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Research Article

# Transcatheter Device Closure of PDA: 2 Year's Experience in Bangladesh Shishu Hospital and Institute

**Md Abu Sayed Munsi[1]*, Maher Akther[2], Md Khalid Ebna Shahid Khan[3] and Rezoana Rima[4]**

*[1]Associate Professor, Department of Paediatric Cardiology, Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh*

*[2]Assistant Professor, Department of Paediatrics, Comilla Medical College and Hospital, Comilla, Bangladesh*

*[3]Registrar, Department of Paediatric Cardiology, Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh*

*[4]Associate Professor and Head, Department of Paediatric Cardiology, Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh*

***Corresponding Author:** Md Abu Sayed Munsi, Associate Professor, Department of Paediatric Cardiology, Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh.

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## Abstract

**Background:** Patent Ductus Arteriosus (PDA) is abnormal vascular communication between aorta and pulmonary artery and it is a common congenital heart anomaly seen in paediatric practice forming 5%-10% of all congenital heart defects.

**Objective:** To determine the efficacy, safety and immediate complications encountered during percutaneous device closure of patent ductus arteriosus (PDA) at Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh.

**Methods:** A retrospective cohort study was carried out in Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh from January 2021 to December 2022. A total of 50 patients with PDA who underwent device closure were included in the study. Among them 23 was male and 27 female patients.

**Results:** Mean age was 3 ± 1.8 years while male 23 and female 27 with female to male ratio was 1.17:1. Mean weight of the patient was 12.09 ± 7.12 Kg. Mean size of PDA by transthoracic echo was 4.54 ± 2.06 mm. Lowest size of PDA was 2.0 mm and highest size of PDA was 11 mm. In 49 cases (98%), PDA was successfully occluded. 1(2%) device embolized and needed surgical retrieval. ADO1 devices used in 38 cases (76%) while muscular device used in 7 cases (14%), Flipper detachable coil used in 4(8%) cases and ADO-11 used in 1(2%) case. Mean Fluoroscopy time was 10.95 minute and mean total procedure time was 37.26 minute.

**Conclusions:** Transcatheter occlusion of PDA by occluder device or muscular device or coil is an effective therapeutic option with high success rate. Though complication rate is low yet it is mandatory to have paediatric cardiac surgical back up cover.

**Keywords:** Patent Ductus Arteriosus; Transcatheter Device Closure; Embolization

## Introduction

Patent ductus arteriosus (PDA), which accounts for approximately 5-10% of all congenital heart defects, is a pathological communication between the descending thoracic aorta distal to the left subclavian artery and the pulmonary artery (PA) due to abnormal persistent patency of the fetal ductus arteriosus [1-3]. The duct can also vary considerably in its shape, as a result it categorizes according to Krinchenko angiographic classification to the following: Type A: where the constriction localized at the pulmonary end of the ductus with well-formed aortic ampulla and this category is the commonest one. Type B: (Window type) where there is constriction at aortic end and the ductus is wide and short and it blends with pulmonary artery. Type C: (Tubular type) where the ductus is long and without constriction. Type D: (Complex type) in which the ductus at least has two constrictions at pulmonary and aortic end. Type E: (Elongated type) in which its shape is elongated with bizarre shape with remote constriction [4]. The hemodynamic consequences of PDA are determined by the size of the shunt, the difference between systemic and PA pressure and vascular resistance, and the length and narrowest diameter of the PDA [1,2]. The natural history of PDA varies from an asymptomatic, incidentally detected defect to congestive heart failure, repeated chest infection, failure to thrive, infective endocarditis, ductal aneurysm, pulmonary vascular disease, and Eisenmenger's syndrome [5]. The successful closure of PDA reduces mortality and decreases the incidence of endocarditis. Hence, surgical or transcatheter closure is indicated for all patients with PDA except those with small, silent defects and patients with irreversible pulmonary artery hypertension (PAH) [1]. Portsmann., *et al*. reported the first transcatheter closure of the Patent Ductus Arteriosus (PDA) in 1971 [6,7]. Since then transcatheter closure has become the mainstay of treatment for PDA and surgical ligation is reserved for complex, large defects not suitable for device closure or PDA in very young infants and neonates [5,8]. The aim of this study was to describe the results of PDA device closure at a tertiary care specialized cardiac department, with special emphasis on duct size, various types of occluder devices, success rate and immediate complications encountered during the procedure.

