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CLINICAL MANAGEMENT

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2024 Statement from Asia expert operators on transcatheter pulmonary valve replacement

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Abstract

Transcatheter pulmonary valve replacement (TPVR), also known as percutaneous pulmonary valve implantation, refers to a minimally invasive technique that replaces the pulmonary valve by delivering an artificial pulmonary prosthesis through a catheter into the diseased pulmonary valve under the guidance of X-ray and/or echocardiogram while the heart is still beating not arrested. In recent years, TPVR has achieved remarkable progress in device development, evidence-based medicine proof and clinical experience. To update the knowledge of TPVR in a timely fashion, and according to the latest research and further facilitate the standardized and healthy development of TPVR in Asia, we have updated this consensus statement. After systematical review of the relevant literature with an in-depth analysis of eight main issues, we finally established eight core viewpoints, including indication recommendation, device selection, perioperative evaluation, procedure precautions, and prevention and treatment of complications.

KEYWORDS
percutaneous pulmonary valve implantation, pulmonary regurgitation, transcatheter pulmonary valve replacement

1 | INTRODUCTION

Transcatheter pulmonary valve replacement (TPVR), also known as percutaneous pulmonary valve implantation, refers to a minimally invasive technique that replaces the pulmonary valve by delivering an artificial pulmonary prosthesis through a catheter into the diseased pulmonary valve under the guidance of X-ray and/or echocardiogram while the heart is still beating. TPVR was the earliest transcatheter valve replacement technology and was mainly used for patients with right ventricular outflow tract dysfunction (RVOTD) after right ventricular outflow tract (RVOT) reconstruction surgery or transcatheter dilatation, which is defined as pulmonary valve regurgitation and/or RVOT obstruction. In 2016, the Structural Heart Disease Group of Chinese College of Cardiovascular Physicians (CCCP) published the "Chinese Expert Advice on Transcatheter Pulmonary Valve Implantation,"[1] which played an important guiding principle in the promotion and development of TPVR in China. In recent years, TPVR has achieved remarkable progress in device development, evidence-based medicine proof, and clinical experience. To update the knowledge of TPVR in a timely fashion, and according to the latest research and further facilitate the standardized and healthy development of TPVR in Asia, we have updated this consensus statement.

A systematic search was conducted on PubMed, Web of Science, Embase, and Cochrane Library, and all relevant studies before February 2023 were collected. After systematical review of the relevant literature with an in-depth analysis of eight main issues, we finally established eight core viewpoints and provided recommended grades and evidence levels accordingly, recommendation level was based on GRADE evidence quality grading and definition: Class I recommendation means there is evidence proving that the treatment or intervention is beneficial, useful and effective with consensus reached; it is recommended to be applied. Class II recommendation means there are conflicting evidence or opinions on the usefulness/effectiveness of the treatment. Among them, Class IIa means that supporting evidence/opinions on its usefulness/effectiveness are more common and should be considered for application; Class IIb means that supporting evidence/opinions for its usefulness/effectiveness remain lacking and can be considered for application. Class III recommendation means there is evidence proving that the treatment or intervention is useless/ineffective and harmful in some cases and it is not recommended for application. The definition of level of evidence (LOE) is presented as follows: Level A evidence comes from multiple randomized clinical trials (RCTs) or their meta-analyses. Level B evidence comes from one randomized trial or large nonrandomized studies. Level C evidence comes from expert opinions or consensus and/or small retrospective studies, registry studies. The references for each core viewpoints were subsequently given.

2 | TECHNIQUE BACKGROUND

Congenital heart diseases (CHD) with RVOT obstruction, such as tetralogy of Fallot (TOF), pulmonary valve stenosis, transposition of the great arteries with RVOT obstruction, double outlet right ventricle with RVOT obstruction, persistent truncus arteriosus and pulmonary atresia, and many other lesions, require RVOT reconstruction during surgical correction to relieve the RVOT obstruction. In the past, RVOT enlargement surgery (transannular patch enlargement or infundibulectomy) was more commonly used in developing countries than valved conduit.[2,3] The former resulted in pulmonary regurgitation (PR) immediately after surgery, whilst PR due to artificial valve degeneration in the

