Percutaneous Pulmonary Valve Implantation: Current Status and Future Perspectives

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Abstract: Patients with congenital heart disease (CHD) with right ventricle outflow tract (RVOT) dysfunction need sequential pulmonary valve replacements throughout their life in the majority of cases. Since their introduction in 2000, the number of percutaneous pulmonary valve implantations (PPVI) has grown and reached over 10,000 procedures worldwide. Overall, PPVI has been proven safe and effective, but some anatomical variations can limit procedural success. This review discusses the current status and future perspectives of the procedure.

Keywords: Congenital heart disease, right ventricular outflow tract dysfunction, percutaneous pulmonary valve implantation, transcatheter pulmonary valve replacement, melody, sapien.

1. INTRODUCTION

Congenital heart disease (CHD) is the most common of all congenital defects. Almost 1% of live births are affected [1]. Around 20% of these patients have right ventricular outflow tract (RVOT) or pulmonary valve anomalies. These include Fallot’s tetralogy (ToF), pulmonary atresia with a ventricular septal defect (PA-VSD), double outlet right ventricle (DORV), isolated pulmonary valve stenosis (PS), and truncus arteriosus communis, which are usually corrected surgically early in life. Additionally, RVOT abnormalities are introduced after both the Ross Procedure, used for the correction of congenital aortic valve disease, as well as after surgical correction of complex transposition of the great arteries.

Improvement in surgical techniques has substantially enhanced short- and long-term outcomes in this patient cohort over the last decades. Nowadays, over 90% of affected children will reach adulthood [2, 3].

Historically, two treatment options for initial (early childhood) surgical repair have been used. First, up to the nineties, excision of the dysplastic PV and implantation of a non-valved trans-annular patch were preferentially used, leading to free regurgitation and right ventricular volume overload. Thereafter, surgeons mainly implanted valved conduits such as homografts (human tissue) or grafts with the use of porcine or bovine material (e.g. Contegra, Freestyle, Shelhigh, Sorin, Hancock). Implantation of a valved conduit in early childhood will eventually lead to degeneration, resulting primarily in stenosis and subsequent right ventricular (RV) pressure overload within 15 years after implantation [4]. Concomitant pulmonary branch stenoses may be present and may need either surgical or transcatheter intervention.

Thus, pulmonary regurgitation (PR) and PS are common problems in patients with congenital heart disease such as ToF, PA-VSD, and DORV, but also in patients post-Ross or post-Rastelli surgery. Most of these patients need multiple RVOT interventions throughout life.

Percutaneous pulmonary valve implantation (PPVI) has been developed as a nonsurgical, less invasive alternative for the treatment of RVOT dysfunction. Bonhoeffer et al. performed transcatheter PV implantation for the first time in 2000 [5]. Hereafter, various percutaneous pulmonary valves have been developed. Since then, experience with percutaneous pulmonary valve implantation has grown rapidly and it has become widely accepted for the treatment of RVOT dysfunction. In this review, we will discuss the indications for percutaneous valve replacement, the available devices and...
techniques, outcomes and complications of the procedure, as well as current developments and future perspectives.

2. INDICATIONS FOR PULMONARY VALVE REPLACEMENT

In clinical practice, the indication for intervention in the case of stenosis is generally reasonably straightforward, since it is mainly based on the Doppler gradient; a peak instantaneous gradient >64 mmHg regardless of symptoms, or a peak instantaneous gradient <64 mmHg with symptoms or decreased RV function is considered an indication for valve replacement in the ESC guideline [6]. In many centers, a mean gradient of 35 mmHg is also used. In the 2018 ACC/AHA guideline, valve replacement in isolated PR is indicated in symptomatic patients with moderate or greater PR with RV dilatation or dysfunction. Valve replacement is appropriate for the preservation of ventricular size and function in asymptomatic patients with repaired TOF and ventricular enlargement or dysfunction and moderate or greater PR [7].

In combined stenosis and regurgitation, the debate remains. As the main goal for intervention in the volume overloaded RV is reverse remodelling, research is concentrated on finding thresholds for valve replacement after which reverse remodelling should still take place. Over the years, various thresholds have been suggested for optimal timing of intervention.

