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Review Article

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Percutaneous Pulmonary Valve Implantation

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ABSTRACT

Percutaneous pulmonary valve implantation (PPVI) is recognized as a feasible and low risk alternative to surgery to treat dysfunctional right ventricular outflow tract (RVOT) in usually pluri-operated patients. Evolving technology allowed to develop different kind of prosthesis and to go from an initial treatment exclusively of stenotic conduit to an actual approach extended also to wide native RVOT. The Melody transcatheter pulmonary valve (TPV) and the Edwards Sapien valve are nowadays the most commonly implanted prostheses. However, other devices have been developed to treat large RVOT (i.e., the Venus p-valve, the Medtronic Harmony TPV, the Alterra Adaptive Prestent, and the Pulsta valve). Indications for PPVI are the same as for surgical interventions on pulmonary valve, with limits related to the maximum diameter of the available percutaneous prosthesis. Therefore, an accurate preoperative evaluation is of paramount importance to select patients who could benefit from this procedure. The overall periprocedural mortality incidence is around 1.4%, while freedom from RVOT reintervention ranges from 100% at 4 months to 70% at 70 months, according to the different published studies.

Keywords: Percutaneous pulmonary valve implantation; Transcatheter procedure; Congenital heart disease

INTRODUCTION

Several congenital heart diseases (CHD) require right ventricular outflow tract (RVOT) reconstruction. This is the case of almost twenty percent of new-borns with CHD that present complex anomalies such as Tetralogy of Fallot, pulmonary atresia with and without ventricular septal defect, truncus arteriosus, transposition of great arteries, some forms of double outlet right ventricle (RV), and congenital aortic valvar anomalies previously treated with Ross procedure, that require surgical reconstruction using a patch (i.e., infundibular and trans-anular), a bioprosthetic valve or a valved conduit. Long-term durability of surgical interventions depends on several factors such as patient age at the time of the operation, heart defect type and surgical approach. In particular, the risk for late reintervention on the RVOT appears to increase with a postoperative ratio between RV and left ventricle (LV) pressure >0.75, a maximum gradient >40 mmHg across the RVOT or >15 mmHg across the left pulmonary artery. Degeneration of bioprostheses and valved conduits results in

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progressive RVOT dysfunction, with possible pulmonary stenosis (PS) or regurgitation (PR), while transannular patch reconstruction of the RVOT usually ends up in PR. That's why these patients tend to face numerous RVOT re-intervention in their life.[1)2)]

MAIN INDICATIONS TO PULMONARY VALVE INTERVENTIONS

Current indications for replacing the pulmonary valve (PV) are symptoms of heart failure requiring pharmacological therapy, severe RV hypertension with an RV/LV pressure >0.7, peak and mean Doppler gradients across the PV of >50 mmHg and 30 mmHg respectively, indexed RV end diastolic volume >160/mL/m^2 or RV end systolic volume >80 mL/m^2, RV end diastolic volume ≥2 times the LV end diastolic volume, RV ejection fraction <0.40–0.45, and a QRS duration ≥180 ms. Adjunctive relevant factors considered when planning PV replacement are sustained atrial or ventricular arrhythmias, significant coexisting lesions (such as significant aortic regurgitation, tricuspid regurgitation [TR], and residual ventricular septal defects), and left ventricular dysfunction. American College of Cardiology/American Heart Association, European, and Canadian guidelines have been published.[3-5)]

In this context, percutaneous PV implantation (PPVI) offers a minimally invasive method to treat RVOT/pulmonary trunk dysfunction in children and adults by restoring acceptable RV loading conditions, avoiding open-heart interventions.

HISTORICAL OVERVIEW

The first report about PPVI was published by Bonhoeffer et al.[6)] in August 2000 demonstrating the feasibility of non-surgical implantation of a fresh bovine jugular vein containing a native valve sutured into a vascular stent in pulmonary position in lambs.[6)] In October 2000, he reported the first human PPVI in a 12-year-old boy with a dysfunctional RV-PA conduit previously implanted for a pulmonary atresia with a ventricular septal defect[7)] and in 2002 the first clinical series was published showing the acute success of the procedure.[8)] The valve was named Melody transcatheter PV (TPV). Its clinical use continued in Europe and Canada and subsequent modifications led to CE Marking in September 2006 and to Health Canada approval in December 2006. The first U.S. implantation occurred in January 2007 in Boston Children's Hospital, and subsequent trials led to U.S. Food and Drug Administration (FDA) approval in 2010.[9)] At this time, the Melody valve is FDA approved, under humanitarian device exemption guidelines, for use only in previously placed surgical conduits and in patients whose surgical bioprosthetic pulmonary heart valves have failed. However, off-label use in native, dysfunctional RV outflow tracts is possible in certain cases, provided that the size of the landing zone is adequate.[10)]

