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ORIGINAL ARTICLE

Mid-term outcomes of mechanical pulmonary valve replacement: a single-institutional experience of 396 patients

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Abstract

Objectives Previous small-sized studies have demonstrated the safety and efficacy of mechanical pulmonary valve replacement (mPVR) in patients with congenital heart disease; however, the predictors of major complications and reoperation remained unclear.

Methods In a retrospective study, we reported the mid-term outcomes of a large-scaled series of patients, 396 patients, with congenital heart diseases who underwent mPVR in a single institution.

Results The patients' mean age at mPVR was 24.3 ± 9 years (4–58 years). Most patients (84.3%) underwent tetralogy of Fallot total correction. The median of follow-up was 36 months (24–49 months). Prosthetic valve malfunction caused by thrombosis or pannus formation developed in 12.1% of patients during follow-up period. Reoperation was performed in 7 cases with pannus formation and 6 cases with mechanical valve thrombosis. Freedom from reoperation at 1, 5, and 10 years was 99%, 97%, and 96%, respectively. Neither early nor mid-term mortalities were detected. Cox regression models showed that male gender and smaller valve size increased the risk of prosthetic valve failure. The age at mPVR, interval between congenital heart defect repair and mPVR, and concomitant procedures predicted reoperation. In multivariate analysis, younger age and the interval between first operation and mPVR predicted reoperation either.

Conclusions The success rate of mPVR is excellent in mid-term follow-up. Younger age, longer interval between the repair of congenital defect and mPVR, and cooperation increased reoperation risk. However, strict adherence to life-long anticoagulation regimen and patient selection are of great importance for the implementation of mPVR.

Keywords Mechanical pulmonary valve replacement · Congenital heart disease · Tetralogy of Fallot · Thrombosis · Reoperation

Introduction

The surgical repair of tetralogy of Fallot (TOF) or some congenital heart defects often leads to pulmonary insufficiency (PI) [1, 2]. Although children often well tolerate the PI, however, if left untreated, the complications of long-standing PI such as consecutive heart failure are inevitable [3]. Pulmonary valve replacement (PVR) is one of the treatment modalities. Based on the latest guidelines of ACC/AHA and ESC for the management of congenital heart defects, PVR was reasonable in patients with severe PI associated with moderate to severe right ventricular dysfunction or enlargement [4, 5]. Previous studies have shown that PVR can be performed with an early mortality of 2.1% after repair of TOF, and most of patients experience an uneventful postoperative period [6].

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The PVR is the most common cardiac surgery performed in adults with congenital heart disease, and it is usually performed using bioprosthetic valves, which do not require long-term anticoagulation; however, a progressive deterioration of prosthetic valves requires an unavoidable redo PVR. Limited experiences exist with mechanical PVR (mPVR) [7–15]. In our daily practice, cardiothoracic surgeons prefer to implant mechanical valve in highly selected patients who insist to have mechanical valve, have a history of multiple prior operations, and those require anticoagulation for other indications. The number of patients undergoing mPVR does not exceed a few hundreds [16]. Herein, we sought to report the outcomes of largest ever series of patients who underwent mPVR due to severe PI associated with congenital heart diseases in a single center during a 13-year period.

Methods

Study protocol, population, and procedure

In a retrospective study, a total of 396 patients who underwent mPVR from April 2003 to December 2015 at our center, Rajaie Cardiovascular Medical and Research Center, Tehran, Iran, were evaluated. The medical records of patients were reviewed. The study protocol was approved by the local ethics committee of our institution.

The type of prosthesis was decided based on the patients' preference and our center experience involving a multidisciplinary team (i.e. cardiologist, cardiothoracic surgeon, and anesthesiologist) to manage patients undergoing PVR. The selection of patients for the implantation of mechanical valve instead of bioprosthetic valve was according to 2 main criteria: (1) patients who were not willing to undergone a repeated PVR, and (2) those were on anticoagulation therapy due to other indications.

