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ORIGINAL RESEARCH

# 1-Year Outcomes of PT-Valve for Pulmonary Regurgitation in Native Outflow Tract

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## ABSTRACT

**BACKGROUND** Severe pulmonary regurgitation (PR) in patients with postoperative congenital heart disease is often accompanied by extensive variability of right ventricular outflow tract (RVOT) anatomy, which limited the wide application of existing transcatheter pulmonary valves device.

**OBJECTIVES** This study sought to evaluate 1-year safety and efficacy of the PT-Valve in the treatment of PR patients presenting with native RVOT from a multicenter, single-arm clinical trial.

**METHODS** We enrolled 130 patients of moderate or greater PR. One-year clinical outcomes are reported.

**RESULTS** Within the cohort (mean age 30 ± 16 years; 52% men), 124 (95%) were diagnosed with tetralogy of Fallot. The procedure success rate was 98.5%. Early explants occurred to 2 device malpositions and 1 pulmonary branch obstruction. At 1 year, there were no procedure- or device-related mortality. Device-related adverse events included 2 arrhythmias, 1 pulmonary thromboembolism, 2 endocarditis, and 1 vascular access complication. Echocardiography examinations showed that 125 (99%) patients had none/trace and mild PR, and no greater than mild paravalvular leak at 1-year visit. The mean peak pulmonary gradient was 20.0 ± 17.4 mm Hg and 16.0 ± 7.8 mm Hg at baseline and 1 year after implantation, respectively. The right ventricular end-diastolic volume index was reduced from 176.3 ± 28.4 mL/m$^2$ at baseline to 121.1 ± 20.7 mL/m$^2$ at 1 year ($P < 0.001$).

**CONCLUSIONS** The PT-Valve demonstrated a high success rate of implantation and favorable safety and efficacy in the treatment of PR through 1 year. This device is anatomically suitable for more than 90% of PR patients with native RVOT. (Prospective, Single Arm, Multi-Center Clinical Study on the Safety And Efficacy of the Sterile Transcatheter Pulmonary Valve and Delivery System; ChiCTR2100043367) (JACC Asia. 2025;5:568-581) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Patients with congenital heart conditions, notably those diagnosed with tetralogy of Fallot, often face the distress of pulmonary regurgitation (PR) either immediately following surgical interventions or as a progressive condition.[1] These surgeries involve complex procedures, such as pulmonary trunk excision, the removal of obstructive muscle bundles, and the utilization of patches to

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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widen the passage from the right ventricular (RV) to the pulmonary artery (PA).[2] The consequence of severe PR is the dilation of either the native right ventricular outflow tract (RVOT) or surgically repaired RVOT, marked by extensive anatomical variations and unpredictable cyclic deformations.[3] These factors render transcatheter therapy uniquely challenging.

Although there have been attempts to address PR using transcatheter pulmonary valves (TPVs), their widespread application has been limited because of the vast RVOT anatomical variability. The existing TPV devices have shown promise, but the lack of large-scale and long-term evidence has constrained their broader adoption.

The Med-Zenith PT-Valve, developed by Beijing Med-Zenith in China, employs a self-expanding deployment method. Our preliminary single-center trial demonstrated promising results, particularly among patients with enlarged native RVOTs.[4,5]

In this comprehensive report, we present the outcomes of our 1-year study, which involved a patient cohort from 17 medical centers across China. This study aims to provide a more robust understanding of the valve's performance and its potential to address PR in native RVOT of congenital heart disease patients over the long term.

## METHODS

**STUDY DESIGN AND PATIENT SELECTION.** To evaluate mid-term safety and effectiveness of the PT-Valve, we conducted a nonrandomized, prospective, single-arm objective performance criteria study at 17 major centers of congenital heart disease in China from December 2020 to March 2023 after approval from the China Food and Drug Administration and Hospital Medical Ethics Committee (ChiCTR2100043367). The principal research institution is Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China.

For screening, all subjects needed to complete transthoracic echocardiography and computed tomography angiography (CTA) to assess their suitability for PT-Valve implantation. Cardiac magnetic resonance (CMR) imaging was performed at several capable centers.

The inclusion criteria of the patients included the following: 1) age ≥10 years or weight >25 kg; 2) PR fraction ≥30% measured by CMR imaging, or no less than moderate PR by echocardiography; 3) meet the clinical indication for pulmonary valve replacement (PVR), defined as symptomatic secondary to PR or a right ventricular end-diastolic volume index (RVEDVI) ≥150 mL/m$^2$ or the ratio of RV end-diastolic volume to left ventricular end-diastolic volume ≥2.0; and 4) with native RVOT.

Patients whose anatomical condition was not suitable for implantation of PT-Valve were excluded. As in those whose diameter of native RVOT all the way to the main pulmonary artery (MPA) was ≥40 mm. Other exclusion criteria are included in Supplemental Table 1.

The suitability for implantation was decided by a dedicated heart team composed of experienced clinical and interventional cardiologists, imaging specialists, cardiovascular surgeons, and anesthesiologists. The protocol and consent forms were approved by site-specific Institutional Review Boards. Written informed consent was obtained from all patients or legal guardians (under 18 years of age).

We screened 193 patients of moderate or greater PR with native RVOT. According to the assessments of CTA, 178 patients were considered to meet the anatomical conditions of implantation. A total of 48 patients were excluded for the following reasons: 1) did not meet the inclusion criteria—insufficient indication for PVR; 2) comorbid with other cardiac or noncardiac diseases—young women who have not yet married or have children/patients combined with severe aortic valve regurgitation or residual ventricular septal leak who need open-heart surgery; or 3) without written informed consent—asymptomatic patients who refused the operation. Eventually 130 patients were enrolled. The patientselection flow is included in **Figure 1**.

**DEVICE DESCRIPTION.** The PT-Valve is a porcine pericardial tissue valve mounted on a symmetric, self-expanding nitinol frame fully covered by porcine pericardium (**Figure 2**). The device has 5 sizes, whose outflow/inflow part ranges from 28 to 44 mm, and the overall length varies from 38 to 54 mm. The diameter of valved section in the middle portion is 20, 23, or 26 mm, smaller than both ends to avoid compression. The TPV is pretreated with a specific alcohol and surfactant to mitigate leaflet calcification. The delivery system is a 21-F integrated catheter including an outer sheath for valve compression, an attachment system for frame placement and a tapered nose cone facilitating delivery.

