
Figulla ASD Occluder versus Amplatzer Septal Occluder: A Comparative Study on Validation of a Novel Device for Percutaneous Closure of Atrial Septal Defects

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Objectives: Occlutech Figulla ASD Occluder (FSO) is an alternative device to Amplatzer Septal Occluder (ASO) with some structural innovations including increased flexibility, minimizing the amount of material implanted, and absence of the left atrial clamp. We aimed to report our experiences with FSO and compare the outcomes of this novel device versus ASO.

Interventions: Between December 2005 and February 2009, 75 patients diagnosed with secundum atrial septal defects underwent transcatheter closure. The FSO device was used in 33 patients, and the ASO was used in 42.

Results: Patient characteristics, stretch size of the defect, device left disc size, procedure, and fluoroscopy time were similar between the groups. However, the difference between device waist size and stretched diameter of the defect was significantly higher, and device delivery sheath was significantly larger in FSO group and device left disc size was significantly lower in the FSO group. In all subjects, the residual shunt was small to trivial during follow-up and the reduction in prevalence of residual shunt with time was similar in both groups ($P = 0.68$). We found no differences in complication rate between the two devices; however, device embolization to the pulmonary bifurcation in one patient was recorded as major complication in FSO device group.

Conclusions: Both devices are clinically safe and effective in ASD closure. FSO device has similar outcomes when compared to ASO device. Difficulties in selecting the correct device size in larger defects and larger venous sheath requirement need to be evaluated in further studies. (J Intervent Cardiol 2009;**:1-7)

Introduction

Successful transcatheter closure of an atrial septal defect (ASD) was first reported by King and Mills in 1974.^{1,2} Since then, multiple devices have emerged with variable degrees of success but also with variable degrees of limitations and drawbacks.³⁻¹⁰ Today, device closure of secundum ASD has become routine practice and Amplatzer Septal Occluder (ASO) is the most widely used device because of the unique structural features versus other devices, including the ability to recapture and redeploy the device before release;

the self-centering mechanism, which leads to high closure rates and is suitable to close a wide range of defects, from small to large (few millimeters to 36 mm) sizes.¹¹⁻¹³ Recently, Occlutech Figulla ASD Occluder (Occlutech GmbH., Jena, Germany) was introduced for transcatheter closure of secundum ASD and is an alternative device that can be used to close small, as well as large, defects. Construction and implantation procedures are similar to ASO. Moreover, there are some important structural innovations encouraging the use of the novel device, such as increased flexibility, minimizing the amount of material implanted, and absence of the left atrial clamp in order to reduce trauma risk and clot formation on the left atrial disc.¹⁴ We formerly used ASO device in our clinic and, recently, intended to use the Figulla ASD Occluder (FSO) to

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examine the above-mentioned advantages. Use of the FSO device for ASD closure remains to be clarified.

In this study, we report our experiences with FSO and compare the outcomes of this novel device versus ASO in a series of 75 patients.

Methods

From December 2005 to February 2009, 75 patients with a mean age of 22.2 ± 15.8 years (median age 16 years, range 4–65 years) underwent percutaneous closure of moderate-to-large secundum ASD. The FSO device was used in 33 patients, while the ASO was used in 42.

Background and Exclusion Criteria. We included all consecutive patients referred to our hospital for secundum ASD closure and right ventricle volume overload. Exclusion criteria were similar for both devices. Patients were excluded if their secundum ASD was associated with complex congenital cardiac malformations, or insufficient septal rims, or angiographically confirmed acquired coronary artery disease, or severe mitral and/or tricuspid regurgitation. Patients diagnosed with a bleeding disorder, untreated ulcer, or any contraindication to aspirin, or nonreactive elevated pulmonary vascular resistance, or small ASD with a pulmonary/systemic flow ratio (Q_p/Q_s) $< 1.5:1$, and no signs of right ventricular dilatation, were also excluded.¹⁵

Procedure. Informed written consent to the procedure was obtained from all patients or parents before the procedure. All procedures were performed under general anesthesia by the same operator. Prior to femoral vein catheterization, transesophageal echocardiography (TEE) was conducted by our experienced pediatric cardiologist. TEE evaluation included the size and position of the defect and its anatomic relationship to the adjacent cardiac structures, including the vena cavae, atrioventricular valves, coronary sinus, and all pulmonary veins. Following confirmation of an anatomically suitable defect by TEE study, access of femoral vessels was performed, and a 6 French (Fr) sheath was placed in the vein and a 5 Fr sheath in the artery. Patients received 75–100 units/kg heparin and 25 mg/kg of cefazolin intravenously. First, hemodynamic study was performed and shunt was calculated.

