




Bioprosthetic pulmonary valve endocarditis: Incidence, risk factors, and clinical outcomes

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Abstract

Background: Pulmonary valve replacement (PVR) is a common operation in patients with congenital heart disease (CHD). As survival with CHD improves, infective endocarditis (IE) is a growing complication after PVR. The aim of this study was to assess the incidence, risk factors, and clinical outcomes of IE after surgical PVR in patients with CHD at our institution.

Methods: Retrospective analysis of all cases of surgical PVR performed at Children's Hospital of Wisconsin between 1975 and 2016 was performed. All cases of IE after PVR were identified and clinical and imaging data were obtained by review of medical records.

Results: Out of 924 surgical PVRs, there were 19 (2%) cases of IE. The incidence of IE after surgical PVR was 333 cases per 100 000 person-years. The median age at diagnosis of IE was 21 years (range = 1.2-34 years) and the median time from PVR to diagnosis of IE was 9.4 years. The overall freedom from IE after PVR was 99.1%, 96.9%, and 93.4%, at 5, 10, and 15 years, respectively. There was no significant difference in freedom from IE based on valve type, including bovine jugular vein grafts. Patients with IE were more likely to have had a history of multiple PVRs, while length of follow-up after PVR, age at time of PVR, and gender were not significant risk factors. Eleven (58%) cases of IE required surgical intervention, while 8 (42%) were successfully treated with intravenous antibiotics alone. There were no deaths and no recurrences of IE after treatment.

Conclusion: The overall risk for IE after PVR is low. There was no association between age or type of pulmonary valve and risk of IE. The majority of cases require surgical intervention, but in general the outcomes of IE after PVR are good with low mortality and risk of recurrence.

KEYWORDS

infective endocarditis, pulmonary valve prosthesis, right ventricular to pulmonary artery conduit

1 | INTRODUCTION

Surgical pulmonary valve replacement (PVR) is often required for treatment of congenital heart disease (CHD) as part of right ventricle outflow tract reconstruction. PVR typically involves placement of a bioprosthetic valve or right ventricle-to-pulmonary artery valved conduit. Survival after PVR has been shown to be excellent at >90% by 10 years after operation,¹ with overall good durability of the various types of bioprosthetic pulmonary valves depending on patient age and other clinical factors.²⁻⁴

Despite this good survival, infective endocarditis (IE) is a growing complication in patients after PVR that can result in significant morbidity and mortality. Case reports and case series have reported that up to 56%-65% of cases of IE after PVR require surgery after diagnosis, and the mortality is as high as 17% to 22%.⁵⁻⁷ In addition, some studies have suggested a higher risk for IE in patients following placement of a heterograft compared to homograft bioprosthetic pulmonary valve.⁸⁻¹⁰ With emerging data regarding the growing challenges of IE after PVR, the aim of the study was to evaluate the overall incidence, risk factors, and treatment outcomes for bioprosthetic pulmonary valve IE at our institution.

2 | METHODS

2.1 | Patients

All cases of surgical PVR at the Children's Hospital of Wisconsin from January 1, 1975 to December 31, 2016 were included in the study. For patients that underwent multiple PVRs during the study period, each PVR was included as a separate entry in the data collection. Patients who died ≤ 30 days after PVR or prior to hospital discharge were excluded from the study cohort. This study was approved by the Children's Hospital of Wisconsin Human Research Review Board and was conducted in accordance with all human research regulatory requirements.

2.2 | Data collection

Retrospective review of all medical records was performed, and data regarding CHD diagnosis, type of bioprosthetic pulmonary valve placed, gender, age at PVR surgery, and number of PVR procedures were collected. Bioprosthetic pulmonary valves were categorized as homograft (pulmonary or aortic) or heterograft valves. Heterograft valves, in turn, were categorized as porcine aortic valve, bovine pericardial tissue valve, or bovine jugular vein valved conduit (ie, Contegra, Medtronic, Minneapolis, Minnesota). Patients with history of IE were identified and details of the diagnosis, echocardiographic findings, microbiologic data, and outcomes of IE were obtained. IE was defined as possible or definitive based on modified Duke criteria.¹¹ At the time of study data collection, there were no cases of IE involving percutaneous PVR, so these cases were not included in the study cohort and the subsequent analysis was confined to surgical PVR only.

