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Original Research

Outcomes of Transcatheter Pulmonary Valve Replacement and Surgical Pulmonary Valve Replacement: A Cohort Analysis

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ABSTRACT

Background: Transcatheter pulmonary valve replacement (TPVR) has become an alternative to surgical pulmonary valve placement (SPVR) for patients after tetralogy of Fallot repair. This study compared the outcomes of TPVR with those of SPVR.

Methods: We reviewed data from patients who underwent pulmonary valve replacement with a median of 2 years of follow-up.

Results: Between 2010 and 2021, 215 patients underwent pulmonary valve replacement (72 TPVR and 143 SPVR). The median size of the right ventricular end-diastolic volume index in the TPVR group was 165 mL/m^2 (IQR, 136-190) and 184 mL/m^2 (IQR, 163-230) in the SPVR group ($P = .001$). The median value of the maximum landing zone at the right ventricular outflow tract (RVOT) in patients with native RVOT was 26 mm (IQR, 24-28) in the 43 patients in the TPVR group and 31 mm (IQR, 28-34) in the 101 patients in the SPVR group ($P < .001$). The median size of the pulmonary valve implant for the native RVOT in the TPVR group was 29.0 mm (IQR, 26.0-29.0) and 24.0 mm (IQR, 24.0-24.0) in the SPVR group ($P < .001$). There were no deaths in the TPVR group and 8 deaths in the SPVR group ($P = .041$). Major complications and the length of hospitalization were lower in the TPVR group ($P = .001$). After 2 years, the mean decrease in QRS duration was 5 milliseconds (IQR, 1-14) in the TPVR group and 1 millisecond (IQR, −4 to 10) in the SPVR group ($P = .006$).

Conclusions: TPVR allows for larger implants, resulting in lower mortality, shorter hospital stays, and fewer major cardiac events. SPVR may be preferable in patients with larger (>30 mm) native RVOT and in those who require concomitant surgical procedures.

Introduction

Tetralogy of Fallot (TOF), or pulmonary atresia with a ventricular septal defect, is the most common cyanotic heart disease.[1] Primary surgical repair may include valvuloplasty, resection of the subvalvular area, or placing a large patch across the stenotic right ventricular outflow tract (RVOT) to allow unobstructed forward flow and close the ventricular septal defect. In pulmonary atresia with a ventricular septal defect, a right ventricle (RV) to pulmonary artery connection must be established using a valve conduit. Over the long-term, patients may develop severe pulmonary regurgitation (PR) from dysfunction of the pulmonary valve (PV) or failure of the RVOT conduit that will lead to pulmonary stenosis or PR and, subsequently, the enlargement of the RV.[2,3] Progressive dilatation of the RV with impaired right ventricular function is associated with right or left heart failure and an increased risk of fatal arrhythmia and sudden death.[4-7] The indications for PV replacement (PVR) for severe PR or pulmonary stenosis have been described elsewhere.[8,9] Our hospital has performed transcatheter pulmonary valve replacement (TPVR) and surgical pulmonary valve replacement (SPVR) over the past decade. We hypothesized that TPVR would be associated with less mortality and

Abbreviations: MRI, cardiac magnetic resonance imaging; PR, pulmonary regurgitation; PV, pulmonary valve; PVR, pulmonary valve replacement; RV, right ventricle; RVOT, right ventricular outflow tract; SPVR, surgical pulmonary valve replacement; TOF, tetralogy of Fallot; TPVR, transcatheter pulmonary valve replacement.

Keywords: surgical pulmonary valve replacement; tetralogy of Fallot; transcatheter pulmonary valve replacement.

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fewer major complications than SPVR. To better understand the optimal indications and outcomes of each method, we aimed to compare the size of the landing zone in the native RVOT and the size of the implanted PV. Finally, we assessed the degree of PR and compared the QRS duration as surrogate variables for RV dilatation after PVR.

Materials and Methods

We conducted a retrospective review of medical records from patients who underwent TPVR or SPVR between 2010 and 2021 at the Faculty of Medicine Siriraj Hospital, Mahidol University. Abstracted data included the patient's biological profile (sex, age, and weight) and clinical details, including functional class, arrhythmias, electrocardiography, echocardiography, cardiac magnetic resonance imaging (MRI), cardiac computed tomography, and cardiac catheterization with balloon sizing of PV to evaluate RVOT and the potential landing zone of the PV with coronary artery and aortic compression testing in patients scheduled for TPVR. All patient data were reviewed, and final treatment decisions were usually made by our Heart Team that includes a pediatric cardiologist–cardiac computed tomography/MRI specialist and a cardiovascular thoracic surgeon conference. The outcomes of PVR were collected by reviewing the size of the implanted PV; procedural time was measured by fluoroscopy time and procedure time in the TPVR group and by cross-clamp and cardiopulmonary bypass time in the SPVR group. Data on major complications, including death, and events that prolong intensive care unit or hospitalization were collected until discharge. We evaluated the echocardiography report measurement of the degree of PR immediately after PVR, at 1 year, and at 2 years. We also compared the electrocardiography findings before and 2 years after PVR.

