

Review

Not peer-reviewed version

Myval Transcatheter Heart Valve: The Future of Transcatheter Valve Replacement and Significance in Current Timeline

[Teoman Kilic](#)*, Senol Coskun, Didar Mirzaminidov, Irem Yilmaz, Sadan Yavuz, Tayfun Sahin

Posted Date: 2 October 2024

doi: 10.20944/preprints202410.0199.v1

Keywords: Myval; Safety; transcatheter aortic valve implantation; transcatheter heart valve; valve-in-valve implantation



Preprints.org is a free multidiscipline platform providing preprint service that is dedicated to making early versions of research outputs permanently available and citable. Preprints posted at Preprints.org appear in Web of Science, Crossref, Google Scholar, Scilit, Europe PMC.

Copyright: This is an open access article distributed under the Creative Commons Attribution License which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Review

Myval Transcatheter Heart Valve: The Future of Transcatheter Valve Replacement and Significance in Current Timeline

Teoman Kilic ^{1,*}, Senol Coskun ², Didar Mirzaminidov ¹, Irem Yilmaz ¹,
Sadanyavuz ³ and Tayfun Sahin ¹

¹ Kocaeli University School of Medicine, Department of Cardiology, Structural Heart Interventions Unit, Kocaeli, Turkey; dmirzaminidov@gmail.com (D.M.); karauzumirem@gmail.com (I.Y.); tayfunsa@yahoo.com (T.S.)

² Kocaeli Health and Technology University, Faculty of Health Sciences, Kocaeli, Turkey; senolcoskun@hotmail.com

³ Kocaeli University School of Medicine, Department of Cardiovascular Surgery, Kocaeli, Turkey; sadanyavuz67@yahoo.com.tr

* Correspondence: kilicteoman@yahoo.com; Tel: (090-262) 3037335; Fax: (090-262) 3038483

Abstract: The Myval is a balloon-expandable transcatheter heart valve (THV) developed by Meril Life Sciences Pvt. Ltd. that has innovative operator-friendly design which aids to improve deliverability and features precise deployment. Various clinical studies demonstrate its effectiveness and safety, making it a promising choice in valvular interventions. Myval has been successfully utilized as a transcatheter aortic valve implantation (TAVI) device in cases with conduction disturbances, bicuspid aortic valve anatomy, non-calcified aortic regurgitation, dysfunctional stenosed right ventricular outflow tract (RVOT) conduits, pulmonary valve replacement, mitral valve replacement, Valve-in-valve and Valve-in-ring implantation procedures. Myval's diverse sizes are also of key importance in complex cases of large and complex annuli anatomy. Further long-term studies are needed to consolidate these results. Its introduction signifies a significant advancement in cardiology, aiming to enhance patient outcomes and quality of life. In the present review, we provide an update on new-generation Myval THVs and review the available clinical data published till date with an emphasis on diverse use in specific clinical scenarios.

Keywords: Myval; Safety; transcatheter aortic valve implantation; transcatheter heart valve; valve-in-valve implantation

1. Introduction

Transcatheter aortic valve implantation (TAVI), pioneered by Cribier in 2002, has become an effective alternative to surgical aortic valve replacement for patients with symptomatic aortic stenosis (AS). [1–3] Complication rates, including mortality, strokes, and vascular problems, have significantly decreased over time owing to technological advancements and expanding indications, all without raising major concerns about the durability of transcatheter heart valves (THVs). [4–6] The current focus lies on a tailored approach, aiming to offer each patient the most suitable THV based on their specific anatomy and ensuring optimal hemodynamic performances after the index procedure and potential for repeatability in patients with increased longevity. [7] The indisputable success of TAVI in patients with severe and high risk quickly altered the treatment of aortic stenosis, prompting studies in patients with intermediate and eventually reduced surgical risks. [8]

Compared to Surgical aortic valve replacement (SAVR), TAVI is linked to a 2-year decrease in all-cause mortality and stroke, regardless of the kind of THV system or baseline surgical risk [hazard ratio (HR) 0.88 [95% confidence interval (CI): 0.78-0.99], $p = 0.030$]. [9] Similarly, in a study done by Blankenberg et al., with severe AS at low or intermediate surgical risk patients; in terms of all-cause mortality or stroke at one year, TAVI was non-inferior to SAVR; the Kaplan-Meier estimate of the primary outcome at one year was 5.4% vs. 10.0% (HR for death or stroke: 0.53; 95% CI, 0.35-0.79;

noninferiority $p < 0.001$). [10] In another nationwide real-world data analysis in Korea, TAVI with current-generation devices showed significantly lower 1-year mortality compared to SAVR in severe AS patients. TAVI was associated with reduced 1-year mortality (HR: 0.55; 95% CI: 0.42–0.70; $p < 0.001$). [11]

Two major types of TAVR are available in the current market: balloon-expandable valves (BEVs) and self-expanding valves (SEVs). In the study done by Senguttuvan et al., data from 6 studies with 2,935 patients (BEV: 1,439 and SEV: 1496) was assessed. The study demonstrated that when compared to SEV, BEV is related with lower risk of all-cause mortality (2.2% vs. 4.5%; RR: 0.51; 95% CI: 0.31–0.82; $p < 0.006$) and cardiovascular mortality (2.5% vs. 4.3%; RR: 0.54; 95% CI: 0.32–0.90; $p = 0.01$) at 30 days. Implantation of >1 valve per procedure (0.78% vs. 5.11%; RR: 0.15; 95% CI: 0.07–0.31; $p < 0.00001$), and moderate/severe aortic regurgitation (AR)/paravalvular leak (PVL) (2.5% vs. 9.01%; RR: 0.3; 95% CI: 0.17–0.48; $p < 0.00001$) were lower in the BEV group. [12] In another recent propensity-matched analysis by Van Belle et al., the first coprimary outcome incidence was higher with SEV group (19.8%) compared with BEV group (11.9%; RR: 1.68 [95% CI, 1.46–1.91]; $p < 0.0001$). SEV group had higher $\geq$ moderate paravalvular regurgitation (15.5% vs. 8.3%; RR: 1.90 [95% CI, 1.63–2.22]; $p < 0.0001$) and in-hospital mortality (5.6% vs. 4.2%; RR: 1.34 [95% CI, 1.07–1.66]; $p = 0.01$). All-cause mortality occurred in 899 patients in SEV group (2-year mortality, 29.8%) and in 801 patients treated with BEV group (2-year mortality, 26.6%; HR: 1.17 [95% CI, 1.06–1.29]; $p = 0.003$). [13]

Meril Lifesciences Pvt. Ltd has developed the Myval, a new-generation BE THV that features innovative operator-friendly design that enhance deliverability and enable precise deployment. In 2018, Myval was approved by the Central Drugs Standard Control Organization (CDSCO) of India, and the European Economic Area granted it a CE mark in 2019. In the present review, we provide an update on new-generation Myval THVs and review available clinical data with an emphasis on diverse use in specific clinical scenarios.

2. Myval Transcatheter Heart Valve System

The Myval consists of MP35N-Cobalt alloy-framed hexagons, configured in a hybrid honeycomb structure. The structure consists of open cells (53%) at the aortic end and closed cells (47%) at the ventricular end, which provide a greater annular radial force. [14] The alternative dark/light band-like pattern produced on crimping serves as reference markers for locating and deploying THV over the native annulus. A polyethylene terephthalate (PET) sealing cuff encases the lower 'closed cell' section of the valve frame externally to reduce PVL. Currently, Myval has following sizes: conventional sizes (20 mm, 23 mm, 26 mm and 29 mm), intermediate sizes (21.5 mm, 24.5 mm and 27.5 mm) and extra-large sizes (30.5 mm and 32 mm). This enables clinicians to select the most optimal valve size for different native annulus shapes. Navigator THV delivery system (Meril Life Sciences Pvt. Ltd., India) is a specialized high-flex, over-the-wire balloon catheter delivery system designed for the administration of Myval. The distal end of this system can be flexed beyond 180 degrees while traversing the native valve and the aortic arch. At the distal end of the delivery system, a shallow, low-profile zone is formed by a balloon with two internal counter-opposing soft stoppers where the Myval THV is directly crimped. The procedure is safer, simpler, and more intuitive with the "deliver and implant" function considering there is no covering sheath, implying the stoppers restrict the valve from dislodging during delivery. The dogbone-shaped balloon's proximal and distal internal inflation ports stabilize the valve during inflation and deployment. The pre-mounted THV can pass through an expanding hydrophilic Python introducer sheath (Meril Life Sciences Pvt. Ltd., India) with an internal diameter of 14 Fr, which expands temporarily to accommodate all sizes of crimped Myval. [14] The sheath design allows for complete valve retrieval from the patient in case the operator is not able to deploy the valve. Before Myval is deployed, the operator may choose to perform a balloon valvuloplasty on the native valve.