Echocardiographic results with transthoracic and transesophageal modalities performed at the time of diagnosis of IE were reviewed. Stenosis of the bioprosthetic pulmonary valve was graded as mild (peak instantaneous Doppler velocity ≤ 3 m/s), moderate (peak velocity 3-4 m/s), or severe (peak velocity ≥ 4 m/s). Grading of the insufficiency of the valve was based on color-flow Doppler and classified as mild (thin jet width $< 1/3$ of pulmonary outflow diameter), moderate (intermediate jet width measuring $1/3$ - $2/3$ of the pulmonary outflow diameter), or severe (jet width $> 2/3$ of the pulmonary outflow diameter and presence of diastolic flow reversal in branch pulmonary arteries).

2.3 | Statistical analysis

Descriptive statistics such as means with standard deviations for continuous variables and counts with percentages for categorical variables were used to summarize sample characteristics. Chi-square test and Kruskal-Wallis test were used for univariate comparison of categorical and continuous variables, respectively. Kaplan-Meier curves were used to summarize the time to IE after PVR in all patients and in patients depending on type of bioprosthetic valve placed. Most recent follow-up date was defined as the date of death, most recent clinic visit, or reoperation to replace the bioprosthetic pulmonary valve. Follow-up was determined by our institution's electronic medical record and those that were lost to follow-up or transferred to another institution were censored at the time of their last contact with our institution. Log-rank test was employed to compare the groups of patients. Cox proportional hazards modeling was used for identifying the risk factors of developing IE. All *P* values are two-sided and alpha of .05 was used throughout. Analyses were carried out using Stata IC 15 statistical software (StataCorp, College Station, Texas).

3 | RESULTS

A total of 924 PVRs were performed during the study period. Table 1 summarizes the clinical characteristics of the patients at the time of PVR. The median age at the time of PVR was 5.3 years (range, 1 day-66.7 years). The valve type used for PVR differed significantly based on age at time of PVR, with bovine jugular vein valved conduits used more commonly in younger patients and bovine pericardial valves used more in older patients. The majority of patients had a homograft replacement (68.6%). The majority of the surgeries, 651 (70%), were performed as first PVR in patients with a native right ventricular outflow tract, while 273 (30%) were performed as re-replacement of an existing bioprosthetic valve. The most common CHD diagnoses were tetralogy of Fallot or pulmonary atresia with ventricular septal defect in 420 (45.5%) and truncus arteriosus in 180 (19.5%). The median follow-up time after PVR was 4.8 years (31 days-39.2 years).

A total of 19 cases of IE occurred during the study period. The overall incidence of IE was 333 cases per 100 000 person-years. Table 2 summarizes the clinical data for the cases of IE. The median

TABLE 1 Baseline patient characteristics overall and by valve type expressed as median (range) or number (%)

Variable	Overall (N = 924)	Homograft (N = 639)	Porcine heterograft (N = 143)	Bovine pericardial (N = 98)	Bovine jugular vein (N = 44)	P value
Median age at time of PVR, y	5.3 (0-67)	4.2 (0-43)	7.6 (0.1-38)	24 (0.3-67)	0.4 (0-40)	.0001
Male gender	588 (64%)	415 (65%)	88 (62%)	58 (59%)	27 (61%)	.64
Number of previous PVR						<.001
0	651 (70%)	462 (72%)	65 (45%)	90 (92%)	33 (75%)	
≥1	273 (30%)	177 (28%)	78 (55%)	8 (8%)	11 (25%)	
Primary diagnosis						<.001
Tetralogy of Fallot or PA/VSD	420 (46%)	273 (43%)	74 (51%)	61 (62%)	12 (27%)	
Truncus arteriosus	180 (20%)	128 (20%)	31 (22%)	4 (4%)	17 (39%)	
DORV or TGA s/p Rastelli repair	135 (15%)	94 (15%)	22 (15%)	8 (8%)	11 (25%)	
Aortic valve disease s/p pulmonary autograft (Ross)	100 (11%)	97 (15%)	1 (1%)	0 (0%)	2 (5%)	
Congenital pulmonary valve stenosis or PA/IVS	70 (8%)	34 (5%)	11 (8%)	25 (26%)	0 (0%)	
Other	19 (2%)	13 (2%)	4 (3%)	0 (0%)	2 (5%)	

Abbreviations: DORV, double outlet right ventricle; PA/IVS, pulmonary atresia with intact ventricular septum; PA/VSD, pulmonary atresia with ventricular septal defect; PVR, pulmonary valve replacement; TGA, transposition of the great arteries.