After placing the patient on cardiopulmonary bypass, the ascending aorta was clamped and antegrade cold blood cardioplegia was administered. The main pulmonary artery (or the previously implanted transannular patch) was then longitudinally opened and the incision was extended towards the right ventricle outflow tract (RVOT) as much as the surgeon needed for exposure. The appropriate size of mechanical prosthetic valve was chosen based on the patient's body surface area and the RVOT size, and it was sutured to the posterior annulus. In most cases, a synthetic patch was used to re-construct the RVOT and to receive sutures for securing the prosthesis anteriorly. The prosthesis was finally checked and it was repaired by direct suturing in cases with any paravalvular defect. The patch was then used to close the pulmonary arteriotomy and the cross clamp was released.

Patients' follow-up

All patients were discharged on oral anticoagulation with warfarin to maintain an international normalized ratio (INR) ranging from 2.5 to 3.5. They were postoperatively followed up in an outpatient clinic (1 week and 1 month after surgery, then every 3 months or whenever they could come to our institution). All patients in our cohort (100%) were followed up and the time of last visit was considered as follow-up duration. All patients underwent complete physical examination and transthoracic echocardiography (TTE) at follow-up. Perioperative and follow-up data included valve-related complications (malfunction due to thrombosis or pannus formation, bleeding events, and reoperation) and death. Patients who had mechanical valve thrombosis presented either with symptoms such as dyspnea and/or palpitation or asymptomatic and those were detected by TTE examination. All patients with mechanical valve thrombosis received thrombolysis.

Statistical analysis

A continuous variable was presented as mean ± SD or median (interquartile range) as appropriate. A dichotomous variable was reported as number (percentage). Continuous variables were analyzed using *t* test or Mann–Whitney *U* test, as appropriate. Kaplan–Meier curve was constructed to identify the event-free survival regarding evaluated complications, including reoperation, bleeding events, mechanical valve thrombosis, prosthetic valve malfunction (PVM) defined as a combination of mechanical valve thrombosis and pannus formation, and reoperation. In addition, we conducted cox regression analyses, backward stepwise model, to identify the predictors of outcomes. Covariates included age at mPVR, sex, prosthetic valve size, prosthetic valve brand, concomitant procedures, interval between mPVR and the first operation for congenital heart disease, INR values at the time of bleeding or thrombosis during follow-up, and postoperative mean values of peak gradient for mechanical valve. 2-sided *P* values were reported. All statistical analyses were performed using SPSS software (IBM Co. New York, USA) and STATA software (College Station, TX).

Results

Baseline characteristics

The patients' mean ages at first operation for congenital heart disease and at mPVR were 8.1 ± 5.3 and 24.3 ± 9 years, respectively. The age distribution is demonstrated in

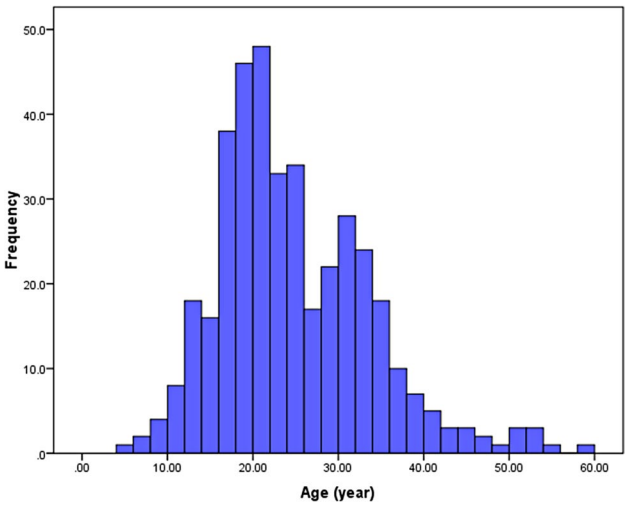

Fig. 1 Graph showing the age distribution of the cohort

Fig. 1. Most patients (84.3%) had undergone tetralogy of Fallot total correction (TFTC). Twenty-four patients (6%) had a history of PVR, either biologic or mechanical. Interval between the first operation for the repair of congenital heart defects and current mPVR was 16.2 ± 6.9 years. Other baseline characteristics are summarized in Table 1.

Intra- and post-operative features

The median size of prosthetic valve was 25 mm (16–29 mm). The most common concomitant operation was tricuspid valve repair or replacement (48 cases, 10.9%), followed by the closure of residual ventricular septal defect (VSD) (33 cases, 8.3%). The remainders are summarized in Table 2.

