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Research Article

# Early Outcomes of a Next-Generation Balloon-Expandable Transcatheter Heart Valve - The Myval System: A Single-Center Experience From Serbia

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## Summary

Transcatheter aortic valve implantation (TAVI) is one of the most effective treatments for severe aortic valve stenosis (AVS). Different genres and generations of transcatheter heart valves (THVs) are accessible, offering operators an opportunity to choose a patient-tailored device. In this single-center study, we present the outcomes of Serbian patients treated with next-generation Myval THV for severe symptomatic AVS. Myval THV was implanted in all consecutive patients who underwent TAVI at the Dedinje Cardiovascular Institute of Belgrade, Serbia between October 2020 and September 2021. The primary endpoint was device success on day 30. Secondary endpoints included 30-day all-cause mortality, cardiovascular death, stroke, moderate/severe paravalvular leak (PVL), and new permanent pacemaker implantation (PPI). TAVI was performed as per the European Society of Cardiology guidelines. The study comprised thirteen patients, aged 72 ± 13 years with mean EuroSCORE (7.17%) and Society of Thoracic Surgeons (2.72%,) scores who underwent TAVI successfully with 92.3% using the percutaneous approach. Myval THV intermediate and extra-large sizes were implanted in 46% and 15% of patients, respectively. This acute procedure success rate was 100%. The primary composite endpoint of early device success was achieved in all patients. None of the patients had clinically significant aortic regurgitation or moderate/severe PVL. No patient experienced stroke, contrast-induced acute kidney injury, device-related vascular complications, or a new PPI. The all-cause mortality rate at 30 days was 0%. Myval THV system demonstrated a favorable safety/efficacy profile within 30 days post-procedure at a single center in Serbia. This is the first report of my experience with Myval THV from Serbia.

**More Information**

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**Keywords:** Aortic valve stenosis; Transcatheter aortic valve implantation; Myval; Balloon-expandable valve; Serbia; Single-centre experience

**Abbreviations:** ACS: Acute Kidney Injury; AVS: Aortic Valve Stenosis; BE: Balloon-Expandable; PPI: Permanent Pacemaker Implantation; PVL: Paravalvular Leak; SE: Self-Expandable; STS: Society Of Thoracic Surgeons; TAVI: Transcatheter Aortic Valve Implantation; THV: Transcatheter Heart Valve; VARC-3: Valve Academic Research Consortium-3



## Introduction

The prevalence of Aortic Valve Stenosis (AVS) is on the rise due to prolonged lifespans and widespread greying in the developed world. Severe AVS, a highly prevalent valvular disease in the elderly, has a poor prognosis if left untreated, with a 50% mortality rate within two years of early symptoms onset [1,2]. Since its inception in 2002 [3], Transcatheter Aortic Valve Implantation (TAVI) has been widely evaluated in inoperable and in high-surgical risk patients; indications have been expanded to intermediate and low-surgical risk patients in recent years [4-6].

There are two genres of TAVI valves: Self-Expandable (SE) Transcatheter Heart Valves (THVs) and balloon-expandable (BE) THVs. The choice of valve type is made by the Institute's Structural Heart Team, in accordance with the patient's native aortic valve anatomy, size, and calcification, distribution of

calcium extending to left ventricular outflow tract, calcification of iliofemoral vessels as well as the need for alternative access [5].

The first BE THV introduced in the Republic of Serbia (in 2020) is the Conformite Europeenne-marked Myval THV (Meril Life Sciences Pvt. Ltd., India). The Myval THV system has a novel design geometry comprising three rows of hexagonal cells in a hybrid honeycomb cell structure. The unique cell design generates alternating sequences of dark-light bands that are visible under fluoroscopy and allows for precise placement and deployment of the THV system, which is associated with a minimal learning curve. Myval THV has some distinctive characteristics such as an expanded size matrix with conventional sizes of 20, 23, 26, and 29 mm, intermediated sizes of 21.5, 24.5, and 27.5 mm, and extra-large sizes of 30.5 and 32 mm. The expanded size matrix was designed with the intent to be suitable for patients with an annular area ranging from 270 to 840 $mm^2$ without the need for excessive over- or under-sizing [7]. The valve was initially evaluated in the MyVal-1 study, which involved 30 intermediate and high-risk patients and demonstrated satisfactory clinical safety and efficacy [8]. Subsequently, the Myval THV has been widely used across different geographies and several investigator-initiated and core lab-initiated studies have shown acceptable outcomes after TAVI using the Myval THV worldwide [9-25]. To our knowledge, this study is the first to report the outcomes of Myval THV in the Serbian population.

