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Cost-comparison of Transcatheter and Operative Pulmonary Valve Replacement (From the Pediatric Health Information Systems Database)

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Abstract

Outcomes for transcatheter (TC-PVR) and operative (S-PVR) replacement of the pulmonary valve (PVR) are excellent. Thus their respective cost is a relevant clinical outcome. We performed a retrospective cohort study of children and adults undergoing PVR at age 8 years from 1/1/2011 to 12/31/2013 at 35 centers contributing data to the Pediatric Health Information Systems database to address this question. A propensity score-adjusted multivariable analysis was performed to adjust for known confounders. Secondary analyses of department-level charges, risk of re-admission, and associated costs were performed. A total of 2,108 PVR procedures were performed in 2,096 subjects (14% transcatheter and 86% operative). The observed cost of S-PVR and TC-PVR was not significantly different (2013US\$50,030 vs. 2013US\$51,297; $p=0.85$). In multivariate analysis, total cost of S-PVR and TC-PVR were not significantly different ($p=0.52$). Length of stay was shorter following TC-PVR ($p<0.0001$). Clinical and supply charges were greater for TC-PVR ($p<0.0001$) while lab, pharmacy, and other charges (all $p<0.0001$) were greater for S-PVR. Risk of both 7- and 30-day readmission were not significantly different. In conclusion, short-term costs of TC-PVR and S-PVR are not significantly different after adjustment.

Keywords

Outcomes research; pediatrics; economic analysis; heart catheterization

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Introduction

Right ventricular outflow tract reconstruction (RVOT) frequently results in stenosis and/or insufficiency. This may not cause symptoms for years but has been implicated in insidious development of RV dysfunction and increased risk of mortality¹⁻³. Operative replacement of the pulmonary valve (S-PVR) has previously been the single definitive treatment for dysfunctional RVOT. Transcatheter pulmonary valve replacement (TC-PVR) is an alternative to S-PVR with excellent safety and efficacy, which potentially avoids the morbidity and mortality associated with open-heart surgery⁴⁻⁹. With clinical equipoise, the economic costs of TC-PVR and S-PVR become relevant as outcomes. Though several studies have assessed the costs of TC-PVR and S-PVR¹⁰⁻¹², small volumes and homogenous practice at single centers make a traditional cohort study challenging. Using administrative data from the Pediatric Health Information System (PHIS) database we performed a multi-center retrospective cohort study to overcome these obstacles.

Methods

The PHIS database is an administrative database containing data from inpatient, emergency department, ambulatory surgery, and observation encounters from 42 not-for-profit, tertiary care pediatric hospitals in the United States, affiliated with the Children's Hospital Association (CHA) (Overland Park, KS). Data quality and reliability are assured through a joint effort between the CHA and participating hospitals. The data warehouse function for PHIS is managed by Truven Health Analytics (Ann Arbor, MI). For the purposes of external benchmarking, participating hospitals provide discharge/encounter data including demographics, diagnoses, and procedures. Forty-two of these hospitals also submit resource utilization data (e.g. pharmacy products, radiologic studies, and laboratory studies) to PHIS. Data are de-identified at the time of data submission and are subjected to a number of reliability and validity checks. A data-use agreement was signed between study investigators and CHA. The institutional review board of The Children's Hospital of Philadelphia reviewed the proposed project and determined that it did not represent human subjects research in accordance with the Common Rule (45 CFR 46.102(f)).

We included children and adults of age ≥ 8 years undergoing pulmonary valve replacement at any of the 43 PHIS centers between 1/1/2011 and 12/31/2013. The age restriction was added to eliminate relatively young subjects who would not be considered candidates for TC-PVR as described previously¹³. Subjects were identified by International Classification of Disease, ninth revision code (ICD-9) and divided between those undergoing 1) transcatheter valve pulmonary valve replacement (ICD-9: 35.07) or 2) open heart surgery for pulmonary valve replacement (ICD-9: 35.25 or 35.26). To restrict analysis to centers with stable reporting and procedural volumes, we also excluded subjects from centers reporting 1) ≥ 25 cardiac catheterization or cardiac operative procedures per year over the study period or 2) failure to report catheterizations and cardiac operations 2 of 3 years of the study period^{13,14}.