Previously, the end-diastolic volume was considered the most important parameter, though no threshold is reported after which RV volumes do not decrease [8]. RVEDV thresholds of >150ml/m² to 170ml/m² were used as cut-off points because normalization of RVEDV was reported by several authors [9, 10] when valve replacement was performed before these cut-off points. Currently, end-systolic volume and RV ejection fraction are used more often as both are markers of RV function. End-systolic volumes (RVESV) of <82ml/m² to < 90ml/m² are used [10-14]. An RV ejection fraction <30% is associated with major adverse clinical outcomes [15].

Furthermore, tricuspid regurgitation (TR) has to be taken into account. In moderate or severe TR, combined PPVI with tricuspid valve repair should be considered because PPVI probably will not reduce TR sufficiently [16, 17]. Therefore, in case of significant TR, there might be an indication for surgical pulmonary valve replacement, instead of PPVI, as it can be combined with tricuspid valve plasty.

Electrocardiography parameters like a broadened QRS width of 140ms to180ms, or progression of QRS duration have been used in decision-making [10, 12, 18-24].

An early intervention strategy will have the most favorable effect on the preservation of RV function. However, such a strategy has to be weighed against the procedural risks of intervention, the risk of endocarditis and the need for repeat interventions. Currently, patients with dilated RVs survive into their ‘60s. It is unknown if prognosis will improve with earlier intervention and a goal of RV normalization.

3. TRANSCATHETER PULMONARY VALVES

Currently, two types of percutaneous implantable pulmonary valves are CE and FDA approved; the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minn, USA) for implantation in valved conduits (Fig. 1) and the Sapien Edwards XT (Edwards Lifesciences, Irvine, Ca, USA) for implantation in valved conduits and non-conduit (native) RVOT (Fig. 2).

Fig. (1). The Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minn, USA).

Fig. (2). The Edwards SApient XT (Edwards Lifesciences, Irvine, Ca, USA) for implantation in valved conduits and non-conduit (native) RVOT.

The valvular component of the Melody valve is similar to that of the surgical Contegra (Medtronic) valved conduit and consists of a bovine jugular vein (BJV) valve. The BJV is sutured within a balloon-expandable Cheatham Platinum stent (CP; NuMED, Hopkinton, NY, USA). The valve comes in two sizes: 16mm (up to 20mm deployment) and 18mm (up to 24mm deployment). The Melody Ensemble transcatheter delivery system comes in three sizes; 18, 20 and 22mm. The valve is crimped on the balloon-in-balloon (BiB) catheter of the Ensemble delivery system. Covered by a flexible 16 Fr shaft, with a true 22 Fr outer diameter profile, the valve/balloon combination is advanced to the landing zone over a stiff exchange guidewire. The maximal outside diameter of the Melody valve with fully inflated balloon reaches about 20mm, 22mm or 24mm, respectively (for the
Ensemble sizes 18, 20 or 22mm). The 34mm stent length will shorten to about 26mm, 24mm or 23mm after delivery using the Ensemble 18mm, 20mm or 22mm, respectively.

The Edwards SAPIEN XT transcatheter heart valve (Edwards Lifesciences, Irvine, Ca, USA) consists of a trileaflet bovine pericardial tissue valve hand-sutured in a balloon expandable cobalt-chromium stent. It is available in sizes 20, 23, 26, and 29mm, allowing for deployment in RVOTs up to 29-30mm. Similar to the Melody valve, the Sapien XT stent shortens after deployment. For example, the cobalt-chromium stent of 26mm valve shortens 2.9mm from 20.1 to 17.2mm after implantation. Accordingly, the stent length after deployment is 13.5, 14.3, 17.2 and 19.1mm for the 20, 23, 26, and 29mm valve, respectively.

The delivery system that is used for the Edwards SAPIEN XT transcatheter heart valve is the NovaFlex+ system (usable length 105 cm) which consists of a 20Fr split sheath. This delivery system includes a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system to facilitate crossing the valve, and a balloon catheter for deployment of the valve. The handle also contains a flex indicator depicting articulation of the flex catheter and a valve alignment wheel for fine adjustment of the valve during valve alignment. The balloon catheter has radiopaque markers defining the valve alignment position and the working length of the balloon. A radiopaque double marker proximal to the balloon indicates flex catheter position during deployment.