Myval is then supplied across the native annulus, and the valve is precisely positioned using the dark and light bands as reference markers, with the second distal dense band aligned with the annular plane. Post-implantation aorto-ventricular depth of 80:20 or 90:10 relative to the annulus will be attained. [15]

Myval Octacor

Myval Octacor THV is the new iteration of the BE Myval THV series. Compared to the previous Myval version, the new device design contains an extra two rows of similar octagonal [16]. In order to reduce the occurrence of PVL, oversizing BE THVs has been described as possible and advised within safe bounds. The median oversizing ratio, as determined by Myval Octacor, was 8.2%, falling within the permitted range of less than 10% [17]. The propensity for PVL is minimized up to 50% of the frame height due to the external skirt in Myval Octacor THV. A landing zone marker towards the ventricular end of the Navigator Inception THV delivery system facilitates precise positioning of Myval Octacor THV at the annulus [18]. Among BE valves, the Myval Octacor stands out as the only one equipped with a technique for commissural alignment [18]. Severe commissural misalignment can hinder coronary flow and access to the coronary ostia after TAVR and redo-TAVR, as well as cause early valve degradation. The proposed OctaAlign technique is easy to practice, doesn't require additional hardware or imaging software, is predictive and replicable, and ensures minimal commissural misalignment. Preliminary experience showed good results in the first 30 cases [19].

The next-generation Myval Octacor THV was evaluated by Jose et.al [16] for safety and effectiveness in 123 patients with severe symptomatic AS across 16 Indian centers. The study demonstrated early safety and effectiveness of Myval Octacor THV in patients with severe AS. The rate of PPI was acceptable, but some of the patients who required PPI had pre-existing conduction disturbances due to complete heart block, left bundle branch block (LBBB), right bundle branch block (RBBB), and atrial fibrillation.

The study by Elkoumy A et al. is the first of its kind to report the post-TAVI residual aortic regurgitation (AR) after real-world implantation of the newly designed BE Myval Octacor THV system and AR analyzed by validated quantitative video densitometry [17]. The study findings demonstrated a reduction in moderate or more AR, with a significant shift from mild to none or trace. Based on the qLVOT-AR results, Myval Octacor THV exhibited a significant reduction in post-TAVI AR, comparable to the best new THV generations (either SE or BE) analyzed using the same technology [20]. The median depth of deployment was minimal (4.1 mm), but with a non-significant association between implantation depth and AR severity [17].

3. Pre-Clinical Evaluation of Myval

The Myval THV development began in 2015; fatigue testing of 200 million cycles (equivalent to 5 years of bioprosthetic life in a patient) as per International Organization for Standardization (ISO) 5840-1:2021 and ISO 5840-3:2021 guidelines was performed. The valves have been tested to 400 million cycles (10 years of usage) and 600 million cycles (15 years of use), with further favorable findings. Additionally, no device-related mortality was seen in animal studies during implantation of Myval THV in a sheep (ovine) model using the innovative technique of external banding at ascending aorta to simulate calcification and deployment of Myval THV (either 20 or 21.5 mm) using a transcarotid TAVI approach [21]. Eleven Myval THVs were implanted via carotid approach. In total, 2 procedure-related deaths and premature deaths each were reported. There was no substantial regurgitation, calcification, thrombi, or vegetation in any of the 7 valves that had finished follow-up at 6 months. An ejection fraction of $53.3 \pm 6\%$ and a mean pressure gradient of 21.9 ± 11 mm Hg were recorded. The biocompatibility and hemodynamic performance of Myval THV were optimal [21].

4. MyVal-1 First-in-Human Study [14]

According to the guidelines set forth by Indian regulatory authorities, this prospective, multicenter, single-arm, open-label study assessed the safety and efficacy of Myval THV in 30 Indian patients who had severe symptomatic native AS and an ejection fraction $\geq 20\%$ were either high- or intermediate-risk for SAVR (CTRI/2016/11/007512) [14]. Survival at 12-month follow-up was the primary safety endpoint. The efficacy endpoints included improvement in effective orifice area (EOA) at echocardiography, the New York Heart Association (NYHA) functional classification, quality of life as determined by the Kansas City Cardiomyopathy Questionnaire (KCCQ), a 6-minute

walk test from baseline, and freedom from major adverse cardiac, cerebrovascular and renal events (MACCRE) at 12-month follow-up. Post-procedure clinical echocardiography was performed at 1-month, 6-month and 12-month. Overall, the mean age of all patients was 75.5 ± 6.7 years. The mean STS Risk score was 6.4 ± 1.8 and 70% of patients were in NYHA functional class III/IV. Femoral access route was utilized in all procedures. Complete 100% Device success was observed. Cumulative all-cause mortality at 1, 6 and 12 months was 3.3%, 6.7% and 13.3%, respectively. Major vascular complications were reported in 2 patients (6.7%) and non-disabling stroke in 1 patient. Post-procedure, the EOA improved from 0.6 ± 0.2 cm² to 1.7 ± 0.3 cm² and the mean aortic valve gradient improved from 47.4 ± 8.8 mmHg to 8.0 ± 2.7 mmHg, these were sustained at 12 months. All patients had markedly enhanced quality of life and were in NYHA class I/II. More than a mild paravalvular leak was reported in no cases. No patient required a permanent pacemaker.

5. Early Clinical and Hemodynamic Outcomes of Myval in Comparison to Other THVs

In a retrospective study by Kawashima et al. utilizing core lab analysis of quantitative video densitometric aortography, angiographic aortic regurgitation (AR) after TAVR was compared among three BEVs – Myval (n=108), Sapien 3 (n=397) and XT (n=239).[22] Myval THV had the lowest moderate/ severe quantitative AR (2.8%) compared to Sapien 3 THV (8.3%) and Sapien XT THV (10.9%). The authors credit this to the external skirt design lowering PVL as well as the availability of diverse intermediate and extra-large sizes, which eliminates the need for hazardous over- and undersizing and results in a more precise and optimal match to the native annulus. Another retrospective analysis of 1,115 patients' Myval implantation revealed that 42% of patients in modern real-world practice adopted intermediate Myval sizes, therefore addressing operators' unmet demands for a better calibrated THV sizing.[23]

Blinded echocardiographic investigation by Delgado-Arana et al. in 2022 demonstrated that Myval BEV was safe, with a low rate of PPI and acceptable residual gradients and PVL rate. In the study, they compared a matched population of patients treated with Myval to patients treated with Sapien 3 (n=103 each).[24] Baseline characteristics were similar. Procedural success rate (Myval: 93.2%, Sapien-3: 94.2%; $p = 0.219$), 30-day mortality (Myval: 0.97%, Sapien-3: 2.9%; $p = 0.625$), clinical efficacy (4.9% vs. 12.6%, $p = 0.057$) and early safety (12.6 vs. 4.9%, $p = 0.096$) were comparable. In addition, in contrast to the Sapien 3 group, the Myval group required fewer PPIs (5.8% vs. 15.5%, $p = 0.02$) and had considerably lower mean gradients ($p < 0.001$). No significant differences were found in terms of $\geq$ moderate aortic regurgitation (0% for Myval, 1% for Sapien-3, $p = 0.314$). Investigators explained this by remarking that in almost 45% of the patients, intermediate Myval sizes were used, which may have produced a more appropriate fit.

Recently, a retrospective analysis of 166 consecutive patients undergoing TAVR with either Myval (n=58) or Evolut R SEV (n=108) was done in the EVAL registry by Barki et al.[25] Primary objectives encompass evaluation of clinical efficacy (freedom from all-cause mortality, stroke, and cardiovascular hospitalization), echocardiographic performance and PPI rates comparing the two THVs.

The Myval group showed significantly higher early device success in comparison to Evolut R group (94.8% vs. 83.3%, $p = 0.048$). However, at 30 days and at 6 months, a significantly lower incidence of moderate or more paravalvular leak (6.9% vs. 19.8%, $p = 0.039$) and PPI (11% vs. 27.5%, $p = 0.02$) was observed in the Myval group. The all-cause mortality and disabling stroke was comparable in both groups.

A retrospective, single-center, propensity matched analysis (91 pairs) of Myval BE vs. Evolut SE valves revealed no significant difference in the rates of cardiac death (1% vs. 2%, $p = 0.56$), stroke (2% vs. 4%, $p = 0.41$), and myocardial infarction (1% vs. 3%, $p = 0.31$).[26] The Myval group needed significantly less PPI (4% vs. 15%, $p = 0.01$). At 1 year, the stroke rate (7% vs. 5%, $p = 0.76$) and cardiac death (2% vs. 4%, $p = 0.41$) were comparable. Valve hemodynamics in both groups were remarkable, with a low rate of moderate-severe PVL.

The implantation of Myval BE was associated with improved valve hemodynamics, absence of moderate to severe PVL and good safety outcomes at 6-month follow-up. In 2023, in a study done by

Halim et al., 120 consecutive patients who underwent TAVI with the Myval BEV were enrolled and clinical outcomes were evaluated at 30-days and 6-months using VARC-2 criteria. [27] An intermediate valve size was elected in 51% of the patients. Cardiac death and all-cause death were reported in 0.8% and 5.8% of the patients, respectively, at 6-month follow-up. Periprocedural stroke and need for PPI were seen in 3.3% of the patients each. There were no access-site-related vascular and bleeding complications. Improved valve hemodynamics and no moderate to severe PVL were reported at 30 days.

