Benchmark Outcomes for Pulmonary Valve Replacement Using The Society of Thoracic Surgeons Databases

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Background. **As less invasive alternatives to surgical pulmonary valve replacement (PVR) are being refined and evaluated, there is a need for benchmark data concerning outcomes from surgical PVR.**

Methods. **We examined in-hospital outcomes from surgical PVR in The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) and Adult Cardiac Surgery Database (STS-ACSD) between 2007 and 2013, with a focus on patients likely to be eligible for transcatheter PVR (ie, ≥ 5 years age and ≥ 30 kg). Patient characteristics, morbidity, and mortality were described.**

Results. **The STS-CHSD included 6,431 eligible patients with a median age of 17 years (interquartile range [IQR], 14–25 years). Preoperative comorbidities were uncommon: arrhythmia (1.7%), renal failure (0.1%), endocarditis (0.3%), neurologic deficit (0.8%), and diabetes (0.5%). In-hospital mortality was 0.9%. A major complication occurred in 2.2%. The STS-ACSD included 3,352 eligible patients; the median age was 41 years (IQR, 30–55 years). Preoperative comorbidities were more common: arrhythmia (24.3%), renal failure (3.8%), endocarditis (12.2%), cerebrovascular disease (7.9%), and diabetes (10.9%). In-hospital mortality was 4.1%. A major complication occurred in 20.9%.**

Conclusions. **Contemporary outcomes from surgical PVR include a low risk of in-hospital death or major complications. Patients in the STS-ACSD are older and have an increased prevalence of preoperative factors, which may contribute to higher morbidity and mortality.**

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Pulmonary valve replacement (PVR) is performed on patients with a wide variety of cardiac anomalies, including tetralogy of Fallot, pulmonary stenosis/insufficiency, pulmonary atresia, and truncus arteriosus. Although it is rarely the initial therapeutic intervention, PVR is the most common congenital operation in adults [1].

Over the past decade, transcatheter PVR (TPVR) has emerged as an alternative to surgical PVR. In the initial experience, serious complications were reported in 6% to 15% of patients, with a procedural mortality of 0.0% to 1.0% [2–5]. Comparative data reporting outcomes after surgical PVR are very limited and further research is needed.

To inform clinical decision making before PVR or in determining surgical PVR versus TPVR, we sought to establish contemporary benchmark data for discharge mortality and major complication rates in patients undergoing surgical PVR in The Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS-ACSD) and The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD).

Material and Methods

Data Source

Two components of the STS National Database—the STS-CHSD and the STS-ACSD—were used. The STS-CHSD is focused on cardiac procedures for congenital cardiac malformations and includes detailed deidentified preoperative, operative, and outcomes data on more than 292,000 operations from 120 pediatric and adult congenital heart surgery programs in North America. The database currently represents approximately 93% of all US congenital heart surgery centers and greater than 96% of all operations [6]. The STS-ACSD was established in 1989 to report surgical preoperative and perioperative

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risk factors and outcomes after cardiothoracic surgical procedures in adults [7] and currently includes data from more than 90% of hospitals performing adult cardiac operations in the United States. The Duke Clinical Research Institute serves as the data warehouse and analysis center for all of the STS national databases. Evaluation of data quality includes the intrinsic verification of data, along with a formal process of in-person site visits and data audits at approximately 10% of participating institutions each year [6, 8, 9]. This study was reviewed and approved by the STS-CHSD Access and Publications Committee and the Duke University Institutional Review Board and was not considered human subject research in accordance with the Common Rule (45 CFR 46.102(f)).

