ORIGINAL ARTICLE

Experience with percutaneous closure of ductus arteriosus using the Amplatzer duct occluder in 243 consecutive patients and long-term results—A single centre study

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ABSTRACT

Background: Percutaneous closure of patent ductus arteriosus (PDA) with Amplatzer duct occluder (ADO) has become increasingly popular in many cardiovascular centres. This study analysed the long-term results of percutaneous closure of PDA with ADO in a single centre. **Materials and Methods:** Between May 2004 and January 2013, 243 patients with median age of 2.5 years (range = 30 months to 38 years) and median weight of 10 Kg (range 4.5–80.5 Kg) underwent percutaneous closure of PDA using the ADO. The devices were implanted under fluoroscopic guidance. Patients were followed-up for any complications. **Results:** The mean diameter of narrow part of PDA was 6.4 ± 2.2 mm. The mean diameter of devices was 7.8 ± 2.3 mm. The devices were successfully implanted in 239 (98.3%) cases. At immediate, 1 day, 1, 6, 12 months and late follow-up, the complete occlusion rate was 33% (79 case), 97.1% (236 case), 97.5% (237 case), 98.3% (238 case), 98.3% (238 case) and 98.3% (238 case), respectively. Residual shunt remained in one case at late follow-up. The device embolisation occurred in five patients. The devices were successful retrieved in three patient and second larger devices were inserted. Two other devices were surgically retrieved and PDAs were ligated. Moderate left pulmonary artery stenosis (LPA) in one child and mild LPA stenosis in one infant were detected. Mild aortic obstruction occurred in one infant. **Conclusions:** Long-term follow-up of patients indicate that percutaneous closure of PDA using ADO is a safe and effective procedure. However, some complications, including device embolisation, left pulmonary stenosis and aortic obstruction may be observed in some cases.

Key words: Amplatzer ductus occluder, patent ductus arteriosus, percutaneous closure

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INTRODUCTION

Percutaneous closure of patent ductus arteriosus (PDA) has evolved with development of various surgical and nonsurgical methods. Although surgical ligation of PDA is a safe procedure with negligible mortality, it is associated with discomfort, morbidity, longer hospital stay and thoracotomy scar.[1] The percutaneous closure of PDA with Ivalon plug was first reported by Porstman *et al.,* in 1967.[2] Since then, a variety of devices has been developed for percutaneous closure of PDA. At present almost all the cardiovascular centers prefer use of Amplatzer duct occluder (ADO) as the safe and effective technique.[3-8]

We herein report the immediate, short, mid-term and long-term results of percutaneous closure of PDA with ADO from a single centre.

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MATERIALS AND METHODS

Between May 2005 and January 2013, 260 consecutive patients with significant PDA were considered for percutaneous closure with ADO.

The 17 infant patients excluded because of weight < 4.5 Kg and severe heart failure after clinical and

echocardiographic evaluation. Therefore, 243 patients underwent percutaneous closure of PDA. The age at the time of procedure raged from 3 month to 38 years (median: 2–5 years) and the weight ranged from 4.5 Kg to 85 Kg (median: 10 Kg). All patients were reviewed for their information from physical examination, electrocardiogram (ECG), chest radiography and echocardiography before the procedure. After obtaining informed consent from adult patients or child's parents, right and left heart catheterisation was performed under heavy sedation for children and local anaesthesia for adults.

Descending aortogram in right anterior oblique or lateral views was performed to measure of PDA size.

Standard technical delivery of the device over a guide wire through the defect and the implantation of device was performed under fluoroscopic guidance, as previously described.[4,9] Prophylactic antibiotic with 30 mg/kg cefazoline (maximum 1 g) was administered intravenously at 30 minute before the beginning of the procedure and two subsequent doses 8 hour apart. Heparin (100 unit/kg/dose maximum 5,000 unit) was administered intravenously after femoral artery access and prior to the procedure. A right anteroposterior or lateral descending aortogram was done to locate PDA and obtain the size at the narrowest part, the aortic ampulla and the centre of PDA [Figure 1].

The device was chosen to be at least 1–2 mm larger than the narrowest diameter of the PDA.

A repeat descending aortogram was done before and after release of device to check for residual shunt and aortic obstruction [Figure 2].

All the patients were discharged 1 day after the procedure. All the patients had complete transthoracic echocardiographic studies at 24 hour, 1, 6 and 12 months and annually thereafter. Special attention was paid to residual shunt, left pulmonary stenosis and descending aorta obstruction. Endocarditis prophylaxis was discontinued at 6 month follow-up if PDA was completely occluded.

Follow-up of the patients including physical examination and echocardiography were performed at 1 day, 1, 6, 12 months and annually thereafter. Special attention was paid to residual shunt, left pulmonary artery stenosis and aortic obstruction or any complication. The patients were recommended to take antibiotic endocarditis prophylaxis at least for 6 month or residual shunt was completely disappeared.

