

Single center experience with the balloon-expandable Myval transcatheter aortic valve system with the first 100 patients: 30-day and 1-year follow-up

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Abstract

Aims: To report our single-center data, regarding the first 100 patients who underwent TAVR procedure with the new balloon-expandable MYVAL system. We report 30-day and 1-year outcomes in low to high-risk TAVR patient population.

Methods: From November 2019 to July 2021, 100 consecutive patients underwent TAVR procedure. Patient outcome was classified according to the VARC-2 definitions. The device performance was assessed using transthoracic echocardiography. Data collection was allowed by the Local Ethical Committee.

Results: The mean age was 74.7 years, 63 (63%) were male. The mean Euroscore II and STS score were 4.8 ± 4.9 and 5.6 ± 3.9 , respectively. Transfemoral access was the most frequent (surgical vs. percutaneous 2% vs. 97%) and in one patient surgical subclavian access was used. VARC-2 outcomes were as follows: device success 99%, STROKE 1%, major and minor vascular complication was 1% and 11%, respectively, the rate of new permanent pacemaker implantation was 30.7%. At discharge, the incidence of grade I, grade II aortic regurgitation was 39% and 1%, respectively, without relevant PVL. In-hospital mortality was only 1%. These results included a high proportion (17%) of patients with bicuspid aortic valves. At 1 year, the all-cause mortality rate was 7% (only two due to cardiac event) and only a single patient had valve-related dysfunction requiring surgical aortic replacement.

Conclusions: TAVR procedure with MYVAL transcatheter heart valve system shows excellent 30-day and 1-year outcomes regarding patient survival, technical success,

Abbreviations: ARI, aortic regurgitation index; AS, aortic stenosis; BAV, bicuspid aortic valve; LFLG-AS, low-flow, low-gradient aortic stenosis; NYHA, New York Heart Association; PLGLG-AS, paradox low-flow, low-gradient aortic stenosis; PPI, permanent pacemaker implantation; PVL, paravalvular leak; SAVR, surgical aortic valve replacement; TAV, tricuspid aortic valve; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve; VARC-2, Valve Academic Research Consortium-2.

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and valve-related adverse events. The limitations of our study comprise a single-center study with retrospective data collection.

KEYWORDS

annular rupture, balloon expandable transcatheter heart valve, bicuspid aortic valve, paravalvular leak, permanent pacemaker implantation, TAVR

1 | INTRODUCTION

The treatment of significant aortic stenosis (AS) developed from surgical aortic valve replacement (SAVR) as a gold standard to transcatheter aortic valve replacement (TAVR) therapy, as the standard of care for patients at high and intermediate risk and an acceptable alternative in low-risk profiles.¹⁻⁵ The first successful human TAVR, performed by Cribier and colleagues, was a balloon expandable aortic prosthesis implantation.⁶ Self-expanding transcatheter heart valve (THV) systems were invented thereafter. Based on successful CE approval (2019), Myval-1 study proved the safety and efficacy of the new, balloon expandable Myval THV system, however, in a limited number of patients ($n = 30$).⁷ Based on these favorable results, Delgado-Arana et al. demonstrated similar safety and efficacy with a lower permanent pacemaker implantation (PPI) rate, a lower rate of paravalvular leak (PVL), and better transvalvular gradient using Myval THV system compared with Sapien THV.⁸ The ongoing LANDMARK trial will provide important data about the short and long-term results of Myval THV system in a randomized, head-to-head comparison trial with Sapien and Evolut THV systems.⁹

In this study, our early postprocedural, 30-day and 1-year experience is reported, using Myval THV system based on the Valve Academic Research Consortium-2 definitions (VARC-2).

2 | METHODS

2.1 | Study design

This study is a single-center experience. Data were collected retrospectively, but they were recorded in our centralized electronic medical data collecting system (e-MedSolution system) as part of standard care, therefore, this procedure can be considered as a real-time, online data collection. Data collection was allowed by the Local Ethical Committee (9435-PTE 2022).

2.2 | Patient population

In our study, we report the detailed data regarding all MyVal cases performed from November 2019 to July 2021. During the examined period, when MyVal THV system was available in our Institute, we used this system in a consecutive manner, and when it was unavailable, we used other devices (Portico-Abbott, CoreValve-Medtronic, Acurate-

Boston Scientific). Nevertheless, in patients with special anatomic features, where TAVR procedure might be challenging, we used this device exclusively. These include patients with a horizontal aorta (where active flexion of the delivery system provides additional feature), patients with bicuspid valve (where balloon expansion provides optimal valve positioning and expansion), and patients who might benefit from an intermediate THV size based on CT scan measurements.

High gradient severe AS was the most common diagnosis, and in patients with low gradient aortic stenosis (LFLG-AS and PLFLG-AS), severity and indication were based on dobutamine stress echocardiography and/or native aortic valve CT calcium score. All of the patients had NYHA class II or higher and were unsuitable or had a high risk for SAVR based on the decision of the Heart Team. Operative risk was calculated using the logistic EuroSCORE II and STS score. The baseline clinical and echocardiographic characteristics of the study population are shown in Table 1 and in Supporting Information: Table 1.

Main exclusion criteria were non-Myval THV specific, rather general exclusion criteria for TAVR. These were acute myocardial infarction within 14 days, left ventricular ejection fraction $\leq 20\%$, ongoing infection (included COVID-19 infection), hemodynamic instability, contraindication for antiplatelet and/or anticoagulant therapy or life expectancy less than 12 months.

2.3 | Device description and procedure

The technical features of Myval THV (Meril Life Sciences Pvt. Ltd.) was well described previously in the MyVal-1 study.⁷ Briefly: bovine pericardium leaflet on nickel-cobalt frame with anticalcification treatment, unique cell design resulting in higher radial force, internal and external sealing tissue minimizing PVL. Based on the company specification, beyond the standard sizes (20 mm, 23 mm, 26 mm, 29 mm), intermediate (21.5 mm, 24.5 mm, 27.5 mm) and extra-large valve sizes (30.5 mm, 32 mm) are available and all of these sizes are compatible with the 14 Fr Python sheath. Relevant data for valve sizing are shown in Table 2. The Navigator balloon catheter system allows active flexion of the distal part, with full retrievability of the undeployed THV system and a dog bone-like expansion of the balloon part to stabilize the valve during deployment (Figures 1-4). The Myval-1 study highly recommended predilatation of the native aortic valve,⁷ therefore we followed this instruction and our experience showed that this technique is very useful, especially in patients with severe aortic calcification detected on CT images. Figure 5 shows the substantial steps of device implantation based on our case example.

TABLE 1 Baseline demographics and clinical parameters of the study population.

Baseline characteristic of study population (n = 100)	
Age (years)	74.7 ± 7.2
Male/female	63/37
Body mass index (kg/m ²)	29.4 ± 4.8
Body surface area (m ²)	1.94 ± 0.2
Hypertension	95 (95%)
Diabetes mellitus	40 (40%)
Hyperlipidemia	84 (84%)
NYHA class I	2 (2%)
NYHA class II	34 (34%)
NYHA class III	60 (60%)
NYHA class IV	4 (4%)
Ischemic heart disease	47 (47%)
Prior MI	24 (24%)
Prior PCI	39 (39%)
Prior CABG	22 (22%)
Peripheral artery disease	10 (10%)
Cerebrovascular disease	8 (8%)
Pulmonary disease	15 (15%)
Previous aortic balloon valvuloplasty	5 (5%)
Permanent pacemaker	9 (9%)
Atrial fibrillation	18 (18%)
Logistic EuroSCORE (%)	15.7 ± 15.5
Euroscore II	4.8 ± 4.9
STS score (%)	5.6 ± 3.9
Aortic valve calcium score	3395 ± 1832
Serum creatinine (umol/L)	102.7 ± 58.8
Estimated GFR (mL/min)	69.6 ± 26.6
Estimated GFR <60 mL/min	40 (40%)
Bicuspid aortic valve	17 (17%)
Prior MVR	0 (0%)
Prior AVR	1 (1%)
Dialysis	2 (2%)
Procedure indication	
Elective	94 (94%)
Urgent	6 (6%)
Acute	0 (0%)

All TAVR procedures were performed in a dedicated hybrid operating room under conscious sedation, general anesthesia was used only in three cases (two femoral and one subclavian access).

