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Percutaneous pulmonary valve implantation as an alternative to repeat open-heart surgery for patients with pulmonary outflow obstruction: a reality in Singapore

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ABSTRACT

Right ventricle to pulmonary artery (RV-PA) conduits have been used for the surgical repair of congenital heart defects. These conduits frequently become stenosed or develop insufficiency with time, necessitating reoperations. Percutaneous pulmonary valve implantation (PPVI) can delay the need for repeated surgeries in patients with congenital heart defects and degenerated RV-PA conduits. We present our first experience with PPVI, and describe in detail the procedural methods and the considerations that need to be taken for this intervention to be successful. The immediate and short-term clinical outcomes of our patients are reported – good haemodynamic results were obtained, both angiographically and on echocardiography. PPVI provides an excellent alternative to repeat open-heart surgery for patients with congenital heart defects and degenerated RV-PA conduits. This represents a paradigm shift in the management of congenital heart disease, which is traditionally managed by open-heart surgery.

Keywords: percutaneous pulmonary valve implantation, pulmonary outflow obstruction

INTRODUCTION

Percutaneous pulmonary valve implantation (PPVI) was first conceptualised by Bonhoeffer et al in 2000,⁽¹⁾ providing patients with congenital heart disease and degenerated right ventricle to pulmonary artery (RV-PA) conduits an alternative treatment option to open surgical replacement. Valved conduits consist of synthetic material, or homograft or xenograft tissue. Their disadvantages are lack of keeping pace with the growth of patient, mechanical distortion and progressive degeneration leading to conduit stenosis over time. Regurgitation may appear with degeneration of the valve leaflets. These patients often require multiple sternotomies throughout their lifespan because the surgical conduits have limited durability, necessitating ongoing intermittent replacement. Each redo cardiac surgery is associated with a higher technical operative difficulty and becomes increasingly hazardous, with an increase in mortality and morbidity risks.^(2,3) PPVI has been shown to extend the duration of these conduits, thus reducing the total burden of redo surgeries for these patients.

The indications and contraindications for this procedure, listed in Box 1, were followed closely when selecting our patients.⁽⁴⁾ A majority of our patients had Tetralogy of Fallot or pulmonary atresia/stenosis, or needed further intervention following complex congenital heart surgery, such as the Ross procedure or the Rastelli procedure. The Ross procedure is a form of cardiac surgery, where a diseased aortic valve is replaced by the patient's own pulmonary valve. A pulmonary allograft (taken from a cadaver) is then used to replace the patient's pulmonary valve. A Rastelli procedure involves using an aortic or pulmonary homograft to relieve right ventricular outlet obstruction. Some studies suggest that 50% of these homografts require replacement after about ten years.⁽⁵⁾

Box 1. Selection criteria for percutaneous pulmonary valve implantation among patients with right ventricle to pulmonary artery conduit obstruction.

Criteria for surgery/intervention
<p>Indication</p> <ul style="list-style-type: none"> • Asymptomatic patients with severe RVOT and/or severe pulmonary regurgitation should be considered when at least one of the following criteria is present <ul style="list-style-type: none"> – Decrease in exercise capacity (CPET) – Progressive right ventricular dilation (> 150 mL/m²) – Progressive right ventricular systolic dysfunction – Progressive TR (at least moderate) – Right ventricular systolic pressure > 80 mmHg (TR velocity > 7.3 m/sec) – Sustained atrial/ventricular arrhythmias <p>Contraindication</p> <ul style="list-style-type: none"> • Occluded central veins • Active infection • Unfavourable morphology of RVOT or conduit (< 16 mm or > 22 mm) • High-risk coronary anatomy • Body weight < 20 kg (issues with cannula size)

CPET: cardiopulmonary exercise testing; RVOT: right ventricular outflow tract; TR: tricuspid regurgitation

In the case of RV-PA conduit obstruction, the efficacy of PPVI on clinical outcome is well-established,^(6,7) and the European Society of Cardiology guidelines⁽⁴⁾ are precise on recommending the timing for early intervention. On the other hand, pulmonary regurgitation is well tolerated for many years and the impact of early PPVI in these patients is more controversial.^(5,7) It has been suggested that, rather than the severity of the pulmonary regurgitation, it is the degree of right ventricular dilation that should prompt the PPVI indication.⁽⁸⁾

