Initial experience with the Myval ballon-expandable valve in Argentina

Experiencia inicial con la válvula transcatéter balón expandible Myval en Argentina

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ABSTRACT

Introduction. Transcatheter valve therapy has revolutionized the treatment of structural cardiovascular disease. The variety of devices developed offers operators the opportunity to choose the most appropriate prosthesis for each type of patient. Balloon-expandable valves can be used as percutaneous treatment in all four cardiac valve positions, and the Myval device, in particular, has unique characteristics that could prove to be advantageous.

Objective. To describe the experience of the first 300 Myval balloon-expandable valves implanted in Argentina, including hemodynamic and clinical outcomes, geographic distribution, and operator opinions.

Materials and methods. A prospective multicenter registry including the first 300 patients who underwent percutaneous valve replacement in our Argentina with the Myval valve. Primary endpoint: procedural success. Secondary endpoints: all-cause mortality, cardiovascular mortality, stroke, moderate or severe paravalvular leak, and new permanent pacemaker implantation during the hospital stay. Additionally, researchers registered operator opinions regarding the device used.

Results. Mean age: 78.7±6.3 years. Mean aortic valve area: 0.72±0.38 cm^2, with a EuroSCORE II of 6.2%±2.3%. Overall, 95% of the cases featured aortic valve implantation, 2.7% were tricuspid valve implantation, 1.3% were pulmonary valve implantation, and 1% mitral valve implantation. Additionally, 52.3% were conventional-size implants and 47.7% were intermediate (21.5, 24.5, 27.5 mm) or extra-large (30.5, 32 mm) size. Procedural success was 98.7%. There were no patients with severe paravalvular leak. The rate of new permanent pacemaker implantation after transcatheter aortic valve implantation (TAVI) was 6.7%. In-hospital mortality was 2.7%. The study included 78 centers in 16 provinces, with very good acceptance by medical operators.

Conclusions. The use of the Myval transcatheter valve prosthesis has proven to be safe and versatile, adapting to cases of high technical complexity. The wide availability of sizes reduces the rate of complications and the need for pacemaker and facilitates the expansion of this alternative to almost all valve areas. The geographic distribution of implants and operator opinions demonstrate broad acceptance and a satisfactory experience.

Keywords: cardiac valve, transcatheter valve implantation, balloon-expandable valve, aortic stenosis, intermediate sizes, extra-large sizes, Myval.

RESUMEN

Introducción. La terapia valvular transcatéter ha revolucionado el tratamiento de la patología estructural cardiovascular. El desarrollo de múltiples dispositivos ofrece al operador la oportunidad de elegir la prótesis más adecuada para cada tipo de paciente. Las válvulas balón expandibles pueden ser utilizadas como tratamiento percutáneo en las cuatro posiciones de las válvulas cardíacas y en especial el dispositivo MyVal presenta características únicas que podrían ser ventajosas.

Objetivo. Comunicar la experiencia de las primeras 300 valvulas balón expandibles MyVal implantadas en Argentina, incluyendo los resultados hemodinámicos y clínicos, la descripción geográfica y la opinión los operadores.

Material y métodos. Registro prospectivo multicéntrico en el que se incluyeron los primeros 300 pacientes sometidos a reemplazo valvular percutáneo en nuestro país con la válvula MyVal. Punto final primario: éxito del procedimiento. Puntos finales secundarios: mortalidad de todas las causas, mortalidad cardiovascular, ACV, leak paravalvular moderado o severo y nuevo implante de marcapasos definitivo en su evolución intrahospitalaria. Además se registraron las opiniones de los operadores respecto del dispositivo utilizado.

Resultados. Edad media: 78,7±6,3 años. Área valvular aortica media: 0,72±0,38 cm, con un EuroSCORE II del 6,2%±2,3%. El 95% de los implantes se realizaron en posición aórtica, 2,7 % tricuspídea, 1,3% pulmonar y 1% mitral; 52,3% de los implantes fueron con talles convencionales y 47,7% con talles intermedios (21.5, 24.5,27.5 mm) o extragrandes (30.5, 32 mm). El éxito del procedimiento fue del 98,7%. Ningún paciente presentó leak paravalvular severo. La tasa de implante de marcapasos definitivo post-TAVI fue del 6,7%. La mortalidad intrahospitalaria fue del 2,7%. Participaron 78 centros de 16 provincias, con muy buena aceptación de los médicos operadores.