**IMPLANT PROCEDURE.** Both the distal and proximal device landing zone diameters, including the pulmonary trunk below the PA bifurcation, mid-PA,

### ABBREVIATIONS AND ACRONYMS

**CMR** = cardiac magnetic resonance

**CTA** = computed tomography angiography

**MPA** = main pulmonary artery

**PA** = pulmonary artery

**PR** = pulmonary regurgitation

**PVL** = paravalvular leak

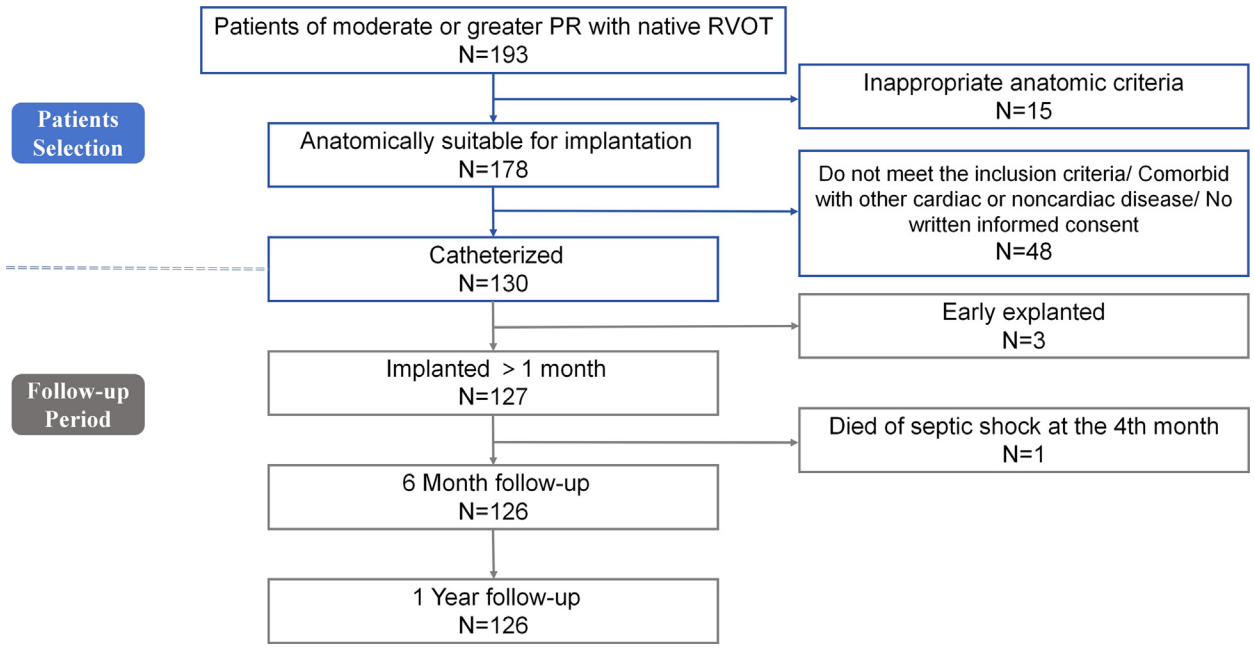
**RVOT** = right ventricular outflow tract

**TOF** = tetralogy of Fallot

**TPV** = transcatheter pulmonary valve

**TPVR** = transcatheter pulmonary valve replacement

**FIGURE 1 Patient Flow in Selection and Follow-Up Period**



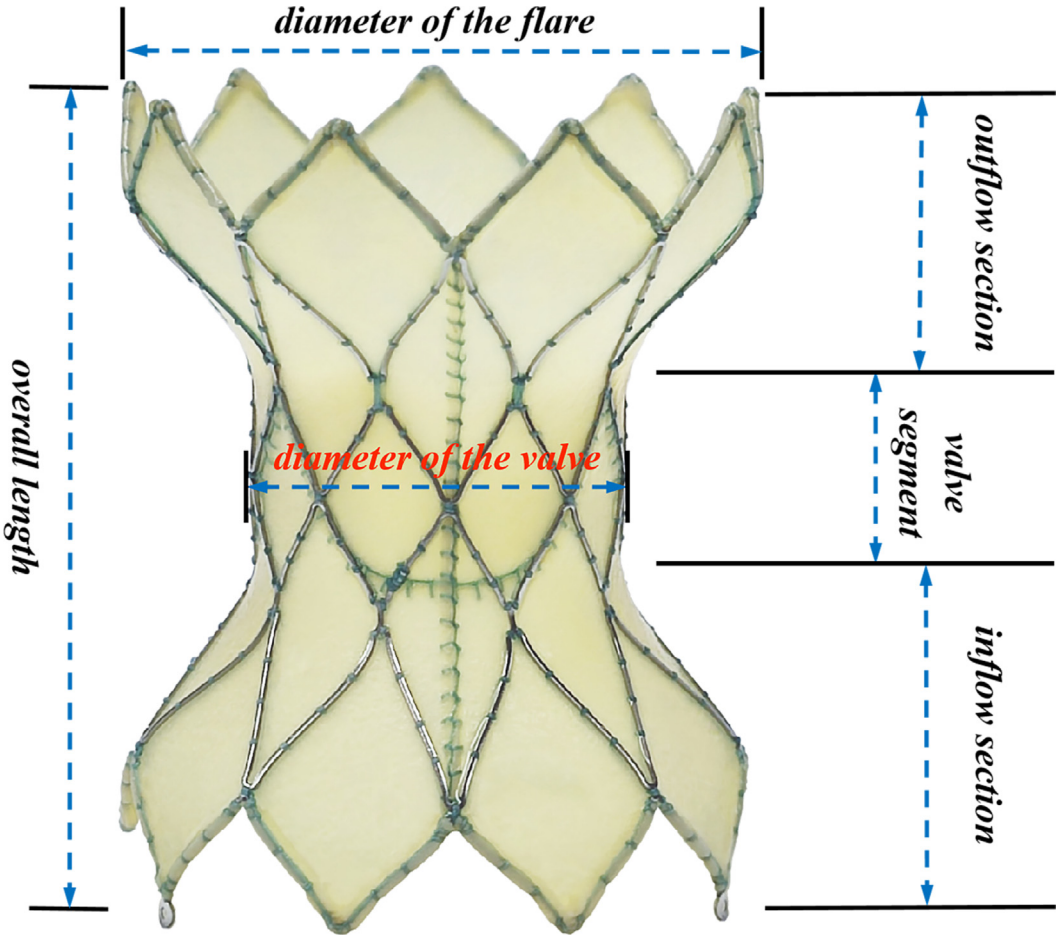

In the patient selection phase, we screened 193 patients with pulmonary regurgitation (PR) with native right ventricular outflow tract (RVOT) initially, and 63 patients were excluded. A total of 130 patients underwent catheterization, and 127 patients remained implanted for more than 1 month. 126 patients completed the 1-year follow-up. TPVR = transcatheter pulmonary valve replacement.

sinotubular junction, sinus, annulus, and the RVOT aneurysm, were measured on the basis of the preoperative CTA images and 3-dimensional reconstruction. The main anchoring mechanism of the PT-Valve relies on the frame suspended at the anatomically narrow ring to sustain the fixation of the device, rather than relying on excessive compression of the valve housing. In most cases, the landing zone of the distal flare is situated in the mid-PA with proximal flare in the RVOT aneurysm, and the relatively narrow ring could be the sinotubular junction or the pulmonary annulus. An oversize of 5 to 10 mm in the diameter of PT-valve flare than the mid-PA (the landing zone) and 8 to 14 mm than the systolic sinotubular junction or annulus was generally used for the sizing strategy to ensure the stability. At the same time, the waist diameter of the selected size is often no larger than the narrowest diameter. It should be noted that the diameter of the pulmonary annulus may be larger in the diastolic phase than in the systolic phase, and diastolic measurements need to be taken into account. For patients comorbid with RVOT obstruction or pulmonary stenosis, it is necessary to evaluate the local expandability and the diameter that can be expanded based on the stenosis characteristics, the length of the stenosis segment, and the diameters of the proximal and distal ends. Under these circumstances, balloon predilation should be conducted during the procedure to verify assessments.

