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Transcatheter closure of patent ductus arteriosus, evaluating the outcome: Single center experience in Mansoura, Egypt

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ABSTRACT

Device closure is considered the treatment of choice for patent ductus arteriosus (PDA). The study presents our experience in transcatheter occlusion of PDA using three different devices between January 2008 and December 2016. The immediate and short-term outcome of 213 pediatric patients with PDA underwent PDA occlusion were analyzed. Aortic angiography was done to evaluate the size, position, and shape of the duct for proper device selection. A second aortic angiography was performed 10 min after device deployment. Echocardiography was repeated at intervals of 24 h, then at one, three, six and 12 months after the procedure to assess the presence of any complications. The mean age of patients was 9.2 ± 5.2 months and their mean weight was 7.6 ± 1.8 kg. Mean PDA diameter at its narrowest point measured by angiography was 2.81 ± 0.51 mm. Nit-Occlud pfm Coil occlusion was performed in 107 (50.2%) patients, Amplatzer ductal occluder was performed in 84 (39.4%) and Nit-Occlud PDA-R was performed in 22 (10.3%). Complete closure was observed in 95.7% of patients prior to discharge and this rate has reached 98.5% after three months of follow up and increased to 100% at 6 and 12-months visits. There was no significant difference regarding the outcome for each of the three devices prior to discharge and at 3 months follow up ($p = 0.9974$ and 0.9729, respectively). Limited complications were reported (e.g. aortic protrusion, mild LPA obstruction, significant blood loss) which were related mainly to the use of large devices (e.g. ADO-1) deployed over large diameter sheaths in young children with small body weight. *In conclusion*, percutaneous transcatheter closure of PDA technique using Nit-Occlud pfm coils, Amplatzer ductal occluder and Nit-Occlud PDA-R is proved to be safe and effective, with limited complications and non-significant hemodynamic consequences.

1. Introduction

The percutaneous transcatheter closure is generally considered as the treatment of choice for patients diagnosed to have patent ductus arteriosus (PDA). Since the primary experience of PDA device occlusion by Porstmann et al. [1], technical advances throughout the years have increased the number of patients who had effective device closure [2,3]. Different techniques for coil occlusion have been developed [4,5]. Other types of occlusion systems, especially the Amplatzer duct occluder (ADO-I) have been accepted worldwide as a safe effective device [6,7].

2. The Aim of the Study

The aim of the study is to analyze the immediate short-term outcome of transcatheter occlusion in patients with PDA in a single center in Egypt in an attempt to provide an evidence for feasibility, safety, and viability of PDA closure using different devices.

3. Patients and Methods

3.1. Subjects

A total of 213 patients, who were planned for catheter occlusion of PDA at Mansoura University Children Hospital- Mansoura – Egypt, were enrolled in this study. Male to Female ratio was 116 (54.46%) to 97

Abbreviations: PDA, Patent ductus arteriosus; ADO-I, Amplatzer duct occluder; VSD, ventricular septal defect; ASD, atrial septal defect; PVRI, irreversible pulmonary vascular obstructive disease; LPA, left pulmonary artery

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(45.54%). Their age ranged from 4 to 36 months (9.2 ± 5.2) and their weight ranged from 5 to 12 kg (7.6 ± 1.8). They underwent successful transcatheter PDA closure between January 2008 and December 2016. Selection criteria for transcatheter ductal closure included patients with hemodynamic significant ductus with increased left ventricular diastolic dimensions, patients had bounding pulsation, and their weight ≥5 kg. Patients with a small ventricular septal defect (VSD), small atrial septal defect (ASD), congenital aortic valve stenosis and congenital valvular pulmonary stenosis were also incorporated in the study. Patients with tiny PDA without murmur and bounding pulse, PDA of complex ductal anatomy, PDA associated with complex cyanotic heart defects, PDA associated with a hemodynamically significant intracardiac shunt, and those with irreversible pulmonary vascular obstructive disease (PVRI > 7 WU·m2) were excluded from the study. The Institutional Review Board of Mansoura University Children Hospital approved the study (proposal code: R.18.07.238). Written informed consent was obtained from the family or the legal representative of the patients participating in this study. We obtained all the medical records (age, sex, and weight), echocardiographic data, angiographic data, hemodynamic information and follow-up results of these patients.

