Early multicenter experience of a new balloon expandable MyVal transcatheter heart valve in dysfunctional stenosed right ventricular outflow tract conduits

Muthukumaran C Sivaprakasam[1], J Raja Vijendra Reddy[1], Sengottuvelu Gunasekaran[1], Kothandam Sivakumar[2], Sreeja Pavithran[2], Gopalavilasam Rajagopalan Rohitraj[2], M Jayranganath[3], Edwin Francis[4]

[1]Department of Pediatric Cardiology, Apollo Children's Hospital, Chennai, Tamil Nadu, India, [2]Department of Pediatric Cardiology, Institute of Cardiovascular Diseases, Madras Medical Mission, Chennai, Tamil Nadu, India, [3]Department of Pediatric Cardiology, Sri Jayadeva Institute of Cardiovascular Sciences and Research Institute, Bengaluru, Karnataka, India, [4]Department of Pediatric Cardiology, Lisie Hospital, Kochi, Kerala, India

ABSTRACT

Background : **Transcatheter pulmonary valve implantation (TPVI) is a surgical alternative for correcting dysfunctional right ventricular outflow tract conduits in previously operated patients. MyVal transcatheter heart valve (THV) (Meril Life Sciences, India), a new transcatheter valve designed for aortic position has not been used for TPVI.**

Methods : **Patients with stenosed dysfunctional conduits from the right ventricle to pulmonary artery (RV-PA) were prestented after initial computed tomography and balloon interrogation before the implantation of MyVal. Size of MyVal was chosen based on the final diameter of the prestent. Procedural details and post-TPVI follow-up were analyzed.**

Results : **Seven patients aged 17–60 years (median 26 years) had stenosed RV-PA conduits implanted 5–17 years (median 9 years) ago for tetralogy of Fallot in three, following Ross procedure in two, repair of pulmonary stenosis, and following PA debanding in one patient each. Prestenting improved the conduit diameter from 9.3 ± 2.8 mm to 20.8 ± 1.1 mm and relieved the gradient from 87.3 ± 31.7 mmHg (50–137 mmHg) to 12.7 ± 6.4 mmHg (5–20 mmHg). A 23 mm MyVal was implanted in all the seven patients successfully; one patient needed an additional 24.5 mm MyVal valve in valve implantation for residual regurgitation. The mean fluoroscopic time and dose area product were 38.7 ± 25.3 min and 66.917 ± 39.211Gray. cm2, respectively. At a median follow-up duration of 16 months (10–22 months), all patients were asymptomatic receiving dual antiplatelet therapy with no PR and the gradient was 12.5 ± 5.8 mmHg on echocardiography. Although one patient needed an additional valve-in-valve implantation, there were no valve-related adverse events.**

Conclusions : **Early experience of TPVI with MyVal THV in prestented conduits is encouraging with procedural success in all patients and acceptable mid-term outcomes.**

Keywords : Congenital heart disease, Transcatheter pulmonary valve, Pulmonary regurgitation, Right ventricular conduit

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Address for correspondence: Dr. Kothandam Sivakumar, Department of Pediatric Cardiology, Institute of Cardio Vascular Diseases, Madras Medical Mission, 4A Dr. J J Nagar, Mogappair, Chennai - 600 037, Tamil Nadu, India.
E-mail: drkumarsiva@hotmail.com

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INTRODUCTION

Various forms of congenital heart diseases associated with abnormalities of right ventricular outflow tract (RVOT) require surgical reconstruction using transannular patches, conduit placement between the right ventricle (RV), and pulmonary artery (PA) or a bioprosthetic valve placement in the pulmonary position.[1] Such clinical situations include tetralogy of Fallot (TOF), pulmonary atresia with ventricular septal defect, congenital pulmonary stenosis (PS), truncus arteriosus, transposition of great vessels repaired by Rastelli procedure, and Ross procedure for aortic valve abnormalities. When the valved conduits or bioprosthetic valves develop stenosis and/or regurgitation (PR), or a combination of both, they lead to progressive RV dilatation and dysfunction, leading to arrhythmias and premature death.[2,3] A redo surgery for correcting the dysfunctional RVOT carries significant morbidity, raising a quest for an alternative, less invasive treatment approach.

Transcatheter pulmonary valve implantation (TPVI) has gained popularity ever since its inception in 2000 by Bonhoeffer in a pediatric patient.[4] The technical advances in TPVI led to recommendation for the use of transcatheter heart valve (THV) by the American Heart Association for treating dysfunctional RV-PA conduit in patients with moderate-to-severe PR or stenosis.[5]

Myval™ THV (Meril Life Sciences Pvt Ltd, Vapi, Gujarat, India) is a newer-generation balloon-expandable bioprosthetic valve, developed as a transcatheter alternative to surgical valve replacement for severe symptomatic native aortic stenosis.[6,7] Based on promising clinical and hemodynamic outcomes after transcatheter aortic valve replacement, the device has been approved by the Central Drugs Standard Control Organization and also received the Conformité Européenne certificate. However, there is a paucity of literature related to its safety and efficacy for treating dysfunctional RVOT conduits. This study presents the initial experience of MyVal THV and assesses its clinical performance in dysfunctional RVOT conduits.

