

Review

Percutaneous Pulmonary Valve Implantation: Lessons We Have Learned

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Percutaneous pulmonary valve implantation (PPVI), introduced two years before transcatheter aortic valve implantation (TAVI) is one of the most successful recent improvements in catheter interventional treatment of patients with congenital heart disease and dysfunction of the right ventricular outflow tract (RVOT). At adolescence, many patients with complex cardiac lesions involving the RVOT have experienced several open heart surgeries. Repeated open heart operations are associated with significant morbidity and even mortality. The Melody[®] valve was initially introduced to expand the life time of a biological valve in the RVOT and hence to reduce the total number of open heart surgeries during a patients life time. The advent of the Sapien[®] valve now enables treatment of RVOT's as large as 31 mm in diameter and even patients with so called "native" right ventricular outflow tracts (without a biological valved conduit) are amenable to treatment with a percutaneous valve. PPVI is safe and effective and patients can be discharged home after a few days in the hospital. Coronary occlusion and conduit rupture are the major hazards of the intervention. Long-term data on valve durability now show similar results in comparison to surgical valve implantation with less morbidity for the patients. Currently new self expanding valves are tested, which could enhance the possibility for patient selection. This review describes current practice, adds own experience, lessons learned and gives an outline on future developments in PPVI.

Keywords: percutaneous pulmonary valve implantation, right ventricular outflow tract dysfunction

Introduction

The incidence of congenital heart disease (CHD) varies between 4 and 8 per 1000 live birth.^{1,2)} Patients with Tetralogy of Fallot, common arterial trunc, pulmonary atresia and ventricular septal defect, transposition of the great arteries after Rastelli operation and patients with valvar aortic stenosis after the Ross procedure require complex cardiothoracic operations, often at infant age, involving the right ventricular outflow tract (RVOT). Today, up to 90% of these patients survive to adulthood.³⁾ However, RVOT dysfunction is a common finding in the above mentioned patients and pulmonary valve replacement with a biological valve may be necessary. The longevity of biological valves is limited and in the past subsequent repeated surgical pulmonary valve exchanges were necessary.⁴⁾ At present, RVOT conduit revision can be performed with a very low mortality,⁵⁻⁷⁾

but repeated redo operations are associated with significant morbidity⁸⁾ and the technical challenge rises with the number of re-operations.

Percutaneous pulmonary valve implantation (PPVI) was introduced as the first successful catheter interventional valve implantation in the year 2000⁹⁾ and is one of the most significant advances in catheter interventional treatment of patient with CHD in the last decades. PPVI emerged to the preferred first line treatment for selected patients with RVOT dysfunction in many centres. The idea of Philip Bonhoeffer was to prolong the functional life-span of a biological valve prosthesis in the RVOT with the final goal to reduce the total number of open heart surgeries required over a patient's lifetime. So far, several studies documented excellent immediate and medium term hemodynamic results after PPVI with the Melody valve (Medtronic, Minneapolis, MN, USA)¹⁰⁻¹⁵⁾ and with the Sapien valve (Edwards, Irvine,

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CA, USA)^{16, 17)} in pulmonic position. Worldwide more than 11,000 PPVI procedures have been performed. The melody valve received the CE mark for Canada and Europe in 2006 and received FDA use approval in 2010. The Sapien XT valve was approved by the FDA for percutaneous implantation in pulmonic position in the year 2016.

Patient Selection and Indication for Treatment

A biological valve in the RVOT has a limited life-span. Due to valve degeneration or outgrowth even adult sized valves (>18mm diameter) have to be exchanged at mean after 10–15 years.⁴⁾ Current guidelines for surgical pulmonary valve replacement evenly apply for PPVI as well (Table 1).^{18–20)}

The pre procedural work-up always includes a patient history, detailed reports of former operations (which

valve is in place?), a clinical examination, an echocardiographic examination, a cardiovascular magnetic resonance tomography and an exercise test with assessment of VO₂ max. At present these examinations are repeated at 6 months, five and ten years after PPVI at our unit. Since large sheaths are necessary for PPVI the femoral or jugular vessels have to be large enough to accommodate an introducer sheath for the specific valve 22F.

