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ORIGINAL ARTICLE

Clinical Outcomes Following Transcatheter Mitral Valve-in-Valve Replacement Using a Meril Myval Transcatheter Heart Valve

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Aim Transcatheter mitral valve-in-valve (TMViV) replacement for degenerated surgically implanted bioprosthetic valves has been described by both transseptal and transapical approaches. The balloon-expandable Myval transcatheter valve (Meril Life Sciences, Vapi, India) is commonly used for transcatheter valve-in-valve procedures in India. This study aimed to report in-hospital, 30-day, and 1-year outcomes of Myval patients who underwent TMViV in a single tertiary care centre in India.

Methods Symptomatic patients with surgical bioprosthetic mitral valve failure with New York Heart Association (NYHA) class III–IV symptoms, despite optimal medical therapy and high or very high risk for redo surgery, were assigned to TMViV following heart team discussions. Data were retrospectively collected and outcomes assessed.

Results Twenty patients were treated, with mean age 64.4 years, 60% were female, and mean Society of Thoracic Surgeons (STS) predicted risk of operative mortality score was 8.1. The failure mechanism was combined stenosis and regurgitation in 60% of patients. Technical success was achieved in 100% of patients. The mean postprocedure and 30-day gradients were 4.6±2.7 and 6.3±2.1, respectively. None of them had significant valvular or paravalvular leaks or left ventricular outflow tract obstruction. All-cause mortality at 1 year was 10%, and all survivors were in New York Heart Association (NYHA) class I or II.

Conclusion TMViV replacement with a Meril Myval can be safely performed with high technical success, and low 30-day and 1-year mortality.

Keywords Degenerative mitral bioprosthesis • Transcatheter mitral valve-in-valve • Meril Myval

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Introduction

Transcatheter mitral valve-in-valve (TMViV) replacement has been described with the SAPIEN 3 (Edwards Lifesciences, Irvine, CA, USA) transcatheter heart valve (THV) with both transseptal and transapical approaches [1]. The Meril Myval (Meril Life Sciences, Vapi, India) THV is used for most TMViV procedures in India. The use of Myval has been described in patients with bioprosthetic heart valve failure in both aortic and mitral positions [2]. This retrospective, observational, single-centre study reviewed 20 patients who underwent a TMViV procedure using the Myval over 3 years. Surgical bioprosthetic valves are prone to failure over time due to degeneration [3]. Redo surgery can be high risk because of comorbidities, re-sternotomy, and elderly age. The TMViV replacement has been found to have good procedural and technical success of 97% and all-cause mortality of 5.4% at 30 days with a SAPIEN 3 valve [4]. Significant residual mitral stenosis or mitral regurgitation after a TMViV procedure and mitral valve in ring have been reported in the Valve-in-Valve International Data (VIVID) registry, warranting repeat surgical valve replacement [5]. This study reviewed the Indian Myval in high-risk patients with previously implanted surgical mitral valve (MV) bioprosthesis. These patients had high surgical Society of Thoracic Surgeons (STS) scores, and TMViV procedures by a transseptal technique following heart team review.

The Myval THV system is a balloon-expandable, tri-leaflet, bovine, pericardial prosthesis. The valve has a novel hybrid honeycomb scaffold design, which, on crimping, results in a distinct pattern of alternate dark and light bands, visible on fluoroscopy (Figure 1). This design helps in precise placement of the pre-crimped valve on its dedicated hi-flex Navigator THV delivery system, which comes with a counter-opposing stopper system. The kit also includes Python (Meril Life Sciences, Vapi, India), a low-profile, lubricious, expandable 14 Fr sheath, which can be dilated with an 18 Fr dilator and allows percutaneous access to all sizes of the crimped Myval THV system.

Methods

This study included all 20 consecutive patients who underwent successive TMViV procedures using the Myval at The Madras Medical Mission, Chennai, India, from August 2019 to December 2022, who had surgical bioprosthetic MV failure with New York Heart Association (NYHA) class III–IV symptoms despite optimal medical therapy, and high or very high risk for redo surgery. Clinical information, including demographic characteristics, functional status, and procedural details, were collected. Mitral valve in ring, valve in mitral annular calcification, and transapical valve-in-valve implantations were excluded. In-hospital, 30-day, and 1-year outcomes were studied in this initial group of patients. This study was approved by the institution's ethics committee (ECR/140/Inst/TN/2013/RR-20). The informed consent for patient enrolment was waived by the ethics committee, as it was a retrospective study. No external funding or sponsorship was received for this study.

