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Original Article

Comparison of surgical vs. non-surgical closure procedures for secundum atrial septal defect

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Abstract

Background Surgery has been the standard therapy for secundum atrial septal defect (ASD) closure, but it has significant associated morbidities related to sternotomy, cardiopulmonary bypass, complications, residual scars, and trauma. A less invasive nonsurgical approach with transcatheter devices was developed to occlude ASD. *Amplatzer*® septal occluder (ASO) is a common device in transcatheter closure.

Objective To compare two secundum ASD closure procedures, transcatheter closure by ASO and surgical closure, in terms of efficacy, complications, length of hospital stay, and total costs.

Methods A retrospective analysis was performed on children with secundum ASD admitted to the Cardiology Center of Cipto Mangunkusumo Hospital from January 2005 to December 2011. Patients received either transcatheter closure with ASO or surgical closure procedures. Data was obtained from patients' medical records.

Results A total of 112 secundum ASD cases were included in this study, consisting of 42 subjects who underwent transcatheter closure procedure by ASO and 70 subjects who underwent surgical closure procedure. Procedure efficacies of surgery and ASO were not significantly different (98.6% vs 95.2%, respectively, P=0.555). However, subjects who underwent surgical procedures had significantly more complications than subjects who underwent transcatheter closure procedure (60% vs 28.6%, respectively, OR 1.61; 95%CI 1.19 to 2.18; P=0.001). Hospital stays were also significantly longer for surgical patients than for transcatheter closure patients (6 days vs 2 days, respectively, P<0.0001). In addition, all surgical subjects required intensive care. Transcatheter closure had a mean total cost of 52.7 (SD 6.7) million Rupiahs while the mean cost of surgery was 47 (SD 9.2) million Rupiahs (P<0.0001). Since the ASO device cost represented 58% of the total cost of transcatheter closure, the mean cost of transcatheter closure procedure without the device itself was less costly than surgery.

Conclusion Transcatheter closure using ASO has a similar efficacy to that of surgical closure procedure. However, subjects who underwent transcatheter closure have lower complication rates and shorter length of hospital stays than subjects who had surgery, but transcatheter closure costs are higher compared to the surgical procedure. [Paediatr Indones. 2013;53:108-16.].

Keywords: secundum ASD, comparison, Amplatzer septal occluder, surgery

trial septal defect (ASD) is a common form of congenital heart disease accounting for 7-10% of congenital cardiac defects, 80% of which is secundum ASD.^{1,2} Surgery has become the standard therapy for secundum ASD closure procedure, with low mortality rates and excellent survival in long term follow-up. However, surgery has significant morbidity related to sternotomy, cardiopulmonary bypass, residual scars, trauma, and other complications.^{3,4} Children undergoing cardiac procedures typically have

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maldevelopment of the chest wall because of altered size and position of the underlying cardiac chambers, possibly leading to future breast and pectoral muscle maldevelopment.⁵

Non-surgical and less invasive approaches with transcatheter devices were developed to occlude secundum ASD. *Amplatzer®* septal occluder (ASO) is one of the most widely used devices in transcatheter closure procedure. In Indonesia, transcatheter closure of secundum ASD has been performed in Cipto Mangunkusumo Hospital (CMH), Jakarta, since 2002, followed by other cardiology centers such as Sardjito Hospital, Yogyakarta, and Soetomo Hospital, Surabaya. All centers reported that transcatheter closure using ASO have had excellent complete closure rates and can be used with few complications. 10

We aimed to compare two secundum ASD closure procedures, transcatheter closure using ASO and surgical closure, in terms of efficacies, complications, lengths of hospital stay, and total costs.

Methods

This was a retrospective analysis study on children aged 1-18 years with secundum ASD and admitted to the Cardiology Center of CMH from January 2005 to December 2011. Subjects had received either transcatheter closure using ASO or surgical repair, and were grouped accordingly. The inclusion criteria was the presence of secundum ASD with a large leftto-right shunt (Qp/Qs > 2:1). We excluded patients with other congenital cardiac anomalies, other ASD (primum, sinus venosus, or sinus coronarius), partial anomalous pulmonary venous drainage, any type of serious infection prior to the procedure, or malignancy. We collected the following data from subjects' medical records: demographic characteristics, baseline clinical data, success and complication rates, lengths of hospital stay, and total cost of procedure.

