Catheterization and Cardiovascular Interventions

WILEY

ORIGINAL ARTICLE - CLINICAL SCIENCE

Comparison of Self-Expandable Acurate Neo-2 and Balloon-Expandable Myval Transcatheter Heart Valves at 4-Year Follow-Up

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Received: 25 May 2025 | Revised: 30 June 2025 | Accepted: 15 July 2025

Funding: The authors received no specific funding for this work.

Keywords: Acurate neo 2 | aortic stenosis | Myval | TAVR

ABSTRACT

Background: Recently, Acurate neo2 (ACN2; Boston Scientific, US) and Sapien-3 series (Edwards Lifesciences, US) were compared in the IDE trial failing to demonstrate non-inferiority of ACN2. The Myval series (MyV), an alternative balloon-expandable device, demonstrated non-inferiority compared to Sapien-3 and Evolut (Medtronic, US) in the LANDMARK trial. However, no direct comparison exists between ACN2 and MyV.

Aims: We aimed to compare mid-term clinical and hemodynamic outcomes of the ACN2 and MyV transcatheter heart valves.

Methods: This multicenter retrospective analysis included patients implanted with ACN2 and MyV series devices. The primary objective was to assess 1-year mortality and stroke rates. Secondary outcomes included technical success, mortality, stroke, residual aortic regurgitation (AR), mean aortic gradients, and new permanent pacemaker implantation (PPI) rates up to 4 years. A matched comparison adjusting for clinical and anatomical characteristics was performed and echocardiograms were centrally analyzed.

Results: A total of 545 patients (ACN2: 144; MyV: 401) from nine institutions were included. Matched technical success rates were 87.6% and 94.4%, $p = 0.180$ (90.3% for ACN2 and 97% for MyV; $p < 0.001$ in unmatched). In-hospital matched PPI rates were 10.1% for ACN2 and 9% for MyV. At 4 years, matched residual ≥ moderate AR rates were similar (ACN2: 15.8% vs. MyV: 21.1%, $p = 0.706$), though ACN2 showed better mean aortic gradients (9.2 ± 4.2 vs. 13.1 ± 5.4, $p = 0.001$) and effective orifice area. Unmatched mortality + stroke rates were comparable but lower for ACN2 after matching (3.4% vs. 15.7%, $p = 0.005$). Importantly, cardiovascular mortality (3.4% for ACN2 and 5.6% for MyV, $p = 0.720$) and valve-related deaths were comparable.

Conclusion: ACN2 showed superior long-term hemodynamics and lower matched 4-year mortality and stroke rates, though cardiovascular mortality and valve-related deaths were comparable.

Abbreviations: ACN2, Acurate Neo 2; AR, aortic regurgitation; BVF, bioprosthetic valve failure; EOA, effective orifice area; HVD, hemodynamic valve deterioration; MyV, Myval series; PPI, permanent pacemaker implantation; PPM, patient prosthesis mismatch; PVL, paravalvular leak; THV, transcatheter heart valves.

1 | Introduction

Continuous technological advancements have led to the development of several new generation transcatheter heart valves (THVs) targeting lower risk populations through improved outcomes in terms of paravalvular leak (PVL), vascular injuries, or conduction disturbances [1–3]. The Acurate neo2 (ACN2; Boston Scientific) and the Myval series (MyV; Meril Life Sciences) were two transcatheter aortic valve replacement (TAVR) devices available in Europe; however, ACN2 has been recently withdrawn from the market in May 2025 [4, 5].

In the SCOPE I trial [5], the ACURATE neo THV (ACN; Boston Scientific) demonstrated lower transvalvular gradients and a larger effective orifice area (EOA) but exhibited higher rates of PVL compared to the SAPIEN 3 THV (S3; Edwards Lifesciences). Similarly, a recent study by Pellegrini et al. [6] comparing ACN2 and Sapien 3 Ultra (Ultra) found that transvalvular gradients were lower with ACN2, translating to higher device success rates. However, mild PVL rates were significantly lower with the Ultra THV. In the recently concluded ACURATE-IDE trial, the ACN2 valve did not demonstrate non-inferiority compared to the commercially available series of Sapien and Evolut [7].

The MyV THV is the only commercially available balloon-expandable alternative to the Sapien series in Europe. In the LANDMARK trial [4], the MyV THV demonstrated favorable safety outcomes and was found to be non-inferior to contemporary devices (S3 series and Evolut). It was comparable to the S3 series in terms of permanent pacemaker implantation (PPI) and PVL, but with superior residual gradients and EOA [8]. The trial confirmed the non-inferiority of the MyV THV series compared to the Sapien (Edwards Lifesciences, Irvine, CA, USA) and Evolut (Medtronic, Minneapolis, MN, USA) series.

To date, no direct comparison exists between ACN2 and MyV. This study aims to compare the early hemodynamic performance and long-term durability of ACN2 and MyV over a 4-year period.

1.1 | Objective

The primary objective was to evaluate the rates of mortality and stroke at 1 year. Secondary objectives included the composite endpoint of mortality, stroke, and valve-related rehospitalization at 1-year, technical success, residual aortic regurgitation (AR), mean aortic gradients, and rates of new PPI both in-hospital, at 1 year, and at 4 years of follow-up. Cardiovascular mortality was also recorded. Clinical safety at 30 days was assessed per VARC-3 criteria. Valve durability was analyzed using hemodynamic valve deterioration (HVD), bioprosthetic valve failure (BVF), and patient-prosthesis mismatch (PPM) according to VARC-3 definitions.

2 | Methods

2.1 | Devices Evaluated

The main differences between the two devices (ACN2 and MyV) are summarized in Table 1.

2.2 | Study Population

This study included consecutive real-world symptomatic patients with severe native aortic stenosis who received either balloon-expandable (MyV) or self-expandable (ACN2) TAVR devices across nine centers across Europe and Asia. Clinical data of patients undergoing TAVR between December 2017 and April 2020 were retrospectively collected in a dedicated database. All centers had access and experience with both devices. Informed consent was waived from the central ethics committee, although a specific consent was obtained from those patients who required an additional echocardiographic study. It was not possible to involve patients or the public in the design, or conduct, or reporting, or dissemination plans of our research.

2.3 | 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 aortic regurgitation (AR). The AR severity was evaluated using a multi-parametric approach and classified following the Valve Academic Research Consortium-3 (VARC-3) recommendations. Images were centrally analyzed (www.icicorelab.es) by two independent experienced cardiologists; interobserver lack of significant differences was assessed. Xcelera Cardiology Information System (Philips Medical System, Andover, MA) was used for all off-line analysis. Although data were gathered retrospectively, those patients without adequate 4-year imaging follow-up were scheduled for an echocardiographic test after informed consent.