3.2. Echocardiographic Parameters

Echocardiography was performed using (SONOS-5500; Hewlett Packard, Andover, MA, USA) with an 8 MHz probe and Philips iE33 X matrix echocardiography machine (Philips Medical Systems, Bothell, WA, USA 2012 equipped with 8 and 5 MHz probes incorporating color flow, pulsed wave, continuous wave Doppler. Echocardiography was used to affirm the ductal left to right shunt, the narrowest diameter of PDA, the pressure gradient at the left pulmonary artery (LPA) and aortic arch.

3.3. Cardiac Catheterization Parameters

The procedure was done under general anesthesia. Both venous access and arterial femoral access were obtained. Full hemodynamic assessment was done with recording of pulmonary artery pressure and calculation of pulmonary blood flow ratio to systemic flow (Qp/Qs ratio) in each patient. The angiographic evaluation was done after crossing the PDA. Angiograms were obtained via pigtail catheter 4F or 5F in descending thoracic aorta. Standard lateral view 90° and right anterior oblique 30° (RAO) views were used for good visualization of PDA morphology and size. After accurate assessment of the size and morphology, PDA was closed by standard technique using the appropriate device. The method of coil or device implantation has been described in detail previously [8]. We used the antegrade method through the main pulmonary artery for device deployment. The cardiac catheterization data were recorded and included the maximum ductal size at the narrowest diameter, the ductal shape, type of the device, the fluoroscopy time and the total procedure time. We used the Nit-Occlud® (*pfm* AG, Cologne, Germany) for patients with PDA narrowest diameter < 2.5 mm and Amplatzer duct occluder® (ADO-I, AGA Medical Corp., Plymouth, MN, USA) or the Nit-Occlud® PDA-R (NOPDA-R; *pfm* Medical) for patients with PDA narrowest diameter > 2.5 mm [9]. A few exemptions to this rule had to be made according to the devices availability during the procedure time. The length and diameter of the coils used were double the PDA length and diameter. The ADO-I sizes used were 2 mm more than the narrowest PDA diameter. A repeat angiogram after the device placement was done to detect any residual leak of the contrast through the ductus. The device is released after the exclusion of significant obstruction in the aorta or left pulmonary artery (LPA). The decision for second coil deployment was made after documenting significant residual shunt following the installing of the first coil. Patients with associated congenital pulmonary valve stenosis and congenital aortic valve stenosis were subjected to balloon valvuloplasty before PDA device closure. One dose of Cefazolin (25 mg/kg/dose) was administered intravenously immediately prior to the procedure. Procedural complications were investigated and included device embolization, failure of device deployment, residual leak, aortic arch obstruction, LPA obstruction, and significant blood loss.

3.4. Follow up Protocol

All patients had scheduled follow up according to a strict protocol. Chest radiography and Doppler echocardiography were done 24 h after the intervention to assess the position and shape of the device. Echocardiography was repeated at intervals of 1, 3, 6 and 12 months after the procedure and afterwards every year from there on.

3.5. Statistical Analysis

Data were analyzed using the Statistical Package for Social Science program (SPSS version 15.0 for windows; SPSS, Chicago, IL, USA). The descriptive statistical analysis of the quantitative variables was done by calculation of the median, mean, and standard deviations. Categorical data were presented as frequencies. The complete closure rate difference and the percentage of successful/failure outcomes between the three devices on the total procedure time were compared using the Chi-square test.

4. Results

Table 1 shows demographic and clinical information of the patients included. The study included 213 patients; 116 males (54.4%) and 97 females (45.6%). Their mean age was 9.2 ± 5.2 months (ranged from 4 to 36 months), and their mean weight was 7.6 ± 1.8 kg (ranged from 5 to 12 kg). PDA narrowest diameter measured by 2-D echocardiography was 2.60 ± 0.32 mm (range 2.5–4.5 mm). PDA was exhibited as a single lesion in the 132 patients (61.9%). Associated cardiac lesions included small ASD in 55 patients (25.8%), small insignificant VSD in 14 patients (6.6%), congenital pulmonary valve stenosis in 10 patients (4.7%), 6 (2.82%) of them had concomitant balloon valvuloplasty at the time of PDA closure and congenital aortic valve stenosis in 2 patients (0.95%) who also had concomitant balloon valvuloplasty at the session of PDA closure.

