REVIEW

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Transcatheter pulmonary valve replacement in congenital heart diseases

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ABSTRACT

Surgical repair of a variety of congenital heart diseases involves repair of the right ventricular outflow tract (RVOT) with valved or non-valved conduit to connect the right ventricle (RV) to the pulmonary artery (PA) or just patch enlargement of the native RVOT. With time, this RV-PA conduit will degenerate with deterioration of function, either causing pulmonary stenosis or pulmonary regurgitation. This RVOT dysfunction may result in RV dilation, RV dysfunction, and eventual RV failure and arrhythmias. Multiple surgical pulmonary valve replacement (PVR) is often required throughout the patient's lifetime. Patients are subjected to increased risks with each additional cardiac operation. Transcatheter PVR (TPVR) has been developed over the past two decades as a valuable non-surgical alternative to restore the RVOT and RV function, and hence reduce patients' lifetime risks related to surgery. This article will discuss the long-term results of TPVR which are demonstrated to be comparable to surgical results and the latest development of large pulmonary valves which will allow TPVR to be performed on native or larger RVOT.

KEYWORDS

Congenital heart disease, Heart valve prosthesis, Pulmonary valve replacement, Transcatheter

INTRODUCTION

About 20% of congenital heart disease (CHD) require surgical repair of the right ventricular outflow tract (RVOT) in initial operations.[1] Many of these CHDs are cyanotic CHDs, including tetralogy of Fallot (TOF), pulmonary atresia with or without ventricular septal defect (VSD), truncus arteriosus, transposition of the arteries (TGA) with VSD and pulmonary stenosis after Rastelli operation, double outlet right ventricle (DORV), and other complex CHD. Patients with aortic stenosis after the Ross procedure also involve pulmonary valve replacement (PVR) in the procedure.

Among these lesions, TOF is the commonest cyanotic heart disease where surgical repair and relief of the RVOT obstruction with patch enlargement will uniformly leave the patient with residual RVOT dysfunction with varying

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degrees of pulmonary stenosis and/or pulmonary regurgitation, leading to deleterious effects on the right ventricle (RV) over the long term. The chronic effects of pressure and volume loading on the RV ultimately lead to RVOT dysfunction, causing RV dilation, RV failure, and arrhythmias. Clinically, the patient may become symptomatic with exercise intolerance, right ventricular failure, and arrhythmias, and may even develop life-threatening ventricular tachyarrhythmias leading to sudden cardiac death.

In the long term, patients with TOF will eventually need pulmonary valve replacement (PVR). In other congenital heart defects, which are mainly conotruncal defects, such as truncus arteriosus, TGA with VSD and pulmonary stenosis, and DORV with VSD and pulmonary stenosis, the RVOT is often repaired with the placement of RV to pulmonary artery (PA) conduits which may be homografts, bioprosthetic valves or non-valved conduits. Bioprosthetic valves may be made from porcine or bovine materials, for example, Contegra, Hancock, Sorin, and Freestyle valves. Non-valved conduits may be a Goretex conduit. Irrespective of the valve type or materials that they are made from, all these RV to PA conduits are subjected to degenerations and deterioration in function over time and need PVR as in the case of TOF.

Conventionally, surgical PVR is utilized for the relief of RVOT dysfunction. Satisfactory results in the long term have been achieved. Many patients manage to survive to adulthood. However, multiple surgical reintervention to replace these valves throughout life are inevitable and surgical risks will increase with each additional operation.

The drawbacks of the need for repeated surgical reintervention have stimulated a search for alternative methods for PVR, the transcatheter technique of PVR. In 2000, Bonhoeffer et al.[2] implanted the first transcatheter pulmonary valve into a human. This led to the development of Melody transcatheter pulmonary valve (Medtronic Inc, Minneapolis, MN, US). Acute success in the first clinical case was reported in 2000.[2] The Melody valve got the Conformite Europeene (CE) marking in Europe in 2006 and was approved for clinical use by Health Canada in the same year. It received Food and Drug Administration (FDA) Humanitarian Device Exemption approval for commercial use in dysfunctional RV to pulmonary conduits in the United States in 2010.

Another valve, the Edwards Sapien valve was first implanted in dysfunctional RV-PA conduits in 2008[3] and this valve can be used for patients with greater RVOT diameter. Subsequent studies allowed for approval of the Sapien XT valve (Edwards Life Sciences LLC, Irvine, California) in transcatheter PVR (TPVR) in failed RV-PA conduits.[4]

In this article, the indications for TPVR, the pre-procedural considerations, the techniques, outcomes as well as the latest developments in the application of TPVR for native and larger RVOT will be reviewed and discussed.