The Edwards Sapien S3 transcatheter heart valve (Edwards Lifesciences, Irvine, Ca, USA) is FDA approved for use in the aortic position. Many centers use the S3 valve also for PPVI. The S3 differs from the XT by a skirt at the proximal part of the valve which was designed to reduce paravalvular leak. The frame is longer than that of the XT and the delivery catheters (Commander) allow for more precise valve positioning. The delivery system uses 14 or 16 French sheaths designed to reduce access site complications. The S3 valve is available in four sizes: 20mm, 23mm, 26mm and 29mm.

4. PROCEDURE

4.1. Pre-procedure

It is common to perform PPVI under conscious sedation or general anaesthesia allowing adequate pain control, the use of rapid pacing and ventilation control. Pre-treatment with antibiotics (cefazolin 2gram in our center) and acetylsalicylic acid (500mg iv, hereafter 80-100mg daily), and periprocedural heparin (unfractionated heparin 100IE/kg) is standard care. In case of an extended procedure (>4hours), an extra dose of cefazolin can be administered. One extra dose of antibiotics is given 8hours after the procedure. Vascular access site for both devices is commonly the femoral vein, but jugular or subclavian access is also possible.

Pre-procedural magnetic resonance angiography (MRA), computed tomography angiography (CTA) or echocardiography can be used as an overlay for roadmapping the procedure, which makes anatomic orientation easier for the operator and enhances safety of the procedure.

4.2. Assessment Pre-valve Implantation

The first step in PPVI after non-invasive pre-procedural imaging is confirming the indication for PPVI by cardiac catheterization for angiography and pressure measurements. The relationships between the main pulmonary artery (MPA), left and right pulmonary arteries, aorta, and coronary arteries should be assessed. It has been shown that approximately 5% of PPVI candidates are at risk for CC [25]. Hereby, also special attention should be made to the presence of pulmonary artery branch stenoses, the RVOT landing zone (diameter and support for stenting), and thus the potential for coronary compression (CC). The latter can be avoided by performing balloon interrogation with simultaneous selective coronary angiography.

Multiple biplane angiography acquisitions or alternatively, a three-dimensional angiography (3DRA) are needed to acquire a reliable assessment. 3DRA allows for views in every angle while radiation and contrast doses are equal to 2-5 biplane acquisitions [26].

4.3. PPVI in Valved Conduits

PPVI in conduits follows a different approach than PPVI in native or patched RVOT’s. In conduits often multiple balloon dilatations and covered stents are necessary before implanting the valve. After careful assessment, especially for CC, one can proceed by pre-stenting the conduit. For Melody valves, pre-stenting is required to reduce stent fractures [27]. Although in Sapien valves, stent fractures have not been reported, pre-stenting is generally advised to create a landing zone.

4.4. PPVI in Native or Patched RVOT’s

In RVOTs >25 mm, sizing can be performed by occluding the RVOT with a large (eg 30mm) balloon and infusing contrast in the RV while executing a push-and-pull manoeuvre to ensure a stable position before stent implantation. In patients with native RVOTs, PPVI can be attempted in RVOT diameters <28 mm measured with balloon testing [28], but pre-stenting may be particularly challenging in these cases. Initially, valve implantation was delayed up to several months after pre-stenting ensuring good stent ingrowth and stable position. Subsequently a combined approach with immediate valve implantation became common practice. Nowadays, more often direct implantation of a Sapien 29mm is performed without pre-stenting [29].

4.5. Post-procedure

The access site vessel can be closed with manual compression or with the Perclose ProGlide (Abbott, Illinois, U.S.A) suture-mediated closure system. Alternatively, a subcutaneous suture using the ‘figure-of-eight’ results in quick hemostasis. Post-interventional observation commonly takes place in telemetry wards and lasts until late afternoon the day after the procedure. An electrocardiogram, chest x-ray and echocardiography are performed to check for valve function and potential complications.

It is of importance to instruct the patient and other health workers to use antibiotic prophylaxis. The use of low-dose
acetylsalicylic acid varies among institutions and ranges from no use at all, to a 6 or 12 month period to life-long use. Though evidence is scarce, life-long acetylsalicylic acid use might be warranted. In a prospective study with 86 patients, discontinuation of acetylsalicylic acid was found to be a risk factor for the development of infective endocarditis [30].