Myval has also been successfully used in a failed sutureless Perceval bioprosthesis. [28]

6. Myval Intermediate Follow-Up Outcomes

The SAPPHERE prospective registry was conducted in two Italian centers between May 2020 and December 2020. The initial 100 patients (mean age 80.7 ± 7.7 ; STS $4.3 \pm 3.3\%$) undergoing TAVR for severe AS were included. [29] Procedural and clinical outcomes were in alignment with VARC-3 criteria. Successful transfemoral implantation of Myval THV was performed with 100% technical success and 99% device success. Vascular access complications were minor and managed by compression/balloon inflation. There were no instances of coronary occlusion and annular dissection or annular rupture; 5% of patients needed an in-hospital PPI. At one year, the rates of overall and cardiovascular mortality were 8% (CI 5%–7%) and 5% (CI 2%–5%), respectively; at two years, they were 12% (CI 9%–14%) and 7% (CI 6–9%). PPI was required by 9 % of the patients within 12 months, and no further PPI cases occurred afterwards. Between discharge and the 2-year follow-up, there were no myocardial infarction, renal failure, or cerebrovascular events. While there were no instances of structural valve deterioration, there was a persistent improvement in echocardiographic parameters. The Myval THV showed a promising safety/efficacy profile at 2-year follow-up.

Similar results were observed in a 2-year follow-up study by Moscarella et al. The Myval compared to the Evolut R showed better clinical efficacy (86% vs. 66%, HR: 2.62, 95% CI 2.2–5.1; $p = 0.006$), with fewer cardiac hospitalizations (3.4% vs. 13.9%, $p = 0.03$). [30] No significant differences in cardiovascular mortality, all-cause mortality, or stroke rates were observed. The proportion of patients with $\geq$ moderate PVL was significantly less in the BE Myval (4% vs. 22%, $p = 0.008$). The mean transvalvular gradient was significantly higher in the SE group compared to the BE group (9.5 ± 4.3 vs. 6.9 ± 2.2 mmHg, $p < 0.001$).

In a recent multi-center, registry-based, observational study conducted by Kilic et al., 1-year and 2-year follow-up post-TAVI with Myval implantation was conducted in 207 consecutive degenerative severe AS patients. [31] Clinical and procedural outcomes were defined in alignment with VARC-3 criteria. Technical success was observed in 99% (204 patients), device success was observed in 91% (189 patients), early safety was observed in 78% (161 patients) and clinical efficacy was observed in 79% (163 patients). The death rate at 30-day was 7.7%; cardiovascular reasons were responsible for 3.4% of these deaths. At 1-year follow-up, all-cause and cardiovascular mortality rates were 9.7% and 4.3% and at 2-year follow-up, 17.4% and 9.7%, respectively. Incidence of $\geq$ moderate PVL at 30 days, 1-year and 2-year of follow-up were 3.4%, 4.3% and 4.8%. A total of 11.1% of patients required a PPI at 30 days after implantation, while the cumulative rate of PPI at 2 years was 12.1%.

These favorable clinical and hemodynamic outcomes of Myval, which have been attributed to its unique design and intermediate valve sizes, are being studied in two current prospective, large, randomized trials: the LANDMARK trial (non-inferiority trial over contemporary THVs – Sapien and Evolut series) and the COMPARE-TAVI trial.

7. The LANDMARK Trial

The LANDMARK trial was designed as a prospective, randomized, multinational, multicenter, open-label, non-inferiority trial ongoing with 768 patients randomized (1:1) to receive either Myval ($n=384$) or contemporary THV ($n=384$) – either from the Sapien THV series ($n=192$) or Evolut THV series ($n=192$). [32] The primary combined safety and effectiveness endpoint at 30 days was a composite of VARC-3 defined endpoints: all-cause mortality, all stroke, bleeding (VARC type 3 and

4), acute kidney injury (stages 2, 3, and 4), major vascular complications, moderate or severe prosthetic valve regurgitation, and conduction system disturbances resulting in a new PPI.

The LANDMARK trial proved that Myval THV series was non-inferior to Contemporary (Sapien THVs and Evolut THVs) THV series at the 30-day follow-up in terms of primary composite endpoint (Primary endpoint rate: 25% vs. 27%; Risk difference: -2.3% (NA to 3.8); $P_{\text{non-inferiority}} < 0.0001$).

The median age and STS score of patients were comparable. In the Myval arm, approximately 48% of patients were implanted with intermediate valve sizes (21.5, 24.5 and 27.5 mm). Post-dilatation rate was significantly higher in Contemporary valve group (21% vs 10%; $p < 0.0001$). Contemporary group had higher rates of RF > 17% in final aortography (6% vs. 2%, $p = 0.025$). The mean pressure gradient and effective orifice area significantly improved from baseline to 30-days in both arms. The technical and device success was also comparable between Myval and contemporary valves [32].

8. Diverse Use of Myval THV in Specific Clinical Scenarios.

Myval THV has been used with reassuring safety and efficacy for a variety of indications, including calcific bicuspid aortic valve stenosis, valve-in-valve for degenerated bio-prosthetic surgical valves in aortic and mitral positions and dysfunctional stenosed right ventricular tract conduits.

Myval and Conduction Disturbances

The Myval group had the lowest rate of permanent pacemaker implantation (7.4%), as reported by Santos-Martinez et al. while analyzing conduction disturbances in 1,131 consecutive patients of the Academic European registry who underwent TAVR with any of the six THVs – Myval, Evolut, Sapien 3, Accurate, Portico and Allegra.[33] Similar rates were observed amongst Sapien-3 (13.4%) and Accurate (9.1%). However, Evolut, Portico, and Allegra demonstrated significantly higher rates (18.5%, $p = 0.003$; 29.5%, $p < 0.001$ and 22%, $p = 0.001$, respectively).

Myval in Low-Risk AS Patients

García-Gómez et al. conducted a retrospective study wherein they observed 100 patients who underwent TAVR using Myval at nine European centers and were at low risk for SAVR. These patients had low predicted operative mortality risk based on scores from the European System for Cardiac operative Risk Evaluation (EuroSCORE-II) and the Society of Thoracic Surgeons (STS).[34] Intermediate sizes were used in 39% cases. Procedural success of 99% was achieved. There were no cases of annulus rupture, valve embolization, coronary occlusion, or procedural death. No deaths were reported. The PPI rate was 8%. At 30-day follow-up, aortic valve area (0.7 ± 0.2 vs. 2.1 ± 0.6 cm²) and mean aortic valve gradient (43.4 ± 11.1 vs. 9.0 ± 3.7 mmHg) improved significantly ($p < 0.001$). Moderate aortic regurgitation occurred in 4%. Endpoints of early safety and clinical efficacy were 3 and 1%, respectively.

Myval in Bicuspid Aortic Valve Severe Stenosis

Nearly 50% of candidates for AVR have Bicuspid aortic valve (BAV).[35] TAVR with the Myval THV in selected BAV anatomy was associated with favorable 1-year hemodynamic and clinical outcomes in a multicenter real-world experience in 62 patients as reported by Elkoumy et al. [36] All-cause mortality was reported in 11.3%, cardiovascular hospitalization in 10.6%, all-stroke in 3.2%, permanent pacemaker implantation in 8.3%, and myocardial infarction in 1.6% patients. Moderate AR was reported in only 2% while mild AR in 27%. Moderate (Stage II) hemodynamic deterioration was seen in 3 (6.4%), and severe (Stage III) hemodynamic deterioration in 1 (2.1%) cases.

Amat-Santos et al. in 2023 published The TRITON study, a multicenter registry of patients with severe BAV stenosis treated with BE THV (Myval and SAPIEN 3 Ultra, S3U) or SE THV: Evolut PRO+ (EP+).[37] A total of 360 patients (age 76.6 ± 7.6 years, 71.9% males) were enrolled: Myval (122-33.9%), S3U (129-35.8%), and EP+ (109-30.3%). TriMatch analysis was done in order to reduce the influence of baseline variations. The 30-day device success was the study's primary goal, while the individual

and composite early safety components at 30 days were its secondary endpoints. The STS score average was $3.6 \pm 1.9\%$. Device success at 30 days was higher with Myval at 100%, as compared to S3U (87.5%) and EP+ (81.3%). In patients with BAV stenosis considered unfit for surgery, Myval, S3U, and EP+ exhibited comparable safety profiles; however, BE Myval demonstrated superior gradients compared to S3U, and both BE devices presented lower residual AR than EP+. This indicates that, when accounting for patient-specific risks, any of these devices may be chosen for optimal outcomes. Aortic dissection, annulus rupture, coronary artery blockage, and procedure mortality were not observed in any instances. This overall difference was mostly caused by S3U's higher residual aortic gradients and EP+'s larger $\geq$ moderate aortic re-gurgitation (AR). The unadjusted pacemaker insertion rate showed no discernible variations.

Myval Balloon-Expandable Valve for Non-Calcified Aortic Regurgitation

The results of a recent meta-analysis of 11 trials, which included 911 patients receiving TAVR for NCAR, showed that the device success rate was 80.4%, that 7.4% of patients had $\geq$ moderate aortic regurgitation (AR), and that the 30-day mortality rate was 9.5%, with up to 3% of patients needing conversion to open surgery.[38] These rates compare unfavorably with the results of TAVR in aortic stenosis (AS). The Trilogy TAVR system (Jena valve Technology), a specially designed device for non-calcified aortic regurgitation (NCAR), does not yet support annuli with diameters greater than 27 mm.[39,40] The Myval balloon-expandable TAVR device (Meril Life Sciences Pvt. Ltd.) offers the potential advantage of covering the largest range of annular areas (up to 840 mm² at nominal inflation volume, 32.7 mm diameter). TAVR in NCAR is an off-label procedure.

