

Four-year durability of the Myval balloon-expandable transcatheter aortic valve

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ABSTRACT

BACKGROUND: The Myval series is the first commercially available balloon-expandable transcatheter aortic valve implantation (TAVI) system designed as an alternative to the SAPIEN series. The LANDMARK trial recently demonstrated its non-inferiority compared to contemporary systems. However, the long-term durability of the Myval series remains unknown.

AIMS: We aimed to evaluate the 4-year durability of the Myval series using Valve Academic Research Consortium (VARC)-3-defined endpoints.

METHODS: We carried out a multicentre ambispective study of patients with severe aortic stenosis who underwent TAVI with the Myval series between December 2017 and April 2020. Baseline characteristics were prospectively recorded in a dedicated database. Clinical and echocardiographic follow-up was performed at 4 years. Outcomes included haemodynamic valve deterioration (HVD), bioprosthetic valve failure (BVF), and patient-prosthesis mismatch (PPM) as defined by the VARC-3 criteria, assessed at a central echocardiography laboratory.

RESULTS: A total of 366 patients from 9 institutions were included, all of whom completed 4-year follow-up or were followed up until death. The 4-year survival rate was 81.8%, with residual \geq moderate aortic regurgitation observed in 9.2% of patients. BVF criterion 1 (symptomatic valve failure) occurred in 3.3%, while no cases of BVF criteria 2 or 3 were reported. Stage 2 HVD was observed in 9.7% of patients and stage 3 HVD in 0.7% at 4 years. Moderate and severe PPM were identified in 3.6% and 2.1% of patients at 1 year, respectively.

CONCLUSIONS: In a real-world cohort, 4-year outcomes with the balloon-expandable Myval series demonstrated acceptable valve durability, low haemodynamic deterioration, and comparable performance to contemporary TAVI systems.

KEYWORDS: durability; Myval series; transcatheter aortic valve implantation; TAVI

With the advent of new-generation transcatheter aortic valve implantation (TAVI) devices, transcatheter therapy has become the primary alternative for treating aortic stenosis in a broad range of patients. Advances in technology have led to the development of several transcatheter heart valves (THVs) that incorporate features such as lower profiles, improved positioning and repositioning capabilities, and recapturability. These innovations aim to reduce procedural complications including paravalvular leak (PVL), vascular injuries, and conduction disturbances, ultimately improving clinical outcomes¹⁻³.

The Myval series (Meril Life Sciences) is the only commercially available balloon-expandable THV designed as an alternative to the SAPIEN series (Edwards Lifesciences). The LANDMARK trial demonstrated the non-inferiority of the Myval series compared to contemporary THVs including the SAPIEN and Evolut series (Medtronic)⁴.

Mid- and long-term durability are critical factors for the success of TAVI, particularly as the procedure is increasingly adopted for younger and lower-risk patients who require durable solutions. Although early clinical outcomes with the Myval device have been promising, data on its mid- and long-term performance remain limited. This study aims to evaluate the 4-year durability of the Myval series based on Valve Academic Research Consortium (VARC)-3-defined parameters.

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Methods

OBJECTIVE

The primary endpoints of this study were haemodynamic valve deterioration (HVD; stages 2-3), bioprosthetic valve failure (BVF; criteria 1-3), and patient-prosthesis mismatch (PPM), as defined by the VARC-3 criteria⁵. Stage 2 HVD was defined as a mean transvalvular gradient increase of ≥ 10 mmHg, resulting in a mean gradient ≥ 20 mmHg, or an increase of ≥ 1 grade of intraprosthetic aortic regurgitation (AR) leading to \geq moderate AR. Stage 3 HVD was characterised by a mean transvalvular gradient increase of ≥ 20 mmHg, resulting in a mean gradient ≥ 30 mmHg, or an increase of ≥ 2 grades of intraprosthetic AR resulting in severe AR.

BVF was categorised as follows: criterion 1, any bioprosthetic valve dysfunction (BVD) with new-onset or worsening symptoms or irreversible stage 3 HVD; criterion 2, BVD requiring aortic valve reintervention; criterion 3, valve-related death⁶. PPM was defined using body mass index-adjusted thresholds according to VARC-3 guidelines.

