

# A Retrospective Study of 1526 Cases of Transcatheter Occlusion of Patent Ductus Arteriosus

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## Abstract

**Background:** Patent ductus arteriosus (PDA) is one of the most common congenital heart diseases and began to get treated by transcatheter occlusion since 1997 in China. Since then, several devices have been invented for occluding PDA. This study aimed to evaluate the technical feasibility, safety, and efficacy of transcatheter occlusion of PDA with different devices.

**Methods:** One thousand five hundred and twenty-six patients (537 boys, 989 girls) with PDA from January 1997 to September 2014 underwent descending aortogram and transcatheter occlusion procedure. We retrospectively analyzed data of these patients, including gender, age, weight, size and morphology of PDA, and devices used in transcatheter occlusion, outcomes, and postoperational complications.

**Results:** Median age and median weight were 4.0 years (range: 0.3–52.0 years old) and 15.3 kg (range: 4.5–91.0 kg), respectively. Mean ductal diameter, aortic ductal diameter, ductal length, and pulmonary artery pressure were  $3.50 \pm 2.15$  mm,  $10.08 \pm 2.46$  mm,  $7.49 \pm 3.02$  mm, and  $30.21 \pm 17.28$  mmHg, respectively. Morphology of PDA assessed by descending aortogram was of type A in 1428 patients, type B in 6 patients, type C in 79 patients, type D in 4 patients, and type E in 9 patients according to the classification of Krichenko. Of all the 1526 patients, 1497 patients underwent transcatheter PDA closure, among which 1492 were successful. Devices used were Amplatzer duct occluder I (ADO I, 1280, 85.8%), Cook detachable coils (116, 7.8%), ADO II (ADO II, 68, 4.6%), muscular VSD occluder (12, 0.8%), and Amplatzer vascular plug (16, 1.0%).

**Conclusions:** Excellent occlusion rates with low complication rates were achieved with all devices regardless of PDA types. With transcatheter occlusion technique and devices developing, more patients with PDA can be treated with transcatheter closure both safely and efficiently.

**Key words:** Congenital Heart Disease; Devices; Patent Ductus Arteriosus; Transcatheter Occlusion

## INTRODUCTION

As an isolated lesion, patent ductus arteriosus (PDA) is a common congenital heart disease and represents 10–15% of all congenital heart lesions. After Porstmann described the first successful transcatheter PDA closure in 1967, the procedure became widespread in the 1980s.<sup>[1]</sup> Since then, multiple devices have been developed including Rashkind umbrella device,<sup>[2]</sup> Sideris adjustable buttoned device,<sup>[3]</sup> and Gianturco coil.<sup>[4,5]</sup> Our pediatric cardiology center started to use the Amplatzer duct occluder (ADO) I in 1997. ADO I is the most established device and has been demonstrated with high occlusion rates and excellent safety,<sup>[6,7]</sup> hence, it has become the most frequently used device in transcatheter PDA closure. A second generation ADO II was released in late 2007 and put into use in China in 2011, mostly used in infants and small-moderate PDA occlusions. Other devices used in transcatheter PDA closure include Amplatzer vascular plug

and muscular VSD occluder. Different types of PDA have respective characteristics. This study analyzed 1526 cases of PDA transcatheter closure in our pediatric cardiological center retrospectively, and discussed some experiences of treating complicated cases of PDA via interventional therapy.

## METHODS

A retrospective review was carried out of all cases of transcatheter PDA closure at the Pediatric Cardiology Center,

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Beijing Anzhen Hospital, from January 1997 to September 2014. All patients completed routine examinations such as complete blood counts, blood biochemistry, coagulation time, blood gas analysis, hepatic and renal function, a standard 12-lead electrocardiogram (ECG), chest radiograph, and transthoracic echocardiography (TTE) before the transcatheter occlusion procedure.

The following data were recorded: Demographics, clinical manifestations, ECG and TTE results, patient weight, device type, device size, and fluoroscopy time. Angiograms recorded before, during, and immediately after the release of the device, were analyzed. PDA length, diameter at its narrowest point, and pulmonary pressure were noted. The PDA anatomy was classified according to Krichenko's classification.<sup>[8]</sup> Whether the device was inserted via an arterial or venous approach was also documented.