Procedures were performed in a hybrid operating room while patients were under general anesthesia. RVOT angiography was performed according to CTA-based optimal view for device implantation. Coronary artery imaging and balloon sizing was performed if a high risk of coronary compression was predicted by the CTA image. A 21-F delivery system was advanced through the right femoral vein into PA after an extra-stiff wire was placed in the distal PA.

The valve was deployed beginning at the distal MPA, just beneath the bifurcation. Angiography was performed during deployment of the valve frame. The proximal strut was deployed into the distal RVOT. The frame containing the bioprosthetic valve was released with a final unsheathing of the 3 recessed attachments. After complete deployment, the

**FIGURE 2** **Diagram of the PT-Valve**



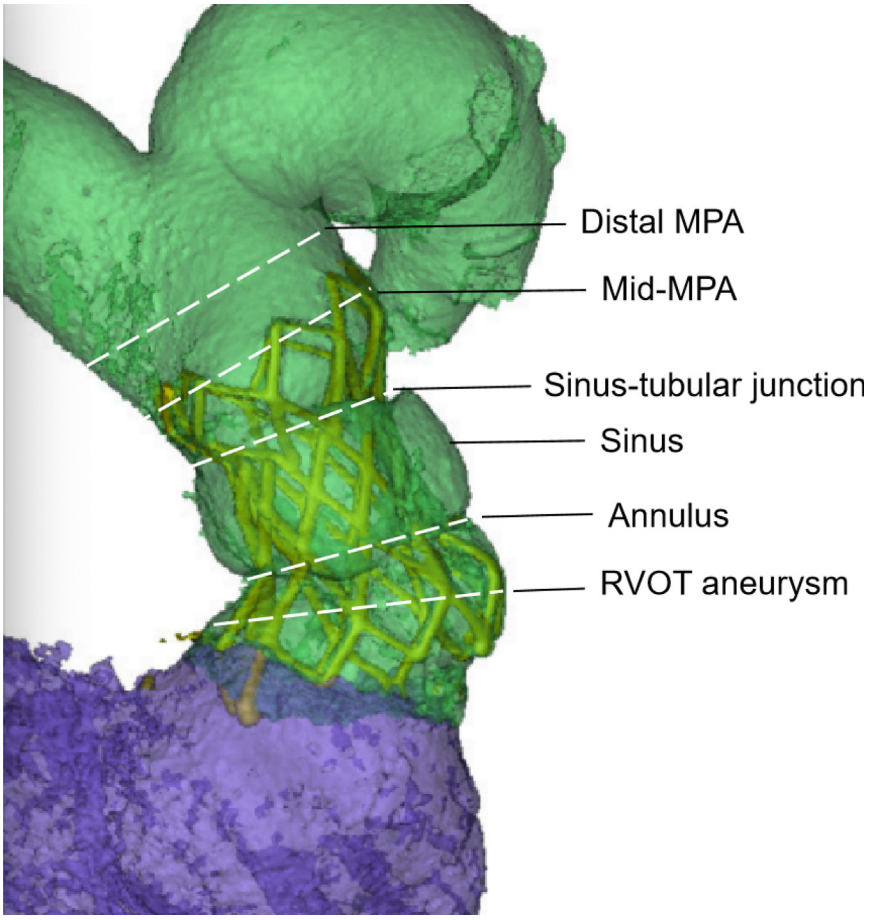

The PT-Valve is a porcine pericardial tissue valve mounted on a dumbbell-shaped nitinol frame fully covered by porcine pericardium. The proximal and distal flares are symmetrically identical. The device has 5 sizes. The diameter of the outflow/inflow flare ranges from 28 to 44 mm, and the overall length varies from 38 to 54 mm. The diameter of the valve in the middle portion is 20, 23, or 26 mm, and the length of the valve segment ranges from 10 to 15 mm.

delivery system was withdrawn carefully. The ideal result of PT-Valve implantation is depicted in Figure 3.

Before the procedure, most patients did not take antithrombotic drugs, except for those with indications for anticoagulation. During the procedure, heparin was injected to keep the activated clotting time more than 200 seconds. Postoperatively, according to the practice for implanted bioprosthetic valves,[6] patients were given dual antiplatelet therapy for 3 to 6 months, followed by long-term single antiplatelet therapy. For patients with indications for anticoagulation, such as atrial fibrillation/flutter or deep vein thrombosis, warfarin was used to maintain an INR between 1.8 and 2.5 preoperatively and postoperatively.

**CLINICAL DATA COLLECTION AND ENDPOINTS.** The follow-up examinations included assessment of NYHA functional classification, transthoracic echocardiography, electrocardiograph, and chest x-ray. Data were collected at preimplant and postimplant, and at follow-up periods of 1, 3, and 6 months and 1 year by investigators from each site and summarized by primary investigator. CMR imaging was performed at several capable centers preimplant and 1 year after device implantation. The CMR imaging included steady-state free precession cine imaging, phase

**FIGURE 3** The Ideal Result of PT-Valve Implantation




Ideally, the PT-Valve is intended to land between the middle plane of the main pulmonary artery (MPA) and the middle right ventricular outflow tract (RVOT), and eventually anchored by distal flare of the stent located in mid-MPA. The main anchoring mechanism relies on the frame suspended at the anatomically narrow ring to sustain the fixation of the device.

contrast flow measurements in the pulmonary arteries. Cine images were used to calculate end-diastolic and end-systolic volumes and ejection fractions, while pulmonary regurgitant fractions were calculated from phase contrast flow curves. Postoperative CTA examinations were performed in volunteer subjects at 1 year.

The primary safety endpoints were procedure success rate and freedom from procedure- or device-related mortality. Other outcomes included device malposition, coronary artery compression, pulmonary branch obstruction, pulmonary thromboembolism, reintervention of the TPV, frame fracture, endocarditis, arrhythmia requiring intervention, and vascular access complications.

Efficacy at 1 year was assessed through hemodynamic performance including severity of PR, paravalvular leak (PVL), and peak transpulmonary gradient in the implanted cohort. The degrees of PR, PVL, and peak transpulmonary gradient were assessed by echocardiography in each site, and the endpoints were self-reported by the sites and then judged by a clinical endpoints committee. PR was graded with color Doppler as none, trace or trivial, mild, moderate, moderate to severe, or severe.

