3 THV cohort. The median EuroSCORE was 3.02 (1.87 – 5.86), the STS score was 2.95% (1.52 – 4.98%) and the Frailty score 4 (3 – 6), as shown in Supplementary Table S1. The mean annulus area was 454.08 ± 112.72 mm^2, with the Sapien-3 THV cohort having the largest annulus area (489.71 ± 103.87 mm^2), followed by the Myval THV series cohort (472.97 ± 109.84 mm^2) and the SE valves cohort having the smallest annulus area (379.19 ± 93.97 mm^2). The mean aortic annulus diameter was 23.97 ± 2.85 mm, with Sapien-3 THV and Myval THV series cohorts having similar diameters, while the SE valves cohort had a significantly smaller diameter (21.86 ± 2.7 mm). Left ventricular outflow tract (LVOT) calcification was higher in the Myval THV series (37.84 %) and SE (48.28 %) valves cohort compared to the Sapien-3 THV cohort (10.81%; Supplementary Table S1).

3.3. Procedural findings

The procedural findings are presented in Supplementary Table S2. The majority of the patients (91.86%) underwent TAVI through the right femoral artery. In the Sapien-3 THV cohort, two patients underwent TAVI through the left radial artery and the right femoral vein transeptal, respectively. Pre-dilatation was performed in 58.14% of the patients, with a significantly higher rate in the Myval THV series cohort (74.42%) compared to Sapien-3 THV (40.7%) ($p < 0.0001$) and SE valves (59.3%)

Table 2
Baseline characteristics of propensity score-matched cohorts.

Parameters	Overall (N = 258)	Myval THV series (*n* = 86)	Sapien-3 THV (*n* = 86)	SE valves (*n* = 86)	*p*-value
Age (years), median (Q1-Q3)	72 (65.25-78.75)	74 (67.25-80)	71.5 (64-78)	71 (65-76.75)	0.058
Gender, n (%)					
Male	165 (63.95)	62 (72.09)	59 (68.6)	44 (51.16)	0.009
Female	93 (36.05)	24 (27.91)	27 (31.4)	42 (48.84)	
BMI (kg/m^2), median (Q1-Q3)	25.41 (22.76-29.03)	24.36 (21.67-27.68)	25.46 (23.44-0.18)	25.99 (23.1-29)	0.023
BSA (m^2), mean ± SD	1.76 ± 0.22	1.73 ± 0.21	1.8 ± 0.2	1.74 ± 0.24	0.101
eGFR (mL/min/1.73m^2), mean ± SD	64.02 ± 24.71	60.92 ± 21.54	69.68 ± 26.11	61.45 ± 25.54	0.033
Creatinine in mg/dL (median, Q-Q3)	1.0 (0.8-1.3) (*n* = 137)	1.2 (0.9-1.4) (*n* = 57)	1.0 (0.8-1.2) (*n* = 45)	0.9 (0.7-1.3) (*n* = 35)	0.024
Comorbidities, n (%)					
Diabetes mellitus, *n* (%)	115 (44.57)	37 (43.02)	37 (43.02)	41 (47.67)	0.778
Hypertension, *n* (%)	181 (70.16)	54 (62.79)	63 (73.26)	64 (74.42)	0.186
Peripheral artery disease, *n* (%)	9 (3.49)	2 (2.33)	3 (3.49)	4 (4.65)	0.620
Syncope, *n* (%)	40 (15.5)	24 (27.91)	9 (10.47)	7 (8.14)	0.0005
Dyspnoea, *n* (%)	249 (96.51)	82 (95.35)	84 (97.67)	83 (96.51)	0.912
COPD, *n* (%)	49 (18.99)	14 (16.28)	16 (18.60)	19 (22.09)	0.285
Chronic kidney disease, *n* (%)	49 (18.99)	15 (17.44)	13 (15.12)	21 (24.42)	0.624
End-stage renal disease, *n* (%)	5 (1.94)	1 (1.16)	1 (1.16)	3 (3.49)	0.443
Cardiac history, n (%)					
Previous CABG, *n* (%)/	36 (13.95)	13 (15.12)	10 (11.63)	13 (15.12)	0.748
Previous PTCA, *n* (%)	34 (13.18)	11 (12.79)	9 (10.47)	14 (16.28)	0.525
Previous bioprosthesis AVR, *n* (%)	14 (5.43)	0 (0.00)	3 (3.49)	11 (12.79)	0.0005
Previous CVA or stroke, *n* (%)	22 (8.53)	7 (8.14)	7 (8.14)	8 (9.30)	0.912
Previous atrial fibrillation or flutter, n (%)	14 (5.43)	4 (4.65)	7 (8.14)	3 (3.49)	0.480
Previous permanent pacemaker implantation, *n* (%)	4 (1.55)	1 (1.16)	2 (2.33)	1 (1.16)	1.000
NYHA class, n (%)					
Class 2	19 (7.36)	8 (9.3)	7 (8.14)	4 (4.65)	0.070
Class 3	197 (76.36)	57 (66.28)	70 (81.4)	70 (81.4)	
Class 4	42 (16.28)	21 (24.42)	9 (10.47)	12 (13.95)	