DEVICE DESCRIPTION

The Myval device is a next-generation, balloon-expandable THV constructed from a nickel-cobalt frame. Its hybrid honeycomb structure, consisting of single-element hexagons, supports three bovine pericardium leaflets treated with the

Impact on daily practice

So far, data regarding the midterm prevalence of haemodynamic structural valve deterioration after balloon-expandable transcatheter aortic valve implantation (TAVI) remain scarce. Sustained haemodynamic performance without significant aortic regurgitation contributes to the overall 4-year durability of the Myval transcatheter heart valve, as it minimises the risk of complications that could require reintervention. Thus, favourable midterm durability data could help to extend the indication of TAVI to a younger population.

proprietary anticalcification process “AntiCa”. To minimise paravalvular leak, the lower cells are lined with polyethylene terephthalate, internally and externally. Myval valves are available in a range of sizes, including conventional (20 mm, 23 mm, 26 mm, 29 mm), intermediate (21.5 mm, 24.5 mm, 27.5 mm), and extra-large sizes (30.5 mm, 32 mm), all compatible with a 14 Fr sheath. The MyVal-1 study previously demonstrated the safety and efficacy of this valve in intermediate- to high-risk patients^{7,8}.

STUDY DESIGN AND POPULATION

This ambispective multicentre study included all consecutive patients who underwent TAVI with the Myval series across 9 centres between December 2017 and April 2020. Baseline clinical and procedural characteristics were prospectively recorded. Informed consent was waived by the central ethics committee, although specific consent was obtained from those patients who required an additional echocardiographic study to complete their 4-year follow-up, which was necessary in 56.8% of the sample. Follow-up was scheduled for 4 years or until death, with clinical and echocardiographic assessments performed at each visit to ensure accurate monitoring of haemodynamic function. A total of 442 patients underwent TAVI with a Myval series device in the aortic position. Of these, 366 patients completed 4 years of follow-up and were evaluated.

IMAGING ANALYSIS

Echocardiographic examinations were performed according to the guidelines of the American Society of Echocardiography. The following measurements were obtained: left ventricular outflow tract diameter; left ventricular ejection fraction (Simpson method); mean/peak transvalvular gradients; area by continuity equation; and presence, degree, and type (transvalvular, paravalvular, global) of AR. AR severity was evaluated using a multiparametric approach and classified following the VARC-3 recommendations. Images were centrally analysed (www.icicorelab.es) by two independent experienced cardiologists blinded to the type of prostheses; the absence of significant interobserver differences was assessed.

Abbreviations

BVD bioprosthetic valve dysfunction
BVF bioprosthetic valve failure
HVD haemodynamic valve deterioration

PPM patient-prosthesis mismatch
TAVI transcatheter aortic valve implantation
THV transcatheter heart valve

The Xcelera Cardiology Information System (Philips Medical Systems) was used for all offline analysis. Although data were gathered retrospectively, patients without adequate 4-year imaging follow-up were scheduled for echocardiographic testing after obtaining informed consent.

STATISTICAL ANALYSIS

Categorical variables are presented as absolute numbers and percentages, while continuous variables are expressed as median (interquartile range). Normality was assessed using the Kolmogorov-Smirnov test and Q-Q plots. Categorical variables were compared using the chi-square or Fisher's exact test, as appropriate, and continuous variables were compared using the Mann-Whitney U test. Kaplan-Meier survival analysis was performed to evaluate all-cause mortality and stroke. Statistical significance was defined as a p -value <0.05 . All analyses were performed using R software, version 3.6.1 (R Foundation for Statistical Computing).

Results

The study cohort consisted of 366 patients who had completed 4-year follow-up (or until death) after TAVI. The mean age was 75.9 ± 9.1 years, 32.5% were female, and the mean European System for Cardiac Operative Risk Evaluation (EuroSCORE) II was 4.2 ± 3.5 . Of the procedures, 98.9% were transfemoral, and post-dilatation was used in 7.9%. Baseline demographic, clinical, electrocardiographic and imaging characteristics are shown in **Table 1**.

PERIPROCEDURAL AND 30-DAY CLINICAL OUTCOMES

The mean aortic valve gradient was 10.3 ± 4.7 mmHg at 30-day follow-up, and the mean aortic valve area was 1.7 ± 0.4 cm². The peak aortic valve velocity and gradient were 2.12 ± 0.47 m/s and 18.90 ± 7.96 mmHg, respectively. At 30 days, 5.5% of patients had moderate aortic regurgitation, and 0.5% had severe AR (**Table 2**).

CLINICAL OUTCOMES

Figure 1 shows the survival rate of 81.8% and freedom from stroke rate of 98.5% at 4-year follow-up. The main outcomes are summarised in **Table 3**.