INDICATIONS OF TPVR

The indications of TPVR are basically similar to that of surgical patients. Most will agree on PVR in symptomatic patients in the TOF group with moderate to severe pulmonary stenosis and pulmonary regurgitation. The issue of asymptomatic patients is more controversial. Indeed, the deleterious effects of progressive RV dilation, RV dysfunction, failure, development of ventricular arrhythmias, and mortality are well known. However, in an asymptomatic patient, the challenge is to define the threshold of RV dilation at which intervention will allow a good chance of reversal of structural and functional abnormalities. Different cardiology societies in different countries may adopt slightly different criteria for TPVR in asymptomatic patients.

The summary of the currently adopted criteria recommended by different countries for TPVR is listed in Table 1.[5–8] Since TPVR is less invasive than surgical PVR, it is likely that more asymptomatic patients may benefit from the procedure. Contraindications for TPVR include lack of venous access from both femoral and jugular route, severe pulmonary stenosis that cannot be relieved by balloon dilatation, active endocarditis or other systemic infection, known allergy to aspirin or heparin, and pregnancy.

PRE-PROCEDURAL EVALUATION

A good history of symptoms, physical examination, chest radiograph, and electrocardiogram are needed. Multiple imaging modalities, including echocardiography, cardiac magnetic resonance, and computerized tomography are required for defining the morphology of the RVOT, the presence of significant pulmonary stenosis or pulmonary regurgitation, the bioprosthetic valve status, as well as associated residual cardiac lesions like branch PA stenosis, residual VSD, tricuspid, and aortic regurgitation. Coronary artery anomalies and their relative positions and courses which might be compressed after TPVR have to be noted. Three-dimensional (3D) reconstructions with all relevant measurements of the RVOT as well as 3D printing of the RVOT are useful for planning the procedure. Cardiopulmonary exercise testing should be performed to assess the functional capacity of patients.

Multidisciplinary discussion among different specialties, including pediatric cardiologists, adult congenital heart cardiologists, cardiac surgeons, and cardiac anesthesia is necessary to determine the best strategy for each individual

TABLE 1 Summary of criteria for transcatheter pulmonary valve replacement

Items	Description
Indications for percutaneous pulmonary valve implantation Guidelines: • AHA / ACC • European • Canadian	1. Symptoms of heart failure, requiring pharmacological therapy 2. Gradient across PV: Peak > 50 mmHg, Mean > 30 mmHg 3. RV hypertension: RV/LV pressure > 0.7 4. Moderate to severe pulmonary regurgitation 5. RVED volume: > 160 ml/m^2 6. RVES volume: > 80 ml/ m^2 7. RVED volume ≥ 2 × LVED volume 8. RVEF < 0.40 – 0.45 9. QRS duration ≥ 180 ms
Adjunctive relevant factors	1. Sustained atrial/ventricular arrhythmias 2. Significant coexisting lesions: TR, AR, residual VSD 3. LV dysfunction

Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; LV, left ventricle; LVED, left ventricular end-diastolic; RV, right ventricle; RVED, right ventricular end-diastolic; RVEF, right ventricular ejection fraction; RVES, right ventricular end-systolic; TR, tricuspid regurgitation; VSD, ventricular septal defect.

patient. Vascular access has to be considered in the planning as well.

THE PROCEDURE OF TPVR

General anesthesia is usually needed with biplane fluoroscopy to understand the RVOT and PA anatomy. The femoral venous route is often the first choice; the jugular, ideally on the right, can also be used if the former is not available.

Because the Melody valve is the first valve used in TPVR for humans, the following descriptions will be more relevant to its implantation. The basic principles actually also apply to other valves that are used at later times, with some modifications of techniques in the procedures.

Anatomical and hemodynamic data

A baseline right and left heart catheterization and hemodynamic assessment are performed together with RVOT, PA, aortic, and coronary angiography. From these data, a plan is worked out for the final balloon sizing, the risk of conduit rupture and coronary artery compression as well as the preparation of the conduit like pre-stenting before implantation of the pulmonary valve. Concurrent PA stenosis may have to be dealt with before the procedure.

Coronary artery and aorta testing

Prior to stenting of the conduit, assessment for risk of coronary artery obstruction is necessary. A variety of coronary artery anomalies can be at risk, including left anterior descending from the right coronary artery, ostial stenosis, and abnormal location secondary to the previous reimplantation. Coronary artery testing is performed with either aortic root angiography and/or selective coronary angiography while a balloon with the intended valve diameter is inflated in the RVOT. Compromise of coronary artery flow is a contraindication for stenting the existing conduit or TPVR. Aortic root distortion leading to aortic regurgitation is a less common problem but has been reported.[9]

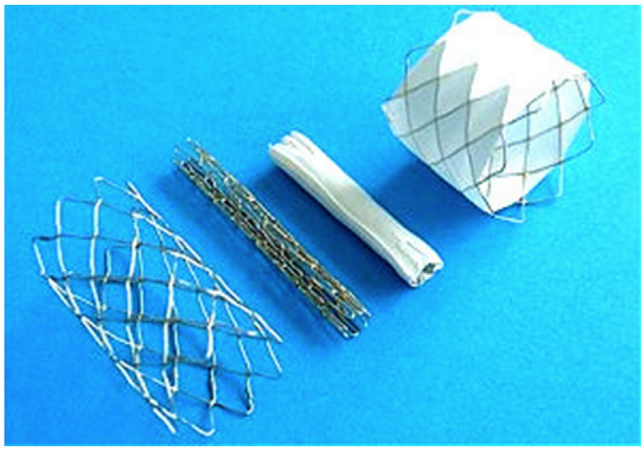


FIGURE 1 Stents: bare and covered stents.