METHODS

Study design and patient population

A retrospective multicenter review of case records was performed of all patients who underwent TPVI with Myval THV for dysfunctional RVOT. The patients were included for TPVI for dysfunctional RVOT according to the standard guidelines.[5] Patients with active endocarditis, sepsis, and pregnancy were excluded. Informed written consent was obtained from patients after detailed explanations about alternate surgical options and other transcatheter valves. The clinical detail of every patient was analyzed before inclusion by a multidisciplinary heart team that included pediatric cardiac surgeons. The Institutional Ethics Committee approved the study.

Valve description

Myval THV is structured on a nickel-cobalt alloy frame with a unique honey-comb design comprising of hexagonal elements.[6] The valve consists of decellularized bovine pericardial tissue crafted into a tri-leaflet valve on the metal frame that has a skirt of polyethylene terephthalate to retard deposition of calcium and minimize paravalvular regurgitation [Figure 1]. The valve is crimped on a unique hi-flex, over the wire Navigator balloon (Meril Life Sciences Pvt Ltd, India) using a mechanical crimping tool, Val-de-Crimp™ (Meril Life Sciences Pvt Ltd, India), prior to insertion into the systemic circulation. The broad size matrix of Myval THV (20, 21.5, 23, 24.5, 26, 27.5, 29, 30.5, and 32 mm) facilitates the optimal sizing of the THV. A 14F Python™ introducer sheath (Meril Life Sciences Pvt., Ltd., India) suitable for all the sizes of Myval THV ensures uneventful retrieval of undeployed THV in adverse conditions. While the same valve used in aortic position is utilized for pulmonary position too, the differences in pulmonary deployment from aortic deployment include mounting and crimping the valve in reverse position to allow antegrade pulmonary blood flow and anteflexing at the tricuspid valve contrary to retroflexion at the aortic arch.

Eligibility for MyVal transcatheter heart valve

This balloon expandable valve was suited for any prestented conduit with a peak systolic gradient across the landing zone of <20 mmHg. Complete circumferential calcifications of conduits with inadequate relief of gradients and/or significant recoil despite covered stent angioplasty were excluded. If there was significant peripheral PA stenosis that increased the central main PA pressures, they were corrected before MyVal THV deployment as it might affect

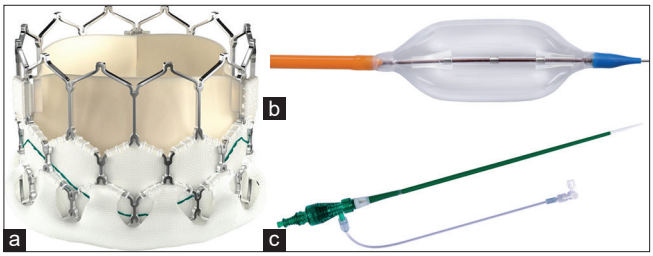

Figure 1: MyVal transcatheter heart valve (a) is made of bovine pericardial leaflets on a nickel cobalt alloy frame whose the upper end has a single row of open hexagonal cells and lower end has two rows of closed cells. The polyethylene terephthlate skirt retards calcium deposition and reduces paravalvular regurgitation. It is mounted directly on the balloon of the Navigator delivery system (b) and introduced in the vascular system through the Python sheath (c)

the durability of the valve. Patients with additional defects requiring surgical intervention were excluded.

Preprocedural evaluation

All the patients underwent clinical examination, routine blood testing, electrocardiography, chest radiography, and transthoracic echocardiography. Echocardiographic data included RVOT gradient, severity of PR, right ventricular systolic pressure, systolic and diastolic function of both the ventricles. Multislice computed tomography (MSCT) was performed to assess RVOT diameter, anatomy and coronary course. In patients with dominant PR, cardiac magnetic resonance imaging was also used to quantify ventricular volumes and function and PR fraction. All patients underwent conduit and selective coronary angiogram and balloon interrogation before the procedure to determine the valve diameter as well as the risk of coronary compression.

Prestenting of the stenosed conduit

After hemodynamic and angiographic assessment of the stenosed conduit, prestenting was done using large vessel stents and high-pressure balloons [Figure 2]. Covered stents were chosen when the balloon chosen to dilate the conduit was larger than the original diameter of the conduit or when calcified conduits posed a risk of rupture. In other cases, uncovered stents were used. While Cheatham Platinum (Numed Inc., Hopkinton, NY, USA) could be expanded to 22 mm, Palmaz 4014 (Cordis endovascular, Miami lakes, FL, USA) or Andra XL (Andramed, Reutlingen, Germany) were capable of maximal expansion to 25 mm. The stents were deployed with semi-compliant balloons, Z-med or BIB (Numed Inc., Hopkinton, NY, USA) and later post dilated with high pressure balloons, Atlas or Atlas Gold (Bard Peripheral Vascular, Tempe, AZ, USA) to the final diameter till the gradient reduced to <20 mmHg [Figure 3]. Additional stents were used for stent recoil or residual stenosis from a thin infundibular sleeve or distal narrowed main PA [Figure 4].

