

Transcatheter Closure of Patent Ductus Arteriosus With Nit-Occlud Coils

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The detachable coils have been successfully used for transcatheter occlusion of small- to moderate-sized patent ductus arteriosus (PDA). We report our experience regarding the use of the Nit-Occlud coils (NOCs) for transcatheter PDA and major aortopulmonary collateral (MAPCA) occlusion. Single NOCs were used to close PDA in 26 patients, and one small and two large MAPCAs in two patients. Mean age and weight of the patients were 7.7 ± 5.4 years and 20.6 ± 11.6 kg. Mean minimum duct diameter was 2.8 ± 0.8 mm; ampulla, 8.7 ± 2.4 mm; and PDA length, 9.3 ± 4.4 mm. Mean pulmonary artery pressure ranged from 9 to 51 mm Hg and pulmonary/systemic flow ratio from 1.1 to 5.8. Ductal shape was conical in 24 patients. Route of approach was venous in 23 and arterial in 3. Successful coil implantation was achieved in 24/26 (92.3%). Mean procedure and fluoroscopy time were 67.2 ± 22.1 and 14.9 ± 6.5 min. The three MAPCAs were also successfully occluded using NOC Medium and Flex. Postimplantation angiograms revealed no leak in 3, a trace or small leak in 17, and a medium leak in 4 patients. Mean follow-up was 7 ± 5 months. Complete occlusion was achieved in 17/24 (71%) at 24 hr, 19/24 (79%) by 1 month, 13/15 (87%) by 3 months, 14/15 (93%) by 6 months, and 10/11 (90%) by 12 months postprocedure. Hemolysis, late embolization, duct recanalization, and flow disturbances were not observed. Transcatheter occlusion of moderate-sized PDAs and MAPCAs using NOCs seems to offer a safe, simple, and controlled method in pediatric patients.

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Key words: patent ductus arteriosus; occlusion of patent ductus arteriosus; Nit-Occlud device; children

INTRODUCTION

Patent ductus arteriosus (PDA) occurs in 5–10% of all congenital heart defects. Once the diagnosis of the uncomplicated PDA is established, elimination is recommended by surgery or catheter occlusion to prevent the risk of infective endocarditis [1]. Since the description of the first transcatheter technique for occlusion of PDA by Portsmann et al. [2] in 1967, a number of transcatheter methods for PDA closure have been developed and used. Transcatheter closure of PDA using the Gianturco coils was first described in 1992 [3,4]. Since 1996, controlled-release Gianturco coils (Cook Cardiology, Bloomington, IN) have been widely used [5–7]. The Duct-Occlud coil system was introduced in 1993 [8]. In contrast to the Gianturco coils, the Duct-Occlud (Pfm, Cologne, Germany) coils had a controlled-release mechanism, retrievability, and did not contain Dacron fibers [8–12]. Successful use of the detachable coils has resulted in acceptance of transcatheter occlusion as the treatment of choice in small- to medium-sized PDAs [2–9].

The Duct-Occlud device has an hourglass or cone-in-cone shape, larger number of loops, and reinforced coils [8–12]. Since its initial use in 1992, it has been

modified several times while the main technical principles have remained unchanged. The Nit-Occlud coil system is a further improvement of the Duct-Occlud coil system. Like the Duct-Occlud coil, the Nit-Occlud coil is specifically designed for PDA closure with one coil only. The main differences are a stronger, more compact coil shape that can be well controlled; a new enforced release mechanism avoids early coil release and offers easy handling with a premounted system. This new system has been used in patients with PDA since 2001. We report our initial experience with Nit-Occlud

