Original Studies

Implantation of the New Nit-Occlud PDA-R Device in Children Below 10 Kilogram

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Background: Interventional closure of patent ductus arteriosus (PDA) has become a common and safe procedure in most pediatric cath labs. Interventional treatment of PDAs still remains a challenge in those children with low body weight and a large PDA. The Nit-Occlud PDA-R® device was developed and especially designed for large PDAs. We report our most recent experience in children with a body weight lower than 10 kg. Materials and Methods: The PDA-R® device was used in seven children (age 1–10, median 6 months) with a body weight from 4.1 to 9.7 kg (median 5.9 kg): ductal length was 12 mm (median), with a large ampulla (median 9 mm) which exceeded the diameter of the aorta (median 6 mm) and large diameter (median minimal diameter 4 mm). In six cases, the Nit-Occlud PDA-R was selected with an aortic disc of 12 mm and in one case an occluder with an aortic disc of 14 mm. Results: Occlusion of the PDA was documented by angiography and/or echocardiography in all cases. At a mean follow-up of 21.4 months, no flow obstruction to the left or right pulmonary artery or new onset coarctation of the aorta was noted. Conclusions: The Nit-Occlud PDA-R® device is suitable in children with a body weight below 10 kg when a relative large PDA is present. © 2014 Wiley Periodicals, Inc.

Key words: pediatric intervention; embolization; coil/device/transcatheter; interventional devices/innovation

INTRODUCTION

Many PDA devices have been developed since Porstmann et al. [1] described the first successful interventional closure of a patent ductus arteriosus (PDA) almost fifty years ago. Most medium size PDAs can be usually closed with small plugs and coils [2–5]. In large PDAs usually larger devices are needed such as large Amplatzer Duct Occluders (ADO) [6–9] or even atrial septal defect occluders [10]. Duct closure of large PDAs in small children is challenging for several reasons [11–14], including the anatomical dimensions of the PDA, the aorta, and the pulmonary arteries compared to the dimensions of the devices and introducers. In these patients, aortal and/or pulmonary obstruction or embolization is reported, especially for the ADO II device [15,16] and the ADO device [17], respectively.

A new device specifically designed to close large PDAs is the Nit-Occlud PDA-R® device (PFM Medical AG, Cologne, Germany). First reports have been published by Freudenthal et al. in 2012 [18]: 88 patients with very large PDAs from Bolivia, living at high altitude, were successfully treated with this new device. The initial clinical trial with this occluder published so far accepted only children with a body weight

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Conflict of interest: NAH is a proctor for PFM Medical.

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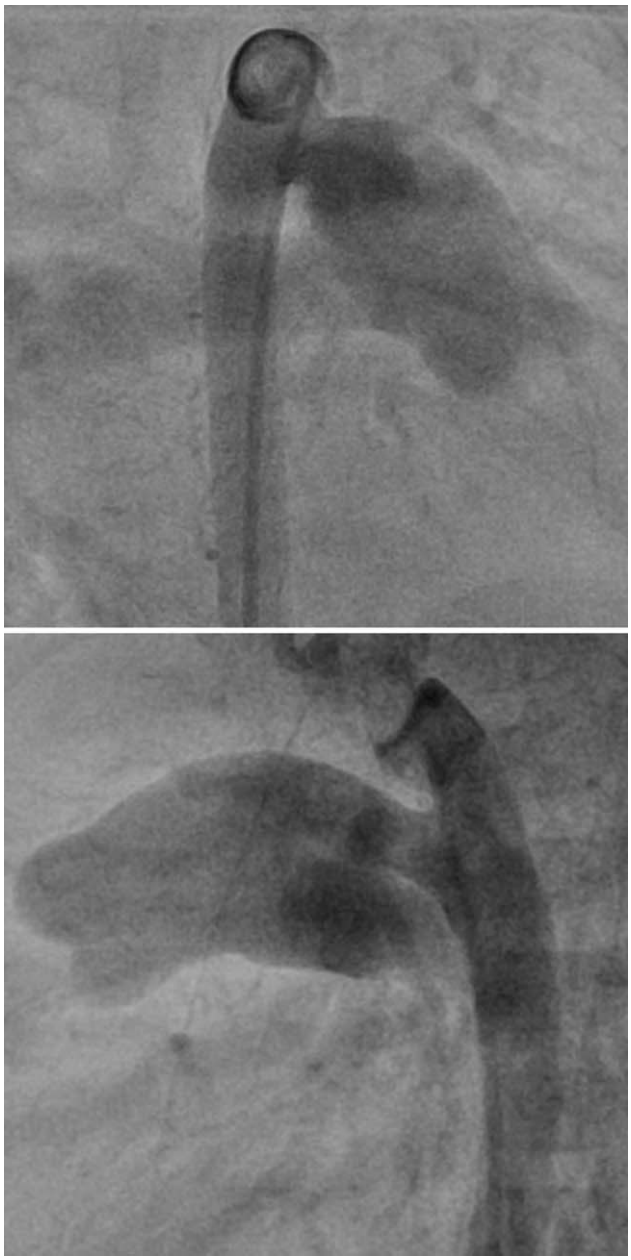