The median of follow-up period was 36 months (25th–75th percentile, 24–49 months). The mean pulmonary valve pressure gradient (MPG) at immediate postoperative time and at last follow-up was 17.9 ± 8.9 mmHg and 18.3 ± 8.2 mmHg, respectively. The major postoperative complications included the following: (1) mechanical valve thrombosis ($n = 41$, 10.3%); (2) pannus formation ($n = 7$, 1.8%); (3) bleeding events, including gastrointestinal bleeding, knee joint bleeding, hematoma formation, hemoptysis, and intraperitoneal bleeding presenting with acute abdomen ($n = 11$, 2.8%); (4) endocarditis ($n = 4$, 1%); (5) the high value of MPG who did not require intervention ($n = 4$, 1%); (6) pericardial effusion ($n = 3$, 0.8%); and (7) paravalvular leakage detected as mild ($n = 23$, 5.8%), of whom none underwent redo operation. No death developed at follow-up period. The means of time from current mPVR to the development of bleeding events, mechanical valve thrombosis, and pannus formation were 15.9 ± 13.1, 26.11 ± 20, and 46 ± 34.7 months, respectively.

Table 1 Baseline characteristics and surgery-related features of patients

Variables	Values[a]
Total number of patients	396
Age at recent mPVR, year	24.31 ± 8.97
Age at first operation, year[b]	8.1 ± 5.3
Male sex	294 (74.2%)
Pre-mPVR diagnosis	
Severe PI after TFTC	289 (73%)
Severe PI after repair of PS	31 (7.8%)
Severe PI after TFTC + moderate to severe TR	24 (6.1%)
Malfunction of prosthetic pulmonary valve	24 (6%)
Severe PI after TFTC + AI	7 (1.8%)
Severe PI after DORV repair	3 (0.75%)
Primary PVR[d]	4 (1%)
Severe PI after TFTC + CAD	4 (1%)
Severe PI after TFTC + MR	2 (0.5%)
Other[e]	8 (2%)
History of PVR	
Biologic prosthesis	10 (2.5%)
Mechanical prosthesis	4 (1%)
Homograft	10 (2.5%)
Type of mechanical valve	
St. Jude[c]	311 (78.5%)
Carbomedics[c]	85 (21.5%)
Mechanical valve size	
16–22 mm	16 (4%)
23 mm	95 (24%)
25 mm	233 (58.8%)
≥ 27 mm	52 (13.2%)
Interval between first operation and mPVR, years	16.2 ± 6.9
Interval between prior PVR and mPVR, years	8.1 ± 6.3

mPVR mechanical pulmonary valve replacement, *PI* pulmonary valve insufficiency, *TFTC* tetralogy of Fallot total correction, *PS* pulmonary stenosis, *TR* tricuspid regurgitation, *AI* aortic valve insufficiency, *DORV* double outlet right ventricle, *CAD* coronary artery disease, *MR* mitral regurgitation

[a]All values are presented as mean ± SD or number (%)

[b]First operation means first repair for congenital heart defects

[c]Prosthetic valve types included St. Jude (St. Jude Medical, St. Paul, Minnesota, United States) and Carbomedics (CarboMedics, Inc.; Austin, Texas, United States)

[d]Primary PVR included PVR at TFTC operation ($n = 2$), DORV repair ($n = 1$), and congenitally corrected transposition of great arteries ($n = 1$)

[e]Other cases included PI after TFTC associated with stenosis in pulmonary artery or its branches ($n = 4$), aortic stenosis ($n = 1$), persistent ductus arteriosus ($n = 1$), and sinus of valsalva aneurysm ($n = 1$). Moreover, one case had PI after percutaneous transluminal balloon valvuloplasty

The mean of INR values in cases developing bleeding events and mechanical valve thrombosis was 9.65 ± 6.37 and 1.6 ± 0.4, respectively. The INR level of each group (group

