Percutaneous closure of patent ductus arteriosus with the Nit-Occlud® patent ductus arteriosus device in 268 consecutive cases

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ABSTRACT

Background : **The pfm Nit-Occlud® patent ductus arteriosus (PDA) device is well established for interventional closure of PDA. However, there are still limited data concerning its efficacy and follow-up in larger patient groups.**

Aims : **This study aimed to evaluate the safety and efficacy of the Nit-Occlud® PDA device, implanted both through transpulmonary and transaortic approach, in a large cohort.**

Methods : **From July 2008 to December 2015, 268 consecutive patients were admitted for transcatheter closure of a PDA and were treated with the Nit-Occlud® coil. Clinical, echocardiographic, and angiographic data were evaluated.**

Results : **The median age was 5.2 years (range, 5 months to 62 years), and the median weight was 19.3 kg (range: 5.5–97 kg). Ten (3.7%) patients had weight <10 kg. The most common ductus types treated were Krichenko Type E and A (44.0% and 33.2%, respectively). Twelve (4.5%) patients were treated for residual shunting after surgical PDA closure. The median diameter at the narrowest point was 1.5 mm (range: 0.4–4 mm), the median size of the ampulla was 5 mm (range: 1–15 mm), and the median length was 9 mm (range: 2–25 mm). Device implantation could be successfully achieved in all cases. Closure rates documented immediately after the procedure, at 3–10 days, 1 month, and 6 months after intervention were 62%, 95.1%, 97.8%, and 98.5%, respectively. With the exception of one minor thromboembolic event, there were no procedure-related complications.**

Conclusion : **Closure of PDA with various anatomic variations and sizes can be performed effectively and safely using the Nit-Occlud® coil.**

Keywords : Interventional closure, interventional devices, patent ductus arteriosus

INTRODUCTION

For 30 years, transcatheter closure of patent ductus arteriosus (PDA) has been considered a standard procedure in most pediatric catheterization laboratories, and the procedure is routinely performed after the neonatal period. Starting with the Ivalon plug in 1967,[1] the interventionalist's armamentarium has steadily grown and improved. Today, the interventionalist has a wide range of occluder types and coils, mostly

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nitinol-based and self-expanding, to choose from.[2-8] The use of coils has gained popularity due to the advantages of smaller and more flexible introducer sheaths, simple handling, and cost efficiency.

Although they are widely used for ductus closure, the Gianturco and Cook coils were actually originally designed for the occlusion of tubular vessels and not the ductus arteriosus.[9-11] In 1996, Grabitz *et al.* introduced a new generation of coil devices specifically designed for the ductal anatomy: the Duct-Occlud coil systems (pfm, Cologne, Germany).[12] After several technical improvements to the original device and to the delivery system, these devices are now known as pfm Nit-Occlud® PDA devices and have been used extensively in Europe since 2001.[13] The Nit-Occlud® PDA device gained the Federal Drug Administration approval in 2013. Despite the routine application of the device in the last decades, there are still limited published data regarding device safety, efficacy, and follow-up performance. We report our recent results with the Nit-Occlud® coil (Flex and Medium) in a cohort of 268 patients with small-to-moderate PDA sizes. The data presented include follow-up data collected up to 6 months after intervention.

METHODS

Study population

Between June 2008 and December 2015, 268 consecutive patients with a PDA size <5 mm (on echocardiography) underwent PDA closure with the Nit-Occlud® coil at our institution. During this period, no other devices were used for this patient population. Cases with a minimum PDA diameter >5 mm and/or with increased pulmonary vascular resistance were excluded and prepared for treatment using other therapeutic options. Informed consent was obtained from either the patient or the patient's parents/legal guardian before the intervention. Clinical, echocardiographic, and angiographic data of all 268 patients were evaluated retrospectively. Ethical approval for the study was obtained from the local ethical board (Local Ethics Committee of the Ukrainian Children's Cardiac Center).

