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The novel balloon-expandable Myval transcatheter heart valve: systematic review of aortic, mitral, tricuspid and pulmonary indications

Nueva prótesis percutánea expandible con balón Myval: revisión sistemática de las indicaciones aórtica, mitral, tricuspídea y pulmonar

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ABSTRACT

Introduction and objectives: Myval technology represents the first balloon-expandable alternative since the Edwards system became commercially available. Despite certain controversies, its use has rapidly expanded. We aimed to gather all the available literature regarding its indications and outcomes.

Methods: A comprehensive search of articles published between December 2016 and May 2024 was conducted using BioMedCentral, Google Scholar, and PubMed to evaluate the main outcomes of Myval for native aortic stenosis (AS) (meta-analysis) and off-label uses (systematic review).

Results: A total of 151 studies were identified, and 74 were included in the analysis, covering aortic (n = 51), mitral (n = 9), tricuspid (n = 6), and pulmonary (n = 8) valve positions. A meta-analysis of studies on native AS demonstrated that Myval is safe and effective, with a 30-day mortality rate of 1.3%, good hemodynamic performance, low rates of pacemaker implantation (8.8%), and ≥ moderate paravalvular regurgitation (1.3%). Compared with other contemporary devices, Myval was competitive and associated with lower rates of pacemaker implantation. In a systematic review of off-label indications, Myval was also found to be safe and effective. In bicuspid AS, pure regurgitation, and aortic valve-in-valve procedures, success rates were 100%, 92%, and 100%, respectively, with pacemaker rates of 9.9%, 22.2%, and 3%, respectively. For mitral valve-in-valve/in-ring procedures, the success rate was 96.9%, while in tricuspid and pulmonary positions, small case series reported 100% success rates for both, with minimal procedural complications.

Conclusions: Myval technology is safe and effective for the treatment of native valvular disease and dysfunctional prostheses or rings in all heart valve positions, although larger scale studies are warranted.

Keywords: Myval. Myval Octacor. Valvular heart disease. Aortic stenosis. Aortic Regurgitation. Valve-in-valve. Valve-in-ring.

RESUMEN

Introducción y objetivos: Myval es el primer dispositivo expandible con balón alternativo desde que el sistema Edwards empezó a comercializarse. Pese a ciertas controversias, se ha extendido rápidamente. Nuestro objetivo es recoger todas las publicaciones sobre sus indicaciones y resultados.

Métodos: Búsqueda sistemática de todos los artículos publicados entre diciembre de 2016 y mayo de 2024 en BioMedCentral, Google Scholar y PubMed para evaluar la seguridad y la eficacia de Myval en la estenosis aórtica (EA) nativa (metanálisis) y en usos *off-label* (revisión sistemática).

Resultados: Se identificaron 151 estudios, de los cuales se incluyeron 74 que comprenden implantes en posición aórtica (n = 51), mitral (n = 9), tricuspídea (n = 6) y pulmonar (n = 8). El metanálisis en EA nativa demostró que el implante de Myval es seguro y eficaz (mortalidad a 30 días, 1,3%), con buena hemodinámica, bajas tasas de marcapasos (8,8%) y fugas perivalvulares al menos moderadas (1,3%). Comparada con dispositivos contemporáneos, Myval fue competitiva y con menor tasa de marcapasos. La revisión sistemática de indicaciones *off-label* también demostró que Myval es segura y eficaz. En la EA bicúspide, la insuficiencia aórtica pura y los procedimientos *valve-in-valve,* las tasas de éxito fueron del 100, el 92 y el 100% respectivamente, y las de marcapasos fueron del 9,9, el 22,2 y el 3%. En *valve-in-valve/in-ring* mitral, la tasa de éxito fue del 96,9%, mientras que en posiciones tricuspídea y pulmonar la tasa de éxito en pequeñas series fue del 100% para ambas, con escasas complicaciones.

Conclusiones: La prótesis Myval es segura y eficaz en el tratamiento de las valvulopatías nativas y de bioprótesis o anillos quirúrgicos disfuncionales en todas las posiciones de las válvulas cardiacas, aunque son necesarios estudios más amplios para confirmarlo.

Palabras clave:

Myval

Myval Octacor

Valvulopatías

Estenosis aórtica

Insuficiencia aórtica

Valve-in-valve

Valve-in-ring

Abbreviations

AR: aortic regurgitation

AS: aortic stenosis

TAVI: transcatheter aortic valve implantation

TMVI: transcatheter mitral valve implantation

TTVI: transcatheter tricuspid valve implantation

TPVI: transcatheter pulmonary valve implantation

Abreviaturas

EA: estenosis aórtica

IAo: insuficiencia aórtica

TAVI: implante percutáneo de válvula aórtica

TMVI: implante percutáneo de válvula mitral

TPVI: implante percutáneo de válvula pulmonar

TTVI: implante percutáneo de válvula tricúspide

INTRODUCTION

The first transcatheter heart valve (THV) device for transcatheter aortic valve implantation (TAVI) was the balloon-expandable (BE) Edwards-SAPIEN, based on a patent developed by Andersen[1] and the preliminary experience in humans by Alain Cribier.[2] Since then, several devices have been developed, but until 2018, all commercially available alternatives to Edwards technology were self-expandable (SE) devices, with indications restricted to the aortic position.[3,4,5] One exception was the mechanically expandable Lotus/Lotus Edge system (Boston Scientific, United States), but it was discontinued in 2020.[6]

The Myval technology (Meril Life Sciences, India)[7,8,9] is the first alternative to Edwards LifeSciences, (United States) also based on the BE concept. The first implants were performed in India in 2017, and the devide received approval for use in Europe in 2019.[10,11] Although not free of controversy regarding its features compared with Edwards, Myval has been widely adopted not only for native aortic disease but also for off-label procedures in the aortic, mitral, tricuspid, and pulmonary positions. One of the most appealing features of Myval is the availability of intermediate sizes, covering the unmet need for more precise sizing, as well as extra large sizes which have been used in more complex anatomies and clinical scenarios, both for native and prosthetic valvular diseases.

Since its introduction, there has been growing experience with this novel device, leading to numerous publications, primarily small observational and retrospective registries, case reports, or small case series, with only one large-scale randomized trial. Given this background, the aim of this investigation was to gather all the current experience with Myval technology through a systematic review of the literature, both for AS and off-label implantations in the aortic, mitral, tricuspid, and pulmonary positions.

METHODS

Search strategy and study selection

A systematic search was conducted for all articles published between December 2016 and May 2024 in BioMedCentral, Google Scholar, and PubMed. The following search terms were used: ("Myval" or "Octacor") and (("tricuspid" or "bicuspid" "aortic stenosis") or ("aortic regurgitation") or ("mitral stenosis" or "regurgitation") or ("tricuspid stenosis" or "regurgitation") or ("pulmonary stenosis" or "regurgitation")) and ("valve-in-valve" or "valve-in-ring"). Additional studies were identified through manual searches of secondary sources, including references from primary articles (backward snowballing) and contacts with international experts. We also searched for relevant case reports presented at major cardiology meetings between 2016 and 2023.

Only studies reporting outcomes on the efficacy and safety of Myval implantation were considered. For transfemoral Myval TAVI in native AS, case series with fewer than 10 patients were excluded. For nontransfemoral TAVI and off-label uses, case reports and case series were included. The outcomes of interest were intraprocedural complications, permanent pacemaker implantation (PPI), paravalvular regurgitation (PVR), and clinical and echocardiographic outcomes. Outcomes were adjudicated according to each study's definitions. Other indications (eg, heterotopic conduits, vascular implants) were excluded from this research, as were studies published in languages other than English.

Citations were first screened at the title and abstract level by 2 independent reviewers (M. García-Gómez and C. Fernández-Cordón). Any discrepancies were resolved by consensus. In cases of duplicate reports from the same study, only the report with the most complete data set was included. Collected data included baseline clinical, echocardiographic, procedural characteristics, as well as in-hospital and follow-up outcomes. Due to the heterogeneity in methodologies and reported outcomes among the studies, and given the broad scope of the planned review, we opted to conduct a narrative systematic review without complex quantitative data analysis, except for native AS.