TABLE 2 Patient characteristics for all cases of IE following PVR (n = 19)

Variable	Median (range) or N (%)
Age at diagnosis of IE (y)	21 (1.2-34)
Male gender	14 (74%)
History of >1 PVR	18 (95%)
Type of bioprosthetic pulmonary valve	
Homograft	14 (74%)
Porcine heterograft	4 (21%)
Bovine pericardial	0 (0%)
Bovine jugular vein	1 (5%)
Primary diagnosis	
Tetralogy of Fallot or PA/VSD	5 (26%)
Truncus arteriosus	5 (26%)
DORV or TGA s/p Rastelli repair	3 (16%)
Aortic valve disease s/p pulmonary autograft (Ross)	0 (0%)
Congenital pulmonary valve stenosis or PA/IVS	2 (11%)
Other	4 (21%)
History of intravenous drug use	4 (21%)

Abbreviations: DORV, double outlet right ventricle; IE, infective endocarditis; PA/IVS, pulmonary atresia with intact ventricular septum; PA/VSD, pulmonary atresia with ventricular septal defect; PVR, pulmonary valve replacement; TGA, transposition of the great arteries.

age at diagnosis of IE was 21 years (range 1.2-34), and the median follow-up time since PVR was 9.4 years (0.4-21). Most patients, 14 (74%) had a homograft, while 5 (26.3%) had a heterograft bioprosthetic valve including 1 bovine jugular vein and 4 porcine heterograft

valves. The majority of patients, 18 (95%), had history of >1 PVR, while only 1 case of IE occurred in a patient after their first PVR.

The overall freedom from IE at 5, 10, and 15 years was 99.1%, 97%, and 93.4%, respectively (Figure 1). There was no significant

difference in the freedom of IE in patients with homograft vs. heterograft valves (Figure 2), or in patients with porcine vs. bovine pericardial vs. bovine jugular vein valves (Figure 3).

By multivariable analysis, the only significant clinical risk factor for IE following PVR was a history of >1 PVR (P value <.01) (Table 3). Type of bioprosthetic pulmonary valve, time since PVR, and gender were not significant risk factors for IE (Table 3).

Based on modified Duke criteria, 14 (74%) of the cases of IE met definition for definitive IE, while 5 (26%) were classified as possible IE. The cases of possible IE all had positive blood cultures that did not meet major criteria and a significant change in pulmonary valve function based on echocardiographic imaging. Of all cases of IE, a vegetation was identified in 7 cases on transthoracic echocardiogram, while an additional 4 cases had a vegetation identified on transesophageal echocardiogram that was not identified on transthoracic echocardiogram. Septic pulmonary emboli was documented in 4 (21%) cases.

Pulmonary valve dysfunction included an increase in stenosis to \geq moderate in 5 (26%) cases, an increase in insufficiency to \geq moderate in 3 (16%) cases, and both \geq moderate stenosis and insufficiency

in 5 (26%) cases. The most common bacteria isolated from blood cultures were *Streptococcus viridans* (26%), *Staphylococcus aureus* (21%), *Enterococcus faecalis* (16%), and *Streptococcus pneumonia* (11%). The remaining 26% of cases had other streptococcus species including *Streptococcus bovis*, *Streptococcus mitis*, and *Lactobacillus* (Table 4).

Out of the 19 cases with IE, 10 (53%) required surgical PVR and 6 weeks of intravenous antibiotics. Indications for surgical PVR included hemodynamically significant valve dysfunction and/or persistently positive blood cultures despite intravenous antibiotics. All of the cases of IE involving *S. aureus* required surgical PVR. There were 8 (42%) that were treated successfully with 6 weeks of antibiotics alone without needing surgical intervention during the acute illness. There was 1 (5%) case that was treated with sternotomy and surgical debridement with drainage of abscess without requiring

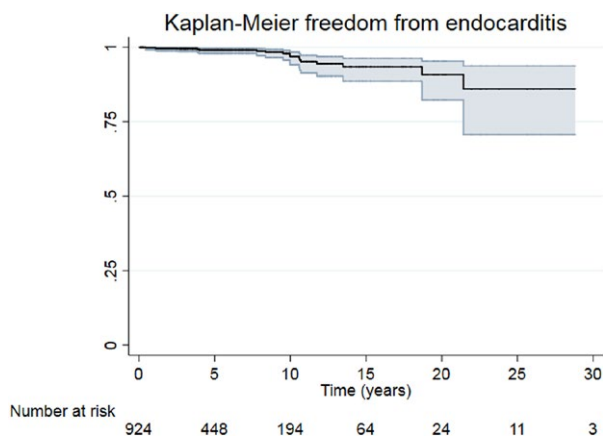


FIGURE 1 Freedom from infective endocarditis in all cases of surgical PVR ($n = 924$)

