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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

A Comparative Study of Cardi-O-Fix Septal Occluder Versus Amplatzer Septal Occluder in Percutaneous Closure of Secundum Atrial Septal Defects

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Aim: We sought to investigate the safety and efficacy of Cardio-O-Fix septal occluder (CSO) in percutaneous closure of atrial septal defects (ASD) as compared to the Amplatzer septal occluder (ASO). Methods: A consecutive of 351 patients received transcatheter ASD closure with CSO or ASO from July 2004 to October 2010 were studied. The ASDs were divided into simple- (isolated defects <26 mm) or complex-types (isolated defect ≥26 mm, double or multifenestrated defects). The procedures were guided by fluoroscopy and transthoracic or transesophageal echocardiography. Clinical and echocardiographic follow-ups were arranged before discharge, at 1 month and then every 6-month after implantation. Results: During the study period, 185 (125 males, aged 18.5 ± 15.6 years) and 166 (103 males, aged 21.0 ± 15.7 years) patients attempted CSO and ASO implants, respectively. The CSO group had similar ASD and device sizes, prevalence of complex lesions (17 vs. 16%, *P* = 0.796), procedural times and success rates (97% vs. 96%, *P* = 0.635) as compared to the ASO group. Acute residual shunts were less prevalent in CSO than ASO group and most shunts closed spontaneously at 6-month follow-ups. The average equipment cost per patient was lower in CSO group (US$ 4,100 vs. US$ 5,900, *P* < 0.001). The prevalence of device embolization and atrial arrhythmia (all <2%) were similar in both patient groups. Conclusion: Transcatheter ASD occlusion with CSO is safe and effective and it appeared to be an attractive alternative to ASO in closing simple-type ASD because of its relatively low cost. © 2013 Wiley Periodicals, Inc.

Key words: secundum atrial septal defect; cardi-o-fix septal occluder; transcatheter closure

INTRODUCTION

Secundum atrial septal defect (ASD) is the most common congenital heart disease encountered by adult cardiologists and most of the defects could now be safely and effectively corrected through a catheter approach [1–4]. Amplatzer septal occluder (ASO, AGA Medical, Golden Valley, MN) is the commonest dedicated device used worldwide for closing ASD in the last two decades due to its novel design, ease of use and proven sustained efficacy. The device is constructed from a nitinol mesh and Dacron and consists of two self-expanding discs connected by a short central waist corresponding to the size of ASD. The AMPLATZER delivery system comprises of a delivery sheath, dilator, loading device, plastic vise, and delivery cable. The

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Conflict of interest: Nothing to report.