Since the 2008, the Edwards Sapien transcatheter heart valve (THV) (Edwards Lifesciences LLC; Irvine, CA, USA), initially designed as a transcatheter alternative to surgical aortic valve replacement in elderly patients, has been implanted in RVOT conduits in a small number of patients enrolled in phase I of the COngenital Multicenter trial of Pulmonic vAlve regurgitation Studying the SAPIEN interventional trial; a prospective, non-randomized, multicentre study that proved safety and efficacy of the SAPIEN THV for the treatment of dysfunctional RV-PA conduits with moderate to severe PR with or without stenosis.[11)] It seemed to be an attractive alternative to the Melody valve for patients with greater RVOT

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dimensions, but also to avoid stent fracture, that was demonstrated to be a later complication after PPVI with the Melody valve. Initially available in two sizes (23 mm and 26 mm), a 29 mm valve was developed later in 2009. The Edwards Sapien THV design progressively evolved leading to Edwards Sapien XT, that received in 2016 both CE mark and FDA approval to replace PVs in adult and paediatric patients who suffer from either a narrowed PV or moderate to severe PR caused by congenital heart disease, and to Edwards Sapien 3, by now approved (by FDE and with the CE mark) just for implantation in aortic position but with recently reports regarding its off-label use in the pulmonary one.[12]

Since the first PPVI by Bonhoeffer et al.[7] in 2000, more than 10,000 procedures have been performed all around the world.[2]

PREOPERATIVE EVALUATION

To establish indication to PPVI, all patients should undergo a standardized assessment protocol[13]:

- Surface electrocardiogram (EKG) and 24-h Holter EKG monitoring to detect arrhythmia and define QRS duration.
- Echocardiography as the first screening tool. On one hand, it allows to determine the presence of a residual RVOT stenosis identifying the site, quantifying the severity and determining the cause of the stenosis itself. The estimation of the systolic pressure gradient is derived from the trans pulmonary velocity flow curve using the simplified Bernoulli equation ($DP=4v^2$), applying continuous-wave Doppler parallel to the flow across the RVOT usually through a parasternal short axis view or, less frequently, through a subcostal window. The grade of stenosis is defined as follow: severe with a peak jet velocity >4 m/s (peak gradient>64 mmHg), moderate with a peak jet velocity of 3–4 m/s (peak gradient 36–64 mmHg), mild with a peak jet velocity <3 m/s (peak gradient less than 36 mmHg).[14] On the other hand, echocardiography allows to assess the severity of PR according to the regurgitant jet width (if more than 65% of the RVOT, is in favour of severe PR) and to the deceleration of continuous wave signal of PR jet assessed qualitatively (steep deceleration is in favour of severe PR).[15] Moreover, this non-invasive tool is also used to evaluate RV dimensions (measuring RV diameters at the base and at the mid-level and the long axis in a 4-chamber view and quantifying the RVOT diameter in a parasternal short axis view), RV systolic function (usually through tricuspid annular plane systolic excursion, S′ wave peak at the tissue Doppler imaging or fractional area change) and to estimate the RV pressure from tricuspid valve regurgitant jet (TR velocity>2.8–2.9 m/s, assuming an RA pressure of 3–5 mmHg, indicates elevated RV systolic pressure) and the RV to systemic pressure ratio. Echocardiography allows also the assessment of the left chambers end of associated lesions.[16]
- Cardiopulmonary exercise testing on a bicycle using a ramp protocol. It provides a comprehensive assessment of the exercise response, and reflects the influences and interactions of the cardiac, respiratory, musculoskeletal and haematological systems. This test provides data on respiratory gas exchange, including oxygen uptake (VO_2), carbon dioxide output (VCO_2), tidal volume, minute ventilation (V_E), oxygen pulse, ventilatory anaerobic threshold, and respiratory quotient and other variables such as EKG trace, blood pressure and oxygen saturation.[17][18]
- Cardiovascular magnetic resonance imaging (MRI), providing that it is not contraindicated, is the gold standard to quantify PR and right ventricular volumes and function. Because of its complex anatomy, the RV is studied best in cardiac long-axis as well as in short axis direction. End-diastolic and end-systolic volumes and derived

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indices such as stroke volume, ejection fraction and myocardial mass are obtained by contouring endocardial and epicardial contours. Regional right ventricular function is described in terms of radial and longitudinal wall motion patterns, which can be assessed either visually or using a centreline method. Volumetric and functional right ventricular assessment is usually part of a more comprehensive right ventricular assessment.[19]

- Computed tomography (CT) scan is performed in complex anatomy to evaluate the relationship between the pulmonary trunk and the aortic root, to assess coronary anatomy and RVOT size. Moreover, it is possible to estimate the risk of coronary artery compression according to the distance between the coronary artery and the landing zone.[20]
- Three-dimensional (3D) printing. Candidates to PPVI can have complex post-surgical anatomies, therefore further imaging approaches can be necessary in order to have as many information as possible prior the percutaneous intervention. In addition to the standard imaging techniques previously reported, 3D printing is a useful tool that can help planning the PPVI. 3D printing (also referred to as rapid prototyping, stereolithography, or additive manufacturing) is a technology which fabricates a physical model from a 3D computerised imaging source file, usually MRI, CT or echocardiographic examination. Fusion of different modalities (e.g. ventricles from CT, valves from echocardiography) to create a single 3D model has been reported. The subsequent post processing image reworking is of fundamental importance. It consists of image segmentation and reconstruction in order to obtain a 3D patient-specific digital model of the target anatomic structures. Then, a 3D model can be printed.[21][22] Its application for the study of the RVOT and the simulation of PPVI preceded by a pre-stenting intervention, to better understand the anatomy and the complex relationship with the coronary arterial course, has already been reported.[23]

