International Journal of Cardiology xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Is the new Occlutech duct occluder an appropriate device for transcatheter closure of patent ductus arteriosus?

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ARTICLE INFO

Article history:
Received 12 February 2018
Accepted 12 March 2018
Available online xxxx

Keywords:
Patent ductus arteriosus
Transcatheter closure
Occlutech duct occluder

ABSTRACT

Aim: To describe our initial experience with the Occlutech Duct Occluder (ODO) for percutaneous closure of patent ductus arteriosus (PDA).
Methods: Retrospective review of patients undergoing transcatheter PDA closure with the ODO in 2 academic centers.
Results: From April 2013 to September 2017, 42 patients underwent PDA closure. Median age at implantation was 34 months (range 4 months–68 years) and median weight was 12 kg (range 4.1–57 kg). Ducts were Krichenko type A duct ($n = 34$), type E ($n = 6$), and type C ($n = 2$). The mean duct diameter was 3.76 mm (range 1.69 to 9.95 mm, median 3.1 mm). Implantation succeeded in all. There was neither device embolization nor hemolysis. At device release, immediate angiogram showed a small residual shunt in 54.7%. During follow-up, Doppler echocardiography demonstrated 71% of full occlusion at day one, rising to 95% at one month and 100% at one year and half after implantation. The mean maximal systolic pressure gradient in left pulmonary artery was 4.2 ± 4.3 mm and across the distal aortic arch 5.4 ± 4.7 mm Hg. No patient had any significant stenosis with clinical relevance.
Conclusions: ODO is safe and effective in transcatheter closure of PDA including relatively large sized ducts. The results are satisfactory with a high level of full occlusion and a low rate of complications. Further evaluation with larger studies and longer follow-up will be required to confirm these preliminary good results.

1. Introduction

Transcatheter closure of patent ductus arteriosus (PDA) was first realized in 1967 by Porstmann using an Ivalon plug. However, this technique did not gain a large audience due to the use of a large delivery sheath (23 F). Since that pioneer experience, many devices have been developed. For many years, the Amplatzer Duct Occluder (ADO I, Abbott) has been mainly employed for medium-to-large sized ducts and has become the gold standard [1], while detachable coils continued to be used for the smallest ducts [2,3], in addition to several different devices that became available. The ADO I was a modification of the Porstmann plug using the nitinol technology. It is a self-expanding, mushroom shaped device with nitinol shank and aortic retention disc. Results for ADO in terms of successful implantation, procedural time, dose of radiation and rate of full occlusion are excellent, making this device quite popular and largely implanted [1,4,5].

The Occlutech duct occluder (ODO) is a new device with also a mushroom shape. It is made of nitinol wires with a tapered "shank" and has also an aortic flat retention disc (Fig. 1). The shank is placed within the duct at its narrowest portion. Its proximal pulmonic end has a diameter that is 1.5–4.0 mm larger than its aortic end in opposition to the ADO in which distal aortic end of the shank is larger than the proximal part. The aortic retention disk is larger than the distal aortic end of the shank by 5.5–10 mm. This design modification in comparison with ADO has been developed to achieve a better conformation of the device with duct anatomy and to reduce the risk of embolization. Moreover, the device has a titanium oxide coating decreasing Nickel release and polyethylene patches are sewn into the distal retention disc and the shank. The ODO is available in 2 lengths: standard (4.25–16 mm) and long shank (7–10.5 mm) and is labeled according to the proximal and distal diameters of the shank. Both ADO and ODO are connected to a delivery cable attached to the proximal pulmonary end using a screwing mechanism. The delivery sheath is ranging from to 6 to 9 F.

The purpose of this study was to report an initial experience with the ODO for PDA occlusion.

