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## CLINICAL RESEARCH

# Melody<sup>®</sup> transcatheter pulmonary valve implantation: Results from a French registry



Implantation de la valve Melody<sup>®</sup> par cathétérisme interventionnel : résultats du registre français

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**Abbreviations:** MRI, magnetic resonance imaging; RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation.

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**KEYWORDS**

Transcatheter;  
Pulmonary valve  
implantation;  
Cardiac  
catheterization

**Summary**

*Background.* – Percutaneous implantation of pulmonary valves has recently been introduced into clinical practice.

*Aim.* – To analyse data of patients treated in France between April 2008 and December 2010.

*Methods.* – Prospective, observational, multi-centric survey by means of a database registry of the Filiale de cardiologie pédiatrique et congénitale.

*Results.* – Sixty-four patients were included, with a median (range) age of 21.4 (10.5–77.3) years. The majority (60.9%) of the patients were New York Heart Association (NYHA) class II. The most common congenital heart disease was tetralogy of Fallot with or without pulmonary atresia (50%). Indication for valve implantation was stenosis in 21.9%, regurgitation in 10.9% and association of stenosis and regurgitation in 67.2%. Implantation was successful in all patients. Pre-stenting was performed in 96.9% of cases. Median (range) procedure time was 92.5 (25–250) minutes. No significant regurgitation was recorded after the procedure, and the trans-pulmonary gradient was significantly reduced. Early minor complications occurred in five cases (7.8%). Three patients died during a median follow-up of 4.6 (0.2–5.2) years, two from infectious endocarditis and one from end-stage cardiac failure. Surgical reintervention was required in three patients. Follow-up with magnetic resonance imaging demonstrated significant improvements in right ventricular volumes and pulmonary regurgitation in mixed and regurgitant lesions.

*Conclusions.* – Transcatheter pulmonary valve implantation is highly feasible and mid-term follow-up demonstrates sustained improvement of right ventricular function. Late endocarditis is of concern, therefore longer follow-up in more patients is urgently needed to better assess long-term outcome.

*Clinical trial registration.* – NCT01250327.

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**MOTS CLÉS**

Trans-cathéter ;  
Cathétérisme  
interventionnel ;  
Implantation de valve  
pulmonaire

**Résumé**

*Contexte.* – La valvulation pulmonaire percutanée a récemment été introduite en pratique clinique.

*Buts.* – Analyser les données des patients traités en France entre avril 2008 et décembre 2010.

*Méthodes.* – Étude prospective, observationnelle, multicentrique sous la forme d'un registre sous l'égide de la filiale de cardiologie pédiatrique et congénitale de la Société française de cardiologie.

*Résultats.* – Soixante-quatre patients ont été inclus à un âge médian de 21,4 (10,5–77,3) ans. La majorité (60,9%) était en classe New York Heart Association (NYHA) II. La cardiopathie congénitale la plus fréquente était la tétralogie de Fallot avec ou sans atrésie pulmonaire (50%). L'indication de valvulation était une sténose pure chez 21,9%, une régurgitation chez 10,9% et l'association d'une sténose et d'une régurgitation chez 67,2%. La valvulation a été réalisée avec succès chez tous les patients. Un préstenting a été fait chez 96,9% des cas. La durée moyenne (intervalle) de la procédure était de 92,5 (25–250) minutes. Il n'y avait pas de régurgitation significative après la procédure, et le gradient transpulmonaire a été significativement réduit. Des complications mineures sont survenues dans cinq cas (7,8%). Trois patients sont décédés durant le suivi médian de 4,6 (0,2–5,2) ans, deux d'une endocardite infectieuse et un d'une insuffisance cardiaque terminale. Des réinterventions chirurgicales ont été pratiquées chez trois patients. Le suivi par l'imagerie à résonance magnétique nucléaire a montré une amélioration significative des volumes ventriculaires droits et de la régurgitation pulmonaire dans les lésions mixtes et régurgitantes.

*Conclusions.* – La valvulation pulmonaire par cathétérisme interventionnel est faisable. Le suivi à moyen terme montre une amélioration significative de la fonction ventriculaire droite. Les endocardites tardives sont une préoccupation importante. Des études avec un suivi plus long et un plus grand nombre de patient sont indispensables afin de mieux évaluer le devenir à long terme.

