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ORIGINAL PAPER

Comparative 30-day echocardiographic outcomes of Myval vs. Sapien and Evolut THVs: insights from LANDMARK trial

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Aims

Several factors, including device design, annulus size, and sizing strategies, influence transcatheter heart valve (THV) haemodynamic outcomes in patients with aortic stenosis (AS). This sub-study evaluates early (30-day) echocardiographic outcomes of the Myval, Sapien, and Evolut THV series, focusing on haemodynamic performance and valve durability.

Methods and results

The LANDMARK trial is a prospective, randomised, multicentre, open-label, non-inferiority trial comparing 384 patients implanted with Myval THV series to 384 receiving Sapien and Evolut THV series. Haemodynamic assessments followed Valve Academic Research Consortium-3 recommendations. At 30-day, haemodynamic device success rates were 85.9%, 77.8, and 85.4% for Myval, Sapien, and Evolut THV series, respectively ($P_{\text{Myval-Sapien}} = 0.03$ and $P_{\text{Myval-Evolut}} = 0.98$). Significant improvements in peak aortic flow velocity, pressure gradients, effective orifice area (EOA), Doppler velocity index (DVI), and cardiac indices were observed across all groups, except for unchanged left ventricular ejection fraction. Moderate prosthesis-patient mismatch (PPM) was less frequent with Myval THV series(11.3%) vs. Sapien THV series(21.8%), but higher than Evolut THV series (5.3%) ($P_{\text{Myval-Sapien}} = 0.0024$, $P_{\text{Myval-Evolut}} = 0.0396$), while severe PPM showed no significant differences (4.2% vs. 6.3% vs. 1.8%; $P_{\text{Myval-Sapien}} = 0.394$, $P_{\text{Myval-Evolut}} = 0.2438$). Rates of ≥ moderate paravalvular leak (PVL) were lower in Myval (3.5%), and Sapien (1.7%) compared with Evolut THV series (8.3%) ($P_{\text{Myval-Sapien}} = 0.3769$, $P_{\text{Myval-Evolut}} = 0.0336$). Myval THV series required minimal oversizing compared with Evolut THV series ($P < 0.0001$).

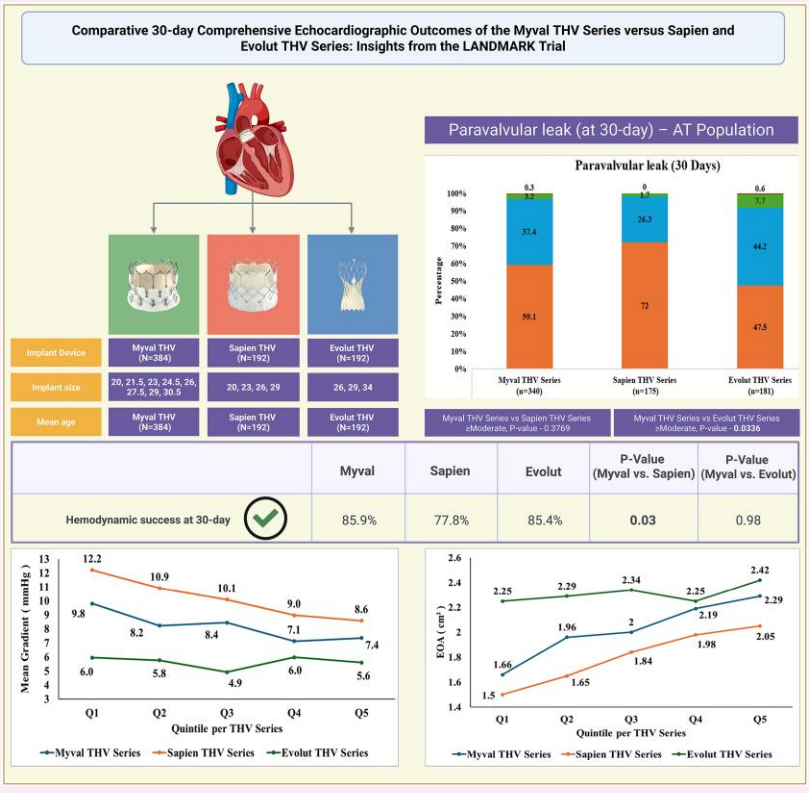
Conclusion

The Myval THV series demonstrates short-term haemodynamic performance comparable to Evolut THV series and superior to Sapien THV series. Including intermediate sizes minimizes oversizing, underscoring its potential as an alternative for TAVI patients. Long-term follow-up is necessary to confirm these findings.

Clinical trial registration

ClinicalTrials.gov: NCT04275726, EudraCT number 2020-000,137-40

Graphical Abstract



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Keywords

aortic stenosis • transcatheter heart valve • THV • randomized trial • non-inferiority • Sapien • Evolut • Myval • self expandable SEV • balloon expandable BEV • haemodynamic • aortic valve • stenosis • TAVI • echocardiography • aortic regurgitation • PPM

Introduction

Transcatheter aortic valve implantation (TAVI) using transcatheter heart valve (THV) is an emerging minimally invasive procedure that has been used frequently as an alternative to surgical aortic valve replacement (SAVR) in patients with severe aortic stenosis (AS).[1,2] Since first used in humans in 2002 by Dr Alain Cribier,[3] THVs were used in several randomized controlled trials comprising varying populations of patients with AS and different surgical risks using either balloon-expandable valves (BEVs) or self-expandable valves.[4–10] Following TAVI, patients undergo echocardiography at different intervals to assess THV function by measuring several parameters such as transvalvular mean pressure gradient, transvalvular peak pressure gradient, effective orifice area (EOA), presence of paravalvular leak (PVL), prosthesis-patient mismatch (PPM) and Doppler velocity index (DVI), which are critical to ascertain the haemodynamic improvement.[11] The LANDMARK is the first randomised controlled trial showing non-inferiority of the Myval THV series to the Contemporary (Sapien and Evolut) THV series in patients with severe AS at 30-day post-TAVI in terms of effectiveness and safety.[4] Data on the Evolut and Sapien THV series was previously published. However, no previous trial reported the haemodynamics of the Myval THV series compared with the Sapien and Evolut THV series. Therefore, this *post hoc* analysis of the LANDMARK trial aimed to investigate the detailed haemodynamic outcomes of the Myval THV series compared with the Contemporary (Sapien or Evolut) THV series.[4]

Methods

Study population and design

The LANDMARK prospective, randomized, multicenter, open-label trial included 768 participants from the 6th of January 2021 till the 5th of December 2023. This study is a *post hoc* analysis of the haemodynamic performance of the three arms of the LANDMARK trial at 30-days following TAVI. The main clinical outcomes of the LANDMARK trial have been previously published.[4] Informed written consent was obtained from all participants. Published details about the trial design are available.[12,13]

Inclusion criteria and clinical information

As previously described in the main manuscript,[4] adult patients with severe symptomatic AS were selected by the local heart team to be recruited into the LANDMARK trial and were randomly assigned to undergo TAVI using either the Myval, Sapien or Evolut THV series.

Echocardiography core laboratory analyses of aortic (THV) valve haemodynamics

Patients underwent transthoracic echocardiography (TTE) at baseline, discharge, and 30-day following TAVI. The echocardiography core laboratory analysed all TTEs up to 30-day post-TAVI. Image analysis and quantification were done according to the American Society of Echocardiography (ASE) and European Association of Echocardiography (EACVI) guidelines using the TOMTEC-ARENA TTA2.51 (Philips, Best, The Netherlands).[14]

Detailed Core Lab methodology was previously described by Soliman *et al.*[15,16] where all TTEs from baseline, discharge and up to 30-day after TAVI were analysed. Several groups of echocardiographic parameters were analysed as follows: (G1) Aortic valve/Prosthetic haemodynamic assessments; (G2) Aortic regurgitation (AR); (G3) Left heart chamber quantification; (G4) Right heart metrics; (G6) Other valvular assessments; (G7) non-conventional parameters. At the baseline visit, the left ventricular outflow tract (LVOT) was measured in the zoomed parasternal long axis view at 5 mm below the annulus as per ASE/EACVI guidance for calcified native valves. Following THV implantation, LVOT measurement was obtained from the outer-to-outer edge of the stent by default in conformance with the most recent guidelines.[11]

Haemodynamic parameters, including the peak and mean aortic pressure gradient, were measured from the continuous-wave Doppler using the Bernoulli formula, and aortic valve area (AVA) was calculated using the continuity equation [(LVOT diameter)^2 × 0.785 × [LVOT VTI/AV velocity time integral (VTI)]. LVOT velocity time integral and LVOT cross-sectional area, yielding LVOT stroke volume, were measured from the pulsed-wave Doppler recordings.

