

Choosing an appropriate size valve for transcatheter pulmonary valve implantation in a native right ventricle outflow tract

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ABSTRACT

Introduction : Transcatheter pulmonary valve implantation has been an effective treatment for dysfunctional right ventricular tract outflow tract (RVOT). Defining a landing zone before the intervention is crucial in patients with native RVOT. Improper sizing and undefined landing zone will lead to embolization. **Methods:** It is a retrospective observational study from August 2020 to December 2020 in native RVOT. Three patients who had significant Right ventricle dilatation were analyzed. The multi-slice computed tomography (MSCT) with magnetic resonance imaging and angiography data of all patients before the procedure were analyzed. All patients underwent an angiogram in the same sitting, before the procedure to assess the landing zone, valve diameter as well as the risk for coronary compression. We chose a valve based on valve area 23%–25% more than the area at the waist during balloon sizing. **Results:** All three patients underwent successful valve implantation. Valve sizes used were 27.5 mm in one and 32 mm in the other two. The mean RVOT gradient postprocedure was 11.5 mm Hg and pre procedure was 43 mmHg. There were no complications during the procedure or at a mean follow-up of 3.6 months. **Conclusion:** The balloon sizing gives the true narrowest diameter in comparison with MSCT, and increasing this area by 23%–25% will give the appropriate valve size for successful implantation.

Keywords: Congenital heart disease, adults, percutaneous intervention, pulmonary valve disease, structural heart disease intervention, transcatheter valve implantation

INTRODUCTION

Transcatheter pulmonary valve (PV) implantation (TPVI) has been proven to be an effective treatment option for dysfunctional native right ventricular tract outflow tract (RVOT).^[1,2] Since the first report in 2000,^[3] several case series have been published using the Melody[®] (Medtronic Minneapolis, MN, USA) and the Sapien[®] S3 (Edwards Lifesciences, Irvine, CA).^[4,5]

In most of the case series, prestenenting was done in patients who require valve implantation to create a reliable and solid landing zone.^[6,7] Recently,

publications showed good results with TPVI in native RVOT.^[8-10] The Sapien[®] S3 valve was used and the largest available valve was 29 mm. A 29 mm valve becomes unsuitable for hugely dilated RVOT (most common). We reported the first TPVI using Myval[®] in a pulmonic position with prestenenting.^[11] Recently, Myval[®] (Meril Life sciences, Surat, India) transcatheter heart valves (THV) introduced 30.5 and 32 mm valve sizes. As there is a large spectrum of valve sizes available, we preferred them in dilated RVOT. We report our experience with three successful TPVI in the native pulmonary artery.

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How to cite this article: Sivaprakasam MC, Reddy JR, Ganesan R, Sridhar A, Solomon N, Moosa MJ, *et al.* Choosing an appropriate size valve for transcatheter pulmonary valve implantation in a native right ventricle outflow tract. *Ann Pediatr Card* 2022;15:154-9.

Access this article online

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10.4103/apc.apc_62_21

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Submitted: 09-Apr-2021

Revised: 18-Jun-2021

Accepted: 23-Aug-2021

Published: 19-Aug-2022

METHODS

Study design and patient population

It is a retrospective study. Three patients who had primary ICR for TOF were included from August 2020 to December 2020 [Table 1]. The symptoms of patients, magnetic resonance imaging (MRI) right ventricle (RV) volume, and PR were in favor of TPVI.^[12] Informed written consent was obtained from all the patients.

Preprocedural evaluation

All the patients underwent clinical examination, routine blood testing, electrocardiography, chest radiography, and echocardiography. Multi-slice computed tomography (MSCT) with MRI was performed to assess RVOT diameter, anatomy, and coronary course. MRI was also used to quantify ventricular volumes and function and PR fractions. All patients underwent Angiogram with balloon sizing in the same sitting, before the procedure to assess the landing zone, valve diameter as well as the risk for coronary compression [Figure 1]. Valve size used was based on area measurements on MSCT and angiogram [Figures 2-5].

Procedure

The procedure was done under general anesthesia. A right internal jugular vein and right radial artery access were obtained for monitoring. The right femoral vein was the primary access point for valve implantation. Intravenous heparin was administered to achieve an activated clotting time of >250 s. All patients were administered antibiotic prophylaxis during the procedure and for the 48 h following the procedure.