Conclusiones. La utilización de la prótesis valvular transcatéter MyVal ha resultado segura y versátil, adaptándose a casos de alta complejidad técnica. La gran disponibilidad de talles disminuye la tasa de complicaciones, necesidad de marcapasos y permite ampliar la terapéutica a casi la totalidad de áreas valvulares. La distribución geográfica de los implantes y la opinión de los operadores demuestran una amplia aceptación y satisfactoria experiencia.

Palabras clave: válvula cardíaca transcatéter, implante valvular transcatéter, válvula balón expandible, estenosis aórtica, tamaños intermedios, tamaños extragrandes, Myval.

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INTRODUCTION

In recent years, valve diseases have become highly prevalent, a trend exacerbated by the aging population[1]. Shortly after its emergence, transcatheter aortic valve implantation (TAVI) has solidified its status as an effective and safe solu-

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Conflicts of interest: Federico Blanco, Juan Pablo De Brahi, and Pablo Lamelas are proctors for Myval (Meril LifeScienses). No conflicts of interest whatsoever for the other authors.

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Figure 1. *A: The Myval valve (Meril Life Sciences Pvt. Ltd., India) is a balloon-expandable prosthesis composed of a cobalt-nickel stent, on which are mounted 3 bovine pericardium leaflets with anti-calcification treatment and an outer PET sealing skirt at the landing zone, which reduces the possibility of residual paravalvular leakage.*

Figure 1. *C: The PythonTM introducer sheath of 14 Fr (Meril Life Sciences Pvt. Ltd., India) is designed for the insertion of the MyVal device. It is compatible with all valve sizes. Additionally, this sheath also offers the exceptional ability to fully retrieve the device if the operator cannot cross the aortic ring due to anatomical challenges.*

tion to this issue, especially for patients whose surgical risk is considered unacceptably high. This advancement has provided new, less invasive treatment options with results comparable, or sometimes even superior, to traditional surgical procedures. The variety of devices developed offers operators the opportunity to choose the most appropriate prosthesis for each type of patient[2-4].

In this context, balloon-expandable devices have further expanded the possibilities of percutaneous treatment for valve disease, as they go beyond aortic valve disease, onto pulmonary, tricuspid, and mitral valve disease. By minimizing procedural complications and improving clinical outcomes, these prostheses have proven to be a promising option in the field of interventional cardiology[5-7].

It is important to remember that the world's first TAVI procedures were performed with balloon-expandable devices (Cribier-Edwards THV, Rouen, France), which validated the technique as safe and reproducible, with sustained outcomes over time[8]. Over the years, the most significant scientific evidence in this field has been generated with balloon-expandable (Sapien XT - Sapien 3, Edwards Lifesciences, Irvine, California) and self-expanding devices (CoreValve - Evolut, Medtronic Inc, Minneapolis, Minnesota)[9-12].

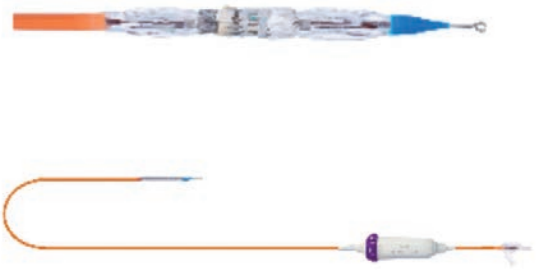

Figure 1. *B: The 'Navigator' delivery system consists of an over-the-wire balloon catheter with a high-flex rotating handle on which the valve is directly crimped, eliminating the need to maneuver or mount the valve on the balloon in the aorta.*

In particular, the Myval™ balloon-expandable prosthesis (Meril Life Sciences Pvt. Ltd., India) shares common features with pre-existing balloon-expandable devices, while also featuring very important distinguishing characteristics. This device is mounted directly on the balloon, is completely removable, and is available in intermediate and extra-large sizes, with a flexible delivery catheter, a stent height shorter than that of other balloon-expandable prostheses, and the possibility of implanting prostheses of all sizes using the same 14-Fr expandable introducer. Additionally, preliminary publications suggest a low pacemaker rate and more favorable hemodynamic behavior[13].