Conduit preparation: balloon dilation and/or pre-stenting

Significant conduit stenosis and/or calcifications often exist in dysfunctional RVOT. Conduit stenosis has to be relieved by balloon dilation and/or pre-stenting to provide a suitable landing zone for the valve and to achieve an acceptable post-procedural RV pressure. Serial balloon dilation with high-pressure angioplasty catheters may be needed. This places the conduit at risk of rupture, necessitating a covered stent angioplasty with a Cheatham-platinum covered stent (NuMED, Hopkinton, NY, US).[10] Additional bare metal stents may be implanted to secure an adequate final desired diameter and to avoid stent fracture, recoil and limit metal fatigue (Figure 1). Multiple stents

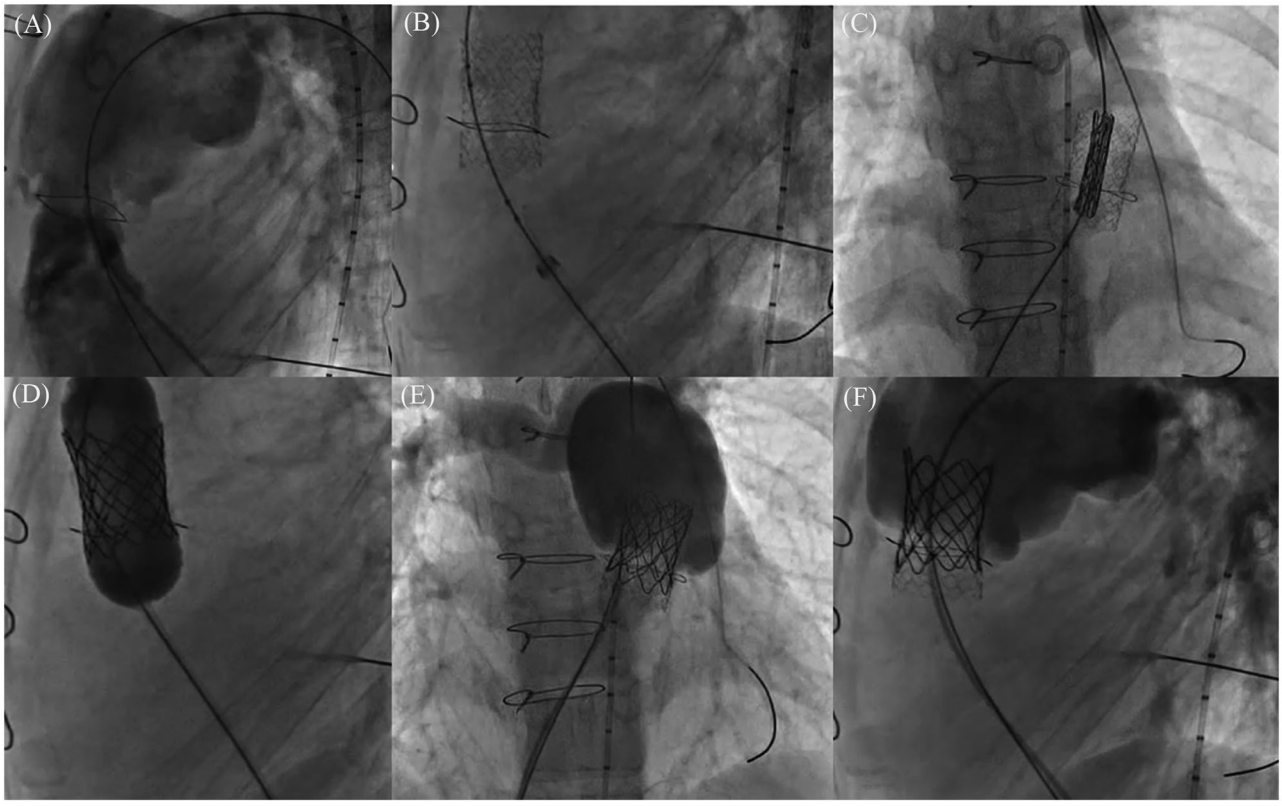


FIGURE 2 Implantation procedure of the Melody valve into a bioprosthetic valve at RVOT. (A) Right ventricle angiogram at RVOT showing the bioprosthetic valve with pulmonary stenosis. (B) Pre-stenting of the bioprosthetic valve to relieve pulmonary stenosis and prepare the landing zone for the Melody valve. (C) The crimped Melody valve on the Ensemble delivery system was positioned at an appropriate site in the RVOT. (D) The fully expanded Melody valve implanted at the RVOT. (E) Pulmonary arteriogram after implantation of the Melody valve showing a competent valve with minimal pulmonary regurgitation (anteroposterior projection). (F) Pulmonary arteriogram after implantation of the Melody valve showing a competent valve with minimal pulmonary regurgitation (lateral projection). RVOT, right ventricular outflow tract.

may be necessary to prevent stent fracture of the Melody valve.

Valve implantation

The Melody valve is hand crimped onto the balloon Ensemble system (Medtronic). Balloon ranges from 18–22 mm and up to 24 mm with the maintenance of valve competency. The outer diameter of the valve is 2 mm larger than the balloon diameter.

