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Balloon-Expandable Myval Octacor Versus Self-Expanding Evolut PRO/PRO+ and Acurate Neo2: Short-Term Outcomes From Propensity-Matched Analysis

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ABSTRACT

Background: With transcatheter aortic valve implantation (TAVI) now extending to lower-risk and younger patients, optimizing procedural and hemodynamic outcomes is critical. The Myval Octacor, a new balloon-expandable valve (BEV), was developed to improve outcomes by reducing paravalvular regurgitation (PVL), minimizing pacemaker implantation (PPI) rates, and enhancing hemodynamic performance. However, limited data are available comparing Myval Octacor to contemporary self-expanding supra-annular valves (SEVs) Evolut PRO/PRO+ and Acurate Neo2.

Aims: This study aimed to compare the safety, efficacy, and short-term clinical outcomes of Myval Octacor with SEVs in transfemoral TAVI patients.

Methods: We conducted a prospective, multicenter registry including patients treated with Myval Octacor, then compared them to SEV recipients from the NEOPRO2 registry. Propensity score matching adjusted for baseline differences between groups. The primary endpoint was 30-day Valve Academic Research Consortium-3 (VARC-3) device success. Secondary endpoints included technical success, valve performance, and early safety outcomes.

Results: Among 252 Myval Octacor patients and 2175 SEV patients, 90 matched pairs were compared. Myval Octacor patients showed higher 30-day VARC-3 device success than SEVs patients (97% vs. 88%, $p = 0.024$), primarily due to a numerically lower

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rate of moderate-to-severe PVL (1% vs. 7%, $p = 0.06$). The Octacor group also exhibited larger indexed effective orifice areas. Mortality, stroke, PPI, and myocardial infarction rates were similar between groups at 30 days.
Conclusions: The Myval Octacor demonstrated comparable early safety and efficacy to supra-annular SEVs, with advantages in device success rate and hemodynamic performance. Adequately sized randomized study is required to confirm these findings.

1 | Introduction

Transfemoral transcatheter aortic valve implantation (TAVI) has emerged as the treatment of choice for patients with symptomatic severe aortic stenosis (AS), regardless of surgical risk, in individuals over 75 years of age [1]. This recent shift in guidelines has led to a substantial increase in the number of TAVI procedures being performed. As a result, the inclusion of younger and lower-risk patients in these procedures has become more common, making it essential to minimize procedural complications and optimize TAVI outcomes. Key goals for these patients include reducing vascular complications, minimizing the need for permanent pacemaker implantation (PPI), and achieving optimal hemodynamic performance.

Several transcatheter heart valves (THV) are available, each offering distinct characteristics and performance profiles. Recently, the balloon-expandable valve (BEV) Myval Octacor (Meril Life Science, Vapi, India) was introduced to the European market, offering unique design features and technical advantages that contribute to its improved performance, including low rates of paravalvular leak (PVL), reduced need of PPI, and a larger effective orifice area (EOA). Despite its innovative design and promising results in both native and valve-in-valve procedures, there is still limited data in the literature comparing this new device to the more widely used THVs [2–7]. The recently published randomized LANDMARK trial showed the non-inferiority of the Myval THV compared to both, the self-expanding valve (SEV) Evolut series (Medtronic, Minneapolis, MN, USA) and the BEV Sapien (Edwards Lifesciences, Irvine, CA, USA) in terms of primary composite endpoint [8]. However, only a small proportion (4%) of Myval THV included in the study were from the latest Octacor generation, leaving a gap in the literature regarding its performance. Moreover, there has been no direct comparison between Myval Octacor THV and the other widely used SEV, the Acurate Neo2 (Boston Scientific). In this context, our study aims to fill this gap by comparing the new Octacor with the latest SEV Evolut PRO/PRO+ and Acurate Neo2. We seek to evaluate the short-term clinical and hemodynamic outcomes, providing crucial data to inform the use of these newer generation THVs in contemporary practice.

2 | Methods

The Myval Octacor EU is a prospective multicentre international registry aimed at assessing the safety and efficacy of the newer generation Myval Octacor in patients with severe symptomatic AS undergoing transfemoral TAVI across 15 Centers from January 2023 to September 2024. The exclusion criteria included valve-in-valve procedures, pure AR, and alternative access approaches.