In this study, we present the initial experience of the first 300 valve implantations conducted in Argentina with the Myval prosthesis. Until Meril was introduced in the Argentine market, only a few centers used balloon-expandable technology as their preferred choice. This work aims to analyze the clinical outcomes and assess the potential advantages of this prosthesis for the treatment of valve disease. The information obtained in this study will contribute to strengthening the scientific evidence surrounding the efficacy and safety of these percutaneous interventions in the Latin American region.

Objective To analyze the initial experience of the first 300 valve implantations conducted with balloon-expandable valve Myval in Argentina. We will include the hemodynamic and clinical outcomes, as well as a detailed geographic description and the opinions of the operators involved in the procedures.

MATERIALS AND METHODS

Design. This is a prospective multicenter registry.

Study population. We included all consecutive patients undergoing percutaneous valve replacement with the Myval valve in Argentina between September 8, 2021, and September 22, 2023.

TABLE 1. Baseline characteristics of the population.

Age (years)	78.7±6.3
Female sex	181 (60.,3)
EuroSCORE II	6.2±2.3
NYHA III Dyspnea	223 (74.3%)
NYHA IV Dyspnea	32 (10.7%)
Coronary disease	173 (57.7%)
Previous cardiac surgery	22 (7.3%)
Diabetes	62 (20.7%)
COPD	70 (23.3%)
Renal dysfunction	176 (58.7%)
Pulmonary hypertension	156 (52%)
Previous pacemaker	24 (8%)
Atrial fibrillation	45 (15%)
Bicuspid aorta	19 (6.3%)
Native aortic position	279 (93%)
Aortic valve in valve position	6 (2%)
Mitral position	3 (1%)
Pulmonary position	4 (1.3%)
Tricuspid position	8 (2.7%)
Ejection fraction (%)	51.5±16
Aortic valve area (cm^2)	0.72±0.38
Maximum aortic gradient (mmHg)	73±16

Age, EuroSCORE II, aortic valve area, and maximum aortic gradient are expressed as mean and standard deviation. The rest of the variables are expressed as number and percentage (%).

TABLE 2. Procedure data. Variables expressed as number and percentage (%).

Procedure success	296 (98.7%)
Local anesthesia and sedation	166 (55.3%)
General anesthesia	134 (44.7%)
Transfemoral access	294 (98%)
Percutaneous access	179 (59.7%)
Prosthesis Size:	
No. 20 % (n)	12 (4%)
No. 21.5 % (n)	11 (3.7%)
No. 23 % (n)	51 (17%)
No. 24.5 % (n)	62 (20.7%)
No. 26 % (n)	52 (17.3%)
No. 27.5 % (n)	60 (20%)
No. 29 % (n)	42 (14%)
No. 30.5 % (n)	0 (0%)
No. 32 % (n)	10 (3.3%)
Predilatation	180 (60%)
Postdilatation	56 (18.7%)
Device embolization	0
Mild paravalvular leak	139 (46.3%)
Moderate paravalvular leak	2 (0.7%)
Severe paravalvular leak	0 (0%)
Cardiac tamponade	4 (1.3%)
Coronary obstruction	0 (0%)
Aortic ring rupture	0 (0%)

All patients were assessed through a thoracic and abdominal aortic CT angiography before they were approved for the intervention with the Myval device. This task was conducted under very strict parameters, as most centers had no prior experience with balloon-expandable devices and proper aortic ring measurement.

All patients provided their consent for the procedure by signing the informed consent form.

Procedure and endpoints

The indication for the procedure, the prosthesis size selection, and the access route were all discussed using a multidisciplinary approach by the local heart team. At each center, procedures for the first five cases were performed by local interventional cardiologists with the mentorship of an expert operator. The procedures were conducted following current technical standards, similar to other devices.

