CLINICAL RESEARCH

Transcatheter closure of atrial septal defect with the Figulla® ASD Occluder: A comparative study with the Amplatzer® Septal Occluder

Fermeture percutanée de communication interauriculaire avec le dispositif Figulla® : étude comparative avec le dispositif Amplatzer®

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Received 18 April 2014; received in revised form 16 June 2014; accepted 9 September 2014
Available online 11 November 2014

Abbreviations: ASD, Atrial septal defect; ASO, Amplatzer® Septal Occluder; CI, Confidence interval; FSO, Figulla® ASD Occluder; OR, Odds ratio; SD, Standard deviation.
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http://dx.doi.org/10.1016/j.acvd.2014.09.005
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Introduction

Transcatheter closure of atrial septal defect (ASD) has become a routine procedure for children and adults with systemic-to-pulmonary flow ratio >1.5:1; it usually carries a low risk of periprocedural complications and achieves good long-term closure results. In fact, many devices are available for ASD occlusion, combining different properties, such as the ability to recapture and redeploy the device within the delivery sheath, the self-centering mechanism...
to simplify and achieve good positioning, leading to a high occlusion rate, and, finally, a wide availability of sizes to close small to large defects. The Amplatzer® Septal Occluder (ASO; Saint-Jude Medical, Zaventem, Belgium) has been used most widely for about 15 years, with favorable follow-up results [1]. More recently, the Figulla® ASD Occluder (FSO; Occlutech GmbH, Jena, Germany) has been developed, with structural innovations. In the present report, we compare FSO and ASO results and outcomes from one tertiary center in a series of 131 consecutive patients treated during the same time period.

Methods

Patient population

From September 2009 to December 2012, 131 patients underwent ASD closure with either an ASO (n = 100) or an FSO (n = 31; Flex I device, n = 16; Flex II device n = 15). A retrospective comparative analysis of the two groups was performed.

Devices

The FSO device is a double disc system, similar to the ASO, with different structural modifications that make it quite attractive. This device is made of a nitinol wire mesh, to create a smooth and flexible outer layer using a unique braiding technique. The two retention discs are connected to a central 4 mm waist, and the size of the device is determined by the diameter of the waist, as usual. The left atrial disc is usually 12–16 mm larger than the waist and the right atrial disc is 8–11 mm larger than the waist [2,3]. Polyester patches are sewn within both discs and the waist to facilitate thrombogenicity and to increase the occlusion rate. Compared with the ASO (Fig. 1), the FSO has a reduced amount of material, with no hub on the left disc to reduce trauma risk and clot formation (Fig. 2). The connecting system from the right disc to the distal tip of the delivery cable has evolved from a microscrew initially—as in the ASO—to a hub attached to the loader by two lateral hooks. With this latter connection, the double disc can be angled some 50° without tension on the system (Fig. 3). All these modifications have increased the flexibility of the device. The FSO is available in different sizes, ranging from 4 mm to 40 mm [2–4].

Implantation technique

For both groups, indications for ASD closure were pulmonary-to-systemic flow ratio > 1.5:1 with right ventricular volume overload. Exclusion criteria were similar for both devices, including:
- small ASD with (mainly) a non-significant shunt;
- no sign of right ventricular dilatation;
- no reactive elevated pulmonary vascular resistance; associated cardiac lesions requiring surgical repair (mainly associated partial anomalous pulmonary venous return);
- deficient rim (the minimal rim accepted was 4–5 mm, except for the anterior rim, which could be completely absent);
- bleeding condition, such as untreated ulcer; and contraindication to aspirin [4–6].

Informed written consent to the procedure was obtained from all patients or their parents before closure.