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## Background

Right ventricular outflow tract (RVOT) dysfunction after repair of congenital and structural heart disease has been treated, during the past four decades, by surgical placement of a conduit between the right ventricle and the pulmonary artery [1]. Due to patient growth and conduit degeneration, these conduits have to be replaced frequently over the course of a lifetime [2–4]. Transcatheter approaches for the management of dysfunctional RVOT have evolved over time, from high-pressure balloon dilation [5] and stent implantation [6] to transcatheter pulmonary valve implantation (TPVI) [7,8]. Since the introduction of TPVI, the majority of studies have reported its feasibility with excellent results [9–13].

Our study reports on a national multicentre registry supported by the Filiale de cardiologie pédiatrique et congénitale (FCPC) and funded by the Ministry of Health (Soutien aux Techniques Innovantes et Coûteuses, 2008).

## Methods

### Selection criteria and study design

From May 2008 to December 2010, a prospective, observational, multicentre registry was used to assess indications, results and complications of TPVI with the Melody® valve (Medtronic Inc., Minneapolis, MN, USA) in patients with dysfunctional RVOT conduits. A grant was offered by the French Ministry of Health under the protocol “Soutien aux Techniques Innovantes et Coûteuses 2008” to study TPVI with the Melody® valve in 64 patients.

Patients with obstruction, pulmonary regurgitation or mixed lesions were included. RVOT procedures included balloon dilatation with or without bare metal stent insertion and TPVI. Patients were enrolled in five tertiary academic centres in France (Necker Hospital for Sick Children, Paris; George-Pompidou European Hospital, Paris; Institut Hospitalier Jacques-Cartier, Massy; Unit for children and adults with congenital heart defects, Bordeaux and La Timone Hospital, Marseille). Patients were included according to each implanting centres’ indications and practice, based on the usual criteria used for surgical or TPVI:

- symptomatic patients with Doppler mean gradient > 35 mmHg and/or at least moderate pulmonary regurgitation;
- asymptomatic patients with the following criteria by: magnetic resonance imaging (MRI) (right ventricular end-diastolic volume index > 150 mL/m<sup>2</sup> or Z-score > 4; right ventricular end-systolic volume index > 80 mL/m<sup>2</sup>; right ventricular ejection fraction < 47%; left ventricular ejection fraction < 55%; large RVOT aneurysm) and/or electrocardiography (sustained tachyarrhythmia related to right heart volume load with QRS duration > 140 ms) and/or echocardiography (mean Doppler gradient > 40 mmHg) and/or haemodynamics (RVOT obstruction with RV systolic pressure  $\geq$  2/3 systemic pressure).

Procedural and follow-up data were entered in to a database approved by an institutional review board. Demographic data, procedural details and immediate and

mid-term outcomes and complications were obtained for all patients. Patients with native RVOT, native pulmonary valve stenosis and age < 5 years and/or weight < 25 kg were excluded. Patients with active endocarditis, infection or sepsis, pregnancy or central vein occlusion were also excluded. During pre-implantation catheterization, patients in whom a coronary compression was diagnosed were also excluded. The survey was approved by the national ethics committee. Written informed consent was obtained from each patient and/or his/her parents or legal guardian. The study is registered at the National Institute of Health website (<http://www.clinicaltrials.gov>) with identifier NCT01250327.

### Pre-procedure evaluation

All patients underwent a pre-procedure clinical evaluation including electrocardiogram (ECG), echocardiography (assessment of biventricular function, pulmonary regurgitation and right ventricular pressure), chest X-ray, exercise testing, MRI (assessment of ventricular volumes by manually tracing the epicardial and endocardial borders and evaluation of ejection fraction and pulmonary regurgitation fraction).

### Diagnostic catheterization

Cardiac catheterization was performed under sedation or general anaesthesia. RVOT stenosis was deemed as the primary indication if the RVOT peak-to-peak gradient and RV pressure were > 25 mmHg and > 2/3 systemic pressure, respectively. Pulmonary regurgitation was deemed to be the primary indication in the presence of angiographically significant pulmonary regurgitation with an RVOT peak systolic pressure  $\leq$  25 mmHg. Patients who did not meet the specific criteria for RVOT stenosis or regurgitation were classified as mixed lesions.

