

# Early multicenter experience of Melody valve implantation in India

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## ABSTRACT

- Background** : Transcatheter valves provide a safe and effective alternative to surgery for treating dysfunctional right ventricular outflow tracts (RVOTs). We present our early multicenter experience of percutaneous pulmonary valve implantation (PPVI) using Melody valve (Medtronic Inc., Minneapolis, MN).
- Methods** : Patients with stenosed conduits or degenerated bioprosthetic valves in RVOT with combined stenosis and regurgitation were evaluated for suitability of Melody valve implantation. After undergoing an initial structured training, PPVI using Melody transcatheter pulmonary valve (TPV) was guided by an approved proctor. Conduits were serially dilated and presented with careful coronary interrogation, and bioprosthetic valves were dilated with high-pressure balloons. Clinical and echocardiographic follow-up was performed at 6 monthly intervals.
- Results** : Fifteen patients (three females) aged  $23.1 \pm 9.5$  years in NYHA Class II-III underwent Melody TPV implantation in four Indian centers. The underlying anatomy comprised surgically implanted bioprosthetic valves for pulmonary regurgitation ( $n = 5$ ), conduit repair for pulmonary atresia ( $n = 4$ ), Rastelli repair ( $n = 3$ ), truncus ( $n = 1$ ), and Ross procedure ( $n = 2$ ). Twelve patients had more than one previous surgery. Doppler gradient decreased from  $74.2 \pm 21.5$  mmHg to  $10.2 \pm 4.5$  mmHg after the PPVI. At a median follow-up of 14 months (1–39 months), all the patients were in NYHA Class I with echocardiographic gradients of  $8 \pm 5.7$  mmHg with no evidence of pulmonary regurgitation. There were no major procedural adverse events or deaths.
- Conclusions** : Our early experience shows encouraging results of the PPVI program in India with proctored case selection and meticulous planning. It also confirms the safety and efficacy of Melody TPV for treating dysfunctional RVOT in postoperative patients.
- Keywords** : Early outcomes, learning curve, transcatheter pulmonary valve replacement

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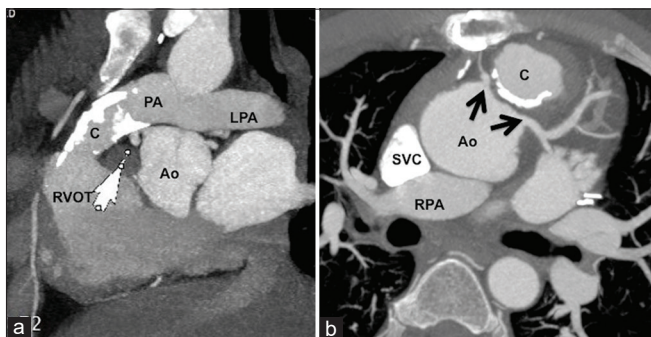
## INTRODUCTION

Long-term durability of surgical intervention on the right ventricular outflow tract (RVOT) for different congenital heart diseases (CHD) is highly variable, with allograft or bioprosthetic valves becoming dysfunctional and requiring further intervention over time.<sup>[1]</sup> Percutaneous pulmonary valve implantation (PPVI) with the Melody transcatheter pulmonary valve (TPV) (Medtronic Inc., Minneapolis, MN) has shown good hemodynamic and clinical outcomes in the treatment of these patients.<sup>[2,3]</sup> Numerous trial and registry data have demonstrated reduced RVOT gradients, elimination of pulmonary regurgitation, and improved symptomatic status after implantation.<sup>[4-8]</sup> Despite its introduction for clinical use in the year 2000 and worldwide experience of over 15,000 global implants, resource-limited settings in India and complex import processes delayed its clinical utility till recently. We present the short-term clinical and hemodynamic outcomes after PPVI with the Melody valve in Indian institutions.