Data were extracted from the PHIS database using ICD-9 codes for diagnoses and procedures. Medical comorbidities were divided by system¹⁵. Several steps were taken to

generate costs that were comparable across the study population. Costs were extracted from PHIS, which PHIS derives from reported charges using ratios of costs to charges (RCC). The PHIS registry also adjusts costs to account for regional differences (based on wage/price indices). The results of this conversion are referred to in this manuscript as “adjusted costs”. We also accounted for inflation by converting all costs to 2013 United States dollars (2013US\$) using the consumer price index for medical care (<http://data.bls.gov/cgi-bin/dsrv>). PHIS also reports cost without adjustment for local wage/price indices (heretofore referred to as “unadjusted costs”)^{16,17}. To be complete, we repeated all analyses with unadjusted costs (Supplementary Tables 1–2).

The primary exposure was method of PVR, dividing the study population into TC-PVR and S-PVR cohorts. TC- and S-PVR were not both performed in a single admission, (i.e. no cross-over was recorded). Since cohorts were identified by ICD-9 codes, there is the possibility of subjects who underwent catheterization and failed to receive TC-PVR and subsequently underwent S-PVR would be included in the S-PVR cohort. The rate at which this occurred could not be measured. Therefore, analysis was performed as treated. Continuous variables were expressed as mean $\pm$ standard deviation or median (range and inter-quartile range) as appropriate. Categorical variables were expressed as percent (count).

Prior to analysis, we suspected that subject characteristics would differ systematically between transcatheter and operative cohorts and also influence cost. Wilcoxon rank sum test, Chi-squared, and Fisher’s exact test were used to test for differences in the distribution of subject characteristics. To adjust for confounding by indication, a propensity score for each subject defining the relative probability of assignment to TC-PVR vs. S-PVR^{18–20}. The factors included in the propensity score were sex, non-cardiac congenital anomaly, known genetic syndrome, age (centered on mean), and each of the following: hematological disorder, malignancy, metabolic disorder, neurologic disorder, or pulmonary disorder. The propensity score was then included in subsequent models as a covariate.

Analysis of cost included direct medical costs (determined from hospital charges and professional charges) with time horizon restricted to hospitalization(s) during which valve replacement was performed. Pre-procedural costs were assumed to be equal between both cohorts. Median costs (total and according to categories) were calculated for both cohorts and compared using Wilcoxon rank-sum tests. Subsequently generalized linear models were used to account for measurable covariates (including propensity score as a covariate) and compare cost between the two cohorts. A log gamma distribution was used to account for the skewed distribution of costs. LOS was analyzed similarly, but because it includes zero as a possible value, a Gaussian probability distribution was used. For all models, conditional standardization was used to generate an adjusted estimate of the outcome of interest. An analysis adding a random intercept for center to adjust for correlation in centers was performed, without any change from reported results (Data not shown).

An analysis of differences in department level charges for S- and TC-PVR was performed using the Wilcoxon rank-sum test. Two sensitivity analyses were performed 1) varying the minimum age of subjects (1 year increment from 8–18 years) to ensure that this did not bias results and 2) restricting the analysis to hospitals that performed both S-PVR and TC-PVR

(eliminating 6 of 36 centers and 8% (172/2133) of total procedures). The results of main effects did not change in either analysis (data not shown).

As a secondary analysis, we studied the distribution of costs between hospital departments to identify aspects of care that could be optimized to improve value. PHIS does not release department-level RCC or costs, so only department-level hospital charges could be analyzed. These charges were inflation-adjusted, but no further normalization was possible. This is a significant limitation of the data source. Charges are strongly influenced by individual hospital charging practices and are imperfect surrogates for cost, but they provide a measure of the relative magnitude of resource utilization that influence cost for each method.

A third analysis was performed assessing the relative risk of re-admission within 7 and 30 days and the cost of these admissions. Other clinical outcomes (in-hospital death, length of stay(LOS)) were also collected and compared between the TC-PVR and S-PVR.

There were no patients with missing data about their age or sex. For patients with missing data about their race or cardiac diagnosis, a separate categorical variable was generated; this allowed them to be included in the analysis and mitigated bias. A sensitivity analysis that did not include cardiac diagnosis (for which there was a high rate of missing data) was performed with no change in coefficients for cost or significance (data not shown). No formal measures were applied to account for multiple comparisons. The primary analysis is specified, and other analyses should be considered exploratory. All data analysis was performed using Stata MP 13 (Statacorp, College Station, TX). The threshold for statistical significance was $p<0.05$.

