

Percutaneous pulmonary valve implantation in patients with right ventricular outflow tract dysfunction: a systematic review and meta-analysis

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Abstract

Background: Pulmonary valve replacement is required for patients with right ventricular outflow tract (RVOT) dysfunction. Surgical and percutaneous pulmonary valve replacement are the treatment options. Percutaneous pulmonary valve implantation (PPVI) provides a less-invasive therapy for patients. The aim of this study was to evaluate the effectiveness and safety of PPVI and the optimal time for implantation.

Methods: We searched *PubMed*, *EMBASE*, *Clinical Trial*, and *Google Scholar* databases covering the period until May 2018. The primary effectiveness endpoint was the mean RVOT gradient; the secondary endpoints were the pulmonary regurgitation fraction, left and right ventricular end-diastolic and systolic volume indexes, and left ventricular ejection fraction. The safety endpoints were the complication rates.

Results: A total of 20 studies with 1246 participants enrolled were conducted. The RVOT gradient decreased significantly [weighted mean difference (WMD) = -19.63 mmHg; 95% confidence interval (CI): -21.15 , -18.11 ; $p < 0.001$]. The right ventricular end-diastolic volume index (RVEDVi) was improved (WMD = -17.59 ml/m²; 95% CI: -20.93 , -14.24 ; $p < 0.001$), but patients with a preoperative RVEDVi >140 ml/m² did not reach the normal size. Pulmonary regurgitation fraction (PRF) was notably decreased (WMD = -26.27% , 95% CI: -34.29 , -18.25 ; $p < 0.001$). The procedure success rate was 99% (95% CI: 98–99), with a stent fracture rate of 5% (95% CI: 4–6), the pooled infective endocarditis rate was 2% (95% CI: 1–4), and the incidence of reintervention was 5% (95% CI: 4–6).

Conclusions: In patients with RVOT dysfunction, PPVI can relieve right ventricular remodeling, improving hemodynamic and clinical outcomes.

Keywords: efficacy, meta-analysis, percutaneous pulmonary valve implantation, right ventricular outflow tract dysfunction, safety

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Introduction

The incidence of congenital heart disease (CHD) varies between 5 and 8 per 1000 live births.^{1,2} Approximately 20% of newborns with CHD have anomalies in the pulmonary valve or right ventricular outflow tract (RVOT), such as tetralogy of Fallot (TOF), truncus arteriosus, or pulmonary atresia.³ For these patients, surgical repair of the

RVOT is needed. Ultimately, however, these patients are subject to progressive RVOT dysfunction,^{4,5} which may take the form of pulmonary valve regurgitation (PR), pulmonary valve stenosis (PS), or both. Currently, surgical pulmonary valve replacement (SPVR) is considered the gold standard of treatment for PR and can be performed with a low mortality rate.^{6,7} However, valved conduits

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have a limited lifespan, often <10 years,^{8–12} thus necessitating an additional open-heart procedure.

In 2000, Dr Phillip Bonhoeffer performed the first percutaneous pulmonary valve implantation (PPVI) in a 12-year-old boy with stenosis and insufficiency of a prosthetic conduit from the right ventricle to the pulmonary artery.¹³ Since then, the number of patients receiving PPVI has increased steadily because PPVI provides a nonsurgical and less invasive alternative for patients. To date, thousands of percutaneous pulmonary valve implantations have been performed worldwide¹⁴; however, the timing of PPVI in patients with severe PR after TOF correction is still controversial. Until now, no meta-analysis has evaluated the effectiveness and safety of PPVI. Therefore, in this study, we aimed to evaluate the effectiveness and safety of PPVI in patients with RVOT dysfunction and to determine the optimal time for PPVI.

Methods

Study search and eligibility criteria

Two authors (L.Y.R. and W.W.W.), independently and in duplicate, searched the *PubMed*, *EMBASE*, *Clinical Trial* and *Google Scholar* databases for the period until May 2018. The terms used for the search were ('transcatheter' OR 'percutaneous') AND 'pulmonary valve' AND ('implantation' OR 'replacement'), as well as 'Melody valve'. The full electronic search strategy is presented in Supplementary File S1. We also manually checked reference lists of the identified reports and relevant reviews.

Studies meeting the following inclusion criteria were adapted: (1) Population: patients with RVOT dysfunction who received PPVI; (2) Intervention: PPVI; (3) Outcomes: changes in volume and function of both right and left ventricles, including valve function as assessed by echocardiography. Complications after PPVI were also estimated. Case reports were also considered. Reviews and studies including no recorded data were excluded. Publication language was not limited to English. To avoid overlapping information, when there were multiple studies from the same population, only one was included in each analysis.

Study selection

The selection procedure was performed in the following manner: (1) records were identified

using a database; (2) duplicates were removed; (3) abstracts were screened and selected; (4) full-text articles were assessed for eligibility; and (5) finally, eligible studies were included.

The inclusion or exclusion criteria were unanimously selected; steps 1 to 3 were carried out by one reviewer, while step 4 was performed by two independent reviewers (L.Y.R. and W.W.W.). In cases of disagreement, a third reviewer (W.H. Shi) made the final decision.

Data extraction

The two independent reviewers reviewed the studies and extracted the following comparative data, which were also obtained for the pre- and post-replacement periods: RVOT gradient (mmHg); pulmonary regurgitation fraction (PRF; %); indexed right ventricular end-diastolic volume (RVEDV; ml/m²), indexed right ventricular end-systolic volume (RVESV; ml/m²), indexed left ventricular end-diastolic volume (LVEDV; ml/m²), indexed left ventricular end-systolic volume (LVESV; ml/m²), left ventricular ejection fraction (LVEF; %), and right ventricular ejection fraction (RVEF; %). Clinical outcomes [reintervention, infective endocarditis (IE), stent fracture, and procedure success] were also collected to evaluate procedure effectiveness and safety.

Methodological quality assessment

The Newcastle–Ottawa scale (NOS) for assessing the quality of nonrandomized studies in meta-analyses¹⁵ was used to assess the risk of bias from three aspects: selection, comparability, and outcome. All included studies were prospective or retrospective; therefore, we considered preimplantation patients to comprise a nonexposed cohort and post-implantation patients to comprise an exposed cohort to assess the risk of bias. Higher numbers of stars mean better quality; study quality was assessed as low (0–4 stars), moderate (5–6 stars), or high (7–9 stars).