Procedural Technique

Preoperative computed tomography (CT) and transthoracic echocardiography were mandated for all patients to analyse the anatomy of the MV bioprosthesis and left ventricle. The characteristics of the mitral bioprosthesis—including the mechanism of failure, type of degenerated bioprosthesis, and size—were assessed by echo and CT scan. The sizing of the transcatheter MV bioprosthesis was estimated by the internal diameter of the surgical bioprosthesis by CT scan (Figure 2A).

The risk of left ventricular outflow tract (LVOT) obstruction was assessed by embedding a virtual valve into the mitral annulus on CT images (Figure 2B) and the neo-LVOT was measured. The neo-LVOT area of >200 mm^2 was used as the cut-off.

The procedure was performed under general anaesthesia with transoesophageal echocardiography (TOE) guidance. A balloon-tipped temporary pacemaker was placed in the right ventricle from the right interior jugular vein for rapid ventricular pacing. Left femoral artery access was obtained with a 6 Fr sheath, and a pigtail catheter was placed in the ascending aorta as a marker for septal puncture and haemodynamics. Right side femoral vein access was obtained with a 6 Fr/7 Fr sheath, pre-closed with one ProGlide suture (Perclose ProGlide, Abbott Cardiovascular, Abbott Park, IL, USA), and exchanged with a 9 Fr Mullin sheath over a 0.032" wire. The 9 Fr Mullin sheath (Medtronic, Minneapolis, MN, USA) was advanced into the left innominate vein over the 0.032" wire, after which a Brockenbrough needle (Abbott Vascular, Abbott Park, IL, USA) was inserted into the sheath and gently directed towards the inferior posterior position of the interatrial septum under TOE guidance. Transeptal puncture was performed under TOE guidance, and electrocautery at 40 watts was used for a thick septum. After a septal puncture, 100 IU/kg of heparin was given, followed by additional doses to maintain the activated clotting time between 300–350 seconds. A coiled wire was then placed in the left atrium (LA). The 9 Fr Mullin sheath was upsized to a 14 Fr Python sheath over the LA wire, and 8.5 Fr Agilis (Abbott Vascular) was then advanced over the LA wire through the Python sheath. The LA coiled wire was removed and exchanged for a 0.035" wire with a pigtail catheter, which was gently advanced across the mitral bioprosthesis by directing the Agilis sheath towards the mitral inflow. A Safari (Boston Scientific, Marlborough, MA, USA) extra small loop wire was advanced through the pigtail catheter into the apex of the left ventricle, and the pigtail catheter was removed. Atrial septostomy was performed using a 12–14 mm diameter x 4 cm length Mustang balloon (Boston Scientific), which was advanced through the Agilis sheath by positioning the balloon across the interatrial septum. The balloon was dilated across the interatrial septum, and the adequacy of the septostomy was evaluated by moving