Fig. 1. Large patent arterious duct in a 4-month-old infant with 4.4 kg, minimal duct diameter comparable in size to the distal aortic arch (RAO 30°/cranial 30°, LAO 90°/0°).

greater than 10 kg. We report on our most recent experience in seven children who presented a moderate to large sized PDA and a body weight below 10 kg.

MATERIAL AND METHODS

This is a retrospective data analysis of the patients treated. However, data acquisition was prospective as all patients referred to the catheter laboratory are monitored prospectively as per routine institutional protocol. The seven infants with a body weight below 10 kg were referred to the pediatric cardiac catheterization laboratory with a PDA for closure between April 2011 and September 2012. Angiography showed large ducts in five of seven infants, the other two had smaller ducts that were suitable for this occluder. The PDA was considered large if it was not suitable for closure with Cook detachable coils (usually minimum diameter of the duct at least 4 mm). In this period of time mentioned above, no other device (e.g., ADO) was used for duct closure. All procedures were performed with deep conscious sedation and spontaneous breathing; routine vital parameters including oxygen saturation, blood pressure, heart rate, and ECG were monitored continuously during the procedure.

Arterial and venous vascular access was obtained. The initial venous sheath was usually 5 Fr, the arterial sheath 4 Fr. Patients received an initial dose of 100 U/kg of sodium heparine. A second generation cephalosporine was administered for antibiotic prohylaxis, and repeated 8 and 16 hr later. Hemodynamic measurements were performed followed by biplane angiography of the PDA: the frontal plane was angulated in a RAO 30° and cranial 30° position to evaluate the aortic end of the PDA as well as the distal aorta; the lateral plane (LAO 90°) was used to evaluate the pulmonic side and the duct morphology (Fig. 1). Demographic information, measurements of the PDA, and procedural data are shown in Table I.

The occluder size was determined by the minimum diameter of the PDA, with the occluder stent at least 1.5 times greater than the minimum diameter of the duct to avoid embolization. The chosen devices were implanted and released from the pulmonary side after exchanging the venous sheath to an adequate delivery system. First, the reinforced retention disc was deployed in the descending aorta retracting the long delivery sheath with the occluder in position so that it was set completely free in the PDA (Fig. 2). Angiography in the descending aorta was performed before releasing to confirm the device position. Finally, the central safety wire was retracted to release the occluder (Fig. 3). After approximately 5–10 min, a final angiogram was performed to document the position of the device and look for residual shunt (Fig. 4). Echocardiography with color Doppler was performed 24 hr and 48 hr after implantation.

RESULTS

Baseline demographic data, measurements of the duct and aorta after angiography, and device data are listed in Table I. Transcatheter PDA closure was

TABLE I. Demographic Information, Measurements of the PDA, and Descending Aorta and Device Data

No.	Age (month)	Sex (f/m)	Weight (kg)	Length (cm)	PDA min. (mm)	Aortic ampulla (mm)	PDA length (mm)	Desc. aorta (mm)	PDA-R (stent/disc/length) (mm)
1	10	f	5.4	62	4.5	11	15	9	7/12/8.5
2	4	f	4.4	58	4	11	16	5	7/12/8.5
3	1	m	4.1	56	3.5	8	11	6	7/12/8.5
4	7	f	9.7	90	4	9	12	10	7/12/8.5
5	6	f	5.9	63	6	12	14	8	8/14/9.5
6	4	m	7.3	64	4	9	10	6	7/12/8.5
7	9	f	7.6	66	2	7	8	6	7/12/8.5
Median	6	4/3	5.9	63	4	9	12	6	