In another multicenter, observational study, 113 consecutive patients with symptomatic severe NCAR undergoing TAVR with the Myval device were enrolled.[41] The mean STS score was $2.7 \pm 1.7\%$. The mean EuroSCORE II was $3.48 \pm 2.7\%$. The mean annular area was 638.6 ± 106.0 mm², 59.3% of patients had aortic root dilatation, and 7.1% had bicuspid valves. The indicated range for extra-large sizes was surpassed in 2.6% of cases, and an additional volume (median 4 cc, up to 9 cc) was added in 92% of cases. In 95 patients (84.1%) the XXL size was used, with a mean oversizing of $17.9 \pm 11.0\%$. Technical success rate was 94.7%. Moreover, 8.9% residual $\geq$ moderate aortic regurgitation rate and a 22.2% pacemaker rate was reported. There were no cases of annular rupture, cardiac tamponade, or aortic dissection. However, in 4 patients (3.5%) valve embolization occurred (1 antegrade and 3 ventricular); all had a tapered left ventricle outflow tract ($p = 0.007$). Mortality at 30 days and 1 year was 5.3% and 9.7%, respectively. Better survival was linked to technical success (97.1% vs. 72.7%; $p = 0.012$), and valve embolization was the primary cause of death ($p = 0.047$). For certain non-operable NCAR patients, Myval was a viable and safe choice that showed good midterm results and no effect of oversizing on device longevity.

Myval Sizing Using Annulus Perimeter

Myval BE valve perimeter sizing results in good clinical outcomes, minimal PPI, and no significant PVL, as well as a major utilization of bigger valve sizes. With minimal PPI and no appreciable PVL, perimeter sizing with the Myval BE valve results in a major utilization of larger valve sizes and positive clinical outcomes. In a prospective single-center study, Halim et al. assessed 60 patients with severe aortic stenosis who had treatment with the Myval BE valve in a prospective single-center trial. [42] A restricted oversizing of $3.7\% \pm 1.3\%$ in relation to the annulus perimeter was employed while using perimeter sizing. Compared to the valve size determined by area sizing, a larger valve size was implanted in 33.3% of the patients. Clinical results were assessed 30 days and 1 year after TAVR. At 30 days, 2% and 3% of the patients, respectively, required a PPI and had a stroke. No cardiac death and moderate-severe PVL were reported at 30 days; however, at 1-year, cardiac death and stroke were observed in 3% and 8% of the patients, respectively.

Myval for Dysfunctional Stenosed RVOT Conduits

Transcatheter pulmonary valve implantation (TPVI) is a surgical alternative for the repair of faulty right ventricular outflow tract conduits in patients who have already undergone surgery. In a study conducted by Sivaprakasam et al, before the implantation of Myval in patients with stenosed dysfunctional conduits from the right ventricle to pulmonary artery (RV-PA), pre-stenting after initial computed tomography and balloon interrogation was done. [43] Size of Myval was selected based on the pre-stent's final diameter. With a median age of 26 years, 7 patients had stenosed RV-PA conduits implanted 5–17 years ago for tetralogy of Fallot (3), after a Ross surgery (2), pulmonary stenosis correction (1), and after PA debanding (1). Pre-stenting reduced the gradient from 87.3 ± 31.7 mmHg to 12.7 ± 6.4 mmHg and increased the conduit diameter from 9.3 ± 2.8 mm to 20.8 ± 1.1 mm. There were no adverse effects associated with the valve, despite the fact that one patient required a second valve-in-valve implantation. The early results of TPVI with Myval THV in pre-stented conduits are encouraging, since all patients had procedural success and the mid-term results were acceptable.

Houeiجه et al. studied a case of a patient who had surgical fallot repair with chronic heart failure.[44] Investigations found severe biventricular dysfunction and enlargement due to chronic pulmonary regurgitation. The RVOT was tortuous and large with a diameter of 35 mm. Percutaneous pulmonary valve implantation (PPVI) with 32 mm Myval valve over-sized to 35 mm, was performed post a challenging presenting, which demonstrated a favorable outcome.

TAVI for AR in Patients with LVAD

In the first year following implantation with a continuous-flow left ventricular assist device (LVAD), 25% to 30% of patients experience aortic regurgitation (AR), which is increasingly being identified as a contributing factor to the return of symptomatic heart failure (HF).[45] It has been suggested that TAVR, often with a self-expanding prosthesis, is a viable choice in this situation. Prosthesis migration and paravalvular leaks can be prevented by ensuring appropriate prosthesis oversizing in the absence of valvular calcification. The size of the existing self-expanding prosthesis might prove insufficient for aortic annulus anatomy, requiring a significant oversize in order to fit without calcification. The first case of a patient with LVAD-related aortic regurgitation receiving a 32 mm balloon expandable Myval prosthesis was documented by Ancona et al.[46] The study concluded that a large balloon-expandable prosthesis can be considered when a significant oversize is needed.

Myval via Trans-Carotid Access and Trans-Axillary Route in Patients with PVD

Recent research indicates that 10% to 15% of individuals are still not suitable candidates for transfemoral access. Trans-subclavian-axillary or transcarotid access, as opposed to transapical and direct aortic access, has become more prevalent in patients with inappropriate femoral routes. [47] Bypassing the difficulties of the aorta-iliofemoral arteries, the transcarotid route provides a relatively straight conduit from the carotid artery to the aortic valve. Transcarotid TAVI (TC-TAVI) with a novel balloon-expandable Myval transcatheter heart valve (THV) system in patients with a prohibitive abdominal aortic disease. Keleş et al. and Ayhan et al. published the paper on the first trans-axillary artery route experience with Myval implantation in Turkey.[48] [49] No short-term complications via carotid artery access were reported.

ViV with Myval THV

The transcatheter ViV technique is now considered the first-line therapy for failed BHV in patients deemed unsuitable for conventional redo surgery. Despite being effective and safe, ViV procedure has been associated with more challenges compared to TAVR.[50] Ielasi et al. published a study of 4 patients who underwent aortic and 1 who underwent mitral ViV implantation.[50] Device success was achieved in all the five presented cases. ViV in a stentless full root bioprosthesis is a risk factor for early (ECO) and delayed coronary obstruction (DCO). [51] Recent evidences demonstrate that ViV procedures with a BE-THV, compared to self-expanding ones, are associated with a lower

DCO risk when coronary protection is managed by stent implantation compared to “wire-only” strategy.

Despite a significant surgical risk, transcatheter ViV/ViR implantation for failing left side cardiac bioprosthesis can be successfully carried out using Myval THV with a high success rate, low early and mid-term mortality and morbidity. This was demonstrated in a study done by Moscarella et al. Myval THV was used for the transcatheter implantation of aortic ViV and mitral ViV/ViR in 97 consecutive patients who had symptomatic, severe aortic (n = 33) and mitral (n = 64) BHVs/ring dysfunction. [52] Ninety-five patients (98%) had technical success. Both aortic and mitral ViV/ViR implantation resulted in a considerable decrease in prosthetic transvalvular pressure gradients and an increase in valve areas after 30 days. At 15 months, the overall survival rate was 92%.

Transcatheter Mitral Valve-in-Valve Implantation (ViV) with Myval THV

Transseptal ViV mitral implantation (TMViV) using BE Myval THV has proven to be a safe and practical means of preventing recurrent surgery in high-risk patients with bioprosthesis degeneration. Transseptal and transapical approaches have been used for replacement for degenerated THVs using TMViV. has been described by both.[53] Blasco-Turrión et al. in 2022, conducted a multicenter retrospective study of 11 high-risk surgical patients across 5 institutions with mitral bioprosthesis degeneration undergoing transcatheter ViV implantation with Myval device.[54] The peak and mean transvalvular gradients were 27 ± 5 mmHg and 14.7 ± 2.3 mmHg, respectively. The predicted neo-left ventricular outflow tract (neo-LVOT) area was 183.4 ± 56 mm² (range: 171 to 221 mm²). The procedures were performed via transfemoral access in all cases. Overall, 100% technical success was achieved, with no significant residual mitral stenosis (peak 7.2 ± 2.7 and mean gradient 3.4 ± 1.7 mmHg) and no complications during the procedure. There were no cases of LVOT obstruction, migration, or paravalvular leak. At a 6-month follow-up, there was one incidence of inadequate anticoagulation with an elevation in transmitral gradients (mean 15 mmHg) that reversed following anticoagulation adjustment, but there were no other noteworthy occurrences.

Similar results were demonstrated in a retrospective study done by Sankardas et al..[55] TMViV replacement with Myval was safely performed with high technical success, and low 30-day and 1-year mortality. In this study, 20 symptomatic patients with surgical bioprosthetic mitral valve failure with New York Heart Association (NYHA) class III-IV symptoms, despite optimal medical therapy and high or very high risk for redo surgery, were assigned to TMViV. In 60% of patients, a combination of stenosis and regurgitation was the cause of failure. In all cases, there was technical success. After the operation, the mean gradient was 4.6 ± 2.7 , and after 30 days, it was 6.3 ± 2.1 . There were no discernible left ventricular outflow tract obstructions or substantial valvular or paravalvular leakage. At one year, 10% of deaths were due to all causes, and all survivors belonged to NYHA classes I or II.