late stage was more common in the latter stages, which may be combined or not combined with RVOT obstruction (i.e., RVOTD). Moreover, transcatheter dilatation of the or transcatheter dilatation may occasionally cause PR. Long-term PR leads to increased right heart volume overload and right heart enlargement, followed by right heart failure, atrial or ventricular arrhythmias, and even sudden death. At the same time, increased right ventricular volume load leads to a paradoxical movement of the interventricular septum and subsequently left heart dysfunction,[4,5] finally contributing to the lower survival rate in the long-term in comparison to healthy population.[6,7] Hence, it is necessary to treat severe PR for improving patient symptoms, reversing right ventricular remodeling, preserving patient cardiac function, and possibly prolonging their survival in the long term.[8–10]

Therapies for PR reduction can be divided into surgical pulmonary valve replacement (SPVR) and TPVR. Although studies showed that SPVR and TPVR have similar perioperative mortality rates, midterm mortality rates, and re-intervention rates; TPVR presents with lower perioperative complication rates and shorter hospital stays.[11–15] TPVR has obvious advantages such as less trauma and faster recovery than SPVR. According to the 2018 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of congenital heart disease, no clear recommendation leaning toward TPVR or SPVR regarding pulmonary valve replacement was made.[16] However, the 2020 European Society of Cardiology (ESC) guidelines for management of congenital heart disease indicated that TPVR is preferred if patients are anatomically suitable.[17] Currently, TPVR has been applied in more than 20,000 patients worldwide. The Chinses domestic interventional pulmonary valve Venus-P has been commercially available since 2022.

Core Viewpoint 1: For patients with moderate-to-severe or severe RVOTD after RVOT reconstruction surgery, TPVR can improve patient symptoms related to RVOTD, reverse volume overload of the right ventricle, and improve the cardiac function (COR I, LOE B).[18–23]

Core Viewpoint 2: For patients in need of pulmonary valve replacement, TPVR is preferred if anatomically feasible; for patients who are not anatomically suitable, SPVR should be considered (COR IIa, LOE B).[11–14]

TPVR devices can be theoretically divided into balloon-expandable valves and self-expandable valves. Balloon-expandable valves include Melody valve (Medtronic) and Sapien valve (Sapien XT and Sapien3) (Edwards Lifesciences). The latter were originally used for transcatheter aortic valve replacement (TAVR), however, evaluation in patients with dysfunctional RVOT proved their suitability for TPVR.[24,25] These two valves are currently the most commonly used valves worldwide and have been certified by CE in Europe and the US Food and Drug Administration (FDA). The Melody valve stent is prone to stent fracture (whilst the Sapien valve is not), and meta-analysis showed the Melody valve to have a high rate of stent fracture, 12.4%.[26] The incidence of this complication has recently been significantly reduced with prior placement of a fixed stent technology (prestenting).[27,28] Studies have also shown that the long-term re-intervention and infective endocarditis rates of Melody valve to be higher than those of Sapien valve.[29]

Self-expandable valves include Harmony valve (Medtronic),[30] which has been certified by the FDA, the Chinse domestic Venus-P[21,31] and PT-Valve,[32] and the Pulsta valve. Venus-P valve has obtained CE and NMPA certification for listing, whilst PT-Valve has completed premarketing clinical trial enrollment before listing in China. Finally, the Pulsta valve from South Korea has completed clinical trials in Europe and is awaiting CE approval.[33]

Balloon-expandable valves adopt a straight tube design, relying on the radial support force for anchoring, and are more suitable for patients with valved conduits and bioprosthetic valves. Self-expandable valves adopt a dumbbell design, which can prevent stent dislodgment, and are more suitable for patients with autologous outflow tracts, also referred to as "native" outflow tracts. However, in some patients post "native outflow tract reconstruction," placement of a stent and then a balloon-expandable valve inside is possible. In 2021, the US FDA approved the combined use of SAPIEN 3 and ALTERRA for those patients.[34] The characteristics of various pulmonary valve devices are shown in Table 1, and the physical image of the valves are shown in Figure 1.

TABLE 1 Summarization of different transcatheter pulmonary valve replacement (TPVR) valve characteristics.

