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Transcatheter Pulmonary Valve Replacement: The Venus P valve-Current Status

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Abstract

There is growing appreciation for the long-term adverse impact of right-sided dysfunction of the pulmonary valve in patients with congenital heart disease. Although pulmonary valve stenosis or regurgitation is often tolerated over the short and intermediate terms, the long-term consequences are numerous and include, but are not limited to, right-sided heart failure, arrhythmias, and sudden cardiac death. Surgical right ventricular outflow tract (RVOT) interventions have been performed for many decades as an initial therapy, but comorbidities associated with repeated surgeries are a concern. Transcatheter pulmonary valve replacement is safe, effective, and performed at an increasing number of centers around the world. It offers an alternative to traditional surgical techniques and may potentially alter the decision-making process whereby valvular replacement is performed prior to the development of long-term sequelae of RVOT dysfunction. However, only ~15% of potential patients with RVOT dysfunction are suitable for currently approved implantable valves (i.e., Melody valve from Medtronic and Edwards Sapien valves from Edwards Lifesciences). These two valve systems are designed and approved for patients with a conduit or bioprosthetic valve between the right ventricle and pulmonary artery, and they exclude most patients who undergo transannular patch repair techniques. The Venus P-valve (Venus Medtech, Shanghai, China) is a recently developed self-expanding transcatheter heart valve designed to adapt to a dilated RVOT and in such it provide patients with a percutaneous interventional option after transannular patch repair.

Key Words

Transcatheter pulmonary valve replacement • Venus P valve-Current status • Congenital heart disease

Introduction

Progress in surgical interventions for congenital heart disease over the past few decades has allowed more children to survive well into adulthood. Most of these patients will require multiple surgical procedures over their lifetime. This can be associated with increased morbidity and mortality [1, 2] due to chest adhesions, bleeding, cardiac ischemia, arrhythmia burden, heart failure, and multi-organ dysfunction [3-7]. Since the introduction of the first balloon-expandable valve in the pulmonary position by Bonhoeffer et al. [8] in 2000, advances in interventional cardiology and transcatheter pulmonary valve replacement (tPVR) have revolutionized the management of these patients. The availability of these minimally invasive and effective therapies may allow for earlier treatment of right ventricular outflow tract (RVOT) dysfunction before the onset of irreversible ventricular remodeling and dysfunction. Moreover, transcatheter options can reduce the need for multiple surgical interventions over a patient's lifetime, thereby minimizing the morbidity of this growing patient popu-

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lation [9]. tPVR is categorized as a class II American Heart Association recommendation for conduits with moderate-to-severe stenosis or regurgitation, provided the patient meets inclusion and exclusion criteria for the available valves [10]. However, only ~15-20% of potential patients with RVOT dysfunction are suitable for currently approved implantable valves [11]. The design and approval of currently available valves (i.e., Melody valve and Edwards Sapien valves) are for patients with a conduit or bioprosthetic valve between the right ventricle (RV) and pulmonary artery (PA), leaving most patients without a percutaneous interventional option after transannular patch repair.

Limitation of Currently Available Devices

Presently, two commercial transcatheter heart valves systems exist: the Melody valve (Medtronic Inc., Minneapolis, Minnesota, USA) and the Edwards Sapien XT valve (Edwards Lifesciences, Irvine, California, USA). The maximum diameter is 22 mm for the Melody valve and 26 mm for the Sapien XT valve [12]. The Edwards valve has evolved over recent years, with an increased range of sizes including the 29-mm Sapien XT and, more recently, the Sapien S3 valve. Both valves are mounted on a balloon-expandable stent platform and require pre-stenting to create an optimal landing zone and reduce the chances of stent fracture or stenosis (for the Melody valve) of the framework after valve implantation [11-13]. For RVOT diameters >26–27 mm or patients with native RVOT post-transannular patch or very expansile RVOT, pre-stenting followed by implantation of these valves is very challenging. Despite these limitations, in the absence of a larger diameter valve, operators have achieved some success of implanting the presently available valves in patients with a native/patched RVOT. Meadows et al. [14] reported on 31 patients with RVOT patch repair who underwent implantation of the Melody valve; at a median follow-up of 15 months, no patient had greater than mild pulmonary regurgitation (PR). Eight patients developed more than mild pulmonary valve obstruction, six of whom experienced stent fractures. Boudjemline et al. described successful implantation of the Melody valve in 13 patients with patched RVOT using technical variations such as implantation of multiple coaxial stents to reduce the diameter (i.e., "Russian doll technique") or anchoring multiple overlapping stents in one PA branch to allow implantation of the valve into the meshwork protruding into the main PA (thereby jailing the opposite PA) [15]. Similar results were reported for the Sapien valve [16]. The 29-mm Sapien XT was recently used successfully for large native or patched RVOT with excellent results [17]. Although several reports of other challenging techniques using the two approved valves describe good immediate hemodynamic results, no data on long-term follow-up are available. Therefore, more recent efforts have concentrated on designing a self-expanding system to provide valve competence despite significant dilation of the native RVOT [18, 19].

