

Short-term follow-up after percutaneous patent ductus arteriosus occlusion between low and high weight pediatric patients: a single center experience

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ABSTRACT

BACKGROUND Device occlusion is a preferred treatment for patent ductus arteriosus (PDA) in adult and children patients; however, the exact limit of body weight requirement has not been established. This study aimed to describe the outcome and safety of transcatheter PDA occlusion in low and high weight pediatric patients.

METHODS This was a retrospective study in Sanglah Hospital, Denpasar, Bali, Indonesia, in patients aged <12 years who had undergone transcatheter PDA occlusions from 2010 to 2017. Data were obtained from the registry including baseline characteristics (age, sex, body weight, and height), procedural-specific data (PDA characteristics, pulmonary and systemic pressures, and flow ratio intra-procedure), and procedural complications. Success rate and adverse events at 24 hours, 1 month, and 3 months after the procedure were assessed.

RESULTS A total of 175 subjects were grouped into two categories: low weight, ≤ 6 kg ($n = 50$) and high weight, > 6 kg ($n = 125$). The success rates (complete closure) in the ≤ 6 and > 6 kg groups were, 90.0% and 75.9% at 24 hours follow-up, 92.9% and 85.5% at 1 month, and 95.8% and 91.1% at 3 months, respectively. Major complications related to the procedure in patients ≤ 6 kg included transient dysrhythmia ($n = 6$) and massive bleeding ($n = 2$), and complications in patients > 6 kg were transient dysrhythmia ($n = 14$), massive bleeding ($n = 1$), embolization ($n = 1$), and death ($n = 1$).

CONCLUSIONS Transcatheter PDA occlusion had similar success rate and safety in both low and high weight pediatric patients.

KEYWORDS catheterization, patent ductus arteriosus, treatment outcome

Patent ductus arteriosus (PDA) is a commonly found congenital heart defect, and accounts for approximately 9–12% of all congenital heart defects. PDA is a non-cyanotic congenital heart disease caused by the patency of the arterial duct after birth. Since three decades ago, several devices have been designed and made to solve this disorder.^{1,2} PDA transcatheter closure has become the treatment of choice for neonates since its introduction in 1967. Coils, the Amplatzer duct occluder (ADO®), and

the Gianturco-Grifka vascular occluder device are current available devices for transcatheter closure of PDA in the United States. When applied on lower weight infants, each of these devices might induce some complications including protrusion risk of the device into the aorta or pulmonary artery, large sheath size for small vessels, unstable hemodynamic, embolization, and difficult retrieval.³ These devices do not have a specific recommendation for weight or age, but the manufacturer recommends ADO to be

used for children weighing >6 kg and older than >6 months.⁴ Therefore, surgical closure was frequently chosen for large PDA in patients weighing ≤ 6 kg.

The outcomes of transcatheter PDA closure collected from multicenter register revealed that the adverse event rates were higher among patients weighing less than 6 kg.⁵ Meanwhile, another report from California stated that the success rate of device placement was achieved in 94% patients weighing less than 6 kg.⁴ The effectiveness of transcatheter PDA closure compared to surgical ligation is similar, but its cost is not as efficient as the surgery. The advantages of transcatheter PDA closure are shorter hospitalization days and less invasiveness, and it remains as the primary choice of PDA treatment.⁶ To our knowledge, no study comparing the outcome (complications and success rate) of transcatheter PDA occlusion based on patients' weight has been published worldwide. Therefore, this study aimed to analyze the outcome of transcatheter PDA occlusion using various devices in low and high weight pediatric patients.

METHODS

This retrospective study was conducted in Sanglah Hospital, Denpasar, Bali, from December 2017 to January 2018. All patients who had undergone transcatheter PDA closure from February 2010 to August 2017 were included. Exclusion criteria were a diagnosis of additional congenital heart lesions, history of cardiac catheterization or cardiac surgery, and age of >12 years because of the cut-off pediatric age in Sanglah Hospital. ADO® I and II (AGA Medical Corporation, USA), HeartR® PDA occlude (Lifetech Scientific, China), and Nit-Occlud® PDA (pfm medical ag, Germany) were used based on the availability in this center.

All data related to PDA procedures were reviewed, and the following information was collected from the medical records: pre-procedural data (age, sex, weight, height, and hemoglobin), intra-procedural data (occluder used), PDA types based on Krichenko classification, ampulla and isthmus size, angiographic findings, and hemodynamic data (mean pulmonary arterial pressure, flow ratio, fluoroscopy time, procedure time, and pulmonary artery resistance index). Major complications were investigated, including failed device implantation, device embolization, residual shunt, significant aortic arch

or left pulmonary artery obstruction, endocarditis due to infection, massive bleeding, and immediate outcome (death or alive) 24 hours after the procedure. Follow-up of device position at 24 hours, 1 month, and 3 months after the procedure were recorded in the medical record.