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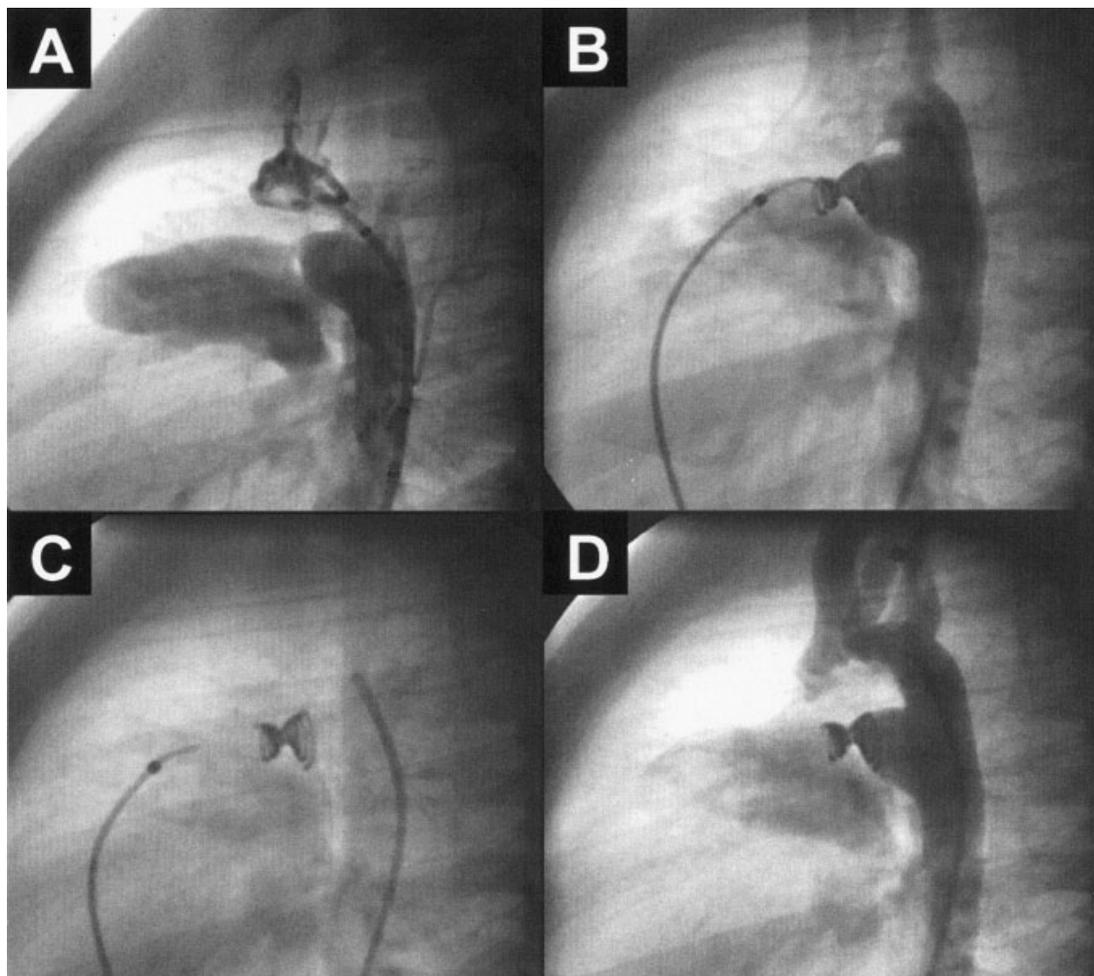


Fig. 1. Implantation of the Nit-Occlud device. **A:** Preprocedural lateral aortogram of a patent ductus arteriosus. **B:** Lateral aortogram before device deployment confirming the device in good position. **C:** View of the coil after deployment. **D:** Lateral aortogram immediate after deployment showing mild to moderate residual leak in the pulmonary artery.

coils (Pfm AG) for transcatheter PDA and major aorto-pulmonary collateral artery (MAPCA) occlusion.

MATERIALS AND METHODS

Patients

Between January 2003 and August 2004, the Nit-Occlud device was used to close PDAs in 26 patients with clinical and echocardiographic evidence of PDA and three MAPCAs in two patients. Patients with increased pulmonary vascular resistance and PDAs larger than 5 mm are excluded. The parents were given information about alternatives of surgical or transcatheter closure and an informed consent was obtained in all cases.