Multidetector computed tomography (CT) exams were performed according to the guidelines of the Society of Cardiovascular Computed Tomography. As part of the protocol study, the following derived parameters were calculated: aortic annulus (maximal and minimal diameters, perimeter and area), perimeter and area-derived diameters, and eccentricity index (defined by $100 \times 1-$[aortic annulus minimum diameter/maximum diameter]). Aortic valve calcification was graded quantitatively (Agatston units) and binary extension of calcium into the left ventricular outflow tract was determined. Finally, the depth of the prosthesis in the left ventricular outflow tract was determined based on angiography as the distance from the left sinus to the edge of the prosthesis into the left ventricular outflow tract.

2.4 | Statistical Analysis

Categorical variables are presented as frequencies and compared using the χ^2 or Fisher's exact test. Continuous variables are expressed as mean ± standard deviation (SD) or median (IQR) and analyzed using Student's *t*-test or Mann–Whitney *U* test, as appropriate. Matched comparisons employed paired Student's *t*-tests or Wilcoxon tests for continuous variables and McNemar tests for categorical variables. Kaplan–Meier survival

TABLE 1 | Summary of difference between self-expandable ACN2 and balloon-expandable MyV.

	Acurate Neo2	Myval series
		
Frames	Nitinol	Nickel−cobalt
Leaflets	Porcine pericardium, supra-annular	Bovine pericardium
Expansion	Self-expanding (top down)	Balloon expanding
Recapturable	No	No
Valve sizes	S (23 mm), M (25 mm), L (27 mm)	conventional sizes (20 mm, 23 mm, 26 mm, and 29 mm), intermediate sizes (21.5 mm, 24.5 mm, 27.5 mm), and extra-large sizes (30.5 mm, 32 mm). Novel 35 mm size.
Sheath inner diameter	14-French	14-French
Paravalvular leakage reduction	Outer and inner skirt	External and internal PET skirt
CE mark	September 2014	April 2019

Abbreviation: PET = polyethylene terephthalate.

curves were generated to visualize survival differences and compared using the log-rank test.

Patients were matched by age, body surface area, gender, aortic annulus area, coronary artery disease (CAD), chronic kidney disease (CKD), baseline NYHA functional status, Society of Thoracic Surgeons (STS) risk score, left ventricular ejection fraction, and baseline mean transaortic valve gradient (Figure S1). Center-specific stratification was performed to eliminate relevant differences. Propensity score matching (1:1) was conducted using the greedy nearest neighbor method with a caliper width of one-fifth of the SD of the logit of the propensity score. Matching was performed using the MatchIt package.

All statistical tests were two-sided, with a significance level of 0.05. Analyses were performed using R (R Core Team, 2019, R Foundation for Statistical Computing, Vienna, Austria).

3 | Results

3.1 | Patient Population

A total of 619 patients underwent TAVI with MyV or ACN2, out of which 545 patients were included. The actual reasons why finally 545 patients were included have been reported in Figure 1. A total of 49 patients were lost after hospital admission but most of the sample completed 4-year follow-up with 144 receiving ACN2 and 401 receiving MyV (99 ACN2 and 366 MyV with echocardiographic follow-up). After propensity score matching, 89 patients were included in each cohort (60 ACN2 and 82 MyV with complete echocardiographic follow-up). The mean age was 77.7 ± 8.59 years, and 39.1% were women. The mean STS score was 5.08 ± 3.82. In the unmatched cohort, the MyV group had higher rates of CAD and CKD. Additionally, CT imaging showed a larger aortic annulus diameter and area in the MyV cohort. These differences were no longer significant in the matched population. No other significant differences in baseline clinical or electrocardiographic variables were observed (Table 2). The results that follow present only outcomes after matching; please see Tables 3 and 4 for the unmatched outcomes.

3.2 | Peri-Procedural and 30-Day Outcomes (Matched Cohort)

In the cohort, the transfemoral approach was used in 98.9% of MyV and 97.8% of ACN2 cases ($p = 0.999$). There were no procedural deaths in either group. Rates of procedural complications, including annular rupture, coronary artery occlusion, and cardiac tamponade, were similar, although two cases of valve embolization occurred in the ACN2 group. In-hospital outcomes, such as major bleeding, vascular complications, and acute kidney injury, were comparable. PPI rates were 10.1% for ACN2 and 9% for MyV ($p = 0.999$). At 30 days, mortality was 0% for ACN2 and 2.3% for MyV ($p = 0.500$), with stroke rates of 1.1% in both groups. ACN2 demonstrated superior hemodynamics, with lower mean gradients (9.4 ± 5.0 vs. 12.2 ± 5.1 mmHg, $p < 0.001$) and larger valve areas (1.90 ± 0.37 vs. 1.70 ± 0.30 cm², $p = 0.002$) (Table 3). The proportion of ≥ moderate AR at 30 days has been reported in Table 3 (10.4% for ACN2 and 6.9% for MyV). The proportions of

FIGURE 1 | Flowchart representing patient inclusion and matching.

paravalvular/central aortic regurgitation were 78.5%/21.5% and 84.6%/15.4% for ACN2 and MyV group in global cohort, respectively; the proportion was 87.5/12.5% for ACN2 and 90%/10% for MyV in the matched cohort.

3.3 | 1-Year and 4-Year Outcomes (Matched Cohort)

At 1 year, mortality rates were 2.2% for ACN2 and 14.6% for MyV ($p = 0.003$), while stroke rates were 1.1% and 2.2% ($p = 0.999$), respectively. The composite endpoint of mortality and stroke was 3.4% for ACN2 versus 15.7% for MyV ($p = 0.014$). Valve-related rehospitalization rates were 7.7% (ACN2) and 2% (MyV, $p = 0.363$). Severe PPM was 0% for ACN2 and 6% for MyV ($p = 0.242$). Rates of ≥ moderate AR were 13.1% for ACN2 and 18.3% for MyV ($p = 0.371$).

At 4 years, mortality rates were 9% for ACN2 and 23.6% for MyV ($p = 0.008$), with survival rates of 83% and 68.3%, respectively ($p = 0.014$) (Figure 2). ACN2 maintained superior hemodynamics, with lower gradients (9.24 ± 4.21 vs. 13.18 ± 5.47 mmHg, $p = 0.001$) and larger valve areas (1.84 ± 0.35 vs. 1.66 ± 0.41 cm², $p = 0.124$) (Table 4, Figure 3). To remark, if only cardiovascular mortality was considered, no differences were detected at 4 years between ACN2 and MyV, both in the unmatched (97% vs. 94.1%, p log-rank = 0.269) and the matched analysis (95.2% vs. 94.1%, $p = 0.419$) (Figure 4).

