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PATENT DUCTUS ARTERIOSUS DEVICE OCCLUSION IN YOUNG CHILDREN LESS THAN 12 KG- IMMEDIATE RESULTS AND COMPLICATIONS

Muhammad Younas[1], Ahsan Beg[2]

[1,2] Department of Paediatric Cardiology, Ch. Pervaiz Elahi Institute of Cardiology, Multan, Pakistan

Address for Correspondence:

Dr. Muhammad Younas,

Assistant Professor,

Department of Paediatric Cardiology, Ch. Pervaiz Elahi Institute of Cardiology, Multan, Pakistan

E-Mail:younasdr@hotmail.com

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ABSTRACT

Objective: To assess the immediate results and complications of transcatheter closure of patent ductus arteriosus (PDA) in young children less than 12kg of weight.

Methodology: This descriptive cross-sectional study was conducted at department of Paediatric Cardiology, Chaudhry Pervaiz Elahi Institute of Cardiology, Multan from September 2009 to October 2013. Patients who under went PDA closure for moderate to large PDA with LV volume overload without severe pulmonary hypertension who were <12kg were included. Pre and Post Procedure Echocardiography was performed. Complications of procedure including mortality were recorded.

Results: A total of 123 patients underwent PDA occlusion of which 44 (36%) patients were <12kg. Mean age was 2±1.034 and weight was 9.5kg ± 1.88. Procedure was successful in all patients without any mortality or major complications. Small residual PDA in Cath Lab was present in 03 (6.8%), which resolved in 24 hours. Loss of arterial pulse was present in 08(18%) patients which recovered within 24 hours with heparin infusion. Protrusion of aortic end of device without aortic obstruction was present in 10(23%) patients. Partial LPA obstruction due to device (Echo gradient between 15-30mmHg) was present in 04(09%) patients. There was no device embolization.

Conclusion: Percutaneous closure of moderate to large PDA in young children weight less than 12kg is a safe procedure without major complications. Loss of arterial pulse, protrusion of aortic end of device without aortic obstruction, partial LPA occlusion and residual PDA were the common immediate post device implantation complications.

Key Words: PDA device, Transcatheter Closure, Children

INTRODUCTION

Patent ductus arteriosus (PDA) is an abnormal communication between pulmonary artery and descending aorta distal to left subclavian artery.[1] PDA is a common congenital heart defect (CHD)having an incidence of 1:2000 live births and 5 -10% of all CHD.[2] The presence of volume overloading of the left atrium and left ventricle is an indication for closure of the defect. The risks of endocarditis and pulmonary vascular disease are also indications for closure. Closure eliminates volume overload of the left-sided circulation, and the risk for pulmonary hypertension and endocarditis. Surgical closure of PDA is safe and effective. However, certain patients may experience some morbidity, including bleeding, inadvertent left pulmonary artery ligation, recurrent laryngeal nerve damage, and residual shunting. Initially surgical ligation of PDA was the only treatment option. PDA was the first example of CHD to be treated by transcatheter closure. PDA device closure has now become an established form of treatment for the majority of patients with PDA and safe alternative to surgery. Surgery is generally reserved for patients with a very large duct with severe PH or symptomatic preterm infants. The feasibility of nonsurgical closure of the PDA was demonstrated when Porstmann et al, in 1967 reported closing a PDA with a plug in a 17 year old boy without thoracotomy.[3] Subsequently, a number of devices and coils have been used for catheter closure of PDA with varying degrees of success.[4-6] Coils are still used especially for small PDA.[7] Coils are technically cumbersome to use, high prevalence of residual defects and relatively high risk of embolization.[8] The Amplatzer duct occluder (ADO) device was designed to provide the most desirable characteristics for percutaneous closure device.[9] Masura et al, reported the successful use of a new self expandable Nitinol device to occlude moderate to large PDAs.[10] Faella et al, reported the immediate and short term results of transcatheter closure with ADO.[11] Three hundred and sixty patients were treated at a median age of 2.1 years. The occlusion rate was up to 100% at one year follow up.

PDA device occlusion is straight forward in older children but more demanding in young children especially infant. This study was designed to analyze the early results of PDA device occlusion in young children less than 12kg.

METHODOLOGY

This descriptive cross-sectional study was conducted at department of Paediatric Cardiology, Chaudhry Pervaiz Elahi Institute of Cardiology, Multan from September 2009 to October 2013. Patients who under went PDA closure for moderate to large PDA with LV volume overload without severe pulmonary hypertension who were less than 12Kg were included. Pre and post-procedural echocardiography was performed.