Table 2 shows the catheterization data for the study population. Femoral artery access was used in the 213 patients (100%), femoral vein was the access in 211 patients (99.1%) and in 2 patients (0.94%) jugular vein was used after difficulty in obtaining access. The ductal types in our series based on the angiographic classification as suggested by Krichenko et al. [10] were as follows: Type A (conical) in 198 patients (93%); Type B (window) in 13 patients (6.1%); Type C (tubular) in 2 patients (0.9%). The mean PDA diameter at its narrowest point measured by angiography was 2.81 ± 0.51 mm (ranged from 2.2–4.3 mm), the mean length was 7.13 ± 1.16 mm (ranged from 4.6–9.1 mm) and the mean diameter of the aortic ampulla was

Table 1
Demographic and clinical data of the patients.

Patients	n = 213
Age (months)	9.2 ± 5.2[a]
Male ratio (%)	54.4% (116)
Weight (kg)	7.6 ± 1.8[a]
PDA narrowest diameter by 2-D echo (mm)	2.60 ± 0.32[a]
Associated lesions	No. (%)[b]
Isolated lesion	132 (61.9%)
ASD	55 (25.8%)
VSD	14 (6.6%)
Pulmonary valve stenosis	10 (4.7%)
Aortic valve stenosis	2 (0.9%)

[a] Data was expressed as mean ± standard deviation.
[b] Data was expressed as percentages, frequencies.

Table 2
Catheterization data for the study population.

Catheterization data	No. (%)
Vascular access (N. and %)[a]	
- Femoral vein	211 (99.1%)
- Jugular Vein	2 (0.9%)
- Femoral artery	213 (100%)
Ductal morphology at angiography (N. and %)	
- Type A (conical)	198 (93%)
- Type B (window)	13 (6.1%)
- Type C (tubular)	2 (0.9%)
PDA dimensions (angiography) (mm)[b]	
- Narrowest pulmonary end	2.81 ± 0.51
- Aortic end (ampulla)	9.32 ± 1.42
- PDA length	7.13 ± 1.16
Qp/Qs ratio[b]	2.2 ± 0.27
Pulmonary artery Mean pressure (mm Hg)[b]	21.5 ± 4.41
Device used (N. and %)	
- Nit-Occlud pfm coil	107 (50.2%), {55 males (25.8%), Bw
● Single coil	(7.8 ± 0.9) kg}
● Double coil	−104/107 (97.2%)
- ADO-1	−3/107 (2.8%)
- Nit-Occlud PDA-R	84 (39.4%), {48 males (22.5%), Bw (5.6 ± 1.3) kg}
	22 (10.3%), {13 males (6.1%), Bw (6.9 ± 1.5) kg}
Fluoroscopy time (minutes)[c]	9.11 (7–25)
Total procedure time (minutes)[c]	49 (28–79)

[a] Data were expressed as frequencies and percentages.
[b] Data were expressed as mean and standard deviation.
[c] Data were expressed as median and interquartile range.

9.32 ± 1.42 mm (ranged from 6 to 12 mm). The mean Qp/Qs ratio was 2.2 ± 0.27 (ranged from 1.5–2.6) and the pulmonary artery mean pressure was 21.5 ± 4.41 mmHg (ranged from 13 to 29 mm Hg).

Nit-Occlude *pfm* occlusion was performed in 107/213 patients (50.2%); single Nit-Occlud *pfm* coil closure was done in 104/107patients (97.2%) (Fig. 1) and double coil closure was done in 3/107 patients (2.8%); all the 107 patients were of type A (conical) morphology. The ADO-I closure was performed in 84/213 patients (39.4%) (Fig. 2); 82 patients have type A (conical) and 2 patients have the type C (tubular). Nit-Occlud PDA-R closure was performed in 22/213 patients (10.3%); 9 patients have type A (conical) and 13 patients have type B (window). The median fluoroscopy time was 9.11 min (ranged from 7 to 25 min) and the mean total procedure time was 49 min (ranged from 28 to 79 min). Devices implantation was performed in 100% of cases.