TABLE 2 Distribution of different THV sizes in the study population and comparison between non-bicuspid (TAV) and bicuspid (BAV) patients.

THV size	BAV (n = 17)	TAV (n = 82)	Overall (n = 99)
21.5	1	6	7
23	2	9	11
24.5	7	21	27
26	1	18	19
27.5	2	14	16
29	1	13	14
30.5	1	1	2
32	2	0	2
Standard size	4	40	44
Intermediate + extra size	13	42	55

Note: Standard size: 23,26,29, Intermediate + extra size: 21.5, 24.5, 27.5, 30.5, 32.

Abbreviations: BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; THV, transcatheter heart valve.

Preferable access site was the femoral artery, trans-subclavian access was used only in one patient. Adjunct pharmacologic therapy included intraoperative ACT-guided heparin treatment followed by dual antiplatelet therapy (DAPT, aspirin 100 mg/day and clopidogrel 75 mg/day) for 6 months. If anticoagulant therapy was needed, clopidogrel (75 mg/day) with DOAC therapy was our standard choice.

It should be emphasized that prior to this study our center had no experience with balloon expandable THV implantation, only self-expandable devices were used. Therefore our results were influenced by the learning curve with this technique.

2.4 | Study endpoints and follow-up

Safety and efficacy parameters were collected before discharge, at the 1-month follow-up, and at the 12-month follow-up. As a primary endpoint, safety was evaluated based on periprocedural outcomes, short and long-term hemodynamic performance based on transthoracic echocardiography by independent sonographers. As a secondary endpoint, the 30-day and 1-year combined safety endpoints were defined by VARC-2. Functional status of the patients was classified based on the NYHA class. All relevant endpoints were defined according to the VARC-2 definitions.¹⁰ Severity of perioperative aortic regurgitation was evaluated by intraoperative echocardiography, angiography, and measurement of the aortic regurgitation index (ARI), described previously.¹¹

2.5 | Statistical analysis

GraphPad Prism (version 9.0, GraphPad Software Inc), and SPSS Statistics (version 28.0, IBM) were used for statistical analysis.

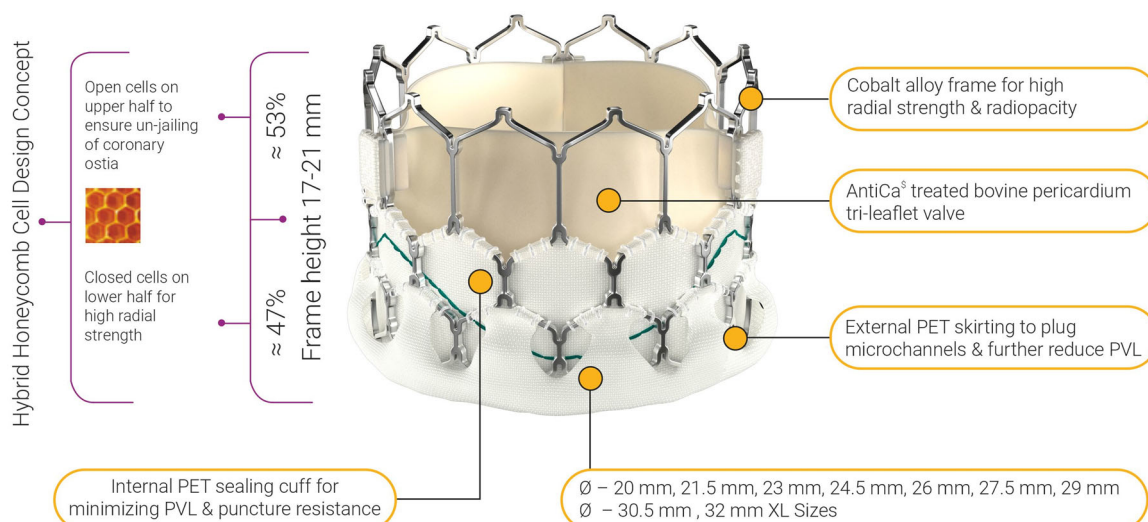


FIGURE 1 Schematic picture from Myval transcatheter heart valve. [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com/doi/10.1002/ccd.30868)]

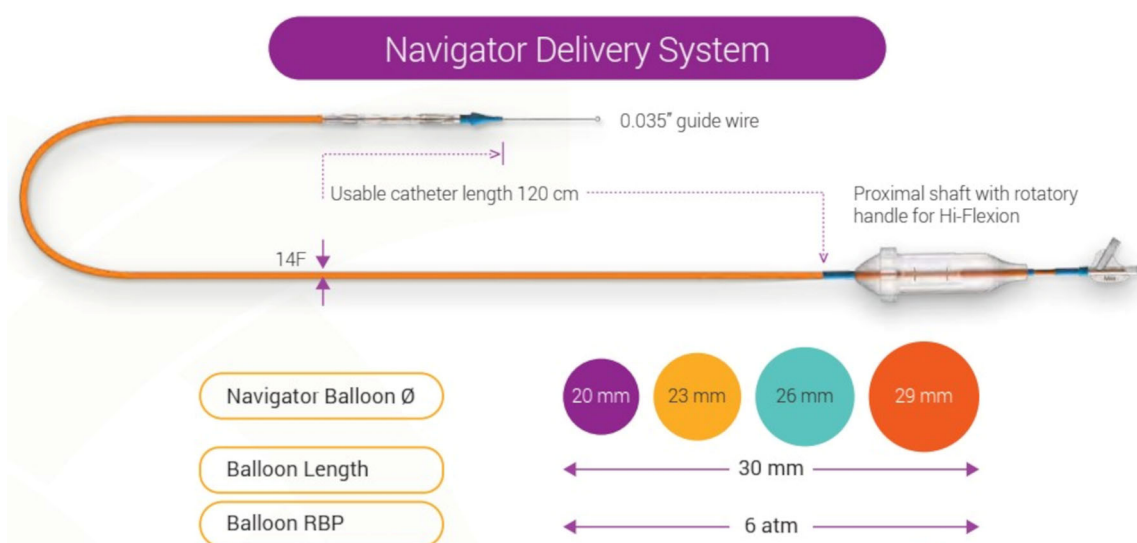


FIGURE 2 Schematic picture of the 14 F Myval Navigator Delivery System. [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com/doi/10.1002/ccd.30868)]

Continuous variables are expressed as a mean \pm standard deviation (SD), and categorical variables are expressed as numbers and percentages. Data distribution was assessed by D'Agostino-Pearson omnibus K2 normality test. Continuous variables were compared using two-tailed unpaired *t* test and paired *t* test, as appropriate. The effect of TAVR on hemodynamic parameters in the whole cohort was evaluated using repeated measures one-way analysis of variance (ANOVA) test with time as a within-subject factor (baseline, discharge, 30-day, and 1-year follow-up), Geisser-Greenhouse correction for sphericity, and Tukey's multiple comparisons test. When the effect of TAVR on hemodynamic parameters was compared between patients with BAV and TAV, we used repeated measures of two-way ANOVA test with time as a within-subject factor (baseline, discharge, 30-day, and 1-year follow-up) and valve type (BAV or TAV) as a between-subject factor, Geisser-Greenhouse

correction for sphericity, and Tukey's multiple comparisons test. For ANOVA tests, the data for each parameter represent only those cases where measurements were available at all time points (baseline, discharge, 30-day, and 1-year follow-up). Categorical variables were compared using an independent sample *z* test or McNemar's test, as appropriate. Differences were considered statistically significant at $p < 0.05$.