Device description

The Nit-Occlud® coil as the successor of the Duct-Occlud coil is a nitinol-based spiral-shaped device for small and medium-sized ducts [Figure 1]. The device is designed with stiffer aortic windings which are meant to prevent "pull-through" into the pulmonary artery. Occlusion is promoted by tight and compact windings without Dacron fibers. The system is premounted and implanted through a 4F or 5F catheter and fully retrievable and repositionable. The device is available in different sizes, from 4 mm × 4 mm to 11 mm × 6 mm and in different

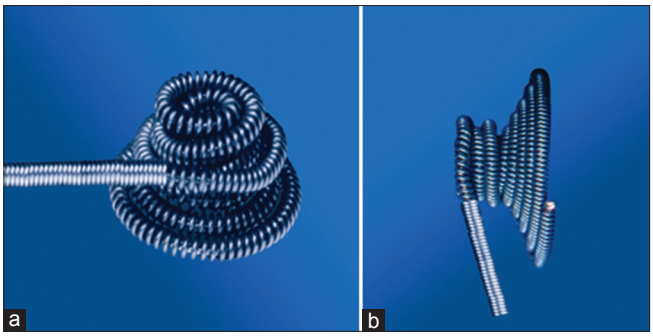

Figure 1: pfm Nit-Occlud® patent ductus arteriosus device. (a and b) Nitinol-based spiral-shape device for small and medium-sized patent ductus arteriosus. Tight and compact windings are thought to enhance efficient occlusion; no thrombogenic fabrics are incorporated

grades of flexibility ("flex" and "medium"). The coil size is chosen according to the duct's minimal diameter, length, and diameter at the ampulla. The coil is radiopaque and magnetic resonance imaging (MRI) compatible.

Implantation procedure

All procedures were carried out using local anesthesia, deep conscious sedation, and spontaneous breathing. Vital parameters were monitored continuously during the intervention. Vascular access was obtained through the femoral artery and vein. The initial sheath size used for arterial access (transaortic approach) was predominantly 4F and the initial sheath size used for venous access (transpulmonary approach) was 4–5F. A single dose of unfractionated heparin (30 U/kg) was administered intravenously before the intervention and again 1 h later. Single-shot antibiotic prophylaxis using a second-generation cephalosporin was administered before every procedure.

Hemodynamic measurements were collected according to the standard methodology. Hemodynamic data included aortic blood pressure and pulmonary artery pressure. Evaluation of the anatomy of the duct was performed with biplane aortography. A 30° right anterior oblique and 20° cranial position was used to evaluate the aortic end of the duct as well as the distal aorta. A 90° straight lateral anterior oblique projection was used to assess the pulmonic side of the duct as well as the duct morphology.

The ductal type was determined according to the Krichenko classification:[14] Type A: conical duct with constriction near the pulmonary end and a well-defined ampulla; Type B: window-like duct (short and narrow); Type C: tubular duct without constrictions; Type D: complex duct with multiple constrictions; and Type E: elongated conical duct with a constriction remote from the anterior border of the trachea. The ideal size of the coils was determined by measurements made after angiography of the duct. The distal diameter of the coil was chosen to be a maximum of 2 mm larger than the

diameter of the ampulla and minimum of 3–4 mm larger than the minimum duct diameter. The coil length was chosen to be slightly shorter than the ductal length. Device selection was performed according to the manufacturer's suggestions and with the goal of preventing protrusion into the pulmonary artery or the aorta.

In general, the implantation of the Nit-Occlud® coil is similar to transvenous implantation of any other coil device. The intraaortic device configuration, the final device deployment, and device release, however, are different to standard coil procedures. If implanted through venous access, the device is advanced through the duct to the descending aorta under fluoroscopic control. All loops located distal to the device waist are deployed within the aorta, and the whole delivery system is retracted into the ductal ampulla. The implantation catheter is simultaneously retracted, while the delivery system is pushed forward slightly to deploy the remaining coil windings anchoring the pulmonary end of the duct [Figure 2]. Implantation through arterial access only is performed similarly, with the first windings released on the pulmonary side and full deployment and compaction of all remaining windings within the ductal ampulla [Figure 3]. Final angiography is performed to confirm unobstructed flow in the aorta and correct device positioning. Successful outcome is defined as delivery of the device within the ductus without resulting pulmonary artery or aortic obstruction; based on the device design, a residual shunt immediately during the implantation or at the end of the procedure is accepted.

Evaluation of procedural success is achieved by color Doppler echocardiography of the ducts directly after the intervention and within the following 3–10 days. Patients are discharged from the hospital and reviewed on outpatients' visits at 1 and 6 months after closure of the duct.

Statistical analysis

Clinical and procedural data of each patient were collected retrospectively from our departmental database. The results are expressed as mean ± standard deviation or median and range. We used the Chi-squared test for the investigation of intergroup differences in categorical variables. Intergroup differences in continuous variables were tested using the Mann–Whitney U-test and Kruskal–Wallis test. To determine adjusted odds ratios (ORs) for the risk of residual shunting, we used logistic regression modeling. Statistical analyses were performed using IBM SPSS Statistics Version 23 (International Business Machines Corporation, Armonk, New York, USA).