Myval in TR (ViV)

Valve dysfunction/degeneration after tricuspid valve replacement or repair utilizing annuloplasty ring is common.[56] It increases morbidity and mortality of the patients. Currently, to overcome this dilemma, the transcatheter tricuspid valve-in-valve (TViV) and valve-in-ring (TViR) implantation procedures have emerged as important alternatives for high-risk patients. Ayhan et al. published the first of its kind case report demonstrating that the novel balloon-expandable Myval THV system is suitable for transcatheter TViR.[48] Recently, Mussayev et al., demonstrated BE Myval THV to be safe and effective, at par with BE Sapien 3 and SE Evolut R THVs. [57] The case series consist of 5 unique cases of high-risk patients with prior surgeries, with clinically indicated tricuspid ViV procedures. Using the BE Myval THV, transcatheter tricuspid ViV implantation achieved good immediate and one-year clinical results that were safe and feasible. The results of this investigation indicated that, in comparison to other commercially available THVs, the larger range of appropriate THV sizes may be associated with the new BE Myval THV's superior performance. The intermediate sizes, in particular mitigate the risks of both oversize or incomplete ViV “sealing” associated with free wall rupture, significant PVL or premature THV dysfunction.

Myval for Pulmonary Valve Replacement

After surgery for CHDs like Rastelli, Ross, and complete repair of the Tetralogy of Fallot, pulmonary regurgitation and pulmonary stenosis are major causes of morbidity. For the past 20 years, percutaneous pulmonary valve implantation has been used as a less intrusive substitute for surgery.[58] Replacing the pulmonary valve in individuals with congenital heart conditions and heart failure presents significant challenges. The Myval® delivery system offers significant advantages for percutaneous pulmonary valve implantation.[59] With a 14-F introducer sheath for the 29-mm valve, it allows easier advancement through the right ventricular outflow tract compared to the 16-F sheath needed for the 29-mm Edwards S3 valve and the 22-F sheath for the 24-mm Melody valve. Its crimping on the balloon catheter enhances deployment in complex anatomical settings. The option of a 32-mm valve is particularly beneficial for larger right ventricular outflow tracts, broadening the patient eligibility for treatment. The Myval® valve's unique "dog bone" configuration during inflation aids precise positioning, especially in valve-in-valve procedures. Follow-up results show functional implanted valves with no paravalvular leakage, likely due to the external polyethylene terephthalate skirt that reduces this risk. Overall, this study highlights Myval® as a clinically feasible, safe, and effective option for pulmonary interventions, with further follow-up needed for long-term efficacy assessment.

Odemis & Yenidogan published a case series of nine patients, aged 8 to 34 years, who underwent Myval implantation in the pulmonary position between June and November 2020.[59] Diagnoses included tetralogy of Fallot and pulmonary stenosis. Stent implantation preceded valve placement, with sizes ranging from 23 mm to 29 mm. No valvular leakage was detected immediately after the procedure. Follow-up evaluations showed competent valve function and no dysrhythmias, with a mean follow-up of 9.8 months.

9. Importance of Extra-Large Size of Myval THV

Sathananthan et al. in their study, reported mechanical valve dysfunction in some Sapien 3 prostheses after bench-testing overexpansion.[60] Overexpansion was examined in a limited number of prosthesis with up to 3 mL of extra volume in this bench test. The authors draw the conclusion that severe overexpansion may be linked to acute leaflet failure, decreased durability, and compromised hydrodynamic performance. The ex vivo studies escalated apprehension of long-term durability of over-expanded THV with regard to damage of tissue in the bioleaflets. Sellers et al. performed an ex vivo study to determine the impact of overexpansion on leaflet ultrastructure across different valve sizes (23, 26, and 29 mm).[61] Leaflet thinning, increased tissue density within the leaflet matrix, and a significant increase in the entropy of fibrillar collagen (on both the aortic and ventricular aspect of the leaflets) were indicators of ultrastructure damage to the leaflets that the authors observed in the overexpanded valves when compared to the nominally expanded control valves. More long-term follow-ups are of key importance for future successful implementation.

The Myval THV series has a vast range of THV sizes (traditional sizes: 20, 23, 26, and 29 mm; intermediate sizes: 21.5, 24.5, and 27.5 mm; and extra-large sizes: 30.5 and 32 mm). The expanded size matrix of the Myval THV especially at the upper range of the portfolio might therefore overcome these concerns in the vast majority of patients. The largest available current standard devices are limited to an annular area of 683 mm² (Sapien 3, Edwards) and annular perimeter of 94.2 mm (Evolut R, Medtronic, USA) by manufacturer's instructions for use. To address the concern of size limitation of the currently available THV portfolio, a wide range of sizes of the device has been developed including extra-large sized Myval THV (30.5 mm and 32 mm). To the best of our knowledge, the 32 mm Myval THV is the largest available aortic THV as it covers annular areas of 700–840 mm². The Myval 32 mm THV is intended for use in aortic annulus areas up to 840 mm².

32 mm Myval for Treatment of AS in Patients with Extremely Large Aortic Annuli in Real-World Scenario: First Global, Multicentre Experience

In a retrospective study by Holzamer et al., data were collected from 10 patients implanted with 32 mm Myval THV, who had AS and very large annular anatomy (mean area 765.5 mm²), 8 centers.[62] VARC-2 device success was achieved in all cases. Mild paravalvular leak was observed in 3 patients and 2 patients required new pacemaker implantation. Three patients had mild paravalvular leaks, and two of them needed replacement pacemaker implantations. Only one patient needed surgical revision because to retroperitoneal bleeding due to contralateral 6 F sheath. There were no complications linked to the device, strokes, or deaths from any cause throughout the 30-day follow-up period. Only 0.27% of patients in a sample of 2219 consecutive TAVR-screened patients from a central European site had anatomy greater than that allowed by the 32 mm Myval device according to use guidelines without off-label overexpansion. Rates were higher for 34 mm Evolut Pro (1.8%) and 29 mm Sapien 3 (2.1%) devices.

Promising preliminary outcomes were observed with the Myval 32 mm prosthesis in a group of patients who had previously been denied TAVR. In order to treat every patient as effectively as possible, it is ideal for all future TAVR systems to support bigger anatomy. The nested XL registry of the LANDMARK study, which is actively recruiting patients, is the first prospectively collected and managed trial cohort that includes individuals with extra-large anatomy. The trial's data should provide some evidence in this area.

XL-Myval 32mm in Large Bicuspid Anatomy

BAV is considered an unfavorable anatomy for TAVR due to its exclusion from randomized trials. The relatively large aortic root architecture, including annulus diameters, that may surpass the size matrix of the currently available commercial TAVR devices, along with the concomitant high calcium burden, fused raphe, and aortic dilatation, is a key challenge within BAV.[63] Elkoumy et al. reported BAV to be safe with promising and acceptable hemodynamic and clinical outcomes, in a case series of three patients with low surgical risk and severe calcific BAV stenosis with large annular dimensions, treated with the novel balloon-expandable (BE) transcatheter Myval-XL 32 mm valve.[64]

Case report of a PVR with 32mm Myval has been reported in native RVOT in a patient with surgically corrected TOF with good result.[65]

10. Conclusions

Compared to the previous generation of balloon-expandable THVs, Myval is a technical development that makes the procedure safer, easier, and perhaps even more successful. The device's efficiency and long-term durability are being compared to contemporary self-expandable and balloon-expandable THV in large prospective randomized trials. If Myval is proven to be long-term non-inferior, it may make valve replacement more accessible and affordable for a far greater number of patients worldwide.

Funding: None to declare

Institutional Review Board Statement: Not applicable

Informed Consent Statement: Not applicable

Data Availability Statement: Not applicable

Acknowledgments: We thank Ms. Vandana Chaudhary and Latheef Kasala for contributing to the literature search and manuscript alignment.

