A retrospective study of the patent ductus arteriosus device closure in Assiut University Children Hospital

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Aim
The aim of the study is to demonstrate the experience of Pediatric Cardiology Unit, Assiut University Children Hospital, in the patent ductus arteriosus (PDA) closure, over 2.5 years, as a newly developing center in catheter interventions.

Patients and methods
The study included 47 patients who underwent transcatheter PDA closure at Pediatric Cardiology Unit of Assiut University Children Hospital from March 2014 till September 2016.

Results
Successful closure of the PDA was achieved in 93.6% (44/47) of patients, regarding efficacy (successful closure of the defect without residual shunt) and safety (no deaths or major complications).

Keywords:
amplatzer duct occluder, complications, device, patent ductus arteriosus

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Introduction

Ductus arteriosus is a vascular structure connecting descending aorta just distal to the origin of left subclavian artery in fetal life and forms an important outflow conduit for right ventricular output to circumvent the high resistance pulmonary arterial circulation. After birth, the duct closes functionally in 12–18 h and anatomically in 2–3 weeks. If it remains open beyond 3 months of life in full-term infants and beyond 1 year in premature infants, it is termed persistently patent ductus arteriosus (PDA) because the incidence of spontaneous closure beyond these time limits is very low. Because of low-resistance pulmonary circulation compared with systemic circulation, in postnatal life, now it creates shunting of blood from the aorta to the pulmonary artery [1].

Before the advent of echocardiography, the incidence of clinically evident persistent PDA was reported to be approximately 1 in 2000 births, excluding complex defects with associated PDA. This accounts for ~5–10% of all congenital heart disease. In the modern era, however, children are not infrequently found to have a clinically 'silent' PDA discovered incidentally by echocardiography done for other purposes.

The true incidence may therefore be as high as 1 in 500. The female-to-male ratio for PDA is approximately 2: 1 in most reports, supporting a genetic influence [2].

Transcatheter PDA closure options have expanded significantly since the first report of this approach in 1979 [3]. Since that time, several devices have been used for PDA closure, including coils, vascular plugs, and devices specifically designed for PDA closure [4]. Currently, transcatheter closure is the standard of care beyond the neonatal period. Advances in device and delivery system design are extending the option of nonsurgical transcatheter PDA closure even to very small infants [5].

Aim

The aim of the study is to demonstrate the experience of Pediatric Cardiology Unit, Assiut University Children Hospital, in the PDA closure, over 2.5 years, as a newly developing center in catheter interventions.

Patients and methods

Research design

A retrospective descriptive study was conducted. According to regulations of the University Pediatrics Hospital, guardians of all children undergoing the intervention signed informed consent before the procedure. The Ethical Review Board in Assiut Faculty of Medicine approved the study.

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Duration of the study

The study was conducted for 2.5 years from March 2014 to September 2016.

Inclusion criteria

The following were the inclusion criteria:

All patients admitted for PDA closure in Assiut University Children Hospital from March 2014 to September 2016.

The patients selected for PDA device occlusion weighed 6 kg and above.

The patients had one or more of the following: symptoms and signs of cardiac failure requiring medications, failure to thrive, bounding pulse, cardiomegaly on chest radiography, and at least moderate dilatation of the left atrium and ventricle on two-dimensional echocardiography, and the presence of other intracardiac lesion and genetic syndromes.

Exclusion criteria

Patients were excluded owing to infection, whether chest infection or other site of infection, or excluded from anesthesia owing to being unfit for closure.

We retrospectively analyzed medical records, echocardiographic findings, angiographic findings, hemodynamic data, and adverse events and some follow-up results of the patients if a second intervention was indicated.

The approval of ethical scientific committee at Assiut University Children Hospital was obtained.

Preparation for catheterization

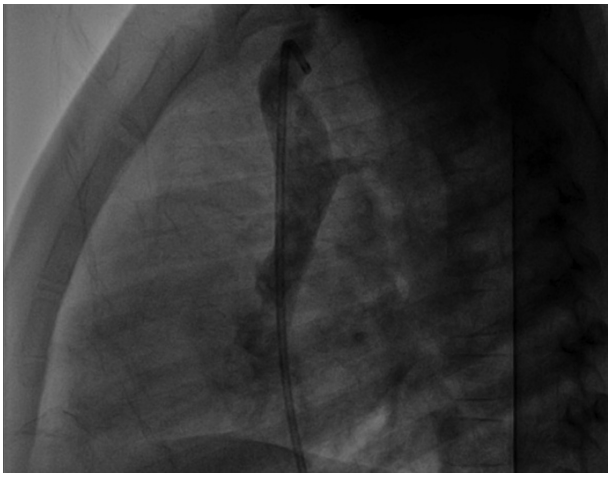
The patients' clinical characteristics (age, sex, and weight) were recorded.