Results

Between January 1, 2011 and December 31, 2013, 2,294 procedures were performed in 2,274 eligible subjects at the 42 centers included in the PHIS database (Figure 1). Data from 6 centers accounting for 185 procedures in 178 subjects were excluded because they failed to meet inclusion criteria. Multiple PVR procedures were performed in a single hospitalization for 2 subjects. For the remaining 2,108 hospitalizations in 2,096 subjects, the median age of subject at PVR was 16.3 years, 39% female, and 73% white.

The cohort was 86% S-PVR (1816/2108 procedures in 1806/2096 individuals) and 14% TC-PVR (292/2108 procedures in 290/2096 individuals). Several significant differences in demographics were seen between the S-PVR and TC-PVR cohorts. The operative cohort was younger ($p<0.0001$) with a different distribution of cardiac diagnoses (<0.001). The distribution of other patient factors was not significantly different between the cohorts (Table 1).

The observed total costs of S-PVR (2013US\$50,030 IQR: 38,639–65,932) and TC-PVR (2013US\$51,297, IQR: 37,858–73,328, $p=0.85$, Table 2) were not significantly different. Observed in-hospital mortality was not significantly different following S-PVR than TC-PVR ($p=0.24$). LOS was longer following S-PVR than TC-PVR ($p<0.0001$). In terms of department level charges, clinical charges and supply charges were greater in the TC-PVR

cohort ($p<0.0001$ for both). Other charges (including room charges), laboratory, and pharmacy charges were all greater for the S-PVR cohort ($p<0.0001$ for all). Imaging costs were not significantly different between the two cohorts ($p=0.27$).

In a propensity score-adjusted multivariate model, there was no significant difference in total cost between S-PVR and TC-PVR ($p=0.52$, Table 3). Using conditional standardization, cost of S-PVR was US\$47,635 (95% CI: 27,537–82,404) vs. cost of TC-PVR which was US\$51,409 (95% CI: 28,978–91,201). A history of malignancy (coefficient: 2.29, 95% CI: 1.26–4.18, $p=0.007$) was associated with increased cost. Previous pulmonary (coefficient: 2.01, $p=0.10$), gastrointestinal (coefficient: 1.43, $p=0.06$), and hematologic (coefficient: 1.30, $p=0.07$) conditions had coefficients consistent with higher cost, but the associations were not statistically significant. History of 22q11.2 micro-deletion syndrome (coefficient: 0.50, 95% $p=0.05$) was suggestive of decreased cost, but this association was not statistically significant.

The rate of readmission within both 7 and 30 days was not significantly different between S-PVR and TC-PVR cohorts (Table 2). Readmission within 30 days occurred in 18.1% of subjects in the S-PVR cohort compared with 15.1% of the TC-PVR cohort ($p=0.17$). The risks of a readmission with a cardiac operation ($p=0.13$) or a cardiac catheterization ($p=0.14$) were not significantly different between S-PVR and TC-PVR cohort. The median adjusted cost of a readmission within 30 days of PVR for a subject in the S-PVR cohort (median: US\$394, IQR: 158–1131) was not significantly different from that for TC-PVR (median: US\$862, IQR: 223–3417, $p=0.07$). Readmissions which included a cardiac operation or cardiac catheterization were associated with much higher adjusted cost (median: US\$42,462, IQR: 11,333–196,694) than those that did not (median: US\$400 IQR: 158–1145, $p=0.0002$).

Discussion

In this multi-center retrospective cohort study using administrative data from 36 centers in the United States, there was no difference in total cost of hospitalization or mortality between S-PVR and TC-PVR. Total cost was independently associated with patient level covariates, but adjustment for these covariates did not result in a significant difference in cost between the two cohorts.

Previous studies comparing methods of PVR have either demonstrated a cost-advantage to TC-PVR or cost-equivalence^{10–12}. These studies were limited to a small numbers of cases from single centers^{17–18} and thus unable to adjust for confounding variables. Some used estimates of anticipated cost rather than empirical data^{18,19}. The current study demonstrates with empirical data from multiple centers that there are not significant differences in cost between S-PVR and TC-PVR, when appropriate adjustment is applied.

There were large-magnitude differences in the component costs for S-PVR and TC-PVR. LOS was longer following S-PVR as well as greater pharmacy and laboratory charges, while clinical and supply costs (related to the cost of the transcatheter valve itself) were much higher in the TC-PVR cohort. Though it is not possible to itemize these charges in the

database, one can hypothesize that the increased charges in S-PVR are the result of longer hospitalizations and more resource-intensive post-procedure care, while the supply and clinical costs that are higher for TC-PVR emerge from the cost of the valve. Post-operative care of S-PVR subjects, therefore, is a potential source of cost savings, especially in regards to length of stay. Though cost of transcatheter valves is multi-factorial, the development of other devices and ensuing price competition may result in reduction in device costs and potentially provide, over time, a cost-advantage to TC-PVR.

