Transcatheter closure of patent ductus arteriosus in children weighing 10 kg or less: Initial experience at Sohag University Hospital

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Aim: **To assess the challenges, feasibility, and efficacy of device closure of patent ductus arteriosus (PDA) in small children weighing ⩽10 kg for different types of devices used in an initial experience at Sohag University hospital.**

Methods: **Between March 2011 and September 2014, 91 patients with PDA underwent transcatheter closure in our institute, among whom 54 weighed ⩽10 kg. All of these patients underwent transcatheter closure of PDA using either a Cook Detachable Coil, PFM Nit-Occlud, or Amplatzer duct occluder. A retrospective review of the treatment results and adverse events was performed.**

Results: **Successful device placement was achieved in 53/54 small children (98.1%). The median minimum PDA diameter was 2.4 mm [interquartile range (IQR, 1.8–3.5 mm), median weight 8 kg (IQR, 7–10 kg), and median age 10 months (IQR, 8–17 months)]. Mild aortic obstruction occurred in one case (1.9%), as the device became displaced towards the aorta after release. The device embolized in one case (1.9%) and no retrieval attempt was made. Five cases (9.3%) had minor vascular complications.**

Conclusion: **With the current availability of devices for PDA closure, transcatheter closure of PDA is considered safe and efficacious in small children weighing ⩽10 kg with good mid-term outcome. The procedure had a low rate of high-severity adverse events even with the initial experience of the catheterization laboratory.**

Keywords: Adverse events, Closure, Device, Patent ductus arteriosus

Introduction

Transcatheter occlusion of the patent ductus arteriosus (PDA) using either coils or device transcatheter therapy is considered to be a well-established procedure both in adults and older children. Since the first experience of the transcatheter occlusion of PDA by Porstmann et al. in 1967 [1], technical improvements over the years have increased the proportion of patients who undergo successful transcatheter closure [2,3].

Disclosure: Authors have nothing to disclose with regard to commercial support.

Received 26 March 2015; revised 15 May 2015; accepted 17 June 2015.
Available online 26 June 2015

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Peer review under responsibility of King Saud University.
URL: www.ksu.edu.sa
http://dx.doi.org/10.1016/j.jsha.2015.06.007

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Despite the advancement in the procedure, there are many problems during performance of transcatheter PDA closure in infants: relatively large sheath size for small vessels, stiffness of the delivery system with resultant hemodynamic instability during device deployment, risk of protrusion of the device into the aorta or pulmonary artery, poor anchoring or stability within the PDA, and difficult retrievability [4,19]. The purpose of this study was to determine efficacy and safety of transcatheter closure of PDA in infants weighing <10 kg and mid-term follow-up of our institution in its initial experience.

Materials and methods

A total of 91 patients underwent transcatheter occlusion of PDA at Sohag University Hospital from April 2011 to September 2013. Among them, 54 (58%) patients (13 male, 38 female), weighing <10 kg, were included in this retrospective study. We retrospectively analyzed medical records, echocardiographic findings, angiographic findings, hemodynamic data, adverse events, and follow-up results of these patients.

Written consent from parents of patients included in the study and the approval of ethical scientific committee of Sohag University Hospital were obtained.

The patients who were selected for this device occlusion were those with clinical and echocardiographic features of PDA who weighed 5 kg. These patients had one or more of the following: symptoms and signs of cardiac failure requiring medications, failure to thrive, bounding pulses, cardiomegaly on chest radiography and at least moderate dilation of the left atrium and ventricle on two-dimensional echocardiography. Two patients had a small restrictive perimemberanous ventricular septal defect (VSD); one patient had mitral valve prolapse with moderate mitral regurgitation; and two patients had small ostium secundum atrial septal defect. Three patients had genetic syndrome: two patients had Down syndrome and the third patient had Turner syndrome.