RESULTS

Of all patients treated, the median patient age was 5.2 years (range: 5 months–62 years) and median body weight 19.3 kg (range: 5.5–97 kg). Ten (3.7%) patients had a body weight under 10 kg, and two patients had a body weight under 6 kg. The PDA was the only cardiac abnormality in 80.6% of the patients. About 4.5% of the patients required treatment for ducts which had reopened after a previous surgical closure. Forty (14.9%) patients had additional cardiac anomalies or had undergone surgical correction of another cardiac defect [Table 1].

Angiographic evaluation before closure showed most of the ducts to be Krichenko Type "E" (118 cases [44.0%]) and "A" (89 cases [33.2%]). Types "B" (3.4%), "C" (7.8%), and "D" (9.0%) were less common. In seven cases, ductal morphology could not be allocated to any

Table 1: Demographic data

Variable	Patients (*n* = 268)	Mean ± SD
	Median (range)	
Age (years)	5.2 (0.4–62)	6.6 ± 5.5
Weight (kg)	19.3 (5.5–97)	24.1 ± 14.3
Weight <10 kg, *n* (%)	10 (3.7)	
Additional cardiac anomalies, *n* (%)	40 (14.9)	

SD: Standard deviation

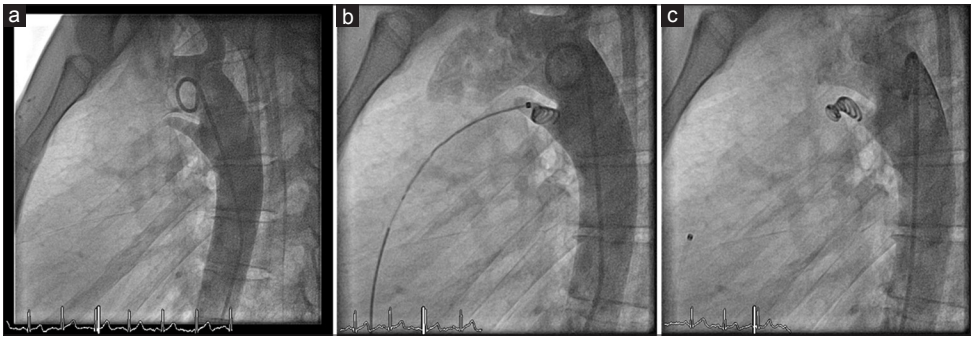

Figure 2: Transvenous closure of a Type A patent ductus arteriosus (a), angiogram in straight lateral view. The device is advanced through the duct to the descending aorta under fluoroscopic control. All loops located distal to the device waist are deployed within the aorta and the whole delivery system is retracted into the ductal ampulla (b). The implantation catheter is simultaneously retracted, while the delivery system is pushed forward slightly to deploy the remaining coil windings anchoring the pulmonary end of the duct (c)

of the Krichenko types. The median duct diameter at the narrowest region was 1.5 mm (range: 0.4–4 mm), the median duct size at the ampulla was 5 mm (range: 1–15 mm), and the median duct length was 9 mm (range: 2–25 mm) [Table 2]. Hemodynamics showed a mean systolic pulmonary artery pressure before closure of 30.7 mmHg (20–47 mmHg) with a mean pulmonary artery pressure/aortic pressure ratio of 0.34 (0.22–0.54).

In 84.7% of the cases (227 patients), arterial as well as venous access was gained for the intervention (sheath sizes: 4–5F); overall, 81% of the ducts were approached through the transpulmonary route. In cases with favorable anatomy (i.e., long small duct or small minimal diameter), retrograde implantation through only arterial access was performed (41 patients [15.3%]). Device implantation was successfully accomplished in all patients. Device sizes implanted ranged from 4 mm × 4 mm (17 pt) to 11 mm × 6 mm (21 pt). The 7-mm × 6-mm device was most frequently used (37.6%). Duct classification and device sizes implanted are shown in Table 2. Mean fluoroscopy time was 9.3 ± 7.37 min and mean hospital stay was 3.3 ± 1.48 days. Angiography confirmed correct device positioning in all cases. Immediately after implantation, echocardiography confirmed complete duct closure in 62% of the cases. The closure rates investigated with color flow Doppler at 3–10 days postintervention were 95.1% and 97.8% after 1 month in the 268 patient cohorts. Six months after the procedure, 98.5% of the ducts were found to be completely closed [Table 3]. In our cohort, 19 patients were lost to follow-up – all these patients had documented complete closure of the duct within the first 10 days after intervention. The minimal diameter of the duct was positively related to residual shunting, i.e., larger ducts were more likely to show residual shunts initially (OR: 2.15; 95% confidence interval [CI] for OR: 1.51–3.06; $P < 0.001$). Residual shunting immediately after intervention was more common in Types A and B PDAs (47.2% in Type A and 55.5% in Type B compared to 30.5% in Type E; difference not statistically significant, $P = 0.239$). The patients' weight did not adversely influence the residual shunt rate (OR: 0.99; 95% CI for OR: 0.90–1.02; $P = 0.75$) or length of hospital stay ($P = 0.31$).