The implantation technique was similar for both devices. Usually, the procedure was carried out under general anaesthesia with transoesophageal echocardiography guidance for device implantation. Patients received intravenous heparin (100 IU/kg) at the beginning of the procedure. Activated clotting time measurements were not usually taken during the procedure. Device choice was determined by measurement of the stretched diameter, using a compliant balloon catheter (Equalizer™ Occlusion Balloon Catheter; Boston Scientific, Natick, MA, USA) placed across the defect and
controlled by colour Doppler transoesophageal echocardiography, using the “stop-flow” technique. The size of the occluder implanted was usually the same as the stretched diameter ± 2 mm [3,4,6,7]. The appropriate Mullins delivery sheath was then advanced into the left atrium over a guidewire previously placed in the left upper pulmonary vein. The introduction of the occluder within the delivery sheath was achieved by a loader for the FSO flushed with saline serum. The connection to the delivery sheath was performed after de-airing the delivery sheath under water to avoid any risk of air embolism. Device positioning techniques were similar for both devices and correct positioning was confirmed by means of transoesophageal echocardiography and fluoroscopy. When placement was judged to be appropriate, the occluder was released by unscrewing the delivery cable or by advancing the two hooks outside the loader for the FSO. The patient left the hospital 1 or 2 days after implantation, and received aspirin 75–160 mg daily for a 6-month period.

During follow-up, control transthoracic echocardiography was carried out 1 month, 3–6 months and 12 months after implantation. Residual shunting was defined on colour Doppler as trivial (<1 mm colour width), small (1–2 mm colour width), moderate (2–4 mm colour width) and large (>4 mm colour width).

**Statistical analysis**

Analysis included patient criteria (i.e. age, sex, weight, size of the defect established from the stretched diameter), success of implantation, procedure duration, fluoroscopy time, radiation dose and rate of full occlusion on colour Doppler transthoracic echocardiography at implantation and during follow-up. For continuous variables, results are expressed as means and standard deviations (SDs) in case of normal distribution and as medians and SDs otherwise. The normality of distribution was tested by the Shapiro–Wilk test. Categorical variables are expressed as frequencies and percentages.

For continuous variables, comparisons between the two groups (patients with the FSO device or the ASO device) were performed using Student’s t-test or the Mann-Whitney test, according to the distribution of the variable. For categorical variables, comparisons were performed using the chi² test or Fisher’s exact test. Odds ratios (ORs) with 95% confidence intervals (CIs) were computed. Because our study was not randomized, we used a propensity score method [8] to adjust the analysis for potential differences between the two groups (FSO—ASO). To compute the propensity score, we used multivariable logistic regression, with the group considered as dependent variable and the following as independent variables: stretched diameter, weight, age, fluoroscopy time, radiation dose and procedure duration. The comparisons between the two groups were then adjusted for the propensity score.

We used an analysis of covariance for continuous variables. For continuous variables, adjusted means with 95% CIs were computed. The adjusted effect of the device on each outcome was assessed by using multivariable logistic regression, with the device and the propensity score as dependent variables. Adjusted ORs with 95% CIs were computed. Statistical significance was defined as p < 0.05. Statistical analyses were performed using SAS software (SAS Institute, Inc., Cary, NC, USA).

**Results**

**Patient population**

Patient characteristics are shown in Table 1; there were 41 children (aged < 18 years) in the ASO group and nine in the FSO group. However, there were no significant differences between the two groups concerning sex, weight, age and stretched diameter at implantation.

**Immediate results of device implantation**

The results of device implantation are shown in Table 2. In the ASO group, implantation succeeded in all but two patients because of deficient rim. Another patient had device embolization in the transverse aortic arch, which was noticed on a chest X-ray in the hours after implantation; this device was retrieved by cardiac catheterization the same day and the patient underwent successful transcatheter ASD occlusion with a larger ASO, 2 months later. There were no other post-procedural complications.
In the FSO group, implantation succeeded in all but two patients: one because of deficient posterior rim; and the other because of the appearance of complete atrioventricular block, which resolved after percutaneous device extraction. There were no other post-procedural complications.

On immediate control echocardiography performed at hospital discharge, full occlusion was observed in 86 (86.0%) patients in the ASO group and 28 (90.3%) patients in the FSO group, with no significant difference between the two groups ($P = 0.29$; Fisher’s exact test) (Table 2).

