Original Article

Transcatheter Atrial Septal Defect Closure Using Occlutech Figulla Device: A Two-Center Experience

Hojat Mortezaeian, MD[1], Keyhan Sayadpour Zanjani, MD[2], Elaheh Malakan Rad, MD, FACC[2*]

[1]*Rajaie Cardiovascular, Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran.*
[2]*Children's Medical Center (Pediatrics Center of Excellence), Tehran University of Medical Sciences, Tehran, Iran.*

Received 24 March 2013; Accepted 01 August 2013

Abstract

Background: *Despite several reports regarding the use of the Occlutech Figulla® Flex septal occluder (OFFSO) in adults, there are few reports on its use in children. We sought to study the result of the transcatheter closure of atrial septal defect (ASD) using the OFFSO in children ≤ 12 years.*

Methods: *We enrolled 45 consecutive patients, ranging from 2.5 to 12 years of age, in two large pediatric cardiovascular centers. All the children underwent complete echocardiographic examination before the procedure. Defect/device ratio and device/weight ratio were measured. The device diameter to the cardiac diameter ratio (DD/CD ratio) in anteroposterior projection after device release and the DD/CD index were calculated by dividing the DD/CD ratio by the body surface area.*

Results: *Of the 45 enrolled patients, 25 (55%) were female. The range and mean ± standard deviation (SD) of age were 2.5 to 12 years and 6.8 ± 2.5 years, respectively. The range and mean ± SD weight were 8.5 to 37.0 kg and 19.7 ± 7.2 kg, respectively. Successful implantation was performed in all the patients. No major complications occurred in any of the subjects. We encountered one cobra head deformity in one patient. Neither residual shunt nor conduction abnormality was observed in any of the cases.*

Conclusion: *Transcatheter ASD closure using the OFFSO was effective in our pediatric patients. Although this device needs relatively larger delivery sheaths, its use is safe while closing even large defects in children.*

J Teh Univ Heart Ctr 2013;8(4):197-201

This paper should be cited as: Mortezaeian H, Sayadpour Zanjani K, Malakan Rad E. Transcatheter Atrial Septal Defect Closure Using Occlutech Figulla Device: A Two-Center Experience. J Teh Univ Heart Ctr 2013;8(4):197-201.

Keywords: *Heart septal defects, atrial • Cardiac catheterization • Septal occluder device*

Introduction

King and Mills[1] performed the first transcatheter atrial septal defect (ASD) closure in 1974. Since then, a large number of transcatheter ASD closures have been done worldwide using various devices with different designs, advantages, and disadvantages. In many centers, this method of therapy is considered the first choice whenever applicable.[2] Introduced recently with some new features, the Occlutech Figulla® Flex septal occluder (OFFSO, Occlutech) is similar in design to the Amplatzer Septal Occluder (ASO, St. Jude). Several reports of its use in adults have been published.[3-7]

[*]**Corresponding Author:** ***Elaheh Malakan Rad,*** *Associate Professor of Pediatric Interventional Cardiology, Children's Medical Center (Pediatrics Center of Excellence), No. 62, Dr. Gharib Street., Keshavarz Blvd., Tehran, Iran. 1419733151. Tel: +98 21 66911029. Fax: +98 21 66923054. E-mail: erad@tums.ac.ir.*

However, excluding the Halabi and Hijazi[8] report on the first cases of the closure of two ASDs in an 8-year-old female child, there are very few reports in children.

To the best of our knowledge, this is the largest series of successful transcatheter ASD closure using the OFFSO in children ≤12 years old in two pediatric interventional cardiovascular centers. The aim of this retrospective review was to investigate the immediate and short-term results of transcatheter ASD closure using the OFFSO in children ≤12 years of age.

Methods

This study was a retrospective review of transcatheter secundum ASD closure using the OFFSO. Between January 2012 and November 2012, 45 consecutive children ≤12 years old (25 females and 20 males) underwent transcatheter ASD closure using the OFFSO in two centers, namely Children's Medical Center and Pediatric Division of Rajaie Cardiovascular, Medical and Research Center.