Standard catheterization of the right heart was performed, and shunt was calculated by Q_p/Q_s flow ratio

and stretched diameter of the defect was measured as previously described.¹⁶

The Devices. The FSO device is constructed from 0.082 to 0.186 mm nitinol wires that are tightly woven into two flat round discs with a 4 mm connecting waist. The size of the device is determined by the diameter of the waist, available ranging from 6 to 40 mm in 1.5 mm increments up to 12 mm and in 3 mm increments thereafter, except from size 36 to 40 mm in 4 mm increment. For device waist diameter ranging from 6 to 9 mm, the left atrial disc is 12 mm and the right atrial disc is 8 mm larger than the waist; for device waist diameter ranging from 12 to 21 mm, the left atrial disc is 14 mm and the right atrial disc is 10 mm larger than the waist; for device waist diameter ranging from 24 to 33 mm, the left disc is 15 mm and the right disc is 11 mm larger than the waist; for device waist diameter 36 mm, the left disc is 16 mm and the right disc is 10 mm larger than the waist; and for device waist diameter 40 mm, the left disc is 15 mm larger and the right disc is 10 mm larger than the waist. The prosthesis is filled with a polyester patch to enhance thrombogenicity. There is only one stainless steel hub (microscrew) at the right atrial disc for cable connection (Fig. 1). Devices ranging in size from 6 to 9 mm require 9 Fr; devices ranging in size from 12 to 15 mm require 10 Fr; devices ranging in size from 18 to 27 mm require 12 Fr; and devices ranging in size from 30 to 40 mm require 14 Fr delivery sheath.¹⁴

The ASO is constructed from 0.004-in to 0.0075-in nitinol wires that are tightly woven into equal size-2 flat round discs with a 4-mm connecting waist. The size of the device is determined by the diameter of the waist, available in the range from 4 to 40 mm with 1 mm increment for sizes 4 to 20 mm and 2 mm increments for sizes 20 to 40 mm. Three Dacron polyester patches are sewn securely with polyester thread into each disc and the connecting waist. The device is delivered through a 6 Fr to 12 Fr sheath (Fig. 2).¹⁷

The device size was selected using stretched diameter of the defect assessed by angiographic measurement plus 1 to 2 mm for both procedures.

Closure Protocol. FSO implantation procedure is analogous to the technique used for ASO implantation. An appropriate Mullins catheter was selected for delivery of the device and advanced over the guidewire, which was positioned in the upper left pulmonary vein. De-airing of the delivery sheath was performed with the sheath in the inferior caval vein, which was then advanced into the left atrium. The device was then vigorously flushed with saline before introduction into the

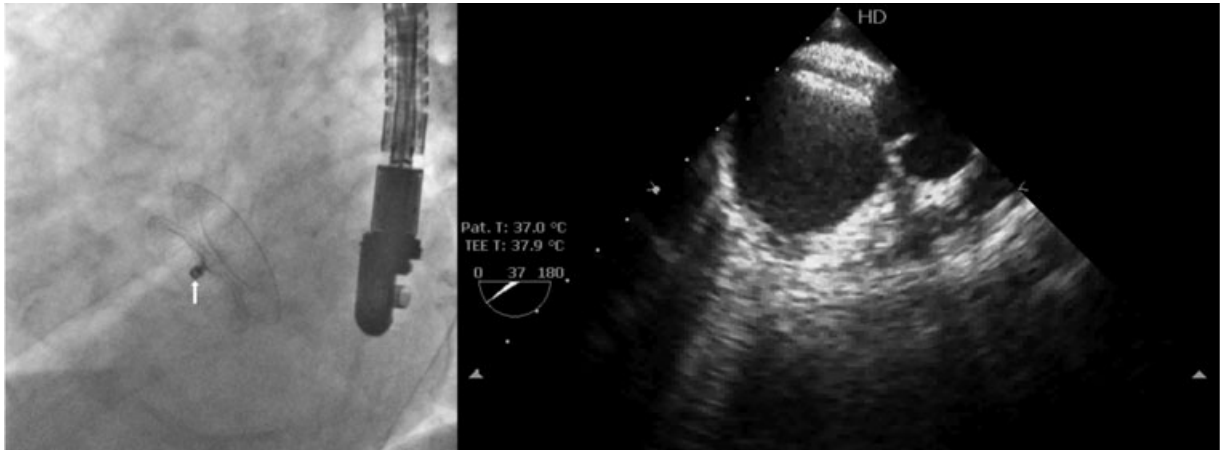


Figure 1. Angiographic and transesophageal echocardiographic view of the Occlutech Figulla device after release. Note the absence of the microcrew hub at the left atrial disc.