## Materials and Methods

This retrospective study was conducted at the Bangladesh Shishu Hospital and Institute from January 2021 to December 2022. A total of 50 patients with PDA who underwent device closure were included in the study. Among them 23 was male and 27 female patients. The data for all consecutive children who underwent transcatheter PDA device closure during the study period were retrieved and included in the study. A complete pre-procedural evaluation included clinical examination, chest X-rays, electrocardiograms (ECG), transthoracic echocardiogram (TTE) and specific laboratory investigations to rule out any bleeding disorders (e.g., complete blood count, platelet count, bleeding time, and clotting time). Patient weighing ≥ 4.5 kg and age ≥ 6 months with PDA was included in the study. Patients were excluded from the study if small, silent PDA and patients with irreversible pulmonary artery hypertension. Also, patients with any additional lesions requiring surgical intervention were excluded from study.

### Procedure

After taking informed consent, patients were taken to the cath laboratory. The procedure was done under general anesthesia with transthoracic echocardiography (TTE) and fluoroscopic guidance. In almost all cases, both femoral vein and artery were canulated percutaneously. A 100 U/kg heparin dose and intravenous antibiotics were given to all patients prior to the procedure. By using a pigtail catheter, aortogram was performed in lateral and RAO position to determine size and shape, narrowest diameter of the PDA and the aortic diameter of the ampulla. Transvenous approach was applied in case of PDA occluder device or muscular device while smaller ducts with favourable anatomy were closed by using coils from retrograde approach. For device closure, an end hole catheter was passed through the PDA from the pulmonary side into the descending aorta and was exchanged for a delivery sheath, over an exchange length super stiff guide wire. Appropriate-sized device (diameter of the pulmonary end to be around 2 mm larger than the narrowest diameter of the duct) was advanced through the delivery sheath into the descending aorta and the retention disk was deployed in the descending aorta. The sheath and the retention disk were pulled back as a single unit into the ampulla of the duct. The rest of the device was then peeled off within the duct by pulling back the delivery sheath. Post-procedural aortogram was performed to confirm the device position and to evaluate residual leak. Device was released only, if correct positioning was ascertained. Post-procedural care included intravenous fluids and one dose of Ceftriaxone (50 - 75 mg/kg), vital signs monitoring,

access site care, examination and echocardiography after 4 hours and discharge echocardiography in the next morning.

## Statistical analysis

Data were analyzed using IBM SPSS software package, version 22.0 windows version. Data were expressed as the mean ± SD for continuous variables and as frequency or percentage for nominal variables.

## Results

Among 50 cases there was slight female predominance as 27 patients were female (54%) and 23 patients were male (46%) with female to male ratio 1.17:1 (Figure 1).

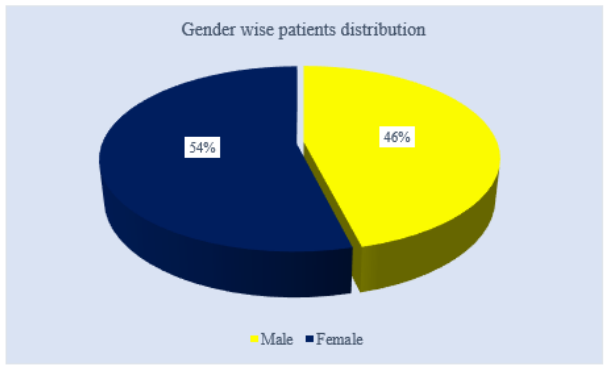


**Figure 1:** Pie chart showed gender wise patients distribution (N = 50).

Out of total 50 patients, 25(50%) patient in between 6 months to 2 year's age group, 15(30%) patients in > 2 years to 5 year's age group and 10(20%) patient in above 5 year's age group.