Additionally, 10 min after ADO release, a descending aortogram was performed to assess the degree of the residual shunt (RS). A left-to-right shunt without a jet was classified as a trivial RS, with a jet of <2 mm in diameter as a small shunt and with a jet diameter of >2 mm as a large shunt. Echocardiograms recorded 24 h after the procedure and at 1–12 months follow-up visits were analyzed. The presence of any RS or device protrusion was noted. Device protrusion was defined as the device visibly protruding into the lumen of the descending aorta or pulmonary artery on echocardiography. Finally, any complications during or after the procedure were documented.

### Procedural technique

Transcatheter PDA occlusion is indicated for treating moderate-sized or large PDA with left-to-right shunt that results in any of the following: Congestive heart failure, failure to thrive, pulmonary overcirculation (with or without pulmonary hypertension), or an enlarged left atrium or left ventricle, provided the anatomy and patient size are suitable.<sup>[8,9]</sup> All procedures were performed by two or more experienced operators and carried out under general anesthesia for infants and children who cannot

coordinate (usually under 12 years old), and local anesthesia for adults and children who can coordinate (usually older than 12 years old). The hemodynamic measurements, determination of the shunts, and pressure measurements of the patients were recorded. Duct morphology was determined according to the classification of Krichenko. The ductus was visualized with contrast medium injections to the descending aorta into the lateral, right oblique, and/or left oblique positions. After considering the weight of the patient and the anatomy of the ductus, the operators selected the device that was considered most appropriate. Devices were deployed according to standard protocols. Descending aortogram was performed before and 10 min after device release to assess the degree of the RS, and to make sure the device is in the appropriate position without protrusion or iatrogenic aorta coarctation [Figures 1 and 2].

### Follow-up protocol

At 24-h follow-up, TTE was performed to assess the position and shape of the occluder, and also to detect and quantify any RS. Follow-up TTE was performed at 1, 3, and 6 months. At each follow-up visit, complications related to occluder implantation were noted. Infective endocarditis prophylaxis and aspirin (5 mg/kg) were recommended for 6 months after the procedure in all patients.

### Statistical analysis

All statistical analyses were conducted using the Statistical Package for Social Sciences, version 13.0 (SPSS Inc., Chicago, IL, USA). Measurement data were expressed as mean  $\pm$  standard deviation (SD) or as median and ranged as appropriate. A  $P < 0.05$  was considered as statistically significant.

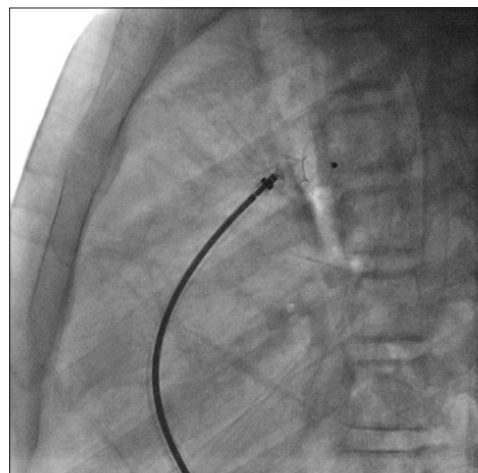
## RESULTS

### Patient demographics and clinical statistics

A total of 1526 PDA patients' (537 males, 989 females) data were included and analyzed. All patients were diagnosed as PDA by physical examination, a standard 12-lead ECG, chest radiograph, and TTE. The median



**Figure 1:** The fluoroscopy image of descending aortography to show the structure of patent ductus arteriosus with typical funnel morphology.