Local multidisciplinary Heart Teams evaluated all cases and confirmed eligibility for transfemoral TAVI for symptomatic, severe stenosis of the native aortic valve (AV). All patients underwent preoperative assessments, which included clinical and laboratory assessment, electrocardiography, echocardiography, laboratory tests, and multi-slice computed tomography (MSCT). AV and left ventricular outflow tract (LVOT) calcifications were classified and graded using a semi-quantitative scoring system, as previously described [9]. The study complied with the Declaration of Helsinki and was approved by local ethics committees. All patients provided written informed consent for the procedure and subsequent data collection. The choice of Myval size, as well as AV pre-dilatation and THV post-dilatation were left to the operator's discretion, taking into account the patients' clinical and anatomical characteristics. Follow-up assessment was performed at 30 days after the procedure, either with telephone interviews or office visits. Transthoracic echocardiography was performed at baseline, pre-discharge, and 30 days after the procedure by experienced cardiologists.

For the purposes of the present study, the Myval Octacor EU-Registry was merged with the NEOPRO 2 (Multicenter Comparison of ACURATE NEO2 vs. Evolut PRO/PRO+ Transcatheter Heart Valves 2) registry that included 2175 patients who underwent trans-femoral TAVI with the latest-generation self-expanding Acurate neo2 ($n = 763$) and Evolut PRO/PRO+ ($n = 1412$) devices at 20 centers between August 2017 and December 2021. The main results of the NEOPRO2 registry have already been reported [10].

The primary endpoint of the present study was 30-day device success, defined according to Valve Academic Research Consortium-3 (VARC-3) criteria [11]. Secondary endpoints of interest included additional VARC-3-defined composite outcomes: technical success, 30-day intended performance of the THV, 30-day early safety, and the single components of these endpoints.

2.1 | Statistical Analysis

Data are shown as either mean and SD or median and interquartile range (IQR), in the case of continuous variables and number and percentage, for categorical variables. The normal/not normal distribution was preliminarily assessed through a Kolmogorov−Smirnov Goodness-of-Fit K–S test.

Propensity score (PS) matching was used to adjust for differences in baseline characteristics. A PS was calculated for each patient to estimate the propensity toward belonging to a specific treatment group (SEV vs. Myval). This was done by means of a non-parsimonious multivariate logistic regression including the

following covariates: age, sex, prior myocardial infarction (MI), prior percutaneous coronary intervention (PCI), peripheral vascular disease (PAD), atrial fibrillation/flutter (AF), prior implantable cardioverter-defibrillator (ICD) implantation, New York Heart Association (NYHA), left ventricular ejection fraction (LVEF), European System for Cardiac Operative Risk Evaluation (EuroSCORE) II, AV regurgitation, moderate-to-heavy AV calcification, moderate-to-heavy LVOT calcification, annulus area, annulus perimeter, and therapeutic access size. The C-statistic for the PS model was 0.73, indicating good discrimination. A 1-to-1 nearest neighbor matching algorithm without replacement (caliper 0.05) was performed to identify PS-matched pairs. The pseudo-R2 value was 0.420 (p = 0.06) before matching and very low (0.08; $p = 0.917$) after matching, thus confirming the adequate balancing of covariate distribution between the matched groups [12].

Prespecified primary and secondary endpoints were compared between the SEV and Octacor groups in the overall and PS-matched cohorts. All tests were two-sided, and a $p < 0.05$ was considered statistically significant. All analyses were conducted using SPSS software (IL, USA) version 20.0.

To further explore the comparative performance of Myval Octacor in the context of currently available SEVs, we performed an additional sub-analysis restricted to patients treated with Evolut PRO/PRO+ THVs ($n = 1412$), excluding Acurate Neo2 recipients. PS matching was repeated in this subgroup, using the same baseline variables described above, and resulted in two well-balanced cohorts of 100 patients each. This focused comparison aimed to evaluate whether the findings of the main analysis remained consistent when restricting the control group to a single, currently available SEV platform.

3 | Results

A total of 252 patients were enrolled in the Octacor EU-Registry and compared to the 2175 patients included in the NEOPRO2 registry. The baseline characteristics are summarized in Table 1. Compared to the patients included in the SEV group, those in the Octacor group were younger (80.6 ± 6.7 vs. 81.7 ± 6.2, $p = 0.008$), more frequently male (69% vs. 37%, $p < 0.001$), had a higher prevalence of hypertension, AF, prior MI and PCI, and prior ICD implantation. They also had a lower incidence of PAD or NYHA class III or IV at presentation and a lower LVEF. Regarding MSCT data, patients in the Octacor group had larger annulus area and perimeter, lower incidence of moderate-to-heavy AV calcifications, and lower incidence of severe LVOT calcification. Moreover, a trend toward a larger therapeutic access size was observed in Octacor versus SEV group.

Procedural and pre-discharge outcomes are depicted in Table 2. Most patients underwent a TAVI procedure under conscious sedation; however, a significantly higher rate of patients in the Octacor group underwent general anesthesia (19% vs. 9%, $p < 0.001$). Pre- and post-dilation were more frequently performed in the SEV group compared to the Octacor group (59% vs. 43%; $p < 0.001$ and 28% vs. 6%; $p < 0.001$, respectively).