3 | RESULTS

3.1 | Baseline patient characteristics

From November 2019 to July 2021, 100 consecutive patients were included in this analysis, including the learning curve with this device.

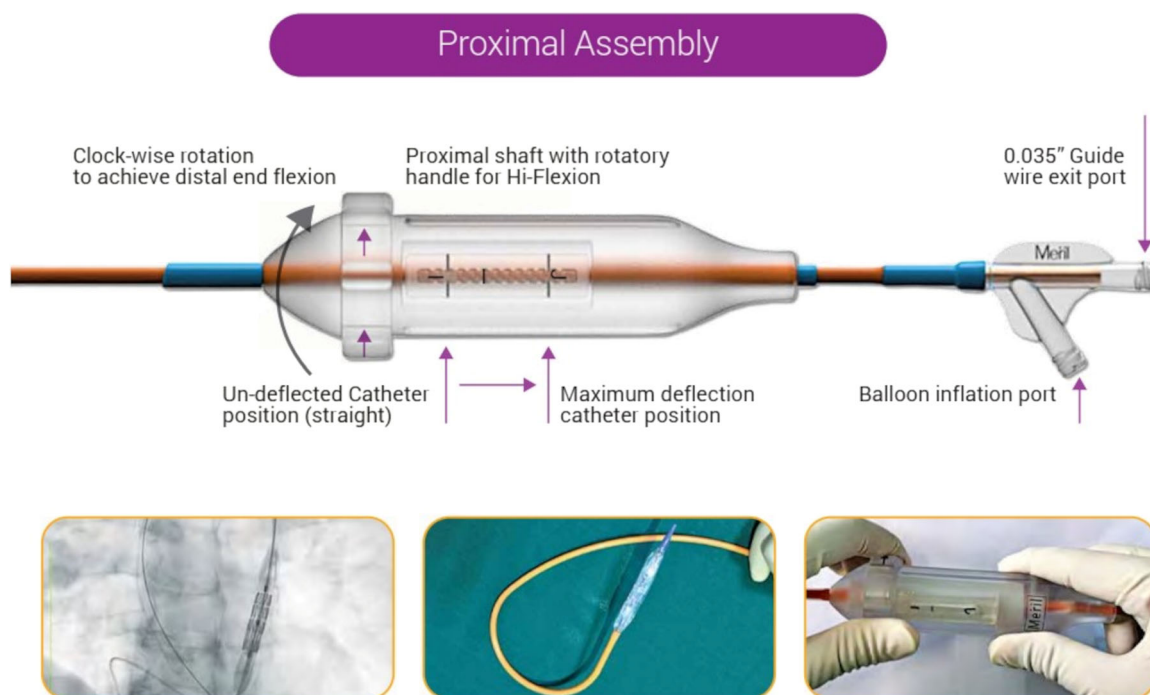


FIGURE 3 Schematic picture of the Proximal Assembly. Clockwise rotation of the rotatory handle leads to the flexion of the distal part. On the rotatory handle, the extent of the flexion is visible, from the straight position to maximum deflection catheter position (the bottom-middle picture). [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.com)]

Schematic of Crimped Myval on Navigator Balloon

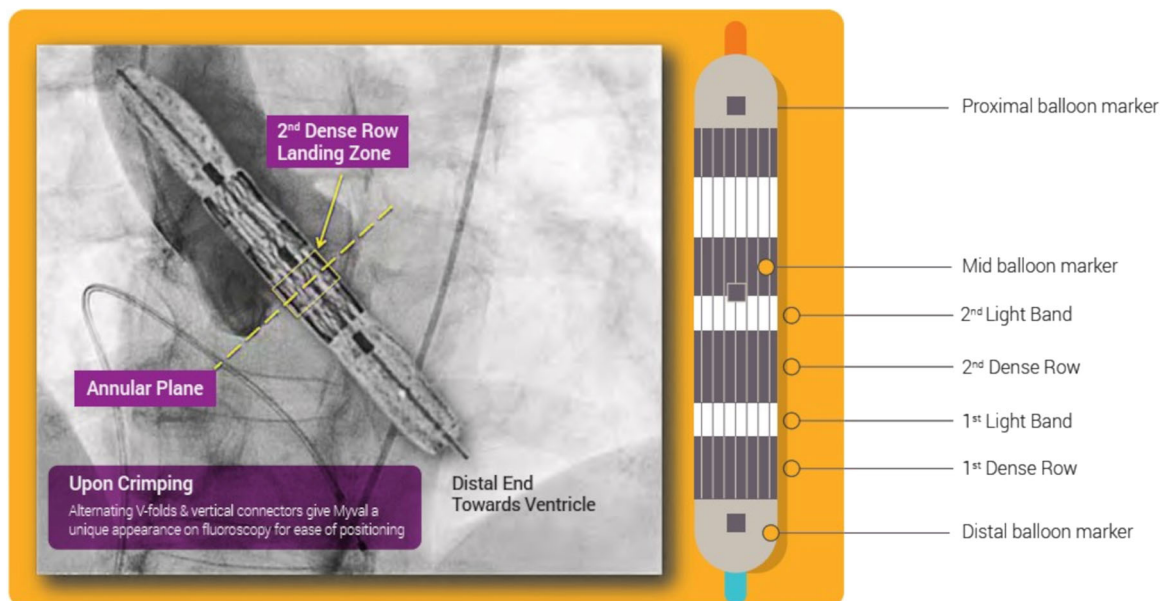


FIGURE 4 Precision implantation techniques based on integrated markers. [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.com)]

Diagnosis of symptomatic AS was based on the latest ESC guidelines for the management of valvular heart disease.¹² Most of the patients had high gradient AS (75%), low-flow, low-gradient AS (LFLG-AS) and paradox low-flow, low-gradient AS (PLFLG-AS) constituted the diagnosis in 17% and 8%, respectively. In patients with LFLG-AS

and PLFLG-AS, the indication for aortic valve replacement was based on stress echocardiography^{13,14} and/or the native aortic valve calcium score.¹⁵⁻¹⁷ Bicuspid aortic valve anatomy (BAV) appeared in 17 patients and one patient (1%) had undergone surgical aortic bioprosthesis implantation previously. The mean age was 74.7 ± 7.2

