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Transcatheter versus surgical closure of atrial septal defect: comparison of early result and complication

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ABSTRACT

Background. Surgical therapy for closure of atrial septal defect with cardiopulmonary bypass is the gold standard. Transcatheter closure has become an alternative for the treatment of atrial septal defect because 80-90% of atrial septal defects can be resolved without surgery. The success of transcatheter closure of atrial septal defect is almost 80% of all patients with atrial septal defect.

Objective. To analyze the differences in the results of transcatheter and surgical closure of atrial septal defects

Method. The type of research is observational analytic with a cross-sectional design. The sample is medical record data from pediatric patients with atrial septal defect who underwent transcatheter and surgical closure of the atrial septal defect between January 1, 2019 and June 30, 2023 at Dr. Soetomo Surabaya. All subjects with incomplete data will be excluded.

Results. The total research subjects were 81 subjects, divided into 2 groups: transcatheter 41/81 (50.6%) and surgical 40/81 (49.6%). Transcatheter and surgical procedures had similar success rates (100% vs 92.5%, p=1.116). Transcatheter procedures had a longer ICU stay (0.07 day vs 3 days, p<0.001) and longer hospital stay (4,8 days vs 7,3 days, p<0.001) than surgical procedures. The total procedure cost of transcatheter procedures was also cheaper than surgical procedures (61 million vs 91 million, p<0.001). Complications of transcatheter procedures were also lower than surgical procedures (12.2% vs 52.5%, p<0.001).

Conclusion. Transcatheter closure of atrial septal defects showed excellent result, shorter ICU and hospital stay, lower costs, and fewer complications.

Keywords: atrial septal defect, transchateter, surgical

INTRODUCTION

The atrial septal defect is one of the most common congenital heart diseases found in children. Atrial septal defects occur due to a hole in the interatrial septum that separates the left and right atria. Its incidence as a single defect is 7-10% of all congenital heart disease incidents. Congenital heart disease, if no closure intervention is carried out, will affect the child's growth and development [1,2]. Surgical therapy for closing an atrial septal defect with a cardiopulmonary bypass is the gold standard [3,4]. Closing an atrial septal defect with conventional surgery which usually requires extracorporeal circulation is safer and more effective for almost all patients with atrial septal defects, but conventional surgical methods still show disadvantages, such as trauma, many complications, and long post-operative recovery time as well as surgical incisions which can cause psychological trauma to the child's growth [2,5]. Transcatheter closure has become an alternative for treating atrial septal defects because 80-90% of atrial septal defects can be resolved without surgery [2]. Transcatheter closure of atrial septal defects can be performed in children and adults, especially for ostium secundum-type atrial septal

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defects. The success of transcatheter closure of atrial septal defects is almost 80% of all patients with atrial septal defects.[6]

OBJECTIVES

This study aims to analyze the differences in results of transcatheter and surgical closure of atrial septal defects.

METHOD

Design

Analytical observational research with cross-sectional design. The data source is secondary data on pediatric patients with atrial septal defects who underwent transcatheter and surgical closure of atrial septal defects from January 1, 2019, to June 30, 2023, at Dr. Soetomo General Hospital Surabaya.

Data collection

The selection of research samples was carried out by total sampling based on inclusion and exclusion criteria. The data taken was medical record data from pediatric patients with atrial septal defects who underwent transcatheter and surgical closure of the defect. Transcatheter and surgical closure of atrial septal defects are independent variables in this study. Meanwhile, the effectiveness of the results, efficiency of the procedure (ICU and hospital stay, procedure costs), and complications are the dependent variables.

Inclusion criteria

Children with atrial septal defects who underwent transcatheter and surgical closure of the defect.

Exclusion criteria

Children with incomplete data were excluded from the study.

Ethical issues

The study protocol was approved by the Institutional Ethics Committee of Dr. Soetomo General Hospital, Surabaya, Indonesia (No. 1293/LOE/301.4.2/IV/2023) on April 16, 2023.

Statistical analysis

This was performed with SPSS, version 20 (SPSS Inc, Chicago, Illinois, USA). Descriptive analysis to get an overview of sample characteristics. The Shapiro-Wilk test is used to see the distribution of data (normal distribution). The chi-square test and Fisher exact test are used for non-parametric comparative tests to examine differences between two independent groups with ordinal or nominal data scales. The Mann-Whitney U Test is used for non-parametric comparative tests, to determine the difference in medians of two independent groups using an interval or ratio scale if the data is not normally distributed. The independent t-test is used for non-parametric comparative tests, to determine the difference in medians of two independent groups on an interval or ratio scale if the data is normally distributed. The level of significance (alpha) is set at 0.05 (5%), so the results are said to be significant if the p-value <0.05.