AVAILABLE PROSTHESIS

The Melody® TPV (Medtronic, Inc., Minneapolis, MN, USA), derived from Philipp Bonhoeffer's prototype of a stent-mounted biological valve, is the first valve designed for percutaneous implantation (**Figure 1**). The current version of the Melody TPV consists of

Figure 1. Melody valve. A modified bovine giugular vein with valve segment sutured on Numed Platinum Iridium stent; the stent can be crimped down to 6 mm, mounted on a BIB balloon and re-expanded up to 18, 20, and 22 mm. The delivery system is shown in the lower part of the figure.

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a 18-mm bovine jugular valve segment that is sutured onto a Cheatham platinum CP stent made of platinum and iridium. The fresh bovine jugular vessels are fixed in glutaraldehyde, and then sutured to the frame using blue suture at the distal end of the valve to ensure proper orientation of the valve on the Ensemble transcatheter delivery system, which has a blue carrot tip on the end. The initial length of the valve is 28 mm, but it is shortened in accordance with the final implanted diameter. The valve can be expanded from 16 to 22 mm in diameter, and in some instances up to 24 mm.

The valve is delivered via a 22F Ensemble® Transcatheter Delivery System (Medtronic, Inc.). It consists of an integrated balloon, long-sheath, and introducer, such that it can be introduced through the skin, delivered over a guidewire to the RVOT, and deployed without any additional vascular sheath or catheters. A balloon-in-balloon angioplasty balloon (BiB; NuMED Inc., Hopkinton, NY, USA) has been modified and mounted within a Teflon sheath that is 22 Fr in outer dimension at its distal portion, where it covers the valve, and 16 Fr along most of its length. The system comprises 2 concentric balloons (an outer balloon and an inner balloon, which is half the diameter and shorter than the outer balloon) which enable the valve to be repositioned, if needed, after the inner balloon has been inflated. The delivery system is manufactured with outer balloon diameters of 18, 20, and 22 mm. The tip of the balloon catheter is equipped with a blue carrot, which tapers distally to act as an introducer, and has a proximal end that engages within the distal end of the sheath to create a smooth contour. Other than the different balloon sizes, 18, 20, and 22 mm, the delivery systems are identical. The full working length of the delivery system is 100 cm.[24]

The Edwards SAPIEN XT THV (Edwards Lifesciences) is a balloon-expandable bovine pericardial valve mounted on a cobalt chromium alloy stent designed for ultralow delivery profile while maintaining radial strength and is available in 3 sizes (23, 26, and 29 mm, respectively 14.3, 17.2, and 19.1 mm high) (**Figure 2**). The valve, manually crimped with a specialized tool, is implanted using the Novaflex delivery system (Edwards Lifesciences) consisting of a guiding catheter and a single-balloon catheter with a sheath size of 18F for the 23 mm valve, of 19F for the 26 mm valve, and of 20F for the 29 mm valve. The valve is crimped on the catheter proximally to the inflatable balloon and is mounted on the balloon in the inferior vena cava.[25]

The Edwards Sapien 3 THV (Edwards Lifesciences) is the third-generation Edwards SAPIEN valve. Similar to the previous generation valve, in addition it has also an outer polyethylene terephthalate (PET) cuff, which is designed to minimize paravalvular leak. The stent itself has different inflow and outflow geometry, which causes the valve to foreshorten more at

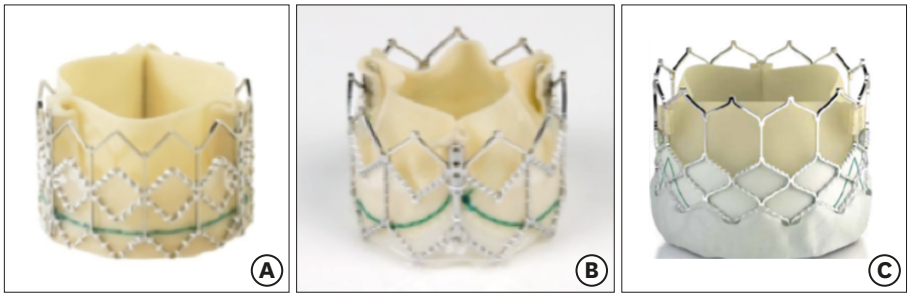

Figure 2. The evolution of Edwards Sapien Valve. (A) Edwards Sapien, (B) Edwards Sapien XT, and (C) Edwards Sapien 3.