The choice for TPVR was based on our experience with the balloon expandible Melody valve system (Medtronic)[10-12] or Edwards SAPIEN 3 (Edwards Lifesciences).[13] We used the self-expandable Venus P-valve (MedTech)[14] and the Pulsta valve (TaeWoong Medical Co, Ltd)[15] for a larger RVOT diameter. Melody or Edwards can also be used in patients with RVOT conduit. For patients with native RVOT, the maximal PV landing zone diameter was 22 to 23 mm for the Melody valve and 28 to 29 mm for the Edwards SAPIEN 3 valve. Venus P-valve or Pulsta valve were used exclusively for native RVOT when the diameter was 30 to 32 mm. Most of the patients who underwent SPVR had an implant made of an in-house sterile trileaflet PV conduit made from a polytetrafluoroethylene Gore-Tex tube (W.L. Gore & Associates). The design and technique were simplified as previously described.[16,17] Other types of surgical valves included the Perimount Magna Ease Aortic Valve (Edwards Lifesciences), the Contegra Conduit (Medtronic), aortic or pulmonary homograft (Thai red cross), and the Freestyle bioprosthesis (Medtronic). Surgeons may also consider resecting and excluding the RVOT aneurysm, which can potentially improve hemodynamic and RV function. Data were analyzed using PASW (Predictive Analytics Software) Statistics 18 (SPSS Inc). Normally distributed variables are presented as mean ± SD. Nonnormally distributed variables are presented as medians with interquartile range (IQR, 25%-75%). A comparison of continuous data was made with the 2 independent samples *t* test or the Mann-Whitney *U* test, depending on the data distribution. Categorical data were compared using the Pearson χ^2 or Fisher exact tests. This study was approved by the Siriraj Institutional Review Board (407/2563[IRB2]). The Thai clinical registry number is TCTR20211025003 (https://www.thaiclinicaltrials.org/show/TCTR20211025003).

Results

A total of 215 patients underwent PVR; 72 patients had TPVR and 143 had SPVR (Table 1). Patients who underwent TPVR were younger than those who underwent SPVR (20.7 years [17.3-26.2] vs 28.2 years [20.7-42.4] years; $P < .001$) and had a shorter time from primary repair to PVR (13.3 years [9.1-19.0] vs 18.7 years [12.4-24.6]; $P = .003$). The proportion of patients with RVOT conduit was not different (40.3% TPVR vs 29.4% SPVR; $P = .109$). However, the TPVR group had a higher preoperative RVOT gradient by echocardiography (30 mm Hg [13.8-40.8] TPVR vs 10 mm Hg [5-25] SPVR; $P \leq .001$), suggesting that the TPVR group included a sizable portion of patients with stenotic RVOT conduit. Six patients had an Edward SAPIEN 3 valve-in-valve procedure, including 1 porcine valve, 4 Stentless valves, and 1 Melody valve.

Table 1. Comparison of demographic data, echocardiography, and cardiac MRI measurement of TPVR with SPVR groups.

