

Original Research Article

Transcatheter closure of patent ductus arteriosus using duct occluder: an eleven year experience from a single tertiary cardiac center

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ABSTRACT

Background: Patent Ductus Arteriosus (PDA) is a common congenital disorder. As an isolated lesion, PDA constitutes 6 to 11% of all congenital heart disease. PDA needs closure to eliminate pulmonary over circulation leading to volume overload of left ventricle, pulmonary vascular obstructed disease.

Methods: This retrospective study was carried out in pediatric cardiology unit of Institute of Postgraduate Medical Education and Research, Kolkata from September 2005 to August 2016, which included 503 patients.

Results: Device closure was attempted in 492 patient's. Procedural success was achieved in 85% cases on table, in who check aortogram revealed complete closure of PDA. In 15% cases, residual shunt was present. In 12% of cases, residual shunt disappeared during follow-up echocardiogram over 6-month follow-up. In 3% cases, small shunt remained at 6-month and 1-year follow up.

Conclusion: Transcatheter closure of PDA by duct occluder is safe and effective with good mid-term outcome. The optimum assessment of ductal size and anatomy is crucial for optimum device size, which prevents residual shunt, device embolization and protrusion.

Keywords: Aortogram, Device size, Patent ductus arteriosus, Patent ductus arteriosus type, Transcatheter closure

INTRODUCTION

Patent Ductus Arteriosus (PDA) is a common congenital disorder. As an isolated lesion, PDA constitutes 6 to 11% of all congenital heart disease.^{1,2} PDA needs closure to eliminate pulmonary over circulation leading to volume overload of left ventricle, pulmonary vascular obstructed disease. However, even small PDA without hemodynamic overload are candidate for closure to prevent infective endocarditis.

Gross and Hubbard first did the surgical ligation of PDA long back in 1939.³ Surgical ligation is a safe and effective procedure with occasional morbidity like left recurrent laryngeal nerve palsy and residual shunting.^{4,5} Portsman et al were the first to describe transcatheter closure of PDA.⁶ Since then, various devices have been used including Rashkind PDA umbrella, button device, coils, duct occluder and vascular plug.⁷⁻¹¹ Amongst all the devices, duct occluder is designed to have all the suitable characteristics for a smooth transcatheter closure of PDA.

The study aimed to evaluate the safety, efficacy and long-term follow up results of transcatheter PDA closure by different duct occluder.

METHODS

This retrospective study was carried out in pediatric cardiology unit of Institute of Postgraduate Medical Education and Research, Kolkata from September 2005 to August 2016, which included 503 patients. A detailed clinical examination was done in each patient. Many of the patients were asymptomatic during presentation. Routine ECG and X-Ray chest were done. Clinical and radiological cardiomegaly was indicator of significant shunt. Echocardiography and color-Doppler evaluation was done critically in every patient. Left atrial and left ventricular dimensions were noted. Ratio of aortic and left atrial diameter, an indirect indicator of grade of shunt was measured. Narrowest diameter of PDA was measured in ductal view. Ampulla and shape of PDA was assessed in suprasternal view. From Doppler spectrum and gradient, hemodynamic effect of PDA was assessed. Exclusion criteria were bodyweight less than 5 kg, severe pulmonary hypertension with bidirectional shunt, silent (small) PDA and associated cardiac lesions, which need surgical correction.

Written consent was taken prior to procedure, which was done under conscious sedation and analgesia, general anesthesia or local anesthesia, depending on the age of patient. Antibiotic protocol was followed.

Procedure

Femoral vein and artery were cannulated by 6-7 F and 5 F sheath respectively. Heparin was used 75 units/kg as bolus dose. Systemic and pulmonary artery pressure were measured. When mean pulmonary artery pressure was found more than 25 mmHg, temporary balloon occlusion with the sizing balloon was done. In case of significant drop in pulmonary artery pressure, the procedure was continued in usual manner. In those selected patients, pulmonary and systemic vascular flow and resistant were calculated.

Aortogram was done in lateral view and in select cases, right anterior oblique view or left anterior oblique view in variable angle. Narrowest diameter of PDA and diameter of ampulla were measured. Shape and length of the ductus were noted. Device size was selected according to the narrowest diameter, usually 2 mm more than narrowest diameter. In larger PDA with adequate ampulla, oversized device was selected.

