Original Research Article

Transcatheter closure of patent ductus arteriosus in children weighing 5 kg or less: Initial experience

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Abstract

Introduction: Trans-catheter closure (TCC) of patent ductus arteriosus (PDAs) is a well-established non-surgical method of closure. **Objectives**: To evaluate safety, feasibility & complications of device closure of patent ductus arteriosus (PDA) in small children weighing ≤ 5 kg with different types of devices for closure. **Methods:** patients with PDA underwent transcatheter closure, among whom 16 (33%) weighed 5 kg or less. All of these patients underwent transcatheter closure of PDA using an Amplatzer duct occluder I, Amplatzer duct occluder II or Amplatzer duct occluder 2 IIAS (Additional size) devices. **Results:** Sixteen patients (9 females & 7 males) between the ages 20 days to 16 months had undergone device closures. Amplatzer Duct Occluder (ADOI) was used in 12 cases, 3 were closed with Amplatzer Duct Occluder (ADO2) and one the smallest of all (1.6 kg) patient were selected for closure with Amplatzer Duct Occluder (ADO2 AS). At 1 month after the closure, the signs and symptoms improved markedly in all patients, and PDAs were completely closed and devices remained in situ on follow-up. Mild obstruction of left pulmonary artery (n=2) and aortic isthmus flow (n=1) was noted at the time of discharge which gradually improved on follow up. **Conclusions**: TCC of PDA in small babies 5 kg or less is feasible & safe alternative to surgical PDA closure in carefully selected patients. The immediate & short-term outcomes have proven this method to be safe & valid.

Keywords: Congenital heart disease, Patent ductus arteriosus (PDA), Device closure

Introduction

Patent ductus arteriosus (PDA) is a common form of CHD, accounts for approximately 8% of congenital heart disease with the incidence of one in 2500 to 5000 live births [1]. PDA is defined as persistent patency in term infants even after three months [2]. It may be asymptomatic and is sometimes not diagnosed early resulting into prolonged abnormal aorto-pulmonary shunt which may result in silently progressing hypertension and left ventricular dysfunction. The presence of volume overloading of the left atrium and left ventricle is an indication for closure of the defect. The shape of the PDA varies; a classification was given by Krichencko et al. [3]. Since the first percutaneous closure of PDA performed by Porstmann in 1968, various devices and coils have been introduced into clinical practice. Although, advances in transcatheter techniques have been made, there is lack of data on patient selection, technical issues, complications, and mid to long term outcomes especially in very small patients. [4,5,6]. In this report, we present our early experiences with and the short-term outcomes of closure of PDA in children 5 kg or less using various devices.

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Materials and Methods

The study was done at a tertiary level hospital having pediatric cardiac unit with dedicated Pediatric cardiac catheterisation lab.

Type of study: This is a retrospective study where relevant data were obtained from the case files and cardiac catheterization records.

Sampling Method: consecutive patients of patent Ductus arteriosus weighing less than 5 kgs were enrolled for the study.

Sample Collection: data was collected from the hospital records

Inclusion criteria: all the children with PDA weighing less than 5 kgs and echo cardiographically the ductus found to be amenable for device closure were included in the study.

Exclusion criteria: All the children having complex cardiac defects having PDA as one of the defect. Not found suitable for device closure on echocardiography. Parents not giving consent for the procedure.

Relevant data were obtained retrospectively from the case files and the catheterization records.

Statistical Methods: Observational study in which the demographic and angiographic data of children with PDA having less than 5 kgs weight was presented.

Ethical Consideration: The procedure was done with the informed consent from the parents.

Patients- All patients were admitted at least 1 day prior to the procedure for clinical, laboratory (pre-cath profile), chest X-ray, ECG, and echocardiograph assessment. Upper and lower limb saturations were recorded in all patients.

Echocardiographic evaluation revealed the size & anatomy of the PDA, and estimation of the pulmonary artery pressure (PAP). Patients were screened for presence of coarctation of Aorta and branch pulmonary artery stenosis.

Procedures- Informed consent was obtained from the guardians of patients prior to the procedure. The procedure was performed under conscious sedation in all the patients.

A single dose of intravenous antibiotic is administered (usually cefuroxime) The femoral vein only was cannulated per-cutaneously in 11 cases while femoral artery only were cannulated in 4 cases as venous access in these cases could not be done while in one case both (Arterial and Venous) accesses were taken. Right heart catheterization was performed, basal systemic pressure and basal pulmonary arterial pressure were taken and Qp/Qs and basal pulmonary arterial resistance were calculated.

Aortogram in the lateral projection and right anterior oblique 30° were recorded using hand injection through sheath after crossing PDA in DTA was done in 12 cases and with pigtail catheter was done in 4 cases to define the duct. Diameter at the pulmonary (Duct size) and aortic ends, and its length were measured.