The Melody™ transcatheter pulmonary valve (Medtronic Inc, Minneapolis, MN, USA), the first commercially available transcatheter valve in the world, received European certification and Health Canada approval in 2006. It is a bioprosthetic valve harvested from the bovine jugular vein and sutured within a balloon-expandable platinum-iridium stent. The valve size is 18 mm in diameter, which is crimped to 6 mm and can then be balloon-expanded to three sizes – 18 mm, 20 mm and 22 mm – depending on the balloon on which it is mounted.

The Melody™ valve is the most commonly used valve in the world in the pulmonary position, and most of the available data for PPVI are from its use.⁽⁹⁾

In this case series, we present our first experience with PPVI using the Melody™ valve for patients with RV-PA conduit stenosis in Singapore. The procedural methods and the considerations that need to be taken for this intervention to be successful are described in detail. The immediate and short-term clinical outcomes of our patients for whom PPVI was performed are also reported.

METHODS

The Melody™ valve was implanted through a dedicated delivery system (Ensemble Transcatheter Delivery System) (Fig. 1). This consists of a balloon-in-balloon system, which allows repositioning during the valve delivery. The outer balloon has three sizes (18 mm, 20 mm or 22 mm), and the valve is manually crimped onto the balloon and a retractable sheath is used to cover the balloon and the valve. The entire system has a profile of 22 Fr (outer diameter) and is delivered via the femoral vein without any additional sheaths.

Careful consideration was essential in selecting the appropriate patients from the cohort of adult congenital heart patients followed in our institution. Investigations, such as transthoracic echocardiography, cardiac magnetic resonance imaging, computed tomographic angiography, cardiopulmonary exercise test and right heart catheterisation, were performed for preprocedural patient screening and assessment. A dedicated heart team comprising paediatric cardiologists, adult cardiologists, imaging specialists and congenital cardiothoracic surgeons made the joint decisions on eligibility for PPVI and procedural planning.

Femoral venous access was obtained percutaneously and haemodynamic assessment was performed to assess conduit stenosis and severity of RV-PA gradient and/or pulmonary regurgitation. Angiography of the right ventricular outflow tract (RVOT) and conduit was

performed for various outflow tract measurements. A 14-Fr 75-cm long Mullins sheath (Cook Medical, Bloomington, IN, USA) was placed, with its tip just distal to the conduit over a 260-cm long stiff guide wire, such as a Lunderquist wire (Cook Medical). A noncompliant balloon was then inflated within the landing zone of the RV-PA conduit to recheck measurements and simultaneous left coronary angiography performed to assess the risk of coronary artery compression. This test step was essential, as inflating the balloon during stent or valve implantation may cause extrinsic compression of the coronary artery, if it is in close proximity. After this, the conduit was pre-stented with bare or covered stents, depending on whether calcification was present. This was an improved procedural modification over the initial cases of Melody™ valve implantation. The additional step of pre-stenting the conduit conveyed radial strength and reduced tension on the Melody™ valve, thereby reducing the risk of fracture of the Melody™ valve stent. Importantly, for conduits, which have developed significant calcification over the years, the use of covered stents acts as a safety harness in case of conduit rupture or dissection during dilation. After pre-stenting the conduit, any residual narrowing could be addressed by repeated balloon dilatation using a higher pressure non-compliant balloon. Thereafter, the Melody™ valve was implanted within this pre-stented scaffold. Invasive haemodynamic assessments were then performed using a multi-track catheter (Numed Inc, Hopkinton, NY, USA) and final angiography was performed to assess the results.