Conflicts of Interest: None to declare

References

1. Cribier, A.; Eltchaninoff, H.; Bash, A.; Borenstein, N.; Tron, C.; Bauer, F.; Derumeaux, G.; Anselme, F.; Laborde, F.; Leon, M.B. Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description. *Circ* **2002**, *106*, 3006–3008, doi:10.1161/01.cir.0000047200.36165.b8.
2. Otto, C.M.; Nishimura, R.A.; Bonow, R.O.; Carabello, B.A.; Erwin, J.P.; Gentile, F.; Jneid, H.; Krieger, E.V.; Mack, M.; McLeod, C.; et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation* **2021**, *143*, e35–e71, doi:10.1161/CIR.0000000000000932.
3. Vahanian, A.; Beyersdorf, F.; Praz, F.; Milojevic, M.; Baldus, S.; Bauersachs, J.; Capodanno, D.; Conradi, L.; De Bonis, M.; De Paulis, R.; et al. 2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease: Developed by the Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Revista Española de Cardiología (English Edition)* **2022**, *75*, 524, doi:10.1016/j.rec.2022.05.006.
4. Mack, M.J.; Leon, M.B.; Thourani, V.H.; Makkar, R.; Kodali, S.K.; Russo, M.; Kapadia, S.R.; Malaisrie, S.C.; Cohen, D.J.; Pibarot, P.; et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *New England Journal of Medicine* **2019**, *380*, 1695–1705, doi:10.1056/NEJMoa1814052.
5. Popma, J.J.; Deeb, G.M.; Yakubov, S.J.; Mumtaz, M.; Gada, H.; O'Hair, D.; Bajwa, T.; Heiser, J.C.; Merhi, W.; Kleiman, N.S.; et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med* **2019**, *380*, 1706–1715, doi:10.1056/NEJMoa1816885.
6. Thyregod, H.G.H.; Steinbrüchel, D.A.; Ihlemann, N.; Nissen, H.; Kjeldsen, B.J.; Petursson, P.; Chang, Y.; Franzen, O.W.; Engström, T.; Clemmensen, P.; et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. *J Am Coll Cardiol* **2015**, *65*, 2184–2194, doi:10.1016/j.jacc.2015.03.014.
7. Akodad, M.; Gall, E. New-Generation Myval Transcatheter Heart Valve in Severe Aortic Stenosis. *The Lancet* **2024**, *403*, 2664–2665, doi:10.1016/S0140-6736(24)00935-8.
8. Hanzel, G.S.; Gersh, B.J. Transcatheter Aortic Valve Replacement in Low-Risk, Young Patients: Natural Expansion or Cause for Concern? *Circulation* **2020**, *142*, 1317–1319, doi:10.1161/CIRCULATIONAHA.120.047874.
9. Gcm, S.; Pavel, O.; Thomas, J. C.; Thomas, M.; Bernard, P.; Fabien, P.; Thomas, P.; Tatjana, P.; Adriani, N.; Georgia, S.; et al. Transcatheter Aortic Valve Implantation vs. Surgical Aortic Valve Replacement for Treatment of Symptomatic Severe Aortic Stenosis: An Updated Meta-Analysis. *European heart journal* **2019**, *40*, doi:10.1093/eurheartj/ehz275.
10. Blankenberg, S.; Seiffert, M.; Vonthein, R.; Baumgartner, H.; Bleiziffer, S.; Borger, M.A.; Choi, Y.-H.; Clemmensen, P.; Cremer, J.; Czerny, M.; et al. Transcatheter or Surgical Treatment of Aortic-Valve Stenosis. *New England Journal of Medicine* **2024**, *390*, 1572–1583, doi:10.1056/NEJMoa2400685.
11. Sa, Y.K.; Hwang, B.-H.; Chung, W.-B.; Lee, K.Y.; Lee, J.; Kang, D.; Ko, Y.-G.; Yu, C.W.; Kim, J.; Choi, S.-H.; et al. Real-World Comparison of Transcatheter Versus Surgical Aortic Valve Replacement in the Era of Current-Generation Devices. *J Clin Med* **2023**, *12*, 571, doi:10.3390/jcm12020571.
12. Senguttuvan, N.B.; Bhatt, H.; Balakrishnan, V.K.; Krishnamoorthy, P.; Goel, S.; Reddy, P.M.K.; Subramanian, V.; Claessen, B.E.; Kumar, A.; Majmundar, M.; et al. The Safety and Efficacy of Balloon-Expandable versus Self-Expanding Trans-Catheter Aortic Valve Replacement in High-Risk Patients with Severe Symptomatic Aortic Stenosis. *Front. Cardiovasc. Med.* **2023**, *10*, doi:10.3389/fcvm.2023.1130354.
13. Van Belle, E.; Vincent, F.; Labreuche, J.; Auffret, V.; Debry, N.; Lefèvre, T.; Eltchaninoff, H.; Manigold, T.; Gilard, M.; Verhoye, J.-P.; et al. Balloon-Expandable Versus Self-Expanding Transcatheter Aortic Valve Replacement. *Circulation* **2020**, *141*, 243–259, doi:10.1161/CIRCULATIONAHA.119.043785.
14. Sharma, S.K.; Rao, R.S.; Chandra, P.; Goel, P.K.; Bharadwaj, P.; Joseph, G.; Jose, J.; Mahajan, A.U.; Mehrotra, S.; Sengottavelu, G.; et al. First-in-Human Evaluation of a Novel Balloon-Expandable Transcatheter Heart Valve in Patients with Severe Symptomatic Native Aortic Stenosis: The MyVal-1 Study. *EuroIntervention* **2020**, *16*, 421–429, doi:10.4244/EIJ-D-19-00413.
15. Seth, A.; Kumar, V.; Singh, V.P.; Kumar, D.; Varma, P.; Rastogi, V. Myval: A Novel Transcatheter Heart Valve for the Treatment of Severe Aortic Stenosis. *Interv Cardiol* **2023**, *18*, e12, doi:10.15420/icr.2020.32.
16. Jose, J.; Mandalay, A.; Cholenahally, M.N.; Khandenahally, R.S.; Budnur, S.C.; Parekh, M.; Rao, R.S.; Seth, A.; Chandra, P.; Kapoor, R.; et al. Safety and Effectiveness of the Novel Myval Octacor Transcatheter Heart Valve in Severe, Symptomatic Aortic Valve Stenosis — A Real-World Indian Experience (The OCTACOR India Study). *Cardiovascular Revascularization Medicine* **2024**, *63*, 1–7, doi:10.1016/j.carrev.2024.01.016.
17. Elkoumy, A.; Jose, J.; Gunasekaran, S.; Kumar, A.; Srinivas, B.C.; Manjunath, C.N.; Ravindranath, K.S.; Parekh, M.; Chandra, P.; Kapoor, R.; et al. Angiographic Quantification of Aortic Regurgitation Following Myval Octacor Implantation; Independent Core Lab Adjudication. *International Journal of Cardiology* **2023**, *382*, 68–75, doi:10.1016/j.ijcard.2023.04.003.