The patients' clinical characteristics (age, sex, and weight) were recorded. Aortic angiogram in lateral and right anterior oblique views was performed to evaluate the size, position, and shape of the duct for appropriately choosing the occluder device type and size. Hemodynamic data including pulmonary artery pressure and the pulmonary-to-systemic flow ratio were recorded. The technique of device deployment was similar to that reported in the literature [5,6]. Detachable

Abbreviations

ADO	Amplatzer duct occluder
AE	Adverse events
PDA	Patent ductus arteriosus
VSD	Ventricular septal defect

or PFM coils were used for patients with small PDAs of ⩽1.5 mm at the narrowest diameter. Amplatzer duct occluders (ADOs) were used for PDAs that were >1.5 mm. ADO size selected was usually 2–3 mm larger than the duct diameter in children [7]. However, some exceptions to this rule had to be made due to unavailability of the devices at the time of procedure. Amplatzer muscular VSD devices (AGA Medical Corporation, Golden Valley, Minnesota) were used in the one type C PDA that had long length. After device deployment in PDA, a second aortic angiogram was performed 10 min after device deployment (Figs. 1 and 2). In four patients, the PDA occluders (ADO I; AGA Medical Corporation, Golden Valley, Minnesota) were implanted using venous access only as the arterial line was not accessible. The angiography for determination of PDA measurements was done by pigtail catheter introduced through PDA from pulmonary artery (Fig. 3). The position of the occluder was determined by angiography through the delivery sheath and by echocardiography.

The fluoroscopy time during the procedure were identified. The transcatheter occlusion was performed under general anesthesia in our 1st year of experience, after which the procedure was performed under deep sedation and local anesthesia.

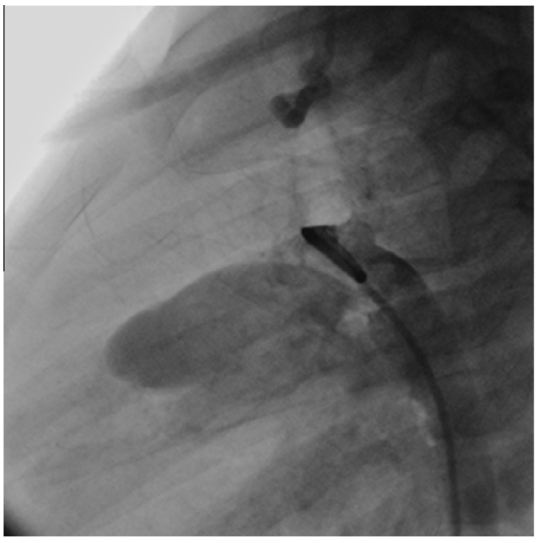

Figure 1. Descending aortogram showing large tubular type C patent ductus arteriosus in lateral view.

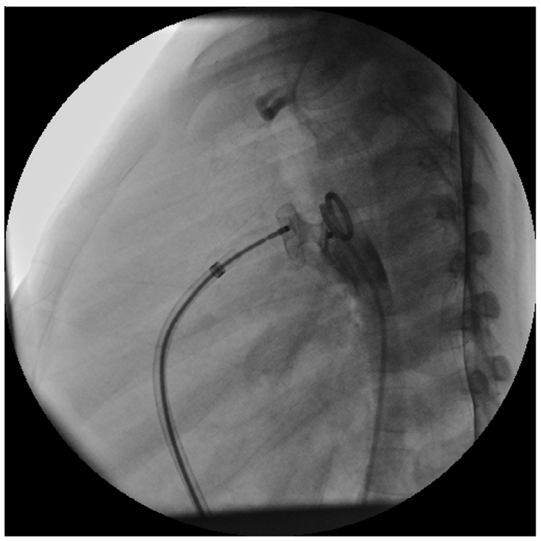

Figure 2. Descending aortogram showing the Amplatzer muscular ventricular septal defect in the patent ductus arteriosus position with foaming through the device.

