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REVIEW

Transcatheter pulmonary valvulation: Current indications and available devices



Revalvulation pulmonaire percutanée : indications et prothèses actuelles

Sebastien Hascoët^{a,b,c,d,*}, Philippe Acar^{a,b},
Younes Boudjemline^{a,e,f}

^a *Groupe de cathétérisme interventionnel pédiatrique et congénital, filiale de cardiologie pédiatrique et congénitale de la Société française de cardiologie, France*

^b *M3C CHU de Toulouse, Paediatric and Congenital Cardiology, Children's Hospital, Paul-Sabatier University, Toulouse, France*

^c *Inserm UMR 1048, équipe 8 – I2MC – Institut des Maladies Métaboliques et Cardiovasculaires, Paul-Sabatier University, Toulouse, France*

^d *CHU de Toulouse, department of cardiology, Ranguel Hospital, Paul-Sabatier University, Toulouse, France*

^e *M3C Necker Hospital for Sick Children, Paediatric cardiology, Paris 5 René Descartes University, Paris, France*

^f *M3C Georges-Pompidou European Hospital, Adult Congenital Cardiology, Paris, France*

Received 30 May 2014; received in revised form 12 July 2014; accepted 23 July 2014
Available online 31 October 2014

KEYWORDS

Transcatheter
pulmonary valve
replacement;

Summary Since the first transcatheter implantation of a pulmonary valve in 2000 in a twelve year-old boy with a dysfunctional right ventricle to pulmonary artery conduit by Philip Bonhoeffer and Younes Boudjemline, the Melody[®] valve has become worldwide used. It represents an efficient alternative to open-heart surgery. We aimed in this comprehensive review to describe

Abbreviations: CP, Cheatham-Platinum; LV, left ventricle/ventricular; PPVI, percutaneous pulmonary valve implantation; RV, right ventricle/ventricular; RVOT, right ventricular outflow tract; RV-PA, right ventricle to pulmonary artery; TOF, tetralogy of Fallot.

* Corresponding author. Cardiologie pédiatrique, hôpital des enfants, CHU de Toulouse, 330, avenue de Grande-Bretagne, TSA 70034, 31059 Toulouse cedex 9, France.

E-mail addresses: hascoets@gmail.com, hascoet.s@chu-toulouse.fr (S. Hascoët).

<http://dx.doi.org/10.1016/j.acvd.2014.07.048>

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Melody®
transcatheter
pulmonary valve;
Congenital heart
diseases;
Pulmonary valve;
Edwards SAPIEN®
pulmonic valve

the current indications of percutaneous pulmonary valve implantation, the devices currently used and the clinical results.

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MOTS CLÉS

Remplacement
valvulaire pulmonaire
percutané ;
Melody® valve ;
Cardiopathies
congénitales ;
Valve pulmonaire ;
Edwards SAPIEN®
valve

Résumé Depuis la première implantation percutanée d'une valve pulmonaire en 2000 chez un garçon de 12 ans avec un conduit défaillant entre le ventricule droit et l'artère pulmonaire, par Philip Bonhoeffer et Younes Boudjemline, la valve Melody® est devenue d'utilisation courante dans de nombreux pays. C'est une alternative efficace à la chirurgie conventionnelle à cœur ouvert. L'objectif de cette revue non systématisée est de décrire les indications actuelles du remplacement pulmonaire percutané, les prothèses actuellement utilisées et les résultats cliniques.

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Historical background

Percutaneous pulmonary valve implantation (PPVI) is a major advance in the interventional treatment of congenital heart diseases. Transcatheter relief of pulmonary valvar stenosis was first performed in 1953 by balloon angioplasty [1]. Since the development of open-heart surgery in the late 1950s [2], treatment of pulmonary valve or right ventricular to pulmonary artery conduit (RVPA) regurgitation was entirely surgical. Need for repeated surgeries in high-risk patients yield the need for a transcatheter solution. The first percutaneous transcatheter implanted valve was described by Davies et al., in 1965 to treat experimentally induced aortic regurgitation in dogs [3]. However, it is not until 1992 that Andersen et al., further reported the successful delivery of a catheter-mounted, balloon-expandable stent valve in the aortic position in pigs [4]. The same year, a prosthetic caged-ball aortic valve was also successfully deployed percutaneously in dogs by Pavcnik et al. [5]. The first transcatheter pulmonary valve was developed by Philipp Bonhoeffer and Younes Boudjemline in the late 1990s. A valved segment of a bovine jugular vein was sewed into a balloon-expandable vascular stent. Transcatheter pulmonary valve replacement was successful in animals [6]. Soon after, the first human transcatheter cardiac valve replacement was successfully reported in a twelve year-old boy with a dysfunctional RVPA conduit [7]. Medtronic inc. further conducted the in-vitro testing to complete the design process of the named Melody® transcatheter pulmonary valve. European certification was obtained in 2006 as well as Health Canada approval, making it the first commercially available transcatheter valve in the world. A Melody® valve was implanted in the 100th patient in 2005

