


Pulmonary Valve Stenosis: From Diagnosis to Current Management Techniques and Future Prospects

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Abstract: Pulmonary stenosis (PS) is mainly a congenital defect that accounts for 7–12% of congenital heart diseases (CHD). It can be isolated or, more frequently, associated with other congenital defects (25–30%) involving anomalies of the pulmonary vascular tree. For the diagnosis of PS an integrated approach with echocardiography, cardiac computed tomography and cardiac magnetic resonance (CMR) is of paramount importance for the planning of the interventional treatment. In recent years, transcatheter approaches for the treatment of PS have increased however, meaning surgery is a possible option for complicated cases with anatomy not suitable for percutaneous treatment. The present review aims to summarize current knowledge regarding diagnosis and treatment of PS.

Keywords: pulmonary valve stenosis, percutaneous treatment, valvotomy, valvuloplasty

Introduction

Pulmonary stenosis (PS) is almost always congenital in origin. Isolated PS is a rare condition that occurs in about 1 per 2000 live births worldwide and it accounts for approximately 8% of all congenital heart disease (CHD).¹

The prevalence seems to be steadily increasing overtime, with a slightly higher birth prevalence in Asia compared to Europe and the USA.¹

The therapeutic approach is determined by the hemodynamic severity of the obstruction. Intervention should be considered in patients with severe PS, but also in non-severe stenosis in the presence of symptoms, such as otherwise unexplained congestive heart failure, cyanosis from interatrial right-to-left communication and exercise intolerance.²

The last decade was characterized by significant improvements in the diagnostic and therapeutic possibilities for diseases of the pulmonary valve, with both the development of new treatments (fetal interventions, new surgical strategies and percutaneous pulmonary valve implantation), and with the improved understanding of the long-term sequelae of pulmonary valve disease.³

The main purpose of this review is to summarize the main findings regarding the diagnosis and therefore the treatment of PS, underlining the importance of the new techniques with percutaneous approach that are being proposed as therapeutic alternatives in the patient with PS.

Methodological Considerations

We performed a review of literature including studies regarding PS. Accordingly, the following terms using medical subject heading (MeSH) strategy were searched: (pulmonary valve stenosis) AND (treatment) NOT (case report) NOT (case series) NOT (artery or vein). The databases analyzed were PubMed, BioMed Central and Google Scholar. The literature search was carried out in December 2022. Only full-text article published in English and in peer-reviewed journals were selected. The following were inclusion criteria: 1) observational or randomized studies on the treatment and diagnosis of PS; and 2) relevant reviews about treatment and diagnosis of PS. Exclusion criteria were: 1) articles not regarding humans; 2) editorials; and 3) case report or case series. Literature search and screening of the literature of selected items was performed by two

independent reviewers (FM and SM). Divergences have been solved by discussion and consensus. In case of discordance a third reviewer (RP) was asked to solve the disagreement and reach consensus. Two reviewers (FM and SM) retrieved data from the included studies. Overall, 125 studies were selected. After evaluation of records, 70 studies published between 1982 and 2022 were included in the review.

Etiology

In the classical form of PS the valve is dome shaped, characterized by a narrow central opening with preserved valve motion. There are generally two to four rudimentary raphes without a real separation into valve leaflets. Valve calcification is rare but it is seen in some elderly patients.^{4,5} Less commonly the valve may be uni, bi or tricuspid with various degrees of commissural fusion and thickened cusps. Approximately 10–20% of cases involve pulmonic valve dysplasia. Dysplastic valves are trileaflet with thickened cusps composed of myxomatous tissue and little or no fusions, with relative valve immobility. This type of valve defect is a common component of Noonan syndrome.^{6–8} PS may also occur as part of complex congenital lesions (i.e., tetralogy of Fallot, complete atrioventricular canal, double outlet RV, univentricular heart).⁸ Most patients develop dilation of the pulmonary trunk (post stenotic dilation), with a degree of dilation not always proportional to the severity of obstruction. One exception to this finding is peripheral pulmonary artery stenosis usually found in Noonan's and Williams syndrome.⁴

Only a small percentage of PS is acquired and caused by rheumatic disease, carcinoid disease and neoplastic lesions or may occur after surgical reconstruction for other complex congenital cardiac disorders: reconstruction often entails the placement of a pulmonary valve prosthesis, right ventricle-to-pulmonary artery homograft, or valved conduit, which degenerates over time, manifesting as stenosis, regurgitation, or both.^{9,10}