Transcatheter pulmonary valve implantation procedure

Based on preprocedural assessment, a detailed plan for implantation included the selection of the valve diameter which was 1–2 mm larger than the stented conduit diameter. Right femoral vein was the preferred route. Heparin achieved activated clotting time more than 250 s. All patients were administered antibiotic prophylaxis during the procedure and for the 48 h following the procedure. After recording hemodynamics and angiograms, the venous sheath was upsized to the Python introducer sheath. Based on the measurements obtained from angiogram and MSCT, Myval THV of appropriate size was crimped on the Navigator THV balloon-expandable delivery system after orienting the polyethylene terephthalate skirt in the proximal part that was opposite to the orientation of the valve in a transcatheter aortic valve implantation. The Navigator THV delivery system with the crimped Myval THV was advanced through the Python sheath over a Lunderquist wire (Cook medical, Bloomington, IN, USA), and the valve was positioned across the conduit stent, followed

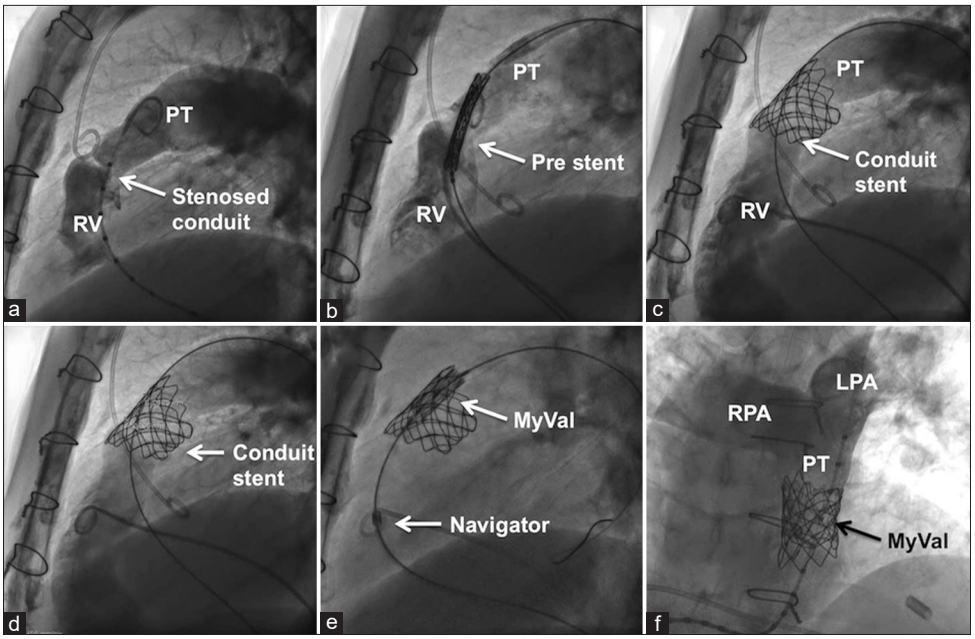

Figure 2: Severe stenosis observed on a lateral view conduit angiogram (a) was prestented using a covered Cheatham platinum stent (b), resulting in restoration of the lumen (c). After measuring the landing zone (d) to be 22 mm, a 23 mm MyVal loaded on Navigator delivery system was deployed within the conduit stent (e). Final pulmonary angiogram (f) shows the absence of pulmonary regurgitation from the pulmonary trunk into the right ventricle

by its deployment by balloon inflation using the measured volume of diluted contrast from the inflation syringe [Figure 5]. After deployment, RV angiograms were performed to assess the functioning of the implanted bioprosthetic valve. Hemostasis at the femoral venous site was achieved with figure of eight suture or Perclose Proglide (Abbott vascular, Santa Clara, CA, USA).

Postprocedural follow-up

Immediate postprocedure transthoracic echocardiography confirmed the absence of RVOT obstruction, RV contractility, and pericardial effusion. Antiplatelet therapy following TPVI comprised 150 mg of aspirin and 75 mg of clopidogrel administered once daily. Antibiotic prophylaxis and patient education about the maintenance of good dental and personal hygiene to prevent endocarditis were advised. Patients were followed at 3 monthly intervals for symptoms, echocardiography for valve function, gradients, presence and degree of regurgitation, electrocardiography for QRS duration and arrhythmias.

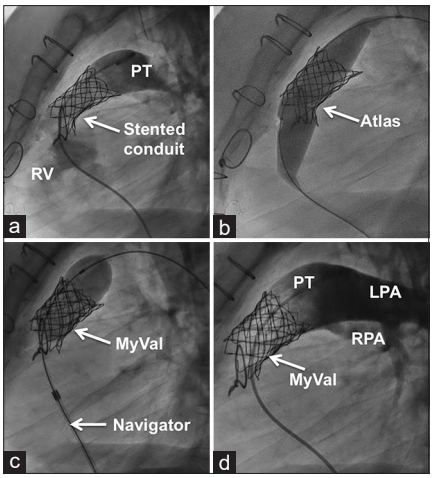

Figure 3: A recoil of the Cheatham Platinum stent (a) within the conduit was postdilated with high pressure balloons (b) before deploying a 23 mm MyVal within the stented conduit (c). Final angiogram from the pulmonary trunk showed the absence of pulmonary regurgitation (d)

RESULTS

Seven patients aged 32.1 ± 18 years (range 17–60 years) met the eligibility criteria for MyVal THV implantation in pulmonary position and formed the study group [Table 1]. All the patients were clinically in NYHA functional class II. All the patients had a stable sinus rhythm. The patients presented with symptoms due to narrowing of the conduit at a median of 9 years (range 5–17 years) after the conduit surgery. While two older patients needed TPVI for a stenosed conduit following Ross procedure performed 17 years earlier, the other five patients were younger and had pulmonary valve conduit placement for TOF or severe valvar PS.