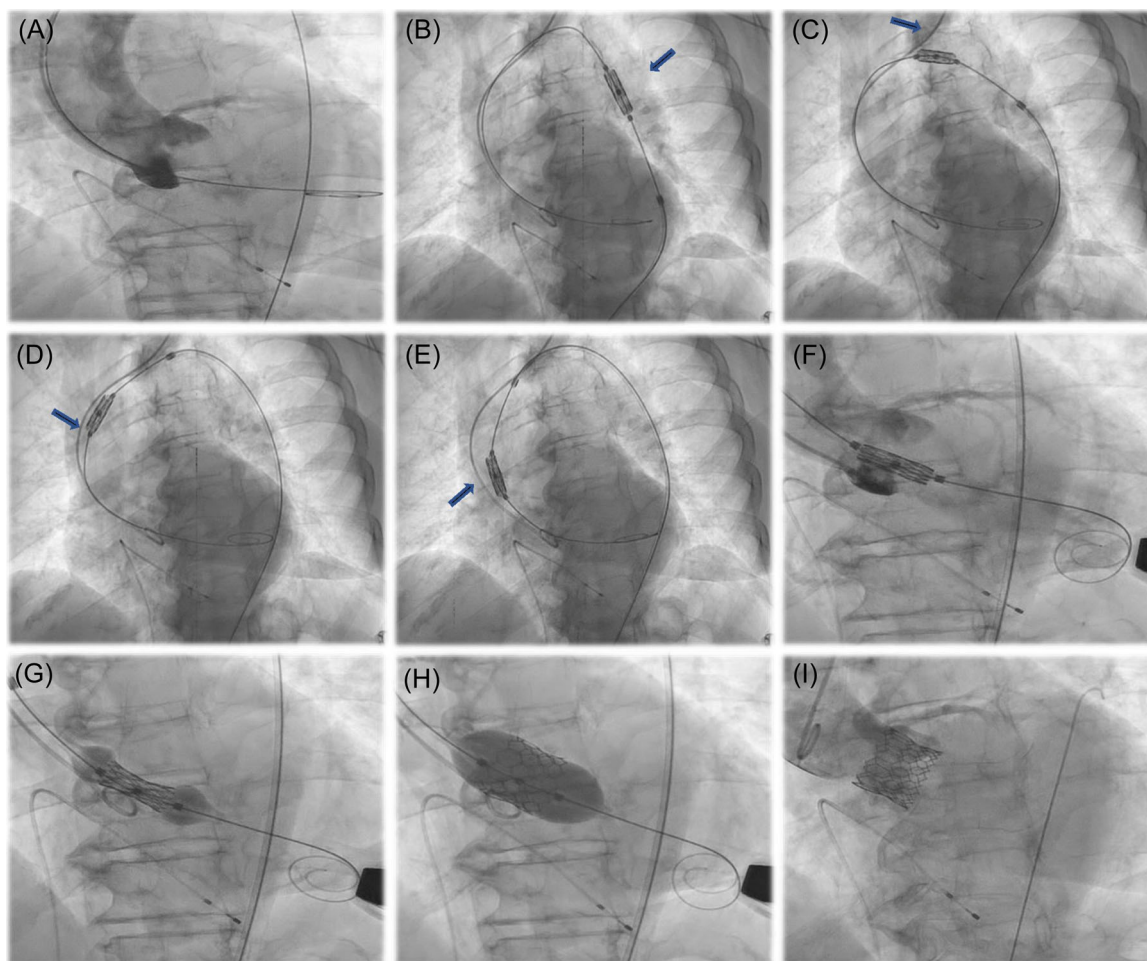


FIGURE 5 Implantation process from our cohort in a patient with special anatomic features (severe horizontal aorta), where the flexibility of this THV system is well demonstrated. (A) Position of the stiff wire prove definite horizontal aorta. (B–E) Using the active flexion of the rotatory handle, THV system can avoid reaching the outer curve of the aorta. Arrows and the guiding pigtail catheter show the border of the outer curve. (F–H) Stable coaxial alignment of the THV system during positioning and inflation, despite severe horizontal aorta. (I) Coaxial alignment of the THV, symmetrical implantation in proportion to the aortic annulus without aortic regurgitation and PVL. PVL, paravalvular leak; THV, transcatheter heart valve.

years, 63% were male. The mean logistic EuroSCORE II was 4.8% and the mean STS score was 5.6%. Detailed data regarding baseline clinical and echocardiographic parameters of the study population are shown in Table 1 and in Supporting Information: Table 1.

3.2 | Procedural outcomes

Transfemoral access was the most frequent (99%) with only a single trans-subclavian implantation (1%). Conscious sedation was the standard of care (97%), general anesthesia was used in minority (3%). In 44 cases (44.5%) standard sizes (23, 26, 29) were implanted and in 55 cases (55.5%) intermediate/extra sizes (21.5, 24.5, 27.5, 30.5, 32) were chosen. In BAV patient group, the intermediate/extra sizes THVs were used in a significantly higher proportion compared with standard sizes (76.5% vs. 23.5%, $p = 0.028$), while this ratio was similar in the tricuspid aortic valve (TAV) group (intermediate/extra

sizes vs. standard sizes 51.2% vs. 48.8%). The mean aortic gradient decreased significantly (55.2 ± 17.9 mmHg vs. 5.3 ± 5.7 mmHg, $p < 0.0001$). Procedural parameters did not differ between BAV versus the TAV group, except for longer operation duration in bicuspid patients (75.7 ± 27.1 min. vs. 102.9 ± 44 min., $p = 0.022$). This longer procedure time in the BAV group was due to: (1) the special anatomic properties of the bicuspid valve often made more difficult to cross the native valve and to find the optimal implantation view; (2) in patients with BAV anatomy, for precise THV sizing, the final size of the implanted THV were decided not just based on the CT scan images but based on the angiogram of the aortic root, while the predilatation balloon was inflated. Therefore, the preparation of the Myval THV was started only after this decision which made procedure time longer. In patients with TAV, this decision could be made more often only based on the CT scan images and therefore the preparation of the patient and the Myval THV were performed simultaneously. Even ARI was favorable in both groups, slightly better

in bicuspid patients (27.3 ± 10.0 vs. 29.1 ± 7.8 , $p = 0.501$). No THV malapposition, annular rupture, coronary obstruction or need for a second THV occurred. We observed only a single device failure, where crossing the predilated native aortic valve was unsuccessful. In that patient (Ca score 7242 with mean aortic gradient of 101,3 Hgmm) standard predilatation was unsuccessful with 22 mm balloon (even the balloon could not cross the native valve), however minimum annulus diameter was 25.2 mm. After predilatation with an 8 mm peripheral vascular balloon, a second stiff guidewire was placed into the left ventricle, kissing balloon predilatation with two 10 mm peripheral vascular balloon was performed and only thereafter was successful the serial predilatation with 12,16,18 and finally 25 mm balloon. Despite the sufficient predilatation based on the CT scan regarding the aortic dimensions, the 29 mm Myval THV (with 7.9% of oversize) was unable to cross the native valve. After several maneuvers, TAVR procedure was terminated to avoid fatal complications (severe damage to the native valve, annular rupture) and a second staged procedure was planned. After the failure of removing the undeployed valve system from the common iliac artery, vascular surgery and direct extraction of the delivery system from the common iliac artery was imperative. The patient died due to the complication of this surgery.

Procedural parameters are summarized in Table 2 and in Supporting Information: Table 2.

Device success is based on VARC-2 definitions was achieved in all but one patient (99%), where the patient died (see above). In one patient with true BAV (Type 0), self-expanding THV implantation was unsuccessful and for safety reasons, to avoid fatal complication (aortic rupture, rupture of the free wall, etc.) TAVR procedure was terminated and 1 week later the TAVR procedure was successful, where Myval THV system was implanted properly.

However, CEP (cerebral embolic protection) devices are not funded for TAVR procedure, and therefore we were unable to use these systems, the ischemic stroke was observed only in one patient. After pharmacological therapy neurological symptoms improved and the patient completed a successful neurologic rehabilitation program.

