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First transcatheter pulmonary valve implantation - An Indian made valve

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ABSTRACT

Transcatheter Pulmonary Valve Implantation has become the treatment of choice in most congenital heart disease patients with degeneration and dysfunction of a previous Right ventricular outflow tract repair. It is less invasive, with a high procedural success rate. Efficacy and safety have been demonstrated for the Medtronic Melody® valve (Medtronic Inc., MN, USA) and Edwards SAPIEN™ valve (Edwards Lifesciences) in pulmonary position. We report the first successful percutaneous pulmonary valve replacement with an Indian made valve Meril Myval™ in a symptomatic patient who had severe Right ventricle-pulmonary artery conduit dysfunction post Tetralogy of Fallot intracardiac repair.

Introduction

Patients with congenital cardiac anomalies affecting the right ventricular outflow tract [RVOT], may require surgical correction with a right ventricle-pulmonary artery [RV-PA] conduit implantation in the early adulthood.[1] Owing to inevitable calcific degeneration and progressive pulmonary regurgitation [PR] and/or stenosis, these conduits have a limited durability, thus requiring multiple revisions.[2] This leads to significant morbidity and mortality in the setting of RV failure in these patients. Additionally, free PR progressively leads to RV dilation that subsequently increases the risk of ventricular arrhythmias, RV dysfunction, and ultimately cardiac death.[3] Transcatheter pulmonary valve implantation [TPVI] is approved for the treatment of dysfunctional RV-PA conduit.[4] This is the first case report of percutaneous use of an Indian made valve Meril Myval™ in pulmonary position in a symptomatic patient who had history of multiple redo surgeries for tetralogy of Fallot [TOF].

Case report

A 26 year old female patient, post TOF intracardiac repair [1998], presented with dyspnea on exertion NYHA class II. She had redo infundibular resection and pulmonary valve replacement for severe residual subvalvar and valvar stenosis in 2009. In 2010, prosthetic pulmonary valve endocarditis necessitated RVOT reconstruction with 22 mm Contegra bovine valved conduit. Cardiac catheterization in 2017 revealed RV systolic pressure to be supra-systemic [135 mm Hg vs. 88 mm Hg]. In addition, there was a significant pull back gradient of 110 mm Hg across the RV-PA conduit. We did transcatheter stenting of the conduit with 45 mm covered Cheatham Platinum (CP) stent dilated to 22 mm, following which the RV pressures were 1/3rd of the systemic pressure. There was grade 2 conduit regurgitation. At a follow up visit in October 2018, she weighed 61 kg. Her SpO2 was 98% on room air. Her echocardiography showed RV dilatation, grade 1 RV diastolic dysfunction and free PR. ECG showed QRS duration of 160 milliseconds. Computed Tomography pulmonary angiogram (CTPA) revealed wide open RV-PA conduit. The measurements of the conduit at upper, mid and lower levels were approximately 16 mm, 14 mm and 14.2 mm respectively. Coronary anatomy was normal. Three redo surgeries made her a high-risk case for another surgery. She was thus

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referred for TPVI. As the valves made in other countries were expensive, we could not offer her TPVI initially. Myval™ [Meril LifeSciences Pvt Ltd] was launched in India in December 2018. It is India's first indigenously designed and manufactured transcatheter aortic heart valve (TAHV). It is a bovine pericardium tri-leaflet valve on a nickel cobalt alloy frame, which is approved for use in aortic position. Being comparatively less expensive than other commercially available valves, we opted for Meril Myval™ in pulmonary position to prevent further deterioration of RV function in our patient. After patient's informed consent and institutional ethical committee clearance, she was taken for the procedure.

Pre-procedural hemodynamics suggested no pressure gradient across the RV-PA conduit. Lateral view RV angiogram showed free PR Fig. 1a. Selective right coronary artery angiography with simultaneous inflation of Z-Med II™ 20 mm × 40 mm balloon in the RVOT ruled out coronary artery compression Fig. 1b.

Second balloon dilatation of RVOT stent was done using 20 mm × 40 mm Atlas® PTA balloon, inflated to nominal pressure of 6 atm. Though we used 20 mm balloon to dilate the RVOT stent and prevent future re-stenosis, we believed that a 20 mm valve will be relatively smaller for an adult. So, we chose a 23 mm valve for this patient. The right femoral venous sheath was upsized to a larger 14 Fr Python expandable introducer sheath. A 23 mm Meril Myval™ was crimped on the Navigator balloon delivery system. The delivery system with the crimped valve was then advanced through the Python sheath. The valve was positioned across the conduit stent, followed by balloon inflation to 8 atm Fig. 1c and d. The Meril Myval™ was thus deployed in pulmonary valve position Fig. 1e. Pre-stented RVOT provided the stable landing zone. Check RV angiogram in lateral view showed good flow across the branch PAs, no PR and no paravalvular leak Fig. 1f. The procedural duration was 1.5 hours. Post procedure transthoracic echocardiography [TTE] showed no RVOT obstruction, good RV contractility and no pericardial effusion. Patient remained hemodynamically stable throughout the procedure and was discharged next day on aspirin. At 6 month follow up, she is asymptomatic. TTE shows no PR, no paravalvular leak, improved RV function and estimated RV systolic pressure as 30 mm Hg.