RV angiogram was performed in the right anterior oblique 30° (cranial 30°) and in lateral views [Figure 1]. The left femoral arterial access was obtained and a 6F sheath was positioned for selective coronary angiography. We accessed the coronary near to the landing zone and kept a guide catheter with a coronary wire. The left femoral venous access was obtained for RV angiogram. The right femoral artery access was obtained for pacing catheter in the LV. The right femoral sheath is upsized to the 14F Python™ sheath (Meril Life Sciences Pvt. Ltd., India) which is suitable for all the sizes of Myval® THV. Then, a Lunderquist wire was positioned deep in the left

pulmonary artery. We used a 30 mm × 50 mm Z-MED™ balloon (NuMed™ Canada Inc) to size the RVOT. On rapid pacing at 250/min, we inflated the balloon and looked for a waist to appear. Then, we did simultaneous RV and coronary angiogram [Figure 1c and d]. We proceeded with the valve implantation only when, we saw a minimal waist on balloon inflation, there was complete occlusion of RVOT without any forward flow and no coronary compression.

The waist diameter was noted and then we proceeded with TPVI. We chose a valve based on valve area 23%–25% more than the area at the waist during balloon sizing. The valve is manually crimped on the Navigator™ THV delivery system. The Navigator™ THV delivery system was advanced through Python™ sheath and the valve was positioned across the defined landing zone. An angiogram was done to confirm the position [Figure 1e]. Then, heart was rapidly paced at 250 beats/min. After the initial

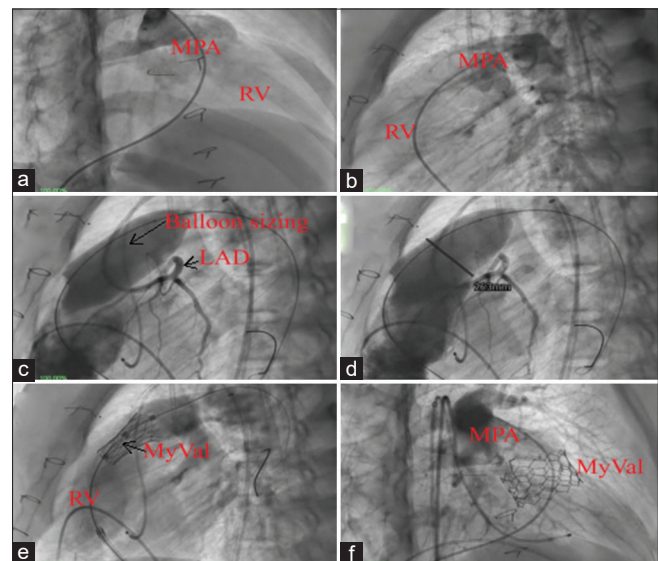


Figure 1: (a and b) Pigtail angiogram in right anterior oblique 30° cranial 30° and in lateral views showing dilated right ventricle and main pulmonary artery. (c and d) showing balloon sizing of main pulmonary artery segment along with simultaneous right ventricle and left anterior descending coronary angiogram using pigtail and an end hole catheter respectively. (e) The positioning of the valve across the defined landing zone simultaneous rapid pacing of the left ventricle with a pacing catheter already placed. (f) Pigtail MPA angiogram postvalve deployment with no paravalvular leak or valvular regurgitation

Table 1: Baseline clinical characteristics of the study population

Patient number	Age (years)/gender	Body mass index (kg/m ²)	Primary diagnosis	Past surgical interventions (year of surgery in brackets)
#1	20/female	19.5	Tetralogy of Fallot with severe pulmonary stenosis	Intracardiac repair (VSD closure + RVOT resection + monocusp pericardial valve) (2009)
#2	60/female	31.2	Tetralogy of Fallot with absent pulmonary valve	Intracardiac repair (VSD closure + RVOT resection + monocusp pericardial valve) (1981)
#3	13/female	21.3	Tetralogy of Fallot with severe pulmonary stenosis	Intracardiac repair (VSD closure + RVOT resection + transannular patch) (2008)