### Procedure

The Medtronic Melody® Transcatheter Pulmonary Valve (Model PB10) was implanted, according to the technique previously described [7–13]. Risk for coronary compression was assessed with aortic root angiogram in two views (lateral and four-chamber views) and/or selective coronary angiogram, prior to and during high-pressure balloon inflation. Importantly, we ensured that the size of the balloon used to assess coronary compression always matched the expected diameter of the bare metal stent or Melody® valve. Most of the patients had pre-stenting of the RVOT with CP (NuMed Inc., Hopkinton, NY, USA) and/or ev3 LD Max (ev3 Endovascular Inc., Plymouth, MN, USA) [14].

### Data reporting

Data collected for each patient included their congenital cardiac lesions, the substrate of RVOT (conduit, bioprosthetic or pericardial patch reconstruction of outflow tract), the number and type of previous surgeries and their New York Heart Association (NYHA) class. The following primary outcomes were collected: procedural success (no or trivial regurgitation on post-implantation angiogram and

a post-implantation peak-to-peak gradient  $\leq 20$  mmHg), complications, TPVI-related death and mid-term follow-up success.

Patients were evaluated (clinical assessment, ECG, chest X-ray and echocardiography) 24 hours after implantation, at 1, 3, 6 and 12 months and every year. Echocardiographic data were collected: any significant (> trivial) pulmonary regurgitation, systolic right ventricular pressure (if tricuspid regurgitation), ventricular diameters and function. MRI was performed within 6 months after TPVI. Cine-angiogram looking for stent fractures was performed at any time during follow-up in case of increased RVOT gradient during follow-up, signs of pulmonary embolism, appearance of or increase in pulmonary regurgitation, with or without stent fractures on standard X-ray. Stent fractures with no clinical repercussion or haemodynamic consequences were disregarded. The follow-up information was collected from the patient's chart. Any death or reintervention occurring during follow-up was fully investigated.

## Statistical analysis

PASW statistics 17.0 (SPSS Inc., SPSS, Chicago, USA) was used for statistical analysis. Data are expressed as mean (standard deviation [SD] or range) if normally distributed or as median (range). Nominal variables are expressed as numbers and percentages. Student's paired *t* test was used to evaluate the difference after TPVI. Categorical variables were compared using the  $\chi^2$  test, the Wilcoxon signed-rank test and the Mann–Whitney U test. Kaplan–Meier actuarial survival curves were obtained. All tests were two-sided and a *P* value of  $< 0.05$  was considered statistically significant.

## Results

### Patient characteristics

Characteristics of the 64 included patients are reported in [Table 1](#). The majority (60.9%) of the patients were NYHA class II, while no patient was class IV. Indications for valve implantation was pure stenosis in 14 patients (21.9%), pure regurgitation in seven (10.9%) and association of stenosis and regurgitation in 43 (67.2%).

### Procedural data and early results

A femoral vein approach was used in 62 cases (96.9%) whereas two patients underwent TPVI through jugular access. The valve was successfully delivered in all patients. Median (range) procedural time was 92.5 (25–250) minutes. Pre-stenting was performed in 96.9% of the patients using bare CP stents (Numed, Hopkinton, NY, USA), covered CP stents (Numed, Hopkinton, NY, USA) or ev3 LD Max (ev3 Endovascular Inc.). A maximum of four stents were implanted. In three of the seven patients with pure pulmonary regurgitation, Russian dolls and/or jailing technique were used [15].

A 22-mm Ensemble delivery system was used to implant the valve ([Fig. 1](#)) in 61 patients (95.3%), whereas a 20-mm system was used in two patients (3.1%) and an 18-mm system in one patient (1.6%).

