Catheterization and Cardiovascular Interventions 82:961–967 (2013)

Cardi-O-Fix Duct Occluder Versus Amplatzer Duct Occluder for Closure of Patent Ductus Arteriosus

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Background: We sought to investigate the safety, efficacy, and follow-up results of percutaneous patent ductus arteriosus (PDA) closure using the novel Cardi-O-Fix duct occluder (CDO), a device similar to but less expensive than the Amplatzer duct occluder (ADO). We also aimed to compare these two devices in terms of results. Methods: Between March 2005 and May 2012, 167 patients diagnosed with moderate-to-large PDA underwent transcatheter closure. ADO was used in 56 (33.5%) patients with a mean age of 8.1 ± 11.9 years (3.6 months–56 years), whereas CDO was used in 111 (66.5%) patients with a mean age of 12.6 ± 14.6 years (4.8 months–63 years). Results: The narrowest PDA diameter, the used device diameter, procedure time, fluoroscopy time, and residual shunt rates were similar between the two groups. Procedural success rate was 100% in both groups. Although the residual shunt rate was higher in the CDO group immediately after the procedure, the difference was not statistically significant (12.6 vs. 8.9%; $P = 0.3$). There was no statistically significant difference between groups at discharge and during follow-up. No deaths occurred in any of the groups, and there were no differences in complication rates during the short- and mid-term follow-up periods (CDO 7/111 vs. ADO 5/56; $P = 0.5$ π). Conclusion: The CDO can be used for PDA closure because of its safety, effectiveness, and simplicity in use. It is available in bigger sizes and can be used in patients with large defects. According to our short- and mid-term findings, the results it yields are similar to those of the ADO; thus, it may be the preferred choice owing to its low cost and large size variability. **© 2013 Wiley Periodicals, Inc.**

Key words: patent ductus arteriosus; Cardi-O-Fix duct occluder; transcatheter closure; novel device; percutaneous treatment; cost effectivity

INTRODUCTION

Transcatheter closure is the preferred method of treatment of patent ductus arteriosus (PDA) [1–6]. Detachable and nondetachable coils are widely used in closure of small ducts [2–4]. Since the first series of cases of percutaneous PDA closure using the Amplatzer duct occluder (ADO) was published by Masura et al., this device has been generally used for moderate and large ducts [5–8].

The Cardio-O-Fix duct occluder (CDO) (Fig. 1) is a new device with occlusion and delivery systems that are similar to those of ADO [9]. Its main advantages are the lower price and larger size variability (Table I). In this study, we have compared the safety and efficacy of transcatheter PDA occlusion using CDO and ADO.

METHODS

Clinical Characteristics of Patients

Between March 2005 and May 2012, transcatheter closure was performed in 618 patients diagnosed with PDA. In general, we prefer to use a duct occluder in patients with PDA larger than 3.5 mm. In total, we used a duct occluder in 167 patients with a mean PDA diameter of 5.5 ± 1.7 mm (range: 3.5–13.4 mm) and a mean age of 11.2 ± 14 years (range: 3.6 months–63 years). We began to use ADO in March 2005, and first introduced CDO, which has received the European Union's CE mark approval, in February 2008. Eight kilograms of weight has been accepted as a cut point

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Conflict of interest: Nothing to report.

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Received 15 October 2012; Revision accepted 9 April 2013

DOI: 10.1002/ccd.24957
Published online 16 April 2013 in Wiley Online Library (wileyonlinelibrary.com).