Statistical analysis

Difference in means, 95% confidence interval (CI), and risk ratio were used to measure the outcomes. The *p* values were considered significant when *p* < 0.05. STATA software (version 12) was used to evaluate the outcomes. Heterogeneity

was assessed based on the Cochrane Q-statistic and I^2 test ($I^2 > 50$ and $p < 0.05$ implying substantial heterogeneity). Across the studies, if no significant heterogeneity (defined as $p > 0.10$ or $I^2 < 50\%$) was found, the weighted mean differences (WMDs) were combined with the fixed-effects model (Mantel–Haenszel)¹⁶; otherwise, the random effects model (DerSimonian–Laird)¹⁷ was used. Moreover, a funnel plot was used to examine publication bias, and Begg and Mazumdar¹⁸ and Egger’s tests¹⁹ were used for statistical assessment. Linear regression was carried out to correlate the endpoint (e.g. RVOT changes) with the impact of independent variables (e.g. age at surgery, type of underlying disease).

Results

Study selection

A total of 4504 citations were identified, and 2095 duplicates were removed, leaving 2409 studies available for screening. After screening the abstracts, 408 studies were assessed as potentially relevant. After a full-text review, 388 studies were excluded primarily because they did not focus on the clinical outcomes or necessary data were unavailable; the remaining 20 studies were included.^{20–39} The study selection is shown in Figure 1.

Study characteristics

Table 1 summarizes the main characteristics of these studies. A total of 1246 patients were enrolled, 1187 patients accepted PPVI for the treatment of RVOT dysfunction, and the sample sizes varied from 17 to 167. The mean age at PPVI ranged from 13.9 to 34 years old. A total of 574 (46%) patients were diagnosed with TOF. The mean follow up ranged from 1 to 55.2 months. Melody valve was utilized in 14 studies, Edwards Sapien was utilized in 3 studies, and both valve systems were chosen in 2 studies. In terms of study design, 16 studies were prospective (80%), and 11 (55%) were multicenter studies. Patient data from the United States (US) Investigational Device Exemption trial were included in three publications,^{22,31,39} and duplicated patients were observed in two publications.^{34,36} Among the included trials, the common primary indications for PPVI were PR and PS or both. All studies were

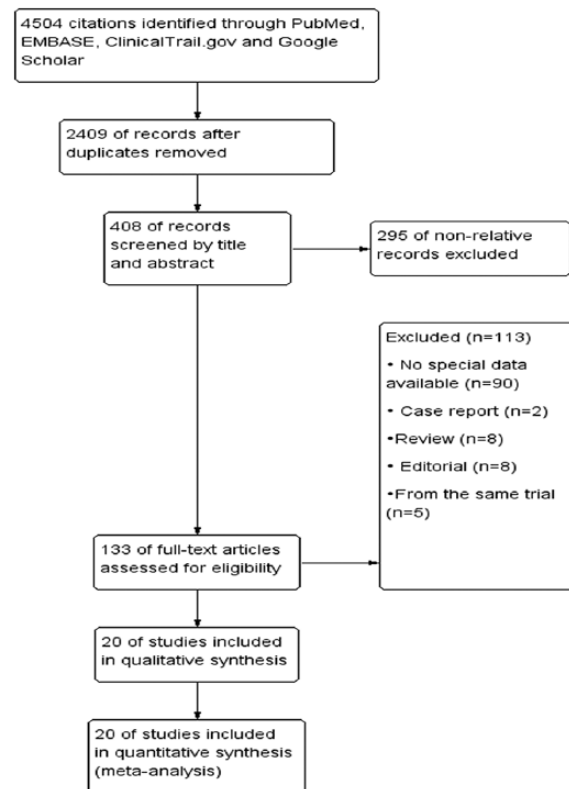


Figure 1. Flow diagram of the study selection.

judged to be of high quality with all scoring more than seven stars (Supplementary File S2), mainly due to the appropriate selection of participants.

Cardiac structure and function indices

RVOT. The mean differences of the Doppler RVOT gradient after PPVI in eight studies^{21,23,24,26,29–31,35} are shown in Figure 2(a). A significant reduction of RVOT gradient was observed in the patients after PPVI (WMD = -19.63 mmHg; 95% CI: -21.15 , -18.11 ; $p < 0.001$). The fixed-effect model was used due to mild heterogeneity ($I^2 = 68.4\%$).

RVEDV. Figure 2(b) shows the mean differences of indexed RVEDV after PPVI in 11 studies.^{20,22,24,25,28,29,32,35–37,40} A significant reduction was observed in the patients after PPVI (WMD = -17.59 ml/m²; 95% CI: -20.93 , -14.24 ; $p < 0.001$). According to a subgroup analysis (Supplementary Figure S1), the RVEDV index was significantly lower in the PR group than in the PS group (-19.39 ; 95% CI: -29.52 , -9.26 ; $p < 0.001$ versus -9.46 ; 95% CI: -17.02 , -1.09 ; $p = 0.014$). After implantation, patients with

Table 1. Characteristics of the included studies.

Studies	Country	Patients/ attempted	Mean follow up (months)	Age (y)	Type of study	Valve	Diagnosis of TOF, n (%)	Primary indication		
								PR	PS	Mixed
Fraisse ²⁰	France	64/NA	55.2	21.4 ± 16.7	P, MC	Melody	32 (50)	7	14	43
Eicken ²¹	Germany	102/NA	12	21.5 ± 10.3	P, MC	Melody	60 (58.8)	18	36	48
Batra ²²	US	150/NA	6	21.7 ± 11.5	P, MC	Melody	NA	NA	NA	NA
Kenny ²³	US	34/36	6	30.3 ± 15.1	P, MC	Edwards	16 (47)	19	15	2
Secchi ²⁴	Italy	40/NA	12	21 ± 8	RP, MC	Melody	12 (30)	17	12	11
Promphan ²⁵	Thailand	6/23	6	18.5 ± 3.4	P, SC	Venus P-valve	6 (100)	6	0	0
Fischer ²⁶	Poland	46/NA	35.2	18.3 ± 6.9	P, MC	Melody Edwards	18 (39)	28	18	0
Butera ²⁷	Italy	61/63	30	24 ± 40	P, MC	Melody	27 (44.2)	12	21	30
Pagourelas ²⁸	Belgium	20/NA	3	13.9 ± 9.2	P, SC	Melody	20 (100)	100	0	0
Müller ²⁹	Germany	59/NA	6	22.2 ± 8.7	P, MC	Melody Edwards	30 (50.8)	13	46	0
Armstrong ³⁰	US	101/120	12	19.9 ± 9.7	P, MC	Melody	47 (46.5)	52	16	32
Cheatham ³¹	US	150/167	54	19 ± 11.5	P, MC	Melody	77 (51.3)	80	39	31
Coats ³²	UK	16/17	3	21.2 ± 8.7	P, SC	Melody	8 (50)	17	0	0
Hass ³³	Germany	22/NA	5.7	21.7 ± 19.3	P, SC	Edwards	11 (50)	11	2	9
Lurz ³⁴	UK	155/163	28.4	21.2 ± 16	P, SC	Melody	94 (60.6)	46	61	44
Lurz ³⁵	UK	65/NA	12	20.4 ± 13.1	P, SC	Melody	41 (63.1)	30	35	0
Lurz ³⁶	UK	17/NA	1	19.2 ± 6.1	P, SC	Melody	9 (52.9)	8	9	0
Borik ³⁷	Canada	51/NA	54	20.2 ± 10.8	RP, SC	Melody	33 (64.7)	2	16	31
Wilson ³⁸	Canada	25/NA	42	34 ± 8.9	RP, MC	Edwards	15 (60)	7	8	10
Harrild ³⁹	US	31/NA	6	19.8 ± 7.65	RP, SC	Melody	18 (58)	13	18	0

