The efficiency and safety of percutaneous closure of secundum atrial septal defects with the Occlutech Figulla device: Initial clinical experience

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Objectives: We evaluated the efficiency and safety of the Occlutech Figulla device in percutaneous closure of secundum atrial septal defects (ASD).

Study design: The study included 28 patients (17 women, 11 men; mean age 43 years) who underwent percutaneous transcatheter closure using the Occlutech Figulla device for secundum ASDs causing a hemodynamically significant shunt. Defect size was estimated by transthoracic (TTE) and transesophageal (TEE) echocardiography, and also by balloon sizing in nine patients. The patients were followed-up for six months and were examined by TTE.

Results: The mean defect size was 20.3±2.1 mm on TTE, 22.1±1.9 mm on TEE, and 24.2±2.4 mm on balloon sizing. The mean device size was 26.8±3.6 mm (range 6 to 36 mm). The mean procedure time was 44.7±21.4 minutes. The device was placed successfully in all the patients. A small residual flow was seen immediately after device placement in three patients (10.7%), which disappeared in two patients at three months, and in one patient at six months. During the procedure, complications were seen in four patients (14.3%), including transient sinus tachycardia in three patients (10.7%) and acute atrial fibrillation in one patient (3.6%). At six months, all the patients were asymptomatic. No ischemic stroke, cardiac perforation, device erosion, embolization, thrombus formation, or malposition of the device were observed.

Conclusion: The Occlutech Figulla occluder is a safe and efficient device to close secundum ASDs. It may be preferred especially in patients with a high risk for thrombus formation.

Key words: Echocardiography; heart catheterization; heart septal defects, atrial/therapy; prosthesis design.

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Atrial septal defect (ASD) is the most common congenital heart disease in adults after bicuspid aortic valve.[1] Although patients with ASD often remain asymptomatic until early adulthood, they can present at any age with a variety of clinical symptoms including right ventricular failure, pulmonary hypertension, atrial arrhythmias, and paradoxical embolism.

Since the first transvenous ASD closure was performed by King and Mills in 1974,[2] a number of transcatheter closure devices have been designed and tested in clinical studies.[3-6] Today, with advances in percutaneous device technology, percutaneous closure has proved to be a safe technique to close ASDs.[2,7,8] Among many closure devices, only two were approved by the FDA in 2001 and 2006, respectively, namely the Amplatzer septal occluder (ASO) and the Gore HELEX septal occluder.

The Occlutech Figulla (Occlutech GmbH., Jena, Germany) is a new occluder that has been designed to close secundum ASDs. The major advantage of this occluder is the absence of the left atrial microscrew, which minimizes the chance for clot formation on the left atrial disc. In the present study, we evaluated the efficiency and safety of the Occlutech Figulla device in patients with a secundum ASD.

PATIENTS AND METHODS

Patients. The study included 28 patients (17 women, 11 men; mean age 43±28 years) who underwent percutaneous transcatheter closure using the Occlutech Figulla occluder for secundum ASD between January 2007 and February 2008. Patients with a hemodynamically significant shunt ratio (Qp:Qs >1.5:1) were offered elective closure soon after
All patients were discharged on treatment with 100+300 mg aspirin and 75 mg clopidogrel daily. Prophylaxis for infective endocarditis was recommended during the first six months. At follow-up, all patients were examined by TTE to evaluate residual shunt, the position and stability of the device, and its relationship with adjacent anatomic structures.

**RESULTS**

**Defect and device sizes.** The measurement of defect size was made by TTE or TEE, and it was repeated during the procedure. All patients had a single hole in the interatrial septum. The mean defect size was measured as 20.3±2.1 mm on TTE examination, 22.1±1.9 mm (range 4.2-28 mm) on TEE examination, and the mean SBD was 24.2±2.4 mm. The mean defect size was larger on SBD due to compression and stretching of the atrial septum. The mean device size was 26.8±3.6 mm (range 6 to 36 mm).

**Device placement.** To guide the device placement during closure, TTE and TEE were used in five patients and 23 patients, respectively. The mean procedure time was 44.7±21.4 minutes. During TEE monitoring, the repair was performed under general anesthesia in three patients and sedation was used in 20 patients with a dose of 2 mg midazolam and bolus dose of 1 mg/kg propofol. If required, propofol was repeated with a bolus dose of 20 mg.

The device was placed successfully in all the patients and no case of embolization was recorded. A small central residual flow was seen immediately after device placement in three patients (10.7%), which disappeared in two patients at the end of three months, and persisted as a hemodynamically insignificant tiny flow in one patient until six-month examination.