Discussion

TPVI was first performed by Bonhoeffer et al., in 2000.[5] It minimizes the need for repeated cardiac surgeries in patients with dysfunctional RV-PA conduit. As per American Heart Association recommendations, percutaneous pulmonary valve replacement should be considered in a patient with a RV-PA conduit with associated moderate-to-severe pulmonary regurgitation or stenosis.[6]

TPVI has advanced into a feasible, less invasive alternative to surgical conduit replacement. The pooled data from a meta-analysis showed the procedural success for TPVI to be greater than 96%, with a complication rate of 10%.[4]

There are currently two available valves for percutaneous replacement in the pulmonary position: Medtronic Melody® valve (Medtronic Inc., MN, USA) and Edwards SAPIEN™ valve (Edwards Lifesciences, CA, USA). Both are balloon-expandable valves. The Melody valve has available diameters ranging from 18 to 22 mm. Results from clinical trials have demonstrated its efficacy and safety.[7,8] However, RVOT at the time of intervention may exceed the available diameters, particularly in patients with transannular patch after TOF repair or in patients with large conduits. The Edwards SAPIEN transcatheter heart valve is available in 20-, 23-, 26-, and 29-mm diameters, which can be used in RVOT conduits of diameters between 20- and 29-mm.[9] J Plessis et al. demonstrated a high rate of procedural success in a large cohort of 71 patients who underwent TPVI with the Edwards SAPIEN valve for dysfunctional RV-PA conduits.[10]

Meril Myval™ is first Indian made valve, recently approved by Central Drugs Standard Control Organization (CDSCO) for use in aortic valve position, based on Myval-1 study results.[11] This study evaluated the safety and effectiveness of Myval-TAVR system in the treatment of severe symptomatic native aortic valve stenosis in 30

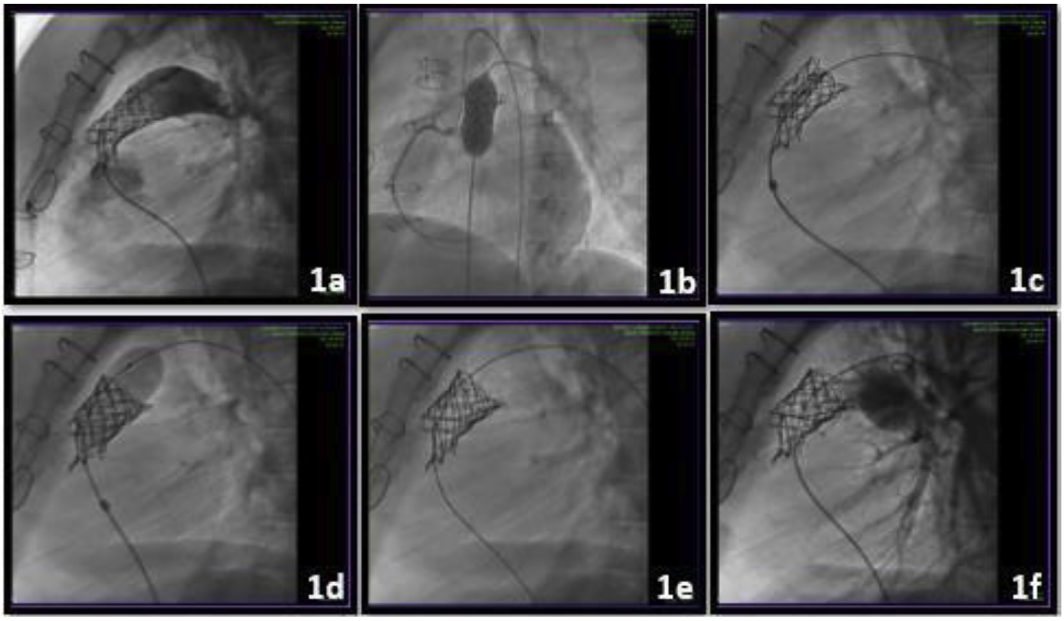

Fig. 1. **(a)** PA Angiography lateral view demonstrating free pulmonary regurgitation. **(b)** Simultaneous selective right coronary angiography and balloon inflation in the right ventricular outflow tract to evaluate for coronary artery compression. **(c)** Positioning of the Meril Myval™ within the covered CP stent in RVOT. **(d)** & **(e)** Implantation of the Meril Myval™ using Navigator balloon inflation. **(f)** PA Angiography Lateral view at end of procedure demonstrating a competent valve with no paravalvular or valvular regurgitation. [PA- Pulmonary artery, RVOT- Right Ventricular Outflow Tract, CP- Cheatham Platinum].