The mean age and weight of the patients were 7.7 ± 5.4 years (range, 1–22 years) and 20.6 ± 11.6 kg (range, 6–54 kg), respectively. Nineteen patients were female

and seven patients were male. Twenty-two patients had an isolated PDA and four patients had additional cardiac abnormalities confirmed by echocardiography and angiography. None of the patients had any previous intervention for PDA closure. Ductal shape was categorized according to previous classifications [13].

Procedure

The closure procedures were performed under local anesthesia following sedation with intravenous midazolam. All patients received prophylactic antibiotic before the procedure; 5 or 6 Fr introducer sheaths were placed in the right femoral vein and the left femoral artery. Intravenous heparin (100 IU/kg) was given when arteries were cannulated. After performing complete cardiac catheterization, a 5 Fr pigtail catheter with marker was placed opposite to the arterial duct in the descending aorta and ductal morphology and sizes were assessed by an aorto-

gram in the lateral or in the right anterior oblique projections if needed. The narrowest part of the duct, aortic ampulla diameter, and axial PDA lengths were measured. The selection of the coil size was based on the following considerations; the largest device loop diameter (D) was equal or slightly larger than the aortic ampulla diameter at maximum and 3–4 mm larger than the narrowest duct diameter at minimum. The lateral projection was used for fluoroscopy throughout the procedure. Venous approach was used in 23 cases and arterial route was used in 3 patients. The tip of the implantation catheter was advanced from the pulmonary artery (PA) to the descending aorta by crossing the PDA and positioned in the descending aorta. The pigtail catheter in the descending aorta was pulled away from the tip of the implantation catheter. The coil delivery system was moved to the tip of the implantation catheter. Approximately 80% of the coil was configured in the descending aorta by advancing the delivery system through the implantation catheter and the whole system was retracted until the configured portion of the coil enters into the ampulla carefully. Then, the tip of the catheter was pulled back into the PA and the remaining loops were delivered on the pulmonary side (Fig. 1). An aortogram was performed to show coil position and PDA occlusion. If the coil size or position was not optimal, it was retrieved or repositioned. When a satisfactory coil position was obtained, which is confirmed by aortogram, the coil was detached from the delivery system. A final aortogram was obtained 10–15 min following the coil implantation to show postimplantation angiographic leak.

The snare-assisted technique was used in a patient with a minimum duct diameter of 2.7 mm. The duct could not be crossed with a guiding catheter from the PA side because of an aneurysmal PA. Therefore, a guidewire was advanced in a retrograde fashion through the PDA into the main PA and was snared with a nitinol Pfm snare, which was advanced from the femoral vein. A guiding catheter was passed over the guidewire through the PDA into the aorta and Nit-Occlud coil was implanted through the PA side.

Coils

Nit-Occlud coils were used in all patients. The Nit-Occlud device is a further improvement of the Duct-Occlud system with a nickel and titanium alloy. Both the Duct-Occlud and the Nit-Occlud device have no Dacron fibers to promote thrombogenesis. The Nit-Occlud device is specially designed for transcatheter closure of PDA of all shapes and sizes up to 6 mm; delivery through a 4 or 5 Fr catheters is possible. It has a graduated stiffness from aortal to proximal windings for optimal adaptation to ductal anatomy; the strong windings avoid pull-through (Fig. 2). Tight and



Fig. 2. Photographic view of the medium-sized Nit-Occlud device. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com]

compact windings in the mid portion ensure fast and efficient occlusion. It is repositionable prior to release and has a flexible delivery system with an atraumatic design, which allows full retrieval of the coil until a satisfactory position is obtained. The delivery system has a radiopaque introducer sheath with distal marker ring and is premounted on a disposable handle, which simplifies the implantation procedure. Nit-Occlud coil system has different designs: Nit-Occlud Flex (flexible coil for closure of small PDAs), Medium (reinforced coil for medium PDAs), Stiff (reinforced coil for medium to large PDA), and Nit-Occlud Double Disk, which is designed for short aortopulmonary windows. A transportation sheath is necessary when Nit-Occlud Flex and Medium are used, which allows an easy transfer into the introducer sheath. The coil is radiopaque and it is magnetic resonance imaging-compatible.