CASE SERIES

Patient 1

A 31-year-old man with Tetralogy of Fallot had undergone initial surgical repair at four years of age and RV-PA conduit insertion using a 21-mm pulmonary homograft 13 years later. This was followed by repeat open-heart surgery for homograft re-replacement using an aortic homograft of 20 mm seven years later. The third open-heart surgery was complicated by severe

bleeding from adhesions and a stormy recovery requiring prolonged stay in the intensive care unit. Subsequently, he was found to have progressive elevation of the RVOT pressure gradients from 25 mmHg to 44 mmHg over five years. The patient became symptomatic with complaints of lethargy and palpitations, and required treatment with oral amiodarone for episodes of supraventricular tachycardia. The cardiac magnetic resonance imaging performed six months prior to PPVI showed moderate homograft stenosis and mild pulmonary regurgitation. The mean right ventricular end-diastolic volume was 160 mL/m². The right ventricular ejection fraction was reduced to 41%. The most recent transthoracic echocardiography (three weeks prior to PPVI) showed an estimated right ventricular systolic pressure of 78 mmHg, with severe right ventricular dysfunction and moderate tricuspid regurgitation. The cardiopulmonary exercise test showed a reduced peak VO₂ max at 18 mL/kg/min (33% of predicted). With these criteria, he fulfilled the indications for PPVI.

The procedure was performed under general anaesthesia. Two ProGlide sutures were used to preclose the femoral venous access, which was sequentially dilated to permit the placement of a 14-Fr 75-cm long Mullins sheath. Pretreatment peak-to-peak gradient was 25 mmHg under general anaesthesia and in the presence of reduced right ventricular function. The initial angiographic measurements were performed to assess the conduit size as well as to ensure no compromise of the coronary artery (Figs. 2a-c). Pre-stenting was performed, with placement of a pre-mounted 24 mm × 45 mm covered Cheatham-Platinum (CP) stent (Figs. 2d & e). Further post-dilatation of the covered stent was performed with a 20-mm × 20-mm Atlas balloon (Bard) to 10 atm initially and then to 12 atm (Fig. 2f). A 22-mm Melody™ valve was implanted subsequently (Figs. 2g & h). Post-implantation assessment showed that the peak-to-peak gradient had reduced to 5 mmHg, with no pulmonary regurgitation. Haemostasis was achieved with the ProGlide sutures for closure.

The patient was treated with aspirin 100 mg once daily and clopidogrel 75 mg once daily for one month and subsequently planned for lifelong aspirin. He was also given intravenous cefazolin perioperatively and five days of oral augmentin. Although transthoracic echocardiography two days after PPVI showed a similar RVOT peak gradient of 40 mmHg (or no change from preprocedure echocardiography), the right ventricular systolic dysfunction improved remarkably from severe to mild. The preprocedure RV-PA gradient was probably underestimated due to severe right ventricular systolic dysfunction. There was no pericardial effusion, and the leaflets were functioning well without pulmonary regurgitation. He was discharged well on the fifth postoperative day.

Patient 2

A 21-year-old man with truncus arteriosus type 1 not associated with DiGeorge syndrome underwent a Rastelli operation, with closure of the ventricular and atrial septal defects and division of patent ductus arteriosus at 29 days of age. A redo cardiac surgery was performed two years later, with a 17-mm homograft revision and right pulmonary artery angioplasty (Fig. 3a). This surgery was complicated by severe bleeding, renal dysfunction, gastrointestinal bleeding, pneumonia and left vocal cord palsy. Subsequently, during the follow-up, serial imaging showed progressive dilatation of the right ventricle to 179 mL/m². The initial moderate stenosis and regurgitation of the conduit (on cardiac magnetic resonance imaging a year previously) had progressed to severe stenosis and regurgitation on follow-up echocardiography. The estimated right ventricular systolic pressure had increased to 80 mmHg, with severe tricuspid valve regurgitation. Although the patient did not report symptoms, functional impairment was demonstrated on cardiopulmonary exercise testing, with a peak VO₂ max of 14 mL/kg/min (48% of predicted).

During pre-procedural planning, extensive calcification of the conduit was noted on the cardiac computed tomography (Fig. 3b). This is indicative that prior stenting of the conduit is required before pulmonary valve implantation. Care should be taken to avoid compression of the left coronary artery during pre-stenting (Fig. 3c), as they are closely related. Pre-procedural echocardiogram showed a high RVOT peak gradient of 65mmHg (Fig. 3d). Pre-stenting was achieved using a 20-mm × 45-mm covered CP stent deployed at 4 atm followed by another 20-mm × 34-mm covered CP stent deployed at 4 atm placed more distally but overlapping with the first (Fig. 3e). This was because there was fracture of the calcification in the conduit noted posteriorly after the first stent was implanted, but without frank extravasation of contrast. A 22-mm Melody™ valve was then implanted (Figs. 3f & g) and the patient recovered uneventfully.

