Original Article

Cost-Minimization Analysis of Transcatheter versus Surgical Closure of Secundum Atrial Septal Defect in Children

Poomiporn Katanyuwong, MD[1], Panupong Seripanu, MD[1], Oraluck Pattanaprateep, PhD[2], Sakda Arj-Ong Vallibhakara, MD, PhD[3,4]

[1] Department of Pediatrics, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

[2] Section for Clinical Epidemiology and Biostatistics, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

[3] Research, Innovation, Academic Services and Education (RISE), ASEAN Institute for Health Development, Mahidol University, Nakhon Pathom, Thailand

[4] Child Safety Promotion and Injury Prevention Research Center (CSIP), Department of Pediatrics, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Objective: Secundum atrial septal defect (ASD) is one of the congenital heart diseases commonly found in children, which can be treated by transcatheter closure as a standard treatment or by surgical treatment. Few studies have analyzed the cost of these two strategies. The present study is aimed to compare the short-term cost-minimization of both procedures.

Materials and Methods: A retrospective single-center study analyzed all children aged 1 to 18 years, diagnosed with isolated secundum atrial septal defect, who were entirely treated by transcatheter or surgical ASD closure at Ramathibodi Hospital, Mahidol University between January 2005 and August 2016. The baseline characteristics, total hospital days, cost per case, clinical outcomes, and complications between these two procedures are compared.

Results: Thirty-five patients were enrolled in the present study, divided into two groups, with 43% in the transcatheter group and 57% in the surgical group. The baseline characteristics of the transcatheter and surgical groups were not significantly different except for weight, which was 28.6 kg versus 16.5 kg (p=0.045), and for medical history of asymptomatic, which was seven versus 16 patients (p=0.04), respectively. Patients with transcatheter procedures had a shorter length of hospital stay at 2.3 days versus 8.1 days (p<0.001), respectively. The direct medical cost per case of surgical procedure was less than the transcatheter procedure at 116,993 Baht or 3,878 US Dollar versus 206,204.7 Baht or 6,835 US Dollar (p<0.001), respectively. The major complication of the transcatheter procedure was bleeding from the puncture site while it was intraoperative arrhythmia for the surgical procedure.

Conclusion: The short-term clinical outcomes of the transcatheter and the surgical ASD closure were excellent. The cost analysis suggests that surgical procedures may incur fewer costs than transcatheter procedures from the hospital's perspective. Surgical ASD closure may be a less costly strategy for Ramathibodi pediatric patients.

Keywords: Atrial septal defect, ASD, Transcatheter, Cost-minimizing analysis, Device, Surgery

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Correspondence to:

Vallibhakara SA.

Research, Innovation, Academic Services and Education (RISE), ASEAN Institute for Health Development, Mahidol University, Nakhon Pathom 73170, Thailand.

Phone: +66-82-5662211

Email: dr.sakda@gmail.com

ORCID: 0000-0001-5343-3297

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Atrial septal defects (ASD) are common congenital heart disease in children, with an estimated 10% of congenital cardiac defects[1]. Secundum defect is the most common type of ASD. The standard treatment for patients with ASD whose secundum defect does not close spontaneously has been surgical closure for many years. In 1976, King and Mills performed the first transcatheter closure of a secundum ASD using a double umbrella device[2]. Since then, the use of transcatheter closure has increased significantly.

Multiple studies have shown that transcatheter closures are as safe and efficacious as surgical closure[3,4]. The short-term clinical outcome of

transcatheter and surgical ASD closure have been excellent. The advantages of device closure are lower lengths of stay, lower infection rate, and less complications[4]. The research about cost-analysis of surgical closure compared with transcatheter closure is based on data from the United States of America, Europe, and some Southeast Asia countries[3-6]. In Thailand, there is no cost-analysis data between transcatheter and surgical strategies for ASD closure. The authors evaluated the costs, complications, and outcomes between these two procedures of treating secundum ASD. The authors hypothesized that surgical ASD closure might be a cost-saving procedure with equal clinical outcome for pediatric patients.