The children were between 2.5 and 12 years of age and weighed between 7.5 and 37 kg. Indications for intervention were right atrial and right ventricular enlargement in addition to calculated pulmonary blood flow to systemic blood flow (Qp/Qs) ratio >1.5 and the absence of any associated congenital heart disease necessitating surgery. Informed written consent was obtained from the parents before the procedure. Complete transthoracic echocardiography was performed preprocedurally. Standard right heart catheterization and pulmonary angiography in anteroposterior (AP) view with levophase angiograms were conducted in all the cases to definitely exclude anomalous pulmonary venous return.

Transcatheter ASD closure was performed under transthoracic echocardiography guidance and general anesthesia, according to the techniques already described.[9,10] In all but one patient, proper placement of the device was achieved via the conventional technique. In the latter case, the left pulmonary vein technique was carried out.[11]

The patients received intravenous Heparin (80 units/kg), and intravenous Cefazolin (50 mg/kg) was administered during the procedure and continued for 24 hours after the procedure. Monitoring the activated clotting time was available for some cases. Twenty-four to 48 hours after the procedure, the patients were discharged on 3-5 mg/kg of Aspirin per day for 6 months. For the large OFFSO's which covered almost all the length of the atrial septum, 12 months of Aspirin administration was recommended.

To determine how large the ASD was in comparison with the patient's size, we measured the device diameter to the cardiac diameter ratio (DD/CD ratio) in anteroposterior projection after device release (Figure 1). The device diameter to the cardiac diameter index (DD/CD index) was calculated by dividing the DD/CD ratio by the body surface area. The ratios of the device size to the patient's weight and to the defect size were also calculated.

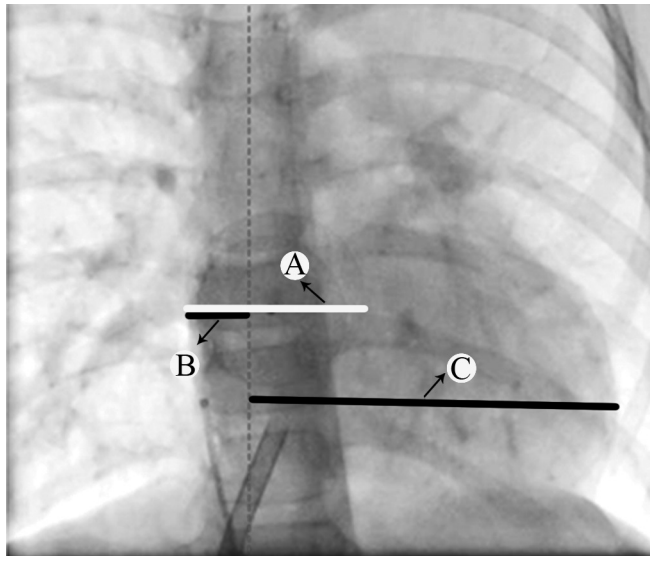

Figure 1. To measure the device/cardiac ratio, we draw a line in the midline of the spine. Then we measure the longest distance of the heart on the right and the left side of this mid-line. We divide the largest device diameter (mm) into the sum of these distances (i.e. A/B+C; A, the largest diameter of the device; B, the largest diameter of the heart on the right-side of the midline; and C, the largest diameter of the heart on the left-side of the midline)

Statistical Analysis

Statistical analysis was performed using SPSS software version 18 (SPSS Inc., Chicago Il, USA). Descriptive analysis was performed to calculate mean ± standard deviation (SD), median, and range of the continuous variables.

Results

Information on the demographic, echocardiographic, and device parameters is provided in Table 1. Successful implantation was performed in all the patients. No major complications occurred in any of the cases. We had one cobra formation of the left disc in a 5-year-old patient, leading to the implantation of another OFFSO (Figure 2). The device/defect ratio was 1.17 in this case.

On the day after the procedure, transthoracic echocardiography showed no residual shunt and no impingement on the neighboring structures in all the patients. No degree of atrioventricular block was observed in our patients after 24 hours and at 3 months' follow-up. There was exacerbation of previous headache in 2 cases, which could not be definitely attributed to device closure. Pulmonary artery pressure was normal in all the patients, with the exception of 2, who had pulmonary hypertension.

