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Transcatheter Versus Surgical Closure of Atrial Septal Defects in Children

A Value Comparison

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ABSTRACT

OBJECTIVES The purpose of this study was to determine whether a transcatheter procedure or surgical closure offers a better value proposition for atrial septal defect (ASD) closure.

BACKGROUND Secundum ASDs are common congenital heart defects with both transcatheter and surgical treatment options. Although both options have been shown to have excellent results in children, the relative value of the 2 procedures is unclear.

METHODS Using data from the Pediatric Hospital Information System for 2004 to 2012, we compared the value of transcatheter versus surgical ASD closure for children ages 1 to 17 years, with value being defined as outcomes relative to costs. Total charges for procedure-related encounters were converted to costs using hospital-specific cost-to-charge ratios, and all costs were adjusted for inflation to reflect 2012 dollars.

RESULTS There were 4,606 transcatheter procedures and 3,159 surgeries at 35 children's hospitals. Those undergoing transcatheter closure were more likely to be older (5.6 years vs. 4.5 years, $p < 0.0001$). There was no mortality in either group. Children with a surgical procedure had a longer length of stay (4.0 days vs. 1.5 days, $p < 0.0001$), were more likely to have an infection (odds ratio: 3.73, $p < 0.0001$) or procedural complication (odds ratio: 6.66, $p < 0.0001$). Costs for transcatheter procedure encounters were lower than costs for surgical encounters (mean of $19,128 vs. $25,359, $p < 0.0001$).

CONCLUSIONS Both transcatheter and surgical ASD closure had excellent short-term outcomes, but transcatheter procedures had lower lengths of stay, rates of infection, and complications, resulting in lower overall costs. For children who are eligible, transcatheter ASD closure provides better short-term value than surgery. (J Am Coll Cardiol Intv 2016;9:79–86) © 2016 by the American College of Cardiology Foundation.

Atrial septal defects (ASD) are a common form of congenital heart disease, accounting for about 10% of all congenital heart defects in children (1). Secundum type ASDs are the most common variant, constituting for approximately 75% of all ASDs.

Historically, the standard treatment for patients with ASDs has always been surgical closure through a median sternotomy using cardiopulmonary bypass. This method has been proven to be safe and effective with excellent long-term results (2,3). Since the first introduction of an ASD device closure using a double-umbrella device in 1976 by King et al. (4), transcatheter ASD closures have undergone tremendous advancements and refinements of device designs and delivery techniques, and is being increasingly used in recent years. Multiple studies have shown transcatheter ASD closures to be equally as safe and efficacious with similar outcomes when compared with surgical ASD closures (5–11). Reported advantages for device closure include better cosmetics with avoidance of a sternotomy scar, avoidance of

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ABBREVIATIONS AND ACRONYMS

ASD = atrial septal defects

CI = confidence interval

OR = odds ratio

PHIS = Pediatric Health Information System

cardiopulmonary bypass, less post-operative discomfort, and shorter hospital stay. In pediatrics, studies have also shown no difference in neurodevelopmental outcomes between the 2 treatments (12). Indeed, transcatheter ASD closure has now become the standard of care in adults (13).