Self-Expanding Platform Design (The Venus P-Valve)

The Venus P-valve (Venus Medtech, Shanghai, China) is a recently developed self-expanding transcatheter heart valve designed to adapt to a dilated RVOT [20].

Valve and Delivery System

The Venus P-valve consists of a stent using a Nitinol frame. The valve leaflets are made of porcine pericardium preserved in low-concentration solutions of buffered gluteraldehyde that are hand-sewn to the multi-level self-expanding Nitinol frame. The frame has proximal and distal flares to anchor the valve in the RVOT and PA bifurcation, respectively. The proximal flare is completely covered by pericardial tissue, whereas the distal flare is an open cell wire frame allowing access into the PA branches. The middle part is tubular and straight, fully houses the valve, and is intended to be expanded in the main PA. For ease of identification, there are two radiopaque platinum markers at the proximal and distal flare junctions with the straight segment. The valve is located approximately 5 mm distal to the proximal marker. The diameters and lengths of the straight segment range from 18 to 34 mm (in 2-mm increments) and from 20 to 35 mm (in 5-mm increments), respectively. After cardiac magnetic resonance (CMR) and angiographic evaluation, the valve length can be selected to match the length of the main PA to reduce the possibility of obstruction of the RV body or PA branches and to

reduce paravalvar leak. The proximal and distal flare diameters are 10 mm larger than the diameter of the straight segment. There are two small "ears" at the proximal part of the valve for attachment to the delivery system. The frame is made of a single Nitinol tube by laser-cutting. This design improves frame integrity; however, manufacturing of different sizes to fit patient anatomy is more time-consuming and costly. There are five (previously six) open cells in the distal flared part to allow easy access to the branch PA, with a wire across to decrease the chance of fracture of the distal stent. Figure 1 depicts the current design of the valve. The delivery system (Figure 2) consists of a 20–22-F capsule and a 16-F, 100-cm-long shaft with a rotating handle for deployment of the valve. The valve prosthesis is loaded into the capsule by submerging the Nitinol frame in sterilized cold saline solution and crimping the frame with a crimper provided by the manufacturer.

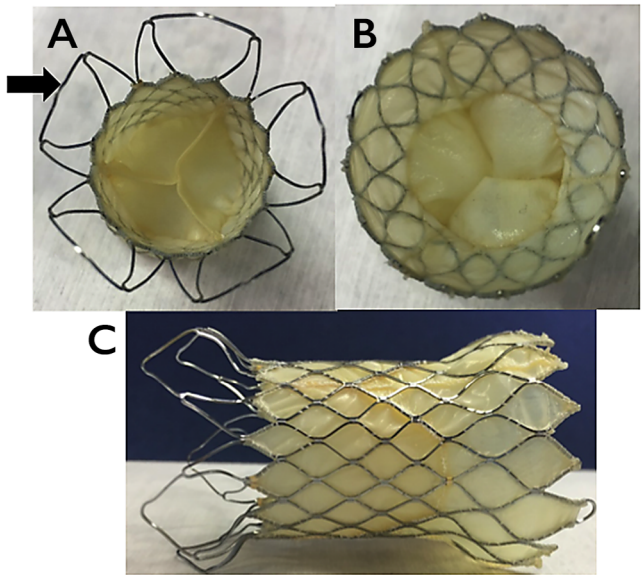

Figure 1. The Venus P-valve Nitinol frame. *Panel A*. Note the new design of the valve with five open cells (**black arrow**). *Panel B*. The valve viewed from below (from the right ventricle outflow portion), with *Panel C* being the straight segment of the valve.