3.4 | Hemodynamic Valve Performance and Durability

Over 4 years, stage 1 BVF occurred in 0% of ACN2 patients and 4.8% of MyV patients ($p = 0.083$). No stage 2 (reintervention) or stage 3 (valve-related death) BVF events were reported. HVD rates were 6.5% for ACN2 and 11.3% for MyV ($p = 0.317$), with no cases of severe HVD (Figure 5). Severe PPM was identified in 0% of ACN2 and 6% of MyV patients ($p = 0.242$) at 1 year.

No differences were detected when the main clinical and hemodynamic outcomes were compared amongst the different institutions.

4 | Discussion

With the rapid advancement of TAVR technology, a variety of devices have been developed, each with unique features designed to improve procedural success, patient outcomes, and ease of use. Two widely used TAVR devices in Europe are the MyV and ACN2. Comparing these devices provides valuable insights into their safety and efficacy which might help to determine patient suitability for each of them. Although the ACN2 device has recently been withdrawn from its commercial use, the insights of our research might provide hints for future investigations of alternative devices.

TABLE 2 | Main clinical, electrocardiographic, and imaging characteristics at baseline of the global and the matched cohorts according to valve type.

Patient characteristics	Global population $n = 545$	Global cohort			Matched cohort		
		ACN2 $n = 144$	MyV $n = 401$	p value[a]	ACN2 $n = 89$	MyV $N = 89$	p value[a]
Age, years	77.7 ± 8.5	81.2 ± 6.3	76.4 ± 9.0	< 0.001	80.5 ± 6.5	80.1 ± 7.9	0.702
Female sex	213 (39.1)	80 (55.6)	133 (33.2)	< 0.001	49 (55.1)	42 (47.2)	0.281
BSA, m^2	1.79 ± 0.20	1.75 ± 0.19	1.80 ± 0.20	0.006	1.77 ± 0.20	1.79 ± 0.20	0.534
BMI, kg/m^2	26.5 ± 4.7	26.4 ± 5.2	26.5 ± 4.5	0.885	26.90 ± 5.51	26.38 ± 4.32	0.493
Diabetes mellitus	197 (36.4)	51 (35.4)	146 (36.8)	0.772	33 (37.1)	32 (36.0)	0.999
Hypertension	428 (78.8)	117 (81.3)	311 (77.9)	0.405	74 (83.1)	70 (78.7)	0.596
Prior pacemaker	42 (7.7)	8 (5.6)	34 (8.5)	0.259	4 (4.5)	7 (7.9)	0.549
Chronic kidney disease	178 (32.8)	37 (25.9)	141 (35.3)	0.039	27 (30.3)	33 (37.1)	0.391
Hemodialysis	8 (1.5)	3 (2.1)	5 (1.3)	0.443	2 (2.2)	1 (1.1)	0.999
Chronic pulmonary disease	65 (12)	20 (13.9)	45 (11.3)	0.414	17 (19.1)	9 (10.1)	0.096
Peripheral artery disease	60 (11.4)	18 (12.5)	42 (11.0)	0.635	9 (10.1)	14 (16.1)	0.359
Previous stroke/TIA	41 (7.6)	10 (6.9)	31 (7.8)	0.748	4 (4.5)	8 (9.0)	0.344
Porcelain aorta, %	8 (1.5)	0 (0.0)	8 (2.1)	0.114	0 (0.0)	3 (3.4)	0.250
Coronary artery disease	256 (47.1)	43 (29.9)	213 (53.3)	< 0.001	29 (32.6)	33 (37.1)	0.626
Prior heart surgery	67 (12.4)	8 (5.6)	59 (14.8)	0.004	7 (7.9)	15 (16.9)	0.625
Prior CABG	53 (9.8)	4 (2.8)	49 (12.3)	< 0.001	4 (4.5)	11 (12.4)	0.118
Prior valvular surgery	24 (6.0)	1 (1.7)	23 (6.8)	0.228	1 (2.9)	7 (10.1)	0.625
Prior atrial fibrillation	132 (24.3)	43 (29.9)	89 (22.3)	0.070	26 (29.2)	26 (29.2)	0.999
NYHA III−IV	263 (49.3)	61 (43)	202 (51.7)	0.076	45 (50.6)	43 (48.3)	0.880
STS score	5.08 ± 3.82	5.57 ± 4.07	4.89 ± 3.71	0.082	5.79 ± 4.64	6.17 ± 5.63	0.627
Electrocardiography							
Pacemaker	30 (5.9)	3 (2.1)	27 (7.4)	0.024	1 (1.2)	4 (4.8)	0.375
Sinus rhythm	385 (76.1)	108 (76.6)	277 (75.9)	0.868	67 (77.9)	66 (79.5)	0.999
Atrial fibrillation	91 (18)	30 (21.3)	61 (16.7)	0.231	18 (20.9)	13 (15.7)	0.541
LBBB	44 (8.1)	13 (9.0)	31 (7.7)	0.624	8 (9.0)	12 (13.5)	0.481
RBBB	45 (8.3)	19 (13.2)	26 (6.5)	0.012	14 (15.7)	8 (9.0)	0.210
AVB (1st degree)	29 (5.3)	9 (6.3)	20 (5.0)	0.563	4 (4.5)	6 (6.7)	0.754
CT							
Maximum AA diameter, mm	27.8 ± 4.1	26.3 ± 2.4	28.6 ± 4.5	< 0.001	26.52 ± 2.64	27.54 ± 4.13	0.072
Minimum AA diameter, mm	21.9 ± 4.2	20.9 ± 2.5	22.3 ± 4.7	< 0.001	21.12 ± 2.53	22.00 ± 4.70	0.128
Eccentricity index	0.21 ± 0.10	0.21 ± 0.08	0.22 ± 0.11	0.574	0.20 ± 0.08	0.20 ± 0.11	0.973
Mean AA diameter, mm	24.7 ± 3.6	23.6 ± 2.1	25.1 ± 3.9	< 0.001	23.95 ± 2.29	24.21 ± 4.10	0.616
AA area, mm^2	457 ± 107	434.5 ± 76.7	467.6 ± 119.6	0.001	442 ± 79	438 ± 129	0.777
Agatson score	2700 ± 1165	2584 ± 1314	2740 ± 1107	0.211	2589 ± 1466	2667 ± 1306	0.720
Echocardiography							
LVEF, %	55.1 ± 12.2	56.9 ± 11.8	54.4 ± 12.2	0.038	57.34 ± 12.64	56.70 ± 13.07	0.758
Peak aortic gradient, mmHg	77.3 ± 23.3	75.8 ± 23.1	77.8 ± 23.3	0.442	73.71 ± 21.14	77.95 ± 23.05	0.301

(Continues)

TABLE 2 | (Continued)

Patient characteristics	Global population $n = 545$	Global cohort			Matched cohort		
		ACN2 $n = 144$	MyV $n = 401$	p value[a]	ACN2 $n = 89$	MyV $N = 89$	p value[a]
Mean aortic gradient, mmHg	48.2 ± 15.7	47.7 ± 13.7	48.3 ± 16.2	0.678	47.61 ± 13.58	47.73 ± 13.70	0.956
Aortic valve area, mm^2	0.71 ± 0.21	0.72 ± 0.17	0.70 ± 0.21	0.480	0.73 ± 0.18	0.73 ± 0.22	0.975
≥ Moderate aortic regurgitation	108 (20.7)	29 (20.6)	79 (20.7)	0.967	23 (25.8)	28 (31.8)	0.532
≥ Moderate mitral regurgitation	69 (21.3)	16 (27.6)	53 (19.9)	0.197	11 (31.4)	20 (39.2)	0.774
≥ Moderate tricuspid regurgitation	57 (18.9)	16 (28.1)	41 (16.7)	0.049	9 (26.5)	14 (31.1)	0.999

Abbreviations: AA, aortic annulus; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass graft; LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; RBBB, right bundle branch block.