4.6. Clinical Outcomes

PPVI has proven to be safe over the years. Excellent early and short-term outcomes have been reported [31-33], which are equal or better than surgical PVR [27]. After PPVI, right ventricular parameters, pulmonary regurgitation [34, 35], left ventricular filling properties [36], and exercise capacity [31, 37-40] improve and electrical remodelling can be seen [41]. PPVI has lower morbidity than PVR [42]. There are few re-operations directly after the procedure [43]. A recent systematic review showed a pooled peri-procedural mortality of 1.4% in 12 studies with 677 patients [44]. Freedom from re-intervention was 76±4% at 5 years in 148 patients studied post-Melody implantation by Cheatham et al. [45]. The presence of a pre-stented conduit and a lower post-interventional RVOT pressure gradient was associated with longer freedom from re-intervention.

A small conduit diameter (<16mm) seems to be associated with early valve failure [46], although the acute hemodynamic results of the Melody implantation were good in these patients.

Besides obvious benefits of percutaneous treatment, such as faster patient recovery and less invasive procedure, cost-benefits have been described as well. Vergales et al. reported a significant cost advantage of PPVI over PVR. In their model, PPVI would only lose its cost-effectiveness with an annual PPVI failure rate of 17% [47]. Currently, in-hospital costs are higher for PPVI mainly due to the high costs of the stent and valve. If device costs would be reduced in the future, PPVI would be cost-saving even with a device cost of five times that of a surgical valve [48].

4.7. Complications

In the most recent systematic review, procedural complications were limited [44]. Coronary compression was present in 1.2%, valve embolization in 2.4%, conduit rupture in 2.6% and pulmonary artery obstruction in 1.2%. Earlier studies reported a CC risk of around 5% [25, 49]. Probably the rate of CC is lower in the review by Virk et al., because of improved pre-procedural risk assessment [44].

4.8. Coronary Compression

Coronary compression is the most important complication to avoid. In case of CC, urgent surgery or percutaneous coronary intervention may be necessary [50-52]. Fatal cases have been described [35]. Abnormal coronary anatomy is common in CHD. These patients are at high risk for CC because the coronaries may be close to the RVOT/stent area.

Patients after Ross procedures are of special concern because the coronaries are re-implanted in a more cranial part of the aorta during their initial treatment. The risk of CC might be as high as 22% in abnormal coronaries, versus 1.8% in normal anatomies [25]. Pre-procedural MRA or CTA do not allow for reliable risk assessment of this phenomenon because they are both off-line, CTA is static and MRA has a low spatial resolution. Another aspect that cannot be anticipated using CTA or MRA alone is the behaviour of the mass between MPA and coronaries. Even if the distance between MPA and coronaries seems enough (>5 mm), the risk of CC exists because this mass might not be compressible, especially if it consists of calcified tissue or residues of stents and conduits. So, real-time assessment in the catheterization laboratory as previously described is warranted.

4.9. Aortic Compression

Similar to CC, compression of the aortic root can occur with or without consequent aortic insufficiency (AI) [53, 54]. In a majority of cases, aortic root compression will occur in native or TAP RVOTs [55], but its clinical significance is unclear. A study by Torres et al. showed no progression of AI during follow-up after PPVI [53]. However, attention should be paid for this potential phenomenon during balloon interrogation because it may constitute an important contra-indication for PPVI.

4.10. Stent Fracture

Stent fracture (SF) used to be one of the most common complications encountered in the earlier era of Melody valve implantation. Since the use of pre-stenting, the incidence of stent fractures has been significantly reduced [45, 56]. SF is only reported for Melody valves. Commonly SF involves the rupture of only one or more stent struts without the loss of stent integrity and therefore usually has no clinical consequences [56]. However, SF may lead to dysfunction of the valve as well and may necessitate repeat intervention. If SF leads to loss of stent integrity or embolization of stent fragments, re-stenting or surgical intervention might be indicated.

4.11. Conduit Rupture

The overall incidence of conduit rupture was reported to be 6% in a retrospective analysis by Bishnoi and coworkers, with no significant differences between homografts or other type of conduits. The only identifiable risk factor was a highly elevated RVOT gradient [57]. Mostly, bleeding is contained by the surrounding scar tissue and only monitoring is necessary, but major bleeding with procedural death can occur. Urgent stenting with covered stents is then indicated [27]. Implantation of the NuMED Covered Cheatham-Platinum Stent can be performed without a negative impact on the TPV function [57]. Urgent surgery might be an option too but will often take far more critical time. Pre-stenting severe calcified homografts over the entire length with a covered stent is probably the only way to prevent conduit rupture or cardiac tamponade.