All data were analyzed using SPSS software version 20.0 (IBM Corp., USA) for Windows. Kolmogorov–Smirnov test was used to assess the normality assumption. The mean (standard deviation) were calculated for all quantitative variables with normal distribution. Median with range was obtained for variables with non-normal distribution. Mean ejection fraction data and outcomes between patients weighing ≤ 6 (low weight) and >6 kg (high weight) at 24 hours, 1 month, and 3 months after the procedure were described. The ethics committee of the Faculty of Medicine, Universitas Udayana approved this study, with ethical clearance number 1889/UN.14.2/Litbang/2015.

RESULTS

A total of 175 patients who underwent the percutaneous PDA closure procedure were analyzed to show the outcome between low and high weight patients. A total of 50 patients weighing ≤ 6 kg and 125 patients >6 kg had transcatheter PDA closure. Patients' characteristics are presented in Table 1.

The device was successfully implanted, and the short-term outcomes are shown in Table 2. Failure of ADO® II no 4–6 placement in small-moderate PDA was observed in one patient because of the coincidence of moderate preductal coarctation of the aorta. One patient who was diagnosed with pulmonary hypertension caused by large PDA and other associated defects (large subarterial doubly committed ventricular septal defect [VSD], Swiss cheese VSD, and hypoplastic left aortic arch) and experienced second-degree atrioventricular (AV) block Mobitz 1 with ventricular tachycardia died in the catheterization laboratory. Five patients experienced transient bradycardia and desaturation caused by the stiffness of the Amplatzer delivery sheath and cables that compressed the conduction system at the right ventricle and pulmonary artery. However, it was only temporary, and it disappeared after catheter removal. Transient ventricular extrasystole occurred related to crossing long

Table 1. Patient's characteristics and immediate outcome

Characteristic	Body weight, median (IQR)	
	Low (N = 50)	High (N = 125)
Age (months)	6 (1–17)	30 (4–144)
Male sex, n (%)	23 (46.0)	46 (36.8)
Weight (kg)	4.8 (2.0–6.0)	10 (6.1–43.0)
Height (cm), mean (SD)	60 (6.8)	92.6 (23.2)
Hemoglobin (mg/dl), mean (SD)	11.2 (1.3)	12.1 (1.2)
Ampulla (mm), mean (SD)	6.29 (2.2)	9.2 (3.3)
Isthmus (mm)	2.9 (1–6.3)	3.7 (0.9–11.5)
Types of PDA,* n (%)		
A1	33 (66.0)	93 (74.4)
A2	2 (4.0)	13 (10.4)
A3	1 (2.0)	5 (4.0)
B	1 (2.0)	2 (1.6)
C	4 (8.0)	1 (0.8)
D	3 (6.0)	3 (2.4)
E	6 (12.0)	8 (6.4)
Types of devices, n (%)		
ADO® I	20 (20.0)	42 (33.6)
ADO® II	23 (46.0)	35 (28.0)
HeartR® PDA	2 (4.0)	34 (27.2)
Nit-Occlud® PDA	5 (10.0)	14 (11.2)
mPAP (mmHg), mean (SD)	27.5 (10.0)	29.2 (9.1)
Flow ratio	1.5 (0.6–9.4)	1.6 (0.3–9.6)
Fluoroscopic time (min)	13.8 (6.2–39.3)	14.3 (5.3–75.7)
Procedure time (min)	86 (41–161)	71.0 (31–420)
PARI	2.6 (0.6–8.2)	2.45 (0.18–12.6)

SD=standard deviation; IQR=interquartile range; PDA=patent ductus arteriosus, ADO=Amplatzer duct occlude; mPAP=mean pulmonary arterial pressure; PARI=pulmonary arteriolar resistance index. Low weight was defined as ≤ 6 kg and high as > 6 kg

*The types of PDAs are based on Krichenko classification

sheath and device. Short-term follow-up (1–3 months) showed no major complications such as hemolysis, thrombus formation, thromboembolism, and infectious endocarditis. Six patients had mild left pulmonary artery stenosis, and three had mild to partial aortic arch stenosis.

