**Původní sdělení** | Original research article

# Midterm Evaluation of Results After Meril Myval Transcatheter Aortic Valve Replacement: One-Year Clinical and Echocardiographic Findings from the MERAM Registry

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*Klíčová slova:*
Balon-expandabilní chlopeň
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Postižení aortální chlopně

SOUHRN

**Kontext:** Srdeční chlopeň Myval™ je balon-expandabilní systém nové generace pro katetrizační náhradu aortální chlopně (transcatheter aortic valve replacement, TAVR) vyvinutý pro přesně provedenou implantaci a příznivější klinické výsledky. V tomto článku popisujeme naše zkušenosti s prvními 101 případy (období 2022–2024), u nichž hodnotíme výsledky po 30 dnech a jednom roce.
**Cíl:** Zhodnotit bezpečnost a účinnost systému Myval™ pro TAVR u pacientů s degenerativní aortální stenózou (AS).
**Materiály a metody:** Do této monocentrické observační studie bylo zařazeno 101 po sobě následujících pacientů s AS, u nichž byla v období mezi lednem 2022 a lednem 2024 provedena TAVR se systémem Myval™. Průměrný věk pacientů dosahoval 76,9 ± 7,0 roku; v 60 (59,4 %) případech se jednalo o ženy. Průměrné hodnoty skórovacích systémů EuroSCORE II a STS byly 4,85 ± 3,91, resp. 5,84 ± 4,82. Všechny výkony se prováděly femorálním přístupem. Pacienti absolvovali echokardiografické kontrolní vyšetření po jednom měsíci a klinické kontrolní vyšetření po jednom roce.
**Výsledky:** Úspěšnost výkonu byla 100 % (101/101). Průměrná délka hospitalizace byla 5,8 ± 2,4 dne. Do 30 dnů prodělali pacienti cévní mozkovou příhodu v 1,98 % (2/101) případů a v 15,8 % (16/101) případů byla nutná implantace nového permanentního kardiostimulátoru. Při propouštění z nemocnice byla u 10,9 % (11/101) pacientů zjištěna mírná aortální regurgitace a u 1,9 % (2/101) středně těžká aortální regurgitace, bez významného paravalvulárního leaku. Mortalita pacientů během jejich pobytu v nemocnici činila 2 % (2/101), přičemž celková mortalita do jednoho roku dosáhla 6 % (6/101).
**Závěr:** Provedení TAVR s použitím katetrizačního systému Myval™ bylo po 30 dnech a jednom roce od výkonu spojeno – z hlediska přežití, úspěšnosti a vzniku nežádoucích příhod v souvislosti s chlopní – s vynikajícími výsledky; potvrzuje se tak bezpečnost a účinnost daného výkonu při léčbě degenerativní AS.



*Keywords:*
Aortic valve disease
Balloon-expandable valve
Degenerative aortic stenosis
Myval™ transcatheter heart valve
Transcatheter aortic valve replacement

ABSTRACT

**Background:** The Myval™ transcatheter heart valve is a next-generation, balloon-expandable transcatheter aortic valve replacement (TAVR) system designed for precise implantation and improved clinical outcomes. This study presents our experience with the first 101 cases (2022–2024), evaluating 30-day and one-year outcomes.
**Aim:** To assess the safety and efficacy of the Myval™ TAVR system in patients with degenerative aortic stenosis (AS).
**Materials and methods:** This single-center observational study included 101 consecutive patients with AS who underwent TAVR with Myval™ between January 2022 and January 2024. The mean age was 76.9 ± 7.0 years, and 60 (59.4%) were females. The mean EuroSCORE II and STS score were 4.85 ± 3.91 and 5.84 ± 4.82, respectively. All procedures were performed via the femoral approach. Patients underwent echocardiographic follow-up at one month and clinical follow-up at one year.
**Results:** The procedural success rate was 100% (101/101). The mean hospital stay was 5.8 ± 2.4 days. Within 30 days, stroke occurred in 1.98% (2/101) of cases, and 15.8% (16/101) required new permanent pacemaker implantation. At discharge, mild aortic regurgitation was observed in 10.9% (11/101) and moderate regurgitation in 1.9% (2/101), with no significant paravalvular leak. Intrahospital mortality was 2% (2/101), while one-year all-cause mortality was 6% (6/101).
**Conclusion:** TAVR with the Myval™ transcatheter heart valve system demonstrates excellent 30-day and one-year outcomes regarding survival, procedural success, and valve-related adverse events, supporting its safety and efficacy in treating degenerative AS.

