

Application of Cardio-O-Fix occluders for transcatheter closure of patent ductus arteriosus and interatrial communications: Preliminary experience

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Abstract

Background: *Transcatheter treatment has become the method of choice for treating many heart defects. Recently, Cardio-O-Fix occluder (COF) — a new, self-expandable nitinol wire-mesh device very similar to the Amplatzer device — has been introduced into clinical practice. To the best of our knowledge, this is the first publication related to its application.*

Methods: *Five patients aged from six months to 69 years were included in the study: two with atrial septal defect (ASD), one with patent foramen ovale (PFO) after cryptogenic stroke, and two with patent ductus arteriosus (PDA). These latter two comprised one six month old infant with co-existent hypertrophied cardiomyopathy, and a 53 year-old woman with recanalized PDA after previous ligation. All were treated percutaneously with COF. There was no preliminary patient selection. The only limitation was the size of the devices in our possession (16 and 22 mm ASD COF, 25 PFO COF, 4/6 and 6/8 PDA COF). The implantation technique was the same as previously described for Amplatzer occluders.*

Results: *All procedures were finished successfully with complete closure of the shunt. No complications were observed during a six month follow-up. In the child with PDA, we observed decrease of gradient from 80 to 60 mm Hg in hypertrophied left ventricular outflow tract, although a small protrusion of PDA-COF device was noted in the descending aorta (8 mm Hg gradient in ECHO). In the patient with recanalized PDA, the procedure was performed after arterio-venous loop creation. Mean fluoroscopy time was 4.4 (range from 1.6 to 11) minutes.*

Conclusions: *Our preliminary experience indicates that the application of Cardio-O-Fix devices is safe and effective. (Cardiol J 2010; 17, 6: 607–611)*

Key words: interventional catheterization, congenital heart defects

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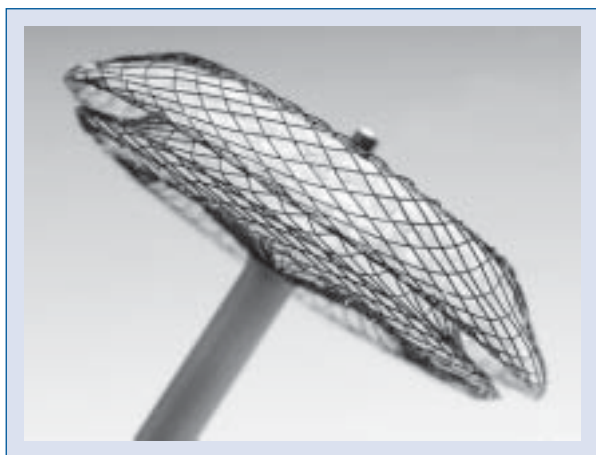


Figure 1. Atrial septal defect Cardio-O-Fix occluder.

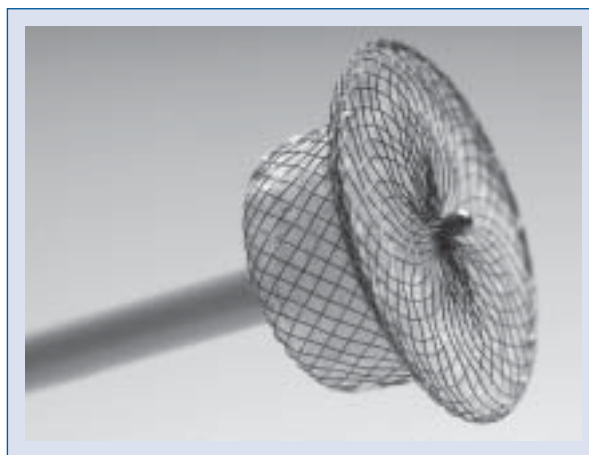


Figure 2. Patent ductus arteriosus Cardio-O-Fix occluder.

Introduction

Transcatheter closure of atrial septal defects (ASD), patent foramen ovale (PFO) and patent ductus arteriosus (PDA) has in recent years become the treatment of choice. For these purposes, the commonest equipment used have been expensive Amplatzer devices. Recently, Figulla occluders, similar to Amplatzer devices, have been introduced to clinical practice [1].

This study sets out our preliminary experience in using new devices from the family of Cardio-O-Fix occluders (COF), which are also similar to Amplatzer devices. All are made from nitinol wire mesh. COF occluders received CE approval (CE 0197) in 2008. To the best of our knowledge, this paper is the first publication reporting the use of these devices for transcatheter ASD, PFO and PDA closure.