Follow-Up

Patients were discharged within 24 hr of the procedure after a repeat chest X-ray to assess coil position, complete blood count, and urine analysis to exclude hemolysis. Two-dimensional and color flow mapping Doppler echocardiography was performed to assess presence of a residual leak at 24 hr and 1, 3, 6, and 12 months postprocedure.

TABLE I. Clinical and Procedure Data of the Patients*

Patient number	Age (years)	Weight (kg)	Qp/Qs ratio	Mean PA pressure (mm Hg)	Procedure/fluoroscopy time (min)	PDA diameter (mm)	PDA length (mm)	Coil size (mm) and type	Route	Result	Postimplant angiographic leak
1	7	18	2.0	21	80/14.6	3.6 × 10.6	9.1	9 × 6 NOM	Venous	S	Small
2	9	22	1.7	24	80/21.5	2.8 × 11.4	9.0	7 × 6 NOM	Venous	S	Trace
3	2.5	13	1.9	26	105/29.2	2.7 × 10.7	26.6	9 × 6 NOM	Venous	S	Small
4	13	35	2.0	21	80/22	3.5 × 8.9	8.3	9 × 6 NOM	Venous	S	Small
5	2	10	1.2	36	85/9.2	3 × 9.1	6.7	11 × 6 NOM	Venous	S	Small
6	11	30	5.8	37	80/23.6	4 × 11	14.2	11 × 6 NOM	Venous	S	Small
7	1.17	8	2.9	25	90/15.3	3 × 11	8.5	9 × 6 NOM	Venous	S	Small
8	1	7	2.3	26	60/6.8	3.4 × 9.2	5.0	9 × 6 NOM	Venous	S	Moderate
9	1.25	12	1.8	15	45/10.1	3 × 10	9.1	9 × 6 NOM	Venous	S	Small
10	2.5	10	3.1	51	75/14.6	3.9 × 9.4	8.2	9 × 6 NOM	Venous	US	Referred to surgery
11	1.25	12	2.4	21	45/7	2.4 × 8.2	9.5	9 × 6 NOM	Venous	S	Moderate
12	1	6	2.6	39	95/16	4.2 × 8	7.2	9 × 6 NOM	Venous	US	Referred to surgery
13	5	20		19	100/29	2.5 × 6.2	7.1	6 × 5 NOM	Venous	S	Small
14	9.5	22	1.8	35	35/7	2.8 × 7.7	7.0	9 × 6 NOM	Venous	S	Small
15	9	20	1.2	15	45/15	1.25 × 5	6.0	4 × 4 NOF	Arterial	S	Trace
16	6	22			50/15	1.7 × 6.7	6.1	4 × 4 NOF	Arterial	S	None
17	2.5	20			60/15	1.6 × 5.8	6.2	6 × 5 NOM	Venous	S	None
18	6	21	1.1	13	55/14	1.2 × 5	7.5	4 × 4 NOF	Arterial	S	None
19	11	30	1.5	22	55/11.4	2.8 × 9.5	7.5	9 × 6 NOM	Venous	S	Small
20	12.5	10		28	75/12.4	2.7 × 12.5	10.5	9 × 6 NOM	Venous	S	Small
21	9	28	2.3	20	50/14.8	2.5 × 11.2	11.6	9 × 6 NOM	Venous	S	Moderate
22	22	54	1.4	9	60/17.4	2.1 × 8.5	5.5	7 × 6 NOM	Venous	S	Trace
23	15	43	2.0	34	70/6.7	2.8 × 11.2	15.8	9 × 6 NOM	Venous	S	Trace
24	1.5	9	2.6	24	105/22	2.5 × 6.5	7.6	6 × 5 NOM	Venous	S	Small
25	9	28	2.4	27	43/9.3	2.5 × 9.6	9.0	9 × 6 NOM	Venous	S	Small
26	4	15	1.9	34	60/7.6	3 × 1.73	12.6	11 × 6 NOM	Venous	S	Moderate
Total	7.7 ± 5.4	20.6 ± 11.6	2.2 ± 1.0	26 ± 9.6	67.2 ± 22.1/14.9 ± 6.5	2.8 ± 0.8/8.7 ± 2.4	9.3 ± 4.4				