and in the 1000th patient in 2009. The Melody® valve was approved for use in the United States of America in 2010. Since 2000, many clinical studies have reported early and mid-term outcome and more than 6000 valves have been implanted worldwide [8–19]. The Edwards® valve (Edwards SAPIEN® pulmonic transcatheter heart valve, Edwards Lifescience, Irvine, CA, USA) was initially used for transcatheter aortic valve replacement but then also for PPVI. It has reached CE certification for PPVI in 2010. First implantation was performed in 2006 in USA [20] and in 2010 in Europe [21]. Clinical results in the first implanted patients have subsequently been published [22–24].

Concept sustaining percutaneous pulmonary valve implantation for the management of congenital heart diseases

Incidence of congenital heart disease is approximately 8 out of 1000 babies. Around 20% of congenital heart diseases involve the right ventricle outflow tract (RVOT) and the pulmonary valve. Surgical palliation of many complex congenital heart diseases, including tetralogy of Fallot (TOF) with pulmonary atresia, truncus arteriosus, some forms of transposition of the great arteries, double-outlet right ventricle, Ross surgery for aortic valve disease and others, involves interposition of a conduit between the right ventricle and the pulmonary artery in the first months of life. Valved conduits are composed of synthetic material or non-viable homograft or xenograft tissue. Inability to follow the child growth, mechanical distortion and progressive degeneration lead to conduit stenosis over time. Regurgitation appears with degeneration of the leaflets. Other congenital

heart diseases require enlargement of the RVOT by a transannular patch during the surgical correction, frequently leading to pulmonary valve regurgitation (TOF with pulmonary stenosis, pulmonary valve agenesis and others). Pulmonary valve regurgitation may complicate transcatheter dilation of pulmonary valvar stenosis and surgical valvulotomy. Isolated congenital pulmonary regurgitation remains an uncommon cause of pulmonary valve replacement [25].

An obstructed RVOT induces a pressure overload in the right ventricle (RV). A pulmonary regurgitation leads to a volume overload and thus to a dilation of the RV [26]. Both obstruction and regurgitation may be combined. These lesions are often long well tolerated but the overload of the RV is progressively deleterious for the right ventricular function [27] and then ultimately for the patient [25,28,29]. Impaired exercise capacity, atrial and ventricular arrhythmias, sudden deaths after complete repair of TOF are related to the severity of the pulmonary regurgitation and lead to an increased overall mortality after the second decade [28,30,31].

Restoration of pulmonary valve competence and relief of RVOT obstruction are beneficial. It reduces ventricular overload, increases right and left ventricular performance [32,33], functional ability and cardio-respiratory exercise performance [33–35]. It may also help to control preexisting atrial and ventricular arrhythmias in TOF patients [36].

RVPA conduit obstruction was the most frequent reason for surgical re-intervention [37]. Transcatheter relief of post-operative RVOT obstruction was early attempted with balloon angioplasty. However, ineffective relief was observed in many cases due to elastic recoil and non-expandable conduit. Intravascular stenting further helped to increase efficiency of these percutaneous procedures [38] but at a price of a free pulmonary regurgitation that may be symptomatic in some cases [39]. PPVI seemed therefore promising to treat RVOT obstruction without inducing pulmonary regurgitation but no studies are available to compare the outcome of both strategies (non valved stent vs. valved stent). Until PPVI, treatment of RVOT regurgitation required open-heart surgery. Despite improved surgical technique and good mid-term outcome, the surgery carries short-time morbidity in these patients with multiple previous procedures. It starts again the conduit duration countdown. Around 50% of conduits still require replacement within 10 years [37]. Second and subsequent conduits have shorter survival than the original implants [37]. Less procedural morbidity existing with PPVI offered a new solution for the management of these patients. PPVI allows concomitantly relief of RVOT obstruction and regurgitation, maintaining pulmonary valve competence [13]. PPVI restores right ventricular load within normal range. An early improvement of biventricular performance is observed following relief of RVOT obstruction, with decrease right ventricular volumes, increased right and left ventricular systolic function and increased cardiac output [19,33,40]. Relief of obstruction also improves early left ventricular filling properties. This improvement is not only related to the increase in right ventricular forward flow but also to a more favorable ventricular interaction [41]. After PPVI, dyspnea degree decreases and exercise tolerance is rapidly improved [19,33,40]. This is less clear in case of PPVI indicated for