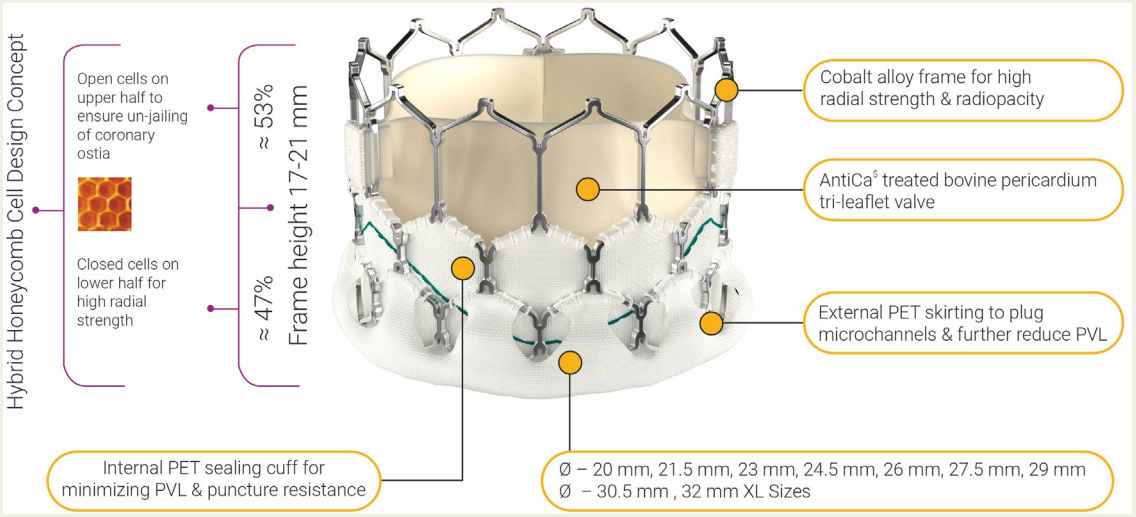

Figure 1 Design of the Meril Myval.
Abbreviations: PET, polyethylene terephthalate; PVL, paravalvular leak; AntiCa$, anti-calcification. (Reproduced with permission from Meril Life Sciences Private Limited: www.merillife.com/medical-devices/vascular-intervention/heart-valves/tavr/myval.)

the partially inflated balloon across the interatrial septum. Pre-dilatation with the same balloon was performed in case of a severely stenosed tissue valve with minimal mitral regurgitation (MR). The device was gently advanced and placed across the surgical bioprosthesis with a position of 10%–20% on the atrial side and 80%–90% on the ventricular side. Slow valve deployment was performed inside the surgical mitral bioprosthesis, usually in the coplanar view with rapid ventricular pacing at 180 bpm and induced apnoea. The valve was made to self-orient itself by pushing it gently to ensure that it aligned with the frame on the atrial side. Rapid inflation was then performed to flare the ventricular side. Once the valve was deployed, TOE was performed to assess the position of the valve, transmitral gradients, gradients across the LVOT, and the presence of paravalvular leaks (PVLs). If PVLs were present, the valve was dilated with the same balloon with an extra 2–3 mm. In patients with a significant right-to-left interatrial shunt, the septostomy was closed with an Amplatzer atrial septal occluder (Abbott Vascular) or a similar device. The delivery system and sheath were removed, and the access site was closed with a ProGlide suture and figure of eight suture if additional haemostasis was needed. Arterial haemostasis was achieved by manual compression.

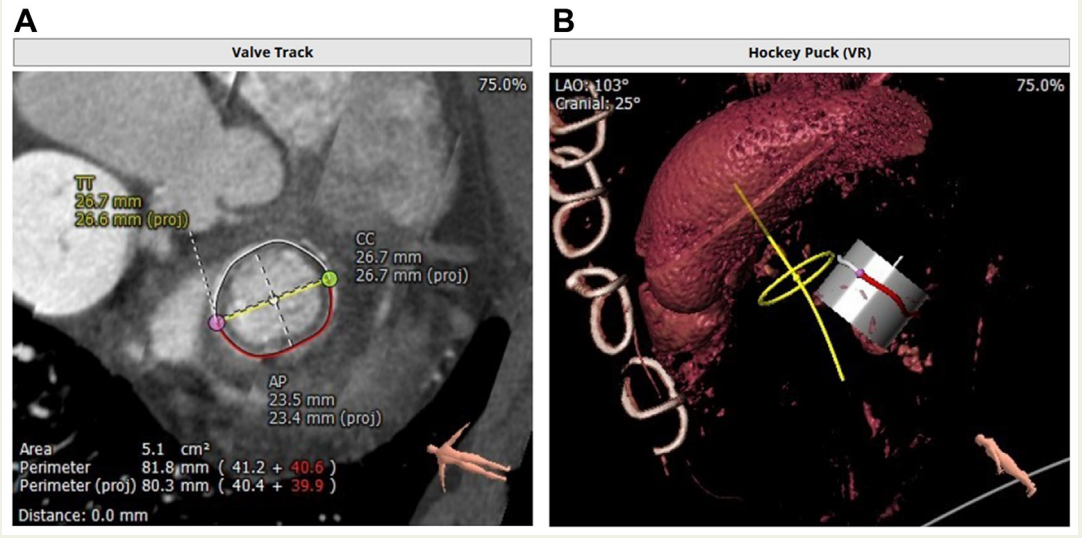

Figure 2 Computed tomography images. A) Internal diameter of the surgical bioprosthesis. B) Reconstruction with a virtual embedding of a mitral prosthesis into the mitral annulus to estimate left ventricular outflow tract obstruction.