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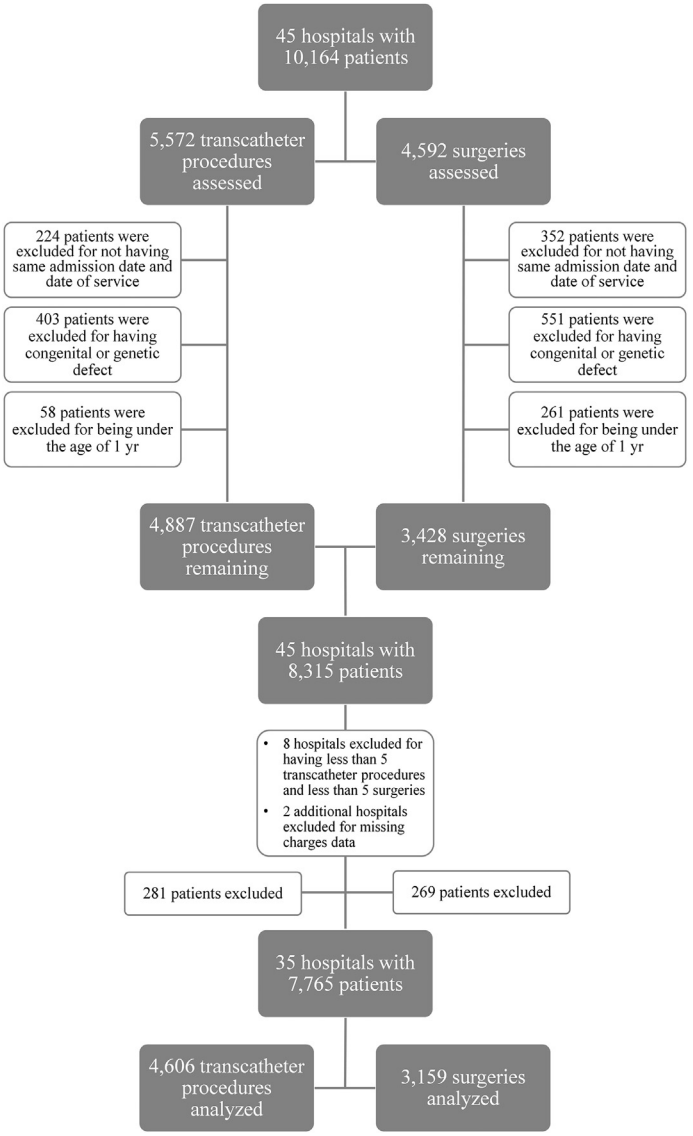
Although both transcatheter and surgical ASD closure appears to have equally favorable outcomes, there is a paucity of data as to which option may offer a better value. With the extensive use of transcatheter ASD closure in the current era, it is paramount to examine its value as an important dimension of comparative effectiveness. In fact, the American College of Cardiology and American Heart Association now stress the importance of value assessments as a criterion when developing guidelines (14). Several small, single-institutional studies have previously reported better value of transcatheter ASD closure when compared with surgery (7–9,11,15). However, recent data have shown tremendous variability in hospital and procedural costs between individual centers (16). The only multicentered study that has addressed this issue to date was done in adults and outside of the United States (17).

We sought to compare the value of transcatheter and surgical ASD closure in children in the United States by comparing the costs and outcomes of the respective procedures. We hypothesized that a transcatheter option confers a better value when compared with surgery.