[a]Bold letters represent significant p-values. To remark, no significant differences existed after matching.

The main findings of our study, summarize in the Central illustration 1, suggest that: (I) The results for the MyV THV were comparable to those for the ACN2 THV at the 30-day follow-up regarding death (2.3% vs. 0%, $p = 0.500$) and stroke (1.1% vs. 1.1%, $p = 0.999$). (ii) Both devices demonstrated similar early safety (78.6% vs. 77.6% [$p = 0.804$] for ACN2 and MyV) and device success rate, with 87.7% for ACN2 and 91.7% for MyV ($p = 0.999$). (iii) However, there were significant differences between the two groups in echocardiographic parameters after 30 days and up to 4 years with MyV showing significantly lower EOA and significantly higher aortic valve mean and peak gradients compared to ACN2. (iv) In addition, greater rates of mortality and stroke were detected at 4-year follow-up in the MyV group, although no differences existed if only cardiovascular mortality was considered.

4.1 | Head-to-Head Clinical Comparison at Short-Term

There have been few head-to-head comparisons of contemporary TAVR devices in recent times. Outcomes at 1 year, including the composite of all-cause mortality, stroke, or hospitalization, were similar for ACN2 and Sapien Ultra THV in a recent study [9]. All-cause mortality (3% vs. 2%) was numerically higher in the self-expandable group, whereas stroke (5% vs. < 1%) was numerically higher in the balloon-expandable group in the SOLVE-TAVI study [10]. In the PORTICO IDE trial, the event rate for the primary safety endpoint at 30 days was higher in the Portico valve group compared with the commercially available intra-annular balloon-expandable valve (Edwards-Sapien, Sapien XT, or Sapien 3) or the supra-annular self-expandable one (CoreValve, Evolut-R, or Evolut-PRO) [11]. The LANDMARK trial showed that among patients with severe aortic stenosis, TAVR with MyV was non-inferior to contemporary prostheses (Sapien or Evolut).

Our study may be the first to provide a comparison of the ACN2 and MyV devices, and the clinical endpoints were comparable between the two devices, as well as with other commercially available devices. Technical success (as defined by VARC-3) was significantly better for MyV and remained higher in the matched cohort (94.4% and 87.6%, $p = 0.096$). Technical success can impact both immediate (patient recovery) and long-term outcomes (valve durability). Both devices achieved high levels of technical success, although differences in their designs and mechanisms can influence outcomes across specific technical benchmarks. The most common cause of technical failure in the ACN2 group was valve embolization. Because MyV is balloon-expandable, its deployment is typically rapid and controlled, which reduces the risk of valve migration and allows for precise anchoring in the target position. Postdilatation after unsatisfactory valve implantation can lead to detrimental outcomes [12, 13], including stroke or an increase in the need for new PPI. In fact, in-hospital new PPI rates remained comparable between both devices (10.1% vs. 9.0%, $p = 0.999$ for ACN2 and MyV), both being significantly lower than what has been reported in prior investigations as in the SOLVE-TAVR trial (23% for self- and 19% for balloon-expandable systems) [10] but in line with previous research including MyV technology (7.4% for MyV, 13.4% for Sapien 3, and 9.1% for Acurate according to Santos-Martínez et al.) [14].

4.2 | Follow-Up Outcomes

The composite endpoint of mortality and stroke at 1 year was significantly higher for MyV compared to ACN2 in our study (Figure 1). Early differences between Acurate Neo and Sapien S3 did not translate into significant differences in clinical outcomes or BVF throughout 3 years [15]. In our study, though the global mortality was higher in MyV group, the rates of cardiovascular death were comparable, and there were no valve-related deaths in either group (Figure 3). In summary, this highlights a relatively higher mortality in the MyV group that might be biased by the baseline characteristics of the population given the relatively low cardiovascular mortality.

The rates of valve-related hospitalization were 7.7% and 2% for ACN2 and MyV in our study. This is in line with the re-hospitalization rate of 5.3% in the ACN2 group (vs. 3.5% in the conventional TAVR group) in the ACURATE-IDE trial.

TABLE 3 | Main procedural, in-hospital, and 30-day outcomes of global and matched cohorts according to valve type.