The correct position of a single THV was achieved in a high percentage of patients in both groups (98.3% vs. 98.8%). No significant differences were noted in terms of procedural mortality or complications such as annular rupture, pericardial tamponade, aortic dissection, or coronary occlusion. However, VARC-3 technical success was significantly higher in Myval versus SEV group (98% vs. 93.7%, $p < 0.001$).

Regarding the pre-discharge echocardiographic outcomes, VARC-3 intended performance of the THV was significantly higher in the Octacor group compared to the SEV group (98% vs. 95%, p = 0.009), due to a lower rate of moderate-to-severe paravalvular AR in the Octacor group. Larger EOA and a trend toward a lower rate of severe patient-prosthesis mismatch (PPM) was also observed in the Octacor group.

Clinical outcomes at 30 days are reported in Table 3. Rates of all-cause death, cardiovascular death, stroke, MI, and cardiac hospitalizations were similar between the groups. VARC-3 bleeding and advanced NYHA class were less frequent in the Octacor group compared to the SEV group, while the need for PPI was significantly higher in the Octacor group. No differences were observed in terms of VARC-3 early safety between groups, although VARC-3 device success was significantly higher in the Octacor group (96% vs. 84%, $p < 0.001$). A larger EOA, lower rate of moderate-to-severe PVL, and a trend toward a higher VARC-3 intended performance of the THV were observed in the Octacor compared to the SEV group.

After 1-to-1 PS matching (based on the variables summarized in the "Methods" section), a total of 90 pairs were obtained from the overall cohort (Table 1). The two matched groups exhibited similar baseline characteristics, as well as echocardiographic and MSCT anatomical features. Following matching, general anesthesia remained more common in the Octacor group, as well as pre- and post-dilation were more frequently performed in the SEV group. In 60% of patients treated with Octacor, intermediate THV sizes were selected. VARC-3 technical success was comparable between the two analyzed cohorts (94% for SEV vs. 97.8% for Octacor; p = 0.2), with no significant differences in terms of in-hospital major adverse events. At discharge, lower rates of moderate-to-severe PVL, as well as larger EOAi and a higher rate of VARC-3 intended performance of the THV were observed in the Myval group compared to the SEV group. The clinical outcomes at 30 days were confirmed in the matched population with numerically lower rates of VARC-3 bleeding, and a higher device success rate in the Myval group compared to SEV group, with no differences in the need for PPI or early safety between groups. Larger EOAi and a trend toward a lower rate of moderate-to-severe PVL (with all cases being moderate and non-severe in both groups) as well as a trend toward better VARC-3 intended performance of the THV, were observed in the Octacor group compared to the SEV group.

In the sub-analysis comparing Myval Octacor to Evolut PRO/PRO+ only, baseline characteristics were again well balanced after PS-matching (Supporting Information S1: Table 1). Procedural details and early outcomes are summarized in Supporting Information S1: Tables 2 and 3. As in the main analysis, Octacor demonstrated a higher VARC-3 device success rate at 30 days compared to Evolut PRO/PRO+, primarily due

TABLE 1 | Baseline patient characteristics.