The Edwards XT valve is crimped onto the Novaflex delivery system using the proprietary process. This system is stiff and manipulation may be difficult. The use of the Sapien S3 with a smaller delivery system is more amenable to traversing the RVOT.

The delivery system is then advanced to the appropriate position and the valve is implanted by balloon dilation (Figure 2).

Following the implant, post-implant hemodynamic data are obtained. An angiogram is performed to evaluate for valve competence and perivalvular leak.

Valve-in-valve situation

Implanting a Melody valve in a bioprosthetic valve tends to be a less complex procedure because the metal frame in it cannot be over-expanded at low pressure to compress the coronary arteries. Pre-stenting may not be necessary unless there is valve stenosis. On the other hand, this kind of valve-in-valve therapy may further decrease the internal diameter of the bioprosthetic valve which is limited by the rigid metal frame, especially in those with smaller bioprosthetic valves to start with, thus leading to functional stenosis. Historically surgical PVR was the treatment option if the internal diameter of the valve-in-valve was considered too small for the patient. However, intentional fracture with a high-pressure balloon of the bioprosthetic valve frame as a means of facilitating further expansion of the valve in the aortic, pulmonary, and

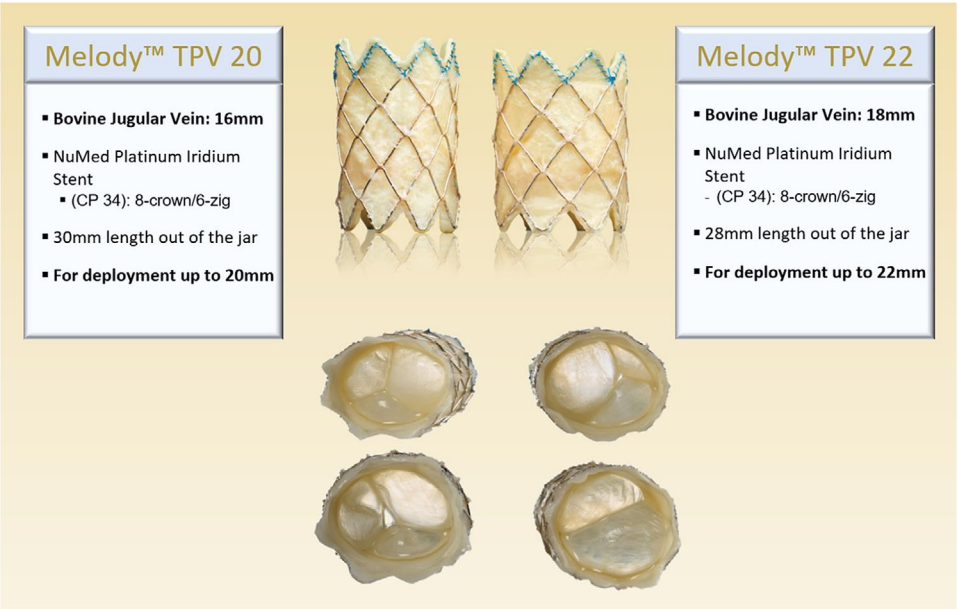


FIGURE 3 The appearance and the two sizes of the Melody transcatheter pulmonary valve.

tricuspid position has been reported. In the pulmonary position, it was demonstrated that fracture can be safely performed prior to valve implantation, thus, achieving a larger internal diameter and better hemodynamic result in valve-in-valve therapy. This procedure obviates the need for a surgical operation to match the patient's size.[11] In this situation, coronary artery anatomy and risks of compression must be considered as described in the aforementioned section.