	Global cohort			Matched cohort		
	ACN2 $n = 144$	MyV $n = 401$	p value[a]	ACN2 $n = 89$	MyV $N = 89$	p value[a]
Procedural outcomes						
Prosthesis size	25.2 ± 1.6	24.9 ± 2.5	0.096	25.4 ± 1.6	24.3 ± 2.4	< 0.001
Transfemoral approach	141 (97.9)	397 (99)	0.388	87 (97.8)	88 (98.9)	0.999
More than 1 prosthesis implanted	3 (2.1)	5 (1.2)	0.441	1 (1.1)	0 (0.0)	0.999
Balloon predilation	136 (96.5)	230 (61.2)	< 0.001	86 (98.9)	54 (62.8)	< 0.001
Balloon postdilation	22 (15.7)	33 (9.0)	0.030	11 (12.8)	4 (4.8)	0.146
Procedural complication						
Valve embolization	3 (2.1)	4 (1.0)	0.388	2 (2.2)	0 (0.0)	0.500
Annulus rupture	0 (0)	0 (0)	0.999	0 (0)	0 (0)	0.999
Coronary artery occlusion	0 (0)	1 (0.2)	0.999	0 (0.0)	1 (1.1)	0.999
Tamponade	1 (0.7)	1 (0.2)	0.459	0 (0)	0 (0)	0.999
Procedural death	0 (0)	2 (0.5)	0.999	0 (0)	1 (1.1)	0.999
Technical success	130 (90.3)	389 (97)	0.001	78 (87.6)	84 (94.4)	0.180
In hospital outcomes						
Major bleeding	3 (2.1)	8 (2)	0.999	2 (2.2)	1 (1.1)	0.999
Major vascular complication	4 (2.8)	9 (2.2)	0.752	3 (3.4)	1 (1.1)	0.625
Acute kidney injury	9 (6.3)	10 (2.5)	0.035	6 (6.7)	5 (5.6)	0.999
New permanent pacemaker implantation	13 (9)	38 (9.5)	0.874	9 (10.1)	8 (9.0)	0.999
Outcomes at 30 days						
Death	2 (1.4)	8 (2.0)	0.999	0 (0.0)	2 (2.3)	0.500
Stroke	3 (2.1)	2 (0.5)	0.118	1 (1.1)	1 (1.1)	0.999
Stroke-free survival (%)	96.5	98	0.320	98.9	96.6	0.309
Early safety (%)	78	78.4	0.950	78.6	77.6	0.804
Device success (%)	88	94.7	0.041	87.7	91.7	0.999
Leaflet thrombosis (%)	1	0.4	0.489	1.8	0.0	0.999
LVEF	58.3 ± 10.1	56.6 ± 10.4	0.096	58.3 ± 10.5	57.8 ± 11.5	0.798
AVA, cm^2	1.8 ± 0.35	2.0 ± 0.44	0.669	1.90 ± 0.37	1.70 ± 0.30	0.002
Peak aortic gradient, mmHg	16.4 ± 8.0	18.8 ± 7.8	0.004	15.9 ± 7.11	21.3 ± 7.7	< 0.001
Mean aortic gradient, mmHg	9.4 ± 5.0	10.3 ± 4.6	0.049	9.4 ± 5.0	12.2 ± 5.1	< 0.001
≥ Moderate aortic regurgitation	14 (10.4)	26 (6.9)	0.197	8 (19.3)	10 (12.3)	0.526

Abbreviations: AVA, aortic valve area; LVEF, left ventricular ejection fraction.

[a]Bold letters represent significant p-values.

Although the mortality at 1 year was higher for MyV compared to ACN2 in our study, the rates were comparable to other commercially available TAVR devices.

Finally, the rate of stroke at 4 years was similar to that at 1 year, and the difference was statistically nonsignificant. The composite endpoint for death, stroke, and rehospitalization was 5.6% and 15.7% ($p = 0.047$) for ACN2 and MyV, respectively. This contrasts with the recently presented ACURATE-IDE trial, where the primary outcome of death, stroke, or rehospitalization was 14.8% in the ACN2 group versus 9.1% in the conventional TAVR group (Sapien or Evolut) (posterior median difference = 6.6%, noninferiority margin = 8.0%; therefore, noninferiority was not achieved) at 1 year.

4.3 | Hemodynamic Performance at Midterm

Severe patient prosthesis mismatch (PPM) was 0% and 6% in ACN2 and MyV groups ($p = 0.242$) (Table 3). Moderate-grade PPM was diagnosed in 6.6% of patients and severe-grade PPM in 0.7% with Acurate TAVR in a recent study [16]. Thus, the

TABLE 4 | 1 year and 4 year outcomes of global and matched cohorts according to valve type.

	Global cohort			Matched cohort		
	ACN2 $n = 144$	MyV $n = 401$	p value[a]	ACN2 $n = 89$	MyV $N = 89$	p value[a]
Outcomes at 1 year						
Global mortality	7 (4.9)	26 (6.5)	0.484	2 (2.2)	13 (14.6)	0.003
Cardiovascular mortality	2 (1.4)	12 (3.0)	0.374	1 (1.1)	5 (5.6)	0.211
Stroke	3 (2.1)	3 (0.7)	0.192	1 (1.1)	2 (2.2)	0.999
Valve-related hospitalization	5 (6.2)	5 (2.4)	0.148	4 (7.7)	1 (2.0)	0.363
Stroke-free survival (%)	93	92.8	0.997	96.6	83.8	0.005
Combined endpoint (death+stroke+rehosp)	13 (9.0)	33 (8.2)	0.768	5 (5.6)	14 (15.7)	0.029
Severe patient prosthesis mismatch	0 (0)	5 (1.8)	0.999	0 (0.0)	3 (6.0)	0.242
Mean aortic gradient, mmHg	8.44 ± 3.84	11.11 ± 5.53	< 0.001	8.24 ± 3.75	12.84 ± 5.55	< 0.001
Peak aortic gradient, mmHg	15.20 ± 6.12	20.55 ± 9.08	< 0.001	14.58 ± 5.73	23.98 ± 8.80	< 0.001
AVA, cm^2	1.90 ± 0.39	1.77 ± 0.47	0.020	1.90 ± 0.38	1.70 ± 0.35	0.005
LVEF (%)	59.61 ± 10.04	56.68 ± 9.58	0.004	59.14 ± 10.25	58.37 ± 9.24	0.620
≥ Moderate aortic regurgitation	14 (10.4)	26 (7)	0.197	11 (13.1)	13 (18.3)	0.371
Outcomes at 4 years						
Global mortality	21 (14.6)	57 (14.2)	0.914	8 (9.0)	21 (23.6)	0.008
Cardiovascular mortality	3 (2.1)	18 (4.5)	0.198	3 (3.4)	6 (6.7)	0.496
Stroke	3 (2.1)	5 (1.2)	0.441	1 (1.1)	2 (2.2)	0.999
Stroke-free survival (%)	74.6	80.5	0.314	83	68.3	0.014
Combined endpoint (death+stroke+rehosp)	27 (18.8)	66 (16.5)	0.531	11 (12.4)	22 (24.7)	0.034
Mean aortic gradient, mmHg	9.3 ± 3.8	11.9 ± 6.2	< 0.001	9.24 ± 4.21	13.18 ± 5.47	0.001
Peak aortic gradient, mmHg	16.5 ± 5.8	21.5 ± 10.3	< 0.001	15.93 ± 5.92	24.25 ± 8.61	< 0.001
AVA, cm^2	1.8 ± 0.32	1.6 ± 0.37	0.001	1.84 ± 0.35	1.66 ± 0.41	0.124
LVEF(%)	59.5 ± 9.66	56.8 ± 9.4	0.018	59.0 ± 9.1	58.2 ± 11.3	0.735
≥ Moderate aortic regurgitation	14 (15.9)	26 (9.2)	0.076	9 (15.8)	12 (21.1)	0.469

Abbreviations: AVA, aortic valve area; LVEF, left ventricular ejection fraction.
[a]Bold letters represent significant p-values.