	Unmatched			Matched		
	SEV $n = 2175$	Octacor $n = 252$	p value	SEV $n = 90$	Octacor $n = 90$	p value
Clinical characteristics						
Age at procedure	81.7 ± 6.2	80.6 ± 6.7	0.008	81.4 ± 5.9	81.5 ± 6.2	0.934
Male sex	809 (37.2)	175 (69.4)	< 0.001	52 (57.8)	56 (62.2)	0.324
BMI	27.1 ± 5.2	27.6 ± 4.9	0.186	28.1 ± 5.1	26.9 ± 4.7	0.120
Active/former smoker	335 (19.4)	60 (23.8)	0.064	24 (27.0)	21 (23.3)	0.349
COPD	320 (14.7)	31 (12.3)	0.172	16 (17.8)	8 (8.9)	0.062
Diabetes	655 (30.2)	71 (28.2)	0.277	23 (25.6)	25 (27.8)	0.433
Hypertension	1850 (85.2)	227 (90.1)	0.020	84 (93.3)	79 (87.8)	0.154
Prior MI	231 (11.6)	40 (15.9)	0.035	23 (25.6)	16 (17.8)	0.139
Prior PCI	497 (22.9)	75 (29.8)	0.010	32 (35.6)	29 (32.2)	0.376
Prior CABG	140 (6.4)	18 (7.1)	0.376	8 (8.9)	7 (7.8)	0.500
Prior stroke	203 (9.4)	22 (8.7)	0.427	6 (6.7)	9 (10.0)	0.296
Peripheral vascular disease	275 (12.7)	15 (6.0)	< 0.001	10 (11.1)	7 (7.8)	0.306
Prior cardiac surgery	180 (8.3)	19 (7.5)	0.395	8 (8.9)	7 (7.8)	0.500
Atrial fibrillation/flutter	579 (26.7)	82 (32.5)	0.032	36 (40.0)	31 (34.4)	0.269
Pacemaker/ICD	191 (8.8)	41 (16.3)	< 0.001	14 (15.6)	10 (11.1)	0.256
eGFR	60.6 ± 26.9	59.9 ± 25.3	0.683	64.6 ± 27.3	58.6 ± 25.0	0.127
NYHA III or IV	1292 (59.7)	121 (48.0)	< 0.001	60 (66.7)	47 (52.2)	0.068
Euroscore II	4.5 ± 4.2	3.9 ± 3.9	0.053	4.3 ± 3.5	3.7 ± 3.5	0.258
STS-PROM	4.2 ± 2.8	4.5 ± 3.4	0.194	4.3 ± 3.6	3.7 ± 3.5	0.060
Echocardiographic data						
Mean AV gradient	46.8 ± 14.9	42.5 ± 15.1	< 0.001	41.6 ± 13.9	43.7 ± 4.7	0.333
AVA	0.70 ± 0.17	0.73 ± 0.23	0.031	0.77 ± 0.15	0.72 ± 0.19	0.060
AVAi	0.39 ± 0.09	0.39 ± 0.13	0.391	0.40 ± 0.72	0.39 ± 0.11	0.234
Moderate to severe AR	343 (16.1)	45 (17.9)	0.260	10 (11.1)	11 (12.2)	0.500
LVEF	56.9 ± 10.4	51.6 ± 11.0	< 0.001	56.0 ± 9.9	55.9 ± 9.4	0.914
Moderate to severe MR	525 (25.7)	57 (23.0)	0.197	20 (22.2)	13 (14.4)	0.124
Severe pulmonary hypertension	143 (7.7)	16 (6.3)	0.271	5 (5.7)	5 (5.6)	0.612
MDCT data						
Minimal AV diameter	20.7 ± 2.1	23.1 ± 2.8	< 0.001	21.5 ± 1.8	22.2 ± 2.3	0.023
Maximal AV diameter	25.9 ± 2.4	28.9 ± 3.1	< 0.001	27.9 ± 2.3	26.8 ± 1.8	< 0.001
Area AV	419 ± 66	523 ± 126	< 0.001	470 ± 117	457 ± 56	0.360
AV annulus perimeter	73.5 ± 5.9	81.6 ± 11	< 0.001	76 ± 7	77 ± 11	0.379
Moderate to severe aortic valve calcifications	1265 (77.4)	181 (71.8)	0.033	59 (65.6)	57 (63.3)	0.438
Moderate-to-severe LVOT calcification	222 (20.7)	35 (17.5)	0.177	15 (16.7)	16 (17.8)	0.500
Severe LVOT calcification	90 (8.4)	6 (3.0)	0.003	4 (4.4)	4 (4.4)	0.640
Access size diameter (mm)	7.3 ± 1.2	7.5 ± 1.5	0.095	7.6 ± 1.3	7.4 ± 1.4	0.235

Abbreviations: AV, aortic valve; AVAi, aortic valve area indexed; BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SEV, self-expanding valve; STS, Society of Thoracic Surgeons Score.

TABLE 2 | Procedural characteristics and pre-discharge echocardiographic outcomes.