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the inflow portion. There are three different sizes: 23, 26, and 29 mm. The expanded valve heights are 18, 20, and 22.5 mm, respectively, but the covered portion (inner skirt height) is significantly shorter at 9.3, 10.2, and 11.6 mm, respectively. The valve is designed to be delivered by the deflectable, Edwards Commander Delivery System. Because of the lower-profile design, the 23- and 26-mm valves require a 14F and the 29-mm valve requires a 16F Edwards eSheath. This low-profile sheath can transiently expand to accommodate the passage of the valve and return to the original diameter.[26]

THREE-DIMENSIONAL ROTATIONAL ANGIOGRAPHY

3D rotational angiography (3D-RA) was introduced in the neurovascular field to improve the assessment of intracranial aneurysms and to guide interventional neurovascular procedures. This technique nowadays is also used in electrophysiological and peripheral vascular procedures, it has been tested for coronary evaluation and it has increasingly been used in paediatric cardiology in the last decade. A 3D-rotational angiogram is acquired with a single rotation of C-arm in a semicircle above the patient while contrast dye is injected in a scanning time of 4–5 seconds, during rapid ventricular pacing in order to adequately dye vascular structures. The angiographic system uses this rotational volumetric data set to reconstruct a 3D vascular model that permits the visualization of complex 3D vascular relationships from different angles. 3D-RA has been shown to add valuable diagnostic information and facilitate interventions in CHD, especially aortic coarctation and complex pulmonary artery interventions. In the PPVI 3D-RA is useful for visualizing PA and branch PA or RV-PA conduits, identifying coronaries or aortic root compression during balloon inflation in the RVOT and defining the most appropriate fluoroscopic projections for optimal interventional guidance[27][28] (**Figure 3**). An example of aortic root distortion demonstrated with balloon test and 3D-RA is shown in **Figure 4**. Results regarding the additional radiation exposure eventually added by 3D-RA in the contest of CHD cardiac catheterization interventions that usually incur in the highest radiation exposure (such as branch pulmonary artery angioplasty and trans-catheter PV placement) are conflicting. Some studies report a significantly higher radiation dose, especially in children, while others disprove it.[29][30] Therefore, a new

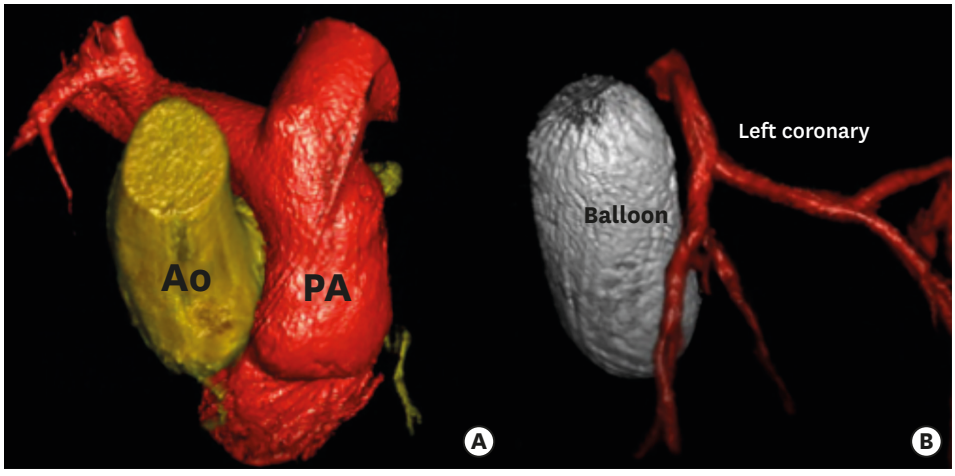

Figure 3. 3D rotational angiography and 3D Examples of reconstruction. (A) Ao and PA reconstruction. (B) Relationship between a balloon inflated into the right ventricular outflow tract (ballon) and the left anterior descending artery (left coronary).
3D = three-dimensional; Ao = aortic; PA = pulmonary artery.

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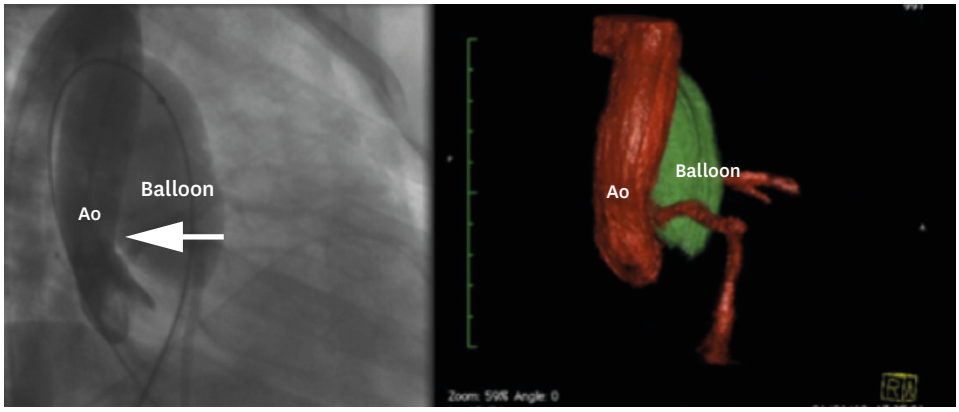