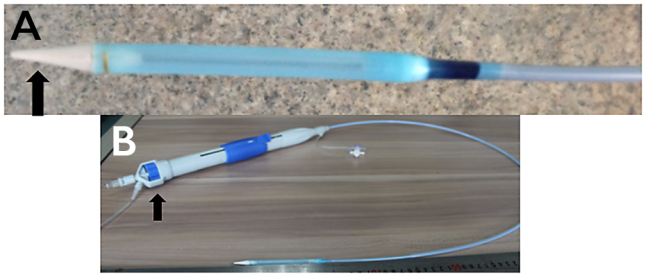

Figure 2. Delivery system with its components. *Panel A*. Carrot at the tip (**arrow**). *Panel B*. Shaft and handle with rotating knob (**arrow**) to allow slow valve deployment.

Pre-Procedural Evaluation

Due to the wide variety of post-operative anatomical variants existing within this group of patients, the most crucial step for Venus P-valve implantation is the initial detailed anatomical assessment of the RVOT. Schievano et al. [21] evaluated variations in postoperative RVOT morphology in 83 patients using CMR, assessing implications for tPVR. Five different morphological subtypes were identified, and although type I morphology (i.e., pyramid-shape) was most commonly seen in those undergoing transannular patch, type II–V morphologies were also seen within this subgroup.

CMR is important for understanding anatomy and initial device size selection. It is advisable to perform cardiac catheterization before valve implantation for better valve selection, especially as different valve sizes may not be available on the shelf. This should be done for complete hemodynamic assessment and measurement of RVOT and PA dimensions. Angiograms in the main PA and RVOT can be done in the antero-posterior or right anterior oblique with cranial angulation and lateral projections. Measurements of the maximum systolic diameter of the RVOT, the main PA at the mid-part and its bifurcation, the maximum systolic diameter of the proximal and distal PA branches, and the length from the RVOT to PA bifurcation can be obtained. Simultaneous selective left coronary angiography (or ascending aorta angiography) and inflation of a sizing balloon in the main PA should be routinely performed to assess expansibility and diameters as well as proximity of the left coronary artery system to the RVOT. Important differences of up to 4.7 mm between CMR and angiographic balloon measurements have been noticed. Undersizing may lead to possible migration of the valve. To prevent valve migration, the implanted valve diameter should be 2–4 mm larger than the maximum diameter of the main PA on balloon interrogation.