Transthoracic echocardiography (TTE) was done aiming to identify any potential associated lesions, to assess left ventricular volume diameters and functions, to assess PDA size, and finally, to assess pulmonary arterial pressure.

The procedure of PDA closure

Once access (femoral) to both arterial and venous was achieved, heparin was given (100 U/kg). Aortic angiogram in lateral and left anterior oblique views was performed to evaluate the size, position, and shape of the duct for appropriately choosing the occluder device type and size using a 5-Fr pigtail catheter positioned in the proximal descending aorta in the straight lateral view (Fig. 1).

Figure 1



An injection in the arch of aorta to show the PDA size and shape. PDA, patent ductus arteriosus.

Hemodynamic data including pulmonary artery pressure and the pulmonary to systemic flow ratio were recorded if pulmonary pressure elevation was suspected.

A multipurpose catheter such as right Judkins catheter was passed prograde through the ductus to the descending aorta and a guide wire was placed via this catheter with its end in the descending aorta.

An introducer delivering sheath was then exchanged transvenously over the guide wire to the descending aorta.

Devices are manufactured of several sizes. In general, device was chosen so that the diameter at the pulmonary arterial end of the device was 2 mm larger than the narrowest diameter of the ductus (usually the pulmonary end of the ductus).

Thus, the devices used were amplatzer duct occluder types I and II (ADO I and ADO II). ADO I sizes 6/4, 8/6, 10/8, 12/10, and 14/12 were used. ADO II sizes 5/6 and 6/6 were used. Gianturco coil sizes 3/4 and 5/5 were used. The first number refers to the diameter at the device adjacent to the retention disk, and the second number refers to the diameter at the attachment point.

Once loaded on the delivery catheter, the device is delivered by initially deploying only the retention disk and pulling it firmly against the orifice of the ductus and embedding it into the ductal ampulla; the rest of the device is then uncovered within the PDA.

Acine loop was taken if the device appeared in the appropriate location and was not projecting into either the aorta or left pulmonary artery to a significant degree; the device was released in the ductus.

An aortogram was then obtained to confirm appropriate positioning of the device and to evaluate any residual left to right shunting (Fig. 2).

The procedure of coil occlusion

The coil occlusion was done with arterial retrograde approach. An initial angiography was performed with 5-Fr pigtail catheter positioned in the proximal descending aorta in lateral and 20° right anterior oblique projection.

The PDA was crossed by 0.035-inch wire, and a delivery catheter was then advanced over the wire into the main pulmonary artery.

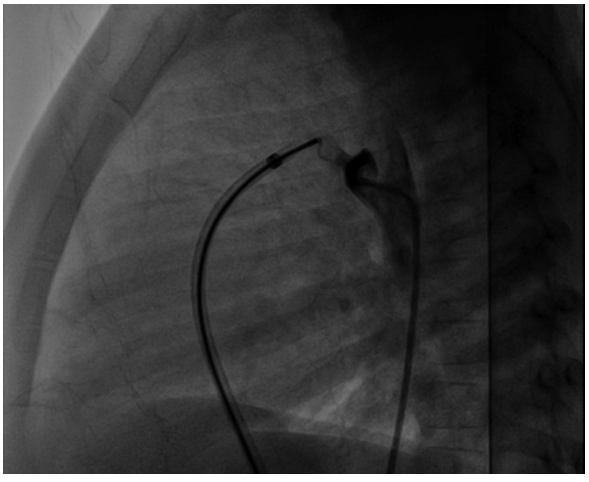
The coil was chosen with a loop diameter that was a minimum at two times the diameter at the narrowest segment of the ductus and the length of coil is suitable to allow for four or five coil loops.

The coil is advanced to the main pulmonary artery and carefully deployed in the PDA under fluoroscopic guidance in lateral view. Half to one loop was extruded at the end of the catheter. The catheter and wire were pulled back together until the distal loop was at the desired position at the main pulmonary artery side of the ductus, and the coil was then delivered with half to one loop at its pulmonary end.

After 10 min, a small hand injection through the end hole catheter documented good positioning of the coil and absence of residual leak.

If arterial access was not achieved, angiography was done by 5-Fr multipurpose catheter with side hole passed antegradely from the pulmonary artery to aorta through the PDA. Angiography was done by placing the tip of the catheter at the junction of the PDA with the aorta.