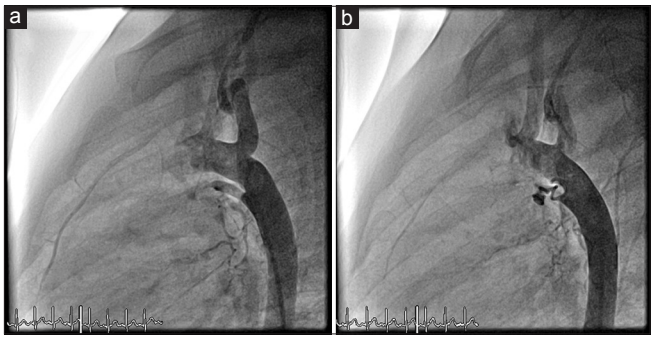

Figure 3: Transaortic closure of a Type E patent ductus arteriosus (a), angiogram in straight lateral view. Implantation through arterial access only is performed similarly, with the first windings released on the pulmonary side and full deployment and compaction of all remaining windings within the ductal ampulla (b)

In one patient, the initial coil needed to be replaced to achieve sufficient duct occlusion. The initial coil (6 mm × 5 mm) was not fixed within the duct due to an underestimation of duct size and subsequent coil undersizing. The coil was removed while still attached to the delivery system and a second larger coil (11 mm × 6 mm) was implanted. In another patient, on implantation, the Nit-Occlud® coil was captured within the pulmonary valve. Retrieval could be achieved without damage to any cardiac structures and a new coil could be placed uneventfully. One patient developed postinterventional headache – MRI verified a minor ischemic stroke. This patient was treated with aspirin for 7 days and recovered completely during follow-up. In our cohort, there were no further adverse events during the 6-month follow-up period. None of our patients developed hemolysis after PDA closure using the Nit-Occlud® coil.

DISCUSSION

The Nit-Occlud® PDA device, consisting of nitinol spirals forming a conical shape when released, has been a well-established device for the treatment of the PDA in Europe since 2001. However, despite its widespread use in Europe and the US, no large study has investigated procedural performance, efficacy, and safety of the device. It is the device of choice for the closure of small-to-medium size PDA in our center. From 2008 to 2015, 268 ducts with a diameter <5 mm were treated with this device with no procedural or postinterventional death, a low incidence of adverse

Table 2: PDA characteristics and device sizes

PDA type		PDA size		Device size (mm)	
A, *n* (%)	89 (33.2)	Minimal diameter, median (range)	1.5 (0.5–4)	4×4, *n* (%)	17 (6.3)
B, *n* (%)	9 (3.4)	Ampulla, median (range)	5 (1–15)	5×4, *n* (%)	18 (6.7)
C, *n* (%)	21 (7.8)	Length, median (range)	9 (2–25)	6×5, *n* (%)	54 (20.1)
D, *n* (%)	24 (9.0)			7×6, *n* (%)	101 (37.6)
E, *n* (%)	118 (44.0)			9×6, *n* (%)	58 (21.6)
Not classified, *n* (%)	7 (2.6)			11×6, *n* (%)	21 (7.8)

PDA: Patent ductus arteriosus

Table 3: Procedural data and follow-up

Variable	
Successful implantation, *n* (%)	268 (100)
Undersizing and change of device, *n* (%)	1 (0.4)
Retrieval and new implantation, *n* (%)	1 (0.4)
Embolization (%)	0.0
Fluoroscopy time (min)	9.3±7.4
Hospital stay (days)	3.3±1.5
Closure rate at follow-up, *n* (%)	
Immediate closure rate	166/268 (62)
Closure after 3–10 days	255/268 (95.1)
Closure after 1 month	262/268 (97.8)
Closure after 6 months	264/268 (98.5)