**STATISTICAL ANALYSES.** The statistical analyses were performed using SPSS version 20.0 (SPSS Inc) and R 4.4.1 (CRAN). Continuous variables are expressed as mean ± SD. Categorical variables are

**TABLE 1 Baseline Characteristics in Catheterized Patients (N = 130)**

| | |
|---|---|
| Male | 67 (51.5) |
| Age, y | 30.2 ± 16.4 |
| Weight, kg | 59.5 ± 15.9 |
| BMI, kg/m$^2$ | 21.9 ± 4.5 |
| Original diagnosis[a] | |
| Tetralogy of Fallot | 124 (95.4) |
| Right ventricular outflow tract obstruction | 5 (3.8) |
| Pulmonary stenosis | 4 (3.1) |
| Dysplastic pulmonary valve | 5 (3.8) |
| Age of surgical repair of right ventricular outflow tract, y | 11.3 ± 13.8 |
| Time between surgical repair and TPVR, y | 18.2 ± 9.2 |
| Echocardiography | |
| Pulmonary regurgitation | |
| Moderate to severe | 21 (16.2) |
| Severe | 109 (83.8) |
| Peak transpulmonary gradient, mm Hg | 19.9 ± 17.4 |
| LV ejection fraction, % | 64.0 ± 7.0 |
| CMR[b] | |
| Pulmonary regurgitation fraction, % | 47.5 ± 7.2 |
| RV end-diastolic volume index, mL/m$^2$ | 176.3 ± 28.4 |
| RV ejection fraction, % | 51.1 ± 9.7 |
| Electrocardiogram | |
| Atrial fibrillation and atrial flutter | 16 (12.3) |
| Ventricular arrhythmia | 4 (3.1) |
| Number of previous open-heart procedures | 1.4 ± 0.7 |
| NYHA functional classification | |
| I | 3 (2.3) |
| II | 102 (78.5) |
| III | 21 (16.2) |
| IV | 4 (3.1) |

Values are n (%) or mean ± SD. [a]Percentage calculated from number of evaluable patients; percentages within original diagnosis may not sum to 100%. [b]Cardiac magnetic resonance (CMR) data were available in 37 patients.

BMI = body mass index; LV = left ventricular; RV = right ventricular; TPVR = transcatheter pulmonary valve replacement.

presented as numbers and proportions (%). To compare the CMR data from preimplantation to 1 year, the *P* value was calculated from the paired Student's *t*-test and Mann-Whitney *U* test. The change in proportions for ordinal categories over time were tested using Stuart-Maxwell's test. A value of $P < 0.05$ was considered significant.

## RESULTS

**PATIENTS.** Between December 2020 and March 2023, 130 patients (67 men, 63 women) were enrolled and underwent transcatheter pulmonary valve replacement (TPVR) with the PT-Valve at mean ages of 30 ± 16 years, and the median follow-up period was 22 months, varying from 12 to 39 months. Overall, 109 (84%) patients had severe PR and 21 (16%) patients had moderate to severe PR at baseline. Besides, 9 patients (7%) were comorbid with RVOT obstruction or pulmonary stenosis, and 6 of them had a peak transpulmonary gradient of >60 mm Hg. All of them qualified for study entry with the clinical indication mentioned above for PVR. In the catheterized cohort, 124 (95%) patients were diagnosed with tetralogy of Fallot and all had augmented native RVOTs or transannular patch repairs. Time from surgical repair to TPVR was 18 ± 9 years. The peak transpulmonary gradient measured by echocardiography was 19.9 ± 17.4 mm Hg. The mean RVEDVI was 176.3 ± 28.4 mL/m$^2$ with RV ejection fraction of 51.1% ± 9.7% and PR fraction of 47.5% ± 7.2% measured by CMR. The preoperative electrocardiogram showed that the proportion of atrial fibrillation and atrial flutter was 12.3%, and ventricular tachycardia and nonsustained ventricular tachycardia (medical history and electrocardiogram) was 3.1%. Ten patients (7.7%) had a history of catheter radiofrequency ablation, and 4 patients (3.1%) had a history of implantable cardioverter-defibrillator implantation (ICD). Demographic and baseline characteristics are listed in Table 1.

**PROCEDURAL OUTCOMES.** The procedure success rate was 98.5% (128 of 130). In 2 patients with device malposition, the anatomical features of the MPA and RVOT exhibited an hourglass-shaped configuration. The diameters of the PA bifurcation and distal MPA were 26 to 30 mm, the sinus-tubular junction 38 to 41 mm, sinuses 46 to 55 mm, annulus 42 to 46 mm, and outflow tract 50 to 60 mm, representing the marginal anatomical conditions for inclusion. The sizes of PT-valves used for the 2 patients were 40 to 26 mm and 44 to 26 mm, respectively. The device was positioned near the bifurcation where it was the narrowest; however, it migrated proximally toward the right ventricular after release. Additionally, pulmonary branch obstruction happened to 1 patient. After valve landing between left PA and MPA, the right pulmonary branch was occluded by distal flare covered by porcine pericardium. Those 3 patients all underwent surgical operations immediately after the events were observed. The rest patients (127 of 130) were free of device explant in 30 days. No other adverse events occurred in 30 days postimplantation, such as tricuspid valve injury, pulmonary artery rupture, and pericardial or thoracic hemorrhage. Balloon inflation tests were performed on 6 patients during the procedure, and no coronary compression was observed. Total fluoroscopic time was 39 ± 12 minutes. The procedural data and distribution of device sizes are shown in Table 2.

**FOLLOW-UP EVALUATION.** Through 1 year, there were no procedure- or device-related mortality

**TABLE 2 Procedural Data in Catheterized Patients (N = 130)**

| | |
|---|---|
| Total fluoroscopic time, min | 39.4 ± 11.7 |
| Total procedural time, min | 129.3 ± 25.5 |
| Successful access, delivery, and retrieval of the delivery system | 128 (98.5) |
| Free of explantation 30 d postimplantation | 127 (97.7) |
| Valve sizes, mm[a] | |
| 28-20 | 9 (6.9) |
| 32-23 | 20 (15.4) |
| 36-26 | 39 ( 30.0) |
| 40-26 | 34 (26.2) |
| 44-26 | 28 (21.5) |

Values are mean ± SD or n (%). [a]The valve size is represented as the outflow/inflow flare diameter-annulus diameter.

events. One patient died of septic shock caused by tuberculosis 4 months after the procedure. All remaining 126 patients finished the 1-year assessments (Figure 1). The proportion of atrial fibrillation and atrial flutter on the postoperative electrocardiogram was 11.1%. Two patients developed arrhythmia requiring intervention. One patient whose preoperative electrocardiogram presented premature ventricular contractions experienced recurrent nonsustained ventricular tachycardia with hypotension and treated with ICD. The other one who had a history of atrial fibrillation ablation developed sinus bradycardia with atrial flutter after implantation, and underwent full automatic pacemaker (DDD) implantation. Two patients experienced infective endocarditis with miliary vegetations in the prosthetic leaflets, both cured by intensive anti-infective treatment with vancomycin/cephalosporin. Neither of them experienced an increase in PA pressure gradient caused by infective endocarditis; one had a gradient range of 32 to 33 mm Hg, and the other ranged from 8 to 14 mm Hg over a year. Pulmonary thromboembolism was detected in 1 patient at the 6-month visit that was treated with anticoagulation therapy and resolved. Before the event was observed, this patient received dual antiplatelet therapy with aspirin 100 mg and clopidogrel 75 mg for 6 months. One vascular access complication was right iliac vein occlusion, which also was alleviated through anticoagulation therapy. One patient who was comorbid with RVOT obstruction had a decrease of peak transpulmonary gradient from 102 to 64 mm Hg after implantation, and the highest gradient detected was 95 mm Hg during the follow-up period. Twenty patients completed a 1-year postoperative CTA examination, which included 3-dimensional reconstruction and maximum intensity projection reconstruction, showing no evidence of stent fractures. From 1-year follow-up, no events of late-onset device malposition, coronary artery compression, and valve reintervention occured (Table 3). The NYHA functional classification was significantly improved as compared with baseline ($P < 0.001$) (Figure 4, Table 4).