**Table 1** Patient characteristics.

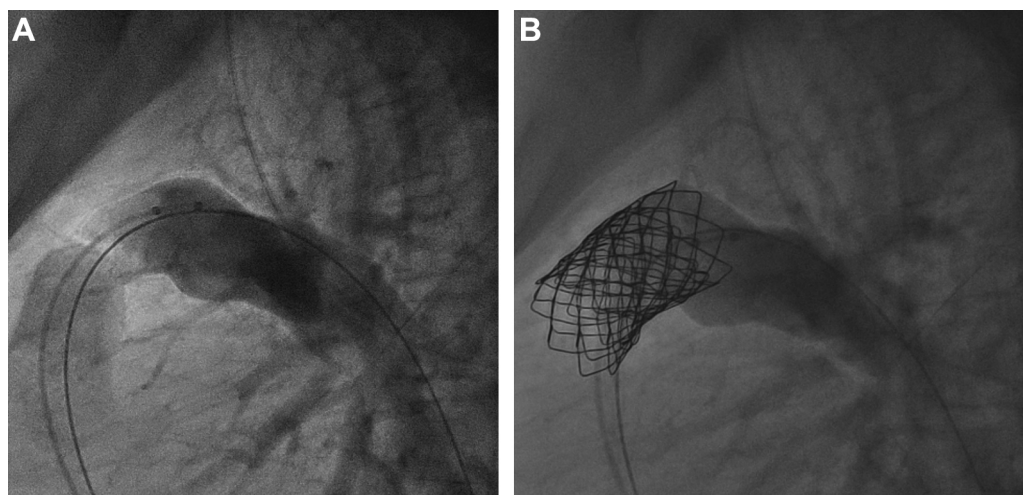
	All patients ( <i>n</i> = 64)
Age at TPVI (years)	21.4 (10.5–77.3)
Women	38 (59.4)
NYHA class	
I	16 (25.0)
II	39 (60.9)
III	9 (14.1)
Congenital heart disease	
TOF–PA-VSD	32 (50.0)
Common arterial trunk	9 (14.1)
LVOT disease post Ross surgery	8 (12.5)
DORV and variants	6 (9.4)
Transposition of the great arteries	5 (7.8)
Pulmonary stenosis	3 (4.7)
cc-TGA	1 (1.6)
Previous surgeries	
1	10 (15.6)
2	24 (37.5)
3	18 (28.1)
4	9 (14.1)
5	3 (4.7)
Primary indication(s) number (%)	
Pulmonary stenosis and regurgitation	43 (67.2)
Pulmonary stenosis	14 (21.9)
Pulmonary regurgitation	7 (10.9)
Pre-stenting	62 (96.9)

Data are median (range) or number (%). cc-TGA: congenitally corrected transposition of the great arteries; DORV: double outlet right ventricle; LVOT: left ventricular outflow tract; NYHA: New York Heart Association; PA-VSD: pulmonary atresia-ventricular septal defect; TOF: tetralogy of Fallot; TPVI: transcatheter pulmonary valve implantation.

Associated procedures were performed in 11 cases (17.2%) and included atrial septal defect closure (*n* = 2), aortic coarctation stenting (*n* = 1), pulmonary artery branch stenting (*n* = 5), main pulmonary artery bifurcation stenting (*n* = 2) and right coronary artery dilation (*n* = 1). In all of these patients, the pulmonary valve was in a stable position. Mean right ventricular systolic pressure, right ventricle to pulmonary artery gradient and right ventricle to aorta pressure ratio were all significantly reduced from pre to post-procedure ([Table 2](#)). Among 57 patients with significant stenosis (43 patients with mixed lesion and 14 with isolated stenosis), right ventricular systolic pressure and peak-to-peak systolic gradient across the RVOT reduced significantly in 51 (89.5%), with  $< 20$  mmHg gradient after the procedure. The other six of these patients (10.5%) had a residual peak-to-peak gradient  $> 20$  mmHg, including five with a non-expandable bioprosthesis.

No patient had mild or a more severe form of pulmonary regurgitation after TPVI.





**Figure 1.** A. Frontal right ventricular outflow tract angiogram showing a purely stenotic lesion. B. A 22-mm Melody® valve has been implanted with no residual regurgitation on the control angiogram.

### Procedural complications

Minor complications occurred in 11 patients (17.2%): a confined tear after balloon dilation of a homograft conduit ( $n=7$ ), treated with covered ( $n=4$ ) or bare ( $n=3$ ) stent implantation; minor bleeding from the oro-tracheal tube ( $n=1$ ) with spontaneous resolution; a false aneurysm of the left femoral artery ( $n=1$ ) with favourable outcome after local compression; blood transfusion requirement ( $n=1$ ) due to significant bleeding at the femoral access; and groin haematoma ( $n=1$ ).