The frequency of the devices used is depicted in Figure 3. We compared delivery sheath sizes between four available devices: OFFSO (Occlutech GmbH, Germany); Amplatzer (St. Jude Medical, USA); Cera™ (Lifetech Scientific Co., Ltd., China); and Cardi-o-Fix ASD occluder (Starway Medical Technology, Inc., China). Depending on the device size, the OFFSO delivery sheaths were one to three French larger than the smallest available sheath for a similar device size of other brands.

Table 1. Demographic, echocardiographic, and device parameters

Age (y)	6.81±2.52
Weight (kg)	19.72±7.21
Atrial Septal Defect Size (mm)	16.60±0.61
Defect /Device Ratio	0.84±0.77
Device /Weight Ratio	0.87±0.16
DD/CD Ratio	0.31±0.02
Indexed DD/CD Ratio	0.40 ±0.24

*Data are presented as mean±SD.
DD/CD ratio, Device diameter to the cardiac diameter ratio

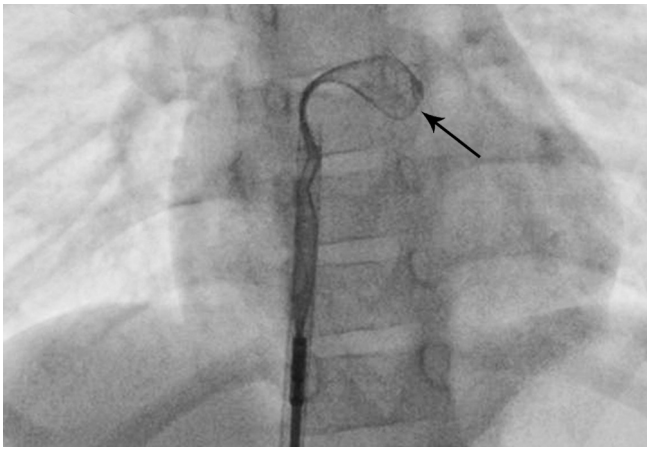

Figure 2. Cobra head formation of the left disc. As is shown, the deformity is caused by the twisting of the device in the waist and a few millimeters above the waist of the device (arrow)

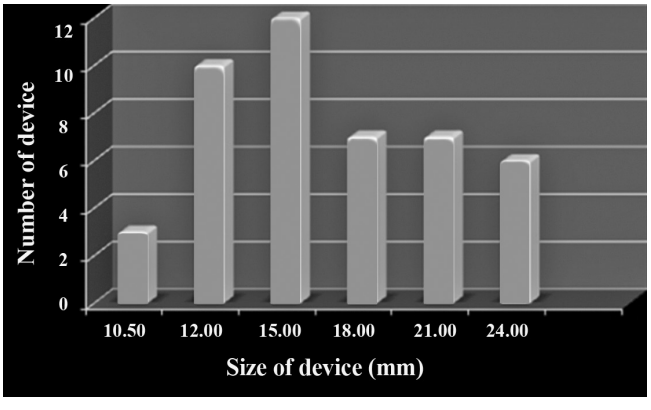

Figure 3. Frequency of the usage of the Occlutech Figulla® Flex septal occluder

Discussion

We report successful transcatheter ASD closure in 45 children ≤12 years old using the OFFSO. To the best of our knowledge, this is the largest series of transcatheter ASD closure using the OFFSO in children. Our patients experienced no major complications during or after the procedure. Jahrome et al.[12] reported late embolization of the Figullar ASD occluder in a 41-year-old female patient.