The technique of device deployment was followed, as described in the literature.^{12,13} Repeat aortogram was done after 10 minutes of deployment. Residual shunt was assessed. Procedural complications were noted. Since 2005, we are not using coils anymore for PDA closure.

Follow-up

All patients were discharged with aspirin for sixth months. Follow-up Doppler echocardiogram was done on day one, one month, six months and one year after the procedure. Degree of residual shunt and any obstruction by the device in descending aorta or pulmonary artery were noted during follow-up echocardiogram. Infective endocarditis prevention protocol followed for 6 months.

Statistical analysis

Statistical analysis was done using SPSS software package, version 17.0 on Window operating system. Continuous variables were summarized using descriptive statistics. Data were expressed as mean and standard deviation versus median and range between maximum-minimum values.

RESULTS

In 11 patients, procedure was abandoned. In 9 patients, pulmonary artery pressure was at systemic level and did not come down significantly on balloon occlusion. In other 2 patients, PDA was tiny sized on aortogram.

Table 1: Demographic profile of patients with PDA.

Demographic profile	Median	Range
Age (Yrs)	5.3	0.5-18
Weight (Kg)	12	0.6-62
Female to Male ratio	1.4:1	290:202

Table 1 shows demographic profile of the patients with PDA. Device closure was attempted in 492 patients. 290 patients were female and 202 patients were male (female to male ratio: 1.4:1). The median age of patients was 5.3 years (Range-0.5 to 18 years) and median weight 12 Kg (Range-0.6 to 62 Kg). Angiographic classification of PDA is shown in Table 2 and 3. Commonest type was Type A, found in 48.3% cases. Median narrowest diameter of PDA was 3.8 mm (2.2 to 12 mm). In 20% patients, mean pulmonary artery pressure was more than 25 mmHg. In all these patients, pulmonary artery pressure response to balloon occlusion was favorable. From the initial patient pool, 9 patients did not respond to balloon occlusion and they were excluded from device deployment. Criteria for favorable response of acute vasodilatory test were extrapolated to decide the favorable result of balloon occlusion.¹⁴ The size of occluders used varied. Largest size used was 14/12 and minimum size was 6/4. Commonest device size was 8/6. Device size and hemodynamic data are shown in Table 4.

Table 2: Anatomical classification of PDA Size.

PDA size	Mean±SD	Range
Narrowest diameter	4.6±2.0	1.8±12
Aortic ampulla	12.4±4.8	5.8±24

Table 3: Anatomical classification of PDA Type.

PDA type	Number (%)
A	230 (46.7)
B	52(10.5)
C	78(15.8)
D	81(16.4)
E	43(8.7)
Unclassified	8 (1.6)

Table 4: Device size and hemodynamic data.

Device size	Number	Mean pulmonary artery pressure	Mean systemic pressure
16/14	9	42.6 (34-46)	80.4±18.4
14/12	31	32.4 (24-42)	82.2±14.6
12/10	63	22.8(18-34)	78.6±15.8
10/8	120	20.6(16-30)	80.8±18.4
8/6	193	18.2(16-28)	80.2±20.4
6/4	76	17.6(12-22)	76.2±16.9

Table 5: Associated cardiac lesions.

Other cardiac lesions	No (%)
Mitral regurgitation	19 (3.86)
VSD	2 (0.4)
ASD	2 (0.4)
Bicuspid aortic valve	6 (1.21)
Aortic stenosis	1(0.2)
Coarctation of aorta	1(0.2)
Subaortic membrane	4 (0.8)
Pulmonary stenosis	1(0.2)
Left-sided superior vena cava	3 (0.6)