Statistical Analysis

The continuous and normally distributed baseline characteristics were presented as mean±standard deviation. Non-normally distributed data were presented as median (interquartile range, IQR); 25th and 75th percentile. Normal distribution was checked with the Shapiro–Wilk test and categorical data were presented as frequency and percentages. The primary and secondary outcomes were presented as frequency and percentages. Statistical analysis was performed using the SPSS statistical package, version 25.0 (IBM Corp., Armonk, NY, USA).

Results

The data of the 20 patients during the study period were analysed. Table 1 shows the study population's baseline clinical characteristics and echocardiographic parameters. The mean age was 64.4±14.3 years, and 12 were female (60%). Eleven had diabetes mellitus (55%), six had systemic hypertension (30%), five had previous coronary artery bypass grafting (25%), and 13 had severe pulmonary hypertension (65%). The mean duration between the previous MV surgery and the TMViV procedure was 10.4±3.6 years, with mean EuroSCOREII and STS scores of 9.2±5.7 and 8.1±6.1, respectively. One patient was diagnosed with corrected transposition of the great arteries and underwent left atrioventricular valve replacement. One patient required a mitral valve-in-valve replacement and native transcatheter aortic valve implantation with another Myval (Figure 3A and B). Amongst these patients, 12 had combined severe stenosis and regurgitation (60%), three had isolated regurgitation (15%), and five had severe stenosis only (25%). Table 2 shows the CT measurements of the patients.

Table 3 shows the procedural data. An intermediate-sized valve (e.g., 24.5 mm, 27.5 mm, or 30.5 mm) that is unavailable in the size matrix of SAPIEN 3 THV was used in 10 patients (50%). Four patients had a technically challenging atrial septostomy due to a thick and calcified septum needing electrocautery (20%). One patient required a second septal puncture due to difficulty in crossing the first puncture with a balloon. In the patient with transposition of the great arteries, a 0.35" Amplatz super-stiff wire was used to cross the bioprosthesis through a pigtail catheter, which was advanced and parked in the ascending aorta for better anchorage (Figure 4A and B). The iatrogenic septal defect was closed in one patient (5%), due to increased right atrial pressure associated with a right-to-left shunt, using a 10 mm atrial septal occluder. Technical success was achieved in all 20 patients (100%), and the procedural duration was 125.7±39.9 minutes. The post-procedural transmitral peak and mean gradients were 7.6±14 mm Hg and 4.6±2.7 mm Hg, respectively.

Table 4 shows the clinical outcome data. Two patients required prolonged ventilation, dobutamine and levosimendan, and diuretic infusion. One of them also required intra-aortic balloon pump (IABP) support. Three patients developed bleeding that required transfusions; one patient required a single-chamber automated implantable cardioverter defibrillator implant for recurrent non-sustained ventricular tachycardia. One patient had oliguria with elevated renal parameters and required haemodialysis. The post-procedural LVEF at discharge improved to 43.1± 3.3%. The median length of hospital stay was 7 days, whereas median post-procedural hospital stay was 5 days, and there was no in-hospital mortality. Two patients developed a femoral artery pseudoaneurysm, one was managed with ultrasound probe compression on the neck of the aneurysm, and another was managed with manual compression. During follow-up, the patient continued to have pain at

Table 1 Baseline characteristics of the 20 patients.

Baseline characteristic	Result
Age, years	64.4±14.3
Male	8 (40)
Female	12 (60)
Height, cm	159.5±9.3
Weight, kg	62.2±9.2
Body mass index	23.8±3.4
Body surface area	1.5±0.3
Diabetes mellitus	11 (55)
Systemic hypertension	6 (30)
Dyslipidaemia	5 (25)
Previous coronary artery bypass grafting	5 (25)
Chronic obstructive pulmonary disease	1 (5)
Severe pulmonary arterial hypertension	13 (65)
Logistic EuroSCORE (%)	14.3±10.3
EuroSCORE II (%)	9.2±5.7
Society of Thoracic Surgeons score (%)	8.1±6.1
Creatinine, mg/dL	1±0.3
Glomerular filtration rate, mL/min/1.73	76.3±25.5
Echocardiographic findings	
Mean gradient, mm Hg	13.7±6.1
Maximum gradient, mm Hg	27.5±11.1
Left ventricular ejection fraction, %	44.4±9.5
Mechanism of failure	
Isolated severe regurgitation	3 (15)
Predominant stenosis	5 (25)
Combined stenosis and regurgitation	12 (60)
Degenerated bioprosthesis	
Epic	2 (10)
Carpentier Edwards Perimount	11 (55)
Hancock	1 (5)
Biocor	3 (15)
Magna	3 (15)
Degenerated bioprosthesis size	
23 mm	3 (15)
25 mm	7 (35)
27 mm	7 (35)
29 mm	1 (5)
31 mm	2 (10)