4.12. Valve Embolization

Embolization or migration of stents and valves is very rare, but cases have been described [34, 58]. Often surgical intervention will be necessary to explant the device, but tran-
scatheter retrieval has also been reported [59]. It may be necessary to implant the device in a pulmonary artery branch or vena cava (valve leaflets can be stented to flatten them out) [60].

4.13. Tricuspid Valve Damage

In PPVI with Sapien XT or S3 valves, there is a risk of tricuspid valve (TV) damage with subsequent tricuspid regurgitation. The valve passes the TV while it is uncovered on the sheath with the risk of entrapment in the TV apparatus.

4.14. Infective endocarditis

Infective endocarditis (IE) is a serious concern in PPVI. For Melody valves, high rates of IE are described, whereas, for Sapien valves, the incidence of IE seems low. However, the later introduction of Sapien valves for the pulmonary position has to be taken into account (less valves implanted and shorter follow-up).

Several reports concerning endocarditis in post-PPVI patients treated with Melody valves have been published [30, 31, 49, 61, 62]. Van Dijck et al. report 7.5% incidence of IE in 107 patients with a mean follow-up of 2 years and an annual event rate of 3%. The 5 years IE free survival was 84.9%. Interestingly, they compared Melody endocarditis to IE in Contegra conduits and homografts, the latter having an annual event rate of only 0.8% [61]. In New-Zealand, higher numbers of IE are reported by O’Donnell. After 2.9 years follow-up, the incidence of Melody IE was 16% in their cohort [63]. The study with the longest follow-up after Melody implantation (7 years) reports a 5-year freedom from IE of 89 ± 3% [45]. The same (89%) 5-year freedom from IE was confirmed in the most recent, and large publication on IE in Melody valves [64].

Recently the longest Sapien follow-up to date (mean 3.5 years), showed no endocarditis [65]. In the prospective multi-institutional COMPASSION trial, freedom from endocarditis at three years was 97.1% with an annualized PPVI related IE of 0.5% per patient per year [66]. Several other publications with relatively short follow-up periods reported a low incidence of IE in Sapien valves in the pulmonary position [67-69]. The study of Hascoët et al. [70] showed no cases of IE after 40 months in 47 patients treated with the Sapien valve and a cumulative incidence of IE of 24% in 32 patients treated with the Melody. In a recent publication of Haas et al. [71] the risk of bacterial endocarditis was 5.8-times higher for Melody valves compared to other valves in a group of 246 patients with all types of pulmonary valves. There was no bacterial endocarditis in the patients treated with Sapien valves during follow-up.

Etiology of IE post-PPVI is unknown; it is suggested, that the type of material might play a role in the risk of developing IE. Melody valves and Contegra conduits compared to pulmonary homografts, demonstrate different flow patterns with high shear stress and turbulence, jet lesions or local stress, whilst blood stasis in and around the conduits might contribute to this increased risk. Both systems are composed of bovine material, and the tissue characteristics might contribute to the IE risk as well [61, 72]. This concept is supported by a small in vitro study by Jalal and coworkers that showed an increased bacterial adhesion of S. Aureus and S. Sanguis on healthy Melody valve tissue, which increased after procedural preparation. The authors hypothesized that immature fractures resulting from procedural preparation to provide a bacterial trap and form the preferred location for bacterial adhesion [73, 74].

Sharma et al. recently reported a higher incidence of endocarditis with BJV valves than other types of right ventricle–to-pulmonary artery conduits. There was no difference in the incidence of endocarditis between catheter-based bovine valves and surgically implanted bovine valves, suggesting that the substrate for future infection is related to the tissue rather than the method of implantation [75]. These results are strengthened by the results of Veloso et al. [76].

Adhesion of Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus sanguinis to bovine pericardium patch, bovine jugular vein, and cryopreserved homograft tissues under static and shear stress conditions indicated similar bacterial adhesion to all tissues. These data provide evidence that the surface composition of BJV and cryopreserved homograft tissues themselves, bacterial surface proteins, and shear forces per se may not be the prime determinant.