MC, multicenter; NA, not available; P, prospective; PI, pulmonary insufficiency; PR, pulmonary regurgitation; PS, pulmonary stenosis; RP, retrospective; RVOT, right ventricular outflow tract; SC, single center; TOF, tetralogy of Fallot; US, United States.

preoperative index RVEDV > 140 ml/m² showed a greater reduction (−25.82 ml/m²; 95% CI: −41.64, −10.00; *p* < 0.001) than those with preoperative index RVEDV < 140 ml/m² (−16.55 ml/m²; 95% CI: −19.73, −13.37; *p* < 0.001; Supplementary Figure S2), but still higher than 100 ml/m².

RVESV. Figure 3(a) shows the mean difference of indexed RVESV after PPVI in seven studies.^{24,28,32,35–37,40} A significant reduction in indexed RVESV was observed in patients after PPVI (WMD = −11.10 ml/m²; 95% CI: −14.98, −7.22; *p* < 0.001). The fixed-effect model was used because there was no heterogeneity (*I*² = 0).

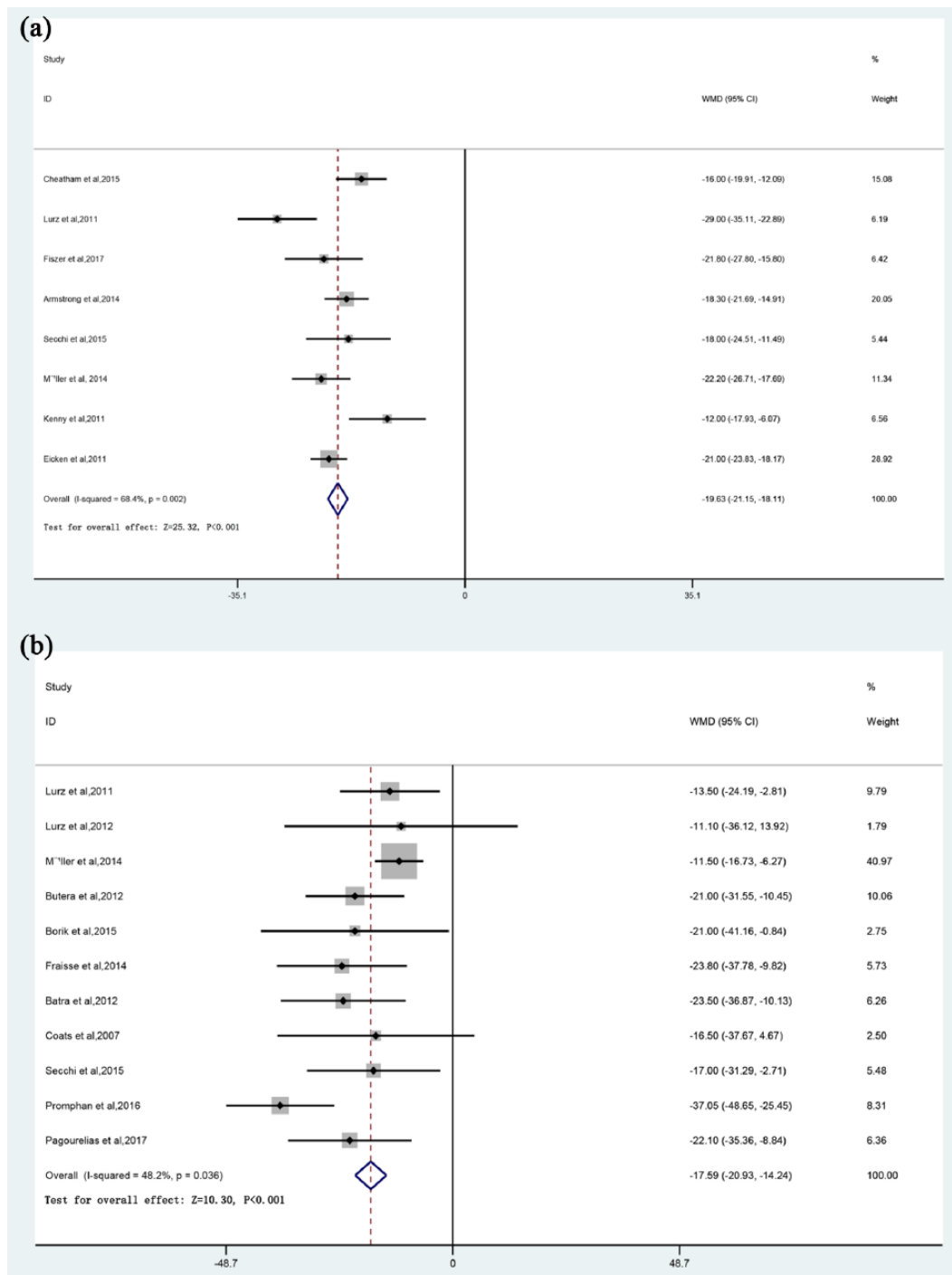


Figure 2. Forest plots of the clinical outcomes for the right side of the heart. Pooled differences in the means for (a) the mean Doppler RVOT, (b) the gradient of the indexed RVEDV. RVEDV, right ventricular end-diastolic volume; RVOT, right ventricular outflow tract.