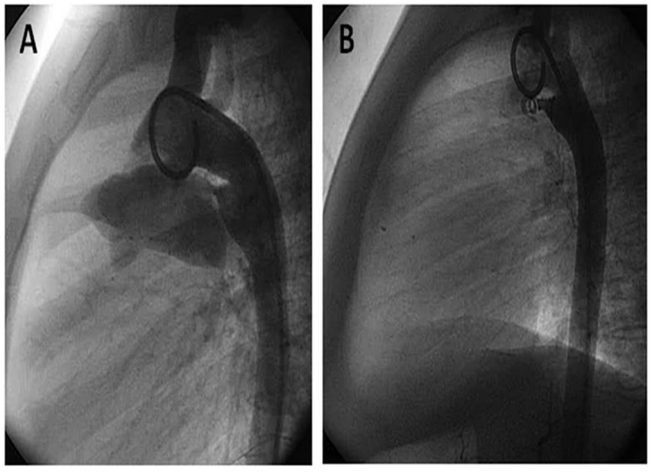

Fig. 1. Aortograms in the lateral view before (A), and after (B) implantation of PFM Nit-Occluded®.

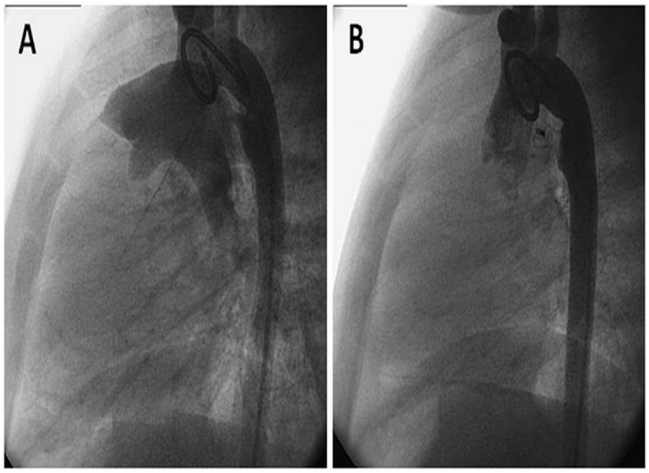

Fig. 2. Aortograms in the lateral view before (A), and after (B) implantation of 8/6 mm Amplatzer duct occluder®.

Table 3
Complications of the procedure and their rates.

Types of complications	No. (%)[a]
Device embolization	
● Nit-Occlud pfm coil	1 (0.46%)
Residual shunt at the end of the procedure	
● Nit-Occlud pfm coil	5 (2.3%)
● ADO-1	3 (1.4%)
● Nit-Occlud PDA-R	1(0.46%)
Aortic protrusion	
● Nit-Occlud pfm coil	1 (0.47%)
● ADO-1	2 (0.93%)
● Nit-Occlud PDA-R	0 (0%)
LPA[b] obstruction	
● Nit-Occlud pfm coil	0 (0%)
● ADO-1	2 (0.93%)
● Nit-Occlud PDA-R	0 (0%)
Blood transfusion	4 (1.8%)

[a] Data was expressed as frequencies.
[b] LPA (Left Pulmonary Artery).

Table 3 shows the complications encountered in our patients. Embolization of one coil (0.49%) occurred to the distal branch of LPA 5 min after the deployment. It did not cause any degree of occlusion and was retrieved safely using snare catheter.

Residual shunt occurred in 5 patients (2.3%) after single Nit-Occlud *pfm* coil closure immediately at the end of the procedure. Three patients only required another coil deployment in the same setting (Fig. 3). Three patients with ADO-I and one patient with Nit-Occlud PDA-R had a minimal residual leak at the end of the procedure and the whole patients showed complete improvement at 3 months follow up period after the procedure.