AVAILABLE VALVE SYSTEM FOR RVOT CONDUITS AND OUTCOMES

The Melody valve

The Melody valve (Medtronic Inc.) is a bovine jugular venous valve mounted on a platinum iridium-covered stent. Two sizes of the valve, 16 and 18 mm venous segments are sutured to 20 and 22 mm covered stents, respectively and each of them can be expanded 4 mm up to 20 and 22 mm, respectively (Figure 3). The valve is delivered via the Medtronic Ensemble delivery system which utilizes a "balloon-in-balloon" (NuMED Inc, Hopkinton, NY, US) available in 18, 20, and 22 mm sizes. The delivery system is 22 Fr. (Figure 4)

Experience from European centers in UK,[5] France,[12] Germany,[13] and Italy,[14] on the Melody valve predates use in the US. Early reports showed a procedural success rate of 90%–98%[5,12–14] with excellent short-term results achieving good relief of pulmonary stenosis and significant reduction or complete elimination of pulmonary regurgitation.

Mid-term results on the use of the Melody valve alone showed an excellent success rate of 96.7%, a freedom from reoperation rate of 70% after 70 months. Further lowering of reoperation rates with increasing experience with the valve system has been reported.[15] The US Investigational Device Exemption trial reported its medium to long-term results in 2015 on a total of 171 patients with 148 (86.5%) successful implants and a reoperation-free rate of 76% at 5 years.[16] The Melody valve received CE mark approval in 2006 and FDA granted Humanitarian Device Exemption approval in 2010 and full post-market approval in 2015. Subsequent US post-market approval study showed a 98% success rate.[17]

Long-term results are now available for the Melody valve because it has the longest history of use for all types of RVOT conduits. Long-term outcomes after Melody TPVR in the US Investigational Device Exemption showed that 10 years after implantation, freedom from mortality is 90% with endocarditis being the most important cause of related death while 56% of deaths are unrelated to TPVR. This survival is comparable to that of surgical series. Freedom from reoperation is 79% while that for any intervention is 60%. Freedom from TPVR-related endocarditis is 81%, with annualized endocarditis rate of 2%. Freedom from TPV dysfunction is 53% of which 71% have only no or trace pulmonary valve regurgitation, 26% have mild regurgitation and 3% have moderate PR. 78% of patients were in New York Heart Association (NYHA) class I and 22% in NYHA class II. Therefore, this long-term study affirms the benefits of Melody TPVR in the lifetime management of patients with RVOT conduits of any type by providing