### Late results of device implantation

In the ASO group, during a mean follow-up of $6.4 \pm 7.7$ months (1–36 months), 88 patients had no residual shunt and nine patients had a residual shunt (small in seven; moderate in two). However, two of the 88 had a persistent tiny interatrial shunt caused by another hole close to the device, with no right ventricular overload (the defect was finally considered as closed by the occluder). In the FSO group, during a mean follow-up of $4.96 \pm 7.1$ months (1–31 months), no shunt was observed in all but one patient (existence of a small shunt). Thus, at late follow-up, full occlusion was seen in 88 (88.0%) patients in the ASO group and in 28 (90.3%) patients in the FSO group (Table 2; Figs. 4 and 5).

The two groups were then compared using the propensity score method. The results of this adjustment are presented in Tables 3 and 4, again showing no significant differences between the two groups in terms of patient characteristics at implantation and during follow-up.

### Discussion

Few studies have been published on the use of the FSO in transcatheter closure of ASD. Because implantation of the FSO device is very similar to that of the ASO, there is no learning curve with this occluder [3]. The main point of this study was to perform a comparative analysis between the FSO and the classic ASO, including the use of a propensity score method. In fact, the two populations were quite similar in terms of weight, age and defect size, making the comparison possible. Moreover, our FSO group had similar characteristics to those in published studies [5,6]. We demonstrated that results with the FSO were similar to those with the ASO, in terms of ASD occlusion.
Table 3  Comparison of continuous variables between groups 1 and 2 after adjustment for the propensity score.

<table>
<thead>
<tr>
<th></th>
<th>ASO group (n = 58)</th>
<th>FSO group (n = 29)</th>
<th>P²</th>
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<tbody>
<tr>
<td>Stretched diameter (mm)</td>
<td>20.3 (19.0—21.6)</td>
<td>20.3 (18.0—22.6)</td>
<td>0.99</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>57.5 (52.3—62.7)</td>
<td>57.5 (48.1—66.9)</td>
<td>0.99</td>
</tr>
<tr>
<td>Age (years)</td>
<td>33.4 (29.3—37.5)</td>
<td>33.4 (26.1—40.8)</td>
<td>0.99</td>
</tr>
<tr>
<td>Fluoroscopy time (minutes)</td>
<td>6.6 (4.9—8.3)</td>
<td>4.4 (1.4—7.4)</td>
<td>0.21</td>
</tr>
<tr>
<td>Radiation dose (Gy/cm²)</td>
<td>20.4 (16.2—24.6)</td>
<td>14.1 (6.5—21.6)</td>
<td>0.15</td>
</tr>
<tr>
<td>Procedure duration (minutes)</td>
<td>43.9 (40.8—47.0)</td>
<td>47.4 (41.9—53.0)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Results are expressed as adjusted means with 95% confidence intervals. ASO: Amplatzer® Septal Occluder; FSO: Figulla® ASD Occluder.

² Analysis of covariance.

Both FSO and ASO handle very well and can be recaptured or redeployed easily within the sheath, allowing appropriate repositioning, if necessary. However, the FSO is characterized by a reduction of material compared with the ASO. The absence of the distal hub on the left disc may be of benefit, in terms of reducing the risk of trauma, clot formation and subsequent systemic embolization [3–5,9]. However, the lack of thrombus on the left disc in both groups in our study could be related to the fact that only transthoracic echocardiography was performed during follow-up, as in many other centres [3,4,9]. Such data may also result from our protocol, and our insistence that the procedure is performed under intravenous heparin at the dose regimen proposed and that patients are given aspirin for at least a 6-month period after implantation. In the same manner, no stroke was reported in the two groups after implantation. Meanwhile, a long-term follow-up study is mandatory to establish that there is no difference in thrombus formation between the two devices.

Rate of full occlusion is very high with the FSO, as is usually observed with the ASO. Immediate residual shunting of up to 24% has been reported with the FSO [3], but mid-term results, usually 6 months after the procedure, showed no residual shunt with the FSO [3,4,6,9,10]. Similar results have been reported with the ASO [7]. Although we noticed more residual shunt in the ASO group than the FSO group in the present study, the amount of shunting was minimal, with no right ventricular overload. In fact, we observed no significant differences between the two groups, showing the real non-inferiority of the FSO. It is likely that these results are also influenced by the imaging modality used to diagnose residual shunting. Once more, transthoracic echocardiography may be less sensitive than transoesophageal echocardiography in the depiction of residual shunt [11]. However, most of these residual shunts are not clinically relevant and will close with time.