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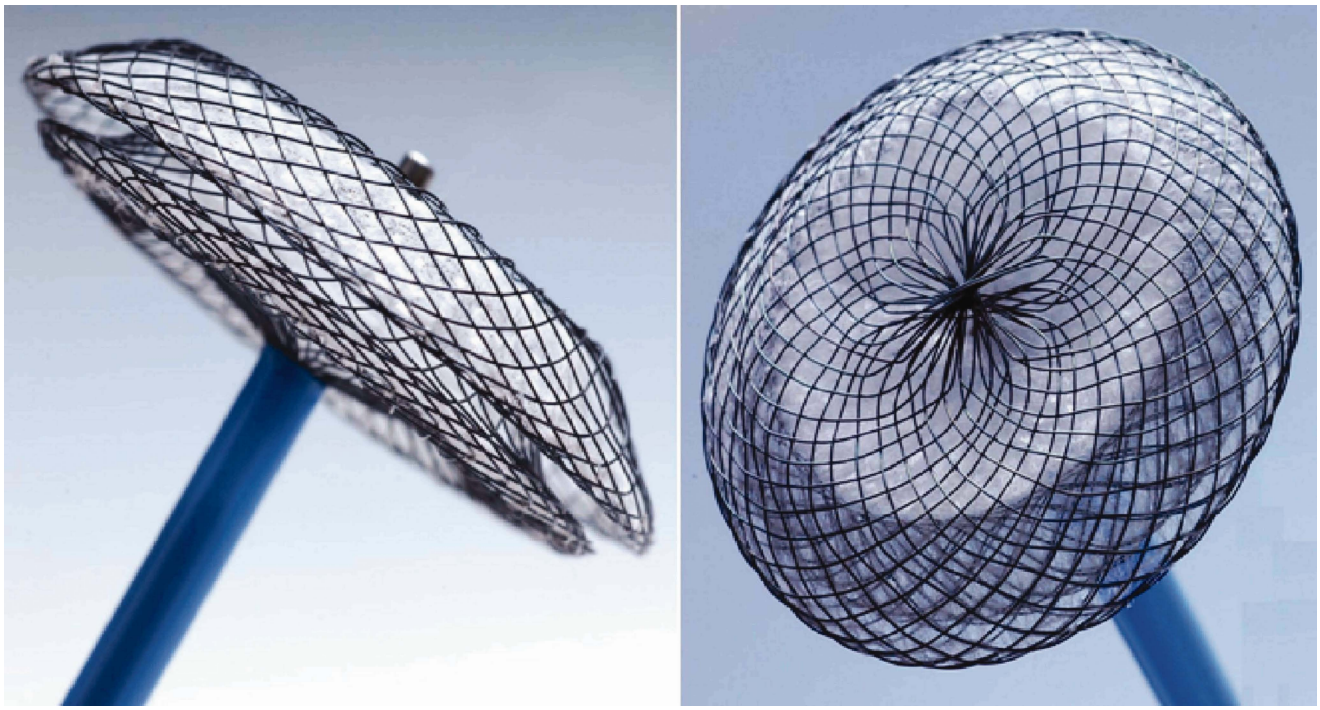


Fig. 1. Cardi-O-Fix septal occluder. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

delivery sheaths range from 6 to 12 Fr. The device is fully recapturable and repositionable if necessary. However, the cost of the device remained a problem that limited its applicability in many parts of the world. The Starway Cardi-O-Fix Septal Occluder (CSO, Starway Medical Technology, Beijing, China) is a new self-expandable, double-disc nitinol-based, less expensive device that received CE approval (CE 0197) in 2008 for safety [5]. There is a lack of reported data on the clinical efficacy of this device despite its wide clinical use in China. In present study, we evaluated the safety and efficacy of CSO in ASD occlusion as compared to ASO.

METHODS

Study Population

A consecutive of 351 patients received percutaneous ASD closure with either ASO or CSO at two Turkey centers by two operators between July 2004 and October 2010 were studied. All patients received transthoracic echocardiography (TTE) prior to intervention. All the participants had a diagnosis of secundum ASD with right heart dilation and the maximal diameter (unstretched diameter) of the defect <38 mm as measured by TTE. The ASDs were further classified into simple- (isolated defects <26 mm) or complex-types (isolated defect ≥ 26 mm or double defects). Patient found to have small shunt (Q_p/Q_s $<1.5:1$) or pulmonary vascular resistance of >8 Woods units under 100% O_2 assessed during cardiac catheterization were excluded from the study. Informed consent was obtained from all studied patients or their relatives and the study was approved by institutional review board. Aspirin and antibiotics were given 12 hr and 1 hr before the procedure, respectively.

Cardi-O-Fix Septal Occluder (CSO)

The Cardi-O-Fix septal occluder (CSO) [5] is a nitinol-based device structurally similar to the Amplatzer device and is delivered to the interatrial septum via a catheter delivery system (Fig. 1). The device consists of two discs, of which the left is larger in diameter than the right. The discs are connected by a short (4 mm) connecting waist that corresponds to the diameter of the ASD. The disc and the waist are filled with polyester fabric to facilitate complete occlusion. The diameter of the connecting waist (size of the occluder) ranges from 4 mm to 40 mm. A total of 27 sizes are available (16 sizes between 4 and 20 mm and 11 sizes between 22 and 40 mm) Two types of CSO are designed, the traditional type (hubs attaching to both disc) and the improved type (absence of left atrial hub).