	TPVR (N = 72)	SPVR (N = 143)	*P* value
Age at primary repair, y	6.6 (3.9-10.1)	8.4 (4.0-17.0)	.04
Age at PVR, y	20.7 (17.3-26.2)	28.2 (20.7-42.4)	<.001
Time from primary repair to PVR, y	13.3 (9.1-19.0)	18.7 (12.4-24.6)	.003
Male	44 (61.1%)	75 (52.4%)	.228
Weight, kg	54.9 (45.9-69.4)	55.8 (46.0-65.0)	.876
TOF	44 (61.1%)	107 (74.8%)	.176
Fc (II, III, IV)	38 (52.8%)	95 (66.4%)	.145
Pre PVR arrhythmia	13 (18.1%)	46 (32.4%)	.021
Echocardiography			
PS indicated	20 (27.8%)	20 (14%)	.049
PR indicated	49 (68.1%)	116 (81.1%)	
PS and PR indicated	3 (4.2%)	7 (4.9%)	
Echo PS gradient, mm Hg	30.0 (13.8-40.8)	10.0 (5.0-25.0)	<.001
Echo showed moderate to severe TR	11 (15.3%)	44 (31%)	<.001
Echo RVSP, mm Hg	49.5 (41.3-60.0)	40.0 (35.0-52.0)	<.001
% Patients with RVOT conduit	29 (40.3%)	42 (29.4%)	.109
Size of conduit average, mm	20.0 (18.0-23.0)	23.0 (21.0-24.0)	.011
Cardiac MRI measurement			
PR regurgitation fraction, %	44.8 (33.5-50.0)	52 (40.5-59.1)	<.001
LVEDVi, mL/m^2	78.0 (66.5-93.2)	82.0 (71.0-94.0)	.273
LV EF, %	60.0 (52.0-63.0)	60.0 (55.6-62.0)	.747
RVEDVi, mL/m^2	165.0 (136.0-190.0)	184.0 (163.0-230.0)	<.001
RVESVi, mL/m^2	84.0 (63.3-102.1)	101.5 (84.8-129.5)	<.001
RV EF, %	43.7 ± 9.8	43.4 ± 8.3	.836
Cardiac catheterization PS gradient, mm Hg	23.5 (11.5-40.0)	10.0 (5.0-24.0)	.001

Nonnormal distribution variables are presented as median with IQR (25%-75%) and RV EF is presented as mean ± SD.

Echo, echocardiography; EF, ejection fraction; Fc, functional class; LV, left ventricle; LVEDVi, left ventricular end-diastolic volume index; MRI, magnetic resonance imaging; PR, pulmonary regurgitation; PS, pulmonary stenosis; PVR, pulmonary valve replacement; RV, right ventricle; RVEDVi, right ventricular end-diastolic volume index; RVESVi, right ventricular end systolic volume index; RVOT, right ventricular outflow tract; RVSP, right ventricular systolic pressure; SPVR, surgical pulmonary valve replacement; TOF, tetralogy of Fallot; TPVR, transcatheter pulmonary valve replacement; TR, tricuspid regurgitation.

For patients with PR, 1 criterion to replace the valve was the measurement of RV chamber enlargement by cardiac MRI using the right ventricular end-diastolic volume index. The right ventricular end-diastolic volume index was greater in the SPVR group (184 mL/m^2 [163-230]) than in the TPVR group (165 mL/m^2 [136-190]; $P = .001$). The maximum PV landing zone diameter measured by balloon sizing (Figure 1) was 24 mm (20-26.5) in the TPVR group and 30 mm (26-33) in the SPVR group ($P < .001$) (Table 2). Excluding patients with RVOT conduit, the median size of the PV landing zone in patients with RVOT was 26 mm (24-28) in the 43 patients who underwent TPVR and 31 mm (28-34) in the 101 patients who

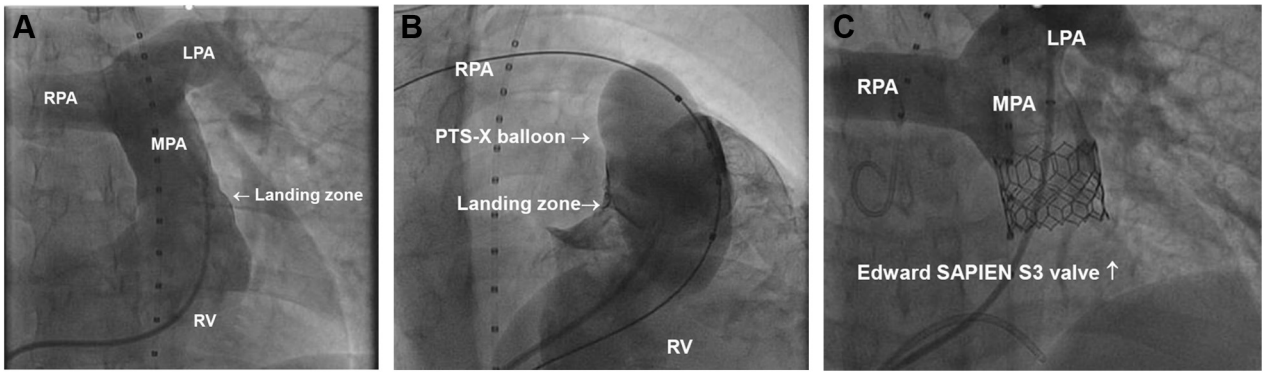


Figure 1. Angiography showing steps of transcatheter pulmonary valve replacment. **(A)** Angiography in RAO delineated PV landing zone and MPA, RPA and LPA, and RV. **(B)** Angiography in RAO view showing balloon sizing using a 30-mm PTS-X balloon (NuMed Inc) with simultaneous right ventricular angiography. **(C)** An example of postimplantation of 29-mm Edward SAPIEN 3 at PV area with main pulmonary artery angiography showing that the implanted valve is competent. LPA, left pulmonary artery; MPA, main pulmonary artery; PV, pulmonary valve; RAO, right anterior oblique; RPA, right pulmonary artery; RV, right ventricle.