pulmonary regurgitation without RVOT obstruction and is related like with surgical replacement to the degree of RV dilation at the time of replacement [19,40,42]. The acute effects of PPVI are maintained over time without evidence for further ventricular remodeling or positive functional evolution beyond the early post-operative period [42].

Indication for percutaneous pulmonary valve implantation, current official guidelines

Recommendations for PPVI match those for surgical pulmonary valve replacement, with specificity regarding feasibility and outcome of the percutaneous implanted valves.

In Europe, the European society guidelines stipulate that pulmonary valve replacement should be performed in symptomatic patient with severe pulmonary regurgitation and/or RVOT obstruction (Tricuspid velocity > 3.5 m/s, right ventricular systolic pressure > 60 mmHg). In asymptomatic patients with severe pulmonary regurgitation and/or RVOT obstruction, PPVI may be considered if there is an objective decrease in exercise capacity, a progressive right ventricular dilation, a progressive right ventricular systolic dysfunction, a progressive tricuspid regurgitation, sustained atrial or ventricular arrhythmias, right ventricular systolic pressure > 80 mmHg or peak tricuspid regurgitation velocity > 4.3 m/s [43].

In France, the "Haute Autorité de santé" stipulates that PPVI is indicated to treat RVPA conduit or xenograft dysfunction, with a minimal internal diameter of 16 mm. PPVI in a native RVOT or in child weighting less than 20 kg is not indicated [44].

The Food and drug administration instructions for use under a humanitarian device exemption stipulate that the Melody® PPVI is indicated in the management of pediatric and adult patients with the existence of a full circumferential dysfunctional RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted. The dysfunctional RVOT conduit is retained as an indication for PPVI if the regurgitation is equal to or greater than moderate and/or if the mean RVOT gradient is equal to or greater than 35 mmHg. The scientific statement from American Heart Association endorsed this recommendation [45].

Current devices

Melody® transcatheter pulmonary valve and Ensemble® delivery system

The Melody® valve (Medtronic Inc., Minneapolis, MN, USA) is the first valve inserted percutaneously in humans. It is the most used valve in the world in pulmonary position. Most of the available data for PPVI are coming from its use. The device is made of a bovine jugular vein valve (Contegra Pulmonary Valved conduit, Medtronic Inc., Minneapolis, MN, USA) sutured within a Cheatham-Platinum stent (CP stent, NuMED Inc., Hopkinton, NY) (Fig. 1). The bovine jugular vein is different from the surgical implant. It is trimmed to reduce