**Figure 2:** The fluoroscopy image of Amplatzer duct occluder-I during the transcatheter closure of patent ductus arteriosus.

age was 4.0 years (range: 0.3–52.0 years old) and median weight was 15.3 kg (range: 4.5–91.0 kg). Of the 1526 patients, 1512 had isolated PDA, 6 with ASD, 5 with unilateral absence of pulmonary artery, 2 with mild aorta coarctation, and 1 with pulmonary stenosis. Among all patients, 360 had a history of pneumonia, 12 patients had a history of congestive heart failure (7 males, 5 females, median age of 6.5 years old, 5 of them associated with pulmonary hypertension). Four patients had a history of infective endocarditis. Normal ECG was documented in 1176 patients. Left ventricular hypertrophy, right atrial enlargement with right ventricular hypertrophy, incomplete right bundle branch block, I degree atrioventricular block, and atrial flutter shown in ECG were noted in 330, 12, 4, 3, and 1 patient (s), respectively. Mean cardiothoracic ratio measured in chest radiograph was  $0.57 \pm 0.06$ . Mean ductal pulmonary diameter measured in TTE was  $3.96 \pm 1.91$  mm (range: 1.00–23.00 mm).

### Patent ductus arteriosus characteristics of angiography

The mean minimum ductal diameter measured by angiography was  $3.50 \pm 2.15$  mm (0.40–19.00 mm); mean ductal aortic diameter was  $10.08 \pm 2.46$  mm, and mean ductal length was  $7.49 \pm 3.02$  mm. Of all the 1526 patients, type A, defined according to Krichenko's classification, was the most common anatomical variant seen in 93.5% (1428/1526) of the cases. This was followed by type B in 0.3% (6/1526), type C in 5.3% (79/1526), type D in 0.3% (4/1526), and type E in 0.6% (9/1526).

### Devices used

Angiography was performed in 1526 PDA patients, and transcatheter PDA closure was attempted in 1497 of them, while the other 29 patients did not meet the indication for transcatheter PDA closure. In all 1497 cases, except 5 (99.6%, 1492/1497), a device was successfully implanted, and the ductus was occluded. The devices used were ADO I, ADO II, flipper coils, Amplatzer vascular plug, and muscular VSD occluder. Table 1 showed patient demographics and PDA characteristics, overall, and by device type.

### Outcomes

In 29 cases, devices were not implanted after the angiography, hemodynamic measurements, determination of the shunts, and pressure measurements. Twenty-one of them did not meet the indication of transcatheter PDA closure (12 due to too elongated ductus; 6 due to ductus too thick to have appropriate occluder; 2 twisted PDA; 1 with left pulmonary stenosis). In other 8 cases, devices were removed, and procedures were aborted after attempted closure. Three of them had severe pulmonary arterial hypertension (PAH), in whom pulmonary arterial pressure could not be decreased, and pulmonary vascular resistance could not be overcome; 5 of them still had significant RS. In the 1497 patients who had PDA closure devices implanted, 5 cases were unsuccessful, including 1 device dislocation during the procedure, 3 device migrations after the procedure, and 1 case using flipper coil that could not be deployed or removed during the transcatheter procedure. These 5 patients underwent surgical PDA ligation successfully.

### Residual shunt

Table 2 shows RS rates immediately following device release, 1-day after the procedure, and at 6-month follow-up for each device. Of all the 1492 cases, no significant immediate RS was noted. Twenty-four patients (24/1492, 1.6%) had small RS, while 42 (42/1492, 2.8%) patients had trivial RS (smoke like shunt) immediately following device release. As for RS of 24 h postprocedure, trivial RS was noted by TTE in 10 cases. RS was not noted at 6-month follow-up in these 10 patients. Moreover, no new case with RS was observed during the study period.

### Fluoroscopy time

Overall, the mean fluoroscopy time was  $9.34 \pm 6.66$  min and the mean procedure time was  $68.11 \pm 19.22$  min. Patients were discharged 1–3 days after the transcatheter PDA closure.