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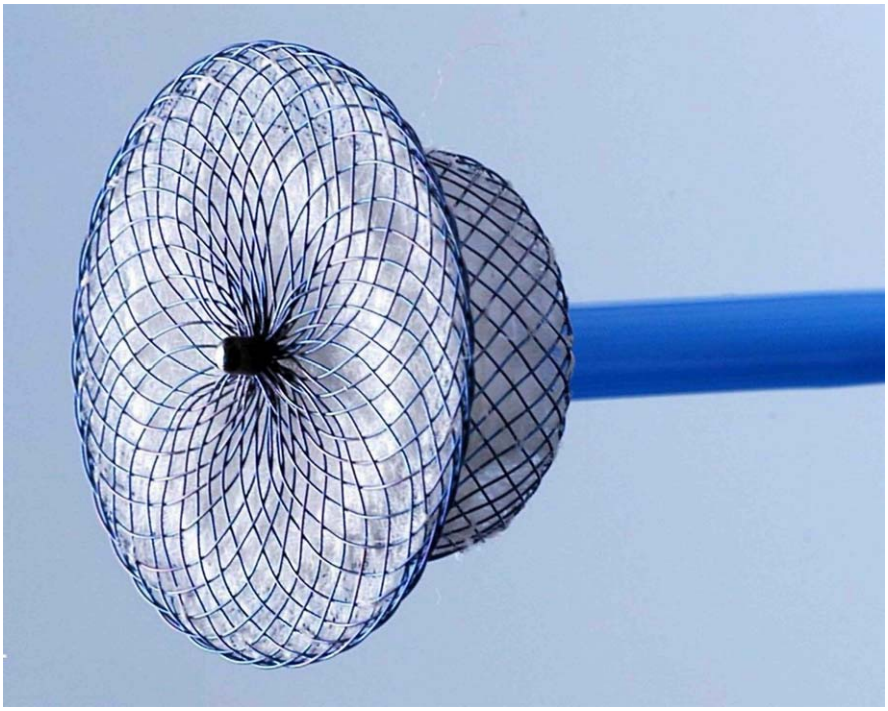


Fig. 1. Cardi-O-Fix PDA occluder. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE I. Device Type, Sizes, and Recommended Sheath Sizes

Type	D_p (mm)	D_a (mm)	Length (mm)	Sheath size (Fr)
P^{1-2} -0406	4	6	7	5
P^{1-2} -0608	6	8	7	6
P^{1-2} -08010	8	10	8	6
P^{1-2} -1012	10	12	8	7
P^{1-2} -1214	12	14	8	8
P^{1-2} -1416	14	16	8	8
P^{1-2} -1618	16	18	9	9
P^{1-2} -1820	18	20	9	9

P, device code; [1], traditional type; [2], improved type; D_p, pulmonary end diameter; D_a, aortic end diameter.

for subgroup analysis. Large ducts in infants less than 8 kg can be difficult to treat because of a relative mismatch of introducers, plugs, or occluders to the small anatomic dimensions [9].

Cardi-O-Fix Duct Occluder

CDO is a self-expandable mushroom-shaped implant device made from Nitinol wire mesh, with a 2-mm retention skirt that assures secure positioning in the mouth of the PDA. The communication is closed by the induction of thrombosis, which is accomplished by polyester patches sewn securely into the device.

Two types of CDO have been designed: the traditional type with double ends and the improved type with a single end. Both can be used for the intended patients, but we have experience only with the traditional type.

ADO is available in seven sizes and can be used to close PDA up to 12 mm in diameter. CDO is available in nine sizes, allowing closure of defects with diameters as large as 16–18 mm.

The CDO delivery system is composed of a delivery sheath, dilator, loader, hemostasis valve, delivery cable, and plastic vise. The long sheath is bendable up to 180°. CDO and its delivery system are similar to the Amplatzer device, and the implantation techniques of both devices are identical. In the past, CDO could only be used with large sheath sizes, but has since been redesigned (Table I) and is now compatible with 5–7 Fr long sheaths.

Patient Selection

Before the procedure, all patients underwent physical examination, electrocardiography, and transthoracic echocardiography (TTE). All patients had clinical and/or echocardiographic findings consistent with PDA. Exclusion criteria included a weight <4.0 kg, pulmonary vascular resistance >8 Wood U/m^2, pulmonary vascular resistance to systemic vascular resistance ratio of >0.5, and associated cardiac anomalies requiring cardiac surgery.