The Amplatzer® septal occluder consists of two expandable round discs, with a 4-mm long connecting waist, and made of 0.004-0.0075 inch Nitinol wire. The prothesis is filled with polyester mesh to facilitate thrombosis. The device size ranges from 4-40 mm.^{7,8,11,12} A detailed description of the transcatheter closure technique has been reported

previously.^{7,8} The device is typically collapsed into a delivery catheter and delivered through a long sheath positioned in the left atrium after percutaneous entry of the femoral vein. Under fluoroscopic and transesophageal echocardiographic (TEE) guidance, both discs of the device are deployed across the defect, and then released.^{6-8,12,13}

Surgery typically involves general anesthesia with the aid of a cardiopulmonary bypass (CPB) machine. The right atrium is usually opened after median thoracotomy or anterolateral right thoracotomy. The defect is then closed either by direct suture or by pericardial patch.^{3,5,14}

Treatment success was determined on the basis of transthoracic echocardiography immediately after procedure (for transcatheter closure) and at 24-hours after the procedure or at the time of discharge from hospital (for both groups). Subjects were considered to have successful ASD closure if they had no or trivial (<1 mm color jet width) or small (color jet width 1-2 mm) residual shunts. Subjects with moderate (color jet width 2-4 mm) or large (color jet width >4 mm) residual shunts, those who had reintervention procedures or those who died were considered to have failed procedures.^{7,8,11,12}

Complications were defined as untoward consequences of the closure procedure, either during the procedure or within 24 hours after the procedure until the subject was discharged from the hospital (post-procedure). Major complications were defined as life-threatening, or requiring immediate intervention or invasive treatment, such as cerebral embolism, cardiac perforation, pericardial effusion, pneumothorax or pleural effusion requiring drainage, arrhythmias requiring pacemaker or cardioversion, device embolization requiring surgical removal, or death due to the procedure. Minor complications were defined as requiring only conservative treatment, such as device embolization with percutaneous retrieval, arrhythmias with medical treatment, fever or wound complications. 7,8,12,15

Length of hospital stay was defined as the total hospital stay required for each subject from the time of admission for the ASD closure procedure until the subject was discharged from the hospital.^{7,13,16}

Total costs of procedures were calculated by summing patient charges for procedure operating theatre, equipment usage, pharmacy, blood products, ASO device, supporting examinations (laboratory and radiology investigations, electrocardiography, and echocardiography), hospital stay, and medical fees. Cost-minimization analysis was used to compare the total costs between the two procedures. Non-medical or indirect costs were not taken into account. 16-19

Measured variables are described as proportion, mean (standard deviation) or median and range, as appropriate. Differences between continuous data were assessed by independent t-test or Mann-Whitney U test as appropriate, while differences between binary data were assessed by using chi-square test or Fisher's exact test, as appropriate. A P value <0.05 was considered to be statistically significant.

Results

A total of 112 subjects with secundum ASD were enrolled in the study. **Figure 1** shows the patient flow diagram for enrollment. There were 42 subjects who underwent transcatheter closure and 70 subjects who underwent surgical repair. **Table 1** shows the demographic and baseline clinical data for each group.

Most subjects were undernourished and the most common clinical manifestations in both groups were failure to thrive, respiratory infection, and exercise intolerance.

Larger median ASD diameter was seen in subjects who underwent surgical closure [median 20 (5-50) mm] compared to subjects who underwent transcatheter closure [median 17 (9.3-28.9) mm] (P=0.006). The degree of left-to-right-shunting was comparable in both groups (Qp/Qs > 2:1). The median procedure duration for subjects who underwent transcatheter closure did not statistically different with subjects who underwent surgical closure [118 (range 43-240) min vs 126.5 (range 50-226) min, respectively; P=0.07]. However, the median duration of anesthesia for subjects who underwent transcatheter closure was shorter than that of subjects who underwent surgical closure [154 (range 60-330) min vs 180 (range 105-330) min, respectively; P=0.017]. In transcatheter closure, the size of devices used ranged from 14 to 36 mm (median 22 mm), and in the surgical closure subjects, most underwent conventional thoracotomy. Only 24% of subjects had anterolateral right thoracotomy, and most of them were female.

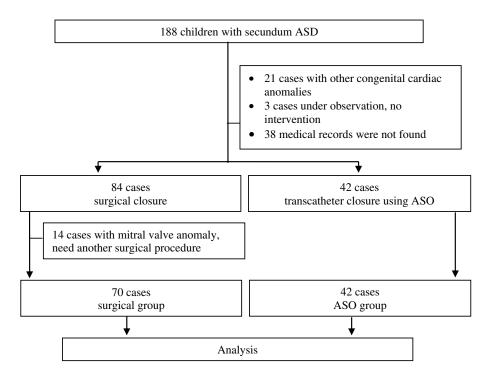


Figure 1. Flow diagram of subject enrollment to the study

Out of 42 subjects in the transcatheter closure group, 39 subjects (93%) had complete closure and 2 subjects (5%) had a small residual shunt at the evaluation immediately after the procedure. In one subject (2%), the attempt to deploy device failed. The subject originally had a 27-28 mm ASD diameter, as measured by precatheterization TEE (balloon stretched diameter), but after the device failed to deploy, the subject underwent reintervention with surgery. During

surgery the ASD diameter was found to be 50 mm, and the defect was closed by direct suture.