RESULTS

The patients' characteristic and procedure-related data are show in Table 1.

During the 8.5 year study, a total 260 patients were scheduled to undergo percutaneous closure of PDA. Seventeen infant patients were excluded from percutaneous closure because of sever congestive heart failure and body weight less than 4.5 Kg. Therefore, 243 patients underwent percutaneous closure of PDA with ADO. Of these, 169 (69.5%) were female and 74 (30.5%) were male. Median age and weight at the time of the procedure were 2.5 year (range: 3 months–38 years) and 10 Kg (range: 4.5–85 Kg). Of the total number of patients, 22.6% (n = 55) were infants, 56.8% (n = 138) children and 20.6% (50) adolescents or adults. The mean ± SD follow-up was 53.9 ± 25.7 months (range: 14.5–102 month).

Percutaneous closure of PDA was performed successfully for 239 of 243 patients (98.3%).

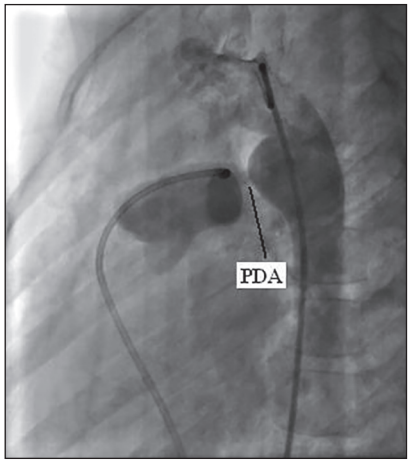

Figure 1: Descending aortogram in the lateral position showing medium sized PDA (Patent ductus arteriosus)

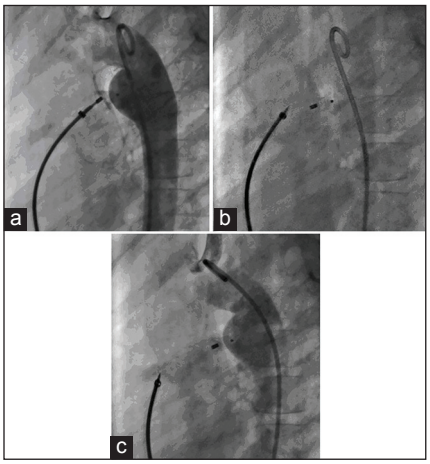

Figure 2: (a) Descending aortogram in lateral position before release of the device showing trivial Mesh leak shunt and appropriate device position (b) Shows release of the device in lateral view (c) Descending aortogram in lateral position immediately after release of the device showing complete closure of PDA and no aortic obstruction

Table 1: The demographic and procedure-related data

	Mean	SD	Median	Range
Age (year)	6.0	7.6	2.5	0.25-38
Weight (kg)	17.3	15.9	10	4.5-80.5
Mean PAP (mmHg)	27.1	15.4	23	6-100
QP/QS	2.3	0.73	2.2	1.25-4.6
PDA size (mm)	6.4	2.2	6	3.1-16
ADO (mm)	7.8	2.3	8	4-18
PT (min)	42.5	11.1	25.7	20-85
FT (min)	6.3	5.3	5	2.1-21
FU (month)	53.9	25.7	35.8	14.5-102

SD – Standard deviation; Qp/QS – Pulmonary to systemic flow; PDA – Patent ductus arteriosus; ADO – Amplatzer ductal occluder; FT – Fluoroscopy time; PT – Procedure time; F/U – Follow-up

Five patients experienced device embolisation immediately in patients and during night in two patients. For three patients, devices were retrieved percutaneously and then a second larger device was successfully implanted. For the other two patients, surgical retrieved and then surgical ligation was performed. One unrelated procedure death occurred 5 days after procedure because of severe aspiration pneumonia during bottle feeding. The patient was a 7-month-old girl with large PDA and sub-systemic pulmonary hypertension, congestive heart failure and failure to thrive.

Immediately after release of the device, descending aortogram showed residual shunt including foaming through the wire mesh of the device in 171 patients (70.4%, small residual shunt in 32 patients (13%) and moderate residual shunt in 3 patient (1.2%) patients.

On color flow Doppler, all trivial and small residual shunting were disappeared at (the time of discharge, 1 day after PDA closure) and only three moderate shunt continued.

At 1-month follow-up, transthoracic echocardiography showed Moderate shunt only in one patient.

In this patient, a moderate residual shunt remained at 6 months, 12 months and during follow-up. The repeat percutaneously closure of PDA was advised for this patient. The patient refused because of pregnancy. Mild aortic obstruction occurred in one infant. The patient did not experience worsened aortic obstruction during follow-up. In one child on the next day of the procedure, mild left pulmonary (LPA) stenosis with 20 mmHg gradient was observed on transthoracic echocardiographic examination.

One the control echocardiography performed 1 month later, pressure gradient across LPA increased from 20 mmHg to 60 mmHg.