### Complications

Device dislocation occurred in four cases (one during the

**Table 1: Patient demographics and PDA characteristics by device**

Items	Overall	ADO I	ADO II	Coil	Vascular plug	VSD occluder
Number of patients, <i>n</i> (%)	1492 (100.0)	1280 (85.8)	68 (4.6)	116 (7.8)	16 (1.0)	12 (0.8)
PDA type, <i>n</i>						
A	1404	1224	62	96	11	11
B	4	2	0	1	0	1
C	74	49	5	15	5	0
D	3	2	0	1	0	0
E	7	3	1	3	0	0
Minimum diameter, mm, mean $\pm$ SD	$3.50 \pm 2.15$	$3.73 \pm 2.10$	$1.61 \pm 0.54$	$1.50 \pm 0.53$	$1.50 \pm 0.64$	$4.87 \pm 2.33$
PAP, mmHg, mean $\pm$ SD	$30.21 \pm 17.28$	$30.75 \pm 16.96$	$16.25 \pm 2.28$	$18.97 \pm 10.15$	$18.67 \pm 3.30$	$49.71 \pm 18.79$
PDA length, mm, mean (range)	7.50 (3.00–20.00)	7.30 (3.00–20.00)	6.28 (4.00–7.00)	8.45 (4.00–17.80)	–	–
Approach, <i>n</i>						
Venous	1298	1280	6	0	0	12
Arterial	194	0	62	116	16	0

SD: Standard deviation; PDA: Patent ductus arteriosus; ADO: Amplatzer duct occluder; PAP: Pulmonary artery pressure.

**Table 2: RS of different devices after the procedure**

Items	Overall	ADO I	ADO II	Coil	Vascular plug	VSD occluder
Number of patients, <i>n</i> (%)	1492 (100.0)	1280 (85.8)	68 (4.6)	116 (7.8)	16 (1.0)	12 (0.8)
Immediate RS, <i>n</i> (%)	66 (4.4)	59 (4.6)	0 (0)	4 (3.4)	0 (0)	3 (25)
RS at 24 h, <i>n</i> (%)	10 (0.7)	8 (0.6)	0 (0)	2 (1.7)	0 (0)	0 (0)
RS at 6 months, <i>n</i> (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

RS: Residual shunt; ADO: Amplatzer duct occluder.

procedure and three after the procedure). The four patients subsequently underwent successful surgical device removal and PDA ligation. Femoral artery thrombosis was seen in cases and was successfully treated with urokinase and heparin, leaving no consequences. There was one case of femoral artery pseudoaneurysm in an 8-year-old obese child. One month after the PDA closure using a coil, this patient started having right groin area pain and was diagnosed with femoral artery pseudoaneurysm. He was then treated successfully by surgery. Transient hemolysis was seen in three cases and resolved after 24 h. Thrombocytopenia was seen in one patient with large PDA that had RS after transcatheter PDA closure. Eight hours after the closure procedure, gross hematuria was noticed and then disappeared 24 h later. While the 24 h postprocedure blood routine test showed thrombocytopenia, with lowest platelet count decreased to 13 g/L, at the 1-month follow-up, TTE showed no more significant RS, and the blood platelet account went back to normal.

### Follow-up

Follow-up took place at a range of 1–12 months after surgery in 1448 patients (1448/1492, 97.1%). Patient follow-up evaluations showed that the PDA was successfully occluded and that no device migration, RS, embolization or recanalization had occurred.

### DISCUSSION

Porstmann described the first successful transcatheter PDA closure in 1967,<sup>[10]</sup> which made PDA the first congenital heart disease that could be treated by the transcatheter closure. As catheterization techniques develop and spread, transcatheter occlusion has become the most common treatment for PDA. Chinese medical association affiliated Chinese society of pediatrics which drew up the guideline of congenital heart disease transcatheter closure and confirmed the indications of coils and ADOs in 2004.<sup>[9]</sup> The guideline pointed out that the indication of transcatheter PDA closure included: Left-to-right shunt PDA without other cardiac anomalies that requires surgical operation; single Cook detachable coil for PDAs of minimum diameter  $\leq 2$  mm, single PFM coil for PDAs of minimum diameter  $\leq 2$  mm, and an ADO for PDAs of minimum diameter  $\geq 2$  mm; patient older than 6 months and heavier than 4 kg.