Table 2 Concomitant procedures during mPVR

Concomitant operations	Values[a]
None	254 (64.1%)
Tricuspid valve repair or replacement	43 (10.9%)
Residual VSD closure	33 (8.3%)
PFO or ASD closure	25 (6.3%)
RVOT plasty	18 (4.5%)
Repair of LPA or RPA stenosis	17 (4.3%)
Aortic valve repair or replacement	12 (3%)
Mitral valve repair or replacement	7 (1.7%)
Coronary artery bypass grafting	4 (1%)
Persistent ductus arteriosus closure	1 (0.25%)
Implantation of permanent pacemaker	1 (0.25%)
Repair of sinus of valsalva aneurysm	1 (0.25%)

VSD ventricular septal defect, *PFO* patent foramen ovale, *ASD* atrial septal defect, *RVOT* right ventricular outflow tract, *LPA* left pulmonary artery, *RPA* right pulmonary artery

[a]All values are presented as number (%)

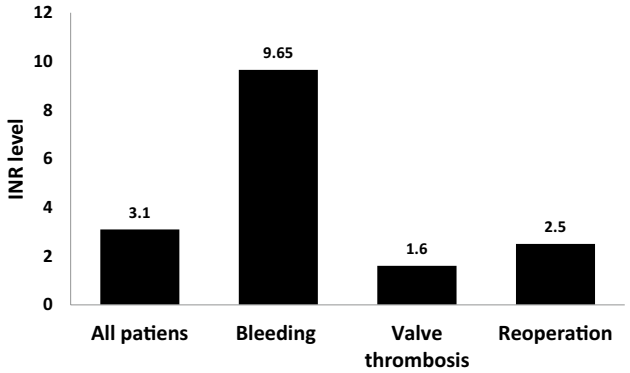

Fig. 2 Graph showing INR level of each group (group 1, overall; group 2, bleeding events; group 3, mechanical valve thrombosis; group 4, reoperation)

1: overall, group 2: bleeding events, group 3, mechanical valve thrombosis, group 4: reoperation) is shown in Fig. 2. When compared MPG level between patients with or without PVM, the amount of postoperative MPG was comparable between patients with or without mechanical valve thrombosis or PVM; however, the MPG at last follow-up was significantly different between groups as shown in the supplement figures.

Thrombolytic therapy was used as the first-line management for mechanical valve thrombosis. Thrombolytic therapy reestablished normal motion of leaflets in 35 cases (success rate of 85.4%). Reoperation was performed in 6 cases with mechanical valve thrombosis and in 7 cases with pannus formation. In cases developed pannus formation, the pannus resection and redo PVR were performed in 6 and 1 patients, respectively. Most of patients with mechanical valve thrombosis who underwent redo PVR were males (4 of 6 cases) and received St. Jude mechanical valve, and most cases with pannus formation (6 of 7 cases) received St. Jude mechanical valve. In addition, the number of reoperation in patients ≥ 18 years and < 18 years was 6 and 7 cases, respectively. All patients with mechanical valve thrombosis who did not respond to thrombolytic therapy and 3 of 7 cases with pannus formation (42.8%) were older than 18 years.

Survival analysis and predictors of study outcomes

Freedom from bleeding events, mechanical valve thrombosis, and reoperation are demonstrated by Kaplan–Meier curves (Fig. 3). Freedom from bleeding events was 99%, 97%, and 97% at 1, 5, and 10 years, respectively. Freedom from mechanical valve thrombosis was 97%, 90%, and 89% at 1, 5, and 10 years, respectively. Freedom from PVM was 97%, 89%, and 88% at 1, 5, and 10 years, respectively. Freedom from reoperation was 99%, 97%, and 96% at 1, 5, and 10 years, respectively. We excluded children and conducted among patients ≥ 18 years. Consequently, values for bleeding events were 99%, 98%, and 98% at 1, 5, and 10 years, respectively. Those for mechanical valve thrombosis were 98%, 92%, and 91% at 1, 5, and 10 years, respectively; and for PVM were 98%, 91%, and 89% at 1, 5, and 10 years, respectively. Freedom from reoperation was 100%, 99%, and 98% at 1, 5, and 10 years, respectively.