**TABLE 3 1-Year Clinical Outcomes in the Implanted Patients (N = 127)**

| | |
|---|---|
| All-cause mortality | 1 (0.8) |
| Procedure- or device-related mortality | 0 |
| Device malposition | 0 |
| Pulmonary branch obstruction | 0 |
| Coronary artery compression | 0 |
| Endocarditis | 2 (1.6) |
| Major stent fracture | 0 |
| Reintervention of the TPV | 0 |
| Pulmonary thromboembolism | 1 (0.8) |
| Pacemaker implantation[a] | 2 (1.6) |
| Vascular access complication | 1 (0.8) |

Values are n (proportion with event, %). [a]Including implantable cardioverter-defibrillator implantation.
TPV = transcatheter pulmonary valve.

**HEMODYNAMIC OUTCOMES.** Based on the data collected during the 1-year visit, overall device integrity and functionality appeared to be well maintained. Echocardiographic assessments of PR, PVL, peak transpulmonary gradient, and tricuspid regurgitation by visit are shown in Table 5 and Figure 5. Following TPV implantation, 125 (99%) patients had none/trace and mild PR at 1-year visit (Figure 5A). There were no cases of greater than mild PVL at 1 year (Figure 5B). The peak transpulmonary gradient was 20.0 ± 17.4 mm Hg preimplantation, 9.0 ± 8.3 mm Hg after procedure immediately, and 16.0 ± 7.8 mm Hg at 1 year (Figure 5C). There were 85 (65%) patients comorbid with moderate or severe tricuspid regurgitation before implant, while the figure decreased to 40 (32%) by 1 year (Figure 5D). The Stuart-Maxwell test was conducted to analyze the change in proportions of PR and tricuspid regurgitation between baseline and 1-year follow-up. The results with $P < 0.001$ indicate a significant difference.

**1-YEAR CMR DATA.** At 1 year, we got the CMR data from 37 patients (Figure 6). As expected with the reduction in regurgitation from 47.5% ± 7.2% of forward flow to 3.3% ± 3.9%, there was a significant reduction in the indexed RV end-diastolic volumes from 176.3 ± 28.4 mL/m$^2$ before implant to 121.1 ± 20.7 mL/m$^2$ ($P < 0.001$). There was no significant change in RV ejection fraction ($P = 0.432$).

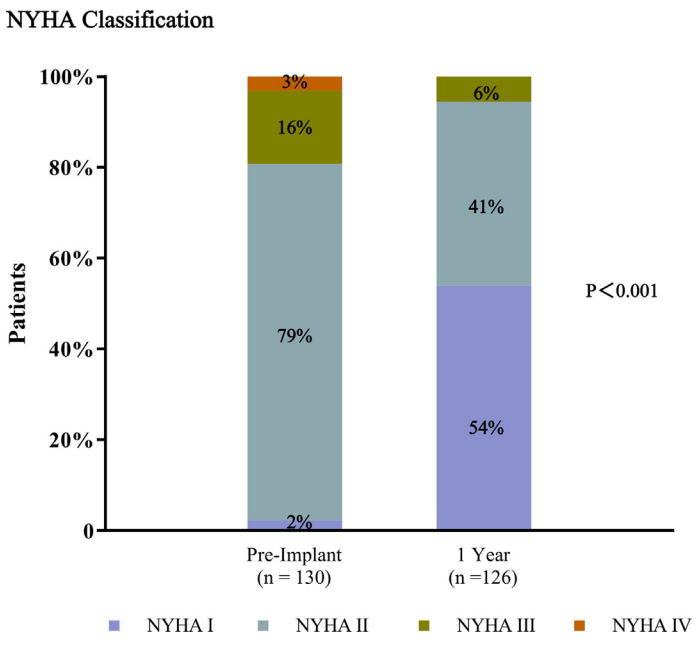
## DISCUSSION

To the best of our knowledge, this is the largest-scale clinical study of a self-expanding percutaneous pulmonary valve. The 1-year outcomes from this cohort revealed the absence of mortality attributable to procedure or device, as well as the satisfactory valve function with 99% of patients absent from significant valve regurgitation and all without significant PVL. Data from the 1-year CMR confirmed the positive remodeling effects on the RV when pulmonary valve competence is established, with significant reductions in RVEDVI (**Central Illustration**).

Over the past 2 decades, TPVR has emerged as a valuable nonsurgical therapeutic modality for addressing PR and restoring RVOT function, effectively mitigating the long-term surgical risks that patients may face. At present, 2 balloon-expandable TPVs, specifically the Melody valve (Medtronic) and the SAPIEN valves (Edwards), have garnered recognition for their applicability in RVOTs featuring homografts or conduits.[7-9] However, their sizing may not be sufficient for dilated native RVOTs without prestenting.[10,11] As a solution, the use of the SAPIEN 3 valve with the Alterra adaptive prestent (Edwards) received approval from the U.S. Food and Drug Administration for patients with severe PR. Regarding self-expanding TPVs, the Harmony valve (Medtronic) has received U.S. Food and Drug Administration approval for use in surgically repaired native RVOTs.[12] Remarkably, the outcomes of its Early Feasibility Study extending over a 5-year follow-up period, have provided substantial evidence of the sustained functionality.[13] In addition to the aforementioned TPVs, the Venus P-valve (Venus MedTech) has demonstrated favorable mid-term performance when employed in patients with PR and enlarged native RVOTs (mean RVOT diameter 30.4 ± 5.7 mm).[14] This valve system has attained CE mark approval in Europe as of April 2022. Furthermore, the Pulsta valve (Taewoong Medical) represents another self-expanding valve system. Its initial feasibility study was reported in 2018.[15]

The PT-Valve is an advanced self-expanding TPV, available in 5 sizes to accommodate a wide spectrum of anatomical variations. Its structural features and anchoring mechanisms are similar to those of the Harmony valve, but they differ in the choice of stent and membrane materials. The features of PT-Valve negate the necessity for an interference fit between the device's valve segment and the pulmonary annulus for secure anchoring. As a result, there is no requirement for intraoperative balloon sizing to determine the optimal valve size generally. Preferably, the selection of the appropriate valve size is guided by preoperative multiplanar measurements based on the 3-dimensional reconstruction of CTA images. Further comprehensive insights into the preoperative CTA assessment and imaging analysis will be expounded upon in a separate report. Currently, PT-valve has been submitted for registration review and is awaiting evaluation and

**FIGURE 4** NYHA Functional Classification at Baseline and 1-Year Follow-Up




The NYHA functional classification at 1-year follow-up was significantly improved compared with baseline. Values reported are proportions. *P* value is calculated from the Stuart-Maxwell test to compare the proportions of NYHA functional classification between preimplant and 1 year. A value of $P < 0.05$ was considered significant.