Prestenting of conduit

Stent angioplasty was performed to achieve a final conduit diameter of 20 mm in one and 22 mm in others. Covered stents were used in three patients and uncovered stents in four patients. The mean conduit gradient

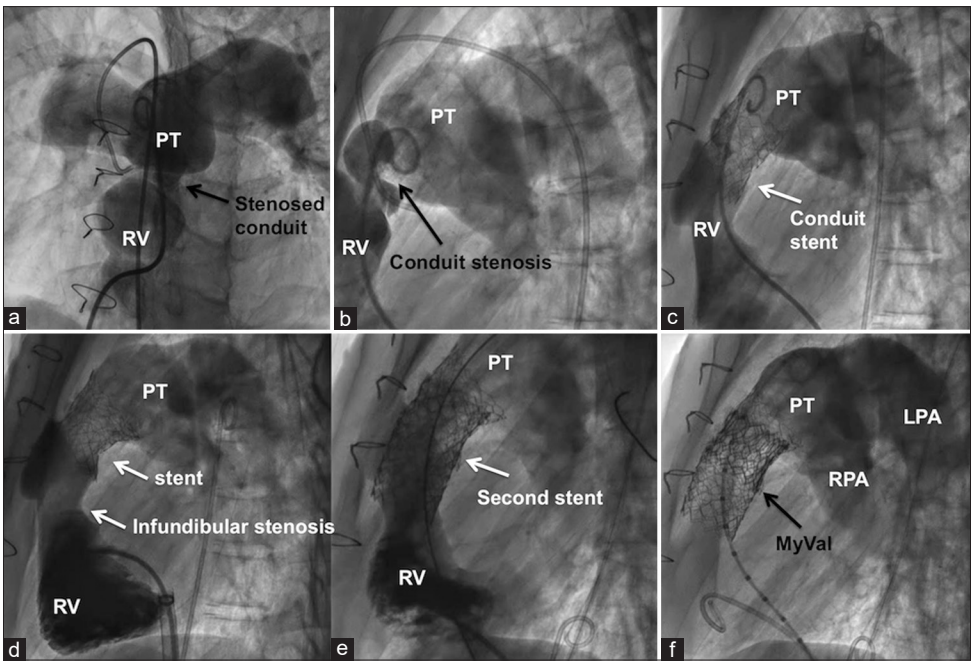

Figure 4: Conduit angiogram in frontal (a) and lateral (b) projections after repair of tetralogy of Fallot, absent pulmonary valve syndrome showed dilated pulmonary trunk and regurgitation into the right ventricle. After stenting with an AndraXXL stent (c), the residual infundibular stenosis (d) required a second overlapping similar stent placement (e) before valvulation with a 23 mm MyVal (f) that eliminated the pulmonary regurgitation

Table 1: Patient clinical parameters

Number	Age sex	Weight (kg), height (cm)	Primary diagnosis	Previous surgeries	Conduit gradient	Conduit used (mm)	Stent	Final gradient	Duration to stent implant (years)
1	56 male	69, 168	Bicuspid aortic valve stenosis	Ross procedure 2002	79	21 homo graft	48 mm covered Andra XL	18	17
2	19 female	39, 152	Tetralogy of Fallot absent pulmonary valve	Conduit repair 2011	137	18 homo graft	39 mm Andra XL	20	5
3	60 male	85, 176	Bicuspid aortic valve stenosis	Ross procedure 2002	70	22 homo graft	48 mm Andra XL	13	17
4	26 female	61, 168	Tetralogy of Fallot	Total repair 1998 pulmonary valve replacement 2009	113	22 Contegra	45 mm covered CP	5	8
5	21 female	40, 163	Pulmonary valve stenosis	Valvotomy 2004 pulmonary valve replacement 2011	50	18 Contegra	43 mm covered Andra XL	15	8
6	26 male	75, 175	Tetralogy of Fallot absent pulmonary valve	Total repair 2001 pulmonary valve replacement 2009	75	22 homo graft	57 mm Andra XL	5	10
7	17 male	38, 157	Ventricular septal defect pulmonary artery deband	Band 2002, surgical repair 2005, conduit replacement 2012	87	18 contegra	Palmaz 4014	12	6