2. Methods

2.1. Study design

A retrospective, descriptive, non-randomized study started in April 2013 including patients from 2 French academic centers. Forty-two patients (29 females, 13 males) were

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https://doi.org/10.1016/j.ijcard.2018.03.059
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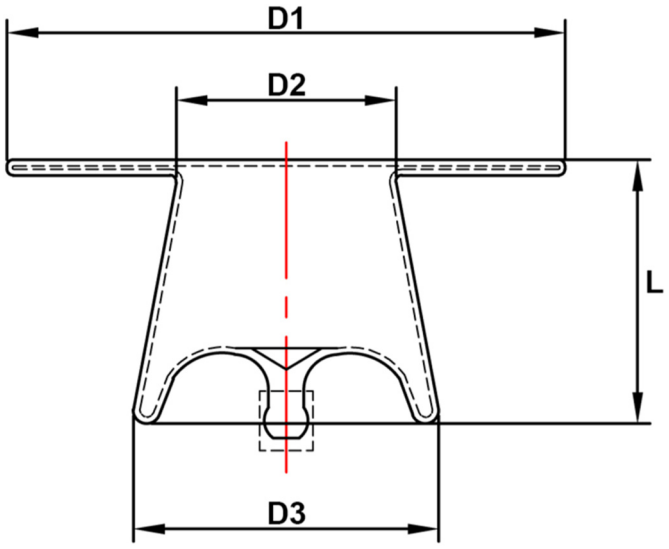

Fig. 1. Graphic representation of the Occlutech Duct Occluder. D1: aortic retention disc diameter. D2: distal aortic end diameter of the shank. D3: proximal pulmonary end diameter.

included up to September 2017. Informed consent was obtained from all patients or their parents. All patients had clinical and echocardiographic evidence of PDA.

2.2. Closure protocol

The procedure was realized after puncture of the femoral artery and vein. Hemodynamic data collected were right ventricular, pulmonary artery, and aortic pressures. An aortography was performed mostly in lateral projection and sometimes in right anterior oblique (30°) projection to delineate the anatomy of the duct according to the Krichenko classification [6]. In all cases, the narrowest PDA diameter was measured to determine the device selection. The ODO was usually chosen with a diameter of the aortic end of the shank (diameter D2, Fig. 1) larger by 1 to 2 mm than the narrowest duct diameter on angiography. Device implantation was performed within a delivery sheath (Mullins sheath, William Cook Europe) advanced from the venous side and positioned into the descending aorta. After placement within the duct while the device remained attached to the delivery cable, an angiography was carried out to assess the device position and to control any residual shunt. If the appropriate position was obtained, the device was released and a final aortography was realized about 1 min later. Patients were discharged within 1–2 days after the procedure. Subsequently, they were reviewed at 1, 6 and 12 months and thereafter every 6–12 months with Doppler echocardiography to assess duct occlusion and patency of the left pulmonary artery (LPA) and aortic isthmus.

2.3. Statistical analysis

Results are expressed as mean value ± standard deviations or median and range.

3. Results

3.1. Baselines results

The median age at implantation was 34 months (range 4 months–68 years) and median weight was 12 kg (range 4.1–57 kg). Thirty-two patients had a continuous murmur and ten a systolic murmur. PDA was isolated in 28 patients while 14 patients presented with associated anomalies (Table 1). Most of the patients had left-to-right shunt with enlarged left ventricular diastolic dimension (mean z-score + 2.04 ± 1.35, range 0.0 to 4.9, median + 1.81). Sixteen patients received diuretic and/or angiotensin-converting enzyme inhibitor before the procedure as medical therapy for heart failure.

3.2. Cardiac procedure

Procedures were performed under either general anesthesia ($n = 23$) or local anesthesia ($n = 19$). The PDA was crossed from the pulmonary artery side in all, but two. In these 2 patients, the duct was crossed from the aorta to create an arterio-venous "circuit" using a snare, to advance finally the delivery sheath from the femoral vein, as already reported [7]. The minimal duct diameter was 3.76 ± 2.0 mm (range 1.69–9.95 mm, median 3.1 mm) on aortography. Thirty-four patients had Krichenko type A duct, six had type E, and two had type C [6]. The oldest patient of the study had also a calcified ampulla. For the whole group, the mean systolic pulmonary artery pressure was 39 ± 15 mm Hg.