## Methods

### Study population and endpoints

Thirteen consecutive patients who underwent TAVI at the Dedinje Cardiovascular Institute of Belgrade, Serbia from October 2020 to September 2021 with Myval THV and provided written informed consent for the procedure and data processing were included in this study. All cases were presented to the Structural Heart Team (consisting of an interventional cardiologist, non-invasive cardiologist, anesthesiologist, radiologist, cardiologist, and vascular surgeon) to assess the feasibility and safety of undergoing the procedure. The primary endpoint was device success at day 30 as determined by the Valve Academic Research Consortium-3 (VARC-3) [26]. The secondary endpoints included 30-day all-cause mortality, cardiovascular death, stroke, moderate or severe Paravalvular Leak (PVL), and new Permanent Pacemaker Implantation (PPI). All TAVI study participants were entered into the Institute's TAVI registry, which also retained track of their baseline traits, procedural details, device information, and acute clinical results. The patients in addition to routine follow-ups at the institute's outpatient clinic also underwent regular echocardiographic follow-ups. All data were collected prospectively.

### Patient selection and pre-TAVI assessment

Pre-interventional patient work-up included transthoracic echocardiography to confirm the diagnosis. A Multislice Computed Tomography (MSCT) was used to assess the dimensions and morphology of the aorta and aortic valve, grade and distribution of the calcifications, annulus dimension, and iliofemoral tract. A coronary angiography, as well as Doppler ultrasound, were performed to evaluate coronary arteries, in addition to the standard laboratory tests. Prior to the TAVI, a percutaneous coronary intervention was performed, if required. The patients' preoperative risk was estimated using the logistic EuroSCORE-II and Society of Thoracic Surgeons (STS) scores.

### TAVI procedure using Myval THV system

The BE Myval THV (Figure 1) was implanted in all patients using the Transfemoral (TF) approach. Myval THV was delivered at the target site (stenosed aortic valve) using a specially designed hi-flex, over-the-wire balloon catheter system – The Navigator™ THV delivery system (Meril Life Sciences Pvt. Ltd., India) using a mechanical crimping tool – Val-de-Crimp™ (Meril Life Sciences Pvt. Ltd., India). Myval THV is directly crimped on the Navigator™ THV delivery system, eliminating the need for any in-aorta maneuvering/mounting of the valve on the balloon. This feature reduces the risk of intra-procedural balloon rupture and has less propensity to traumatize the delivery catheter balloon. Once positioned, the THV can be deployed precisely and rapidly (within 13 - 15 seconds) across the aortic annulus (in its orthotopic position) with simple inflation by connecting a high-pressure inflation syringe at the proximal designated inflation port, filled with 75:25 saline: contrast media mixture. This is done while the patient's heart is stabilized under rapid pacing.

The 14 Fr Python™ introducer sheath (Meril Life Sciences Pvt. Ltd., India) is intended for the insertion of the Myval THV. It is compatible with all Myval THV sizes, ranging from 20 mm to 32 mm. Moreover, this sheath also offers the exceptional capability of completely retrieving the THV, if the operator is unable to cross the aortic annulus due to anatomical challenges.

### Statistical analysis

The continuous variables are presented as mean ± standard deviation. Categorical variables are described as frequencies with percentages, wherever necessary. The analysis did not include imputation for missing data. The statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 21 (IBM Corporation, Chicago, IL, USA).