RVOT: Right ventricular outflow tract, VSD: Ventricular septal defect

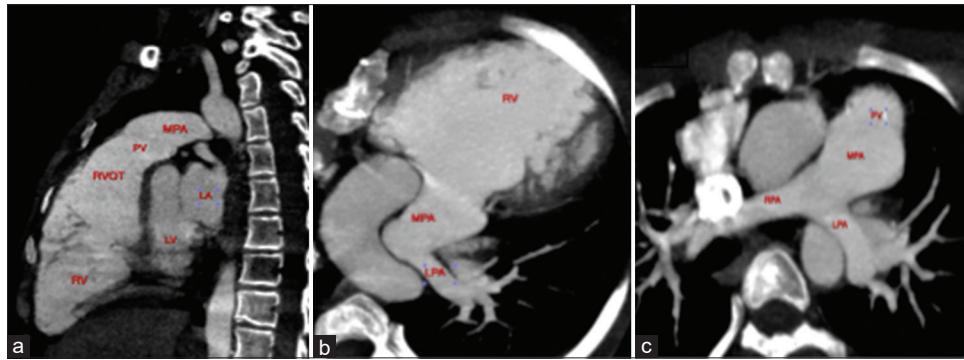


Figure 2: (a-c) Multislice computed tomography images showing delineation of right ventricular, right ventricular outflow, pulmonary valve, and the pulmonary artery to identify landing zone

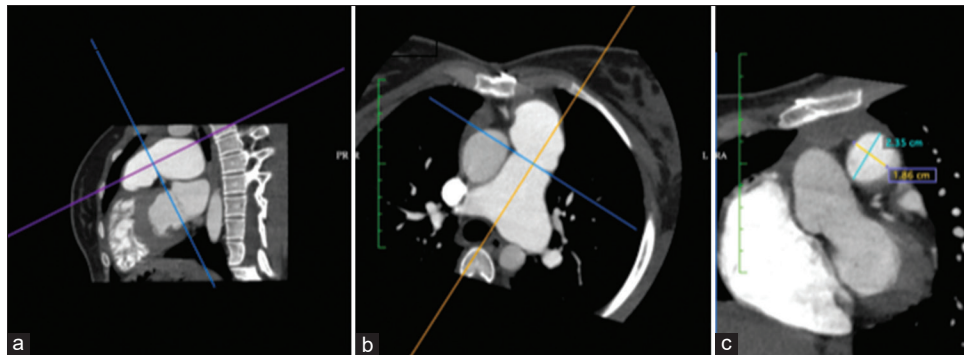


Figure 3: (a-c) Multi-slice computed tomography three-dimension correlation of identifying narrowest zone for implantation and narrowest area measurements

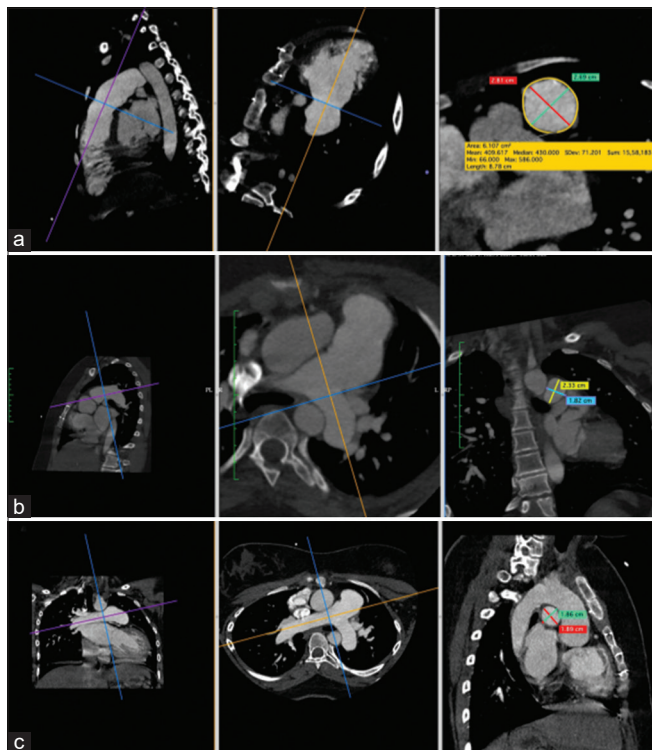


Figure 4: Multi-slice computed tomography images (a) Calculation of the narrowest landing zone dimensions, perimeter, and area. (b) Calculation of the ostioproximal left pulmonary artery dimensions, perimeter, and area. (c) Calculation of the ostioproximal right pulmonary artery dimensions, perimeter and area

angiogram on pacing, the balloon was inflated slowly. Midway through the inflation, we performed another angiogram to reconfirm the position, followed by full inflation. A selective coronary angiogram was done to make sure there is no coronary obstruction. After deployment pulmonary artery (PA) angiogram was performed to assess the functioning of the valve [Figure 1f]. A catheter gradient across the valve was documented. Postprocedure echocardiography confirmed the valve position, RVOT gradient, RV function, and pericardial effusion.