Study endpoints

For the treatment of native AS, our aim was to evaluate procedural, in-hospital, and follow-up outcomes. Additionally, we aim to explore potential differences between Myval and other contemporary THVs in terms of short-term hemodynamic performance, as well as rates of residual aortic regurgitation (AR) and PPI.

For the off-label uses of Myval, including bicuspid aortic stenosis (BAS), AR, and mitral, tricuspid, and pulmonary valve diseases, our goal is to describe the gathered clinical experience, with a focus on procedural and short-term outcomes.

Statistical analysis

Categorical variables are reported as No. (%), and continuous variables as mean ± standard deviation or median [25th-75th interquartile range] depending on the distribution of the variables.

The effect size for the meta-analysis was defined prior to combining the results, using forest plots based on the individual results of each study and their confidence interval. In cases where the median and interquartile range were reported, the mean and standard deviation were approximated by $\bar{x} = \frac{q1+m+q3}{3}$ and $s = \frac{q3-q1}{1.35}$. Statistical heterogeneity was evaluated using the chi-square test and the I^2 statistic. A Q value was considered to be significant ($P < .05$). A high I^2 value was considered to indicate substantial heterogeneity. Results were considered statistically significant with $P < .05$. All analyses were conducted using the statistical software R (metafor v 4.4-0 and meta 7.0-0); . *R Core Team (2023). R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria.*

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed to ensure transparency and integrity in the presentation of the results. The quality of the included studies was assessed using standardized tools recommended by PRISMA, and the results were synthesized qualitatively, and when possible, quantitatively through meta-analysis.

The Myval transcatheter heart valve system

Myval[7,8,9] is composed of a nickel-cobalt frame with hexagonal cells and a sealing cuff. The second-generation Myval Octacor has 2 rows of identical octagonal cells and a higher circumferential external skirt, designed to reduce the risk of paravalvular regurgitation (PVR).[12] Both Myval generations (**figure 1**) contain a tri-leaflet valve made of bovine pericardium tissue treated with anticalcification technology and are available in traditional (20, 23, 26 and 29 mm), intermediate (21.5, 24.5, 27.5 mm) and XL (30.5 and 32 mm) sizes.

RESULTS

A total of 122 studies were identified using the prespecified query terms, and 19 additional studies were found through manual searching. After removing duplicates, 61 studies were excluded at the title and abstract level, and 11 studies were excluded due to being non-English (n = 2) or having fewer than 10 patients (n = 9). Ultimately, 74 studies were included in the analysis: 51 studies examined aortic indications, and 9, 6, and 8 studies analyzed mitral, tricuspid, and pulmonary indications, respectively (figure 2 and table 1 of the supplementary data). For mitral, tricuspid, and pulmonary diseases, most studies were case reports or small case series, with no study including a direct comparison with Edwards.

Myval for the treatment of native aortic stenosis

Meta-analysis of main studies evaluating Myval for the treatment of native aortic stenosis

Based on the initial experience reported in early registries and case reports,10–31 a combined analysis of 13 studies, including 1,313 patients (mean age 78.27 years, 45.42% female) with an STS score of 4.0% [3.08-4.92], was performed. At baseline, echocardiographic parameters

included an AVA of 0.7 cm² [0.67-0.73], a mean gradient of 43.99 mmHg [41.37-46.61], and an LVEF of 53.57% [51.18-55.95]. After Myval implantation, AVA improved to 1.92 cm² [1.83–2.01] and the mean gradient decreased to 8.53 mmHg [7.85-9.21], with a rate of ≥ moderate paravalvular regurgitation (PVR) of 1.26% and PPI of 8.81%. At the 30-day follow-up, mortality and stroke rates were 1.95% and 1.33%, respectively (**figure 3 and figure 1 of the supplementary data)**.

Studies comparing Myval with other contemporary transcatheter heart valves

The MATCHBALL study compared Myval and SAPIEN-3 with favorable outcomes: procedural success (93.2 vs 94.2%, *P* = .219), clinical efficacy as a composite endpoint of all-cause mortality, all stroke, the need for hospitalization for valve-related symptoms or worsening heart failure, NYHA III–IV and valve-related dysfunction (4.9 vs 12.6%, *P* = .057), early safety (4.9 vs 12.6%, *P* = .096) and lower PPI (5.8 vs 15.5%, *P* = .02). Although no differences were found in ≥ moderate PVR (0 vs 1%, *P* = .314), mean gradient was lower following Myval (8 vs 12 mmHg, *P* < .001)[32]. The EVAL registry compared Myval vs Evolut R, showing that the incidence of all-cause mortality and stroke did not significantly differ, while rates of PPI (11.0 vs 27.5%, *P* = .02) and ≥ moderate PVR (6.9 vs 19.8%, *P* = .0396) were lower.[33,34] Similar results were described in a matched comparison of Myval vs Evolut.[35] The lower rate of PPI was later confirmed in a central analysis of conduction disturbances that showed that Myval presented the lowest rate of PPI when compared with Evolut, Portico and Allegra, but not vs SAPIEN 3 or Acurate neo.[36] In this context, Kawashima et al.[37,38] demonstrated that intermediate sizes could reduce annular overexpansion, thus minimizing the rates of conduction system injuries and the need for PPI. Lastly, the noninferiority of Myval compared with contemporary THV (Evolut and SAPIEN) was demonstrated in the LANDMARK trial for the composite primary endpoint of all-cause mortality, all stroke, bleeding (types 3 and 4), acute kidney injury (stages 2-4), major vascular complications, moderate or severe AR,

and PPI at 30 days (25 vs 27%; *P* < .0001).[39] For a more detailed review of main studies of Myval implantation in native AS see **table 1**. An example is shown in **figure 4**.

Off-label uses of Myval for the treatment of valvular heart disease

Bicuspid aortic stenosis

Elkoumy et al. have shown favorable 1-year clinical outcomes in 62 BAS patients, with all-cause mortality of 11.3%, all stroke of 3.2%, and PPI of 8.3%.[40,41] Although Kumar et al.[42] showed good results with CoreValve/Evolut R, SAPIEN 3 and Myval in a cohort of 70 BAS Indian patients at 2 years of follow-up, a head-to-head comparison of the latest-iteration BE and SE THVs was lacking until the TRITON study. This was a multicenter registry including 360 patients treated with new-iteration THVs, showing a higher device success at 30 days after Myval (100%) compared with SAPIEN 3 (87.5%, *P* = .002) and Evolut PRO+ (81.3%, *P* < .001), but with no differences in PPI (9.9%, 10.9%, and 18.3%, respectively).[43] Moreover, the good performance of the 32-mm Myval in BAS has been reported elsewhere.[44] More recently, the new 35 mm Myval has been used in a patient with BAS and a large aortic annulus (area 883 mm^2, perimeter 107 mm)[45]. For a more detailed review of main studies of Myval implantation in BAS see **table 1**. See **video 1 of the supplementary data** as a case example.

Noncalcified aortic regurgitation

Although the off-label use of Myval in AR has been reported in the PANTHEON registry[46,47] and LVAD-related-AR case reports,[48,49] the first systematic evaluation of the safety and feasibility has been reported in a retrospective registry (**table 2**) including 113 patients with a mean area of 638.6 ± 106.0 mm^2. The mean oversizing was 17.9 ± 11.0%, achieved by adding a mean extra volume of 4 ± 2.3 cc (up to 9 cc in 3 cases). Technical and procedural success rates were 94.7% and 92.0%,

respectively, with 4 cases (3.5%) of valve embolization, 1 antegrade and 3 ventricular, the latter being significantly associated with a tapered left ventricular outflow tract (LVOT) (12.5 vs 0%, *P* = .007). At the 1-year follow-up, all-cause mortality was 9.7% and the PPI rate was 22.2%, with technical success (97.1 vs 72.7%, *P* = .012) and valve embolization (18.2 vs 2%, *P* = .047) as predictors of mortality.[50] An example of Myval implantation for pure AR after HeartMate III is shown in **figure 5** and **video 2 of the supplementary data**.