## Results

### Baseline and clinical characteristics

The patients [7 (53.7%) male and 6 (46.3%) female] were 72 ± 13 years old (range 59 years - 85 years). The mean logistic EuroSCORE was 7.17% and the mean STS score was 2.72%. All

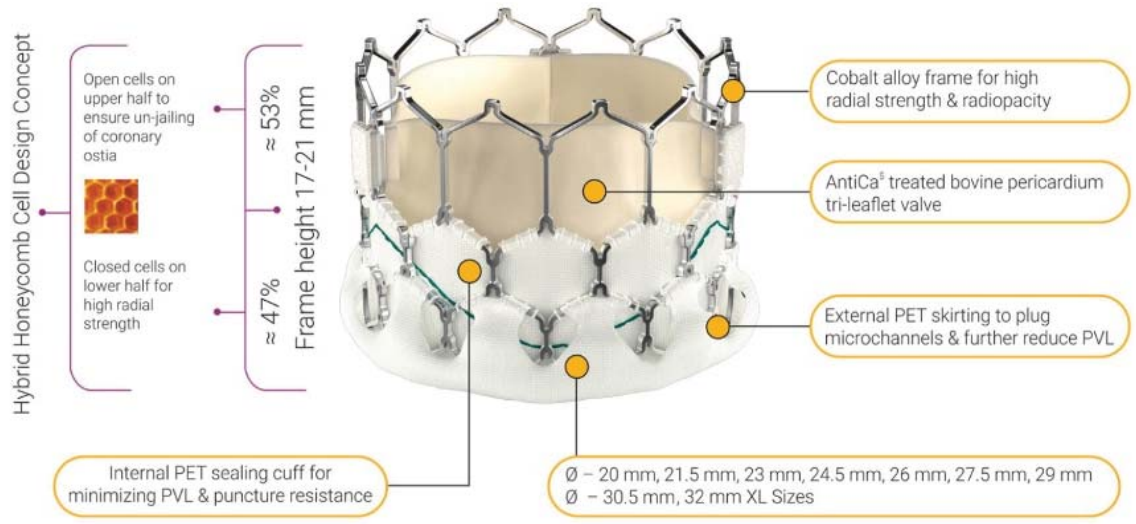


**Figure 1:** The design of a Myval transcatheter heart valve - www.myval.com.

patients had tricuspid anatomy of the aortic valve. Six patients had concomitant coronary artery disease (46.1%). The mean aortic area was 0.61 ± 0.28 $cm^2$ while the mean aortic gradient was 48 ± 48 mmHg. Other baseline demographics and clinical characteristics of the study population are summarized in Table 1.

**Table 1:** Baseline demographics and clinical characteristics.

| Variables | N = 13, *n* (%) |
|---|---|
| Age, years (mean ± SD) | 72 ± 13 |
| Male | 7 (53.8) |
| STS score (mean) | 2.72 |
| Logistic EuroSCORE (mean) | 7.17 |
| NYHA class | |
| NYHA II | 11 (84.6) |
| NYHA III or IV | 2 (15.4) |
| Coronary artery disease | 6 (46.1) |
| Previous myocardial infarction | 4 (30.8) |
| Previous cardiac intervention | 5 (38.5) |
| Percutaneous coronary intervention | 1 (7.7) |
| Coronary artery bypass graft | 4 (30.8) |
| Bicuspid aortic valve (BAV) | 0 |
| Cerebral vascular disease | 3 (23.1) |
| Peripheral vascular disease | 3 (23.1) |
| COPD or pulmonary fibrosis | 0 |
| Oxygen dependence | 0 |
| Creatinine more than 2 mg/dl | 1 (7.7) |
| Atrial fibrillation | 2 (15.4) |
| Pre-existing permanent pacemaker | 1 (7.7) |
| Pulmonary hypertension | 4 (30.8) |
| Extensive aortic calcification | 2 (15.4) |
| Liver disease | 1 (7.7) |
| Aortic valve area, $cm^2$ (mean ± SD) | 0.61 ± 0.28 |
| Mean aortic gradient, mmHg (mean ± SD) | 48 ± 48 |
| Left ventricular ejection fraction (LVEF), % (mean) | 42 ± 23 |
| Moderate to severe mitral regurgitation | 4 (30.8) |