Figure 2



An injection in the aortic end to exclude big residual shunts and device encroachment from the aortic or pulmonary ends.

The retrograde blood flow into the pulmonary artery from the proximal descending thoracic aorta allows definition of the PDA.

The ductal size was measured and was compared with the echocardiographic measurements. The size of the device was determined by echocardiographic and angiographic measurements.

After deploying the device and before release, angiography was performed through the side part at the long sheath leading to opacification at the main pulmonary artery and visualization of the pulmonary artery end of the device within the PDA–pulmonary artery junction; the aortic arch could be seen in the levo phase, which allowed exclusion of any arch obstruction by the device.

Results

The study included 47 patients who underwent transcatheter PDA device closure, at Pediatric Cardiology Unit of Assiut University Children Hospital from March 2014 till September 2016 (Figs. 3 and 4, Tables 1–6).

Success rate

Successful closure of the PDA was achieved in 93.6% (44/47) of patients with respect to efficacy

Table 1 The demographic data of studied patients (*n*=47)

Age (years)	Range (years)	Mean±SD
	0.5-33	3.2±5.2
Age (years) [*n* (%)]		
<1	11 (23.4)	
1-<7	32 (68.1)	
7-18	3 (6.4)	
>18	1 (2.1)	
Sex		
Male	16 (34)	
Female	31 (66)	
Residence		
Rural	27 (57.4)	
Urban	20 (42.6)	

Table 2 Size of patent ductus arteriosus on echo and size of patent ductus arteriosus on angiography

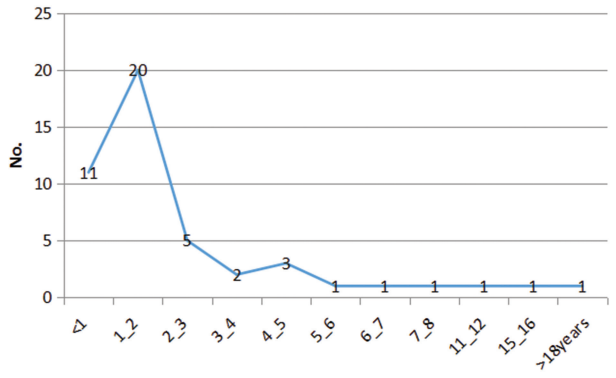
Size of PDA	Range (mm)	Mean±SD
Echo	2-11	4±1.8
Angiography	AO 2.5-26	9.5±4.1
	PA 1-11.7	3.34±2.3

AO, aortic end; PA, pulmonary end; PDA, patent ductus arteriosus.

Table 3 Access arterial or venous or both

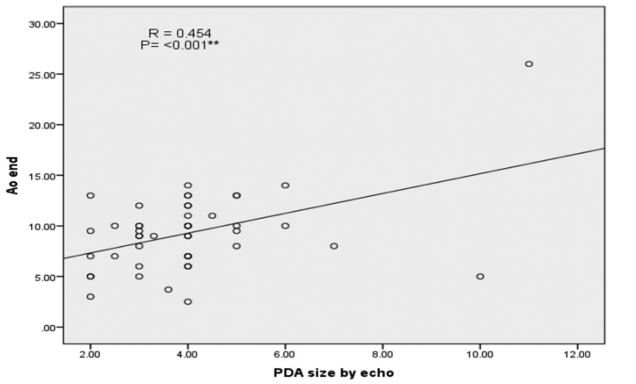
Access	*n* (%)
Arterial only	4 (8.5)
Venous only	9 (19.2)
Both	33 (70.2)
Internal jugular vein	1 (2.1)

Figure 3



Number of cases in each year according to the age.

Figure 4



The correlation between the PDA size by ECHO and size of the PDA by angiography at aortic end.

Table 4 Procedure time and fluoroscopy time

	Range (min)	Mean±SD
Procedure time	30-100	45±12.4
Fluoroscopy time	4.5-45	10.6±6.2

Table 5 Type and size of device used

Type of device	Size of device	Number
ADO I	6/4	11
ADO I	8/6	24
ADO I	10/8	3
ADO I	12/10	1
ADO I	14/12	1
ADO II	5/6	3
ADO II	6/6	1
COIL	3/4	1
COIL	5/5	2

ADO, amplatzer duct occluder.

Table 6 The correlation between the patent ductus arteriosus size by echo and size of the patent ductus arteriosus by angiography at aortic end and at pulmonary end

	PDA size by echo
AO end	
R	0.454**
P	0.001
PA end	
R	0.315*
P	0.031

AO, aortic end; PA, pulmonary end; PDA, patent ductus arteriosus.**Correlation is significant at the 0.01.*Correlation is significant at the 0.05 level (two-tailed).