Values are given as mean±SD or *n* (%). SD: Standard deviation

events and a high closure rate. The results presented herein are comparable to those found in the literature for the Nit-Occlud® coil.[4,13,15] One of the larger studies dealing with this device is the US Multicenter Pivotal Study (results published by Moore *et al.*) performed in conjunction with the previously received Food and Drug Administration's clearance.[4] The authors published an overall technical success rate of 97.2% (347 cases total). Residual shunting was detected in 3.2% of the patients after 1 year and was predominantly seen in Type A and Type B ducts. This matches our experience with the Nit-Occlud® PDA device. After 6 months, we found 1.6% of the treated PDAs to show residual shunting. In our study, we also found postinterventional shunting more frequently in Types A and B ducts. This observation may indicate that a Type B anatomy with a short or window-like duct may be less suitable for treatment through such coil devices in general, as these devices are primarily designed for funnel-like PDAs. Both our study and the Pivotal Study showed that the Nit-Occlud® coil is well suited for PDA closure. The distribution of the different duct types (especially our high incidence of Type E ducts) in our cohort differs from the distribution of the duct types found in other studies. This may be due to the differences in the ethnicity of the patients found in the various studies, but finally, the cause remains unclear.

In 2010, Ghasemi *et al.* compared the success and complication rate of four different devices for PDA occlusion and showed that the Nit-Occlud® coil and the Amplatzer Duct Occluder (St. Jude Medical, Saint Paul, Minnesota, USA) are comparable to Gianturco or Flipper coils (Cook Medical, Bloomington, Indianapolis, USA) regarding complications and are even superior regarding complete closure. Nevertheless, the authors emphasize that each occluder type has drawbacks and advantages and that there is no ideal device matching all requirements of each individual duct.[13] Based on the high variation in the anatomy of the ducts, different types of devices are required for adequate individualized treatment of a diverse patient population. In the Ghasemi *et al.*'s study, closure rates with the Nit-Occlud® device were 48% immediately after implantation and 98% at 6-month follow-up, mirroring our own experience.[13] The Nit-Occlud® coil does not incorporate a thrombogenic fabric like the Amplatzer Duct Occluder I. The tight and compact nitinol coil structure in the Nit-Occlud® system is thought to promote complete occlusion in the same way that the Amplatzer's fabric does. The higher degree of residual shunting found immediately after device implantation is a feature which has been reported for other devices as well, especially when used to close larger ducts.[7,13,16-18] In our opinion, this initial high rate of residual shunting is not a sign of an ineffective device as it does not indicate the long-term success of PDA closure by the device. In our patient population, there were no cases of postinterventional hemolysis or endocarditis during the complete follow-up period, and we did not see further thromboembolic complications apart from one patient with an ischemic stroke with no residual sequelae. In one patient, a second device was implanted after undersizing of the initial coil. This undersizing was most likely due to an increased distensibility of the duct in this individual patient. In none of our patients, not even in those with a weight under 10 kg, did we encounter relevant left pulmonary artery stenosis or aortic obstruction as described with other devices (especially when used in smaller children).[3,19,20] The coil structure of the Nit-Occlud® device with no protruding retention discs, thus, seems to be beneficial. The small (4/5 French) and flexible delivery catheters (no further sheaths required) add a further positive feature to the device's profile. According to our data, lower weight did not adversely influence the development of residual shunting or overall hospital stay. The only strong parameter, which had a significant influence on the immediate initial postinterventional shunt rate, was the minimal duct diameter ($P < 0.001$). Larger ducts were found to have a higher rate of residual shunting immediately after the intervention. This is consistent with the results presented by Ghasemi *et al.*, who report that a minimal duct diameter >3 mm is associated with residual shunting both immediately and 6 months after the procedure.[13] In our cohort of patients with small-to-medium size ducts, the Nit-Occlud® coil was effective and safe with a high follow-up closure rate.

Limitations

This study carries all potential limitations of a single-center study with retrospective data analysis. However, we are able to present follow-up results of a considerably large cohort of consecutively treated patients.

CONCLUSION

Closure of PDA with sizes up to 4 mm and various anatomic configurations can be performed effectively and safely using the Nit-Occlud® PDA device. Six-month

postprocedural follow-up showed an uneventful postinterventional course in all patients and excellent closure rates.

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Conflicts of interest

There no conflicts of interest.

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