The PDA was crossed from the pulmonary end in 13 cases while in 3 cases where only femoral arterial access was taken; it was crossed from arterial side.

Delivery sheath was introduced from the venous side over the Amplatzer super stiff guide wire (Boston Scientific, Natick, MA, USA), and was kept in the descending thoracic aorta.

In cases where arterial line only was done PDA was crossed from arterial side through 0.25 inch straight tip terumoand parked deep in MPA through which guiding JR catheter was placed and device was deployed through that.

The device size used was the one size more as the angiographic size. Device was delivered as per the standard technique [2-4]. Post procedure the patients were monitored in the intensive cardiac care unit for 24 hrs. A close watch was kept for any evidence of intravascular hemolysis and device embolization. Patients were discharged after 48 hours of observation.

All cases were followed at 6 weeks, 3 months, and every six months thereafter. Improvement in functional class and weight gain was noted. The patients were evaluated clinically for any evidence of worsening.

At follow up echocardiography, the position of the device was confirmed and residual shunt if any was noted. The presence of turbulence in the left pulmonary artery (LPA) and aortic isthmus was looked for and the velocities/gradients across these structures were recorded.

Results

From March 2018 to January 2019, 16 patients (9 females, 7 males) between 20 days to 16 months of life underwent trans-catheter closure of PDA (ranging from 2.5 mm to 5.5 mm at PA end) as an alternative to standard surgical ligation with use of different devices. Out of these1 patient was less than 1 month, 6 patients were between 1 to 6 months, 8 were

between 6 months to 12 months and only 1 were more than 1 year. In this case series 7 patients had PDA sizes between 2.5 to 3 mm, 4 had between 3- 4mm, 4 had between 4-4.5 mm and only 1 patient had large PDA more than 4.5 mm at PA end. On Simultaneous measurements of PA pressure and Aortic pressure 6 patients showed PA pressure > 2/3rd of systemic pressure which was reversible on oximetry testing, while other 10 patients had PA pressure between ½ to 2/3rd of systemic pressure with good reversibility.

In all patients there was a significant fall in pulmonary artery systolic pressure (>20% of baseline) post device occlusion of PDA.

As far as devices are concerned we used Amplatzer Duct Occluder (ADOI) in 11 cases, Amplatzer duct Occluder (ADOII) in 4 cases and only one PDA was closed with Amplatzer Duct Occluder (ADOIIAS).

All the 16patients underwent successful closure of PDA. There was no incidence of device migration or embolization. At the time of post deployment angiogram, 7 out of 16 patients showed residual shunt through the device.

However, it disappeared over a period of time and there was no residual shunt in any of the patients at the time of the last follow up

Table-1: Demographic data of patients.

No	Sex	Age (months)	Weight (Kg)	Major complications	Associated cardiac anomaly	Associated Non cardiac anomaly
1	F	1	2.2	None	None	None
2	M	7	3.8	None	None	None
3	F	3	3.0	None	None	None
4	M	4	2.5	None	None	None
5	F	7	3.6	None	BL Branch PA stenosis	Sensory neural hearing defect
6	F	9	3.2	None	None	None
7	F	5	3.0	None	Small VSD	None
8	M	8		None	None	None
9	M	6	3.0	None	None	None
10	M	9	3.9	None	None	None
11	F	16	5.0	None	None	None
12	M	10	4.0	None	None	None
13	F	2	2.8	None	None	None
14	F	11	4.8	None	None	Cleft palate
15	M	20 days*	1.6	None	None	None
16	F	5	2.9	None	None	None

*36 weeks Preterm baby
Median age -6.4 months
Median weight- 3.2 kg

Table-2: Angiographic data of patients.

No.	PDA Size (mm)	Qp/Qs	Device size	Type of device	Major complications	Minor complications	Vascular access	Closure side
1	2.5	1.8	6/4	ADO I	None	None	Venous	Venous
2	3.2	2.1	8/6	ADO I	None	LPA obstruction	Venous	Venous
3	2.8	1.6	6/4	ADO I	None	None	Venous	Venous
4	4.2	1.5	8/6	ADO I	None	None	Venous	Venous
5	3.0	1.8	5/4	ADO II	None	None	Arterial	Arterial
6	3.5	2.0	6/6	ADO II	None	None	Arterial	Arterial
7	2.6	2.1	6/4	ADO I	None	None	Venous	Venous
8	4.4	2.1	5/4	ADO II	None	None	Arterial	Arterial
9	2.6	1/8	6/4	ADO I	None	None	Venous	Venous
10	4.5	1.5	10/8	ADO I	None	Mild aortic obstruction	Both arterial and venous	Venous
11	3.5	1.6	6/6	ADO II	None	LPA obstruction	Arterial	Arterial
12	2.8	1.6	6/4	ADO I	None	None	Venous	Venous
13	5.2	1.8	10/8	ADO I	None	LPA obstruction	Venous	Venous
14	3.2	2.0	8/6	ADO I	None	None	Venous	Venous
15	3.0	1.9	6/6	ADO II AS	None	None	Venous	Venous
16	4.4	2.0	8/6	ADO I	None	None	Venous	Venous