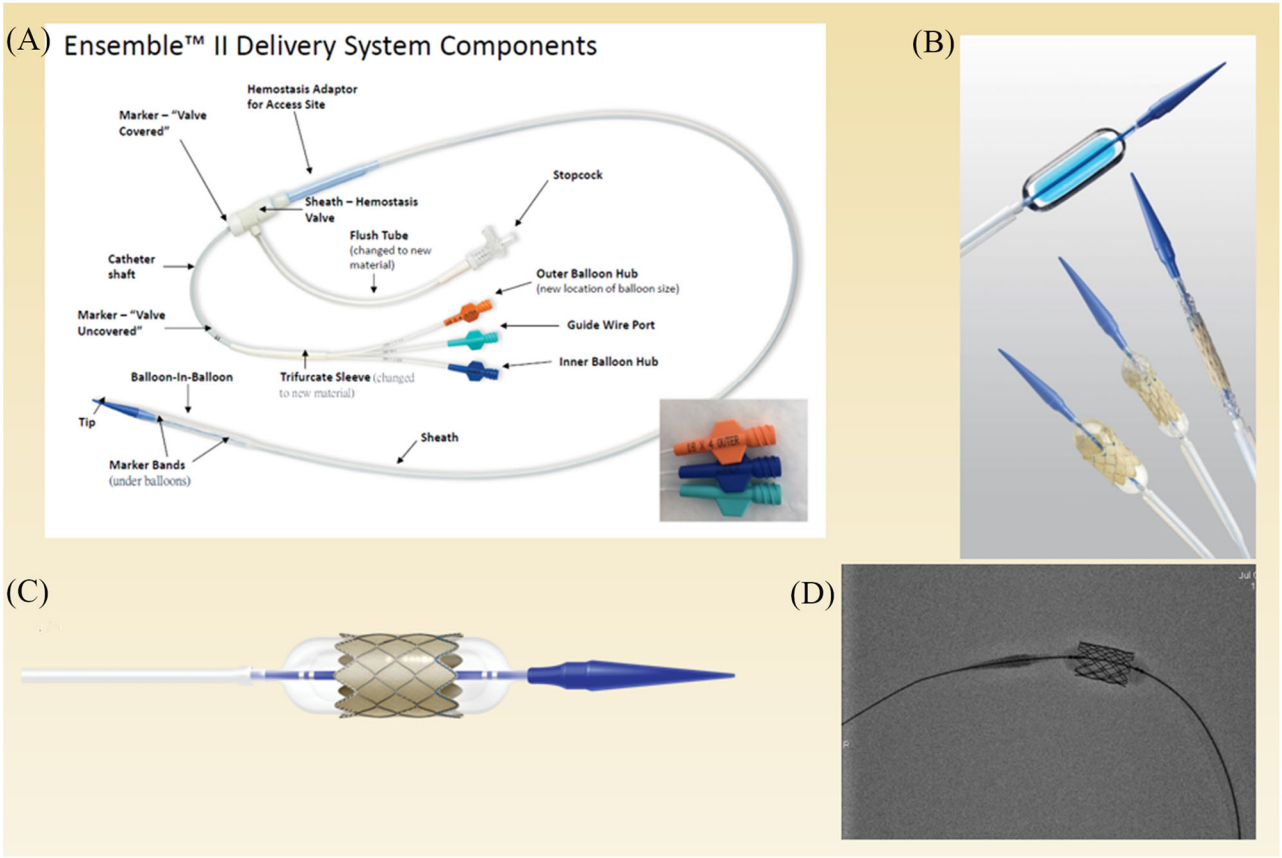


FIGURE 4 The Ensemble delivery system of the Melody valve. (A) The Ensemble II Delivery system (B) The Ensemble system loaded with the Melody valve. (C) The appearance of the expanded Melody valve after the inflation of the balloon-in-balloon catheter. (D) The appearance of the expanded Melody valve on the balloon catheter under fluoroscopy.

sustained symptomatic and hemodynamic improvements in the majority of patients.[18]

The Edwards Sapien XT and Sapien S3 valves

The Edwards Sapien XT (Edwards Life Sciences) transcatheter heart valve (THV) was approved by the FDA for use in the pulmonary position in 2016. The valve is made of bovine pericardial tissue and mounted on a cobalt-chromium stent with a fabric skirt on the outside lower part of the stent to minimize perivalvular regurgitation. The valve sizes are 23, 26, and 29 mm, and they are delivered via the Edward Novaflex delivery system.

The Sapien 3 valve expands the valve sizes with a 20 mm option with the Commander valve delivery system which allows better delivery into the RVOT. Data from a series of 56 patients from Germany suggested excellent procedural success and no reinterventions were needed up to two years of follow-up.[19]

The COMPASSION multicenter clinical trial enrolled 81 patients and implanted the Sapien XT THV in 69 with a 93.7% freedom from reintervention at 3 years.[4] There are ongoing clinical trials for post-market approval surveillance on the use of this valve.

Another multicenter large cohort study on the Sapien XT and Sapien S3 valves on 774 patients showed that technical success was achieved in 97.4% of patients. Serious adverse events were reported in 10% of patients. Fourteen patients underwent urgent surgery and nine patients had a second valve implanted. Tricuspid valve injury occurred in 1.7% of patients and 1.3% of patients had new moderate or severe tricuspid regurgitation. In total, therefore, about 3% of patients had tricuspid valve complications. The function of the implanted valves at discharge was excellent for the most patient but 8.5% had moderate or greater pulmonary regurgitation or maximum Doppler pressure gradient >40 mmHg. During follow-up from 5 to 24 months (median 12 months), nine patients had endocarditis and another 17 additional patients require reintervention either by surgical valve replacement or valve-in-valve TPVR. Medium-term results of the Sapien valves are generally good but long-term data are needed.[20]

Long-term results of TPVR

Long-term results on reintervention and survival after TPVR using both Melody valves (82.3%) and all Sapien valves (XT, S3, and Sapien) (17.7%) on all RVOT conduit types in the largest multicenter cohort of 2476 patients followed for 8475 patient-years are available at the time of writing up this article. There were 95/2476 (3.8%) deaths mostly caused by heart failure. The cumulative incidence of death at 8 years post-TPVR is 8.9%. Risk factors for death are age at TPVR (Hazard Ratio [HR] 1.04/year), prosthetic valve in other positions like aorta, mitral and tricuspid valves (HR 2:1), and existing transvenous pacemaker/implantable cardioverter-defibrillator. There were 258/2476 (10.4%) TPVR reintervention. The cumulative incidence of TPVR reintervention is 25.1% at 8 years post-TPVR while that for surgical reintervention is 14.4%. The risk factors for surgical reintervention are age, prior endocarditis, TPVR into a stented bioprosthetic valve, and post-implant gradient. These long-term results showed that survival and freedom from reintervention after TPVR are comparable to outcomes of surgical conduit/valve replacement across a wide age range.[21]

Using the same cohort of patients, it was found that 184/2476 (7.35%) patients developed endocarditis with a median of 2.7 years after TPVR. Cumulative incidence is 9.5% at 5 years and 16.9% at 8 years post-implant, and annualized incidence is 2.2 per 100 patient-years. A large proportion of bacteria identified were *Staphylococcus aureus* and the viridans group of streptococcus. Risk factors were young age, previous history of endocarditis, and high residual gradient. Management strategy is either valve explant or RVOT reintervention. Endocarditis mortality was 12/2476 (6.6%). All patients' deaths were due to *S. aureus*. Severe endocarditis occurred in 44% of patients.[22] From these long-term results, endocarditis is certainly a serious adverse outcome after TPVR that needs vigilant surveillance despite the fact that TPVR remains an important tool in the management of RVOT dysfunction.