AVR, aortic valve replacement; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass graft; CAD, coronary artery disease; CAG, coronary angiography; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; eGFR, estimated glomerular filtration rate; LRA, left radial artery; NYHA, New York Heart Association; PTCA, percutaneous transluminal coronary angioplasty; SD, standard deviation.

($p = 0.052$) cohort. The Sapien-3 THV cohort also had a higher pre-dilatation rate compared to the SE valves cohort ($p < 0.022$).

The size-wise distribution of implanted THVs is summarised in Supplementary Table S2. Post-dilatation was required in about 21.71% of the patients, with the highest in the SE valves cohort (46.51%). The fluoroscopy time was significantly shorter in the Myval THV series cohort [20.21 min, (15-28.11 min)] and longest in the SE valves cohort [28 min (20.63-43.5 min)]. The mean procedure time was 60 min, with the Myval THV series cohort having significantly shortest time (45-70 min) and the SE valves cohort the longest (60-90 min) procedural time. The mean contrast volume used was 150 mL.

3.4. Pre- and post-TAVI echo findings

Supplementary Table S3 presents a comparison of pre- and post-TAVI hemodynamics. The LVEF percentages were similar pre- and post-TAVI. The aortic valve area increased significantly in both the Myval THV series (0.57 ± 0.18 cm^2 vs. 2.93 ± 0.49 cm^2, $p = 0.008$) and SE valves (0.60 ± 0.23 cm^2 vs. 2.66 ± 0.92 cm^2, $p = 0.024$) cohort. There was no significant difference in AVA between BE Myval THV series and SE valves cohort at baseline and post-procedure. Following TAVI, there was a significant reduction ($p < 0.0001$) in the peak and mean aortic gradients in all cohorts.

3.5. Clinical outcomes

No intraprocedural deaths were noted in any of the cohorts. The median post-procedure hospital stay was 4 days, with Myval THV series patients staying between 3 and 5 days. The median ICU stay was 24 h. In-hospital stroke was noted in 2 (2.33%) patients of the Myval THV series cohort and 3 (3.49%) patients in the SE valves cohort. Of the total 14 new PPIs, the Myval THV series cohort had significantly fewer ($n = 1$) compared to the Sapien-3 THV ($n = 4$) and SE valves ($n = 9$) cohort. There were 4 in-hospital deaths: one in the Myval THV series cohort and 3 in the SE valves cohort. At 30 days, a total of 6 (2.34%) deaths were noted, three (3.49%) in the SE valves cohort, two in the Myval THV series cohort, and one in the Sapien-3 THV cohort (Table 3).

3.6. Procedural and clinical complications

Table 4 presents procedural and clinical complications. None of the cohorts experienced new or worsening MR, coronary obstruction, ventricular perforation, aortic dissection, or surgical cutdown. No blood transfusions were needed in any of the cohorts.

In the Myval THV series cohort, there were no instances of valve embolization, snaring, device recapture/retrieval, second valve implantation, pericardial tamponade, or annulus rupture. In the Sapien-3 THV cohort, there was one device retrieval, 1 second valve implantation, one pericardial tamponade, and one annulus rupture. In the SE valves cohort, there were three valve embolizations, one snaring, two device recapture/retrievals, and 2 second valve implantations.

A total of 8 (3.1%) minor vascular complications were noted – 5 (5.81%) in the Myval THV series cohort, 1 (1.16%) in the Sapien-3 THV cohort, and 2 (2.33%) in the SE valves cohort. Three major vascular complications were noted in the Myval THV series and SE valves (3.49% each) cohort. Stroke/Transient ischemic attack (TIA) was noted in one (1.16%) patient in the Myval THV series cohort and two (2.33%) patients in the SE valves cohort. The peripheral intervention was required in 4 patients in both the Myval THV series and SE valves cohorts. Placement of in-situ temporary pacing leads was required in 41 (47.67%) patients in the SE valve cohort, 15 (17.44%) in the Sapien-3 THV cohort, and 14 (16.28%) in the Myval THV series cohort.