### Post-TPVI course and outcome

The median (range) hospital stay was 3 (2–5) days, and median follow-up time was 4.6 (0.2–5.2) years. Three patients died. Firstly, a 26-year-old man with corrected tetralogy of Fallot-pulmonary atresia died 2.6 months after TPVI. He presented in acute heart failure after a 10-day history of low-grade fever. By echocardiography, the RVOT was obstructed by valve vegetation and *Staphylococcus epidermidis* was obtained from blood culture. He was scheduled for surgery the day after his admission but died during the night from ventricular fibrillation. Infective endocarditis was confirmed at autopsy. Secondly, an 18-year-old woman with corrected tetralogy of Fallot-pulmonary atresia experienced endocarditis 28.3 months after TPVI. She presented after 1 week of low-grade fever in septic shock with severe right ventricular and liver failure. RVOT was obstructed by

echocardiography Doppler with 121 mmHg peak gradient. Surgery was planned in the afternoon of her admission. She went into ventricular fibrillation upon entering the operating room. She was rapidly put onto extracorporeal membrane oxygenation support. The RVOT conduit was extracted, but the patient subsequently died from multiorgan failure (severe neurological impairment). *Streptococcus sanguinis* was found on blood culture with large obstructive vegetations on the Melody® valve. Thirdly, a 57-year-old man with a corrected tetralogy of Fallot died. He had a severely depressed right ventricular function that did not improve after TPVI. He died 23.7 months after TPVI from end-stage cardiac failure while he was considered for heart transplantation.

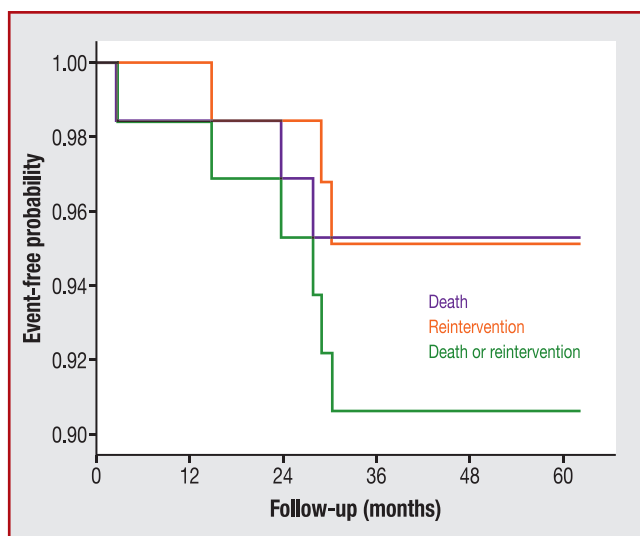
Surgical reoperation was performed in three patients because of resurgence of conduit obstruction (24 and 29 months after TPVI) in two and severe tricuspid insufficiency in one. In the last patient, the existing tricuspid regurgitation did not improve after TPVI. Surgery was performed 30 months after TPVI. Melody valve was replaced by a homograft during the tricuspid annuloplasty.

The only other patient who experienced late complications during follow-up was a 21-year-old woman who suffered from infective endocarditis 4.2 years after TPVI. She had been lost to follow-up and has discontinued aspirin. She experienced frequent cystitis in the setting of an associated urogenital malformation and she was not compliant to bacterial endocarditis prophylaxis. She presented with a moderately increased mean RVOT gradient

**Table 2** Haemodynamic results.

	Pre-procedure ( $n=64$ )	Post-procedure ( $n=64$ )	<i>P</i>
RV systolic pressure (mmHg)	74 (25–130)	42 (20–67)	< 0.001
Peak-to-peak systolic RV-PA gradient (mmHg)	50 (5–115)	14 (0–33)	< 0.001
RV/aorta pressure ratio	0.82 (0.19–1.44)	0.41 (0.17–0.72)	< 0.001

Data are mean (range). PA: pulmonary artery; RV: right ventricle.