Andra XL: Andrastent extra length. CP: Cheatham Platinum

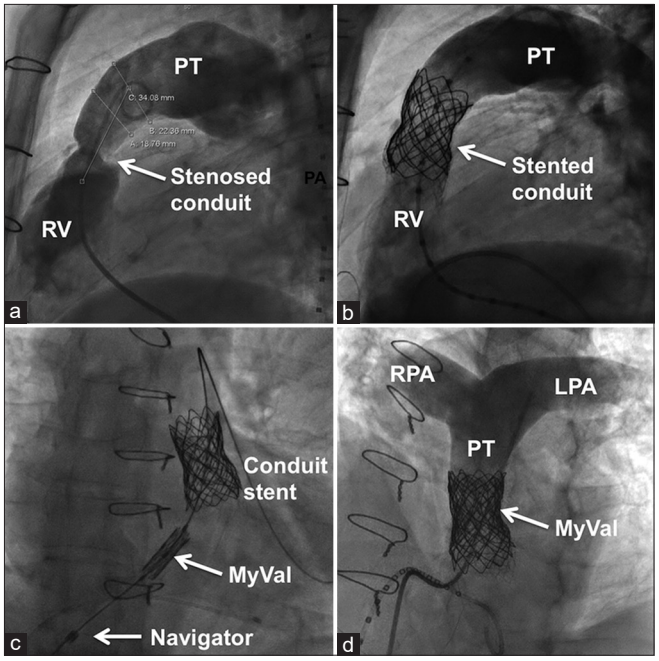

Figure 5: Conduit angiogram in the lateral view (a) after Ross procedure showed severe stenosis and regurgitation of the conduit. Prestenting was done with one AndraXXL stent and two Cheatham Platinum stents (b) due to relieve the recoil of the stent. After deploying a 23 mm MyVal (c), there was no pulmonary regurgitation (d)

reduced from 87.3 ± 31.7 mmHg (range 50–137 mmHg) to 12.7 ± 6.4 mmHg (range 5–20 mmHg). The stenosis diameter improved from 9.3 ± 2.8 mm (range 6–14 mm) to 20.8 ± 1.1 mm (range 20–22 mm) following the prestenting. The TPVI was performed immediately after prestenting in a single sitting in two patients, as a second procedure after 2–6 weeks in two patients, but after 2 years in three patients.

MyVal implantation

The original surgical conduit diameter was 18–22 mm, made of pulmonary homograft in four patients and Contegra conduit (Medtronic Inc., Minneapolis, MN, USA) in three patients. The stenosed conduits were dilated to 20–22 mm after the stent angioplasty. All the patients underwent transcatheter RVOT treatment with 23 mm Myval THV. The mean procedural and fluoroscopic time was 133.57 ± 39.44 min and 38.7 ± 25.3 min, respectively [Table 2]. The mean dose area product was 66.917 ± 39.211 Gray.cm^2.

Complications during prestenting and MyVal implantation

There were two complications during the prestenting managed successfully. Embolized distal balloon tip after a transverse balloon rupture in hilar right PA in one patient with a calcified Ross conduit was successfully snared out entirely before the MyVal implantation. Stent migration of a partially expanded covered AndraXL stent in another patient was managed with an overlapping second uncovered AndraXL stent to result in optimal reduction of the conduit gradient. These two complications resulted in prolongation of fluoroscopic time beyond 50 min in these two patients.

There was one complication with valve implantation. A degenerated 22 mm pulmonary homograft conduit in a 60-year-old patient after 17 years following Ross surgery was prestented with a covered CP stent using

a 22 mm balloon with full relief of the gradients. A 23 mm MyVal THV deployed within the stented conduit was malfunctioning resulting in severe pulmonary regurgitation and complete ventricularization of the PA pressures without any explainable reasons [Figure 6]. An immediate valve-in-valve implantation of a second 24.5 mm MyVal THV corrected the regurgitation successfully.

Follow-up

The seven patients were followed for a median of 16 months (range 10–22 months). All patients reported improvement in physical activity at follow-up, even though no objective exercise tests were performed. There were no rhythm abnormalities on electrocardiography. Echocardiography showed a Doppler gradient of 12.5 ± 5.8 mmHg on follow-up. All patients showed normal RV systolic function on eye-balling without any PR on color Doppler imaging. None of the patients experienced infective endocarditis, valve dysfunction, or clot formation during the follow-up visits. The two older patients also received antihypertensives with optimal control of systemic hypertension.

DISCUSSION

The present study is an early report showing the safety and feasibility of implantation of MyVal THV in the pulmonary position within narrowed conduits that were prestented to relieve the narrowing. A recent systematic review and meta-analysis using the two United Stated Food and Drug Administration approved valves that

Table 2: Preprocedural and postprocedural characteristics of the study population

Patient	RV dilatation	Procedure duration (min)	Fluoro time (min)	Dose area product Gy.cm²	Size of Myval (mm)	Procedural complications	Hospital stay	Follow-up (months)	RV function	Gradient (mmHg)	Pulmonary regurgitation
1	Insignificant	120	145	58.5	23	Balloon rupture	6	19	Good	15	None
2	Present	120	38.9	28.3	23	Nil	7	13	Good	22	None
3	Present	195	60	22.1	24.5	23 mm Myval frozen leaflet	5	13	Good	25	None
4	Present	90	50	20.1	23	Nil	1	22	Good	10	None
5	Insignificant	180	55.7	81.1	23	Migration of prestent	2	16	Good	12	None
6	Present	100	51	22.1	23	Nil	3	13	Good	15	None
7	Present	130	66.9	38.7	23	Nil	4	10	Good	12	None

