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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Closure of Patent Ductus Arteriosus in Children, Small Infants, and Premature Babies with Amplatzer Duct Occluder II Additional Sizes: Multicenter Study

Metin Sungur,[1*] MD, Cemsit Karakurt,[2] MD, Nazan Ozbarlas,[3] MD, and Osman Baspinar,[4] MD

Objectives: To evaluate safety and efficacy of closure of patent ductus arteriosus (PDA) with Amplatzer duct occluder II Additional Sizes (ADO II AS) and to report early and midterm results of the device in children and very young symptomatic infants. Methods: Retrospective analysis of angiographic data of 60 children from four pediatric cardiology centers. Results: The median patient age and weight were 6.5 (0.5–168) months and 6.8 (1.19–57) kg, respectively. In the study, 26 children had a body weight of ≤6 kg. Of these 26 children, 9 had a body weight of ≤3 kg. The median narrowest diameter of PDA was 2 (1.2–4) mm. Ductal anatomy was Type A in 29, Type B in 2, Type C in 11, Type D in 1, and Type E in 16 patients, and a residual PDA after surgery in 1 patient. Closure with ADO II AS was achieved in 58 (96.6%) of 60 attempted cases. In two infants, the device was not released because of significant residual shunt. ADO II was used in one, and the other was sent to surgery. Complete closure was observed in all ADO II AS deployed children by the next day on echocardiography. Median follow-up was 12 (1–18) months. Neither death nor any major complications occurred. Conclusions: Our study shows that closure of medium and small sized PDA by using ADO II AS device is effective and safe in children. The use of the device will expand the field of application of PDA closure in small infants. © **2013 Wiley Periodicals, Inc.**

Key words: patent ductus arteriosus; duct occluder; children; premature baby; pediatric interventions

INTRODUCTION

Transcatheter closure of patent ductus arteriosus (PDA) has been well established treatment modality for more than three decades. Currently, transcatheter closure of PDA can be performed with different types of vascular plugs [1–3], Cook coil (COOK Medical, Bloomington, IN) [4,5], Amplatzer duct occluder (ADO, ADO II, AGA Medical, Plymouth, MN) [6–9] and Nit-Occlud (pfm AG, Köln, Germany) [10].

Shape and size variability of ductus arteriosus and small patient size necessitate development of new devices or modifications of currently available devices. There are limitations for successful closure of PDA with currently available duct occluders in children with weight less than 10 kg and especially in infants with weight less than 6 kg. These limitations are handling large introducer sheaths, stiff delivery systems, and

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Conflict of interest: Nothing to report.

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protrusion of the occluder discs in aorta and pulmonary artery.

Amplatzer ductal occluder series continue to expand. The new member named Amplatzer Duct Occluder II additional sizes (ADO II AS) was recently released by Amplatzer (St. Jude Medical, Plymouth, MN). Bass and Wilson have demonstrated first successful closure results of ADO II AS in eight small pigs [11]. There is a limited clinical experience in the use of ADO II AS in children [12–15]. The efficacy and safety of the closure of PDA with ADO II AS occluder have not been evaluated in large pediatric case series. In this article, we report short and midterm results of 60 children who underwent transcatheter closure of PDA with ADO II AS in four pediatric cardiology centers.

METHODS

Study Population and Data Collection

From March 2011 to October 2012, a total of 60 children in the four Pediatric Cardiology Departments' Catheterization laboratories underwent attempts of PDA occlusion using the ADO II AS. The decision to use ADO II AS device was based on the narrowest diameter of PDA, which ranged between 1 and 4 mm as measured on lateral or right oblique descending aortography. Patients with significant additional cardiac anomalies that would require immediate surgical procedures were ruled out from the study. Informed parental consent was obtained for each patient.

Retrospective analysis of angiographic data regarding intervention success and complications were performed by a single investigator (MS). Demographic data, clinical characteristics, and angiographic parameters at the time of intervention were recorded.

Currently, routine use of the device is not recommended by the manufacturer for children less than 6 kg. Therefore, the study group was divided into two subgroups in order to show separately the outcomes of children whose body weights were $\leq$6 kg and >6 kg.