Patients were excluded if weight < 5kg, PDA with severe PH, small PDA, associated cardiac anomalies requiring surgery, current local or generalized infection. Informed consent was obtained from their guardians.

The device used was a self-expandable, mushroom-shaped device made from Nitinol wire mesh. It has retention disk, aortic and pulmonary ends. Polyester fibers are sewn securely into the device for rapid thrombosis. All devices are cone-shaped, 7 mm in length with a recessed screw. The delivery system consists of a delivery cable, long Mullins-type sheath, loader and pin vise.

Procedure was performed under heavy sedation with local anesthesia. Access in the femoral vein was obtained with placement of a 5-6F sheath. A 5F sheath was placed in the femoral artery. Heparin was used for all patients. Main PA pressure and aortic pressure was recorded. Angiogram in the lateral projection was then performed with a catheter in the proximal descending aorta to clarify the PDA. The PDA size was measured and the PDA was classified by its shape according to Krichenko's classification.[12] The device was selected so that the smaller pulmonary end was at least 2 mm larger than the narrowest portion of the PDA. An end-hole catheter was passed from the main PA through the PDA into the descending aorta. A stiff exchange guide wire was placed with the tip in the distal descending aorta. A 6-7F long sheath was then passed over the wire into the descending aorta. The appropriate-sized device was then screwed onto the delivery cable and pulled into the loader under water to prevent air entry into the device or sheath. The device was then advanced to the tip of the sheath in the descending aorta without rotation of the cable. The sheath and device were then pulled back into a position just distal to the ampulla. The position of the device was confirmed with repeated angiograms in the descending aorta and adjusted until the retention skirt was well seated in the ampulla. When good position was achieved, the sheath was retracted further and distal part of the device was opened within the PDA. Another angiogram was performed in the descending aorta to confirm final device position and PDA occlusion. Sometime an angiogram was repeated after 10 minutes to confirm full occlusion. If device position was satisfactory, the device was released with counter-clockwise rotation. The patients were given intravenous antibiotics for 24 hours and were discharged after 24 hours after evaluation by chest X-ray and echocardiography. Complications of procedure including mortality were recorded. Oral antibiotics were given for 3 days post discharge from hospital.

Data was entered and processed using SPSS version 11. Frequencies, proportions were computed for categorical variables like symptoms, signs and means were computed for numerical variables like age of the patient and measurements.

RESULTS

A total of 123 patients underwent PDA occlusion of which 44 patients were with weight less than 12kg. Mean age was 2 ± 1.034 and 16(36%) patients were less than 01 year of age. Mean weight was 9.5 kg ± 1.88 and 29(54%) were less than 10 kg. and 29(54%). Female to male PDA ratio was 1.3:1 (25 (56.8 %) female and 19 male (43.2%). Pre-procedural characteristics are shown in Table 1.

Table 2 shows procedural characteristics pre and post-implantation of PDA device. Table 3 shows angiographic classification of PDA as first described by Krichenko et al.[12]

Implantation was successful in all 44 patients. Complete angiographic closure was documented at the end of the procedure in 29 patients (66%). Little insignificant foaming through device was present 13 (29.5%). Small residual PDA observed in 03 (6.8%) patients. Foaming through PDA device and small residual leak disappeared within 10 minutes or 24 hours in all patients. After device deployment, no gradient recorded by pullback from the ascending to descending aorta. We could not record post occlusion PA pressures. The majority (68.9%) of ducts were closed using a 7F transvenous delivery sheath. We used 5/4 PDA device in 02 (4.4%), 6/4 in 15 (34%), 8/6 in 23 (52%) and 10/8 in 04 (9.6) patients. AGA Amplatzer duct occluder was used in 29 (65.9) and SHSMA Chinese PDA device in 18 (40.9) patients.

Echocardiograms and physical examinations were performed for all patients on post-catheterization day 1. There was complete closure of the PDA seen on echocardiography in all patients. No aortic obstruction (gradient > 10 mm Hg) observed. Partial obstruction of LPA

Table 1: Pre-Procedural Characteristics of Patients

Variables		Values
Clinical Features		
Tachypnea		12 (27.3%)
Continuous Murmur		44 (100%)
Echocardiographic Features		
Mean PDA size (mm)		3.5±0.757
Severity of PDA	Moderate	24 (54.5%)
	Moderately large	6 (13.6%)
	Large	14 (31.8%)
Mean Gradient across PDA (mm Hg)		92.7±14.99
Mean LV end Diastolic Dimension (mm)		36±3.65