RV: Right ventricle

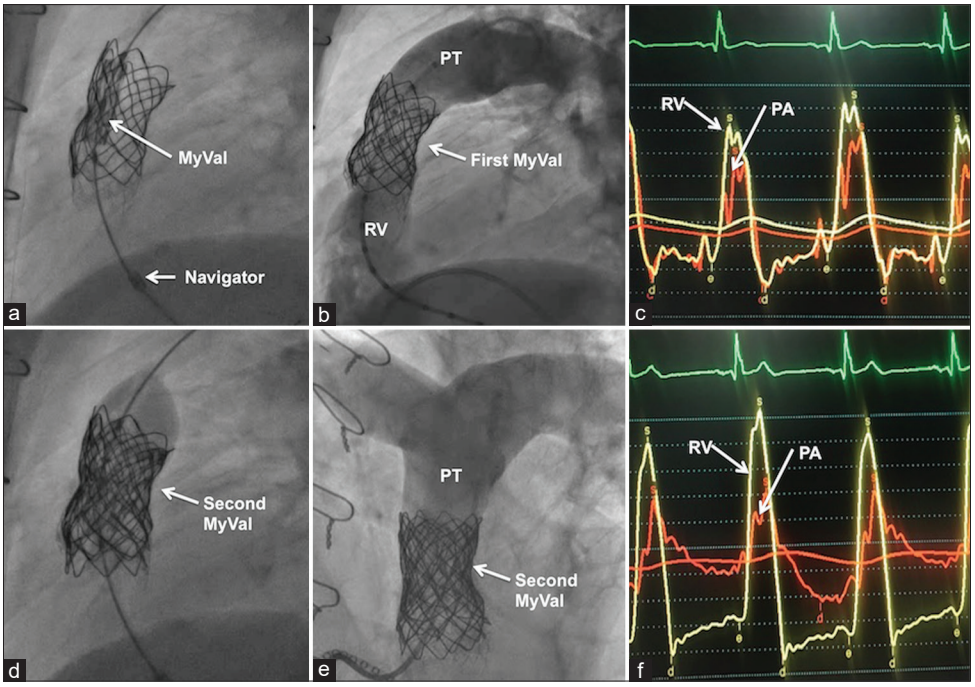

Figure 6: Valvulation of a prestented conduit after Ross surgery with a 23 mm MyVal (a) was followed by observation of severe regurgitation (b) from pulmonary trunk into the right ventricle and pressure traces from the pulmonary trunk confirmed persistent ventricularization (c). A second 24.5 mm MyVal deployed within the previous valve (d) resulted in good valve function (e) and diastolic separation of pressures (f) recorded from the pulmonary artery and right ventricle with a gradient of 10 mm of mercury

showed follow-up data of 1044 patients on a pooled follow-up of 2271 person-years demonstrated procedural success of 96.2%, reinterventions in 2.9%, and pooled endocarditis incidence of 1.4%.[8] Our preliminary study with the new MyVal showed procedural success in all seven patients, without any reinterventions in the short follow-up of 10–22 months and no incidence of endocarditis. The valve functioned without any regurgitation and gradients were within acceptable levels in these seven patients.

Design of MyVal transcatheter heart valve

Myval THV has been introduced for the treatment of native aortic valve stenosis where the clinical need is larger than dysfunctional RVOT.[6] Implantation of Myval THV ensures restoration of normal hemodynamics and optimal effective orifice area owing to its firm anchoring at orthotopic position of the annulus. The entire Myval THV system is designed so perfectly that precise positioning of the THV can be achieved with minimal efforts. Moreover, several attributes of the valve such as inclusion of intermediate-size and extra-large size THVs, unique design, and unique delivery system that allow retrieval of unexpanded valves in challenging conditions through the Python sheath facilitate its routine clinical practice. The device performed well in a prospective, multicenter clinical trial that enrolled intermediate and high-risk patients with severe symptomatic native aortic stenosis.[6]

Choice of valves in narrowed right ventricular outflow tract conduits

Till date, Melody valve (Medtronic Inc., Minneapolis, MN, USA) and Sapien THV series (Edwards Lifesciences, Irvine, CA, USA) has been approved by the United States Food and Drug Administration for TPVI.[8] Their safety and efficacy in the management of dysfunctional RVOT have been documented in several registries.[9-11] It is noteworthy that Melody valve is available in diameters ranging from 18 to 22 mm whereas the SAPIEN THV is available in 20, 23, 26, and 29 mm diameters [Table 3]. The design of MyVal THV is similar to Sapien 3, the latest generation in the Sapien THV series in most aspects including a surrounding polymer skirt that retards calcification and prevents paravalvar regurgitation.[6] However, a wider size matrix of MyVal THV allows implantation of intermediate sized valves, as noted in use of 24.5 mm valve in one of our patients. Another heart valve with a similar balloon expandable design and a potential application in prestented conduits is Inovare (Braile Biomedica, Sao Jose do Rio Preto, Brazil) though it has not been used in pulmonary position so far.[12] Even though a self-expanding valve prosthesis may not be an attractive option in heavily calcified stenotic conduits due to its unknown radial strength, it has been shown to be an effective strategy in fully prestented conduits without residual stenosis. A straight segment Venus-P valve (Venus Medtech, Hangzhou, PRC), a self-expanding valve prosthesis, has shown successful utility in prestented RVOT conduits with a midterm follow-up up to 6 years.[13]