Table 2. Comparison of size of pulmonary valve landing zone between TPVR and SPVR groups measured by 3 different methods as follows: cardiac MRI or CT, angiography cardiac catheterization, and balloon sizing both in maximal and minimal diameters.

Method of measurement	MRI/CT		Catheterization		Balloon sizing	
Diameter	Maximal	Minimal	Maximal	Minimal	Maximal	Minimal
TPVR, mm	24.0 (20.0-26.5)	22.9 (18.8-25.7)	24.0 (20.0-27.0)	23.0 (20.0-26.0)	25.0 (21.0-28.8)	24.5 (20.0-27.0)
SPVR, mm	30.0 (25.9-33.0)	30.0 (24.8-33.0)	27.0 (20.0-33.0)	27.5 (20.0-32.0)	31.0 (25.5-34.0)	30.0 (24.8-32.0)
P value	<.001	<.001	.005	<.001	<.001	<.001

Nonnormal distribution variables are presented as median with IQR (25%-75%).
CT, computerized tomography; MRI, magnetic resonance imaging; SPVR, surgical pulmonary valve replacement; TPVR, transcatheter pulmonary valve replacement.

underwent SPVR ($P < 0.001$) (Table 2). The sizes and types of implants of PV are given in Table 3. There were 143 patients who underwent SPVR. The indications for sending patients for SPVR are shown in Table 4.[18]

Deaths and complications

There were 8 deaths in the SPVR group; 2 patients had intracranial hemorrhage from cardiopulmonary bypass, 2 patients had severe right ventricular failure post bypass, 2 patients had ventricular tachycardia/ventricular fibrillation that led to heart failure, 1 patient had transection of the right coronary artery during bypass, and 1 patient had RV rupture. Two patients who died had aortic valve and mitral valve replacement, and 6 patients had an explant of mismatch conduit. Patients who died had cardiopulmonary bypass time (137 ± 72 minutes) compared with cardiopulmonary bypass time (102 ± 49 minutes) of patients who survived the surgery up to discharge, with *P* values of 0.265. Patients who died had compared cross-clamp time (41 ± 55 minutes) compared with cross-clamp time (39 ± 39 minutes) of patients who survived the surgery up to discharge, with *P* values of 0.937. Two of 8 patients died 90 days after SPVR from prolonged RV failure and endocarditis in the same admission. There was no mortality in the TPVR group. The major reasons for repeated surgery at the same admission in 13 patients in the SPVR group (9.1%) were to stop bleeding or reimplant the PV because of malposition, such as stenotic conduit. In the TPVR group, 3 patients had a dissection of the RVOT conduit (2 patients required a covered stent, and 1 patient required thoracotomy to evacuate a clot in the left chest). One patient in the TPVR group had embolization of an Edwards SAPIEN 3 valve, required surgical removal of the implanted valve, and had an uneventful SPVR. One patient had endocarditis and required PV removal and SPVR. The number of major complications (defined as events that need cardiopulmonary resuscitation or prolonged intensive care unit or hospital stay) is shown in Table 3. Finally, the length of hospital stay was longer in the SPVR group than in the TPVR group (6.0 days [5.0-8.0] vs 2.0 days [2.0-3.0]; $P < .001$).

PV function immediately postreplacement and at the 1- and 2-year follow-up

The immediate echocardiography measurement of the RVOT gradient was similar between groups: TPVR (15.0 mm Hg [11.3-22.0]) and SPVR (15.0 mm Hg [13.0-20.5]) ($P = .752$). In the TPVR group, there were 62 (83.1%) patients with no PR and 5 (6.9%) patients with mild PR. Two patients with Edward SAPIEN 3 valve and native RVOT had moderate PR because the valve had been implanted too proximally. One patient with bilateral pulmonary artery implantation using a Melody valve had moderate PR at RVOT. A comparison of the proportion and severity of PR between TPVR and SPVR preprocedure, immediately postoperative, and at 1 and 2 years is shown in the Central Illustration. In the TPVR group, there were 70 patients who had no or mild PR at the end of 2 years. One (1.4%) patient who had a Melody valve implanted had severe PR from endocarditis, underwent surgery, and died of left ventricular failure. Another patient with an Edward SAPIEN S3 valve that was implanted too proximally had moderate PR. There were no progressive PR cases in the TPVR group after 1 year. In the SPVR group, immediately after the surgery, there were 65 (45.5%) patients with no PR, 30 (21%) patients with mild PR, and 9 (6.3%) patients with moderate PR. All patients with moderate PR underwent concomitant surgery. At the end of the 2-year follow-up, a few patients in the SPVR group had developed moderate PR (3.9%) or severe PR (4.9%) from valve or conduit compression.