In summary, the long-term outcome of TPVR on conduit at RVOT is excellent. Reasons for reintervention, be it surgical or transcatheter TPVR are usually due to dysfunction of the implanted valve, endocarditis, and stent fractures. The problem of stent fractures should become less by implanting multiple stents to enhance the landing zone for the valve. Coronary artery compression, though a dreadful complication of TPVR in the early years, should also be mostly avoided by vigilant testing before the procedure.

IMPLANTATION OF VALVES IN NATIVE OR LARGE RVOT

After transannular patch repair for TOF, the native RVOT tend to expand to larger diameters with time, lacks a tubular landing zone, and can assume variable shapes and morphology. These anatomical characteristics pose more difficulties for TPVR and make it more challenging. Only a small proportion of these RVOTs, about 15%, has anatomy suitable for off-label use of the smaller Melody valve or Sapien valves. There is a need to develop larger valves to cater to the native RVOTs.

To circumvent this difficulty, alternative methods have been sought. First, the Alterra Adaptive Pre-stent, a self-expanding partially covered stent (Edwards Life Sciences LLC), was designed to internally remodel a wide variety of RVOT morphologies, thereby creating a suitable landing zone for implantation of a standard balloon-expandable THV, thus enabling TPVR to be used to treat a broader range of patients. The first successful human implant of this device with subsequent implantation of a 29 mm Sapien 3 was reported in 2018.[23] This is still undergoing clinical trials. Secondly, valves implanted into one or both of the proximal branch pulmonary arteries[24] has been shown to be effective in reducing the degree of pulmonary regurgitation but this does not render a competent RVOT which should be the ultimate goal of the intervention.

Larger RVOT valves suitable for transcatheter implantation into native RVOT are actively sought and undergone clinical trials in the past decade. These included the Medtronic Harmony valve,[25] the Venus P valve (Venus Med tech, Hangzhou, China),[26,27] the Pulsta valve (TaeWoong Medical Co, Gyeonggi-do, South Korea)[28] and the Med-Zenith PT valve (Beijing Med-Zenith, Beijing, China).[29,30] These newer and larger pulmonary valves are described and discussed in the following section.

AVAILABLE VALVE SYSTEMS FOR NATIVE OR LARGE RVOT AND OUTCOMES

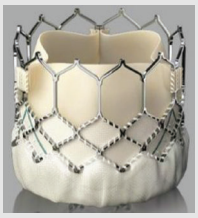
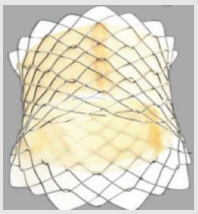
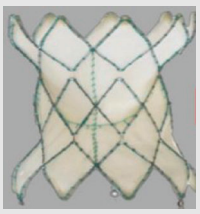
The Harmony valve

The Harmony valve (Medtronic Inc.) is made of porcine pericardium mounted on a covered nickel-titanium (nitinol) self-expanding stent with flaring at both proximal and distal ends (Table 2) and is delivered by a 25 Fr delivery system. Two sizes, 22 and 25 mm valve diameters are available. This is the first valve that is developed to cater to native RVOTs with larger diameters.

Clinical trials on its use started from 2013 to 2015. Acute and short-term outcomes were favorable and demonstrated a high procedural success rate, safety, and good device performance.[25]

The FDA trial results from a prospective, non-randomized multicentre clinical study on 66 patients with follow-up to 5 years demonstrated no procedure or device-related

TABLE 2 Currently available transcatheter pulmonary valves for native / patched right ventricular outflow tract

Items	Harmony	Edward Sapien XT and Sapien S3	Venus P	Pulsta	Med-Zenith PT
Country	United States	United States	China	South Korea	China
Market status	FDA approval	FDA approval	Trial	Trial	Trial
Expanding mechanism	Self-expanding	Balloon-expanding	Self-expanding	Self-expanding	Self-expanding
Stents	Nickel-titanium (nitinol)	Cobalt-chromium	Nickel-titanium (nitinol)	Nickel-titanium (nitinol)	Nickel-titanium (nitinol)
Material of valves	Porcine pericardium	Bovine pericardium	Porcine pericardium	Porcine pericardium	Porcine pericardium
Diameter (mm)	22, 25	20, 23, 26, 29	22–34 (2 mm increments)	18–28 (2 mm increments)	20, 23, 26
Delivery system (Fr)	25	22–24	19–24	18	21
Appearance					

Abbreviation: FDA, Food and Drug Administration.

death within 30 days of implant and 89.2% freedom from surgical or reintervention procedures related to the device as well as acceptable valve function at 6 months.[25] Adverse events included irregular or abnormal heart rhythm in 23.9% (14.1% ventricular tachycardia), leakage around the valve in 8.5% (1.4% major leak), minor bleeding in 7.0%, narrowing of PV in 4.2% and movement of the implant in 4.2%. Contraindications for implantation of the Harmony valve are infection in the heart or elsewhere, patient intolerance to anti-platelet agents or anti-coagulants, and sensitivity to nitinol.