Age, gender and medical history, type of approach, type of anesthesia, and prosthesis size were the analyzed variables. The primary endpoint was procedural success, and secondary endpoints included all-cause mortality, cardiovascular mortality, stroke, moderate or severe paravalvular leak, and new permanent pacemaker implantation during the hospital stay (criteria determined by the Valve Academic Research Consortium-3 [VARC-3])[14]. Additionally, researchers recorded operator opinions regarding the device, highlighting differences, advantages, and disadvantages compared to other known devices through a semi-structured survey sent to each operator after the procedure.

Device characteristics

The *Myval* valve (Meril Life Sciences Pvt. Ltd., India) is a balloon-expandable prosthesis that has a nickel-cobalt stent. Three bovine pericardial leaflets that have undergone anti-calcification treatment are mounted on the aforementioned stent, and the device also includes an outer PET sealing skirt in the inflow or landing zone, which reduces the possibility of residual paravalvular leakage **(Figure 1A)**.

There are four standard prosthesis sizes (20, 23, 26, and 29 mm), three intermediate sizes (21.5, 24.5, 27.5 mm), and two extra-large sizes (30.5 and 32 mm), which cover a ring area range between 270 mm^2 and 840 mm^2 using the oversizing recommended by the manufacturer. It should be noted that the last five sizes mentioned are exclusive to Myval, without being available in any other device.

Myval prosthesis kit

This device came with a kit for each intervention in all treated patients, consisting of the following supplies:

- Balloon-expandable prosthesis **(Figure 1A).**
- Navigator release system, with high flexibility and navigability **(Figure 1B).**
- 14-Fr Python™ **expandable** introducer sheath (Meril LifeSciences Pvt. Ltd., India) **(Figure 1C).**
- Mammoth™ semi-compliant balloon for predilation (Meril LifeSciences Pvt. Ltd., India).
- Val-de-Crimp crimping device.

The Myval device was guided to the target valve ring using a delivery system consisting of a specially designed over-the-wire high-flexibility balloon catheter: the Navigator™ (Meril LifeSciences Pvt. Ltd., India), which uses a crimping tool, the Val-de-Crimp™ (Meril LifeSciences Pvt. Ltd., India). This valve is crimped directly onto the balloon of the Navigator™ delivery system, thus eliminating the need to maneuver or mount the valve onto the balloon in the aorta **(Figure 1B).** This feature reduces the risk of balloon rupture during the procedure and is also less likely to traumatize the delivery system balloon. Once in position, the valve can be precisely deployed at the target site (in its orthotopic position) through simple inflation, by connecting to a high-pressure inflator at the proximal port while stabilizing the patient's heart through rapid pacing.

The 14-Fr Python™ introducer sheath (Meril LifeSciences Pvt. Ltd., India) is specifically designed for the insertion of the Myval device. It is compatible with all valve sizes, from

TABLE 3. Endpoints in their hospital evolution according to VARC-3 criteria.

All-cause mortality	8 (2.7%)
Cardiovascular mortality	8 (2.7%)
Myocardial infarction	0 (0%)
Stroke	2 (0.7%)
Access site vascular injuries	25 (8.3%)
Permanent pacemaker implantation	20 (6.7%)
Major bleeding	14 (4.7%)
Renal insufficiency	52 (17.3%)
Endocarditis	0 (0%)

Variables expressed as number and percentage (%).

20 mm to 32 mm. Additionally, this sheath can fully retrieve the device—an exceptional feature—if the operator is unable to cross the aortic ring due to anatomical challenges **(Figure 1C).** The Mammoth™ semi-compliant balloon for predilation (Meril LifeSciences Pvt. is included in the kit and available in the following sizes: 14 mm, 16 mm, 18 mm, 20 mm, 23 mm, and 25 mm.

Statistical analysis

Categorical variables are expressed as percentages. Continuous variables with a normal distribution are presented as mean and standard deviation, and, in cases of non-Gaussian distribution, as median and interquartile range. Categorical variables were compared using contingency tables, with Yates' corrected chi-square test or Fisher's exact test, as appropriate. The comparison of continuous variables was performed using the t-test or through non-parametric tests (Wilcoxon and Kruskal-Wallis), depending on distribution. The analysis was conducted using the Statistix 7.0 software, and $p < 0.05$ was considered significant.