HAEMODYNAMIC VALVE PERFORMANCE AND DURABILITY

The mean aortic valve gradients were 11.18 ± 5.59 mmHg and 11.96 ± 6.21 mmHg at 1- and 4-year follow-up, respectively ($p<0.001$ for progression), and the mean aortic valve areas were 1.75 ± 0.47 cm² and 1.66 ± 0.38 cm² at 1- and 4-year follow-up, respectively ($p=0.010$ for progression). At 1 and 4 years, the peak aortic valve gradients were 20.75 ± 9.15 mmHg and 21.56 ± 10.32 mmHg, respectively. A total of 6.8% and 7.8% of the patients had moderate aortic regurgitation, and 1% and 1.4% had severe AR, at 1 and 4 years, respectively ($p=0.206$ for progression) (**Central illustration, Supplementary Table 1**).

As presented in **Supplementary Figure 1**, during follow-up, BVF criterion 1 (symptomatic failure) occurred in 3.3%, and there were no instances of BVF criterion 2 (aortic valve reintervention) or BVF criterion 3 (valve-related death). Finally, the rates of stage 2 and stage 3 HVD were 9.7% and 0.7%, respectively, with severe PPM present in 2.0% and 2.1% of patients at 30 days and 1 year (**Figure 2**).

Table 1. Main clinical, electrocardiographic, and imaging characteristics at baseline of study population.

Clinical characteristics	
Age, years	75.9 \pm 9.1
Female sex	32.5%
BSA, m ²	1.8 \pm 0.2
BMI, kg/m ²	26.5 \pm 4.3
Diabetes mellitus	136 (37.2)
Prior pacemaker	32 (8.7)
Chronic kidney disease	137 (37.4)
Haemodialysis	4 (1.1)
Chronic pulmonary disease	44 (12.0)
Peripheral artery disease	42 (11.5)
Previous stroke/TIA	28 (7.7)
Porcelain aorta	8 (2.2)
Coronary artery disease	202 (55.2)
Prior heart surgery	58 (15.8)
Prior CABG	48 (13.1)
Prior valvular surgery	23 (6.3)
Prior atrial fibrillation	80 (21.9)
NYHA III-IV	50.4%
STS-PROM score, %	4.8 \pm 4.3
EuroSCORE II, %	4.2 \pm 3.5
Electrocardiography	
Sinus rhythm	252 (68.9)
Atrial fibrillation	54 (14.8)
LBbB	27 (7.4)
RBbB	23 (6.3)
AVB (1 st degree)	18 (4.9)
Computed tomography	
Maximum AA diameter, mm	28.6 \pm 4.7
Minimum AA diameter, mm	22.3 \pm 4.8
Eccentricity index	0.30 \pm 0.19
Mean AA diameter, mm	25.1 \pm 3.9
AA area, mm ²	458.4 \pm 114.6
Agatston score	2,553.6 \pm 1,419.4
Echocardiography	
LVEF, %	54.4 \pm 12.2
Peak aortic gradient, mmHg	77.8 \pm 23.5
Mean aortic gradient, mmHg	48.1 \pm 16.4
\geq Moderate aortic regurgitation	72 (19.7)
\geq Moderate mitral regurgitation	52 (14.2)
\geq Moderate tricuspid regurgitation	43 (11.7)

Data are %, n (%), or mean \pm standard deviation. AA: aortic annulus; AVB: atrioventricular block; BMI: body mass index; BSA: body surface area; CABG: coronary artery bypass graft; EuroSCORE: European System for Cardiac Operative Risk Evaluation; LBbB: left bundle branch block; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; RBbB: right bundle branch block; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TIA: transient ischaemic attack

Table 2. Thirty-day, 1- and 4-year (VARC-3) outcomes of patients with Myval implantation.