PRF. A total of 12 studies^{20–23,25,28,29,32,35,36,39,40} reported PRF. Figure 3(b) showed a significant reduction of PRF in the patients after PPVI (WMD = -26.27%; 95% CI: -34.29, -18.25; p

< 0.001). The results showed severe heterogeneity: $I^2 = 98.40\%$. PRF decreased by 33.2% after PPVI (95% CI: -35.47, -30.93; $p < 0.001$) in the PR group. In the PS group, PRF decreased by

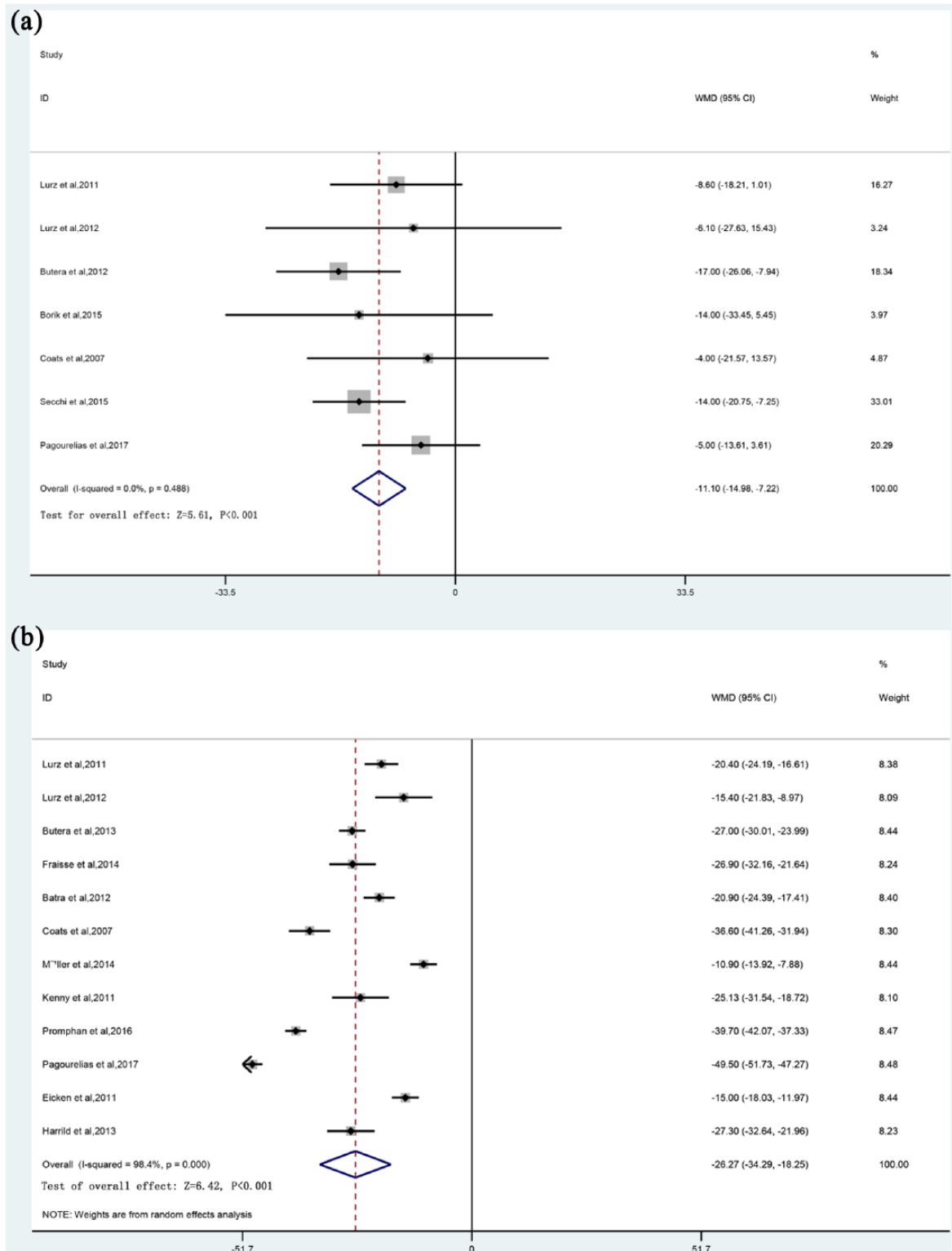


Figure 3. Forest plots of the clinical outcomes for the (a) the indexed RVESV. Pooled differences in the means for (b) the PRF. PRF, pulmonary regurgitation fraction; RVESV, right ventricular end-systolic volume.

7.08% after PPVI (95%CI: -8.77, -5.39; $p < 0.001$). The results of the subgroup analysis are shown in Supplementary Figure S3. The regression analysis showed that PRF was corrected to diagnosis of TOF ($p = 0.012$), PRF decreased as TOF increased (Supplementary Figure S4).

LVEDV. Figure 4(a) shows the mean difference of indexed LVEDV after PPVI in eight studies.^{22,24,28,32,35-37,40} No heterogeneity was observed. Overall, a significant increase in the indexed LVEDV after PPVI was found (WMD = 7.13 ml/m²; 95% CI: 4.30, 9.96; $p < 0.001$).

LVESV. Figure 4(b) shows the mean difference for indexed LVESV after PPVI in eight studies.^{20,24,28,32,35-37,40} However, no significant difference was observed in the patients after PPVI (WMD = 1.92 ml/m²; 95% CI: -0.05, 3.88; $p = 0.056$). No heterogeneity was found after pooling the data.

Ejection fraction. Figure 5(a) shows the mean difference of LVEF after PPVI in nine studies.^{20,24,28,32,35-37,40} A significant increase was observed in the patients after PPVI (WMD = 1.83%, 95% CI: 0.67, 3.00; $p = 0.002$) with no evidence of heterogeneity. RVEF [Figure 5(b)] showed a significant improvement in the PS group (WMD = 4.76%; 95% CI: 1.66, 7.85; $p = 0.003$), but no significant difference was found for the PR group (WMD = 1.09%; 95% CI: -3.01, 5.19; $p = 0.603$).

