

Transcatheter Device Closure of Patent Ductus Arteriosus

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ABSTRACT

Objective: To determine the efficacy, safety and immediate complications encountered during percutaneous device closure of patent ductus arteriosus (PDA).

Study Design: Case series.

Place and Duration of Study: Department of Paediatric Cardiology, AFIC/NIHD, Rawalpindi, from January 2005 to December 2010.

Methodology: Consecutive 500 patients who underwent attempted transcatheter PDA device closure were included in the study. Device type position, success of closure and complications were described as frequency percentage.

Results: In 491 cases (98.2%), PDA was successfully occluded including 4 cases (0.8%) where devices were dislodged but retrieved and redeployed in Cath laboratory. PDA occluder devices used in 448 cases (91%) while coils (single or multiple) were used in 42 cases (8.5%) and in one case (0.2%) ASD occluder device was used to occlude the PDA. There were 09 (1.8%) unsuccessful cases, 06 (1.2%) were abandoned as ducts were considered unsuitable for device closure, 02 (0.4%) devices dislodged and needed surgical retrieval and one case (0.2%) was abandoned due to faulty equipment. The narrowest PDA diameter ranged from 0.5 - 14 mm with mean of 4.5 ± 2.4 mm. There was a single (0.2%) mortality.

Conclusion: Transcatheter occlusion of PDA by coil or occluder device is an effective therapeutic option with high success rate. Complication rate is low in the hands of skilled operators yet paediatric cardiac surgical back-up cover is mandatory.

Key Words: Patent ductus arteriosus. Device closure. Device embolization.

INTRODUCTION

Isolated PDA accounts for around 10% of all congenital heart diseases.^{1,2} Except in premature babies, PDA is not likely to close naturally. Associated complications are congestive cardiac failure, infective endarteritis, pulmonary hypertension and Eisenmenger physiology depending upon PDA size and relative lung compliance.^{3,4} The general acceptance is to close all PDAs except silent ducts, patent ducts in premature neonates, Eisenmenger ducts and where pulmonary or systemic flow is dependent on patency of the ductus arteriosus. In recent reports, closure of silent ducts is now also advocated, preventing infective endocarditis and its consequence.⁵ Currently, transcatheter PDA device occlusion is considered as safe and effective in all age groups.⁶⁻¹⁰

In Pakistan, by virtue of fertility rate of 2.5 - 3% and population of 18 million, there are about 2500 new patients with PDA every year, who requires treatment. In a developing country like ours, the facilities for cardiac surgery are very limited and it is practically not possible to surgically treat all cases of PDAs. Our institution

started percutaneous PDA device closure in year 2000 with increasing numbers every year.

The aim of this study was to describe the results of PDA device closure at a tertiary care specialized cardiac institute, with special emphasis on duct size, various types of occluder devices, success rate and immediate complications encountered during the procedure.

METHODOLOGY

This case series analyzed the PDA device closure procedure done from January 2005 to December 2010 at the Armed Forces Institute of Cardiology-National Institute of Heart Diseases (AFIC-NIHD), Rawalpindi, by reviewing the clinical records including catheterization data, echocardiography reports and follow-up record. Total 500 patients with percutaneous PDA device closure were included in the study. Device closure was attempted in uncomplicated / isolated PDA with no duct dependent circulation, no signs of pulmonary vascular obstructive disease, age 06 months or more and body weight of at least 6 kgs. All patients underwent detailed pre-procedural assessment especially detailed 2D-echocardiography and Doppler scanning. Narrowest diameter and length of PDA was measured in ductal view using 2D-echocardiography (high parasternal short axis) confirmed on color Doppler and pressure gradient across duct was calculated by applying CW Doppler.

After taking informed consent, patients were taken to the cath laboratory. In almost all cases, both femoral vein and artery were cannulated percutaneously. By using a pigtail catheter, aortogram was performed in lateral

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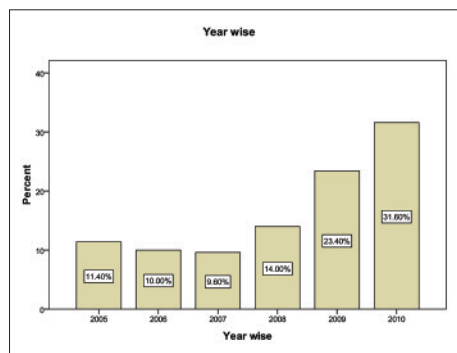


Figure 1: Year-wise distribution of PDA device closures (n=500).