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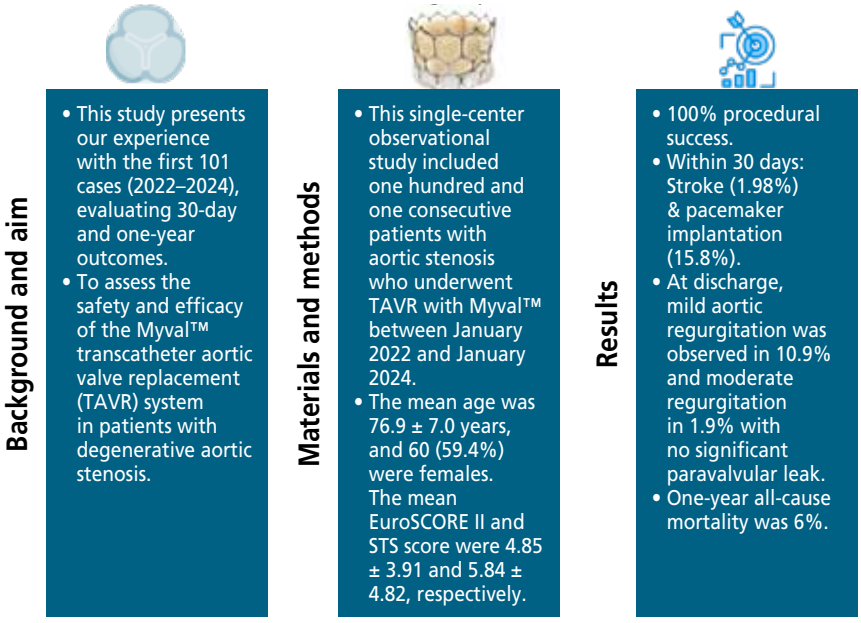
**Midterm Evaluation of Results After Meril Myval Transcatheter Aortic Valve Replacement: One-Year Clinical and Echocardiographic Findings from the MERAM Registry**




## Introduction

Degenerative aortic stenosis (AS) is the most prevalent valvular disorder in Western populations, contributing to a substantial and progressively increasing disease burden in aging individuals.[1] Currently, no effective medical therapies exist to prevent or slow the progression of AS; thus, aortic valve (AV) replacement remains the only definitive treatment.[2] Consequently, it remains the leading primary valvular pathology necessitating surgical or transcatheter intervention in both Europe and North America.[3] Clinical guidelines advocate for surgical aortic valve replacement (SAVR) as the preferred approach for younger patients (<65 years according to American College of Cardiology and <75 years according to European Society of Cardiology), while transcatheter aortic valve replacement (TAVR) is generally reserved for older individuals.[2–5]

Several randomized trials in patients with inoperable, high-, and intermediate surgical risk have led to the global approval of various TAVR devices. Among these, two valve types are widely used: the self-expandable valve (SEV) and the balloon-expandable valve (BEV).[6] A large propensity-matched patient study found no significant differences in one-year mortality or stroke rates between patients treated with BEV or SEV.[7] According to a meta-analysis, paravalvular leak is more common after TAVR with SEV compared to BEV, and the risk of permanent pacemaker implantation (PPMI) is also higher in the SEV group than in the BEV group.[8,9]

Myval™ transcatheter heart valve (THV) (Meril Life Sciences, India), which has received CE (Conformité Européenne) approval, is a next-generation balloon-expandable TAVR system designed for precise implantation and improved clinical outcomes. Its safety and efficacy were evaluated in patients with severe symptomatic native AS at intermediate or high surgical risk.[10–12] The valve features a tri-leaflet, decellularized bovine pericardial design with anti-calcification treatment, mounted on a metal frame with three evenly spaced commissural posts (**Fig. 1**).[11] The valve incorporates a hybrid honeycomb scaffold, with the upper frame featuring large, open-cell structures for coronary ostia unobstruction and flow preservation, while the lower frame uses tightly packed, close-cell hexagonal configurations for radial strength at the annular base. This design facilitates precise valve placement and ensures proper deployment.[13,14] The Myval BE valve offers a broader range of sizes, including intermediate and extra-large options, enhancing flexibility in sizing to reduce the risk of under- or over-sizing.[15]

In this study, we present our experience with the first 101 cases from 2022 to 2024, including 30-day outcomes and one-year outcomes.

## Materials and methods

### *Study design*

This study is based on a single-center experience. Data were collected retrospectively and recorded in our centralized electronic medical database as part of standard care, allowing for real-time, online data collection. The data collection was approved by the Local Ethics Committee (approval ID: 23262). The study was performed in