The natural history of PS leads to secondary changes in other cardiac structures. In particular, the right ventricular systolic pressures needed to override the outlet stenosis can be even higher than systemic left ventricular pressures. Pressure overload increases wall stress and, in order to maintain a normal cardiac output, there is an increase in contractility and a compensatory right ventricular hypertrophy, an increase of end-systolic volume and end-diastolic volume and high right ventricular end-diastolic pressures. At first, these compensatory adaptations enable the right ventricle (RV) to maintain stroke volume in presence of increased afterload. Over time, progressive right ventricular hypertrophy and stiffness can determine right ventricular diastolic and systolic dysfunction and this leads to fibrosis of the endocardium and of the tricuspid valve apparatus, right ventricular ischemia, hypertension and hypertrophy of the right atrium and even arrhythmias.¹¹ Therefore, elevated levels of NT-proBNP in neonates might be used as a biomarker for diagnosis of severe PS.^{12,13}

Diagnosis

For the diagnosis of PS and planning of treatment it is of paramount importance the application of multimodality imaging (Table 1), with the integrated use of echocardiography, cardiac magnetic resonance (CMR) and of cardiac computer tomography (CCT).

Transthoracic Echocardiography

The primary method for determining PS is the echocardiogram: in fact, it can assess severity, anatomy of the stenosis, etiology, associated lesions, and impact on the RV. The conventional and modified views of two-dimensional transthoracic echocardiography used to evaluate PS are parasternal short axis view (PSAX – great vessels plane), subcostal view, modified parasternal long axis (PLAX) and five chamber views (5 Ch) for RVOT and pulmonary arteries (PA)¹⁴ (Table 1).

First, qualitative examination of PS is necessary to determinate the mechanism of valve dysfunction (e.g., abnormal cusps number, dysplastic valve, prolapse, atresia or agenesis) and associated lesions, like RV hypertrophy or dilatation and right atria dilatation.^{6,14}

The quantitative assessment of PS, instead, is mostly based on transvalvular pressure gradient because the calculation of planimetric PV area is not possible and continuity equation or proximal isovelocity surface area method are rarely performed (Figure 1). Through the simplified Bernoulli equation ($\Delta P = 4V^2$) the systolic pressure gradient is estimated using the transpulmonary velocity flow curve calculated by continuous wave (CW) doppler from PSAX view (Figure 1).

Table 1 Main Available Diagnostic Methods for Evaluation of Pulmonary Valve Stenosis

	Sequences	Structures Evaluated
TTE	<ul style="list-style-type: none"> • PSAX great vessel view • Modified PLAX • Subcostal view • 5Ch view for RVOT 	<ul style="list-style-type: none"> • PV morphology • RV morphology and dimension • Transvalvular gradient
TOE	<ul style="list-style-type: none"> • ME RV inflow-outflow view • UE esophageal (50°–70°) view • TG inflow-outflow view • TG RV basal view • Volume rendering 	<ul style="list-style-type: none"> • RVOT morphology • Proximal PA morphology and dimension • PV morphology
CMR	<ul style="list-style-type: none"> • SSFP cine imaging • Phase contrast • Angiography of PA 	<ul style="list-style-type: none"> • PV morphology and area • RV, RVOT and PA morphology and dimension • Transvalvular velocity
CCT	<ul style="list-style-type: none"> • Axial, sagittal and coronal planes • MPR reconstruction for pulmonary valve • Volume rendering 	<ul style="list-style-type: none"> • PV morphology • RV and RVOT morphology • Pulmonary tree morphology and dimension • Coronary arteries origin and pathway

Abbreviations: TTE, transthoracic echocardiogram; TOE, transesophageal echocardiogram; CMR, cardiac magnetic resonance; CCT, cardiac computed tomography; PSAX, parasternal short axis; PLAX, parasternal long axis; 5Ch, five chamber; ME, mid esophageal; TG, trans-gastric; RV, right ventricle; SSFP, steady state free precession; MPR, Multi Planar Reconstruction; PV, pulmonary valve; RVOT, right ventricle output tract; PA, pulmonary artery.