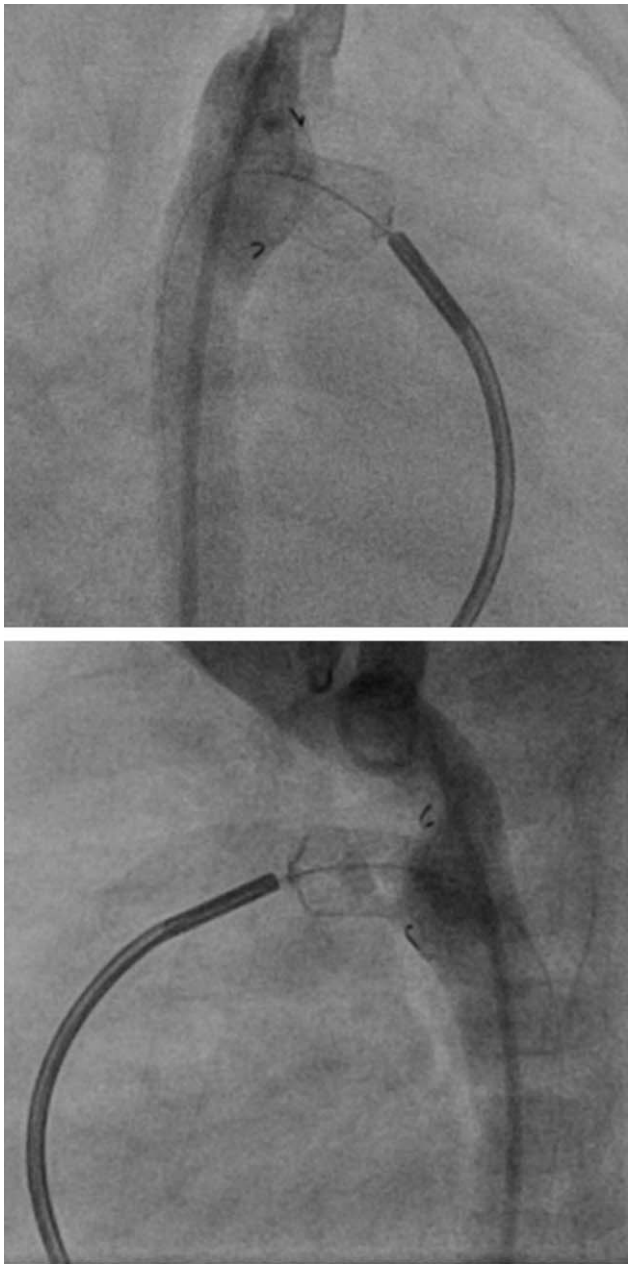
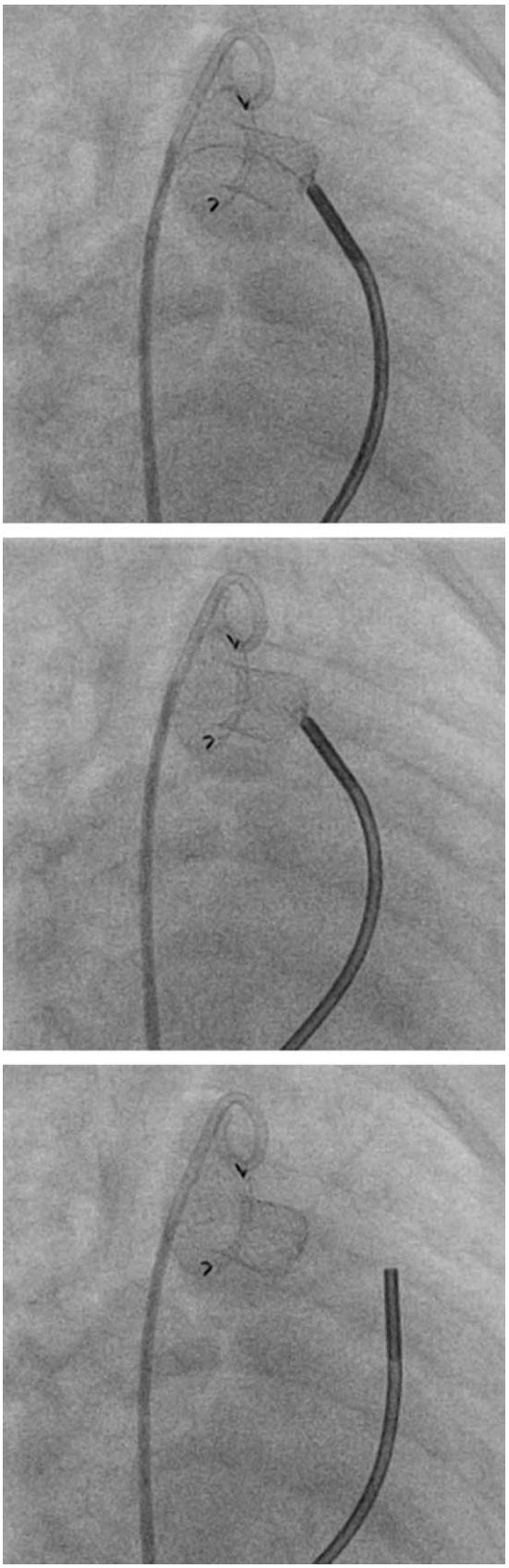