loading catheter. It was then engaged into the delivery sheath and advanced into the left atrium. Under fluoroscopic guidance, withdrawal of the Mullins sheath allowed the release of the right atrial disc and the whole system was withdrawn so that the disc engaged the septum. If the position of the left disc was satisfactory under TEE study, the right disc was extruded by pulling back the sheath. The operator then pushed and pulled the loading catheter several times to confirm the stability of the device. Once the device was implanted well in the position, it was released by unscrewing from the loader.

Techniques of implantation with ASO device have been previously reported.¹⁷

Residual Shunt. A residual shunt was considered to be present if color Doppler flow mapping showed a left-to-right shunt across the interatrial septum. Residual shunt was defined as shunt occurring from along the device rims and was defined 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). Trivial shunt occurring across the device fabric immediately after the deployment of the device was not considered significant.¹⁵

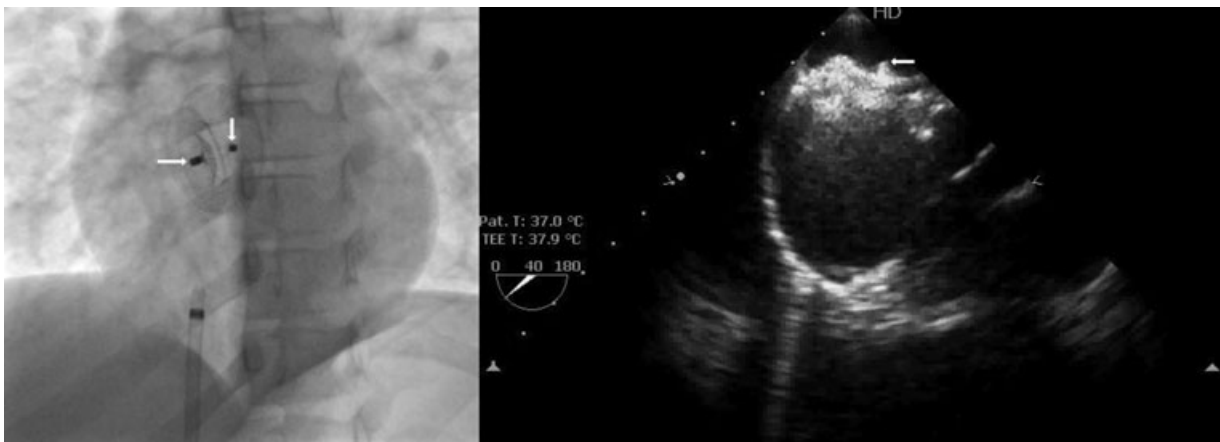


Figure 2. Angiographic and transesophageal echocardiographic view of the Amplatzer Septal Occluder after release. Note the microcrew hub located in both atrial discs (white arrows).

Postimplantation Care and Follow-Up. All patients underwent clinical examination, electrocardiography, chest radiographs, and transthoracic echocardiography before discharge, at 1, 6, and 12 months after the procedure, and yearly thereafter. Antiaggregation with aspirin, 5 mg/kg orally per day, was prescribed for 6 months.

Statistical Analysis. All analyses were performed using SPSS version 10.0 (SPSS, Inc., Chicago, IL) statistical software. The results were expressed as the mean ± SD, unless otherwise stated. Differences between outcomes with different devices were analyzed by unpaired Student's *t*-test or the Mann-Whitney test. Incidences in the groups were tested for significance with the chi-squared test. The reduction in prevalence of residual ductal shunt with time was analyzed by Kaplan-Meier survival analysis and differences in prevalence among different groups were assessed by the log rank test. A P value of 0.05 was regarded as statistically significant.

Results

Patient Characteristics and Procedure Variables. Patient characteristics, procedure variables, and follow-up outcomes are shown in Table 1. There were no significant differences among the groups regarding age, weight, sex ratio, mean pulmonary arterial pressure, or Qp/Qs ratio.