Device implantation succeeded in all. The immediate control angiography after release showed a smoke-like residual trans-prosthetic shunt in 23 patients (54.7%, Fig. 2), whereas 19 had no shunt (Fig. 3). The fluoroscopy time was 6.7 ± 3.2 min (range 1.7–16 min, median 6.36 min) and the radiation dose was 6.2 ± 8.5 Gy·cm^2 (range 0.4–40 Gy·cm^2, median 3.1). All devices implanted had a standard short shank and included: 4/6 device ($n = 15$), 5/7 device ($n = 12$), 6/8 device ($n = 5$), 3.5/5 device ($n = 4$), 10/12 device ($n = 4$), and 8/10 device ($n = 2$). The diameter D2 of the device was usually oversized and difference between D2 and the minimum diameter of the ductus arteriosus on angiography was 1.47 ± 0.74 mm (0.05 to 3.43 mm, median 1.55 mm). Occluders were positioned through a 6 or 7 F delivery sheaths. In one of them, an 8/10 device to occlude a large duct had to be replaced by a 10/12 device because it slipped twice from the aorta to the main pulmonary artery during implantation leading to a final good positioning. At discharge the following day, 30 patients (71%) had no residual shunt on control Doppler echocardiography and 12 had a trivial to small residual shunt.

3.3. Follow-up data

During follow up (range 1–79 months), 10 patients with initial residual shunt had no residual shunt on echocardiography performed one-month after closure. At that time, the last 2 patients had a trivial shunt which was no longer found 5 and 12 months later. The mean maximal systolic pressure gradient in left pulmonary artery was 4.2 ± 4.3 mm Hg (range 1–19 mm Hg, median 3.5 mm Hg) with four patients having a gradient above 10 mm Hg. The mean maximal systolic pressure gradient across the distal aortic arch was 5.4 ± 4.7 mm Hg (range 1–17 mm Hg, median 4 mm Hg) with six patients having a gradient above 10 mm Hg. None had any significant stenosis with clinical relevance.

3.4. Complications

There was neither device embolization nor hemolysis after implantation and during follow-up. No patient received blood transfusion. In three patients, right femoral artery thrombosis was noticed just after the procedure that fully resolved under heparinization with complete recovery of pedal pulse and wide arterial patency controlled by echography.

4. Discussion

The ODO appears safe and effective for transcatheter PDA closure. The rate of successful implantation is very high, up to 100% here, as already reported with this device [8–14] and also with the ADO I [1,4,5,15].

Table 1
Associated pathology.

Associated pathology	$N = 14$ patients
Cardiac disease	$N = 6$ VSD: $n = 3$ ASD: $n = 1$ Aortic regurgitation: $n = 1$ Scimitar syndrome: $n = 1$
Trisomy 21	$N = 7$
Others	$N = 3$ High blood pressure: $n = 1$ Renal failure: $n = 1$ Currarino syndrome: $n = 1$

ASD: atrial septal defect, VSD: ventricular septal defect.

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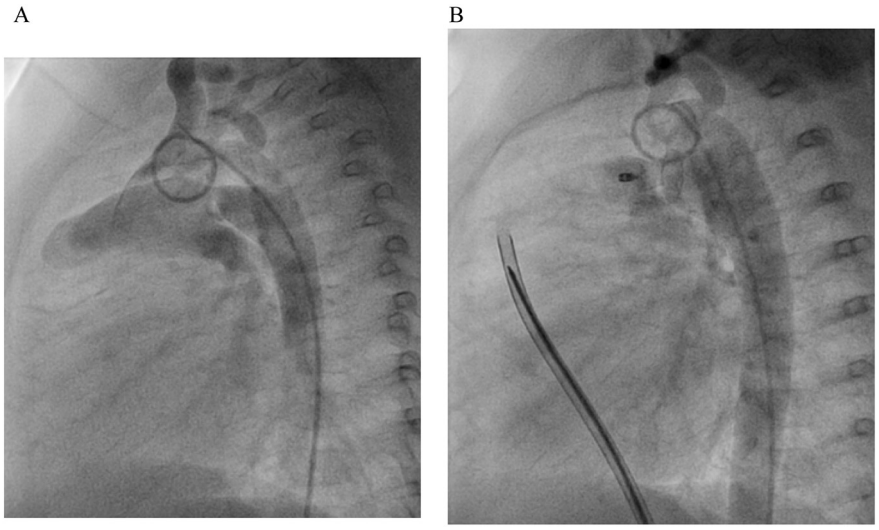

Fig. 2. (A) Aortography in lateral projection. Large type A PDA measuring 2.81 mm at its narrowest diameter. (B) Control angiography after implantation of a 5/7 short shank device showing a small residual shunt. This shunt was fully closed on control echocardiography at day one.