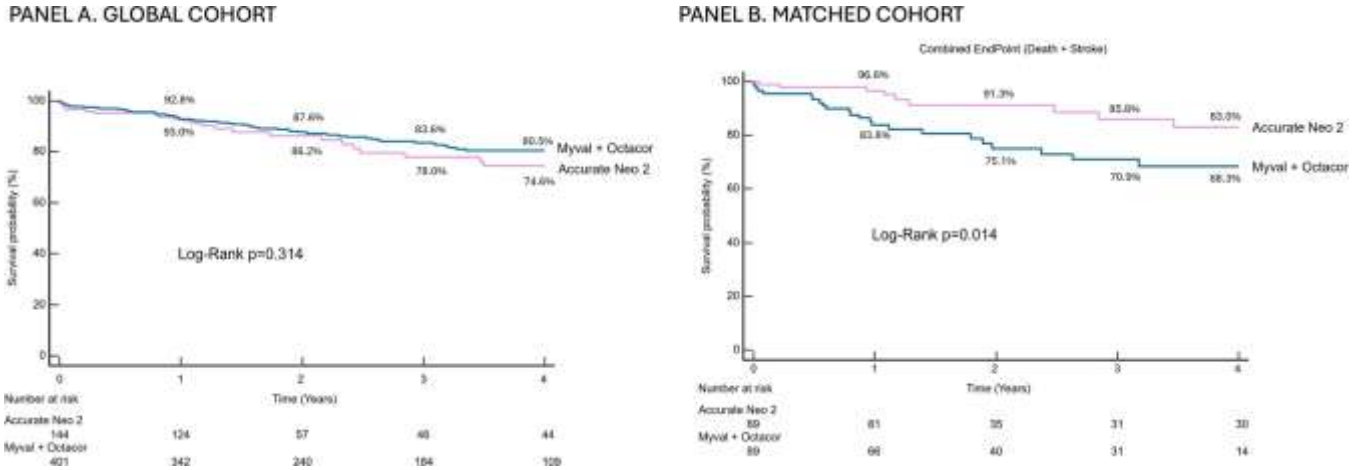


FIGURE 2 | Freedom from composite endpoint of mortality and stroke over 4 years for global (A) and matched (B) populations. [Color figure can be viewed at wileyonlinelibrary.com]

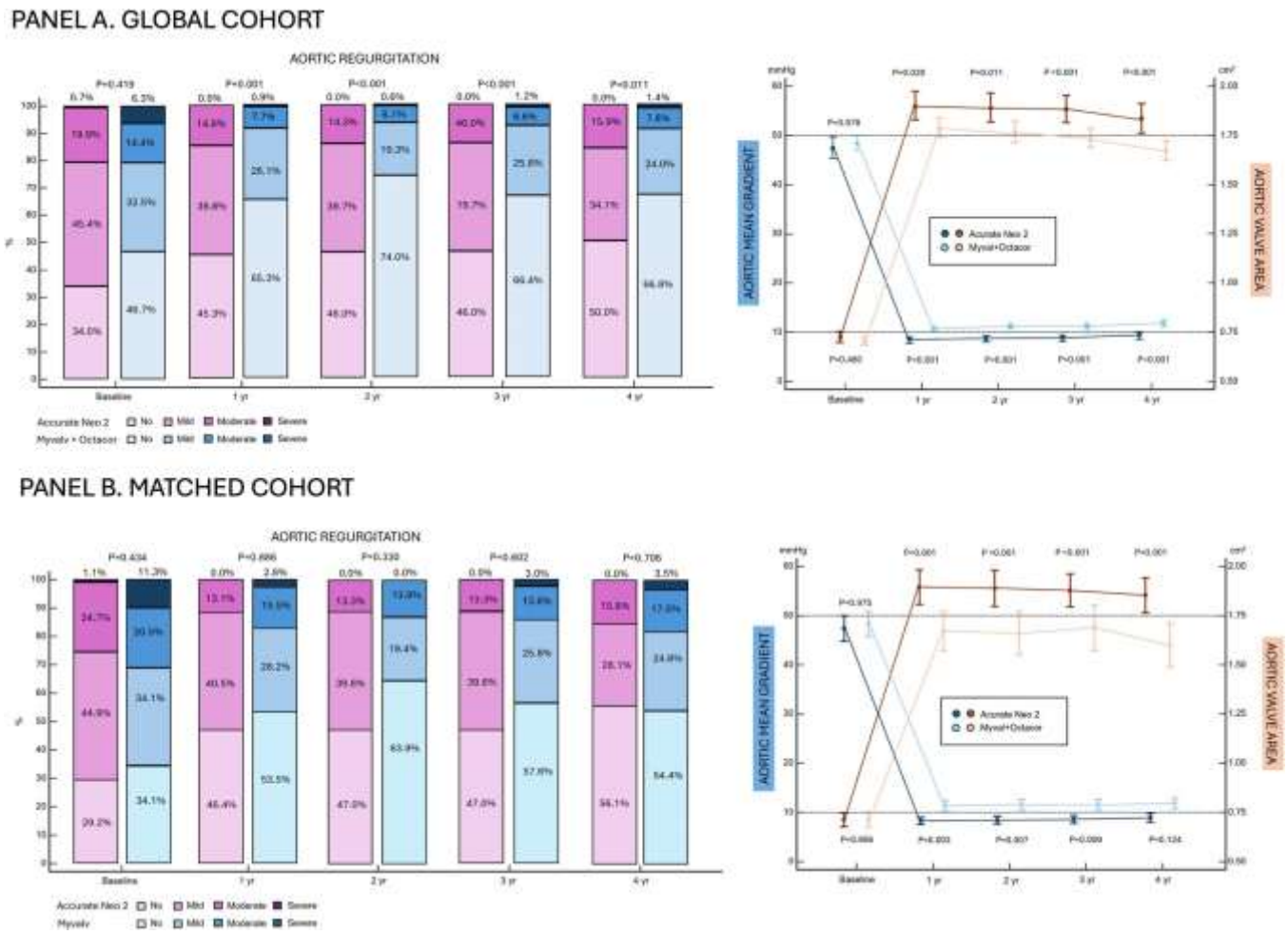


FIGURE 3 | Mean aortic valve gradient, aortic regurgitation, and aortic valve area for global (A) and matched (B) populations. [Color figure can be viewed at wileyonlinelibrary.com]