Aortic valve-in-valve

Previous reports have shown the feasibility of Myval TAViV,[51-58] but longer-term outcomes are reported in a multicenter registry (**table 2**) which included 33 patients with failing bioprosthesis. Technical success was achieved in all cases, and only 1 patient underwent PPI.[59] An example of TAViV is shown in **figure 6** and **video 3 of the supplementary data**. One case reported a direct transaortic 27.5 mm Myval ViV into a mechanical aortic prosthesis after the removal of carbon discs, leaving a mechanical ring, during HeartMate III implantation.[60] In addition, Pya et al.[61] have described a novel technique of direct transaortic 30.5 mm Myval valve-in-ring (ViR) simultaneous to left ventricular assist device implantation.

Mitral valve-in-valve and valve-in-ring

Although SAPIEN is the only prosthesis approved for transcatheter mitral valve-in-valve (TMViV),[62] the feasibility of Myval TMViV has been shown in 10 patients in which Myval was transeptally implanted with 100% technical and device success rates.[63] Additionally, short case series have shown good clinical outcomes with Myval TMViV,[51,64-66] and Blasco-Turrión et al.[67] have shown its feasibility and safety in a retrospective analysis of 11 patients with stenotic bioprostheses, where intermediate sizes were used in 54% of the cases, achieving a technical success rate of 100%. Similar results have recently been

reported in a cohort of 20 patients with a technical success rate of 100% and an all-cause mortality rate at 1 year of 10%.[68] For a more detailed review of the main case reports of TMViV in dysfunctional bioprostheses see **table 3**. An example of TMViV is shown in **figure 7**.

On the other hand, transcatheter mitral valve-in-ring (TMViR) represents a more challenging scenario, and a novel antegrade tip-to-base LAMPOON procedure has been described in a 78-year-old woman harboring a failing 30mm complete rigid ring, resolved by 26mm Myval TMViR with no procedural complications.[69] Moscarella et al. have reported the longest follow-up of 64 patients undergoing TMVI (84.4% TMViV, 15.6% TMViR) with a technical success rate of 96.9%, but with relatively worse survival compared with patients undergoing TAViV (89% vs 97%, HR, 2.7; 95%CI, 0.33-22.7; *P* = .34) at 15 months.[59] For a more detailed review of the main case reports of TMViR see **table 3**.

Tricuspid valve disease

Although transcatheter tricuspid valve-in-valve (TTViV) and valve-in-ring (TTViR) procedures have been performed with Melody and SAPIEN, the safety and efficacy of Myval have been reported mainly in case reports. The first TTViV procedure was performed in a 58-year-old woman with severe stenosis due to a dysfunctional bioprosthesis implanted 27 years previously, corrected with a 32-mm Myval.[70] The same year, a case of 29 mm Myval TTViV was reported in a 59-year-old man with Ebstein anomaly and a stenotic 31-mm bioprosthesis implanted 11 years earlier.[71] Myval TTViV is also feasible in patients experiencing symptoms of tricuspid regurgitation due to bioprosthesis failure, as shown in a report of 5 cases with 100% procedural and device success rates.[72] The use of Myval has also been reported in a 21-year-old male with Tetralogy of Fallot (ToF) harboring a dysfunctional 29 mm bioprosthesis treated with a 26-mm Myval TTViV.[73]

A more complex TTViR procedure was reported in a 59-year-old woman with a degenerated 34-mm rigid partial ring implanted 6 years ago. Due to the higher risk of valve overexpansion, a 32-mm Myval was very slowly implanted, with no procedural or in-hospital complications.[74] An example of Myval

TTViR is shown in **figure 8**. Finally, transjugular access was used in a 67-year-old man with previous infective endocarditis, for which he had undergone cardiac surgery 26 years earlier, and treated with a 26-mm Myval.[75] For a more detailed review of the main case reports of Myval TTViV and TTViR see **table 4**.

Pulmonary valve disease

Early reports have shown the safety and feasibility of off-label Myval transcatheter pulmonary valve implantation (TPVI) within narrowed conduits, although Melody and SAPIEN are the only CE-marked and FDA-approved prostheses.[76] The first-in-human case was described in 2020 in a 26-year-old woman with 3 redo surgeries for failing corrected ToF and symptomatic pulmonary regurgitation across a Contegra conduit, corrected with a 23 mm Myval.[77] Later, in 2021, 23-mm Myval TPVI was reported in 7 patients with prestented conduits, showing a 100% procedural success rate without any reinterventions at 10 to 22 months of follow-up.[78] That same year, TPVI using 23, 26 and 29 mm Myval in 9 patients with large native right ventricular outflow tract (RVOT) was reported, with no complications at 6 months follow-up.[79] Some case reports have shown the possibility of TPVI without prestenting when XL Myval is inflated with 48 cc (nominal volume +8 cc).[80-83] In the largest experience, including 53 patients with different coronary heart diseases, the feasibility of pulmonary ViV was described for the first time in 6 patients with no procedural complications.[84] For a more detailed review of the main case reports of Myval TPVI, see **table 5**. An example of Myval TPVI is shown in **figure 9**.

DISCUSSION

The continuous availability of new THV devices requires constant attention to prevent undetected malfunction or early deterioration. In this context, the novel Myval is the first commercially available BE THV alternative to the Edwards series. Although it was initially intended for implantation in the

orthotopic aortic position for treating native AS, its use has rapidly expanded to include off-label indications **(figure 10).**

For the treatment of native tricuspid AS, the main findings our study can be summarized as follows: *a)* Myval is safe and effective, with a low rate of procedural and in-hospital complications; *b)* Myval is competitive with the most commonly used BE and SE devices, demonstrating better short-term hemodynamic performance in terms of residual gradients and paravalvular leak; *c)* Myval is associated with a nonsignificant lower frequency of PPI compared with other contemporary THVs. Regarding off-label indications, Myval implantation is safe and effective, at least in the short-term, for treating both native valvular diseases and dysfunctional prostheses or rings.

Aortic valve disease

The key role of TAVI in treating AS is now well established. There is now a race for the ideal device that offers a therapeutic alternative with the lowest risk of procedural and in-hospital complications, as well as the longest-term durability. In this regard, several properties of the Myval system must be highlighted. First, it features a more flexible and softer delivery system that facilitates trauma-free navigation through tortuous anatomies; however, this may make crossing severely stenotic valves with eccentric calcium distribution more difficult, such as in patients with BAS or in ViV procedures, thereby suggesting a greater need for predilation. Secondly, the radial strength of the valve is impressive and allows for proper expansion, as demonstrated by the reported rates of PVR. However, when XL sizes are required, careful advancement of the device through the femoral sheath is necessary to avoid valve displacement over the balloon. Third, the novel Octalign technique offers an advantage as it eliminates the need to torque or rotate the delivery system, thereby reducing the risk of embolic events and vascular complications. The availability of XL devices has opened new possibilities for treating aortic diseases in complex scenarios, such as BAS and AR, where prosthesis overexpansion may be a safe and effective anchoring mechanism. Despite these advantages, long-

term data beyond 1 year have not yet been reported in controlled trials and are needed to confirm the long-term safety of the Myval device.

Mitral valve disease

In patients with a mitral bioprosthesis or ring, redo surgery is known to be a high-risk procedure, and TMVI using BE THVs has been proposed as an alternative for those not suitable for surgery. Evidence in this clinical scenario mainly comes from clinical registries using SAPIEN, the only device approved for TMViV. However, there is already experience, although limited, with the off-label use of Myval, which has several advantages. First, the availability of intermediate and XL sizes may allow more precise sizing when treating dysfunctional surgical prostheses or rings. As there is no official recommendation, a new valve sizing chart has been developed based on the internal diameter of the bioprosthesis.[67] Second, the low profile of Myval may also facilitate septal crossing, as there have been no reported cases of septal tears. Finally, Myval is the only THV that can be retracted if the device cannot be passed through the interatrial septum. Myval implantation has proven feasible in the mitral position, with a low rate of procedural complications and favorable short-term outcomes, but larger scale studies with longer follow-ups are needed to establish this novel device as a treatment option

Tricuspid valve disease

Redo surgery in patients with prior surgical interventions for left-sided valvular heart disease who develop tricuspid regurgitation poses significant risks; isolated tricuspid surgery is rare and remains associated with the highest surgical risk among all valve procedures. As an alternative, the off-label use of Myval has been reported for the percutaneous treatment of

tricuspid valve disease with a low rate of procedural complications. Moreover, in some adverse anatomies, such as patients with more horizontal tricuspid valves, Myval implantation via transjugular access may be the only transcatheter option. This is because Myval is crimped directly on the balloon outside the patient, making it potentially more suitable for the transjugular route compared to SAPIEN, as the distance for loading the valve is much shorter than with transfemoral access. Once again, long-term follow-up studies are warranted.