In our study population, nine patients already had a permanent pacemaker before the TAVR procedure. New PPI was necessary for 28 cases (30.7%). In one patient, pacemaker (PM) was implanted due to cardiac resynchronization therapy. No significant differences occurred in patients with new PPI versus patients without new PPI regarding age, Euroscore II, STS score, calcium score of the aortic valve, and the percentage of THV sizing, however, Euroscore data were significantly higher in patients without PPI. The mean implantation depth (including patients with PM implantation before the TAVR) was 5.55 ± 2.25 mm at the left coronary side, 5.9 ± 2.16 mm at the right coronary side, 6.15 ± 2.3 at the noncoronary side and on average 5.9 ± 2.15 mm. Excluding patients with PPI before the TAVR procedure, there was no significant difference between patients with and without PPI regarding any of the implantation depths. The rate of calcium in the LVOT tract tended to be higher in the PPI group (44.8% vs. 36.6%), although statistically significant differences could not be detected. However, the presence

of calcium in the LVOT tract is a definite risk factor for PPI, the use of intermediate sizes could decrease the chance of this nondisabling complication. In the PPI group, the rate of standard size was higher than the intermediate size (53.5% vs. 46.5%) and in the non-PPI group, the intermediate sizes were almost twice as frequent as standard sizes (61.3% vs. 38.7%). PPI was less frequent with intermediate sizes than with standard ones (25.49% vs. 38.46%, $p = 0.094$). The rate of BAV patients tended to be lower in the PPI group compared with the TAV patients (14.3% vs. 20.9%). However, it was not statistically significant, this could represent our effort to avoid oversizing in BAV patients, choosing the optimal intermediate size THV. The reason why we could observe only a trend regarding calcium in the LVOT tract and the existence of BAV feature, could be the small sample size, and further investigation would be recommended. All the relevant data are shown in Table 3.

During the hospitalization period, there was no significant impairment of renal function, with only three patients (3%) in the AKIN stage 2 or 3. There was no need for regular, intermittent renal replacement therapy (IRRT). In 70 cases, improvement of the renal function was detected, which phenomenon might be due to the improved cardiac output resulting in better renal blood flow. Postprocedural outcomes within 72 h after the index procedure are listed in Table 4.

Vascular complications occurred in 11 cases, from them in 10 patients due to the failure of the percutaneous closure device (two-Proglide technique) and in the trans-subclavian approach the insufficiency of surgical suture. Based on the VARC-2 criteria, major vascular complication (due to the used amount of transfusion) occurred in six patients, and minor vascular complication was detected in five patients. In all cases, interventional or surgical procedures can achieve a patent flow at the donor artery. Direct device extraction due to unsuccessful retrieval of undeployed system via vascular surgery was the only major complication, which occurred mainly due to device failure. Details are given in Supporting Information: Table 3.

3.3 | VARC-2 outcomes at 30-day and 1-year follow-up

At 30 days all-cause mortality was 1%, there were no more cases of death except for 1 in-hospital death (for details see the above). After patient discharge, there were no new strokes, no need for intermittent, regular renal replacement therapy (IRRT), or repeated TAVR procedure during the 30-day follow-up period.

Between the 30-day and 1-year period, six additional cases of death occurred: two patients died due to noncardiac infections leading to multiorgan failure, two patients had endocarditis leading to death (1 patient underwent SAVR) and two patients died due to out-of-hospital acquired COVID-19 pneumonia. However, all-cause mortality rate at 1 year was 7%, the cardiac mortality rate was only 2%. In the follow-up period four patients had ischemic stroke, therefore, the 1-year all stroke rates appeared to be 5%. After 30

TABLE 3 Detailed data of comparison between patients with and without permanent pacemaker implantation.

	Non PM (n = 62)	PM (n = 28)	p Value
Age	74.4 ± 7.0	75.8 ± 7.8	0.382
Euroscore	17.0 ± 17.6	11.6 ± 7.9	0.035*
Euroscore II	5.2 ± 5.4	4.0 ± 3.2	0.286
STS score	5.7 ± 3.4	5.4 ± 5.1	0.681
Ca score	3332 ± 1702	3545 ± 2135	0.601
Ca in LVOT	26 (41.3%)	13 (46.4%)	ns
Bicuspid	13 (20.9%)	4 (14.3%)	ns
Oversizing	7.8 ± 4.0	7.2 ± 3.9	0.516
THV implantation depth			
Left coronary side (mm)	5.34 ± 2.35	6.01 ± 1.99	0.197
Noncoronary side (mm)	6.11 ± 2.43	6.26 ± 2.03	0.775
Right coronary side (mm)	5.88 ± 2.25	6.2 ± 1.97	0.514
Average implantation depth (mm)	5.78 ± 2.25	6.16 ± 1.9	0.441
THV size			
21.5	6	1	
23	7	4	
24.5	18	8	
26	11	6	
27.5	13	2	
29	6	5	
30.5	0	1	
32	1	1	
Standard size	24 (38.7%)	15 (53.5%)	ns
Intermediate/extra size	38 (61.3%)	13 (46.5%)	ns

Abbreviations: Ca in LVOT, existence of calcium nodules in the left ventricle outflow tract based on CT examination; Ca score, Agatston calcium score of the aortic valve based on CT examination; ns, statistically nonsignificant with independent samples z test for proportions test; THV, transcatheter heart valve.

*Statistically significant.

days, only one patient was admitted due to progression of heart failure, and cardiac resynchronization therapy pacemaker (CRT-PM) was necessary. In addition, one more pacemaker implantation was mandatory due to complete third-degree AV block. Otherwise, at 1 year no patient was lost during the follow-up period. All the relevant data from 30-day and 1-year outcomes are summarized in Table 5.

The functional capacity of the patient based on NYHA classification improved significantly even till the 30 days control and sustained throughout the follow-up period, as shown in Figure 6.

TABLE 4 Detailed data of postprocedural outcomes (<72 h after the index procedure) of the study population based on VARC-2 definition.

Postprocedural outcomes (<72 h after the index procedure) of the study population (n = 100)	
Outcome	No. (%) of events
In-hospital mortality	1 (1%)
Device success	99 (99%)
Myocardial infarction	0 (0%)
Coronary obstruction	0 (0%)
Stroke or TIA	1 (1%)
Acute kidney injury, stage 2 or 3	3 (3%)
Major vascular complications	6 (6%)
Minor vascular complications	5 (5%)
Cardiac tamponade	0 (0%)
Annulus rupture	0 (0%)
Valve malpositioning	0 (0%)
Need for a second valve	0 (0%)
Postprocedural AR grade III or IV	0 (0%)

The rate of prosthetic valve endocarditis (PVE) at 1 year was 2%, which seems to be higher than expected.^{18,19} At the first, high risk patient (Euroscore: 20,46; STS score: 5,26) the IE occurred after 3 months. Based on the known, severe, diffuse atherosclerosis with diabetes mellitus, this patient was at very high risk of bacteremia (*Enterococcus faecalis* was identified). The second patient was also a high risk patient (Euroscore: 20,82; STS score: 7,98) with high risk of bacteremia and IE occurred after 9 months, when due to C.0-19 sepsis induced bradycardia, temporary pacemaker was implanted and PVE occurred after that (*Staphylococcus Aureus* was identified). Taking these facts into consideration, these PVE complications seem to be as not procedure-related rather patient-related complications and might partially explain our PVE rate.