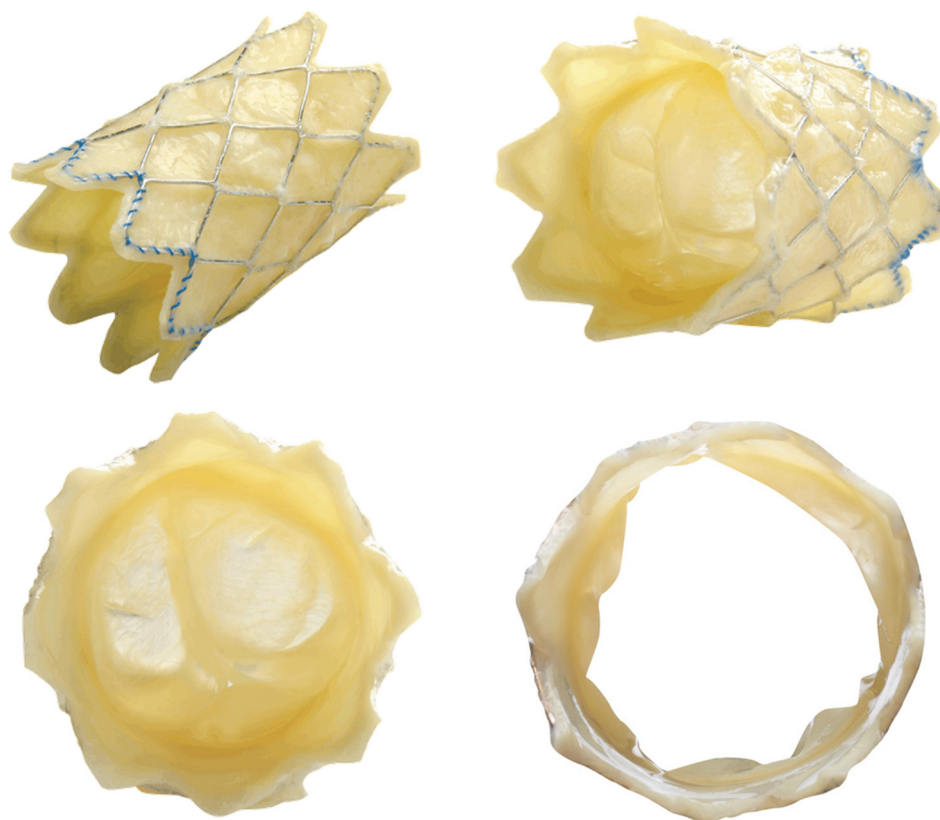


Figure 1. Melody® transcatheter pulmonary valve.

its thickness before suturing in the vascular stent. Its length is shorter than the Contegra and equal to the length of the CP stent (CP8Z34).

At the moment, there is only one size. It is a one-sized valve of 18 mm in diameter that is crimped to 6 mm and balloon expanded from 18 to 22 mm in diameter. The bovine jugular vein has thin, compliant leaflets with deep commissures that provide exceptional coaptation of the leaflets at various internal diameters. It opens fully and close readily with a minimum of pressure. The vein tissue has a thickness of less than 0.5 mm. The vein segment is manually sutured to the stent frame at every stent node. Complete suture lines are also done at the inflow and outflow part of the stent. The CP stent has a closed-cell design with six rows of circumferential struts. Each row is made of a platinum-iridium wire that is welded in a zig pattern to form eight crowns. The zig-to-zig welds are gold-brazed to increase their strength. The stent measures 3 mm in length in an unexpanded configuration and 26.2, 24.2 and 23 mm when implanted at 18, 20 and 22 mm respectively. This stent was chosen by Bonhoeffer and Boudjemline because it is a good compromise between rigidity for the radial force and malleability for the manual crimping. It has a good radio-opacity, a good conformation, is easy to crimp on a balloon and has a foreshortening to a degree that does not distort the valve leaflets. The Melody® valve manufacturing follows a step-by-step rigorous process and testing before commercialization [46]. As a result, less than 5% of bovine jugular veins are available for PPVI. Because of availability problem with the

bovine jugular vein, Medtronic is introducing a new Melody® manufactured with a 16-mm valve that would work for patients up to 20-mm. Its introduction is programmed for Europe at the end of 2014.

The Melody® valve is implanted through a dedicated delivery system (Ensemble® Transcatheter Delivery System, Medtronic Inc., Minneapolis, MN, USA). It consists of a balloon-in-balloon (BiB, NuMED Inc., Hopkinton, NY) catheter delivery system with a retractable sheath that covers the Melody® valve once it is crimped over the balloon (Fig. 2). The BiB balloon allows repositioning during the valve delivery (Fig. 3). The outer balloon is available in 3 sizes: 18 mm, 20 mm and 22 mm in diameter. The thickness of the valve stent assembly is approximately 1 mm resulting in an outer diameter of 2 mm more than the diameter of the delivery balloon. A sheath with side port allows flushing the system and acts as a homeostatic sleeve to minimize bleeding at the insertion site. The outer diameter at the top of the delivery system is 22 Fr [46].

Edwards SAPIEN® pulmonic transcatheter heart valve and Retroflex® delivery system

The Edwards® valve (Edwards SAPIEN® pulmonic transcatheter heart valve, Edwards Lifescience, Irvine, CA, USA) was introduced later. Results with this device remain limited. It is made of a radiopaque, stainless steel, balloon-expandable support structure, with an integrated, unidirectional, tri-leaflets bovine pericardium valve and a polyethylene terephthalate fabric cuff. It is available