Procedure

All patients and/or their parents gave informed consent and signed the protocol approved by the

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institutional ethics committee. Cardiac catheterization was performed under deep sedation induced by midazolam and ketamine. Local anesthesia with lidocaine was used as well. After cannulation of femoral artery and vein, hemodynamic parameters such as ascending and descending aortic pressure and pulmonary artery pressure were measured. Angiography was performed in a 90° lateral position and a 40° right anterior oblique position to evaluate PDA size and morphology. After duct size and dimensions were determined, duct occluders 1–2 mm larger than the narrowest duct diameter were used in infants and younger patients, whereas duct occluders 2–3 mm larger than the narrowest duct diameter were used in older patients.

A right heart catheter (mainly Right Judkins) was retrogradely fed over the exchange wire through the PDA to descending aorta and then removed together with the vessel sheath. The delivery sheath was introduced over the wire and positioned in the descending aorta.

The delivery cable was passed through the loader, the occluder was screwed clockwise into the tip of the delivery cable, and then screwed and unscrewed one to two times to control the releasing mechanism but not overtightened. The device and the loader were immersed in saline solution as the device was pulled into the loader to remove the air. After flushing via the side arm of the loader, the loader was introduced into the delivery sheath and the occluder was advanced into the descending aorta. The delivery sheath was retracted until the retention disc was opened, and the sheath with the delivery cable inside was pulled back as one unit until the disc was up against the aortic side of the ductus. The sheath was further retracted with constant tension on the delivery cable and the round waist was deployed in the PDA. Aortography was performed to confirm correct placement and detect residual shunt. If misplaced, the device was retrieved into the delivery sheath and redeployed, or replaced by another device if necessary. Device deployment was completed by turning the delivery cable counterclockwise. Hemodynamic measurements were repeated to detect any increase in right ventricular pressure indicating pulmonary stenosis or gradient between the ascending and descending aorta before and after deployment. A repeat angiogram was performed 10 min later to check for residual shunt and complications.

The loading and implantation procedures were the same for both devices.

Residual Shunt

Residual shunt was considered to be present if the repeat angiogram performed 10 min after device deployment showed any left-to-right shunt, or if Doppler color flow mapping showed left-to-right shunt across the duct the day after the procedure.

Post-Procedure Care and Follow-Up

All patients underwent clinical examination and TTE before discharge at 1, 6, and 12 months after the procedure and yearly thereafter in order to monitor for residual shunt, migration, erosion, and other complications.

Statistical Analysis

The SPSS 15.0 for Windows (SPSS, Chicago, IL) was used for data analysis. The Shapiro–Wilk test was used for the analysis of compliance with normal distribution. Normally distributed continuous data are presented as mean ± standard deviation (SD) and nominal variables as counts and/or percentages. Non-normally distributed continuous data are presented as mean ± SD and median and interquartile range. For comparison of groups, Student's *t*-test was used for continuous normally distributed variables and the Mann–Whitney *U*-test was used for non-normally distributed variables. The chi-squared test and Fisher's exact test were used to test incidences in groups for significance. All statistical tests were two-sided. A P value of <0.05 was considered statistically significant.

RESULTS

Transcatheter PDA closure was successfully performed in 618 patients. Two patients with very high pulmonary vascular resistance (>10 Wood U/m^2) and two patients with hemodynamically and anatomically significant coarctation detected after catheterization were excluded from the study. CDO was used in 111 patients and ADO was used in 56 patients. Patient characteristics and cardiac catheterization features are shown in Table II. The narrowest PDA diameter, the used PDA device diameter, procedure time, and fluoroscopy time were similar between the groups. Characteristics, procedure variables, and follow-up features of patients weighing <8 kg are shown in Table III. There was no difference between the two groups in terms of age, weight, echocardiographic measurements, PDA diameters, used PDA device diameter, or other procedural features.