Pulmonary valve disease

Percutaneous treatment of pulmonary valve disease is a highly challenging scenario, particularly when associated with complex coronary heart disease. The most commonly used THVs in this setting are Melody and SAPIEN, which are not recommended for RVOTs larger than 24 mm and 31 mm, respectively. For these anatomies, the XL 32 mm Myval could play an important role, as it can be oversized to reach 35 mm if the balloon is inflated with 48 cc (nominal volume +8 cc). For that reason, it has been proposed as an alternative to avoid prestenting, although this should be further validated, as the current experience is based mainly on short case series

Limitations

Our systematic review of the use of the novel Myval THV in various clinical scenarios has some limitations that should be noted. For the treatment of native AS, all studies included in the analysis, except for the LANDMARK trial, are observational and retrospective, with inherent limitations such as the lack of randomization and data-gathering monitoring, which hinder conclusive statements. Second, some studies in the meta-analysis included a low percentage of patients with BAS, affecting

the generalizability of the results. Third, most studies did not have a central core imaging laboratory for transthoracic echocardiography analysis and lacked a steering committee for event adjudication, leading to mainly self-reported outcomes. For the few studies comparing Myval with other THVs, a temporal trend may have biased the outcomes, as Myval was introduced later, with more experienced operators performing procedures, and therefore the learning curve may have impacted the results of patients treated with earlier devices. Regarding off-label uses of Myval, a significant limitation is the absence of large-scale studies; the gathered experience is mainly based on case reports or small case series, preventing robust conclusions. Overall, we considered only articles published in English, introducing a potential publication bias due to nonstandardized case reporting. Moreover, endpoint definitions are inconsistent among articles, with some using VARC-2 criteria while most recent reports use VARC-3 criteria. Finally, no articles report long-term outcomes after Myval implantation, and therefore our results should be interpreted with caution and viewed as hypothesis-generating regarding cardiovascular mortality and the durability of this novel prosthesis.

CONCLUSIONS

The next-generation BE Myval is safe and effective for the treatment of AS, with lower mean gradients and PVR rates compared with the most commonly used BE and SE devices. The off-label uses of Myval should be explored in larger clinical studies to properly assess its safety and efficacy. Finally, intermediate and XL sizes may be alternatives in more complex cases with larger annulus dimensions, such as BAS, AR, or tortuous RVOT, which should also be validated in well-designed trials. Long-term results are still pending.

ETHICAL CONSIDERATIONS

The preparation of this manuscript was communicated to the Ethics and Research Committee of the Valladolid Este Health Area. Since this is a literature review, it was not necessary to

draft or obtain informed consent. The SAGER guidelines regarding potential sex/gender biases have been followed.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used while drafting this manuscript.

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AUTHORS' CONTRIBUTIONS

M. García-Gómez and I.J. Amat-Santos designed the systematic review and conducted the data collection, analysis, interpretation, and writing of the manuscript. C. Fernández-Cordón, J. C. González-Gutiérrez, A. Serrador, A. Campo, C. Cortés Villar, S. Blasco Turrión, C. Aristizábal, J. Peral Oliveira, A. Stepanenko, M. González Arribas, L. Scorpiglione, A. Jain, D. Carnicero Martínez and J. A. San Román performed data collection, analysis, interpretation and discussion. All authors approved the final version.

CONFLICTS OF INTEREST

I. J. Amat-Santos is proctor for Meril Life.

WHAT IS KNOWN ABOUT THE TOPIC?

-As the use of TAVI is expanding to a younger and lower-risk population, special care should be taken to improve outcomes after the procedure. In this context, Myval technology is the first BE alternative to the SAPIEN family, featuring unique capabilities designed to overcome.

WHAT DOES THIS STUDY ADD?

- The use of the novel Myval device has rapidly expanded for the treatment of all types of valvular heart disease and dysfunctional surgical bioprostheses or rings. The availability of intermediate and XL sizes addresses the need for more precise sizing and allows the use of this prosthesis in complex anatomies such as bicuspid AS, AR, or large RVOTs.

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FIGURE LEGENDS

Figure 1. Design differences between the first generation Myval and second-generation Myval Octacor. Top-left: angio view of the Myval THV; top-right: angio view of the Myval Octacor; mid-left: Myval THV; mid-right: Myval Octacor THV; lower-left: cell design of Myval THV stent frame, 3 rows of hexagonal cells with the large upper one 6 mm in diameter; lower-right: cells design of the Myval Octacor THV stent frame, 2 rows of identical octagonal cells, 6 mm in diameter.

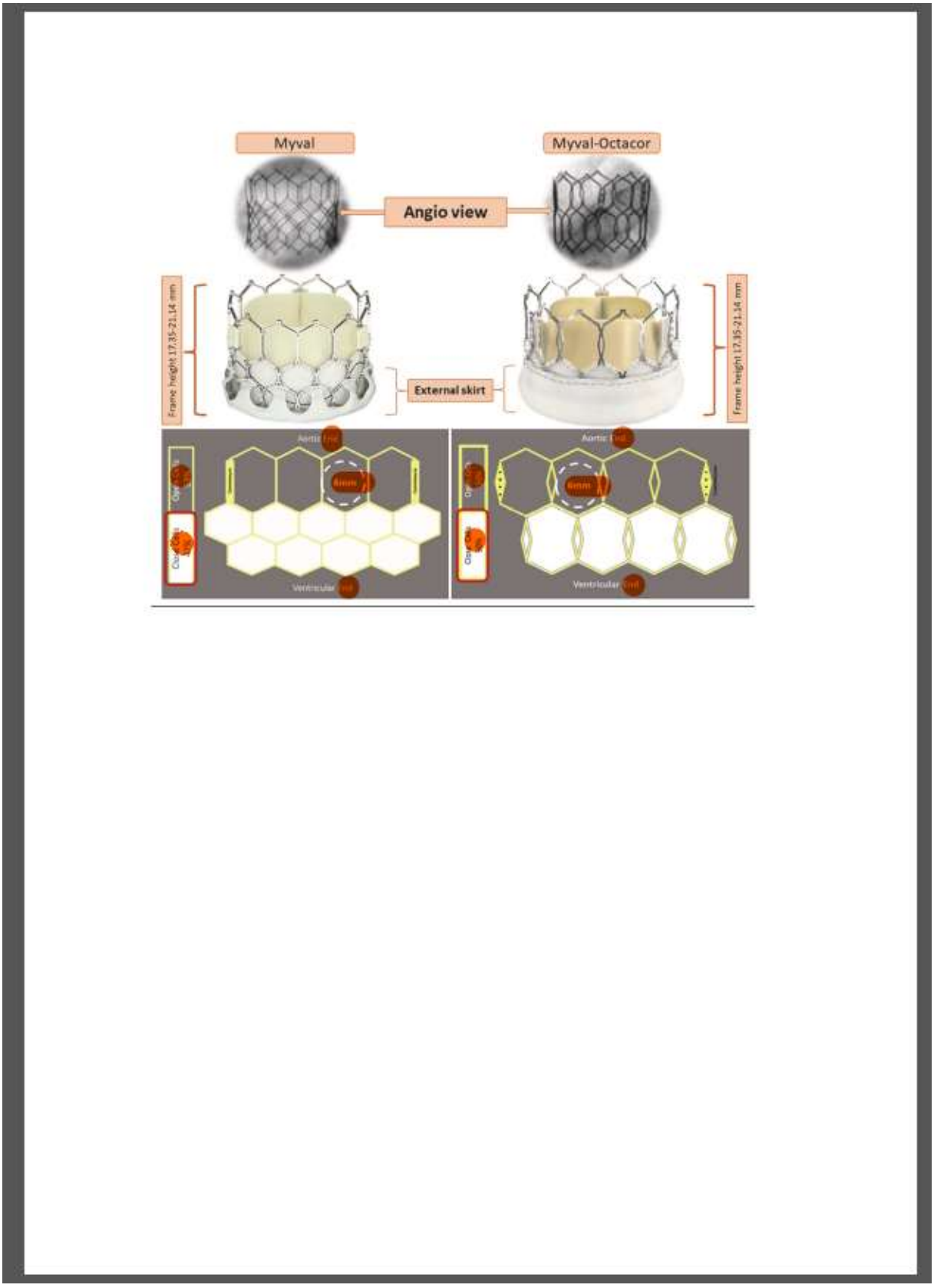

Myval
Myval-Octacor
Angio view
Frame height 17.35-21.14 mm
External skirt
Frame height 17.35-21.14 mm
Aortic
6mm
Ventricular
Aortic
6mm
Ventricular

Figure 1

Figure 2. Diagram flow of selected studies for the systematic review. AS, aortic stenosis.