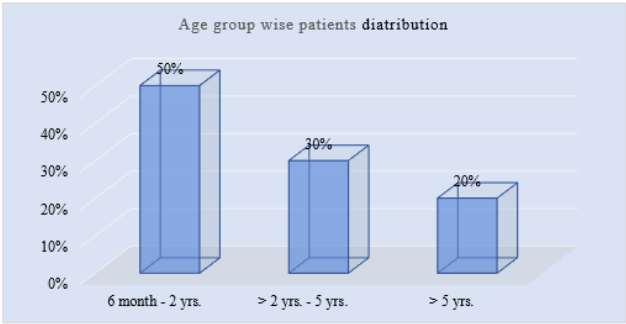


**Figure 2:** Column chart showed age group wise patients distribution (N = 50).

| AGE | Mean Weight in kg | Standard Deviation of Weight in kg |
|---|---|---|
| 6 Month - 2 years (n = 25) | 7.216 | 1.07 |
| >2 Years- 5 Years (n = 15) | 12.647 | 2.86 |
| >5 Years (n = 10) | 23.440 | 7.15 |
| Total | 12.090 | 7.12 |

**Table 1:** Weight distribution of patient (N = 50).

Mean weight of the patient was 12.09 ± 7.12 kg, lowest weight was 5.4 kg and highest weight was 42 kg.

| AGE | Mean Size of PDA by TTE | Standard Deviation |
|---|---|---|
| 6 Month - 2 years (n = 25) | 3.928 | 1.55 |
| >2 Years- 5 Years (n = 15) | 5.393 | 2.80 |
| >5 Years (n = 10) | 4.820 | 1.49 |
| Total (N = 50) | 4.546 | 2.06 |

**Table 2:** Mean size of PDA by Transthoracic echo (N = 50).

Mean size of PDA by transthoracic echo was 4.54 ± 2.06 mm. Narrowest size of PDA was 2.0 mm and highest size of PDA was 11 mm.

| Types of Device used | Size of Device Used | Frequency (n) | Percentage (%) |
|---|---|---|---|
| ADO-1 Device | 5/4 mm | 3 | 6 |
| | 6/4 mm | 4 | 8 |
| | 8/6 mm | 15 | 30 |
| | 10/8 mm | 11 | 22 |
| | 12/10 mm | 4 | 8 |
| | 14/12 mm | 1 | 2 |
| Muscular Device | 14 mm | 2 | 4 |
| | 12 mm | 2 | 4 |
| | 10 mm | 3 | 6 |
| PDA Coil | 5/4 mm | 3 | 6 |
| | 5/3 mm | 1 | 2 |
| ADO-11 | 4/4 mm | 1 | 2 |
| Total | | 50 | 100.0 |

**Table 3:** Types and size of device used in PDA (n = 50).

ADO-1 device used in 38(76%) patient. Among them, 8/6 mm device is maximum and that is used in 15 patients' and 10/8 mm device used in 11 patients', muscular device used in 7 (14%) patient, PDA coil used in 4 (8%) patient and ADO-11 used in 1 (2%) patient.

Mean fluoroscopy time and mean total procedure time in 6 months -2 year's age group were 10.21 min and 36.84 min respectively, > 2 year's -5 year's age group were 12.0 min and 38.0 min respectively and >5 year's age group were 11.21 min and 37.20 min respectively. Mean fluoroscopy time and mean total procedure time was almost equal in all age group.