Figure 4. Balloon interrogation showing Ao root distorsion (arrow).
Ao = aortic.

technique has been proposed to reduce radiation and contrast medium dose that is based on a 3D image software which uses pre-registered images (CT scan or MRI) that are fused with fluoroscopic images to guide percutaneous intervention. However, contradictory results have been published by now also regarding this new tool.[31]

TECHNIQUE

PPVI is usually performed under general anaesthesia. Peripheral venous and arterial accesses are obtained. Femoral access is preferred, as it allows an easier working position in the catheterization laboratory; however, jugular access can also be performed safely if required. Preprocedural intravenous antibiotics are usually administered, and intraprocedural intravenous heparin is recommended to maintain activated clotting time longer than 200 seconds. Standard right-heart catheterization is carried out, including pressure measurements in the right atrium, RV, pulmonary trunk and branch pulmonary arteries. Invasively measured systemic pressure is recorded throughout the procedure. After positioning a stiff guidewire into one of the distal pulmonary artery branches, biplane and/or 3D rotational angiographies of the RV and the pulmonary trunk are performed. Measurements are made of the minimum diameter, the largest diameter, and the length of the landing zone. To enable precise measurements of the native RVOT or conduit diameter and to test possible coronary artery compression, a balloon interrogation is performed with simultaneous selective left and right coronary angiography or aortography (**Figure 5**). On one hand, semi-compliant high-pressure balloons (i.e., Cristal balloon; BALT extrusion, Montmorency, France) and/or non-compliant high-pressure balloons (i.e., Atlas Gold; Bard Inc., Tempe, AZ, USA) are usually inflated in stenotic conduit in order both to dilate the conduit itself and to test coronary artery compression. In patients with dysfunctioning RV-PA conduits pre stenting was almost invariably performed prior Melody implantation, in order to provide an adequate landing zone and to prevent stent valvular fracture and paravalvular leak (**Figure 6**). Pre stenting with covered stents is preferable in stenotic conduit with great amount of calcifications to avoid rupture and dissection (**Figure 7**). Prestenting was also commonly used before Sapien valve implantation in native RVOTs; more recently, a direct implantation is carried out, thanks to the high radial force and no tendency to fracture of the Edwards Sapien valve.[32][33] In order to choose the best Edwards Sapien valve size, a balloon waste or a complete RVOT occlusion by the balloon itself, evaluated with simultaneous RV angiography, are considered. The maximum balloon

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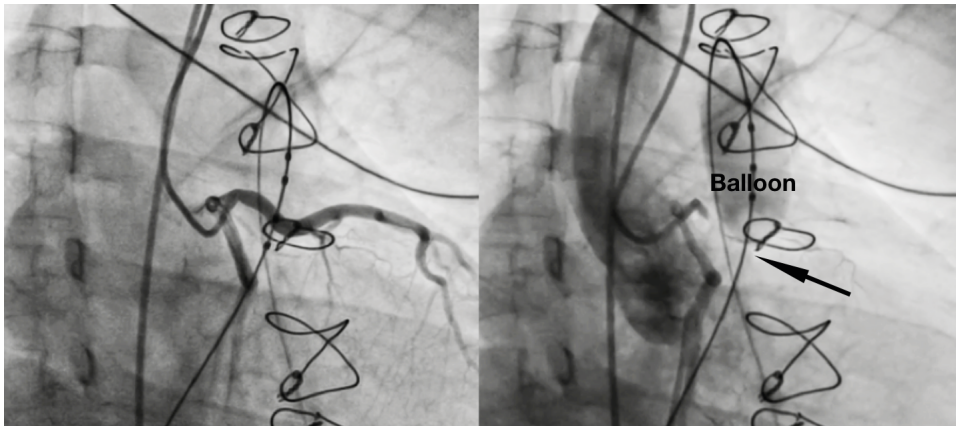

Figure 5. Balloon interrogation showing compression of the left coronary artery (arrow).