18. Revaiah, P.C.; Tsai, T.-Y.; Tobe, A.; Chandra, P.; Serruys, P.W. 31 NOVEL TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEMS FROM INDIA. *Transcatheter Aortic Valve Implantation*.
19. Revaiah, P.C.; Mandalay, A.; Sengottuvelu, G.; Elkoumy, A.; Elzomor, H.; Abdelshafy, M.; Bhatt, S.; Onuma, Y.; Soliman, O.; Serruys, P.W. CRT-700.47 Commissural/Coronary Alignment With the Novel Myval Octacor THV - The Octa Align Technique. *JACC: Cardiovascular Interventions* **2023**, *16*, S94–S95, doi:10.1016/j.jcin.2023.01.295.
20. Abdelshafy, M.; Serruys, P.W.; Kim, W.-K.; Rück, A.; Wang, R.; Tao, L.; Elkoumy, A.; Elzomor, H.; Garg, S.; Onuma, Y.; et al. Quantitative Angiographic Assessment of Aortic Regurgitation Following 11 TAVR Devices: An Update of a Multicenter Pooled Analysis. *Journal of the Society for Cardiovascular Angiography & Interventions* **2022**, *1*, 100037, doi:10.1016/j.jscai.2022.100037.
21. Buszman, P.P.; Kachel, M.; Ceballos, C.F.; Łukasik, K.; Domaradzki, W.; Pruski, M.; Tellez, A.; Rousselle, S.; Konopko, M.; Glanc, M.; et al. 6-Month Evaluation of a Transcatheter Aortic Valve (Myval) in a Novel Ovine, Supra-Aortic Banding Model. *JACC Basic Transl Sci* **2022**, *7*, 486–495, doi:10.1016/j.jacbs.2022.01.008.
22. Kawashima, H.; Wang, R.; Mylotte, D.; Jagielak, D.; De Marco, F.; Ielasi, A.; Onuma, Y.; Den Heijer, P.; Terkelsen, C.J.; Wijns, W.; et al. Quantitative Angiographic Assessment of Aortic Regurgitation after Transcatheter Aortic Valve Implantation among Three Balloon-Expandable Valves. *Global Heart* **2021**, *16*, 20, doi:10.5334/gh.959.
23. Kawashima, H.; Serruys, P.W.; Mylotte, D.; Rosseel, L.; Amat-Santos, I.J.; Rao, R.S.; Onuma, Y.; Wijns, W.; Abdel-Wahab, M.; Baumbach, A.; et al. Operator Preference and Determinants of Size Selection When Additional Intermediate-Size Aortic Transcatheter Heart Valves Are Made Available. *International Journal of Cardiology* **2021**, *338*, 168–173, doi:10.1016/j.ijcard.2021.06.029.
24. Delgado-Arana, J.R.; Gordillo-Monge, M.X.; Halim, J.; De Marco, F.; Trani, C.; Martin, P.; Infusino, F.; Ancona, M.; den Heijer, P.; Bedogni, F.; et al. Early Clinical and Haemodynamic Matched Comparison of Balloon-Expandable Valves. *Heart* **2022**, *108*, 725–732, doi:10.1136/heartjnl-2021-319349.
25. Barki, M.; Ielasi, A.; Buono, A.; Maliandi, G.; Pellicano, M.; Bande, M.; Casilli, F.; Messina, F.; Uccello, G.; Briguglia, D.; et al. Clinical Comparison of a Novel Balloon-Expandable Versus a Self-Expanding Transcatheter Heart Valve for the Treatment of Patients with Severe Aortic Valve Stenosis: The EVAL Registry. *JCM* **2022**, *11*, 959, doi:10.3390/jcm11040959.
26. Halim, J.; Rooijackers, M.; Den Heijer, P.; El Haddad, M.; Van Den Branden, B.; Vos, J.; Schölzel, B.; Meuwissen, M.; Van Gameren, M.; El Messaoudi, S.; et al. Assessing the Novel Myval Balloon-Expandable Valve with the Evolut Valve: A Propensity-Matched Study. *JCM* **2023**, *12*, 4213, doi:10.3390/jcm12134213.
27. Halim, J.; Den Heijer, P.; Van Den Branden, B.; Meuwissen, M.; Vos, J.; Schölzel, B.; Ijsselmuiden, A. Short-Term Outcome after Transcatheter Aortic Valve Replacement with a Novel Balloon-Expandable Valve. *Neth Heart J* **2023**, *31*, 500–505, doi:10.1007/s12471-022-01738-z.
28. Igor Belluschi First-in-man Valve-in-Valve with the New Balloon-expandable Myval Transcatheter Heart Valve in a Failed Sutureless Perceval Bioprosthesis - Belluschi - 2021 - Journal of Cardiac Surgery - Wiley Online Library Available online: <https://onlinelibrary.wiley.com/doi/10.1111/jocs.15533> (accessed on 17 September 2024).
29. Testa, L.; Criscione, E.; Popolo Rubbio, A.; Squillace, M.; Ielasi, A.; Tespili, M.; Brambilla, N.; Bedogni, F. Safety and Performance Parameters of the Myval Transcatheter Aortic Valve Bioprosthesis: The SAPPHERE Prospective Registry. *Cardiovascular Revascularization Medicine* **2023**, *55*, 22–27, doi:10.1016/j.carrev.2023.04.014.
30. Moscarella, E.; Ielasi, A.; Montonati, C.; Pellegrini, D.; Pellicano, M.; Briguglia, D.; D'Alessandro, V.; Giannini, F.; Gamardella, M.; Medda, M.; et al. Comparing Two-Year Outcomes of Balloon-Expandable Myval and Self-Expanding Evolut R in Severe Aortic Valve Stenosis. *International Journal of Cardiology* **2024**, *400*, doi:10.1016/j.ijcard.2023.131701.
31. Kilic, T.; Ielasi, A.; Ninios, V.; Korkmaz, L.; Panagiotakos, D.; Yerlikaya, G.; Ozderya, A.; Montonati, C.; Tespili, M.; Coskun, S.; et al. Clinical Outcomes of the Myval Transcatheter Heart Valve System in Patients with Severe Aortic Valve Stenosis: A Two-Year Follow-up Observational Study. *Arch Med Sci* **2024**, *20*, 410–419, doi:10.5114/aoms/176937.
32. Baumbach A, van Royen N, Amat-Santos IJ, Hudec M, Bunc M, Ijsselmuiden A, Laanmets P, Unic D, Merkely B, Hermanides RS. LANDMARK comparison of early outcomes of newer-generation Myval transcatheter heart valve series with contemporary valves (Sapien and Evolut) in real-world individuals with severe symptomatic native aortic stenosis: a randomised non-inferiority trial. *Lancet*. 2024 Jun 22;403(10445):2695-2708. doi: 10.1016/S0140-6736(24)00821-3.
33. Santos-Martinez, S.; Halim, J.; Castro-Mejía, A.; Marco, F.D.; Trani, C.; Martin, P.; Infusino, F.; Ancona, M.; Moreno, R.; Heijer, P. den; et al. Myval versus Alternative Balloon- and Self-Expandable Transcatheter Heart Valves: A Central Core Lab Analysis of Conduction Disturbances. *International Journal of Cardiology* **2022**, *351*, 25–31, doi:10.1016/j.ijcard.2021.12.049.
34. García-Gómez, M.; Delgado-Arana, J.R.; Halim, J.; De Marco, F.; Trani, C.; Martin, P.; Won-Keun, K.; Montorfano, M.; Den Heijer, P.; Bedogni, F.; et al. Next-generation Balloon-expandable Myval

- Transcatheter Heart Valve in Low-risk Aortic Stenosis Patients. *Cathet Cardio Intervent* **2022**, *99*, 889–895, doi:10.1002/ccd.29923.
35. Roberts, W.C.; Ko, J.M. Frequency by Decades of Unicuspid, Bicuspid, and Tricuspid Aortic Valves in Adults Having Isolated Aortic Valve Replacement for Aortic Stenosis, With or Without Associated Aortic Regurgitation. *Circulation* **2005**, *111*, 920–925, doi:10.1161/01.CIR.0000155623.48408.C5.
 36. Elkoumy, A.; Jose, J.; Terkelsen, C.J.; Nissen, H.; Gunasekaran, S.; Abdelshafy, M.; Seth, A.; Elzomor, H.; Kumar, S.; Bedogni, F.; et al. One-Year Outcomes after Myval Implantation in Patients with Bicuspid Aortic Valve Stenosis—A Multicentre Real-World Experience. *JCM* **2023**, *12*, 2398, doi:10.3390/jcm12062398.
 37. Amat-Santos, I.J.; García-Gómez, M.; De Marco, F.; Won-Keun, K.; Brito, J.; Halim, J.; Jose, J.; Sengotuelu, G.; Seth, A.; Terkelsen, C.; et al. Latest-Iteration Balloon- and Self-Expandable Transcatheter Valves for Severe Bicuspid Aortic Stenosis: The TRITON Study. *Revista Española de Cardiología (English Edition)* **2023**, *76*, 872–880, doi:10.1016/j.rec.2023.03.002.
 38. Takagi, H.; Hari, Y.; Kawai, N.; Ando, T. Meta-Analysis and Meta-Regression of Transcatheter Aortic Valve Implantation for Pure Native Aortic Regurgitation. *Heart, Lung and Circulation* **2020**, *29*, 729–741, doi:10.1016/j.hlc.2019.04.012.
 39. Hensey, M.; Murdoch, D.J.; Sathananthan, J.; Alenezi, A.; Sathananthan, G.; Moss, R.; Blanke, P.; Leipsic, J.; Wood, D.A.; Cheung, A.; et al. First-in-Human Experience of a New-Generation Transfemoral Transcatheter Aortic Valve for the Treatment of Severe Aortic Regurgitation: The J-Valve Transfemoral System. *EuroIntervention* **2019**, *14*, e1553–e1555, doi:10.4244/eij-d-18-00935.
 40. Wienemann, H.; Elzomor, H.; Kuhn, E.; Sinning, J.-M.; Baldus, S.; Serruys, P.W.; Adam, M. Transcatheter Aortic Valve Implantation of a Novel System for Severe Pure Native Aortic Regurgitation in a Patient with an Ascending Aorta Aneurysm. *EuroIntervention* **2023**, *18*, 1442–1443, doi:10.4244/EIJ-D-22-00747.
 41. Sanchez-Luna, J.P.; Martín, P.; Dager, A.E.; Charry, P.D.; Beltrán, J.R.; Sánchez-Recalde, Á.; Giannini, F.; Gómez-Menchero, A.; Pan, M.; Ielasi, A.; et al. Clinical Outcomes of TAVI with the Myval Balloon-Expandable Valve for Non-Calcified Aortic Regurgitation. *EuroIntervention* **2023**, *19*, 580–588, doi:10.4244/EIJ-D-23-00344.
 42. Halim, J.; Den Heijer, P.; Vos, J.; Schölzel, B.E.; Meuwissen, M.; Van Den Branden, B.; Baumbach, A.; Ijsselmuiden, A.J.J. Balloon-Expandable TAVR Bioprotheses: Area or Perimeter Sizing? A Prospective Pilot Study. *Journal of Interventional Cardiology* **2022**, *2022*, 1–5, doi:10.1155/2022/3139476.
 43. Sivaprakasam, M.C.; Reddy, J.R.V.; Gunasekaran, S.; Sivakumar, K.; Pavithran, S.; Rohitraj, G.R.; Jayranganath, M.; Francis, E. Early Multicenter Experience of a New Balloon Expandable MyVal Transcatheter Heart Valve in Dysfunctional Stenosed Right Ventricular Outflow Tract Conduits. *Ann Pediatr Cardiol* **2021**, *14*, 293–301, doi:10.4103/apc.apc_242_20.
 44. Houeijeh, A.; Sudre, A.; Juthier, F.; Godart, F. Pulmonary Valve Replacement in a Large and Tortuous Right Ventricle Outflow Tract with a 32 Mm Myval Valve under Local Anaesthesia: Challenges and Technical Considerations: A Case Report. *Eur Heart J Case Rep* **2023**, *7*, ydad322, doi:10.1093/ehjcr/ydad322.
 45. Bouabdallaoui, N.; El-Hamamsy, I.; Pham, M.; Giraldeau, G.; Parent, M.-C.; Carrier, M.; Rouleau, J.L.; Ducharme, A. Aortic Regurgitation in Patients with a Left Ventricular Assist Device: A Contemporary Review. *J Heart Lung Transplant* **2018**, *37*, 1289–1297, doi:10.1016/j.healun.2018.07.002.
 46. Ancona, M.B.; Moroni, F.; Romano, V.; Agricola, E.; Esposito, A.; Ajello, S.; De Bonis, M.; Cappelletti, A.M.; Zangrillo, A.; Scandroglio, A.M.; et al. [Transcatheter aortic valve implantation for aortic regurgitation in patients with left ventricular assist device]. *G Ital Cardiol (Rome)* **2021**, *22*, 395–425, doi:10.1714/3578.35633.
 47. Tagliari, A.P.; Saadi, R.P.; Ferrari, E.; Taramasso, M.; Saadi, E.K. The Role of the Axillary Artery as a Second Access Choice in TAVI Procedures. *Braz J Cardiovasc Surg* **2021**, *36*, 237–243, doi:10.21470/1678-9741-2020-0343.
 48. Ayhan, H.; Karaduman, B.D.; Keleş, T.; Uğuz, E.; Boysan, E.; Bozkurt, E. Transcarotid Transcatheter Aortic Valve Implantation with a Novel Balloon Expandable Myval® THV under the Local Anesthesia. *J Geriatr Cardiol* **2022**, *19*, 562–564, doi:10.11909/j.issn.1671-5411.2022.07.006.
 49. Keleş, T.; Özcan Çelebi, Ö.; Uğuz, E.; Balci, K.; Bozkurt, E. Transcatheter Aortic Valve Implantation via the Left Axillary Artery Route in a Patient with a Permanent Pacemaker: The First Transaxillary Artery Route Experience with a Meril's Myval™ Transaortic Valve in Turkey. *Anatol J Cardiol* **2021**, *25*, 517–519, doi:10.5152/AnatolJCardiol.2021.54857.
 50. Ielasi, A.; Buono, A.; Medda, M.; Casilli, F.; Bande, M.; Pellicano, M.; Glauber, M.; Donatelli, F.; Tespili, M. Transcatheter Valve-in-Valve Implantation With a Novel Balloon-Expandable Device in Patients With Bioprosthetic Heart Valve Failure: A Case Series. *Cardiovascular Revascularization Medicine* **2021**, *28*, 98–101, doi:10.1016/j.carrev.2020.11.018.
 51. Ielasi, A.; Buono, A.; Medda, M.; Tespili, M. MyVal and Mini-Chimney Stenting to Prevent Coronary Obstruction During Full Root Stent-Less Aortic Valve-In-Valve Procedure. *Cardiovascular Revascularization Medicine* **2021**, *22*, 122–123, doi:10.1016/j.carrev.2020.03.028.
 52. Moscarella, E.; Ielasi, A.; Mussayev, A.; Montorfano, M.; Mullassari, A.; Martin, P.; Testa, L.; Jose, J.; Ninios, V.; Toutouzas, K.; et al. Transcatheter Valve-in-Valve or Valve-in-Ring Implantation with a Novel Balloon-