One of the major risk factors for IE has been shown to be the post-interventional RVOT gradient [31, 76]. The higher flow velocity might cause endothelial damage with non-bacterial thrombus formation, which might get infected later. This observation might explain the higher rates of IE reported in patients who discontinued acetylic salicylic acid [30, 49, 67]. Buber et al. reported male sex, longer procedure time and multiple RVOT stents as risk factors [76]. Additionally, traditional IE risk factors like previous IE, unprotected dental procedures, skin wounds and personal hygiene (like nail biting), all contribute to IE risk.

When patients present with IE, urgent intervention seems warranted, because of a 50% mortality rate as reported by Fraisse et al. Two of their patients died before urgent (next-day) surgery could be performed [49].

So far, it seems that the risk of IE is lower in the Sapien valve as compared to the Melody valve, although no head-to-head comparison has been made up till now. A different patient selection for the 26 to 29 mm Sapien valve, i.e. larger sized conduits and valve implantation in native RVOT’s might explain the reported differences in the incidence of IE. Future studies, preferably a randomized trial comparing the Melody and the Sapien valves, are needed to definitely answer the IE issue.

5. FUTURE PERSPECTIVES

5.1. Patient Selection and Timing

In the last decades, knowledge concerning RV volumes and function, and changes in electrocardiographic parameters and exercise parameters has grown. A wide range of thresholds for valve replacement has been proposed, after which reverse remodelling can still take place and right ventricular function recovers (RVEDV, RVESV, QRS width, EKG parameters and others). However, little is known about the RV
histopathology and the long-term functional outcomes of pulmonary valve implantation. More research is needed to better define the ideal timing for (re-)intervention in RVOT dysfunction.

Currently, the team is performing a study with magnetic resonance imaging of irreversible RV fibrosis using T1 and T1rho mapping (The RV-REPAIR study, NL53771.041.15). Strain measurements using speckle-tracking echocardiography and feature tracking cardiac MR, combined with the investigation of novel biomarkers of RV function will probably aid in a better patient selection, earlier intervention and possibly even improved long-term outcomes. The fact that earlier intervention can lead to improved outcomes has been shown in a recent study of Pagourelias and co-workers. They reported a more pronounced biventricular remodelling reaching near normal values in patients with PPVI <7 years after the last RVOT operation [77]. Ideally, large cohorts with very long (life-long) follow-up will be created and timing might shift to earlier intervention in the future.

6. ADVANCED IMAGING

6.1. Advanced Imaging in the Assessment of RV Function

Pressure-volume loops would be ideal (load-independent) for the assessment of the RV in RVOT dysfunction. But PV-loops are not routinely used because of several disadvantages including the invasiveness of the procedure. Therefore, non-invasive methods are used to determine the RV function. In clinical practice, echocardiography and MRI are the routine diagnostics for follow-up of RVOT dysfunction. Their measurements are load-dependent. Strain and strain-rate are less load dependent than other parameters and therefore increasingly used for assessment of intrinsic function. Different strain and strain rate parameters are associated with volume overloading, RV dys-synchrony and RVEF [78, 79]. Other authors report a significant correlation between RV contractility (RV peak longitudinal systolic strain) and TAPSE [80]. TAPSE, in general, is not reliable in post-operative hearts but can be used for follow-up of the longitudinal function when the RV declines. Real-time 3D echocardiographic assessment of RVEF in congenital heart disease has proven to be reliable and feasible in small studies but as to be examined further [81].

In CMR, T1 mapping is increasingly used to quantify the extracellular volume (ECV). ECV is a validated surrogate marker of diffuse fibrosis. When excess collagen appears in the interstitium native T1 and ECV increase and post-contrast T1 decreases [82]. ECV has a good correlation with histological global fibrosis [83] and is correlated with arrhythmia in TOF patients with volume overloading due to PR [82]. With the evolving ability for non-invasive assessment of RV fibrosis, preservation of RV myocardium might take the lead over volumes and pressures in determining the timing of PV replacement [82, 84]. However, it is unclear how to translate ECV to function and prognosis. Moreover, it is still not possible to reliably measure T1 in the RV free wall [84, 85] since the spatial resolution approaches the thickness of the myocardium [82]. It is questionable if septal ECV represents fibrosis of the RV since there is a regional difference in RV wall stress due to its complex geometry. Chen et al. did measure ECV of the RV and reported elevated ECV values in rTOF patients, these were associated with RV volume overload and arrhythmia [86].