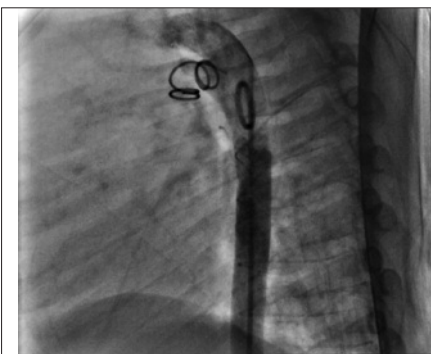


Figure 2: PDA coil used for duct occlusion.

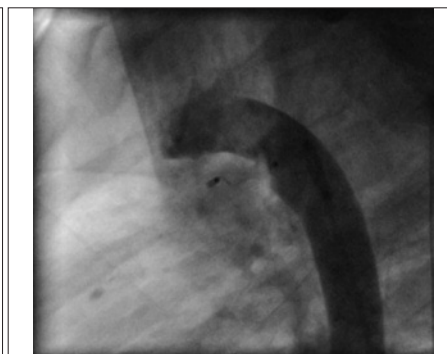


Figure 3: PDA device occlusion.

Table I: Age and gender distribution in study population (n=500).

	Up to one year	1 - 5 years	5 - 15 years	15 - 50 years	> 50 years
Male	30 (52%)	82 (40%)	53 (36%)	26 (29%)	01 (50%)
Female	28 (48%)	121 (60%)	95 (64%)	63 (71%)	01 (50%)
Total	58 (100%)	203 (100%)	148 (100%)	89 (100%)	02 (100%)

Table II: Size of PDA occluder devices used in successful attempts (n=448).

Size of device	Number	Percent (%)
5/4 (AGA)	03	0.7%
6/4	69	15.4%
8/6	181	40.4%
10/8	119	26.6%
12/10	46	10.3%
14/12	17	3.8%
16/14	12	2.7%
18/16	1	0.2%
Total	448	100%

position and RAO 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 while smaller ducts with favourable anatomy were closed by using coils from retrograde approach (Figure 1). For device closure, an endhole 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 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 (Figure 2). 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.

Data was entered in computer based statistical programme, Statistical Package for Social Sciences (SPSS) version 17 and descriptive analysis including frequencies with percentages, mean and standard deviations were done. Continuous variables with normal distribution were expressed as mean ± SD; otherwise, reported as median.

RESULTS

Consecutive 500 patients with male to female ratio 0.6:1 (n = 92:308) underwent attempted PDA device closure with mean age of 09 ± 10.2 years (range: 06 months - 65 years). Table I is showing number of cases in different age groups and 203 (40.6%) were in the bracket of 1 - 5 years followed by 148 (29.6%) cases in 5 - 15 years age group. Three (79.8%) cases were done under GA. Figure 1 is depicting the year-wise breakdown of the cases with increasing trend in device closures every next year. The narrowest PDA diameter ranged from 0.5 - 14 mm with mean of 4.5 ± 2.4 mm.

Successful PDA occlusion was achieved in 491 (98.2%) cases. In 9 (1.8%) unsuccessful attempts, 06 cases were abandoned as ducts were considered unsuitable for device closure, 02 devices dislodged and retrieved surgically and one case was abandoned due to faulty equipment. Out of 491 successful cases, there were 04 cases where devices were dislodged, retrieved and redeployed in cath laboratory effectively. Out of 491 successful PDA device occlusion, occluder devices were used in 448 (91%) patients while coils (either single or multiple) were used in 42 (8.5%) and in one case (0.2%) ASD occluder device was used to occlude the duct. Table II is showing various sizes of PDA occluders used in 448 successful cases. Two cases where PDA occluders were dislodged and needed surgical retrieval are not included in Table II. Immediate post-procedural aortogram (within 10 - 15 minutes of deployment) revealed complete occlusion (with foaming in some cases) of the ducts in 486 (99%) cases out of 491, with mild residual leak in 05 patients. At one month follow-up

no residual leak was detected on transthoracic echocardiography in 100% patients. The major complications encountered in 5 (01%) cases including single mortality, 02 devices dislodged and retrieved surgically (from main and right pulmonary artery), and ventricular tachycardia in 2 patients needing external defibrillation. The child who expired during the study period was a 1.5 years female child with 2.5 mm PDA with adequate ampulla; PDA device closure with device 6/4 was done successfully. After about 28 hours of device occlusion, baby aspirated milk and died after unsuccessful CPR.

Minor problems encountered in 38 (7.6%) cases and included pulse loss for 06 - 24 hours (femoral artery) [25], pulse loss > 24 hours (10), local hematoma (03). There was no case of cardiac perforation or tamponade.