Cobra formation has been reported with the OFFSO before. Aaron et al.[13] reported 4 cases of cobra formation in a 42 case series using the OFFSO and suggested that cobra deformity is more common (0.1%) with the OFFSO than with the ASO. We had one case of cobra head deformity in our 45 patients (0.02%). It may be posited that the ball-cage shape of the delivery system of the OFFSO may allow excessive and undue twisting of the discs during the advancement through the long delivery sheath. However, since this complication happened in only one case in our series, we cannot make any definite inference on it. Careful evaluation of the cobra figure in the Aaron et al. study and in our cases shows that the twisting started from the waist and then extended a few millimeters above it. Aaron and his colleagues managed to prevent the re-occurrence of this phenomenon in their 3 other cases by releasing both discs in the left atrium. This also confirms that the main culprit lies in the twisting of the wires in the waist segment of the device. Bearing that in mind as well as considering the manufacturer's tip, it may be postulated that "strengthening the Nitinol wires in the waist" of the device may prevent or reduce this complication.

We also introduced the new index of DD/CD, which may be used as an adjunctive parameter to judge the size of an ASD.

Cansel et al.[14] reported transcatheter ASD closure using the OFFSO in 74 consecutive adult patients with a 91.9% success rate and reported atrial arrhythmia in 2 of their patients: in one it disappeared spontaneously and in the other, it was treated with antiarrhythmic drugs. The higher rates of complications and failures in their study may be attributed to the fact that they dealt with larger ASDs (mean ± SD for device/defect ratio of 1.1 ± 0.05 in their study vs. 0.84 ± 0.77 in ours) with a more complex case mix. They had one case with residual ASD at 6 months› follow-up. Interestingly, the authors reported no single case of cobra head deformity.

In comparison with the ASO, the OFFSO has several advantages. It has no left atrial hub, so the risk of clot formation in the left atrium is much less and its tip is less traumatic. It has the ability of 45-degree tilt of the delivery sheath; accordingly, the device shape before release is much more similar to its final shape. The screw mechanism of other devices has been replaced by a lock system which is easier to use and safer. More importantly, no case of erosion after the OFFSO implantation has been reported so far. Nevertheless, one may argue that this finding can be partly

explained by its less frequent use and lower age (16 years) since its invention in comparison to the ASO (5 years).[8, 15]

The OFFSO device sizes range from 6 to 40 mm (15 sizes), while the same spectrum of the defect size can be covered by 25 sizes of the ASO. A 3-mm increment in size has created this advantage, making stocking easier. Another advantage is that the appropriate size of the delivery sheath for each device is already written on the outer box. This is a simple, but important, point that increases the user-friendliness of this device.

Although the OFFSO has less implanted material, its Nitinol wires are more than 20 times thicker than the Nitinol wires used in the ASO (0.082 to 0.186 vs. 0.004 to 0.0075 inch). Therefore, the OFFSO needs larger venous delivery sheaths in comparison to the other similar devices. This is not a problem in adults but may limit its use in small children.

The number of the reported cases of OFFSO implantation in children is limited. The first pediatric implantation was reported by Halabi and Hijazi[8] with excellent results in an 8-year-old girl. Pac et al.[16] compared the OFFSO and the ASO in 75 patients at a mean age of 22.2 ± 15.8 years. The authors used the OFFSO in 33 and the ASO in 42 of their cases and concluded that the lower price of the OFFSO is its advantage, but difficulty in selecting the correct device size in larger defects and the need for larger venous sheaths are two disadvantages of this device.

To the best of our knowledge, the present study is the largest series of the OFFSO implantation in children to date. We showed that the OFFSO is safe for use in children, despite the need for relatively larger delivery sheaths. The introduction of the second generation of this device (Figulla Flex II) eliminates this potential fear as it will need smaller delivery sheaths.

This study was limited by a relatively large amount of missing information about the type of delivery sheaths. The complication rate of transcatheter ASD closure is less than 1%. There were 45 patients recruited in the present study; consequently, the absence of complications may be explained by the relatively low number of the patients enrolled in this study.

This study was performed in two different centres. All information, such as the size of the delivery sheaths, was not available for all the patients.

Conclusion

Transcatheter ASD closure using the OFFSO was effective in our pediatric patients. Although this device needs relatively larger delivery sheaths, its use can be safe while closing even large defects in children.