RESULT

In this study, a total of 93 research subjects were obtained for both groups in the period 1 January 2019 to 30 June 2023. For the catheterization group, there were 45 research subjects, 41 subjects met the inclusion criteria, and four subjects were excluded because the data was incomplete. For the surgical group of 48 research subjects, 40 subjects met the inclusion criteria, and eight subjects were excluded because the data was incomplete. The total number of research subjects in both groups after inclusion and exclusion was 81 subjects who were included in the research data analysis (Figure 1).

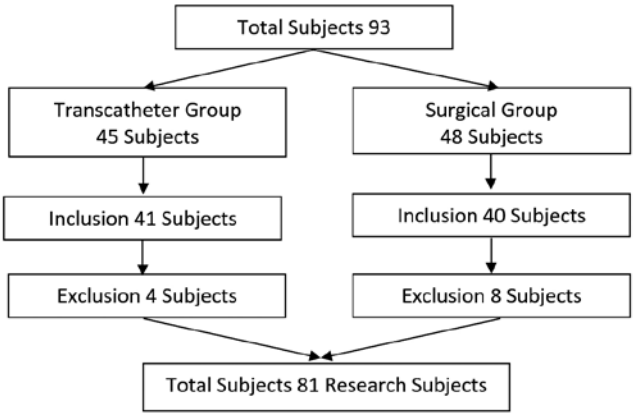

FIGURE 1. Flowchart of determining research subjects

The transcatheter group had a median age of 7.5 years (range 1.1 -17 years), while the surgical group had a median age of 10.2 years (range 1.1-17.6 years). There were more women than men in both groups. Most of the patients in the transcatheter group had normal nutritional status (65.9), whereas in the surgical group, the status of normal nutritional status (40%), moderate malnutrition (30%), and severe malnutrition (30%) had almost the same proportions. The types of atrial septal defects in the transcatheter group were all secundum types because this is an indication of transcatheter closure, whereas, in the surgical group, there were also primum and sinus venosus types besides the secundum type.

In the surgical group, the mean atrial septal defect size was 18.2 mm (range 4-34 mm) smaller than the surgical group with a mean of 28.4 mm (range 2-50 mm), this is in line with the finding that pulmonary hypertension was also higher in the surgical group (72.5%) than the transcatheter group (26.9%). The duration of the transcatheter procedure was a median of 1.3 hours (55 minutes-2.5 hours), while in the surgical group, the median was 6 hours (3.45 hours-11.05 hours). In both groups, there was only one patient with a family history of congenital heart disease in the transcatheter group (Table 1).

TABLE 1. Characteristics of research subjects

Characteristics		Group	
		Transchateter (n=41)	Surgical (n=40)
Sex	Male	20/41 (48,8%)	11/40 (27,5%)
	Female	21/41 (51,2%)	29/40(72,5%)
Age	Median	7,5 years	10,2 years
	Range	1,1-17 years	1,1-17,6 years
Nutritional Status	Normal	27/41 (65,9%)	16/40 (40 %)
	Wasted-Moderate Malnutrition	11/41 (26,9%)	12/40 (30%)
	Severly Wasted-Severe Malnutrition	1/41 (2,4%)	12/40 (30%)
	Overweight	1/41 (2,4%)	0/40 (0%)
		1/41 (2,4%)	0/40 (0%)
ASD Type	Secundum	41/41 (100 %)	38/40 (95%)
	Primum	0/41 (0%)	1/40 (5%)
	Sinus Venosus	0/41 (0%)	1/40 (5%)
ASD Size	Mean	18,2 mm	28,4 mm
	Range	4-34 mm	2-50 mm
Duration of Procedure	Median	1,3 hours	6 hours
	Range	55 minute-2,5 hours	3,45-11,05 hours
Family History	Yes	1/41 (2,4%)	0/40 (0%)
	No	40/41 (97,6%)	40/40 (100%)
Hypertension Pulmonal	Yes	11/41 (26,9%)	29/40 (72,5%)
		30/41 (73,1%)	11/40 (27,5%)

DIFFERENCES RESULTS OF TRANSCATHETER AND SURGICAL CLOSURE OF ATRIAL SEPTAL DEFECTS

In Table 2, show the differences in the results of transcatheter and surgical closure of atrial septal defects. The assessment of the outcome of atrial septal defect closure in the transcatheter procedure was carried out in two stages, immediately after the procedure and before the patient was discharged, whereas in the surgical group, the assessment of the closure outcomes was carried out before the patient was discharged. In the transcatheter group, the outcome was perfect closure in 41 of 41 patients (100%), while in the surgical group, the outcome was perfect closure in 37 of 40 patients (92.5%) and there were 3 of 40 patients (7.5%) who still had residual shunt. This residual shunt is generally needed to anticipate a pulmonary hypertension crisis, especially in patients with severe pulmonary hypertension.