Device	Type	Year of first-in-human implantation	bioprosthetic valve material	Stent material	Size (mm)	Approval agency
Melody	Balloon-expandable valve	2000	Bovine jugular vessels	Platinum iridium	20, 22, 24	CE/FDA
Sapien XT/3	Balloon-expandable valve	2006	Bovine pericardium	Cobalt chromium alloy	20, 23, 26, 29	CE/FDA
Harmony	Self-expandable valve	2010	Porcine pericardium	Nitinol	23.5	FDA
Pulsta	Self-expandable valve	2017	Porcine pericardium	Nitinol	18, 20, 22, 24, 26, 28	Clinical trial in progress
Venus P	Self-expandable valve	2013	Porcine pericardium	Nitinol	18–34	CE/NMPA
PT-valve	Self-expandable valve	2018	Porcine pericardium	Nitinol	20, 23, 26	Clinical trial enrollment completion
ALTERRA	Self-expandable valve	2017	No bioprosthetic valve	Nitinol	27	FDA

Abbreviations: CE, Conformite Europeene; FDA, United States Food and Drug Administration; NMPA, National Medical Products Administration (China).

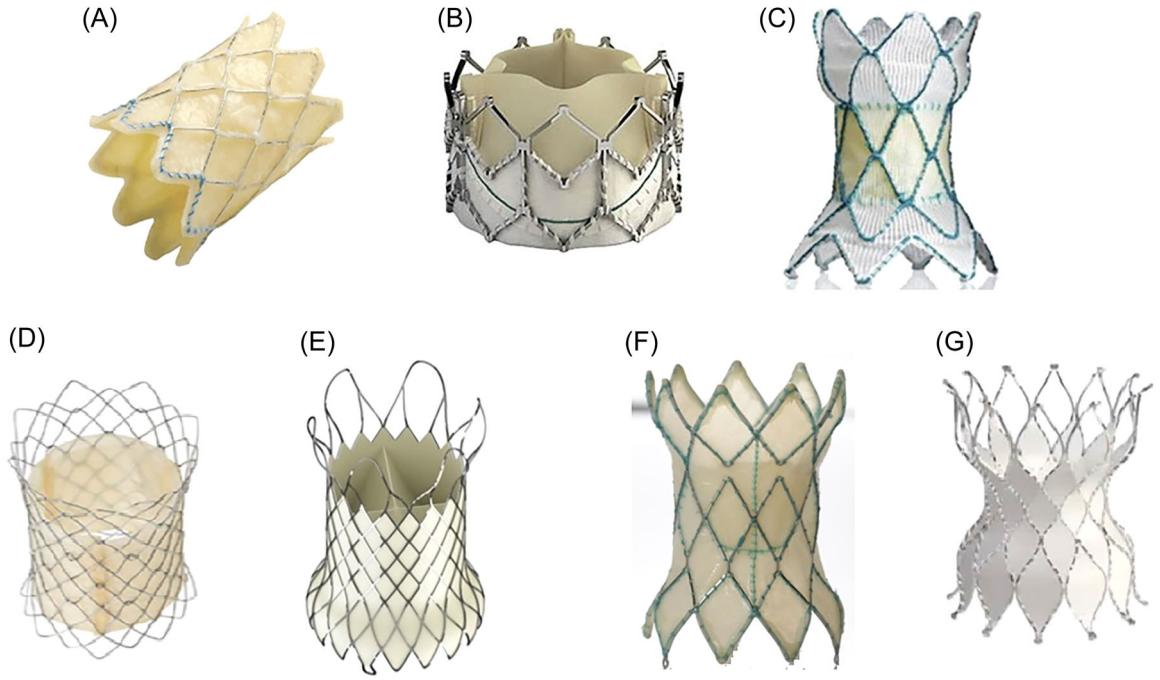

FIGURE 1 Physical images of major transcatheter pulmonary valve replacement (TPVR) devices. (A) Melody; (B) sapien XT; (C) harmony; (D) pulsta; (E) venus P; (F) PT-valve; (G) ALTERRA. [Color figure can be viewed at wileyonlinelibrary.com]

Core Viewpoint 3: For patients with valved conduit, selection of balloon-expandable valves is more prevalent; for patients with native outflow tract, selection of self-expandable valves is more prevalent (COR IIb, LOE C).