Table 3. Comparison of PVR immediate outcome during hospitalization between TPVR and SPVR groups.

	TPVR (N = 72)[a]	SPVR (N = 143)[a]	*P* value
Type of PVR	Edward S3 44 (61.1%) Melody 18 (25%) Venus P-valve 4 (5.6%) Pulsta 6 (8.3%)	Gore-Tex valve 81 (56.6%) Perimount 28 (19.6%) Contegra 14 (9.8%) Homograft 12 (8.4%) Stentless 7 (4.9%)	
Implanted PV size, mm all patients	26.0 (21.0-29.0)	24.0 (24.0-25.0)	.002
Implanted PV size, mm Native RVOT	29.0 (26.0-29.0)	24.0 (24.0-24.0)	<.001
Implanted PV size, mm Conduit RVOT	20.0 (20.0-23.0)	24.0 (22.0-25.0)	.007
Time for procedure	Fluoroscopy time 27.5 min (19.1-34.9) Procedure time 115.0 min (91.5-134.5)	Cross-clamp time 47.0 min (0.05-9.3) Bypass time 91.0 min (75.0-124.0)	
ETT, h		7.0 (4.0-15.0)	
ICU, d		2.0 (1.0-3.0)	
Hospitalization, d	2.0 (2.0-3.0)	6.0 (5.0-8.0)	<.001
Death	0	8 (5.6%)	.041
All major complications[b]	8 (11.1%)	47 (32.9%)	.001
Major events needed CPR, postpericardiotomy, reintubation, arrhythmia	2 (2.8%)	24 (16.7%)	
Reopen/Redo/Recath or embolization from PVR	5 (6.9%)	13 (9.1%)	
Endocarditis	1 (1.4%)	1 (0.7%)	

Nonnormal distribution variables are presented as median with IQR (25%-75%).
CPR, cardiopulmonary resuscitation; ETT, endotracheal tube intubation after procedure; ICU, intensive care unit; PV, pulmonary valve; PVR, pulmonary valve replacement; RVOT, right ventricular outflow tract; SPVR, surgical pulmonary valve replacement; TPVR, transcatheter pulmonary valve replacement.

[a] Edwards S3, Edward SAPIEN 3 (Edwards Lifesciences); Melody, the Melody valve (Medtronic); Venus P-valve, Venus P-Valve (MedTech); Pulsta, Pulsta valve (TaeWoong Medical Co, Ltd); Gore-Tex, in-house made Gore-Tex suture valve (Siriraj Hospital); Perimount, Edwards Perimount Magna Ease Aortic Valve (Edwards Lifesciences); Contegra, the Contegra Conduit (Medtronic); Homograft, aortic or pulmonary homograft (Thai red cross); and Stentless, The Freestyle bioprosthesis (Medtronic).

[b] The number of major complications (defined as events that need cardiopulmonary resuscitation or prolong ICU or hospital stay).

Table 4. Reason for SPVR.

Reason for SPVR	No. of patients (%), N = 143
Too large landing zone	70 (49.3%)
Concomitant surgery	32 (22.5%) (tricuspid annuloplasty [13], subvalvular resection of pulmonary valve [5], aortic valve replacement [5], mitral valve replacement [3], left pulmonary artery patch angioplasty [4], and residual ventricular septal defect closure [2])
Complex RVOT anatomy such as pyramidal or aneurysm[18]	15 (10.6%)
Explant of small conduit (<14 mm)	14 (9.9%)
Coronary artery compression	8 (5.6%)
Severe aortic root compression	2 (1.5%)
Previous endocarditis	2 (1.5%)

Surgeons can also be considered resect and exclude RVOT aneurysms, potentially improving hemodynamic and right ventricle function.
RVOT, right ventricular outflow tract; SPVR, surgical pulmonary valve replacement.

