Pulmonary Valve Replacement: A Single-Institution Comparison of Surgical and Transcatheter Valves

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Background. **Transcatheter pulmonary valve replacement (TPVR) is increasingly utilized to address residual or recurrent right ventricular outflow tract pathology in congenital heart disease patients. We aimed to evaluate clinical outcomes and resource utilization comparing TPVR to surgical pulmonary valve replacement (SPVR) for this patient population.**

Methods. **From January 2010 until December 2015, 224 patients underwent pulmonary valve replacement (SPVR = 100 and TPVR = 124). These groups were assessed and compared for survival, reoperation, reintervention (surgical or catheter based), hospital costs, and hemodynamic performance.**

Results. **There were no mortalities in either group. Despite SPVR patients being significantly younger (12 ± 7 years of age versus 19 ± 13 years of age; $p < 0.001$) and smaller (body surface area 1.2 ± 0.5 m^2 versus 1.4 ± 0.5 m^2; $p < 0.001$), they had similar median valve size implanted (23 mm [interquartile range, 21 to 27 mm) versus 22 mm [interquartile range, 20 to 22 mm]). There was no difference in the adjusted peak gradient (SPVR 24.1 ± 15.1 mm Hg versus TPVR 20.7 ± 11.4 mm Hg; $p = 017$) at last follow-up. Cumulative freedom from reintervention at 4 years was similar between groups ($p = 0.98$). TPVR could not be placed in 34 patients either due to coronary compression or excessive outflow tract diameter. SPVR patients had longer hospital length of stay (4.1 ± 1.8 days versus 1.2 ± 0.7 days; $p < 0.001$). TPVR patients had higher rates of infective endocarditis (4.8% versus 0%; $p < 0.001$) and overall hospital costs ($57,221 ± $13091 versus $44,366 ± $16,519; $p < 0.001$).**

Conclusions. **Hemodynamic performance is similar between SPVR and TPVR with similar rates of reintervention. While SPVR patients have a longer hospital length of stay, TPVR was associated with higher rates of infective endocarditis, hospital costs, and failure to implant.**

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Right ventricular outflow tract (RVOT) disease is a component of many congenital heart defects. Initial treatment typically involves surgical placement of a transannular patch or a right ventricle (RV) to pulmonary artery (PA) conduit. Traditionally, maintenance of a functional RVOT has been achieved by surgical pulmonary valve replacement (SPVR) using either a bioprosthetic valve or an RV-to-PA conduit. The durability of these valves is limited and variable, subjecting these children to additional surgical interventions of increasing difficulty with higher risk for each successive surgery throughout their life [1–3].

Transcatheter pulmonary valve replacement (TPVR) was first described in 2000 as an alternate means of managing patients with RVOT disease [4, 5]. In the United States, the Melody transcatheter valve (Medtronic Inc, Minneapolis, MN) was initially studied using a 5-center Investigational Device Exemption protocol [6]. Since then, several studies have documented the feasibility and short-term performance of TPVR [7–9].

TPVR is increasingly employed due to its less invasive mode of delivery and perceived lower morbidity. However, data comparing clinical outcomes and resource utilization between SPVR and TPVR are limited. The purpose of this study is to evaluate the clinical outcomes, valve durability, and costs associated with both SPVR and TPVR.

Patients and Methods

The Institutional Review Boards at Primary Children's Hospital and the University of Utah approved this retrospective review with a waiver of parental consent.

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All patients undergoing pulmonary valve replacement at Primary Children's Hospital from January 2010 through December 2015 were identified. For the purposes of this study, all TPVR patients received the Melody Transcatheter Pulmonary Valve (Medtronic Inc) dilated to 18, 20, or 22 mm in diameter at placement. To maintain uniformity, the SPVR cohort included only patients receiving stentless porcine heterografts (Freestyle stentless full root bioprosthesis; Medtronic Inc, Fridley, MN) for 19-mm valves and Prima Plus (Edwards Lifesciences, Irvine, CA) for sizes of 21, 23, 25, 27, and 29 mm. Of note, the labeled valve size for the stentless porcine valves refers to the external diameter. Per the manufacturer, the internal diameter of the 19 mm Freestyle is 16 mm and the internal diameter of the Prima valves is 1.5 mm less than the listed external diameter. While the internal diameters are not exactly the same, we created 3 substrata so that TPVR and SPVR patients with similar-sized valves could be compared, allowing slightly larger Melody valves to be compared with a smaller internal diameter surgical counterpart. The technique for stentless porcine SPVR has previously been described [10].