Procedure success and complications. Overall, 1003 of 1020 patients successfully underwent PPVI, and the pooled procedural success rate was 99% (95% CI: 98-99%). The mortality during the follow-up period was 2% (95% CI: 1-3%). Among 15 patients who died, 5 suffered sepsis/endocarditis, 2 were found to have arrhythmia, 1 was due to cardiac failure and 1 had compression of the left coronary artery. However, six patients died of causes unrelated to valve implantation. No patient died during the operation.

Table 2 shows the success rate and complications after the procedure. After PPVI, the most common complications were stent fractures during follow up, the pooled incidence of stent fracture was 5% (95% CI: 4-6%). Overall, the pooled incidence rate of IE was 2% (95% CI: 1-4%). In addition,

the pooled incidence rate of reintervention in 12 studies was 5% (95% CI: 4-6%), and the surgical conversion rate was 1.2% (95% CI: 0.5-1.9%). Overall, three patients experienced coronary artery compression. Among them, one patient was performed, surgical conduit replacement, and another died due to severe compression. There were significant differences between various variables (except for endocarditis or bloodstream) and the date of publication (Supplementary File S3).

Publication bias

Funnel plot analysis (Supplementary Figure S5A and S5B) revealed no potential publication bias among the included studies according to Begg's rank correlation test and Egger's linear regression test.

Discussion

The present study investigated the outcomes of PPVI in patients with RVOT dysfunction. The major findings are as follows: (1) the left and right ventricle structure were improved after PPVI, including ejection fraction; however, patients with a preoperative indexed RVEDVi > 140 ml/m² did not return to normal size; (2) RVOT gradient decreased; (3) PR decreased to normal; (4) stent fractures after PPVI were more likely to occur in patients with obstructed RVOT conduits, and IE was a threat to valve durability.

Previous study demonstrated that RVOT gradient is the only independent predictor of exercise capacity early after PPVI,³² and significant RVOT obstruction reduces exercise capacity. The present study showed a significant reduction in RVOT gradient after PPVI. The exercise capacity was also improved.

In one study, 7-10years after SPVR, the indexed RVEDV was significantly increased, and the value returned to 84% of the pre-SPVR volume.⁴¹ This might be mainly because the preoperative indexed RVEDV of the patients was 200 ± 43 ml/m². A previous study found that patients with a preoperative indexed RVEDV >170ml/m² did not show 'normalized' RV volumes after implantation.⁴² The American College of Cardiology/American Heart Association guidelines (2014) recommend that in the absence of symptoms, magnetic resonance imaging criteria for severe pulmonary insufficiency include the following: indexed RVEDV > 150ml/m²;

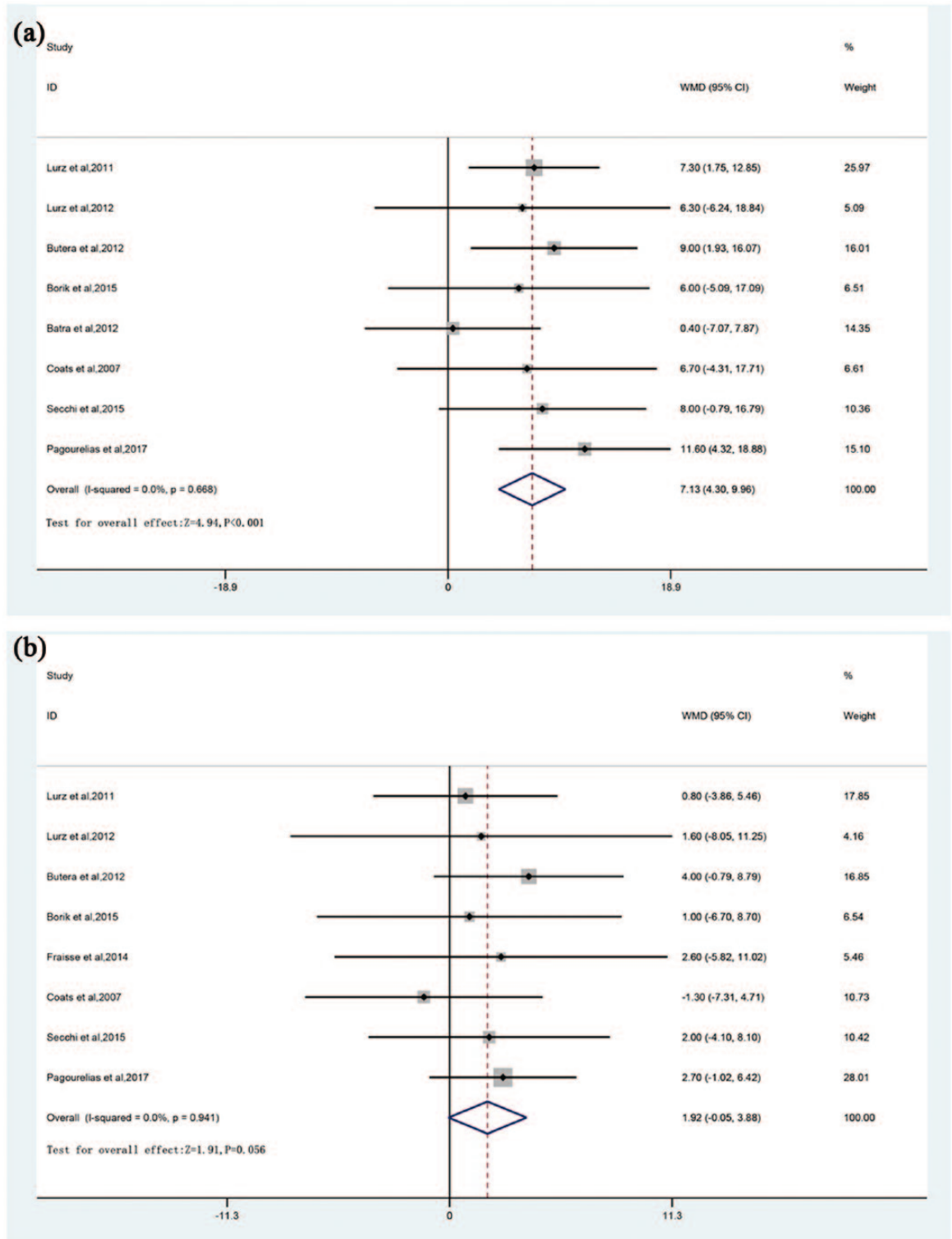


Figure 4. Forest plots of the clinical outcomes for the (a) the indexed LVEDV, and (b) the indexed LVESV. LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume.