Materials and Methods

The present project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki, Faculty of Medicine Ramathibodi Hospital, Mahidol University (IRB No. 02-60-93).

Data sources and study population

The present study was a retrospective observational single-center study. Medical records of 62 patients aged 1 to 18 years diagnosed with isolated secundum atrial septal defect between January 2005 and August 2016 from the Medical Record Section of Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, were retrieved and reviewed. Inclusion criteria were pediatric patients with no other underlying disease with completed treatment of isolated secundum atrial septal defect by transcatheter or surgical closure. Exclusion criteria were patients who have a chromosomal anomaly, extra-cardiac anomalies, or ASD with Eisenmenger physiology.

Baselines characteristics included age, gender, geography, height, weight, medical history, functional class, and physical examination before the received intervention. Laboratories had film chest X-rays, electrocardiogram, and echocardiogram before the intervention. The authors also collected length of stay, complications during the procedure, and comorbidities after one year following ASD closure.

Statistical analysis

Cost-minimization analysis: The Cost-minimization analysis compares the cost of two or more health care technologies proved to be equivalent in terms of clinical effectiveness[4,7].

Data input for cost parameters: The types of cost were estimated from the Data Warehouse Informatics & Information service of Ramathibodi Hospital, Mahidol University, and evaluated in the Ramathibodi Hospital perspective. The authors focused on the direct medical cost associated with ASD closure such as anesthetic, drug, nursing services, and room cost. The authors also included the cost of adverse outcomes during the one-year follow-up. All costs were expressed in 2017 Baht using the Consumer Price Index from the Bank of Thailand[8].

The present study compared the transcatheter group and the surgical group, and statistical analyses were performed using Stata SE 15. The p-value is statistically significant at an alpha level of 0.05. Statistical tests used for analysis were the Student's t-test for continuous data, which are normally distributed, median regression for continuous data that are both non-normally distributed, chi-square test, and the Fisher's exact test categorical data. Descriptive statistics of the two intervention groups were presented as percentages, mean, and median.

Sensitivity and threshold analysis: A one-way sensitivity analysis (OWSA) was performed using TreeAge Pro 2018. The authors plotted the results of OWSA by using Tornado analysis to provide a graphical representation of the degree to which the result is sensitive to the specified independent variables where the y axis was the cost parameters, and the x-axis was the expected value (EV), which is the average cost of the device group minus the surgical group. Then, the authors performed a threshold analysis to calculate the breakeven point of variables.

Results

Sixty-two patients were diagnosed with isolated secundum ASD between January 2005 and August 2016. Spontaneous closure of the secundum ASD was documented in twelve patients. Six patients have followed up in the cardiology outpatient department. Nineteen of them underwent device closure, and twenty-five patients underwent surgical closure. After collecting the information, the authors enrolled thirty-five patients in the present study because of no important missing data (15 device patients and 20 surgical patients).

Baseline characteristics of the present study population are summarized in Table 1. There was no difference in age at the procedure, gender, geography, and height between these two procedures. The patients who underwent transcatheter ASD closure were heavier than those who underwent surgical

