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# **Cost comparison of transcatheter and operative closures of ostium secundum atrial septal defects**

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# **Abstract**

**Background—**Clinical outcomes for transcatheter and operative closures of atrial septal defects (ASDs) are similar. Economic cost for each method has not been well described.

**Methods—**A single-center retrospective cohort study of children and adults <30 years of age undergoing closure for single secundum ASD from January 1, 2007, to April 1, 2012, was performed to measure differences in inflation-adjusted cost of operative and transcatheter closures of ASD. A propensity score weight-adjusted multivariate regression model was used in an intention-to-treat analysis. Costs for reintervention and crossover admissions were included in primary analysis.

**Results—**A total of 244 subjects were included in the study (64% transcatheter and 36% operative), of which 2%  $(n = 5)$  were 18 years. Crossover rate from transcatheter to operative group was 3%. Risk of reintervention ( $P = .66$ ) and 30-day mortality ( $P = .37$ ) were not significantly different. In a multivariate model, adjusted cost of operative closure was 2012 US \$60,992 versus 2012 US \$55,841 for transcatheter closure (*P* < .001). Components of total cost favoring transcatheter closure were length of stay, medications, and follow-up radiologic and laboratory testing, overcoming higher costs of procedure and echocardiography. Professional costs did not differ. The rate of 30-day readmission was greater in the operative cohort, further increasing the cost advantage of transcatheter closure. Sensitivity analyses demonstrated that costs of follow-up visits influenced relative cost but that device closure remained favorable over a broad range of crossover and reintervention rates.

**Conclusion—**For single secundum ASD, cost comparison analysis favors transcatheter closure over the short term. The cost of follow-up regimens influences the cost advantage of transcatheter closure.

> Since transcatheter closure of atrial septal defects (ASDs) was first reported in 1976,<sup>1</sup> device closure of secundum ASD has been widely adopted with excellent rates of success and

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favorable risk of adverse events relative to operative closure.<sup>2,3</sup> Currently, both operative and transcatheter ASD closures are offered at many centers. In choosing between operative and transcatheter closures, economic cost is potentially important. Cost both is an end unto itself and a means of combining the relative probability and impact of different outcomes on the comparison.

Several studies have compared costs of operative and transcatheter closures of  $ASD<sup>4-7</sup>$  with equivocal results. These studies were small and did not (1) include costs of adverse events and reinterventions or (2) control for factors that influenced both the choice of therapy and cost. We performed a single-center retrospective cohort study using propensity score weighted multivariable analysis to compare the cost of transcatheter and operative closures of ASD.

#### **Methods**

#### **Study population**

The Institutional Review Board of The Children's Hospital of Philadelphia (CHOP) approved the study protocol and granted a waiver of consent. A retrospective cohort study was performed with subjects identified by query of our cardiac catheterization laboratory and surgical databases. Children and adults age 0 to 30 years undergoing closure of single ostium secundum ASD by (1) transcatheter device or (2) open heart operation at CHOP between June 1, 2007, and April 1, 2012, were included. Exclusion criteria were presence of additional congenital heart defects and performance of multiple cardiac procedures on the same date with eligibility determined by chart review.

#### **Data sources**

Demographics, chronic medical conditions, procedural data, and postprocedural course including adverse events were extracted by chart review. A single member of the study team (M.L.O.) reviewed preprocedural transthoracic echocardiograms and measured defect size and septal length (in 2 orthogonal planes) as well as retroaortic rim length, as previously described.<sup>8,9</sup> Charge data were extracted from billing records and converted to inflationadjusted costs (expressed in 2012 US\$) as described in the online Appendix.

#### **Analysis**

The study population was divided between transcatheter device and operative closure cohorts. Subjects who failed transcatheter device closure and underwent subsequent operative closure were included in the transcatheter device closure cohort (ie, intention to treat). If >1 hospitalization was necessary, due to crossover or need for reintervention, the total cost of all hospitalizations was used. For additional analyses, data for emergency department (ED) visits and inpatient hospitalizations within 30 days of discharge were collected. The primary outcome was the sum of hospital costs and professional charges for hospitalization(s) necessary to close the defect. Standard descriptive statistics were calculated. Continuous variables were expressed as mean  $\pm$  SD or median (range) as appropriate. Categorical variables were expressed as percentages (count).