The Cardi-O-Fix delivery system is composed of a delivery sheath, dilator, loader, hemostasis valve, and a delivery cable with plastic vise. The long sheath is bendable up to 45°. The size of the delivery sheaths varies

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from 7 to 14 Fr which are bigger in size compared to the Amplatzer sheaths which ranges from 6 to 12 Fr.

Implantation Procedure and Follow-Up

All patients received invasive hemodynamic evaluation before closure. The pulmonary arterial pressures were obtained with standard fluid-filled catheters. With oxygen uptake at rest, Q_p/Q_s ratio is calculated by oximetry with the Fick's principle. Patients were given 75–100 U kg^{-1} heparin intravenously to achieve ACT $>$ 250 sec during the procedure. Percutaneous closure was performed with continuous TTE or transesophageal echocardiographic guidance. Balloon sizing method was used to evaluate the size of occluder needed. The sizing balloon was tracked to the defect through the stiffwire positioned at left upper pulmonary vein under echocardiographic guidance. The diameter of the balloon was increased slowly until the echocardiographic color Doppler flow disappeared at the defect. The stretched balloon diameter (SBD) was measured under echocardiography when the balloon occluded the defect completely. The stop-flow SBD diameter was used as reference for selection of device size in patients. In general, an occluder 1–2 mm larger than the SBD was chosen. More oversizing of the device was needed in patients with flimsy septum or large defects with relatively deficient rims [6–8]. The occluder was placed using the standard technique. The position and stability of the device were checked by Minnesota maneuver [8]. The procedure was repeated in patients with double ASDs. Presence of residual shunt was checked with echocardiography. Finally the device was released by disconnecting the delivery cable from the occluder. Acute procedural success was defined as stable and proper placement of the occluder to the defect. Residual shunt was represented by the presence of color Doppler echocardiographic flow along the edge of the implanted occluder. The degree of shunt was graded as trivial (<1 mm color jet width), small (1–2 mm color jet width), moderate (2–4 mm color jet width), or large (>4 mm color jet width). Presence of trivial shunt through the device immediately after device deployment was not considered clinically significant [9].

All patients were prescribed aspirin for 6 months after the procedure. Chest radiograph and TTE were performed at day 1 postimplantation to exclude device embolization and pericardial effusion, respectively. Clinical follow-up and TEE was arranged at 1-, 6-, and 12-months after device implantation to assess the clinical outcomes and monitoring treatment results.

Occurrence of Events

The safety end-points were defined as occurrence of events related to aspirin or heparin (e.g., intracranial or gastrointestinal bleeding, other major bleeding requiring transfusion), or procedure (e.g., catheter-related thrombus formation, air embolism, serious pericardial effusion, acute device embolization, procedural-related transient ischaemic attack or stroke). End-points assessed during TTE follow-ups included the presence of thrombus at the device, residual shunt, progressive valvular regurgitation, aortic wall erosion, or delayed device embolization. Clinical end-points collected during follow-ups included new onset arrythmias or cardiovascular death.

Statistics

All analyses were performed using SPSS version 13.0 for Windows (SPSS, Chicago, IL). Categorical variables were expressed as absolute numbers or percentage and were compared using chi-square test, whereas the continuous variables were summarized by mean value $\pm$ standard deviations and comparisons were made using Mann-Whitney U test or unpaired Student's t test as appropriate. A P-value <0.05 was considered to be significant.

RESULTS

Clinical Characteristics

Table I listed the patient characteristics, echocardiographic, and procedural data. During the study period, 185 (125 males, aged 18.5 $\pm$ 15.6 years) and 166 (103 males, aged 21.0 $\pm$ 15.7 years) patients received transcatheter ASD closure with CSO and ASO, respectively. The CSO patient group had similar prevalence of complex lesions (17% vs. 16%, $P = 0.796$) and acute procedural success rate (97% vs. 96%, $P = 0.635$) as compared to the ASO group. Four patients had double ASDs and three of them received CSO and the remaining patient received ASO. The two-patient groups also did not differ in ASD (both unstretched/balloon-stretched diameters) and occluder sizes. The procedural times were similar in both group but the CSO group did has a shorter fluoroscopy time (15.5 $\pm$ 8.1 vs. 18.3 $\pm$ 10.6 min, $P = 0.010$). Acute more-than-trivial residual shunt tended to be less prevalent in CSO group as compared to ASO and most of the shunts closed spontaneously during subsequent follow-up. The average equipment cost per patient was lower in CSO group (US$ 4,100 vs. US$ 5,900, $P < 0.001$).