FIGURE 1 Exclusion/Inclusion Diagram

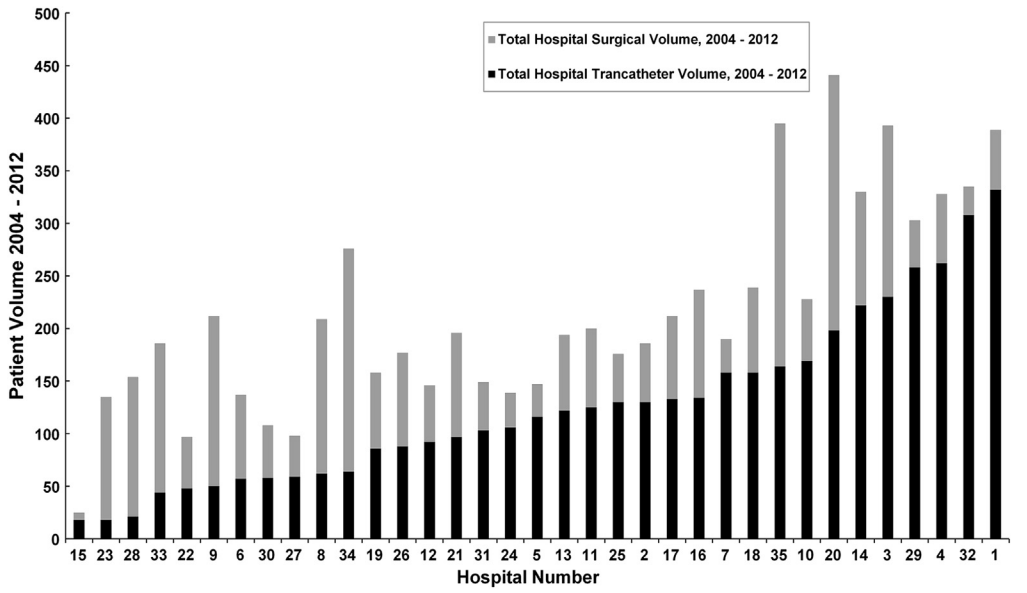


METHODS

A retrospective cohort study was conducted using data from the Pediatric Health Information System (PHIS) database; a large, multicenter administrative database (18). Data such as demographics, diagnoses, procedures, interventions, outcomes and charges for all inpatient encounters are collected from over 40 U.S. pediatric tertiary care hospitals that are members of the Children's Hospital Association. This organization provides a range of services to its member hospitals in efforts to reduce hospital costs, increase revenue, advance competitiveness, and improve the quality of care for children. Data quality is ensured by careful systemic monitoring, including coding consensus meetings bimonthly, coding consistency reviews, and quarterly data quality reports. It has proven itself in the past to be a good platform for outcomes and quality based research.

We included in our analyses all children ages 1 to 17 years that underwent either transcatheter or surgical ASD closure from January 1, 2004, to December 31, 2012, at institutions that contributed to the PHIS database. Hospitals were excluded if they had <5 transcatheter procedures or <5 open-heart ASD surgeries, or if they did not have hospital charge data available for review. Patients were also excluded if they were <1 year old, had presence of complex congenital heart disease, genetic defects, or if their date of service was not the same as their date of admission (inpatient referral), because we

FIGURE 2 Transcatheter and Surgical ASD Closure Distribution by Hospital



ASD = atrial septal defect.

wanted to focus our study on otherwise healthy individuals to avoid skewing our data. We then compared the values of both the procedures, with value in health care being defined as "outcomes relative to costs" (19).

Our primary variables were age, sex, race (White, Black, Asian, other), concomitant comorbidities, date of procedure, and hospital of encounter. Concomitant comorbidities were determined using the definition of a Pediatric Complex Condition (20). Our primary outcomes of interest were in-hospital mortality, length of stay, rates of infection, complications, and hospital charges. Infection rates and complications were included per PHIS usage guidelines in a manner consistent with prior publications (21,22). Total hospital charges for procedure-related encounters were converted to costs using hospital-specific cost-to-charge ratios, and all costs were adjusted for inflation to reflect 2012 dollars. Finally, we examined the relationship between hospital costs and volume for both transcatheter and surgical closure.

Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina). Statistical significance was assessed at the 0.05 level unless otherwise noted. Descriptive statistics were calculated for all variables of interest and included: medians and interquartile ranges, and counts and percentages, when appropriate. Normality of continuous variables was assessed using histograms, normal probability plots, and the Anderson-Darling test for normality. Characteristics of transcatheter patients and surgery patients were compared using chi-square tests for categorical variables or the Wilcoxon rank

TABLE 1 Comparison of ASD Repair Groups

	Transcatheter (n = 4,606)	Surgical (n = 3,159)	p Value
Age at procedure, yrs, N = 7,765	5.6 (3.7–11.0)	4.5 (3.0–7.8)	<0.0001
Male, N = 7,765	1,693 (36.8)	1,188 (37.6)	0.45
Race, N = 7,185			
Asian	131 (3.1)	103 (3.5)	
Black	351 (8.3)	300 (10.1)	0.03
Other	821 (19.5)	536 (18.1)	
White	2,913 (69.1)	2,030 (68.4)	
Comorbidities, N = 7,765			
Gastrointestinal	5 (0.1)	5 (0.2)	0.54
Hematologic/Immunologic	41 (0.9)	27 (0.9)	0.87
Malignancy	14 (0.3)	9 (0.3)	0.88
Metabolic	19 (0.4)	22 (0.7)	0.09
Neuromuscular	85 (1.9)	70 (2.2)	0.25
Renal	12 (0.3)	13 (0.4)	0.25
Respiratory	30 (0.7)	28 (0.9)	0.24
Any	196 (4.3)	155 (4.9)	0.17

Values are median (range) or n (%).
ASD = atrial septal defect.

