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ORIGINAL INVESTIGATION

Short-Term Outcomes of Patent Ductus Arteriosus Closure With New Occlutech® Duct Occluder: A Multicenter Study

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***Aim**: Over the past 2 decades, transcatheter occlusion of patent ductus arteriosus (PDA) with coils and the duct occluders evolved to be the procedure of choice. A new device, the Occlutech PDA® occluder (ODO) device has been designed. Herein, we aimed to evaluate the characteristics and short-term results of patients who underwent transcatheter closure of PDA using the ODO.*

***Methods**: We reviewed the clinical records of 60 patients from different centers in Turkey between December 2013 and January 2016. The medical records were reviewed for demographic characteristics and echocardiographic findings. Device size was selected on the narrowest diameter of PDA.*

***Results**: The median patient age was 2.5 years (6 months–35 years), and median PDA diameter was 2.5 mm (1.2–11 mm). Fifty-eight of 60 patients (96.6%) had successful ODO implantation. The occlusion rates were 37/58 (63.7%) at the end of the procedure, 51/58 (87.9%) at 24–48 hours post-procedure, and 57/58 (98.2%) on echocardiography at a median follow-up of 7.6 months.*

***Conclusion**: Our results indicate that transcatheter closure of PDA using the ODO is effective. Larger studies and longer follow-up are required to assess whether its shape and longer length make it superior to other duct occluders in large, tubular, or window-type ducts.* (J Interven Cardiol 2016;9999:1–7)

Introduction

The incidence of PDA has been reported to be ≈1 in 2000 at term births.[1,2] Percutaneous closure of a patent ductus arteriosus (PDA) was first described by Porstmann in 1966.[3,4] Since then, various devices such as Rashkind PDA umbrella,[5] button device[6] have been introduced and transcatheter occlusion of PDA has evolved to be the procedure of choice.[7] Currently, the most commonly implanted devices are coils and the duct occluders.[8–12] Beginning with Amplatzer duct occluder (ADO), occluders provided an excellent procedural success rates (99%) and a very low incidence of embolization. Subsequently, ADO II and ADO II AS were developed for closure of different types of PDAs.[13–20] Later on, a new device, the Occlutech PDA® occluder (ODO), has been designed.

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New Device: Occlutech® PDA Occluder. The ODO is a self-expanding nitinol device with a shape that is reminiscent of a "champagne cork." The ODO is constructed with braided nitinol wires, has an aortic retention disc, and is attached to its delivery cable with a screw thread mechanism. Its body is wider at the pulmonary artery end than the aortic end and has no distal protruding hub. The device has a titanium oxide coating, which gives it a characteristic golden color, and 2 polyethylene terephthalate (PET) patches sewn into the device, 1 in the aortic retention disc and 1 at the pulmonary end of the device, to promote rapid occlusion (Fig. 1). Striking structural differences from other duct occluders are as follows: its "champagne cork" shape, it is being also available in longer lengths at same size (Table 1); third, screw attachment of device protrudes from pulmonary end of device after releasing and finally its PET patches for rapid occlusion.