Residual Shunt

Although the residual shunt rate was higher in the CDO group immediately after the procedure, the difference was not statistically significant (12.6 vs. 8.9%; $P = 0.3$). There was no statistically significant difference

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TABLE II. Patient Characteristics, Procedure Variables, and Follow-Up

	CDO ($n = 111$)		ADO ($n = 56$)		
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	*P*
Age (years)	12.6 ± 14.6	7.2 (14.5)	8.1 ± 11.9	2 (12.5)	0.07[a]
Weight	31.6 ± 24.1	21 (45.5)	23.9 ± 23.5	10.8 (35)	0.06[a]
Gender (male/female)	26/85		22/34		0.02[b]
LVEDd index (cm/m^2)	5.9 ± 3	5.4 (3.8)	6.2 ± 2.4	7.2 (4.9)	0.4[a]
LAd/Aod ratio	1.6 ± 0.4	1.6 (0.5)	1.6 ± 0.2	1.5 (0.4)	0.8[a]
Mean PA pressure (mm Hg)	29.3 ± 14.8	25 (18)	30.2 ± 12.3	28 (17)	0.9[a]
PDA diameters (mm) D_1	5.1 ± 1.7	4.7 (2)	5.6 ± 1.6	5.4 (2)	0.2[a]
D_2	13.9 ± 5.9	13 (6.3)	12.9 ± 6.1	11 (10.2)	0.09[a]
Length	10.2 ± 3.8		9.7 ± 3.2		0.3[c]
Occluder size (mm)	9.8 ± 2.1	10 (4)	9.9 ± 2.1	10 (4)	0.2[a]
Procedure time (min)	60 ± 21	60 (30)	63 ± 18	60 (25)	0.5[a]
Fluoroscopy time (min)	15.7 ± 7.6	15.0 (9)	16.8 ± 6.6	15 (7)	0.2[a]
Procedural success, *n* (%)	100%		100%		
Complication rate	7 (6.3%)		5 (8.9%)		0.5[b]
Residual shunt %					
After closure	14 (12.6%)		5 (8.9%)		0.3[b]
Before discharge—1 day	5 (4.5%)		3 (3.5%)		0.1[d]
1 month	1 (0.9%)		1 (1.7%)		0.6[d]
6 months	1 (0.9%)		1 (1.7%)		0.6[d]
At the end of follow-up	1 (0.9%)		1 (1.7%)		0.6[d]
Follow-up time (months)	32.3 ± 14	36 (21)	69.2 ± 11.3	70 (19)	<0.0001[a]
Approximate average cost per patient (Euro)	870		1,700		

CDO, Cardi-O-Fix ductal occluder; ADO, ampatzer ductal occluder; SD, standard deviation; IQR, interquartile range; D_1, the narrowest diameter of PDA; D_2, ampulla; LVEDd, left ventricle end-diastolic diameter; LAd/Aod, ratio of left atrium to aorta; PA, pulmonary artery.
[a]Mann–Whitney *U*-test.
[b]Chi-squared test.
[c]Student's *t*-test.
[d]Fisher's exact test.

between the groups at discharge (Table II). At the 6-month visit and after a mean follow-up of 3.7 years, there was no significant difference between the CDO and the ADO groups in terms of residual shunt (1/111, 0.9 vs. 1/56, 1.86%; $P = 0.6$) (Table II). Residual shunt was trivial-to-small during procedure and follow-up in all patients.

Residual shunt ratios of patients under 8 kg in both groups were similar immediately after the procedure. There was no statistically significant difference between groups at discharge and during follow-up (Table III).

Complications

Kinking of the long sheath occurred at the angle of the right ventricular outflow tract as a minor complication in five patients (two in ADO and three in CDO). In terms of major complications, device protrusion to the aorta causing mild coarctation occurred because of inadequate PDA length in two patients (one in each group). In one of these patients, aged 4 months and weighing 4.2 kg, there was no pressure gradient between the ascending and descending aorta before device release. After deployment, we detected a 20 mm Hg pressure gradient due to device protrusion and relatively large aortic disc compared with aortic dimension. Although we attempted to reposition the device to the ampulla by balloon inflation, a 10 mm Hg pressure gradient at the upper side remained. In the other patient, aged 4 years and weighing 12.5 kg, the procedure was completed without complications, but an echocardiogram taken a day later showed that the device had migrated to the aorta without completely leaving the ductal ampulla, causing both large residual shunt and coarctation. Recatheterization was performed and the device was repositioned with a bioptome. No residual shunt or displacement was seen in either of these cases during follow-up.