All patients in the surgical group required treatment in the ICU, while there was one patient in the transcatheter group who required treatment in the ICU. One patient required intensive care for three days because this patient also had a malpositioned ASO device removed during the previous defect closure. The median total length of hospital stay in the transcatheter group was 4.8 days (range 2-20 days), while in the surgical group, it was 7.3 days (4-13 days). Statistical test results showed significant differences in the two procedure groups, both in terms of length of ICU stay and length of hospital stay ($p<0.001$).

The calculation of total treatment costs includes costs for procedural facilities, pharmaceuticals and medical equipment, supporting examinations, treatment rooms, and medical services. Based on data analysis, it was found that the transcatheter group had cheaper total treatment costs than the surgical group ($p<0.001$).

Procedural complications can occur both during the closure procedure and during treatment. Procedure complications assessed in both groups were during the procedure and until the patient was discharged. In the transcateter group, complications were 12.2% lower than in the surgical group at 52.5% ($p<0.001$).

COMPLICATION

During the defect closure procedure, complications that often arise are heart rhythm disturbances. Based on univariat analysis, in the transcatheter group, there were two cases of arrhythmia, namely non-sustained ventricular tachycardia and multiple premature atrial contractions, both of which were treated conservatively. There were four cases of arrhythmia in the surgical group with ventricular tachycardia and ventricular fibrillation so cardioversion was performed during the procedure. One patient in the transcatheter group experienced a rare complication, namely acute thromboembolic infarction which occurred 24 hours after the procedure. These patients require anticoagulant therapy so they require longer treatment. In the surgical group, there were two cases of serious complications, namely during the procedure there was a lacerations in the pulmonary vein and one case of massive pericardial effusion after the procedure which required drainage (Table 3).

TABLE 2. Differences Results of Atrial Septal Defects Closure

Variable		Transchateter (n=41)	Surgical (n=40)	P
Effectiveness of Results				
Outcome	Perfect closing	41/41 (100%)	37/40 (92,5%)	0,116[3]
	Residual shunt	0/41 (0%)	3/40 (7,5%)	
Procedural Efficiency				
ICU Stay	Median	0,07 days	3 days	<0,001[1]
	Range	0-3 days	0-7 days	
Hospital Stay	Median	4,8 days	7,3 days	<0,001[1]
	Range	2-20 days	4-13 days	
Cost	Median	61 million	91 million	<0,001[1]
	Range	24-172 million	41-157 million	
Complication	Yes	5/41 (12,2%)	21/40 (52,5%)	<0,001[2]
	No	36/41 (87,8%)	19/41 (47,5%)	

[1] Mann-Whitney Test
[2] Contuinity Correction
[3] Fisher's Exact Test

TABLE 3. Complication of Atrial Septal Defect Closure

Complications	Transchateter (n=41)	Surgical (n=40)
Severe Complications		
Acute thromboembolic infarction	1 case	-
Arrhythmia, need cardioversion	-	4 case
PE Massive	-	1 case
PV Lacerations	-	1 case
Mild Complications		
Anemia	1 case	1 case
Arrhythmia, Conservative	2 case	-
Infection	-	1 case
Chest pain	1 case	1 case
Surgical wound pain	-	8 case
Operation wound bleeding	-	2 case

DISCUSSION

In the transcatheter group, the success rate was 100%. This study is in line with research by Han et al (2019), which reported the success rate of atrial septal defect closure was 97.7% immediately after the procedure and 100% during a one-year follow-up in the transcatheter group [4]. Research by Du et al (2002) also obtained a success rate for closing atrial septal defects immediately after the procedure of 97.6% [7]. Durongpisitkul et al (2002), also showed a success rate of around 90-100% both at 24-hour post-procedure monitoring and 6-12 month post-procedure monitoring.[8] Research Vida et al (2006) obtained a lower success rate immediately after the procedure of 87.5%, but after evaluation 24 hours after the procedure showed a success rate of 95.2%. [9] The high success rate in the transcatheter procedure was due to the basic shape of the tool. It is used in the form of two discs connected to the waist of the heart so that the device can be fixed in the center of the defect. The polyester material that fills the disc causes the process of forming new endothelium so that the defect will be closed [7,10].