RESULTS

All the three patients underwent successful TPVI with Myval+ without prestenosing. The mean procedural time from placement to the removal of the sheaths was 95 min (range 90–100 min). The mean fluoroscopic time and dose area product were 26 min (range 24–28 min) and 75.2 Gy.cm² (range 49.3–109.5 Gy.cm²), respectively. Valve sizes used were 27.5 mm in patient #1, 32 mm in patient #2 and #3. Diluted contrast saline was taken to inflate the balloon which contains a nominal volume of 28 ml for patient #1 who required a 27.5 mm valve. A 40 ml diluted contrast was recommended for the 32 mm valve which we implanted for patients #2 and #3. However, we have taken additional 2 ml and 5 ml to nominal volume for them, respectively. Dual antiplatelet agents were started and continued for 6 months. The

mean follow-up duration is 3.6 months (range 2 to 5 months). Symptom status improved to New York Heart Association (NYHA) II (compared to pre-procedure NYHA III). Mean QRS duration postprocedure was reduced to 120 ms (compared to preprocedure 153 msec). The mean RVOT gradient postprocedure was 11.5 mmHg, compared to preprocedure was 43 mmHg [Table 2]. No stent fractures were seen in Chest X-ray which was taken 2–3 months postprocedure. None had valvular regurgitation or para-valvular leak postprocedure or on follow-up.

DISCUSSION

In this case series, we have demonstrated that Myval® can be implanted successfully across the native PA. Myval® offers enough grip to be implanted without a pre-stent [Figure 6]. Previously, Tanase *et al.*^[8] have demonstrated that Sapien® S3 can be safely implanted in native PA. However, the limitation of the Sapien® S3 is the largest valve for implantation available is 29 mm.^[13] However, the majority of native PA is dilated and would require a large diameter than 29 mm.^[14,15] The largest available Myval® comes with a 32 mm valve with an outer diameter of 33 mm which gives a large spectrum for PV implantation.^[16] Additional diluted contrast saline was required to add 2 ml and 5 ml in patient # 2 and # 3, respectively, to the nominal volume to increase the diameter.

Currently, there are four different types of balloon-expandable valves available for the pulmonic position: the Melody®, the Sapien® S3, Inovare® (Braile Biomedica, Sao Jose do Rio Preto, Brazil), and the Myval®.

The next generations of valves are self-expandable Harmony TPV (Medtronic Inc, Minneapolis, Minn) and Venus P valve (Venus Medtech, Shanghai, China) in large RVOT's.^[17-19]

According to the latest meta-analysis study published, while comparing with balloon-expanding valve (BEV), the self-expanding valve (SEV) was associated with better postprocedural effective orifice area, which reduces the risk of patient–prosthesis mismatch.^[20] However, SEV was associated with higher rates of postprocedural pacemaker implantation and it stents the RVOT and thus prevents RV re-modelling.

The real challenge in BEV is to choose a proper valve size in native RVOT without an obstruction. We assessed the valve area by MSCT/angiographic balloon sizing and compared it with an area of the valve finally implanted [Table 3]. Between MSCT scan and balloon sizing, we felt that the balloon sizing gives the true narrowest diameter and increasing this area by 23%–25% will give the appropriate valve size for successful implantation. In fact, we increased the nominal volume by 5 ml to give an inner diameter of 33 mm for patient #3, which was based on the previous two valve experiences. The specific risks involved in oversizing are:

Rupture of pulmonary artery

In a dilated native PA without circumferential calcification, this is unlikely as the elasticity of the native PA is good

Coronary obstruction

The balloon sizing is 23%–25% less in the area compared to the final valve area. Hence, a coronary occlusion on