Values are expressed as *n* (%) or mean ± SD
BAV: Bicuspid aortic valve; COPD: Chronic obstructive pulmonary disorder; NYHA: New York Heart Association Class; SD: Standard deviation; STS: Society of Thoracic Surgeons

## Procedural outcomes

Procedural success was achieved in 100% of patients. The majority of procedures were performed under local anesthesia and/or conscious sedation, except when general anesthesia was required for a surgical cut to access the common femoral artery. The TF approach was achieved in 100% of cases and percutaneous in 92.3%. The valve was directly implanted in 10 patients, while the native aortic valve was predicated in three patients. Intermediate sizes of Myval THV were implanted in 46.16% of patients while extra-large Myval THV was implanted in 15.38% of patients. Post-TAVI, clinically significant PVL was not observed. Table 2 summarizes the procedural outcomes. Figure 2 depicts the typical image of the Myval THV system deployed orthotopically with no PVL.

## Safety endpoints and clinical outcomes at 30 days

All patients underwent follow-up until hospital discharge and 30-day and clinical follow-up data were obtained for 100% of the patients as per VARC-3 definitions. None of the patient's needed open heart surgery. There were no reports of a new PPI, stroke, or contrast-induced Acute Kidney Injury (AKI). Furthermore, no device-related vascular complications were observed. Table 3 depicts device success and early clinical safety at 30 days.

# Discussion

To our knowledge, this is the first study to examine the clinical efficacy and early safety of the next-generation BE Myval THV in the patient population of Serbia. Our findings from a small cohort study demonstrated favorable clinical outcomes, especially with regard to the absence of conduction disturbances, clinically significant Aortic Regurgitation (AR), or moderate/severe PVL. The primary composite endpoint of early device success was achieved in 100% of the patients

**Table 2:** Procedural outcomes.

| Variables | Patients N = 13, *n* (%) |
|---|---|
| Procedure success | 13 (100) |
| Transfemoral | 13 (100) |
| Percutaneous | 12 (92.3) |
| **Myval THV size** | |
| 21.5 mm | 1 (7.7) |
| 23 mm | 3 (23.1) |
| 24.5 mm | 2 (15.4) |
| 26 mm | 2 (15.4) |
| 27.5 mm | 3 (23.1) |
| 30.5 mm | 1 (7.6) |
| 32 mm | 1 (7.6) |
| Predilatation | 3 (23.1) |
| Postdilatation | 0 |
| Second valve required | 0 |
| **Post-procedural aortic regurgitation** | |
| Moderate | 0 |
| Severe | 0 |
| Open heart surgery (tamponade) | 0 |
| Annular rupture | 0 |
| Coronary obstruction | 0 |

Values are expressed as *n* (%) THV: Transcatheter Heart Valve

**Table 3:** Clinical outcomes as per VARC-3 at 30-day follow-up.

| Endpoints as per VARC 3 | N = 13, *n* (%) |
|---|---|
| Device success | 13 (100%) |
| Early safety | 13 (100%) |
| All-cause mortality | 0 |
| Cardiovascular death | 0 |
| Neurological event | |
| Disabling stroke | 0 |
| Nondisabled stroke | 0 |
| Transient ischemic attack | 0 |
| Bleeding | 0 |
| Minor | 0 |
| Major | |
| Vascular complications | |
| Major | 0 |
| Minor | 0 |
| Myocardial infarction | 0 |
| Conduction disturbances | 0 |
| Ventricular arrythmia | 0 |
| New atrial fibrillation | 0 |
| New pacemaker implantation | 0 |
| Acute kidney injury | 0 |
| Re-transcatheter aortic valve implantation | 0 |
| Surgical aortic valve replacement | 0 |
| Endocarditis | 0 |

VARC: Valve Academic Research Consortium

with no all-cause mortality at 30 days. It is noteworthy that none of the patients required a new PPI, had a stroke, an AKI, or had device-related vascular complications.