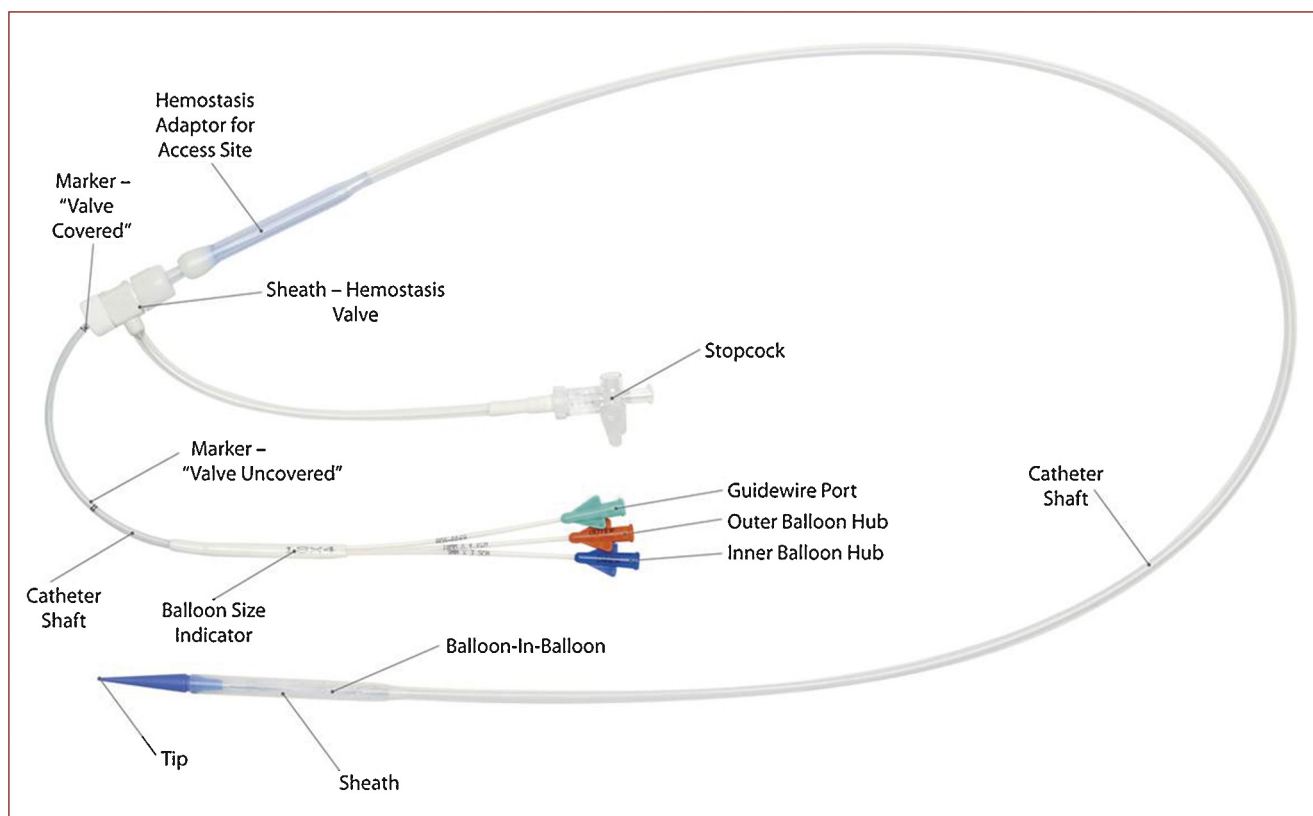


Figure 2. Ensemble® delivery system.

in 23, 26 and 29-mm in diameter (14.3 and 17.2 and 19.1 mm in height respectively) (Fig. 4). The valve is treated according to the Edwards ThermaFix process. There are generations of valves. The Edwards valve is implanted through the Retroflex® delivery system. It consists of balloon catheter and a deflectable guiding catheter. It requires either a 22 Fr or a 24 Fr (outer diameter 28 Fr) insertion sheath for the 23 and 26 mm valves respectively. A manual crimping tool is used to symmetrically compress the valve onto the 30mm-balloon. The Edwards® valve was initially introduced for transcatheter aortic valve replacement in elderly patients with degenerative aortic valve stenosis. Melody® valve size limits, concerns about stent fractures and

endocarditis encourage some physicians to successfully use the Edwards valve in the pulmonary position [20–24,47,48]. The results in the first implanted patients seem promising. The Edwards® valve is efficient and safe in reducing RVOT pressure gradient and restore pulmonary valve competence. But more data are needed particularly regarding long-term outcome. Some operators raised concerns about asymmetrical valve expansion, residual pulmonary regurgitation and device embolization that were not confirmed in the last series [22,49]. The Edwards® valve is currently not reimbursed in France and only available in research programs.