Quantifying chamber size and function of the left ventricle was done from the 2D apical two-chamber (A2C) and four-chamber (A4C) views. The biplane Simpson method was primarily used to estimate left ventricular ejection fraction and left ventricular volumes. All analyses were performed per Core Lab SOPs in accordance with the ASE/EACVI guidelines.[17,18]

AR assessment

As previously described by Soliman *et al.*[15,16] AR presence (yes, no), location (central, paravalvular), and severity (granular and collapsed scheme) were assessed according to the guidelines using an integrated approach from multiple echocardiographic views according to the guidelines.[19–21] PVL severity adjudication using the granular grading scheme[22] included none/trace, mild, mild-to-moderate, moderate, moderate-to-severe, and severe,[23] was finally collapsed into four grades: none-trace, mild, moderate, and severe[24] in line with the Valve Academic Research Consortium 3 (VARC-3).[25]

Haemodynamic outcomes

Haemodynamic Outcomes were reported as individual parameters and composite endpoints per VARC-3 guidelines and ASE/EACVI guidelines.

Individual echocardiographic outcomes were assessed at baseline, discharge and 30-day following the TAVI.[25] Haemodynamic parameters included peak aortic flow velocity, peak aortic pressure gradient, mean aortic pressure gradient, effective aortic orifice area, effective aortic orifice area index, DVI, left ventricular ejection fraction, stroke volume, stroke index, cardiac output, and cardiac index.

Derived parameters and composite outcomes

These included (i) PPM, (ii) haemodynamic success, and (iii) energy loss index (ELI).

PPM was identified across THVs, and the THV (Myval, Sapien, Evolut) haemodynamic performance per device size was estimated and presented. It was measured at 30-days for the as-treated (AT) population. Following the VARC-3 definition,[25] PPM in patients with a body mass index <30 was defined as follows: severe PPM was defined as EOAi ≤ 0.65 cm^2/m^2, moderate PPM as 0.66 cm^2/m^2 ≤ EOAi ≤ 0.85 cm^2/m^2, and no PPM was defined as EOAi > 0.85 cm^2/m^2. While for patients with body mass index ≥30, severe PPM was defined as EOAi < 0.55 cm^2/m^2, moderate PPM as 0.56 cm^2/m^2 ≤ EOAi ≤ 0.70 cm^2/m^2, and no PPM as EOAi > 0.70 cm^2/m^2.

The haemodynamic success (composite endpoint) was defined as patients with all of the following: (i) mean gradient <20 mmHg; (ii) peak flow velocity <3 m/s; (iii) DVI >0.35; (iv) EOA > 1.1 cm^2 for BSA ≥1.6 m^2 or EOA >0.9 cm^2 for BSA <1.6 m^2; (v) No moderate or severe PVL; and (vi) No severe patient-prosthesis mismatch (PPM), defined as EOA index (EOAi) ≤ 0.65 cm^2/m^2 if BMI <30 kg/m^2 or EOAi ≤0.55 cm^2/m^2 if BMI ≥30 kg/m^2. The threshold of EOA >0.9 cm^2 was chosen per VARC-2 criteria for patients with BSA <1.6 m^2.[25,26] PVL was measured at 30-days for the AT population.

The ELI is a haemodynamic parameter that accounts for the pressure recovery phenomenon observed in prosthetic aortic valves. Pressure recovery occurs when kinetic energy from high-velocity blood flow through a valve is partially converted back into static pressure downstream, especially in smaller aortic roots. ELI adjusts the EOA by considering the aortic cross-sectional area, providing a more accurate representation of the energy available for blood flow beyond the valve. The ELI is calculated as [(EOA × Aortic Cross-Sectional Area)/(Aortic Cross-Sectional Area—EOA)].[27]

MSCT-based THV oversizing

Pre-procedural aortic annulus characteristics and measurements are critical for selecting the appropriate THV size. Annulus oversizing was calculated from the formula [Annulus area Oversizing = (Valve annulus area–Aortic annulus area)/Aortic annulus area × 100%]. In addition, perimeter oversizing was calculated from the formula [(Valve perimeter—Aortic perimeter)/Aortic perimeter × 100%]. Area-derived diameter oversizing was calculated as [(Valve area-derived diameter–Aortic area-derived diameter)/Aortic area-derived diameter × 100%]. Moreover, perimeter-derived diameter oversizing was calculated as [(valve perimeter-derived diameter—Aortic perimeter-derived diameter)/Aortic perimeter-derived diameter × 100%].

Echocardiographic reproducibility

To ensure the highest standards of accuracy and reliability, we conducted a rigorous reproducibility analysis of echocardiographic measurements. A randomly selected subset comprising 10% of the 30-day TTEs was independently analysed by two experienced observers to assess inter-observer variability. Additionally, the same subset was re-analysed by one observer at a different time point to evaluate intra-observer variability. Results are in Supplementary data online, *Table S1*.

Statistics

Participants' clinical characteristics, baseline data, and haemodynamic outcomes were presented as counts and percentages for categorical data, and continuous variables were reported as mean (standard deviation; SD). Differences in haemodynamic outcomes at 30-day from baseline visit were calculated across the variables. No data imputation was carried out for the missing values. One-way ANOVA and post-hoc test with Bonferroni correction were used for intergroup comparison of continuous variables. Pearson's χ^2 test or Fisher's exact test was used to compare categorical variables as appropriate. The two groups' mean difference and risk ratio are presented with 95% CIs. Statistical analysis was performed using R (version 4.3.3). A *P*-value ≤ 0.05 was considered statistically significant.

Results

Study population

A total of 768 participants were included in the study, with 384 assigned to the Myval THV series group and 192 each to the Sapien and Evolut THV series groups. The majority of patients treated with Myval were women (51.4%), compared with 47.9% for Sapien and 44.3% for Evolut ($P_{\text{Myval-Sapien}} = 0.25$ and $P_{\text{Myval-Evolut}} = 0.50$). Additional details are provided in *Table 1*.

Multi-slice computer tomography (MSCT) characteristics and THV sizing

Oversizing calculations based on annulus area, perimeter, and derived diameters revealed significant differences. The Myval THV series exhibited minimal oversizing (8.4 ± 8.2 mm^2) compared with the Evolut THV series (41.5 ± 13.6 mm^2) and comparable results to the Sapien THV series (8.4 ± 9.7 mm^2) ($P_{\text{Myval-Evolut}}$=<0.0001 and $P_{\text{Myval-Sapien}}$=>0.99). Oversizing related to annulus area-derived diameter was negligible for the Myval THV series (0.3 ± 4.9 mm) compared with Sapien (1.9 ± 4.5 mm) and Evolut (16.3 ± 5.6 mm) THV series ($P_{\text{Myval-Sapien}} = 0.004$ and $P_{\text{Myval-Evolut}}$=<0.0001). Additional details are provided in *Table 2*.

Procedural characteristics

TAVI was performed predominantly via the transfemoral approach, with rates of 99.7% in the Myval THV series, 97.5% in the Sapien THV series, and 100% in the Evolut THV series (*Table 1*). The distribution of valve sizes included 20 mm ($n = 11$), 21.5 mm ($n = 17$), 23 mm ($n = 136$), 24.5 mm ($n = 95$), 26 mm ($n = 204$), 27.5 mm ($n = 65$), 29 mm ($n = 182$), 30.5 mm ($n = 1$), and 34 mm ($n = 44$) (see Supplementary data online, *Table S2* and Supplementary data online, *Figure S1*).

A unique feature of the Myval THV series is the availability of intermediate sizes. A total of 177 patients were randomised into these intermediate sizes, and additional details for these patients are provided in Supplementary data online, *Table S3*.

Haemodynamic success of the Myval, Evolut, and Sapien THVs series

At 30-day, the haemodynamic success rates were 85.9%, 77.8%, and 85.4% for the Myval, Sapien, Evolut and THV series, respectively ($P_{\text{Myval-Sapien}} = 0.03$, $P_{\text{Myval-Evolut}} = 0.98$). Detailed results on haemodynamic success are provided in Supplementary data online, *Table S4*. All THV series demonstrated significant improvement in haemodynamic outcomes, except for the left ventricular ejection fraction, which showed no significant change at 30-day (see Supplementary data online, *Figure S2*).

The Myval THV series significantly reduced the mean aortic pressure gradient from 40.1 ± 14.1 mmHg at baseline to 8.2 ± 3.5 mmHg at 30-day ($P < 0.0001$) (*Table 3*). Similar improvements were observed for the Sapien series (baseline:39.3 ± 14.1 mmHg; 30-day:10.1 ± 4.5 mmHg; $P < 0.0001$) and the Evolut series (baseline:38.7 ± 13.1 mmHg; 30-day:5.7 ± 2.4 mmHg; $P < 0.0001$) (*Table 3*). Also, the improvement in the Stroke volume was due to the increased VTI, as LVOT diameter remained unchanged.