DISCUSSION

Five hundred consecutive PDAs were attempted for device closure over 5 years with an overall 98.2% of success. In Pakistan, there are only few centres where paediatric cardiac surgery is being practiced, roughly, less than 2000 cardiac surgeries per annum. In view of this, cardiac surgery virtually can not be offered to every patient with PDA; and device occlusion remains the only viable option for large majority of cases. PDA closure by device at the study centre was started in the year 2000, after about three decades of first PDA device closure by Porstmann *et al.*¹³ Percutaneous PDA device closure is safe and effective option in the experienced hands, and is now widely accepted as an attractive alternative to surgery,^{8,9,12} by avoiding thoracotomy scar, shorter hospital stay, minimal discomfort or pain and avoidance of general anaesthesia in older children.

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,⁷ Brunetti *et al.* reported success in 357 out of 359 patients with diameter 2.1 mm.¹⁴ In this study, the mean narrowest PDA diameter was 4.5 ± 2.4 mm. Female patients (62%) outnumbered the male as PDA is more common in female gender. Hong *et al.* reported more than 3:1 ratio and Atiq *et al.* reported the ratio to be 2:1 in the favour of female in patients underwent device closure.^{6,15} Protocol followed at study centre was to close PDA by device if weight was > 6 kg with surgical interruption in smaller symptomatic infants. Nevertheless, Dimas *et al.* has recently reported their experience of 62 infants with weight < 6 kg with 94% success in PDA device occlusion.¹⁶

In this study, out of 491 successful cases, various occluder devices were used in 448 (91%) while coils were used in 42 (8.5%) and in one case ASD occluder device was used to occlude the PDA. Atiq *et al.* reported occlusion of PDA with muscular VSD device in 2 patients.⁶ Table II is showing different sizes of occluder

devices used during the study and it is clear that the maximum size used was 8/6 in 181 patients followed by 10/8 in 119 cases. The operators preferred to use an occluder device with at least 02 mm extra (pulmonary end) in comparison to the narrowest duct diameter. Coils were used in small (< 02 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.¹⁷ Complete early occlusion (defined as no leak in check aortogram or after 24 hours on echocardiography) occurred in 486 (99%) patients, out of successful 491 cases which are in accordance to recently reported 98% in children with less than 10 kg of weight, by Park *et al.* and 92.5% by Koch *et al.*^{17,18} In this study, check aortogram was performed after waiting for about 10 - 15 minutes following deployment of the device.

There were 6 (1.2%) cases where the device dislodged after its deployment, and 4 of them retrieved with snare and redeployed in the cath laboratory. There were 02 cases where device dislodged 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 1.2% (6/491).⁸ 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.^{2,19} 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.¹² The unfortunate child who expired in the study population, was direct result of procedure needing more attention. She was a 1.5 years female child with small PDA, closed successfully with device 6/4 and shifted to post-angio ward in stable status. Intravenous heparin was started for absent right leg pulse. After about 28 hours of device occlusion, baby aspirated milk without any warning signs and died after unsuccessful CPR. There has been a procedure-related death, reported in literature, including a case of PDA device embolization into the descending aorta, and after retrieval, developing mesenteric vascular complications and sepsis eventually died as direct complication of PDA device occlusion.²⁰

The overall incidence of major and minor complications reported by Brunetti *et al.* was 2.2% and 2.2% respectively.¹⁴ In this study, major complications occurred in 01% and minor in 7.6% of the total patients. There were 7 cases where procedure was abandoned (not considered as procedural complications), including 04 large tubular PDA unsuitable for device closure and 02 too small PDA to be closed (after performing aortogram) and in patient procedure abandoned due to faulty delivery sheaths as device could not be inserted

into the sheaths in spite of changing 2 - 3 kits. Parra-Bravo *et al.* reported 02 out of 39 cases where procedure was abandoned due to difficulty in placing the device along with 20% complication rate.⁷ Similarly, 2 cases of procedural failure were reported by Wang *et al.* in their series of 68, due to ductus calcification and kink in the sheath.⁸ Other minor complications or problems in this study population included pulse loss for 06 - 24 hours (femoral artery) in 25, pulse loss for > 24 hours in 10, local hematoma in 03 and ventricular tachycardia in 02 cases. The incidence of complications after the procedure is higher in patients under 10 kg of body weight.⁷ There was no case of cardiac perforation or tamponade. The impact of operator learning curve is important in reducing rate of complication and increasing chances of success in PDA device closure.²

CONCLUSION

Transcatheter closure of the PDA is effective percutaneous intervention by the use of coil or occluder device with high success rate and good safety profile in skilled operators. Though number of device dislodgment is small yet it is mandatory to have paediatric cardiac surgical back up cover.

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