Cox regression model showed that the INR at the event time was the only predictor of bleeding [hazard ratio (HR), 1.333; 95% confidence interval (CI), 1.180–1.506; $p < 0.0001$]. The predictors of mechanical valve thrombosis included the prosthetic valve size (HR, 0.758; 95% CI, 0.615–0.935; $p = 0.010$) and INR at event time (HR, 0.257; 95% CI, 0.103–0.640; $p = 0.004$). Male sex (HR, 2.109; 95% CI, 1.018–4.371; $p = 0.045$) increased the risk of PVM, and valve size (HR, 0.766; 95% CI, 0.632–0.928; $p = 0.007$) and INR (HR, 0.490; 95% CI, 0.254–0.946; $p = 0.034$) inversely predicted the PVM. Moreover, age at mPVR (HR, 0.661; 95% CI, 0.511–0.855; $p = 0.002$), the interval between first operation for congenital heart defects and mPVR (HR, 1.707; 95% CI, 1.199–2.430; $p = 0.003$), and concomitant operation (HR, 6.057; 95% CI, 1.398–26.254; $p = 0.016$) predicted reoperation (Table 3).

Discussion

In this retrospective study, we demonstrated the mid-term outcomes of a large single-center series of patients with congenital heart defects who underwent mPVR. Our experience showed excellent survival and a low rate of reoperation. Based on the cox regression model, male sex and smaller