Outcome	30 days	1 year	4 years
Freedom from death	98.6%	93.6%	81.8%
Freedom from stroke	99.5%	99.2%	98.5%
Valve-related hospitalisation	0 (0)	5 (1.4)	6 (1.6)
Severe patient-prosthesis mismatch	2.0%	2.1%	2.1%
Mean aortic gradient, mmHg	10.3±4.7	11.2±5.6	12.0±6.2
Peak aortic gradient, mmHg	18.9±7.9	20.7±9.1	21.6±10.3
AVA, cm ²	1.7±0.4	1.7±0.5	1.7±0.4
LVEF, %	56.4±10.3	56.4±9.7	56.8±9.4
≥Moderate aortic regurgitation	5.9%	7.9%	9.2%
Early safety	83.0%	-	-
Device success	95.5%	-	-
Leaflet thrombosis	0.5%	-	-
Endocarditis	0 (0)	-	-

Data are %, n (%) or mean±standard deviation. AVA: aortic valve area; LVEF: left ventricular ejection fraction; VARC: Valve Academic Research Consortium

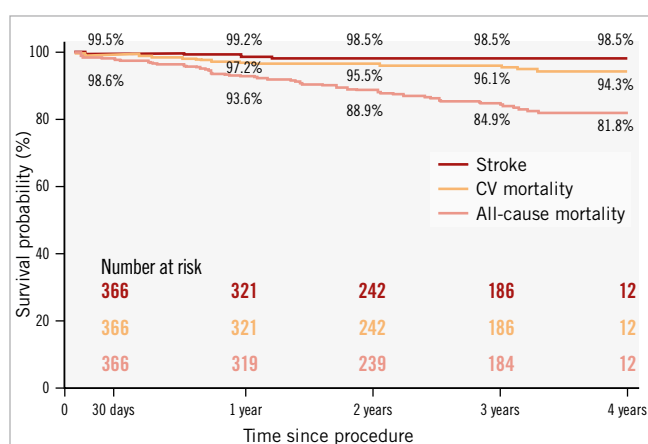


Figure 1. Kaplan-Meier survival curves for all-cause mortality, cardiovascular mortality and stroke at 4 years. CV: cardiovascular

The rate of stage 2 HVD developing over time was almost equally attributable to the increases in the aortic gradient and AR. At 1 year, 6.2% of patients developed stage 2 HVD (48% due to the increase in the gradient and 52% due to the increase in AR); at 2 years, 7.1% (54% due to the increase in gradient, 46% due to the increase in AR); at 3 years, 8.9% (48% due to the increase in gradient, 52% due to the increase in AR); and at 4 years, 9.7% (45% due to the increase in gradient, 55% due to the increase in AR). All cases of stage 3 HVD were due to increased gradient. Structural BVF was attributed to 1.9% of all cases, and a non-structural cause of BVF was seen in 1.4% of cases.

Discussion

A summary of the durability reported for the main current balloon-expandable and self-expanding devices is presented in **Table 4**⁹⁻¹⁵. To our knowledge, this study represents one of the largest midterm follow-up analyses of the Myval

Table 3. Main procedural and in-hospital (VARC-3) outcomes of the study population.