**TABLE 4** NYHA Functional Classification

| | Baseline | 1 mo | 3 mo | 6 mo | 1 y |
|---|---|---|---|---|---|
| I | 3 (2.3) | 28 (22.0) | 47 (37.0) | 55 (43.7) | 68 (54.0) |
| II | 102 (78.5) | 85 (66.9) | 72 (56.7) | 62 (49.2) | 51 (40.5) |
| III | 21 (16.2) | 14 (11.0) | 8 (6.3) | 9 (7.1) | 7 (5.6) |
| IV | 4 (3.1) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |

Values are n (%). Patients with NYHA functional classification V were not included in this study.

**TABLE 5 Echocardiography Follow-Up Data**

| Measurement | Preimplant (n = 130) | Postimplant (n = 127) | 1 mo (n = 127) | 3 mo (n = 127) | 6 mo (n = 126) | 1 y (n = 126) |
|---|---|---|---|---|---|---|
| Pulmonary regurgitation | | | | | | |
| None | 0 | 91 (71.7) | 80 (63.0) | 77 (60.6) | 76 (60.3) | 72 (57.1) |
| Trace/trivial | 0 | 27 (21.3) | 41 (32.3) | 44 (34.6) | 43 (34.1) | 47 (37.3) |
| Mild | 0 | 7 (5.5) | 4 (3.1) | 5 (3.9) | 6 (4.8) | 6 (4.8) |
| Moderate | 21 (16.2)[a] | 2 (1.6) | 1 (0.8) | 0 (0) | 0 (0) | 0 (0) |
| Severe | 109 (83.8) | 0 (0) | 1 (0.8) | 1 (0.8) | 1 (0.8) | 1 (0.8) |
| Paravalvular leak | | | | | | |
| None | – | 107 (84.3) | 117 (92.1) | 116 (91.3) | 115 (91.3) | 117 (92.9) |
| Trace/trivial | – | 11 (8.7) | 8 (6.3) | 7 (5.5) | 8 (6.3) | 5 (4.0) |
| Mild | – | 9 (7.0) | 2 (1.6) | 4 (3.1) | 3 (2.4) | 4 (3.2) |
| Moderate | – | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Severe | – | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Peak transpulmonary gradient, mm Hg | 20.0 ± 17.4 | 9.0 ± 8.3 | 11.8 ± 9.0 | 12.5 ± 6.6 | 14.2 ± 10.4 | 16.0 ± 7.8 |
| Tricuspid regurgitation | | | | | | |
| None/trace | 10 (7.7) | 14 (11.0) | 18 (14.2) | 16 (12.6) | 20 (15.9) | 20 (15.9) |
| Mild | 35 (26.9) | 57 (44.9) | 66 (52.0) | 64 (50.4) | 64 (50.8) | 66 (52.4) |
| Moderate | 68 (52.3) | 45 (35.4) | 37 (29.1) | 40 (31.5) | 36 (28.6) | 31 (24.6) |
| Severe | 17 (13.1) | 11 (8.7) | 6 (4.7) | 7 (5.5) | 6 (4.8) | 9 (7.1) |

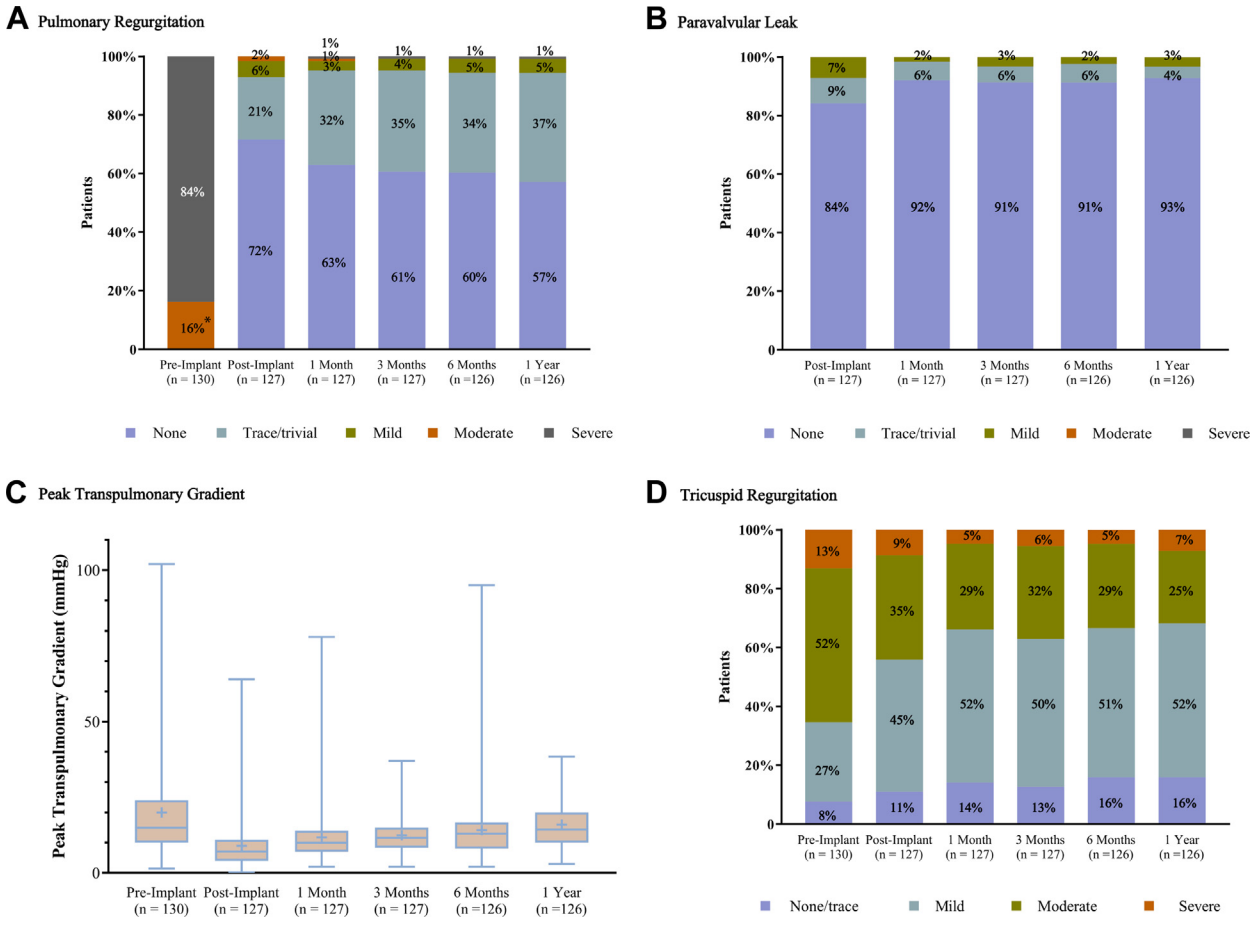
Values are n (%) or mean ± SD. [a]The grade of pulmonary regurgitation in preimplant measurement is moderate to severe.

supplementary requests from the National Medical Products Administration.