At the 24-hour follow up or at the time of hospital discharge, 40 subjects (95%) in the transcatheter closure group had successful ASD closure (**Table 2**). One subject had device migration at 24 hours after the procedure, so he underwent surgical removal of the device and surgical closure. In the surgical closure group, 69 subjects (99%) had successful ASD closure.

Table 1. Demographic and baseline clinical data

Characteristics Median age (range), years Gender, n (%)	Procedures			
	Surgery (n = 70)		ASO (n = 42)	
	7.7	(1-17.9)	6.6	(1.7-17.9)
Male	28	(40)	6	(14)
Female	42	(60)	36	(86)
Median weight (range), kg	18.5	(6.3-66)	18.7	(10.7-54)
Median height (range), cm	117.3	(66-170)	119	(85-160)
Nutritional status, n (%)		()		
Well-nourished	23	(33)	19	(45)
Undernourished	47	(67)	23	(55)
Clinical manifestations, n (%)				
Difficulty breathing	16	(23)	5	(12)
Failure to thrive	37	(53)	17	(41)
Respiratory infection	38	(54)	28	(67)
Exercise intolerance	22	(31)	10	(24)
Asymptomatic	9	(13)	5	(12)
Ejection murmur	69	(99)	39	(93)
Wide fixed split on 2 nd heart sound	47	(67)	31	(74)
Pulmonary hypertension	40	(57)	14	(33)
Other	8	(11)	3	(7)
X-ray findings, n (%)				
Cardiomegaly	42	(61)	11	(26)
Prominent pulmonary conus	25	(36)	6	(14)
Increased pulmonary vascularity	35	(50)	8	(19)
Electrocardiogram findings, n (%)		, ,		
Right bundle branch block	23	(33)	6	(14)
Right axis deviation	35	(50)	13	(31)
Right ventricle enlargement	42	(60)	20	(48)

Table 2. Comparison of efficacy between surgical closure and transcatheter closure at the 24-hour follow-up or at the time of hospital discharge

Defect closure	Proced	Divolue	
	Surgery (n = 70)	ASO (n = 42)	P value
Successful, n (%)	69 (99)	40 (95)	0.555
No residual shunt	66 (95)	40 (95)	
Trivial residual shunt	1 (1)	0 (0)	
Small residual shunt	2 (3)	0 (0)	
Failed, n (%)	1 (1)	2 (5)	
Moderate residual shunt	0 (0)	0 (0)	
Large residual shunt	0 (0)	0 (0)	
Reintervention	1 (1)	2 (5)	
Death	0 (0)	0 (0)	

Reoperation was required in one subject because the patch position was at the inferior vena cava. The defect closure rates for both groups were not significantly different.

There were no device- nor surgical-related deaths in either group. Complication rates were higher in the surgical closure group than in the transcatheter closure group, either during or post-

Table 3. Comparison of complications in the surgical closure and transcatheter closure groups

	Proced	dures		
Complications	Surgery	ASO	P value	OR (95% CI)
	(n = 70)	(n = 42)		
During procedure, n (%)	16 (23)	4 (9)	0.074	1.36 (1.03 to 1.8)
Post-procedure, n (%)	38 (54)	9 (21)	0.001	1.64 (1.24 to 2.18)
Total number of patients with complications, n (%)	42 (60)	12 (29)	0.001	1.61 (1.19 to 2.18)