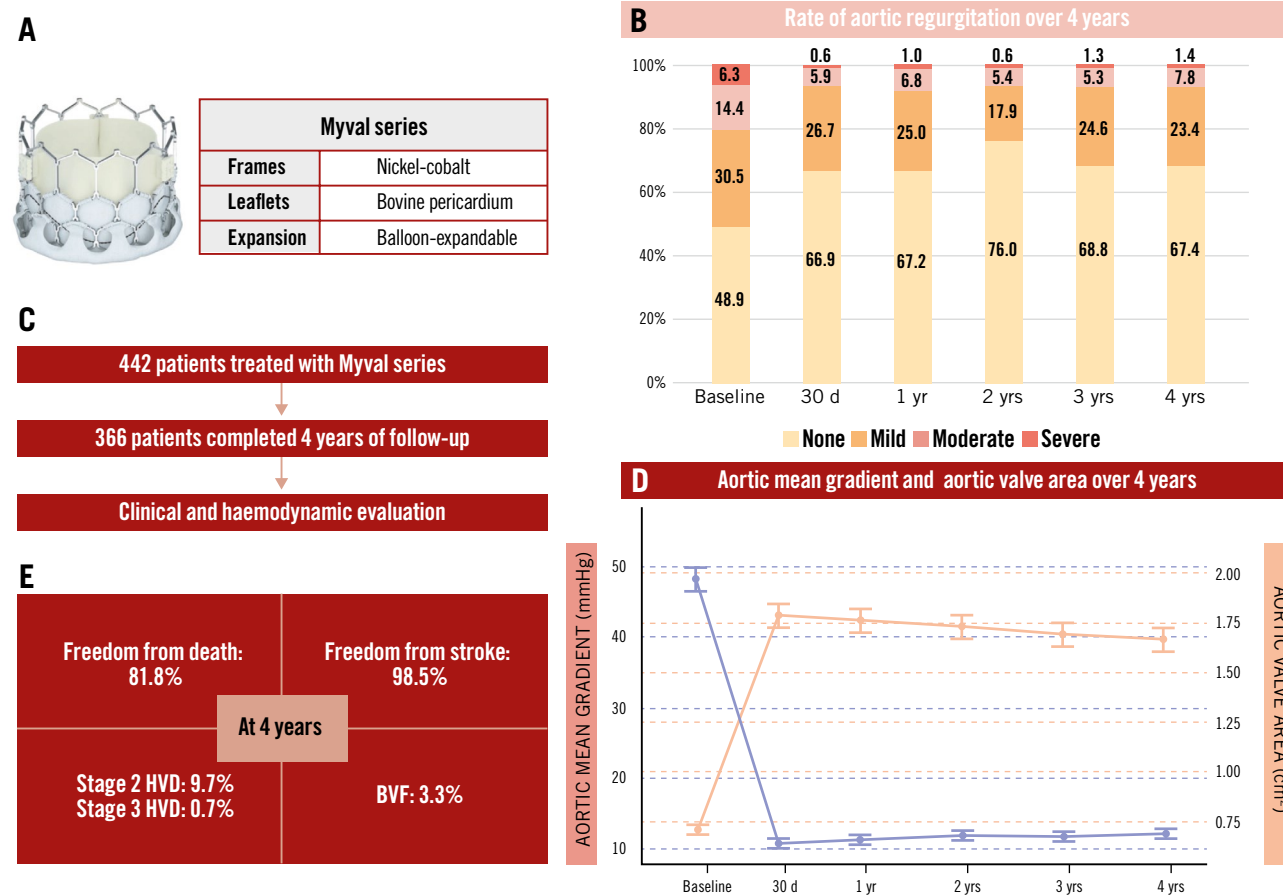
Procedural outcomes	
Transfemoral approach	362 (98.9)
More than 1 prosthesis implanted	4 (1.1)
Balloon predilatation	199 (54.4)
Balloon post-dilatation	29 (7.9)
Procedural complications	
Valve embolisation	2 (0.5)
Annulus rupture	0 (0)
Coronary artery occlusion	1 (0.3)
Tamponade	1 (0.3)
Aortic dissection	1 (0.3)
Conversion to open surgery	0 (0)
Arrhythmia	21 (5.7)
Need for haemodynamic support	5 (1.4)
Procedural death	1 (0.3)
Technical success	355 (97)
In-hospital outcomes	
Major bleeding	8 (2.2)
Major vascular complication	9 (2.5)
Acute kidney injury	8 (2.2)
New permanent pacemaker implantation	29 (7.9)
Stroke	2 (0.5)
Myocardial infarction	1 (0.3)

Data are n (%). VARC: Valve Academic Research Consortium

prosthesis, with a median follow-up of nearly 4 years and a robust dataset of echocardiographic assessments. In our cohort of 366 patients, we observed a 4-year survival rate of 81.8%, comparable to similar high-risk populations¹⁶. This survival rate reflects the advanced age and significant comorbid burden of our study group, including high rates of coronary artery disease and chronic kidney disease.

The durability of the Myval prosthesis appears promising, with favourable haemodynamic performance sustained over the follow-up period. At 4 years, the rates

Summary of the study population and main findings.



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A) Device description. B) Rates of aortic regurgitation at follow-up. C) Study population. D) Aortic mean gradient and aortic valve area at follow-up. E) Clinical and haemodynamic outcomes at 4 years. BVF: bioprosthetic valve failure; HVD: haemodynamic valve deterioration

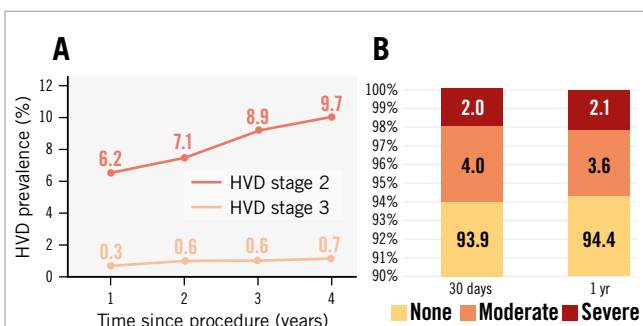


Figure 2. Haemodynamic valve deterioration and patient-prosthesis mismatch at follow-up. A) Prevalence of stage 2 and stage 3 haemodynamic valve deterioration (HVD) over 4 years. B) Rates of moderate and severe patient-prosthesis mismatch at 30 days and 1 year.