An important concern in an observational study is the risk of confounding by indication. During the study period, referring cardiologists in conjunction with families chose between transcatheter and operative closures of ASD at their discretion. Although operative cases were reviewed at weekly divisional conferences, there were no institutional protocols or criteria guiding referral. Before analysis, we suspected that baseline characteristics (age, height, weight, insurance payor, and prevalence of chronic medical conditions) might influence the choice between transcatheter and operative cohorts and/or influence cost of hospitalization. Wilcoxon rank sum,  $\chi^2$ , and Fisher exact tests were used as appropriate to test for differences in the distribution of these factors. Confounding by indication was accounted for by generating a propensity score for these preidentified factors (online Appendix), with the score included in subsequent multivariable models. Atrial septal defect anatomy was not included in the initial propensity score for this reason. A post hoc sensitivity analysis was performed, redoing the propensity score including ASD anatomy. A second post hoc sensitivity analysis was performed, assessing the whether age divided into infants ( $1$  year), children (1–18 years), and adults ( $18$  years) affected cost.

Median costs (total and by department) were calculated for both cohorts and compared using Wilcoxon rank sum test. Factors that were felt to influence cost alone were included in the multivariable models. Generalized linear models were used to adjust for these covariates (including propensity score) and compare cost and length of stay (LOS) between the 2 cohorts (online Appendix). Conditional standardization was used to generate an adjusted estimate of cost and LOS.

Prespecified secondary analyses were performed to characterize which aspects of care influenced cost for each cohort considering (1) hospital costs and professional charges, (2) department-specific hospital costs, and (3) the additional cost of ED visits and inpatient hospitalizations within 30 days. These acute care visits, in excess of routine follow-up, were assessed separately. For both cohorts, risk of acute care visits (ED visits and hospitalizations) was calculated, and mean cost of these visits was determined. To determine the marginal cost over the population, the median cost of acute care visits was multiplied by the risk of representation. This method was chosen to facilitate sensitivity analyses.

Finally, a series of 1-way sensitivity analyses were performed varying rates of (1) technical failure for transcatheter device closure (ie, crossover), (2) reintervention necessary after transcatheter closure, and (3) readmission after operative and transcatheter device closures. In addition, an analysis varying the cost of follow-up visits after transcatheter closure was performed. These analyses identify the point for each variable at which cost equality occurred between the 2 closure methods and test the degree to which each variable influences our relative cost of procedures and confidence in any conclusions based on a single study.<sup>10</sup> For the first 3 analyses, the adjusted cost of operative and transcatheter closures was used as baselines, and then the rate of each event was varied from 0% to 100% holding all other factors constant.

Ratios of cost to charge (RCCs) for outpatient visits and services were not accessible. Instead of varying hypothetical event rates, we varied the cost of an outpatient visit over a broad range (2012 US \$100–10,000) and calculated the cost of several preproscribed follow-

up regimens. The purpose of this was to determine the cost of an individual outpatient follow-up at which cost equality was achieved. Two models were created. The first assumed (1) no follow-up for operative cohort and (2) follow-up in the ASD cohort as per Food and Drug Administration (FDA) recommendations<sup>11,12</sup> with a visit at 1 week, 1 month, 1 year, and then annual visits to 5 years. The second model assumed (1) follow-up visits for surgical cohort at 1 week, 1 year, and 5 years and (2) the same FDA-recommended follow-up schedule for the device cohort. The 2 models provide a range of plausible follow-up strategies. A 5% discount rate was applied for future costs.<sup>10,13</sup> Total costs of procedure and follow-up regimens were calculated and compared to determine the cost of a follow-up visit that resulted in cost equality.

All data analysis was performed using Stata MP version 13 (StataCorp, College Station, TX). The threshold for statistical significance was  $P < .05$ .