To date to our knowledge only one single center retrospective non-randomized comparative study between the

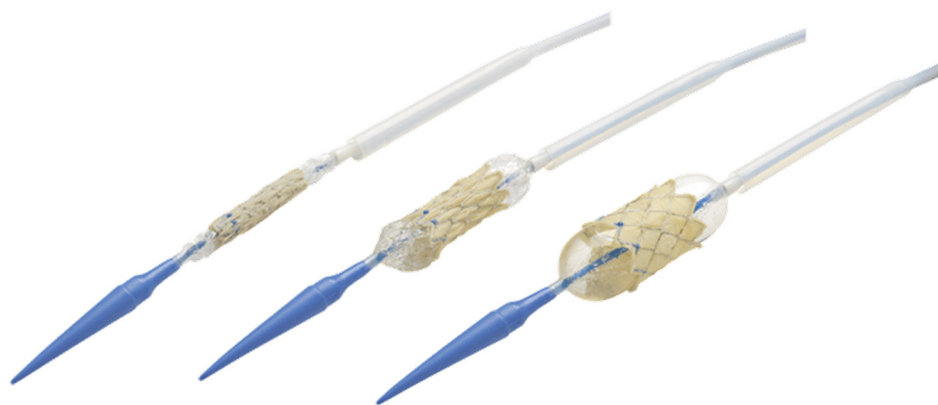


Figure 3. The Melody® valve is manually crimped on the Ensemble® delivery system balloon. The inner balloon is inflated first allowing repositioning of the valve and then the outer balloon fully expands the Melody® valve.

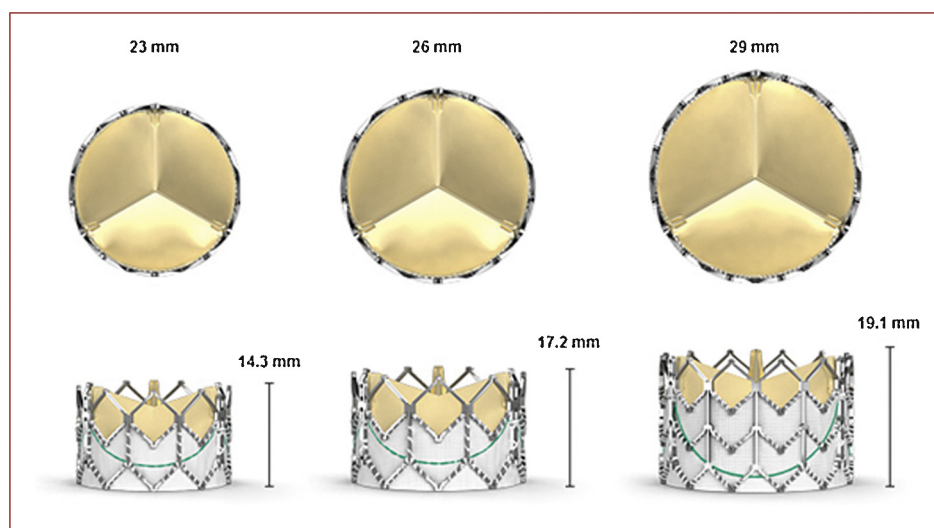


Figure 4. Edwards SAPIEN® pulmonic valve.

Melody® valve and the Edwards® valve, involving 30 patients has been published [50]. Short-term outcome was good and similar regarding RVOT gradient and valve function. One patient from the Edwards® valve group had valve migration. This observation was also observed in some other patients [24]. This may be due to the smaller length of the Edwards valve, long length of the balloon catheter and a less potential for staged repositioning during deployment with the single balloon delivery catheter. Higher peak and mean gradients were also observed with the Edwards® valve during follow-up. However, if this observation results from methodological bias or from valve difference remains unclear, data are not sufficient to date to compare risk specificities within the 2 valves. However, in case of failed implantation, extracorporeal Edwards valve retraction is not possible given the design of the retroflex® delivery system contrary to the Ensemble® system.

General implant considerations

Operator

PPVI remains a long and challenging procedure. Success rate and risk of adverse events is related to operator experience [13]. In France, around 60 procedures are performed every year. Thus, only a few specialized operators are experienced or have been certified for this procedure after having completed a training program. A minimum of 5 PPVI per operator per year is recommended. Life-threatening adverse events although rare, may require rescue surgery. Thus, in France, PPVI are only performed in centers specialized in congenital heart diseases with a surgery platform (M3C network) with a surgeon having experience in congenital heart diseases.