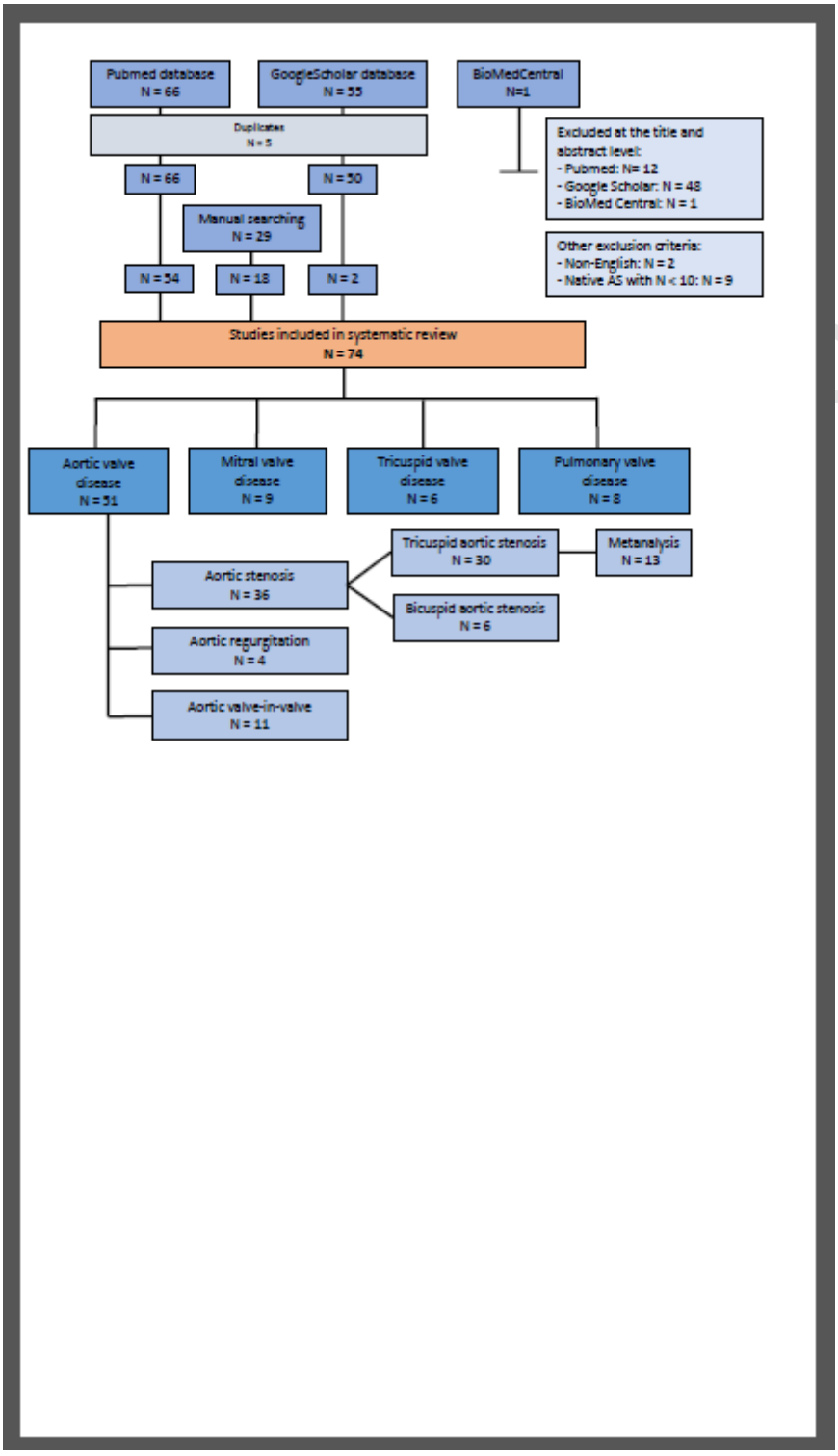


Figure 3. Meta-analysis evaluating main hemodynamic, postprocedural and clinical outcomes of Myval implantation in patients with native AS at 30 days of follow-up. A: aortic valve area. B: mean gradient. C: > moderate PVR. D: new PPI rate. E: mortality. F: stroke. PPI: permanent pacemaker implantation.

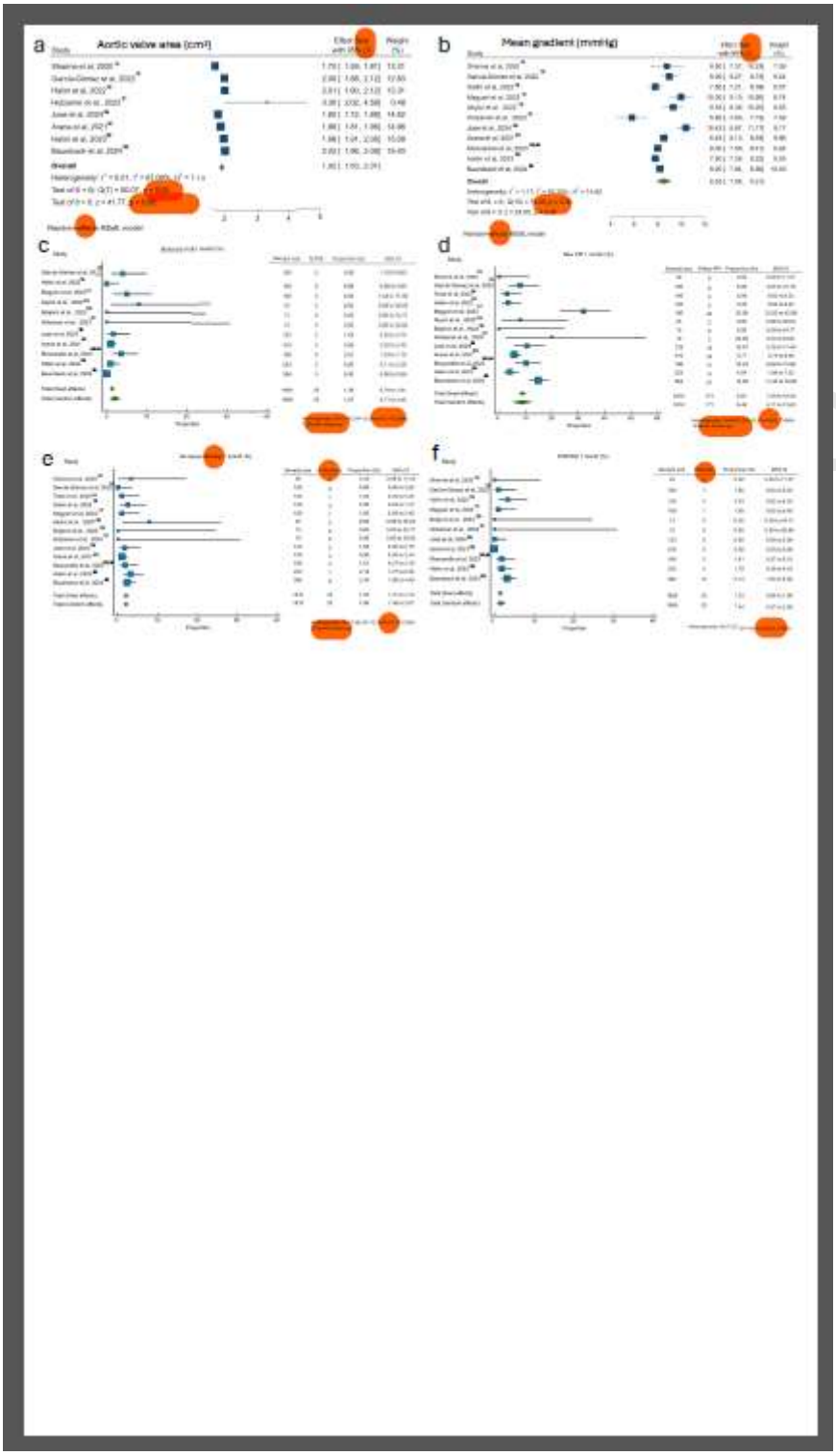


Figure 4. Transcatheter aortic Myval valve implantation in a patient with native severe aortic stenosis. A: baseline aortography showing calcification of the annulus and outflow tract and mild aortic regurgitation with restricted opening of the valve. B: predilation with 20 x 40 mm Mammoth balloon. C: positioning of the crimped 23-mm valve with the second dense landing zone at the level of the annulus. D: initial valve deployment with simultaneous distal and proximal balloon expansion (dog bone shape). E: implantation of the valve. F: final result with the valve in position, no paravalvular regurgitation and patency of both coronary arteries.