TABLE 2 Odds of Any Complication and Infection for ASD Surgical Repair vs. ASD Transcatheter Repair

Outcome	Transcatheter	Surgical	OR (95% CI)	p Value*
Procedural complication	170 (3.7)	626 (19.8)	6.66 (5.46–8.14)	<0.0001
Infection	42 (0.9)	106 (3.4)	3.73 (2.51–5.54)	<0.0001

Values are n (%). *Models were adjusted for race, presence of comorbidity, age at surgery, sex, and hospital. The odds ratio (OR) and 95% confidence interval (CI) were determined using transcatheter patients as the reference group.

ASD = atrial septal defect.

sum test for nonnormal continuous data. When expected cell counts were small (<5), the Fisher exact test was used in place of the chi-square test.

To account for the clustering of patients within a hospital and to model the variation in cost and length of stay across hospitals, we constructed mixed-effects linear and generalized linear models with hospital as a random intercept. Procedure type and patient characteristics were modeled as fixed effects and included race, age, sex, presence of comorbidities, and complication. For the cost model, procedure type was included as a hospital-specific random effect and length of stay was added to the model as a fixed effect. In addition, model estimates were adjusted for other patient characteristics chosen a priori that could potentially influence the outcome. The model adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were determined using transcatheter patients as the reference group. For the continuous outcome, cost, residual errors were gauged for normality via histograms and quantile-quantile probability plots. Failing to meet this assumption, cost was log-transformed and reassessed for differences between procedures. Model-based mean estimates were back-transformed via exponentiation for interpretation purposes. For length of stay, we used a log linear model, and for complication, we used a logistic model. To determine whether hospitals significantly varied in their mean cost associated with each procedure type, the mean cost was allowed to vary randomly among hospitals using our random-effects models. The estimated between-hospital variance and associated standard error were extracted from the covariance parameter estimates based on unstructured covariance and tested for significance (against zero) using a Z-test. Additionally, for the cost model, the variability of hospital-specific estimates for procedure type was also tested for significance. Finally, we assessed the potential relationship between hospital procedural volume and median costs for both transcatheter and surgical closures using Spearman correlation.

TABLE 3 Adjusted Estimates of Cost and Length of Stay for ASD Surgical Repair vs. ASD Transcatheter Repair

Outcome	Transcatheter	Surgical	p Value*
Length of stay, days			
Overall	1.5 (1.4–1.6)	4.0 (3.8–4.2)	<0.0001
No complication	1.2 (1.1–1.2)	3.6 (3.4–3.8)	<0.0001
Complication	1.9 (1.6–2.1)	4.3 (4.1–4.6)	<0.0001
Charges			
Overall	$19,128 ($17,237–$21,226)	$25,359 ($23,353–$27,537)	<0.0001
No complication	$17,351 ($15,753–$19,111)	$24,627 ($22,763–$26,646)	<0.0001
Complication	$21,087 ($18,845– $23,598)	$26,113 ($24,017–$29,030)	<0.0001

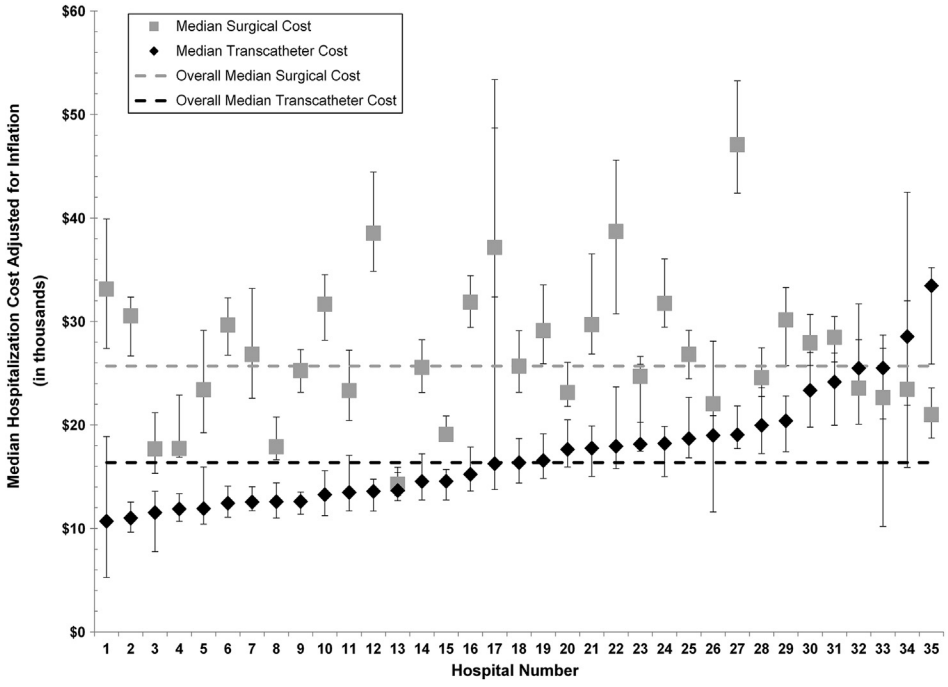
Values are mean (95% CI). *Mean estimates and 95% confidence intervals (CI) as based on the back-transformed log function. Model for length of stay was adjusted for race, presence of comorbidity, age at surgery, sex, and hospital. Model for charges was adjusted for race, presence of comorbidity, age at surgery, sex, hospital, and length of stay.