Discussion on initial TAVI experience with other contemporary devices in Serbia is crucial. A first case series study was carried out at the Catheterization Laboratory of the Clinic for Cardiology, Clinical Center of Serbia. TAVI was performed using SE THVs (CoreValve, Medtronic, MN, USA) on five patients with severe/symptomatic AVS who either had

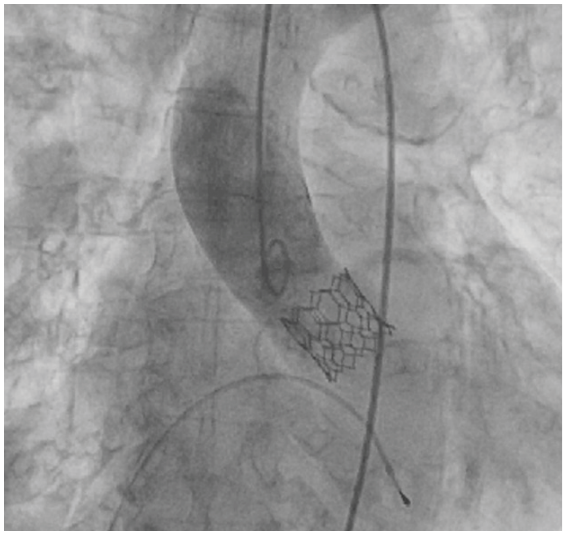

**Figure 2:** A representative of an aortic CT angiogram of intermediate-size 21.5 mm Myval THV deployed orthotopically without paravalvular leakage.

surgical contraindications or high surgical risk. All procedures were performed successfully with an immediate improvement in their hemodynamics. After six months, all patients had improved NYHA functional status, and the survival rate was 100% [27]. Secondly, our earlier report on Serbia's first systematic TAVI program presented that SE [34 Evolut R, Medtronic, MN, USA; 9 Acurate Neo, 1 Acurate Neo 2 M, Boston Scientific, MA, USA] and BE [13 Myval] valves were implanted in the cohort of patients ($n$ = 56) with AVS to assess 30-day early outcomes. Based on the patient's native aortic valve, the size and calcification of the iliofemoral arteries, and the need for alternative access, the Structural Heart Team at the Institute decided the type of valve to be implanted. Procedural success was achieved in 100% of patients via the TF approach. Post-procedure, no patient had moderate/severe AR, while 30.3% experienced trace or mild AR. A PPI was required in one patient (1.78%), one patient (1.78%) suffered from AKI, three pseudo-aneurysms required surgical repair, and blood transfusion was needed in three (5.33%). All-cause mortality at 30 days was 1.78% [28]. These data suggest that TAVI's preliminary results are in line with prior large randomized trials. Thus, this favorable first-hand experience with SE and BE THVs offered a strong foundation for managing a wider group of untreated patients with AVS in Serbia.

In the current study, we describe early clinical outcomes and device performance of Myval THV, explicitly comparing with other commercially available THV systems considering the benefits and limitations of the Myval THV system. The first-in-human study using BE Sapien 3 (Edwards Lifesciences, CA, USA) demonstrated short-term clinical outcomes in patients ($n$ = 15) with AVS. Paravalvular AR at discharge was none in 2 (13%), trivial in 9 (60%), and mild in 4 (27%) patients whereas only mild AR was observed during the procedure, pre-discharge, or at 30-day follow-up. There were no fatalities, strokes, or vascular complications observed, although one (6.7%) patient required a PPI at a 30-day follow-up [29]. In