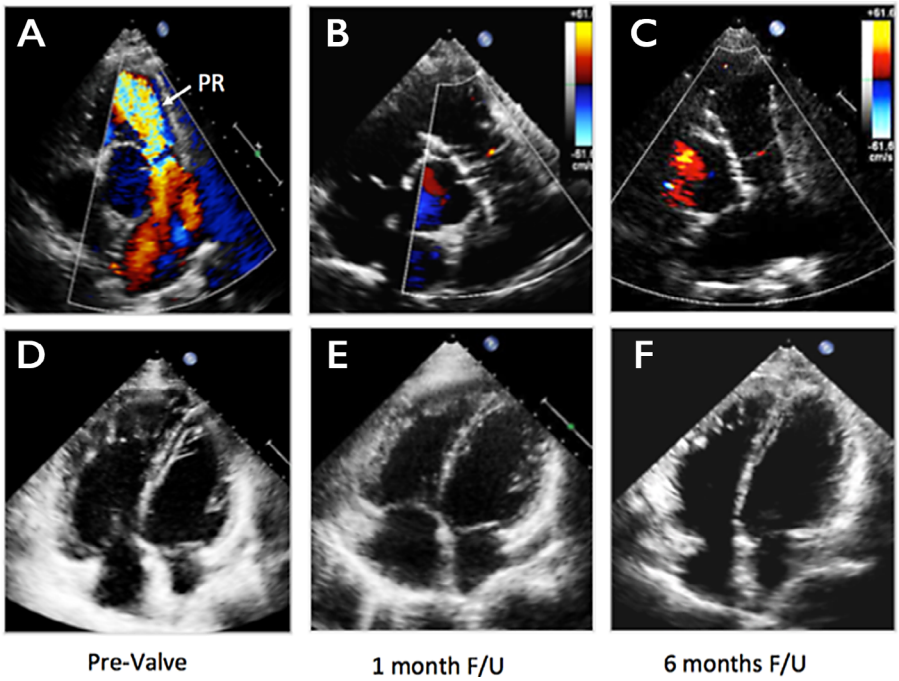

Figure 3. Series of color (*Panels A, B, C*) and two-dimensional transthoracic echocardiography four-chamber view images performed at baseline (*Panels A, D*), 1-month follow-up (*Panels B, E*), and 6-month follow-up (*Panels C, F*) in a 20-year-old female patient after surgical closure of ventricular septal defect and right ventricle outflow obstruction using a patch. She had severe pulmonary regurgitation. These images demonstrate sustained resolution of free pulmonary regurgitation and significant remodeling of the right ventricle. The **white arrow** in the *Panel A* image indicates severe pulmonary regurgitation, and the images in *Panels B and C* demonstrate a competent Venus P-valve (26 mm) with trivial if any regurgitation. The *Panel D* image shows a large right ventricle, and the images in *Panels E and F* show significant remodeling of the right ventricle at 1- and 6-month follow-up, respectively.

Procedure and Follow-Up

It is advisable to perform the procedures under general endotracheal anesthesia. Access should be via both right and left femoral veins (right femoral for device deployment and left for angiographic control), and the femoral artery should also be accessed to assess coronary artery proximity to the RVOT. Heparin 100 U/kg should be administered to maintain activated clotting time of >250 s. Intravenous antibiotics should be given at the beginning of the procedure followed by two doses 8 hours apart. Transesophageal echocardiography (TEE) or intracardiac echocardiography can be performed during the procedure to monitor the RVOT before and after valve implantation. However, this step is optional. Hemodynamic assessment and detailed angiography including balloon sizing can be repeated if needed. A 260-cm long 0.035" Lunderquist extra-stiff guide wire (Cook Medical, Bloomington, Indiana, USA) or any other stiff wire can be positioned in the PA, preferably in the distal left lower PA branch. Intended valve diameter selection should be 2–4 mm larger than the balloon inflation diameter at its waist, whereas mid-body length selection should be equivalent to the distance from the RVOT to PA bifurcation.

After preparation of the valve by rinsing with 2,000 ml normal saline for at least 10 min, the valve is manually crimped in a bath of cold normal saline onto a 20–22-F delivery system. The valve assembly is then passed through a 22-F Check-Flo® Performer Extra-Large Introducer sheath (Cook Medical) and manipulated over the Lunderquist guide wire. The distal carrot tip of the assembly then is advanced into the proximal left PA. Frequent check angiograms through a pigtail catheter placed in the main PA should be done as the distal flare of the valve is slowly deployed by clockwise rotation of the releasing knob. The valve position can be adjusted after check angiograms