Table 1. Baseline characteristics of the study population

	Transcatheter group (n=15) n (%)	Surgical group (n=20) n (%)	p-value
Age at procedure (year); median (range)	6 (1 to 16)	5.5 (1 to 14)	1.00
Sex			0.16
Male	8 (53.3)	6 (30.0)	
Female	7 (46.6)	14 (70.0)	
Geography			0.54
Bangkok	6 (40.0)	6 (30.0)	
Non-Bangkok	9 (60.0)	14 (70.0)	
Height (cm); mean±SD	121.4±26.9	118.2±23.4	0.72
Weight (kg), median (range)	28.6 (12 to 46.7)	16.5 (7.1 to 75)	0.04*
Medical history			
Failure to thrive	2 (13.3)	1 (5.0)	0.56
Congestive heart failure	-	-	-
Respiratory tract infection	3 (20.0)	1 (5.0)	0.29
Fatigue/exercise intolerance	5 (33.3)	4 (20.0)	0.45
Asymptomatic	7 (46.6)	16 (80.0)	0.04*
Functional class			0.45
Class I	10 (66.6)	16 (80.0)	
Class II	5 (33.3)	4 (20.0)	
Physical examination			
Systolic murmur	14 (93.3)	20 (100)	0.43
Wide fixed split S_2	13 (86.6)	17 (85.0)	1.00
RV heaving	6 (40.0)	7 (35.0)	0.76
Preoperative chest X-rays			
CT ratio; mean±SD	0.53±0.05	0.53±0.04	0.62
Preoperative ECG			
Right atrial enlargement	1 (6.6)	6 (30.0)	0.20
1st degree AV block	1 (6.6)	1 (5.0)	1.00
Incomplete RBBB	6 (40.0)	11 (55.0)	0.38
Preoperative echocardiogram			
Presence of RAE	14 (93.3)	20 (100)	0.43
Presence of RVE	15 (100)	20 (100)	-
Presence of TR	8 (53.3)	12 (60.0)	0.69
ASD dimension (mm); mean±SD	15.4±4.7	19.4±6.3	0.05
LVEF (%); mean±SD	70.8±7.7	70.5±10	0.92

SD=standard deviation; RV=right ventricular; CT=cardiothoracic; AV=atrioventricular; RBBB=right bundle branch block; RAE=right atrial enlargement; RVE=right ventricular enlargement; TR=tricuspid regurgitation; LVEF=left ventricular ejection fraction

* Statistical significant was p<0.05

ASD closure at 28.6 kg versus 16.5 kg (p=0.045), respectively. About the medical history, most of the pediatric patients did not have symptoms, which were more common in the surgical group with seven patients versus 16 patients (p=0.04), respectively. The second most common medical history was exercise intolerance. There was no difference in functional class between the two groups (p=0.451). More than half of the patients were functional class I. The authors also collected data of physical examination, preoperative chest X-rays, preoperative ECG, and preoperative echocardiogram. Those characteristics

Table 2. Intubation time and complications

	Transcatheter group (n=15) n (%)	Surgical group (n=20) n (%)	p-value
Intubation time of procedure (minute); mean±SD	150.3±41.3	176.7±26.1	0.06
Complication			1.00
Arrhythmia	0 (0.0)	1 (5.0)	
Device embolization	0 (0.0)	0 (0.0)	
Postpericardiotomy syndrome	0 (0.0)	0 (0.0)	
Pericardial effusion	0 (0.0)	0 (0.0)	
Aortic root erosion	0 (0.0)	0 (0.0)	
Infection	0 (0.0)	0 (0.0)	
Bleeding	1 (6.6)	0 (0.0)	
Death	0 (0.0)	0 (0.0)	

SD=standard deviation

Table 3. Length of stay between the transcatheter group versus the surgical group

	Transcatheter group (n=15) Mean±SD	Surgical group (n=20) Mean±SD	p-value
Length of stay (days)			<0.001*
ICU stay	0	1.7±0.5	
Hospital stay	2.3±0.4	8.1±2.2	

SD=standard deviation; ICU=intensive care unit
* Statistical significant was p<0.05

Table 4. Functional class and adverse outcomes after follow-up 1 year

	Transcatheter group (n=15) n (%)	Surgical group (n=20) n (%)	p-value
Functional class			0.74
Class I	15 (100)	20 (100)	
Class II	0 (0.0)	0 (0.0)	
Cost of adverse outcome (Baht)			-
Stroke	0 (0.0)	0 (0.0)	
Arrhythmia	0 (0.0)	0 (0.0)	
Congestive heart failure	0 (0.0)	0 (0.0)	

showed no statistically significant difference between the two groups. One major complication of the transcatheter procedure was bleeding from the puncture site (6.6%). The surgical procedure group also had a complication, which was intraoperative arrhythmia (5.0%), see Table 2.