of stage 2 and 3 HVD were 9.7% and 0.7%, respectively. This performance at 4-year follow-up is in line with contemporary devices and is likely related to an adequate prosthesis design and the anticalcification process of the bovine pericardium leaflets. The study found the valve had low susceptibility to endocarditis, a complication that can significantly impair valve durability^{17,18}. Clinically overt leaflet thrombosis was rare in our cohort, occurring in only 0.5% of patients. However, no comment can be made on hypoattenuated leaflet thickening (HALT) as systematic computed tomography was not performed at follow-up. These findings highlight the importance of maintaining appropriate antithrombotic therapy post-TAVI to further enhance valve durability.

The rate of BVF criterion 1, which includes symptomatic valve dysfunction, was 3.3% at 4 years. No cases of BVF criterion 2 (requiring reintervention) or BVF criterion 3 (valve-related death) were reported, underscoring the

Table 4. TAVI durability data.

Study	Number of patients	Definition of BVD/BVF	TAVI device	Stage 2-3 SVD-related BVD	All-cause BVF	Duration of follow-up
PARTNER II-S3i Pibarot et al ⁹ 2020	1,665	VARC-3	SAPIEN XT ^a SAPIEN 3 ^a SAVR	9.5% 3.9% 3.5%	4.7% 2.6% 1.3%	5 years
Ferreira-Neto et al ¹⁰ 2020	212	VARC-3	TAVI-SAPIEN ^a / SAPIEN XT	30.2%		8 years
Rheude et al ¹¹ 2020	691	VARC-2	SAPIEN 3	10.3%	1.88%	1 year
UK TAVI Ali et al ¹² 2023	221	EAPCI/EACTS	TAVI-SAPIEN/ SAPIEN XT TAVI-COREVALVE ^b	22.4% 9.8%		7 years
PARTNER 3 Mack et al ¹³ 2023	280 (low-risk patients)	VARC-3	SAPIEN 3 ^a SAVR	4.2% 3.8%	3.3% 3.8%	5 years
NOTION Thyregod et al ¹⁴ 2024	280 (low-risk patients)	VARC-3	TAVI-COREVALVE SAVR	12.5% 13.9%	9.7% 13.8%	10 years
Rück et al ¹⁵ 2024	433	VARC-3	ACURATE neo ^c	2.2%	1.4%	39 months

^aBy Edwards Lifesciences; ^bby Medtronic; ^cby Boston Scientific. BVD: bioprosthetic valve dysfunction; BVF: bioprosthetic valve failure; EACTS: European Association for Cardio-Thoracic Surgery; EAPCI: European Association of Percutaneous Cardiovascular Interventions; SAVR: surgical aortic valve replacement; SVD: structural valve deterioration; TAVI: transcatheter aortic valve implantation; VARC: Valve Academic Research Consortium

valve's structural integrity. Additionally, procedural success was high, with technical failure occurring in only 3% of patients, largely due to rare complications such as valve embolisation and aortic dissection which likely did not differ to the complications reported for alternative contemporary alternatives, as highlighted by LANDMARK⁴.

Balloon pre- or post-dilatation, a strategy to optimise valve seating and minimise PPM, was required in only 7.9% of cases. Severe PPM was noted in 2% of patients at 30 days and in 2.1% at 1 year, rates that compare favourably to other intra-annular TAVI devices¹⁹.

The rates of mortality, stroke, and valve-related rehospitalisation at 1 year and 4 years align with recent findings from the ACURATE IDE trial, where comparable rates for these endpoints were observed with other contemporary TAVI devices²⁰.

The Myval valve's design has been previously associated with optimised transvalvular gradients and effective orifice areas^{4,21}, which might be a determinant factor in the sustained haemodynamic performance reported herein. Our study found mean transvalvular gradients and aortic valve areas at 4 years that were comparable to those with other balloon-expandable and self-expanding devices, emphasising its competitive haemodynamic profile. However, direct comparisons with other studies should be approached with caution due to differences in patient populations and the criteria used to define structural valve deterioration and BVF. Importantly, this is one of the first durability studies that used VARC-3 criteria. A similar reflection can be made regarding the rate of moderate or severe PVL; although in our research, it was proportionally greater than in other low-risk studies such as SMART or PARTNER 3, from our perspective one of the main reasons is the treatment of extra-large annuli (indeed for the 32 mm valve, the rate of PVL of moderate or severe degree was 25% at 4 years). This kind of anatomy is usually excluded in other trials and might be the baseline anatomical condition explaining the higher rate of PVL rather than device-related technical aspects, since Myval seems to perform

comparably to other devices according to LANDMARK (where the extra-large sizes were also excluded). Regarding the new Myval iterations, the Octacor and Octapro devices (Meril Life Sciences), a technical modification in the skirt might help to mitigate the degree of PVL, but this has not been explored yet.