The effective aortic orifice area (EOA) also increased significantly at 30-day in all groups: Myval THV series (baseline:0.74 ± 0.23 cm^2; 30-day:2.02 ± 0.54 cm^2; $P < 0.0001$), Sapien THV series (baseline: 0.69 ± 0.20 cm^2; 30-day:1.78 ± 0.50 cm^2; $P < 0.0001$), and Evolut THV series (baseline:0.74 ± 0.23 cm^2; 30-day:2.32 ± 0.55 cm^2; $P < 0.0001$) (*Table 3*). The Myval THV demonstrated significant haemodynamic improvements at 30 days in both men and women, with marked reductions in transvalvular gradients and increases in EOA, comparable to or better than established devices. These favourable outcomes highlight Myval's consistent valve performance across sexes, with a balanced profile of gradient reduction and cardiac output enhancement, supporting its utility in diverse patient populations (see Supplementary data online, *Tables S5* and *S6*). Supplementary data online, *Table S7* provides further details on haemodynamic outcomes per device size.

Analysis by annulus area quintiles revealed variations in the mean aortic gradient and EOA across all THV series (*Figure 1A–D*). Additionally, significantly lower mean gradient compared with the Sapien THV series in quintiles Q1 and Q2, and higher mean gradient than the Evolut THV series in quintiles Q1, Q2, Q3, and Q5. The EOA per annulus quintiles showed significantly higher EOA compared with the Sapien series in quintiles Q2, Q4, and Q5, while lower EOA than the Evolut THV series in quintiles Q1, Q2, and Q3 (*Figure 1C* and *D*). Additional data on EOA and DVI is provided in Supplementary data online, *Table S8*.

Beyond conventional parameters, ELI values were 2.2 ± 0.7 for Myval THV series, 2.0 ± 0.6 for Sapien THV series, and 2.6 ± 0.7 for Evolut THV series, with significant differences between the Myval THV series and the other two groups ($P < 0.0001$) (see Supplementary data online, *Table S9*).

Haemodynamic performance of intermediate sizes of Myval THV series

Intermediate sizes of the Myval THV series showed significant improvements in mean aortic gradients at discharge and 30-day, with values decreasing with increased THV size. All other haemodynamic parameters improved except for left ventricular ejection fraction, which remained unchanged (see Supplementary data online, *Table S7*).

Table 1 Baseline data and procedure characteristics of Myval, Sapien, and Evolut THV series

Baseline characteristics	Myval THV series ($n = 384$)	Sapien THV series ($n = 192$)	Evolut THV series ($n = 192$)
Age, (year)	80.0 ± 5.7	81.1 ± 5.4	79.7 ± 5.4
Female, (%)	193 (50.3)	86 (44.8)	90 (46.9)
Body mass index (kg/m^2)	28.2 ± 4.9 ($n = 382$)	27.9 ± 4.4 ($n = 192$)	28.2 ± 5.3 ($n = 191$)
Body surface area (m^2)	1.9 ± 0.2 ($n = 382$)	1.9 ± 0.2 ($n = 192$)	1.9 ± 0.2 ($n = 191$)
Society of Thoracic Surgeons score, mean ± SD	3.3 ± 2.6	3.3 ± 2.2	3.2 ± 2.2
New York Heart Association class III or IV (%)	206 (53.8)	98 (51.0)	98 (51.3)
Current diabetes mellitus (%)	111 (28.9)	56 (29.2)	58 (30.2)
Hypercholesterolaemia (%)	42 (10.9)	3 (1.6)	33 (17.2)
Hypertension (%)	256 (66.7)	129 (67.2)	125 (65.1)
Alcohol consumption (%)	89 (23.2)	21 (10.9)	57 (29.7)
Atrial fibrillation (%)	94 (24.5)	45 (23.4)	54 (28.1)
Chronic obstructive pulmonary disease (%)	42 (10.9)	20 (10.4)	20 (10.4)
Myocardial infarction (%)	26 (6.8)	12 (6.3)	11 (5.7)
Coronary artery disease (%)	55 (14.3)	33 (17.2)	25 (13.0)
Prior coronary artery bypass grafting (%)	13 (3.4)	10 (5.2)	11 (5.7)
Prior percutaneous coronary intervention (%)	30 (7.8)	9 (4.7)	16 (8.3)
Prior balloon aortic valvuloplasty, (%)	4 (1.0)	0 (0.0)	0 (0.0)
Cerebrovascular accident (%)	5 (1.3)	0 (0.0)	1 (0.5)
Porcelain aorta or hostile chest procedural characteristics (%)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral vascular disease (%)	3 (0.8)	2 (1.04)	1 (0.5)
Pulmonary hypertension (%)	10 (2.6)	2 (1.0)	3 (1.6)
Permanent pacemaker (%)	11 (2.9)	6 (3.1)	12 (6.3)
Left bundle branch block (%)	9 (2.3)	9 (4.7)	11 (5.7)
Right bundle branch block (%)	13 (3.4)	17 (8.9)	12 (6.2)
Procedural characteristics			
Transfemoral approach (%)	378 (99.7)	188 (97.5)	188 (100.0)
Subclavian approach (%)	1 (0.3)	1 (0.5)	0 (0.0)
Transaortic approach (%)	0 (0.0)	0 (0.0)	0 (0.0)
Balloon pre-dilatation (%)	164 (43.3) $n = 379$	58 (30.7) ($n = 189$)	86 (45.7) ($n = 188$)
Procedure time (min)	77.0 ± 40.3 ($n = 378$)	76.5 ± 43.2 ($n = 189$)	78.7 ± 37.1 ($n = 188$)
Pre-dilation (BAV) performed	164 (43.3) ($n = 379$)	58 (30.7) ($n = 189$)	86 (45.7) ($n = 188$)
Post dilation performed	38 (10.0) ($n = 379$)	19 (10.1) ($n = 189$)	61 (32.4) ($n = 188$)
Conversion from TAVR to SAVR (%)	0 (0.0)	1 (0.5)	0 (0.0)
Procedural deaths (index hospitalization) (%)	0 (0.0)	0 (0.0)	0 (0.0)
≥2 Transcatheter valves implanted (%)	2 (0.5)	0 (0.0)	1 (0.5)
Valve embolization (%)	2 (0.5)	0 (0.0)	3 (1.6)
Annulus rupture (%)	1 (0.3)	0 (0.0)	0 (0.0)
Coronary obstruction (%)	1 (0.3)	0 (0.0)	0 (0.0)
Ventricular perforation (%)	2 (0.5)	0 (0.0)	0 (0.0)

VARC-3 intended valve performance parameters

Post-TAVI, the number of patients with a mean aortic pressure gradient ≥20 mmHg remained unchanged at discharge and 30-day and showed the following results at 30-day: Myval THV series: 3 (0.8%), Sapien THV series: 5 (2.9%), and Evolut THV series: 0 (0%) ($P_{\text{Myval-Sapien}} = 0.12$ and $P_{\text{Myval-Evolut}} = 0.55$). The Myval THV series showed lower DVI <0.35 compared with Sapien (4.9% vs. 13.4%, $P = 0.001$) and higher compared with Evolut THV series (4.9% vs. 0.6%, $P = 0.02$) (*Table 4*).

Prosthesis patient mismatch

At 30-days for the AT population, moderate PPM was significantly lower in Myval THV series (11.3%), compared with Sapien THV series