| Table 1 – Demographical variables of patients before TAVR | |
|---|---|
| Age (mean ± std) | 76.91 ± 7.01 |
| Gender (female) (n/%) | 60 (59.4) |
| Diabetes mellitus (n/%) | 36 (35.6) |
| Hypertension (n/%) | 67 (66.3) |
| Smoking (n%) | 23 (22.8) |
| Coronary artery disease (n/%) | 53 (52.5) |
| Percutaneous coronary intervention (n/%) | 21 (20.8) |
| Coronary artery by-pass (n/%) | 10 (9.9) |
| Mitral valve prosthesis (n/%) | 2 (2) |
| Aortic valve prosthesis (n/%) | 2 (2) |
| Bicuspid aortic valve (n/%) | 3 (3) |
| Chronic obstructive pulmonary disease (n/%) | 19 (18.8) |
| Malignancy (n/%) | 11 (10.9) |
| Obesity (n/%) | 13 (12.9) |
| Cerebrovascular accidant (n/%) | 5 (5) |
| Chronic renal disease, hemodialys (n / %) | 3 (3) |
| Pacemaker implantation, previously ( n / %) | 3 (3) |
| Heart rhythm<br>Sinus rhythm<br>Atrial fibrillation<br>Pace rhytm<br>Right bundle branch block<br>Left bundle branch block | <br>71 (70.3)<br>25 (24.8)<br>3 (3)<br>4 (3.9)<br>4 (3.9) |
| STS score (mean ± std) | 5.84 ± 4.82 |
| EuroScore II (mean ± std) | 4.85 ± 3.91 |

accordance with the Declaration of Helsinki. All patients gave written informed consent for the collection of their data within the scope of scientific research.

The study included one hundred and one patients with symptomatic severe aortic stenosis who had visited or had been referred to the outpatient cardiology clinic of Necmettin Erbakan University Faculty of Medicine between January 2022 and January 2024. Symptomatic aortic stenosis was diagnosed according to the 2021 European Society of Cardiology Guidelines for the Management of Valvular Heart Disease.[3] The indication for the procedure, prosthesis size selection, and access route were determined through a multidisciplinary approach by the local heart team. Patients with a bicuspid aortic valve were excluded. Prior to approval for intervention with the Myval device, all patients underwent thoracic and abdominal aortic computed tomography angiography. The patients were also evaluated for baseline characteristics, including medical history, clinical examination, and electrocardiographic and echocardiographic data. The baseline clinical and echocardiographic characteristics of the study population are shown in **Table 1**.

### *Myval™ THV device*

The Myval™ THV system, a next-generation balloon-expandable device, is constructed using a nickel-cobalt alloy (MP35N) frame, which provides optimal radial strength and radiopacity. The valve features a hybrid honeycomb cell structure with large open cells in the upper half (53% of expanded frame height) and tightly packed closed cells in the lower half (47% of expanded frame height). This design preserves coronary flow and ensures high radial strength at the annular base for proper valve fixation. The tri-leaflet valve is made from decellularized bovine pericardium and is mounted on three vertical commissural posts at the valve outflow zone. The lower closed-cell portion of the frame is lined with an internal polyethylene terephthalate skirt, which helps minimize paravalvular leak (PVL). Additionally, the external skirt enhances the sealing at the anchor site to further reduce PVL. The Myval™ THV is delivered via the Navigator™ high-flexibility, over-the-wire balloon catheter system, which enables accurate deployment. Myval™ is available in a wide range of sizes, including conventional (20, 23, 26, 29 mm),