Persistent new bundle branch block was least common in the Myval THV series cohort (3.49%) and most common in the SE valves cohort (10.59 %). New onset atrial fibrillation was noted in 3 (3.49 %) patients in the SE valves cohort and one (1.16 %) in the Myval THV series cohort.

Table 3
Clinical outcomes during hospital stay and at 30 days.

Parameter	Overall (n = 258)	Myval THV series (n = 86)	Sapien-3 THV (n = 86)	SE valves (n = 86)	p-value	p-value (Myval THV series vs Sapien-3 THV)	p-value (Myval THV series vs SE valves)	p-value (Sapien-3 THV vs SE valves)
Intraprocedural death, n (%)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1.000	1.000	1.000	1.000
Post-procedure hospital stay, days, median (range)	4 (3.25-5)	4 (3-5)	4 (4-6)	5 (4-6)	0.030	0.171	0.013	0.442
ICU stay, hours, median (range)	24 (22-27)	24 (22-37.5)	23 (22-24)	24 (21.25-40)	0.089	0.010	1.000	0.074
In-hospital stroke, n (%)	5 (1.94)	2 (2.33)	0 (0.00)	3 (3.49)	0.376	0.497	1.000	0.246
New permanent pacemaker implantation, n (%)	14 (5.43)	1 (1.16)	4 (4.65)	9 (10.47)	0.028	0.368	0.023	0.249
In-hospital mortality, n (%)	4 (1.55)	1 (1.16)	0 (0.00)	3 (3.49)	0.328	1.000	0.621	0.246
30 days mortality, n (%)	6 (2.34)	2 (2.33)	1 (1.19)	3 (3.49)	0.874	1.000	1.000	0.621

ICU, intensive care unit; SE, self-expandable; vs, versus.

Table 4
Procedural and clinical complications.

Outcomes, n (%)	Overall (n = 258)	Myval THV series (n = 86)	Sapien-3 THV (n = 86)	SE valves (n = 86)	p-value	p-value (Myval THV series vs Sapien-3 THV)	p-value (Myval THV series vs SE valves)	p-value (Sapien-3 THV vs SE valves)
Valve embolization	3 (1.16)	0 (0.00)	0 (0.00)	3 (3.49)	0.109	1.000	0.246	0.246
Snaring	1 (0.39)	0 (0.00)	0 (0.00)	1 (1.16)	1.000	1.000	1.000	1.000
Device recapture or retrieval	3 (1.16)	0 (0.00)	1 (1.16)	2 (2.33)	0.775	1.000	0.497	1.000
Second valve implantation	3 (1.16)	0 (0.00)	1 (1.16)	2 (2.33)	0.775	1.000	0.497	1.000
Pericardial tamponade	1 (0.39)	0 (0.00)	1 (1.16)	0 (0.00)	1.000	1.000	1.000	1.000
Annulus rupture	1 (0.39)	0 (0.00)	1 (1.16)	0 (0.00)	1.000	1.000	1.000	1.000
Aortic dissection	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1.000	1.000	1.000	1.000
Stroke/TIA	3 (1.16)	1 (1.16)	0 (0.00)	2 (2.33)	0.775	1.000	1.000	0.497
Vascular complications								
Minor	8 (3.1)	5 (5.81)	1 (1.16)	2 (2.33)	0.285	0.211	0.443	1.000
Major	6 (2.33)	3 (3.49)	0 (0.00)	3 (3.49)	0.252	0.246	1.000	0.246
Peripheral intervention required	8 (3.1)	4 (4.65)	0 (0.00)	4 (4.65)	0.134	0.121	1.000	0.121
Temporary pacing lead in situ	70 (27.13)	14 (16.28)	15 (17.44)	41 (47.67)	<0.0001	1.000	<0.0001	<0.0001
Clinical complications								
Persistent new bundle branch block	17 (6.61) (n = 257)	3 (3.49)	5 (5.81)	9 (10.59) (n = 85)	0.163	0.720	0.129	0.390
New onset atrial fibrillation	4 (1.55)	1 (1.16)	0 (0.00)	3 (3.49)	0.328	1.000	0.621	0.246
New onset acute kidney injury	7 (2.71)	4 (4.65)	2 (2.33)	1 (1.16)	0.511	0.682	0.368	1.000
Access site hematoma	11 (4.26)	2 (2.33)	5 (5.81)	4 (4.65)	0.636	0.443	0.682	1.000
Pseudo aneurysm	1 (0.39)	0 (0.00)	0 (0.00)	1 (1.16)	1.000	1.000	1.000	1.000
Aortic paravalvular regurgitation	**n = 34**	**n = 5**	**n = 6**	**n = 23**				
Trace	3 (8.82)	1 (20.00)	1 (16.67)	1 (4.35)	0.659	0.697	0.362	0.816
Trivial	19 (55.88)	4 (80.00)	3 (50.00)	12 (52.17)				
Mild	9 (26.47)	0 (0.00)	2 (33.33)	7 (30.43)				
Moderate	2 (5.88)	0 (0.00)	0 (0.00)	2 (8.70)				
Severe	1 (2.94)	0 (0.00)	0 (0.00)	1 (4.35)				