As delineated earlier, the distinctive narrow-waist configuration within the PT-Valve design averts the consequences of excessive stent compression and incomplete expansion. This design element not only safeguards the durability of the valve by preempting mechanical shear forces between the stent and leaflets, but also significantly reduces the risk of coronary artery compression. According to current guidelines, coronary angiography with concomitant RVOT balloon dilation is recommended to check for coronary compression before valve implantation.[16] Within the context of this clinical trial, balloon inflation tests were selectively employed in merely 6 patients. Their left coronary arteries originated from a relatively anterior and superior position of the left coronary sinus, closely following the mid-segment and sinus part of the MPA, which corresponds to the position where the distal flare is riveted. Moreover, no stenosis was observed in pulmonary annulus or sinotubular junction of these patients; hence, the fixation of the PT-valve relied on a larger oversize (the flare diameter exceeds the local PA diameter by more than 20%). Once the valve is fully expanded, there is a risk that the distal flare may compress the left coronary artery. Thereafter, the intraoperative results and 1-year follow-up results revealed no clinical incidents related to coronary artery compression. This outcome underscores the potential advantage offered by the PT-Valve in streamlining the implantation procedure. Of note, we did not perform coronary compression testing in most patients based on careful evaluation of preoperative CTA and patient-specific characteristics. For high-risk or suspected high-risk cases, coronary compression testing is indispensable. So far, no cases of stent fracture have been observed in the application of PT-Valve, which may also benefit from the device design. Stent fractures were reported in one-quarter of implants in International Venus P-valve study,[17] whereas stent fracture of Venus P-valve is mostly type I with no progression and no effect on the patient's hemodynamics.

Within our cohort, 3 patients experienced surgical device explants perioperatively, because of device malposition in 2 cases and pulmonary branch obstruction in one. Device malposition predominantly manifested as an acute complication. We have noticed that the Early Feasibility Study of the Harmony valve reported 2 cases of proximal migration, with one occurring during the removal of the delivery system and another before discharge caused by device undersizing.[18] The China Venus P-valve study similarly documented a proximal migration event, which transpired 2 days following the procedure and may be attributed to the unique anatomical characteristics of an inverted cone-shaped RVOT and MPA.[14] Valve malposition is related to unsuitable anatomy,

**FIGURE 5** 1-Year Hemodynamic Outcomes: Echocardiography Assessment

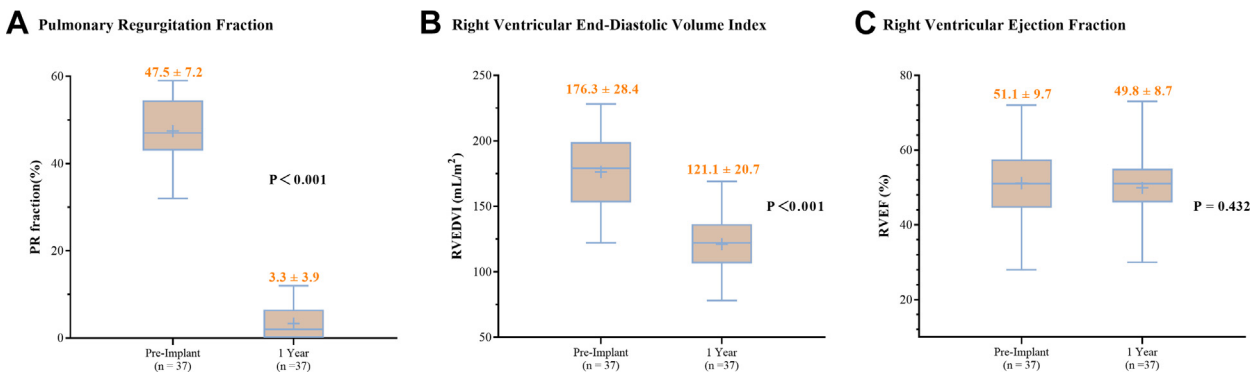



Echocardiography assessment of pulmonary regurgitation (A), paravalvular leak (B), peak transpulmonary gradient (C) and tricuspid regurgitation (D) through 1 year. At 1 year, 99% of patients had none/trace and mild pulmonary regurgitation, and no paravalvular leak greater than mild. The average peak transpulmonary gradient was similar to baseline. The proportion of patients with moderate and severe tricuspid regurgitation had decreased. Assessment of pulmonary regurgitation included both central and paravalvular regurgitation. *Pulmonary regurgitation grade in this bar is moderate to severe. Values are reported as proportions or mean ± SD. In C, the box is centered around the median, with the mean depicted by a blue cross. Upper and lower bounds of the box represent the IQR. Whiskers represent the minimum and maximum.

inaccurate positioning of the prosthetic valve, poor alignment with native structures, or operator inexperience. If the deployment of the distal flare begins too high and extends into one PA without being detected under x-ray fluoroscopy, the other PA may be covered by the stent's membrane. Conversely, starting too low and failing to accurately position in the target anchoring area of the distal MPA can lead to valve migration caused by inadequate anchoring. Besides, an insufficient valve size also contributes to valve migration. In the event of device malposition, it is imperative to undertake an urgent assessment or even emergency surgery to avert more severe hemodynamic consequences. When it comes to pulmonary artery obstruction, a systematic review illustrated that the incidence was 1.2% (95% CI: 0.5%-2.6%) after Melody valve implantation.[19] However, this kind of events was rare in studies involving self-expanding valves. We consider it essential to avoid placing the valve over distally to prevent pulmonary branch obstruction.

During the 1-year follow-up, aside from 1 patient who died of a nonoperative cause, there were several severe adverse events related to the procedure.