According to the 2020 ESC guidelines for the management of adult CHD, PS can be classified as follow:⁵

- Severe stenosis: peak gradient ≥ 64 mmHg;
- Moderate stenosis: peak gradient between 36 and 64 mmHg;
- Mild stenosis: peak gradient ≤ 36 mmHg.

Finally, in individuals with PS, determining the RV systolic pressure from the tricuspid regurgitant velocity and adding an estimate of right atrial pressure might be a helpful measure of severity.¹⁴

Transesophageal Echocardiography

Pulmonary valve may also be evaluated through transesophageal echocardiography (TOE). The mid-esophageal (ME) RV inflow-outflow view (45°–60°) explores the long axis of the RVOT and of pulmonary valve, anterior to the aortic valve. The sub-pulmonary region is examined from this projection to assess muscle bundles or constriction at the infundibular outflow septum, which may indicate a double-chambered RV. Although there may be color Doppler turbulence, the ultrasound beam angle is insufficient to generate a valid peak Doppler gradient for sub valvular or valvular stenosis.¹⁵ From ME RV inflow-outflow view, withdrawing the probe up to the upper esophageal (UE) view may optimize imaging of the main and proximal branch PA. Doppler evaluation of valvular and supra- valvular PS is optimum from this angle; however, supra- valvular stenosis can be visualized only approximately 50% of the time because this probe position is particularly uncomfortable for the patients. The best window to visualize the role of the infundibulum and moderator band in dynamic sub- valvular stenosis is from the transgastric view (TG): TG inflow-outflow view is obtained at 0° to 20°, while a long-axis view of the entire RVOT is best visualized at 40° to 70°. 3D rendering of the valve is quite difficult since the PV appears in the far field at all imaging levels: because the annular plane is more perpendicular to the ultrasound beam, the UE view often offers the best imaging of the leaflets to improve 3D capture¹⁵ (Table 1).

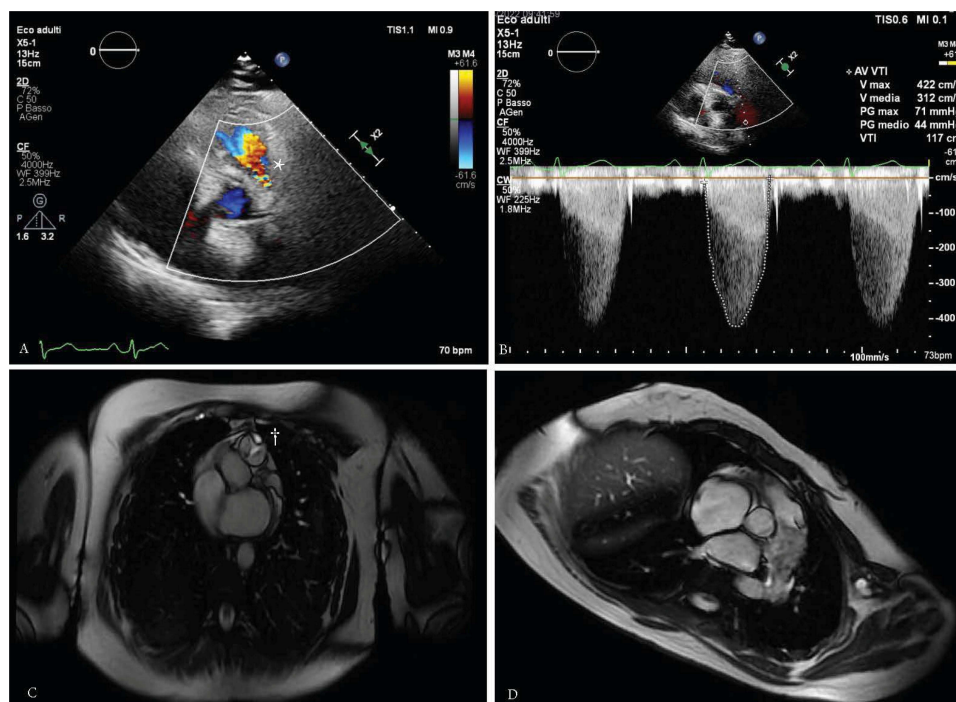


Figure 1 Multimodality imaging evaluation of PS. (A) PSAX view with Color Doppler showing flow turbulence in RVOT[†]; (B) CW Doppler of severe PS; (C) Reduce PV opening[†] on SSFP cine imaging; (D) PA trunk dilatation with flow turbulence due to Jet lesion.