RESULTS

The study included the first 300 consecutive patients who underwent percutaneous Myval valve implantation in Argentina from September 8, 2021, to September 22, 2023.

The characteristics of the population can be found in **Table 1**, where the patient comorbidities and intermediate-to-high cardiovascular risk stand out. Overall, 74.3% of the patients were functional class III, and 10.7% were functional class IV.

Notably, 95% of all implantations were in the aortic valve. Of these, 97.9% were in native valves and, of these, 93.7% were in tricuspid valves and 6.3% in bicuspid valves. Additionally, 2.7% of all implantations were in the tricuspid valve (seven valve-in-valve cases and one valve-in-ring case); 1.3% in the pulmonary valve (all cases with prior stent implantation), and 1% in the mitral valve (one valve-in-valve case, one valve-in-ring case, and one Mac case).

When analyzing aortic valve disease, 98.7% of the procedures were conducted in cases of severe aortic stenosis, and 1.3% in cases of pure aortic regurgitation. Regarding the stenosis cases, the mean aortic valve area, as measured by Doppler echocardiography, was 0.72±0.38 cm^2 **(Table 1).**

In 55.3% of the cases, the procedure was performed under deep sedation and local anesthesia, while 44.7% were performed under general anesthesia. In 59.7% of the cases, percutaneous access was used, while 40.3% had surgical access. About 52.3% of all implantations required standard-size valves, 44.3% required intermediate sizes, and 3.3% required extra-large sizes. Predilation was performed in 60% of the cases, while only 18.3% of the procedures required postdilation **(Table 2).**

Figure 2. *Distribution of implanting centers.*

In cases of aortic implantation due to stenosis, there was a significant reduction in the peak transvalvular gradient (73±16 vs. 5±3 mmHg; $p < 0.001$), with no severe aortic regurgitation after the procedure. Conduction disorders were infrequent, with a rate of post-procedural permanent pacemaker implantation of 6.7%—7%, when only considering aortic valve implantations.

Mortality during the procedure (including all procedures) was 0.7% (2 cases): one case due to ventricular perforation caused by an unshaped stiff guidewire and another due to a vascular complication at the access site. In-hospital mortality (including all implantations) was 2.7% (8 patients). The cases were caused by complications secondary to ventricular perforation due to the use of unshaped guidewires, vascular access issues, and cardiogenic shock. In-hospital outcomes and safety endpoints are detailed in **Table 3.**

The procedures were conducted in 78 centers across 16 of the 24 districts that make up Argentina (**Figure 2**). The valve was successfully implanted in 99.3% of the patients, and procedural success was achieved in 98.7% of the cases. The operators' opinions on device characteristics are described in **Table 4.**

TABLE 4. Operators' opinion regarding the Myval device.

	-5	-4	-3	-2	-1	0	1	2	3	4	5	Valoración
Trackability	0%	0%	0%	0%	0%	0%	0%	1%	2%	77%	20%	4.16/5
Pushability	0%	0%	0%	0%	0%	0%	1%	12%	37%	42%	8%	3.44/5
Ease of positioning	0%	0%	0%	1%	0%	0%	0%	2%	28%	60%	9%	3.73/5
Radiopacity	0%	0%	0%	0%	0%	1%	1%	8%	48%	35%	7%	3.36/5
Valve inflation	0%	0%	0%	0%	1%	0%	2%	4%	13%	32%	48%	4.16/5
Hemodynamic outcome	0%	0%	0%	0%	0%	1%	1%	0%	1%	41%	56%	4.48/5
Paravalvular insufficiency	0%	0%	0%	0%	1%	1%	2%	2%	3%	32%	59%	4.37/5
Comparison with other valves												
Self-expandable	0%	0%	0%	3%	4%	20%	13%	18%	15%	6%	21%	2.13
Balloon-expandable	1%	0%	0%	4%	7%	29%	17%	10%	4%	5%	23%	1.64

DISCUSSION

The revolution spurred by transcatheter aortic therapy is based on two major advancements: technological device improvements and technique optimization. These result in increasingly effective and less invasive treatment. Recent years have seen the development of multiple devices, facilitating the expansion of both the patient spectrum for this treatment and its scope of application to valves beyond the aortic valve[15-20].