The patient was referred for surgical retrieved of the device and PDA ligation. The patient refused, due to fear of open cardiac surgery. The patient was asymptomatic during follow-up. No other major complications such as late migration of the device, haemolysis, nickel allergy or bacterial endocarditis were detected during follow-up.

Minor complications related to the procedure such as femoral artery thrombosis (nine patients) or blood loss with the need for blood transfusion (two patients), only occurred in infant age-group.

Heparin (Intravenous continues effusion) was used successfully in six patients with femoral thrombosis. Heparin was ineffective in three other patients, therefore streptokinase was administered. Streptokinase intravenous infusion (loading does 10,000 IU/Kg over 1 hour followed by 10,000 IU/Kg for 6 hours) produced a complete and successful turn of pulse in two patients with mild and asymptomatic groin haematoma .Another one patient underwent femoral artery thrombectomy.

DISCUSSION

PDA is one of the most common congenital heart disease, and various devices are available to close of PDA percutaneously.[5,10-12]

The ADO (AGA Medical Corporation, Golden valley, minnosota) is one of the commonly used devices.[3-9,11]

In 1998, Masure *et al.,* reported the first clinical trial of percutaneously closure of PDA using Amplatzer duct occluder. The immediate success rate was 96%.[9]

In our study, six (2.4%) major complications (device embolisation in four patient, moderate LPA obstruction in one patient and moderate residual shunt in one other patient) were noted among 243 patients with PDA. Device embolisation sometimes occur necessitating surgical removal or transcatheter retrieval.

One the most significant complication of percutaneously closure of PDA is device embolisation.[2,4,13-17] The reported rate of the major complication with ADO was 2.3% in a multi-centre registry.[18]

We believe selection of the device with appropriate size is of utmost important. Undersized device can result in residual shunting or embolisation. The important concern with most devices is the irretrievability during implantation resulting in the need for catheter or surgical removal of displaced device. A major advantage of ADO is that is can be easily retracted in to delivery sheath and re-deployed several time before final release. This greatly reduced the chance of displacement, risk for surgical or percutaneously retrieval of embolisation device and the cost obviating the introduction of a new device.[19,20]

Bilkis *et al.,* described on a large series of 209 patients with a PDA closed with ADO. Complications detected in

six cases (3 %,).[15] Three experienced device embolisation that required surgery. An infant patient of 5 Kg developed mild aortic obstruction after implantation a large device and two other patients needed blood transfusion because of significant blood loss.

In several studies, the reported incidence of distal embolisation of ADO varies between 0-2%.[15,18,21]

In current study, device embolisation rate was 2% (n = 5). This complication occurred only in infants and children groups.

In our study, no device embolisation was noted in adolescent or adult patients. Another common complication of percutaneously Amplatzer PDA closure is left pulmonary artery (LPA) obstruction.[3,5,12,13,18,19,21-23] The reported rate of LPA stenosis varies, between 0-12%.[12,16,24]

Contrary to PDA closure in infants and children, LPA stenosis is not a problem in adult patients.

In current study, in one patient, (0.4%) after the deployment of the ADO, device was observed to protrude into proximal of LPA, resulting in a pressure gradient of 20 mmHg on Doppler echocardiography. The pressure gradient in LPA increased from 20 mmHg to 60 mmHg at 1 month after procedure.

Several studies reported aortic obstruction after the percutaneous Amplatzer PDA closure.[13,15,18,19] In our study, one patient had protrusion of the device in to the descending aorta resulting in a pressure gradient 18 mmHg on Doppler echocardiography.

On Doppler color echocardiography at 6 months and 12 months after procedure obstruction of descending aorta was evaluated. Although the device was detected to protrude into descending aorta, pressure gradient decreased from 18 mmHg to 12 mmHg. We speculate that this type of mild aortic obstruction is expected to improve gradually with subsequent growth of the child. Other complications such as infective endocarditis, haemolysis, and nickel hypersensitivity after device implantation are rare.[13] The complications such as haemolysis infective endocarditis, nickel allergy were not encountered in our series. Late complications were more rarely described and only late device embolisation were reported.[25]

At follow-up (8.5 years), we have recognised no late complications such as device migration, aortic obstruction, LPA stenosis, haemolysis or recanalisation.

Based on our findings with the use of the ADO, it suggests that this occluder is a promising device for percutaneous closure of PDA. Device closure was successful in all patients including infants, children, adolescent and adult with PDA.

CONCLUSION

Percutaneous closure of PDA using ADO, regardless of patient's age at the time of the procedure is associated with high efficacy and a low complication rate. Although some complications such as device embolisation, left pulmonary artery or aortic obstruction may occur in some patients, we believe that risk of attempting percutaneous closure of PDA with ADO is overall very low, therefore it should be considered as a primary choice for treating a PDA in all age-groups including infants, children and adults.

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