Our approach—We recommend percutaneous pulmonary valve implantation for patients with right ventricle to pulmonary artery conduits, native right ventricular outflow tracts (“off label” indication), or failing bioprosthetic valves in the pulmonary position meeting the following criteria for severe RVOT obstruction or severe pulmonic regurgitation (Table 2). Most patients show a combination of stenosis and regurgitation in the RVOT.

Table 1 Indications for surgical valve replacement in the right ventricular outflow tract Canadian Cardiovascular Society: Guidelines for surgical PVR¹⁸⁾

<p>The following situations may warrant intervention following repair:</p> <ul style="list-style-type: none"> — Free pulmonary regurgitation associated with: <ul style="list-style-type: none"> ◦ Progressive or moderate to severe RV enlargement (RV end-diastolic volume of greater than 170mL/m²) ◦ Moderate to severe RV dysfunction ◦ Important tricuspid regurgitation ◦ Atrial or ventricular arrhythmias ◦ Symptoms such as deteriorating exercise performance <p>European Society of Cardiology guidelines for surgical PVR¹⁹⁾:</p> <ul style="list-style-type: none"> — PVR should be performed in symptomatic patients with severe PR and/or stenosis (RV systolic pressure >60mmHg, TR velocity >3,5m/s) — PVR should be considered in asymptomatic patients with severe PR and/or stenosis when at least one of the following criteria is present: <ul style="list-style-type: none"> ◦ Decrease in objective exercise capacity ◦ Progressive RV dilatation ◦ Progressive RV systolic dysfunction ◦ Progressive TR (at least moderate) ◦ RVOT with systolic pressure >80mmHg (TR velocity >4,3m/s) ◦ Sustained atrial/ventricular arrhythmias
<p>PR: Pulmonary regurgitation, PS: Pulmonary stenosis, PVR: Pulmonary valve replacement, RVOT: Right ventricular outflow tract.</p>

Table 2 Indication for PPVI at the German Heart Centre Munich

<ul style="list-style-type: none"> — Severe RVOT obstruction with no or mild pulmonary regurgitation, with either of the following: <ul style="list-style-type: none"> ◦ Symptoms related to RVOT obstruction (<65% of expected or a significant decrease in exercise tolerance) plus a peak Doppler velocity at the tricuspid valve >3,5m/s or ◦ No symptoms plus an increased RV pressure >4,3m/s (measured at tricuspid regurgitation), >2/3 systemic pressure in the right ventricle — Severe pulmonary regurgitation, with right ventricular end-diastolic volume index >150mL/m² by cardiovascular magnetic resonance imaging²¹⁾ <p>Candidates for PPVI must also meet the following criteria:</p> <ul style="list-style-type: none"> — Adequate RVOT conduit size to accommodate a covered stent. We do not have a lower size limitation. The upper size limitation is usually a diameter >29mm. In selected cases, a patient with a slightly larger RVOT diameter may be successfully treated after pre-stenting to a smaller diameter, or by overfilling the dilatation balloon (Sapien S3 29 may be overdilated to 31 mm outer diameter). — Adequate body size. There is no absolute lower age limit but an adequate body size (eg, weight >20kg) is required to accommodate femoral placement of the introducer.
<p>PPVI: Percutaneous pulmonary valve implantation, RVOT: Right ventricular outflow tract</p>

PPVI is not possible, if there is occlusion of all central veins, active infection (such as infective endocarditis) or high risk of infection, or if the “balloon test” show severe proximity of a coronary vessel to the RVOT landing zone.²²⁾