Furthermore, we reported a shorter fluoroscopy time that the one previously described with the same occluder [9,10,12] or by Bilkis using ADO I [4]. Shorter fluoroscopy time with ODO has also been recently reported by Kudumula [8] and Boudjemline [11]. In fact, the technique of implantation with the ODO appeared very similar to the ADO one, with almost no learning curve for the one initially trained with the classic ADO I. Persistence of a small initial residual shunt is frequent (54.7% here), and once more very similar to the 51.5% observed by Aldelbasit [9] using ODO. In addition, the rate of full occlusion on the echo control realized one day after implantation is very high, 71% in the present study, and similar to rates reported with ADO I: 66 to 100% [1,4,5,16,17] or with ODO: 50 to 100% [8–14]. Thus there is no need to wait longer than one or 2 min after release to perform control angiography [8]. In addition, due to device in thrombosis and endothelialisation, we observed an increase in full occlusion during follow-up: 95% at one month, and 100% at one year and a half. Similar late results have also already been published with ither the ADO I [1,4,15,16] or the ODO [8–14]. The new ODO compares thus very favorably with the ADO in term of effective PDA occlusion.

The design of the ODO is different to the ADO, as such, the choice of the device size is important. Our policy was to use a device whose aortic end of the shank adjacent to the aortic retention disc - designated as the "waist" or diameter D2 - was around 1 to 2 mm (mean 1.47, median 1.5 mm) larger than the narrowest portion of the duct. By doing so, we expected adequate device compression and appropriate anchoring within the duct to avoid any risk of immediate or delayed embolization. With practice, the amount of device oversizing is probably not as much necessary [10,14]. Thus, we oversized <1 mm in 8 patients of the present study without adverse events or results confirming the good stability and the efficacy of the device within the duct.

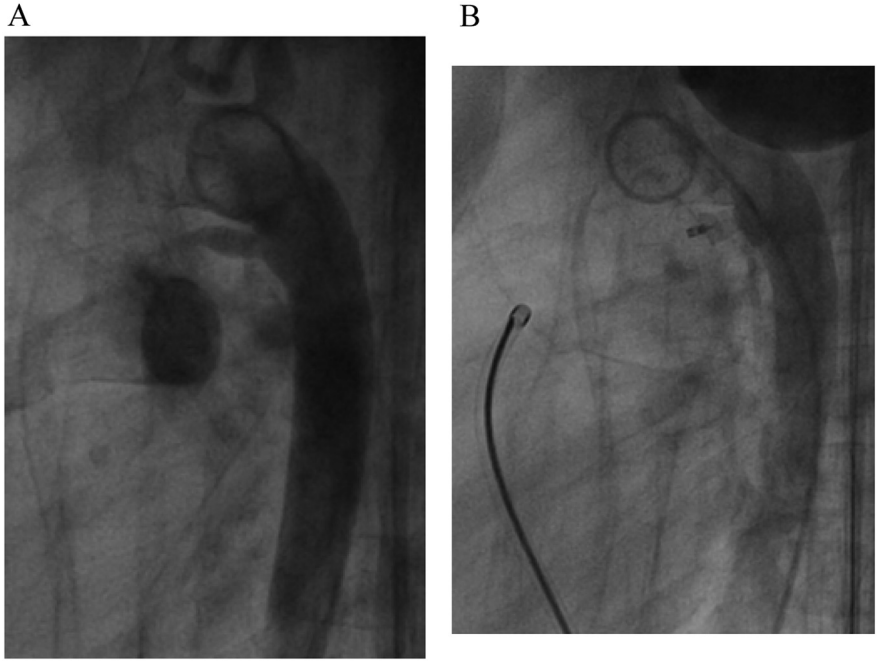

Fig. 3. (A) Aortography in lateral projection. Large type E PDA measuring 1.69 mm at its narrowest diameter. (B) Control angiography after implantation of a 4/6 short shank device showing no residual shunt. The aortic retention is within the isthmic portion but without generating any gradient.