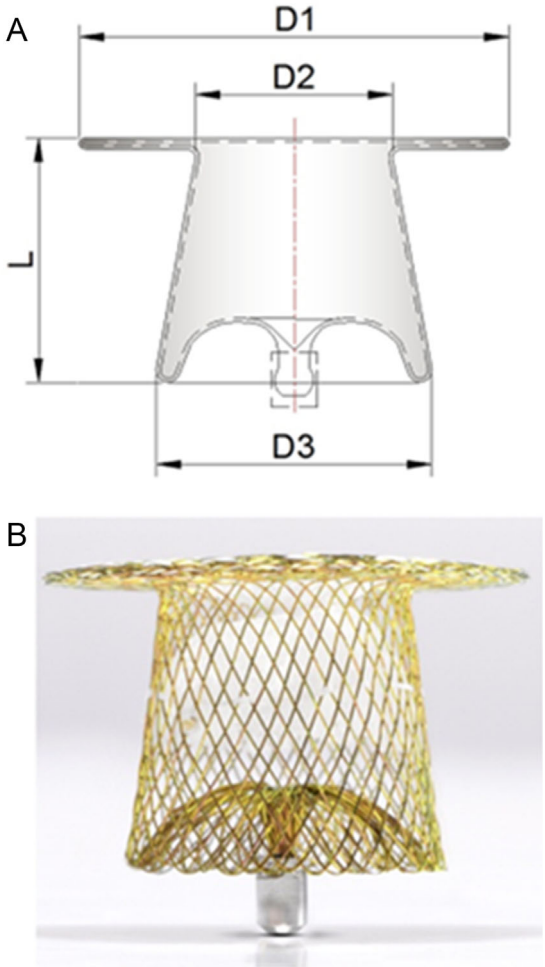

Figure 1. Schematic representation and image of Occlutech duct occluder. D1, diameter of aortic retention disc; D2, diameter of waist at the aortic end of the device; D3, diameter of the pulmonary end of the device.

Herein, we aimed to evaluate the characteristics and short-term results of patients who underwent transcatheter closure of PDA using the ODO.

Materials and Methods

We reviewed the clinical records of 60 patients from 13 different centers in Turkey, who underwent percutaneous closure of a PDA with an ODO between December 2013 and January 2016. The details of the patients and reasons for ODO device selection of the centers are summarized in Table 2. The medical records were reviewed for demographic characteristics, clinical details, and echocardiographic findings. Approval of the Institutional Review Boards (IRB) and informed consent to participate in the study according to the recommendations of the Declaration of Helsinki on Biomedical Research Involving Human Studies from the families/legal guardians of patients were obtained prior to patient enrollment in all centers included in the study.

Cardiac catheterization was performed under deep sedation or general anaesthesia. Next, 5–6F sheaths were positioned in the femoral artery and vein. Aortography was performed in lateral (LAO 90°) and right anterior oblique (RAO 30°) views to evaluate the aortic ampulla, ductal morphology and ductal size, using a 4F or 5F pigtail catheter. PDA was classified according to the classification described by Krichenko et al.[21] An end-hole multipurpose catheter was advanced into the pulmonary artery from the femoral vein and a 0.035″ length 150 cm (260 cm long for older patients) guide-wire inside the catheter was advanced into the aorta through the PDA, and the catheter was advanced over the guide-wire to the aorta. Then, catheter was withdrawn and guide-wire left in the aorta for the delivery system. The size of the Occlutech® PDA occluder was selected according to the narrowest diameter of the PDA. The narrowest part of the device (the aortic end of the occluder) was sized at least 2.0 mm larger than the narrowest diameter of the ductus. The positioning of the device was verified by the injection of contrast medium during the process to ensure that the aortic retention disc was seated on the

Table 1. Occlutech® Duct Occluder Ordering Information of Manufacturer

	D1 (mm)	D2 (mm)	D3 (mm)	Length (mm)	Recommended Delivery Sheath
Standard occlutech duct occluder					
3.5/5	9	3.5	5	4.25	6 Fr
4/6	10	4	6	5.00	6 Fr
5/7	11	5	7	6.05	6 Fr
6/8	13	6	8	6.30	6 Fr
8/10	16	8	10	7.00	7 Fr
10/12	18	10	12	12.00	7 Fr
12/15	20	12	15	14.00	8 Fr
14/18	24	14	18	16.00	9 Fr
Occlutech duct occluder with long shank					
3.5/5	9	3.5	5	7.00	6 Fr
4/6	10	4	6	7.50	6 Fr
5/7	11	5	7	8.50	6 Fr
6/8	13	6	8	9.00	6 Fr
8/10	16	8	10	10.50	7 Fr

D1, diameter of aortic retention disc; D2, diameter of waist at the aortic end of the device; D3, diameter of the pulmonary end of the device.

ampulla. Before releasing the device, the location of the device and whether it protruded into the aorta were determined by transthoracic echocardiography using a high parasternal short axis and suprasternal window. This technique has been developed over time and had been used by some of our operators.[22]