3 | INDICATIONS AND CONTRAINDICATIONS

Based on recent research progress and international guidelines,[16,17] the indications and contraindications for TPVR have been updated as follows:

3.1 | Indications

(1) Moderate to severe or severe PR after cardiac surgery or transcatheter dilatation for congenital heart disease with RVOT stenosis, with or without RVOT obstruction;
(2) Anatomically (including vascular approach) suitable for TPVR;
(3) With clinical symptoms related to RVOTD, including decreased exercise tolerance, right heart failure, and symptoms caused by related arrhythmia (palpitations, amaurosis, syncope, etc);
(4) No clinical symptoms but having any of the following conditions: (a) Right ventricular enlargement, right ventricular end diastolic volume index (RVEDVi) ≥ 150 mL/m² and/or right ventricular end-systolic volume index (RVESVi) ≥ 80 mL/m² measured by cardiac magnetic resonance imaging (CMR); (b) Moderate or severe tricuspid valve insufficiency; (c) Severe right ventricular dysfunction (right ventricular ejection fraction <45%) or progressive decline in right ventricular ejection fraction during follow-up within 6 months; (d) Severe RVOT obstruction: right ventricular systolic pressure >80 mmHg and/or right ventricular systolic pressure ≥2/3 systemic pressure (indication for using balloon expandable valve); (e) Existing high-risk factors for sudden death, such as QRS duration ≥180 ms, ventricular tachycardia induced by electrophysiological examination, and so on.[35,36]

3.2 | Contraindications

(1) Severe pulmonary hypertension that cannot be corrected;
(2) Anatomically unsuitable, including inability to insert valves through vascular pathways or inability to place valves in RVOT-pulmonary artery (PA), or prediction that valve stents may compress the coronary artery;
(3) Active endocarditis or other systemic infection;
(4) Contraindications to perform cardiac catheterization.

***Core Viewpoint 4:** TPVR is suitable for patients with moderate to severe PR or severe PR after surgical correction or transcatheter dilatation of congenital heart disease with RVOT stenosis, with or without RVOT obstruction, with suitable anatomy, and RVOTD-related clinical symptoms[24,37–43] (COR I, LOE B).

***Core Viewpoint 5:** TPVR is suitable for patients with moderate to severe PR or severe PR after surgical correction of congenital heart disease with RVOT stenosis, with or without RVOT obstruction, with suitable anatomy, without relevant clinical symptoms but accompanied by right ventricular enlargement, tricuspid valve regurgitation, severe RVOT obstruction, severe or progressive right ventricular dysfunction or at high risk for sudden death[24,37–43] (COR IIa, LOE B).

4 | PERIOPERATIVE IMAGING EVALUATION

Accurate imaging evaluation is the foundation for the success of TPVR. The main purpose of preoperative evaluation is to clarify the anatomical characteristics, to screen patients who meet the indications for TPVR, and to assist the operator in selecting the appropriate prosthetic valve type, determining the surgical approach, and simulating the release process. Intraoperative imaging evaluation aims to evaluate the accurate localization and function of prosthetic valve. Postoperative imaging evaluation aims to evaluate the effectiveness of the operation and the presence of complications.[44]

4.1 | Echocardiogram

Echocardiogram is the most preferred noninvasive imaging evaluation method for screening suitable populations for TPVR.

4.1.1 | Preoperative evaluation

Transthoracic echocardiography (TTE) can accurately evaluate the morphology and functional status of the heart and pulmonary valve, providing evidence for patient screening and selecting prosthetic valve types. The main echocardiographic parameters to be evaluated for patients preparing for TPVR include the size and function of right ventricle and left ventricle, the estimated endsystolic pressure of the right ventricle and pulmonary artery, the severity of pulmonary valve regurgitation/stenosis, the inner diameter and length of RVOT, PA and the origin of the branches and to rule in or out any associated cardiac lesions (atrial septal defect, ventricular septal defect, etc).