## METHODS

### Patient selection

Patients with CHD operated with the use of allograft conduits or bioprosthetic valves for reconstruction of RVOT were clinically monitored and evaluated by echocardiography. Worsening of symptoms due to RVOT dysfunction, right ventricular systolic pressure exceeding two-thirds of systemic pressure, peak RVOT gradient exceeding 80 mmHg on Doppler, severe pulmonary regurgitation and right ventricular dysfunction with ejection fraction below 47% were considered as indications for PPVI.<sup>[9-12]</sup> These patients were subjected to a comprehensive contrast-enhanced computed tomography (CECT) for delineating the RVOT and pulmonary artery anatomy, relationship of coronary arteries to the conduit [Figure 1],



**Figure 1: Coronary artery relation to conduit.** Multiplanar reformatted computed tomographic image (a) demonstrates the distal part of the calcified conduit (C) overlying the right coronary artery origin from aorta. Another patient after Ross surgery (b) with a calcified conduit (c) which is in close relation to both the coronary artery origins (black arrows) from a dilated aortic root. PA: Pulmonary artery, LPA: Left pulmonary artery, RVOT: Right ventricular outflow tract, SVC: Superior vena cava, RPA: Right pulmonary artery

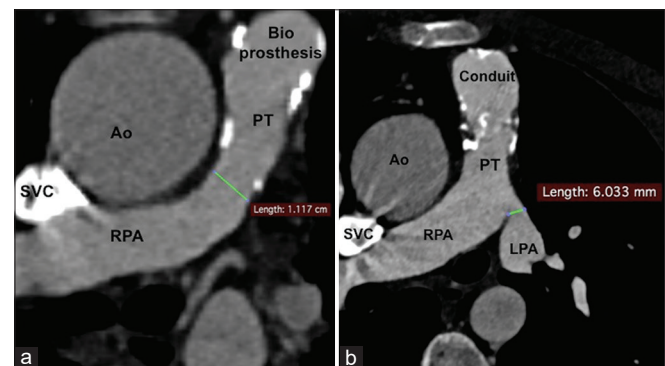
and measuring the conduit dimensions. Cardiac magnetic resonance imaging (MRI) was done in selected patients who had predominant pulmonary regurgitation and dilated dysfunctional right ventricle. Details of the size and model of bioprosthetic valve were reviewed to obtain information about their true internal diameter before a valve-in-valve implantation.<sup>[13]</sup> Hemodynamically significant branch pulmonary artery stenosis with documented perfusion anomaly was addressed by stent angioplasty or high-pressure balloons before PPVI [Figure 2].

### Initiating a melody program in India

Implanting physicians were initially given off-site training with didactic lectures on case selection based on analysis of three-dimensional imaging, device preparation, and device implantation. This was followed by step-by-step observation of Melody valve implantation. Patients were evaluated in the respective institutions with special emphasis on planning the procedure with CECT which was shared with the proctor for confirming the indication, assessing the suitability for PPVI in terms of the coronary anatomy and extent of calcifications, and also acquiring the necessary hardware required for the procedure. This was extremely important in the resource-limited environment due to limited shelf inventory. Being a more expensive alternative to surgery, there was an additional challenge in arranging the finances for the procedure.

### Initial steps

Standard protocol after obtaining detailed informed consent from patients included preadmission screening for dental, skin and other infections, periprocedural intravenous antibiotics for 24 h, general anesthesia, heparinization to maintain activated clotting time more



**Figure 2: Distal branch pulmonary artery stenosis.** Axial computed tomographic image of a patient with a degenerated bioprosthetic valve (a) implanted for pulmonary regurgitation after truncus repair with absent left pulmonary artery shows stenosis between the pulmonary trunk and the lone right pulmonary artery. A second patient (b) after initial left modified Blalock–Taussig shunt followed by conduit repair for tetralogy has stenosis of origin of left pulmonary artery near the shunt insertion. PA: Pulmonary artery, LPA: Left pulmonary artery, SVC: Superior vena cava, RPA: Right pulmonary artery

than 250 s, acquisition of hemodynamic data, RVOT angiography in right anterior oblique, lateral and cranial projections to define its dimensions, and branch pulmonary artery anatomy. Following this, coronary artery interrogation was done with simultaneous coronary angiography and inflation of a compliant Amplatzer sizing balloon (Abbott, Plymouth, MN) or a semicompliant Z-med balloon (NuMED corporation, Cornwall, ON). In case of a severely calcific conduit, coronary arteries were interrogated only after partial deployment of the covered stent, which was gradually dilated with repeated coronary injections to assess their proximity to the conduit [Figure 3]. In pliable conduits with minimal calcification, serial balloon interrogation was performed using progressively larger balloons having a diameter of 18–22 mm [Figure 4].