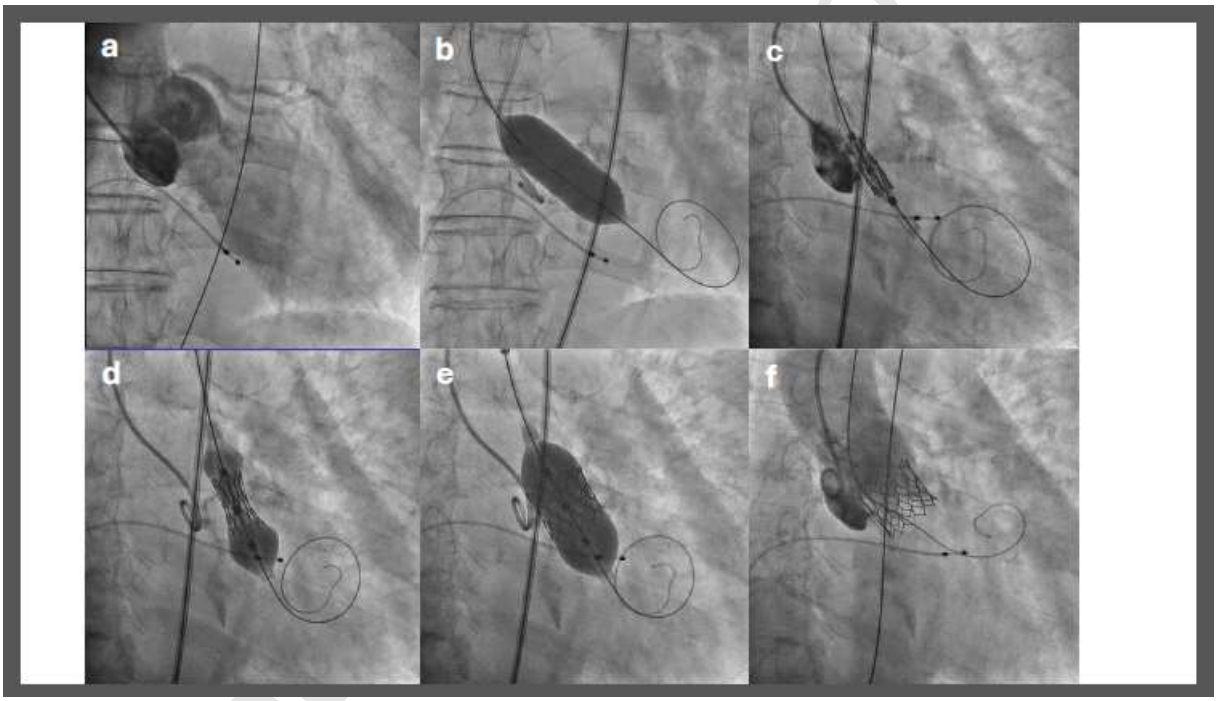


Figure 5. Transcatheter aortic Myval implantation in a patient with pure noncalcified aortic regurgitation developed 8 months after left ventricular assist device implantation. A: baseline aortography with no annulus calcification and severe aortic regurgitation. B: initial deployment of a 30.5 mm Myval prosthesis after downgrading the power pump to avoid retrograde migration. C: implantation of the valve. D: final result with the valve in position, no paravalvular regurgitation and patency of both coronary arteries.

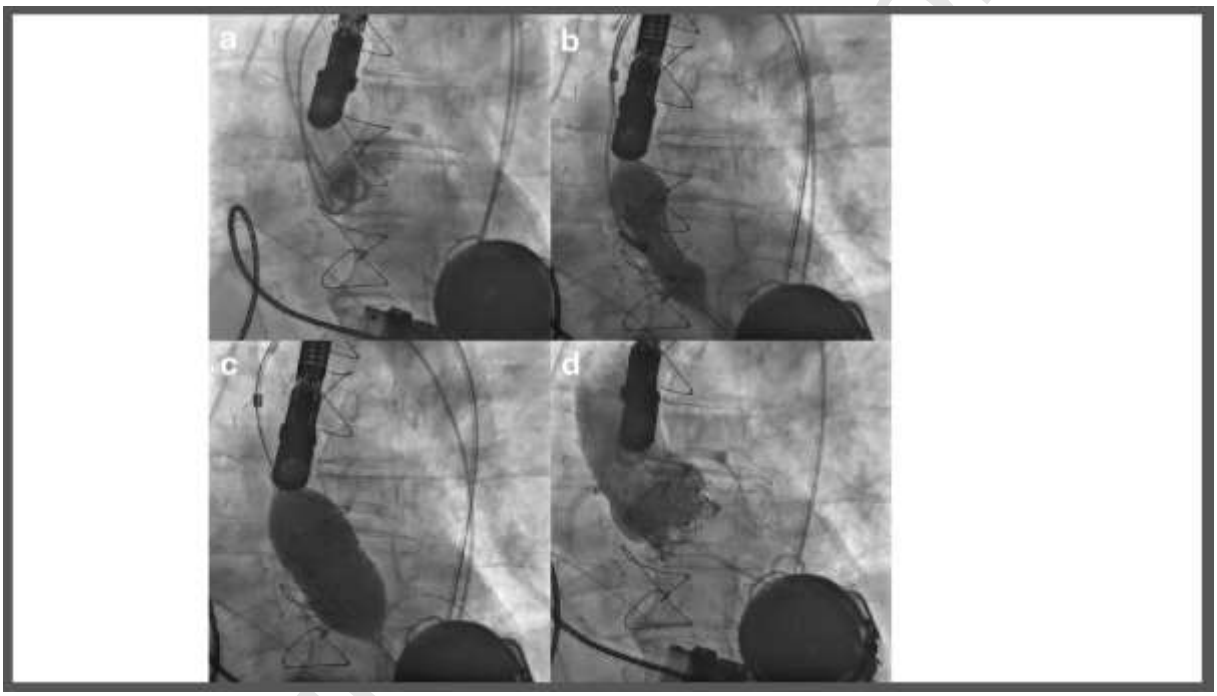


Figure 6. Transcatheter aortic Myval valve-in-valve implantation in a patient with a degenerated 23 mm Trifecta bioprosthesis implanted 8 years ago and high risk of left main coronary artery occlusion. A: baseline aortography showing moderate aortic regurgitation and restricted opening of the prosthesis. B: placement of a SteelCore guidewire and a snare in the left ventricle and perforation of the left coronary leaflet base with an electrified Astato XS 20 guidewire. C: performance of BASILICA (bioprosthetic aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction). D: predilation of the bioprosthesis with a 20 x 40 mm Mammoth balloon. E: implantation of a 23 mm Myval prosthesis. F: final result with the valve in the correct position, no residual regurgitation, and patency of the left coronary artery.