Table 2 MSCT characteristics and valve sizing

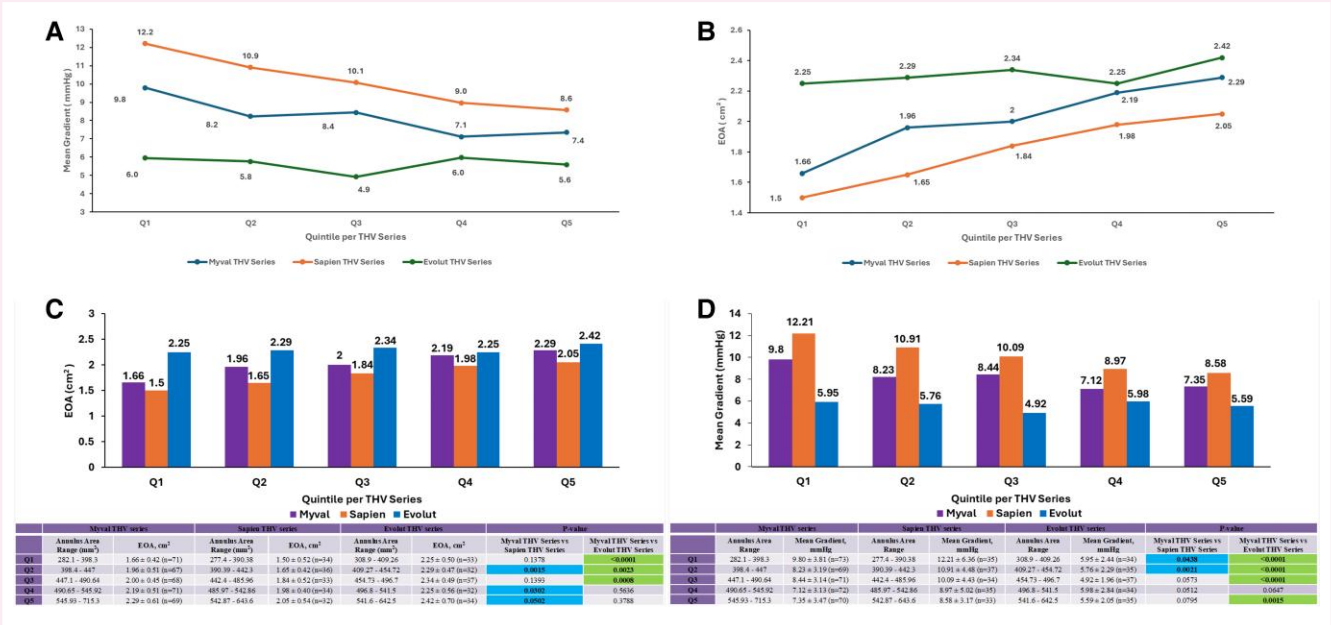
Anatomic characteristics (On MSCT)	Myval THV series ($n = 384$)	Sapien THV series ($n = 192$)	Evolut THV series ($n = 192$)	*P*-value (Overall)	*P*-value (Myval vs. Sapien)	*P*-value (Myval vs. Evolut)
Aortic annulus characteristics						
• Min diameters, mm	21.8 ± 2.1	21.8 ± 2.2	21.9 ± 2.1	0.66	0.95	0.40
• Max diameter, mm	27.5 ± 2.5	27.4 ± 2.6	27.5 ± 2.3	0.88	0.79	0.75
• Mean diameter, mm	24.6 ± 2.1	24.6 ± 2.2	24.7 ± 2.0	0.76	0.82	0.55
• Perimeter derived diameter, mm	24.8 ± 2.1	24.7 ± 2.2	24.9 ± 1.9	0.78	0.78	0.60
• Annulus derived diameter, mm	24.4 ± 2.1	24.4 ± 2.2	24.5 ± 1.9	0.83	0.82	0.64
• Perimeter, mm	77.8 ± 6.7	77.7 ± 6.9	78.1 ± 6.1	0.78	0.77	0.60
• Area, mm^2	470.5 ± 80.0	469.3 ± 82.6	473.5 ± 74.2	0.86	0.86	0.66
Ascending aorta characteristics						
• Min diameters, mm	34.1 ± 3.9	34.4 ± 4.3	33.8 ± 3.6	0.36	0.56	0.73
• Max diameter, mm	35.8 ± 3.9	36.1 ± 4.3	35.6 ± 3.6	0.37	0.74	0.32
• Mean diameter, mm	35.0 ± 3.9	35.3 ± 4.3	34.7 ± 3.6	0.37	0.90	0.46
• Perimeter derived diameter, mm	35.0 ± 3.9	35.3 ± 4.3	34.7 ± 3.5	0.35	0.91	0.36
• Annulus derived diameter, mm	34.9 ± 3.9	35.3 ± 4.3	34.7 ± 3.5	0.35	0.93	035
• Perimeter, mm	109.9 ± 12.2	110.9 ± 13.5	109.2 ± 11.1	0.37	0.91	0.34
• Area, mm^2	969.8 ± 218.7	990.6 ± 246.1	954.6 ± 196.3	0.27	0.96	0.28
Calcification (quantitative)						
Aortic valve calcification volume Median (IQR)	845.05 (540.75–1310.00)	775.15 (448.35–1291.00)	874 (533.05–1295.90)	0.21	0.13	0.26
Calcification (qualitative)						
Aortic valve calcification severity (qualitative)	***n* = 383**	***n* = 192**	***n* = 192**			
• No aortic valve calcification	0 (0.00)	4 (2.1)	2 (1.0)	0.08	**0.02**	0.20
• Mild aortic valve calcification	60 (15.7)	39 (20.3)	34 (17.7)			
• Moderate aortic valve calcification	146 (38.1)	70 (36.5)	65 (33.9)			
• Severe aortic valve calcification	177 (46.2)	79 (41.1)	91 (47.4)			
Quintiles of annulus area						
Q1	282.1 to 398.3	277.4 to 390.4	308.9 to 409.3			
Q2	398.4 to 447	390.4 to 442.3	409.3 to 454.7			
Q3	447.1 to 490.6	442.4 to 486.0	454.7 to 496.7			
Q4	490.7 to 545.9	486.0 to 542.9	496.8 to 541.5			
Q5	545.9 to 715.3	542.9 to 643.6	541.6 to 642.5			
Quintiles of annulus perimeter						
Q1	61.1 to 71.8	62.1 to 71.4	62.9 to 72.5			
Q2	71.9 to 76	71.5 to 75.6	72.6 to 76.8			
Q3	76.1 to 79.7	75.7 to 79.4	76.9 to 80			
Q4	79.8 to 83.9	79.5 to 83.8	80.1 to 83.7			
Q5	84 to 96.5	83.9 to 91.7	83.8 to 90.4			
Oversizing						
Oversizing related to the annulus area	8.4 ± 8.2	8.4 ± 9.7	41.5 ± 13.6	**<0.0001**	>0.99	**<0.0001**
Oversizing related to annulus perimeter	2.4 ± 3.9	2.4 ± 4.6	16.9 ± 5.5	**<0.0001**	>0.99	**<0.0001**
Oversizing related to annulus area-derived diameter	0.3 ± 4.9	1.9 ± 4.5	16.3 ± 5.6	**<0.0001**	**0.004**	**<0.0001**
Oversizing related to annulus perimeter-derived diameter	2.5 ± 3.9	2.5 ± 4.6	17.0 ± 5.6	**<0.0001**	>0.99	**<0.0001**

Bold values refer significant differences.

Table 3 Haemodynamic outcomes of Myval, Sapien and Evolut THV series

Parameter	THV	Baseline (BL)[a]	30 days[a]	Difference (BL—30D)	95% CI of mean difference	*P*-value[b]
Peak aortic flow velocity, m/s	Myval THV series ($n = 335$)	4.0 ± 0.7	1.9 ± 0.4	−2.1 ± 0.7	(−2.2, −2.0)	**<0.0001**
	Sapien THV series ($n = 161$)	3.9 ± 0.7	2.1 ± 0.5	−1.8 ± 0.6	(−1.9, −1.7)	**<0.0001**
	Evolut THV series ($n = 164$)	3.9 ± 0.6	1.6 ± 0.3	−2.3 ± 0.6	(−2.4, −2.2)	**<0.0001**
Peak aortic pressure gradient, mmHg	Myval THV series ($n = 335$)	65.5 ± 21.5	15.4 ± 6.4	−50.2 ± 20.6	(−52.6, −47.8)	**<0.0001**
	Sapien THV ($n = 161$)	63.5 ± 21.2	18.7 ± 8.0	−44.9 ± 19.6	(−48.4, −41.4)	**<0.0001**
	Evolut THV series ($n = 164$)	63.7 ± 20.4	10.9 ± 4.4	−52.8 ± 19.8	(−56.0, −49.7)	**<0.0001**
Mean aortic pressure gradient, mmHg	Myval THV series ($n = 335$)	40.1 ± 14.1	8.2 ± 3.5	−31.9 ± 13.5	(−33.5, −30.4)	**<0.0001**
	Sapien THV series ($n = 161$)	39.3 ± 14.1	10.1 ± 4.5	−29.2 ± 13.0	(−31.5, −17.0)	**<0.0001**
	Evolut THV series ($n = 164$)	38.7 ± 13.1	5.7 ± 2.4	−33.0 ± 12.8	(−35.1, −31.0)	**<0.0001**
Effective aortic orifice area, cm^2	Myval THV series ($n = 316$)	0.74 ± 0.23	2.02 ± 0.54	1.3 ± 0.5	(1.22, 1.34)	**<0.0001**
	Sapien THV series ($n = 149$)	0.69 ± 0.20	1.78 ± 0.50	1.1 ± 0.5	(1.00, 1.18)	**<0.0001**
	Evolut THV series ($n = 156$)	0.74 ± 0.23	2.32 ± 0.55	1.6 ± 0.5	(1.49, 1.67)	**<0.0001**
Effective aortic orifice area index, cm^2/m^2	Myval THV series ($n = 313$)	0.39 ± 0.12	1.08 ± 0.29	0.7 ± 0.3	(0.66, 0.72)	**<0.0001**
	Sapien THV series ($n = 147$)	0.37 ± 0.1	0.97 ± 0.28	0.6 ± 0.3	(0.55, 0.65)	**<0.0001**
	Evolut THV series ($n = 155$)	0.39 ± 0.12	1.23 ± 0.33	0.8 ± 0.3	(0.79, 0.89)	**<0.0001**
Doppler velocity index	Myval THV series ($n = 324$)	0.2 ± 0.1	0.5 ± 0.1	0.3 ± 0.1	(0.28, 0.32)	**<0.0001**
	Sapien THV series ($n = 156$)	0.2 ± 0.1	0.5 ± 0.1	0.3 ± 0.1	(0.28, 0.32)	**<0.0001**
	Evolut THV series ($n = 158$)	0.2 ± 0.1	0.6 ± 0.2	0.4 ± 0.1	(0.37, 0.43)	**<0.0001**
Left ventricular ejection fraction, %	Myval THV series ($n = 144$)	58.1 ± 1.0	58.5 ± 9.4	0.3 ± 8.6	(−1.9, 2.6)	0.65
	Sapien THV series ($n = 89$)	57.8 ± 11.2	58.2 ± 10.7	0.3 ± 8.8	(−2.9, 3.6)	0.72
	Evolut THV series ($n = 69$)	58.2 ± 8.3	58.5 ± 9.6	0.2 ± 9.8	(−2.8, 3.2)	0.86
Stroke volume, mL	Myval THV series ($n = 319$)	68.9 ± 17.6	75.0 ± 19.4	6.1 ± 18.8	(3.2, 9.0)	**<0.0001**
	Sapien THV series ($n = 152$)	63.8 ± 17.4	71.7 ± 19.5	7.9 ± 17.2	(3.8, 12.1)	**<0.0001**
	Evolut THV series ($n = 159$)	68.0 ± 19.0	72.2 ± 19.0	4.1 ± 16.3	(−0.03, 8.3)	**0.002**
Stroke index, mL/m^2/beat	Myval THV series ($n = 316$)	36.6 ± 9.6	40.1 ± 10.6	3.5 ± 9.9	(1.9, 5.1)	**<0.0001**
	Sapien THV series ($n = 150$)	34.4 ± 9.3	38.9 ± 10.7	4.4 ± 9.1	(2.2, 6.7)	**<0.0001**
	Evolut THV series ($n = 158$)	35.7 ± 10.4	37.9 ± 10.0	2.2 ± 8.5	(−0.01, 4.5)	**0.0013**
Cardiac output, L/min	Myval THV series ($n = 312$)	4.6 ± 1.2	5.2 ± 1.4	0.6 ± 1.5	(0.4, 0.8)	**<0.0001**
	Sapien THV series ($n = 145$)	4.3 ± 1.2	4.9 ± 1.3	0.5 ± 1.2	(0.3, 0.8)	**<0.0001**
	Evolut THV series ($n = 152$)	4.5 ± 1.4	4.9 ± 1.4	0.4 ± 1.4	(0.1, 0.7)	**0.0005**
Cardiac index, L/m^2/min	Myval THV series ($n = 309$)	2.5 ± 0.7	2.8 ± 0.8	0.3 ± 0.8	(0.2, 0.4)	**<0.0001**
	Sapien THV series ($n = 143$)	2.3 ± 076	2.6 ± 0.7	0.3 ± 0.7	(0.2, 0.5)	**<0.0001**
	Evolut THV series ($n = 151$)	2.3 ± 0.7	2.6 ± 0.7	0.3 ± 0.7	(0.1, 0.4)	**0.0003**