(successful closure of the defect without residual shunt) and safety (no deaths or major complications).

Complications during the procedure

Complications occurred in three cases: the first case had residual shunt and was closed later on by coil. The second case arrested during the procedure, Cardiopulmonary resuscitation (CPR) was done, and the patient returned alive; this was explained as the heart stunned owing to big PDA closure, so the device was retrieved, and the patient was stabilized, and his PDA closed successful after 6 months. The third case had embolization of the device that was left with no acute or long-term consequences identified.

Follow-up

Follow-up of all patients was done clinically and by TTE on the second day of the procedure, 1 week, 1 month, and 6 months after the procedure, and the patients were going well with prompt PDA closure with no residual blood flow across the device; follow-up by TTE was done once per year, but there was no compliance by the patients.

Discussion

In this study, 47 patients with the PDA were included. There were 16/47 (34%) males and 31/47 (66%) females. This was in agreement with Ali and El Sisi [6], where 72.2% of the patients were female and 27.8% of the patients were male, and Devanagondi *et al.* [7], who had 103 patients, and the patients were mostly female, [*n* = 84 (82%)', although there is no documentation why there is increased incidence of PDA in female than male.

The number of the studied patients under 1 year of age was 11/47 (23.4%), those aged from 1 to less than 7 years represented 68.1%, those aged from more than 7–18 years represented 6.4%, and those aged more than 18 years represented 2.1%. The youngest age was 6 months, and this age was suitable for Assiut University Children Hospital intervention, because at this age, the weight of the patient was 6 kg, which was suitable for the procedure to avoid complications mainly with the access. This agrees with El-Said *et al.* [8] where they found that complications of the procedure increased with smaller weight of the patients especially the complications of the access.

The transcatheter approach is limited in low-body-weight infants because of sheath size, stiffness of the delivery system, protrusion risk of the device in the left pulmonary artery or aorta, and technical difficulties for device retrieval if needed [9].

Most patients in this study aged from 1 to 2 years, representing 42.5% of the patients. Some studies chose to have less age up to neonatal period, such as Morville and Akhavi, who had a total of 31 PDA successful closures performed in 32 neonates. Their mean ± SD gestational age at birth was 28 ± 3 weeks (range, 23 weeks 1 + 4 days–36 weeks), and the mean birth weight was 1054 ± 406 g (range, 530–2080 g). The mean weight at procedure was 1373 ± 535 g (range, 680–2380 g); 10 neonates weighed less than 1001 g. The mean age at procedure was 25 days (range, 8 days–9 weeks) [10]. Thanopoulos *et al.* [11] reported that the age of the patient ranged from 2–24 months. Francis *et al.* [12] had eight preterm infants who underwent coil closure of PDA, with gestational age was 28 ± 1.9 weeks with a range of 27–32 weeks. Backes *et al.* [13] studied PDA transcatheter closure in preterm infants, and the age of all infants was more than 28 days at the time of catheterization, with more than half (27/52, 52%) older than 2 months.

In this study, the access was successful through both arterial and venous approach in 33 (70.2%) of cases, but closure was achieved by venous access only in nine (19.2%) of cases, arterial access only in four (8.5%) of cases, and internal jugular venous access was used in one (2.1%) case after failure of femoral access. This case was a female patient aged 9 months, and her weight was 8 kg. The PDA size by echo was 2.5 mm, and ADO I size 6/4 was used. This was in line with a recent case report study by Fernandes *et al.* [14], where they reported a case of successful occlusion of PDA using ADO via trans-jugular approach following difficulties encountered in gaining femoral venous access.

Venous access was used only when arterial access failed; avoiding the arterial access by single venous approach could eliminate nearly all possible complications associated with arterial puncture: occlusion, embolism, dissection, pseudoaneurysm formation, and bleeding. However, the lack of precise angiographic imaging immediately before the deployment of the device makes it tough method; good echocardiographic image is sufficient for the safety of the procedure [15].

Liu *et al.* [15] reported that, among the total 1088 children, transcatheter closure of PDA was accomplished through single venous approach in 686 cases.

Moreover, the advantages of avoiding arterial access include avoiding heparinization thereby potentially accelerating flow elimination across the duct and elimination of inherent risks of arterial puncture (bleeding and femoral artery thrombosis). The procedure is considerably short as indicated by the short fluoroscopy time, and many patients can potentially be discharged early [16].