Projection of the occluding device into the aorta was encountered in 3 patients; one patient with double Nit-Occlud pfm coils (0.47%) and two patients with ADO-I (0.93). Mild LPA obstruction occurred in 2 patients with ADO-I occlusion (0.93%). None of the patients showed LPA obstruction with Nit-Occlud *pfm* coil or Nit-Occlud PDA-R. Four patients had significant blood loss requiring blood transfusion after the technique (1.8%). These complications were related mainly to the use of large devices (e.g. ADO-1) deployed over large diameter sheaths (size 6 & 7) in young children with small body weight. All patients were discharged home the next day.

By follow up; an improvement of device protrusion into the aorta occurred in one patient with a coil at 12-months follow-up period. No changes could be observed in patients with mild LPA obstruction at 1, 3, 6 or 12 months follow-up.

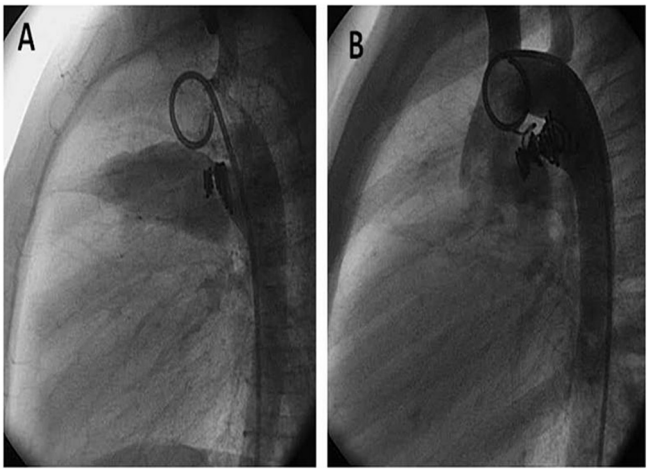

Fig. 3. Aortograms in the lateral view showing significant residual leak after single PFM Nit-Occluded (A), and after (B) implantation of second coil.

Assessing the closure rate in our study; complete closure was observed in 204 of the patients (95.7%) prior to discharge as seen by color Doppler echocardiography. This rate has increased to 210 patients (98.5%) after 3 months period of follow up and increased to 213 patients (100%) at 6 and 12-months visits. Table 4 shows the closure rate for each device; prior to discharge, after 3, 6, and 12 months follow up; with no significant difference between them.

5. Discussion

The closure of hemodynamically significant PDA is considered now a standard practice either surgical or interventional to guard against high pulmonary blood flow [11–16]. The first surgical ductal ligation was in the 1930s by Gross and Hubbard [15]. It was considered the treatment of choice until the catheter closure emerged. Nevertheless, ductal ligation is still reserved for either premature babies with PDA that does not respond to pharmacological closure or in cases with ductal diameter exceeding 14 mm [17]. The first device closure of PDA was done in the late 1960s by Portsman et al. [1] followed by Rashkind et al. [18] in the late 1970s. Thereafter, it was gradually spreading all over the world [12–15].

Transcatheter device closure of PDA is considered a safe procedure that has no mortality and low morbidity with closure rate exceeding 94%, and the major events were only in 1.5% of cases [19]. Over the past four decades, different coils, devices, and procedures have been introduced. Yet, there is still no general consensus for selection of the best coil, device and technique in terms of safety, efficacy, and cost-effectiveness for percutaneous PDA occlusion. Part of the explanation lays on the variability of ductal morphologies and sizes to preclude the use of a single coil or device for closure. Furthermore, there has been off-label use of devices that were not specifically designed for this lesion and are utilized either in very unusual ductal anatomies or in patients with high pulmonary artery pressures [20,21].

Our study is basically centered upon the clinical outcome using Nit-Occlud *pfm* Coil®, ADO-I or Nit-Occlud PDA® for device ductal closure in children weighing between 5 and 12 kg. Successful complete ductal closure was accomplished in 98.5% of the patients by 3 months after the procedure. This affirms the efficacy of device closure of PDA in children. The main factors for a successful procedure are vascular accessibility, suitable ductal morphology, different device availability, and imaging methodology [22].