In one patient, the CDO embolized to the pulmonary artery, was snared out, and replaced by a device one size larger.

Hemodynamically insignificant pulmonary artery stenosis developed in four patients (two in each group), all weighing under 8 kg. Increased flow gradient eventually decreased in all patients.

No deaths occurred in either group. Considering all patients there were no differences in complication rates

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TABLE III. Characteristics, Procedure Variables, and Follow-Up Features of Patients Below 8 kg

	CDO ($n = 21$)		ADO ($n = 20$)		
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	*P*
Age (months)	9 ± 3.2	8.4 (3.1)	10.1 ± 4.4	9 (7.8)	0.6[a]
Weight	6.2 ± 0.9		5.8 ± 1.2		0.2[b]
Gender (male/female)	7/14		9/11		0.1[c]
Clinical Tachypnea	11 (52%)		10 (50%)		0.8[c]
findings Poor weight gain	15 (71%)		13 (65%)		0.6[c]
LVEDd index (cm/m^2)	10.5 ± 3.3	9.5 (2.7)	8.5 ± 0.6	8.7 (1.3)	0.07[a]
LAd/Aod ratio	1.7 ± 0.1		1.56 ± 0.2		0.08[b]
Mean PA pressure (mm Hg)	35 ± 12		34 ± 11		0.5[b]
PDA diameters (mm) D_1	4.6 ± 0.9	4.7 (1.7)	5.2 ± 1.6	4.9 (1.5)	0.4[a]
D_2	9.5 ± 2.2		9.1 ± 1.9		0.8[b]
Length	8.8 ± 3.1	8.2 (4.9)	9.6 ± 2.7	9.3 (3.9)	0.2[a]
Occluder size (mm)	8.6 ± 1.4	8 (2)	8.9 ± 1.3	8 (2)	0.9[a]
Procedure time (min)	58 ± 18		71 ± 19		0.08[b]
Fluoroscopy time (min)	15.6 ± 5.4	16 (11)	18.5 ± 7.6	16 (7)	0.4[a]
Procedural success, *n* (%)	100%		100%		
Complication rate	2 (9.5%)		3 (15%)		0.01[d]
Residual shunt %		After closure	3 (14.2%)	3 (15%)	0.5[d]
Before discharge—1 day	3 (14.2%)		2 (10%)		0.3[d]
1 month	1 (4.7%)		1 (5%)		0.6[d]
6 months	1 (4.7%)		1 (5%)		0.6[d]
At the end of follow-up	1 (4.7%)		1 (5%)		0.6[d]
Follow-up time (months)	12 ± 7.8	12.5 (15)	71.5 ± 12.4	73.5 (17)	<0.0001[a]

CDO, Cardi-O-Fix ductal occluder; ADO, ampatzer ductal occluder; SD, standard deviation; IQR, interquartile range; D_1, the narrowest diameter of PDA; D_2, ampulla; LVEDd, left ventricle end-diastolic diameter; LAd/Aod, ratio of left atrium to aorta; PA, pulmonary artery.
[a]Mann–Whitney *U*-test.
[b]Student's *t*-test.
[c]Chi-squared test.
[d]Fisher's exact test.

during short- and mid-term follow-up periods (Table II). Complications in patients under 8 kg were found to be slightly higher statistically in ADO (20/3) group than CDO (21/2) (Table III).

Follow-Up

Mean follow-up duration was 69.2 ± 11.3 months (35–87) in the ADO group and 32.3 ± 14 months (3–51) in the CDO group ($P < 0.001$). No device malposition was observed in any of the patients during follow-up except the two patients described above. No significant complications such as procedure-related arrhythmia, jamming or obstruction, cardiac tamponade, thrombosis or air embolisms, aortic rupture, or increased valve failure were observed.