Table 2: Pre- and post-procedural characteristics of study population

Functional class (NYHA)	MRI data RVEDV/ RVESV (ml/m ²)	Procedure/ fluoroscopy duration (min)	Follow-up duration (months)	ECG-QRS duration (ms)		RVOT gradient (mmHg)		Pulmonary regurgitation	
				Preprocedure	Follow-up	Preprocedure	Follow-up	Preprocedure	Follow-up
II	152/90	100/26	5	140	100	55	15	Severe	Nil
III	154/102	90/24	4	160	120	35	10	Severe	Nil
II	145/83	95/28	2	160	140	40	10	Severe	Mild

ECG: Electrocardiogram, MRI: Magnetic resonance imaging, NYHA: New York heart association, RVEDV: Right ventricular end-diastolic volume, RVESV: Right ventricular end-systolic volume, RVOT: Right ventricular outflow tract, ECG measurement QRS duration do not have expansion

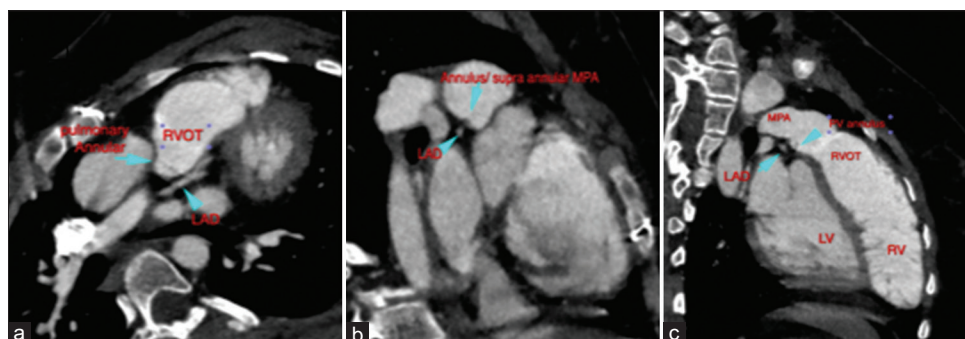
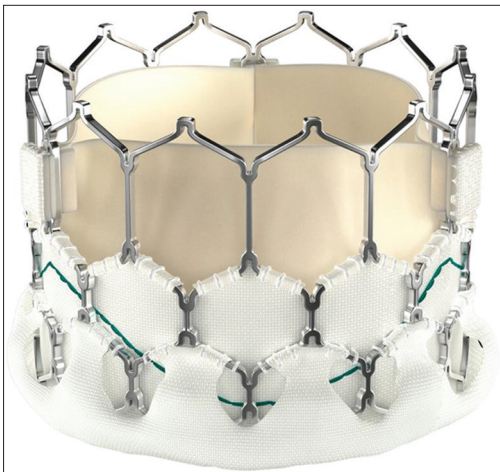


Figure 5: (a-c) Multi-slice computed tomography image relation of proximal left anterior descending coronary artery to the landing zone

Table 3: Valve size assessment by comparing angiogram balloon sizing and multislice computed tomography measurements

Patient number	Angiogram balloon sizing (narrowest diameter) (mm)	MSCT narrowest diameter (mm)	Native valve area by MSCT (mm ²)	Native valve area by angiogram balloon sizing (mm ²)	Valve size used (mm)	Valve area of Myval® used (internal diameter) (mm ²)	Percentage increase to valve area (angiogram balloon sizing)	Percentage increase to valve area (MSCT scan)
#1	24	21	346	452	27.5	589	23	41
#2	28	28.5	637	615	32 (increased volume)	804	23	20
#3	28.5	27.5	593	637	33 (increased volume)	854	25	30

MSCT: Multislice computed tomography

**Figure 6: Myval® (Meril Life Sciences Pvt. Ltd., India)**

the final diameter cannot be ruled out. We recommend a selective coronary wire placement in the nearest coronary artery to the landing zone.

Limitations

This is a retrospective study. The procedural safety must be proven in further larger studies. Long-term follow-up data are required to assess the durability.

CONCLUSION

TPVI is feasible in large native PA with or without obstruction using the new Myval®. Defining the landing zone by MSCT scan is crucial. We recommend a 23%–25% increase in the balloon sizing area to achieve a stable valve size.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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