Adverse Events

No major bleeding event was observed during the procedure. There was no serious procedural-related complication except the occurrence of acute device embolization in five patients (two with CSO and three with ASO). We were able to retrieve the CSO from

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TABLE I. Clinical Characteristics of the Patients

	CSO ($n = 185$)	ASO ($n = 166$)	P-value
Age (years)	18.5 ± 15.6	21.0 ± 15.7	0.135
Gender (male/female)	125/60	103/63	0.279
Defects			
Ratio of complex atrial septal defect, *n* (%)	32/185, 17%	27/166, 16%	0.796
Unstretched ASD diameter (mm)	15.4 ± 4.4	16.2 ± 4.4	0.112
Stretched Balloon ASD diameter (mm)	18.0 ± 4.5	19.1 ± 5.5	0.338
Right ventricle end-diastolic diameter (mm m^{-2})	28.4 ± 8.6	27.5 ± 6.9	0.464
Q_p/Q_s ratio	2.0 ± 0.6	2.1 ± 0.6	0.482
Mean pulmonary artery pressure (mm Hg)	17.3 ± 4.9	17.4 ± 5.5	0.907
Procedure			
Procedure time (min)	65.7 ± 30.1	68.2 ± 26.7	0.450
Fluoroscopy time (min)	15.5 ± 8.1	18.3 ± 10.6	0.010
Procedural success, *n%*	185/190, 97%	166/172, 96%	0.635
Use of transthoracic echocardiography, *n%*	136/185, 74%	120/166, 72%	0.797
Size of the occluder (mm)	18.9 ± 4.8	20.1 ± 5.6	0.168
Prevalence of residual shunt			
Immediate postimplant, *n%*	26, 14.0%	40, 24.2%	0.016
Before discharge, *n%*	9, 4.9%	5, 3.0%	0.376
1-month follow-up, *n%*	2, 1.1%	4, 2.4%	0.567
6-month follow-up, *n%*	2, 1.1%	2, 1.2%	0.913
At the end of follow-up, *n%*	1, 0.5%	1, 0.6%	0.939
Follow-up time (months)	11 ± 9	40 ± 15	<0.001
Average device cost per patient (US$)	4,100	5,900	<0.001

the pulmonary artery in one patient and his ASD was subsequently occluded by a bigger CSO. The other four patients eventually required surgical removal of the devices and repair of the ASDs. One 18-month-old boy, who received a 17-mm ASO through an 8Fr femoral venous sheath, was found to have large groin hematoma confirmed by ultrasound scan the day after the procedure. He was treated conservatively and no surgery was required. No similar problem was found in other patients.

All the devices were in good position during TEE follow-ups. There were neither device-related thrombus formation, device erosion into aortic wall, progressive valvular regurgitation nor delayed occluder embolization. No cardiovascular death occurred during follow-ups. New onset cardiac arrhythmia was detected in six patients within 1 month after ASD closure (two supraventricular tachycardias [SVT] and one atrial fibrillation in CSO group and two SVT and one complete heart block in ASO group). Rate-controlling agents were prescribed to patients developing SVT or atrial fibrillation, resulting in symptomatic relief. The patient with complete heart block was treated with a course of high dose dexamethasone and the heart block disappeared after 1 week of therapy.

DISCUSSION

We have shown that ASD closure with Cardio-O-Fix occluder is safe and feasible. The immediate-, short- and mid-term closure rates of CSO are comparable to that of ASO.