Bold values refer significant differences.
Data represented as mean +/− SD.
[a]Paired data analysis in ITT population.



	Myval THV series		Sapien THV series		Evolut THV series		P-value	
	Annulus Area Range (mm²)	EOA, cm²	Annulus Area Range (mm²)	EOA, cm²	Annulus Area Range (mm²)	EOA, cm²	Myval THV Series vs Sapien THV Series	Myval THV Series vs Evolut THV Series
Q1	282.1 - 398.3	1.66 ± 0.42 (n=71)	277.4 - 390.38	1.50 ± 0.52 (n=34)	308.9 - 409.26	2.25 ± 0.50 (n=33)	0.1578	<0.0001
Q2	398.4 - 447	1.96 ± 0.51 (n=67)	390.39 - 442.3	1.65 ± 0.42 (n=36)	409.27 - 454.72	2.29 ± 0.47 (n=32)	0.0015	0.0023
Q3	447.1 - 490.64	2.00 ± 0.45 (n=68)	442.4 - 485.96	1.84 ± 0.52 (n=33)	454.73 - 496.7	2.34 ± 0.49 (n=37)	0.1395	0.0008
Q4	490.65 - 545.92	2.19 ± 0.51 (n=71)	485.97 - 542.86	1.98 ± 0.40 (n=34)	496.8 - 541.5	2.25 ± 0.56 (n=32)	0.0302	0.5636
Q5	545.93 - 715.3	2.29 ± 0.61 (n=69)	542.87 - 643.6	2.05 ± 0.54 (n=32)	541.6 - 642.5	2.42 ± 0.70 (n=34)	0.0502	0.3788

	Myval THV series		Sapien THV series		Evolut THV series		P-value	
	Annulus Area Range	Mean Gradient, mmHg	Annulus Area Range	Mean Gradient, mmHg	Annulus Area Range	Mean Gradient, mmHg	Myval THV Series vs Sapien THV Series	Myval THV Series vs Evolut THV Series
Q1	282.1 - 398.3	9.80 ± 3.81 (n=73)	277.4 - 390.38	12.21 ± 6.36 (n=35)	308.9 - 409.26	5.95 ± 2.44 (n=34)	0.0420	<0.0001
Q2	398.4 - 447	8.23 ± 3.19 (n=69)	390.39 - 442.3	10.91 ± 4.48 (n=37)	409.27 - 454.72	5.76 ± 2.29 (n=35)	0.0021	<0.0001
Q3	447.1 - 490.64	8.44 ± 3.14 (n=71)	442.4 - 485.96	10.09 ± 4.43 (n=34)	454.73 - 496.7	4.92 ± 1.96 (n=37)	0.0573	<0.0001
Q4	490.65 - 545.92	7.12 ± 3.13 (n=72)	485.97 - 542.86	8.97 ± 5.02 (n=35)	496.8 - 541.5	5.98 ± 2.84 (n=34)	0.0512	0.0647
Q5	545.93 - 715.3	7.35 ± 3.47 (n=70)	542.87 - 643.6	8.58 ± 3.17 (n=33)	541.6 - 642.5	5.59 ± 2.05 (n=35)	0.0795	0.0015

Figure 1 MSCT annulus quintiles for (*A*) mean aortic gradient at 30-day, (*B*) EOA at 30-day, (*C*) comparison of EOA in Myval, Sapien, and Evolut THV series (*D*) comparison of mean gradient in Myval, Sapien, and Evolut THV series.

(21.8%), while results were higher than Evolut THV series (5.3%) ($P_{\text{Myval-Sapien}} = 0.0024$ and $P_{\text{Myval-Evolut}} = 0.0396$). Severe PPM was less frequent and showed no significant differences: (Myval THV series: 14 (4.2%), Sapien THV series: 11 (6.3%), and Evolut THV series: 3 (1.8%), $P_{\text{Myval-Sapien}} = 0.394$ and $P_{\text{Myval-Evolut}} = 0.2438$) (*Figure 2A*).

AR severity per THV series

At 30-day, 9 patients (2.6%) in the Myval THV series had total AR ≥ Moderate, compared with 3 patients (1.8%) in the Sapien THV series and 11 patients (6.3%) in the Evolut THV series ($P = 0.03$) (*Table 4*). At 30-days for AT population, moderate PVL were comparable for BEVs which showed 11 patients (3.2%) in the Myval THV series group, 3 patients (1.7%) in the Sapien THV series group, and both were lower than Evolut THV series group ($n = 14$, 7.7%) ($P_{\text{Myval-Sapien}} = 0.4005$ and $P_{\text{Myval-Evolut}} = 0.0382$) (*Figure 2B*). Additional details by THV size are available in Supplementary data online, *Table S10*.

Aortic flow patterns and left ventricular functions

The baseline distribution of aortic flow patterns was comparable across all groups. By 30-day, the Myval THV series had the lowest proportion of patients with low aortic flow (32.0%), compared with Sapien (40.4%) and Evolut (47.8%) ($P = 0.001$). Left ventricular function remained consistent, with similar numbers of patients demonstrating normal function at both baseline and 30-day (*Table 5*).

Left and right ventricular function and valvular function

The assessment of mitral and tricuspid valve regurgitation revealed changes in severity following TAVI. Moderate mitral regurgitation was observed in 25 patients (7.8%) in the Myval THV series group, 10 (5.7%) in the Sapien THV series group, and 9 (5.1%) in the Evolut THV series group, with no significant differences ($P = 0.75$). Severe mitral regurgitation was rare across all THV series (see Supplementary data online, *Table S7*), with changes in severity illustrated in *Figure 3A*.

Tricuspid regurgitation displayed a similar trend, with no significant differences across groups ($P = 0.76$). Moderate tricuspid regurgitation was reported in 24 patients (7.5%) in the Myval THV series group, 16 (9.3%) in the Sapien THV series group, and 14 (8.2%) in the Evolut THV series group. Changes in tricuspid regurgitation severity by THV type are depicted in *Figure 3B* and Supplementary data online, *Table S7*. Off note, the AT population's data is being reported here.