During the follow-up, 7 (11.3%) patients in the TPVR group had reintervention (3 with late endocarditis, 3 with conduit redilate, and 1 with left ventricular outflow tract obstruction from the Rastelli procedure). In the SPVR group, there were 14 (10.4%) patients with reintervention; 3 patients with endocarditis, 7 patients with the rehabilitation of conduit/pulmonary artery, 3 patients had automated implantable cardioverter-defibrillator, and 1 patient had pacemaker implantation. There were 2 late deaths in the TPVR group: 1 from endocarditis with RV failure and 1 from ventricular fibrillation/sudden cardiac death. Two late deaths occurred in the SPVR group from ventricular fibrillation/sudden cardiac death. Overall, endocarditis developed in 4 (5.6%) patients in the TPVR group and in 4 (3%) patients in the SPVR group.

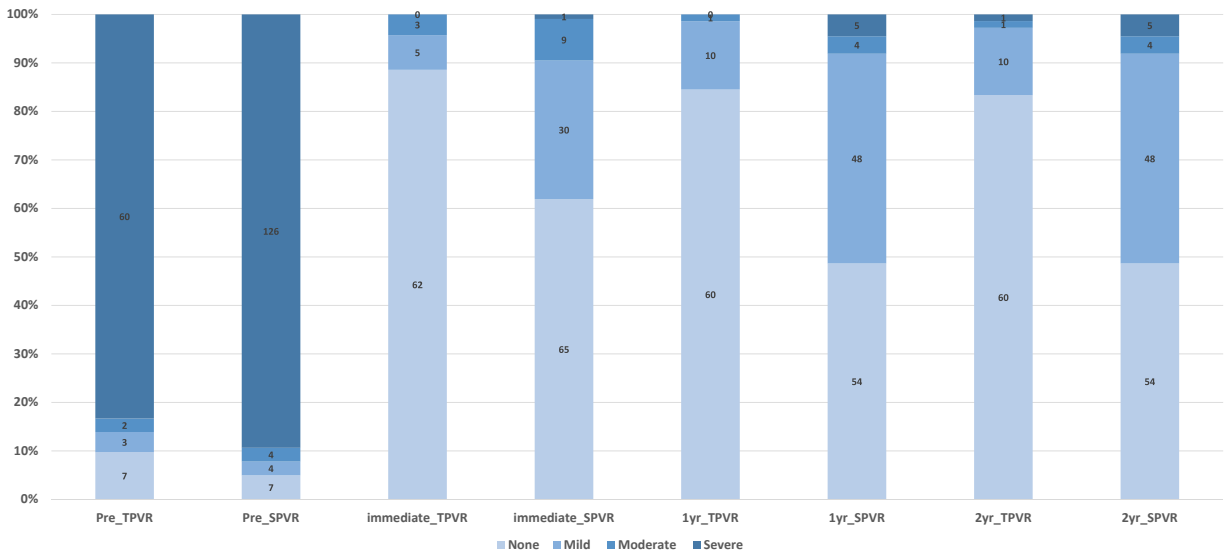
Arrhythmia burden between the TPVR and SPVR groups

There were more patients with preprocedure arrhythmia in the SPVR group (32.4%) than in the TPVR group (18.1%; $P = .021$) (Table 4). However, during the immediate postoperative period, there was no significant difference in arrhythmia symptoms (Table 5). The SPVR group had a longer QRS duration preoperatively and at the 2-year follow-up. There was a median regression in QRS duration of 5 milliseconds (1-14) in the TPVR group and 2 (−4 to 10) milliseconds in the SPVR group ($P = .006$). This represents an average reduction of QRS duration of 2.9% (0.7%-8.4%) in the TPVR group and 1.3% (−2.8% to 5.7%) in the SPVR group ($P = .004$).

Discussion

Post-TOF repair SPVR carries a mortality risk of up to 1.2% and a risk of morbidity because of procedural complications.[19-22] Since 2010, we found 5.8% mortality in the SPVR group. At our institute, RVOT conduit replacement for obstruction carries an additional mortality risk compared with initial placement. This is because, in addition to an increased number of previous surgeries, more dissection is required to explant at least some part of the fibrocalcific wall to place the stitch for the new conduit, which can lead to inadvertent injury of the RV and surroundings. TPVR could be an alternative in this group of patients if the anatomy is feasible (such as RVOT conduit could be safely dilated/stents up to 18 mm, which is the narrowest recommended for Melody valve). TPVR provides outcomes comparable with SPVR and is intended to extend the longevity of a conduit, hence reducing the number of reoperations during a patient's lifetime.[12] TPVR was associated with lower morbidity, shorter intensive care unit stays, and reduced length of hospitalization. Both procedures had comparable immediate outcomes of implanted PV function (measured by gradient across PV). The ultimate size of the PV landing zone (by balloon sizing) in all 144 patients native with RVOT was 26 mm (24-28) in the 43 patients who underwent TPVR, which was smaller than the 31 mm (28-34) seen in the 101 patients who underwent SPVR ($P < .001$). Currently, TPVR valve size is limited to 29 to 32 mm of the intended landing zone diameter. Hence, patients selected for TPVR were younger and had smaller RV volume measured by cardiac MRI.