Transthoracic echocardiography performed the next day after PPVI showed an improvement of RVOT peak gradient by 40 mmHg to 25 mmHg (Fig. 3h). The moderate right ventricular dysfunction remained unchanged, but improvements in right ventricular function may only become more apparent in repeat imaging after a few weeks. There was no pericardial effusion and the leaflets were functioning well without pulmonary regurgitation. The patient was treated with oral augmentin for five days. Repeat computed tomography pulmonary angiography was performed after 14 days, which showed improvement. He was discharged well on the fifth postoperative day.

DISCUSSION

To the best of our knowledge, this is the first experience of transcatheter PPVI for patients with congenital heart defects and degenerated RV-PA conduits in Singapore.

Given the overall improved life expectancy of patients with surgically corrected congenital heart defects over the decades,⁽¹⁰⁾ the role for interventional therapy, such as PPVI,

should be expected to expand, as this cohort continues to survive longer and grow in number. The short-term safety profile of the procedure is well established and mid-term data has been reassuring, with up to a seven-year follow-up of the Melody™ valve having been published recently, with a median follow-up of 4.5 years.⁽¹¹⁾ Risks for such procedures, however, persist and include: (a) conduit rupture; (b) coronary artery compression/occlusion; (c) infective endocarditis; and (d) valve stent fracture.

Partial or total conduit rupture may follow balloon predilation and can occur especially in very stenotic and highly calcified conduits. The risk of conduit rupture requiring rescue surgery can be up to 2%.^(12,13) In our patients, we used covered stents to mitigate against this risk, so that any extravasation due to conduit rupture may be confined. Most of the time, this complication of conduit rupture may be managed in the catheterisation laboratory.^(14,15)

Coronary artery compression/occlusion can be fatal, as it may lead to acute myocardial infarction and may occur in about 1% of Melody™ valve implantations.^(12,13) Evaluation with prior computed tomography coronary angiography and balloon testing during the procedure is useful for identifying high-risk cases, allowing timely preventive measures to be taken. The incidence of coronary artery compression during balloon testing ranges from 4.7%–6%.⁽¹⁶⁾

There has been some recent concern with the rate of infective endocarditis reported post-PPVI.^(12,13) To date, the estimated annualised rate of a first episode of infective endocarditis is 2.4% per patient-year.⁽¹⁷⁾ This could be related to the slow flow and residual turbulence in the conduits. There could also be occult infection in the previous homograft/conduit for which the Melody™ valve was implanted. Infection rates of the Contegra conduit has been reported to be as high as 11.3% (12/106 patients) in those implanted, at a median follow-up of 4.4 years.⁽¹⁸⁾ It is important to emphasise that, for these patients, antibiotic prophylaxis and good dental hygiene are of utmost importance to reduce the risk of subsequent endocarditis.⁽¹⁹⁾

Valve stent fracture seems to be mitigated with modification of the procedure by adopting systematic pre-stenting of the conduit.⁽²⁰⁾ In earlier series, this complication occurred at a rate of about 20%,⁽²¹⁾ which has now been reduced to 5%–16% after pre-stenting.^(12,13) Melody™ valve stent fractures are generally well tolerated but can potentially lead to the loss of structural integrity, embolisation or restenosis.⁽²²⁾

Post procedure, it is recommended to start patients undergoing PPVI on dual antiplatelet therapy for one month and subsequent lifelong aspirin. In the immediate follow-up period, the patient should also be advised to report any new-onset arrhythmias or worsening of pre-existing arrhythmia. The occurrence of post-implant arrhythmias has been reported to be 15% in a recent study, but a majority of these arrhythmias were resolved by six months on follow-up.⁽²³⁾ Finally, it is imperative that patients are educated on the need for antibiotic prophylaxis, and encouraged to be meticulous in maintaining good dental hygiene.