3.4 | Echocardiographic outcomes

As shown in Figure 7, TAVR significantly improved peak aortic valve gradient during the 1-year follow-up ($p < 0.0001$). Significant reduction was observed between baseline versus discharge values (81.4 ± 23.4 vs. 19.1 ± 6.8 mmHg, $p < 0.0001$) and no significant change could be detected from discharge to 30-day follow-up (19.1 ± 6.8 vs. 19.8 ± 7.4 mmHg, $p = 0.676$). A statistically significant but modest increase occurred when this parameter was compared at discharge and 1-year follow-up (19.1 ± 6.8 vs. 21.4 ± 7.4 mmHg $p = 0.006$) (Figure 7, for detailed statistical analyses, see Supporting Information: Table 4). TAVR had a significant overall effect on mean aortic valve gradient during the follow-up period ($p < 0.0001$, Figure 7). There was a substantial decrease between baseline and

TABLE 5 Detailed data of outcomes at 30-day and 1-year follow-up of the study population based on VARC-2 definition.

VARC-2 outcomes at 30-day and one-year follow-up			
Outcome	Postprocedure outcomes (n = 100)	30 days follow-up (n = 100)	1 year follow-up (n = 100)
All-cause mortality	1 (1%)	1 (1%)	7 (7%)
Cardiac mortality	0 (0%)	0 (0%)	2 (2%)
All stroke	1 (1%)	1 (1%)	5 (5%)
Life-threatening bleeding	5 (5%)	5 (5%)	5 (5%)
Acute kidney injury, stage 2 or 3	3 (3%)	3 (3%)	3 (3%)
Coronary artery obstruction	0 (0%)	0 (0%)	0 (0%)
Major vascular complication	6 (6%)	6 (6%)	6 (6%)
New pacemaker implantation	28 (30.7%)	29 (31.8%)	31 (31%)
Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)	0 (0%)	0 (0%)	1 (1%)
Requiring hospitalizations for worsening heart failure		0 (0%)	1 (1%)
NYHA class III or IV		0 (0%)	1 (1%)
Valve thrombosis	NA	0 (0%)	0 (0%)
Endocarditis	NA	0 (0%)	2 (2%)

Abbreviations: BAV, bicuspid aortic valve; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

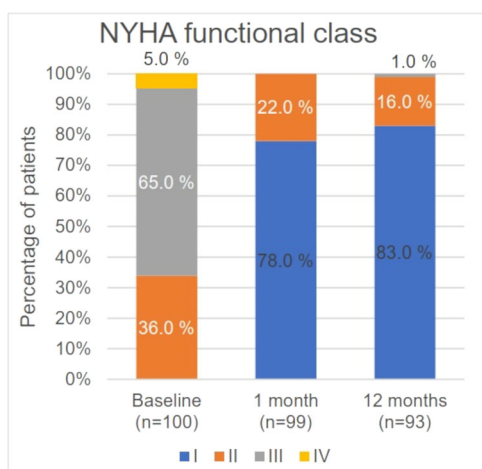


FIGURE 6 Baseline and follow-up clinical status of the patients based on classification by the New York Heart Association. Values are n (%). [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

discharge values (47.9 ± 14.4 vs. 10.0 ± 4.3 mmHg, $p < 0.0001$) and no further significant change in mean aortic gradient was detected at later time points (discharge vs. 30-day follow-up: 10.0 ± 4.3 vs. 9.9 ± 4.3 mmHg, $p = 0.977$; 30-day follow-up vs. 1-year follow-up: 9.9 ± 4.3 vs. 10.7 ± 4.2 mmHg, $p = 0.105$) (Figure 7, Supporting Information: Table 5). The minor unfavorable change in peak aortic valve gradient was accompanied by a significant increase ($p < 0.001$) in global ejection fraction over the follow-up period (discharge vs. 1-year follow-up: $55.48 \pm 9.9\%$ vs. $59.4 \pm 11.1\%$, $p = 0.001$, Figure 8, Supporting Information: Table 6).

The percentage of patients with mitral regurgitation (MR) grade 3 or 4 decreased significantly after the procedure [18 (18.2%) versus 9 (9.1%), $p = 0.022$] and was stable during the follow-up: discharge versus 30-day follow-up [9 (9.2%) versus 6 (6.1%), $p = 0.375$] and 30-day versus 1-year follow-up [6 (6.1%) versus 6 (6.5%), $p = 1.0$]. The percentage of patients with aortic regurgitation grade 2 or above decreased significantly [29 (29.3%) versus 5 (5.1%), $p < 0.0001$] and no significant change could be seen in the follow-up period: discharge versus 30-day follow-up [5 (5.1%) versus 5 (5.1%), $p = 1.0$] and 30-day versus 1-year follow-up [4 (4.3%) versus 4 (4.3%), $p = 1.0$]. It should be emphasized that during the follow-up period, there were no aortic regurgitation grade 3 or 4.

3.5 | Outcomes according to valve type

Tricuspid patients were significantly older than bicuspid patients but no further significant differences could be detected regarding Euroscore, Euroscore II, STS score, calcium score of the aortic valve, and the percentage of THV sizing. Detailed data are given in Table 6.

Overall, TAVR had a significant effect on peak and mean aortic valve gradient during the follow-up period in both the tricuspid and bicuspid groups ($p < 0.0001$ for all; Figure 2). Post hoc analysis revealed a significant decrease in peak and mean aortic valve gradients from baseline to discharge in both groups ($p < 0.0001$ for all). Notably, a modest increase occurred in peak aortic valve gradients in tricuspid patients from discharge to 1-year follow-up (19.0 ± 6.8 vs. 21.6 ± 7.6 mmHg, $p = 0.004$). Otherwise, no significant changes regarding discharge versus 30-day follow-up and 30-day