Amplatzer Duct Occluder II Additional Sizes, Delivery Wire, and TorqueVue Low Profile Delivery Catheter

The design and characteristics of the new ADO II AS was described previously in detail [11–14]. In brief, ADO II AS is a self-expanding nitinol mesh occlusion device with a central waist and retention discs deployed on both ends. The discs of the device are 1 mm greater than the central waist. The device can be delivered forward from a 4 French delivery catheter either by the aortic or venous route. The central waist is designed to fill the ductal lumen, and the retention discs are designed to deploy in the pulmonary and the aortic end of the ductus arteriosus.

The new ADO II AS comes preattached to a delivery cable. The delivery cable's distal tip is extremely flexible and has angiographically visible properties, which help precise placement of the proximal disc during device placement and unscrewing procedure. TorqueVue Low Profile Delivery Catheter has 4F outer diameter compatible with all 9 ADO II AS occluders.

Deployment Technique

All procedures were performed under heavy sedation and local anesthesia except for those in seven preterm infants and the four patients that needed additional interventions (three pulmonary balloon valvuloplasty and a VSD closure). These 11 procedures were performed under general anesthesia with intubation. Percutaneous femoral vein and/or artery access were obtained. The hemodynamic measurements of the patients were recorded. The ductal configuration was visualized with contrast-medium injections using a 4–5F NIH or pigtail catheter to the descending aorta in lateral angiographic position (Fig. 1A–C). In some patients, additional right oblique projection was needed for precise measurements of PDA. The device was usually selected 2–3 mm larger than the narrowest ductal diameter. Duct anatomy was determined according to the classification of Krichenko et al. [16].

Procedural approach was performed either by retrograde aortic or antegrade venous route. The retrograde aortic approach was performed by operator preference or for the ducts, which could not be crossed from the pulmonary artery. In premature babies, as far as possible, catheter manipulation within the cardiac chambers was avoided. We entered to the right ventricle with 4F Judkins right coronary or Cobra 2 glide catheter with helping a 0.025-inch Terumo guidewire (Terumo Medical Corporation, Somerset, NJ). After then with small rotation of the catheter with guiding of the guidewire, we entered to the PDA. Coronary guidewire was exchanged of the hydrophilic guidewire. Hand-injection was used for the aortic approach group except one patient whose aortography was performed with an automatic injector. Contrast medium was administered through the sidearm of a Touhy-Borst adapter on a TorqueVue delivery catheter that was placed over a floppy delivery cable in order to confirm the correct device position and presence of a shunt prior to release of the device (Fig. 1D–F). In the ex-premature babies and the small infants weighing less than 4 kg, antegrade venous approach without arterial access was especially preferred with echocardiographic guidance. In this group of patients, shunt size was not measured