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## **Results**

#### **Study population**

In total, 244 subjects met inclusion criteria,  $36\%$  (n = 89) in the operative cohort and 64% (n  $= 155$ ) in the transcatheter device cohort (Figure 1). Of the study cohort, 5 patients (2%) were  $>18$  years, with 1 in the operative cohort (1%) and 4 in the transcatheter cohort (3%). The members of the operative cohort were younger and smaller (both in height and weight) than the members of the transcatheter device cohort  $(P < .001$  for each) and were more likely to have a history of prematurity  $(P = .01)$  (Table I). There was no significant difference in defect size in either frontal ( $P = .05$ ) or sagittal ( $P = .18$ ) dimensions, but the septal length was greater in both dimensions  $(P < .0001$  for both) in the transcatheter group. The retroaortic rim was smaller in the transcatheter device closure cohort  $(P = .03)$ , and a greater proportion had deficient retroaortic rim  $(63\% \text{ vs } 43\%, P = .001)$ .

#### **Procedural outcomes**

Of the 155 subjects initially referred for catheterization,  $3\%$  (n = 4, 95% CI 0.7%–6.5%) were not closed successfully in the catheterization laboratory (Figure 1, Table II). In 2 subjects, no attempt was made because the anatomy was deemed unfavorable. In 1 subject, the retroaortic rim was deficient and a sufficiently sized device impinged excessively on the aorta, and in another, the superior rim was deficient with impingement on the superior vena cava. In both cases, the devices were deployed but not released from their delivery cable and were resheathed and removed from the body without incident. All 4 recovered from catheterization and were readmitted for operative closure. No crossover from operative to

transcatheter closure occurred. In 1 subject, sutures dehisced after surgery, and they were readmitted and underwent a successful reoperation. Device embolization occurred in 4 subjects. All were diagnosed before discharge and underwent recatheterization, device retrieval, and successful transcatheter ASD closure with no repeat embolization. Reintervention rates were not significantly different between operative (1%, 95% CI 0.02%– 6%) and transcatheter (3%, 95% CI 0.7%–7%, *P* = .66) cohorts.

Median LOS was longer for the operative cohort (median 3 days, range 1–25 days) than for the transcatheter device cohort (median 1 day, range 1–4 days, *P* < .001). There were no inhospital deaths.

Within 30 days of hospital discharge, 9% (9 visits in 8 subjects, 95% CI 4.0%–16.9%) of subjects with operative ASD closure presented for acute care to an ED or were directly admitted to the hospital, which was significantly higher than the rate in the transcatheter device cohort (2%, 95% CI 0.4%–5.6%,  $P = .03$ ). The rate of ED visits was not significantly different, but the rate of hospitalization was higher in the operative (7%, 95% CI 2.5%– 14.1%) than the transcatheter cohort (0%, 95% CI 0%–2.4%, *P* = .002). Of the 9 visits in the operative cohort, 1 was for dehiscence of the ASD patch, and 8 (89%) were for postpericardiotomy syndrome (PPS). One of these subjects had a cardiac arrest at an outside hospital and was transferred to our institution, where a diagnosis of brain death was made. This was the only death in either cohort. The resultant 1% mortality rate (95% CI 0.03%– 6%) in the operative cohort was not significantly different that in the transcatheter cohort  $(0\%, 97.5\% \text{ CI } 0\% - 2\%, P = .34)$ . All acute visits in the transcatheter group were ED visits, which were made for either headache ( $n = 2$ ) and viral gastroenteritis ( $n = 1$ ).

#### **Cost of ASD closure**

Unadjusted median charges for operative closure cohort (2012 US \$55,304, range 30,535– 194,479) were significantly greater than that for transcatheter cohort (median US \$46,687, range 4,852–106,184, *P* = .0004) (Table II).

Using conditional standardization from multivariate model, the standardized cost for surgical closure was 2012 US \$60,992 (95% CI 53,841–69,092) (Table III), which was significantly greater than for transcatheter closure (2012 US \$55,841, 95% CI 48,992– 63,648, *P* < .001). This is a cost advantage of 8% or 2012 US \$5,151.