DISCUSSION

Transcatheter PDA closure is challenging in patients weighing ≤ 6 kg since large devices may protrude into the relatively small aorta and left pulmonary artery. Sheath kink at acute turns of the right ventricular outflow tract may hinder device deployment; therefore, institutions prefer surgery in infants weighing ≤ 6 kg.^{5,7} ADO® is a self-expandable,

repositionable, mushroom-shaped device that was approved for children aged > 6 months and weighing 6 kg. It is usually used for > 2 mm PDA with sufficient aortic ampulla. Percutaneous PDA closure in children weighing < 10 kg by using Nit-Occlud® or ADO® was 100% successfully implanted, thus confirming the safety of transcatheter closure of PDA in children weighing < 10 kg.⁸ In this study, the device selection is based on its availability. Studies have reported that transcatheter closure of PDA is a quite safely established technique with low morbidity and mortality, especially among infants > 6 kg.^{9,10} Of selected infants ≤ 6 kg having transcatheter PDA occlusion, 89.7% had successful device implantation.⁸ The success rates of the procedure in this study were 100% and 99.2% in the low and high weight group,

Table 2. Short-term follow-up after procedure between the low and high weight group

Parameter	Immediate postprocedure, n (%)		1 day postprocedure,* n (%)		1 month postprocedure, [†] n (%)		3 months postprocedure, [‡] n (%)	
	Low weight, N = 50	High weight, N = 125	Low weight, N = 30	High weight, N = 83	Low weight, N = 28	High weight, N = 69	Low weight, N = 24	High weight, N = 56
EF, mean (SD)	NA	NA	72.4 (6.3)	67.5 (8.4)	72.0 (5.0)	69.7 (7.4)	73.0 (5.9)	72.0 (6.8)
Outcome								
Complete closure	22 (44.0)	52 (41.6)	27 (90.0)	64 (77.1)	26 (92.9)	59 (85.5)	23 (95.8)	51 (91.1)
Small/smoky residual	28 (56.0)	72 (57.6)	3 (10.0)	19 (22.9)	2 (7.1)	10 (14.5)	1 (4.2)	5 (8.9)
Failure	0 (0.0)	1 (0.8)						
Complication								
Massive bleeding	4 (8.0)	1 (0.8)						
Transient dysrhythmia	6 (12.0)	14 (11.2)						
Embolization	0 (0.0)	1 (0.8)						
Total death	0 (0.0)	1 (0.8)						

EF=ejection fraction; NA=not applicable. Low weight was defined as ≤ 6 kg and high weight as >6 kg
Loss to follow-up: *62 subjects; [†]16 subjects; [‡]17 subjects

respectively; the success was higher in low weight infants than in other studies.^{11,12}

In most studies, the complete closure rate exceeds 90–95% during follow-up.^{13,14} This success rate was similar to our study. At 3-month follow-up, complete occlusion rates were 95.8% and 91.1% in the low and high weight group, respectively. After a 3-month follow-up, the residual shunt was found only in one patient weighing 6 kg and five weighing >6 kg. The ejection fraction between these groups was also within normal limit after 3 months of follow-up. This study showed similar follow-up results after transcatheter PDA closure between groups using various devices. There are several devices with different characteristics that can be used in transcatheter closure of PDA. In our study, various devices were used and chosen based on the PDA varieties that were encountered.

Transcatheter PDA closure rarely has serious complications. Transient dysrhythmia in the form of ventricular extrasystole, ventricular tachycardia, AV block, bradycardia, and junctional rhythm frequently occurred in our studies. Most dysrhythmias are associated with inadvertently probing or compressing on the myocardium or conductive tissue.¹⁵ Device embolization is the most common complication due to coil measurement mismatch with the pulmonary end. Retrieval of embolized coils are usually feasible. Otherwise, it is a rare adverse consequence, with a 1% occurrence

rate.¹⁶ In this study, we found one case with device embolization after the procedure, whereas other minor complications were similar between the two groups. A study found that complications were more severe in patients weighing <6 kg. Vascular access was more difficult, and the rate of compromised limb circulations or hematomas was higher in smaller patients.¹³ The skills and experiences of operators contributed to the marked variability of complication reports in patients weighing <6 kg. Transcatheter closure of PDA in small infants is expected to help avoid surgical morbidity, and it can be a treatment of choice in certain circumstances such as when cardiac surgery is unavailable.

This study has some limitations. Data were taken retrospectively; therefore, they depended on the availability of medical records. Missing data and loss to follow-up were related to the retrospective nature of our study so statistical difference cannot be measured. In addition, a long-term follow-up is needed to assess the long-term outcome and safety of the procedure. In conclusion, based on our experience, transcatheter PDA occlusion has similar outcomes and safety in low and high weight pediatric patients.

Conflict of Interest

The authors affirm no conflict of interest in this study.

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