Data are shown as n (%) or mean±SD.

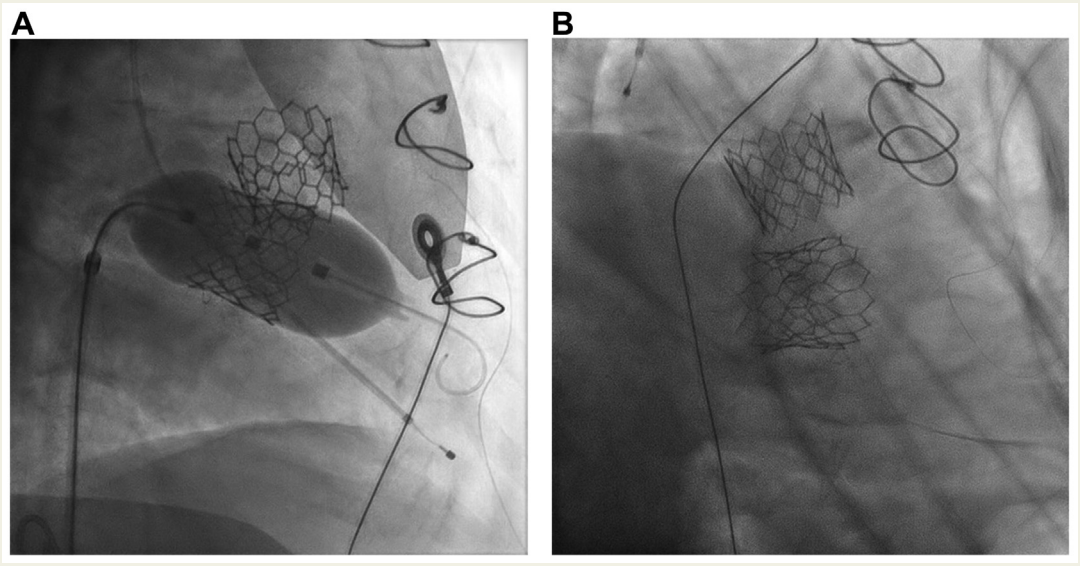

Figure 3 Fluoroscopy images. A) Implantation of Myval in the mitral position following native aortic valve implantation. B) Myval in aortic and mitral positions in the same patient.

the right femoral site, and CT femoral artery showed a pseudoaneurysm of >5 cm with a narrow mouth and was treated using a covered stent. One patient succumbed to COVID-19 infection within the first 30 days. All-cause mortality at 30 days was 5% (n=1), and at 1 year was 10% (n=2). Table 5 shows 30-days and 1-year echocardiography gradients. Eleven patients completed 1-year follow-up, and their mean transmitral gradient was 6±1.2 mmHg with no significant MR. These patients remained in NYHA class I or II functional status. Oral anticoagulant was continued in all patients. Table 6 shows the comparison of the current data with the MITRAL trial [6].

Discussion

This study evaluated the feasibility and safety of transeptal TMViV using an indigenously developed Myval balloon-expandable THV prosthesis. The following were found: high technical success rates; there was no valve-related 30-day mortality; and there were sustained low gradients during follow-up with consistent improvements in functional status.

Outcomes

Transcatheter TMViV is emerging as a non-surgical alternative for redo surgery in high-risk or very high-risk patients

Table 2 Computerised tomography measurements.

Measurement	Mean±SD
Annulus short diameter, mm	39.6±6.3
Annulus long diameter, mm	41.2±5.6
Annulus average diameter, mm	40.5±5.7
Annulus area, cm^2	5.4±1.1
Major diameter of LVOT, mm	29.1±3.9
Minor diameter of LVOT, mm	20.2±3.2
Mitral angle, degree	58.1±11.9
Neo LVOT area, mm^2	382±95.8

Abbreviation: LVOT, left ventricular outflow tract.