Demographic and outcome data were obtained through a detailed chart review of each patient and included description of the underlying congenital heart disease, surgical history, indication for intervention, preprocedural and postprocedural diagnostic imaging, and postprocedural morbidity and mortality.

Our primary outcomes were reintervention for valvar dysfunction and mortality in hospital and at latest follow-up. Secondary outcomes include echocardiographic gradients and severity of regurgitation at the time of discharge and latest echocardiogram, length of stay, and hospital cost from the index procedure to discharge.

The peak velocities across the RVOT obtained with pulsed or continuous-wave Doppler evaluation and the gradient determined with the modified Bernoulli equation were collected from the echocardiogram reports. Valve regurgitation was graded as 1+ to 4+. Data from magnetic resonance imaging (MRI) for RV function and dimensions were obtained as available.

Valve-related reintervention was defined as any operation or catheter-based intervention for either RVOT insufficiency or stenosis. In general, the indication for reintervention included peak instantaneous Doppler gradient of greater than 50 mm Hg or greater than or equal to 2+ conduit or valve regurgitation in combination with symptoms, progressive RV enlargement or diminished RV function.

Hospital cost was obtained through the financial department for an encounter. The cost data excluded the preoperative workup in both the groups. Total hospitalization cost was generated from an itemized list detailing all direct (e.g. medications, medical devices, supplies, labor) and indirect (e.g. overhead) costs.

Patient demographics, preoperative and operative variables, and follow-up time were summarized as mean ± SD for continuous variables and number (percentage) for categorical variables. Variables were compared between SPVR and TPVR using a Fisher's exact test, chi-square test, t test, or Wilcoxon rank sum test as appropriate. Time to reoperation was presented as Kaplan-Meier curves and the SPVR and TPVR groups were compared using a log-rank test. For the outcome pulmonary stenosis at the last follow-up, we performed both unadjusted comparison using Wilcoxon rank sum test and adjusted comparison between SPVR and TPVR groups in a multivariable linear regression analysis, adjusting for clinically important variables that differed between groups ($p < 0.05$): duration of echocardiographic follow-up, age, and body surface area (BSA). Mortality and reintervention could not be analyzed in multivariable analysis due to too few events. To account for the inherent difference in valve sizes between SPVR and TPVR, pulmonary stenosis was also analyzed using a meta-analytic approach by pooling results in 3 substrata based on comparable valve sizes (SPVR 19 mm and TPVR 18 mm; SPVR 21 mm and TPVR 20 mm; SPVR 23 to 25 mm and TPVR 22 mm) using a random-effects model with inverse variance weighting employing Review Manager 3.0 (R Foundation for Statistical Computing, Vienna, Austria). Otherwise, analyses were performed using R version 3.3.2 (R Project for Statistical Computing, Vienna, Austria).

Results

Study Population

Of the 293 patients who underwent pulmonary valve replacement during the study period, 54 surgical patients received a valve smaller than 19 mm and 15 received a stented valve; thus, they were excluded from the analysis. The remaining 224 patients (SPVR = 100 and TPVR = 124) formed the study population (Fig 1). Patients in the SPVR cohort were younger (12 ± 7 years of age versus 19 ± 13 years of age; $p < 0.001$), had lower BSA (1.2 ± 0.5 m^2 versus 1.4 ± 0.5 m^2; $p < 0.001$), and had fewer prior sternotomies (<2 prior sternotomies: 58 [58%] versus 35 [29%]; $p < 0.01$) compared with the TPVR cohort. More SPVR patients reported symptoms at the time of valve or conduit implantation (75% versus 66%; $p = 0.05$) (Table 1). The overall number of pulmonary valve replacements more than doubled from the beginning to the end of the study; TPVR had an almost 7-fold increase while SPVR volumes remained relatively stable (Fig 2).

Preoperative moderate or severe pulmonary insufficiency (>2+) was the major indication for intervention in 75 (75%) patients in the SPVR group compared with 49 (40%) patients in the TPVR group. MRI data were available in 75 (33%) patients. Compared with TPVR patients, SPVR patients had larger RV volume indices: end-diastolic volume index (141 ± 37 mL/m^2 versus 110 ± 30 mL/m^2; $p < 0.001$) and end-systolic volume index (74 ± 22 mL/m^2 versus 52 ± 18 mL/m^2; $p < 0.001$).

Clinical Outcomes

The mean duration of clinical follow-up in the SPVR group was 31.6 ± 22 months compared with 18.7 ± 17 months in the TPVR group ($p < 0.001$). There was no