To our knowledge, this is the first study to examine the clinical efficacy and early safety of the Myval THV balloon-expandable valve in the Argentine population. Our findings have shown favorable clinical outcomes, particularly regarding the low rate of conduction disorders and the lack of severe residual aortic regurgitation. The primary endpoint, early procedural success, was achieved in 98.7% of patients.

This is a descriptive, prospective, non-randomized series, without a control group and without follow-up beyond in-hospital evolution. However, the population described here reflects the real-world scenario of valve implantation in Argentina, with patients of varying characteristics and complexity. It is worth noting that data collected corresponded to procedures conducted in 78 centers across 16 of the 24 districts that make up the country (66.7%). This is a highly representative sample of the reality for this technique in Argentina, including operator progress and skill, considering that many had no prior experience with balloon-expandable prostheses or were still in the learning curve[21].

Since these were consecutive patients, there was no selection bias or other restrictions that could have distorted the experience. We believe that, unlike in other countries, the population undergoing percutaneous implantation in Argentina remains a high-risk or inoperable population. This assertion is based on the age of the treated patients, their EuroSCORE II, their functional class before implantation, and the presence of comorbidities. It is important to highlight that despite the cited limitations, the results found are similar to those reported in major international registries with this prosthesis[6, 7, 22, 23]. These encouraging clinical findings for Myval could be attributed to its outstanding design features, which facilitate precise positioning and deployment, as well as a size matrix that allows for the treatment of a very high percentage of patients.

When analyzing the size of the valves used, nearly half of the cases required intermediate or extra-large sizes, which could have the advantage of not excessively oversizing or underexpanding a prosthesis to cover the annular area (that is, adding or subtracting more than 2 mL from the nominal inflation value). This could improve the hemodynamic profile and, in turn, reduce complications such as central valve leak, annular rupture, and device embolization, especially when dealing with complex anatomies[22-24]. Extra-large sizes can, in many cases, be the valve of choice for patients with extremely large aortic rings, or in cases of mitral or tricuspid valve implantation, or non-calcified pure aortic regurgitation[15, 18, 25, 26]. It is worth noting that during the first year of this experience, the extra-large devices had not yet been approved by the National Administration of Drugs, Food, and Medical Technology (ANMAT), which would explain their low use in the registry.

Moreover, considering that nearly 60% of the cases had a history of coronary artery disease, the Myval design allows for easy new access to the coronary *ostium*, if needed[27].

It should be noted that 5% of the procedures were performed in the tricuspid, mitral, or pulmonary valve. The tricuspid valve implantations were performed on prosthetic valves or rings; pulmonary valve implantations, on native valves with prior stent placement; and mitral valve implantations on prostheses, rings, and native valves, thus demonstrating the device's versatility[15-20]. It should be remembered that this device, unlike its balloon-expandable competitors, can be completely retrieved from the body after insertion, which offers a special advantage for mitral or tricuspid procedures, where the likelihood of losing guidewire position is higher[18, 19].

When analyzing the in-hospital mortality for the registry, 2.7% (8 patients) is an expected value for this type of procedure, especially considering the previously mentioned high-risk population and the fact that, in most cases, the physicians involved were in the learning curve for the device[21].

Another noteworthy aspect is the rate of pacemaker implantation after the procedure (20 patients, 7% when considering only aortic valve implantation)[28, 29]. The values for hemodynamic parameters after the procedure demonstrate the efficacy of this new valve. The aortic transvalvular gradients decreased significantly (73±16 vs. 5±3 mmHg; $p < 0.001$), with a low need for post-dilation (18.7%) and no severe perivalvular leak, a variable associated with good long-term prognosis[8, 30].

Finally, considering all the previously described virtues, operator acceptance of the device was very good (**Table 4**), not only due to its technical characteristics but also because it is easy to use and its results are easily reproducible.

Limitations

In this multicenter registry, we analyzed the results of the first 300 Myval aortic valve implantations conducted in Argentina, without long-term follow-up. This group of patients, being the first, possibly includes higher rates of complex anatomy, non-aortic valve disease, and large annular

area, which are cases that can only be treated with this device. Additionally, endpoint assessment was not centralized but provided by operators at each center. We believe that larger registries with follow-up are necessary to evaluate the efficacy and safety of the device.