Abbreviations: PSAX, parasternal short axis; RVOT, right ventricle outflow tract; CW, continuous wave; PS, pulmonary stenosis; PV, pulmonary valve; SSFP, steady state free precession; PA, pulmonary artery.

Cardiac Magnetic Resonance

In most cases, echocardiography remains the first-line imaging method for PS, however CMR allows the reconstruction of unlimited image planes and views of PV and RVOT, even when cardiac anatomy or heart position in the chest are challenging¹⁶ (Figure 1). In fact, the optimal visualization of the RVOT with CMR allows identification of site and severity of PS. Compared to the evaluation of the left valves, the pulmonary valve requires specific image views for the RVOT, which can be used to provide a qualitative assessment of severity by observing the valve motion and stenotic jet. Quantitative evaluation of valve dysfunction can be assessed by the combination of high image quality and phase contrast flow mapping sequences.^{17,18} CMR guarantees direct planimetry of the valve orifice from an image acquired through the valve tips at peak opening during systole. It may provide ideal assessment of valve anatomy and quantifies the degree of stenosis. When precise echo beam alignment with the jet is not possible, phase-contrast velocity mapping can be used to quantify transvalvular velocity. This is especially useful in angulated roots or when the stenotic jet is not parallel to the RVOT. From the outflow tract planes, identifying sub-valvular and supra-valvular stenosis is easy and the site of maximal velocity can be identified by in-plane velocity mapping. Finally, RV anatomy and function can be correctly assessed with cine imaging and any concomitant pulmonary trunk or branch artery stenosis can also be recognized through angiography sequences of the PA¹⁹ (Table 1).

Cardiac Computed Tomography

Thanks to its high spatial resolution, CCT scan is a useful diagnostic tool which can provide detailed anatomical information regarding the pulmonary valve and surrounding anatomical structures such as the RVOT, distal PAs, and coronary arteries. Moreover, it gives detailed information about prosthetic valves, and it is also essential for surgical and transcatheter intervention planning.²⁰ To correctly visualize the pulmonary valve and its surrounding structures, the right heart chambers must be appropriately opacified using optimal imaging methodology and ECG-gated acquisitions: in particular, the split-bolus injection offers adequate attenuation for right heart chambers avoiding streak artifacts from high-attenuation contrast medium.²¹

In PS, CT typically shows a thickened and fused pulmonary valve with reduced opening area.^{22,23} With developments in CT scan technology, axial data may now be rebuilt into sagittal and coronal images using multiplanar reformation (MPR). Furthermore, maximum intensity projection (MIP) and volumetric rendering (VR) have increased diagnostic sensibility and specificity of post-processing software.²⁴ Finally, accurate three-dimensional views produced by CCT scan can aid in determining the degree of stenosis and the effects of flow abnormalities (Table 1).

Treatment

According to the American Heart Association/American College of Cardiology (AHA/ACC) guidelines, in case of domed pulmonic valve with moderate or severe valvular stenosis and less than moderate pulmonic valve regurgitation, balloon valvotomy is recommended²⁵ (Figure 2).

Otherwise, surgical repair is recommended in case of symptomatic patients with moderate or severe valvular pulmonic stenosis who are ineligible for balloon valvotomy or who have failed it. This includes patients with severe PS and an associated hypoplastic pulmonary annulus, severe pulmonary regurgitation (PR), sub-valvular PS or supra-valvular pulmonic stenosis. Surgery is also preferred for most dysplastic valves and when there is associated severe tricuspid regurgitation or other cardiopathy that warrants operative intervention^{25, 26} (Figure 2).

At last, pulmonary valve replacement may be necessary when there is a failure with repair or severe residual symptomatic PR, in particular in cases with marked dysplasia of the pulmonary valve or significant hypoplasia of the annulus.²⁵

Balloon Pulmonary Valvuloplasty (BPV)

Balloon pulmonary valvuloplasty represents the first line of treatment for PS and should be performed as soon as the diagnosis is made, without waiting for the development of symptoms or the patients to reach a certain size. It has been described for the first time in 1982 by Kan et al, who used the approach of Gruntzing to alleviate PS using the radial forces of balloon inflation of a balloon catheter positioned across the pulmonary valve.²⁷ BPV is usually indicated when peak-to-peak gradient is more than 50 mmHg with normal cardiac index. It is currently the preferred therapeutic strategy for “doming” valvular PS.²⁸ However, it has also a palliative function in some diseases like tetralogy of Fallot.²⁹ Nowadays it has replaced surgical intervention as the initial treatment for moderate and severe PS thank to its safety and excellent early and intermediate outcome.³⁰ In fact, it is associated with low PR than surgery, but the same relief from