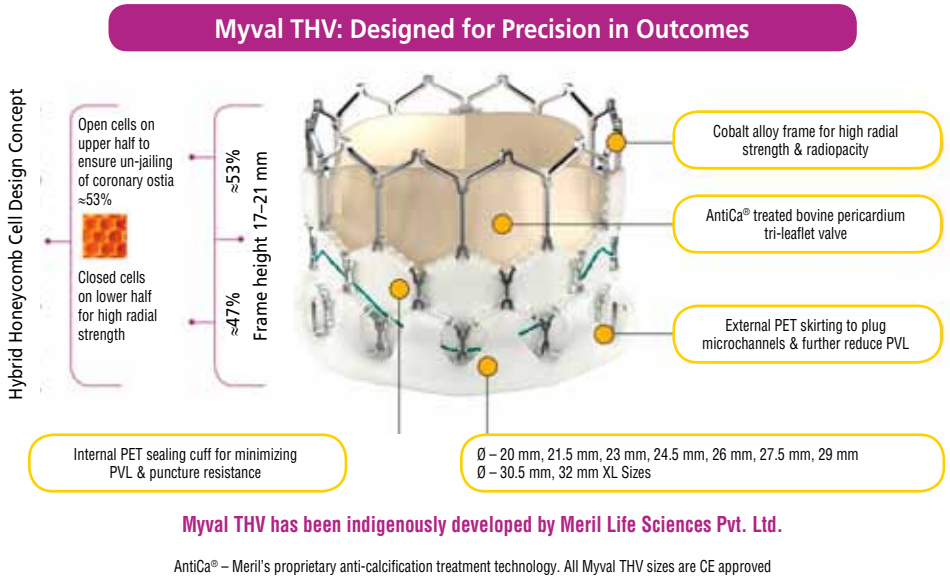



**Fig. 1 – Myval balloon-expandable transcatheter heart valve design features.[37]**

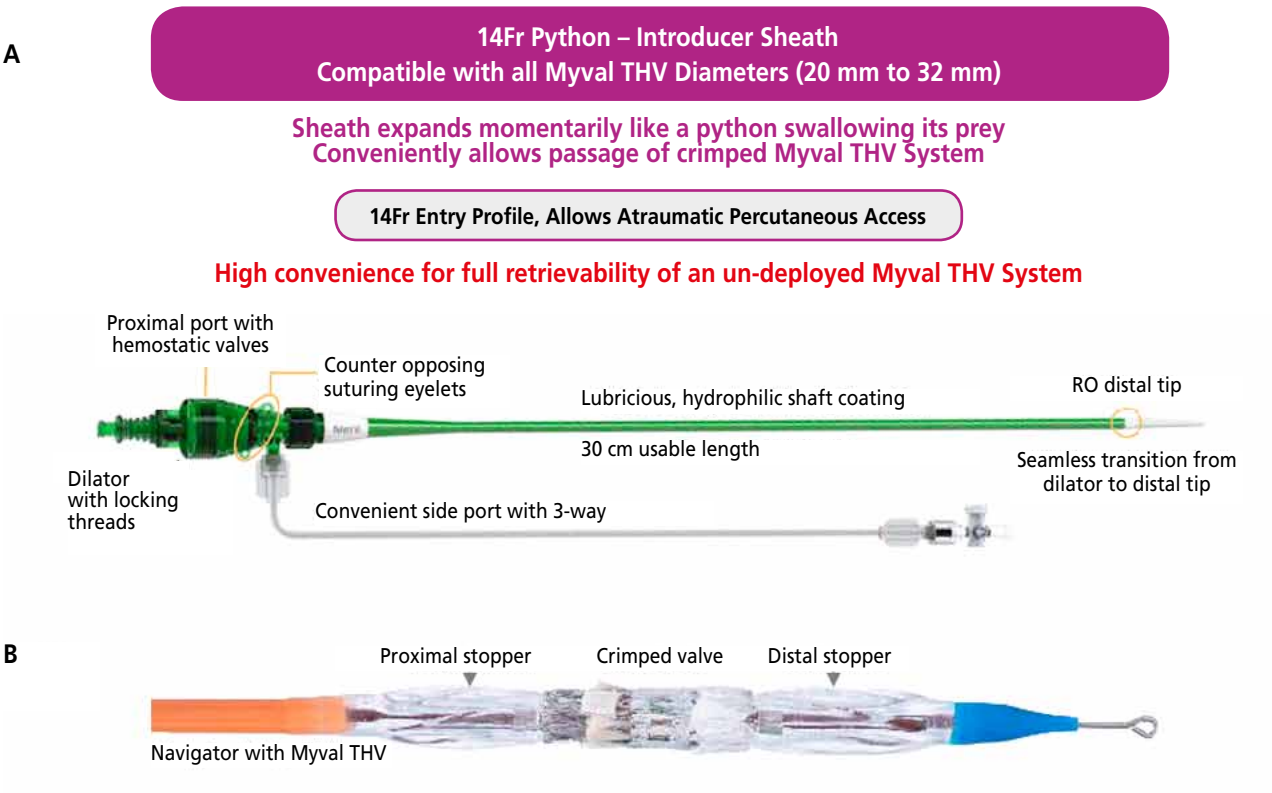



**Fig. 2 – (A) 14Fr Python – Introducer Sheath,[37] (B) Myval crimped directly on the Navigator delivery balloon system.[37]**

intermediate (21.5, 24.5, 27.5 mm), and extra-large (30.5, 32 mm) options, ensuring optimal sizing for individual patient anatomies. All sizes are compatible with a 14 Fr Python™ introducer sheath, allowing for easy retrieval of the undeployed valve if necessary (**Fig. 2**). During fluoroscopy, the crimped hexagonal pattern of the valve frame appears as alternating dark-light bands, facilitating precise placement (**Fig. 3**). The Navigator™ delivery system's design provides flexibility for safer navigation through the aortic arch, minimizing the risk of periprocedural complications (**Fig. 2**).