4.1.2 | Intraoperative monitoring and postoperative follow-up

During TPVR procedure, transesophageal echocardiography (TEE) or TTE can be used to evaluate prosthetic valve function after implantation and comprehensive cardiac function evaluation. During the procedure, TTE can assist in the early diagnosis of acute or subacute procedure-related complications, such as pericardial effusion, abnormal prosthetic valve position and function. Mid to long-term follow-up echocardiogram can further evaluate the cardiac function, morphology, and functional status of prosthetic valve after TPVR.

4.2 | Electronic computed tomography angiography (CTA) imaging

CTA of the heart and the pulmonary arteries can clearly display the anatomical structure of the RVOT-PA through three-dimensional imaging, and measure the lumen diameter, circumference, and length, providing evidence for prosthetic valve type selection. Meanwhile, the operator can evaluate the anatomical characteristics of coronary arteries and adjacent structures from multiple angles to assess the risk of coronary artery compression during the procedure through 3D CT modeling. It should be noted that RVOT-PA has great elasticity, and its inner diameter changes during systolic and diastole phases of the cardiac cycle. Therefore, CTA scanning should implement electrocardiographic gating, measuring the values of end-systolic and end-diastolic phases respectively.

4.3 | Cardiac magnetic resonance (CMR)

CMR is the "gold standard" for evaluating right ventricular size, function, and pulmonary valve regurgitation in PR patients receiving TPVR.

4.3.1 | Preoperative evaluation

CMR mainly includes three-dimensional steady-state free-precession (3D-SSFP), whole heart systolic, diastolic, and contrast enhanced MR angiography (CE-MRA). Among them, 3D-SSFP is triggered by heart and respiratory signals, this sequence can comprehensively evaluate left and right ventricular function, calculate ejection fraction, end-diastolic, end-systolic volume and volume index, stroke volume, cardiac output, and myocardial mass.[45] Furthermore, late gadolinium enhancement is important to evaluate for scar tissue that may lead to malignant ventricular dysrhythmias.[46]

4.3.2 | Postoperative follow-up

CMR can assist in evaluating the improvement of right ventricular volume and function in patients after TPVR.[47]

***Core Viewpoint 6:** Preoperative, intraoperative, and postoperative echocardiogram should be performed on patients undergoing TPVR, to assess the patient's cardiac function, heart size, right ventricular end-systolic pressure, and pulmonary valve function. Furthermore, preoperative pulmonary artery CTA will help to evaluate RVOT-PA anatomy, which provides the main evidence for patient screening and prosthetic valve type selection[48,49] (COR I, LOE C).

5 | ESSENTIAL OPERATING PRINCIPLES

5.1 | Preparation in general

In a hybrid operating room or cardiac catheterization room, TPVR procedure is typically carried out under general or local anesthesia. Echocardiography and digital subtraction angiography (DSA) are needed for guidance throughout the procedure. Biplane catheterization DSA is preferred choice. The femoral vein is the preferred invasive approach (when the patient's femoral vein approach is not appropriate, the patient's jugular vein can be chosen as an

alternative). To perform intraoperative angiography and other procedures, the femoral artery and vein on the opposite side are also needed for the procedure. Afterward, an appropriate dose of heparin is given to keep an activated clotting time (ACT) of >200 s.

5.2 | Intraoperative assessment

First, a right heart catheterization examination must be carried out, frequently using a multipurpose (MPA) catheter. Secondly, a pigtail catheter is used to perform angiography in the right ventricle or the pulmonary artery to evaluate pulmonary valve regurgitation, and the morphology, length and diameter of RVOT, main PA and left and right PA. Typically, biplane angiography is performed using the frontal camera in the right anterior oblique view with cranial angulation or left anterior oblique with cranial angulation and the lateral tube as straight lateral. Preoperative CTA can help determine the ideal projection degree, allowing intraoperative angiography to clearly display the main PA and the left and right PA. Balloon testing and measurement are performed after the angiography. An exchange length, ultra-stiff or super-stiff guide guidewire is positioned in the distal branch of the pulmonary artery, and the sizing balloon is advanced over the guidewire to the RVOT-PA junction. Balloon testing is necessary for two important things: to measure the size of the outflow tract and the coronary compression test. For the size of the outflow tract, this is performed by inflating the balloon in the RVOT-PA junction whilst injecting in the body of the right ventricle using the contralateral femoral vein; for coronary compression this is performed by injection in the ascending aorta whilst the balloon is occluding the RVOT-PA junction. The balloon measurement (sizing) can serve as a reference for determining the size of the valve to be used. We recommend select a valve 2–4 mm larger than the diameter of the balloon occluding the RVOT-PA junction.