CONCLUSIONS:

In our initial experience, transcatheter implantation with the Myval prosthesis for the treatment of different types of severe valve disease has been feasible, effective, and safe. This prosthesis has proven to be versatile and has been favorably used in very diverse and highly complex scenarios, with a low need for pacemaker implantation. The intermediate and extra-large sizes allowed for the coverage of annular areas up to 840 mm², thus constituting the only alternative recommended by manufacturers for such cases. The geographic distribution of implants and operator opinions demonstrate broad acceptance and a satisfactory experience.

CONFLICTS OF INTERESTS

Federico Blanco, Juan Pablo De Brahi, and Pablo Lamelas are proctors for Myval (Meril LifeScienses). No conflicts of interest whatsoever for the other authors.

REFERENCES

1. *Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, et al. Burden of valvular heart diseases: a population-based study. Lancet. 2006 Sep 16; 368(9540):1005-1011. doi: 10.1016/S0140-6736(06)69208-8.*
2. *Webb JG, Pasupati S, Humphries K, Thompson C, Altwegg L, et al. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. Circulation. 2007 Aug 14;116(7):755-763. doi: 10.1161/ CIRCULATIONAHA.107.698258.*
3. *Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP, et al. 2020 ACC/ AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. Circulation. 2021;143(5):e35–e71. doi: 10.1161/CIR.0000000000000932.*
4. *Cahill TJ, Chen M, Hayashida K, Latib A, Modine T, et al. Transcatheter aortic valve implantation: current status and future perspectives. Eur Heart J. 2018 Jul 21;39(28):2625-2634. doi: 10.1093/eurheartj/ehy244.*
5. *Sharma SK, Rao RS, Chandra P, Goel PK, Bharadwaj P, 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.*
6. *Moscarella E, Ielasi A, Montonati C, Pellegrini D, Pellicano M, et al. Comparing two-year outcomes of balloon-expandable Myval and self-expanding Evolut R in severe aortic valve stenosis. Int J Cardiol. 2023 Dec 31:131701. doi: 10.1016/j.ijcard.2023.131701.*
7. *Magyari B, Kittka B, Goják I, Kasza G, Schönfeld K, et al. Single center experience with the balloon-expandable Myval transcatheter aortic valve system with the first 100 patients: 30-day and 1-year follow-up. Catheter Cardiovasc Interv. 2023 Dec; 102(7):1317-1330. doi: 10.1002/ccd.30868.*
8. *Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002 Dec 10;106(24):3006-8.doi: 10.1161/01.cir.0000047200.36165.b8. PMID:*
9. *Leon MB, Smith CR, Mack M, Miller DC, Moses JW, et al. PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363:1597– 1607. doi: 10.1056/NEJMoa1008232.*
10. *Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, et al. PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364:2187–2198. doi: 10.1056/ NEJMoa1103510.*
11. *Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695-1705. https://doi.org/10.1056/ NEJMoa1814052.*
12. *Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada Het al. Evolut Low Risk Trial Investigators. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1706-1715. doi: 10.1056/NEJMoa1816885. Epub 2019 Mar 16. PMID: 30883053.*
13. *Delgado-Arana JR, Gordillo-Monge MX, Halim J, De Marco F, Trani C, et al. Early clinical and haemodynamic matched comparison of balloon-expandable valves. Heart. 2022 May;108(9):725-732. doi: 10.1136/heartjnl-2021-319349. Epub 2021 Jul 20. PMID: 34285104.*
14. *Genereux P, Piazza N, Alu MC, Nazif T, Hahn RT, et al. Valve Academic Research Consortium 3: Updated Endpoint Definitions for aortic valve clinical research. J Am Coll Cardiol. 2021 Jun 1; 77(21): 2717-2746. doi:10.1016/j.jacc.2021.02.038. PMID: 33888385*
