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TAVI in Patients with Large Aortic Annuli: A Single-Center Experience with Balloon-Expandable Valves

SCIENTIFIC LETTER

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INTRODUCTION

Treating patients with aortic stenosis and large annuli can be challenging. In previous TAVI studies, a large annulus has been defined as CT-derived annular area ≥ 575 mm^2.[1] In selected anatomies, balloon-expandable valves (BEV) are commonly used. The Sapien 3 is the most widely used BEV. Overexpansion of the Sapien 3 in patients with large annuli has been described.[2] The Myval is a newer BEV available in larger sizes and has shown promising preliminary results.[3] Recent evidence has demonstrated its short-term safety and efficacy compared with contemporary transcatheter valve platforms.[4] Furthermore, real-world registry has shown that Myval is safe and effective in long-term follow-up extending to 2 years.[5] However, comparative data on Sapien 3 vs. Myval in patients with large annuli are limited. The study aimed to explore differences in procedural and early clinical outcomes between Sapien 3 and Myval in patients with large annuli.

METHODS

Data from consecutive patients undergoing TAVI who received either the Sapien 3 (Edwards Lifesciences, Irvine, CA, USA) or Myval valve (Meril Life Sciences, Vapi, India) at the tertiary care center between January 2024 and December 2025 were analyzed. The study population consisted exclusively of patients with a large aortic annulus and was consequently entirely male. Device selection was at the discretion of the implanting team following discussion within the institutional heart team, based on anatomical and clinical considerations. Echocardiographic assessment was performed at baseline and before discharge. Given the exploratory nature of the study, no formal primary endpoint was defined. Outcomes were assessed descriptively according to VARC-3 definitions,[6] including in-hospital mortality, stroke, major vascular complications, and permanent pacemaker implantation.

Continuous variables are presented as mean ± SD, and categorical variables as counts and percentages. Continuous variables were compared using the unpaired *t*-test. Categorical variables were compared using Fisher's exact test, and ordinal variables were compared using the Mann–Whitney *U*-test. A *P*-value < .05 was considered statistically significant. Given the limited sample size, no multivariable adjustment or propensity-based analyses were performed, and the analysis should be considered exploratory.

RESULTS

A total of 40 patients (all males) were included. Twenty-four patients received a Sapien 3 (29 mm) and 16 patients a Myval prosthesis (6 [29 mm], 6 [30.5 mm], and 4 [32 mm]). Baseline clinical characteristics, echocardiographic parameters, and annular dimensions were comparable between groups (Table 1).

Table 1. Baseline Characteristics and Outcome of the Study Population

	All (n = 40)	S3 (n = 24)	Myval (n = 16)	*P*
Clinical characteristics				
Age (years)	74.3 ± 8.3	72.7 ± 9.1	76.7 ± 6.4	.111
DM, n (%)	21 (53)	13 (54)	8 (50)	1.000
Art. HTN, n (%)	30 (75)	20 (83)	10 (63)	.159
CAD, n (%)	23 (58)	13 (54)	10 (63)	.747
Pulmonary disease, n (%)	13 (33)	9 (38)	4 (25)	.503
Atrial fibrillation, n (%)	21 (53)	12 (50)	9 (56)	.755
CIED, n (%)	4 (10)	1 (4)	3 (19)	.283
Stroke, n (%)	3 (8)	2 (8)	1 (6)	1.000
eGFR < 60 mL/min, n (%)	25 (63)	14 (58)	11 (69)	.740
Dialysis, n (%)	2 (5)	1 (4)	1 (6)	>.99
Echocardiography				
EF, %	46.3 ± 13.9	47.8 ± 13.5	44.1 ± 14.6	.425
P mean, mm Hg	41.9 ± 12.2	42.7 ± 10.8	40.7 ± 14.3	.638
AVA, cm^2	0.75 ± 0.16	0.74 ± 0.18	0.76 ± 0.15	.705
Annulus measurements (CT)				
Avg. annulus dia. (mm)	28.7 ± 2.4	28.9 ± 2.3	28.5 ± 2.6	.622
Annulus area (mm^2)	650.2 ± 87.4	654.6 ± 91.1	643.5 ± 83.5	.694
Annulus perimeter (mm)	90.4 ± 6.3	90.7 ± 6.6	90.0 ± 6.1	.733
Outcome				
Vascular complication, n (%)	3 (7.5)	1 (4.2)	2 (12.5)	.553
Stroke, n (%)	1 (2.5)	0 (0)	1 (6.3)	.400
Pacemaker, n (%)	6 (15)	4 (16.7)	2 (12.5)	>.99
In-hospital mortality, n (%)	1 (2.5)	1 (4.2)	0 (0)	.400
Echocardiography				
Invasive *P* mean (mm Hg)	3.13 ± 2.41	3.39 ± 2.54	2.75 ± 2.24	.407
P max (mm Hg)	17.1 ± 7.5	19.7 ± 7.9	13.9 ± 6.0	.012
P mean (mm Hg)	10.1 ± 4.4	11.4 ± 4.2	8.5 ± 4.2	.040
Aortic regurgitation				.053
None	17 (42.5)	13 (54.2)	4 (25)	
Mild	22 (55)	11 (45.8)	11 (68.8)	
Moderate	0 (0)	0 (0)	0 (0)	
Severe	1 (2.5)	0 (0)	1 (6.3)	

TAVI, Transcatheter Aortic Valve Implantation, DM, Diabetes Mellitus, CAD, coronary artery disease, CIED, cardiac implantable electronic devices, EF, Ejection Fraction, HTN, Hypertension.