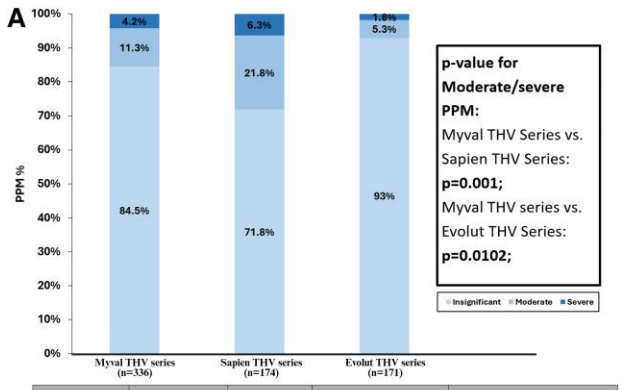
Discussion

This study provides a detailed comparative analysis of the haemodynamic outcomes of the Myval THV series against the Sapien and Evolut THV series, as assessed in the LANDMARK trial. Key findings include: (i) *Significant Haemodynamic Improvements Across All THV Series*: At 30-day, all three THV types demonstrated notable improvements in haemodynamic parameters, underscoring the efficacy of TAVI for severe AS. (ii) *Comparable Performance Across Haemodynamic Metrics*: The Myval THV series exhibited performance comparable to the Sapien and Evolut THVs in improving key parameters such as EOA, mean gradients, and PVL, as well as in minimizing severe PPM. (iii) *Edge of Myval THV series in Moderate PPM, DVI <0.35 and Composite Haemodynamic Success compared with Sapien THV series, and comparable in DVI <0.35 compared with Evolut THV series:* The Myval THV series exhibited an advantage over the Sapien THV series and was comparable to the Evolut THV series in achieving composite haemodynamic success and reduced the incidence of moderate PPM compared with Sapien THV series, but showed higher PPM than Evolut THV series. Furthermore, the incidence of DVI <0.35 was lower with the Myval THV series compared with the Sapien THV series and higher compared with the Evolut THV series. These results highlight its potential as a robust alternative. (iv) *Effectiveness of Intermediate Sizing in Myval THV series:* Intermediate sizes of the Myval THV series provided haemodynamic outcomes

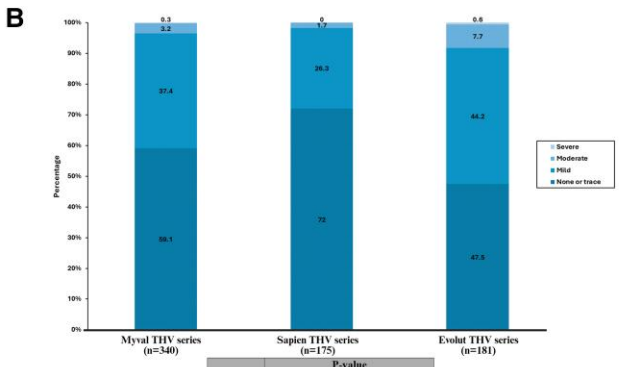
Table 4 VARC-3 device intended performance parameters (ITT population)

Parameter	Visit	Total			*P*-Value	Risk difference (95% CI)	*P*-Value (Myval vs. Sapien)	Risk difference (95% CI)	*P*-Value (Myval vs. Evolut)
		Myval THV series	Sapien THV series	Evolut THV series					
	D 1M	*n* = 368 *n* = 355	*n* = 186 *n* = 176	*n* = 178 *n* = 178	(Myval vs. Sapien vs. Evolut)	Myval vs. Sapien		Myval vs. Evolut	
Mean pressure gradient ≥20 mmHg	D	3 (0.8) (*n* = 362)	5 (2.8) (*n* = 181)	0 (0) (*n* = 175)	**0.04**	−1.93 (−4.91, 1.04)	0.12	0.83 (−0.53, 2.19)	0.56
	1M	3 (0.8) (*n* = 355)	5 (2.9) (*n* = 174)	0 (0) (*n* = 175)	**0.03**	−2.02 (−5.12, 1.06)	0.12	0.85 (−0.53, 2.22)	0.55
Peak aortic flow velocity ≥ 3 m/s	D	5 (1.4) (*n* = 362)	7 (3.9) (*n* = 181)	0 (0) (*n* = 175)	**0.01**	−2.49 (−5.96, 0.98)	0.12	1.38 (−0.24, 3.01)	0.18
	1M	2 (0.6) (*n* = 355)	6 (3.4) (*n* = 174)	0 (0) (*n* = 175)	**0.01**	−2.89 (−6.13, 0.36)	**0.02**	0.56 (−0.64, 1.77)	>0.99
Doppler velocity index <0.35	D	10 (2.8) (*n* = 356)	11 (6.2) (*n* = 178)	1 (0.6) (*n* = 172)	**0.01**	−3.37 (−7.72, 0.98)	0.1	2.23 (−0.26, 4.72)	0.11
	1M	17 (4.9) (*n* = 350)	23 (13.4) (*n* = 172)	1 (0.6) (*n* = 171)	**<0.0001**	−8.51 (−14.51, −2.52)	**0.001**	4.28 (1.31, 7.23)	**0.02**
No PPM	D	304 (86.6) (*n* = 351)	128 (73.1) (*n* = 175)	160 (93.6) (*n* = 171)	**<0.0001**	13.47 (5.57, 21.37)	**0.0002**	−6.96 (−12.51, −1.40)	**0.03**
	1M	294 (85.0) (*n* = 346)	120 (71.0) (*n* = 169)	154 (92.2) (*n* = 167)	**<0.0001**	13.97 (5.72, 22.21)	**0.0002**	−7.24 (−13.23, −1.26)	**0.03**
Moderate PPM	D	41 (11.7) (*n* = 351)	40 (22.9) (*n* = 175)	11 (6.4) (*n* = 171)	**<0.0001**	−11.18 (−18.68, −3.68)	**0.001**	5.25 (−0.17, 10.66)	0.08
	1M	37 (10.7) (*n* = 346)	38 (22.5) (*n* = 169)	10 (6.0) (*n* = 167)	**<0.0001**	−11.7 (−19.32, −4.26)	**0.0006**	4.70 (−0.59, 10.00)	0.12
Severe PPM	D	6 (1.7) (*n* = 351)	7 (4.0) (*n* = 175)	0 (0.0) (*n* = 171)	**0.02**	−2.29 (−5.92, 1.34)	0.14	1.7 (−0.08, 3.50)	0.18
	1M	15 (4.3) (*n* = 346)	11 (6.5) (*n* = 169)	3 (1.8) (*n* = 167)	0.10	−2.17 (−6.91, 2.56)	0.40	2.54 (−0.85, 5.93)	0.23
Transvalvular AR ≥ moderate	D	0 (0.0)	0 (0.0)	0 (0.0)					
	1M	0 (0.0)	0 (0.0)	0 (0.0)					
PVL none/trace	D	231 (64.53) (*n* = 358)	144 (79.56) (*n* = 181)	89 (51.74) (*n* = 172)	**<0.0001**	−15.1 (−23.1, −6.9)	**0.0005**	12.8 (3.4, 22.2)	**0.0065**
	1M	204 (58.29) (*n* = 350)	124 (72.94) (*n* = 170)	86 (48.59) (*n* = 177)	**<0.0001**	−14.6 (−23.5, −5.8)	**0.0016**	9.7 (0.3, 19.1)	**0.0433**
PVL mild	D	115 (32.12) (*n* = 358)	34 (18.78) (*n* = 181)	71 (41.28) (*n* = 172)	**<0.0001**	13.3 (5.5, 21.2)	**0.0015**	−9.2 (−18.4, 0.1)	**0.0488**
	1M	133 (38.0) (*n* = 350)	43 (25.29) (*n* = 170)	77 (43.50) (*n* = 177)	**0.0013**	12.7 (4.0, 21.4)	**0.0055**	−5.5 (−14.8, 3.8)	0.2608
PVL moderate	D	12 (3.4) (*n* = 358)	3 (1.7) (*n* = 181)	12 (7.0) (*n* = 172)	**0.03**	1.69 (−1.35, 4.74)	0.39	−3.63 (−8.29, 1.04)	0.1
	1M	12 (3.4) (*n* = 350)	3 (1.8) (*n* = 170)	13 (7.3) (*n* = 177)	**0.0220**	1.6 (−1.5, 4.8)	0.4330	−3.9 (−8.6, 0.8)	0.0750
PVL severe	D	0 (0.0)	0 (0.0)	0 (0.0)					
	1M	1 (0.3) (*n* = 350)	0 (0.0) (*n* = 170)	1 (0.6) (*n* = 177)	>0.99	0.3 (−0.6, 1.1)	>0.99	−0.3 (−1.8, 1.2)	>0.99
Total AR ≥ moderate	D	11 (3.0) (*n* = 362)	3 (1.6) (*n* = 184)	12 (6.9) (*n* = 173)	**0.02**	1.41 (−1.55, 4.36)	0.40	−3.90 (−8.50, 0.71)	0.06
	1M	9 (2.6) (*n* = 350)	3 (1.8) (*n* = 171)	11 (6.3) (*n* = 174)	**0.03**	0.82 (−2.19, 3.83)	0.76	−3.75 (−8.16, 0.66)	0.06

Bold values refer significant differences.