Long-term data from surgical bioprostheses show rates of 10-year freedom from valvular failure rates of between 60% and 95%²²⁻²⁴. However, these studies often include younger, lower-risk patients who may not be directly comparable to TAVI cohorts. Interestingly, recent analyses show no significant difference in outcomes between TAVI and surgical aortic valve replacement after 5 years, supporting the expanding role of TAVI in diverse patient populations^{25,26}.

Our study, the largest focused solely on midterm Myval outcomes, highlights stable valve performance at 4 years, with acceptable rates of regurgitation, HVD, and PPM.

Limitations

This study has several limitations. As a non-randomised, observational analysis, its findings may be influenced by selection bias. Additionally, despite our central analysis of echocardiographic images at follow-up, the exams did not follow a standardised protocol, and operators varied widely. However, the inclusion of consecutive patients and the rigorous review of health records enhance data reliability. The symptomatic evaluation at follow-up is subjective, as it was reported by the patient and the clinician; this may have affected the rates of BVF.

Conclusions

Four-year follow-up in real-world patients undergoing TAVI with the Myval prosthesis demonstrates acceptable durability, with results comparable to contemporary balloon-expandable and self-expanding devices. Further studies with extended follow-up and multimodal imaging are warranted to confirm these findings and explore predictors of valve deterioration.

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Conflict of interest statement

I.J. Amat-Santos is a proctor for Meril Life Sciences; the institution received an unrestricted grant for the LANDMARK trial. M. Montorfano received consultant fees from Abbott, Boston Scientific, AliveCor, and Medtronic. G. Sengottuvelu is a proctor for Meril Life Sciences and Boston Scientific; and has received honoraria from Meril Life Sciences and Boston Scientific. A. Sethi is a proctor for Meril Life Sciences, Boston Scientific, and Sentinel Devices; Principal Investigator of the MyVal-1 study; and has received honoraria for speaker's bureau from Meril Life Sciences and Boston Scientific. A. Jain received consultant fees from Meril Life Sciences. The other authors have no conflict of interest to declare.

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Supplementary data

Supplementary Table 1. Haemodynamic outcomes at 30 days, 1 year and 4 years according to device size.

Supplementary Figure 1. Prevalence of cumulative all-cause bioprosthesis valve failure over 4 years.

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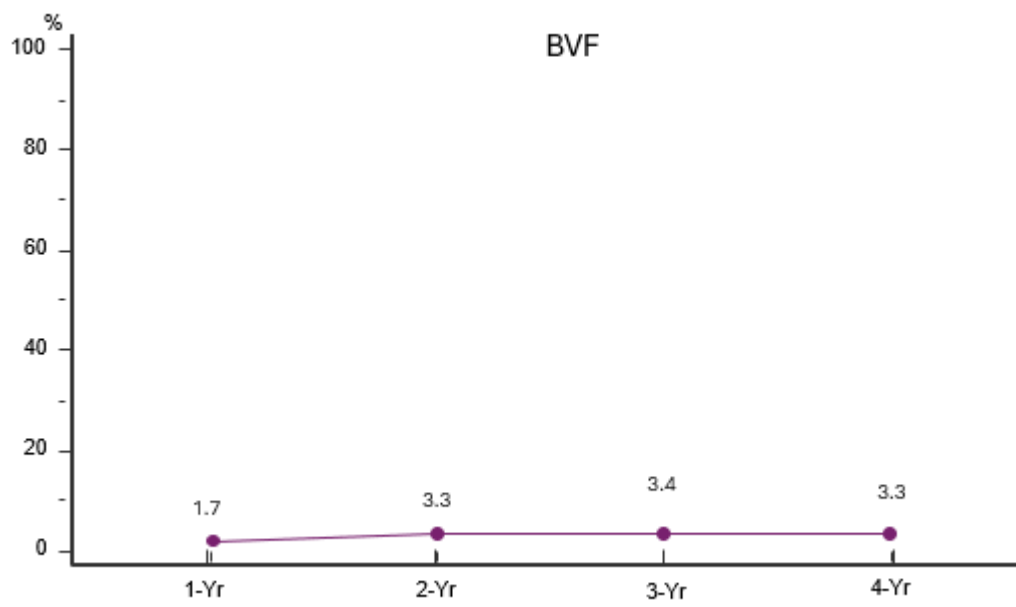
Supplementary data

Supplementary Table 1. Haemodynamic outcomes at 30 days, 1 year and 4 years according to device size.