Fig. 2. Nit-Occlud PDA-R device in ductal position before releasing (RAO 30°/cranial 30°, LAO 90°/0°).

achieved in all cases. The most common device used was the Nit-Occlud PDA-R® device with a 7 mm stent, a 12 mm disc, and a length of 8.5 mm. This device was delivered through a 6 Fr delivery sheath. In one case, an occluder with an 8.5 mm stent, a 14 mm disc, and a length of 9.5 mm was chosen to obtain sufficient closure of the duct. This device required a 7 Fr sheath. No procedural hemodynamic compromise or other complications occurred, including device embolization, aortic or pulmonic obstruction, or vascular access occlusion. Residual shunt was observed in 5 of 7 cases on final angiography, in 4 of 7 infants 24 hr later, and in 2 of 7 cases 48 hr after implantation by echocardiography. In all infants, pulmonary pressure decreased immediately after device implantation.

Follow-Up Data

The patients were followed for 21.4 (± 7) months. After four weeks, six of the seven PDAs were successfully closed by the Nit-Occlud PDA-R device; in the remaining infant, no residual shunt was detected with color Doppler echocardiography at three months follow-up. None of the patients developed a coarctation of the aorta or a pulmonary artery stenosis with need of intervention. In one baby, the occluder protruded about 2–3 mm into the aortic lumen, without causing a relevant increase in flow velocity measured by Doppler echocardiography (maximum 2 m/sec) or a blood pressure gradient. In another baby, we observed a maximal flow velocity of 3 m/sec at the aortic isthmus, which was not related to a protrusion of the coil, but due to an anatomical narrowing of the aortic arch present before device implantation. In this child, no blood pressure gradient was detectable. By echocardiography, we detected in one child the pulmonary end of the device protruding into the bifurcation; there was, however, no flow acceleration or narrowing of the left or right pulmonary artery detectable that needed additional measures. One child additionally had a ventricular septal defect which was surgically closed 3 months



later. At surgery no residual flow via the closed PDA was noted.

DISCUSSION

In this case series of seven patients, we implanted the Nit-Occlud PDA® occluder. This device was especially designed to treat large PDAs and may be utilized in infants with a body weight of less than 10 kg. Previous studies showed that patent arterious duct closure with the Nit-Occlud PDA-R® occluder is feasible and safe in large and long ducts [19,20] located in children more than 10 kg in weight. In these children, initial closure rate was 58% at the end of the procedure, but after 3 month in follow-up, all 43 duct were completely closed. In our study, the infants had a large and/or long PDA (median minimal diameter 4 mm and median length 12 mm) for their bodyweight (median 5.9 kg).

Large PDAs (4–12 mm) are often closed with the classical ADO device. El-Said et al. [21] analyzed in a prospective multicenter trial that the device selection was dependent on the patient's size. The multicenter USA Amplatzer Patent Ductus Arteriosus Occlusion Device Trial reported results with the ADO device in 435 patient with a moderate to large duct, with body weight ranging from 4.5 to 164.5 kg (median 11 kg) and the age from 0.2 to 70.7 years (median 1.8 years). Closure rates were high (76% immediate closure rates, increasing to 89% after 1 day), and the complication rate was low (only two cases with partial left pulmonary artery obstruction, no aortic obstruction). For many years, the ADO was the only device available to close moderate and large PDAs.

Despite similarities to the ADO device, we chose to utilize Nit-Occlud PDA-R® device because of the small diameter of the descending aorta in our children (median, 6 mm). We postulated that the aortic retention disc would not be obstructive because of the reverse development of the device, with the more proximal parts of the retention disc delivered first and folding back on themselves to form a very thin aortic disc. Then, while anchoring the retention disc into the duct, it assumes a concave shape to adapt better to the aortic wall. The stent is also more flexible than the ADO device. Due to this architecture, the PDA-R® occluder seems to adapt well to the individual shape of the PDAs in our series. The device is locked with a single central safety wire that comes out of the pusher cable

Fig. 3. Pull-back-wire system: releasing by retracting the central wire into the pusher cable. This connection is flexible and helps to keep the occluder in the same position as deployed. (RAO 30°/cranial 30°).