Failure of valve function

There was a failure of valve function resulting in free pulmonary regurgitation in one of the patients whose conduit was prestented 22 mm diameter before implanting a 23 mm MyVal. It was unexplained and was presumably due to the lack of separation of one of the valve leaflets from the outer frame described as "frozen leaflets," after full expansion of the valve.[14] This could be attributed to low diastolic pressures in the pulmonary circulation unlike higher pressures in the aorta, where the valve was originally intended and designed for transcatheter aortic valve implantation. However, availability of a wider size matrix of the MyVal inventory made us perform a valve-in-valve implantation of a 24.5 mm valve within the previous malfunctioning 23 mm valve resulting in complete relief of regurgitation. A similar strategy of valve-in-valve implantation was adopted for frozen leaflets following unexplained severe valvar regurgitation after Sapien THV valve implantation in the aortic position.[14] The residual gradient despite the use of two valves within the conduit was 13 mmHg indicating an adequate hemodynamic relief of stenosis of the conduit.

Complications

The limited experience of MyVal THV in seven patients in the past 18 months had been satisfactory and was devoid of major device-related serious adverse effects.

Table 3: Currently available transcatheter heart valve used for implantation in pulmonary position

Name of the THV	Manufacturer	Type of the valve	Available sizes (mm)
Melody	Medtronic, MN, US	Balloon-expandable valve	18, 20, 22
Sapien THV	Edwards Lifesciences, CA, US	Balloon-expandable valve	20, 23, 26, 29
Myval THV	Meril Life Sciences Pvt. Ltd., India	Balloon-expandable valve	20, 21.5, 23, 24.5, 26, 27.5, 29, 30.5, 32
Inovare	Braile Biomedica, Sao Jose do Rio Preto, Brazil	Balloon expandable valve	20, 22, 24, 26, 28, 30
Harmony	Medtronic, MN, US	Self-expandable valve	22, 25 waist
Venus-P	MedTech, Shanghai, China	Self-expandable valve	20–36 waist 2 increments
Pulsta	TaeWoong Medical Co, Gyeonggi-do, South Korea	Self-expandable valve	18, 20, 22, 24, 26, 28, 30 and 32
Med-Zenith PT	Beijing Med-Zenith, Beijing, China	Self-expandable valve	20, 23, 26

THV: Transcatheter heart valve

Apart from one patient with a frozen leaflet, there were no valve-related complications. A valve-in-valve implantation for acute transvalvular regurgitation from the frozen leaflet was managed with the availability of an intermediate-sized 24.5 mm Myval THV. This report highlights the utility of including intermediate-size THV in the size matrix of Myval THV system. A complete lack of significant pulmonary regurgitation was noted in all the patients along with minimal pressure gradient across the valve. The right ventricular function also remained good on follow-up. There was no incidence of infective endocarditis, valve dysfunction, or clot formation during follow-up visits. Among the complications encountered during prestenting, using high-pressure balloons could prevent balloon rupture and meticulous choice of balloon and crimping of the stent could prevent stent migration.

Comparisons with other available valves

While Melody and Sapien valves are available in limited sizes, MyVal is available with a very wide size matrix. Sapien and MyVal need dedicated crimpers unlike Melody, which is handcrimped before deployment. The initial venous access needs to be 22F from Melody valve but an expansile 14F venous sheath is placed for a Sapien and MyVal implantation. Apart from these three balloon-expandable valves, a self-expanding straight Venus-P valve, specifically designed for stented conduits has also shown clinical utility.[13] Native RVOT reconstructed with transannular patch repair has unique characteristics that include larger diameter, heterogeneous anatomic shapes and expansile nature, and they need different valve systems.[15] Many valve are being developed to fulfil this unmet clinical need and await regulatory approvals.[16-22]

Limitations

We should acknowledge the limitations of the study. The sample size is relatively small. However, the outcomes of such small population are promising and encourage the use of Myval THV in TPVI as well. Postprocedures follow-up MRI study needs to be done, which we are planning on later follow-ups.