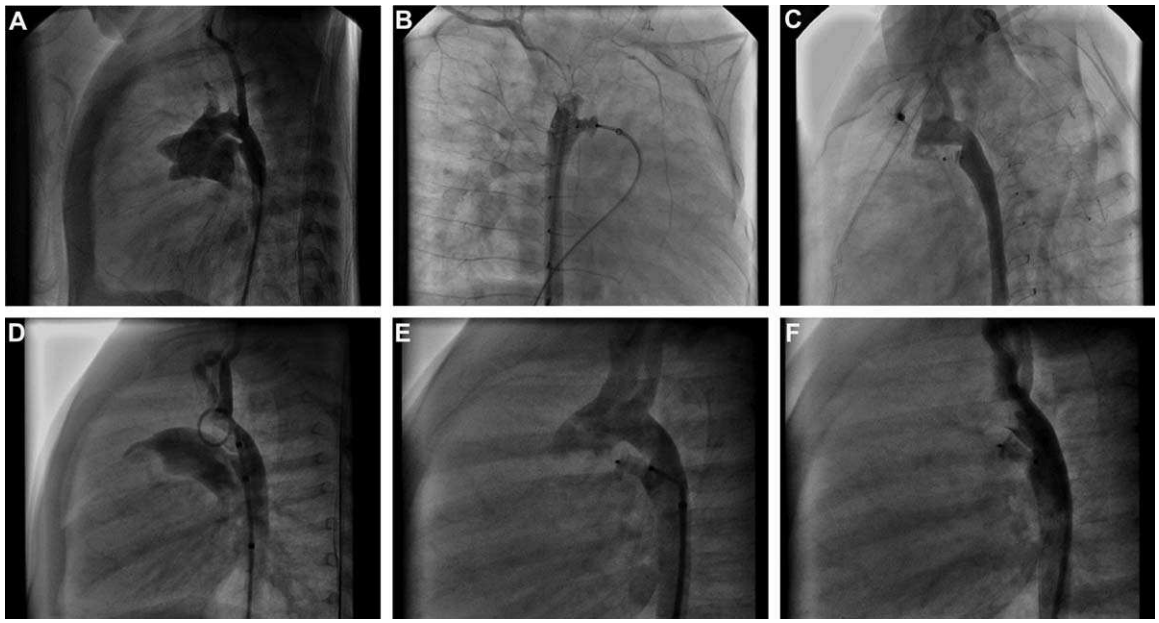

Fig. 1. (A–C) Lateral, right oblique angiogram with venous approach showing a tubular duct before occlusion and device release and after occlusion with 5 × 2 ADO II AS. (D–F) Lateral angiogram with arterial approach demonstrating a Type A duct before occlusion and device release and after occlusion with 5 × 4 ADO II AS.

during catheterization because of potential femoral artery injury, and the potential for blood loss. In the artery-accessed patients, a descending aortogram and pullback gradient measurement were performed 5 min after the device release to confirm the position and the existence of a residual shunt, and to exclude the presence of obstruction on the aortic side. Aortic disc of the device was mostly pulled within arterial duct in patients with the long ducts (Fig. 2). The position of the aortic discs of the device were labeled with an "a" and "b'' in Tables I and II. The aortic disc of the device was pulled into ampulla in 12/29 of Type A, 5/11 of Type C, 1/1 of Type D, 10/16 of Type E, respectively. In two patients with Type B ducts, the waist of the device was placed into the pulmonary side of ductal artery. Obstruction of the left pulmonary artery or descending aorta in antegrade venous approach group was excluded by echocardiography. Follow-up echocardiography was performed within next day post implantation and at 1, 3, 6, 12, and 18 months.

RESULTS

PDA implantation with the ADO II AS was achieved in 96.6% (58/60) of attempted cases on children, small infants, and premature babies within the period between March 2011 and October 2012. Of the 60, 41 (68.3%) were female. The patients were evaluated in the two groups according to body weight $\leq$6 kg (Table I) and >6 kg (Table II). The median patient age and weight were 6.5 months (range 0.5–168 months) and 6.8 kg (range 1.19–57 kg), respectively. In the study, 26 children had a body weight of $\leq$6 kg. Of these 26 children, 9 had a body weight of $\leq$3 kg. The median narrowest ductal diameter measured by angiography in Groups I and II were 2.24 mm (range 1.3–4 mm) and 1.8 mm (range 1.2–3.2 mm), respectively. The ductal diameters of both groups statistically were not different ($p > 0.05$). In Group I, seven patients were expremature babies that were followed in neonatal ICU, had medical treatment, and comorbid prematurity related problems. One patient had postsurgical significant residual shunt. Of the 60 patients, 40 had evidence of significant shunt through the PDA with left atrial enlargement and left ventricular volume overload. The indication for closure in the other 20 patients was continuous murmur.

PDA was presented as an isolated lesion in 45 (75%) patients and associated cardiac lesions were as follows: perimembranous ventricular septal defect (pmVSD, $n = 3$), small muscular ventricular septal defect ($n = 5$), small atrial septal defect ($n = 4$) and moderate and severe pulmonary valvular stenosis (PS), which required intervention ($n = 3$). Pulmonary balloon valvuloplasty procedure in these three patients and a pmVSD closure with Amplatzer Perimembranous Ventricular septal device were deployed successfully in the same session. One patient with history of surgical ligation had a residual PDA (Table II case 34). The PDA was crossed from the venous side in 32 of 60 (53.3%)