Independent risk factors for higher charges were endocrine disorder, history of premature gestation <34 weeks, and other systemic disease. A genetic syndrome was associated with a suggestive but not statistically significant increase in cost (ratio 1.2,  $P = .05$ ). The propensity score was also significantly associated with cost (relative cost ratio 0.16,  $P < .001$ ).

The addition of ASD anatomy to the propensity score did not change the observed association between device closure and reduced cost (Supplementary Table 1). Separating subject age into 3 groups did not change previously described associations (Supplementary Table 2).

#### **Multivariable analysis of LOS**

In a multivariate model, standardized LOS was 3.7 days in the operative cohort (95% CI 2.6–4.7 days) (Table IV) versus 2.0 days in the transcatheter cohort (95% CI 1.1–2.9 days, *P*   $< .001$ ). History of endocrine disorder ( $P = .04$ ), prematurity ( $P = .02$ ), and miscellaneous systemic diseases  $(P = .02)$  were associated with increased LOS. The propensity score was significantly associated with LOS (coefficient −9.94, *P* = .02).

#### **Components of cost**

Professional charges did not differ between the 2 cohorts (Table I, *P* = .4), with differences originating in differences in hospital costs. Procedure-related costs ( $P < .0001$ ) and echocardiography  $(P < .0001)$  were greater in the transcatheter device cohort. Length of stay  $(P < .0001)$  and the cost from both room charges  $(P < .001)$  and pharmacy  $(P < .001)$  were greater in the operative cohort, along with costs from laboratory, electrocardiogram (ECG), and radiologic testing  $(P < .0001$  for each).

#### **Readmission costs**

The median cost of the 3 ED visits and 6 inpatient hospitalizations in the operative cohort was 2012 US \$30,407 (range 530–68,775) compared to a median cost of 2012 US \$819 (range 409–3,148) in the transcatheter group (over 3 ED visits and 0 hospitalizations), which was not significant ( $P = .06$ ). Assuming an even distribution, the additional cost is 2012 US \$2,736 to each surgical case. For the transcatheter group, the marginal increase in cost is 2012 US \$16 per subject. Including the additional costs of acute care in both cohorts increased the cost advantage of transcatheter closure an additional 2012 US \$2,720 for a total cost advantage of 2012 US \$7,871.

#### **Effect of crossover, reintervention, and 30-day readmission rates on cost**

Sensitivity analyses for each of the following rates were performed as follows: (1) crossover rate from catheterization to operative cohort, (2) repeat catheterization rate due to device embolization or malposition, (3) readmission rate for operative cohort, and (4) readmission rate of transcatheter cohorts. These are summarized in Figure 2A to D. Holding all other factors equal, the rate of technical failure and crossover from catheterization to operative closure would have to be 25.2% to result in cost equality. Similarly, the rate of device embolization would have to be 17.4% for the cost of transcatheter device closure to be equal to that of operative closure.

Two additional models were constructed: varying the rate of post-closure ED and inpatient admissions for (1) the operative cohort and (2) the transcatheter cohort. In the model varying the rate of readmission/representation rate in the operative cohort, no hypothetical rate of readmission would result in cost equality of the operative and transcatheter closures. If readmission rate for operative closure was zero, the difference in cost between the 2 procedures would be 2012 US \$5,151. The same is true for the cost of readmission/ representation after device closure. For the extreme case that 100% of subjects undergoing transcatheter closure had a representation at the observed cost, device closure still

maintained a cost advantage of 2012 US \$7,044. Thus, the risk of acute care presentation did not appear to exert leverage on cost of ASD closure.

#### **Effect of varying cost of follow-up regimen on cost**

Additional sensitivity analyses were performed to investigate the influence of longer term outpatient follow-up regimens on relative cost differences. The first sensitivity analysis modeled no follow-up in the operative cohort and the follow-up recommended by the FDA for the device cohort. In this model, cost equality was achieved at a cost of 2012 US \$1,559 per outpatient visit (Figure 3). The second model modeled visits at 1 week, 1 year, and 5 years in the operative cohort and follow-up as per FDA recommendations for the device cohort, resulting in cost equality at a cost 2012 US \$2,494 per visit. Cost of follow-up does affect the cost advantage of device closure.