another retrospective analysis, patients (*n* = 10) with AVS were implanted with BE Sapien XT (Edwards Lifesciences, CA, USA) THV, 2 cases had a slight PVL, with no 30-day mortality [30]. Further, in the case series, favorable short-term clinical endpoints were achieved with Sapien 3 THV in high-risk patients (*n* = 8) with non- or moderately calcified AR. Even after 100% device success, two periprocedural nonfatal complications were noted: one pericardial tamponade and one patient required the placement of a covered stent due to laceration of the common femoral artery; two patients required PPI for complete atrioventricular block. At the 30-day follow-up, none of the patients had more than minimal AR [31]. Several prospective, single-center nonrandomized trials have demonstrated the short-term efficacy of SE THVs in high-risk patients (*n* = 25/60) with symptomatic AVS [32,33]. Thus, when compared to earlier small cohort studies employing contemporary SE or BE THVs, our study with Myval THV provides adequate evidence in terms of early safety data.

When comparing the Myval THV with commercially available devices, the overall trend turned out to be consistent in expanded sample size groups and follow-up periods. For instance, in a single-center first study employing Sapien 3 Ultra THV (Edwards Lifesciences, California, US) follow-up involving consecutive patients (*n* = 79) with severe calcified AVS, mortality was found to be 2.5% at the 30-day. Although device (97.5%) and procedural success (94.9%) rates were acceptable, postprocedural PPI was required in 7.6% of the patients whereas mild PVL was seen in 18.9% of the patients. With minimal mortality, and no residual PVL, this BE THV demonstrated adequate 30-day outcomes and hemodynamic results [34]. Garcia-Gomez, et al. in a multi-center retrospective study in patients (*n* = 100) with high, intermediate, or low surgical risk, the Myval THV has proven to be safe and effective [8,9]. In a very recent SAPPHIRE study, TAVI was performed at two Italian centers on consecutive patients (*n* = 100) with severe AVS. The performance and one-year clinical outcome were attained with no intra-hospital mortality (technical success 100%), no cases of annular rupture, and no coronary obstruction. At a two-year follow-up, the Myval THV exhibited a promising safety/efficacy profile [35].

In order to assess the comparative safety and feasibility of Myval in combination with contemporary THVs, several randomized trials are conducted in a moderate to large sample size population. In the MATCH-BALL—an investigator-initiated retrospective study, first-time early clinical (30-day) and matched hemodynamic outcomes of consecutive real-world patients (*n* = 416) with symptomatic AVS treated with Sapien 3 (*n* = 286) or Myval THV (*n* = 130) were compared. The Myval THV was found to be favorable in terms of safety, low rate of PPI (15.5 *vs*. 5.8%), residual gradients, and PVL as per the blinded echocardiographic analysis [10]. The EVAL Registry compared the Myval with SE Evolut THV in patients with severe AVS. In terms of primary composite endpoint, Myval showed comparable performance, lower rate of PPI, and moderate or severe PVL at 30 days and 6 months follow-up [11]. Further, Kawashima et al. conducted a retrospective quantitative angiographic assessment of AR after TAVI among three BE (Myval *vs.* Sapien 3 and Sapien XT) THVs. Myval THV (2.8%) had a lower incidence of moderate or severe post-TAVI AR compared to the Sapien 3 (8.3%) and Sapien XT (10.9%) THVs [12]. Another core laboratory assessment of ECG from 9 European centers (*n* = 1131 patients) compared the early conduction disturbances between Myval and contemporary THVs [Sapien 3, Evolut, Acurate Neo, Portico (Abbott Structural Heart, MN, USA), and Allegra (NVT AG, Switzerland, and Biosensors, Singapore)]. Myval THV system had lower rates of early conduction disturbances compared to other THV systems [13]. Direct randomized comparisons between SE and BE THVs in the CHOICE trial (*n* = 240; 120 each) and SOLVE-TAVI trial (*n* = 447; 225 *vs*. 222) show that the BE THVs have a reduced and comparable risk of PPI, respectively [36,37]. Additionally, Sapien Ultra THV's have shown superior annular sealing qualities in patients with AVS over Sapien, confirmed by a considerable reduction in mild PVL [38]. Our findings are in good compliance with these studies and we found that in this small sample cohort, none of the patients exhibited severe PVL and only one patient had clinically insignificant PVL.