Another advance in CMR is four-dimensional flow cardiac magnetic resonance (4D flow CMR). This technique can be used to derive advanced hemodynamic measures such as wall shear stress, pressure difference maps, pulse wave velocity, energy loss, turbulent kinetic energy and others [87] without radiation burden. The use of 4D flow in RVOT dysfunction in the future might result in an improved understanding of RV physiology and remodelling [88, 89].

6.2. Advanced Imaging in Performing PPVI

Computational fluid dynamics (CFD) is a tool to derive the same hemodynamic measurements as 4D flow CMR. This tool calculates flow patterns and pressure changes within a virtual model of the cardiovascular system [90]. It can predict physiological responses to intervention and compute hemodynamic parameters [91]. CFD tools may support the assessment of pulmonary valve dysfunction and treatment decisions, especially by predicting the post-treatment changes [92, 93]. Recently the use of finite element modelling was described to predict RVOT intervention outcomes and periprocedural risks [54].

Three-dimensional rotational angiography (3DRA) is used in an increasing number of clinics. Superior imaging quality has been reported [94] and may facilitate higher procedural success and decreased the risk of serious adverse events by assessment of coronary compression and vessel-airway interactions (Fig. 3) [95, 96]. It has been shown that the use of 3DRA does not result in increased radiation or contrast dose [26, 97], on the contrary, lower radiation dose can be achieved [98]. Furthermore, adequate and safe balloon interrogation in large (native) RVOTs is possible, potentially resulting in more PPVI’s in patients with native RVOT’s and wide conduits.

Fig. (3). 3DRA showing critical proximity of LCA to posterior MPA, not suitable for PPVI.

6.3. 3D-models

Three-dimensional printed models may aid in patient education [99]. In vitro simulation with 3D models might help planning PPVI in native RVOTs [100].

6.4. New Device Technology

Several devices for the reduction of large diameter (native) RVOT’s are being developed and tested to broaden the treatment scope for PPVI. The first-in-man use of the Alterra Adaptive Prestent (Edwards Lifesciences, Irvine, CA, USA)
was reported recently (Fig. 4) [101]. Devices under development are; the Harmony Transcatheter Pulmonary valve (Medtronic, Minneapolis, MN, USA) (Fig. 5), which was formerly known as Native Outflow Tract Device [102]. Alternative new devices include the Venus P-valve (MedTech, Shanghai, China) [103], the Pulsta valve by TaeWoong Medical Company (Gyeonggi-do, Republic of Korea) [104, 105], the RVOT reducer (Fig. 6) [106], and the Downsize stent [107].

**Fig. (4).** A and B; 3D rotational angiography in patient with severe homograft stenosis. C and D; angiographic images after implantation of 3 covered CP stents and Sapien 20mm.tif.

**Fig. (5).** The Alterra Adaptive Prestent (Edwards Lifesciences, Irvine, CA, USA).

The Harmony valve has an hourglass geometry with the smaller central diameter holding the (porcine pericardium) valve. The system uses a self-expanding nitinol stent with a polymeric graft, which aims to improve the stability of the device in various RVOT anatomies [106]. Recently the results of the first FDA approved early feasibility study were presented, which revealed high procedural success and favorable acute hemodynamics [65].

The Venus p-valve (MedTech, Shanghai, China) is a self-expanding percutaneous heart valve designed to be implanted in a native patched right ventricle outflow tract. This valve is currently available up to a maximum diameter of 34 mm for use in an RVOT diameter up to 30–32 mm. Three in-man studies have been published so far in tetralogy of Fallot patients with trans-annular patch repair. Results are encouraging and the use of the Venus p-valve in large (native) RVOTs seems possible [103, 108].

A feasibility study of the Pulsta valve (by TaeWoong Medical Company, Korea) was recently reported. The Pulsta self-expandable valve consists of a knitted nitinol wire stent mounted with a treated trileaflet α-Gal–free porcine pericardial valve. Implantation of this valve was feasible and showed short-term effectiveness without serious adverse events [104].

Besides these innovations, existing valves with a bigger diameter will become available and will be increasingly used. Although the SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA), available in 23, 26, and 29 mm sizes, was designed and FDA approved for the aortic position, this valve is also used in the pulmonary position [109]. Direct implantation (without pre-stenting) of the S3 valve, which has a strong stent frame, is being performed in native RVOT’s. With sizes up to 29 mm, clearly, the spectrum of patients that can be treated with a percutaneous procedure grows.