**Figure 2.** Kaplan–Meier curves showing freedom from death, reintervention and death and reintervention.

(25 mmHg by Doppler). *Staphylococcus haemolyticus* was found in blood cultures and she was treated medically with triple antibiotherapy. Her outcome was favourable, with a moderate residual RVOT obstruction of 30–35 mmHg (mean Doppler gradient) at last follow-up.

Freedom from death, reintervention and death/reintervention is shown in Fig. 2. No significant stent fractures were noted during follow-up.

### MRI data

Coupled data pre-implantation and 6 months after implantation were available in 43 cases. By 6-month post-procedure MRI, reductions in right ventricular volumes and pulmonary regurgitation fractions had occurred, and these varied by indication for TPVI (stenosis, regurgitation or mixed lesion) (Table 3). Right ventricular end-diastolic volumes and pulmonary regurgitation fractions improved significantly in patients with mixed and regurgitant lesion while the change was much less pronounced in purely stenotic RVOT. Left ventricular volumes and biventricular function did not change significantly after TPVI (Table 3).

### Discussion

TPVI is used worldwide, and recent studies have demonstrated very good early and short-term results [8–13]. However, medium- and long-term follow-up is currently lacking. With the exception of an Italian registry, that reported a median follow-up of 2.5 years [13], the present study is the only one to provide mid-term data, with a median follow-up of 4.6 years. Although Lurz et al. [9] reported a median follow-up of 2.4 years, their study does not reflect TPVI in the current era as they included the very first cases of TPVI [9].

With a median (range) procedure duration of 92.5 (25–250) minutes, our implantation time compares favourably to other studies [8–13]. With a 100% successful implantation rate, our registry demonstrates excellent

procedural results. This is comparable to the Italian registry that reported a 95.6% successful implantation rate [13]. Our procedural complication rate was low. Most were minor complications. There were no cases of procedural mortality and no patients were sent for surgery. Conduit rupture that occurred during balloon interrogation for coronary compression was the most frequent procedural complication. Although this occurred in almost 11%, no coronary compression was misdiagnosed using the diagnostic modality followed in the present registry. Because diagnosis of coronary compression by pre-procedural imaging (e.g. computed tomography and/or MRI) is not very accurate, angiography during balloon dilation was performed in every patient, with aortic root angiograms in at least two projections and/or a selective coronary angiogram. Importantly, we tend to use a non-compliant balloon that matches the intended Melody® implant diameter and length [14].

Three patients (4.7%) died during the present study, including two from infectious endocarditis. In this study, infective endocarditis occurred in four patients (6.3%), including three cases that presented > 18 months after TPVI. Information about three of these four patients has been previously published [16] and this problem has been reported in other studies [12,13] as well as in a small cohort of patients [17]. Late infective endocarditis with the Melody® valve raises some important concerns. In the current study, a 50% mortality rate from infective endocarditis was particularly high, as was the need for emergency surgery. Of interest, aspirin had been discontinued in three of the four cases and one of them was not compliant to bacterial endocarditis prophylaxis. In a recent literature review, the overall mortality was 13% and over half of the patients underwent surgical bioprosthesis explantation [17]. The most common microorganisms were *Staphylococcus* and *Streptococcus* species [17], as in our study. Data from larger multicentre registries may help to identify the true incidences of explantation and death, and possible risk factors. Strict antibiotic prophylaxis and extensive preprocedure infectious disease evaluation must be done in all patients. Urgent intervention to relieve acute obstruction is likely to reduce mortality and should always be considered along with aggressive management of infective endocarditis.

The last patient – who died from progressive heart failure – had TPVI in the setting of advanced heart failure with biventricular dysfunction. Clearly, patients should undergo surgical or TPVI before they become symptomatic. Recent studies on repaired tetralogy of Fallot have demonstrated that relying on symptoms related to heart failure as the major criteria for surgical or TPVI results in patients receiving a pulmonary valve when their right ventricle is markedly dilated. In such patients, right ventricular size will often not return to normal and patients will continue to deteriorate. In the present study, indication for TPVI was mainly considered in asymptomatic patients with MRI, electrocardiographic and haemodynamic criteria. Right and left ventricular ejection fractions did not change significantly after the procedure because TPVI was performed before significant ventricular function deterioration. Right ventricular end-diastolic volume and pulmonary regurgitation improved significantly by 6-month post-procedure MRI among patients with regurgitant or mixed lesions.

