Surgical pulmonary valve replacement: A benchmark for outcomes comparisons

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Background: Patients with right heart obstructive lesions develop residual or recurrent right ventricle outflow tract pathology as a result of native or implanted pulmonary valve (PV) dysfunction. Until recently, the standard of care has been surgical placement of a PV or valved right ventricle to pulmonary artery conduit. Catheter-based options are being increasingly applied in patients with PV dysfunction. The purpose of our study was to evaluate outcomes of surgical pulmonary valve/conduit replacement (PVR) at a large pediatric hospital to provide contemporary benchmark data for comparison with developing technologies.

Methods: Retrospective review of patients undergoing PVR not associated with complex concomitant procedures from July 1995 to December 2010 was completed. Inclusion criteria were designed to generally match those applied to patients promoted for catheter-based valve replacement based on age and weight (age $\geq$5 years and weight $\geq$30 kg).

Results: There were 148 PVRs with all patients having undergone $\geq$ 1 previous interventions (tetralogy of Fallot [53%] and pulmonary atresia [17%]). Surgical indications were PV insufficiency (60%), PV stenosis (26%), and both (13%). Valves used included bioprosthetic (n = 108; 73%) and homografts (n = 40; 27%). Time-to-extubation, intensive care unit stay, and hospital length of stay were <1 day (interquartile range, 0-1 day), 2 days (interquartile range, 1-2 days), and 5 days (interquartile range, 4-6 days), respectively, with no hospital deaths. Freedom from PV reintervention at 1, 3, and 5 years was 99%, 99%, and 94%, respectively. Multivariable analysis showed age <13 years (P = .003), and smaller valve size (P = .025) were associated with increased risk of valve reintervention. Patient survival at follow-up (mean, 5.0 $\pm$ 3.9 years) was 99%.

Conclusions: Surgical PVR is safe with low in-hospital and midterm follow-up mortality and reoperation rates. These outcomes provide a useful benchmark for treatment strategy comparisons. (J Thorac Cardiovasc Surg 2014;148:1450-3)

CHD

Most patients born with right heart obstructive lesions develop residual or recurrent right ventricle (RV) outflow tract pathology as a result of native or implanted pulmonary valve (PV) dysfunction. When intervention is required, the standard of care has been surgical placement of a competent PV or valved RV to pulmonary artery conduit. Recently, percutaneous pulmonary valve (PPV) placement has become a viable therapeutic alternative in selected patients when intervention is necessary.[1] Advocates of PPV placement justify the use of this novel but unproven therapy because it is less invasive. It is not clear that PPV placement is safer or more effective than surgical PV placement. Advocates of PPV placement and the patients offered this alternative need current outcome data for surgical PV replacement (PVR) so that informed decisions may be made when both percutaneous and surgical options are available.

METHODS

This was a retrospective review of all patients who underwent a surgical PVR without concomitant complex cardiac procedure at Texas Children's Hospital from June 1995 to December 2010. Institutional review board approval from the Baylor College of Medicine was obtained for conducting this study.

Study Groups

We conducted an analysis of patients who matched the age and weight criteria for catheter-based valve replacement, as per an earlier published report[1]; that is, aged $\geq$5 years and weight $\geq$30 kg at the time surgical PVR was completed.

Outcomes and Data Collection

The primary outcome was patient survival. Freedom from reintervention of the replaced valve was also measured as a secondary outcome.

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Abbreviations and Acronyms
PPV = percutaneous pulmonary valve
PV = pulmonary valve
PVR = pulmonary valve replacement
RV = right ventricle

Variables collected included age, weight at valve replacement, diagnosis, prior procedures, type and size of valve or valved conduit, cardiopulmonary bypass and crossclamp times, days of ventilator use, duration of intensive care unit and hospital stays, complications after valve replacement and at last clinic visit, and surgical or catheter-based reinterventions. Data were collected on study participants from electronic databases (congenital heart surgery database and pediatric cardiology/echocardiogram databases) and clinical records. Completion of follow-up, defined as follow-up in clinic or by telephone within a 2-year period of the study, was 75%.