Study Population

The study inclusion and exclusion criteria were designed to allow meaningful comparisons with the TPVR trials [2–5]. For the STS-CHSD, all index PVR operations or right ventricle–to–pulmonary artery conduit placement operations (or both) from 2007 to 2013 were potentially eligible for inclusion (n = 15,520). Initial Ross or Ross-Konno operations (n = 108) and operations in patients weighing less than 30 kg or in patients younger than 5 years (n = 8,981) were excluded. The resultant population from the STS-CHSD included 6,431 operations from 114 centers. For the STS-ACSD, all pulmonary valve procedures from 2007 to 2013 were potentially eligible for inclusion (n = 3,612). Initial Ross procedures (n = 116) and patients weighing less than 30 kg (n = 11) were excluded. Some surgeons entered patients into both the STS-CHSD and the STS-ACSD. Comparing date of birth, sex, and date of operation identified 133 duplicate entries. These were evaluated for geographic proximity of the centers and felt to represent true duplicates. These patients were removed from the STS-ACSD. The resultant population from the STS-ACSD included 3,352 operations from 446 centers. Although the majority of PVR procedures in the STS-ACSD are performed for congenital heart disease, because of limitations in data collection fields in the STS-ACSD, congenital pulmonary valve disease was not a requirement.

Data Collection and Definitions

Data collected from the STS-ACSD and STS-CHSD included demographic information, preoperative risk factors, and diagnostic and operative variables as defined in the respective databases. Outcomes data included in-hospital mortality, total postoperative length of stay, and postoperative complications. Major complications were compiled as previously defined by the respective databases. In the STS-CHSD, major complications included temporary or permanent renal failure at discharge requiring dialysis, neurologic deficit persisting at discharge, atrioventricular block or arrhythmia requiring a permanent pacemaker, postoperative mechanical circulatory support, phrenic nerve injury, or any unplanned reintervention before discharge [10]. Reports from the STS-ACSD have defined major complications to include permanent stroke, renal failure, prolonged ventilation, deep sternal wound infection, and reoperation for any reason [11].

Statistical Analysis

A descriptive analysis of patient characteristics and outcomes was performed. Because of the differences in procedural coding and data element definitions, outcomes data from the 2 databases were compiled separately. Results were summarized using frequencies and proportions for categorical variables and medians and interquartile ranges (IQRs) for continuous variables. Standard statistical tests including χ^2 tests of association and Wilcoxon rank sum tests were used to compare the distribution of categorical and continuous variables among the different procedural groups. All analyses were performed using SAS, version 9.3 (SAS Institute, Inc, Cary, NC). A p value less than 0.05 was considered statistically significant.

Results

STS Congenital Heart Surgery Database

The STS-CHSD included 6,431 pulmonary valve operations: 1,470 were isolated PVRs, 333 were isolated right ventricle–to–pulmonary artery conduits, and 4,628 were accompanied by concomitant procedures (Table 1). Median age at operation was 17 years (IQR, 14–25 years). Preoperative risk factors were uncommon overall (3.1%), with arrhythmia most commonly identified (1.7%). Operations represented a first cardiovascular procedure in 11% of patients, a first reoperation in 42% of patients, a second reoperation in 27% of patients, a third reoperation in 12% of patients, and a fourth or further reoperation in 8% of patients. The most common primary diagnoses and underlying fundamental diagnosis of each patient are listed in Table 2. For the entire cohort in the STS-CHSD, cardiopulmonary bypass time was 92 minutes (range, 65–134 minutes). Intraoperative blood products were used in 38% of the cases—less often in isolated PVR (26%) and isolated conduit (24%) procedures and more often with concomitant procedures (42%) ($p < 0.001$). Mortality was low after isolated PVR (0.3%), isolated conduit replacement (1.5%), and operations with concomitant procedures (1.0%) (Table 3). The most common major complication was an unplanned reoperation (0.7%).

In the STS-CHSD, as age increased, prevalence of obesity (body mass index [BMI] > 30) increased (20% in the group aged 20–29 years and 34% in the group aged 50+ years). Prevalence of preoperative factors also tended to increase with increasing age (Fig 1). As the number of previous operations increased from 0 to 4 or more, preoperative factors tended to increase. Unadjusted mortality increased with an increasing number of previous operations (0.6%, 0.6%, 1.2%, 2.3%, and 2.9% for 0, 1, 2, 3, and 4 or more previous cardiovascular operations, respectively) (Fig 2). Unadjusted mortality also increased with increasing age (0.7%, 0.8%, and 3.0%, for ages < 20, 20–39, and 40+ years).