Moreover, the BAV, due to its intricate anatomical concerns necessitates dedicated trials and registries to validate the safety and effectiveness of THVs in this patient population. Elkoumy, et al. have established Myval THV's safety and efficacy in patients (*n* = 68) with AVS and BAV anatomy and is associated with favorable short-term (30-day) hemodynamic and clinical outcomes at one-year [14,15]. Among Indian patients with AVS, BAV is relatively prevalent. Kumar, et al. discussed their experience utilizing TAVI in BAV cases in India. Patients (*n* = 70) with BAV anatomy had their procedure and in-hospital imaging data examined, and they were then monitored for two years. The THVs evaluated in the study were the SE CoreValve and Evolut R and the BE Sapien 3 (Edwards Lifesciences, California, US), and Myval THV. The study revealed acceptable procedural success rates and clinical outcomes. Both SE and BE THVs were successful in achieving adequate hemodynamics after two years. The rates of PVL, PPI, and stroke were comparable to that of other observational studies and registries [16]. Further, the findings of the TRITON study for severe bicuspid AVS with BE Myval THV (*n* = 122), Sapien 3 Ultra (*n* = 129), and SE Evolut Pro+ (*n* = 109) further validated that the safety outcomes are comparable between the three devices. The Myval group had a much higher device success rate at 30 days (Myval: 100%; S3U: 87.5%; and EP+: 81.3%) and exhibited better gradients compared to Sapien 3 Ultra, while both BE devices had lower residual AR than Evolut Pro+ [17]. Besides, in a prospective analysis of low-risk AVS patients (*n* = 107) with bicuspid and tricuspid anatomy, the geometry of the Sapien 3 valve was assessed. Patients with bicuspid, as well as tricuspid anatomy, experienced similar rates of all-cause mortality, stroke, and

new PPI at discharge, 30 days, and at one-year follow-up. This further supports the hypothesis that the Sapien 3 THV possesses a similar THV geometry in these patients' subsets [39]. Our observations from the aforementioned studies imply that BE THVs may be a suitable option for addressing bicuspid morphology in patients with AVS.

In a pooled analysis, aortograms from a multicenter, multicontinental cohort of consecutive patients ($n$ = 2665) who underwent TAVI were analyzed retrospectively. Based on angiography time-density analysis, the core laboratory conducted a video densitometric analysis to assess AR. Aortograms of patients treated with SE [Evolut Pro, Evolut R, Acurate neo, CoreValve, and Acurate neo2, VitaFlow (MicroPort, Shanghai, China) and Venus-A (Venus MedTech, Hangzhou, China)], BE (Sapien, Sapien XT, Edwards Lifesciences, California, US, Myval) and one mechanically-expandable (Lotus, Boston Scientific, MA, USA) valves were included in the analysis. Data revealed that the Lotus valve had the lowest mean AR compared to other SE THVs Among BE THVs, the lowest AR was observed in Myval, highlighting the potential option in the THV arsenal [40]. In a related observational analysis, the baseline characteristics, procedural specifics, and one-year outcomes of Acurate Neo, Evolut Pro/R, Lotus, Portico, and Sapien/Sapien S3/ Ultra were compared. The frequency of major vascular complications was found to be more with Accurate and Sapien, whereas PPI was more prevalent with Lotus and Evolut [41]. Additionally, according to a systematic review of a pooled analysis of BE and new-generation SE THVs, the mortality rate in patients receiving TAVI with BE and SE THVs was not substantially different at 30-day follow-up. However, patients implanted with BE THVs had a threefold reduced risk of PPI [42]. These collective statistics indicate that, BE THVs are more likely to deliver favorable results than SE THVs in terms of pre-/post-procedural complications and early safety.