RESULTS

For the period of January 1, 2004, to December 31, 2012, the PHIS database included 10,164 eligible patients who underwent ASD closures at 45 children's hospitals. Of those patients, 5,572 were transcatheter procedures and 4,592 were surgeries. After applying the inclusion and exclusion criteria, our data yielded 35 pediatric hospitals with 4,606 transcatheter patients and 3,159 surgery patients for the final analysis. A summary of patients excluded is provided in Figure 1. The distribution of transcatheter and surgical volume by hospital is summarized in Figure 2.

Patient characteristics are summarized in Table 1. When comparing the variables between the 2 procedures, those undergoing transcatheter ASD closure were more likely to be older (5.6 years vs. 4.5 years, $p < 0.0001$). There was no difference in sex or comorbidities between the 2 procedures. Although there was a statistical significance when comparing racial distribution, the difference was small, with white patients accounting for 69.1% of transcatheter procedure and 68.4% of surgery. In regard to the outcomes, there was no reported in-hospital mortality in both the transcatheter and surgical groups. Children with a surgical procedure were more likely to have an infection (OR: 3.73, $p < 0.0001$) and more likely to have post-procedural complications (OR: 6.66, $p < 0.0001$) (Table 2). Patients who underwent a transcatheter ASD closure also had a shorter length of stay (1.5 days vs. 4.0 days, $p < 0.0001$) with less cost when compared with surgical ASD closures (mean of $19,128 vs. $25,359, $p < 0.0001$) (Table 3). Further stratifying length of stay and cost estimates by presence of complication, we still found that

FIGURE 3 Median Transcatheter and Surgical Cost of ASD Closure by Hospital



Upper and lower **error bars** indicate 25th and 75th percentiles, respectively. ASD = atrial septal defect.

transcatheter ASD closures had shorter length of stay (1.9 days vs. 4.3 days, $p < 0.0001$) and cost less (mean of $21,087 vs. $26,113, $p < 0.0001$) when compared with surgical ASD closures. The overall contribution of complication to length of stay was 0.7 days in both ASD closure groups. In addition, complication increased cost by about $3,700 in the transcatheter ASD closure group and $1,500 in the surgical ASD closure group. The effect of complication on cost was almost 3 times higher in the transcatheter ASD group than surgical ASD group ($p < 0.0001$).