### *Procedural technique*

The structural heart interventional team comprised two trained operators, two nurses, a cath-lab technician, and an anesthetist. All study participants underwent the TAVI procedure using the Myval™ THV at a single center, following a standardized protocol with local anesthesia and conscious sedation. The transfemoral approach was used in all cases. Valve deployment was performed using rapid pacing. The procedure was carried out in a coplanar view, ensuring the three cusps were equidistant and aligned in a straight line. The access site was closed using two

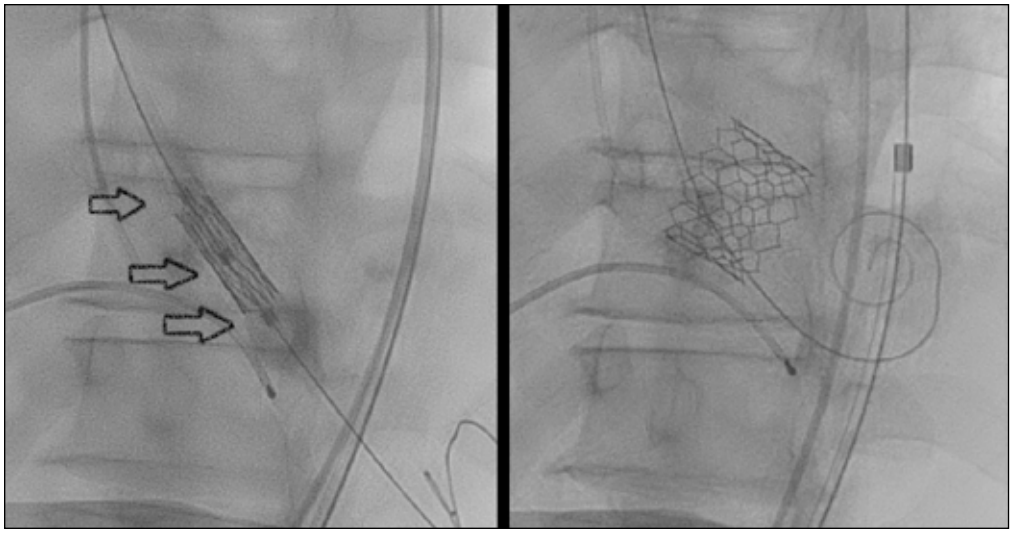


**Fig. 3 – During fluoroscopy, the crimped hexagonal pattern of the valve frame appears as alternating dark-light bands.**

| Table 2 – Laboratory parameters of patients before TAVR | |
|---|---|
| Creatinine (mean ± std) | 1.150.72 |
| Glomerular filtration rate (mean ± std) | 65.17 |
| Hemoglobuline (mean ± std) | 11.82 ±1.64 |
| Hematocrite (mean ± std) | 37.05 ± 4.36 |
| White blood cells (mean ± std) | 7.79 ± 2.37 |
| Platelets (mean ± std) | 234.72 ± 74.32 |
| Albumine (mean ± std) | 3.81 ± 0.51 |
| Pro-brain natriuretic peptides (median, min-max) | 1820 (87–59440) |
| Total cholesterol (mean ± std) | 170.17 ± 47.87 |
| Low density lipoprotein cholesterol (mean ± std) | 98.52 ± 38.63 |
| Triglyceride (median, min–max) | 110 (60–1205) |
| Aspartate aminotransferase (mean ±std) | 20.93 ± 15.63 |
| International normalized ratio (INR) (mean ± std) | 1.11 ± 0.14 |

| Table 3 – Echocardiographic variables of patients before TAVR | |
|---|---|
| Aortic valve area (mean ± std) | 0.76 ± 0.32 |
| Maximal aortic valve gradient (mean ± std) | 79.48 ± 17.84 |
| Mean aortic valve gradient (mean ± std) | 48.86 ± 11.07 |
| Ejection fraction (mean ± std) | 52.69 ± 9.63 |
| Systolic pulmonary artery pressure (mean ± std) | 43.74 ± 14.71 |
| Type of aortic valve stenosis (n/%)<br>• High flow high gradient<br>• Low flow low gradient<br>• Bioprosthetic valve degeneration<br>• Paradoxical aortic stenosis | <br>88 (87.1)<br>10 (9.9)<br>2 (2)<br>1 (1) |
| Aortic regurgitation (n/%)<br>• Mild<br>• Moderate<br>• Severe | <br>79 (78.2)<br>12 (11.8)<br>10 (9.9) |
| Mitral stenosis (n/%)<br>• None<br>• Mild<br>• Moderate<br>• Severe | <br>71 (70.3)<br>22 (21.8)<br>6 (5.9)<br>2 (1.9) |
| Mitral regurgitation (n/%)<br>• None<br>• Mild<br>• Moderate<br>• Severe | <br>28 (27.72)<br>50 (49.51)<br>20 (19.81)<br>3 (2.97) |
| Tricuspid regurgitation (n/%)<br>• None<br>• Mild<br>• Moderate<br>• Severe | <br>18 (17.82)<br>56 (55.44)<br>17 (16.83)<br>10 (9.9) |

6F vascular closure devices (Perclose ProGlide™ system, Abbott Vascular, CA, USA).