The longevity of surgical RV-PA conduits is known, but long-term data with PPVI is relatively scarce. Around 50% of RV-PA conduits require replacement within ten years.⁽⁵⁾ Subsequent conduits may have shorter survival than the original.⁽²⁴⁾ PPVI allows concomitant relief of RVOT obstruction and regurgitation, while maintaining pulmonary valve competence.⁽¹⁴⁾ At five years after PPVI, 76% of patients remain free from reintervention and 92% of patients remain free from explant.⁽¹¹⁾

The risks described above and the longevity of the valve implant have to be taken into careful consideration during patient selection, weighing against the increased operative risks associated with redo open-heart surgery. Generally, the overall lower procedure-related morbidity, together with other advantages of a shorter hospitalisation stay, lesser pain and faster recovery, make PPVI an attractive alternative to repeated sternotomies.

In conclusion, PPVI provides an excellent alternative to open-heart surgery in patients with congenital heart disease and degenerated RV-PA conduits. The importance of a heart team

collaboration, detailed preprocedural assessment and postprocedural care, especially that for preventing infective endocarditis post-PPVI, cannot be overemphasised

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FIGURES

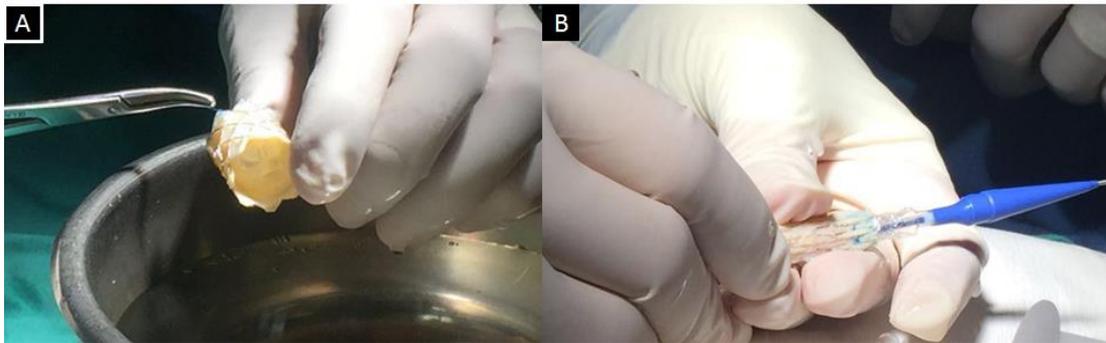


Fig. 1 Photographs of the (a) Melody™ valve and (b) Ensemble Transcatheter Delivery System