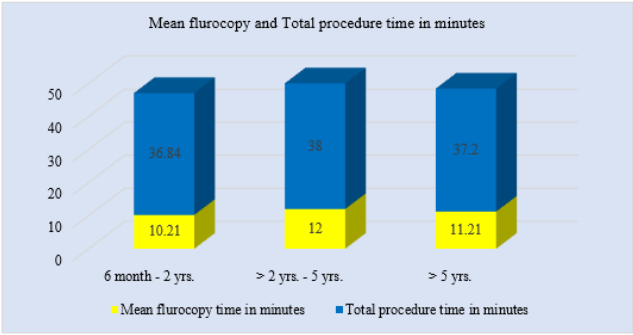


**Figure 3:** Mean fluoroscopy time and mean total procedure time in minutes (N = 50).

## Discussion

Among 50 patients', female patients 27(54%) outnumbered the male as PDA is more common in female gender. Atiq., *et al*. reported the ratio to be 2:1 in the favour of female in patients underwent device closure [9]. 50 consecutive PDAs were attempted for device closure over 2 years by the author with an overall 98% of success. In Bangladesh, there are only few centers where paediatric cardiac surgery is being practiced. In view of this, cardiac surgery virtually can't be offered to every patient with PDA; and device occlusion remains the only viable option for large majority of cases. Since first PDA device closure by Porstmann., *et al.* [7]. Percutaneous PDA device closure is safe and effective option in the experienced hands, and is now widely accepted as an attractive alternative to surgery [10,11]. by avoiding thoracotomy scar, shorter hospital stay, minimal discomfort or pain. The success rate of more than 98% in this study population is in accordance to the international figures. Parra-Bravo., *et al*. reported 92.3% success in their small study [12]. Brunetti., *et al*. reported success in 357 out of 359 patients with diameter 2.1 mm [13]. In this study, the mean narrowest PDA diameter was 4.55 ± 2.06 mm. Protocol followed at study center was to close PDA by device if weight was >4.5 kg with surgical interruption in smaller symptomatic infants. Dimas., *et al*. has recently reported their experience of 62 infants with weight < 6 kg with 94% success in PDA device occlusion [14]. The type and the size of device were planned from aortogram as per Krinchenko classification [4]. Among 50 cases, 42 cases were type A, 2 cases were type B, 5 cases were type C and 1 case was type E according to Krinchenko classification. We used ADO1 and Flipper detachable coil in type A, Muscular device in type B and C, ADO11 in type E PDA. In this study, out of 50 cases, ADO1 were used in 38(76%) patient while Muscular device were used in 7(14%), coils were used in 4(8%) and in one case ADO-11 device was used to occlude the PDA. Atiq., *et al*. reported occlusion of PDA with muscular VSD device in 2 patients [9] is showing different type and sizes of occlude devices used during the study and it is clear that the maximum size used was 8/6 in 15 patients followed by 10/8 in 11 cases. The operators preferred to use an occluder device with at least 2 mm extra (pulmonary end) in comparison to the narrowest duct diameter. Coils were used in small (≤2 mm) ducts with favourable anatomy and there was no case of residual leak, coil embolization or haemolysis. Koch., *et al*. reported occlusion rate of 92% for detachable coils with two instances of coil embolization into the pulmonary artery [15]. There were 1(2%) case where device embolized and retrieved surgically from main and right pulmonary artery. Wang., *et al*. reported 1.5% risk of device embolization quite similar to this study where it was 2% (1/50) [10]. The reasons for these dislodgments were primarily the choice of smaller occluder in view of small ampulla. The authors strongly feel that PDA device occlusion should only be performed in setup where facilities of paediatric cardiac surgery are readily available [16,17]. In a large study from Saudi Arabia, device embolization to a pulmonary artery occurred in 6 patients out of 205 procedures including 04 cases needing surgical retrieval [18]. The overall incidence of major and minor complications reported by Brunetti., *et al*. was 2.2% and 2.2% respectively [13]. In this study, major complications occurred in 2% and minor in 2% of the total patients. Minor complications or problems in this study population included pulse loss for 24 hours (femoral artery) in 1 cases. The incidence

of complications after the procedure is higher in patients under 10 kg of body weight [12]. There was no case of cardiac perforation or tamponade. Mean Fluoroscopy time was 10.95 minute and mean total procedure time was 37.26 minute. Mean fluoroscopy time and mean total procedure time was almost equal in all age group.

## Conclusion

Percutaneous PDA closure with the duct occluder, coil or muscular device is an effective method for the treatment of PDA. Though number of device dislodgment is small yet it is mandatory to have paediatric cardiac surgical back up cover.

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