Stretch size of the defect, device size and device left disc size, procedure, and fluoroscopy time were also similar between the groups. However, the difference between device waist size and stretched diameter of the defect was significantly higher, and device delivery sheath was significantly larger, in the FSO group and device left disc size was significantly lower in the FSO group. Recurrent attempts to achieve satisfactory device position were recorded for each procedure and were significantly higher in ASO group. Finally, mean cost of procedure per patient was significantly higher in patients treated with the ASO. Length of follow-up was longer in the ASO group (23.8 ± 5.1 vs. 12.2 ± 4.9 months; P < 0.001). In all subjects, the residual shunt was small-to-trivial during follow-up and the reduction in prevalence of residual shunt with time was similar in both groups (P = 0.68, Fig. 3). The prevalence of residual shunt in the FSO group was 24.3% at procedure, 6% at discharge, 3% at 1 month, and 0% beyond 6 months after

Table 1. Patient Characteristics, Procedure Variables, and Follow-Up

	FSO (n = 33)	ASO (n = 42)	P
Age (years)	23.1 (16.5)	21.5 (16.6)	0.69
Sex (female/male)	19/14	26/16	0.71
Weight (kg)	36.1.6 (3.7)	34.1 (4.9)	0.65
Qp/Qs	1.9 (0.4)	2.1 (0.5)	0.36
Mean pulmonary artery pressure (mmHg)	22.1 (3.8)	23.9 (4.8)	0.79
Stretch diameter (mm)	14.8 (4.6)	15.2 (3.7)	0.62
Device size (mm)	17.1 (5.1)	16.3 (4.1)	0.47
Device size–stretch size (mm)	2.3 (1.3)	1.1 (0.83)	<0.001
Device left disc size (mm)	31.2 (5.3)	30.6 (3.9)	0.57
Device right disc size (mm)	27.6 (4.9)	30.6 (3.9)	0.006
Device delivery sheath (French)	11.1 (1.1)	7.5 (0.92)	<0.001
Number of attempts	1.3 (0.45)	2.1 (1.1)	<0.001
Procedure time (min)	124 (8.4)	102 (8.1)	0.83
Fluoroscopy time (min)	76 (8.8)	68 (6.7)	0.87
Residual shunt at procedure	8 (24.3%)	3 (7.1%)	0.037
Residual shunt at discharge	2 (6%)	1 (2.3%)	0.58
Residual shunt at 1 month	1 (3%)	0 (0%)	0.44
Residual shunt at 6 months	0	0	
Residual shunt at 1 year	0	0	
Follow-up (months)	12.2 (4.9)	23.8 (5.1)	<0.001
Mean cost per patient (\$)	3565 (741)	5062 (1512)	<0.001

Values are expressed as means with standard deviation shown in parentheses.

FSO = Figulla Septal Occluder; ASO = Amplatzer Septal Occluder; Qp/Qs = pulmonary/systemic flow ratio.

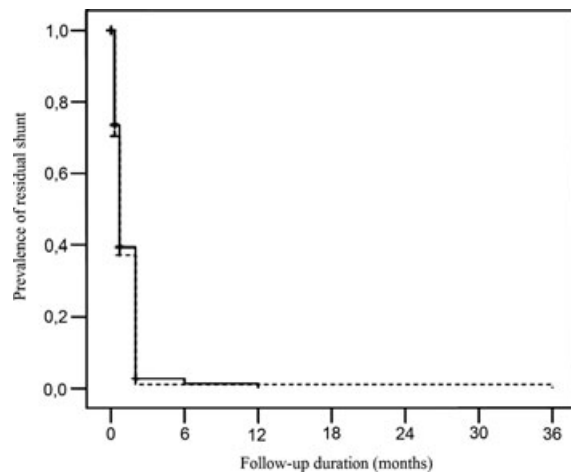


Figure 3. Kaplan-Meier analysis of residual shunt in Figulla ASD Occluder group (solid line) and Amplatzer Septal Occluder group (dashed line).

Table 2. Procedure Complications

No	Sex	Age	SD	Device		Complication
				Type	Size	
1	F	6	15	FSO	18	Emb./retrieved percutaneously
2	F	15	18	ASO	20	AE/subset with time
3	F	40	18	FSO	21	SVT/required no treatment
4	M	12	21	ASO	22	AE/subset with time
5	F	50	18	ASO	19	AE-AF/required no treatment
6	M	49	15	FSO	18	AE/subset with time
7	M	16	16	ASO	17	SVT/required no treatment
8	F	10	18	ASO	20	AE/subset with time
9	F	65	22	ASO	24	AE/subset with time
10	M	8	15	FSO	18	SVT/required no treatment
11	F	44	20	FSO	21	AE/subset with time
12	F	8	17	ASO	18	SVT/late onset/ managed medically