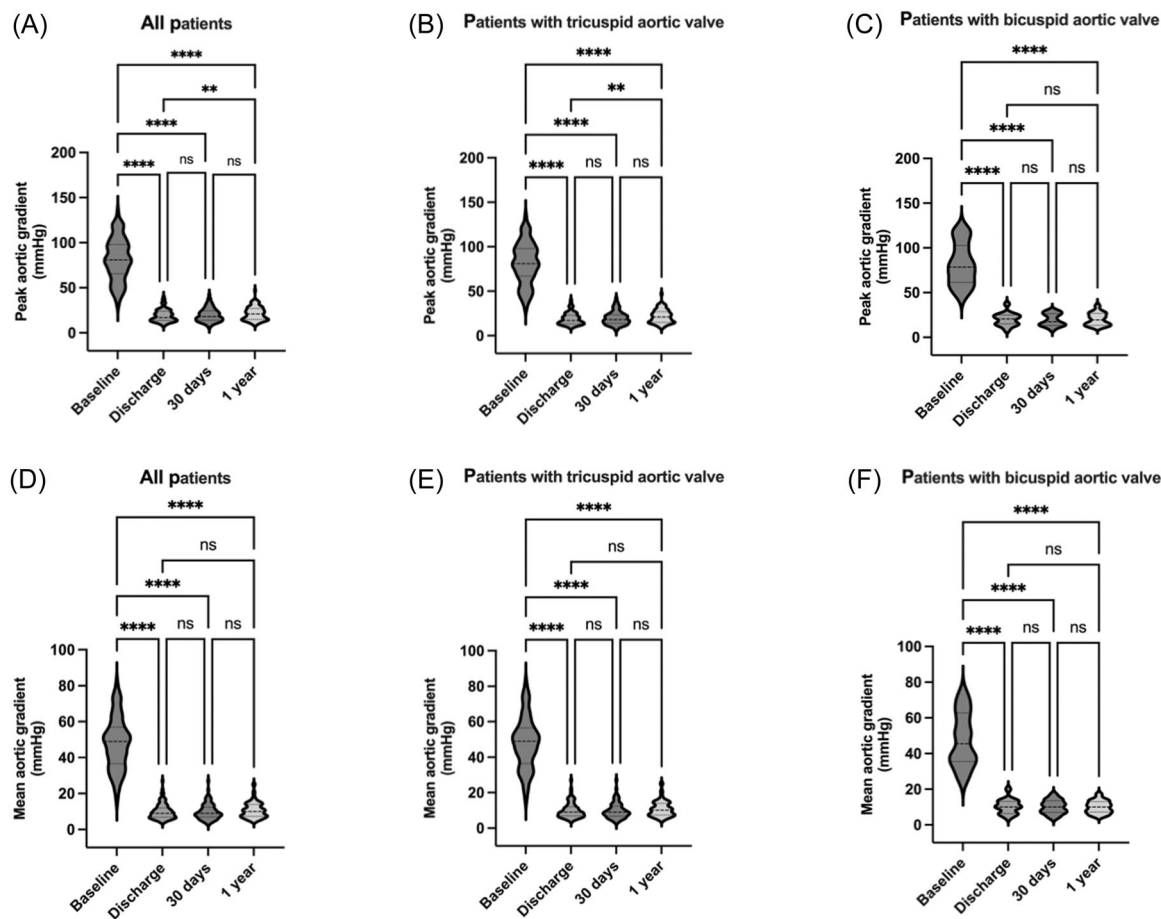


FIGURE 7 Violin plots compare the effect of transcatheter aortic valve replacement on peak aortic valve gradient (A–C) and mean aortic valve gradient (D–F) measured by echocardiography in patients who survived up to 1 year. Data refer to the whole cohort (A, D; $n = 93$), patients with tricuspid aortic valve (B, E; $n = 77$), and patients with bicuspid aortic valve (C, F; $n = 16$). Medians and the 75th and 25th percentiles are shown within the violin plots. Data were analyzed by repeated measures one-way ANOVA followed by Tukey's multiple comparison test. ns, no statistical significance. ** $p < 0.01$, **** $p < 0.001$.

versus 1-year follow-up occurred in the groups ($p = ns$ for all) (Figure 7; for details, see Table 7 and Supporting Information: Tables 4 and 5). Type of valve (i.e., BAV vs. TAV) had no effect on changes in the peak and mean aortic valve gradients over time ($p = ns$ for all) (Supporting Information: Tables 4 and 5). Global ejection fraction increased modestly over the follow-up period in the tricuspid group (discharge vs. 1-year follow-up: $55.7 \pm 9.8\%$ vs. $59.9 \pm 11.4\%$, $p = 0.001$), but not in the bicuspid group ($p = ns$) (Figure 8, Supporting Information: Table 6).

4 | DISCUSSION

The main findings of the MyVal-1 study were the safety (96.6% of implantation success), the efficacy (100% of the patients in NYHA functional Class I/II during the follow-up) of the MyVal THV system, significantly improved and stable hemodynamic parameters based on echocardiographic measurements with no moderate/severe PVL or aortic regurgitation or need for PPI. In our all-comer patient cohort,

we found an excellent device implantation rate (99%), low in-hospital mortality and stroke rate (only 1.1%) with acceptable vascular complications rate and aortic regurgitation rate. Considering that our results were influenced by our learning curve with the balloon expandable THV implantation technique, they are comparable with those of other studies,^{3,7,20–22} except our high PPI rate, however, the impact of this, is not obvious. No major mechanical complications such as cardiac tamponade, annular rupture, valve malpositioning and/or need for second THV implantation were seen. Furthermore, mortality and stroke rate were the same at 30 days follow-up. Using the steerable delivery system of the MyVal THV system, the operator can avoid reaching atherosclerotic plaques of the outer curve of the ascending aorta, which may explain our low stroke rate even though cerebral protection devices were not used.

We found excellent hemodynamic and echocardiographic improvements overall and beyond in comparison between patients with BAV and TAV. Patients with BAV anatomy play a special role, while most of the landmark trials exclude these patients, therefore high volume, prospective, randomized studies are missing in this field.

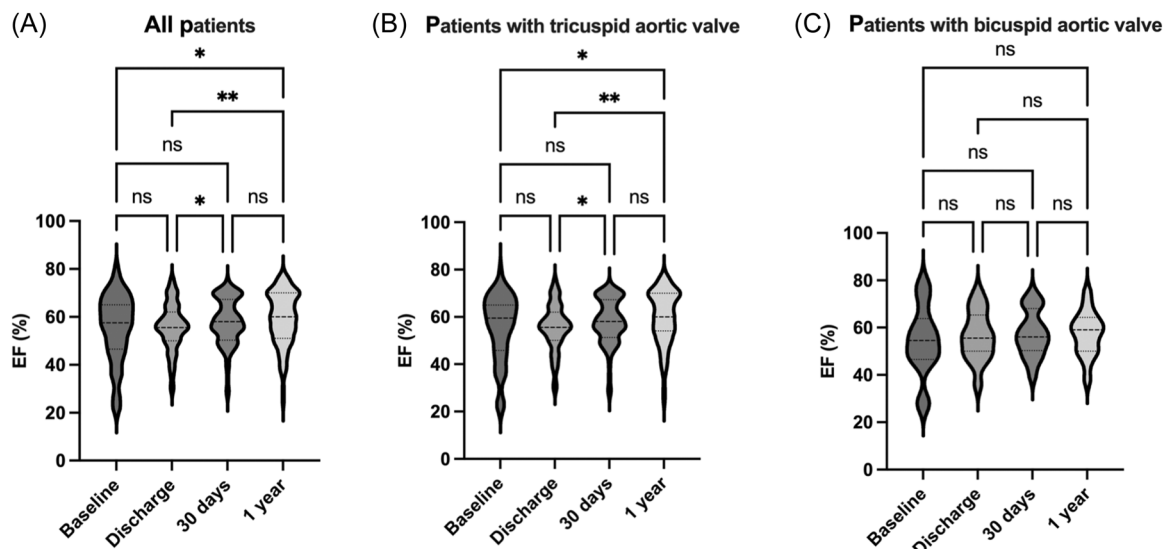


FIGURE 8 Violin plots compare the effect of transcatheter aortic valve replacement on ejection fraction (EF) measured by echocardiography in patients who survived up to 1 year. Data refer to the whole cohort (A; $n = 92$), patients with tricuspid aortic valve (B; $n = 76$), and patients with bicuspid aortic valve (C; $n = 16$). Medians and the 75th and 25th percentiles are shown within the violin plots. Data were analyzed by repeated measures 1-way ANOVA followed by Tukey's multiple comparison test. ns, no statistical significance. * $p < 0.05$, ** $p < 0.01$.

TABLE 6 Differences of baseline characteristics between non-bicuspid (TAV) and bicuspid (BAV) patients.

	TAV ($n = 83$)	BAV ($n = 17$)	p Value
Age	76.0 ± 6.9	68.5 ± 5.7	$p < 0.0001$
Euroscore	16.2 ± 16.6	11.9 ± 8.17	0.304
Euroscore II	5.11 ± 5.25	3.38 ± 2.14	0.186
STS score	5.7 ± 4.0	5.2 ± 3.6	0.630
Ca score	3432.7 ± 1790.3	3216.0 ± 2070.8	0.660
Oversizing	$7.8 \pm 4.0\%$	$6.6 \pm 3.5\%$	0.221

Abbreviations: BAV, bicuspid aortic valve; Ca score, Agatston calcium score of the aortic valve based on CT examination; TAV, tricuspid aortic valve.