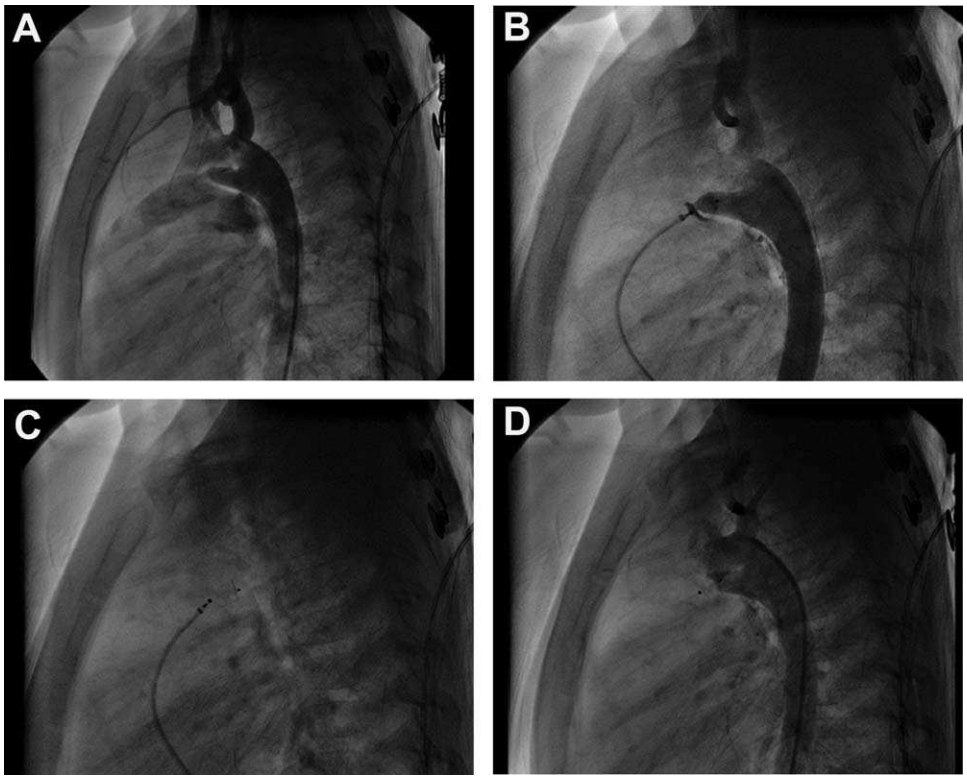

Fig. 2. Lateral angiograms showing; (A) a Type E ductus, (B) ADO II AS positioned within the PDA with minimal residual shunt, (C) before device release, (D) the aortic disc embedded into the duct with complete occlusion with 5 × 4 ADO II AS.

patients. Ductal anatomy defined by angiography showed Type A in 29, Type B in 2, Type C in 11, Type D in 1, and Type E in 16 patients and a residual PDA after surgery in 1 patient. Two patients had Down syndrome. Implantation with ADO II AS was successfully achieved in all children, except in two patients (Table I patients 6 and 24) with Type C duct with 3 and 3.8 mm ductal diameters. In these patients, the devices had to be withdrawn due to underestimation of the diameter of ducts, which resulted in significant residual shunting that was observed during the procedure before the release of the devices. ADO II 5 × 4 mm was deployed in the first case with 7 mm Hg pullback aortic gradient and the second case was sent to surgical ligation. In the aortic approach group, automatic contrast injector with 400 PSI was used in only one patient. During contrast media injection soft delivery cable was blown out of delivery catheter toward aortic arch without displacement of the device (Video 1, 2, and 3). Immediate angiographic or echocardiographic (venous antegrade approach patients) closure was achieved in 21/24 (87.5%) in Group I and 33/34 (97%) in Group II. Complete closure of PDA was achieved in 100% of both group confirmed next day by echocardiographic examination. The central waist of the occluder was displaced toward the pulmonary side of ductal artery during unscrewing procedure in the patient with Type A ductal morphology and the pulmonary disc of the device freely floated out in the LPA without any residual shunt or left pulmonary artery gradient. The disc float was observed in 1 and 3 months follow-up and it disappeared in the 6-month echocardiographic follow-up. Two patients required heparin therapy for diminished right-sided pedal pulses, which recovered by the next day. Red blood cell transfusion was needed for a small infant because of blood loss. All patients except the seven small babies that required additional medical support were discharged on the day after the procedure. All children showed complete ductal closure in to the next day after the procedure. Median follow-up period in Groups I and II were 6 months (range 1–18 months) and 12 months (range 1–18 months), respectively. No evidence of obstruction or Doppler flow acceleration in the aortic arch or the left pulmonary artery was observed during the procedure or follow-up. There was no procedure related death.