Recently interest has arisen regarding the possibility of increased incidence of endocarditis following TC-PVR^{4,21–25}. Endocarditis risk was not explicitly assessed in this study. However, the risk of re-admission, the risks of catheterization or cardiac operation, and the costs of these admissions were not different between S-PVR and TC-PVR cohorts. This suggests that endocarditis does not result in significant immediate differences in morbidity or cost between TC-PVR and S-PVR. Since much of the endocarditis burden appears to be remote from PVR, further research is necessary to measure the true risk of endocarditis following PVR.

Marginal cost-effectiveness between therapies is superior to cost-comparison as a means of comparing the value of different interventions. To date, the morbidity and effect of either intervention on health-related quality of life of children and adults undergoing TC-PVR and S-PVR has not been measured, which makes calculation of the relative effectiveness of each operation challenging. One might hypothesize that, in the absence of evidence for increased re-admission or re-intervention, avoiding a sternotomy and bypass might give TC-PVR an advantage in terms of morbidity but this is conjecture at this time.

There are several other limitations to this study. The data are derived from an administrative database, which does not include all clinically relevant information each subject: 1) whether the procedure is a first, second, or third attempt at PVR, 2) medical frailty of the subject, 3) underlying cardiac anatomy, and 4) results of cardiopulmonary exercise testing or cardiac imaging. The inability to measure them represents sources of unmeasured confounding. Even in this relatively large sample, there is the potential for type II error. Post-hoc power calculations have the potential to introduce bias^{26,27}, and for clustered multi-variable analysis it is challenging to produce power calculations without making assumptions about both variance patterns of all included variables. TC-PVR remains novel and clinical results and cost may shift with increased experience with it and as new products are introduced. Repeating this analysis in the future would be informative. We acknowledge that analysis focused on short-term follow-up. Measuring cost and clinical outcomes with longer follow-up would be valuable, but is beyond the scope of this study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Study Population

Table 1

Study population

	Operative	Trans-catheter	<i>p</i>
Procedures	1,816	292	n/a
Individuals	1,806	290	n/a
Age (years)	16.2 (IQR: 12.5–21.3)	17.7 (IQR: 13.1–24.8)	<0.0001
Female sex	39% (703)	38% (112)	0.96
Race			
<i>White</i>	73% (1,334)	72% (209)	0.70
<i>Black</i>	8% (153)	10% (28)	
<i>Asian</i>	4% (66)	5% (15)	
<i>Other</i>	11% (198)	10% (29)	
<i>Missing</i>	4% (65)	4% (11)	
Payor			
<i>Private</i>	51% (935)	44% (130)	<0.001
<i>Public</i>	33% (596)	33% (96)	
<i>Other</i>	14% (252)	23% (66)	
<i>Missing</i>	2% (33)	0.3% (1)	
Primary cardiac diagnosis			
<i>Tetralogy of Fallot</i>	14% (255)	14% (42)	<0.001
<i>Transposition of the great arteries</i>	0% (0)	0.7% (2)	
<i>Truncus arteriosus</i>	0.2% (3)	2% (7)	
<i>Double outlet right ventricle</i>	4% (64)	2% (5)	
<i>Other pulmonary valve disease</i>	1% (18)	0% (0)	
<i>Other</i>	30% (549)	11% (33)	
<i>Missing</i>	51% (927)	70% (203)	
Genetic syndrome			
<i>None recorded</i>	97.0% (1,762)	97.3% (284)	0.41
<i>22q11.2 microdeletion</i>	1.5% (28)	0.7% (2)	
<i>Trisomy 21</i>	1.3% (23)	2.1% (6)	
Non-cardiac congenital anomaly	3% (60)	2% (7)	0.41
History of gastrointestinal condition	0.7% (24)	1.4% (4)	0.20
History of hematologic condition	5.0% (91)	7.5% (22)	0.08
History of malignancy	0.4% (7)	0.3% (1)	0.91
History of metabolic condition	3.3% (60)	2.1% (6)	0.25
History of neurologic condition	3.6% (66)	4.8% (14)	0.34
History of renal condition	1.2% (22)	0.3% (1)	0.18
History of respiratory condition	0.4% (8)	0.3% (1)	0.81