All implantations of Melody® valve in France are registered in an on-going prospective observational post market study (www.clinicaltrials.gov identifier NCT02023775). This study was requested by French health authorities for reimbursement renewal, to maintain reimbursement for PPVI in approved indication in France.

Pre-procedural assessment

Pre-procedural assessment includes a complete detailed history and a detailed echocardiographic assessment (right ventricular pressure, dilation and function, left ventricular systolic and diastolic function [51] and associated lesions). Cardio-pulmonary testing investigates functional performance. Myocardial resonance imaging (MRI) remains the gold standard to quantify pulmonary regurgitation and right ventricular volumes and function. Cardiac tomography is useful to specify the spatial relationship between the RVOT and the surrounding structures, coronary anatomy at risk of compression but unfortunately is not accurate to predict the compression. Most of the centers performed therefore only MRI to avoid radiation exposure. PPVI indication can be discussed during a medico-surgical meeting dedicated to congenital heart diseases management. The PPVI indication is retained after assessing the long-term global strategy for the patient with surgeons and cardiologists. A particular attention is paid on the absence of any clinical or biological signs of infections before the PPVI. Active infection of any type is a contra-indication to PPVI. Dental and sinus X-rays and dental referral are performed before the PPVI to check for some possible sources of infection similar to what is done prior to surgical valve replacement.

Percutaneous pulmonary valve implantation

The PPVI is generally performed under general anesthesia. A strict asepsis is maintained throughout the procedure. Full heparinization and antibiotics are performed according to local practice. The procedure is standardized [49] and begins with arterial and venous access, complete hemodynamic study and RVOT angiographies in at least two projections. In case of RVOT obstruction, pre-dilation of the landing zone is performed with high-pressure balloon to see if a RVOT substitute can be opened to an acceptable diameter for PPVI and to check for coronary compression. Achieving a minimal residual gradient and a diameter suitable for valve implantation are uncommon with solely balloon dilation. Most of the

patients require stent implantation to achieve these goals. A successful pre-dilation decreases the risk of stent malposition and residual gradient [38]. In case of pulmonary regurgitation, low-pressure balloon inflation is performed to delineate the landing zone, its length and diameter. It is evaluated whether the valve will be safely stabilized in the dilated conduit without embolization. A pre-stenting is performed with a bare metal stent or a covered stent in case of extravasation or anticipated conduit fracture. Pre-stenting is continued until there is no residual significant obstruction and enough rigidity of the landing zone without any recoil, any compression or any dynamic motion. Finally, the valve is crimped on the delivery system, advanced and carefully positioned in the landing zone. Valve post-dilation at the valve diameter is performed if there is a residual gradient higher than 20 mmHg across the valve. Usually the pre-stenting and the PPVI are performed within the same procedure. In case of enlarged RVOT with doubt about the stability of the pre-stented landing zone, the PPVI may be postponed for some weeks to allow ingrowth and stabilization of the stent.

Post-procedural recommendation

Home discharge is usually feasible within one to two days after the PPVI with anti-platelet medication for at least 6 months. Some centers recommend long life aspirin and prevention of infective endocarditis [52,53].

Imaging modality

Success rate of PPVI is higher than 97% in most series [11,13,19,24,54]. The success of PPVI depends on the precision of the stents and valve positioning. It remains a long procedure performed under fluoroscopy guidance with repeated angiographies. A bi-plane angiographic system decreases the need for repeated iodine contrast injections and allows bi-plane imaging without moving the X-ray tubes [49]. But the procedure can be performed in monoplane system with excellent results. Modern fluoroscopic angiography systems also permit rendering of three-dimensional volumetric data sets using rotational angiography. Along with magnetic resonance imaging or multi-detector-row computed tomography datasets, they can be fused with live fluoroscopy images for road-mapping during therapeutic procedures. Three-dimensional guidance was shown to simplify catheter manipulations and interventions, to allow pre-selection of ideal projection angles to reduce fluoroscopic time and the number of control angiographies in catheterization of congenital heart diseases and may be useful for PPVI [55]. The real benefits of the new imaging modalities remain to be demonstrated in this indication.

Adverse events

During the first 4200 PPVI, eight deaths following PPVI were recorded. Most of them were related to coronary compression in 6 patients, coronary dissection during selective coronary angiography in one patient and conduit rupture in one patient. Acute complication rate is less than 2%. With increasing experience, most complications could potentially

be avoided with careful patient selection and appropriate procedural technique.