In the surgical group, evaluation of the results of atrial septal defect closure showed a success rate of 92.5%. Research by Han et al (2019) showed that the success rate for atrial septal defect closure in the intraoperative group was 95.6% immediately after surgery and 100% after monitoring.[4] The retrospective cohort study by Ooi et al (2018) was also in line with this study, which reported that both transcatheter and surgical closure of atrial septal defects in the pediatric population had excellent clinical results, with no in-hospital deaths for both procedures. The number of patients in the two groups was the same. The incidence of residual shunt after surgical closure varies from 2% to 7.9% in long-term follow-up data, whereas in that study, minimal residual shunt was found more frequently in subjects treated with percutaneous transcatheter [12]. The process of endothelialization takes several weeks, so residual shunt will decrease significantly during the follow-up time. In this study, for the surgical group, it was found that there were residual shunts in three patients, this is because, in severe pulmonary hypertension conditions, a defect in the atrial septum will be left to anticipate if a pulmonary hypertensive crisis occurs, even though the morbidity of pulmonary hypertension is higher in the surgical group. The successful closure rate obtained was also not significantly different from the transcatheter procedure.

In this study, the transcatheter group had a shorter ICU and hospital stay than the surgical group. This research is in line with research by Butera et al (2006), who stated that in their research it was found that surgical procedures required a much longer period in the hospital than percutaneous transcatheter closure of atrial septal defects. Other studies indicate that shorter hospital stays can be achieved in patients treated with midline sternotomy or minimally invasive approaches without complications. According to Butera, even by removing the pleural drain on the second postoperative day, patients still need at least two to three days for complete mobilization.[12] Another study by Ooi et al (2018) is also in line with this study, which shows a significant difference in terms of duration. Hospital stay for both procedures was 1.5 days for the transcatheter procedure and 4 days for open heart surgery [11]. Post-hospitalization, surgical patients will need more time at home to recover from the sternotomy scar, while the longer hospital stay is shorter, theoretically allowing transcatheter patients and their parents to resume their normal activities more quickly, and encouraging patients and parents to return to work more quickly, so this would have an indirect impact on the economy.

Recapitulation and analysis of the total cost of atrial septal defect closure in this study showed that the transcatheter procedure had a cheaper total cost than the surgical procedure (61 million vs 91 million, $p<0.001$). This is in line with a retrospective cohort study by O'Bryne and Levi et al (2015), which states that transcatheter closure of atrial septal defects has lower costs than surgical closure.[13] The difference in costs is the result of a longer hospital stay, increased costs in-hospital laboratory testing and medication for surgical subjects, whereas with the transcatheter method, costs incurred related to procedures and echocardiography are higher as well as costs for transcatheter subjects. After surgical closure, the higher risk of acute medical care after discharge also increases costs. The rate of technical failure and device embolization can lead to higher costs so that the cost of surgical closure becomes equivalent to the cost of transcatheter closure. The secondary aim of the study was to identify factors that influence the costs of both methods. Professional fees do not differ significantly from hospital fees. Specifically, procedure-related costs would be higher for the transcatheter group, likely due to the cost of the device. The cost of echocardiography is higher, because transesophageal echocardiography is the standard imaging technique for transcatheter closure, whereas surgical closure of an atrial septal defect does not use an imaging procedure.

In this study, it was found that the proportion of complications in the transcatheter group was lower than in the surgical group (12.2% vs 52.5%, $p<0.001$). This study is in line with research by Butera et al (2006), who reported that the overall rate of complications was significantly higher in the surgical group, including severe complications [12]. Another study that is in line with this research is the study by Formigari et al (2001), who studied 171 patients, 51 with transcatheter, 72 underwent minimally invasive surgery, and 50 underwent conventional sternotomy surgery. The number of complications was found to be higher in the surgical group 12.6% vs 3.8% for transcatheter closure, however, stratifying complications by pure clinical impact score, conventional surgery was the safest technique (0% vs 2.8% for minimally invasive surgery vs 3.8% for interventional therapy).[14]

In this study, the complications that most frequently occurred during the procedure, both in the transcatheter and surgical groups, were heart rhythm disturbances, such as ventricular fibrillation and ventricular tachycardia which resolved with cardioversion. During treatment, complications that often appeared in the differentiation group were surgical wound pain, anemia, bleeding, infection, and pericardial effusion. In transcatheter procedures, a type of serious complications that rarely arises is thromboembolic infarction. In this study, there was one patient with acute thromboembolic infarction who required anticoagulant therapy and longer inpatient treatment.

Limitation of the study

This study has several limitation because it was carried out only in one hospital, for the type of atrial septal defect was also not specific to the ostium secundum because only this type can be closed transchateterically and surgically and assesmemt of the results of the closure was only carried out in short term observations.

CONCLUSION

We conclude that, transcatheter atrial septal defect closure provides excellent results, shorter ICU length of stay and hospitalization, lower costs and fewer complications.

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