Methods

In September 2009, five consecutive patients were treated with COF: two with ASD, two with PDA and one with PFO. There was no preliminary patient selection — the only limitation was the size of the devices we possessed. ASD, PDA and PFO COF occluders (Starway Medical Technology Inc. Beijing, China) show many similarities in their structure, size, diameter, implantation technique and application to Amplatzer devices. The ASD COF occluder is a self-expandable double disc device (Fig. 1). Before implantation, the stretched diameter of the defect was measured using a calibrating balloon. The PDA COF occluder is a self-expandable, mushroom-shaped device (Fig. 2). After aortography in lateral projection, the anatomy of the PDA was assessed. According to the measured size



Figure 3. Patent foramen ovale Cardio-O-Fix occluder.

of PDA, a device between 2–4 mm larger than its narrowest diameter was chosen for closure. The PFO COF occluder is a self-expandable double disc implant device (Fig. 3). In the 25 mm PFO COF occluder, the right disc diameter is 25 mm and the left is 18 mm. No measurement of the stretched diameter of PFO was made before transcatheter closure. In the case of ASD and PFO COF applications after procedures, heparin infusions were administered for two days. Thereafter, aspirin (3–5 mg/kg) was prescribed for six months.

The study was approved by the local bioethical committee and all patients gave their informed consent.

Patients 1 and 2

These were a 24 year-old man (weight 84 kg) and a 69 year-old woman (weight 60 kg) with ASD.

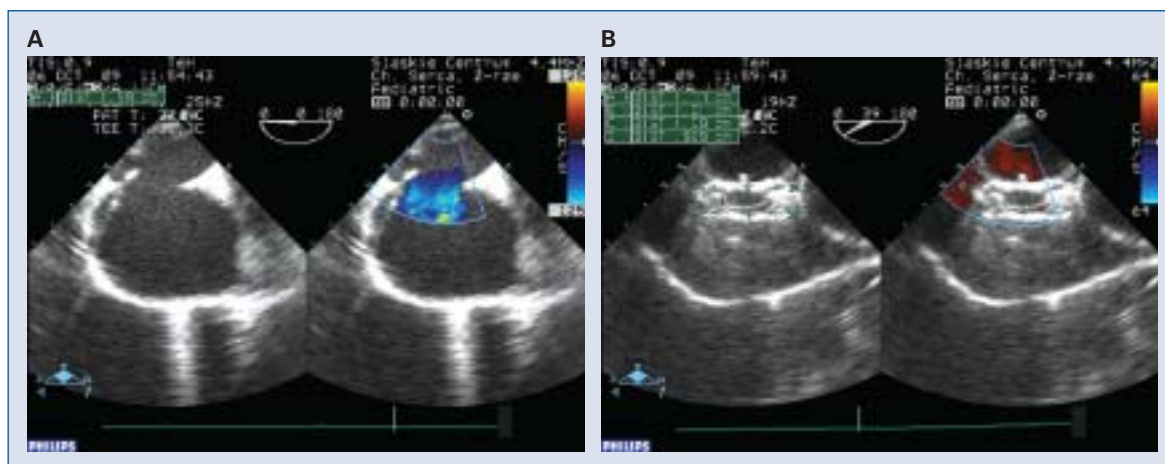


Figure 4. Echocardiographic images of atrial septal defect: **A.** Before and; **B.** After transcatheter closure with Cardio-O-Fix occluder atrial septal defect occluder.

In transthoracic echocardiography (TTE), right atrium and right ventricle overload was observed. The diameter of the defect was estimated as 15 mm in the first patient and 10 mm in the second. In transesophageal echocardiography (TEE), ASD diameters were 17 mm and 12 mm respectively. Procedures were performed under local anesthesia with TEE and fluoroscopic guidance. Stretch diameters of ASD were 20 mm and 16 mm respectively. Through a 12 F delivery sheath, the 22 mm ASD COF was implanted in the first patient, and through a 9 F sheath the 16 mm ASD COF in the second (Fig. 4). Procedural times were 30 and 40 min, and fluoroscopy times 2.3 and 2 min respectively. Complete closure of ASD was confirmed in TTE the day after the procedure in both patients.

Patient 3

This was a 32 year-old woman (weight 62 kg) with PFO and a history of previous cryptogenic stroke (six months earlier). In cerebral TC, ischemic stroke was confirmed. TEE (with contrast right atrium study) and transcranial Doppler (TCD) study in the middle cerebral artery (with saline injected into the peripheral vein) demonstrated positive signs of significant right to left shunt during Valsalva maneuver. Procedure was performed under local anesthesia and both TEE and fluoroscopic control. Through an 8 F delivery sheath, the 25 mm PFO COF occluder was implanted. Procedural time was 45 min, fluoroscopy time 1.6 min. The next day, control TCD revealed no shunt and bubbles in the medial cerebral artery (before the procedure 'shower' was present).

Patient 4

This was 53 year-old woman (weight 66 kg) with PDA previously ligated surgically (in 1976). Recanalization of PDA was stated few years ago. In diagnostic catheterization, the pressure in the aorta was 173/76/116 mm Hg and in the pulmonary artery 37/14/26 mm Hg. Due to the difficulty of precisely measuring the PDA diameter during conventional aortography (wide aorta and duct), it was estimated as 3.5 mm using a calibrating balloon [2]. Another technical problem was catheterization of PDA from the venous side. An arterio-venous loop was created with a guidewire 0.035 × 260 cm [3]. From the venous side through a 7 F delivery sheath (with angulation of 180 degrees), a 8/6 mm PDA COF was implanted. After release of the device, aortography proved its proper position and complete closure of PDA. Procedural time was 50 min, fluoroscopy time 11 min.