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One of the major advantages of the ODO is the possibility to close successfully large sized ducts. In this cohort, the mean duct diameter was 3.76 mm which is larger than previous reports with ODO [8–10,12,13] or with ADO [1,3,17]. We also include the successful closure of a duct as large as 9.95 mm in dimensions; similarly as mentioned by Lehner with closure of large ducts (median diameter of 10 mm) using ODO [14]. Another advantage of this device is the possibility to close a large variety of duct – even if the majority of ducts were type A ducts – because the device fits very well with the duct anatomy. Devices with a long shank may also fit well with some long tubular PDAs [12,13]. Whereas long devices were not used in this study, we report a successful and uneventful closure of 2 types C ducts using only a short skank ODO.

The most frequent complication observed here was femoral thrombosis ($n = 3$), which is a classic drawback of this procedure. It has been reported with all types of device [1,8,12,15,16]. It is probably explained by the initial absence of routine use of heparin for this procedure in one of the 2 centers. However, this was fully resolved under heparin with no need for fibrinolytic therapy. These results led to a recent modification of practice with nowadays use of heparin 50–100 UI/kg, especially in younger patients. The other possible complication is device embolization to the pulmonary artery or descending aorta as rarely reported with ODO [10,11,13] or other occluders. Such embolization was not observed in the present study probably because of device design (inverted proximal pulmonary artery end) that could generate more stability reducing this risk. Hemolysis, groin hematoma, severe bleeding, cardiac arrhythmia requiring cardioversion or medication are other classic complications reported with the other devices [1,3,4,16] but none of them was observed here or previously reported with ODO [8–11,13,14]. However, it should be kept in mind because these risks remain obviously possible.

Moreover, device protrusion to LPA or descending aorta is another matter of concern [1,18]. It may result from oversized device [17]. This is not frequent and has been studied by Pass [1] with the ADO who reported at 6-month follow-up in about one third of patients, a small median pressure gradient of 5 mm Hg (range 1 to 21 mm Hg) or 7 mm Hg (range 1–38 mm Hg) across either the aortic arch or proximal LPA, respectively. While at one year follow up, gradient above 20 mm Hg was not observed in the aorta and < 1% on LPA. Ghessami has reported similar results in a series of 152 patients treated with ADO (LPA stenosis in 0.7%) [17]. Thus, low weight or particular duct anatomy with short duct or a relatively shallow duct having abrupt narrowing of a large ampulla may be risk factors for LPA stenosis [19]. With ODO, the sole case of aortic protrusion during implantation has been reported using a long shank in a tubular duct; the operator decided not to release the device [10]. In the present study, the LPA and aortic gradients compare favorably with those reported by Pass [1]. This is once more the consequence of the low profile of this device with a flat aortic retention disc creating no real obstruction within the isthmus. In addition, the hub on the opposite side pointing out of the shank is not a problem in term of pulmonary obstruction and probably safer for device extraction by a snare in comparison with the ADO whose hub is placed within the shank making the screwing mechanism nearly impossible to catch.

This study carries some limitations such as its retrospective non-randomized design including limited number of patients. Although all angiographic types of PDA were not observed in the same distribution - ducts having mainly a conical shape – it seems that most of them will be amenable to closure with the ODO with possible restriction in small patients and type B duct. For very long ducts, the long-shank device may also be implanted [11]. More experience is also required in low-weight patients <6 kg, even if 2 patients with a weight of 4.1 and 4.9 kg were included in our study with no adverse event. At last, there is a need for further evaluation including more patients, longer follow-up, and for comparative data with other devices to confirm these preliminary results.

5. Conclusion

The new ODO appears safe and effective in transcatheter occlusion of median-to-large ducts (up to 10 mm) with a 100% procedural success. The new device configuration with an inverted shank seems interesting with appropriate device stability, no embolization, less protrusion to the aortic or pulmonary sides, and mainly a very high rate of full occlusion in this cohort. The ODO appears already as a real alternative for transcatheter PDA occlusion among all the devices available.

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