	Unmatched			Matched		
	SEV $n = 2175$	Octacor $n = 252$	p value	SEV $n = 90$	Octacor $n = 90$	p value
Procedural characteristics						
Valve size			—			—
21.5	—	3 (1.2)		—	1 (1.1)	
23 (or S size)	234 (11.7)	18 (7.2)		2 (2.3)	7 (7.8)	
24.5	—	61 (24.3)		—	37 (41.1)	
25 (or M size)	327 (16.4)	—		14 (16.3)	—	
26	468 (23.4)	43 (17.1)		10 (11.6)	15 (16.7)	
27 (or L size)	251 (12.6)	—		24 (27.9)	—	
27.5	—	57 (22.7)		—	14 (15.6)	
29	682 (34.2)	40 (15.9)		36 (41.9)	11 (12.2)	
30.5	—	11 (4.4)		—	5 (5.5)	
32	—	18 (7.2)		—	—	
34	24 (1.7)	—			—	
General anesthesia	198 (9.1)	48 (19.0)	< 0.001	0 (0)	19 (21.1)	< 0.001
Predilatation	1278 (58.9)	109 (43.3)	< 0.001	57 (63.3)	33 (36.7)	< 0.001
Postdilatation	587 (28.8)	15 (6.0)	< 0.001	17 (19.1)	8 (8.9)	0.039
Procedural outcomes						
VARC-3 technical success	2037 (93.7)	249 (98.8)	< 0.001	85 (94.4)	88 (97.8)	0.222
Procedural mortality	8 (0.4)	0 (0)	0.415	0 (0)	0 (0)	—
Second THV implanted	19 (0.9)	3 (1.2)	0.405	0 (0)	2 (2.2)	0.249
Valve embolization	22 (1.0)	3 (1.2)	0.491	0 (0)	2 (2.2)	0.249
Annular rupture	4 (0.2)	0 (0)	0.645	1 (1.1)	0 (0)	0.500
Pericardial tamponade	19 (0.9)	0 (0)	0.124	1 (1.1)	0 (0)	0.500
Aortic dissection	1 (0.05)	0 (0)	0.896	0 (0)	0 (0)	—
Coronary occlusion	10 (0.5)	0 (0)	0.333	0 (0)	0 (0)	—
Conversion to open heart surgery	7 (0.3)	0 (0)	0.464	0 (0)	0 (0)	—
Vascular access complications			0.005			0.374
Minor	159 (7.3)	7 (2.8)		3 (4.4)	1 (1.1)	
Major	80 (3.7)	4 (1.6)		4 (4.4)	1 (1.1)	
Correct positioning of a single valve	2139 (98.3)	249 (98.8)	0.411	90 (100)	88 (97.8)	0.249
Pre-discharge echocardiographic outcomes						
Total AR			0.020			0.100
None/trace	1238 (58.0)	123 (50.8)		49 (54.4)	48 (56.5)	
Mild	824 (38.6)	116 (47.9)		36 (40.0)	36 (42.4)	
Moderate	68 (3.2)	3 (1.2)		5 (5.6)	1 (1.2)	
Severe	4 (0.2)	0 (0)		0 (0)	0 (0)	
Moderate-to-severe PVL	69 (3.2)	3 (0.8)	0.050	5 (5.6)	0 (0)	0.039
Mean gradient ≥ 20 mmHg	24 (1.6)	2 (0.9)	0.298	2 (2.3)	0 (0)	0.254
Mean AV gradient	8.2 ± 4.1	8.6 ± 3.8	0.132	8.3 ± 3.9	8.2 ± 3.5	0.866
Max AV gradient	15.1 ± 7.4	15.2 ± 6.0	0.846	15.0 ± 6.9	14.5 ± 5.9	0.600
Aortic EOA	1.9 ± 0.5	2.1 ± 0.6	< 0.001	1.9 ± 0.5	2.2 ± 0.7	0.095

(Continues)

TABLE 2 | (Continued)

	Unmatched			Matched		
	SEV $n = 2175$	Octacor $n = 252$	p value	SEV $n = 90$	Octacor $n = 90$	p value
Aortic EOAi	1.04 ± 0.3	1.13 ± 0.3	0.005	1.0 ± 0.3	1.2 ± 0.3	0.029
Severe PPM (EOAi < 0.65)	50 (4.9)	1 (1.1)	0.058	2 (3.6)	0 (0)	0.294
LVEF	57.9 ± 9.2	53.2 ± 10.4	< 0.001	55 ± 8	57 ± 8	0.524
VARC-3 intended performance of the valve	2004 (94.8)	237 (97.9)	0.015	80 (92.0)	83 (98.8)	0.036

Abbreviations: EOAi, effective orifice area indexed; LVEF, left ventricular ejection fraction; PPM, prosthesis-patient mismatch; PVL, paravalvular leak; SEV, self-expanding valve; THV, transcatheter heart valve; VARC, Valve Academic Research Consortium.

to a lower incidence of moderate-to-severe PVL. Early safety outcomes were comparable between the two groups, confirming the robustness of the main study findings.

4 | Discussion

To the best of our knowledge, we report the first study using PS matching to compare the newer generation BE Myval Octacor THV with the currently available SE, supra-annular Evolut PRO/PRO+, and Acurate Neo2 THVs. The results of our study can be summarized as follows (Central Illustration 1).

- At 30-day follow-up, the clinical outcomes of patients treated with the Octacor THV were comparable to those treated with SEVs.
- A higher rate of VARC-3 device success was observed in the Octacor group, with a trend toward better VARC-3 intended performance, mainly driven by a numerically lower rate of moderate-to severe PVL.
- Despite being an intra-annular THV, patients treated with Octacor showed better EOAi compared to those treated with SEV with a supra-annular design.
- In both the overall population and the PS-matched population, intermediate THV sizes were chosen in more than half of the patients treated with Octacor, based on aortic annular area measurements from preprocedural MSCT data.