Procedural Data and Outcome

The majority of procedures were performed via transfemoral access. One patient in the Sapien 3 group underwent a transapical approach, and 2 patients in each group underwent a subclavian approach. Balloon post dilation was performed in 3 patients in the Sapien 3 group and in 1 patient in the Myval group.

One patient in the Sapien 3 group died due to annular rupture. In the Myval group, 1 patient developed severe aortic regurgitation requiring a valve-in-valve implantation. Apart from these events, in-hospital clinical outcomes were comparable between both groups (Table 1).

Invasive mean transvalvular gradients did not differ between patients with Sapien 3 and Myval. However, mean echocardiographic gradients were significantly lower in the Myval group compared with the Sapien 3 group (Pmean 11.4 ± 4.2 vs. 8.5 ± 4.2 mmHg, *P* = .04). Overall, mild aortic regurgitation

HIGHLIGHTS

- TAVI in patients with large aortic annuli was feasible using Sapien 3 or Myval, with similar in-hospital clinical outcomes.
- Myval was associated with significantly lower echocardiographic post-procedural gradients compared with Sapien 3.
- A trend toward mild paravalvular leak was observed in the Myval group.

was observed in 22 patients (55%), exclusively due to paravalvular leak (PVL). There was a trend toward more PVL in the Myval group ($P = .053$) (Table 1).

DISCUSSION

The data suggest that TAVI in patients with large annuli using either Sapien 3 or Myval is feasible. In the COMPARE TAVI 1 trial, Myval was non-inferior to Sapien 3 at 1 year;[7] however, annular areas in that study (472-485 mm^2) were substantially smaller than those observed in the cohort, highlighting the relevance of the findings in a more challenging anatomical subset.

In the present analysis, echocardiographic post-procedural gradients were modestly but significantly lower with Myval. While lower gradients have been associated with improved long-term valve performance,[8] the clinical relevance of the observed differences remains uncertain given the small sample size and short follow-up. The use of larger Myval prostheses (30.5 or 32 mm) may provide an alternative to overexpansion of Sapien 3 in patients with very large annuli.

However, this potential hemodynamic advantage may be associated with an increased risk of PVL. In the cohort, a trend toward a higher incidence of PVL was observed in the Myval group, although the difference did not reach statistical significance, likely due to limited statistical power. Importantly, prior studies such as COMPARE TAVI 1 reported only moderate or severe aortic regurgitation, whereas even mild PVL has been associated with adverse long-term outcomes after TAVI,[9] which is particularly relevant in younger patients.

This study has several limitations. The sample size limits statistical power, and treatment-selection bias cannot be excluded. No multivariable adjustment was performed. The preliminary findings should therefore be considered exploratory and hypothesis-generating and may serve as a basis for future larger studies in this specific anatomical setting. Echocardiographic assessment was not centrally adjudicated and may be subject to interobserver variability. Finally, only in-hospital outcomes were evaluated, precluding any conclusions regarding long-term outcomes.

CONCLUSION

In this small cohort of patients with large aortic annuli, TAVI with either Sapien 3 or Myval appeared feasible. Myval was associated with lower echocardiographic post-procedural gradients, but with a trend toward increased PVL. These findings should be interpreted with caution and require confirmation in larger studies.

Ethics Committee Approval: Ethics committee approval was not required due to the retrospective observational nature of the study.

The study was conducted in accordance with the Declaration of Helsinki.

Informed Consent: Informed consent was not required due to the retrospective observational nature of the studyPeer-review: Externally peer-reviewed.

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REFERENCES

1. Abushouk AI, Spilias N, Isogai T, et al. Three-year outcomes of balloon-expandable transcatheter aortic valve implantation according to annular size. *Am J Cardiol*. 2023;194:9-16. [CrossRef]
2. Tang GHL, Zaid S, George I, et al. Impact of aortic root anatomy and geometry on paravalvular leak in transcatheter aortic valve replacement with extremely large annuli using the Edwards SAPIEN 3 valve. *JACC Cardiovasc Interv*. 2018;11(14):1377-1387. [CrossRef]
3. Akyüz AR, Konuş AH, Çırakoğlu ÖF, et al. First experiences with a new balloon-expandable Myval transcatheter aortic valve: a preliminary study. *Herz*. 2022;47(5):449-455. [CrossRef]
4. Mansuri Z, Rajith G, Taikadan T, et al. Myval versus Contemporary Valves in Patients Undergoing transcatheter Aortic Valve Implantation: a Systematic Review and Meta-Analysis. *Anatol J Cardiol*. 2025;29(12):675-686. [CrossRef]
5. Kilic T, Ielasi A, Ninios V, et al. Clinical outcomes of the Myval transcatheter heart valve system in patients with severe aortic valve stenosis: a two-year follow-up observational study. *Arch Med Sci*. 2024;20(2):410-419. [CrossRef]
6. VARC-3 WRITING COMMITTEE:, Généreux P, Piazza N, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *J Am Coll Cardiol*. 2021;77(21):2717-2746. [CrossRef]
7. Terkelsen CJ, Freeman P, Dahl JS, et al. SAPIEN 3 versus Myval transcatheter heart valves for transcatheter aortic valve implantation (COMPARE-TAVI 1): a multicentre, randomised, non-inferiority trial. *Lancet*. 2025;405(10487):1362-1372. [CrossRef]
8. Capodanno D, Petronio AS, Prendergast B, et al. Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2017;38(45):3382-3390. [CrossRef]
9. Okuno T, Tomii D, Heg D, et al. Five-year outcomes of mild paravalvular regurgitation after transcatheter aortic valve implantation. *EuroIntervention*. 2022;18(1):33-42. [CrossRef]