In this study, 198 of the patients (93%) have Type A (conical) ductus, which is more suitable for device closure as suggested by Krichenko et al. [10], Type B (window) in 13 patients (6.1%) and Type C in 2 patients (0.9%). We excluded Type D and Type E due to non-availability of different devices like Amplatzer septal occluder (ASO) and Amplatzer ductal occluder-II (ADO-II) in our catheterization laboratory at the time of the procedure.

Our strategy is to close the ductus using a coil if the ductal narrowest diameter is ≤2.5 mm; otherwise, it is closed by ductal occluder device. We utilized the Nit-Occlud *pfm* coil in 50.2% of the cases with complete successful closure was achieved in the majority of patients and the rate of significant residual shunt was 2.3% at the end of the procedure. Second coil deployment was achieved in three patients in the same interventional session due to significant residual leak after the first coil deployment. The remaining 2 patients showed complete resolution of the leakage at 6 months follow up visit. This leakage may be due to inappropriate sizing of the ductus and using relatively smaller coils. Disposal of the residual leak is very important to counteract haemolysis [23,24].

The use of the Nit-Occlud coil exhibits high levels of efficacy and associated with low level of adverse effects and no mortality. In 2001, the European PDA Registry retrospectively reported on 1291 PDA coil occlusion procedures [25]. The procedure success was 94.3% in patients with PDA smaller diameter 6 mm and the adverse events rate was around 10%. In 2013 the U.S. FDA [26] documented that, with the use of Nit-Occlud *pfm* coil, the 12-month clinical closure rate was 98.1%, the 12-month echocardiographic closure rate was 96.8% and the 12-month serious adverse event rate was 0%. In a most recent patients series done by Moore et al. [27], they reported that, out of 314 patients who presented, 308 (98.1%) had no PDA murmur clinically and 309 patients having Doppler echocardiography, 299 (96.8%) had no residual shunt at one year follow up.

The decision for utilizing ADO-I or Nit-Occlud PDA-R depends on the availability of the device in the catheterization laboratory during the procedure. The ADO-I closure was performed in 84/213 patients (39.4%), and Nit-Occlud PDA-R closure was performed in 22/213

Table 4
The closure rate and outcome for each device; prior to discharge, after 3, 6, and 12 months follow up.

	Nit-Occlud pfm coil (Total = 107 patients)		Amplatzer ductal occluder (Total = 84 patients)		Nit-Occlud PDA-R (Total = 22 patient2)		p-Value
	No.	%	No.	%	No.	%	
Prior to discharge							
Complete closure[a]	102	95.32	81	96.43	21	95.45	0.9974
Residual shunt	5	4.67	3	3.57	1	4.55	
At 3 months follow up							
Complete closure[a]	105	98.13	83	98.81	22	100	0.9729
Residual shunt	2	1.87	1	1.19	0	0	
At 6 & 12 months follow up							
Complete closure[a]	107	100	84	100	22	100	–
Residual shunt	0	0	0	0	0	0	

[a] Data were expressed as percentages and frequencies. The outcome of the 3 devices was compared using the Chi-square test.

patients (10.3%). Complete implantation achieved in 100% of patients with both devices, no patient had embolization with both devices. We compare the efficacy and safety of the two used devices. The rate of the residual leak was very low with both devices. Three patients with ADO-I and one patient with Nit-Occlud PDA-R had a minimal residual leak at the end of the procedure, which disappeared within 3 months after the procedure when evaluated by echocardiography during the routine follow-up period. In a recent prospective multicenter study from Argentina, the use of Nit-Occlud PDA-R in 43 patients showed trivial residual shunt was observed in 42% at the end of the procedure, in 28% at 24 h, in 12.1% at one week, and none at three months [28].

A significant complication of percutaneous closure of PDA is a device embolization [2,3,29–33]. We encountered only one coil embolization to the distal branch of the LPA 5 min after its deployment without significant obstruction and was retrieved safely. This embolization may be related to the choice of a relatively smaller sized coil. We believe that careful coil selection with an appropriate size is the most critical step during this procedure. The undersized coil can result in residual shunting or embolization. Moreover, an important concern with most devices is the possible irretrievability during implantation process resulting in the need for a transcatheter or surgical removal of the device. A noteworthy point of interest regarding ADO-I over the coil is that it can be effortlessly withdrawn into the delivery sheath and redeployed many times before the final release.