As indications for TAVI have broadened to include lower-risk and consequently younger patient populations, achieving optimal procedural and hemodynamic results, as well as minimizing complications, has become increasingly critical as these can significantly impact long-term valve durability and patients' outcomes. In response to these needs, a variety of THVs have been developed, each with distinct design features and performance profiles.

The randomized LANDMARK trial [8] recently compared Myval THV with contemporary THVs, including both the Evolut and Sapien series, demonstrating the non-inferiority of Myval for composite safety and effectiveness endpoints at 30 days, with no significant differences in early clinical and hemodynamic parameters between groups. Reported device success at 30 days was similar (91% for the Myval and 90% for the contemporary THVs).

In our study, however, the 30-day VARC-3 device success rate was significantly higher in the Octacor group compared to SEVs, even after PS-matching (97% vs. 88%, $p = 0.02$); this finding remained consistent when restricting the comparison to Evolut PRO/PRO+ only, further reinforcing the robustness of the result. This result can be partially attributed to the numerically lower incidence of moderate-to-severe PVL observed with Octacor compared to SEVs (1% vs. 7%, $p = 0.06$), consistent with recent data showing a 1.6% rate of moderate-to-severe PVL with new generation Octacor [4]. This result aligns with previous observations that BEVs generally demonstrate a lower rate of severe PVL compared to SEVs, likely due to their higher radial force and improved adaptation to the AV annulus. The Octacor differs in design from both the first-generation Myval and the Sapien THV. Specifically, the Octacor features a two-row interlacing octagonal cell structure, in contrast to the three-row hybrid honeycomb hexagonal cell geometry. The open cells in the outflow zone are designed to preserve coronary flow, while the closed cells in the inflow zone aim to minimize PVL. This structural configuration is intended to reduce foreshortening during THV deployment compared to a three-row design, facilitating precise positioning of the inflow. Additionally, the Octacor includes an external skirt extending up to 50% of the frame height, which is designed to seal microchannels and potentially reduce the risk of PVL. The availability of a wider range of sizes further minimizes the risk of relative undersizing.

Reducing the incidence of PVL is crucial. Indeed, significant PVL can negatively impact clinical outcomes and may even offset the survival benefits of TAVI, with a twofold increase in all-cause mortality observed in patients with more than moderate PVL following TAVI [13, 14]. In our study, however, there were no differences in mortality between the two THV types. It should be noted, though, that our follow-up period was limited to 30 days. Interestingly, the rate of NYHA class 3–4 was significantly higher in the SEV group, despite a better ejection fraction compared to the Myval group. This discrepancy may be explained by the higher incidence of PVL observed in the SEV group, which can contribute to symptomatic heart failure even when left ventricular function appears preserved. Longer-term follow-up will be essential to determine whether these differences in symptomatic burden and PVL incidence translate into divergent outcomes over time.

Another important consideration following TAVI is the hemodynamic performance of THVs, specifically regarding mean transvalvular gradient and EOA/EOAi. The risk of severe PPM is indeed higher with THVs featuring an intra-annular design, especially when implanted in smaller annuli [15]. Severe PPM has