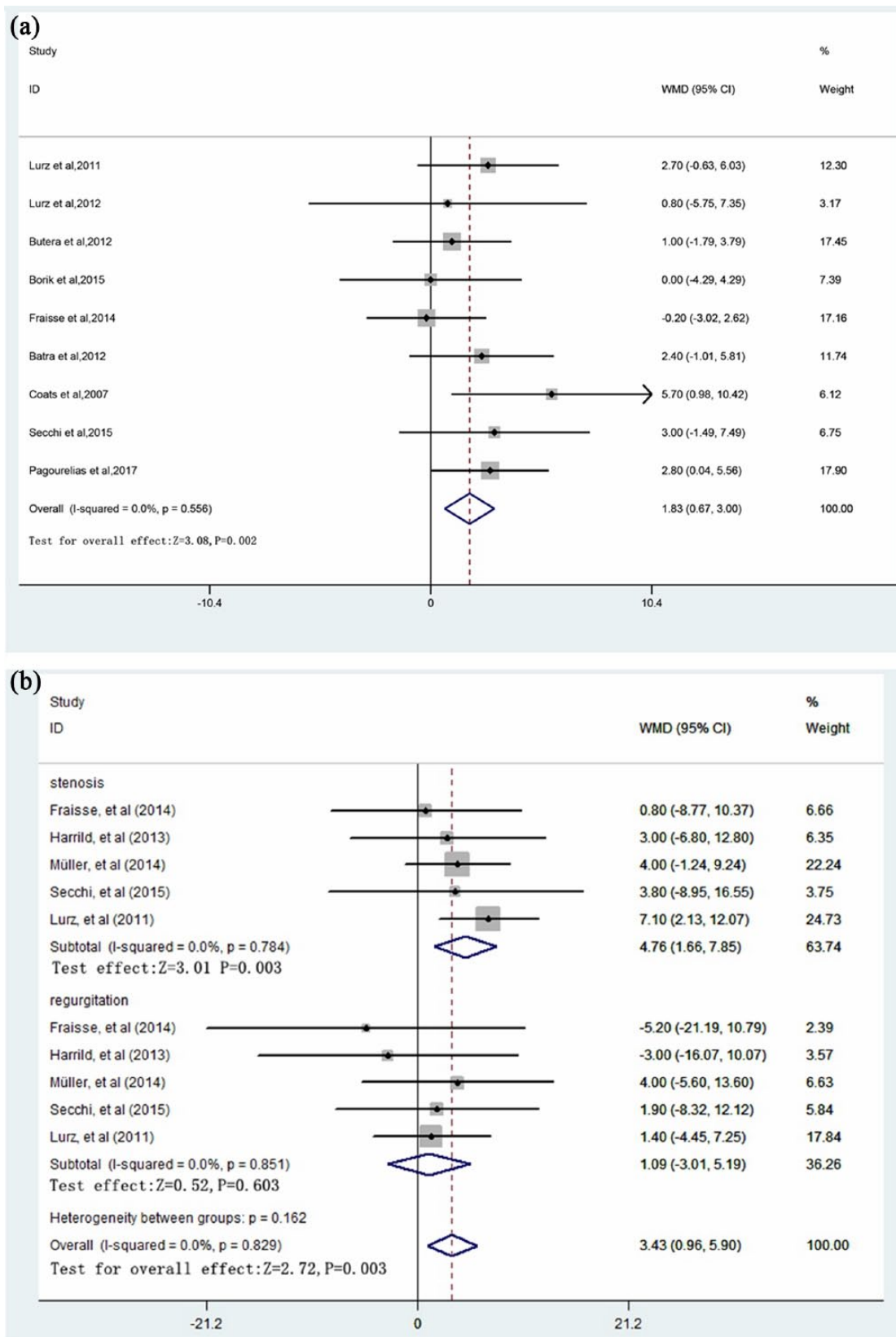


Figure 5. Forest plots of the clinical outcomes. Pooled differences in the means for (a) the LVEF and (b) the RVEF. LVEF, left ventricular ejection fraction; RVEF, right ventricular ejection fraction.

Table 2. Pooled estimates for procedure success and complications.

	Number of studies	Pooled estimate (%)	<i>I</i> ²	<i>p</i> value
Procedure success	17	99 [98–99]	0	0.904
Reintervention ^a	12	5 (4–6)	82.9	0
Surgical conversion ^a	9	3 (2–5)	0	0.716
Stent fracture ^a	13	5 (4–6)	89.4	0
Endocarditis ^a	12	2 (1–4)	21.3	0.235
Coronary compression ^a	10	1 (0–2)	0	0.557
Death ^a	12	1 (1–2)	0	0.763

^aDenotes incidence at latest follow up.

PRF > 40%; and RV ejection fraction < 40%.⁴³ In the present study, four studies recruited patients with preoperative indexed RVEDV > 140 ml/m²; after valve implantation, the patients failed to return to the normal level (100 ml/m²). Early valve implantation is associated with more favorable RV reverse remodeling.^{28,37} Therefore, to prevent symptoms and RV damage becoming more apparent, we suggest PPVI to be performed before the RVEDV index reaches 140 ml/m².

PRF decreased to normal levels in all patients despite the severity of preimplantation pulmonary regurgitation, but the long-term function remains to be further evaluated. RVEDV decreased more in the PR group than in the PS group. However, no change was observed in RVEF among the PR patients. Further study needs to investigate whether PPVI could improve RVEF and the underlying mechanisms.

In the included studies, a significant increase in LVEDV was seen after PPVI. However, no change was found in LVESV. Left heart systolic function improved due to increased LVEF and LVEDV. The increase in LVEDV after PPVI may reflect late remodeling as a response to the noticeable improvement in filling over time.³⁵ It is worth noting that almost all included patients with RVEF > 40% and LVEF > 50%. Therefore, the results may not represent the actual effect for patients with poor ejection function.

Pre-stenting with a bare metal stent before PPVI provides a good solution for stent fracture, and it

was frequently observed in studies with lower rates of pre-stenting prior to PPVI.⁴⁴ Nordmeyer and colleagues reported that patients presented a 65% reduction in the risk of stent fracture when a bare metal stent was implanted.⁴⁵

IE of the valve is a potential threat to long-term heart function^{46–48} and may result in valve explantation.^{21,34} This complication necessitates a repeat of PPVI and can result in sepsis-related mortality.⁴⁶ IE is an acute adverse event. Therefore, minimization of the infection rate is important. Antibiotic prophylaxis and adequate dental hygiene are recommended to prevent infectious events.^{27,46} Other severe complications including valve migration or embolization,^{23,27} pulmonary artery occlusion or rupture,⁴⁵ and coronary artery compression⁴⁹ are reportedly rare.