The mean length of hospital stay was different with statistical significance for the device group at 2.3 days compared with 8.1 days in the surgical group (p<0.001), see Table 3. The patients in the device group did not need to be in ICU, while the surgical group patients were required to be monitored and cared in ICU for 1.7 days. After one year of intervention, all patients had functional class 1 with no additional complications, see Table 4.

Base case analysis

The total cost per case is shown in Table 5. In this analysis from the hospital perspective, the mean total direct medical cost of the transcatheter group

Table 5. Total cost per case

Cost (Baht)	Transcatheter group (n=15) Mean±SD	Surgical group (n=20) Mean±SD	p-valve
Total cost	206,204.7±35,443.6	116,993±31,775.5	<0.001*
Anesthetic cost	5,397.9±837.6	8,875.8±3,300	<0.001*
Drug; median (range)	628 (112 to 1,341)	4,391 (1,268 to 34,536)	<0.001*
Nursing services; median (range)	601 (564 to 2,044)	5,144 (663 to 8,234)	<0.001*
Room; median (range)	693 (526 to 6,011)	3,377.5 (503 to 20,686)	0.01*
Device/Surgical cost	68,714.1±13,000	28,199.8±6,535.3	<0.001*

SD=standard deviation

* Statistical significant was p<0.05

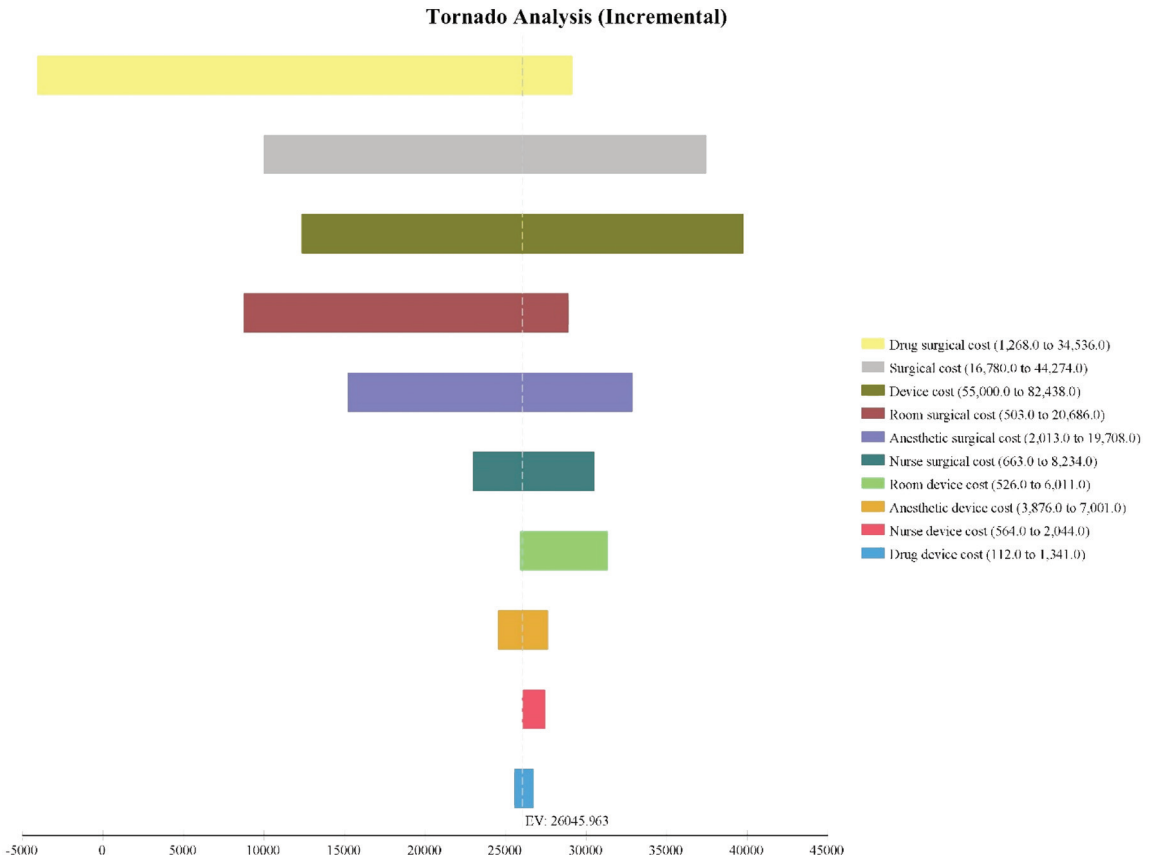

Figure 1. Tornado analysis of data input for five cost parameters from OWSA.

EV=expected value

was 206,204.7 baht or $6,834.8 US Dollar, using an exchange rate of 1 US Dollar = 30.17 Thai Baht. That was more expensive than the total direct medical cost of the surgical group, which was about 89,211.7 baht or $2,957.0 US Dollar. The cost of anesthesia, drugs, nursing services, and the room was relatively higher for patients in the surgical group. Still, the device cost was the most expensive from the overall costs.

Sensitivity analysis

For the sake of brevity, the results of OWSA, including the five parameters from the transcatheter

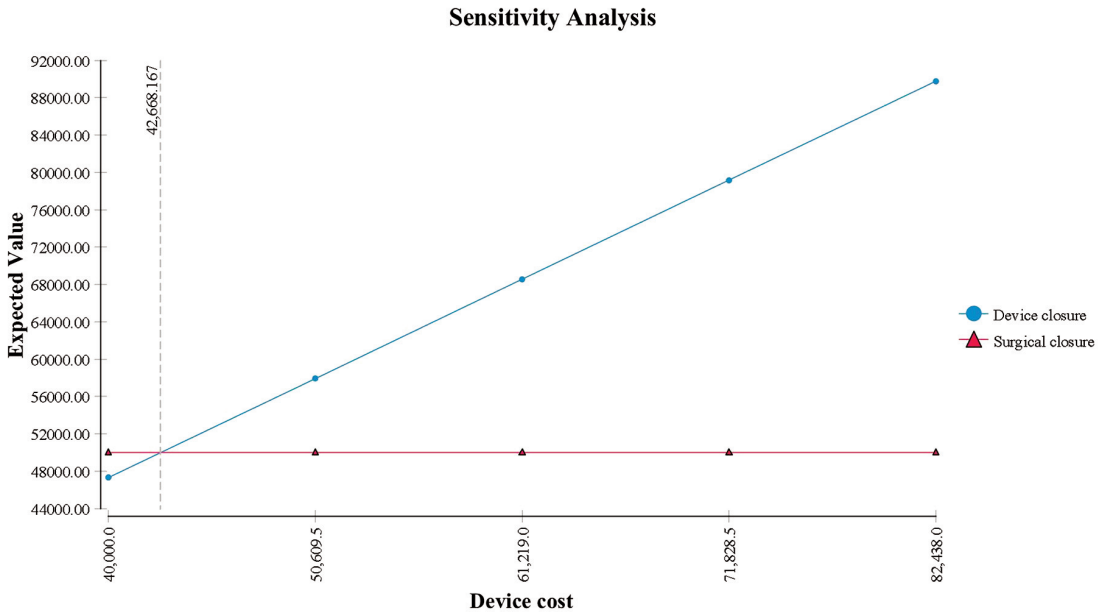

Figure 2. Threshold analysis from device cost (x-axis) versus expected value (y-axis).

and the surgical group causing the widest variation in base case findings, are shown in the Tornado chart (Figure 1) to see which charges were the biggest impact on average costs.