Table 4. Type of complications found in each group

O a marking time a	Procedures		
Complications	Surgery	ASO	
During procedure (total cases) Major complications	30 cases	5 cases	
Device failed to deploy, requiring reintervention	-	1	
Arrhythmias, requiring cardioversion	17	-	
Arrhythmias, requiring reapplication of CPB machine	2	-	
Bleeding, requiring blood tranfusion	2	-	
Minor complications			
Arrhythmias, requiring conservative treatment	6	3	
Hemodynamic instability	3	1	
Post-procedure (total cases)	86 cases	9 cases	
Major complications	_		
Acute respiratory distress syndrome (ARDS)	2	-	
Device migration, requiring reintervention	-	1	
Pericardial effusion, requiring drainage	1	-	
Pleural effusion, requiring drainage	1	-	
Bronchus hyperreactivity, requiring mechanical ventilation	1	-	
Pulmonary bleeding	1	-	
Pneumothorax, requiring drainage	5	-	
Reoperation	1	-	
Minor complications	_		
Anemia	5	-	
Arrhythmias, requiring conservative treatment	10	1	
Atelectasis	4	-	
Fever	11	3	
Pulmonary edema	1	-	
Pericardial effusion, requiring conservative treatment	4	-	
Pleural effusion, requiring conservative treatment	1	-	
Subcutaneous emphysema	2	-	
Heart failure	2	-	
Hemodynamic instability	3	-	
Bronchial hyperreactivity	5	1	
Hypertension	7	-	
Pulmonary hypertension crisis	1	-	
Wound or puncture pain	4	2	
Wound bleeding	1	-	
Pneumomediastinum	2	-	
Pneumonia	4	-	
Pneumothorax, requiring conservative treatment	2	-	
Weaken dorsalis pedis artery pulse	-	1	
Sepsis	5	-	

procedure (Table 3). Table 4 summarizes the type of complications encountered by the subjects. There were 130 complications in 112 subjects, consisting of 35 cases that occurred during the procedure and 95 cases that occurred post-procedure. From the 35 major complications, 33 cases occurred in the surgical closure group.

There was a significantly longer median length of hospital stays for the surgical group than for the transcatheter group [6 (range 4-20) days and 2 (range 2-7) days, respectively; (P<0.0001)]. All subjects in the surgical closure group required intensive care unit (ICU) stays, with a median length of 1 (range 1-7) days as compared with only 3 subjects in the transcatheter closure group who required the ICU, with each subject requiring only 1 day (P<0.0001).

The mean total patient charges for transcatheter closure procedure was higher than that of surgery. Despite the lower cost of the procedure, supporting examinations, hospital stays, and medical fees for the transcatheter closure group, the pharmacy costs were higher than that of the surgery group, as the ASO device was considered to be part of the pharmacy category (Table 5).

Cost calculation in the CMH Cardiology Center is a package system, which covers all expenses required for one surgical procedure or transcatheter procedure, hence the cost of the ASO is included in the pharmacy cost. Total cost analysis without the cost of device (approximately Rp. 30,000,000.00) reduced the mean total cost of the transcatheter closure procedure, making it less costly than the mean total cost of surgery (Table 5).

Discussion

Transcatheter closure of secundum ASD has become a feasible alternative to surgical closure. The ASO has many advantages including a selfcentering mechanism that leads to simple placement technique and better complete closure rates.^{7,20} This retrospective study showed that transcatheter closure using ASO and surgical closure had similar successful closure rates, in agreement with previous reports that compared both procedures with closure rate range of 90-100%.7,13,16,18 Both procedures were also similarly effective in reducing right ventricular dilatation at six month follow-up. 18 Our surgical closure group had larger ASD diameters than that of the transcatheter closure group, also found in previous reports. 13,20,21 These findings imply that larger defects may require surgery. However, Vida et al. 16 found that their transcatheter closure group had larger ASD than that of the surgical closure group. Hence, both procedures can be equally useful in secundum ASD closure. Nevertheless, surgical intervention will still be required for patients with defects unsuitable for transcatheter closure.7

In our study, 5% of subjects in the transcatheter closure group had failed procedures. These failures were due to the large ASD size, inaccurate measurement of ASD size, or undersizing of the device. Failure rates have been reported to be between 4-20%. ^{7,13,16} Better screening for patients using transesophageal echocardiography with three-dimensional reconstruction imaging and increasing operator experience would better identify patients who should not be

Table 5. Comparison of patient charges between surgical closure and transcatheter closure

Patient charges	Prod		
	Surgery	ASO	P value
	(n = 70)	(n = 42)	
Mean procedure (SD), Rupiah	4,151,000 (2,356,000)	2,878,000 (935,000)	0.030
Mean pharmacy (SD), Rupiah	18,162,000 (4,327,000)	40,331,000 (5,576,000)	< 0.0001
Mean supporting examination (SD), Rupiah	2,152,000 (985,000)	1,118,000 (568,000)	< 0.0001
Mean hospital stay (SD), Rupiah	2,333,000 (1,763,000)	669,000 (444,000)	< 0.0001
Mean medical fees (SD), Rupiah	20,228,000 (5,168,000)	7,762,000 (4,669,000)	< 0.0001
Mean total cost (SD), Rupiah	46,995,000 (9,246,000)	52,732,000 (6,716,000)	< 0.0001
Mean total cost (without ASO cost) (SD), Rupiah	46,995,000 (9,246,000)	24,160,000 (8,982,000)	< 0.0001