### *Study endpoints and follow-up*

The primary endpoint was procedural success, while secondary endpoints included all-cause mortality, cardiovascular mortality, stroke, moderate or severe paravalvular leak, and new PPMI during the hospital stay and the first month, as defined by the Valve Academic Research Consortium-3 (VARC-3) criteria. Hemodynamic outcomes included aortic valve effective orifice area, mean pressure gradient, and the degree of aortic valve regurgitation and PVL, measured by echocardiography. Follow-up assessments were conducted at 30 days and 1 year post-procedure through telephone interviews or office visits. Transthoracic echocardiography was performed at baseline and 30 days and 1 year after the procedure by experienced cardiologists.

### *Statistical analysis*

Data were analyzed using SPSS (version 28.0, IBM) Continuous variables are presented as mean ± standard deviation (SD) for normally distributed data and as median (interquartile range) for nonparametric data. Categorical variables are expressed as frequencies and percentages.

## Results

### *Baseline characteristics*

From 2022 to 2024, one hundred and one consecutive patients were included in this analysis. The mean age of the study population was 76.91 ± 7.01 years, with 59.4% being female. The most prevalent medical conditions (**Table 1**) were hypertension (66.3%), coronary artery disease (52.5%), diabetes (35.6%), and smoking history (22.8%). Three patients had a bicuspid aortic valve. Ten patients had a history of coronary artery bypass surgery, while four had undergone previous valve surgery, including two with aortic valve surgery. The mean logistic EuroSCORE II was 4.85 ± 3.91and the mean STS score was 5.84 ± 4.82. Detailed baseline clinical characteristics of the study population are provided in **Table 1**.

The mean estimated glomerular filtration rate was 65.17 ± 23.31 mL/min/1.73 m², and the mean hemoglobin level was 11.82 ± 1.64 g/dL before the intervention. Detailed laboratory parameters are shown in **Table 2**.

The mean ejection fraction was 52.69 ± 9.63%, and the mean aortic valve area (AVA) was 0.76 ± 0.32 cm². The mean pulmonary artery pressure, calculated from the tricuspid jet, was 43.74 ± 14.71 mmHg. Most patients had high-gradient AS (87.1%), while 9.9% had low-flow, low-gradient AS, and 1% had paradoxical low-flow, low-gradient AS. AR was classified as mild in 78.2% of patients, moderate in 11.8%, and severe in 9.9%. Detailed echocardiographic parameters before the intervention are shown in **Table 3**.

Before the intervention, 3.9% of patients had left bundle branch block (LBBB), and the same percentage had right bundle branch block (RBBB) (**Table 3**).

### *Procedural outcomes*

The femoral artery was the preferred access route for all patients. The mean valve size was 25.48 ± 2.47 mm. All procedures were performed under conscious sedation, with a procedural success rate of 100%. One valve popped out during implantation, and a second valve was successfully implanted. Pre-dilation was performed in 9.9% of cases, while post-dilation was required in only

| Table 4 – Procedure related details and outcomes | |
|---|---|
| Sizes of valves (mean ± std) | 25.48 ± 2.47 |
| Procedural succes (n/%) | 101 (100) |
| Predilatation (n/%) | 10 (9.9) |
| Postdilatation (n/%) | 15 (14.85) |
| Aortic regurgitation (n/%)<br>• None<br>• Trivial<br>• Mild | <br>88 (87.12)<br>11 (10.89)<br>2 (1.91) |
| Maximal aortic gradient (mean ± std) | 14.49 ± 4.32 |
| Mean aortic gradient (mean ± std) | 9.95 ± 3.42 |
| Ejection fraction (mean ± std) | 53.29 ± 8.72 |
| Hospitalization duration after procedure (mean ± std) | 5.78 ± 2.44 |
| Femoral access (n/%) | 101 (100) |
| Vascular access closure devices (Proglide) (n/%) | 98 (97) |
| Surgical, femoral cut-down (n/%) | 3 (2.9) |
| Failure of proglide, switch to surgical repair (n/%) | 3 (2.9) |
| Pacemaker implantation during follow-up (1 month) (n/%) | 16 (15.84) |
| Pacemaker implantation, intrahospital period (n/%) | 12 (11.88) |
| Left bundle branch block after procedure (n/%) | 10(10) |
| Cerebrovascular accident after procedure (n/%) | 2 (1.98) |
| Intrahospital mortality after procedure (n/%) | 3 (2.97) |
| One-year follow-up mortality | 6 (6) |
| Pacemaker implantation during follow-up (1 year) (n/%) | 16 (15.84) |

14.85% of procedures. The majority of patients (87.12%) had no aortic regurgitation (AR), while trivial AR was observed in 10.89%, and mild regurgitation in 1.91%. The mean hospitalization duration after the procedure was 5.78 ± 2.44 days. Vascular access closure devices (ProGlide) were used successfully in 97% of cases; however, in three patients (3%), device failure required conversion to surgical repair.