*Qp/Qs, pulmonary flow/systemic flow ratio, PA, pulmonary artery; PDA, patent ductus arteriosus; S, successful; US, unsuccessful. At the bottom of the table the values of mean ± SD for numeric data were given.

RESULTS

Transcatheter closure using Nit-Occlud coils were attempted in 26 patients with PDA and in 2 patients with three MAPCAs (Table I). The mean age and weight of the patients were 7.7 ± 5.4 years (range, 1–22 years) and 20.6 ± 11.6 kg (range, 6–54 kg), respectively. Mean procedure and fluoroscopy times for PDA closure were 67.2 ± 22.1 min (range, 35–105 min) and 14.9 ± 6.5 min (range, 6.7–29.2 min). PA pressure ranged from 9 to 51 mm Hg (mean, 26 ± 9.6 mm Hg) and pulmonary/systemic flow ratio (Qp/Qs) from 1.1 to 5.8 (mean, 2.2 ± 1.0). The mean minimum duct diameter was 2.8 ± 0.8 mm (range, 1.2–4.2 mm), ampulla diameter was 8.7 ± 2.4 mm (range, 3.0–12.5 mm), and PDA length was 9.3 ± 4.4 mm (range, 5.0–26.6 mm). According to the classification of Krichenko et al. [13], ductal shape was conical in 24 patients, elongated conical (group E) in 1 patient, and another patient had two constrictions at aortic and pulmonary sides (group D).

Route of approach was venous in 23 cases and arterial in 3. Successful PDA coil implantation was achieved in 24/26 (92.3% of patients; Fig. 3). In two patients, the procedure was abandoned and patients were referred for surgery, because the coils easily slipped into the pulmonary artery before release. Postimplantation angiograms revealed no leak in 3 patients, a trace leak as a thin jet of contrast limited to the area of the coil in 4, a small leak characterized by opacification of part of the main pulmonary artery (MPA) in 13, and a moderate leak determined as opacification of the MPA to the level of the pulmonary valve in 4 patients.

Follow-up period ranged from 1 to 12 months (mean, 7 ± 5 months). Two-dimensional and color Doppler echocardiographic assessment showed complete occlusion was achieved in 71% (17/24) at 24 hr, 79% (19/24) by 1 month, 87% (13/15) by 3 months, 93% (14/15) by 6 months, and 90% (10/11) by 12 months postprocedure. Eleven patients are still in immediate postimplant period and nine of them had no residual leak by 1 month postprocedure.

A second coil embolization was attempted in one of the patients who had a small residual leak by 8 months postprocedure with Qp/Qs of 1.07. Despite using a guidewire, advancing a guiding catheter was not possible from both the aortic and the PA sides and the procedure was abandoned. Further plan was clinical follow-up, since the residual shunt was small.

There were no procedure-related complications. Hemolysis, late embolization, duct recanalization, and flow disturbances in the PA or ascending aorta were not observed in any of the patients in the follow-up period.