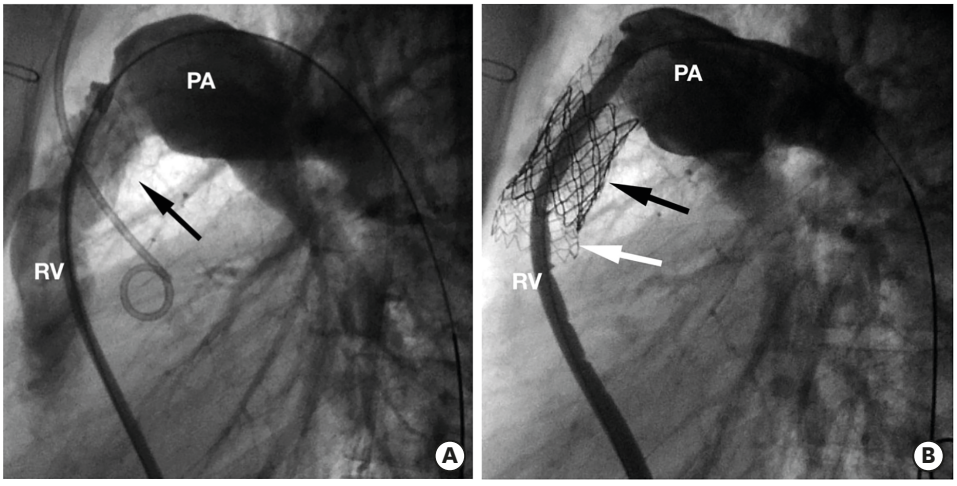

Figure 6. Prestenting + Melody. (A) Right ventricular angiogram in a case of stenotic right ventricular to pulmonary artery conduit (arrow). (B) Angiogram after Melody implantation (black arrow), after prestenting with bare metal stent Andra (white arrow).
PA = pulmonary artery; RV = right ventricle.

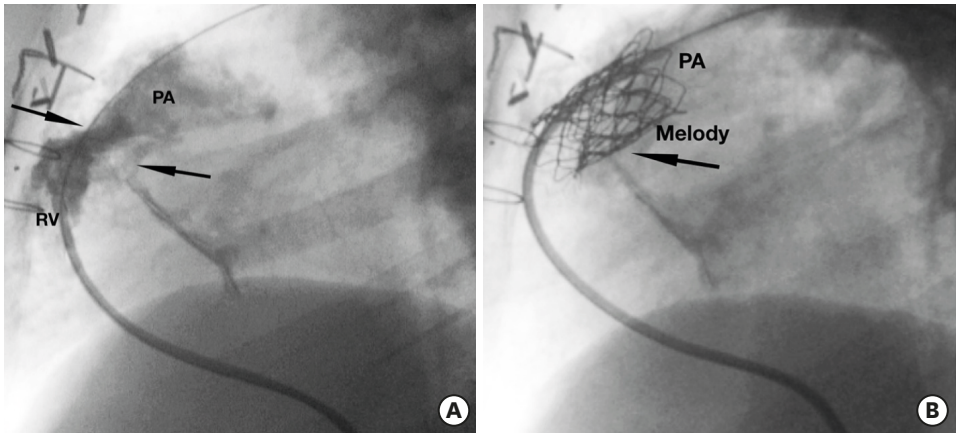

Figure 7. Melody implantation + prestenting with covered stent in a conduit with extensive calcifications (arrows). (A) Basal angiogram. (B) Angiogram after Melody implantation.
PA = pulmonary artery; RV = right ventricle.

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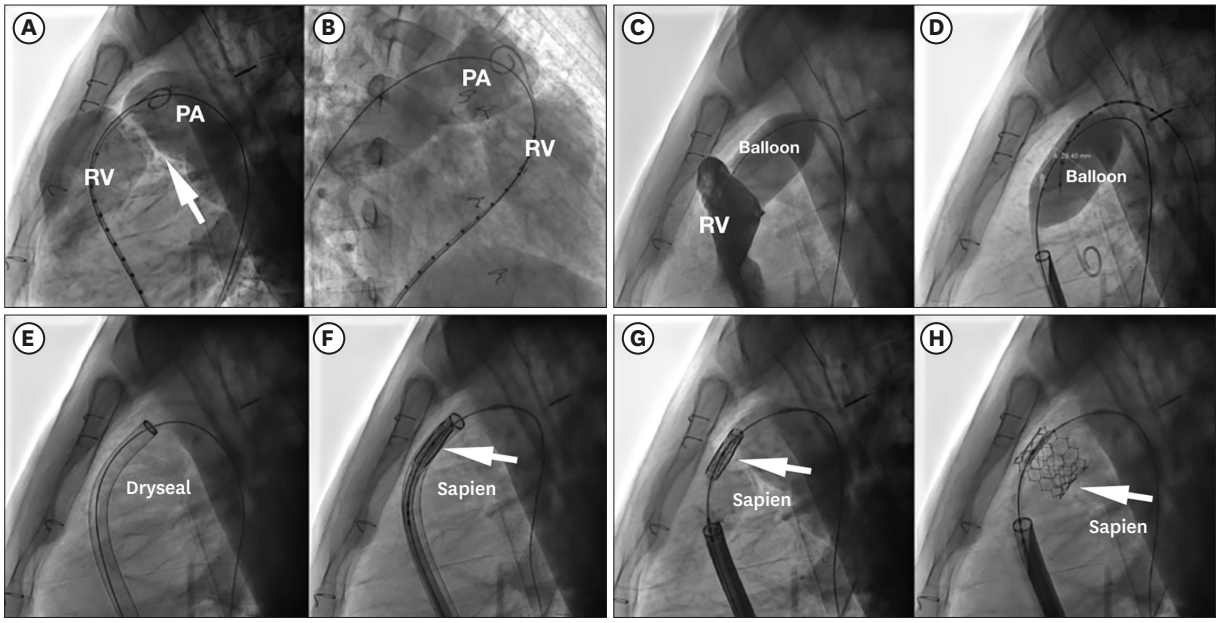