Table 3 Intraprocedural and postprocedural data for the 20 patients.

Procedural data	Result
Myval size	
23 mm	3 (15)
24.5 mm	6 (30)
26 mm	5 (25%)
27.5 mm	3 (15)
29 mm	2 (10%)
30.5 mm	1 (5)
Pre dilatations	1 (5)
Post dilatations	1 (5)
Procedural duration, mins	125.7±39.9
Fluoroscopy time, mins	38.7±18
Post echocardiographic findings	
Mean gradient, mm Hg	4.6±2.7
Maximum gradient, mm Hg	17.6±14
left ventricular ejection fraction, %	44.9±8.7
At discharge echocardiographic findings	
Mean gradient, mm Hg	5.5±2.3
Maximum gradient, mm Hg	11.8±4.5
Left ventricular ejection fraction, %	43.1±3.3

Data are shown as mean±SD and n (%).

Table 4 Clinical outcomes for the 20 patients.

Clinical outcome	Result
Procedural success	20 (100)
Duration of total hospital stay, days[a]	7 (3; 6, 9)
Post procedure length of stay, days[a]	5 (3.75; 4, 7)
In hospital MACE events	
1. In-hospital mortality	0
2. Stroke	0
3. Myocardial infarction	0
4. Renal impairment requiring dialysis	1 (5%)
5. Bleeding requiring transfusion	3 (15%)
6. Pseudoaneurysm	2 (10%)
Single chamber AICD implantation	1 (5%)
ASD device closure	1 (5%)
All-cause mortality at 30 days	1 (5%)
All-cause mortality at 1 year	2 (10%)

Data are presented as n (%).

[a]n (Median with Interquartile range).

Abbreviations: MACE, major adverse cardiac event; AICD, automated implantable cardioverter defibrillator; ASD, atrial septal defect.

with failed mitral bioprosthetic valves. Few retrospective/prospective registries have so far evaluated the outcomes of these patients. Early registries involved old-generation balloon-expandable valves, and a significant proportion of patients underwent procedures through the transapical approach. The mean STS score in the VIVID registry was 13.4%, and 64.4% of the patients underwent valve replacement through a transapical approach. In the TVT registry, the STS score was 10%, and 44.8% were transapical procedures. The 30-day mortality in VIVID and TVT was 7.7% and 10.1%, respectively [7,8]. In the subsequent multicentre registries of patients treated through the transseptal approach, the 30-day mortality varied between 5%–6.2% [9,10]. In the recent prospective multicentre MITRAL registry, all procedures were performed through a transseptal approach and using the SAPIEN 3 valve. The 30-day and 1-year mortality rates were both 3.3% [6].

Unlike the MITRAL registry, the STS score was lower in the current study (8.1±6.1% vs 10.2±6.5%). The younger patient population (64.4±14.3 vs 76.4±9.6) might have

Table 5 Follow-up echocardiography.

Transthoracic echocardiography gradient	1 month (n=17)	1 year (n=11)
Mean gradient, mm Hg	6.3±2.1	6±1.2
Maximum gradient, mm Hg	14.2±4.9	17.8±6.9
Left ventricular ejection fraction, %	44.2±8.9	46.5±9.1

Data are shown as mean±SD.

Table 6 Baseline data and outcomes compared with MITRAL trial [6].

Characteristic	This study (n=20)	MITRAL trial (n=30)
Age, years	64.4±14.3	76.4±9.6
Society of Thoracic Surgeons (STS) score	8.1±6.1	10.2±6.5
Stenosis	25%	73.3%
Regurgitation	15%	10%
Mixed	60%	16.7%
Mean gradient	13.7±6.1	-
Technical success	100%	100%
Post gradient	5.5±2.3	6±1.9
All-cause mortality at 30 days	5%	3.3%
All-cause mortality at 1 year	10%	3.3%

Data are shown as mean±SD or as %.

contributed to the low STS scores, as most of these patients had surgery for rheumatic heart disease-related MV involvement, which occurs at an earlier age than degenerative MV disease. Even though patients were younger, they were at high risk of redo surgery because of additional right ventricular dysfunction and general fragility, as assessed by the heart team; these aspects were not reflected in the STS score [11]. The mortality in the current study was similar to the MITRAL trial. There was one mortality (5%) at a 30-day follow-up; this patient underwent the procedure during the peak of the COVID-19 pandemic and developed an infection post-discharge. She was readmitted and died of COVID-19 pneumonia. Mortality at 1 year was 10% (n=2) due to congestive cardiac failure.