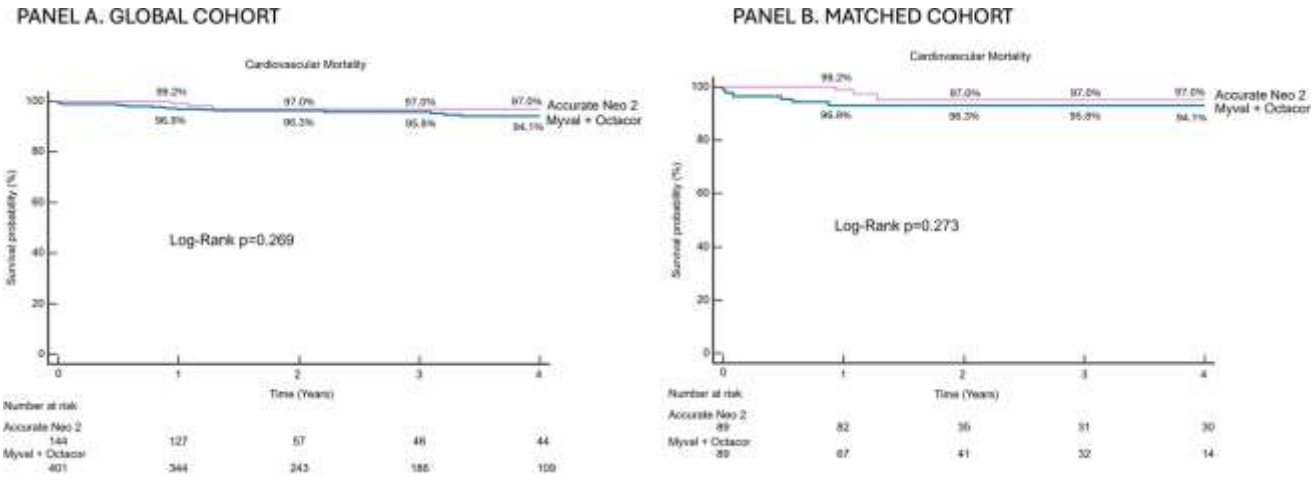


FIGURE 4 | Kaplan−Meier curve showing 4-year freedom from cardiovascular mortality in the global (A) and the matched (B) populations. [Color figure can be viewed at wileyonlinelibrary.com]

outcomes of stroke and PPM were comparable between the devices at 1 year. The rates of HVD for ACN2 and MyV were comparable to each other and to other contemporary devices (Table 5). Valve thrombosis and endocarditis have been linked to transcatheter valve dysfunction. In our study, there was no incidence of endocarditis in either group leading to transcatheter valve dysfunction, and only one case of leaflet thrombosis was observed in the ACN2 group. However, the difference was also

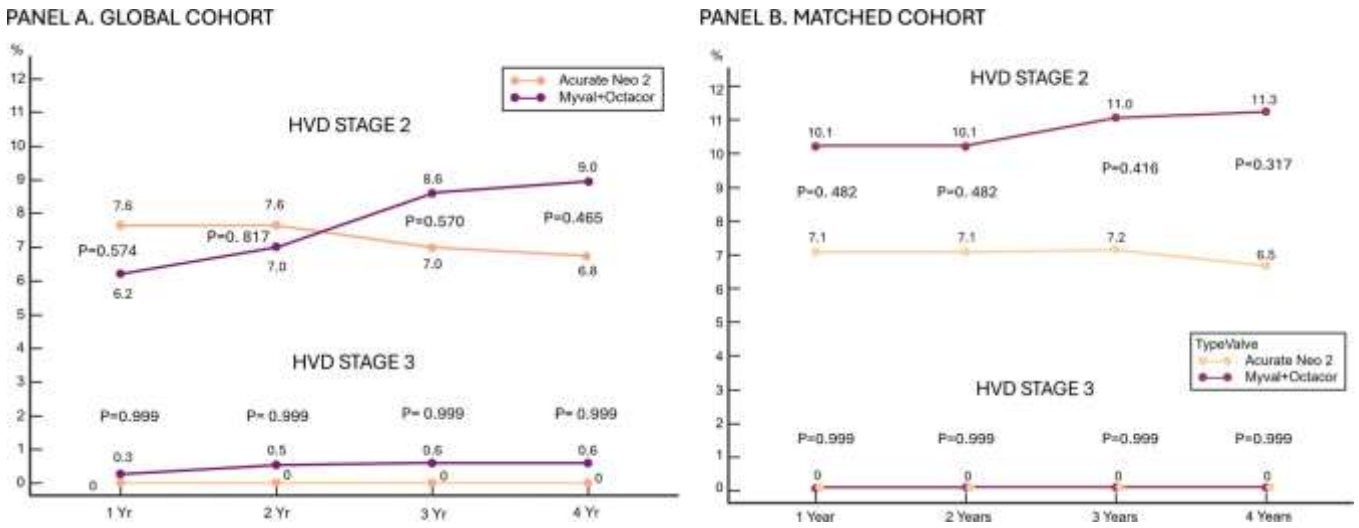
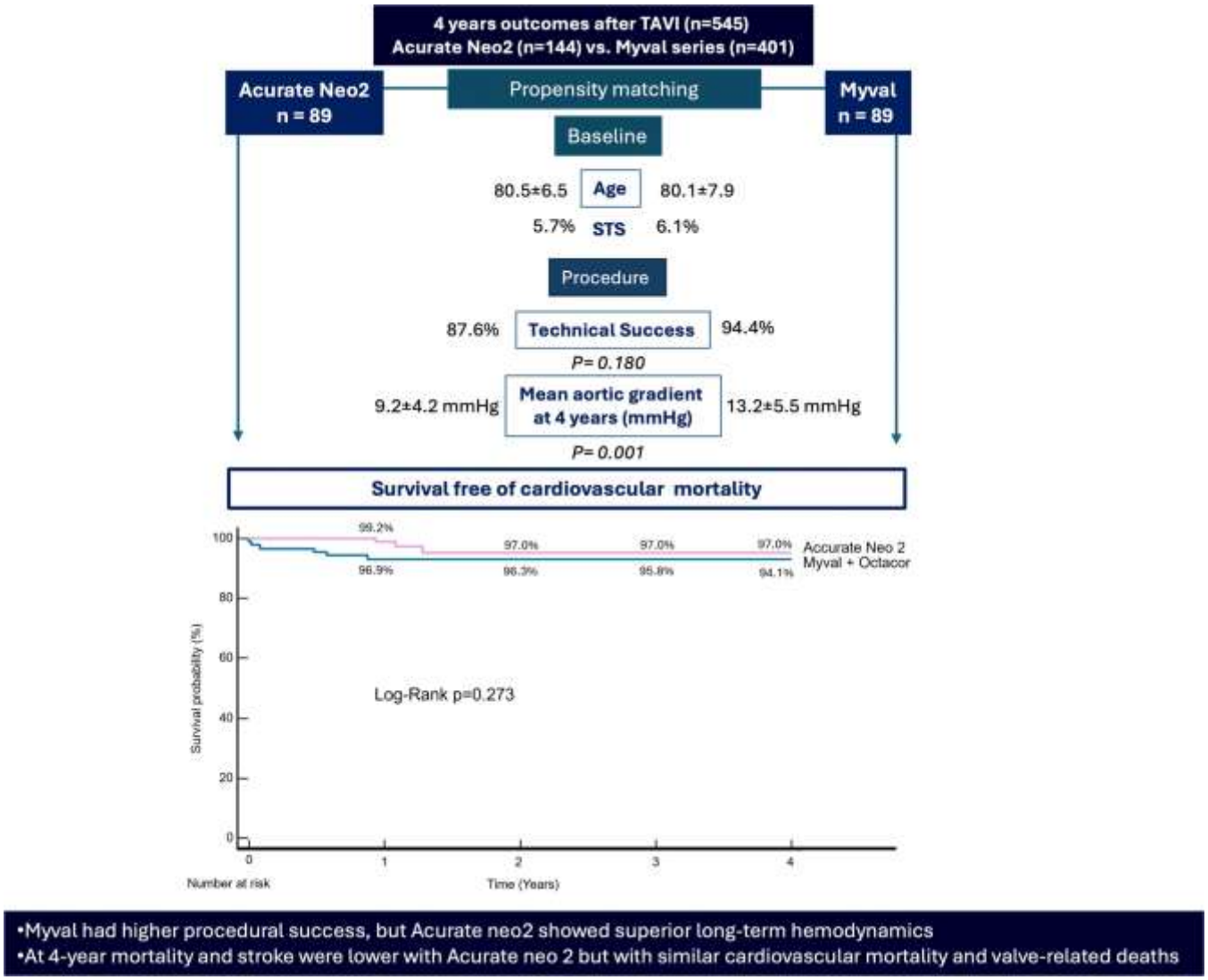