Figure 8. Step by step Sapien valve implantation tecnique in native RVOT. (A, B) Basal RVOT angiography. (C, D) Balloon inflation test + simultaneous right ventricular injection, showing no residual dye passage. (E) Dryseal long sheath advanced up to main pulmonary artery. (F) Sapien valve advanced into the sheath (arrow). (G, H) Sapien valve implanted (arrow).
PA = pulmonary artery; RV = right ventricle; RVOT = right ventricular outflow tract.

diameter is 30 mm. If no balloon waste or no complete RVOT occlusion are reached with a 30-mm balloon completely inflated, PPVI cannot be performed and the patient will be sent to surgery. If a balloon waist between 23 and 25 mm is measured, a 26 mm—Edwards Sapien valve is preferred, while with a waste between 26 and 29 mm, a 29 mm—Edwards Sapien valve implantation is considered. In presence of RVOT complete occlusion with no waste, the 29-mm Edwards Sapien valve can be over dilated inflating additional 3–9 cc of saline solution.[34]

A recent technical innovation has been proposed and used in order to facilitate Edwards Sapien valve deployment and reduce the risk of TV damage: the use of 26Fr Oversized Gore DrySeal sheath[35] (**Figure 8**). An example of transesophageal picture of Sapien valve immediately after implantation is shown in **Figure 9**.

After the procedure, an antiplatelet therapy is usually prescribed for 6–12 months.[2]

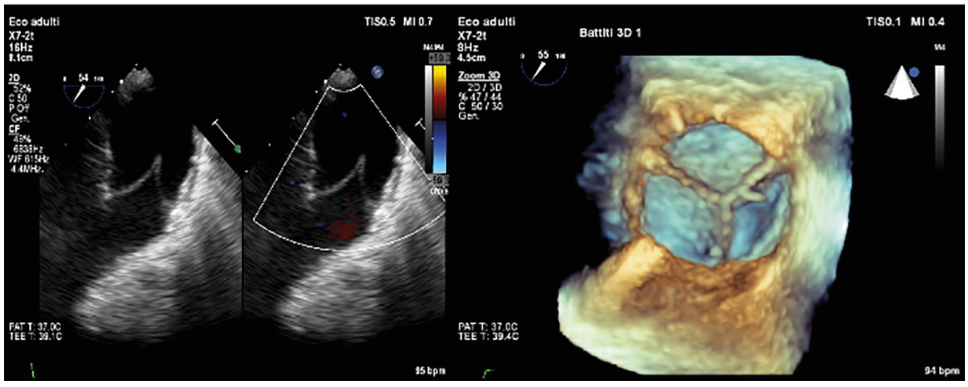

Figure 9. Transesophageal echo pictures of Sapien valve.

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COMPLICATIONS AND LIMITATIONS IN PERCUTANEOUS PULMONARY VALVE IMPLANTATION

Periprocedural time

Acute complication rate reported in the literature varies from 2% to 6% for the Melody valve and from 10% to 20% for the Edwards Sapien Valve.[36][37]

Approximately 5% of patients that undergo PPVI are at risk of coronary compression by the stent or the prosthesis with subsequent acute myocardial infarction. Therefore, coronary angiogram with simultaneously balloon inflation in the landing zone in the RVOT at the targeted outer valve diameter is recommended prior to valve implantation. An abnormal coronary artery anatomy is considered a possible risk factor.[38] With the advent of bigger prosthesis, aortic root deformation with consequent severe aortic regurgitation has emerged as another possible acute complication that can be identified with an aortography with a balloon inflated in the RVOT. It is especially true for patients with native RVOT. In case of this occurrence, as for coronary artery compression, the PPVI cannot be performed and the patient is candidate to surgical intervention.[39]

Possible rare acute complications are: partial or total conduit rupture following balloon pre-dilation, usually confined using covered stents (3%); tricuspid valve damage,[40] guide-wire related injuries of distal pulmonary artery branches leading to bronchial bleeding or haemothorax (0.05%); valve or stent migration (2.4%); acute flash pulmonary oedema episodes in high-risk patients with abnormal LV diastolic function for whom priming diuretics treatment before the procedure is necessary. Minor complications can rarely occur at the vascular access site because of the large size of the delivery system.[11][13][36]

The overall periprocedural mortality incidence is around 1.4%.[41]

Follow-up

Stent fractures are the most common complication detected at follow-up after Melody valve implantation (12.4%), with a particularly high incidence in studies that reported lower rates of pre-stenting of the ROVT prior to PPVI. They range from minor, hemodynamically insignificant alterations in stent structure to complete separation and embolization of stent segments, with more severe forms of stent fractures strongly associated with restenosis and subsequent RVOT re-intervention. However, monitoring may be justified to detect even minor fractures, as they demonstrated the propensity to deteriorate and cause subsequent valve dysfunction. Risk factors associated with stent fractures include younger age, higher pre- and postprocedural RVOT gradient, smaller angiographic conduit diameter, stent recoil or compression after deployment and valve position directly under the sternum. Pre-stenting has been shown to decrease the incidence of fractures and prolong freedom from fracture-related reinterventions.[32] No stent fracture has been described in Edwards Sapien valve.