As an alternative to percutaneous device techniques, a hybrid plication technique has been reported by Sosnowski et al. [110]. After full median sternotomy and minimal dissection of the heart and great vessels, RVOT angiography was performed to measure the main RVOT and pulmonary artery diameter and to determine the extent of plication. A sizing balloon was used for procedural guidance and plica-
tion was performed with a pledged longitudinal running suture to provide a more elongated reduction of the RVOT. In case of calcification of a pre-existing RVOT patch, a mattress suture was used to provide a focal narrowing of the RVOT size to approximately 22-24 mm. After this plication, a PPVI was performed [110].

7. DECELLULARIZED HUMAN VALVES

Small studies, with conflicting results, have described the use of decellularized human valves [111-113]. High immunogenic competence in children and young adults contributes to allo- and xeno-graft (i.e. cryopreserved homografts and bovine jugular vein grafts) degeneration. With heart valve tissue engineering it is possible to eliminate immunogenic cells from the valvarular matrix, hereby creating viable, non-immunogenic, and biologically active grafts. Elimination of immunogenic cells from the valvarular matrix seems to significantly decrease immunologic response in valve recipients. Extensive remodelling in vivo by repopulation with autologous cells and reduced re-operation rates compared to cryopreserved homografts and BJV’s were reported in pre-clinical and mid-term outcomes of clinical studies [111, 112]. Another publication reported disappointing results of the use of decellularized valves; abnormal immunologic response leading to significant and long-standing xenograft inflammation appeared to be the reason for graft stenosis and failure early after surgery. Moreover, the asserted endothelialization of the valve leaflets could not be confirmed by histology [114].

Other innovations are tissue-engineered valves (feasibility in sheep) [115], new wire and sheath techniques [116], and promising results on the valve in valve replacements [117]. A double stent technique was reported by Valverde et al. [99]. A 3D print was used to test double stent implantation in a 36 mm RVOT. Subsequently, two stents were implanted adjacent to each other, after which one stent was used as a landing zone for PPVI and the other stent was occluded with a vascular plug.

8. INFECTIVE ENDOCARDITIS

Further research and long-term outcome results are required to address the risk for endocarditis. Results of the Sapien valves have scarcely been available till now. Results of the currently running COMPASSION trial will give further insight into the infection risk in Sapien valves. The association between IE and bovine material (Contegra and Melody) has to be examined further [73]. In addition, randomized clinical trials have to be conducted to investigate whether the life-long use of acetylsalicylic acid prevents IE. Patient instructions concern dealing with unexplained fever, aspirin use, dental procedures and personal hygiene (including tattoos and piercings) remain of utmost importance.

SUMMARY

PPVI has become an accepted and widely used technique for treating RVOT dysfunction in several congenital heart disease states, particularly after initial surgical repair. In short- and medium-term follow-up reports, outcomes are excellent. Coronary compression, with possibly dramatic consequences, is the most important complication to avoid. Post-PPVI, infective endocarditis is a concern. In this, a possible predisposition of the Melody valve should be elucidated. In the near future, RVOT reducer devices will become available that make PPVI in large (native) RVOTs feasible (Fig. 7). Advances in imaging techniques such as 3DRA, 4D flow CMR and CFD will improve understanding of RV (reverse) remodelling and perhaps (possibly?) influence the timing of intervention. Larger sizes studies with long-term follow-up will also contribute to improved timing of pulmonary valve replacement.

AUTHORS CONTRIBUTIONS

Bart. W. Driesen conceptualized this study, assisted with design, led data analysis/interpretation and drafted and edited the manuscript.

Evangeline. G. Warmerdam: Assisted with drafting the manuscript.

Gert-Jan Sieswerda: Assisted with data collection and critical revision of the manuscript.

Folkert. J. Meijboom: Assisted with data collection and critical revision of the manuscript.

Mirella. M.C. Molenschot: Assisted with data collection.

Pieter. A. Doevendans: Assisted with critical revision of the manuscript.

Gregor. J. Krings: Assisted with design, data analysis/interpretation and drafting and critical revision of the manuscript.

Arie. P.J. van Dijk: Assisted with critical revision of the manuscript.
Michiel Voskuil: Assisted with design, data analysis/interpretation and drafting and critical revision of the manuscript.

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