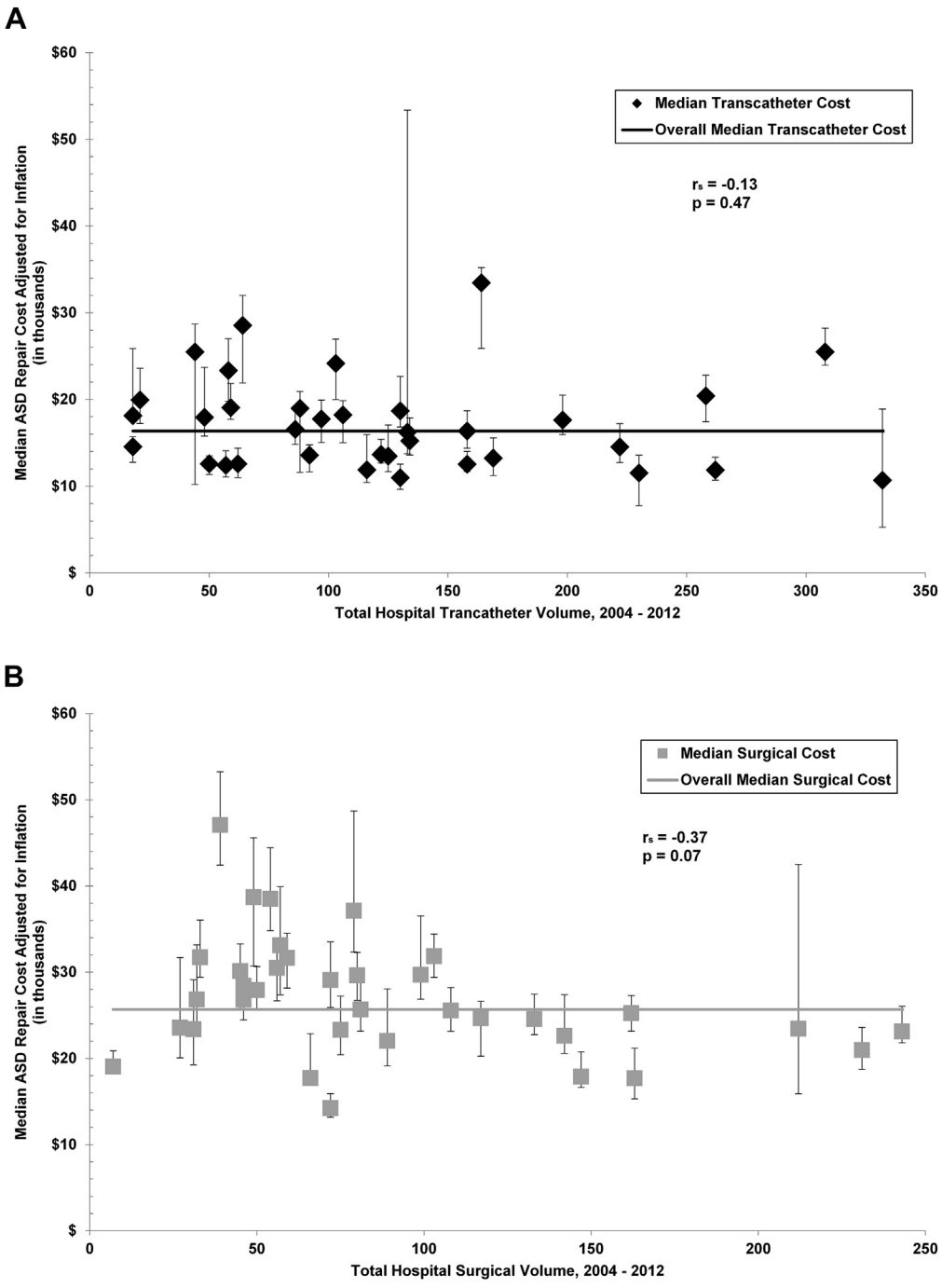
Based on the random-effects models, there was significant variation in hospital mean cost for each procedure type ($p < 0.001$ for each type, respectively). We compared the distribution of cost of both procedures by hospital, and found no significant correlation between the costs of transcatheter and surgical ASD closure, that is, although we did find that surgical costs were on average higher than the transcatheter costs, the magnitude of this difference varied by hospital, and was sometimes inverted (**Figure 3**). We then tried to see whether there was an association between the transcatheter cost and hospital volume, investigating to see whether higher volume would lower cost, and found no significant relationship between the cost of either procedures and procedural volume per center (**Figure 4**).

DISCUSSION

In this large, multicenter, retrospective cohort study, both transcatheter and surgical ASD closures in the pediatric population had excellent clinical outcomes, with no in-hospital mortality for both procedures, although transcatheter procedure had somewhat lower rates of complications, infections, and length of stay. Furthermore, transcatheter closure was significantly cheaper compared to surgery. This remained true even when factoring in cost of complications, which is higher in the transcatheter group. With these clinical outcomes and significantly lower costs, the transcatheter procedure was shown to confer better value when compared with surgery for closure of secundum ASD.