DISCUSSION

The results of the present multicenter study have demonstrated that implantation of ADO II AS was feasible for all types of PDA with a diameter $\leq$4 mm

TABLE I. Clinical Characteristics and Angiographic Data of the Patients Less Than or Equal to 6 kg

Pt. No	Sex	Age (Mo)	Weight (kg)	PDA type	Ductal measurements (mm)			Aortic diameter opposite PDA (mm)	Device size W × L (mm)	Occlusion at angiography	Closure side	FU (Mo)
					Min	L	A					
1	F	3.5	4.4	E	3.2	5	7	5.3	5 × 4[a]	Complete	Venous	12
2	F	7	4	A	1.5	4.1	3.9	4.6	3 × 2[b]	Complete	Arterial	18
3	F	3	4.1	C	4	4	4.3	5.57	5 × 2[b]	Complete	Arterial	12
4	F	2	4.4	A	1.6	4.2	2.3	5.08	3 × 2[b]	Complete	Venous	12
5	F	4	4.4	A	1.45	3.65	1.67	4.25	4 × 2[a]	Complete	Venous	12
6	F	4	5.3	C	3.8	4.3	5.8	4.7	ADO II	Complete	Arterial	-
7	F	1.5	1.9	C	2.2	4.1	4.7	4.2	4 × 2[b]	Complete	Venous	12
8	M	0.5	1.19	C	2.35	4.3	NS	3.69	4 × 2[a]	Minimal	Venous	6
9	F	4	4.2	C	2.5	12.45	6.54	6.81	5 × 4[b]	Complete	Venous	6
10	F	1	3.2	A	1.4	4.36	6.4	3.87	4 × 2[a]	Complete	Venous	6
11	F	3	2.39	A	2.3	5	NS	5.68	3 × 4[b]	Complete	Venous	6
12	M	0.75	1.5	C	3	5.8	NS	3.2	5 × 6[b]	Complete	Venous	6
13	M	1	1.6	C	2.35	7.28	NS	4.17	4 × 6[b]	Complete	Venous	6
14	F	3.5	5.1	A	1.8	4.8	6.68	6.1	4 × 4[a]	Complete	Venous	18
15	F	1.5	1.7	E	1.5	10	6	6	4 × 6[b]	Complete	Venous	18
16	F	7	5.5	A	1.66	4.73	6.8	6.9	3 × 4[b]	Complete	Venous	12
17	F	2	2.9	E	2.97	7.54	4.98	5.8	4 × 6[b]	Minimal	Venous	6
18	F	2.5	4.5	B	2.68	4.41	5.62	5.9	5 × 2	Complete	Venous	6
19	F	5.5	5.5	E	1.3	7.22	5.47	6.6	3 × 4[b]	Complete	Venous	6
20	F	3.5	3	A	2.28	4.78	5.1	6.9	3 × 4[b]	Moderate	Venous	6
21	F	1.5	4.3	A	1.99	12.99	6.56	5.8	4 × 6[b]	Complete	Arterial	6
22	M	2.5	4.5	A	1.6	5.5	7.2	6.3	3 × 4[a]	Complete	Arterial	6
23	F	3	3.6	E	1.5	7	3.5	5.4	3 × 6[a]	Complete	Venous	12
24	F	2	2.2	C	3	5.5	5	5.1	5 × 4	Surgery	Venous	-
25	F	4	5.5	A	2	5	6	5.9	4 × 6[a]	Complete	Arterial	3
26	F	8	6	A	3.1	9.7	6.2	6.9	5 × 4[b]	Complete	Arterial	1

L: Length; A: Ampulla; W: Waist; NS: Not stated; FU: Follow-up duration.
[a]The aortic disc of the device against the aortic wall.
[b]The aortic disc of the device pulled into ampulla.

and for wide variety sizes of children and even for small infants.