FSO = Figulla Septal Occluder; ASO = Amplatzer Septal Occluder; SD = stretched diameter of the defect assessed by angiographic measurement; Emb = device embolization; AE = atrial extrasystoles; AF = atrial fibrillation.

procedure. The prevalence of residual shunt in ASO group was 7.1% at procedure, 2.3% at discharge, 0% beyond 1 month after procedure. Residual shunt at procedure was significantly more frequent in FSO group ($P = 0.037$); however, no significant difference was observed at discharge ($P = 0.58$). Comparing residual shunting at late follow-up, there were no significant differences between the FSO and the ASO devices (Table 1).

Complications and Technical Problems Managed Percutaneously. No deaths occurred. There were no differences for complication rate in the two groups (FSO 5/33 vs. ASO 7/4) (Table 2).

FSO Group. In three patients, the device had an unsatisfactory position across the interatrial septum. This situation occurred with 15 mm device for ASD with a stretched diameter of 14 mm, 12 mm device for ASD with a stretched diameter of 11 mm, and 18 mm device for ASD with a stretched diameter of 18 mm. A larger FSO device was used successfully in former two. We did not prefer 3 mm larger FSO device in latter one because total septum diameter was 35 mm in this patient, thus device-atrial septum mismatch might occur with 21 mm FSO device. The same device was repositioned and properly deployed at the third attempt. Although the device was redeployed in a satisfactory position, device embolization to the pulmonary bifurcation was observed at second-day follow-up. The de-

vice was retrieved via transcatheter approach and defect was closed surgically.

Arrhythmias occurred in four subjects: atrial extrasystoles occurred in two patients following device deployment and subsided by the time after device's release. Two patients developed supraventricular tachycardia (SVT) during catheter manipulation in the right atrium. It was transient in both cases, requiring no treatment.

ASO Group. In nine patients, the device had an unsatisfactory position across the interatrial septum. The same device was repositioned and properly deployed in five and larger ASO device was used successfully in four.

Arrhythmias occurred in seven subjects: atrial extrasystoles occurred in six patients following device deployment, and one of them precipitated into short-duration atrial fibrillation immediately after implantation. All subsided in some time and required no treatment. Finally, SVT occurred in the remaining subject 2 months after the procedure. He underwent medical treatment with beta blockers for 1 year with no recurrence either during the therapy or during 24 months of follow-up.

Discussion

The ASO is one of the most frequently used devices to close ASD and has been proven to be highly effective and safe in the early–long term. Previous reports have confirmed that transcatheter closure of ASD with the ASO not only achieved a comparable efficacy and safety with that of surgical closure but had an additional advantage of causing fewer complications, requiring a shorter hospital stay, and avoidance of a permanent scar.^{18,19}

The Occlutech Figulla device is another device designed to close the full range of defects. It looks similar to the ASO. There will be no learning curve using this device since the implantation technique is similar to the ASO. The device handles very well and can be recaptured after deployment of both discs and thus can be repositioned quite easily.

However, there are important differences between the two devices. The ASO is made up of a nitinol wire tube that is clamped in two stainless steel hubs, one on each side of the disc. In contrast, the Occlutech Figulla device is individually braided, avoiding a distal clamp. This may be of potential benefit to decrease the