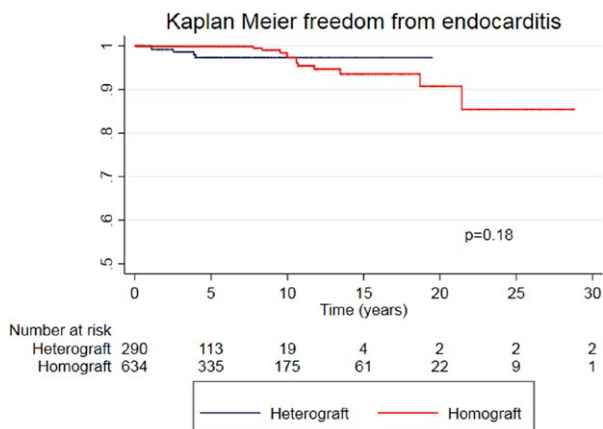


FIGURE 2 Freedom from infective endocarditis in patients with heterograft vs. homograft bioprosthetic pulmonary valves (Log-rank $P = 0.18$)

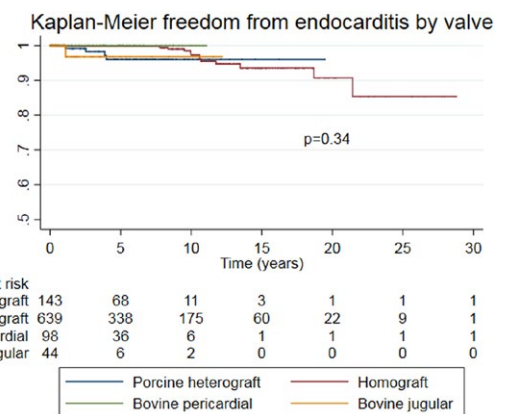


FIGURE 3 Freedom from infective endocarditis in porcine heterograft vs. homograft vs. bovine pericardial vs. bovine jugular valves (Log rank $P = 0.34$)

TABLE 3 Multivariable risk factors for IE after PVR

Risk factor	Hazard Ratio	95% CI	P value
History of >1 PVR	4.5	1.5-13.3	.007
Time since PVR	1	0.99-1	.4
Male gender	1.8	0.6-5.5	.3
Valve type	0.8	0.3-2.2	.6

Abbreviations: IE, infective endocarditis; PVR, pulmonary valve replacement.

TABLE 4 Types of bacteria isolated from blood cultures in cases of endocarditis after bioprosthetic pulmonary valve replacement

Type of bacteria	# of cases (%)
<i>Streptococcus viridans</i>	5 (26)
<i>Staphylococcus aureus</i>	4 (21)
<i>Enterococcus faecalis</i>	3 (16)
<i>Streptococcus pneumonia</i>	2 (11)
<i>Streptococcus mitis</i>	2 (11)
<i>Streptococcus bovis</i>	1 (5)
Group C Streptococcus	1 (5)
<i>Lactobacillus</i> species	1 (5)

PVR, along with 6 weeks of intravenous IV antibiotics. There were no deaths during treatment for IE and there were no recurrences of the same IE in any of the cases.

4 | DISCUSSION

The goals of this large single-institution study were to determine the incidence of bioprosthetic pulmonary valve endocarditis in 924 surgical PVRs, elucidate risk factors for developing endocarditis, and examine the outcomes after diagnosis. We found that the incidence of endocarditis was relatively low, with a freedom from IE of 93.4% at 15 years after PVR. Interestingly, there was no significant difference in risk for IE based on type of valve used for PVR.

Previous studies have reported a similar overall incidence of IE after PVR, however, many suggest the risk is higher for bovine jugular vein grafts compared with a homograft valve and other heterograft valves. Mery et al conducted a single-center retrospective analysis of 792 surgical PVRs and identified a 15-year overall freedom from IE of 92% for all types of PVR.¹⁰ However, unlike our study, bovine jugular vein grafts had a 9-fold greater risk for endocarditis compared with homografts. Van Dijck et al also reported a significant difference in risk for IE based on valve type, with 10-year freedom from IE of 97.3% in homografts compared with 77.3% in bovine jugular vein grafts.⁸ Albanesi et al examined 106 cases of bovine jugular vein PVRs, and demonstrated a freedom of IE as low as 82% at 12.7 years follow-up.¹²