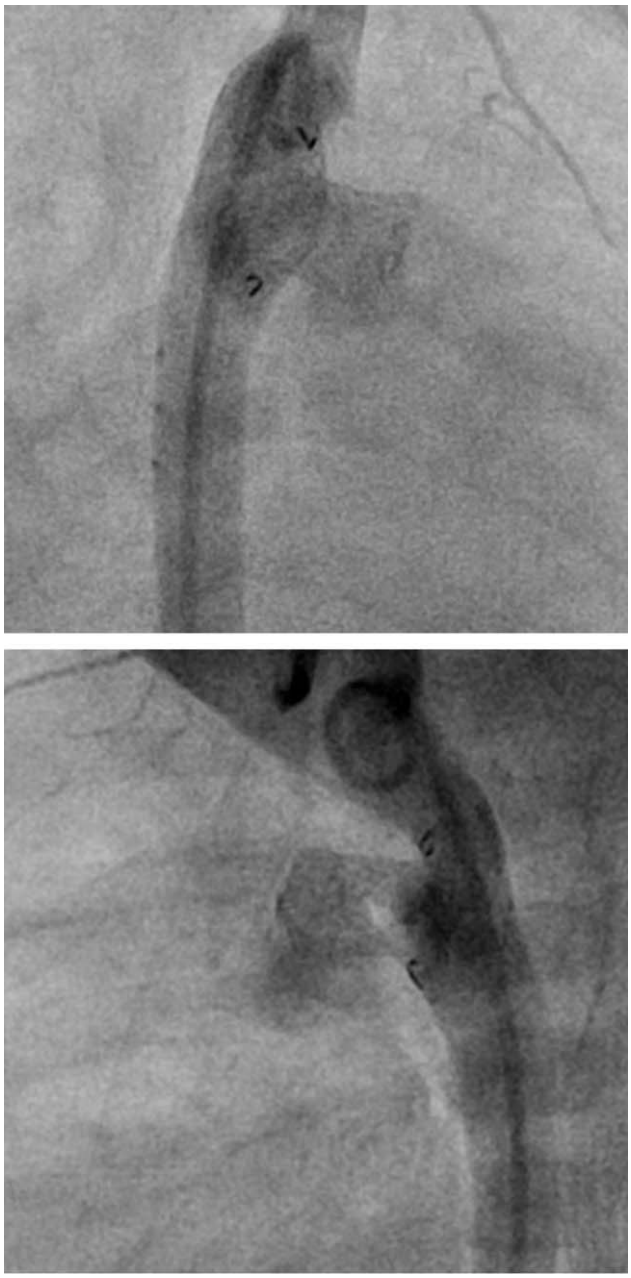


Fig. 4. Nit-Occlud PDA-R after releasing. Note that the position of the device did not change compared to predeployment. A slight residual shunt 5 min after implantation can be observed.

and crosses the occluder. The flexible pusher cable allows the device to be delivered in a safe anatomical position without disturbing the anatomy of the small children. Before detaching, retrieval of the device for repositioning is possible by retracting the device with the pusher cable into the long sheath. In our cohort, we removed one occluder to change it for a larger device without difficulty. While releasing, the PDA-R® occluder keeps the position and the angle of the device between the duct, and the descending aortic anatomy is unchanged (Fig. 3). Sheath sizes are comparable to those needed for the Amplatzer device.

One clinically important drawback remains the relatively low immediate closure rate. For the ADO device, higher immediate duct closure rates are reported [7]. In our cohort, 5 of 7 infants had a residual shunt at the end of the catheterization procedure (Fig. 4) and complete closure was achieved only after 3 months in 1 patient. Compared to other devices, the Nit-Occlud PDA-R® has sutured polyester membranes inside the occluder. This material is more porous so that the immediate closure rate is low. Similar results were shown in the initial clinical study by Freudenthal et al. in 29 patients and in the 51 children reported by Heath et al. (100% closure rates after 6 months).

CONCLUSION

In this study, PDA closure with Nit-Occlud PDA-R device was safe and effective in all our infants. The Nit-Occlud PDA-R® device may be considered a suitable option for children with a bodyweight below 10 kg presenting with moderate to large PDAs up to 6 mm minimal diameter. This small study did not aim to demonstrate any superiority results compared with other closure devices for children with PDA. This new devices adds up to the armentarium of PDA devices for large PDAs even in smaller children.

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