Coronary compression

In some patients with a surgically implanted RVPA conduit or even in native RVOT, the coronary arteries may pass in close apposition. Coronary extrinsic compression following the PPVI leads to acute myocardial infarction [8,13,56,57]. Pre-procedural imaging by cardiac computed tomography or magnetic resonance imaging is not accurate to predict the risk. Coronary angiogram with simultaneously a balloon inflated in the landing zone in the RVOT at the targeted outer valve diameter is thus recommended prior to valve implantation [49,58,59]. Aortic root angiogram is performed first given that selective coronary angiogram may mask proximal compression. Complementary selective coronary angiogram is performed if aortic root angiogram is inconclusive (in less than 10% of the patients in our experience). Incidence of coronary compression during this dynamic testing ranges from 4.7 to 6% [58,59]. An abnormal coronary artery anatomy is a possible risk factor [58].

RVOT conduit rupture

Partial or total conduit rupture may follow balloon pre-dilation especially in heavily calcified homografts. Most of the time, this complication is managed during the catheterization [13,49]. Covered stents are used to confine the extravasation. Rescue surgery is sometimes needed.

Pulmonary artery injury

Guide-wire related injuries of distal pulmonary artery branches leading to bronchial bleeding or hemothorax managed medically have been described in few cases [13].

Pulmonary edema

Acute flash pulmonary edema following PPVI has been reported [51]. This rare procedural complication may be due to the sudden increase in cardiac output that overwhelms the left ventricle. An unprepared chronically under-filled left ventricle and a reverse Bernheim effect may be risk factors. In high-risk patients with abnormal left ventricle diastolic function, priming diuretics treatment before the procedure is necessary.

Infective endocarditis

Great concerns were raised with the PPVI (Melody® and Edwards®) following infective endocarditis reports [8,13,18,52]. To date the estimated annualized rate of a first episode of infective endocarditis is 2.4% per patient-year [53]. A whole review is dedicated to this topic in this special issue.

Stent fractures

Melody® valve stent fractures following PPVI for RVOT obstruction were frequent in early experience, up to 21%. Absence of calcification, non-conduit outflow tracts and

valve recoil were predisposing factors [54]. Prominent mechanical stresses on the RVOT stent, such as compression between the anterior chest wall and heart, appear to increase stent fracture risk. Melody® valve fractures were well tolerated but led to an increase risk of valve restenosis [18]. New stenting is often necessary associated to a valve-in-valve implantation [60]. Increasing experience with systematic pre-stenting of the RVOT [61] and choice of the landing zone decreases the risk of stent fractures below 5% in last reports [8,18].

Vessel access injury

The large size of the delivery system increases the risk of bleeding and hematoma at the vessel access.

All together the risk of complications remains very low.

Timing of pulmonary valve implantation

The optimal timing of dysfunctional RVPA conduit replacement remains controversial. The risk of irreversible deterioration of right ventricle function has to be balanced with the risk of repeated pulmonary valve replacement. The decreased procedural morbidity of PPVI compared to surgery may allow earlier intervention in the evolving process of conduit degeneration to reverse the effect of pressure and/or volume overload on the right ventricle. However long-term outcome after repeated valve-in-valve procedures is unknown. In case of RVOT obstruction, there is growing evidence for the efficiency of PPVI on clinical outcome and ESC guidelines are quite precise [40–43]. An early intervention is necessary. However, stenting alone may be as efficient and may delay the need for PPVI [38].

Pulmonary regurgitation is long well tolerated and impact of early PPVI in these cases is more controversial [40,42]. Rather than the severity of the pulmonary regurgitation, it is the degree of RV dilation that should prompt the PPVI indication [19]. A threshold of RV end-diastolic volume measured by myocardial resonance imaging between 150–170 ml/m² seems the limit to a reversible RV dilation [62,63]. In patients with severe pulmonary regurgitation, indications of revalvulation continue to evolve and were recently up-dated including MRI and rythmologic criteria [64]. In the future, the longevity of the percutaneous valves will impact their uses.

Conclusion

Since the first implantation in 2000, PPVI has emerged as a safe and efficient alternative to open-heart surgery with less morbidity. It is now considered as the treatment of choice in patients with a hemodynamically significant dysfunctional RVPA conduit when RVOT anatomy is suitable. New devices are expected to extend indication in enlarged RVOT. Long-term follow-up will help redefine PPVI indication compared to surgery and global management of patients with dysfunctional RVOT.

Disclosure of interest

Y.B. is a proctor for Medtronic Inc.

The other authors declare that they have no conflicts of interest concerning this article.

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