DISCUSSION

PDA closure is indicated electively in every patient with a continuous murmur to prevent endarteritis at 1 year of age, and recommended earlier if the patient is symptomatic [3,5,10,11]. Percutaneous closure is an established method of treatment for most patients with PDA, with the exception of low-weight (<4–5 kg) infants and preterm infants [11]. Currently, coils are the most widely used device for closure of small-to-moderate PDA. The introduction of the ADO made it possible to safely close defects up to 12 mm in diameter [6–8,12]. The recently introduced CDO has similar characteristics and implantation techniques but initially required larger sheath sizes. Meanwhile, there have not been any clinical trials comparing the two devices. In our study, we compared the results of moderate-to-large PDA closure using CDO and ADO.

Our preliminary expectation for CDO was success rates and complication rates similar to ADO and superior cost effectivity. Our experience confirmed that percutaneous closure of PDA using both devices was a safe and effective procedure even in infants weighing < 8 kg. The rate of device-related complications was not higher in the CDO group. In one patient, the device embolized to the pulmonary artery as it was smaller than the duct diameter. In another patient, who had significant pulmonary hypertension, the malpositioned device migrated toward the descending aorta. The complications were managed transcatheterally in both patients. In the CDO group, residual leaks were more

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frequent immediately after implantation; however, residual shunt did not persist during 24-hr follow-up with a high rate of closure, which reached ~99% during 1-year follow-up. Previous reports also mention similar residual leaks for ADO [6–8,11–13]. According to the manufacturer, the communication is closed by the induction of thrombosis, which is accomplished by polyester patches sewn securely into the device. Mild left-to-right shunt seen in patients after the procedure is considered normal if it eventually disappears, usually in 1–3 months. As the two devices are similar in structure, there must be microscopic structural difference or different polyester patch materials. Whatever the reason, most of the residual shunt seen in our patients disappeared within the first 24 hr.

Complications such as obstruction of the aorta or left pulmonary artery, embolization, and hemolysis have been reported in other studies [6–8,14,15]. In our study, left pulmonary artery stenosis was seen in two of the patients in the ADO group, both small infants weighing <8 kg and with moderately large defects, and in two patients in the CDO group. Echocardiographic examination during follow-up revealed that the stenosis had no clinical significance, while scintigraphic control confirmed that it eventually decreased. Complications are more frequently reported in infants and young children with relatively low body weight, particularly those with a large PDA [16,17].

ADO is available in seven sizes, allowing closure of defects up to 12 mm in diameter, whereas CDO is available in nine sizes and can be used to close defects as large as 18 mm in diameter. Before the approval of CDO in 2008, surgery was the main treatment in very large defects >12 mm, apart from few case reports [18,19]. We used CDO in 11 patients with PDA >12 mm, with no complications.

Another major advantage of the CDO device is its relatively low cost. The cost of the ADO device alone equals twice the total cost for the CDO device group. In terms of disadvantages, CDO required sheaths of large sizes in the past. However, the device has since been redesigned and is now compatible with smaller sheaths. Another important point is that no long-term follow-up results have been declared in literature as of yet.

Although CDO and ADO are similarly effective, the low cost of CDO makes it the superior option, particularly in low-income countries where healthcare resources are limited and healthcare professionals have to take cost effectiveness into account. To the best of our knowledge, no studies have compared the cost effectiveness of CDO and ADO before. Studies with a larger number of cases and longer follow-up periods are necessary to confirm our results. Deficiency of long-term follow-up is one of the major restrictions of this study. Unfortunately, we had no change to use both devices together. So that could be another restriction of our study. It would be better to design the study to use devices randomizely at the same time.

CONCLUSION

The CDO can be used for PDA closure because of its safety, effectiveness, and simplicity in use. According to our short- and mid-term findings, the results it yields are similar to those of the ADO; thus, it may be the preferred choice owing to its low cost and large size variability.

ACKNOWLEDGMENTS

The authors have no multiplicity of interest to disclose. This research did not receive any specific grant from any funding agency in the public, commercial, or not-for-profit sector. They thank Assoc. Prof. Dr. Ahmet Topuzoglu for statistical procedure control.

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