Procedure time range was 30–100 min, with mean ± SD of 45 ± 12.4 min. Fluoroscopy time range was 4.5–45 min, with mean ± SD of 10.6 ± 6.2 min. This is in agreement with Thanopoulos *et al.* [11], where the mean procedural and fluoroscopy times were 44.2 ± 7.8 and 6.2 ± 4.5 min, respectively. Ali and El Sisi [6] reported that the mean procedural and fluoroscopy times were 47 and 18 min, respectively.

In this study, the most used device in closure of PDA in the studied cases was ADO. This is in agreement with Baruteau *et al.* [17], where the ADO was approved in children aged more than 6 months and weighing more than 6 kg; it was placed with an antegrade approach and was usually used for PDAs more than 2 mm with a sufficient aortic ampulla. Both venous and arterial femoral accesses were usually needed, for device progression and simultaneous angiographic controls, respectively.

In this study, the ADO I was used in most cases because of the availability of the device, and it is cheaper in comparison to ADO II, although the ADO II is more flexible than the ADO I and the symmetrical design of the ADO II permits its delivery by either a venous or arterial approach [17].

The ADO II was used in four cases: in two cases, device was used because of the access was arterial and there was no available coil, whereas in the other two cases, device was used because the size of PDA is small.

The cook detachable coil is the most cost-effective device for closure of small- to medium-sized PDAs. Calculations of the incremental cost-effectiveness revealed that the Cook detachable coil had less incremental cost-effectiveness than the ADO II. Despite the versatility of the ADO II and its smaller caliber delivery systems, its use was correlated with a higher complication rate. The device's flexible configuration has negative effects [18].

Coil was used in closure of PDA in three cases where the PDA size was less than 2.5 mm, and the type of the coil used in this study was Gianturco Coil.

Francis *et al.* [12] used coil occlusion with a 3-Fr delivery system in eight infants weighing less than

2 kg (range, 930–1800 g). Complete PDA occlusion was obtained in all, without major procedure-related or access-related complications, leading some to consider coil occlusion as a feasible and safe strategy in selected symptomatic preterm infants and in experienced hands.

In this study, it was found that there were significant positive correlations between the PDA size that was measured by echo and the size of the PDA that was measured by angiography at aortic end (r = 0.454, P = 0.001) and at pulmonary end (r = 0.315, P = 0.031), and there were significant positive correlations between the PDA size that was measured by echo and the size of the PDA device that was used (r = 0.382, P =0.020). This explains the importance and the efficacy of echo in helping decision of PDA closure for size and the choice of the device. This is in line with recent studies that examined the use of echo in PDA catheter closure in comparison with the use of the fluoroscopy. Pan *et al.* [19] studied 100 patients who were randomly assigned in a 1: 1 ratio to TTE group (n = 50) or to fluoroscopy group (n = 50), and the success rate of occlusion for the TTE group was 98 and in the fluoroscopy group was 100%.

Complications occurred in three cases. The first case had residual shunt and was closed later on by coil. The incidence of residual shunt was 2.1%, and this was a lower incidence than other studies. Behjati-Ardakani *et al.* [20] reported that immediately after release of the device, descending aortogram showed residual shunt including foaming through the wire mesh of the device in 171 (70.4%) patients, small residual shunt in 32 (13%) patients, and moderate residual shunt in three (1.2%) patients.

The second case arrested during the procedure, CPR was done, and the patient return alive; this was explained as the heart stunned owing to big PDA closure, so the device was retrieved, and patient stabilized, and his PDA was closed successful after 6 months.

The third case had embolization of the device that was left with no acute or long-term consequences identified. The incidence of device embolization was 2.1%. This is similar to Amoozgar *et al.* [21], who reported 2.7% incidence of device embolization during the procedure. Younas and Beg [22] and Beg *et al.* [23] reported no incidence of device embolization with PDA device closure.

In this study, successful closure of the PDA was achieved in 93.6% (44/47) of patients. This is in line with the other studies such as Pavlek *et al.* [24], who had success closure rate of 94.4%. Moreover, Backes *et al.* [25] in a recent meta-analysis that included 38 studies encompassing 635 infants reported that technical success rate with catheter-based PDA closure was 92.2%.

Conclusion

Transcatheter closure of PDA is considered safe and efficacious in children weighing 6 kg with good outcome, with the current availability of devices for PDA closure. The procedure had a low rate of high-severity adverse events even with the initial experience of a catheterization laboratory. Several devices are being evolving to easily access and variety in the shape of the PDA.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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