Percutaneous Pulmonary Valve Implantation

The intervention is carried out in general anaesthesia, or in deep conscious sedation. After vascular access is achieved for both the femoral vein and artery a complete diagnostic catheterization is performed. If femoral veins are occluded, a jugular venous access may be used. A weight adjusted dose of heparin (100 units/kg, max. 5,000 units) is given. The gradient between the right ventricle (RV) and the pulmonary artery is assessed and the systolic pressure ratio between the aorta and the RV is calculated. An angiogram into the RVOT defines the dimensions and according to the measured diameters a balloon test with a concomitant aortogram is performed to depict the anatomy of the RVOT in relation to the coronary arterial system.²²⁾ If the coronary anatomy is doubtful a balloon test with a high pressure balloon (Atlas gold Bard, Tempe, AZ, USA) through a 14F long sheath and selective injections into the coronary arteries in different X-ray planes may be necessary. It is safer to perform the high pressure dilatation through a long sheath, because RVOT rupture can rapidly be depicted by dye injections through the sheath and once the rupture has occurred a covered stent can then rapidly be delivered through the long sheath. Then a pre-stent is implanted with a balloon catheter into the RVOT landing zone over a superstiff guide wire (Amplatz ultrastiff, Lunderquist, Meier wire), which had been placed distally into one pulmonary artery. In calcified RVOT's we prefer the use of a covered stent (for example a covered CP-stent NuMED, Inc. Hopkinton, NY,

USA). If stent-recoil is visible during balloon dilation the implantation of additional stents (bare metal stents) may be indicated and the prepared landing zone is dilated with high pressure balloons to the desired final internal diameter. Depending on the patient's age, weight and the anatomical situation, the largest possible internal diameter of the landing zone should be achieved to have the best possible hemodynamic result. An appropriately sized pulmonic valve (Melody or Sapien valve) is prepared and implanted over the guide wire. The pressure recordings are repeated and final angiograms document correct valve position and intact vessels. The intervention is successful if the post interventional gradient between the subpulmonary ventricle and the pulmonary arteries is <20 mmHg. Whenever the gradient exceeds this value, high pressure balloon dilatation may be necessary to achieve a better result.

Available Percutaneous Valves

The Medtronic Melody[®] valve (Fig. 1) system involves a balloon-expandable prosthesis that is available in two sizes, 16 and 18 mm, suited for RVOT dimensions from 16–24 mm. The bovine jugular vein is sutured into a bare metal 34 mm 8 zig Cheatham platinum stent (Cheatham Platinum stent, NuMED Inc., Hopkinton, NY). Expanded to 22 mm internal diameter the stent shortens to a length of 24 mm. The valve is hand crimped onto a 18, 20 or 22 mm balloon-in-balloon delivery catheter (Ensemble Transcatheter Delivery System, Minneapolis, MN, USA) with a maximal outer diameter of 22F. The delivery system is then closed over the valve and the ensemble is guided over the wire into the final landing zone, where it can be re-opened, after which the BiB balloons are inflated. The 16 mm Melody[®] valve can only be expanded to a maximum of 20 mm internal diameter.



Fig. 1 Depiction of the Medtronic Melody[®] Transcatheter Pulmonary Valve (18 mm bovine jugular vein valve with platinum iridium frame)

It can be expanded to 24 mm external diameter with a 22 mm Ensemble[®] Delivery System. The length of the Melody[®] Transcatheter Pulmonary Valve varies between 26.2, 24.2 or 23 mm respectively, depending upon the size of the Ensemble[®] Delivery System used (18, 20, 22 mm, respectively, Medtronic Inc. Minneapolis, MN). The smaller 16 mm valve can only be expanded to 20 mm internal diameter.

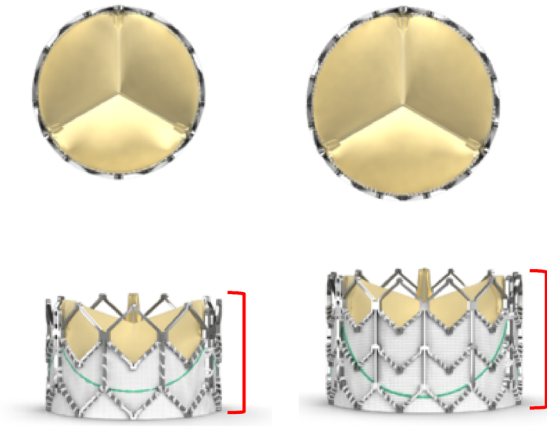


Fig. 2 The Edwards Sapien® XT valve: trileaflet bovine pericardium valve hand-sutured in a stainless steel stent

The length of the expanded Sapien 26mm valve is 17.2mm and of the Sapien 29mm valve is 19.1mm. The valve is available in 23, 26 and 29mm external diameters.