The early reports of transcatheter closure of ASD were published in 1976 by King and Mills and in 1983 by Rashkind [10,11]. Various devices have been developed over the last two decades [10–13]. The ASO remains the most popular device used worldwide with excellent safety and sustained efficacy results in both pediatric and adult patients [14–17]. One important limitation that plagued its wide clinical application is the relatively high device cost. The HELEX septal occluder ((WL Gore and Associates, Flagstaff, AZ) is another dedicated device that obtained FDA approval but the device is not suitable for closing ASD with stretched balloon diameter >18 mm [18]. In current study we reported the largest experience with CSO outside China. This device is structurally similar to the ASO although there is an absence of hub on left atrial disc in CSO. This design, also being adopted by Figulla ASD occluder (Occlutech GmbH, Jena, Germany), may reduce the risk of thrombus formation on the left atrial disc and increase the flexibility of the device [19]. On the other hand, this structural design may be a disadvantage when trying to snare the device in case of embolization.

The implantation technique of CSO is also similar that for ASO and there is no additional skill needed for deploying this new device. This was evident by the comparable procedural times for implanting either device in our series. Moreover, we demonstrated it was feasible to implant CSO in patients with large or double defects. In eight patients with large defects and

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relatively deficient rims, in whom standard deployment failed, we attempted left upper pulmonary vein method [20] with success and without serious complications. The largest available size of CSO is 40 mm and it has the potential to close the larger defects that normally could not be achieved by the HELEX septal occluders. We also deployed CSO in three patients with double ASDs and all the smaller CSOs were firmly sandwiched between two discs of the larger CSOs.

It is worth mentioning that the rate of immediate, more-than-trivial residual shunt was less prevalent in CSO group as compared to ASO group (14.0% vs. 24.2%, $P = 0.016$). And the residual shunt observed in CSO group should not bear any long term hemodynamic consequence as most of them disappeared spontaneously at 6-month follow-up (14.0% vs. 1.1%, $P < 0.001$).

Of all patients attempted CSO implantation, there was no serious procedural-related complication except the occurrence of acute device embolization in two patients. The prevalence was similar to that of ASO (three patients with acute device embolization). All patients have large defects with either deficient rims or floppy interatrial septal tissues. We believed these complications were more attributed to the anatomy rather than the devices.

The occurrence of device-related thrombus especially on left atrial disc could potentially lead to disabling stroke. Previous studies reported the risk of thrombus formation is probably lower with the ASO device as compared to other occluders like StarFLEX, CardioSEAL, and PFO-Star [21–22]. We did not observe any thrombus formation on CSO and no patient experienced any cerebrovascular events during subsequent follow-ups. We postulated the risk of thrombus formation should be very low in CSO because of the absence of left atrial hub and this hypothesis should be tested in larger-scaled studies. Three patients developed new onset self-limiting atrial arrhythmias shortly after CSO implant. This was also observed in patients received ASO implant and the development of atrial arrhythmia may be inherent to the inflammatory response triggered by implantation of foreign body [23].

Limitations of CSO

One of the limitations being the requirement of bigger delivery sheaths, sometimes up to 14 Fr, in closing large defects. This may increase the risk of vascular complications especially in pediatric patients. However, this complication has not been observed in our series. Moreover, the higher prevalence of acute residual shunt seen in ASO than CSO patients may be biased by the fact that ASO were used a few years ahead of CSO. The initial lack of experience may lead to less accurate choice of devices' size. Furthermore, the finding of a similar performance in both devices cannot be extrapolated to patients having complex-type defects because these patients constituted less than 20% of all the cases. Lastly, there is limited follow-up duration (an average of 11 months) for patients receiving CSO implants and no definite conclusion could be drawn regarding the risks of late complications (e.g., late onset arrhythmia or device erosions).

CONCLUSION

In conclusion, transcatheter ASD occlusion with Cardi-O-Fix septal occluder is safe and effective and it appeared to be an attractive alternative to Amplatzer septal occluder in closing simple-type ASD because of its relatively low cost.

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