Surgical implantation of PV in RVOT is a difficult procedure because the oversize prostheses will invariably get compressed anteriorly by the sternum or compromised at the bifurcation of the pulmonary artery.[20-22] Interestingly, we found that the median size of the implanted PV was larger in the TPVR group (26.0 mm [21.0-29.0]) than in the SPVR group 24.0 mm [24.0-25.0]; $P = .002$). This was more obvious in patients with native RVOT, where the median implanted PV size in the TPVR group was 29.0 mm (26.0-29.0), compared with 24.0 mm (24.0-24.0) in the SPVR group ($P < .001$). A study by Capp et al[23] reported that the mean PV diameter in men was 26.2 ± 2.3 mm (n = 2589), and the mean PV diameter in women was 23.9 ± 2.2 mm (n = 1408). This underscores the



Central Illustration. Comparison of proportion and severity of PR between TPVR and SPVR, preprocedure (denoted by "pre_"), immediately postoperative, and at 1 and 2 years. The number of patients in each degree of PR is also shown. The degree of PR is shown as none, mild, moderate, or severe. PR, pulmonary regurgitation; SPVR, surgical pulmonary valve replacement; TPVR, transcatheter pulmonary valve replacement.

importance of a large PV size over the long-term. The largest Gore-Tex tube available was 24 mm, limiting the conduit's size. We found that during 1 and 2 years of follow-up, a small number of patients in the SPVR group developed moderate PR (3.9%) or severe PR (4.9%), which was higher than in the TPVR group. The larger size and stented implanted PV in TPVR may contribute to the long-term valvular function. In addition, most patients who had TPVR with native RVOT had a balloon-expandable valve (Edward SAPIEN 3) that was made from a cobalt-chromium frame and was likely to maintain the integrity of valve function compared with the Gore-Tex valve in the SPVR group. The lack of a metallic framework nature of surgical conduit poses some risk of sternal compression and distortion of the leaflet-baring region. Despite modification of the coaptation height and valve position close to the pulmonary artery bifurcation, some patients experienced mild valve insufficiency. Alternatively, the surgeon may decide to use commercially available surgical valves with sizes as large as 29 mm, such as the Perimount Magna Ease Aortic Valve (Edwards Lifesciences).

Arrhythmia is one of the major complications in postoperative adult TOF. This included premature ventricular contraction and atrial and ventricular arrhythmias.[22,24] A repeated surgical incision in the RV often creates more scars and inevitably leads to the substrate for more arrhythmia.[19] We found a slightly higher incidence of these arrhythmias preoperatively in the SPVR group. This may be explained by the larger RV size in these patients. However, this was not significant in the immediate postoperative period. QRS duration and cardiac MRI findings are correlated with postoperative patients with TOF,[25-27] and these arrhythmias can predict survival.[2-4,28] Therefore, we assessed the QRS duration as a surrogate variable for RV dilatation. Interestingly, at the 2-year follow-up, there was an average regression of the duration of QRS of 5 milliseconds (1-14) in the TPVR group compared with 2 milliseconds (−4 to 10) in the SPVR group ($P = .006$). This finding represented a median reduction of QRS duration of 2.9 milliseconds (0.7-8.4) in the TPVR group compared with 1.3 milliseconds (−2.8 to 5.7) in the SPVR group ($P = .004$). The QRS duration was previously known to be reduced in small but important studies of TOF patients.[29,30] This might be explained by the less regression of the right ventricular end-diastolic volume index in the SPVR group. A recent study reported that PVR reduced the burden of appropriate implantable cardioverter-defibrillator shock.[31] If the regression in QRS duration reflects a certain degree of risk reduction for ventricular arrhythmia, it is likely that this effect was more attenuated in the TPVR group than in the SPVR group. It is also likely that the longer QRS duration with less regression at the 2-year follow-up may have resulted from larger RV volume and redo-ventriculotomy with an incision in the RV or RVOT in the SPVR group. We did not have complete cardiac MRI results in all patients to be able to compare the RV function or volume among both groups. Finally, we saw no difference in reintervention and late endocarditis between both methods.