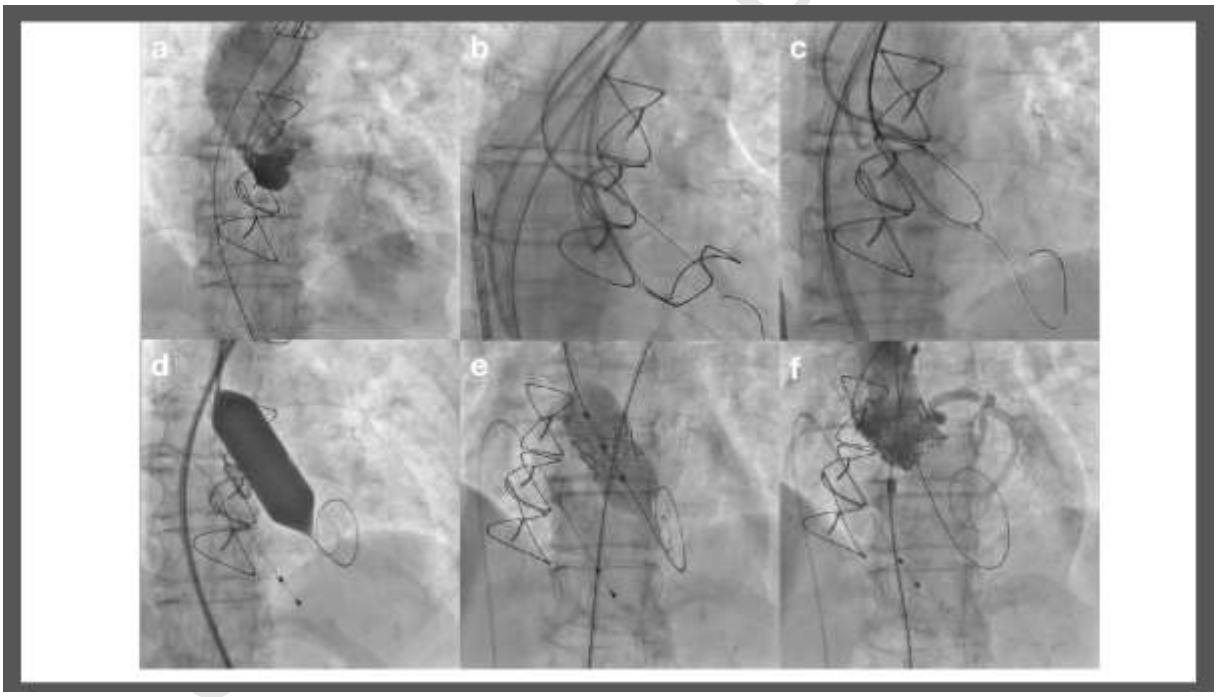


Figure 7. Transcatheter mitral Myval valve-in-valve implantation in a patient with a degenerated 27 mm Perimount bioprosthesis implanted 9 years ago. A: transseptal puncture guided with intracardiac ultrasonography and crossing of the degenerated bioprosthesis. B: predilation of the interatrial septum. C: predilation of the bioprosthesis. D: implantation of a 23 mm Myval prosthesis. E: left ventriculography showing no regurgitation to the left atrium. F: final result with the valve in the correct position (20% in the left atrium and 80% in the left ventricle).

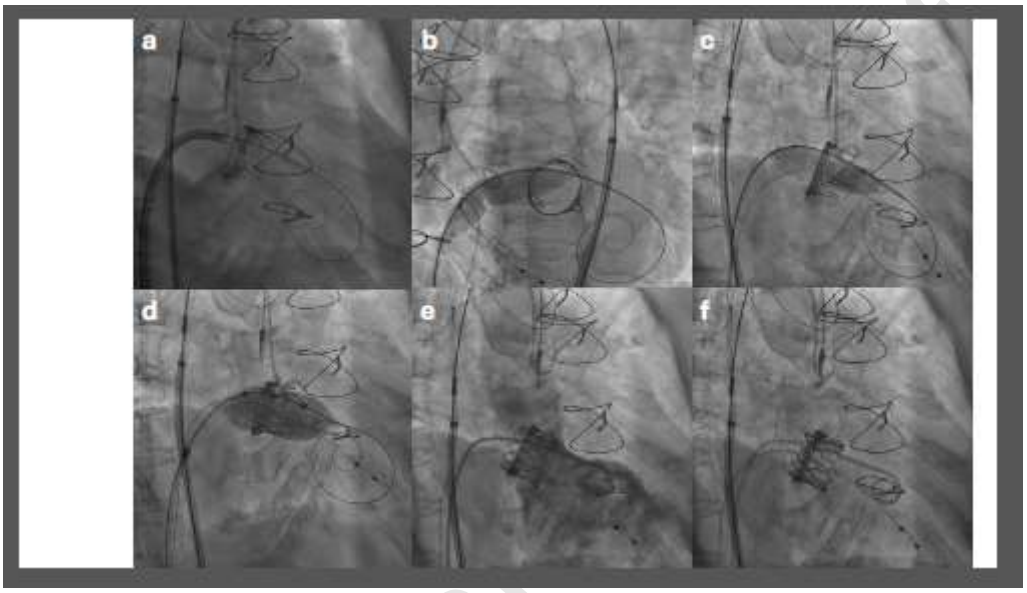


Figure 8. Transcatheter tricuspid Myval valve-in-ring implantation in a patient with dysfunctional annuloplasty 32 mm Physio ring implanted 9 years ago. A: crossing of the annuloplasty ring. B: positioning of the prosthesis (80% in the right ventricle and 20% in the right atrium). C, D: deployment of a 30.5 mm Myval prosthesis. E, F: final result with the correct position of the prosthesis within the annuloplasty ring.

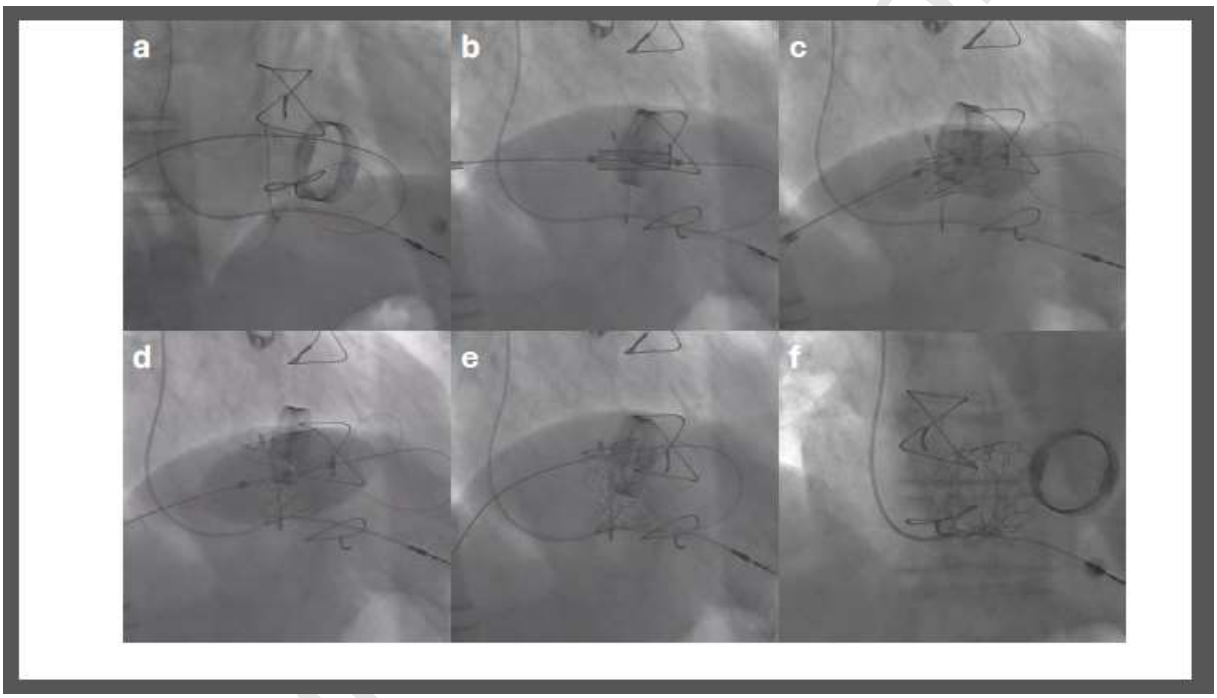


Figure 9. Transcatheter pulmonary Myval implantation in the native right ventricle outflow tract in a patient with free pulmonary regurgitation after surgical correction of Tetralogy of Fallot during childhood. A: baseline angiography in lateral view showing free pulmonary regurgitation. B: simultaneous selective left coronary artery angiography and balloon inflation in the right ventricle outflow tract to evaluate the risk of coronary artery compression. C: positioning and initial deployment of a 32 mm Myval valve with simultaneous left coronary artery angiography; D, E: implantation of the valve; F: final angiography showing a competent valve with no regurgitation.