candidates for transcatheter closure and minimize the failure rates.^{7,13}

As the closure rate with transcatheter closure was identical to that of surgery, a comparison of procedures should focus on safety. The mortality in both groups was zero. However, the surgical closure group was at a higher risk for complications. Previous reports found that the number of complications was significantly higher in the surgical closure group compared to that of the transcatheter closure group. 7,13,14,20 Arrhythmias were the most common complication in our study. Possible explanations could be heart muscle disturbance during the surgical procedure or stretching of the interatrial septum by the central waist of the device in the transcatheter procedure. 15 Other complications in our subjects included fever, pericardial effusion, anemia, and pneumothorax, which were also found in previous reports. 7,13,15,22 Furthermore, we found that most major complications occurred in the surgery patients. In previous reports, surgical procedures had major complication rates ranging from 5-16%, as compared with 1-3% for transcatheter procedure. 7,22,23

The number of days spent in the hospital was much higher in surgical closure group than in the transcatheter closure group, with a median difference in hospital stay of more than 3 days. These findings confirmed previously described results, in which surgery procedure patients spent 3-8 days in the hospital as compared with 1-3 days for transcatheter procedure patients.^{7,13,21,24} All subjects in the surgical closure group required stays in the ICU for at least 1 day. Quek et al.²⁵ reported that all patients who underwent surgery were required to be in the ICU for at least 1 day, with 40% having to spend 2 - 3 days. Shorter hospital stay in the transcatheter closure group was due to the simpler procedure, with fewer morbidities or complications, hence, patients required only regular ward care. On the contrary, surgery patients required ICU stays to monitor complications after thoracotomies and usage of the cardiopulmonary bypass machine. 7,13,20,24 These findings imply that children who undergo transcatheter closure could return to normal activities in a much shorter time and with less psychological trauma for both children and parents. 7,13,23

Our cost analysis showed that the mean total cost of the transcatheter procedure was 12% more expensive than surgery. The ASO cost represented

58% of the total cost of the transcatheter procedure, and the percutaneous approach without the device cost was less expensive than the surgical procedure. This cost analysis was also found in a previous report that compared the costs of the two procedures for ASD closure without taking into account the cost of the device. Vida et al. showed that the cost of the ASO also represented about 65% of the total cost of the transcatheter procedure. 16 Based on this study and previous reports, the main areas of cost differences between the two groups were the high cost of the ASO in the transcatheter group and longer hospital stay and higher pharmacy costs due to higher morbidity in the surgery group. 14,16-18,20 We did not take into account non-medical or indirect costs due to the limited study design. However, those non-medical costs (family costs) could have a role in increasing the total cost of surgery. The economic cost of a family member's time will have to be considered due to a patient's longer recuperation period after surgery.^{7,17,25}

A limitation of this study was the retrospective design, since we used medical records as our data source. Some data from medical records of subjects in the transcatheter closure group was incomplete, as seen in X-ray findings and electrocardiogram findings. These findings could result bias that subject in surgery group had more severe problems. These fact should be confirmed with another study. Also, the 38 medical records which were not found could have led to a result bias. Another limitation was cost analysis by cost-minimization instead of cost-effectiveness, as most common cost analysis used in health policy evaluation. Cost-effectiveness analysis need unit cost calculation for every service product (procedure, pharmacy, supporting examination, hospital stay). Cost-minimization analysis compare total cost of both procedure directly, and the aim of this analysis is try to find procedure with minimal total cost and similar outcome. Hence, cost-minimization analysis was preferable due to our cost calculation system (package system) in the CMH Cardiology Center.

In conclusion, we report here on the feasibility of transcatheter closure using *Amplatzer*® septal occluder as an alternative to surgery in secundum ASD closure patients. This transcatheter procedure is effective, with a closure rate similar to that of surgery, the standard therapy. Furthermore, the complication rate is lower and the length of hospital

stay is shorter for transcatheter patients compare to those of surgical patients. There is no cost savings with the transcatheter closure as compare to cost of surgery, despite the shorter hospital stay, due to the high cost of the ASO device. However, the benefits for patients who undergo transcatheter closure, such as avoidance of thoracotomy and cardiopulmonary bypass, fewer morbidities, shorter hospitalization and avoiding psychological trauma, are major advantages for patients and families. Additional studies with long-term follow-up are required to determine long term efficacy, morbidity, and the cost-benefit value in a larger number of patients.

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