The second most common complication identified at follow-up is infective endocarditis (4.9%). Most of the cases reported involved Melody valves[41] and it seems to be 4.5 times more frequent after PPVI than after surgical PV replacement. Several factors have been hypothesized to be responsible for this difference and the possible valvular damage before percutaneous implantation during crimping and during balloon expansion seems to be the more procedure-related. Prior infective endocarditis increases relative risk to 3.3. Some authors suggest suboptimal hemodynamic results (residual gradient, eccentric turbulence,

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pockets due to incomplete apposition, thrombus formation, asymmetric or incomplete opening with redundancy of leaflet tissue) as possible risk elements. Among other traditional factors for infective endocarditis, poor dental hygiene, unprotected dental care, piercing, tattoo and nail biting have been investigated.[2]

OUTCOMES

Exercise capacity and RV systolic function usually improve within one month since the PPVI, with patients with predominant PS showing more benefit than patients with predominant PR. However, no further RV remodelling and functional improvement have been demonstrated occurring beyond the first month, even if the early acute hemodynamic outcomes are maintained at 1 year.[42] An associated reduction of severity of TR has been reported.[43] Both a younger age at the intervention and an early PPVI operation (less than 7 years since the surgical intervention) seem to be related with a more favourable reverse remodelling and with a greater functional improvement.[44][45]

Freedom from RVOT reintervention is reported to vary widely according to duration of follow-up in individual studies, ranging from 100% at 4 months to 70% at 70 months.[41]

FUTURE PERSPECTIVES

In order to extend PPVI possibilities also to patients with particularly enlarged RVOT in which stable balloon-expandable valves implantation can be difficult, other valves or systems have been designed. One of them is the the Venus p-valve (Venus MedTech, Shanghai, China), a percutaneous valve designed to be implanted in a native patched RVOT, that is still not CE certified or FDA approved.[46][47] It is a self-expanding stent made of nitinol with a tri-leaflet porcine pericardial tissue valve preserved in a low-concentration solution of buffered glutaraldehyde and hand-sewn inside of the nitinol frame. The stent has proximal and distal flares to anchor the valve in the RVOT and in the pulmonary artery bifurcation. The proximal flare is covered by pericardial tissue, whereas the distal flare is an open cell wire frame to avoid obstruction of the pulmonary artery branches. The middle part is fully covered by pericardium and accommodates the valve. There are three radiopaque platinum markers at the proximal flare to identify the valve location. The diameter of the middle part ranges from 18 to 34 mm with 2 mm-increments and the length ranges from 20 to 35 mm with 5 mm-increments. The proximal and distal flare diameters are 10 mm larger than the middle segment. There are two small hooks at the proximal part of the valve for attachment to the delivery system. The delivery system consists of a 16 Fr 100-cm-long shaft catheter with a 20–22 Fr capsule and a handle rotating mechanism for controlled deployment of the valve. The valved stent is crimped and loaded onto the delivery system under sterile cold saline solution which helps to reduce the memory property of nitinol. The delivery system is advanced through a 22–24 Fr sheath.[46][47]

Another one is the Medtronic Harmony TPV (Medtronic, Inc.), a self-expanding nitinol stent with a woven polyester covering and a porcine pericardial valve sewn into its centre. Its feasibility by now has been proved in an ovine model, therefore it is available for investigational use only. However, after an early feasibility study on 20 patients, it is now under investigation for implantation in humans in an ongoing prospective trial.[48]

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The Alterra Adaptive Present is an anchoring adaptor for the 29 mm Edwards Sapien 3 within native RVOT. It is made of a self-expanding, radiopaque, nitinol frame assembly and PET fabric covering and has designated inflow and outflow ends. The inflow section is identifiable by the presence of two triangular tabs that are attached to the delivery system and circumferential covering of all cells. The outflow section is distinguished by open cells designed to facilitate blood flow into the branch pulmonary arteries. The device has a symmetrical frame design with the inflow and outflow diameters equal to 40 mm and the central section 27 mm to provide a rigid landing zone. Only one case of Alterra use in humans has been described by now in the literature.[49)]

The Pulsta valve (TaeWoong Medical Co, Gimpo, Korea) is a self-expandable valve with flared-ends to adapt to larger native RVOT and is using a relatively low-profile delivery catheter from knitted nitinol wire backbone and trileaflets made of treated porcine pericardial tissue. The valve diameter ranges from 18 to 32 mm with 2 mm increments. Both ends of the valve are flared to 4 mm wider than the outer diameter for stable valve adaptation to various RVOT geometries. The total length of the valve is 28 to 38 mm according to outer diameter.[50)]

CONCLUSION

PPVI can be a valid and safe alternative to surgical interventions in patients that usually face surgery more than once in their lives. A careful anatomical and haemodynamic assessment is mandatory in order to select good candidates for this procedure. The implantation technique has evolved over time in order to overcome possible complications, Moreover, new valves and developing technology will allow to extend indications also to patients with very large RVOT.

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