The overall outcomes achieved in the current study are in good agreement with those reported by other investigators that have been published in the literature. These encouraging clinical outcomes of Myval THV could be attributed to its prominent design features that facilitate precise positioning and deployment and expanded size matrix. In addition, the expanded size matrix contributes to achieving optimal post-procedural outcomes. In over 42% of patients in real-world settings, operators have apparently chosen intermediate-size Myval THVs [21]. In our study, intermediates and extra-large sizes of Myval THV were utilized in 46% and 15% of patients, respectively.

## Conclusion

To the highest degree in state-of-the-art, this is the first-ever study with the Myval THV system in Serbia. The Serbian experience of TAVI in the AVS patient population is quite similar to that described in other literature from across the globe. This study demonstrates the early feasibility, safety, and efficacy of a BE Myval THV for the treatment of patients with AVS in Serbia. The outcomes of the study are believed to be clinically significant since Myval THV is distinguished by its unique features including a short learning curve, a novel design, size matrix, and orthotopic deployment. Additionally, it can be implanted across a broad spectrum of surgical risks, anatomical variances, and in a heterogeneous population. Post-TAVI, patients regain valve function, which may improve health and in turn, quality of life among those who would not have many options for valve repair.

A multidisciplinary review is crucial to handle the shared decision-making process for potential patients undergoing TAVI on a case-by-case basis, particularly from the standpoint of medical ethics. The value of rigorous patient selection by the Structural Heart Valve team cannot be overemphasized. Based on patients' traits and clinical factors, prior to the treatment itself, realistic expectations regarding the procedure, including the management of potential complications, must be disclosed.

Patients with valve dysfunction or failure have limited treatment options and the situation further worsens in high surgical risk patients. This study provides the first evidence of Serbian patients using BE Myval THVs for low to high-risk patients and may serve as a potential platform for future interventions. We strongly believe that TAVI procedures using the BE THV via trans-femoral access allow an alternative approach to treating AVS.

TAVI has culminated in a paradigm shift in the treatment of patients with severe AVS. However, thorough anatomical screening is imperative using successful modern imaging techniques, including fusion imaging, to maximize the procedural success rates. Indeed, the durability of TAVI is relatively shorter than the expected durability for surgical valve replacement, which can be improved by a supra-annular design of the valves for an elliptical annulus. Further, subclinical cardiac variations in myocardial deformation are often present but not reflected by LVEF. To overcome this issue, strain measurement, especially Global Longitudinal Strain (GLS) is the most valuable matrix. Pre-and post-procedural GLS assessment correlates with LV function recovery, symptoms, and prognosis in patients with AVS. Recently, new valve designs incorporate synthetic polymeric valves that may allow for enhanced durability, in addition to advances in terms of accurate positioning and repositioning to minimize the complication rate. These innovations in technology could provide a potential base for successful future interventions.

In a nutshell, long-term comparative studies with novel valve designs are required, particularly in low-risk, asymptomatic patients, bicuspid valves, moderate aortic stenosis, and in the subset of pure native aortic valve regurgitation.

## Limitations

This study is limited in its scope due to its small sample size and single-center experience. However, it is noteworthy that the small sample size is due to the launch of a TAVI program in which the patient number was intentionally reduced due to the low count of procedures. Additionally, since TAVI is not a commonly performed procedure in Serbia, this small cohort offered valuable results and established a platform for future new procedures in the country. The findings of our study might encourage young interventionalists to pursue research in this area. Our study depicts results that can be anticipated in real-world clinical practice. All patients at the end of 30 days remain stable, which itself is evidence of the effectiveness and safety of TAVI with Myval THV in Serbian patients with AVS. Further larger randomized studies are required to compare the safety and efficacy of the Myval THV system with other commercially available THVs such as the BE Sapien 3 THV and the SE Evolut R THV. The clinical performance of this device, which can be linked to its structural features, can be further illustrated by the large-scale ongoing trials like LANDMARK (NCT04275726) and the Compare-TAVI (NCT04443023).

### Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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