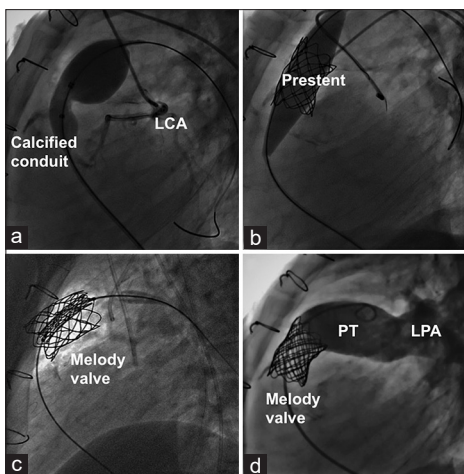
**Creation of landing zone**

To prepare a landing zone, a long 14Fr sheath was tracked over a 0.035” Lunderquist wire (Cook Medical, Bloomington, USA). A 0.035” E-wire (Jotec, GmbH, Hechingen, Germany) was used occasionally for additional support. The landing zone was prepared using 8-zig CP stent (NuMED, Hopkinton, NY) or AndraStent XL (AndraMed, GmbH, Reutlingen, Germany) mounted on Z-med or BIB balloon (NuMED, Hopkinton, NY). Covered stents were preferred in densely calcified conduits at a risk of rupture. Size and length of the stent used were decided based on CECT data, which was confirmed with angiographic measurements. Angiographic assessment was done to confirm the integrity of the conduit after the

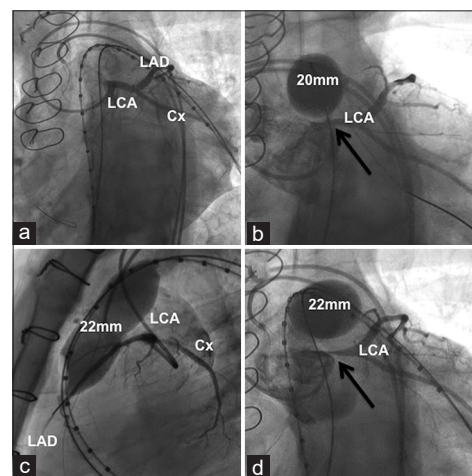
stent placement. While residual gradients (>10 mmHg) were addressed by postdilatation using 20/22 mm Atlas Gold PTA balloon (Bard Peripheral Vascular, Tempe, AZ), a nonuniform stent expansion with an oval configuration visualized on a barrel-view observed on caudal projection was addressed by reinforcing additional stent. Procedural optimization was done to achieve a stent diameter of 20–22 mm with a gradient < 10 mmHg. Bioprosthetic valves were predilated with Atlas Gold PTA balloon to assess their compliance and were not routinely pre-dilated [Figure 5].

**Melody valve implantation**

An 18 mm Melody TPV was deployed using 20 or 22 mm Ensemble II system (Medtronic, Minneapolis, MN) within the landing zone or bioprosthetic valve ring.<sup>[14]</sup> Following the deployment of Melody valve, pressure gradient was recorded across the valve and pulmonary artery angiogram was done in cranial and lateral projections to identify pulmonary regurgitation. Hemostasis was obtained using ProGlide (Abbott, Plymouth, MN) or figure-of-eight suture. Postprocedural protocol included 48 h in-hospital observation, continuation of heparin for 48 h, pre-discharge electrocardiogram (ECG), chest X-ray, Echo-Doppler study, antiplatelet therapy with aspirin and/or clopidogrel for life, and counseling on lifelong infective endocarditis prophylaxis. Follow-up evaluation at 4 weeks, 6 months, and 1 year comprised of physical examination, ECG and Echo Doppler evaluation, and CECT in selected patients.