Prosthesis-patient mismatch	Myval THV Series (n=336)	Sapien THV Series (n=174)	Evolut THV Series (n=171)	P-value	
				Myval vs Sapien	Myval vs Evolut
Insignificant	284 (84.5)	125 (71.8)	159 (93)	0.0009	0.0102
Moderate	38 (11.3)	38 (21.8)	9 (5.3)	0.0024	0.0396
Severe	14 (4.2)	11 (6.3)	3 (1.8)	0.394	0.2438



PVL	P-value	
	Myval vs Sapien	Myval vs Evolut
Moderate	0.4005	0.0382
Severe	1	1
≥Moderate	0.3769	0.0336

Paravalvular leak	1 Month		
	Myval THV Series (n=340)	Sapien THV Series (n=175)	Evolut THV Series (n=181)
None or trace	201 (59.1)	126 (72)	86 (47.5)
Mild	127 (37.4)	46 (26.3)	80 (44.2)
Moderate	11 (3.2)	3 (1.7)	14 (7.7)
Severe	1 (0.3)	0 (0)	1 (0.6)

Figure 2 Percentage of participants up to 30-day visit with (*A*) PPM, and (*B*) PVL for Myval, Sapien and Evolut THV series.

comparable to both Sapien and Evolut THV series, with a reduced incidence of PVL and PPM. This highlights the advantage of tailored sizing in optimizing outcomes. (v) *Minimal Oversizing with Myval THV series:* Both Myval and Sapien THV series, as BEVs, had lower oversizing and PVL ≥ Moderate compared with the self-expanding Evolut THV series. Notably, the Myval THV series achieved near-minimal oversizing, particularly when assessed by annulus area-derived diameter, demonstrating its better fit and reduced anatomic mismatch.

Haemodynamic outcomes of the Myval, Evolut, and Sapien THVs series

Haemodynamic outcomes of the THV are essential in evaluating its performance. This *post hoc* analysis of the LANDMARK showed that the Myval THV series dramatically improved mean aortic gradient (baseline:40.1 ± 14.1 mmHg, 30-day:8.2 ± 3.5 mmHg), EOA (baseline:0.74 ± 0.23 cm^2, 30-day:2.02 ± 0.54 cm^2), aortic flow velocity (baseline:4.0 ± 0.7 m^2, 30-day:1.9 ± 0.4 m^2), and other parameters estimating the haemodynamics of the THV, except Left ventricular ejection fraction, which did not show significant improvement following TAVI. These findings were also comparable with the Evolut and Sapien THV series. The TAVI arm—Sapien 3—in the PARTNER-3 trial of low-risk patients reported significant reduction from baseline till 30-day in mean aortic gradient (49.4 ± 12.7 vs. 12.8 ± 4.3 mmHg), AVA (0.77 ± 0.16 vs. 1.74 ± 0.36 cm^2), and aortic flow velocity (4.47 ± 0.53 vs. 2.41 ± 0.39 m^2)[28] aligning with the findings in the LANDMARK trial in terms of mean aortic gradient (baseline vs. 30-day;39.3 ± 14.1 vs. 10.1 ± 4.5 mmHg) and AVA (baseline vs. 30-day; 0.69 ± 0.20 vs. 1.78 ± 0.50 cm^2) and other haemodynamic outcome parameters.

The COMPARE-TAVI 1 trial established non-inferiority between the SAPIEN 3 and Myval THV series and reported a slightly higher incidence of moderate or severe AR at 30 days in the Myval group compared with the SAPIEN 3 group (2% vs. 1%, $P = 0.031$).[29] While a similar trend was observed in the LANDMARK trial, the difference in moderate/severe AR was not statistically significant, likely reflecting differences in study power or patient selection. Notably, LANDMARK reported a higher rate of mild AR with Myval. Despite this, both trials consistently showed that Myval offers favourable haemodynamic performance and clinical outcomes, supporting its role as a reliable contemporary THV platform.

The Evolut low-risk trial yielded similar results of improvement in the mean aortic gradient (baseline: 7.0 ± 12.1, 30-day:8.4 ± 3.5 mmHg) and AVA (baseline:0.8 ± 0.2, 30-day:2.2 ± 0.6 cm^2) of the TAVI arm.[5] This is comparable to the results of the same type of valve in this post-hoc analysis from baseline to 30-day visit (38.7 ± 13.1 vs. 5.7 ± 2.4 mmHg for mean aortic gradient, and 0.74 ± 0.23 vs. 2.32 ± 0.55 cm^2 for AVA). This confirms the excellent haemodynamic results of the Myval THV series and the other Evolut THV series, which align with the previous similar randomized control trials.

Additionally, patients ideally should have a mean aortic gradient of less than 20 following TAVI. Otherwise, those patients would be considered high gradient. Our findings reported a low number of patients with mean aortic pressure gradient ≥20 mmHg in the Myval THVs series (0.8%) compared with the Sapien THV (2.9%) and Evolut THV series (0%), showing closer results of different types of THVs.

Patients with smaller annuli present a procedural challenge, as highlighted by the SMART trial, which reported superior haemodynamic performance of self-expanding valves over BEVs in this subgroup.[30] Our results support these findings, showing that Evolut THVs achieved higher effective orifice areas and lower mean gradients compared with Myval THV series and Sapien THV series in the smallest annulus quintiles. However, the Myval THV series demonstrated comparable performance to Sapien THV series, emphasizing its versatility across patient anatomies.

Haemodynamic performance of intermediate sizes of Myval THV series

Intermediate sizes of the Myval THV series demonstrated significant improvements in mean aortic gradients at discharge and 30-day, with larger sizes yielding better results. All haemodynamic parameters showed improvement except for left ventricular ejection fraction, which remained unchanged.

The intermediate sizes of Myval THV have been used in The COMPARE-TAVI 1 trial, which assessed SAPIEN 3 vs. Myval THV,[29] and in a European multicentre registry involving low-risk patients.[31] In the European registry, intermediate-sized Myval THVs significantly

Table 5 Flow patterns and ventricular functions among the three groups

Parameter (All valve size)	Baseline				30 days			
	Myval THV series ($n = 366$)	Sapien THV series ($n = 182$)	Evolut THV series ($n = 181$)	*P*-value	Myval THV series ($n = 372$)	Sapien THV series ($n = 188$)	Evolut THV series ($n = 180$)	*P*-value
Stroke volume index	36.56 ± 9.58	34.54 ± 9.12	35.53 ± 10.00	0.06	39.97 ± 10.65	39.21 ± 10.59	37.75 ± 9.90	0.08
Aortic flow pattern								
• Low flow (stroke volume index <35 mL/m^2)	170 (46.4)	100 (54.9)	88 (48.6)	0.17	119 (32.0)	76 (40.4)	86 (47.8)	**0.001**
• Normal flow (stroke volume index >35 mL/m 2)	196 (53.6)	82 (45.05)	93 (51.4)		253 (68.0)	112 (59.6)	94 (52.2)	
Left ventricular function	**Myval THV series ($n = 259$)**	**Sapien THV series ($n = 140$)**	**Evolut THV series ($n = 138$)**	***P*-value**	**Myval THV series ($n = 299$)**	**Sapien THV series ($n = 156$)**	**Evolut THV series ($n = 146$)**	***P*-value**
• Normal >50%	223 (86.1)	109 (77.9)	113 (81.9)	0.11	251 (83.95)	126 (80.77)	121 (82.88)	0.69
• Moderately impaired 30–50%	29 (11.2)	29 (20.7)	23 (16.7)	**0.03**	45 (15.05)	27 (17.31)	24 (16.44)	0.81
• Severely impaired <30%	7 (2.7)	2 (1.4)	2 (1.4)	0.73	3 (1)	3 (1.92)	1 (0.68)	0.61

Bold values refer significant differences.

increased AVA and reduced mean aortic gradients at 30-day post-TAVI.[31] These findings align with the current study, suggesting the efficacy of intermediate sizes for optimizing outcomes in anatomically diverse patients.

PVL and PPM

PVL remains a common concern post-TAVI.[32] In this study, Moderate PVL incidence at 30-day was low across all groups, with Myval THV series (3.2%) performing comparably to Sapien THV series (1.7%) and lower than Evolut THV series (7.7%). These results are consistent with prior trials, such as the Evolut low-risk trial[5] and Partner-3,[28] which reported similarly low PVL rates.