Acknowledgements

The authors deeply appreciate the efforts of Dr. Ziyad M. Hijazi for his kind review of the initial draft of this manuscript and his invaluable guidance.

References

1. King TD, Mills NL. Nonoperative closure of atrial septal defects. Surgery 1974;75:383-388.
2. Zanjani KS, Zeinaloo A, Malekan-Rad E, Kiani A, Bagheri MM. transcatheter atrial septal defect closure under transthorasic echocardiography in children. Iran J Pediatr 2011;21:473-478.
3. Oto MA, Aytemir K, Ozkutlu S, Kaya EB, Kabakcı G, Ateş AH, Yorgun H, Canpolat U. Percutaneous closure of interatrial septal defects: mid-term follow-up results. Turk Kardiyol Dern Ars 2011;39:385-395.
4. Van Den Branden BJ, Post MC, Plokker HW, Ten Berg JM, Suttorp MJ. Percutaneous atrial shunt closure using the novel Occlutech Figulla device: 6-month efficacy and safety. J Interv Cardiol 2011;24:264-270.
5. Demir B, Türeli HO, Kutlu G, Karakaya O. Percutaneous closure of a postoperative residual atrial septal defect with the Occlutech Figulla Occluder device. Turk Kardiyol Dern Ars 2012;40:55-58.
6. Ilkay E, Kaçmaz F, Ozeke O, Turan RS, Firat S, Pampal K, Ozer E, Bilgin S. The efficiency and safety of percutaneous closure of secundum atrial septal defects with the Occlutech Figulla device: initial clinical experience. Turk Kardiyol Dern Ars 2010;38:189-193.
7. Aytemir K, Oto A, Ozkutlu S, Kaya EB, Canpolat U, Yorgun H, Sahiner L, Kabakçi G. Early-mid term follow-up results of percutaneous closure of the interatrial septal defects with occlutech figulla devices: a single center experience. J Interv Cardiol 2012;25:375-381.
8. Halabi A, Hijazi ZM. A new device to close secundum atrial septal defects: first clinical use to close multiple defects in a child. Catheter Cardiovasc Interv 2008;71:853-856.
9. Amin Z. Transcatheter closure of secundum atrial septal defects. Catheter Cardiovasc Interv 2006;68:778-787.
10. Harper RW, Mottram PM, McGaw DJ. Closure of secundum atrial septal defects with the Amplatzer septal occluder device: techniques and problems. Catheter Cardiovasc Interv 2002;57:508-524.
11. Varma C, Benson LN, Silversides C, Yip J, Warr MR, Webb G, Siu SC, McLaughlin PR. Outcomes and alternative techniques for device closure of the large secundum atrial septal defect. Catheter Cardiovasc Interv 2004;61:131-139.
12. Jahrome A, Stella PR, Leijdekkers VJ, Guyomi SH, Moll FL. Abdominal aortic embolization of a Figulla atrial septum occluder device, at the level of the celiac axis, after an atrial septal defect closure: hybrid attempt. Vascular 2010;18:59-61.
13. Aaron S, Mainzer G, Lorber A. Taming the «cobra»: an approach to "cobra-like" formation seen in the Occlutech atrial septal defect and patent foramen ovale occluders. Catheter Cardiovasc Interv 2012;1;79:678-680.
14. Cansel M, Pekdemir H, Yağmur J, Tasolar H, Ermis N, Kurtoglu E, Acıkgoz N, Atas H, Ozdemir R. Early single clinical experience with the new Figulla ASD Occluder for transcatheter closure of atrial septal defect in adults. Arch Cardiovasc Dis 2011;104:155-160.
15. Masura J, Gavora P, Formanek A, Hijazi ZM. Transcatheter closure of secundum atrial septal defects using the new self-centering amplatzer septal occluder: initial human experience. Cathet Cardiovasc Diagn 1997;42:388-393.
16. Pac A, Polat TB, Cetin I, Oflaz MB, Balli S. Figulla ASD

occluder versus Amplatzer Septal Occluder: a comparative study on validation of a novel device for percutaneous closure of atrial septal defects. J Interv Cardiol 2009;22:489-495.