Among the RBBB group, one patient developed a trifascicular block after the TAVR procedure, requiring PPMI, while another progressed to atrioventricular (AV) block and also required a pacemaker. After the procedure, LBBB occurred in 10.8% of patients. Among them, five patients required PPMI due to a PR interval exceeding 300 ms. However, six patients with post-TAVR LBBB had normal PR intervals and electrical conduction and were followed up without the need for a pacemaker.

Asystole was observed immediately after the procedure in four patients. Among them, two underwent PPMI immediately after the completion of the TAVR procedure, while the remaining two underwent pacemaker implantation 24 hours later due to persistent AV complete block.

For the patients with conduction abnormalities requiring pacing in the last six months, the decision for pacemaker implantation was made based on electrophysiological study (EPS) results. In the patients with first-degree AV block and QRS widening, pacemaker implantation was performed if HV interval prolongation was observed in intracardiac measurements. Approximately four patients were managed with medical follow-up after EPS, and narrowing of the PR interval was observed during follow-up. Consequently, PPMI was required in 12 patients (11.88%) before discharge.

Cerebrovascular accidents occurred in 2 patients (1.98%) post-procedure. The in-hospital mortality rate following the procedure was 2.97%.

The mean maximal aortic gradient after the procedure was 14.49 ± 4.32 mmHg, while the mean aortic gradient was 9.95 ± 3.42 mmHg. The mean ejection fraction was 53.29 ± 8.72%. Detailed data on postprocedural outcomes are presented in **Table 4**.

### *Clinical outcomes at 30 days and 1 year*

At the 30-day follow-up, the procedural success rate remained high. The incidence of new left bundle branch block was 10.8%. PPMI was required in 15.84% of patients. When procedural rates were examined, the pacemaker implantation rate was found to be higher in the first 60 cases (20%, 12 patients) compared to the last 43 cases (11.6%, 5 patients). In the most recent cases requiring pacing, pacemaker implantation was performed using left bundle branch pacing.

According to the one-month echocardiographic assessment, 97% of patients had no or trivial AR, while mild regurgitation was observed in 3%. The one-year echocardiographic assessment showed similar results, with no significant PVL or changes in the mean aortic gradients. The overall 30-day mortality rate was 2.97%, with no mortality reported after discharge. One-year all-cause mortality was observed in 6% of patients. Echocardiographic outcomes were similar at 30 days (**Table 4**).

## Discussion

In this prospective single-centre study, we consecutively enrolled one hundred and one patients with native severe AS who all underwent TAVR with the Myval BE valve. Our principal findings are that: 1) the Myval BE valve was associated with a 100% procedural success rate and an acceptable rate of periprocedural complications, with an intrahospital mortality rate of 2.97%; 2) successful implantation of the Myval BE valve resulted in improved valve hemodynamics, with a mean maximal aortic gradient of 14.49 ± 4.32 mmHg, a mean aortic gradient of 9.95 ± 3.42 mmHg, and the absence of moderate to severe PVL in all patients; 3) the availability of additional valve sizes was beneficial, with a mean implanted valve size of 25.48 ± 2.47 mm; 4) the rate of new PPMI was 11.88%, and left bundle branch block occurred in 10 patient ; 5) vascular closure with the ProGlide system was successful in 97% of cases, with three patients requiring surgical repair.

The first TAVR in a human was performed in 2002 on a 57-year-old patient with severe aortic stenosis, cardiogenic shock, and significant left ventricular dysfunction (ejection fraction of 12%). Due to multiple comorbidities contraindicating surgical aortic valve replacement, the patient underwent the procedure as a lifesaving inter-

vention.[16] Following this, the Edwards SAPIEN valve was introduced, featuring a tri-leaflet bovine pericardium valve, pretreated to minimize calcification, and mounted on a balloon-expandable stainless-steel stent. Initially, it was available in two sizes: 23 mm and 26 mm.[17] Over the past two decades, THV technology has evolved significantly, with newer-generation THVs incorporating smaller delivery sheaths, improved deployment control, and circumferential sealing cuffs to minimize complications. According to the LANDMARK and COMPARE TAVI trials, the use of Myval in patients with severe symptomatic native AS indicated for TAVR is non-inferior.[18,19] As mentioned above, the Myval™ THV system represents the latest advancement in this field, designed to further reduce procedural complications and improve patient outcomes.