Moderate PPM was notably less frequent with Myval THV series (11.3%) than Sapien THV series (21.8%) and higher than Evolut THV series (5.3%). Severe PPM incidence was low and not significantly different among the groups. Partner-3 reported high numbers of moderate (23.5%) and severe (6.3%) PPM for Sapien THV,[28] which is comparable to the reported PPM in the LANDMARK trial. The COMPARE-TAVI 1 trial demonstrated a significantly lower incidence of moderate or severe PPM at 30 days with the Myval THV compared with the SAPIEN 3 THV (19% vs. 30%; $P < 0.0001$).[31] These findings of PPM from the COMPARE-TAVI 1 trial are consistent with the LANDMARK trial, highlighting the clinical importance of minimizing PPM, particularly in patients with small annuli. This difference underscores Myval's haemodynamic advantage, with lower rates of both moderate and severe PPM, likely due to its intermediate sizing and EOA. The higher incidence of moderate PPM with Sapien THV may partly reflect the greater proportion of small prostheses implanted (≤23 mm) compared with Myval and Evolut, rather than intrinsic device haemodynamics. Moreover, operator preference, annulus sizing strategy, and lack of intermediate sizes in Sapien THV may have contributed to this pattern.

Oversizing in Myval THV series vs. Sapien and Evolut THVs series

Proper sizing is crucial in TAVI to minimize oversizing and its associated complications. The Myval THV series demonstrated minimal oversizing, particularly for area-derived diameters, likely due to its unique intermediate sizes (21.5, 24.5, and 27.5 mm) and large sizes (30.5 and 32 mm). In contrast, Sapien and Evolut THVs required greater oversizing, consistent with findings from trials such as Partner-3.[33] This flexibility in sizing enhances Myval's applicability across diverse patient populations.

Energy loss index

The ELI, a measure of valve energy efficiency, offers additional insights into THV performance. Evolut THVs showed the highest ELI, suggesting favourable performance in patients with smaller annuli or where energy conservation is critical. Myval THV series achieved a balanced ELI, outperforming Sapien, which had the lowest ELI. Myval's intermediate sizing and reasonable energy efficiency make it a versatile option for minimizing PPM and maintaining favourable flow dynamics.

Limitations

This study is limited by its short follow-up duration of 30-day, preventing assessment of long-term outcomes, and annulus splines were not part of the imaging protocol, and aortic valve calcification volume was included qualitatively, which may limit the precision of device performance comparisons. Additionally, PPM adjudication via TTE alone may be limited, per VARC-3 definitions, and the sample size for different THV sizes was relatively small, necessitating further investigation to validate these findings.

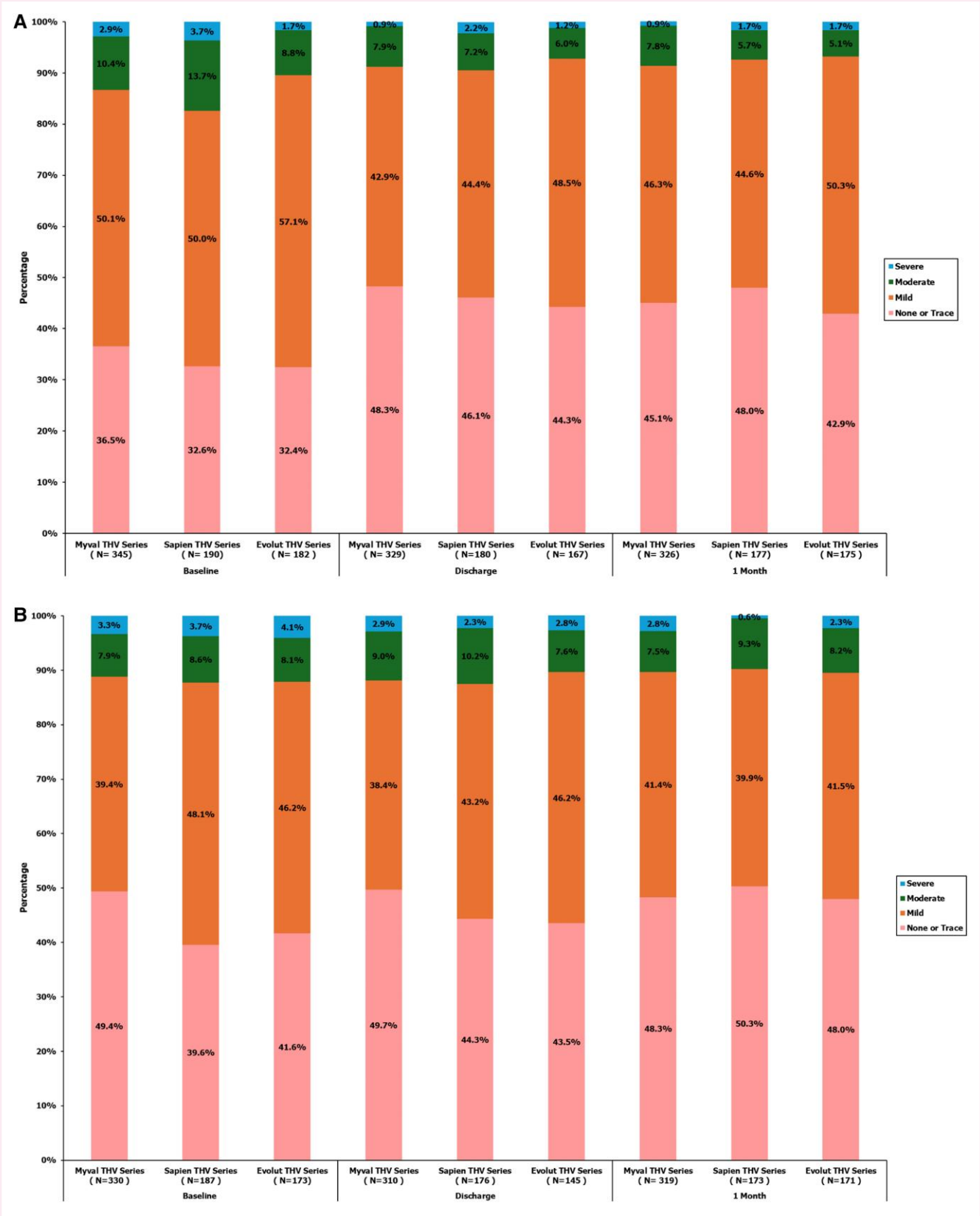


Figure 3 Changes from baseline to 30-day visit per THV series [AT population] in (*A*) mitral regurgitation and (*B*) tricuspid regurgitation.

Conclusion

The Myval THV series demonstrated excellent haemodynamic performance, reduced moderate PPM, and minimal oversizing compared with Sapien and Evolut THVs. Its unique intermediate sizes offer added flexibility, enhancing suitability for diverse anatomies. These findings position the Myval THV series as a strong alternative to contemporary THVs. Long-term follow-up studies are essential to confirm these results and assess their impact on clinical outcomes.

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Supplementary data

Supplementary data are available at *European Heart Journal - Cardiovascular Imaging* online.

Author contributions

Osama Soliman (Conceptualization [lead]; Data curation [lead]; Formal analysis [equal]; Funding acquisition [lead]; Investigation [supporting]; Methodology [equal]; Project administration [lead]; Resources [lead]; Software [lead]; Supervision [lead]; Visualization [lead]; Writing—original draft [equal]; Writing—review & editing [equal]), Elfatih A. Hasabo (Data curation [equal]; Formal analysis [equal]; Software [equal]; Writing—original draft [lead]; Writing—review & editing [equal]), Niels van Royen (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Ignacio J. Amat-Santos (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Martin Hudec (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Matjaz Bunc (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Alexander IJsselmuiden (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Peep Laanmets (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Daniel Unic (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Bela Merkely (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Renicus S. Hermanides (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Mohamed Mouden (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Vlasis Ninios (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Marcin Protasiewicz (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Benno J.W.M. Rensing (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Pedro L. Martin (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Fausto Feres (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Manuel De Sousa Almeida (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Eric van Belle (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Axel Linke (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Alfonso Ielasi (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Matteo Montorfano (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Mark Webster (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Konstantinos Toutouzas (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Emmanuel Teiger (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Francesco Bedogni (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Michiel Voskuil (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Dolores Mesa Rubio (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Oskar Angerås (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Won-Keun Kim (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Jürgen Rothe (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Ivica Kristić (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Vicente Peral (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Ben J.L. Van den Branden (Data curation [equal]; Investigation [equal]; Writing—review & editing [equal]), Ashokkumar Thakkar (Conceptualization [equal]; Data curation [lead]; Resources [equal]; Writing—review & editing [equal]), Udita Chandra (Project administration [supporting]; Resources [equal]; Writing—review & editing [equal]), Dina Neiroukh (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Cagri Ayhan (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Mahmoud Y. Nosir (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Magdi S. Yacoub (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Sanaa Ali (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Mohamad Altamimi (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Hesham Elzomor (Data curation [equal]; Formal analysis [equal]; Writing—review & editing [equal]), Patrick W. Serruys (Conceptualization [equal]; Methodology [equal]; Project administration [equal]; Writing—review & editing [equal]), and Andreas Baumbach (Conceptualization [equal]; Investigation [lead]; Project administration [equal]; Writing—review & editing [equal])

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Data availability

The data associated with this publication will be made available upon reasonable request to the corresponding author.

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