### **Discussion**

In this retrospective cohort study, transcatheter closure of ASD had lower cost than operative closure. The difference in cost was the result of longer LOS and increased cost of in-hospital laboratory testing and medications for operative subjects, which overcame higher procedure-related costs and echocardiography costs for transcatheter subjects. After operative closure, higher risk of acute medical care after discharge increased this cost advantage. Rates of technical failure and device embolization would have to be many-fold higher for operative closure to be cost equivalent to transcatheter closure. Follow-up regimens, in comparison, were influential on long-term cost.

Several studies have compared the costs for transcatheter and operative ASD closure $4-7$  with equivocal results. The study populations were small so adjusting for confounding and covariates was impossible, and because of low even rates, assessing the contributions of crossover, reintervention, and early readmission was not possible. In addition, hospital charges were not converted to costs, nor was inflation accounted for, limiting generalizability beyond an individual center due to differential billing practices. In the current study, the operative and transcatheter cohorts were systematically different for several factors. The influence of these factors on both cost and choice of therapy was demonstrated by the observation that the propensity score was independently associated with cost and LOS, underscoring the importance of confounding by indication.

A secondary goal was to identify factors that influenced costs of both methods. Professional costs were not significantly different, with differences emerging from hospital costs. Specifically, procedure-related costs were higher for the transcatheter group, likely reflecting the cost of the device. Echocardiography costs were also higher, reflecting that transesophageal echocardiography is the standard imaging technique for transcatheter closure, whereas operative ASD closure does not use procedural imaging. Both groups typically receive predischarge echocardiograms. However, the largest magnitude difference in costs was from room charges, which are directly related to the longer LOS after surgery. Length of stay was accompanied by increased costs of other postprocedural testing (laboratory test results, noncardiac imaging studies, and ECGs). An important question is whether these increased costs are modifiable, either through optimization of care delivery

such as clinical pathway or reduction in surgical morbidity (eg, minimally invasive techniques). Anesthesia cost was lower in the transcatheter device group but still quite high. Replacing anesthesia with procedural sedation might reduce cost of device closure further but would necessitate changes in procedural imaging (such as use of intracardiac or transthoracic echocardiography) whose costs would need to be considered.

Accounting for postdischarge acute care magnifies differences in cost. In this study, PPS was the most common cause of acute care visits after surgery. Although the difference in rates of acute care visits was not statistically significant, this may have been due to very low event rates. Postpericardiotomy syndrome is a common complication of cardiac surgery, with an incidence of between 3% and 28% depending on the diagnostic criteria used.<sup>14–17</sup> As demonstrated in this study, PPS does not only incur economic cost but also can cause morbidity and, tragically, mortality. It thus should be considered in analyses comparing outcome after operative and transcatheter ASD closures.

Sensitivity analyses were performed for several reasons. They identify variables that have a great potential effect on the primary outcome. Identification of factors that strongly influence outcome should motivate research and alter practice to improve quality of care. With outcomes frequently tabulated continuously in clinical registries, centers can determine whether their specific rates of reintervention or crossover and determine what represents good value by comparing their rates against the inflection points identified. At the individual patient level, quantifying the risk also can inform choice between surgery and transcatheter intervention. In this study, the readmission rate for operative closure, risk of embolization, and crossover all potentially exert influence over cost of the procedure, but only at rates/ risks that dramatically exceed that observed in the study. However, the cost of follow-up visits strongly influences the difference in cost of the 2 strategies.

A key issue in the current era is postprocedure follow-up in subjects who have undergone transcatheter ASD closure, with special attention to erosion of the ASD device. Current recommendations include annual follow-up with physical examination, ECG, and echocardiogram. The current study demonstrates that the cost advantage of device closure of ASD is eliminated at a cost (per follow-up visit) between 2012 US \$1,559 and 2,449. It is, therefore, important to examine the incremental value of each component of these visits. It is important to consider whether serial echocardiography and ECG in an otherwise well patients provides prognostic or safety benefit for erosions beyond a history and physical examination. Perhaps these measures should be reserved for patients with these risk factors or in patients who cannot communicate symptoms.