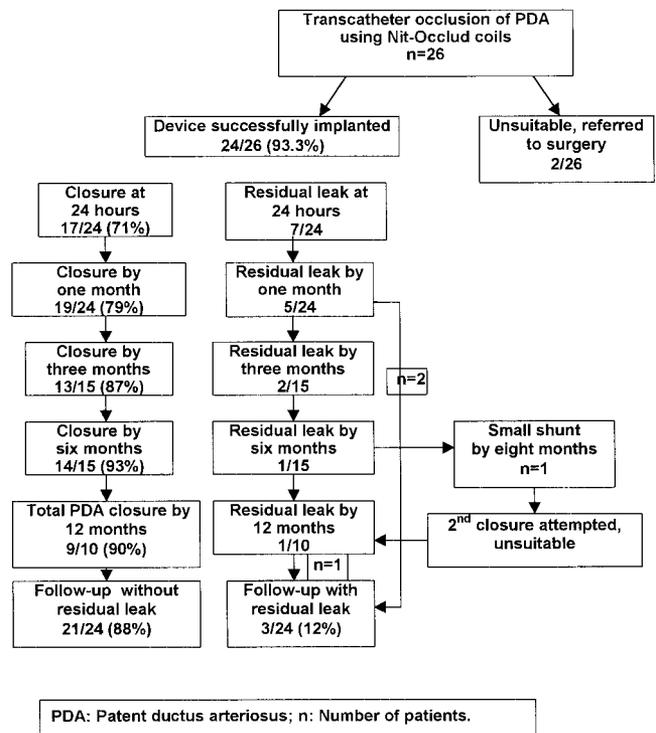


Fig. 3. Transcatheter occlusion results.

Nit-Occlud coils were also used for transcatheter occlusion of MAPCAs in a 2-year-old girl with tetralogy of Fallot (TOF). During open heart surgery, Blalock-Taussig (B-T) shunt and one MAPCA were closed. In the early postoperative period, she had congestive heart failure (CHF) due to flow from other MAPCAs. The first MAPCA was originating from the thoracic aorta and draining into the left PA (diameter, 4.5 mm; Fig. 4) and the second between the beginning of the left subclavian artery and right upper PA (diameter, 2.9 mm; Fig. 4). Both were successfully occluded by using 11×6 mm Nit-Occlud Medium (NOM) and 4×4 mm Nit-Occlud Flex coils, respectively (Fig. 4). By transcatheter occlusion of these two MAPCAs, CHF was immediately treated.

The second patient was an 18-year-old girl who had a prior unifocalization procedure for truncus arteriosus, ventricular septal defect, and 4 mm MAPCA between the thoracic aorta and left PA. MAPCA was successfully occluded using a 7×6 NOM coil. Arterial route was used in both patients for transcatheter occlusion of these MAPCAs.

DISCUSSION

The Duct-Occlud device was developed in the early 1990s and used in several animal models [14,15]. In