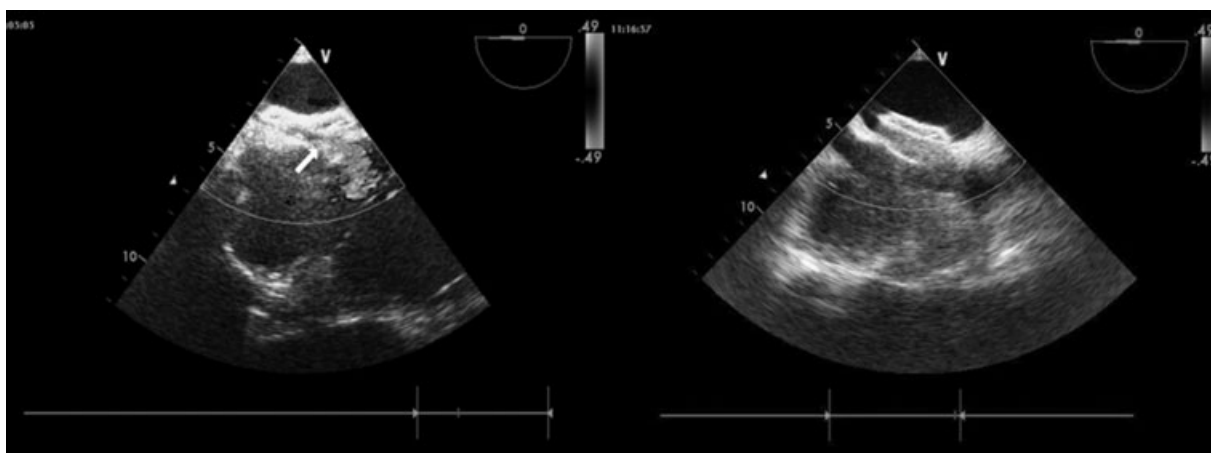


Figure 4. Transesophageal echocardiographic view of the Occlutech Figulla device immediately after releasing and before discharge. Note that small residual shunt (white arrow) detected at the edge of the device had disappeared by the following morning.

chance of a clot formation on the left atrial disc and increase flexibility of the device.¹⁴ We did not experience any complications related to the clot formation in both groups; however, we rarely encountered device malposition and made fewer attempts to close the defect successfully in FSO group. However, interventions in ASO group were already ahead of our learning curve period, thus somewhat higher rates of deployment attempts encountered in this group may arise due to this limitation.

We observed slightly more significant residual shunting immediately after the procedure in FSO group (Fig. 4). This may be related to smaller right disc that causes single layer at the edges of the device, or thrombogenicity of Dacron patch used in this device. Nevertheless, the residual shunts were mostly trivial and small in remainings in both groups and had disappeared in almost all by the following morning, and both devices had excellent occlusion rates at early and subsequent follow-up.

We considered two major disadvantages of this device. First, FSO device is constructed using thicker diameter nitinol wire as compared to ASO device, and so FSO devices require larger delivery catheters. Although the device sizes were similar in the two groups, delivery catheter sizes were significantly larger in FSO group in our study. However, we did not demonstrate any complications due to larger delivery sheath and this seemed to be related to high median age of FSO group with a range of 5 to 65 years. It is well known that complications of femoral vein access may be slightly increased with larger venous sheaths,²⁰ thus FSO de-

vice should be carefully evaluated at younger ages in further studies. Second, the FSO device is available in 15 separate sizes, whereas the ASO is available in 27 different sizes. Although this seems to be an advantage in reducing the cost spent on these devices for stocking, this may cause difficulties in selecting the correct device size recommended, especially stretched defects larger than 12 mm diameter. In the present study, the difference between device waist size and stretched diameter of the defect was significantly higher in FSO group and we observed the higher difference in larger than 12 mm devices manufactured in 3 mm increments.

Although we found no differences in complication rate between the two devices, device embolization to the pulmonary bifurcation in one patient was recorded as major complication in FSO device group. We considered this complication related to above-mentioned limitation of this device. The stretched diameter of the defect was 18 mm and total septum diameter was 35 mm in this patient. We decided to use 18 mm device because larger FSO device was 21 mm with a 3 mm increment and might preclude safe device closure due to device-atrial septum mismatch and location of the defect extended inferiorly and posteriorly toward the mouth of the coronary sinus. We retrieved the embolized device percutaneously through the femoral vein using a snare. Although the microscrew of device was snared at pulmonary artery, we could not pull the device back into the sheath. Thus, bare device was withdrawn and retrieved via the right femoral vein slowly and gently. Echocardiographic evaluation of tricuspid valve and its supporting apparatus appeared

normal after procedure. We administered heparin intravenously for continuous 48 hours, and did not come across a major vein complication.

Complications, including arrhythmias, pericardial effusions, and perforations may be related to oversizing ASDs and choosing larger devices. In a recent report, it was mentioned that the device size should not exceed the defect size more than 5 mm and the ratio of device size to the defect size should not be more than 1.5 at TEE.²¹ Although the overstretching of the ASD was much more with FSO device, the device size to stretched diameter difference was acceptable in both groups. Therefore, the fewer number of arrhythmias that occurred in FSO group may be attributed to the flexibility of the device and leaving less material on the right atrial side of the atrium.

Conclusion

In conclusion, our study confirmed that percutaneous transcatheter closure of ASD with the FSO device was safe and effective. It has similar outcomes, and costs less, than the ASO device. However, difficulties in selecting the correct device size in larger defects and larger venous sheath requirement seemed to be the problems existing in current manufactured FSO devices. In this context, further studies are needed to evaluate these two disadvantages of the device.

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