The Edwards Sapien® valve (Fig. 2) is a trileaflet bovine pericardial valve, hand sutured onto a rigid chromium-cobalt stent frame and is available in four sizes, 20 mm, 23 mm, 26 mm and 29 mm external diameter. Once dilated the stent length ranges from 14.3 mm for the 23 mm valve to 19.1 mm for the 29 mm valve. The valve is crimped using a specially designed tool to mount it onto a 30 mm long, noncompliant high pressure balloon. The valve is delivered through a 14 or 16F sheath into the femoral vein. The French size refers to the internal diameter of the expandable sheaths. The outer diameter of the Melody® valve is 22F, but it can be delivered through the Edwards 16F e-sheath. Hence, the external diameters of the valves (Melody® and Sapien® 23, 26, 29) do not differ significantly. Once in the inferior vena cava the valve is pushed forward onto the balloon. It is then advanced unguarded through the tricuspid valve into the final landing zone in the RVOT over the guide wire, where the valve is balloon dilated.

Immediate Procedural Results

Three prospective studies in the US, Canada and Europe documented excellent immediate procedural results with the Melody® valve, which persist to medium term follow-up.²³⁻²⁶ These studies report on a high incidence of successful valve implantations with a significant RVOT gradient reduction, sustained abolishment of pulmonary regurgitation, a low incidence of procedural

adverse events and low rate of adverse device related events. The same, with smaller patient numbers and shorter follow-up, is published for the Sapien® valve in pulmonic position.¹⁷⁾

Possible Major Procedure Related Complications

The incidence of major life threatening procedural complications is very low (< 1%). However, there are two possible major procedure related complications. Coronary compression caused by the stents of the valve or the prestents may occur resulting in acute myocardial ischemia. The balloon test was suggested to rule out possible coronary compression.²²⁾ In one multicenter study 5% of all patients showed signs of coronary compression during a balloon test.²⁷⁾ On the other hand a balloon test, especially with a high pressure balloon, may lead to conduit rupture.^{28, 29)} In case of a non-contained RVOT rupture, covered stents must be available to control this dangerous and potentially fatal complication. If catheter interventional means are not successful, a skilled surgical team may be able to save the life of the patient in this dramatic situation.³⁰⁾

Stent Fractures after PPVI

In the initial Melody® patient group, a stent fracture rate of 21% was reported and a classification of stent fractures after PPVI was developed.³¹⁾ Pre-stenting and meticulous preparation of the RVOT landing zone reduced the incidence of clinically significant stent fractures of the Melody® valve.^{11, 32, 33)}

Infective Endocarditis (IE) after PPVI

Infective endocarditis (IE) is a potential late complication associated with all types of bioprosthetic valve implants no matter if the valve is implanted surgically, or by percutaneous means. The original Duke criteria to diagnose IE were introduced by Durack et al. in 1994³⁴⁾ and later modified by Li et al.³⁵⁾ The Duke criteria were developed for native valve IE and do not apply for patients after prosthetic valve implantation. Hence, it may be very difficult or impossible to visualize the valve leaflets using regular echocardiographic means due to multiple artefacts. PET-CT, SPECT and intracardiac echocardiography were suggested as additional diagnostic tools to diagnose valve related IE.³⁶⁻³⁸⁾ Estimates of its incidence after PPVI with the Melody valve vary widely

with a general range from 2.5–4% per patient year.^{39–41)} Combined results of 3 prospective North American, Canadian and European studies identified an annualized rate of a first episode of IE of a Melody[®] valve at 2.4% per patient year. The proven valve related rate of IE was 0.88% per patient year for the Melody[®] valve.⁴²⁾ Risk factors include unprotected dental treatment, male gender, multiple stents, aspirin non-compliance and a previous history of IE.^{39–42)} The risk of IE appears to be higher in patients who undergo Melody[®] valve implantation compared to surgical pulmonary valve replacement.⁴⁰⁾ However, no prospectively examined comparison between surgery and PPVI is yet available. IE after PPVI can be effectively managed with antibiotics, though severe cases may require instant surgical explantation of the valve,⁴²⁾ or a palliative bare metal stent implantation for relief of severe RVOT obstruction.