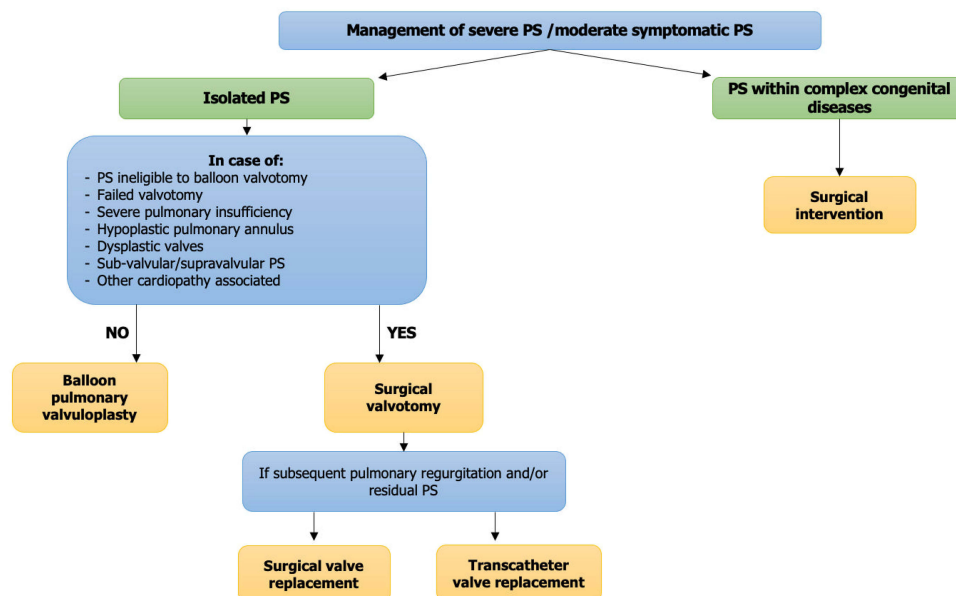


Figure 2 Flow chart for the management of patients with PS.
Abbreviation: PS, pulmonary stenosis.

restenosis. The procedure is usually performed through percutaneous femoral access and consists of introducing one or more balloon catheters across the stenotic valve, commonly over an extra-stiff guide wire, and inflating the balloons with diluted contrast material.

Procedural complications are rare, like transient bradycardia, premature beats and drop in systemic pressure, which usually regress after balloon deflation. Other complications reported are blood loss requiring transfusions, complete right bundle branch block, permanent or transient heart block, cerebrovascular accident, and cardiac arrest.³¹ Moreover, in nearly 30% of patients it's possible to develop a severe infundibular obstruction, which usually decreases during follow-up and rarely require surgical intervention.³² Complications are generally low in children and adults but more prevalent in infants and neonates. Immediately after the dilatation, a rapid reduction in gradient, increase in jet width, and free mobility of the pulmonary valve leaflets with reduced doming are usually seen with an improvement in RV and tricuspid valve function. Immediate and mid-term results (<2 years) are usually good: in the study of Hong et al,³¹ residual transvalvular pressure gradients of 67.31 ± 15.19 mmHg (range: 50–92 mmHg) were found in only 8.2% of patients, 6.4% of patients had variable-staged restenosis at follow-up and 3.8% underwent reintervention by balloon dilatation or surgical repairs.³³ The long-term outcome has historically considered excellent, but the most of available data comes from small, single center studies. The study of Hansen et al³⁴ aimed to evaluate long-term outcomes (25 years) following BPV for PS. Among 254 patients, 69 (29%) had \geq moderate PR, 41 (17%) had residual PS with peak gradient > 40 mmHg, and 31 (13%) had re-intervention.