Table 1
Comparison of the Edwards SAPIEN™ valve and Meril Myval™ valve.

	Edwards SAPIEN™ valve (Edwards Lifesciences, CA, USA)	Myval™ [Meril Lifesciences Private Limited, India
Stent material	Stainless steel	Nickel cobalt alloy
Valve material	Bovine pericardium	Bovine pericardium
Available diameter size (mm)	20,23,26,29	20,23,26,29
Stent height (mm)	14–19	17–20
Delivery sheath size (Fr)	14 expandable E sheath	14 expandable python sheath

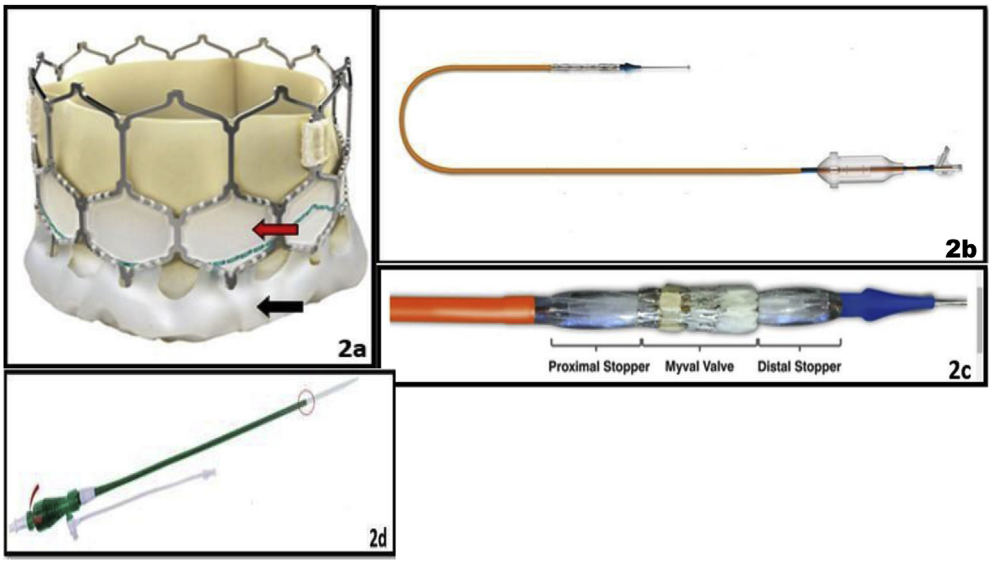

Fig. 2. **(a)** Meril Myval™ [Meril Lifesciences Private Limited, India] in long axis view. Internal PET sealing cuff [red arrow]. External PET buffing [black arrow].**(b)** Navigator Balloon Dual- Stopper Delivery System **(c)** Crimped Myval™ on the Navigator Balloon. **(d)** Python - 14Fr Expandable Introducer Sheath. One-way hemostatic valve [red arrow]. Seamless transition from dilator to distal tip [red circle]. . (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

patients across India. It is a prospective, multicentre single-arm, open label study. This study demonstrated high safety at 30-days and 6-months, with 100% device success and no device related mortality. Meril Myval™ is morphologically similar to Edwards SAPIEN valve, with some variation in design and delivery system Table 1.

Myval™ is a balloon expandable valve Fig. 2a. It is a bovine pericardium tri-leaflet valve, on a nickel cobalt alloy frame for high radial strength and radiopacity. It has a hybrid honeycomb cell design [open cells 53%, closed cells 47%]. It has an internal poly-ethylene terephthalate (PET) sealing cuff for lower profile and puncture resistance. The external PET buffing minimizes para-valvular leak. Meril Myval™ is currently commercially available in 20 mm, 23 mm, 26 mm and 29 mm diameters. The height of the valve varies from 17 to 20 mm.[12] The Navigator balloon delivery system has a set of proximal and distal stoppers which ensure that valve crimping is precise and snug Fig. 2b and c. This also prevents inadvertent valve embolization during delivery. Python sheath is 14 Fr atraumatic, expandable introducer sheath which allows smooth passage of Myval™ crimped balloon catheter Fig. 2d. It has a 30 cm useable length. The 14 Fr profile is used for all MyVal diameters.[13]

This is the first case report of Meril Myval™ use in pulmonary position in a patient who had history of multiple redo surgeries for tetralogy of Fallot, and now had presented with RV-PA conduit dysfunction with free PR. We conclude that Meril Myval™ can be safely and effectively used in pulmonary position, for dysfunctional RV-PA conduits. Long-term studies, however, are required to confirm the safety and efficacy of the Meril Myval™ implanted in the pulmonary position.

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Nil

Declaration of competing interest

There are no conflicts of interest.

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