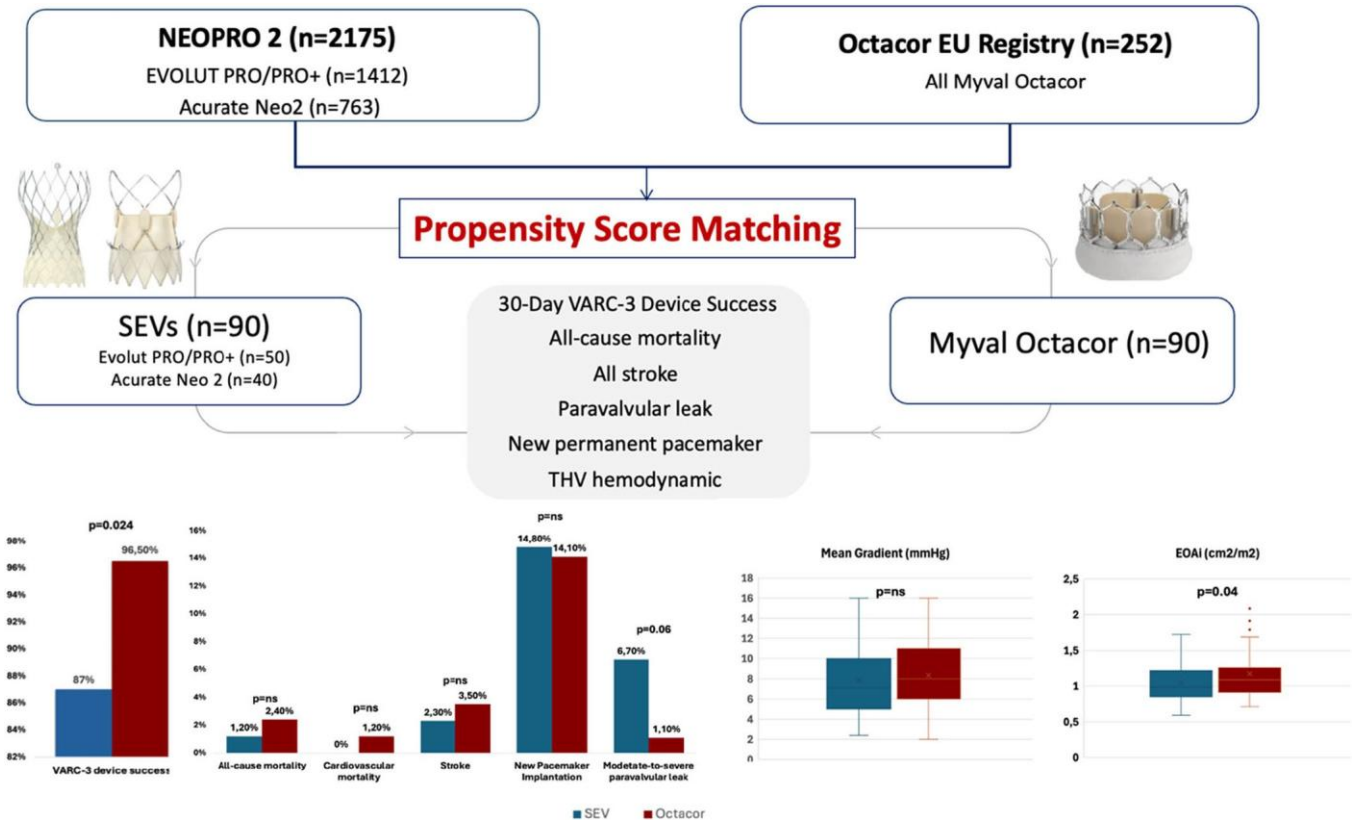
TABLE 3 | 30-day outcomes.

	Unmatched			Matched		
	SEV $n = 2175$	Octacor $n = 252$	p value	SEV $n = 90$	Octacor $n = 90$	p value
Clinical outcomes						
VARC-3 device success	1752 (83.9)	223 (95.7)	< 0.001	79 (87.8)	87 (96.7)	0.024
All-cause mortality	57 (2.6)	6 (2.6)	0.583	1 (1.1)	2 (2.2)	0.500
Cardiovascular mortality	25 (2.1)	3 (1.3)	0.297	0 (0)	1 (1.1)	0.497
Surgery for vascular access complications	20 (0.9)	2 (0.8)	0.582	0 (0)	0 (0)	—
Valve dysfunction requiring repeat intervention (BAV, TAVR, SAVR)	6 (0.3)	2 (0.8)	0.204	0 (0)	1 (1.1)	0.509
VARC-3 Intended performance of the valve	2003 (94.9)	235 (97.1)	0.085	81/86 (94.2)	81/89 (99.8)	0.098
VARC-3 early safety	1547 (73.8)	179 (76.8)	0.180	69 (76.7)	73 (81.1)	0.291
Stroke	60 (2.8)	8 (3.4)	0.363	2 (2.3)	3 (3.5)	0.494
Cardiac hospitalization	61 (2.9)	6 (2.6)	0.495	1 (1.2)	1 (1.2)	0.749
MI	5 (0.2)	0 (0)	0.592	0 (0)	0 (0)	—
VARC-3 bleeding			< 0.001			0.073
Type 1	181 (8.6)	0 (0)		3 (3.5)	0 (0)	
Type 2	94 (4.5)	1 (0.4)		4 (4.7)	1(1.1)	
Type 3	45 (2.1)	0 (0)		0 (0)	0 (0)	
Type 4	6 (0.3)	1 (0.4)		0 (0)	0 (0)	
AKI stage 3 or 4	34 (1.6)	2 (0.8)	0.250	0 (0)	0 (0)	—
New pacemaker implantation	249 (12.9)	37 (15.9)	0.117	13 (14.8)	12 (14.1)	0.538
Endocarditis	3 (0.1)	0 (0)	0.715	0 (0)	0 (0)	—
Valve thrombosis	3 (0.1)	0 (0)	0.715	0 (0)	0 (0)	—
NYHA class III or IV	43 (4.0)	3 (1.4)	0.037	1 (1.7)	0 (0)	0.414
Echocardiographic data 30-day follow-up						
Moderate-to-severe AR	73 (3.4)	5 (2.0)	0.163	6/86 (6.7)	1/89 (1.1)	0.059
Moderate-to-severe PVL	73 (3.5)	4 (1.6)	0.008	6/86 (6.7)	1/89 (1.1)	0.059
Mean AV gradient	8.0 ± 4.0	8.6 ± 4.0	0.129	7.9 ± 3.4	8.0 ± 3.6	0.824
Max AV gradient	14.7 ± 7.1	14.8 ± 6.7	0.901	14.4 ± 6.5	14.2 ± 6.3	0.859
Mean gradient ≥ 20 mmHg	35 (1.7)	0 (0)	0.105	2/87 (0)	0/80 (0)	0.270
EOA	1.8 ± 0.5	2.1 ± 0.5	< 0.001	1.9 ± 0.5	2.2 ± 0.6	0.197
EOAi	1.0 ± 0.3	1.1 ± 0.3	0.012	1.0 ± 0.3	1.2 ± 0.3	0.037
Severe PPM (EOAi < 0.65)	48 (5.4)	0 (0)	0.093	2/55 (3.8)	0/46 (0)	0.273
LVEF	58.2 ± 8.6	53.6 ± 9.6	< 0.001	57 ± 9	56 ± 7	0.680