Data Analysis

Continuous variables were reported as median with minimum and maximums or means ± standard deviations. Frequencies were calculated for categorical variables with percentages. Categorical variables were compared using Fisher exact test, whereas continuous variables were compared with Mann-Whitney *U* test. Survival and freedom from reinterventions analysis using Kaplan-Meier and life-table methods was carried out. Univariable and multivariable analysis, reported as odds ratios with 95% confidence interval, was carried out for risk factors of PV reintervention. All data was analyzed using IBM SPSS version 19 (IBM-SPSS Statistics Inc, Armonk, NY).

RESULTS

Overall, 247 patients were identified during the study period to have undergone PVR not associated with a concomitant complex cardiac procedure at a median age and weight of 12.6 years (interquartile range [IQR], 6.6-17.1 years) and 40.2 kg (IQR, 18.8-57.8 kg), respectively. There were 99 women (40%). The most common fundamental diagnoses were tetralogy of Fallot (n = 103; 42%), pulmonary atresia (n = 53; 21%), and truncus arteriosus (n = 33; 13%). Indications for surgery included PV regurgitation in 123 patients (50%), PV stenosis in 80 patients (33%), both PV stenosis and regurgitation in 38 patients (15%), and 6 patients (2%) had other reasons for surgery, including development of pseudoaneurysm, endocarditis, and other conditions. All patients had either surgical or percutaneous intervention before noncomplex PVR. One hundred eighty-two (74%) bioprosthetic valves and 65 homografts (26%) were implanted surgically. Hospital discharge survival for the entire cohort was 99.6% (Table 1).

Analysis of Patients Eligible for PPV Who Underwent Surgical PVR

There were 148 PVRs in 143 patients who matched the age and weight criteria for PPV. The most common concomitant procedures included main or branch PA reconstruction in 62 patients (42%), RV or RV outflow tract reconstruction in 32 patients (22%), and atrial septal defect/ventricular septal defect/patent ductus arteriosus closure in 12 patients (8%). Aortic crossclamping and myocardial arrest was only used when a residual intracardiac shunt was identified. Forty-one of 148 patients (28%) received an average of 1.9 ± 1 of the following products during their admission (includes inside and outside of the odds ratio): red blood cells, fresh frozen plasma, platelets, or cryoprecipitate. Of these 41 patients, 17 (42%) received red blood cells and/or platelets intraoperatively. None had transfusion reactions. All patients had ≥ 1 previous interventions with most common fundamental diagnosis of tetralogy of Fallot (n = 79; 53%). Valves used included 108 bioprosthetic valves (73%) (n = 39 Carpentier-Edward Perimount [Edwards Lifesciences, Irvine, Calif], n = 33 Medtronic Hancock [Medtronic Inc, Minneapolis, Minn], n = 18 Medtronic Contegra [Medtronic Inc], n = 17 St Jude Medical Epic [St Jude Medical Inc, St Paul, Minn], and n = 1 Medtronic Freestyle [Medtronic, Inc]) and 40 homografts (27%) (Table 1).

Hospital Course, Outcomes at Follow-up, and Risk Factors for Reintervention

The median ventilator support was <1 day (IQR, 0-1 days), median intensive care unit stay was 2 days (IQR, 1-2 days), whereas median hospital length of stay was 5 days (IQR, 4-6 days). There was 1 reexploration secondary to mediastinal hematoma (0.7%) but no active bleeding was identified. There were no other major complications during the hospital stay. The hospital survival was 100%. Freedom from PV reintervention at 1, 3, and 5 years was 99%, 99%, and 94% (Figure 1). Multivariable analysis showed that age younger than 13 years at surgery ($P = .003$) and small valve size ($P = .025$) were associated with increased risk of valve reintervention (Table 2). There were 2 deaths on follow-up after 2 years and after 11 years of noncomplex surgical PVR. One patient died secondary to severe cardiac dysfunction and 1 patient developed respiratory tract infection leading to respiratory failure and death. Patient survival at a mean follow-up of 5.0 ± 3.9 years in this cohort was 99%.

DISCUSSION

With growing experience with PPV placement, our goal was to describe a contemporary experience with surgical PVR in a patient population comparable to candidates for the percutaneous approach. If interventional cardiologists and patients are to make well-informed decisions regarding PPV placement, the alternative surgical approach must be understood. Although less invasive procedures are attractive to both patients and physicians, they only benefit a patient if they achieve a result comparable with the more invasive procedure without increased risk. The early