In the current literature, there are limited reports on the ADO II AS experience for PDA closure [12–15]. Agnoletti et al., [12] reported initial experience in seven children with use of ADO II AS. Immediate complete closure has been achieved in 6/7 of the children. Complete closure at the echocardiographic evaluation has been reached in all patients at next day. In their report, the children were followed for median two months period without complication. In our study, the success rates of immediate closure confirmed by either angiography or echocardiography were 87.5% and 97% in the small infants' $\leq$6 kg and children >6 kg, respectively. Complete closure was achieved on next day after the procedure in 100% of the children, regardless of patient size.

Several studies have reported that percutaneous closure of almost any PDA beyond neonatal age can be efficiently done by using the detachable coils for small ducts and Amplatzer duct occluders for larger ducts [8,9,13,17–23]. However, with the use of these devices, some problems have been encountered including procedural failure, high incidence of residual shunts, aortic protrusion, LPA stenosis, device migration, and femoral arterial damage. Moreover, PDA closure in preterm small infants is considered technically challenging [24–26]. In our study, in follow-up with echocardiographic examinations, no signs of protrusion or obstruction of discs were observed. There were no procedure related major complications in either group.

Short profiled and flatdisc is the most important property of the ADO II AS facilitating complete closure and avoiding aortic and pulmonary artery obstruction. In addition, its vascular plug-like design makes the ADO II AS a suitable occluder for closure of the most anatomic PDA types. The central waist of the device is designed to fill the ductal lumen and the retention discs are designed to deploy in the pulmonary and aortic ends of the ductus arteriosus. When compared with ADO II AS, AVP II device is cheaper, and has smaller proximal and distal disc with equal occlusion rates [1]. In this study, aortic disc of the device was mostly embedded inside the long duct with Type A

TABLE II. Clinical Characteristics and Angiographic Data of the Patients Greater Than 6 kg

Pt. No	Sex	Age (Mo)	Weight (kg)	PDA type	Ductal measurements (mm)			Aortic diameter opposite PDA (mm)	Device size W × L (mm)	Occlusion at angiography	Closure side	FU (Mo)
					Min	L	A					
1	F	19	11	A	2	4.5	6.4	10	4 × 4[a]	Complete	Venous	6
2	M	36	13	E	1.4	4.8	3.8	8.8	4 × 6[a]	Complete	Arterial	6
3	F	16	9	C	2	3	7	10.5	5 × 2[a]	Complete	Venous	12
4	F	12	8.2	A	1.3	4.2	6.1	7.2	4 × 4[a]	Complete	Venous	12
5	M	15	10.8	E	2.1	10	3.6	11	4 × 6[b]	Complete	Arterial	12
6	F	13	8.8	C	1.4	2	2.7	9	4 × 2[a]	Complete	Venous	12
7	F	168	42	A	3.1	3.1	4.1	14.1	5 × 2[a]	Complete	Venous	18
8	F	23	11.7	A	2.3	5.4	2.8	9.9	4 × 4[a]	Complete	Venous	6
9	F	19	9	E	2.1	3.1	5.1	8.6	4 × 2[b]	Complete	Venous	6
10	M	96	20	E	2.2	6.9	5.2	11.7	4 × 4[b]	Complete	Arterial	6
11	M	24	12.5	A	1.5	3.6	10.6	8.6	3 × 2[a]	Complete	Arterial	6
12	F	96	25	C	3.2	2.8	3.8	10.4	5 × 2[a]	Complete	Arterial	18
13	M	5	9.5	D	1.8	6.25	NS	6	3 × 2[b]	Minimal	Arterial	12
14	M	19	10	A	2.43	11.2	9.8	7.2	4 × 6[b]	Complete	Venous	18
15	M	4.5	6.36	A	2.01	7.33	8.45	6.8	4 × 6[a]	Complete	Venous	18
16	F	6.5	6.9	E	1.5	8.87	5.64	5.8	3 × 6[b]	Complete	Venous	18
17	M	22	12	E	2.35	9.3	11	9.3	5 × 4[b]	Complete	Venous	12
18	F	10	10	E	1.8	9.9	10	9	4 × 4[b]	Complete	Venous	12
19	M	10	9	A	1.72	8.1	7.41	7.1	4 × 6[a]	Complete	Venous	6
20	M	129	33	E	1.6	8	6	12.9	3 × 6[a]	Complete	Arterial	6
21	F	14	10	A	2	5.1	4.45	8	4 × 4[a]	Complete	Arterial	1
22	M	31	15	E	1.7	8	6	11.8	3 × 4[b]	Complete	Arterial	12
23	F	5.5	6.2	A	1.8	5.8	3	6.7	3 × 4[a]	Complete	Arterial	18
24	F	60	15	E	1.9	7.8	6.7	10.3	3 × 6[a]	Complete	Arterial	12
25	M	12	8.6	E	1.4	8	5	9	3 × 6[a]	Complete	Arterial	6
26	F	5	6.3	A	1.3	9	4	6.5	3 × 6[b]	Complete	Arterial	18
27	M	96	38.8	A	1.6	8	4.5	11.2	3 × 6[b]	Complete	Arterial	18
28	F	15	6.7	A	1.7	6.7	6	7.3	3 × 6[a]	Complete	Arterial	12
29	F	12	9	A	1.2	11	3	8.7	3 × 6[b]	Complete	Arterial	6
30	F	144	57	B	2	3	3	14.2	3 × 4	Complete	Arterial	12
31	M	156	56	A	2.5	8	6	14.3	4 × 6[a]	Complete	Arterial	12
32	F	4	7	A	2	7	6	7	4 × 4[b]	Complete	Arterial	12
33	F	5	7.5	A	1.6	8	5	7.2	3 × 6[a]	Complete	Arterial	1
34	M	6.5	8	-	1.6	8	6	7.6	3 × 6[a]	Complete	Arterial	1