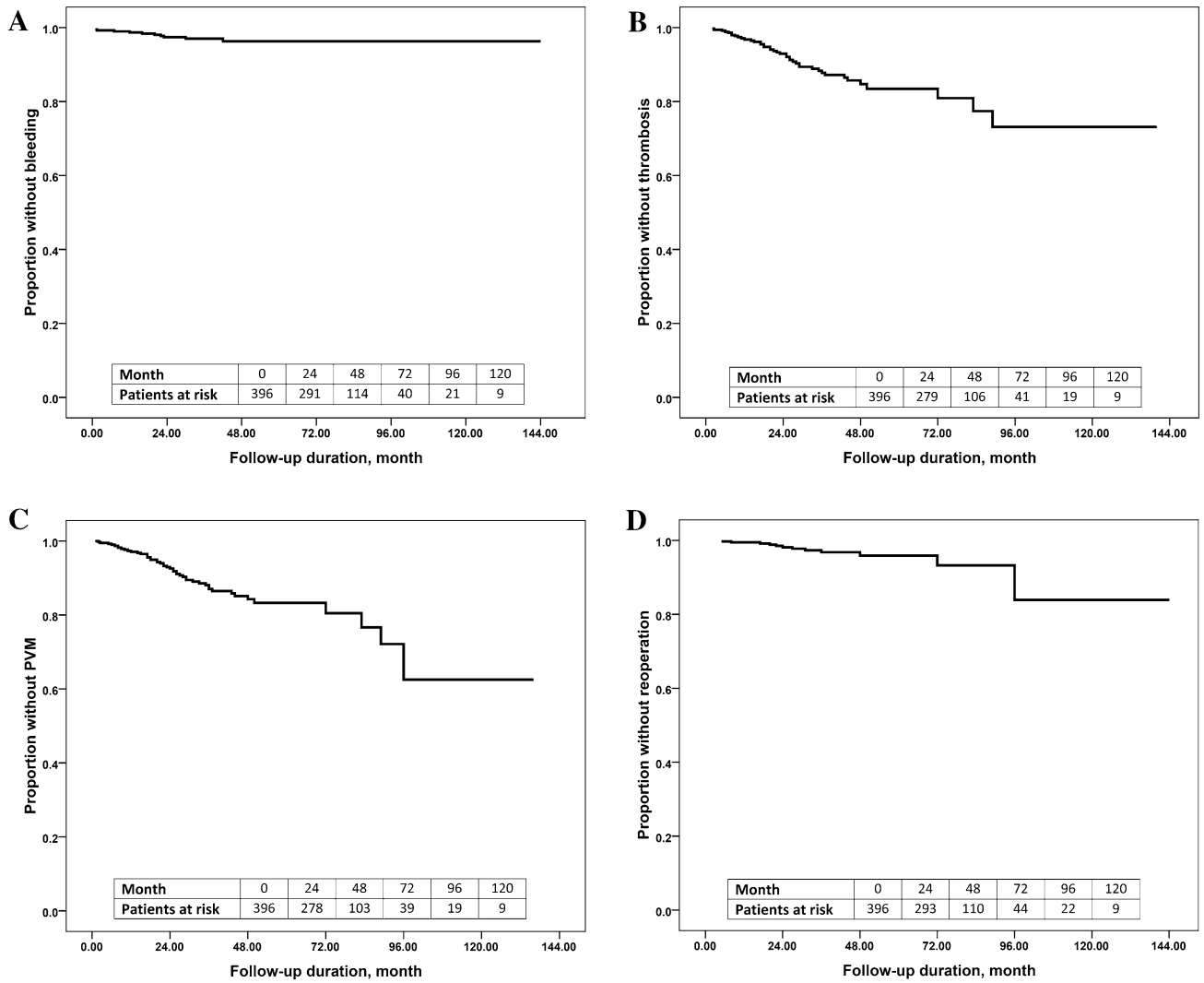

Fig. 3 Kaplan–Meier curves showing freedom from **a** bleeding events; **b** mechanical valve thrombosis; **c** PVM; and **d** reoperation. *PVM* pulmonary valve malfunction

Table 3 Cox regression analysis showing the predictors of reoperation at follow-up

Covariates in the models*	HR	95% CI	*p* value
Age at mPVR	0.661	0.511–0.855	0.002
Interval between first operation and mPVR	1.707	1.199–2.430	0.003
Concomitant operation	6.057	1.398–26.254	0.016
St. Jude versus Carbomedics prosthetic valve	6.611	1.398–26.254	0.113

HR hazard ratio, *CI* confidence interval, *mPVR* mechanical pulmonary valve replacement, *MPG* mean pressure gradient

*Variables of the last step of backward regression models are reported

size of prosthetic valves were associated with an increased hazard of PVM. In addition, younger age at mPVR, interval between the repair of congenital heart defects and mPVR, and concomitant procedure significantly increased the hazards of reoperation. After exclusion of patients younger than 18-year-old, the age and interval between first operation and mPVR were predictors of reoperation.

The main valve types used for PVR include bioprosthetic valves, allografts, hand-sewn Polytetrafluoroethylene valves, mechanical valves, and transcatheter valves

[17–19]. Although the bioprosthetic valve s are widely used for PVR; however, the durability of such valves is suboptimal [18]. There are many studies reporting the outcomes of bioprosthetic pulmonary valve. Chen et al. [20] showed that freedom from reoperation and PVM was 94% and 74% at 5 years, respectively. They found that younger age and valve oversizing predicted the PVM. Nomoto et al. [21] also showed that the rate of reintervention was 6.7%. They also found that younger age and valve type predicted the reintervention. In addition, Lee et al. [22] have demonstrated that approximately 80% required reoperation or developed PVM. Overall freedom from redo PVR at 5 and 10 years was 93.9% and 51.7%, respectively. Freedom from PVM at 5 and 10 years was 92.2% and 20.2%, respectively. Additionally, a meta-analysis of 3118 patients undergoing PVR after TOF repair showed that 5-year mortality and re-PVR were 2.2% and 4.9%, respectively [23]. Our findings regarding 5- and 10-year freedom from PVM and reoperation are better than those for the bioprosthetic valves.

Buchholz et al. [24] have shown a good longevity for stented bioprosthetic valves implanted using either surgery or transcatheter intervention. The rates of freedom from valve replacement were 81% and 60% after 10 and 15 years, respectively. Younger age was the only significant risk factor for valve degeneration [24]. In addition, Kwak et al. [25] have also reported acceptable durability for stented bioprosthetic valves in patients $\geq$ 20 years; however, its outcomes were suboptimal in patients younger than 20 years even with larger valve sizes. Another emerged pulmonary valve type includes transcatheter pulmonary valves. Although long-term follow-up is unavailable, but freedom from reintervention has been reported to be 76% at 5 years. In addition, transcatheter pulmonary valve was associated with good outcomes up to 7 years [26]. The main and promising advantage of transcatheter valves is the possibility of implantation of such valves within failed surgical bioprosthetic valves. In contrast, the major disadvantage of mechanical valve is the lack of possibility for using transcatheter valves in failed cases. Given these points, although it seems that the overall outcomes of mPVR is superior over other valves, but further large-scale studies and comparative studies with long-term follow-up are deemed indicated to identify the best option.