Predictor of worst outcome after BPV are a dysplastic valve, a small annular size, an higher gradient immediately after the procedure and being neonates (< 1 year).⁴

Surgical Valvotomy

Surgical relief of PS was one of the first congenital heart operation and was described independently by Sellors and Brock in 1948.^{35,36} This first surgical procedure consists in a closed transventricular pulmonary valvotomy via the RV outflow tract. The Brock technique dilates and cuts the stenotic pulmonary valve and likely the pulmonary infundibulum using a valvulotome and dilators through a purse string in the RV below the native valves.^{37,38}

Surgical treatment was the preferred procedure for PS until the late 1980s, when the less invasive balloon valvuloplasty replaced surgery.^{27,31} Indeed, relieving the stenosis by splitting the valve leaflets is efficient but this relief occurs at the cost of PR, leading to right ventricular dilatation and tricuspid regurgitation. Nowadays surgical valvuloplasty is reserved for those patients with a hypoplastic pulmonary annulus, diminutive main pulmonary artery, or dysplastic pulmonary valves. In these patients, surgical repair is required to excise thickened and obstructive valve leaflets and place a transannular patch. Surgery is also the intervention of choice for patients with sub-valvular and supra-valvular PS.^{26,39,40}

Current surgery is associated with low early mortality and excellent long-term survival that is nearly as good as survival in the general population. Less favorable outcome is found only in patients operated at older age. An explanation for this may be the longer period of right ventricular pressure overload with subsequent right ventricular failure.^{41,42}

The most important sequel after successful valvotomy is residual PR requiring reintervention in one-quarter of the patients. The need for reoperation is not correlated with the pre-operative severity of stenosis, but rather with the surgical technique used and the amount of pulmonary regurgitation, which occurred after surgery.⁴³

Between possible complications, the incidence of supraventricular arrhythmias after repair of PS is very low and they are mainly present in patients with severe PR needing of reoperation and they generally disappear after reintervention.⁴⁴

Surgical Valve Replacement

A wide spectrum of CHDs requires pulmonary valve replacement with or without reconstruction of the right ventricular outflow tract.⁴⁵ Pulmonary valve replacement is also the main reintervention in patients with PS who have previously undergone valvotomy with subsequent PR and/or residual PS. Pulmonary valve replacement, if appropriately implemented, effectively alleviates right ventricular dilatation and dysfunction and resolves the related symptoms.^{46–49}

There are several options for pulmonary valve replacement, including:^{45, 50}

- Homograft conduits;
- Bovine jugular vein grafts;
- Mechanical prosthetic valves;
- Biological prosthetic valves.

Pulmonary Homograft

Homografts for pulmonary valve replacement have some advantages (low associate gradients, no need of anticoagulation) and some disadvantages (calcifications, valve insufficiency necessitating replacement).³³ However, compared to biological valves^{34, 35} no differences has been seen in terms of durability, rate of valve dysfunction, reintervention, acute complications. Finally, homografts as well as bovine jugular vein conduits have limited availability and sizes, therefore in most cases heterograft are preferred.^{27, 36}

Bioprosthetic Valves

Bioprosthesis are predominantly used for pulmonary valve replacement as they are associated with the minimal risk of a thromboembolic event and the lower rate of prosthesis failure in the pulmonary position.⁵¹ Furthermore, bioprosthetic valves have occupied a solid position with the advent of percutaneous pulmonary valve replacement, owing to the possibility of valve-in-valve implantation of a transcatheter prosthesis.⁵²

Because of the structural similarities between the pulmonary and aortic valves, the commercial valves that were originally developed for the aortic valve position have been used in the pulmonic position in patients with CHDs, especially those patients with RVOT dysfunction.⁵³

The most implanted bioprosthetic valves in the pulmonary position are the stented bovine pericardial valves. Originally designed for left-sided valvular heart disease, they have shown excellent results in the aortic and mitral valve position, and later in the pulmonary valve position and have become a leading choice for pulmonary valve replacement.^{45, 50}

Stented porcine valves represent another option for pulmonary valve replacement. The published experience with this type of bioprosthetic valves is significant, and most studies have reported favorable performance and durability with no relevant differences in freedom from replacement compared to bovine pericardial valves.^{50, 54–56}

Mechanical Valves

There are limited experiences about implanting mechanical valve in the pulmonary position.^{57, 58} However, while the age at pulmonary valve replacement is getting lower and life expectancy of the patients with CHDs increases, durability of the prosthesis has become a relevant issue, particularly in younger patients under high risk of repeated surgery. Consequently, mechanical prosthesis has received attention as an alternative for pulmonary valve replacement to minimize the risk of reoperation, because it does not need to be replaced again theoretically, if adult-sized prosthesis could be implanted.^{46, 57, 59}