L: Length; A: Ampulla; W: Waist; NS: Not stated; FU: Follow-up duration.

[a]The aortic disc of the device against the aortic wall.

[b]The aortic disc of the device pulled into ampulla.

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Supplementary Information

and E. This might have provided us with high immediate closure success.

During deployment of the device, placement of the central waist into duct lumen and close contact of the pulmonary disc with pulmonary side of ductus is important. Free float of the pulmonary disc was observed in an infant that disappeared at 6-month control. This may have resulted from thrombosis and endothelization processes of the pulmonary disc.

Delivery cable blows up while using an automatic injector was encountered in a patient. Hand-injection of contrast medium through the side arm of a Touhy-Borst adapter has some disadvantages. It is not comfortable for the operator and it is likely to provide less informative imaging about device position and magnitude of residual shunt. Despite these disadvantages, hand injection is a safer method. We recommend the use of hand injection method to avoid displacement of the soft delivery cable.

In contrast to the ADO I and some ADO II sizes, ADO II AS can be delivered through a 4Fr delivery sheath, allowing its application in very small infants. The symmetrical design of the device allows delivery from the venous or arterial side. Kenny et al.,

[14] have preferred arterial approach in preterm infants in terms avoiding the hemodynamic impacts of relatively stiff sheaths within a small heart. Excellent views of device position were obtained in small babies from echocardiography, in the study of Bentham et al. [27]. In our small babies, only venous antegrade route was used with echocardiographic guidance without arterial access. We believe that this approach provide us low femoral artery complication rates. In our children, reduced pedal pulse was observed in only two small babies who recovered the next day.

In our series, there were two unsuccessful attempts with ADO II AS in two small infants because of undersized ductal measurement resulting in obvious shunt. Careful ductal diameter sizing and obtaining good images have paramount importance in small infants with relative large ducts. Children with arterial ductus larger than 4 mm are out of range of this device. Both patients with unsuccessful attempts were beyond the limits of this device. Patients weighing less than 6 kg may encounter device related complications such as disc protrusion of Duct occluders or need large delivery systems. There is an open field of small sized patients with large ducts that are very challenging to close with transcatheter method. The device may be improved with additional larger sizes to overcome the hurdles in closure of large ducts in small children.

CONCLUSION

Our study shows that percutaneous closure of medium and small sized PDA by using ADO II AS device is effective and safe in children. The use of the device will expand field of application of PDA closure, especially in small infants and expremature babies.

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