**FIGURE 6 1-Year Paired CMR Data**



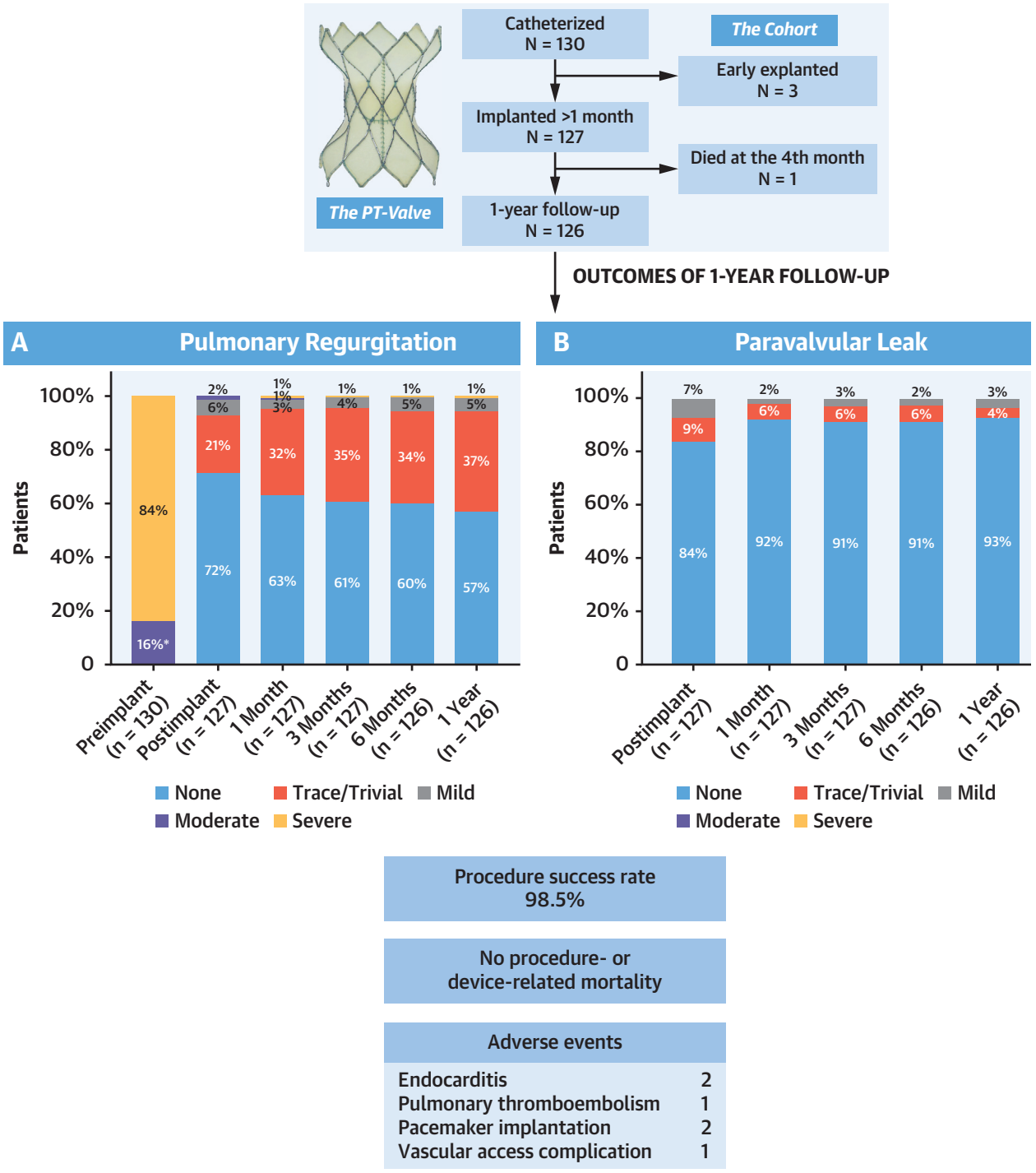

Pulmonary regurgitation (PR) fraction (A), right ventricular end-diastolic volume index (RVEDVI) (B), and right ventricular ejection fraction (RVEF) (C) at baseline and 1 year. Available data from 37 patients were reported. CMR data showed significant reductions in PR fraction and RVEDVI, with no significant change in RVEF. Values are mean ± SD. The difference in PR fraction between preimplant and 1 year was calculated using the Mann-Whitney *U* test. The *P* values for RVEDVI and RVEF were calculated from paired Student's *t*-test. $P < 0.05$ was considered significant.

Fortunately, all of these complications were successfully addressed with prompt and appropriate interventions, resulting in resolution without lasting sequelae. Regarding arrhythmias, severe PR after surgery for tetralogy of Fallot can cause significant RV enlargement, right heart failure, and related atrial and ventricular arrhythmias. In some patients, arrhythmias may also be associated with the scar tissue formation. Therefore, after TPVR, the occurrence of arrhythmias may improve caused by the amelioration of right heart failure, or it may not improve. We speculate that postimplantation arrhythmias are more related to the patient's preoperative condition. In addition, endocarditis represents a non-negligible complication with a notable incidence rate. In a large multicenter cohort, the cumulative incidence of endocarditis after TPVR with a Melody valve or any generation of Sapien valve was reported as 9.5% (95% CI: 0.5%-2.6%) at 5 years and the annualized incidence was 2.2 per 100 patient-years.[20] In severe cases, endocarditis may result in fatalities and occasionally necessitate surgical pulmonary valve replacement. Certain factors associated with a higher rate of endocarditis following TPVR were gender, balloon postdilation, smaller RVOT, conduits, stenotic lesions, younger age at implant, history of endocarditis, discontinuation of antiplatelet or anticoagulant therapy and percutaneous intervention, dental care, or noncardiac surgery after TPVR.[20-22] Implementing stringent measures, including perioperative antibiotic prophylaxis and preoperative screening of nasal carriage for S.aureus, are imperative to diminish the incidence of endocarditis.[23]

It is worth mentioning that among the 6 patients who had a high transpulmonary gradient, the condition of 5 of 6 was caused by compression of the elastic annulus tissue of pulmonary valve and the RVOT muscle tissue. The radial support provided by the PT-Valve stent could expand the stenotic area to the implanted-valve size. During the procedure, we performed balloon predilation and postdilation on the narrowest segment, significantly reducing the transpulmonary gradient after valve implantation. Whereas another patient had a calcified and stenotic RVOT, with a long segment of obstruction. The artificial valve implantation did not effectively expand this obstructive segment. Despite the reduction in the transpulmonary gradient after balloon postdilation, there was still an increase during the follow-up period. Therefore, the preoperative assessment for cases with calcific stenosis needs to be conducted rigorously. For severe or long calcified stenosis, it is more advisable to use a balloon-expandable valve with strong support. Alternatively, a balloon-expandable stent may be used to address the stenosis before implanting a PT-Valve.

In summary, the extant body of evidence supports the use of self-expanding TPVs for the treatment of

**CENTRAL ILLUSTRATION** **The PT-Valve and its 1-Year Outcomes for Pulmonary Regurgitation**




**Qin C, et al. JACC Asia. 2025;5(4):568–581.**

(Top) The PT-Valve is a novel self-expanding percutaneous pulmonary valve. A total of 130 patients received the implantation of PT-Valve and 126 patients completed the 1-year follow-up. (Bottom) The procedure success rate was 98.5%. The 1-year outcomes showed no procedure- or device-related mortality events; 125 (99%) patients had none/trace and mild PR, and no greater than mild paravalvular leak.

patients with PR, even in cases involving previously patched and enlarged RVOTs. Among these TPVs, the PT-Valve exhibits distinct advantages. Nonetheless, it is crucial to meticulously manage and systematically summarize the complications observed in clinical trials and practice to further standardize treatment protocols.

**STUDY LIMITATIONS.** The limitation of our study is that the follow-up time of whole cohort was only 1 year. The follow-up process is continual, and the 5-year or further outcomes are underway. In addition, CMR scans were not obtained in all centers to better understand the impact of resolution of PR on the RV remodeling.

## CONCLUSIONS

The PT-Valve is a novel self-expanding TPV device. The 1-year clinical results of this study support the safety and efficacy of the PT-Valve in the treatment of patients with moderate or greater PR. Good valve function, absence of PVL, no coronary artery compression, and frame fracture was observed through the 1-year follow-up. The results are promising, but further follow-up is required to validate long-term performance and durability.

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**KEY WORDS** clinical trials, native right ventricular outflow tract, pulmonary regurgitation, tetralogy of Fallot, transcatheter pulmonary valve

**APPENDIX** For a supplemental table, please see the online version of this paper.