- Expandable Device in Patients with Bioprosthetic Left Side Heart Valves Failure: 1-Year Follow-up from a Multicenter Experience. *International Journal of Cardiology* **2023**, 376, 35–45, doi:10.1016/j.ijcard.2023.01.017.
53. Transcatheter Mitral Valve-in-valve Replacement Transeptally Using a Novel Balloon-expandable Device - Drakopoulou - 2022 - Journal of Cardiac Surgery - Wiley Online Library Available online: <https://onlinelibrary.wiley.com/doi/10.1111/jocs.16819> (accessed on 17 September 2024).
 54. Blasco-Turrión, S.; Serrador-Frutos, A.; Jose, J.; Sengotuelu, G.; Seth, A.; Aldana, V.G.; Sánchez-Luna, J.P.; Gonzalez-Gutiérrez, J.C.; García-Gómez, M.; Gómez-Herrero, J.; et al. Transcatheter Mitral Valve-in-Valve Implantation with the Balloon-Expandable Myval Device. *JCM* **2022**, 11, 5210, doi:10.3390/jcm11175210.
 55. Sankardas, M.A.; Subban, V.; Kothandam, S.; Chopra, A.; Kalidoss, L.; Udhayakumar, K.; Sollimuthu, R.; Chidambaram, K.; Anandan, H.; Rao, R.S. Clinical Outcomes Following Transcatheter Mitral Valve-in-Valve Replacement Using a Meril Myval Transcatheter Heart Valve. *Heart, Lung and Circulation* **2024**, 33, 222–229, doi:10.1016/j.hlc.2023.11.011.
 56. Mahboobi, S.K.; Ahmed, A.A. Tricuspid Valve Repair. In *StatPearls*; StatPearls Publishing: Treasure Island (FL), 2024.
 57. Mussayev, A.; Alimbayev, S.; Tanaliev, N.; Kuanyshbek, A.; Marat, A.; Lesbekov, T.; Raissov, Y.; Sadykova, A.; Kamila, A.K.; Mukarov, M.; et al. Case Report: Transcatheter Tricuspid Valve-in-Valve Implantation Using Novel Balloon-Expandable Aortic Valve with 1 Year Follow-Up. *Front Cardiovasc Med* **2023**, 10, 1152280, doi:10.3389/fcvm.2023.1152280.
 58. Bonhoeffer, P.; Boudjemline, Y.; Saliba, Z.; Merckx, J.; Aggoun, Y.; Bonnet, D.; Acar, P.; Le Bidois, J.; Sidi, D.; Kachaner, J. Percutaneous Replacement of Pulmonary Valve in a Right-Ventricle to Pulmonary-Artery Prosthetic Conduit with Valve Dysfunction. *Lancet* **2000**, 356, 1403–1405, doi:10.1016/S0140-6736(00)02844-0.
 59. Odemis, E.; Yenidogan, I. First Experiences with Myval Transcatheter Heart Valve System in the Treatment of Severe Pulmonary Regurgitation in Native Right Ventricular Outflow Tract and Conduit Dysfunction. *Cardiol Young* **2022**, 32, 1609–1615, doi:10.1017/S1047951121004650.
 60. Sathananthan, J.; Sellers, S.; Barlow, A.; Fraser, R.; Stanová, V.; Cheung, A.; Ye, J.; Alenezi, A.; Murdoch, D.J.; Hensey, M.; et al. Overexpansion of the SAPIEN 3 Transcatheter Heart Valve. *JACC: Cardiovascular Interventions* **2018**, 11, 1696–1705, doi:10.1016/j.jcin.2018.06.027.
 61. Sellers, S.L.; Sathananthan, J.; Bouchareb, R.; Mostaçõ-Guidolin, L.B.; Lau, K.P.; Bugis, J.; Hensey, M.; Blanke, P.; Payne, G.W.; Lebeche, D.; et al. Impact of Over-Expansion on SAPIEN 3 Transcatheter Heart Valve Pericardial Leaflets. *Structural Heart* **2020**, 4, 214–220, doi:10.1080/24748706.2020.1742950.
 62. Holzamer, A.; Bedogni, F.; Van Wyk, P.; Barwad, P.; Protasiewicz, M.; Ielasi, A.; Nombela-Franco, L.; Seidler, T.; Hilker, M. Performance of the 32 Mm Myval Transcatheter Heart Valve for Treatment of Aortic Stenosis in Patients with Extremely Large Aortic Annuli in Real-world Scenario: First Global, Multicenter Experience. *Cathet Cardio Intervent* **2023**, 102, 1364–1375, doi:10.1002/ccd.30820.
 63. Xiong, T.-Y.; Ali, W.B.; Feng, Y.; Hayashida, K.; Jilaihawi, H.; Latib, A.; Lee, M.K.-Y.; Leon, M.B.; Makkar, R.R.; Modine, T.; et al. Transcatheter Aortic Valve Implantation in Patients with Bicuspid Valve Morphology: A Roadmap towards Standardization. *Nat Rev Cardiol* **2023**, 20, 52–67, doi:10.1038/s41569-022-00734-5.
 64. Elkoumy, A.; Terkelsen, C.J.; Abdelshafy, M.; Ellert-Gregersen, J.; Elzomor, H.; Thim, T.; Serruys, P.W.; Soliman, O.; Nissen, H. Case Report: Transcatheter Aortic Valve Replacement in a Large Bicuspid Anatomy Using the XL-Myval 32 Mm. *Front. Cardiovasc. Med.* **2022**, 9, doi:10.3389/fcvm.2022.1045280.
 65. Rodriguez Ogando, A.; Ballesteros, F.; Martínez, J.L.Z. Pulmonary Percutaneous Valve Implantation in Large Native Right Ventricular Outflow Tract with 32 Mm Myval Transcatheter Heart Valve. *Catheter Cardiovasc Interv* **2022**, 99, E38–E42, doi:10.1002/ccd.29985.

Disclaimer/Publisher's Note: The statements, opinions and data contained in all publications are solely those of the individual author(s) and contributor(s) and not of MDPI and/or the editor(s). MDPI and/or the editor(s) disclaim responsibility for any injury to people or property resulting from any ideas, methods, instructions or products referred to in the content.