In addition, a previous study found shorter hospitalization and lower complication rates in patients who received PPVI compared with surgical replacement.⁵⁰ Therefore, PPVI seems to be a well-tolerated therapy for patients.

Some limitations of this meta-analysis should be noted. Firstly, all included studies were nonrandomized observational studies. Secondly, different studies had different follow-up periods. Long-term outcomes remain unclear. Thirdly, all publications reported data for both PR and PS. However, only five studies were available to perform a subgroup analysis in which outcomes were extracted separately from these two subgroups.

Few randomized controlled trials comparing PPVI with surgery have been published; thus, the meta-analysis was limited to perform the head-to-head comparison; however, PPVI has been found to be an effective treatment for patients with RVOT dysfunction. Thus, further long-term follow-up studies with large sample sizes are needed to evaluate the clinical outcomes of PPVI in patients with RVOT dysfunction.

Conclusions

In the present study, PPVI was found to improve RV and LV function in patients with RVOT dysfunction. PRF and RVOT gradient were decreased significantly, the complications after the procedure were within an acceptable range. Therefore, PPVI is considered an effective and well-tolerated treatment for patients with RVOT dysfunction.² This conclusion should be considered carefully and confirmed based on further, randomized, large-scale studies.

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Conflict of interest statement

The author(s) declare that there is no conflict of interest.

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Supplemental material

Supplemental material for this article is available online.

References

1. Reller MD, Strickland MJ, Riehle-Colarusso T, *et al.* Prevalence of congenital heart defects in metropolitan Atlanta, 1998–2005. *J Pediatr* 2008; 153: 807–813.
2. Tanner K, Sabine N and Wren C. Cardiovascular malformations among preterm infants. *Pediatrics* 2005; 116: e833–e838.
3. McElhinney DB and Hennesen JT. The Melody® valve and Ensemble® delivery system for transcatheter pulmonary valve replacement. *Ann NY Acad Sci* 2013; 1291: 77–85.
4. Yuan S-M, Mishaly D, Shinfeld A, *et al.* Right ventricular outflow tract reconstruction: valved conduit of choice and clinical outcomes. *J Cardiovasc Med* 2008; 9: 327–337.
5. Wells WJ, Arroyo H Jr, Bremner RM, *et al.* Homograft conduit failure in infants is not due to somatic outgrowth. *J Thorac Cardiovasc Surg* 2002; 124: 88–96.
6. Kanter KR, Budde JM, Parks WJ, *et al.* One hundred pulmonary valve replacements in children after relief of right ventricular outflow tract obstruction. *Ann Thorac Surg* 2002; 73: 1801–1806; discussion 6–7.
7. Bielefeld MR, Bishop DA, Campbell DN, *et al.* Reoperative homograft right ventricular outflow tract reconstruction. *Ann Thorac Surg* 2001; 71: 482–487; discussion 7–8.
8. Askovich B, Hawkins JA, Sower CT, *et al.* Right ventricle-to-pulmonary artery conduit longevity: is it related to allograft size? *Ann Thorac Surg* 2007; 84: 907–911; discussion 11–2.
9. Brown JW, Ruzmetov M, Rodefeld MD, *et al.* Right ventricular outflow tract reconstruction with an allograft conduit in non-ross patients: risk factors for allograft dysfunction and failure. *Ann Thorac Surg* 2005; 80: 655–663; discussion 63–4.
10. Stark J, Bull C, Stajevic M, *et al.* Fate of subpulmonary homograft conduits: determinants of late homograft failure. *J Thorac Cardiovasc Surg* 1998; 115: 506–514; discussion 14–6.
11. Tweddell JS, Pelech AN, Frommelt PC, *et al.* Factors affecting longevity of homograft valves used in right ventricular outflow tract reconstruction for congenital heart disease. *Circulation* 2000; 102: Iii130–5.
12. Oosterhof T, Meijboom FJ, Vliegen HW, *et al.* Long-term follow-up of homograft function after pulmonary valve replacement in patients with tetralogy of Fallot. *Eur Heart J* 2006; 27: 1478–1484.
13. Bonhoeffer P, Boudjemline Y, Saliba Z, *et al.* Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction. *Lancet (London, England)* 2000; 356: 1403–1405.