The main disadvantage of mechanical valves is the higher rates of valve thrombosis, requiring lifelong use of anticoagulation medication.⁶⁰ Therefore, currently they are mainly used in patients with multiple prior operations or another need for anticoagulation, such as presence of a mechanical valve in other positions.⁶¹

Percutaneous Treatment

Symptomatic PS is frequently treated in childhood. However, even if severe PS is less prevalent in adults, sometimes it is possible to come across unrepaired PS or residual pulmonary valve stenosis after a previous intervention. Over the years, clinicians have focused on postponing surgical treatments for as long as feasible to reduce the number of surgical operations: in fact, long-term durability of conduits, bioprosthetic valves, and trans-anular patch (TAP) may be affected by the materials used, the age of the patient and the type of surgery.⁶² Significant PR after RVOT correction with TAP is seen in 48% of individuals

immediately after the operation and in 85% after 2 years;⁶² moreover, following an implantation of valved homograft, RVOT degenerative dysfunction, PR, and/or PS are detected in half of the patients during the first 10 years after the first operation and after 5–6 years after the second operation.^{63,64} This is associated to multiple surgical interventions which can increase morbidity and mortality. The management of these diseases has been radically changed by the introduction of the transcatheter pulmonary valve replacement (tPVR), leading to a reduction in the number of surgical interventions over lifetime.⁶⁵ The main available valves for transcatheter replacement are the Melody Valve and the Edwards SAPIEN XT and S3 Valves.

The Melody Valve

The Melody transcatheter pulmonary valve is a percutaneous valve system designed to treat obstruction or regurgitation of prosthetic conduits positioned between the RV and PAs.⁶⁶ The device consists of an 18 mm valved bovine jugular venous conduit sutured into a Cheatham platinum Stent. The bovine derived tissue and the valve morphology allows a good adaptation to several conduit diameter. The valve is implanted through femoral access using a Medtronic 22F Ensemble[®] Transcatheter Delivery System, which is a balloon-in-balloon system that allows the valve to be replaced after the inner balloon has been inflated, if necessary.⁶⁶ The main indications for Melody Valve use (from the US Melody Valve Investigational Device Exemption trial) are the following:^{9,67–69}

- Age \geq 5 years or weight \geq 30 kg;
- Original conduit diameter \geq 16 cm;
- Echocardiographic signs of RVOT conduit dysfunction;
- Patients in NYHA class $>$ I;
- Doppler mean gradient \geq 35 mmHg or \geq moderate PR;
- Patients in NYHA class I with Doppler mean gradient \geq 40 mmHg or severe PR associated with TV annulus Z-score \geq 2 RVEF $<$ 40%.

Procedural success is typically high, with a mean valve deployment success rate of 95%, an acute reduction of RV pressure to a median of 42 mmHg and a reduction in peak gradient across the RVOT to a median of 12 mmHg.⁹

Moreover, short and long-term outcomes are generally good. In the updated report from the multicenter US Melody trial from Mc Elhinney et al, freedom from diagnosis of stent fracture was $77.8 \pm 4.3\%$ at 14 months.⁷ Freedom from Melody valve dysfunction or reintervention was $93.5 \pm 2.4\%$ at 1 year.⁹ Furthermore, valvular replacement can reduce RV volumes and improve left ventricular diastolic function. In patients with significant RVOT obstruction, the Melody valve implantation improves exercise, cardiopulmonary function, ventricular systolic function, and early left ventricular diastolic filling pressure. Finally, transcatheter replacement with the Melody valve provides good hemodynamic and clinical outcomes up to 7 years after the intervention. In the work of Cheatman et al, the five-year freedom from reintervention and explanation was $76 \pm 4\%$ and $92 \pm 3\%$ respectively, and almost all patients were in NYHA class \leq II.⁶⁶

The main complication remains the stent fracture, which is associated with restenosis and need for reintervention. Other rare complications are conduit fracture, valve migration or embolization and, in the follow-up, endocarditis.⁶²