Abbreviations: IQR interquartile range

Table 2

Outcomes following pulmonary valve replacement

	Operative	Transcatheter	<i>p</i>
Total cost (2013US\$)	50,030 (IQR: 38,639–65,932)	51,297 (IQR: 37,858–72,328)	0.85
Hospital length of stay (days)	4 (Range: 1–198, IQR: 3–5.5)	1 (Range: 0–49, IQR: 1–1)	<0.0001
In-hospital mortality	0.8% (36)*	0% (0)*	0.24**
Department level charges (2013\$US)			
<i>Clinical</i>	7,316 (IQR: 3,602–23,820)	23,753 (IQR: 12,805–30,727)	<0.0001
<i>Imaging</i>	7,475 (IQR: 4,853–11,808)	6,578 (IQR: 2,966–17,737)	0.27
<i>Lab</i>	12,661 (IQR: 6,619–20,303)	1,502 (IQR: 692–2,941)	<0.0001
<i>Pharmacy</i>	10,329 (IQR: 5,797–18,768)	1,724 (IQR: 1,018–3,901)	<0.0001
<i>Supply</i>	33,127 (IQR: 20,796–48,234)	83,288 (IQR: 51,992–116,246)	<0.0001
<i>Other</i>	51,943 (IQR: 32,651–73,870)	10,383 (IQR: 6,999–14,776)	<0.0001
7-day readmission	8.2% (163)	6.4% (20)	0.26
30-day readmission	18.1% (401)	15.1% (52)	0.17
<i>With operation</i>	0% (0)	0.3% (1)	0.13
<i>With catheterization</i>	0.2% (3)	0.7% (2)	0.14

* 95% CI for S-PVR: is 0.4–1.2%. One-sided 97.5% CI for TC-PVR is 0–1.3%

** Fisher's exact test

Table 3

Multivariable model for adjusted total costs

	Coefficient	95% CI	p
TC-PVR (vs. S-PVR)	1.07	0.85–1.35	0.55
Race			
<i>White</i>	1	n/a	n/a
<i>Black</i>	1.15	0.98–1.35	0.10
<i>Asian or Pacific Islander</i>	1.14	0.88–1.48	0.33
<i>Other</i>	1.14	0.88–1.47	0.32
<i>Missing</i>	0.93	0.78–1.09	0.36
Sex			
<i>Male</i>	1	n/a	n/a
<i>Female</i>	0.94	0.84–1.06	0.32
Age (per year)	1.00	0.99–1.00	0.49
Insurance payor			
<i>Private</i>	1	n/a	n/a
<i>Public</i>	1.07	0.94–1.22	0.28
<i>Other</i>	0.88	0.79–0.99	0.04
<i>Missing</i>	0.77	0.54–1.10	0.15
Cardiac diagnosis			
<i>Tetralogy of Fallot</i>	1	n/a	n/a
<i>Transposition of the great arteries</i>	0.79	0.49–1.29	0.34
<i>Truncus arteriosus communis</i>	1.30	0.88–1.93	0.19
<i>Double outlet right ventricle</i>	1.22	0.93–1.62	0.15
<i>Pulmonary stenosis and/or pulmonary insufficiency</i>	1.29	0.83–2.00	0.26
<i>Other</i>	1.11	0.96–1.28	0.17
<i>Missing</i>	1.18	1.01–1.38	0.03
Genetic syndrome			
<i>Trisomy 21</i>	0.55	0.25–1.24	0.15
<i>22q11.2 micro-deletion</i>	0.50	0.25–0.99	0.05
<i>Other</i>	1.79	0.71–4.50	0.21
Non-cardiac congenital anomaly	1.46	0.70–3.08	0.32
Non-cardiac systemic disease			
<i>Gastrointestinal condition</i>	1.43	0.98–2.07	0.06
<i>Hematologic condition</i>	1.30	0.98–1.71	0.07
<i>Malignancy</i>	2.29	1.26–4.18	0.007
<i>Metabolic disorder</i>	1.21	0.83–2.14	0.23
<i>Neurologic condition</i>	1.24	0.86–1.80	0.25
<i>Renal disease</i>	1.05	0.73–1.51	0.78
<i>Pulmonary disease</i>	2.01	0.87–4.63	0.10
Propensity score	0.56	0.14–2.28	0.42

Standardized cost of S-PVR was US2013\$47,635 (95% CI: 27,537–82,404), and standardized cost of TC-PVR was 2013US\$51,409 (95% CI: 28,978–91,201).