#### **Limitations**

The current study was performed in a single center with a relatively uniform practice and referral pattern. Rates of crossover and embolization may vary, which was why sensitivity analyses were performed. Second, cost analysis was limited to direct medical costs. We did not measure costs to patients or indirect costs (ie, lost productivity to patients and families), but this would likely magnify differences between transcatheter and operative closures. Third, we acknowledge that cost-effectiveness is a superior technique for measuring value to cost comparison, which was performed in this study. Measurement of differences in patient-

reported quality of life (or utility) between operative and transcatheter ASD closures was beyond the scope of this study. Further research in this area would be useful. Finally, the study population did not contain a large number of adults, limiting generalizability to this group and practices at general hospitals.

# **Conclusions**

Acknowledging these limitations, this study demonstrates that device closure of ASD has lower cost than operative closure. Accounting for acute care after hospital discharge magnifies the observed difference. Decisions regarding longer term follow-up after closure of ASD influences the cost difference between strategies.

# **Supplementary Material**

Refer to Web version on PubMed Central for supplementary material.

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# **Figure 2.**

Effect of crossover, reintervention, and 30-day readmission rates on cost. Graphs depict total cost of closure of ASD (2012 US\$) over a range of possible event rates (percentages) for crossover to from transcatheter to operative closure (**A**), device embolization and repeat catheterization (**B**), acute care after device closure (**C**), and acute care after operative closure (**D**). Adjusted costs of device closure (dotted line) and operative closure (dashed line) are identified. The cost of transcatheter closure as risk ascends is depicted (solid line). In **D**, the cost of operative closure as risk of readmission increases is depicted (dash-dot line) rather than the cost of transcatheter closure. The risk at which the 2 procedures are cost equivalent is marked with red dotted line. In **C** and **D**, there is no risk of readmission that results in cost equivalence.



#### **Figure 3.**

Effect of cost of follow-up visits on total cost. Graphs depict total cost of closure of ASD (2012 US\$) over a range of possible costs for follow-up visits. In both analyses, total cost of transcatheter closure (solid line) and operative closure (dashed line) are depicted. The cost of follow-up visit at which there is cost equivalence is depicted (red dotted line). Panel **A**  depicts the most conservative model in which the operative cohort does not receive followup and transcatheter cohort receives follow-up for 5 years as per FDA recommendations. Cost equality is reached at a cost of 2012 US \$1,559 per visit. Panel **B** depicts a model in

which operative cohort receives 1-week, 1-year, and 5-year follow-up visits. Cost equality is reached at a cost of 2012 US \$2,494 per visit.

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#### **Table I**

#### Subject characteristics



*\** Including hydrocephalus with ventriculoperitoneal shunt (n = 3), Chiari malformation (n = 2), complete heart block and pacemaker (n = 2), craniofacial abnormalities  $(n = 2)$ , epilepsy  $(n = 2)$ , hypotonia  $(n = 2)$ , and von Willebrand syndrome  $(n = 2)$  as well as abdominal migraine, automated implantable defibrillator, factor V Leiden deficiency, history of B-cell leukemia currently in remission, mitochondrial disorder, neutropenia, prothrombin gene mutation, postural orthostatic tachycardia syndrome, repaired tracheoesophageal fistula, and undifferentiated clotting disorder (all  $n = 1$ ). Three subjects had multiple miscellaneous chronic medical conditions.

*†* Aortic rim measurements were missing in 5 subjects in transcatheter group and 1 subject in the operative group.

#### **Table II**

# Unadjusted costs and outcomes of closure



#### **Table III**

Mixed effects multivariable model for cost of ASD closure



*\** The propensity score is a number from 0–1 which reflects the probability of being referred for device closure, given the factors that were included in the original propensity score model.

#### **Table IV**

#### Multivariable regression model for LOS after ASD closure