5.3 | Artificial valve: Size selection and deployment process

Preoperative CTA (or CMR) data, echocardiography data, intraoperative angiograms, balloon measurements, and manufacturer guidelines are all used to determine the appropriate valve size. However, balloon sizing is currently considered as the most important measurement.

Subsequently, the valve is loaded into the valve delivery system and delivered to the RVOT-PA over the guidewire, which has been positioned in the distal branch PA. To prevent potential valve displacement and PA blockage risks, it is recommended to release the valve from a relatively high position and slowly release the starting segment to provide the operator with a certain amount of space and time to adjust, based on the shape of the valve and the influence of surrounding structures.

Multiple angiographies are necessary throughout this phase to confirm the location of the valve to make sure the valve does not obstruct the PAs and that the majority of body of the valve is situated in PA rather than RVOT. Once the optimal valve position has been determined, the valve is completely released and the delivery system withdrawn.

5.4 | Evaluation following valve deployment and procedural approach management

Right heart catheterization examination is repeated to reassess the pressure of the right heart system. PA angiography is necessary to evaluate the function of the implanted pulmonary valve and its location. Using echocardiography, determine the pulmonary valve position and function as well as whether complications occurred during the procedure. To confirm that the coronary artery is not obstructed, coronary angiography is also required. Last but not least, withdraw the guiding sheath and achieve hemostasis either by direct compression or figure-of-eight stitch.

5.5 | Special strategies

The most difficult step of this procedure is advancing the delivery system into the pulmonary artery. Normally, to help move the delivery system into the PA, the guidewire can be slightly withdrawn whilst the delivery catheter is rotated and pushed. Special strategies can be used for some truly difficult instances, including:

(1) Long sheath introduction: Place a long-enough delivery sheath to the PA to serve as a delivery approach.
(2) Auxiliary approach supporting strategy: place a long delivery sheath and super-stiff guide wire through the auxiliary approach to straighten the twisted RVOT-PA.
(3) PASS technology: place a long delivery sheath through the auxiliary approach to PA, through which passed over a snare to capture the distal end of the super-stiff wire and to strengthen the support force of the super-stiff guide wire of the main pathway.[50]

***Core viewpoint 7:** During TPVR, right heart catheterization should be performed to evaluate the pulmonary artery pressure before and after valve implantation; Balloon dilation testing should be performed as a reference for device selection and coronary artery compression risk assessment[38,51,52] (COR I, LOE C).

6 | PREVENTION AND TREATMENT OF COMPLICATIONS

6.1 | Coronary artery compression

Coronary artery compression is one of the most serious complications in the early stage of TPVR, which can lead to intraoperative

death in patients.[51] In patients with coronary artery dysplasia or abnormal relationship between RVOT and coronary artery anatomy, the incidence of coronary artery compression after TPVR may be up to 22%.[52] At present, the standard method for detecting the risk of coronary artery compression during TPVR is to conduct compression tests using balloons of the same size as the planned valve.[17] Preoperative coronary CTA can also help predict the risk of coronary compression.

6.2 | Infective endocarditis

Infective endocarditis is an important adverse event that affects the prognosis of TPVR, and it is also one of the relatively frequent complications. According to the literature, the incidence of infective endocarditis after TPVR may be 2%–25%,[53] mostly within 9 months after TPVR.[26] However, recent studies suggest that the risk of endocarditis after TPVR is always present,[54] and multivariate analysis suggests that the high-pressure gradient in the RVOT and young age are independent predictors of endocarditis after TPVR. Other risk factors include previous implantation of valved conduits, previous history of endocarditis, previous implantation of bovine jugular vein valves, no prophylactic use of antibiotics, dental and other invasive procedures, bacteremia (skin, nail infection), and so on.[55–57] To reduce the incidence of infective endocarditis after TPVR, prophylactic antibiotics should be used in strict accordance with the recommendations of the guidelines for the prevention of infective endocarditis after TPVR. Once this complication occurs, anti-infective treatment should be given first, but some patients may still require surgical valve removal and replacement.[58]