Most of the patients had a mixed mode of failure (stenosis+regurgitation) compared with predominant stenosis in the MITRAL registry. Similar to the MITRAL registry, the valve was successfully deployed in all patients, with a 100% technical success rate and no intraprocedural mortality, valve embolisation/malposition, need for second valve implantation, emergency surgery, or LVOT obstruction. The procedures were performed by operators experienced in balloon mitral valvuloplasty and transcatheter aortic valve replacement (TAVR) with Myval prosthesis. Two patients developed after-load mismatch with acute left ventricular failure postprocedure. One patient was managed with prolonged ventilation, dobutamine, levosimendan, and diuretic infusion. In addition, another patient required intra-aortic balloon pump (IABP) support for 3 days, gradually improved symptomatically, and was discharged. At the 30-day follow-up, the patient remained at NYHA class II functional status but developed a pseudoaneurysm at the IABP insertion site, which required covered stent implantation. Two patients were readmitted after 30 days: one with acute abdomen and the other with atrial fibrillation with a fast ventricular rate.

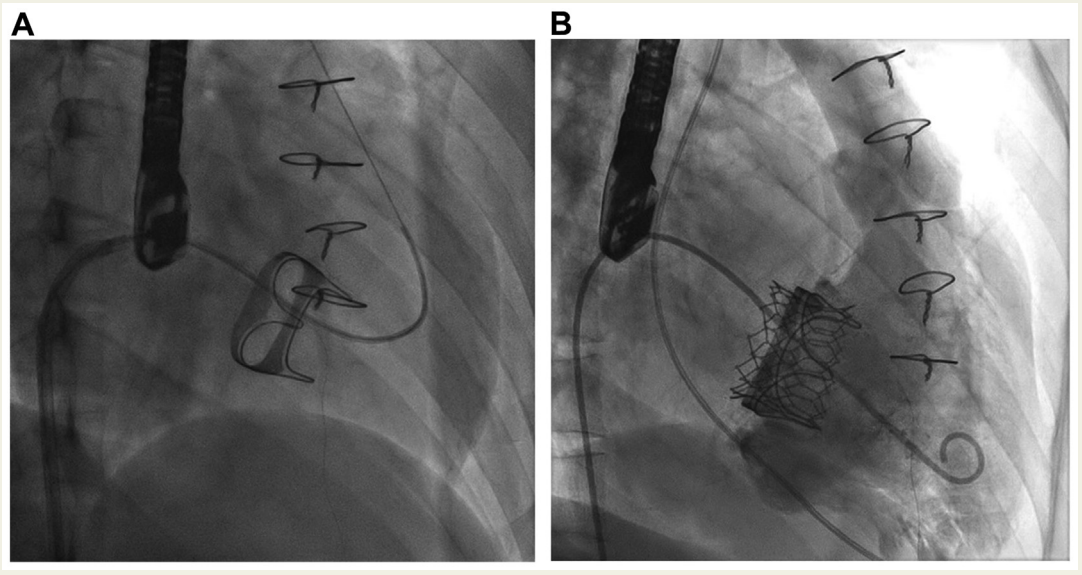

Figure 4 Fluoroscopy images. A) 0.35″ Amplatz super stiff wire across the bioprosthesis into the ascending aorta, which provides support for tracking the Myval. B) The Myval can be seen across the previous left surgical atrioventricular valve in a patient with corrected transposition of the great artery.