15. *Ayhan H, Duran-Karaduman B, Keels T, Bozkurt E. Transcatheter treatment tricuspid regurgitation by valve-in-ring implantation with a novel balloon- expandable Myval(R) THV. Kardiol Pol. (2022) 80:363–4. doi: 10.33963/ KP.a2022.0013.*
16. *Mussayev A, Alimbayev S, Tanaliev N, Kuanyshbek A, Marat A, et al. Case report: Transcatheter tricuspid valve-in-valve implantation using novel balloon- expandable aortic valve with 1 year follow-up. Front. Cardiovasc. Med. 10:1152280. doi: 10.3389/fcvm.2023.1152280*
17. *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 Aug 2;7(8):ytad322. doi: 10.1093/ehjcr/ytad322.*
18. *Blasco-Turrión S, Serrador-Frutos A, Jose J, Sengotuvelu G, Seth A, et al. Transcatheter Mitral Valve-in-Valve Implantation with the Balloon-Expandable Myval Device. J Clin Med. 2022 Sep 2;11(17):5210. doi: 10.3390/jcm11175210.*
19. *Pirelli L, Hong E, Steffen R, Vahl TP, Kodali SK, et al. Mitral valve-in-valve and valve-in-ring: tips, tricks, and outcomes. Ann Cardiothorac Surg. 2021 Jan;10(1):96-112. doi: 10.21037/acs-2019-mv-169.*
20. *Hascoët S, Bentham JR, Giugno L, Betrián-Blasco P, Kempny A, et al. Outcomes of transcatheter pulmonary SAPIEN 3 valve implantation: an international registry, European Heart Journal, Volume 45, Issue 3, 14 January 2024, Pages 198–210, https://doi.org/10.1093/eurheartj/ehad663*
21. *Caponi G, Fava C, Fraguas H, Valdivieso L, Lev G, et al. Evolución de la experiencia con reemplazo de válvula aórtica (TAVR) en un centro de Argentina. Revista Argentina de Cardioangiología Intervencionista 2016;7(4):211-216.*
22. *Barki M, Ielasi A, Buono A, Maliandi G, Pellicano M, 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. J. Clin. Med. 2022;11:959. doi: 10.3390/ jcm11040959.*
23. *De Backer O, Sathananthan J, Landes U, Danenberg HD, Webb J, et al. Redo- Tavi with a balloon-expandable valve and the impact of index Transcateter aortic valve design. EuroIntervention2023;19:714-716. doi: 10.4244/EIJ-D-23-00363.*
24. *Halim J, Rooijakkers M, den Heijer P, El Haddad M, van den Branden B, et al. Assessing the Novel Myval Balloon-Expandable Valve with the Evolut Valve: A Propensity-Matched Study. J Clin Med. 2023 Jun 22;12(13):4213. doi: 10.3390/ jcm12134213.*
25. *Holzamer A, Bedogni F, Wyk P, Barwad P, Protasiewicz M, et al. 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. Catheter. Cardiovasc. Interv. 2023;102(7):1364-1375. doi: 10.1002/ccd.30820.*
26. *Sanchez-Luna JP, Martín P, Dager AE, ; Charry PD, Beltrán JR, et al. Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation. EuroIntervention2023;19:580-588. doi: 10.4244/EIJ- D-23-00344.*
27. *Valvo R, Costa G, Tamburino C, Barbanti M. Coronary artery cannulation*

after transcatheter aortic valve implantation. EuroIntervention. 2021 Nov 19;17(10):835-847. doi: 10.4244/EIJ-D-21-00158.

28. *Santos-Martinez S, Halim J, Castro-Mejía A, De Marco F, Trani C, et al. Myval versus alternative balloon- and self-expandable transcatheter heart valves: A central core lab analysis of conduction disturbances. Int J Cardiol. 2022: 15:351:25-31. doi: 10.1016/j.ijcard.2021.12.049.*
29. *Sawaya FJ, Spaziano M, Lefèvre T, Roy A, Garot P, et al. Comparison between the SAPIEN S3 and the SAPIEN XT transcatheter heart valves: a single-center experience. World J Cardiol. 2016;8(12):735–745. doi: 10.4330/wjc.v8.i12.735.*
30. *Jilaihawi H. Paravalvular regurgitation after transcatheter aortic valve replacement: striving to perfect its prognostic evaluation with hemodynamic data. JACC Cardiovasc Interv. 2016;9(7):712–714. doi: 10.1016/j.jcin.2016.01.023.*