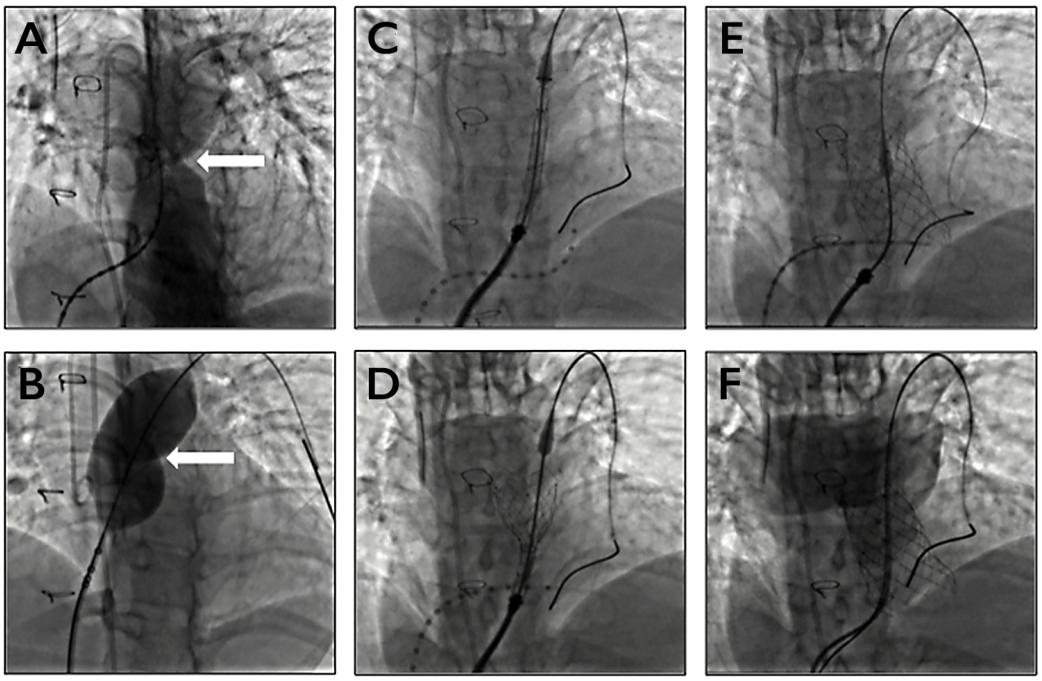

Figure 4. Series of cineangiographic images in frontal projection in a 20-year-old female patient (same as in Figure 3) with severe pulmonary regurgitation. *Panel A*. Angiography of the main pulmonary artery showing severe regurgitation and mild narrowing (**arrow**). *Panel B*. Cinefluoroscopy during balloon sizing and simultaneous ascending aortography showing indentation at the pulmonary annulus (**arrow**) measuring 22–24 mm. *Panel C*. Cinefluoroscopy of the valve assembly in the main pulmonary artery. *Panel D*. Cinefluoroscopy during gradual deployment of a 26-mm Venus P-valve. *Panel E*. Cinefluoroscopy after complete valve deployment. *Panel F*. Cineangiography of the main pulmonary artery showing competent valve.

are performed before it is fully deployed. When the middle segment of the valve is exposed, if it is fully opposed to the main PA, and because this stent segment is fully covered, there may be hypotension or bradycardia from low pulmonary blood flow for a brief period. The valve has to be deployed rapidly to allow normalization of cardiac output. After deployment and release of the valve, RV and PA pressures should be measured and angiography performed in the main PA to assess valve function. Hemostasis of the femoral venous access site can be achieved using direct pressure or a figure-of-eight suture. Alternatively, prior to introducing the large sheath, one or two Perclose ProGlide 6-F Suture-Mediated Closure Systems (Abbott Vascular, Santa Clara, California, USA) may be used [22].

After the procedure, the patient should be monitored in a cardiac intensive care unit or cardiac ward, depending on the hospital system. The patient should receive 81 mg aspirin for 6–12 months. Electrocardiogram (ECG), chest X-ray, and transthoracic echocardiography (TTE) should be performed before discharge. Patients should be followed up in the outpatient clinic at 1-, 3-, and 6-month intervals and yearly thereafter. The follow-up includes clinical evaluation, ECG, chest X-ray, and TTE. In addition, 6 months after the procedure, a CMR can be performed to assess RV volume and performance. Figures 3 and 4 show a patient with severe PR who underwent tPVR using a 26-mm Venus P-valve. Note the sustained competent valve function and remodeling of the RV upon follow-up.

Clinical Experience

The early results with this valve are encouraging. The first clinical human experience using a self-expanding percutaneous stent valve (Venus P-valve) was reported by Cao et al. [20]. In this study, five patients (four females) with a mean weight of 54.9 kg were selected for attempted valve deployment. Patients were NYHA class II (n = 3) or class III (n = 2) at baseline. Pulmonary insufficiency was grade 4 in all

cases, with mean RV end-diastolic volumes (RVEDVi) of 155 ml/m^2 on CMR. Mean minimum "annular" diameter on TTE was 22.8 mm and mean RVOT diameter was 31.8 mm. The valve was successfully implanted in all patients, with implanted valve diameters ranging from 26 to 32 mm. The mean fluoroscopy time (FT) was 22.8 min. Upon mean follow-up of 3.4 months, PR grade was 0 (n = 3) or 1 (n = 2) in all cases. NYHA class improved at least one class in all cases, and RV volumes assessed by TTE normalized in all three patients with follow-up to 3 months. This first cohort of patients is still being followed up and shows continued good valve function up to 3 years post-procedure.