The EV represents the average cost of the transcatheter group minus the surgical group. The EV was about 26,045.9 Baht. If the most expensive device were about 82,438 Baht, the EV would increase to about 39,769.8 Baht. From this result, changing the cost of the device had the highest impact on overall hospital charges. Interestingly, if the surgical group's medical expenses increased to the upper limit to 34,536 Baht or $1,145 US Dollar, the EV would become negative. Therefore, it might be one of the five parameters that impacted overall the hospital charges when the authors compared both groups' input.

Threshold analysis

From the Tornado analysis, the authors paid attention to the device cost to find the breakeven point by Threshold analysis (Figure 2). Thus, this analysis showed that the breakeven point of the device cost was 42,668.1 Baht. Therefore, if the cost of the device was reduced to that point, there would be no cost difference between the two groups.

Discussion

Device closure of secundum ASD has become an alternative treatment to surgical closure in suitable secundum ASD. In many retrospective studies from Southeast Asia and Europe, both device and surgical ASD closures had excellent clinical outcomes in the pediatric population with no mortality[4,6,9-12]. Device closure had lower rates of complications and length of stay[4,6,12]. Furthermore, device closure was cheaper than surgical closure in Europe but not in Southeast Asia[3,4,6]. Thus, several studies have attempted to describe and compare the cost of both groups. An accurate comparison of cost-minimization analysis requires consideration of direct medical costs, direct non-medical costs, and indirect costs, but the authors focused only on hospital charges in the present studies.

In the authors' base-case analysis, the authors found that surgical ASD closure was less expensive than transcatheter ASD closure with a statistically significant difference. Although the surgical group had a statistically significant longer length of stay, the cost was reduced by 43.2% with surgical closure. The cost of the device was the most significant contributor to the transcatheter costs, and the cost of medications in surgical ASD closure was the greatest contributor in the surgical group.

All patients had successful ASD closure. The complications after both transcatheter and surgical ASD closure were similarly low, but both treatment options may not be completely safe. The critical factor that parents were favoring device closure is the absence of surgical scar. A surgical scar is a significant disadvantage in female patients[6], especially with a

tendency to be keloids or hypertrophic scars.

Limitation

The present study had some limitations. Firstly, it was a single-center study, and the sample size of the study population was small. Therefore, the results are limited to the authors' own experience. Secondly, the direct medical cost had to be estimated using hospital charges, so the authors' costs may not be entirely accurate because costs vary across centers. The data input for cost parameters in the Tornado chart was not completely fulfilled due to the limitation of finding data from the authors' data information service. Thus, the breakeven point may be variable. Finally, the present study was a short-term follow up to one year. However, longer follow-up data may have been more informative.

Conclusion

The transcatheter ASD closure is effective and safe for the treatment of secundum ASD as compared with surgical closure in a suitable case. Still, the mean cost of the transcatheter procedure is higher than the surgical procedure with the benefit of a shorter length of hospital stay. The cost analysis suggests that surgical ASD closure may be a cost-saving procedure for Ramathibodi pediatric patients from the hospital perspective. Additional studies with long-term follow-up and multi-center data are required to establish its cost-utility analysis in a larger number of Thai pediatric patients.

What is already known on this topic?

Both transcatheter and surgical ASD closure had many reports of excellent short-term outcomes. Many Western studies showed favorable outcome of the transcatheter procedures above the surgical ASD closure. They demonstrated the lower lengths of stay, lower infection rate, and complications, resulting in lower overall costs.

What this study adds?

This study was based on Thailand. Thailand is one member of the developing and the under-developed country in ASEAN that takes care of congenital heart patients. The transcatheter closure begins to be accepted as a standard of treatment of ASD closure as the surgical treatment already is. However, transcatheter closure is still costly, depending on their materials and commercial company, despite its safer and shorter hospital stay than traditional surgical treatment. This present study was aimed at weighting the benefit of minimizing cost among both methods in cost, length of stay in ICU, and their complications.

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Conflicts of interest

The authors declare no conflict of interest.

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