SE, self-expandable; TIA, transient ischemic attack; vs, versus.

New onset acute kidney injury was noted in 7 patients (Myval THV series: 4, Sapien-3 THV: 2, and SE valves: 1). Access site hematoma was least common in the Myval THV series cohort ($n = 2$), followed by the SE valves cohort ($n = 4$) and the Sapien-3 THV cohort ($n = 5$). Only one patient in the SE valves cohort had a pseudoaneurysm. None of the patients in the Myval THV series and Sapien-3 THV cohort reported moderate or severe PVR. In the SE valves cohort, moderate and severe PVR were reported in 8.7% and 4.35% of patients, respectively.

4. Discussion

The present registry compares the safety and outcomes of three contemporary THV systems. Myval THV series, Sapien-3 THV, and various self-expanding (SE) valves in patients with AS. This study represents the first real-world propensity score-matched analysis of new-generation THV systems conducted across two centers in India. Our short-term findings indicate that Myval THV series is comparable to the Sapien-3 THV in terms of clinical outcomes, with all three THV systems significantly improving aortic valve hemodynamics and without any intraprocedural mortality. Notably, the incidence of new permanent pacemaker implantation (PPI) was lower in the Myval THV series cohort compared to both the Sapien-3 THV and SE valves cohort, suggesting a potential procedural advantage. Differences observed in conduction disturbances and PVR are consistent with known device-specific characteristics.

A key difference among the cohorts was observed in the rate of new

PPIs. Among 258 patients (86 patients per propensity-matched cohort), 14 new PPIs occurred following TAVI. The Myval THV series cohort exhibited the lowest incidence (1.16%), compared to 4.65% in the Sapien-3 THV cohort and 10.46% in the SE valves cohort. Similarly, the LANDMARK trial also reported relatively lower incidences of PPI in the Myval THV series group (15%) compared to the Sapien THV series (17.3%) and Evolut THV series groups (16.8%).[26] The findings are consistent with randomized data from the COMPARE-TAVI and LANDMARK trials, which demonstrated non-inferiority of Myval THV series compared with Sapien 3 THV series and contemporary valve platforms (Sapien THV series and Evolut THV series) respectively.

Previous retrospective studies have consistently demonstrated higher PPI rates with Evolut SE valves compared to Myval.[12,27] Additionally, SE Evolut valves have shown relatively higher PPI rates compared to Sapien-3 THV.[2,3,28,29] Although prior data suggest that PPI following TAVI may be associated with increased mortality, our study found no significant difference in mortality rates.[30–32]

The availability of intermediate valve sizes in the Myval THV series reduces the risk of oversizing, consequently lowering the need for pre- and post-dilatation and decreasing the incidence of atrioventricular (AV) block.[33] Recently, Soliman O. et al, reported that the Myval THV series shows short-term hemodynamic outcomes similar to the Evolut THV series and comparable to the Sapien THV series at 30 days in the LANDMARK trial. Its range of intermediate sizes helps prevent oversizing, emphasizing its promise as an effective alternative for patients undergoing TAVI.[17] In our study, post-dilatation was required in 21.71% of patients, with the highest rate observed in the SE valves cohort (46.51%). Fluoroscopy time was significantly shorter in the Myval THV series cohort and longest in the SE valves cohort. These findings are consistent with the SCOPE 1 trial, which demonstrated a significantly lower requirement for post-dilatation in balloon-expandable (BE) valves compared to SE valves ($p < 0.0001$).[34]

In our registry, the majority of patients underwent transfemoral TAVI, which, although not considered standard in all centers, likely contributed to the absence of major vascular or bleeding complications. Echocardiographic assessment post-TAVI revealed excellent outcomes across all cohorts, with significant improvement in aortic valve area (AVA) and mean aortic valve gradient.