### Transcatheter closure of large patent ductus arteriosus

Selecting the appropriate closure device for large PDA is a conundrum, considering the PDA diameter, morphology together with the children vessel endurance for the relatively

large closure device. The most commonly used ADO is usually used for PDAs of diameter  $\leq 11$  mm.<sup>[11]</sup> As for PDAs of diameter  $> 11$  mm, Huang *et al.* reported that they used Amplatzer ASD occluder in the transcatheter closure, but the RS rate immediately after device release was 60%, and may result in hemolysis. That the polyester film filled in the ASD occluder was not able to block the blood flow at high pressure from running through the PDA, might be the reason of the high RS rate. Then Thanopoulos reported using Amplatzer muscular VSD occluder for large PDAs with severe PAH. In their study, the largest PDA diameter was 13 mm, which provided a new method to treat large PDA.<sup>[12]</sup> In our study, 12 cases were treated using Amplatzer muscular VSD occluder, the mean age of them was 1.35 years old (range: 0.5–9.6 years old), and the mean weight was 8.5 kg (range: 5.5–30.0 kg). The reason why we chose these relatively young children with low body weight is that with their narrow aortic diameter, it is less likely to cause iatrogenic aorta or pulmonary artery coarctation using muscular VSD occluder instead of ADO I with large size. In addition, the thin delivery wire of Amplatzer muscular VSD occluder can reduce the possibility of iatrogenic vessel damage. With its symmetric retention discs, the muscular VSD occluder can sit firmly inside the ductus, thus, we can choose the occluder with a smaller diameter. In conclusion, according to our experience, to treat large PDAs in infants with low body weight, when ADO I attempted closure is not successful, muscular VSD occluder can be taken into consideration.

### Transcatheter closure of patent ductus arteriosus with severe pulmonary arterial hypertension

For patients of PDA with severe PAH, the correct classification of PAH is crucial for treatment strategy. Sometimes, only with clinical statistics and transcatheter parameters, it's hard to determine whether the transcatheter closure would be safe and efficient. In surgeries, temporary ligation and pulmonary arterial pressure measurement are usually used to determine the type of PAH, however, it's not safe and may cause severe damage. ADO is a withdrawable device, thus, temporary attempted occlusion of PDA with occluder has been used to decide on the contribution of left to right shunt and pulmonary vascular resistance to PAH, which is safe and efficient.<sup>[13,14]</sup> The systemic and pulmonary artery pressure (PAP) were compared before and after the balloon occlusion for 10–30 min, if the PAP decreased by 20% of the level before the attempted closure or decreased by more than 30 mmHg, without significant fluctuation in aortic pressure and blood oxygen saturation, without patient discomfort, this kind of PAH can be considered as dynamic PAH and the



closure device can be released permanently.<sup>[15]</sup> In our study, 43 patients with severe PAH underwent transcatheter closure using ADO. Three of them did not have a device implanted after attempted closure because the PAP did not fall, but the aortic pressure got decreased. In conclusion, according to our experience, if PAP falls after attempted closure, without RS, the device can be released. But if PAP does not fall, although without patient discomfort or significant fluctuation in aortic pressure and blood oxygen saturation, it is still difficult to judge the reversibility of pulmonary vascular resistance. Hence, pulmonary vasodilator test should be performed during the procedure to determine the reversibility of pulmonary vascular resistance. Then after the procedure, appropriate medication for PAH should be prescribed, and follow-up visits are highly recommended.

### **Transcatheter closure of small-moderate tubular and elongated patent ductus arteriosus**

As for the closure of small-moderate tubular and elongated PDA in infants and small children, coil occlusion had usually been used before ADO II came into use.<sup>[16,17]</sup> The technique of coil occlusion is relatively complicated, requiring femoral artery punctures twice, but still leaves RS after the occlusion sometimes. ADO II is designed for PDA whose diameter is smaller than 6 mm. Device sizes (connecting waist diameters) range from 3 to 6 mm. With a stretchable and spiral articulated connecting waist, it can be used to treat many different types of PDA with various morphology and length, especially for tubular and elongated PDA. TorqVue LP (Low Profile) Delivery System for ADO II makes it possible to go through some small vessels in infants, reducing the possibility of arterial or venous complications. In our study, 68 cases underwent transcatheter PDA closure using ADO II successfully, median age of 5.15 years old (range 1–18 years old), median weight of 19 kg, and PDA minimal diameter of  $1.84 \pm 0.63$  mm, without vascular complications. A few PDA still had RS after surgery, but the morphology and shape of the ductus varied, which made the catheter or delivery wire difficult to go through the ductus from the pulmonary arterial end. Under this circumstance, operating via femoral arterial approach retrograde using ADO II is safe and feasible. Few cases underwent transfixion in surgical ligation and left the RS in bicavitary or latticed type, and the design of six potential planes enhances the effect of PDA occlusion.