Once proper device positioning was confirmed, the device was released. After releasing the device, control angiograms were performed. In the post-implantation angiograms, residual shunts were graded as follows: minimal, where the dye only fills the device and the proximal pulmonary artery branches (Fig. 2); mild, the dye fills the main pulmonary artery; moderate, the dye can be seen during pulmonary venous return. The implantation was declared successful when the ODO occluded the duct after post-angiography without the dye filling the device and the pulmonary artery branches. The procedural time, fluoroscopy time, and the size of device implanted were recorded. Control echocardiography and a clinical examination were performed the following day (24 hour later) and after 1 month, or earlier if there had been a residual shunt. A routine clinical examination and echocardiography were performed at 6 months after the occlusion. In addition, the operators were questioned regarding their personal opinions of the device. Statistical analyses were performed using SPSS 15. The data were expressed as mean and median.

Results

The data were collected from 13 pediatric cardiology centers in Turkey. The median patient age was 2.5 years (range, 6 months–35 years), median weight was 15 kg (range, 5–60 kg), and median PDA diameter was 2.5 mm (range, 1.2–11 mm) of 60 patients. Twenty-four of 60 patients was male and 36 was female. The additional cardiac anomalies were ventricular septal defect in 1, bicuspid aortic valve and aortic stenosis in 1, mild mitral regurgitation + trivial aortic regurgitation in 2 patients. Additional non-cardiac anomaly was Down syndrome in 1 patient. Narrowest diameter of the ductus measured during aortic angiogram were <2,5 mm in 31 patients, between 2.5 and 3.5 mm in 15 patients and >3.5 mm in 14 patients. The angiographic appearance of the duct according to the Krischenko classification was type A in 50 (83%) patients, type B in 2 (3.3%) patient, type C in 3 (5%) patients, and type E in 5 (8.4%) patients. In 2 patients, one of whom was an adult patient, we used balloon sizing for large PDA. We

Table 2. Details of Patent Ductus Arteriosus (PDA) Occluders and Device Selection Reasons for Each Center in the Study

Center	No of Occluded PDA With ODO	Number of Occluded PDA Between December 2013 and January 2016	Reason for ODO Selection
1	5	20 (ADO I, ADO II, Coils)	For trying new different device
2	1	10 (ADO I, ADO II)	For trying new different device
3	2	Unavailable	For trying new different device
4	2	202 (ADOI, ADO II, ADO AS, Coils)	Legal procedures for technical agreement of centre with other companies
5	2	Unavailable	
6	2	Unavailable	
7	26	62 (ADO I, ADO II, SERA Duct occluder, Nit-Occlud coil)	Legal agreement with ODO device company (cost effectiveness)
8	4	6 (ADO I)	Cost effectiveness
9	4	Unavailable	
10	2	12 (ADO I, ADO II, coils)	
11	2	6 (ADO I, ADO II)	For trying new different device
12	7	32 (ADOI, ADO II, ADO AS, Coils)	
13	1	5 (ADO I, ADO II, Coils)	Different size options for long, tubular defects

ODO, Occlutech duct occluder; ADO, Amplatzer duct occluder.

used the largest size 14/18 mm ODO for adult patient because of large defect and 10/12 mm ODO for 7 mm sized large defect in a 6-year-old patient. We used 8 long shank device for long ducts. The sizes of devices were summarized in Table 3. The mean fluoroscopy time was 14 minutes (range, 4.2–30 minutes), median 8.5 minutes for 45/60 patients. Fifty-eight of 60 patients (96.6%) had successful ODO implantation at the end of follow-up time on echocardiography in which no residual shunts was detected. The occlusion rates were 37/58 (63.7%) at the end of the procedure, 51/58 (87.9%) at 24–48 hours post-procedure, and 57/58 (98.2%) on echocardiography at a median follow-up of 7.6 months (range, 6–23 months). The device-related complication was observed (embolization to aorta) in only 1 patient. Defect size was 3.3 mm and 3.5/5 mm ODO device was chosen for occlusion in 5-year-old patient but after releasing the device, it embolized to the aorta. Afterward, device was taken and defect closed with surgery. In another 6-year-old girl, defect was tubular and sized 2.4 mm 3.5/5. Long shank ODO was chosen for occlusion but the device was withdrawn before releasing because of protruding through the aorta after unsheatting and operators decided to abandon the procedure. After consulting with the family the defect was closed surgically because of parents' own accord. Angiocardiographic data were summarized in Table 3.