PDA was isolated lesion in 92% cases. Commonest association was mild mitral regurgitation, which disappeared after PDA closure. Ostium secundum ASD and perimembranous VSD were associated in 2 cases each. Device closure of those lesions was done in same sitting. Balloon aortic valvuloplasty and coarctoplasty was done in 2 patients for associated bicuspid aortic stenosis and coarctation of aorta respectively. Associated cardiac lesions are shown in Table 5. Procedural success was achieved in 85% cases on table, in who check aortogram revealed complete closure of PDA. In 15% cases, residual shunt was present. In 12% of cases, residual shunt disappeared during follow-up echocardiogram over 6-month follow-up. In 3% cases, small shunt remained at 6-month and 1-year follow up. Major procedural complication was device embolization, which occurred in 3 patients. One device was retrieved on trans-catheter route. Following retrieval, PDA was closed by higher-sized device. In other 2 cases, surgical retrieval and PDA closure were done. One of the patients died on 5th post-operative day, due to sepsis. Hemodynamically insignificant obstruction in the left pulmonary artery and descending aorta by the device was

observed, particularly in infants. During follow-up, those patients did not show any clinical consequences. Amongst minor complications, transient loss of femoral arterial pulse and febrile reactions were common. Procedural complications are shown in Table 6.

Table 6: Complications.

Complications	No (%)
Device embolization	3(0.6)
Device protrusion	32(7%)
Death	1(0.2)
Febrile reaction	87(17.6)
Loss of femoral pulse	28(5.6)

DISCUSSION

Till 1980s, surgical closure was the gold standard for PDA management. In the major series, surgical ligation was successful in 100% cases with minimum mortality and morbidity as low as 4.4%.¹⁵ Portsmouth first did transcatheter PDA closure in 1967 with Evalonfoam plug prosthesis. This method was not popularized because for the bulky size of the device. Then came Gianturco embolization coil. A high rate of coil embolization led to redesign of simple coil to detachable coil. Since then, advancement has been made both in procedural technique as well as in device design. Search for ideal device went on. Then came Amplatzer Duct occluder in 1998.¹⁶ An ideal device is one, which is low profile, which is retrievable, which can be delivered with user-friendly delivery system and which seals shunt most effectively. Duct occluder device fits in the most of those characteristics. The present study retrospectively analyzed the immediate result and follow up of device closure of PDA in 492 patients over 11 years. Overall closure rate was achieved in 97% cases. Angiographic closure was achieved in 85% of cases. Residual shunt disappeared over 6-month follow up in another 12% of cases. In 3% of cases, mild shunt persisted at 6 and 12-month follows up. There was no audible murmur and those small shunts were left alone.¹⁷ Success rate was in accordance to other studies. Brunetti et al, described 98% closure rate in their 359 patients. Parra-Brave et al, reported 94% success. Sultan M, et al, reported 98% closure rate in their large series of 500 patients.¹⁸⁻²⁰ Ali SH et al, reported 98.4% closure rate.²¹ Commonest type was Type A, found in 48.3% cases. Median narrowest diameter of PDA was 3.8 mm. Commonest association was mitral regurgitation (3.86%), mostly trace to mild, which disappeared after device closure. Pulmonary arterial hypertension, defined as mean pulmonary artery pressure more than 25 mmHg was found in 20% of cases. All of them had relatively larger PDA. They were responders to balloon occlusion as per criteria.^{14,22} Devices deployed in them were larger in size. Residual shunt was more common in them. Major adverse event, device embolization occurred in 3 patients (0.6 %). In them, PDA was large in diameter and tubular in shape (Type C) in 2 patients and window like (Type B) in

another patient.²³ This is comparable to other series. Sultan et al, reported 1.2% embolization in their series.²⁰ Ali SH et al, reported 1.5% embolization rate.²¹ The mortality rate for device closure in PDA is nearly zero (0-0.9%).²⁴ In our series, one patient died due to sepsis on 5th day of procedure. Minor complications included loss of femoral pulse in 5.6% of cases, which reappeared within 24 hours. Febrile reaction occurred in 17.6% of cases. Device protrusion in left pulmonary artery and descending aorta was found in 5% and 2% of patients respectively. Protrusion occurred mostly in smaller children with large PDA. This was as per report in other study.²⁵ In none of these patients protrusion did produce any significant obstruction.

CONCLUSION

Transcatheter closure of PDA by duct occluder is safe and effective with good mid-term outcome. Excepting residual shunt, device embolization and device protrusion, there are no major morbidities. The optimum assessment of ductal size and anatomy is crucial for optimum device size, which prevents residual shunt, device embolization and protrusion.

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