### **Transcatheter closure of patent ductus arteriosus with unilateral absence of pulmonary artery**

The clinical characteristics of PDA with unilateral absence of pulmonary artery include:<sup>[18,19]</sup> (1) Recurrent pulmonary infection: Unilateral absence of pulmonary artery results in intrapulmonary hypopnea, declined clearance ability of cilia and accumulation of inflammatory cells, and left-to-right shunt of PDA increases pulmonary blood supply, these factors result in recurrent pulmonary infection; (2) hemoptysis: Hemoptysis is the original symptom of 20% PDA patients with unilateral absence of pulmonary artery. Although hemoptysis is self-limiting in some patients, it

can lead to massive hemoptysis or even death. However, it is usually misdiagnosed with bronchiectasis. Diagnosis can be confirmed by chest X-ray and computed tomography (CT) scan; (3) signs of PAH. For congenital heart disease, patient with severe PAH, TTE should be performed to check bilateral pulmonary arteries and to exclude unilateral absence of pulmonary artery, if a clear TTE image is not possible, CT angiography or cardioangiography can also be performed. Surgical treatment presents elevated risks and potential complications due to cardiopulmonary bypass. In our study, five cases were diagnosed with PDA with unilateral absence of pulmonary artery and PAH by TTE. Of the five cases, PDA diameter was relatively large. Four of them had a recurrent pulmonary infection and 1 had recurrent hemoptysis. Transcatheter PDA closure was performed successfully after hemodynamic assessment, pulmonary arterial pressure, and pulmonary vascular resistance measurement. The 1-month to 4 years follow-up visits of the five patients showed normal pulmonary arterial pressure and normal diameter of atrium and ventricle. In addition, recurrent pulmonary infection and hemoptysis were not noted anymore after the transcatheter PDA closure during the study period.

### **Transcatheter patent ductus arteriosus closure of infants**

In our study, 177 infants ( $\leq 12$  months) underwent transcatheter PDA closure and three cases were unsuccessful (1 – With device dislocation during the procedure; 2 – With device migration postprocedure). Two cases had femoral artery thrombosis and were successfully treated by urokinase and heparin, without any sequelae. Because of the thin femoral artery and vein of infants, the piercing sheath with a smaller diameter and 1<sup>st</sup>-time success of puncture are highly recommended in order to reduce the damage to blood vessels. Postoperative observation and care including noticing the skin color, temperature, and bilateral dorsalis pedis artery pulse should be reinforced. The selection of the appropriate size of the device is crucial in PDA closure of infants, due to the elastic PDA ductus of infants, narrow aortic ampulla region, and relatively small diameter of the aorta and pulmonary artery. During the procedure, the pressure gradient should be detected after device release to assure the reversibility of PAH and to avoid iatrogenic aorta coarctation or iatrogenic left pulmonary artery stenosis. Twenty-nine infants had trivial to small RS immediately after device release which all resolved in the 6-month follow-up visits. Transcatheter PDA closure of infants is relatively difficult in procedural technique and higher in complication rates, hence, proper case selection is very important.<sup>[20,21]</sup> According to our experience, if the PDA ductus of infants do not cause any hemodynamic changes including PAH, cardiomegalia, decline in heart function or congestive heart failure, the PDA closure procedure can be performed when the patient is at the age of 2 or 3 years old under regular follow-up visits. As for large PDA of infants, with no appropriate closure device available, surgical ligation may be safer and more efficient.

In conclusion, all devices achieved excellent occlusion rates with low complication rates, regardless of PDA type. As for some special types of PDA, with proper case selection, comprehensive knowledge of hemodynamics measurement, and PDA morphology, transcatheter PDA closure can also be safe and efficient. With transcatheter closure techniques and devices develop; more patients with PDA can be treated by transcatheter closure safely and efficiently.

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### Conflicts of interest

There are no conflicts of interest.

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