14. O'Byrne ML, Glatz AC, Mercer-Rosa L, *et al.* Trends in pulmonary valve replacement in children and adults with tetralogy of fallot. *Am J Cardiol* 2015; 115: 118–124.
15. Wells GA, Shea BJ, O'Connell D, *et al.* The Newcastle–Ottawa Scale (NOS) for assessing the quality of non-randomized studies in meta-analysis. *Appl Eng Agric* 2000; 18: 727–734.
16. Overton RC. A comparison of fixed-effects and mixed (random-effects) models for meta-analysis tests of moderator variable effects. *Psychol Methods* 1998; 3: 354–379.
17. DerSimonian R and Kacker R. Random-effects model for meta-analysis of clinical trials: an update. *Contemp Clin Trials* 2007; 28: 105–114.
18. Begg CB and Mazumdar M. Operating characteristics of a rank correlation test for publication bias. *Biometrics* 1994; 50: 1088–1101.
19. Egger M, Davey Smith G, Schneider M, *et al.* Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997; 315: 629–634.
20. Fraisse A, Aldebert P, Malekzadeh-Milani S, *et al.* Melody® transcatheter pulmonary valve implantation: results from a French registry. *Arch Cardiovasc Dis* 2014; 107: 607–614.
21. Eicken A, Ewert P, Hager A, *et al.* Percutaneous pulmonary valve implantation: two-centre experience with more than 100 patients. *Eur Heart J* 2011; 32: 1260–1265.
22. Batra AS, McElhinney DB, Wang W, *et al.* Cardiopulmonary exercise function among patients undergoing transcatheter pulmonary valve implantation in the US Melody valve investigational trial. *Am Heart J* 2012; 163: 280–287.
23. Kenny D, Hijazi ZM, Kar S, *et al.* Percutaneous implantation of the Edwards SAPIEN transcatheter heart valve for conduit failure in the pulmonary position: early phase 1 results from an international multicenter clinical trial. *J Am Coll Cardiol* 2011; 58: 2248–2256.
24. Secchi F, Resta EC, Cannà PM, *et al.* Four-year cardiac magnetic resonance (CMR) follow-up of patients treated with percutaneous pulmonary valve stent implantation. *Eur Radiol* 2015; 25: 3606–3613.
25. Promphan W, Prachasilchai P, Siripornpitak S, *et al.* Percutaneous pulmonary valve implantation with the Venus P-valve: clinical experience and early results. *Cardiol Young* 2016; 26: 698–710.
26. Fiszer R, Dryzek P, Szkutnik M, *et al.* Immediate and long-term outcomes of percutaneous transcatheter pulmonary valve implantation. *Cardiol J* 2017; 24: 606–611.
27. Butera G, Milanese O, Spadoni I, *et al.* Melody transcatheter pulmonary valve implantation. Results from the registry of the Italian society of pediatric cardiology. *Catheter Cardiovasc Interv* 2013; 81: 310–316.
28. Pagourelis ED, Daraban AM and Mada RO. Right ventricular remodelling after transcatheter pulmonary valve implantation: Time Matters! *Catheter Cardiovasc Interv* 2017; 90: 407–417.
29. Müller J, Engelhardt A, Fratz S, *et al.* Improved exercise performance and quality of life after percutaneous pulmonary valve implantation. *Int J Cardiol* 2014; 173: 388–392.
30. Armstrong AK, Balzer DT, Cabalka AK, *et al.* One-year follow-up of the Melody transcatheter pulmonary valve multicenter post-approval study. *JACC Cardiovasc Interv* 2014; 7: 1254–1262.
31. Cheatham JP, Hellenbrand WE, Zahn EM, *et al.* Clinical and hemodynamic outcomes up to 7 years after transcatheter pulmonary valve replacement in the US melody valve investigational device exemption trial. *Circulation* 2015; 131: 1960–1970.
32. Coats L, Khambadkone S, Derrick G, *et al.* Physiological consequences of percutaneous pulmonary valve implantation: the different behaviour of volume- and pressure-overloaded ventricles. *Eur Heart J* 2007; 28: 1886–1893.
33. Haas NA, Moysich A, Neudorf U, *et al.* Percutaneous implantation of the Edwards SAPIEN™ pulmonic valve: Initial results in the first 22 patients. *Clin Res Cardiol* 2013; 102: 119–128.
34. Lurz P, Coats L, Khambadkone S, *et al.* Percutaneous pulmonary valve implantation: impact of evolving technology and learning curve on clinical outcome. *Circulation* 2008; 117: 1964–1972.
35. Lurz P, Nordmeyer J, Giardini A, *et al.* Early versus late functional outcome after successful percutaneous pulmonary valve implantation: are the acute effects of altered right ventricular loading all we can expect? *J Am Coll Cardiol* 2011; 57: 724–731.
36. Lurz P, Muthurangu V, Schuler PK, *et al.* Impact of reduction in right ventricular pressure and/or volume overload by percutaneous pulmonary valve implantation on biventricular response to

- exercise: an exercise stress real-time CMR study. *Eur Heart J* 2012; 33: 2434–2441.
37. Borik S, Crean A, Horlick E, *et al.* Percutaneous pulmonary valve implantation: 5 years of follow-up does age influence outcomes? *Circ Cardiovasc Interv* 2015; 8: e001745.
 38. Wilson WM, Benson LN, Osten MD, *et al.* Transcatheter Pulmonary Valve Replacement with the Edwards Sapien System: The Toronto Experience. *JACC Cardiovasc Interv* 2015; 8: 1819–1827.
 39. Harrild DM, Marcus E, Hasan B, *et al.* Impact of transcatheter pulmonary valve replacement on biventricular strain and synchrony assessed by cardiac magnetic resonance feature tracking. *Circ Cardiovasc Interv* 2013; 6: 680–687.
 40. Butera G, Milanese O, Spadoni I, *et al.* Melody transcatheter pulmonary valve implantation. Results from the Registry of the Italian Society of Pediatric Cardiology (SICP). *Cardiol Young* 2012; 22: S26.
 41. Hallbergson A, Gauvreau K, Powell AJ, *et al.* Right ventricular remodeling after pulmonary valve replacement: early gains, late losses. *Ann Thorac Surg* 2015; 99: 660–666.
 42. Therrien J, Provost Y, Merchant N, *et al.* Optimal timing for pulmonary valve replacement in adults after tetralogy of Fallot repair. *Am J Cardiol* 2005; 95: 779–782.
 43. Hijazi ZM, Ruiz CE, Zahn E, *et al.* SCAI/AATS/ACC/STS operator and institutional requirements for transcatheter valve repair and replacement, part III: pulmonic valve. *J Am Coll Cardiol* 2015; 65: 2556–2563.
 44. McElhinney DB, Cheatham JP, Jones TK, *et al.* Stent fracture, valve dysfunction, and right ventricular outflow tract reintervention after transcatheter pulmonary valve implantation: patient-related and procedural risk factors in the US melody valve trial. *Circ Cardiovasc Interv* 2011; 4: 602–614.
 45. Nordmeyer J, Lurz P, Khambadkone S, *et al.* Pre-stenting with a bare metal stent before percutaneous pulmonary valve implantation: acute and 1-year outcomes. *Heart* 2011; 97: 118–123.
 46. McElhinney DB, Benson LN, Eicken A, *et al.* Infective endocarditis after transcatheter pulmonary valve replacement using the melody valve: combined results of 3 prospective North American and European studies. *Circ Cardiovasc Interv* 2013; 6: 292–300.
 47. Buber J, Bergersen L, Lock JE, *et al.* Bloodstream infections occurring in patients with percutaneously implanted bioprosthetic pulmonary valve: a single-center experience. *Circ Cardiovasc Interv* 2013; 6: 301–310.
 48. Villafañe J, Baker GH, Austin EH, *et al.* Melody® pulmonary valve bacterial endocarditis: experience in four pediatric patients and a review of the literature. *Catheter Cardiovasc Interv* 2014; 84: 212–218.
 49. Kostolny M, Tsang V, Nordmeyer J, *et al.* Rescue surgery following percutaneous pulmonary valve implantation. *Eur J Cardiothorac Surg* 2008; 33: 607–612.
 50. Dilber D, Hörer J, Malcic I, *et al.* Percutaneous pulmonary valve implantation and surgical valve replacement in patients with right ventricular outflow tract dysfunction - A complementary treatment concept. *Int J Cardiol* 2013; 169: e3–e5.

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