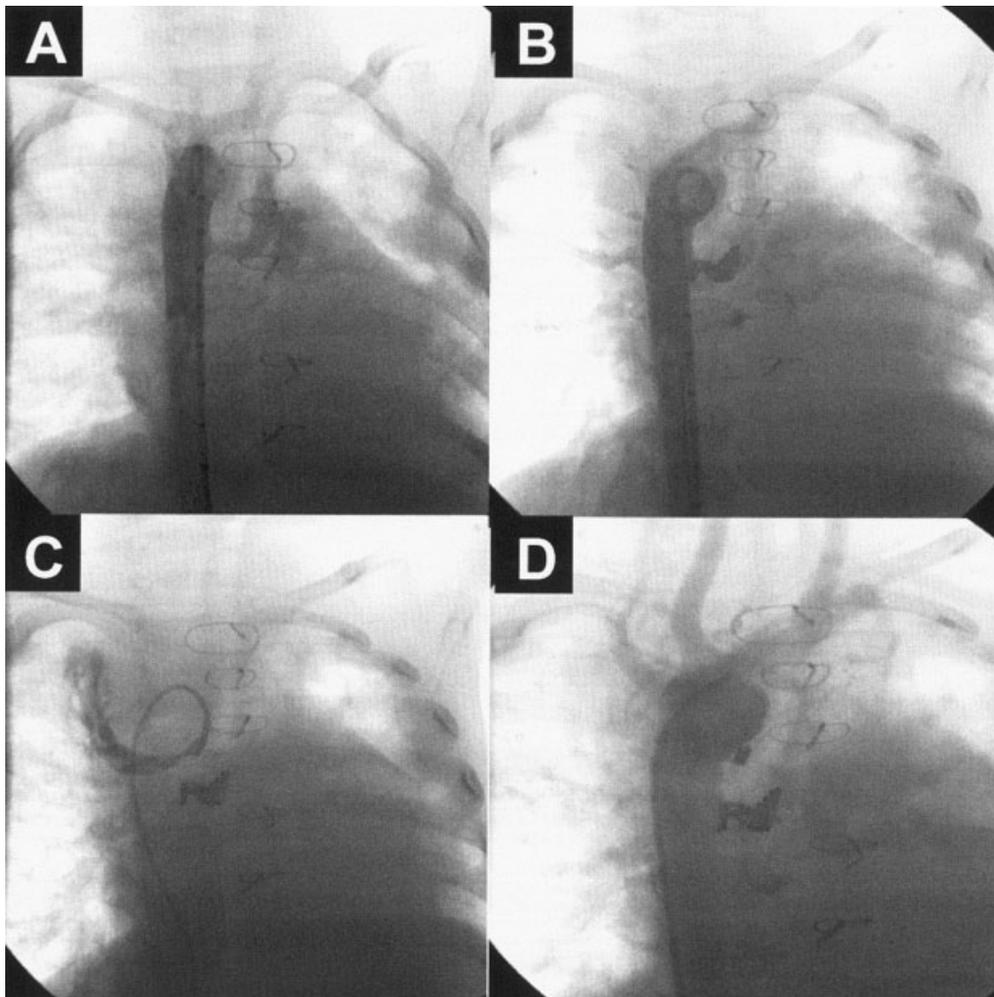


Fig. 4. A: Aortogram showing MAPCA-1, originating from the thoracic aorta and draining into the left pulmonary artery. B: Aortogram showing successful occlusion of MAPCA-1 by medium-sized Nit-Occlud device. C: Aortogram showing MAPCA-2, between the beginning of the left subclavian artery and right pulmonary artery. D: Aortogram showing successful occlusion of both MAPCAs by two different (Medium and Flex) Nit-Occlud device.

1996, Tometzki et al. [9] reported the first experience of transcatheter occlusion of PDA with a Duct-Occlud device in humans. Device implantation feasibility was 44/51 (86%), device dislodgment was 3/44 (7.1%), and residual shunt at 24 hr was 9%. The authors also reported the first use of the device for transcatheter occlusion of a surgically created modified B-T shunt and MAPCA and concluded that transcatheter occlusion of aortopulmonary connections either native, residual, or surgically created can be achieved effectively and safely with the device. Lê et al. [16] reported 91% (466/514) implantation feasibility with the Duct-Occlud device, dislodgment rate of 4% (6/466), residual shunt at 24 hr of 42% and at follow-up of 5.5%. Other clinical studies have demonstrated device safety and efficacy [10–12].

Results of the phase 1 U.S. Food and Drug Administration clinical trial of the Duct-Occlud device for occlusion of PDAs with less than 4 mm minimum duct diameter have shown that out of 62 patients, 48 had successful implantation of the device without any complications during the procedure or in the follow-up period [11]. Complete echocardiographic closure was noted in 55% of the patients at hospital discharge and 94% 12 months later. Although initial angiographic and echocardiographic rates of residual leak were high (45%), there was a high rate of spontaneous closure in stable properly positioned devices. Therefore, the authors concluded that optimally sized and positioned devices should be implanted even if angiography demonstrates residual leak.