**Complications.** Complications were seen in four patients (14.3%), but none affected the procedural success. Acute atrial fibrillation developed in a 48-year-old woman (3.6%) whose large defect (26 mm) was closed with a 30-mm occluder. Atrial fibrillation resolved and sinus rhythm was obtained after an intravenous single dose of 5 mg metoprolol. Transient sinus tachycardia was recorded in three patients (10.7%) during the procedure, but it recovered to normal rhythm spontaneously in all.

**Follow-up.** All patients were evaluated by TTE during the follow-up. At six months, no residual flow was found and all the patients were asymptomatic. No ischemic stroke, cardiac perforation, device erosion, or embolization were observed during the follow-up. The position of the device remained stable on TTE examination in all the patients.

**DISCUSSION**

The Occlutech Figulla occluder is a safe and efficient device to close secundum ASDs. Immediate-, short-, and mid-term clinical results and success rates are comparable with those obtained by the ASO device reported in previous studies.[8,9]

The ASO is the most widely used device worldwide and its excellent results in pediatric and adult patients have been demonstrated in several studies.[13-16] The Gore HELEX septal occluder, on the other hand, has been approved by the FDA to close defects up to 18 mm stretched diameter,[17] The Occlutech Figulla has been designed to close the whole range of defects for which percutaneous closure is indicated. Although it looks similar to the ASO, there are two main differences between the two devices. The ASO consists of a nitinol wire tube that is clamped in two stainless steel tubes on each side of the discs, whereas nitinol wires on the Occlutech Figulla device are braided to avoid a distal clamp,
which offers potential benefits to decrease the chance of clot formation on the left atrial disc and to increase flexibility of the disc for better adaptation in the interatrial septum.

There are several reports on defect closure with the Occlutech Figulla occluder. Krecki et al.[18] used this new device successfully in a patient with patent foramen ovale and history of embolic stroke. Halabi and Hijazi[17] used 12 and 15 mm devices to close multiple ASDs in a child and concluded that this device could be used to close multiple defects with good results. The first clinical results regarding the use of the Occlutech Figulla occluder were reported by Krizanic et al.[19] in 36 patients undergoing percutaneous closure for patent foramen ovale. The authors did not observe thrombus formation on the left atrial disc during the follow-up, possibly due to the absence of a stainless steel hub. Similarly, after percutaneous closure of ASDs, no thrombus was recorded in our study group during the follow-up period.

The rate of residual shunt was reported as 11.8% for the first-generation Occlutech Figulla devices.[19] In the present study, the incidence of residual shunt was 10.7%, which was comparable with the rates associated with the ASO use in large series. Çeliker et al.[20] reported the immediate residual shunt rate as 43.8% in a group of 80 children undergoing percutaneous closure of ASDs, of which two patients (2.5%) had trivial shunt during the follow-up period. Despite high rates of immediate residual shunts reported with the ASO device, subsequent residual shunts usually do not have hemodynamic significance and mostly disappear spontaneously within a year follow-up.[13,16,21]

Procedure-related complications including transient ischemic attacks, atrioventricular block, atrial arrhythmias, thrombosis, cardiac perforation, and pulmonary thromboembolism are usually associated with transcatheter closure of large defects and large device use.[22-25] In our study, only atrial tachyarrhythmias (atrial fibrillation in one and sinus tachycardia in three patients) were observed.

Thrombus formation is an important complication that causes severe adverse results and is often seen on the left atrial side. The type of the device and amount of material in the left atrium are the most common risk factors for thrombus formation. The risk is lower with the ASO device compared with other devices such as CardioSEAL, StarFLEX, and PFO-STAR.[12,26] Kaya et al.[27] reported no thrombus formation in 12 patients undergoing percutaneous transcatheter sepal closure of ASDs using the ASO device during a follow-up period of 11.6±2.3 months. We believe that the risk for thrombus formation is lower in the Occlutech Figulla device due to the lesser amount of material on the left atrial side. However, there is still need for randomized studies comparing the two devices with respect to thrombus formation or other complications.

Study limitations. In the present study, we just evaluated the clinical use and safety of the Occlutech Figulla device in a small study group. Thus, comparative data with other devices are not provided. Another limitation is that the long-term (>3 years) results evaluating late complications (device erosion) have not been obtained yet.

In conclusion, the Occlutech Figulla occluder is a safe and effective device to close a wide range of defects, with a potentially lower thrombus risk due to lesser material on the left atrial side, rendering it more flexible for adaptation in the interatrial septum.

REFERENCES