FIGURE 5 | Trends of HVD (hemodynamic valve deterioration) in global (A) and matched (B) populations. [Color figure can be viewed at wileyonlinelibrary.com]



CENTRAL ILLUSTRATION 1 | Main baseline, procedural, and 4-year follow-up outcomes of the study population. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 | Transcatheter aortic valve replacement devices: Durability data.

Study	Number of patients	Definition of BVD/BVF	Type of AVR	Stage 2−3 SVD-related BVD	All cause BVF	Duration of follow-up
PARTNER II-S3i	1665	VARC-3	TAVR-SAPIEN XT	9.5%	4.7%	5 years
Pibarot et al. [17]			TAVR-SAPIEN 3	3.9%	2.6%	
			SAVR	3.5%	1.3%	
Ferreira-Neto et al. [18]	212	VARC-3	TAVR- SAPIEN/XT	30.2%		8 years
Rheude et al. [19]	691	VARC-2	TAVR-SAPIEN 3	10.3%	1.88%	1 year
CHOICE	241	EAPCI/EACTS	TAVR-SAPIEN XT	6.6%		5 years
Abdel-Wahab et al. [20]			TAVR- COREVALVE	0.0%		
UK TAVI	221	EAPCI/EACTS	TAVR-SAPIEN/XT	22.4%		7 years
Ali et al. [21]			TAVR-COREVALVE	9.8%		
PARTNER 3	280	VARC-3	TAVR-SAPIEN 3 SAVR	4.2%	3.3%	5 years
Mack et al. [22]	(Low-risk patients)			3.8%	3.8%	
NOTION	280	VARC-3	TAVR- COREVALVE SAVR	12.5%	9.7%	10 years
Thyregod et al. [23]	(Low-risk patients)			13.9%	13.8%	
Ruck et al. [16]	433	VARC-3	TAVR-ACURATE NEO	2.2%	1.4%	39 months

Abbreviations: AVR, aortic valve replacement; BEV, balloon-expandable valve; 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; SEV, self-expanding valve; SVD, structural valve deterioration; TAVR, transcatheter aortic valve replacement; VARC, Valve Academic Research Consortium.

nonsignificant. The all-cause stage 1 BVF rates of 0% and 4.8% ($p = 0.083$) in the ACN2 and MyV groups could be attributable to both structural and nonstructural deterioration. The MyV series, being a balloon-expandable valve with intermediate sizing, was associated with comparable rates of ≥ moderate AR at 4 years. It is important to note that in the patients with 32 mm MyV, the rate of ≥ moderate AR was 57% 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 ≥ moderate AR more than device-related technical aspects which seem to perform comparably to other devices according to LANDMARK (where the extra-large sizes were also excluded). While this is preliminary, further studies are needed to determine the long-term durability of these devices.

Both MyV and ACN2 provide comparable outcomes across a broad range of clinical and procedural parameters, with minimal differences in early safety and effectiveness. Although differences were observed in some hemodynamic measures and longer-term outcomes, both devices have demonstrated overall high levels of safety and efficacy in the treatment of severe aortic stenosis.

5 | Limitations

This study has several limitations. Its retrospective design, while robust in capturing consecutive real-world cases, lacks the rigor of randomized controlled trials. Echocardiographic assessments were core lab-analyzed but mostly retrospectively acquired, potentially introducing variability. Additionally, incomplete data on variables like valve implant depth limit certain analyses. Despite these limitations, the study provides valuable long-term data on device performance.

6 | Conclusion

This study highlights the comparable safety and durability of MyV and ACN2 over 4 years, with differences in hemodynamic performance and technical success influencing device selection. ACN2's superior long-term hemodynamics and lower mortality in matched cohorts position it favorably in certain clinical settings as small annuli, while MyV offers advantages in procedural precision and outcomes in more challenging interventions. Larger, prospective studies are needed to confirm these findings and further refine device selection strategies.

Clinical Perspective

What is known? In 2024, Acurate neo 2 did not met non-inferiority compared to the Sapien-3 balloon-expandable valve in the IDE trial. On the contrary, Myval demonstrated non-inferiority compared to Sapien-3 balloon-expandable valve in the LANDMARK trial. However, Acurate Neo 2 and Myval TAVR devices have not been compared before.

What does this study add? After matching for baseline differences, technical success rates were similar, and 4-year mortality + stroke rates were better for ACN2 as compared to MyV, also with better mean gradients and effective orifice area and similar residual aortic regurgitation. Cardiovascular mortality and valve-related deaths were comparable underscoring the safety of both devices at long-term.

Disclosure

Dr Ignacio J. Amat-Santos is a proctor for Meril Life and Boston Scientific. Prof. Matteo Montorfano received consultant fees from Abbott, Boston Scientific, Kardia, and Medtronic. The institution received a nonconditioned grant for the LANDMARK trial. Dr Sengottuvelu Gunasekaran is a proctor for Myval and Acurate Neo 2 and has received honoraria from Meril Life Science and Boston Scientific. Dr Ashok Seth is a proctor for Myval, Acurate neo2, and Sentinel devices, principal investigator of the Myval-1 Study, and has received honoraria for speakers' bureau from Meril Lifesciences and Boston Scientific. Dr Akash Jain received consultant fees from Meril Life Science.

Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Supplemental Figure 1: Baseline matched parameters in both cohorts.AA, aortic annulus; BSA, body surface area; CAD, Coronary Artery Disease; CKD, Chronic Kidney Disease; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons risk score.