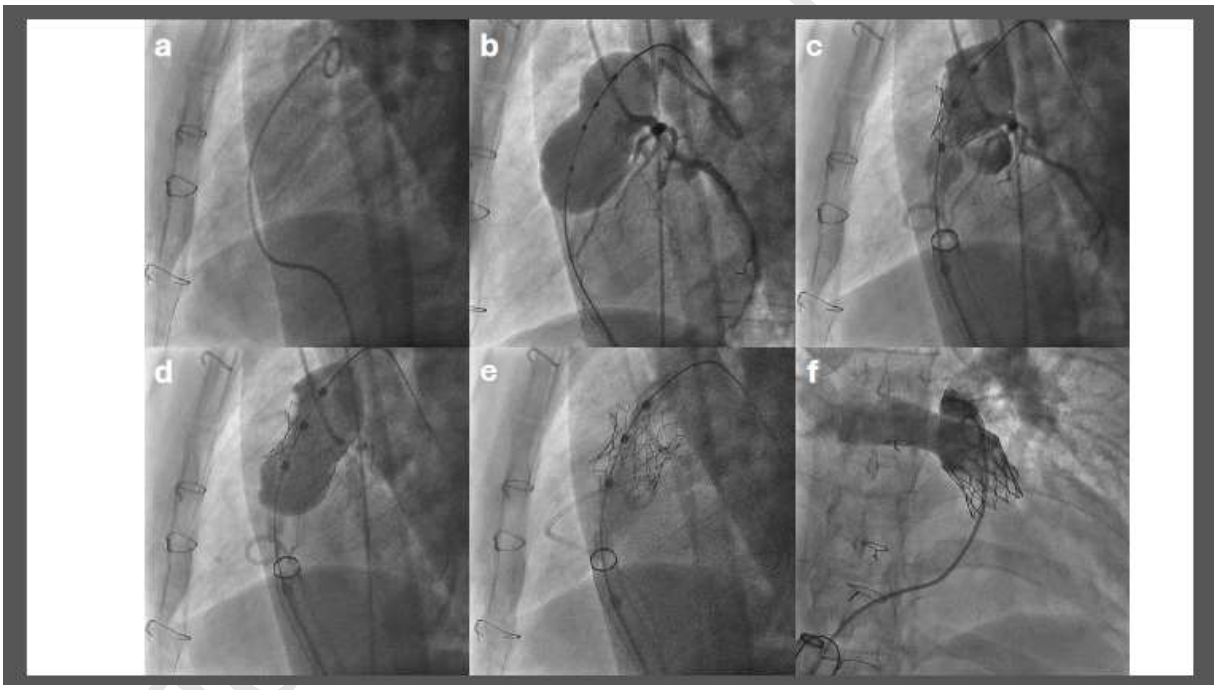
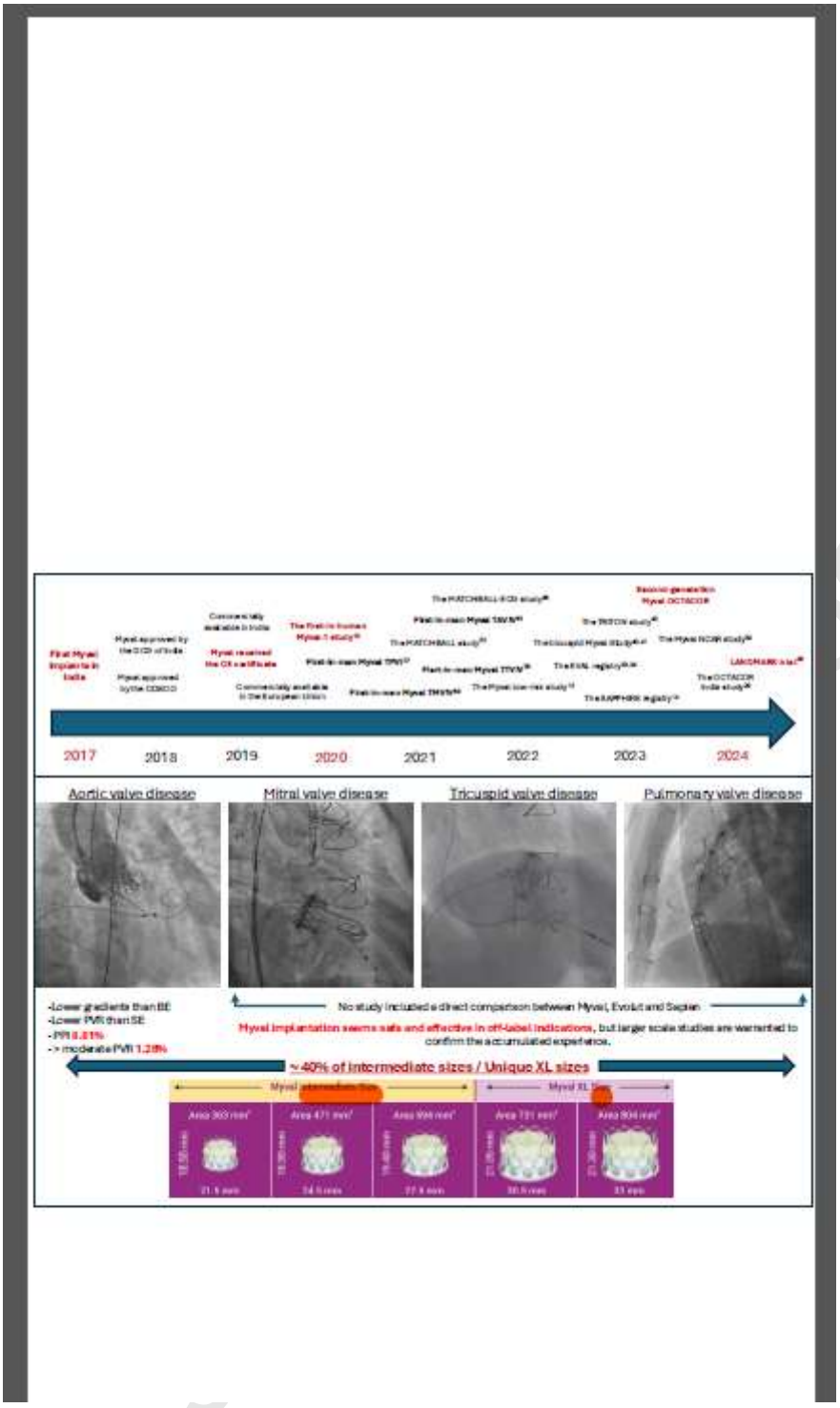


Figure 10. Central illustration. Timeline of the main studies and registries since Myval technology became available and main findings regarding its use for the treatment of aortic, mitral, tricuspid and pulmonary valve diseases. AR, aortic regurgitation; BAS, bicuspid aortic stenosis; CE, Conformité Europeenne; DCG, drug controller general; CDSCO, Central Drugs Standard Control Organization; PVR, paravalvular regurgitation; TMViV, transcatheter mitral valve-in-valve implantation; TPVI, transcatheter pulmonary valve implantation; TTVI, transcatheter tricuspid valve implantation; ViR, valve-in-ring; ViV, valve-in-valve.


2017
2018
2019
2020
2021
2022
2023
2024
Aortic valve disease
Mitral valve disease
Tricuspid valve disease
Pulmonary valve disease
-Lower gradients than SE
-Lower PVR than SE
- PVR 0.01%
- > moderate PVR 1.28%
No study included a direct comparison between Hyvai, Evolut and Sapien
Hyvai implantation seems safe and effective in off-label indications, but larger scale studies are warranted to confirm the accumulated experience.
~40% of intermediate sizes / Unique XL sizes