Abbreviations: AKI, acute kidney injury; AV, aortic valve; BAV, balloon aortic valvuloplasty; EOAi, effective orifice area indexed; LVEF, left ventricular ejection fraction; PPM, prosthesis-patient mismatch; PVL, paravalvular leak; SAVR, surgical aortic valve replacement; SEV, self-expanding valve; TAVI, transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium.

been shown to correlate with an increased and ongoing risk of mortality after TAVR [16]. However, Myval demonstrated lower gradients compared to both the Sapien BEV with an intra-annular leaflets design [17] and the Evolut R SEV with a supra-annular design [3]. In our study, we also found that Myval was associated with larger EOA/EOAi compared to contemporary supra-annular SEVs. A possible explanation for this is that the availability of intermediate-sized prostheses with Myval and Octacor enables more precise sizing, which may help achieve a larger EOA. Nevertheless, the impact of these hemodynamic advantages on long-term valve durability remains to be determined.

While previous studies have shown that PPI following TAVI is associated with a higher incidence of heart failure hospitalizations,



CENTRAL ILLUSTRATION 1 | Study overview and key short-term outcomes comparing balloon-expandable Myval Octacor versus self-expanding Evolut PRO/PRO+ and Acurate Neo2 following propensity-matched analysis. [Color figure can be viewed at wileyonlinelibrary.com]

its impact on mortality has produced conflicting results [18–21]. In our study, the 30-day rate of PPI was similar between groups (14% in the Octacor group vs. 15% in the SEVs group) and consistent with that reported in the LANDMARK trial (15% in the Myval group vs. 17% in contemporary THVs) [8]. The availability of intermediate sizes with Myval and Octacor may likely allow for a more precise anatomical fit, which may reduce the need for excessive oversizing and the associated risk of conduction disturbances, especially in cases of small LVOT diameter or severe LVOT calcification. However, when comparing only with Acurate Neo 2 THV, we observed a significantly higher rate of PPI in the Myval group (16% vs. 7%, $p < 0.001$). The reduced incidence of PPI in the Acurate Neo2 group may be due to its lower radial force, which minimizes the risk of damage to conduction pathways. Yet, recent data from the ACURATE IDE [22] trial suggest that this lower radial force may lead to THV under-expansion (with improper pre- and post-dilatation techniques), which is associated with an increased risk of stroke at 1 year.

Finally, we did not correct for the presence of a pre-existing right bundle branch block before TAVI, which is known to be a major risk factor for developing a high-grade AV block after TAVI.

5 | Limitations

The main limitation of our study is its nonrandomized design. Despite the use of PS-matching analysis, the possibility of bias due to unmeasured confounders cannot be entirely ruled out. The decision to use PPI was left to the investigator's discretion, and the follow-up period was limited to 30 days. Additionally, the choice to use the Myval Octacor valve rather than another valve was also at the discretion of the operator. The absence of a pre-specified protocol or a formal prospective registry design in a multicenter study could introduce biases, such as the under-reporting of adverse events.

6 | Conclusions

Our multicentre propensity-matched study comparing the novel Myval Octacor BEV with the contemporary supra-annular SEVs provides evidence that the early safety and efficacy outcomes of patients treated with Octacor are comparable to those treated with SEVs. Moreover, the use of Octacor was associated with a higher rate of 30-day VARC-3 device success mainly driven by numerically lower rate of PVL. Finally, despite being an intra-annular THV, patients treated with Octacor showed better EOAi compared to those treated with SEVs with a supra-annular design. Further long-term follow-up is required to confirm these findings.

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.

Table S1: Baseline patient characteristics. Table S2: Procedural characteristic and predischage echocardiographic outcomes. Table S3: 30-day outcomes.