**Figure 3: Strategy in densely calcified conduit.** Calcified conduits at risk of rupture are initially interrogated with compliant sizing balloons during coronary injection (a) before presenting of the conduit with a covered stent. This covered stent is later expanded to larger diameter of 20 mm (b) with high-pressure balloons. Once the conduit gradient is eliminated, Melody valve is positioned in the landing zone present (c) and expanded. A competent pulmonary valve is shown in pulmonary arteriogram recorded in lateral view (d). PA: Pulmonary artery, LPA: Left pulmonary artery, LCA: Left coronary artery



**Figure 4: Balloon interrogation of coronary arteries.** Left coronary artery origin and its left anterior descending and circumflex (Cx) branches are demonstrated in caudal projection (a) before balloon interrogation of the conduit. Inflation of a 20 mm balloon (b) in the conduit does not cause any compression of the left coronary artery. Even though a left coronary angiogram in a lateral projection (c) after inflation of a larger 22 mm balloon fails to show the coronary ostium, the caudal projection (d) shows that the shift of calcium in the postero-inferior wall of the conduit causes extrinsic left coronary artery compression

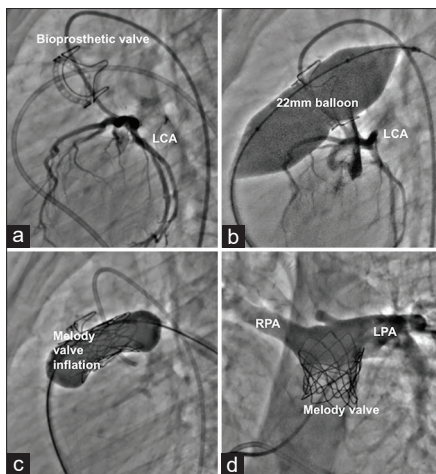


## RESULTS

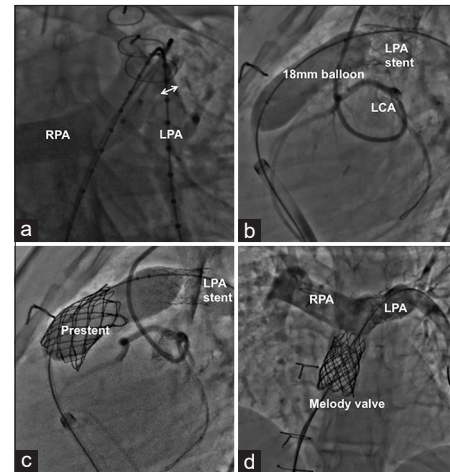
### Cardiac anatomy in patients

A total of 15 patients including three females underwent Melody TPV implantation in four institutions in the past 3 years since January 2018 [Table 1]. The mean age of the patients was  $23.1 \pm 9.5$  years and their weight ranged from 26 to 81 kg. The basic anatomy was variable and comprised degenerated bioprosthetic valves that were previously implanted for severe pulmonary regurgitation following tetralogy of Fallot (TOF) repair in four patients and truncus repair in one patient ( $n = 5$ ), conduit repair for TOF with pulmonary atresia ( $n = 3$ ) and TOF with absent pulmonary valve ( $n = 1$ ), Rastelli repair for transposition of great arteries ( $n = 3$ ),

repair of truncus ( $n = 1$ ), and Ross procedure ( $n = 2$ ). Twelve patients had more than at least one previous cardiac surgery. Significant comorbidities included tracheoesophageal fistula repair in one patient and medical treatment for infective endocarditis many years earlier in another patient. None of the patients exhibited features of known syndromes. All patients were symptomatic with NYHA Class III in four patients and Class II in the rest. The coronary artery anatomy was favorable on CECT in all except one where there was close proximity of both coronaries to the partially calcified conduit. Being an expensive procedure, some patients were partly funded through institutional concessions, insurance, and other charities.