Complications- No mortality noted in this study. Significant hypotension (50% drops in aortic systolic pressure) along with ST-T changes in inferior leads were noted in one case. Hemodynamic stability was regained in as soon as stiff wire was removed after placing the delivery sheath in the descending aorta. Transient loss of lower limb pulses was observed in 4cases. At the time of pre discharge echocardiography, two patients had a mild flow acceleration in their LPA with a maximum velocity of > 2 m/s but < 2.5 m/s while one patient had peak velocity of > 2 m/s but less than 2.5 m/s in the region of the aortic isthmus due to the protrusion of aortic retention disc into the aortic lumen which gradually improved on 6 months follow up.

Discussion

Every patient of 5kg or less with PDA should be evaluated carefully before attempting device closure of PDA for evidence of significant left to right shunt utilizing clinical examination, chest X ray, ECG, Echo Doppler and if necessary, hemodynamic assessment at cardiac catheterization to ensure satisfactory long-term outcome after device closure [2,3].

Assessment of PVR at cardiac catheterization after administering 100% oxygen, and after nitric oxide has several limitations in a patient with PDA especially in very small babies [5,7]. Transcatheter closure of PDA has been the mainstay of treatment in children and adults [11]. Fortes *et al* presented a retrospective case series of 1808 patients with transcatheter closure of PDA in a report published in 2010. Overall PDA closure rate was 94% and major complications were 1.5% [12]. There have been only a few minor complications compared with the initial interventional data [13,14]. Never the less, procedure-associated complications have been described in different age groups, and they are relatively major in infants [7,15,16].

In this study, we evaluated 16 small children who weighed 5kg or less and underwent percutaneous transcatheter PDA closure during a period of 12 months, which was the initial experience of our institution, and found high success rate (100%) without any mortality which shows the safety of transcatheter

closure of PDA in children weighing 5 kg or less. In a previous report by Park et al. [17], the median age of 115 patients was 8 months and mean body weight was 7.8kg while in our study median age was 6 months and median weight was 3.2 kg.

The success rate was 98%, nearly similar to our results. El-Said et al. [18] reported a large prospective multicenter study unbiased to patient or device selection of transcatheter closure of PDA.

The study evaluated 290 small children of 496 patients; the success rate of PDA closure was 97–99%. Also, the rate of high-severity complications of this study was low (2.2%). Complications were more likely to occur in young patients (<6 months), and in patients <6kg. In Dimas et al.'s multicenter study [19], the age of the infants studied was younger and their weights were lower. Successful device placement was achieved in 58 of 62 patients (94%).

In our study, the incidence of device embolization was none. In eleven patients in the current study, the PDA occluder (ADO I) were implanted using venous access only deliberately to avoid complications related arterial puncture, although in four cases venous line could not be done instead we took the arterial line only and the device (ADOII) was deployed from arterial side safely and in one case both arterial and venous access was done for better delineation as anatomy and size of PDA in that particular patient was not clear on echocardiogram. Based on our experience we suggest that this method of avoiding arterial line to avoid certain complications is good and efficient approach there were no immediate or delayed major complications in our study such as protrusion of the occlusion device into the aorta or obstruction to the left pulmonary artery, hemolysis, or endocarditis.

We have not used any coil in our study due to bigger size of PDA for coil occlusion. We used Amplatzer Duct Occluder (ADOI) in 11 cases, Amplatzer duct Occluder (ADOII) in 4 cases and only one PDA was closed with Amplatzer Duct Occluder (ADOIIAS). The results documented in our series are in accordance with theresults reported by other interventional paediatric cardiac centres [6,17–19,22].

Study limitations- Limitations of the present study include its retrospective nature and the relatively small number of patients. More studies with a larger number of patients and younger patients are needed to analyze the safety and efficacy of transcatheter closure of PDA in this age group.

Conclusions

Although surgical repair of large PDA is a safe, widely accepted procedure with negligible mortality, it is associated with morbidity, discomfort and a thoracotomy scar. As an alternative to surgery trans-catheter closure of PDA with different devices is a good option with better results.

With the current availability of devices for PDA closure, transcatheter closure of PDA is considered safe and efficacious in small children weighing 5kg or less with good mid-term outcome. The procedure had a low rate of complications even with the initial experience of a catheterization laboratory.

Authors Contribution- Dr MMK and SA collected the data, SA, MMK and AH prepared the manuscript, Dr SA and Dr SG did the statistical analysis and MMK and FMI reviewed the manuscript.

What this study adds to existing knowledge? PDA device closure even in younger and less weight infants is a safer alternative to surgical ligation.

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