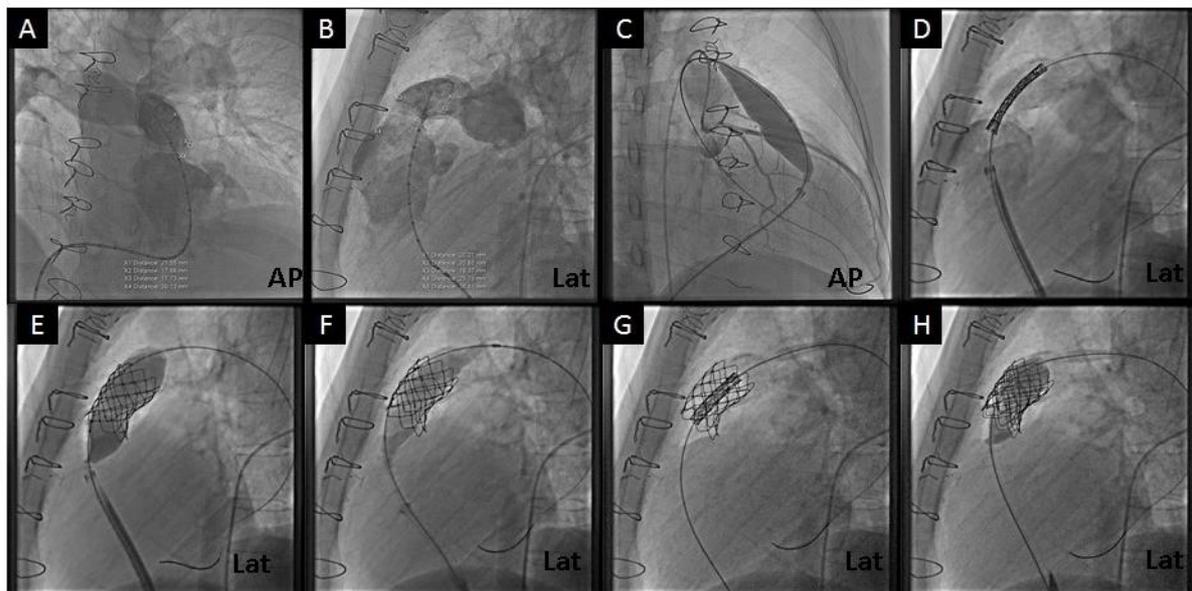


Fig. 2 Angiographic projections of Patient 1 in the (a & c) anteroposterior and (b & d-h) lateral views during procedure show (a & b) measurements of the conduit; (c) balloon inflation for assessment of the conduit and coronary artery interaction; pre-stenting, with (d) placement and (e) deployment of the covered stent; (f) post-dilatation of the covered stent with the Atlas balloon; and implantation, with (g) placement and (h) deployment of the Melody™ valve. AP: anteroposterior; Lat: lateral

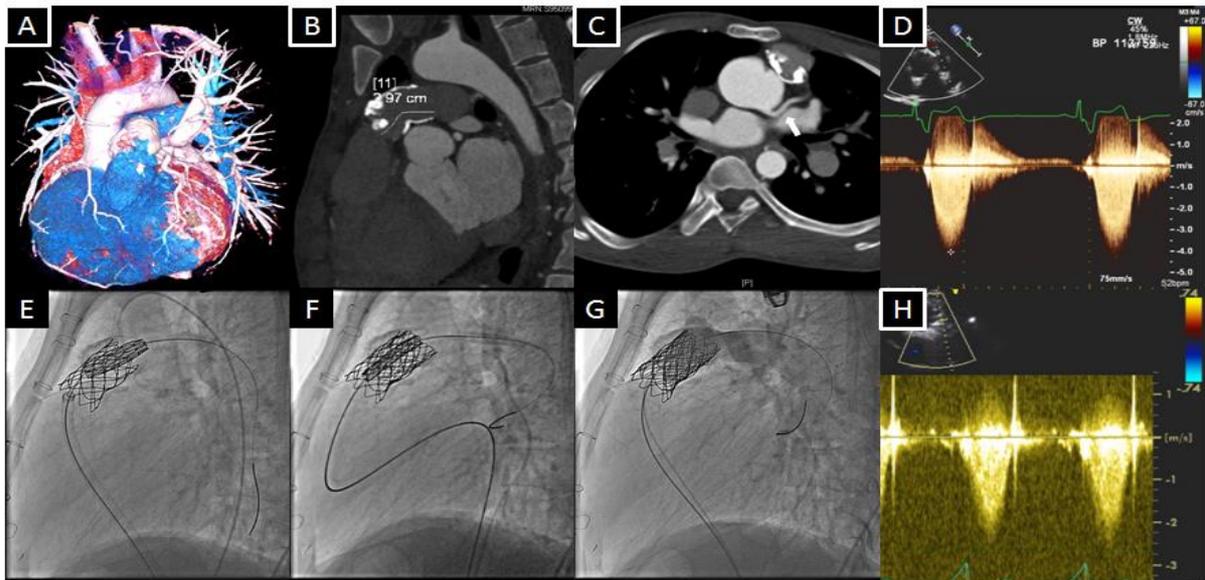


Fig. 3 Images of Patient 2 show (a) anatomy of the conduit post-Rastelli repair for truncus arteriosus; computed tomography findings of (b) the calcified conduit (length, 2.97 cm), and (c) relationship of the left coronary artery (while arrow) and the conduit; (d) high RVOT pressure gradients before Melody valve implantation; (e) pre-stenting, with placement of a second covered stent; implantation, with (f) placement and (g) deployment of the Melody valve; and (h) improvement in RVOT pressure gradients after Melody valve implantation. RVOT: right ventricular outflow tract