Table 2: Procedural Characteristics

Variables		Values
Catheterization Data		
Pre-Occlusion	Mean Systolic Pulmonary Artery Pressure (mmHg)	43 ± 13.33
	Mean Diastolic Pulmonary Artery Pressure (mmHg)	27 ± 10.24
	Mean Systolic Aortic Pressure (mmHg)	104 ± 14.27
	Mean Diastolic Aortic Pressure (mmHg)	59 ± 12.68
Post Occlusion	Mean Systolic Aortic Pressure (mmHg)	122 ± 26.25
	Mean Diastolic Aortic Pressure (mmHg)	75 ± 17.43
Severity of PDA on Fluoroscopy		
	Moderate (2.5-3 mm)	25 (56.8%)
	Moderate to large (3-3.5mm)	5 (11.4%)
	Large (>3.5 mm)	14 (31.8%)
Mean PDA size on Fluoroscopy area (mm)		3.3 ± 0.69
Mean Fluoroscopic Time (Minutes)		15 ± 5.76
Mean Procedural Time (Minutes)		45 ± 8.24

(Gradient between 15 -30) observed in 04 (09 %) patients.

Serious procedural complications were rare in our study. There was no device embolization during the procedure. There was no mortality. Pulse loss requiring heparin for 24 hours was seen in 8(18%) patients. Procedural complications are summarized in Table 4.

DISCUSSION

Amplatzer duct occluder (ADO) is an ideal device for transcatheter closure of PDA. Device and delivery system provide full control till release. Device is easy to deploy and has complete closure with low residual shunt rate. Though cost has reduced due to availability of Chinese products but we could not offer this procedure to all patients particularly in developing countries.[13] PDA device occlusion is relatively

Table 3: Angiographic Classification of PDA (n=44)

PDA Types (Krichenko classification)		No (%)
Classical-Conical shape	(A)	30 (68.2)
AP window type	(B)	02 (4.5)
Tubular without constriction	(C)	00
Complex-multiple constrictions	(D)	00
Long ampulla	(E)	12 (27.3)

Table 4: Procedural Complications

Complications	No (%)
Small residual PDA in cath lab. (resolved within 24 hrs)	3 (6.8 %)
Arterial pulse loss (resolved with 24 hrs heparin infusion)	8 (18 %)
Protrusion of aortic end of device without aortic obstruction	10 (23 %)
Aortic obstruction (Iatrogenic coarctation of aorta)	00 (0%)
Partial LPA obstruction due to device (Echo gradient between 15 -30 mm Hg)	04 (9 %)
Device embolization	00 (0%)
Mortality	00 (0%)

straight forward in older children but it is more demanding in young children especially infant. This study was designed to analyze the early results of PDA device occlusion in young children less than 12kg. Initial experience of PDA device occlusion in younger babies indicated problems due to delivery sheath. Fishers et al, study considered transcatheter closure of PDA with ADO device in twelve patients less than one year of age and showed that it is possible to use this device successfully in this age group. Duct closure was achieved in all but two symptomatic babies who were abandoned because of excessive procedural and fluoroscopy time. They experienced some specific technical difficulties involving kinking of the long sheath at the angle of the right ventricular outflow tract. [14] Subsequently delivery system improved. In our series, complete closure was achieved in all patients. Butera et al study in which 16 symptomatic children with mean age of 18.8 ± 10 months were included. Their PDAs were successfully occluded by ADO device without any complication. So they concluded that closure of moderate to large PDA in very young symptomatic children is safe and effective and resolves the patient's clinical problems.[15] Another recent study from Iraq by Sadiq M et al, showed that in all infants except one (five months old baby in which the device caused aortic obstruction and removed before release) all PDAs were successfully occluded. [16]

As far as complications are concerned we encountered no major complication. Several complications had been encountered by other case series. A significant aortic obstruction, requiring surgical removal of the device was reported by Duke.[17] Published results of the international clinical trial with ADO, reported several procedure related complications like hemolysis, LPA stenosis, device protrusion into aorta causing coarctation and device misplacement.[1,18] Bilkis et al, reported one death following device embolization, while no death recorded in other case series.[18-19] For affording patients, percutaneous closure of moderate to large PDA is recommended as first line treatment in children. It is safe and effective in closing the PDA and in solving clinical problems. It can avoid general anesthesia, shortens hospital stay and can avoid complication related to PDA surgical ligation.

CONCLUSION

Percutaneous closure of moderate to large PDA in young children weight less than 12kg is a safe procedure without major complications. Loss of arterial pulse, protrusion of aortic end of device without aortic obstruction, partial LPA occlusion and residual PDA were the common immediate post device implantation complications.

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