**Table 3** Magnetic resonance imaging data.

	Pre-procedure (n = 43)	Post-procedure (6-month follow-up) (n = 43)	P
<i>End-diastolic RV volume (mL/m<sup>2</sup>)</i>	111.1 ± 39.7	87.3 ± 24.7	0.0002
Mixed (n = 27)	114.2 ± 37.4	86.9 ± 21.0	0.0002
Stenosis (n = 9)	95.0 ± 35.9	85.0 ± 30.2	0.49
Regurgitation (n = 7)	119.3 ± 36.5	92.0 ± 34.5	0.02
<i>RV ejection fraction (%)</i>	48.1 ± 11.2	48.4 ± 13.3	0.6
Mixed (n = 27)	49.3 ± 12.3	50.8 ± 15.9	0.8
Stenosis (n = 9)	48.6 ± 7.8	49.4 ± 12.4	0.93
Regurgitation (n = 7)	40.6 ± 14.6	35.4 ± 15.9	0.48
<i>Pulmonary regurgitation fraction (%)</i>	30.4 ± 16.3	3.5 ± 6.6	0.03
Mixed (n = 27)	31.5 ± 12.2	2.9 ± 6.5	0.05
Stenosis (n = 9)	10.5 ± 15.0	5.1 ± 8.0	0.3
Regurgitation (n = 7)	46.4 ± 24.0	1.4 ± 3.5	0.01
<i>End-systolic LV volume (mL/m<sup>2</sup>)</i>	78.0 ± 14.1	80.6 ± 24.4	0.59
Mixed (n = 27)	77.7 ± 22.1	82.8 ± 22.1	0.75
Stenosis (n = 9)	83.1 ± 22.5	79.0 ± 25.2	0.88
Regurgitation (n = 7)	71.5 ± 37.8	73.0 ± 34.7	0.6
<i>LV ejection fraction (%)</i>	56.6 ± 2.8	56.4 ± 9.0	0.68
Mixed (n = 27)	56.2 ± 9.2	57.7 ± 9.9	0.46
Stenosis (n = 9)	59.9 ± 7.9	55.0 ± 10.0	0.82
Regurgitation (n = 7)	53.0 ± 11.8	53.0 ± 11.8	0.81

Data are mean ± standard deviation. LV: left ventricle/ventricular; RV: right ventricle/ventricular.

Conversely, in stenotic RVOT, ventricular end-diastolic volume and pulmonary regurgitation did not change significantly after TPVI. The lack of change was due to lower starting values rather than higher end values. Our results are in agreement with a recent study that reported that the type of right ventricular loading (pressure versus volume) before pulmonary valve replacement affects the remodelling pattern [18]. In purely stenotic RVOT, a decrease in the end-diastolic volume after TPVI was absent [18].

No severe fractures with clinical or haemodynamic consequences were reported in our study. However, stent fracture has been reported with a rate as high as 30% at 6 months [11], although further studies have shown that pre-stenting reduces this rate significantly [12]. The majority of our patients were prestented, which could help to explain our low rate. This may also be due to the non-systematic search of this complication. We only counted significant stent fractures (i.e. those with a clinical impact or haemodynamic disturbance), whereas some studies have included all type of fractures. Some authors recommend a systematic search for stent fracture using high-radiation dose imaging modalities including X-ray and cine-angiogram (which is a more sensitive tool) in all patients during follow-up. We performed cine-angiogram only in patients with suspected stent fractures based on clinical and echographic parameters. Resurgence of RVOT obstruction after TPVI in non-infected patients usually relates to stent fractures secondary to multiple stent fractures with loss of stent integrity and radial force.

## Limitations

The number of patients treated in the current study was not very high and, despite reasonably long follow-up, ideally this would be longer, especially to assess the frequency of late complications such as infectious endocarditis.

## Conclusions

In the current era, the feasibility of TPVI is excellent and mid-term follow-up with MRI demonstrates sustained improvement of RVOT function. However, late occurrence of endocarditis is of concern. Longer follow-up with more patients treated is urgently needed to better assess the long-term outcome of RVOT function after TPVI.

## Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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