In the present study, all-cause and cardiovascular mortality, as well as stroke and TIA rates, were comparable to those reported in other real-world studies throughout the entire follow-up period.[12,13,15,20–22] Only three patients died during the in-hospital period after TAVR, and there were no deaths within the first 30 days following the procedure. According to a meta-analysis including 1,256 patients with the Myval valve system, the 30-day all-cause mortality rate was 1.8%, which is similar to our experience.[23]

The Myval-1 study preferred and recommended balloon pre-dilatation of the native aortic valve.[10] However, in our study, balloon pre-dilatation was performed in only 10 patients (9.9%). In contrast, Teoman et al. reported balloon pre-dilatation in 44% of patients in a multi-center study, while all patients underwent balloon pre-dilatation in a single-center experience from Iraq.[12,13] Similarly, in Argentina's initial experience, 60% of patients received balloon pre-dilatation.[20] Conversely, Halim et al. reported balloon pre-dilatation in only 4.1% of patients.[15] Despite these variations, none of these studies, including ours, observed severe paravalvular leak, and there were no significant differences in primary outcomes among the studies.[10,12,13,15] According to the DIRECTAVI trial, there was no significant difference in outcomes between patients who underwent balloon pre-dilatation before BEV implantation and those who did not.[24] Therefore, the decision for balloon pre-dilatation should be individualized based on patient anatomy and aortic calcification.

According to a multi-center study involving 12,804 patients, the mean length of hospital stay during the TAVR procedure was 7 days (5–9) in France.[25] In a separate study from Japan with 1,148 patients, the mean hospital stay was 8 days (7–9).[26] In our study, the mean length of stay was shorter, at 5.78 ± 2.44 days. A large meta-analysis found that, compared to general anesthesia, local anesthesia for TAVR can reduce hospital length of stay, procedure time, and 30-day mortality rates.[27] Additional analyses have shown that neither mortality nor the incidence of major adverse cardiac and cerebrovascular events after TAVR are influenced by the choice between local anesthesia and general anesthesia.[28] In our study, all patients underwent TAVR under conscious sedation. Similarly, in an Argentinian study, nearly half of the patients received conscious sedation.[20] Importantly, there were no significant differences in outcomes between these studies and our study.

TAVR procedures lead to significantly more conduction abnormalities compared to surgical AVR.[29] Among these, new-onset LBBB after TAVR is the most common electrical complication, with an incidence ranging from 13.3% to 37%.[30,31] LBBB occurs more frequently with self-expandable prostheses than with BEVs.[32] Moreover, post-TAVR LBBB is a known risk factor for PPMI, with pre-existing RBBB being the strongest predictor.[33] Other key risk factors for PPMI after TAVR include preexisting RBBB, the use of self-expandable valves, and the depth of implantation.[34] In our experience, pacemaker implantation was lower in the last 60 cases compared to the first 60 cases. This highlights the importance of expertise.

In our study, the incidence of new-onset LBBB after the procedure was 10.8%, which is comparable to previous studies. The rate of PPMI during the intrahospital period was 11.88%. In comparison, Myval experience from Iraq reported a 6% PPMI rate, whereas Balázs et al. observed a significantly higher rate of 30%.[12,22] While the incidence of new conduction abnormalities and pacemaker implantation has declined over time, several factors still influence PPMI rates, leading to variability across studies.[35] In our experience, PPMI decisions for patients with conduction abnormalities in the last six months were based on electrophysiological study results. This represents a novel approach to PPMI.

Most PPMI cases occur within the first five days post-procedure; in our study, the majority of pacemaker implantations were performed before discharge, consistent with existing literature.[36] At the one-month follow-up, the pacemaker implantation rate was 15.84%, which is higher than in some studies[12,18,37] but lower than others.[13,22]

Among the new generation of TAVR devices, the Myval platform stands out as competitive in terms of both acute and mid-term outcomes, particularly in experienced centers.[37] According to studies comparing BEV, the unique features of the Myval THV may help mitigate PVL and reduce the need for PPMI.[18,37] These benefits are attributed to optimized valve sizing and controlled depth of implantation, which contribute to improved device-host interaction.[18]

The findings of the study can be summarized as follows on graphical abstract.

In a conclusion, our single-center experience in Turkey demonstrated that the Myval™ THV system is a safe and effective treatment for patients with severe aortic stenosis, with outcomes comparable to other transcatheter heart valve systems. The prosthesis showed excellent procedural success, low rates of paravalvular leak, and an acceptable need for pacemaker implantation. Our findings support the Myval THV as a reliable option, especially in complex cases, and further studies are needed to confirm its long-term clinical benefits.

### *Study limitations*

This study has several limitations. First, it is a single-center study reflecting our initial experience with the Myval THV system, with a relatively small sample size and a short follow-up period. Therefore, we cannot provide long-term safety and performance outcomes. Second, the observational nature of the study limits the ability to establish

direct comparisons with other THV systems. Future large--scale, randomized controlled trials are essential to determine whether the Myval BE valve can compete with contemporary transcatheter heart valve systems.

**Conflict of interest**

The authors have no competing interests or relevant affiliations with any organization or entity with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, stock ownership or options and expert testimony.

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