CONCLUSIONS

The results of the study ensure satisfactory clinical performance of Myval THV for the treatment of dysfunctional RVOT in patients who underwent multiple surgical interventions. Although short-term clinical outcomes are excellent in the small cohort of the patients, long-term outcomes of the device need to be evaluated in the broad range of patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Kheiwa A, Divanji P, Mahadevan VS. Transcatheter pulmonary valve implantation: Will it replace surgical pulmonary valve replacement? Expert Rev Cardiovasc Ther 2018;16:197-207.
2. de Ruijter FT, Weenink I, Hitchcock FJ, Meijboom EJ, Bennink GB. Right ventricular dysfunction and pulmonary valve replacement after correction of tetralogy of Fallot. Ann Thorac Surg 2002;73:1794-800.
3. Gatzoulis MA, Balaji S, Webber SA, Siu SC, Hokanson JS, Poile C, *et al.* Risk factors for arrhythmia and sudden cardiac death late after repair of tetralogy of Fallot: A multicentre study. Lancet 2000;356:975-81.
4. Bonhoeffer P, Boudjemline Y, Saliba Z, Merckx J, Aggoun Y, Bonnet D, *et al.* Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction. Lancet 2000;356:1403-5.
5. Stout KK, Daniels CJ, Aboulhosn JA, Bozkurt B, Broberg CS, Colman JM, *et al.* 2018 AHA/ACC Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2019;139:e698-800.
6. Sharma SK, Rao RS, Chopra M, Sonawane A, Jose J, Sengottuvelu G. Myval transcatheter heart valve system in the treatment of severe symptomatic aortic stenosis. Future Cardiol 2021;17:73-80. [doi: 10.2217/fca-2020-0020].
7. Sivaprakasam MC, Arvind A, Sridhar A, Gunasekaran S. First transcatheter pulmonary valve implantation – An Indian made valve. IHJ Cardiovasc Case Rep CVCR 2020;4:13-6.
8. Chatterjee A, Bajaj NS, McMahon WS, Cribbs MG, White JS, Mukherjee A, *et al.* Transcatheter pulmonary valve implantation: A comprehensive systematic review and meta-analyses of observational studies. J Am Heart Assoc 2017;6:e006432.
9. Haas NA, Carere RG, Kretschmar O, Horlick E, Rodés-Cabau J, de Wolf D, *et al.* Early outcomes of percutaneous pulmonary valve implantation using the Edwards SAPIEN XT transcatheter heart valve system. Int J Cardiol 2018;250:86-91.
10. Plessis J, Hascoët S, Baruteau A, Godart F, Le Gloan L, Warin Fresse K, *et al.* Edwards SAPIEN transcatheter pulmonary valve implantation: Results from a french registry. JACC Cardiovasc Interv 2018;11:1909-16.
11. Morray BH, Jones TK, Coe JY, Gitter R, Martinez JZ, Turner DR, *et al.* Implantation of the Melody transcatheter pulmonary valve PB1016 in patients with dysfunctional right ventricular outflow tract conduits. Catheter Cardiovasc Interv 2019;93:474-80.
12. Gaia DF, Breda JR, Duarte Ferreira CB, Marcondes de Souza JA, Macedo MT, Gimenes MV, *et al.* New Braile Inovare transcatheter aortic prosthesis: Clinical results and

follow-up. EuroIntervention 2015;11:682-9.

13. Morgan GJ, Sivakumar K, Promphan W, Goreczny S, Prachasilchai P, Qureshi S. Early clinical experience with the straight design of Venus P-valve in dysfunctional right ventricular outflow tracts. Catheter Cardiovasc Interv 2020;96:E653-9.
14. Toggweiler S, Wood DA, Rodés-Cabau J, Kapadia S, Willson AB, Ye J, *et al*. Transcatheter valve-in-valve implantation for failed balloon-expandable transcatheter aortic valves. JACC Cardiovasc Interv 2012;5:571-7.
15. Schievano S, Coats L, Migliavacca F, Norman W, Frigiola A, Deanfield J, *et al*. Variations in right ventricular outflow tract morphology following repair of congenital heart disease: Implications for percutaneous pulmonary valve implantation. J Cardiovasc Magn Reson 2007;9:687-95.
16. Benson LN, Gillespie MJ, Bergersen L, Cheatham SL, Hor KN, Horlick EM, *et al*. Three-year outcomes from the harmony native outflow tract early feasibility study. Circ Cardiovasc Interv 2020;13:e008320.
17. Kim GB, Song MK, Bae EJ, Park EA, Lee W, Lim HG, *et al*. Successful feasibility human trial of a new self-expandable percutaneous pulmonary valve (Pulsta Valve) implantation using knitted nitinol wire backbone and trileaflet α-gal-free porcine pericardial valve in the native right ventricular outflow tract. Circ Cardiovasc Interv 2018;11:e006494.
18. Cao QL, Kenny D, Zhou D, Pan W, Guan L, Ge J, *et al*. Early clinical experience with a novel self-expanding percutaneous stent-valve in the native right ventricular outflow tract. Catheter Cardiovasc Interv 2014;84:1131-7.
19. Garay F, Pan X, Zhang YJ, Wang C, Springmuller D. Early experience with the Venus pvalve for percutaneous pulmonary valve implantation in native outflow tract. Neth Heart J 2017;25:76-81.
20. Promphan W, Prachasilchai P, Siripornpitak S, Qureshi SA, Layangool T. Percutaneous pulmonary valve implantation with the Venus P-valve: Clinical experience and early results. Cardiol Young 2016;26:698-710.
21. Shang X, Chen S, Zhang C, Wang B, Cheatham SL, Lu R, *et al*. First-in-man implantation of med-zenith PT-valve in right ventricular outflow tract for pulmonary regurgitation. JACC Cardiovasc Interv 2019;12:1989-90.
22. Zahn EM. The Edwards SAPIEN valve in the pulmonic position: The not-so-new kid on the block. JACC Cardiovasc Interv 2018;11:1917-9.