**Figure 5: Valve-in-valve implantation within bioprosthetic valves.** Left coronary artery injection in lateral view (a) shows its relation to the bioprosthetic valve before its interrogation using a high pressure 22 mm balloon (b) across the valve. A Melody valve is expanded within the bioprosthetic valve, which acts as the landing zone (c). Final pulmonary arteriogram in cranial projection (d) shows absence of regurgitation



**Figure 6: Left pulmonary artery stent followed by Melody valve.** Pulmonary angiogram in caudal projection (a) demonstrates narrowing of the origin of the left pulmonary artery shown in arrow and large right pulmonary artery. After stent angioplasty of the left pulmonary artery, interrogation of the left coronary artery after inflating an 18 mm balloon in the conduit (b) demonstrates normal coronary flows. The conduit is pre-stented with a Cheatham platinum stent (c) followed by implantation of Melody valve (d) within the pre-stented landing zone

**Table 1: Patient details**

No	Age	Diagnosis	Previous surgeries	Final surgery	Conduit/Bioprostheses Size (millimeter)	Initial gradient mmHg	Final gradient mmHg	Post Melody PR	Follow-up months
1	18	TOF	BTS ICR	PVR	Carpentier Edwards 23	60	9	no	32
2	24	TOF PA	Conduit repair	Conduit revision	Contegra 20	70	9	no	14
3	16	TOF	BTS ICR	Conduit revision	Perimount 21	40	10	no	12
4	12	TOF	BTS ICR	PVR	Perimount 23	60	13	trace	1
5	14	TOF PA	BTS	Conduit repair	Contegra 22	62	11	no	1
6	19	Truncus	Conduit repair	PVR	Perimount 21	64	10	trace	1
7	31	TOF PA	Conduit repair	VSD closure	Contegra 22	88	9	no	18
8	31	CTGA VSD PS	Senning-Rastelli		Pericardial	96	12	no	14
9	19	Truncus	Conduit repair	Conduit revision	Pericardial	120	22	no	14
10	18	DTGA VSD PS	Rastelli		Pericardial	84	8	no	12
11	16	DTGA VSD PS	BTS, Rastelli		Homograft 20	90	10	no	7
12	27	Aortic stenosis	Ross	AVR	Homograft 21	87	9	no	36
13	27	TOF APV	Conduit repair		Homograft 22	37	0	no	24
14	50	Severe AR	Ross		Homograft 21	70	10	no	1
15	25	TOF	ICR	PVR	Carpentier Edwards 23	85	12	no	24

TOF: Tetralogy of Fallot; PA: pulmonary atresia; CTGA: Corrected transposition of great arteries; VSD: ventricular septal defect; PS: pulmonary stenosis; DTGA: transposition of great arteries; APV: absent pulmonary valve; AR: aortic regurgitation; BTS: Blalock Taussig shunt; ICR: intra cardiac repair; AVR: aortic valve replacement; PVR: pulmonary valve replacement

## Hemodynamic parameters

The peak gradient across the RVOT on catheterization was  $74.2 \pm 21.5$  mmHg in the 15 patients. The right ventricular systolic pressure was near-systemic in 11 patients, subsystemic in 2, and supra-systemic in 2 patients. While five dysfunctional RVOT was contributed by degenerating bioprosthetic valves, dysfunctional conduits in the other ten patients included four homografts and six xenografts. Cardiac MRI performed in four patients to quantify severe pulmonary regurgitation showed indexed right ventricular end-diastolic volume exceeding 160 ml in all of them. The patients had varying combinations of moderate to severe pulmonary stenosis with moderate to severe pulmonary regurgitation. Predominant regurgitant RVOT requires a different pre-stenting strategy as the risk of stent migration is high and larger pre-stents are required.

## Preparation of the landing zone

Five patients with degenerated bioprosthetic valves underwent high-pressure balloon dilatation to a final diameter of 22 mm to confirm the adequacy of the landing zone without any pre-stents. The other ten patients with conduits were serially balloon interrogated with initial compliant balloons followed by guarded use of semi-compliant balloons depending on the expansion of the conduit. Pre-stenting was done with covered stent in eight patients with severely calcified conduits and uncovered stent in two other patients. Covered stents were used in all three patients with hand-fashioned pericardial