In the STS/ACC TVT registry (5412 BAV patients vs. 165,547 TAV patients) comparable results could be detected regarding procedural, in-hospital and 1 year outcomes. These results were more favorable when newer generation devices were used.²³ Furthermore, when the morphology of the bicuspid valve based on the classification by Sievers²⁴ are taken into account, mortality and procedural complication can be decreased.²⁵ The most fearful complications in the special BAV anatomy are annular rupture, device migration and higher incidence of grade 2 or above aortic regurgitation. Thanks to the improvement of the devices available, the incidence of these complications are decreasing, however, they still occur.²³ In our study 17 BAV patients were implanted without any mechanical complications, however low case numbers might limit our findings. With intermediate sizes, over and undersizing is avoidable, which is especially crucial in BAV patients. The wide range of sizing scale provides possibility for accurate THV implantation and this optimal

patient-prosthesis matching is very likely responsible for our low incidence of grade 2 or above aortic regurgitation and the lack of fatal mechanical complications. Overall, intermediate-size implantation was more frequent than standard size (55.5% vs. 44.5%), but this difference was more obvious in the BAV patient group (76.5% vs. 23.5%). However, oversizing was nonsignificantly lower in BAV patients ($6.5\% \pm 3.5$ vs. 7.8 ± 4.0 , $p = 0.221$), this represents our effort for oversizing in TAV patients and for normal sizing in BAV patients, based on CT measurements. The significantly higher proportion of intermediate size in the BAV group might explain the fact that peak gradient increased only in the TAV group, see above. Nevertheless, the rising experience with TAVR in bicuspid patients showed favorable results compared with tricuspid patients,^{26,27} randomized, adequately powered studies are still lacking.

The minor unfavorable change in peak aortic valve gradient could be explained with the significantly increased global ejection fraction over the follow-up period (see above). The fact that mean aortic valve gradients were stable during the follow-up can support this hypothesis.

The new PPI rate was 30.7% (28 patients from 91) in our cohort, which remained unchanged until 30 days of follow-up, and only two patients had PPI after this period. One patient was implanted due to new onset of critical bradycardia, and the second patient required CRT-PM implantation due to worsening heart failure. The rate of new PM implantation after TAVR can vary in a wide range, from 3.4%²⁸ to as high as 25.9%–32.8%.^{5,29,30} Taking this into account, our pacemaker implantation rate seems high, but still within the expected range, based on the literature. It should be emphasized that trials showing a favorable PM implantation rate had exclusion criteria for BAV and no data of patients' calcium burden are available. In their study, Delgado-Arana et al. reported a

TABLE 7 Echocardiographic parameters of the study population during the follow-up period regarding overall, non-bicuspid (TAV) and bicuspid (BAV) patients.

Transthoracic echocardiography follow-up data					
Variable	Peak aortic gradient, mmHg*	Mean aortic gradient, mmHg*	LVEF, %	Mitral regurgitation grade 3 or 4	Aortic regurgitation grade 2 or above
Baseline (n = 100)					
Overall (n = 100)	82.3 ± 24.3	48.4 ± 14.6	55.8 ± 13.6	18	29
TAV (n = 83)	83.4 ± 25.4	48.9 ± 14.9	55.9 ± 13.5	17	25
BAV (n = 17)	80.8 ± 23.5	46.9 ± 14.8	53.9 ± 14.3	1	4
Discharge (n = 99)					
Overall (n = 99)	19.5 ± 7.6	10.6 ± 4.7	56.2 ± 9.9	9	5
TAV (n = 82)	19.3 ± 7.7	10.2 ± 4.8	56.1 ± 9.9	8	4
BAV (n = 17)	20.1 ± 6.9	10.3 ± 3.9	56.9 ± 10.2	1	1
30 days follow-up					
Overall (n = 99)	19.9 ± 8	10 ± 4.6	58 ± 9.6	6	5
TAV (n = 82)	20.1 ± 8.3	10.1 ± 4.8	58.1 ± 9.6	5	4
BAV (n = 17)	19.5 ± 6.7	10.1 ± 3.7	57.8 ± 9.6	1	1
1-year follow-up					
Overall (n = 93)	21.4 ± 7.5	10.7 ± 4.2	59.4 ± 11.1	6	4
TAV (n = 77)	21.6 ± 7.6	10.8 ± 4.3	59.9 ± 11.4	6	2
BAV (n = 16)	20.4 ± 7.1	10.0 ± 3.5	57.4 ± 9.4	0	2

Abbreviations: BAV, bicuspid aortic valve; LVEF, left ventricular ejection fraction; TAV, tricuspid aortic valve.

low incidence of new PM implantation, with a mean Agatston calcium score of 2314 and only 8.4% of calcium in the LVOT,⁸ whereas in our patient cohort, the calcium score was significantly higher (3395) and a higher rate of calcium presence in the LVOT (39%) could be detected. The impact of the aortic valve calcium score and the existence of calcium in the LVOT on PPI is controversial. Gonska et al. observed a significant impact of calcium score on PPI rate in 283 patients using Edwards Sapien 3 (ES3), whereas no similar association was found regarding oversizing and implantation depth.³¹ On the other hand, Mauri et al. demonstrated that LVOT calcification was an independent risk factor for PPI in 229 patients using ES3.³² In our cohort, the implantation depth was similar to that in the study by Gonska et al., in accordance with this, we found no significant correlation between the implantation depth and PPI rate. Another possible explanation for the higher PM implantation rate could be that during the learning curve and later in the COVID-19 era, we chose PM implantation in patients with borderline PPI indication, to avoid potential hospital readmission.^{33,34} Analyzing the baseline ECG of those patients who underwent PPI, six patients should have had the pacemaker implanted before TAVR procedure (five patients LBBB with PQ > 240 and one patient LAH + RBBB with PQ > 240), and therefore, did not constitute a complication of THV implantation and may decrease the PPI rate. On the one hand, our patients with PPI were at higher risk for onset of conduction disturbances, and

on the other hand, it should be emphasized that results regarding the real impact of PPI rate on patients survival are controversial. Therefore, further assessment is required in this field.

5 | CONCLUSIONS

Based on our results, excellent safety and efficacy of Myval THV system in patients with significant aortic valve stenosis could be detected, and these results are comparable with studies using other THV systems. Nevertheless, little is known about this new balloon expandable THV system in patients with BAV disease, which subgroup (with a higher potential complication rate) showed comparable results to patients with TAV disease thanks to a wide range of intermediate THV sizes. We observed higher new PPI rate without any negative consequence on the survival rate. The single-center and retrospective collection of data could limit our results but on the other hand, we reported real-time, online collected, real-world data. Further limitation could be the selection bias, however, with this patient enrollment strategy (see above) our patient cohort included patient with special anatomic properties, in whom TAVR procedure might be more complicated. Longer-term follow-up (3, 5 years) with a larger cohort is required to evaluate outcomes and durability of Myval THV in patients with BAV and TAV stenosis. Based on our experience, till the preparation of this article more than 200 patients

have been implanted with this THV system, therefore we can publish robust data later-on.

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CONFLICT OF INTEREST STATEMENT

Our conflict of interest that Iván Horváth, MD, PhD and Balázs Magyari, MD have a proctorship agreement with Meril Life Sciences. The remaining authors declare no conflict of interest. Although Iván Horváth, MD, PhD and Balázs Magyari, MD have proctorship agreement, there were no conflicts of interest associated with this publication, and there has been no financial support for this work, that could have influenced its outcome.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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