In our study, moderate or severe aortic PVL was absent in both the Myval THV series and Sapien-3 THV cohort, whereas it was observed in 8.7% and 4.35% of SE valves patients, respectively at procedural follow-up. This suggests that the extensive device selection provided by the BE Myval THV series can minimize the risk of relative under-sizing, potentially leading to a numerically lower rate of PVR. The rates of moderate and severe PVR in this registry are similar to the SCOPE 1 trial[34] and SOLVE-TAVI trials and show that the SE valves will have numerically higher rates of moderate and severe PVR than BE valves.[35,36] Similarly, Royen NV. et al, also reported numerically higher moderate-to-severe PVR with Evolut THV series compared to Myval THV series (7.4% vs. 3.4%, $p = 0.06$), while no significant difference was observed between Myval THV series and Sapien-3 THV (3.4% vs. 1.6%, $p = 0.32$).[26]

Comparing the propensity score-matched cohorts, it can be concluded that the new-generation Myval THV series is safe and associated with favorable clinical outcomes at 30 days. Safety and efficacy endpoints were comparable among the cohorts, with a lower rate of new PPI in the Myval THV series. The availability of more customized valve sizes allows optimal anatomical matching, which may reduce procedure-related adverse events such as conduction disturbances leading to new PPI or PVL. Furthermore, intermediate valve sizes appear to reduce the need for pre- and post-dilatation, a known risk factor for conduction disturbances.[13]

Ongoing prospective, large, randomized trials as the LANDMARK trial[16] and the COMPARE-TAVI trial[18] will provide further insights into the long-term performance and durability of the Myval THV series compared to commonly used SE and BE THVs. The early outcomes of the LANDMARK trial demonstrated that the new-generation Myval THV series is non-inferior to contemporary THV series (Sapien THV series and Evolut THV series) in terms of the primary combined safety and effectiveness endpoint which is composite of all-cause mortality, all stroke, bleeding (type 3 and 4), acute kidney injury (stage 2-4), moderate or severe PVR, conduction disturbances resulting in a new PPI and major vascular complications at 30 days.[16] The LANDMARK trial demonstrated that the Myval THV series was non-inferior to the contemporary (Sapien and Evolut) THV series in terms of clinical efficacy at 1-year.[37]

4.1. Limitations

This study has several important limitations. First, its retrospective, observational registry design introduces the potential for selection bias, and residual confounding cannot be excluded despite the use of propensity score matching. Notably, certain baseline imbalances persisted after matching, including differences in prior aortic valve replacement, renal function, and gender distribution, which may have influenced clinical outcomes. Second, the relatively modest sample size of the matched cohort limits the ability to detect small but clinically meaningful differences between valve platforms. Accordingly, the findings should be considered exploratory and hypothesis-generating. Third, the self-expandable (SE) valves cohort comprised multiple valve types and generations (including Evolut, Hydra, ACURATE neo, Portico, and Navitor), each with distinct design characteristics and performance profiles. This heterogeneity limits direct comparability with balloon-expandable valves and may have influenced observed differences in outcomes such as paravalvular regurgitation and conduction disturbances. Fourth, the short duration of follow-up (30 days) precludes assessment of mid- and long-term clinical outcomes, valve durability, and late complications.[14] Finally, as a real-world study conducted in a limited number of centers, procedural decisions including valve selection, pre- and post-dilatation, and implantation technique were operator-dependent and may not be generalizable to other settings.

5. Conclusion

In this real-world, propensity score–matched analysis, early safety and hemodynamic outcomes at 30 days were broadly comparable among balloon-expandable (Myval THV series and Sapien-3 THV) and self-expandable valve platforms in patients undergoing TAVI. Differences observed in rates of conduction disturbances and paravalvular regurgitation appear consistent with known device-specific characteristics rather than indicative of superiority of any single valve system. Larger, prospective randomized studies with longer follow-up are warranted to further define comparative performance across valve platforms in diverse patient populations.

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Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ihj.2026.05.002.

Central illustration:

Propensity-Matched Comparison of Early Safety and Efficacy Among Myval, sapien-3, and Self-Expandable Valves in Aortic Stenosis

Propensity score–matched analysis (N = 258) compared early outcomes of next-generation balloon-expandable Myval THV series, Sapien-3 THV, and self-expanding valves in severe aortic stenosis. Myval THV series showed comparable post-TAVI gradients with a larger aortic valve area and lower rates of paravalvular regurgitation, pacemaker implantation, and acute kidney injury. These findings highlight the favorable early safety and efficacy profile of the Myval transcatheter heart valve.

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