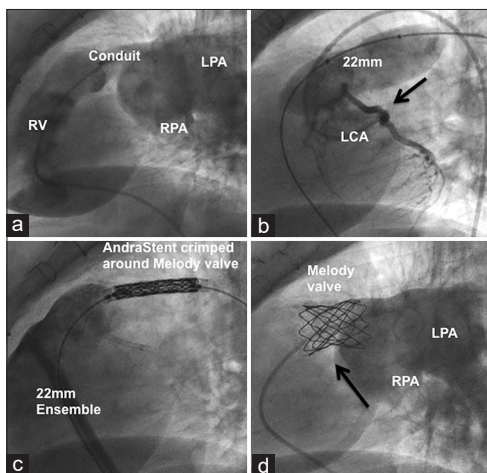
conduits and they were not significantly over dilated. One patient with both coronaries arising close to the proximal end of the conduit on CECT was serially tested with progressively larger semi-compliant balloons until a 22 mm balloon showed mild external compression of the left coronary artery. As the earlier use of a 20 mm balloon did not compromise coronary flows, pre-stenting was done using 20 mm balloon. Interventions on pulmonary arteries were done in three patients. One patient with left pulmonary artery stenosis and documented 70:30 perfusion anomaly underwent stent angioplasty using a 22 mm AndraStent XL using a 16 mm balloon [Figure 6]. Another patient with bilateral moderate pulmonary artery stenosis underwent balloon angioplasty without stenting, as the right ventricular pressures reduced to less than half-systemic following the balloon dilatation. The third patient after conduit repair for truncus arteriosus and absent left pulmonary artery underwent a bioprosthetic valve replacement for conduit dysfunction along with pericardial patch repair of right pulmonary artery. This patient had a narrowing of the lone right pulmonary artery origin that was stented to 18 mm using a CP stent followed by deployment of Melody valve.

## Melody valve implantation

Melody TPV 18 mm was chosen in all patients and deployed using 22 mm Ensemble delivery system in 9 patients and 20 mm delivery system in the rest. While 8 patients had pre-stenting to enlarge the conduit to 20–22 mm before Melody valve implantation, two patients had a bare-stent crimped manually over the Melody valve within the Ensemble delivery system [Figure 7] and delivered as a one-step procedure. [15] None of the five bioprosthetic valves were pre-stented. The valve was successfully deployed in the landing zone in all patients. The postprocedural gradient across the valve was  $10.2 \pm 4.5$  mmHg. Pulmonary artery angiogram after valve implantation did not show any regurgitation. Hemostasis was achieved with ProGlide in five patients and manual figure-of-eight suture in the rest.

## Complications

There were no major complications. Four minor complications were noted. One guidewire injury to the lung parenchyma spontaneously resolved in 48 h. Brachial plexus neurapraxia was seen in one patient due to nerve stretch related to the upper limb positioning during the prolonged procedure recovered completely over the next 3 months. A small femoral arteriovenous fistula identified at 24 h was managed by ultrasound-guided compression for 30 min. One patient had fever for 4 days following the valve implantation, responded to nonsteroidal drugs suspected to be due to persistence of glutaraldehyde elution from the valve. At a median follow-up of 14 months (1–39 months), all the patients were in NYHA Class I with echocardiographic gradients of  $8 \pm 5.7$  mmHg



**Figure 7: One-step combined pre-stenting and implantation of Melody valve. Right ventriculogram (a) shows a narrow dysfunctional conduit and dilated left (left pulmonary artery) and right (right pulmonary artery) pulmonary arteries after repair of tetralogy of Fallot with absent pulmonary valve syndrome. Left coronary artery interrogation with a 22 mm balloon in the conduit (b) shows unobstructed flows. A 42 mm AndraStent XL is crimped around the Melody valve within the 22 mm Ensemble delivery system (c) as an one-step procedure and positioned across the narrowed conduit. Pulmonary arteriogram after expansion of the Melody valve (d) shows absence of pulmonary regurgitation**

with no evidence of pulmonary regurgitation. One patient with bilateral balloon angioplasty of pulmonary arteries had Doppler gradients of 26 and 30 mmHg across the branch pulmonary arteries.