FDA approval for its full use in native RVOT has been obtained in 2022. The FDA statement states that compared with surgery, it is a less invasive and effective treatment option to treat PR in patients with native or surgically repaired RVOT. It can delay the time for additional open-heart surgery and potentially reduce the total number of open-heart surgery required over an individual's lifetime.[31]

Up to the time of writing this article, the Harmony TPV System is the only system with FDA approval in use for native and repaired RVOTs.

The Venus P valve

The Venus P valve (Venus Medtech, Hangzhou, China) is a new generation valve using porcine pericardium leaflets mounted in the middle segment of a self-expanding nitinol stent. The middle segment measures 22–36 mm in diameter and 20–35 mm in length. The proximal and distal ends, like the Harmony valve, are flared to provide an hourglass shape to help anchor in the RVOT and main PA. The delivery system consists of a 19–29 Fr capsule which accommodates the crimped stent valve on a 15 Fr shaft. (Table 2)

This valve enables TPVR in RVOT larger than 30 mm. Reports on mid-term results using the Venus P valve are favorable. High success rates with mid-term maintenance of valvar function and high freedom from reintervention were reported. However, stent fractures were reported in up to 27% of patients but the significance of this in the long term is not known yet.[32] Anyhow, this system obtained the CE mark approval in Europe in April 2022.

The Pulsta valve

The Pulsta valve (TaeWoong Medical Co) is another valve system with a similar concept. Its valve leaflets are also made of porcine pericardium (same as the Harmony and Venus P valves) sutured on a knitted double strand Nitinol wire frame which is also self-expanding. The valve is available in sizes from 18–28 mm with 2 mm increments. The length of the stent is 28–38 mm depending on the valve size and the ends are also flared 4 mm wider than the outer diameter for anchoring (Table 2). The shaft of the delivery system is 12 Fr while that of the sheath is 18 Fr. There is a "hook block" to minimize chances of abrupt delivery and migration.

In a Korean feasibility study reported in 2018, 10 TOF patients with PR in native RVOT were treated with the Pulsta valve, five with 26 mm and five with the 28 mm

valve. All had successful implantation with no major complications and all 10 implants have good valve function and a significant reduction in RV volume.[28]

The Med-Zenith PT valve

The Med-Zenith PT vale (Beijing Med-Zenith) is a newer generation valve whose leaflets are also made of the porcine pericardium and mounted on a self-expanding nitinol stent (Table 2). The first human implantation was reported in 2019 with success. So far, about 130 implantations are done with encouraging results.[29,30] The clinical trial is still ongoing in China.

Comparison of TPVR to surgical PVR

Only a few reports comparing TPVR and surgical PVR are available. Reports found no differences in mortality, repeat intervention, and cardiovascular readmissions between the two groups.[33] A meta-analysis of 1132 TPVR and 4939 surgical PVR also did not show any difference in mortality and reintervention. However, there are fewer procedure-related complications but a higher rate of endocarditis with TPVR.[34] Another study showed a higher in-hospital mortality rate and other cardiac complications in surgical PVR. TPVR, on the other hand, had shorter hospital length of stay and therefore less impact on societal loss of wages for patients or caregivers.[35]

CONCLUSIONS

The main purpose of TPVR is 2-fold. First, it is used to restore RVOT function, that is, relieving pulmonary stenosis and eliminating pulmonary regurgitation, so as to restore an acceptable RV loading condition. Secondly, it is used to avoid repeated open-heart operations after surgical PVR as each additional surgical operation will pose increasing risks to patients.

The TPVR procedure is rapidly evolving. Being a less invasive procedure with continuous improvement in efficacy and safety, TPVR is capable of providing comparable long-term results as surgical PVR. This procedure becomes a valuable alternative or even the preferred procedure for patients who require PVR in the future because it can be repeated several times, thus avoiding repeated surgical operations.

In perspective, firstly, long terms results are still needed as the history of the use of TPVR is still short, particularly for those larger valves for native RVOT. Secondly, smaller and more flexible delivery systems should be developed for use in younger children. Thirdly, the success of TPVR may also impact modification or innovations of surgical techniques at the initial surgical repair in growing children such that further expansion of small conduits is possible.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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