Promphan et al. reported one of the earliest clinical human experiences using the Venus P-valve [23]. In this study, six patients (four males) with a median age of 18.5 years and mean body weight of 53.8 kg were selected. All patients were NYHA class II and had severe PR with mean RVEDVi of 146 ml/m^2 on CMR. The valve was successfully implanted in all patients, with implanted valve diameters ranging from 24 to 32 mm. The mean FT was 29.8 min. No patients had significant RVOT gradient or PR immediately after valve implantation. Only one patient had unexpected mild proximal valve migration to the RV body during withdrawal of the delivery system, causing mild paravalvar leak and significant tricuspid regurgitation. At 6-month follow-up, the median RVEDVi decreased from 146 to 108 ml/m^2. Additionally, the Doppler systolic peak gradient across the valve ranged from 4 to 40 mmHg, there was no evidence of stent fracture on fluoroscopy or structural valve failure, and patients' symptoms improved significantly.

Recently, Husain and colleagues reported their experience implanting the Venus P-valve in Europe [24]. In this study, five patients with a median age of 14 years and mean body weight of 88.4 kg were selected. Two patients were NYHA class II, and three patients were class I. All patients had significant PR with a mean RVEDVi of 131 ml/m^2 on CMR. The valve was successfully implanted in all patients, with implanted valve diameters ranging from 28 to 32 mm. The mean procedure duration was 136.2 min. No patients had significant RVOT gradient or PR immediately after valve implantation. There was no mortality and no major morbidity. Only one patient had jailing of the right PA requiring right PA stent implantation. Post-procedural follow-up (median follow-up 8.5 months, range 3–15 months) with TTE and CMR showed no restenosis or regurgitation with significant improvement in RVEDVi.

In 2017, Garay et al. reported successful implantation of the Venus P-valve in 10 patients (seven female) [25]. The patients' mean age was 32 years and mean weight was 59.6 kg. Seven patients were NYHA class II, and three patients were class III. All patients had moderate to severe PR with mean RVEDVi of 139 ml/m^2 on CMR. The valve was successfully implanted in all patients, with implanted valve diameters ranging from 26 to 32 mm. The mean FT was 29 min. There were no procedure-related complications and no evidence of paravalvular leak in any of the patients. During a mean follow-up of 12 months (range 4–21 months), all patients remained NYHA class I. TTE and CMR 6 months after implantation of the valve showed sustained and significant reduction of PR in all patients. In six patients, the median pulmonary regurgitant fraction was 1% (range 0–5%) and the RVEDVi was 78 ml/m^2 (range 66–100 ml/m^2). No stent fracture was demonstrated on fluoroscopic follow-up at 6 months.

Current Status of the Valve

As of August 2017, the Venus P-valve has been implanted in 110 patients with very good initial results worldwide (China, United Kingdom, India, Thailand, Ireland, Indonesia, Chile, Jordan, Qatar, and Argentina). All patients are undergoing rigorous follow-up protocols, and obtained data will be published in the future. The manufacturer has submitted a protocol to the notified bodies in a few European countries to evaluate the valve in patients after transannular patch repair with severe PR. Data obtained will be used to seek a CE mark approval.

Summary

It is challenging to deal with patients who have undergone tetralogy of Fallot repair using the transannular patch repair technique and who have a larger dilated RVOT that exceeds the size of commercially available balloon expandable valves. Several techniques have been described to adapt these valves for patients with native RVOT; although they show good

immediate hemodynamic effect, there are no long-term follow-up data. In addition, these techniques require extensive pre-stenting. Later generations of the Sapien valve (Sapien XT and Sapien 3) are FDA-approved for use in the aortic position and are being used by multiple centers for off-label implantation in the pulmonary position. Larger diameter Sapien valves (26 and 29 mm) allow for implantation in large dysfunctional native or patched RVOTs [26].

With a self-expanding platform design, the Venus P-valve can conform to a dilated and curved structure of the RVOT. Furthermore, there is no need for pre-stenting to create a landing zone. Initial studies reveal that Venus P-valve implantation is feasible and safe in patients with severe PR after previous correction of tetralogy of Fallot, in whom a transannular patch has been used. The valve is durable in the short-term and has not shown any stent fracture or valve malfunction 6–12 months after implantation. The valve restores early, sustained pulmonary competence with RV remodeling and improved clinical symptoms. Further long-term studies are warranted.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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