## DISCUSSION

### Managing the learning curve

There is a learning curve for every procedure, and Melody valve implantation is no exception. Detailed history with assessment of previous surgical notes was very important for planning. This helped in deciding the size of stent in preparing the landing zone. Preprocedure workup including CECT helped in deciding and acquiring the stents and balloons needed for preenting. Unlike most other percutaneous valves that require specialized crimping tools and complex valve loading, Melody valve has simple preparatory steps that can easily be performed by the implanting clinician rather than specially trained technicians from the industry thereby minimizing the learning curve. This was clearly evident from the early experience in all the four centers. Institutional and operator experience in complex structural heart interventions plays a major role in success of these procedures.

### Valve and patient selection

PPVI has become an accepted alternative to surgical conduit replacement, with low morbidity and mortality rates.<sup>[16,17]</sup> A large experience using Melody valve has been demonstrated in various trials and registries across the globe.<sup>[4-8]</sup> The alternative options of Sapien S3 and straight Venus-P valve have been used only in a few patients.<sup>[18,19]</sup> Indications for PPVI are identical to surgical indications. The essential prerequisites for Melody valve implantation include patients above 25 kg having dysfunctional conduit or bioprosthetic valve measuring >16 mm and <22 mm and favorable RVOT morphology in terms of its relation to the adjacent coronary arteries.<sup>[5,6,16]</sup> Contraindications consist of sepsis, active endocarditis, pregnancy, and a conduit size that is incompatible with the valve size and coronary artery running very close to the conduit at the level of the area of interest.<sup>[16,17]</sup> All the patients in this cohort were symptomatic with severe conduit dysfunction and fulfilled the necessary prerequisites for Melody implantation.

### Role of contrast-enhanced computed tomography

Computed tomography is one of the most essential investigations, providing information regarding anatomical aspect of RVOT, level, severity, and extent of calcification of RVOT and spatial relation of conduit to the coronary arteries. This information is of utmost importance in deciding the number, length and size of the stents, and requirement of balloons for deployment

and postdeployment dilatation. Being an infrequently performed procedure, this planning was crucial in arranging the hardware in our resource-limited environment. Even though a likelihood of coronary artery compression was predicted on CECT, the ultimate decision was based on balloon interrogation.

### Acquiring appropriate hardware before procedure

Role of appropriate long sheaths, guidewires, balloons, and stents was very crucial for the successful outcome in these procedures. With angulated outflow tract and with unpredictable lie of the calcific conduit, tracking of large 14F or 16F sheaths was challenging. Use of heavy Lunderquist or E-wires, braided sheaths, gentle manipulations using pull-push technique, and gentle rotation of the sheath-dilator assembly were needed to precisely place the preent. A wide range of balloons was needed for serial balloon interrogations and expansion of the landing zone stents. In this study, a checklist of the inventory of all the hardware required for the case was made, and the delivery of all the items was checked to prevent nonavailability of any of the essential consumables. This was important since PPVI is not a routinely done procedure and most of the catheterization laboratories in India, as was the case in all the four centers, do not have on shelf availability of the wide spectrum of consumables required to do these procedures safely and effectively.

### Preparing the landing zone

#### *Fear of conduit rupture*

The most important step in PPVI was preparation of the landing zone or preenting. In noncalcified conduits or bioprosthetic valves, coronary interrogation is safe even with high-pressure balloons.<sup>[13]</sup> Assessment of the coronary artery relationship with the conduit when it is heavily calcified is challenging as interrogation with semicompliant balloon may risk conduit rupture. In one of the patients who had undergone Rastelli surgery for transposition of great arteries, CECT identified left anterior descending coronary artery arising from right coronary artery crossing just below the conduit. As this conduit was heavily calcified, a covered stent was partially deployed initially and followed by serial balloon dilatation with coronary interrogation after each increment. Conduit rupture was also carefully assessed in all patients by repeated angiography following each increment of inflation during interrogation as well as stent deployment.