Follow-up protocol

Chest radiography and transthoracic echocardiography were conducted 24 h after the procedure to evaluate the shape and position of the device. Patients had follow up in the Pediatric Cardiology Out-patient Clinic at intervals of 24 h then at 1 month, 6 months, and 12 months after the procedure. Patients were checked clinically for any evidence of cardiac murmur during each follow-up. Complete echocardiographic data (left pulmonary artery and aortic Doppler interrogation) in addition to evaluation for residual shunting was performed by using a Vivid S5 (GE health care, Norway) echocardiography machine (General Electric).

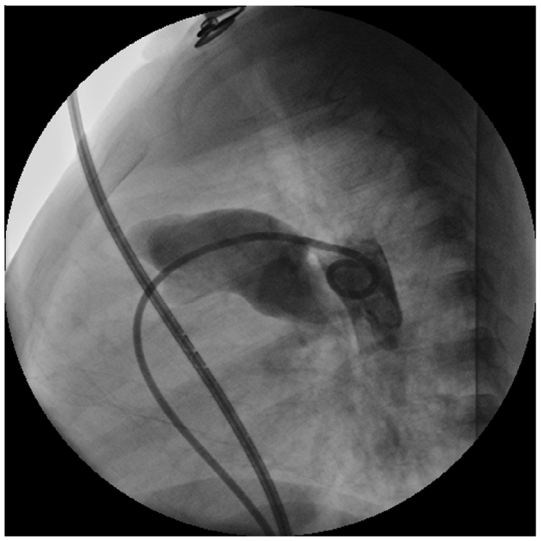

Figure 3. Angiography in lateral view performed with the pigtail catheter introduced through the pulmonary artery and patent ductus arteriosus. The loop of the catheter is placed in the aortic arch.

Statistical analysis

Univariate analyses were performed using SPSS Statistics 17.0 (SPSS, Chicago, IL, USA). The patients' clinical characteristics and outcome were expressed as median and interquartile range for all continuous variables and frequency with percentages for categorical variables.

Results

The demographic and catheterization data of the patients undergoing transcatheter closure of PDA are listed in Table 1. The median pulmonary end of PDAs was 2.4 mm by angiography. The median pulmonary-to-systematic flow ratio was 1.9:1. The mean pulmonary pressure was 28.4 mmHg. The device was successfully deployed in 53 (98.1%) patients.

Twenty-four patients had trace angiographic residual shunt with foaming through the device with contrast jet. On the following day, this foaming leak disappeared completely in all cases.

The median fluoroscopy time was 18 min and the median total procedure time was 47 min (Table 1).

Using the classification adopted by Krichenko et al. [8], 51 patients had type A (well-defined ampulla at the aortic end and constriction at pulmonary artery end), three patients had type E (long with remote constriction), and one infant had type C PDA.

In our experience, ADO I was the most common device used in this study (85.2%). Our protocol in

Table 1. Demographic and catheterization data.

Variable	Median, IQR (range) or Number (%)
Age (months)	10 (IQR 8 to 17)
Sex (M/F)	(15/39) (27.8%/72.2%)
Weight (kg)	8 (IQR 7 to 10)
Genetic syndromes	3 (5.6%)
Intracardiac disease and PDA	5 (9.3%)
Mean pulmonary artery pressure (mmHg)	27 (IQR 23 to 31)
Size of pulmonary end of PDA (mm)	2.4 (IQR 1.8 to 3.5)
Size of aortic ampula of PDA (mm)	8.5 (IQR 7 to 10.5)
Qp/Qs	1.6/1 (IQR 1.5/1 to 2.3/1)
Fluroscopy time (min)	18 (IQR 16 to 23)
Procedure time	47 (IQR 45 to 49)
Follow up duration (months)	34 (IQR 7 to 34)

Qp/Qs: pulmonary to systematic flow ratio.

Table 2. Description of devices used for closure.