Discussion

Our results indicate that transcatheter closure of PDA using the ODO is effective in small-to-moderate sized PDAs. Although the early residual shunt ratio was higher than with the other duct occluders, during the follow-up, the residual shunt ratio was equivalent to that of other devices. One of the main differences between ADO-I and ODO is the shape of the device with wider pulmonary artery end than the aortic end. Device stability and occlusion within the PDA with ADO-I are provided with compression by the duct and radial forces of the device. The narrow point of the duct strangles the main body of the ADO-I device just proximal to retention disc. This compression produces a "champagne cork" like shape which Occlutech® device is already designed to take this shape without compression by the wider pulmonary artery end than the aortic end.

Occlusion Rates. The course of the ductal occlusion with ODO device has some differences

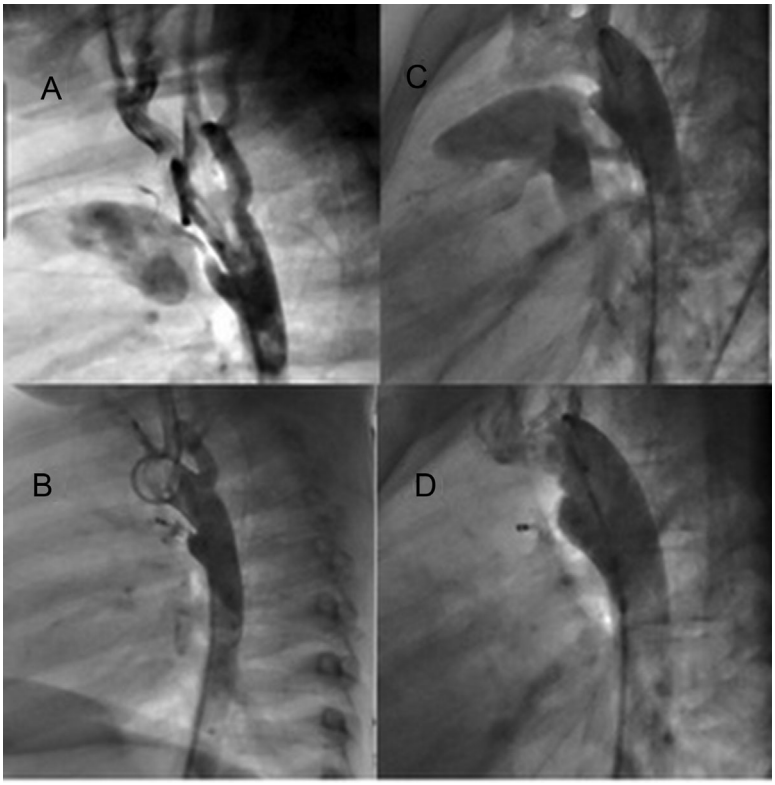

Figure 2. New Occlutech® PDA occluder. A: Aortic angiogram of long PDA of 14 months old infant with 2 mm at narrowest diameter and 8.2 mm long. B: Post-implantation of 4/6 long shank Occlutech PDA occluder. C: Aortic angiogram of 12-year-old girl measured 3.5 mm narrowest diameter of PDA, D: Post-implantation aortic angiogram of 6/8 standart shank Occlutech PDA occluder.

from the ADO-I. Kudumula et al. reported that ductal occlusion did not occur immediately in patients who underwent transcatheter closure of PDA using the ODO.[23] Also, Abdelbasit et al. indicated 48.5% complete occlusion rate at 10 minutes post-implant, they stated patients having large PDAs tend to have residual shunt but it achieves complete closure about 90 days.[24] According to our data, complete occlusion at the end of procedure was achieved only in 63% of the patients supporting the results of Kudumula et al. Despite the differences in early occlusion rates, final occlusion rates are similar with ADO-I. In this collaborative study, there was 98.2% final occlusion rate at a median follow-up of 7.6 months.