No major studies have compared the outcomes of TMViV with redo surgical valve replacement. In a retrospective study by Kamioka et al. [12], 62 patients treated with TMViV were compared with 59 patients who underwent redo surgical valve replacement. The 1-year mortality rates were 11.3% and 11.9%, respectively [12]. In another study by Simonetto et al. [13], 29 patients treated with redo surgery were compared with 49 patients who underwent TMViV, and 22 patients were treated with a transapical approach. The 1-year mortality rates for redo surgery, transseptal, and transapical TMViV were 17.2%, 14.8%, and 18.2%, respectively [13]. The mortality rates in the MITRAL trial and current study were much lower than those of these studies. The Mitral Valve Academic Research Consortium defined valve performance endpoint as an absence of mean gradient $\geq$10 mm Hg and MR grade $\geq$2+, which was attained in all patients. The mean gradient was 6.3$\pm$2.1 mm Hg at 30 days of follow-up, and 6$\pm$1.2 mm Hg for patients who completed 1 year of follow-up, which was similar to the MITRAL trial (6 mm Hg and 6.6 mm Hg). All patients who completed 1-year follow-up remained in NYHA class I or II functional status. In the MITRAL study, five patients did not meet the performance endpoint at 1 year, all due to a MV gradient >10 mm Hg. However, all of these patients had symptomatic improvement despite high residual gradients. As intermediate sizing is available with the Myval prosthesis, all patients underwent appropriately sized THV implantation, which might have contributed to a MV gradient of <10 mm Hg in all patients.

The few advantages of the Myval THV prosthesis over the SAPIEN 3 valve are that, in contrast to SAPIEN3 THV, Myval THV prosthesis is directly crimped over a delivery balloon, and there is no need to realign the valve once it is outside the delivery sheath. Hence, the Python sheath can be positioned inside the femoral vein and inferior vena cava. The design of the Python sheath enables a single 14 Fr size to fit all valve sizes and it allows retrieval of the valve prosthesis if needed. Further, it has a set of proximal and distal stoppers, which ensure precise valve crimping and no risk of inadvertent migration during entry through the sheath or negotiating the delivery system across the aorta. The delivery system is more flexible, has a lower profile, and has enhanced manoeuvrability, enables user-friendly valve design without a pusher, and helps to better orientate the THV inside the surgical valve prosthesis. Implanting an appropriately sized transcatheter valve in a degenerated prosthetic valves is vital. Valve sizing is based on the true internal diameter of the surgical prosthetic valve. The recommendation is to upsize the valve by 2 mm and add 2–3 mL extra contrast volume to flare the ventricular side of the valve. As the transcatheter valves are available in limited sizes, this led to either implanting a smaller valve with an additional volume of contrast or a more oversized valve with a lesser contrast volume. Valve overexpansion may result in poor coaptation of leaflets and central valvular leak. Although bench studies have shown the over-expanding capacity of the SAPIEN 3 valve without affecting leaflet coaptation, this was meant to be implantation in oversized aortic annuli [14]. Other studies have shown that implanting an oversized valve inside bioprosthetic valves may result in a less foreshortened stent frame, central overlap of leaflets (pin wheeling effect), increased gradients, and early valve degeneration [15]. The exact long-term consequences of over-expanding or under-expanding balloon expandable transcatheter valves are currently unknown. In contrast, Myval is manufactured in intermediate (21.5 mm, 24.5 mm, 27.5 mm) and extra-large sizes (30.5 mm and 32 mm), which helps in

implanting appropriate-sized valves in most cases. This was evident in this study, as 50% of patients were implanted with intermediate size valves, mostly 24.5 mm and 26 mm. The outcomes of the same size valves need to be evaluated in extensive studies. The smaller-size valves are commonly used in India. Intermediate sizes are an additional advantage with the Meril Myval, which are unavailable with the SAPIEN 3 valve and, most importantly, the cost of the valve. Pre-procedure CT imaging is important for sizing the valve and predicting virtual LVOT obstruction. All patients in this registry were discharged with oral anticoagulant with vitamin K antagonist to achieve an international normalised ratio of 2.5–3.

Limitations

This study had some limitations, including a small number of patients, and 55% of patients had completed a 1-year follow-up at the time of submission. A complete extended follow-up duration will be required to understand the long-term outcomes of this procedure.

Conclusion

Transcatheter mitral valve-in-valve replacement with the Meril Myval THV can be safely performed with high technical success and low 30-day mortality, with a significantly improved post-procedural valve performance. The easy deliverability, availability in intermediate sizes, and reduced costs compared with the SAPIEN 3 valve make it an ideal balloon-expandable valve for TMViV globally and in developing nations.

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Disclosures

There are no conflicts of interest to disclose.

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