The Edwards SAPIEN XT and SAPIEN 3 Percutaneous Pulmonary Valve

If the Melody Valve was originally used only for stenotic RVOT conduits, the introduction of larger Edwards SAPIEN valves (SAPIEN XT valve and its next generation SAPIEN 3 valve) allowed tPVR to be performed also in native and wider RVOTs.^{70, 71} The SAPIEN XT valve is made of three bovine pericardial leaflets stitched to a cobalt chromium balloon expandable stent; SAPIEN 3 valve, on the other side, shows an improved frame geometry thanks to its low frame height and outer skirt made of polyethylene terephthalate which minimize paravalvular leak. Both valves are available in several diameters (20 mm only for SAPIEN XT, 23, 26, and 29 mm for both valves) which allow implantation in larger RVOT than the Melody.⁶² The 29 mm valves, in fact, suit with native or patched RVOT larger than 26 mm. Recently, the Altera stent has been released by Edwards Lifesciences: it is a single-size (40 \times 45 mm) nitinol self-expanding covered stent (hourglass) with a firm landing zone for SAPIEN S3 29 mm, suited for RVOT sizes up to 38 mm.^{72, 73}

The implantation procedure is often carried out through percutaneous femoral access using the NovaFlex catheter (Edwards Lifesciences Inc.) but, as a result of the engineering development in valve prosthesis, two recent technical changes in tPVR were introduced: the use of a 26-F larger Gore DrySeal sheath (Gore Medical, Flagstaff, Arizona)⁷⁴ and direct valve insertion without pre-stenting.⁷⁵ This more effective approach allows the valve to be directly implanted in the precise available landing zone, using angiography to deliver the valve in the correct position. Complications are similar to the ones reported for the Melody valve, with the exception of stent fracture which has not been reported for SAPIEN valves.

The short outcomes show excellent results with all types of RVOT: in a large cohort of patients who underwent tPVR with either a Sapien XT or S3 valve, the implant was technically successful in 754 (97.4%) patients, serious adverse events were described in 67 patients (10%), without difference between RVOT anatomy groups. Valve function at discharge was excellent in most patients, and only 58 (8.5%) had moderate or greater PR or maximum Doppler gradients >40 mm Hg. During the follow-up (median 12 months), 9 patients were diagnosed with endocarditis, and 17 additional patients underwent surgical valve replacement or valve-in-valve.⁷⁶ About the long-term outcomes of the XT valve, in the study of Le Ruz et al, the primary efficacy outcome (freedom from valve-reintervention) was met for 87.1% patients after a mean follow-up of 4.6 ± 1.8 years, corresponding to a freedom of reintervention at 5 years of 89% (95% CI 74.8–95.6%).⁷⁷ The ongoing COMPASSION S3 (ClinicalTrials.gov Identifier: NCT02744677) aims to demonstrate the safety and effectiveness of the Edwards Lifesciences SAPIEN 3 Transcatheter Heart Valve System in subjects with a dysfunctional right ventricular outflow tract (RVOT) conduit or previously implanted valve in the pulmonic position with a clinical indication for intervention.

New Prospective and Future Directions of tPVR

There is worldwide great interest in developing new devices (valves or RVOT reducers) and technologies to make more patients suitable for tPVR. In fact, even if indications for tPVR are limited to patients with RVOT diameter up to 22 mm for the Melody valve and up to 27 mm for the SAPIEN valve,⁷⁸ more than 80% of patients who are potential candidates for tPVR do not satisfy these criteria.^{79, 80} To face this problem, several RVOT reducing techniques have been proposed, as well as self-expanding valve systems. RVOT reducing techniques usually consist on the implantation of several stents before the insertion of the valve or anchoring multiple overlapping stents in one of the branch of the PA to allow the implantation of the valve into the protruding frame.^{62, 81} The first small experiences with self-expanding valve systems were in 2010 with the Valve Harmony[®] and in 2014 with the Venus P Valve (Venus Medtech, Shanghai, China): short term outcomes of first case series seem encouraging but larger studies are needed to evaluate long term efficacy and safety.^{82, 83}

Conclusions

PS is mostly a congenital disease, but it can also develop later in life due to other medical conditions. The severity of the stenosis can vary widely, ranging from mild to severe and potentially life-threatening. Although it is primarily a disease of childhood, its sequelae have become increasingly prevalent in the adult population due to improvements in diagnosis and treatment. One of the most significant advances in the treatment of PS is the development of percutaneous procedures and devices that can correct the condition without surgical intervention. This approach has proven to be effective and less invasive, offering patients a safe and efficient option for managing their condition.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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