Patient 5

This was a six and a half month old boy (weight 8.9 kg) with PDA and diagnosis of hypertrophied cardiomyopathy (with obstruction of left ventricular outflow tract (LVOT) with 80 mm Hg gradient in Doppler echocardiography). The procedure was performed under general anesthesia with fluoroscopic control. After diagnostic catheterization, (pressure in left ventricle 150/0/5 mm Hg, in aorta 75/42/56 mm Hg, in pulmonary artery 35/15/21 mm Hg), the diameter of PDA (in aortography) was estimated as 2.5 mm Hg. Through a 6 F delivery sheath (with angulation of 180 degrees), a 6/4 mm PDA COF was implanted. The only difficulty which occurred during the procedure was kinking of the



Figure 5. Small protrusion of 6/4 Cardio-O-Fix occluder patent ductus arteriosus disc to aorta in six month old infant after percutaneous closure of the duct.

trans-septal sheath in the aorta close to PDA during the introduction of the device. This problem was resolved by repositioning the long sheath in the descending aorta. As a consequence, kinking of the sheath disappeared, possibly because it was stabilized by a stiff delivery system. Complete occlusion of PDA was observed after unscrewing the device, although a small protrusion of the device into the aorta was observed (with 8 mm gradient in ECHO Doppler) (Fig. 5). Procedural time was 40 min, fluoroscopy time 5.2 min. ECHO examination, performed after the procedure, revealed total occlusion of PDA as well as the reduction of LVOT gradient from 80 to 60 mm Hg.

Follow-up examinations of all patients were scheduled: one, three, six and 12 months after the procedure, and yearly thereafter. To date, no complications at the six month follow-up have been observed in the described group.

Discussion

Amplatzer occluders have been used worldwide since the late 1990s and our experience confirmed the good clinical results obtained with these devices for closure of 823 ASD, 100 PFO and 131 PDA. The important limitation in their application is their high cost. Recently, new devices called Occlutech Figulla and Cardio-O-Fix occluders, both similar to Amplatzer, have been introduced to clinical practice.

Comparative study of the Figulla ASD occluder *versus* the Amplatzer Septal Occluder (ASO) have shown that both devices are clinically safe and effective in ASD closure. The Figulla occluder, however, has some disadvantages, such as difficulties in selecting the correct size in larger defects (fewer available sizes) and larger sheath requirements [1]. Considering the greater variety of size of Cardio-O-Fix occluders, there should be no problem using this device. However, similarly to the observations of Pac et al. [1] related to the Figulla occluder, we have found that COF devices also required a larger sheath compared to the ASO. This may also limit its application in smaller children. The great advantage of applying both the above mentioned devices is their ability to close larger ASDs (in contrast to other new devices, such as Helex or Cardia, which are suitable only for smaller ASDs and have more frequent complication rates) [4]. Moreover, our experience shows that there need be no learning curve using COF devices, because the implantation technique is similar to that for Amplatzer devices. We decided to use these devices after receiving many positive opinions on the subject from internationally recognized leaders in interventional cardiology, who have used these devices in practice. Our decision was also strongly influenced by data from Chinese investigations (unfortunately not published yet) according to which, more than 10,000 COF have been implanted with good results. One important advantage of these devices is their relatively low cost.

Two of the patients presented in this paper with PDA had some peculiarities. The first adult patient had recanalized PDA after a previous history of its surgical ligation. This case confirmed our experience that percutaneous closure of such PDAs is feasible, although sometimes more laborious [4]. Zhang et al. [3] stated that in cases of abnormal PDA morphology (as usually is seen in residual post-surgical PDAs), the retrograde wire-guided technique (applied by us in this patient as an arterio-venous loop) offers an alternative approach to cannulate a PDA that cannot be achieved by the traditional antegrade wire-guided method.

The second case was an infant with PDA and additionally hypertrophied cardiomyopathy causing obstruction in LVOT (80 mm Hg in ECHO Doppler study). We decided to close his PDA, expecting reduction of his left cavities overload. Our expectations were confirmed in practice (LVOT gradient diminished from 80 to 60 mm). Although the final result of PDA closure was positive, this case un-

fortunately indicated that probably PDA COF devices are not optimal for PDA closure in small children. It is worth pointing out that the trans-septal sheath was too soft, which explains its kinking. On the other hand, Al Ata et al. [6] found a much higher rate of problems and complications in patients with PDA with weight below 10 kg, in whom Amplatzer Duct Occluder was used (our infant's weight was 8.9 kg). Probably, the new generation of Amplatzer Duct Occluder type II (with two retentional discs connected by a waist) is a better solution for such patients [7].

Conclusions

Our preliminary experience with the application of Cardio-O-Fix occluders for the closure of atrial septal defect, foramen ovale and patent ductus arteriosus, indicate that they are good and safe devices, at least as shown in short term follow-up.

Acknowledgements

The authors do not report any conflict of interest regarding this work.

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