Device	*n*	Arterial sheath	Venous sheath
Coil		4- to 5-F	4- to 6-F
Nit Occlud PFM	4		
Detachable Cook	2		
ADO1		4- to 5-F	4- to 7-F
5/4	6		
6/4	23		
8/6	17		
ADO114/6	1	4-F	6-F
MVSD	1	5-F	7-F

ADO: Amplatzer Duct Occluder, MVSD: Amplatzer muscular VSD device.

this study was to use the ADO I in moderate and large PDA, in contrast the Nit-Occlud PFM (Pfm, Cologn, Germany) and detachable Cook coils (Cook Cardiology, Bloomington, IN) were used in small PDA (Table 2). Amplatzer muscular VSD occlude 6 mm used in one children who had PDA type C (Figs. 1 and 2). ADO II was used in one child who had small type A PDA (Figs. 4 and 5).

No patient required blood transfusion. All patients except those who had adverse events, were discharged home 1 day after the closure and no patient had residual shunt on color Doppler echocardiography after 24 h.

Forty-four out of 51 (81.5%) patients had completed 6-month and 12-month follow-up and all patients were found to have complete closure with no evidence of device migration, recanalization, thromboembolic episodes, wire fracture, hemolysis, or endocarditis.

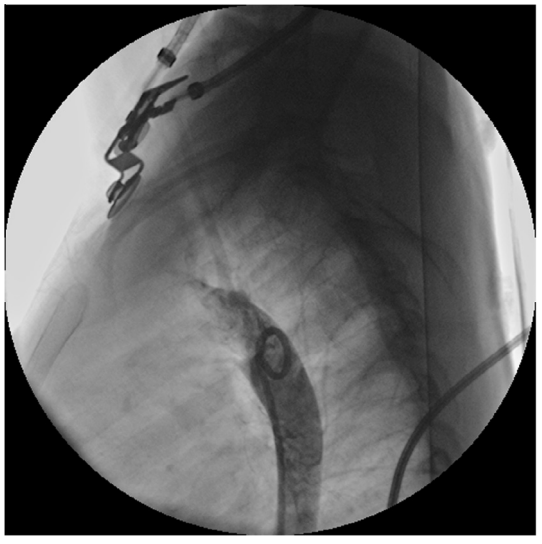

Figure 4. Descending aortogram showing small tubular patent ductus arteriosus size in lateral view.

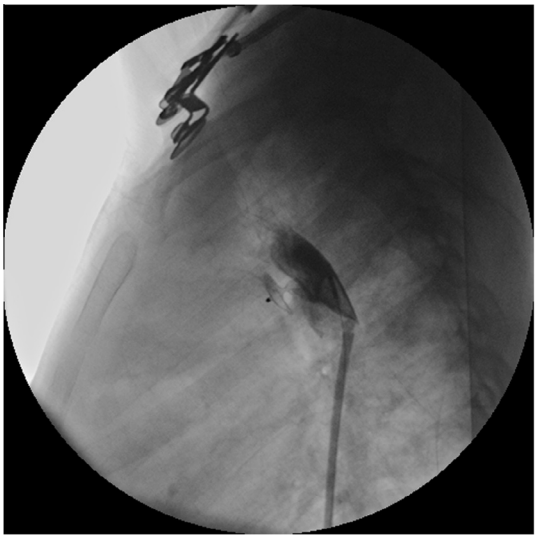

Figure 5. Descending aortogram showing an Amplatzer duct occluder II in the patent ductus arteriosus position with foaming after deployment.

There was no evidence of obstruction of left pulmonary artery, as confirmed by two-dimensional-Doppler echocardiography during follow up. There was flow acceleration in the descending aorta in one patient on follow-up echocardiogram. This patient had large tubular PDA (type C), which was closed using the Amplatzer muscular VSD 6 mm; the patient weighed 6 kg and was noted to have a peak velocity in the descending aorta of 2.8 m/s at the 6-month follow up. This patient continued to be followed as an outpatient without further intervention for 2 years.