Device Sizing and Implantation Technique. In most of the arterial ducts, the pulmonary end is the narrowest part. The main aim of transcathether ductal occlusion by ODO is to place the narrowest part of the device to the narrowest point of the ductus and left retention disc in aorta. Device selection with a waist at least 2 mm larger than the minimum diameter of duct is recommended. In our patient cohort, we used up to 2 mm larger device at 39/60 patients. Defect was oversized more than 2 mm at 21/60 patient (mean 2.88, range 2.3–3.5 mm oversizing). On the other hand, Kudumula et al. mentioned that to implant a device with a waist, at least 2 mm larger than the minimum diameter of the duct will result in the pulmonary end of the device being 3–4 mm larger than the aortic end, which is significantly larger than the original diameter. According to their study, choosing devices with a waist only 1–2 mm larger than the minimum diameter of the duct did not seem to adversely affect stability of the device.[5]

We had 3 tubular ducts in our study. Two of them was small and operators decided to use 2 mm larger device from narrowest part of the duct. One had total occlusion but in the other patient device was protruded through the aorta after positioning and unsheatting. Operator decided not to release the device because of embolization risk. A large and tubular duct was oversized 3 mm and occluded successfully with standard shank device. There was minimal residual shunt that was disappeared on echocardiography in the following day. Although we have few tubular ducts in our cohort, we think it is sensible to oversize the defect in tubular or window-type ducts.

Table 3. Angiocardiographic Details of Patients

Narrowest Defect Diameter of PDA	Size of the Device Used (ODO)	Unusual Procedure/Complication
≤2.5 mm (n = 31)	3.5/5 (n = 12) 3.5/5* (n = 2) 4/6 (n = 10) 4/6* (n = 2) 5/7 (n = 5)	3.5/5* mm device was protruded through the aorta after unsheathing, thereafter device was withdrawn; the procedure was abandoned; defect was surgically closed after consulting with the family
2.5 to ≤3.5 mm (n = 15)	3/5 (n = 1) 4/6 (n = 3) 5/7 (n = 7) 6/8 (n = 2) 6/8* (n = 2)	The 3/5 device embolized and was taken with surgery
>3.5 mm (n = 14)	4/6 (n = 1) 4/6* (n = 1) 5/7 (n = 3) 5/7* (n = 1) 6/8 (n = 3) 8/10 (n = 2) 10/12 (n = 2) 14/18 (n = 1)	Following balloon sizing a 7 mm defect was occluded with a 10/12 device and a 9 mm defect in an adult patient was occluded with a 14/18 ODO device

*Long shank device.

Device Related Technical Aspects. Most of our operators complained about inadequate visualization of the device on fluoroscopy. During positioning of the device, we relied on radiographic and anatomic landmarks instead of device structure. Also operators declared problems with the Occlutech delivery cable. The vise that is attached to the distal end of the cable would not grip the cable despite maximal tightening of its screw. When the vise was rotated to turn the cable, torque would not pass down the cable to release the device. One of the operators in our collaborative study had pointed out that the device had embolized because of dislocation from its proper position during the course of releasing. In this patient Mullins sheath (William Cook Europe) was used for deployment of the device. In the other patient, in whom the device had been withdrawn, the operator decided not to release the device because of the same problems to avoid the risk of embolization. As a solution, we recommend to hold the cable near the sheath with mosquito forceps and to spin the forceps around the axis of the cable. As we had not to retrieve an embolized device in our cohort, the hub housing pointing out of the shank of the ODO is a positive feature which could make retrieval of the ODO by snaring the hub easier than the hub housing placed on a recess.

Conclusion

Our results indicate that transcatheter closure of PDA using the ODO is effective at the end of mean follow-up time of 7.6 months. Although early residual shunt ratio was higher than the other duct occluders, the residual shunt ratio was equivalent to other devices during the follow-up. Larger studies and longer follow-up are required to assess whether its shape and longer length make it superior to other duct occluders in large, tubular, or window-type ducts.

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