Outcomes at 30 days									
Device sizes	20mm n=20	21.5mm n=26	23mm n=94	24.5mm n=51	26mm n=77	27.5mm n=32	29mm n=31	30.5mm n=2	32mm n=4
Mean Ao gradient, mmHg	13.3±6.8	11.6±4.8	11.8±5.2	10.2±4.1	9.0±3.8	9.2±3.2	8.4±3.8	6.5±3.5	7.2±2.6
Peak Ao gradient, mmHg	23±14.2	22.1±8.0	21±7.8	19.5±7.9	16.9±5.5	16.8±5.5	14.9±6.2	10.0±5.6	12.0±3.0
AVA, mm ²	1.5±0.3	1.6±0.3	1.6±0.3	1.8±0.3	1.8±0.3	1.9±0.5	2.0±0.5	2.15±0.2	2.2±0.5
LVEF(%)	59.8±6.0	55.0±12.5	57.7±7.9	57.7±11.1	55.7±9.6	54.3±13.4	55.0±11.7	56.7±18.8	49.2±24.2
≥ moderate AoReg (n,%)	0 (0)	1(3.8)	5(5.4)	4(8)	6(8)	2(6.7)	3(10)	0(0)	1(25)
Outcomes at 1 year									
Device sizes	20mm n=18	21.5mm n=25	23mm n=90	24.5mm n=49	26mm n=74	27.5mm n=31	29mm n=30	30.5mm n=2	32mm n=3
Mean Ao gradient, mmHg	14.8±8.2	14.9±8	12.3±5.3	10.8±4.3	9.9±4.5	9.0±4.4	9.0±5.0	9.5±7.7	8.0±2.6
Peak Ao gradient, mmHg	28.2±13.8	26.4±12.1	22.2±8.9	20.5±8.1	18.7±7.5	19.1±6.3	17.3±8.5	16.5±14.8	14.6±2.5
AVA, mm ²	1.4±0.3	1.4±0.3	1.6±0.3	1.8±0.3	1.7±0.3	1.9±0.6	2.0±0.6	1.9±0.2	1.9±0.1

LVEF(%)	60±6	55.7±10.4	57.7±8.1	58.4±9.7	55.9±9.1	54.6±12.7	54.1±11.2	40.7±3.8	50.3±19.5
≥ moderate AoReg (n,%)	0(0)	0(0)	8(9.6)	5(10.4)	6(9)	2(7.4)	2(7.7)	0(0)	1(33.3)
Outcomes at 4 years									
Device sizes	20mm	21.5mm	23mm	24.5mm	26mm	27.5mm	29mm	30.5mm	32mm
	n=17	n=24	n=84	n=42	n=67	n=26	n=25	n=2	n=4
Mean Ao gradient, mmHg	19±9.8	15.4±9.1	12.9±6.1	11.5±4.7	10.3±4.4	9.5±3.7	10.2±4.6	9.5±7.7	7.5±1.7
Peak Ao gradient, mmHg	32.8±14.9	27.3±15.3	23.5±10.5	20.8±8.0	18.9±7.4	18.1±7.3	18.3±8.7	18.0±12.7	14.5±2.3
AVA, mm ²	1.3±0.2	1.3±0.4	1.6±0.3	1.7±0.4	1.6±0.3	1.7±0.4	1.8±0.4	1.4±0.1	2±0.1
LVEF(%)	59.1±6.1	53.9±11.8	58.0±9	58.2±9.2	57±8.4	56.3±11	54.7±10.5	40.7±3.8	46±13.4
≥ moderate AoReg (n,%)	0(0)	1(5.6)	9(11.8)	3(7.3)	10(15.9)	1(4)	1(4.2)	0(0)	1(25)

Ao: Aortic; AoReg: Aortic regurgitation; AVA: Aortic valve area; LVEF: Left Ventricular Ejection Fraction



Supplementary Figure 1. Prevalence of cumulative all-cause bioprosthesis valve failure over 4 years.