In our cohort, only 1 of 19 cases of IE involved bovine jugular vein grafts. The 10-year freedom from endocarditis in this group of 97%. The lower incidence of IE in this group can be attributed to patient-related factors including younger age at time of PVR and shorter length of follow-up, which limited the analysis of bovine jugular vein grafts as a risk factor in this study. Bovine jugular vein grafts are more commonly placed in smaller children, who often have more prolonged or complicated postoperative courses with delayed sternal closure that can increase risk for infection, and may be more important risk factors than the valve type itself.¹³ With the growing use of transcatheter bovine jugular graft valve (Melody, Medtronic Inc., Minneapolis, Minnesota) for PVR in older patients, there continues to be concern about long-term risk for IE with this valve type.^{8,14}

The only risk factor for developing IE in this study was having a history of multiple PVRs. In other words, patients that underwent their first PVR were less likely to develop IE compared to patients that had a PVR to replace a preexisting bioprosthetic pulmonary valve. This finding may relate to increased risk for infection in patients that have had multiple sternotomies. Or there may be changes in healing, inflammation, endothelialization, or scar formation after multiple PVRs that may increase risk for platelet-fibrin thrombi, which forms the site for adherence of microorganisms. This is a clinically important finding from this study given that the majority of patients with IE in this study required surgical intervention and

repeat PVR. An episode of IE would likely result in a greater number of sternotomies over the lifetime in these patients.

The need for reoperation for PVR after IE of 53% in our cohort is similar to previous studies. Miranda et al described 17 adult patients with IE after PVR, and 11 (64.5%) required surgical intervention.⁷ Criteria for intervention were similar to our study and included persistent bacteremia, recurrent fever, or hemodynamically significant pulmonary valve dysfunction. Malekzadeh-Milani et al also reported need for surgical intervention in 13 of 23 (56.5%) of cases of IE after surgical PVR.⁵ However, our mortality rate of 0% differs from these other series, which report mortality of up to 13%-17% after diagnosis of IE.^{5,7} The decreased mortality in our series may be due to the younger age of IE presentation of our cases at a median of 21 years compared to median of 39 years in the series by Miranda et al.

In general, our institution follows the American College of Cardiology/American Heart Association recommendations regarding indications for surgical intervention in the setting of bacterial endocarditis, which includes persistent fever and/or bacteremia or valve dysfunction resulting in heart failure.¹⁵ However, we also would consider *S. aureus* for right-sided endocarditis as a relative indication for intervention given the lower success rates of treatment with antibiotics alone. Septic pulmonary emboli, in isolation, was not an indication for surgical intervention at our center.

Our study also demonstrates the challenges with echocardiographic imaging as part of the diagnosis of bioprosthetic pulmonary valve endocarditis. Imaging of a vegetation in the bioprosthetic pulmonary valve was present in only 11 of the cases. Interestingly, while TEE is considered the preferred modality for evaluation of prosthetic valve endocarditis,¹¹ 7 of the 11 cases with bioprosthetic pulmonary valve vegetations were identified by transthoracic echocardiogram, and only 4 required additional evaluation with transesophageal echocardiogram. The previous study by Miranda et al also highlighted challenges with imaging of bioprosthetic pulmonary valve endocarditis.⁷ Similar to our study, they demonstrated that since the bioprosthetic pulmonary valve is an anterior structure, that visualization by transthoracic echocardiogram may have advantages over transesophageal echocardiogram and should be performed as part of initial assessment.⁷

4.1 | Limitations

The limitations of this study include a retrospective study design at a single-center, with variable follow-up after PVR. There may have been patients who received their surgery at Children's Hospital of Wisconsin and were followed elsewhere for clinical care, and therefore would not have been identified in this study if they developed IE during follow-up. Additionally, we did not include transcatheter, or Melody valves due to relatively low numbers of patients and limited duration of follow-up. Data regarding risk factors for endocarditis were not readily available including previous dental visits and antibiotic prophylaxis prior to dental visits or other procedures at risk for bacteremia.

5 | CONCLUSION

The overall incidence of IE following PVR in patients with CHD is low. Patients that did develop endocarditis were more likely to have had multiple pulmonary valve replacements in the past, and present with significant valvular dysfunction at the time of diagnosis. Surgical intervention for treatment of endocarditis in this setting is more common than medical treatment alone, but the overall outcomes for both are good, with a low risk for mortality or recurrences.

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CONFLICTS OF INTEREST

None of the authors have any potential conflicts of interest, including financial interests or relationships to industry, relevant to the subject matter or materials discussed in the manuscript.

AUTHOR CONTRIBUTIONS

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