Results of the European registry on 1,291 attempted coil occlusions of PDA in 1,258 patients using different coils in which Duct-Occlud coils were used in 143 procedures (11%) also showed that the immediate occlusion rate was 59%, which rose to 95% at 1 year with all coil types [12]. Although the number of patients in our study who had been followed for 1 year is considerably low when compared with the European registry's study, the immediate occlusion rate increased from 11% to 71% at 24 hr and to 90% by 12 months postprocedure.

According to the European registry's study, an increasing minimum duct diameter and the presence of tubular duct morphology were positively associated with an unfavorable outcome. When tubular ducts were excluded from the analysis, transcatheter closure of the ducts larger than 4 mm was found to result with an unfavorable outcome. In our study, the mean minimum duct diameter was 2.8 mm and duct diameter ranged from 1.2 to 4.2 mm, which could be categorized as medium-sized PDAs and occlusion rate was 90% by 12 months postprocedure. We had successful coil implantation and no residual leak in two of our patients who had an elongated conical PDA and PDA with multiple constrictions.

When the PDA diameter seems to be inappropriate for the Nit-Occlud device to be implanted or the procedure is perceived to be at high-risk based on morphology of the duct, the snare-assisted technique can be considered to aid coil occlusion before abandoning the procedure. We have managed to close a PDA with a minimum duct diameter of 2.7 mm and which could not be crossed with a guiding catheter from the PA side, with the Nit-Occlud device using the snare-assisted technique.

Arterial ducts that are not suitable for coil implantation may still require surgical intervention or occlusion using an alternative catheter system [17,18]. The cost is somewhat higher with Amplatzer PDA system. Two of our patients who had unsuccessful outcome with Nit-Occlud device were referred for surgery since the other transcatheter PDA closure devices such as Amplatzer was not available.

There are two different types of the Duct-Occlud device currently available: the standard Duct-Occlud device with an asymmetrical hourglass appearance due to a larger distal diameter than the proximal diameter, and the reinforced Duct-Occlud device that has a cone-in-cone shape, where the proximal windings are wound in the reverse direction [16]. The diabolo configuration of the device after releasing into the duct mimics its shape in many cases. One other advantage of the Duct-Occlud and the Nit-Occlud device is that they are fully retrievable, allowing removal, exchange for a larger or more suitable device, or reimplantation if a

satisfactory position is not obtained. The Duct-Occlud device is suitable for PDAs with a minimum duct diameter smaller than 4 mm; the further improved Nit-Occlud device is suitable for PDAs up to 6 mm, has a nickel and titanium alloy, and has three different designs.

Like the Cook PDA coils, both can be delivered through a small catheter, which allows its use in infants. Cook coils can be used to close ducts up to 4–6 mm. Transcatheter occlusion of PDA using other detachable coils such as Cook coils revealed similar results [5–7,19–21]. Implantation feasibility, device dislodgment, residual shunt rate at 24 hr after implantation and at last follow-up control had ranges of 94–99%, 1.5–7%, 7–28%, and 3–12%, respectively, in these studies. However, in larger ducts if a single coil is deployed, there is increased risk of significant residual flow and hemolysis and multiple coil implantation may be necessary [7]. The Nit-Occlud device offers a cost-effective technique for closing PDAs up to 4–6 mm using a single coil technique. We report 92.3% (24/26) implantation feasibility by using a single Nit-Occlud device, residual shunt at 24 hr as 29% (7/24) and at follow-up as 10% (1/11) without any complications such as hemolysis, late embolization, duct recanalization, or flow disturbances in the pulmonary artery or aorta in the follow-up period. Furthermore, device dislodgment, embolization, or misplacement were not observed.

Our preliminary experience suggests that transcatheter occlusion of moderate-sized PDAs and MAPCAs using Nit-Occlud coils offer a safe, simple, controlled, and successful method in pediatric patients. Clinical trials on larger patient populations are necessary to confirm these findings.

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