Adverse events

We used previously established and tested definitions for adverse event (AE) severity ranging from Level 1 to Level 5. For this analysis, clinically important higher severity AEs were defined as Levels 3, 4, or 5 AEs [9,10]. One patient (1.9%) experienced higher severity adverse events during the procedure with Amplatzer duct occluder embolization to the main pulmonary artery. The patient's weight was 6 kg, age 9 months, and the PDA was closed with ADO I size 8/6 mm without residual shunt in the second aortogram. During release of device, embolization occurred spontaneously. We thought embolization occurred secondary to increased flow through the PDA with possible under-sizing of the device. The patient was referred to surgery for device removal and ligation of PDA. No catheter retrieval was attempt.

There were five infants who had temporary loss of femoral arterial for 2 days, which considered a minor degree of AE (9.8%). They received low

molecular weight heparin and the pulse regained without sequelae.

Discussion

Transcatheter closure of PDA has been the mainstay of treatment in children and adults [11]. Fortescue 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 AEs were 1.5% [12]. There have been only a few minor complications compared with the initial interventional data [13,14]. Nevertheless, 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 54 small children who weighed ⩽10 kg and underwent percutaneous transcatheter PDA closure during a period of 42 months, which was the initial experience of our institution, and found that the high-severity AE rate (Levels 3, 4, and 5) was 1.9% without any mortality.

The success rate of PDA closure was 98% in our experience. This confirms the safety of transcatheter closure of PDA in children weighing <10 kg. In a previous report by Park et al. [17], the median age of 115 patients was 8 months and mean body weight was 7.8 kg. The success rate was 98%, 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%). AEs were more likely to occur in young patients (<6 months), and in patients <6 kg. Among these young patients, there were three high-severity AEs: device embolization, difficulty to arouse after anesthesia and requiring reintubation, and hypotension requiring inotrope support.

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%). Retrospective review of the four implant failures in this study revealed favorable ductal morphology for ADO device occlusion but ADO device was not available.

In our study, the rate of AEs, including high-severity AEs (Levels 3, 4, and 5) was 1.9% in form of ADO embolization and the child was referred to cardiac surgery without retrieval attempt. ADO embolization is a well-known complication, especially in early experience of any cardiac center. The reported rate varies from 0% to 3% [5,6,18–20].

In four patients in the current study, the PDA occluders (ADO I) were implanted using venous access only as the arterial line was not accessible. Based on our experience we preserved this method of implantation when an arterial line was not accessible to avoid vasoconstriction of the duct tissue, which may lead to underestimation of duct diameters. However, this method is effective to avoid postponing the procedure especially when PDA closure is indicated in small children.

In the current study, one infant developed flow acceleration (2.8 m/s) in the descending aorta on a 6-month follow-up echocardiogram. This patient continues to be followed as an outpatient without further intervention for 2 years. However, no late major AEs had occurred such as protrusion of the occlusion device into the aorta or obstruction to the left pulmonary artery, hemolysis, or endocarditis.

A coil is still the preferred device for small PDAs (<2.5 mm) [6,11,21]. In the present study, two types of coil were used: the Nit Occlud PFM coil in four patients and the Detachable Cook Coil in two. The ADO was used in moderate and large PDA. The Amplatzer VSD occluder was used in one infant and ADO II in another with small tubular PDA.

The results documented in our series are in accordance with the results reported by other interventional pediatric cardiac centers [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. Finally, the learning curve for the technique of transcatheter PDA closure in our institution was not conducted in this study.

Conclusion

With the current availability of devices for PDA closure, transcatheter closure of PDA is considered safe and efficacious in small children weighing ⩽10 kg with good mid-term outcome. The procedure had a low rate of high-severity AEs even with the initial experience of a catheterization laboratory.

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