Although several other studies have shown similar results previously, they were mostly small, single-institution studies (7-9,11,15). Our study revealed very large interinstitutional variations in hospital charges for each procedure, with no significant correlation between the costs of transcatheter and

FIGURE 4 Median Transcatheter and Surgical Cost of ASD Closure by Patient Volume



Relationship between **(A)** median transcatheter cost of atrial septal defect (ASD) closure and patient volume, and **(B)** median surgical cost of ASD closure and patient volume. Upper and lower **error bars** indicate 25th and 75th percentiles, respectively.

surgical ASD closure in each individual hospital. Therefore it is important to compare costs across several different institutions to draw meaningful comparisons and conclusions of the value between the procedures. The only multicentered study in the literature so far was performed on adults and outside

the United States (17). To the best of our knowledge, our study is the only large multicentered study focused on addressing this issue in the pediatric population in the United States.

The relatively lower cost of transcatheter group likely reflects shorter length of hospitalization and shorter/lack of intensive care unit stays. These lead to a subsequent reduction of pharmacy, respiratory, nursing, radiology, laboratory and transfusion costs (8,9,11,15,17). Also, the steep cost of transcatheter devices may have been compensated by the expense of extracorporeal circulation equipment needed for cardiac bypass (7).

Another important element that needs to be considered is the societal burden and cost that is incurred during the convalescent period after each intervention. Our study has shown a significant difference in the length of hospital stay for both procedures, 1.5 days for the interventional procedure versus 4 days for open-heart surgery. Post-discharge, surgical patients will need even more time at home to recover from their sternotomy. Earlier discharge could theoretically allow transcatheter patients and parents to resume their normal activities much sooner, and encourage working patients and parents to return to work more quickly. Although the actual dollar effects of these advantages are difficult to quantify, it definitely has a considerable economic impact on the family and society. This increases the relative value of transcatheter approach, and should be factored into the decision-making process when choosing an intervention.

STUDY LIMITATIONS. Our study, which looked into data obtained from a large administrative database, has its limitations. Firstly, our data are short-term and limited to the procedural encounter. Patients who developed complications in the mid- to long-term periods will not be identified by our data. However, previous studies have reported comparable mid- to long-term outcomes between the transcatheter and surgical group. Mylotte et al. (17) and Kotowycz et al. (10) looked at adults over a 5-year period each and noted similar long-term outcomes. Du et al. (6) looked at both children and adults, and described no difference in the mid-term outcomes for both surgical and transcatheter ASD closures at 1 year. With similar mid- and long-term outcomes, the transcatheter option would still provide a better value on the account of lower cost. Secondly, International Classification of Diseases, Ninth Edition codes from administrative databases have been validated in identifying cases of congenital heart disease, but also result in some false positives (23,24). Because our study includes both diagnosis and procedural codes, we would expect the false-positive rates to be lower.

Another limitation to consider is that our procedural cost had to be estimated using cost-to-charge ratios to convert hospital charges to actual cost, so our calculated costs may not be entirely accurate. However hospital cost-to-charge ratios should affect both transcatheter and surgical cases equally, so the relative costs of the procedures should be the same. Finally, as this was a nonrandomized study, there could be some bias as to what types of procedures for which particular patients were referred. If more severe cases were routinely referred for surgery, this may have a negative impact on the outcomes, costs, and subsequent value for the surgical option. We attempted to control for this and other potential biases by adjusting for race, presence of comorbidity, age at surgery, sex, and hospital. Some clinically significant pre-procedural data such as hemodynamic and anatomic differences are unavailable, factors that may affect the decision to pursue surgery versus catheterization (25).

On the basis of our findings, we conclude that transcatheter ASD closure is as safe and provides better value when compared with surgical ASD closure, at least in the short term. For children who are eligible, these data suggest that there should be a strong consideration for transcatheter method when referring a patient for ASD closure. There still remains a very important role for surgical ASD closures, however, especially in patients with anatomy that may not be favorable for transcatheter closure.

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PERSPECTIVES

WHAT IS KNOWN? Previous studies have shown that both transcatheter and surgical ASD closures in children have equally favorable outcomes.

WHAT IS NEW? Our study showed that transcatheter ASD closure is as safe and provides better value when compared with surgical ASD closure, at least in the short term.

WHAT IS NEXT? The next step is to evaluate the long-term value of these procedures.

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KEY WORDS atrial septal defect, outcome, surgery, transcatheter, value