Projection of the occluding device into the aorta is a common complication of device closure of PDA [34,35]. Protrusion into the aorta occurred in two patients with ADO-I closure (0.93%), while this was not observed with Nit-Occlud PDA-R. Only one patient with double coils showed mild protrusion into the aorta without causing significant obstruction to the flow. The main reason was a shallow aortic ampulla which did not accommodate all released coils loops. The improvement was observed after 12-months follow up. The duct morphology has a great role in the development of this complication. The primary reason was the size of the Amplatzer retention disc, which was larger than the size of the ductal ampulla in these two patients. However, this degree of protrusion didn't affect the peak to peak pressure gradient between ascending and descending aorta measured at the end of the procedure or Doppler estimated pressure gradient during the routine follow-up. This complication was observed particularly in patients with Type C ductus. We expect that this sort of mild aortic obstruction will improve gradually with further growth of the child. Moysich et al. [36] postulated that the aortic retention disc will not cause obstruction because of the reverse development of the device. The proximal parts of the retention disc delivered first and folding back on themselves forming a very thin aortic disc. This could explain the absence of aortic protrusion with Nit-Occlud PDA-R in our patient series.

Obstruction to the LPA is another common complication of the technique [25,26]. The reported rate of LPA stenosis varies, between 0 and 12% [31,35,37]. We encountered mild LPA obstruction in two patients (0.93%) with ADO-I occlusion and this was not observed with Nit-Occlud PDA-R nor with Nit-Occlud *pfm* coil in our study. This obstruction degree did not compromise the distal flow pattern. None of them had clinical manifestations, and the Doppler estimated pressure gradient was 22 mm Hg during the serial follow-up. None of the patients showed an improvement of mild LPA obstruction throughout the follow-up period up to one year. This problem has been questioned by Kharouf et al. [38]. and according to their experience, patients undergoing PDA device occlusion should be investigated using lung perfusion radionuclide scintigraphy to assess the left lung perfusion. They reported a critical risk of decreased perfusion to the left lung after device occlusion of the PDA, although most of the lesions were graded as mild. No correlation was found comparing this finding with echocardiographic data or hemodynamic direct measurement. They believe that Doppler echocardiography may not be an accurate tool for identifying LPA obstruction caused by devices. In the current study, we did not evaluate the lung perfusion in patients with LPA obstruction using lung perfusion radionuclide scintigraphy.

Other complications including infective endocarditis, haemolysis, and nickel hypersensitivity are rare after device implantation [3]. Femoral vessel thrombosis, haemolysis and infective endocarditis were not encountered in our patients. Our outcomes and complications are comparable to the results reported previously in different interventional pediatric cardiac centers worldwide [39–41]. The low rate of complications in our patient series confirms the safety of catheter closure of ductus arteriosus in children.

The radiation dosage is especially relevant while treating kids. The growing tissues are more sensitive to radiation and may develop a malignancy later in life. Additionally, a larger body surface area of the child is exposed to radiation at the time of the procedure when compared to an adult. In our study, the mean fluoroscopy time was 9.11 min (ranged from 7 to 25 min) and the mean total technique time was 49 min (ranged from 28 to 79 min). This is in an agreement with other previously published studies [42–44].

Study limitations, one of the limitations in our study is that the closure of type D and E ductus was not tested. The unavailability of ADO-II in our catheterization laboratory -at the time of the study- limits the intervention in patients with complex ductal morphology. In addition, a larger number of patients with Nit-Occlud PDA-R need to be evaluated.

5.1. In Conclusion

Our experience with transcatheter closure of PDA utilizing Nit-Occlud *pfm* coils, Nit-Occlud PDA-R and Amplatzer ductal occluder proved to be safe and effective. A residual leak was insignificant in our series. The risk of attempting percutaneous closure of PDA is very low. The learning curve and experience assume a noteworthy part in the appropriate device selection and implantation to minimize the complications.

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Conflict of Interest

No authors have any conflict of interests, financial or otherwise, related to the content of this paper.

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