#### *Coronary compression*

A systematic plan helped in avoiding coronary compression in our patients. One patient with left and right coronary artery origin very close to the proximal conduit showed an uninterrupted left coronary flow during a 20 mm balloon interrogation but developed extrinsic compression of left coronary ostium due to a



shift of calcium from the wall of the conduit following the use of a larger 22 mm balloon. This resulted in a careful guarded choice of 20 mm pre-stent and a valve with a 20 mm Ensemble delivery system. After Melody valve deployment, the gradient reduced to 10 mmHg and there were normal coronary flows. Coronary compression is the most frequent exclusion criterion and the most common cause of procedure-related deaths.<sup>[20]</sup>

#### *Importance of optimal hemodynamic results*

Hemodynamic results are crucial as gradients <10 mmHg across the landing zone produce an ideal substrate for Melody valve and delays its degeneration.<sup>[21]</sup> All the 15 patients had a landing zone gradient of  $\leq 10$  mmHg. One out of 15 patients needed a second stent proximal to the first to relieve the stenosis. Additional stents are needed in longer conduit stenosis, recoil of first stent, or asymmetric oval expansion of the stent identified on a “barrel” view from a caudal projection. Smaller pre-stents <18 mm diameters are not ideal, as they do not provide adequate long-term hemodynamic results. A 20 mm Ensemble system was used in 8 patients and 22 mm in seven patients, which ensured good-sized prosthesis from the point of view of long-term outcomes. In one patient with branch pulmonary artery stenosis, minimal gradients after high-pressure balloon dilatation were accepted as stents had a potential to protrude into the distal conduit thereby compromising the placement of landing zone stent. In two patients with significant pulmonary artery stenosis, stent angioplasty was performed before Melody valve implantation.

#### **Complications**

The major complications such as valve embolization, conduit rupture, or coronary compression can be life-threatening and therefore need minute attention and meticulous planning.<sup>[20-23]</sup> Proper patient selection in terms of conduit/bioprosthesis valve size, generous use of covered stents for preparation of the landing zone, and frequent coronary artery injections during deployment and dilatation of the pre-stent helped in preventing these complications in this study. However, in rare instances when the balloon interrogation shows a pliable conduit that can be dilated to the target diameter of 20–22 mm, one-step crimping of a bare-stent around the Melody valve within the Ensemble delivery system can simplify the procedure as was done in two patients.<sup>[15]</sup> The four minor complications noted in our group were non-disabling and self-limiting and did not need any prolonged treatment. Late complications include stent fracture and endocarditis.<sup>[24]</sup> Stent fractures are reduced by preparation of the landing zone by pre-stenting which was done in all the patients.<sup>[25]</sup> Pre-implant screening for dental and skin infections and post-implant continued counseling of patients during each follow-up visit, as was done in this study, was crucial to reduce incidence

of endocarditis.<sup>[26]</sup> Furthermore, the follow-up of this cohort is too short to draw any definitive conclusions about Melody stent fractures and incidence of infective endocarditis.

#### **Problems faced in initiating a percutaneous pulmonary valve implantation program and economics**

Pre-implantation training to the clinicians and observation of live cases using Melody TPV before initiating the program was certainly useful. Having a proctor with good training skills was equally essential to avoid early hiccups. These definitely helped in initiating successful programs in multiple centers as evident from our early results. One of the major reasons for the delay in initiating PPVI programs in India was the cost consideration. Significant support from charities and institutional concessions were vital to initiate and more importantly sustain such a program. The average cost of a Melody PPVI is Rs. 1,800,000 and is more than twice the cost for a surgical pulmonary valve implantation. During the initial part of this experience, a special import license was necessary from the regulatory authorities on a case-to-case basis, which contributed to additional administrative burden. Fortunately, Melody TPV got approval for use and distribution within India in the past 6 months thereby making the process of valve acquisition much simpler and easier.

## **CONCLUSIONS**

Our early experience shows encouraging results of the PPVI program in India with appropriate case selection and meticulous planning of hardware. The results confirm the safety and efficacy of Melody TPV for treating dysfunctional RVOT in repaired heart defects. Proper training and good proctoring are vital to start the program. High procedural costs may be a deterrent to economically weaker sections, and they will need financial aid and concessions. With these caveats, the procedure is applicable for selected dysfunctional RVOTs.

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Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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