One group postulates an enhanced selective adhesion of *S. aureus* and *S. sanguinis* pathogenic strains to Melody[®] valve tissue after balloon dilatation of the valve tissue.⁴³⁾ Hence, tissue micro lacerations may occur at high pressure ballooning of the bovine valve, which may be a cite for early thrombus formation. Other experimental evidence showed that the surface composition of bovine jugular valves and homograft tissue themselves, bacterial surface proteins, and shear forces per se are not the prime determinants of bacterial adherence.⁴⁴⁾ Finally, one group proposes that the risk for IE is lower after PPVI with a Sapien[®] valve compared to the Melody[®] valve.⁴⁵⁾ At present this question is still open and more solid information is required for a definite answer.

Long-term Results after PPVI

Contemporary data suggests that in patients after PPVI, rates of freedom from re-intervention are greater than 90% at 1 year, down to 76% at 5 years in patients without stent fracture.⁴⁶⁾ Risk factors for re-intervention include the presence of a homograft, no pre-stenting, post PPVI RVOT gradient greater than 25 mmHg, and a pre-implantation moderate-to-severe tricuspid regurgitation.^{10, 46)} However, it was demonstrated that PPVI had a positive effect on RV remodeling, even in the presence of moderate to severe tricuspid regurgitation.^{47, 48)} Patients with RVOT dysfunction (stenosis, regurgitation or both) show an improved exercise capacity after PPVI.⁴⁹⁾ Finally, in current practice, survival is approxi-

mately 98% at 5 years and 97% at 7 years.^{10, 46)}

In our own experience of 240 patients after PPVI the incidence of IE was 2.0% per patient year and 91% of our patients still live with their first percutaneously implanted valve.⁵⁰⁾

Conclusion and View to the Future

Percutaneous pulmonary valve implantation with the Melody[®] and Sapien[®] valves equally proved to be safe, effective and with sustained improvement of the hemodynamics, the exercise capacity and the functional class of the patients. Hence, PPVI is one of the major advances of catheter interventional treatment of patients with CHD and RVOT dysfunction in the last two decades. This method appears similar in terms of suspected long-term outcomes to open heart surgery, though further data are necessary to prove this.

However, today not all patients with RVOT dysfunction are amenable to PPVI. The largest external diameter of the currently available valves is 31 mm, if a Sapien[®] 29 valve is overdilated. A significant number of patients with large RVOT's with treatment indication still need surgical pulmonary valve replacement.

To overcome this limitation, a self-expanding valve was developed and firstly implanted into a patient with a large RVOT and significant pulmonary regurgitation in the year 2009.⁵¹⁾ Based on this experience the Harmony[®] valve (Medtronic, Minneapolis, MN, USA) a self-expanding porcine pericardial tissue valve with asymmetric hourglass configuration was developed. Recently, the results of the patients selection process and the six months outcomes after Harmony[®] implantation in the first 20 patients were published. Device implantation was safe, with a high procedural success rate.^{52, 53)} Currently, further 40 patients are scheduled for treatment with this device under study conditions in North America.

The venous P[®] transcatheter valve system (Venus Medtech, Shanghai, China) is composed of a tri-leaflet porcine pericardial tissue valve, mounted on a self-expanding nitinol stent. To accommodate larger diameter conduits, the stent has proximal and distal flares to anchor the valve. The valve is crimped and loaded onto the delivery system, which is then advanced through a 22–24F sheath. Valve sizes range from 20–32 mm diameter⁵⁴⁾ and the valve is implanted in Europe under study conditions.

Finally, the Altera® device (Edwards Lifesciences, Irvine, CA, USA) is a self-expanding covered nitinol stent (40×45 mm) which could serve as a rigid landing zone for the 29 mm Sapien valve. There is an ongoing clinical feasibility trial, approved by the FDA. Once all these technical innovations are clinically available more patients with RVOT dysfunction will be amenable to catheter interventional treatment.

Conflicts of Interest

Andreas Eicken is a proctor for the Medtronic Melody valve, and Peter Ewert is a proctor for the Medtronic Melody valve and for the Edwards Sapien valve.

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