Our study compared the same cohort of patients who underwent TPVR and SPVR at the same institute during the same period (2010-2021). The techniques of both methods have naturally evolved. The TPVR valve choice increased from balloon expandible Melody[10,12,32] and Edward SAPIEN S3 valve[13] to the self-expandible Venus P-valve[14] and the Pulsta valve.[15,33] The Edward SAPIEN S3 valve is also particularly useful for a patient with a previously implanted bioprosthesis valve that needs a large valve-in-valve procedure, as did 6 of our patients. In fact, to

Table 5. Immediate early postoperative period and 2 years of follow-up on arrhythmia burden after pulmonary valve replacement in TPVR and SPVR groups.

	TPVR (N = 61)	SPVR (N = 137)	*P* value
Preoperative symptomatic arrhythmia	13 (18.1%)	46 (32.4%)	.021
Immediate postoperative arrhythmia			.036
SVT/VT	2 (2.8%)	11 (7.7%)	.614
AVB	0	2 (1.5%)	
QRS duration comparison			
QRS duration before procedure, msec	160 (147.8-171.0)	169.5 (150-180)	.039
QRS duration 2 y after procedure, msec	154 (140-170)	165 (148.5-180)	.011
Duration of QRS regression from before to 2 y after the procedure, msec	5 (1-14)	2 (−4 to 10)	.006
Percentage of QRS regression from before to 2 y after the procedure, IQR	2.9 (0.7-8.4)	1.3 (−2.8 to 5.7)	.004

Nonnormal distribution variables are presented as median with IQR (25%-75%).
AVB, atrioventricular block; SPVR, surgical pulmonary valve replacement; SVT, supraventricular tachycardia; TPVR, transcatheter pulmonary valve replacement; VT, ventricular tachycardia.

the best of our knowledge, this is the only study that involved all 4 valves in the same group of patients. Because of the higher failure rate of homograft, Contegra, or Dacron-type valves, our surgeons developed a technique of suturing the Gore-Tex tube to better respect the RVOT anatomy, supported by a previous report of longer-term durability.[34,35] However, this came with the limitation of 24-mm diameter in Gore-Tex tube size. Therefore, the design and technique were simplified as previously described.[16,17] Other types of surgical valves included the Perimount Magna Ease Aortic Valve (Edwards Lifesciences). Our observed mortality and morbidity, although lower in the current era, reflect a learning curve for both TPVR and SPVR in our institute. Nevertheless, the retrospective nature of our study limited our ability to accurately pinpoint all sources of morbidity related to the procedure.

The development of Melody valve implantation in the early 2000s[36] was originally intended to extend the longevity of the RVOT conduit. Although these procedures were performed in >12,000 patients worldwide,[10,21,37] they were not readily applicable in most patients with TOF with native RVOT and severe PR. The Edwards SAPIEN S3 valve[13,38,39] could be invertedly mounted on the Commander system for PV implantation. Large, balloon-expandable stent placement in the right side of the heart, such as in the conduit or branch pulmonary artery, is a familiar procedure performed in our biplane congenital heart intervention cardiac catheterization suites for decades. This relevant experience can shorten the learning curve for the operator and team, with success rates as high as 80%[13,37-40] for patients with RVOT conduit and obtained a class I indication for TPVR by the European Society of Cardiology.[9] For patients with native RVOT, the success rate could also be improved by an additional type of TPVR system, such as a self-expandible system Venus P-valve[14] or Pulsta valve[15] to accommodate different types of RVOT anatomy.[18,41] The Harmony self-expanding transcatheter PV that can accommodate larger sizes, already available in the United States, will become available in South East Asia/Thailand.[42,43]

Conclusions

To our knowledge, this is the first study to involve 4 types of TPVR valves (Melody, Edwards, Venus P, and Pulsta) in the same cohort. TPVR resulted in lower mortality and fewer major adverse events than SPVR. In addition, TPVR allowed for a larger diameter of PV implants, which can positively impact the PV function. SPVR was preferable in patients with larger (>30 mm) native RVOT and in patients who required concomitant surgical procedures, explant of the conduit, or resect of RVOT aneurysm. During the 2 years of follow-up, patients who underwent TPVR were more likely to experience a regression in the QRS duration.

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Declaration of competing interest

Dr Durongpisitkul has been certified for Edwards Lifesciences SAPIEN Transcatheter Heart Valve Proctors for Japan, Asia and Pacific since January 7, 2021. Drs Dangrungroj, Chungsomprasong, Vijarnsorn, Chanthong, Pacharapakornpong, Kanjanauthai, Soongswang, Panjasamanvong, Plearntummakun, Tocharoenchok, Nitiyarom, Tantiwongkosri, Thongcharoen, Subtaweesin, and Sriyoschati reported no financial interests.

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Ethics statement

This study was approved by the Siriraj Institutional Review Board (407/2563[IRB2]) which followed National Policy and Guidelines for Human Research 2015 (translated to Thai language).

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