6.3 | Valve displacement

A meta-analysis showed that the incidence of artificial valve displacement after TPVR was 2.4%.[26] Device placement is often associated with inaccurate preoperative measurement of the valve annulus, an inadequate size valve, and adverse RVOT anatomical morphology (conical shape).[40] Accurate preoperative evaluation and measurement are the key to avoiding valve displacement. To prevent valve tugging and displacement, cautious operation is also necessary when withdrawing the delivery system. Once valve displacement occurs, surgical treatment is generally adopted.

6.4 | PA injury

During TPVR, ultra-stiff or super-stiff guidewires must be used to insert the delivery system into the PA. However, the stiffness of the guidewire may lead to PA injury (including PA dissection and perforation), which in turn can cause pulmonary hemorrhage or hemothorax. Once PA dissection or perforation occurs, the size of the injury should be evaluated by selective PA angiography. Balloon dilation for hemostasis and thoracic drainage can be performed first. If necessary, interventional embolization or covered stent placement can be performed to isolate the ruptured PA. Surgical repair is an option in serious situations.

6.5 | Pulmonary artery obstruction

The meta-analysis showed that the incidence of pulmonary artery occlusion was 1.2%.[26] By placing the valve body in the main PA, the risk of PA blockage can be reduced. Once PA occlusion develops, techniques like employing a snare to pull the valve stent down or using a balloon to enlarge the valve stent mesh can be utilized as treatments.

6.6 | Tricuspid valve chordae tendineae damage

Tricuspid valve chordae tendineae may be damaged during TPVR, which can then result in or worsen tricuspid regurgitation. Carefully manipulate the catheter and if it appears that the catheter may have wrapped around the chordae tendineae of the tricuspid valve, the catheter should be withdrawn first. Balloon-tipped catheters or pigtail catheters can be utilized to lessen the chance of tricuspid valve tendinous cord tangling whilst entering the pulmonary artery from the right atrium.

6.7 | RVOT conduits rupture

In individuals with calcification of valved conduits, when utilizing high-pressure balloon dilatation, conduits may rupture.[59] Balloon dilation for these individuals must be done carefully and with prudence.

6.8 | Valve stent fracture

Valve stent fracture is one of the most common complications after Melody valve implantation. At present, the use of preimplanted stent technology has been proven to significantly reduce the incidence of stent fracture.[60] This complication is rare in other types of pulmonary valves.

6.9 | Failure of the bioprosthetic valve

The implanted **bioprosthetic** valve may develop deterioration during follow-up. The process of valve deterioration may occur gradually after TPVR because the pulmonary circulation blood flow shear force and flow rates are lower than those of the systemic circulation. Long-term follow-up revealed that the majority of bioprosthetic pulmonary valves (including domestic VenusP-valves) without infective

endocarditis may still retain satisfactory function even after more than 8–10 years of usage.[11,61] Once a valve fails (stenosis or regurgitation), further TPVR or surgical valve replacement is required.

7 | POSTOPERATIVE MANAGEMENT

Following TPVR, it is advised to administer antibiotics intravenously for 3 days. Single antiplatelet medication has to be taken orally for 6 months in patients who have no reasons to be given anticoagulation. It is recommended that patients undergo outpatient follow-up in the first, third, sixth, and twelfth months after TPVR, as well as annually thereafter. Echocardiogram, electrocardiogram, and CMR (if necessary), are recommended to evaluate the integrity of the valve stent, the function of the valve, and the structure and function of the heart. Infective endocarditis should be actively prevented.

* **Core Viewpoint 8:** Following TPVR, patients should actively prevent the occurrence of infective endocarditis, that is, strict adherence to the recommendations of the guidelines for the prevention of infective endocarditis of bioprosthetic valves, and use antibiotics prophylactically under the conditions of invasive operation and exposure to high-risk factors[54–58] (COR I, LOE C).

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in PubMed, Web of Science, Embase, and Cochrane Library.

ETHICS STATEMENT

This study was conducted in accordance with the principles of the Declaration of Helsinki.

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