The main causes of PVM include mechanical valve thrombosis or pannus formation. Right-sided heart valves are subjected more to thrombosis due to low pressures. However, the previous studies of mPVR have shown acceptable outcomes, proposing mechanical valve as a good alternative for the pulmonary position. Prosthetic valve thrombosis is often attributed to poor adherence to the anticoagulation regimen [27]. In our cohort, six cases (1.5%) with mechanical valve thrombosis were unresponsive to thrombolytic therapy who underwent redo PVR. All these cases had INR values below the desired level, and all were younger than 18 years. Additionally, we also showed that the INR was inversely associated with mechanical valve thrombosis and younger age predicted reoperation. The rate of thrombosis in our cohort was more than overall rate (10.3% versus 7%) reported in previous studies [7–16]. Although the valve thrombosis has been 0% in some reports [9–11], this complication is more likely to occur. Therefore, we should select patients who are willing to follow the strict adherence to the anticoagulation regimen. On the other hand, we should keep in mind that bleeding events are inevitable in such cases. Moreover, more than half of reoperations in our cohort were attributed to the pannus formation which is not related to anticoagulation. Its pathophysiology has been proposed to be a chronic inflammatory process resulting in fibrous tissue ingrowth [28]. Therefore, other factors rather than anticoagulation regimen can lead to PVM, which need to be investigated, particularly among patients undergoing mPVR procedures.

Early and late mortality may also develop in patients undergoing mPVR. The causes of mortalities can be due to thromboembolic and bleeding events, heart failure, or some other causes rather than cardiac-related problems [16, 20]. The overall rate of mortality in previous studies has been approximately 4.5% [7–16], although it varied from 0% [7–10, 13, 15] to 18.2% [16]. The rate of mortality in patients undergoing bioprosthetic PVR has also been varied among different studies, including 3% [21], 5.5% [22], and 3.1% [20]. The exact rate of mortality in the setting of mPVR, especially not valve-related one, is not clear in evidences due to short-term follow-up and the lack of proper evaluation of such events. However, it seems that mechanical valves have similar mortality, even better, compared with other valves in the pulmonary position.

The longevity of prosthetic pulmonary valve is influenced by age, valve size, and valve type; however, our experience with mechanical pulmonary valve is undetermined [29]. For the first time ever, we demonstrated that younger age, longer interval between first operation and mPVR, and concomitant operation predicted reoperation, and also small valve size, INR, and male sex predicted the development of PVM. These findings are in accordance with the findings of pulmonary bioprosthetic valve. Caldarone et al. [29] have found that younger age and small valve size were independent predictors of prosthetic failure. Zubairi et al. [30] also showed that male sex and younger age were associated with bioprosthetic failure. We believe that less adherence to anticoagulation among children, more turbulence of blood flow in smaller prosthetic valves, clinical features, and immunologic mechanisms might be the main causes for more reoperation rate in younger patients.

When interpreting our findings, some limitations should be considered. Our study was a retrospective evaluation and follow-up period was relatively short to evaluate the

long-term outcomes of mechanical pulmonary valves. In addition, the lack of comparison with bioprosthetic valves may be another limitation to this study which may preclude us to definitely conclude and recommend this procedure as the best option for the pulmonary position. Further large-scale studies with long-term follow-up and comparison with bioprosthetic valves can provide valuable results to help cardiac surgeons for selecting the valve of choice for the pulmonary position.

Conclusions

The success rate of mPVR is good regarding the development of PVM and reoperation in a mid-term follow-up period, proposing an appropriate alternative for PVR in highly selected patients. The younger age, longer interval between the repair of congenital defect and mPVR, and concomitant procedures increased the risk of reoperation. Moreover, smaller valve size, INR, and male sex predicted the development of PVM. In addition to these findings, the strict adherence to life-long anticoagulation and the selection of appropriate cases for such an intervention are of great importance for the implementation of mechanical valves in the pulmonary position.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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