Complications following ASD occlusion with the FSO are rare; the most frequent (up to 8.9%) is the occurrence of palpitations due atrial extrasystoles or supraventricular tachycardia, which are usually transient and rarely require anti-arrhythmic therapy [3,6,11,12]. Other drawbacks included device embolization in the pulmonary artery [3] or aorta [13], groin haematoma [11,12] and “Cobra formation” [14]. In fact, there is no complication associated specifically with the FSO compared with the ASO [15]. We observed one case of complete atrioventricular block after placement of the FSO in a 4-year-old boy, probably related to tension on the atrial septum; this disappeared after extraction of the device and the patient is awaiting another percutaneous ASD closure. In fact, such a complication is very rare, but it has also been reported with the ASO [7,15]. In the ASO group, one embolization was noticed in the aorta and the device was retrieved in the hours after implantation by cardiac catheterization. This is probably the major complication of transcatheter ASD occlusion, but it has also been reported with many devices [7,15]. Similar aortic embolization has also been observed with the FSO [13]; the device was extracted percutaneously using a bioptome and a large sheath. The authors – as we recommend – highlighted the need for balloon sizing of the defect before implantation, to assess the defect size and to avoid undersizing, with subsequent risk of device migration.

The FSO carries some drawbacks. First, it is available mainly in 3 mm increments for the large device size. This was not a real problem in our population, but may be not adequate for all patients. On the other hand, it may reduce the number of devices that need to be stocked in the cardiac laboratory [4]. The second limitation is the need for a larger introducing sheath for a device of equivalent size to the ASO. Once more, this may be a limiting factor in young children because of the risk of vascular damage [5]. However, the use of the FSO has also been reported below the age of 2 years, with no major complications [12]. Clearly, for older children and adults, the use of a larger sheath will not be a problem. We do think that additional care should be taken when implanting the FSO in children.

Table 4  Comparison of outcomes between groups 1 and 2 (multivariable logistic regression with adjustment for the propensity score).

<table>
<thead>
<tr>
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<th>Odds ratio⁴</th>
<th>95% CI</th>
<th>P</th>
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<tbody>
<tr>
<td>Immediate full occlusion</td>
<td>1.7</td>
<td>0.4—6.2</td>
<td>0.46</td>
</tr>
<tr>
<td>Late full occlusion</td>
<td>1.4</td>
<td>0.4—5.3</td>
<td>0.64</td>
</tr>
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</table>

⁴ Adjusted odds ratio (with 95% confidence interval [CI]) of full occlusion, with the ASO group (Amplatzer® Septal Occluder) as reference.

Study limitations

In the present study, a comparison was performed between the recently developed FSO and the classic ASO — used in
our centre since November 1997 — for transcatheter closure of ASD during the same time period. Our study is limited by its non-randomization regarding patient selection, as are all published studies, to our best knowledge. In the sole comparison by Pac et al. [3], there were no initial statistical differences in terms of stretched diameter, device size procedure and fluoroscopy time between the ASO and FSO groups. Although residual shunting was higher at implantation with the FSO in this study compared with ours, there was no difference observed between the two groups during late follow-up, in terms of persistent shunting. However, the defect size was smaller (around 15 mm) than that observed in our present report (20 mm), reflecting reality more accurately. Despite larger size defects in our study, the two groups were very similar in characteristics, and non-inferiority was observed with the FSO compared with the ASO, in terms of late results. In fact, if the increased flexibility of the FSO is of benefit in clinical practice, this was not related to better results in terms of full occlusion, and it is not yet possible to make any recommendations about the choice of FSO or ASO according to defect anatomy. Finally, long-term study results are not available, and we could not draw conclusions about the risk of device erosion with the FSO, but this should be very low due to the increased flexibility related to the new nitinol meshwork.

**Conclusion**

To conclude, the present study has shown that the FSO is safe and effective in transcatheter ASD closure. Despite a trend towards lower fluoroscopy time and radiation dose with the FSO compared with the ASO, the results were very similar in both groups. The FSO achieved the same level of full occlusion during follow-up as is usually reported with the ASO. Among all the new devices available, therefore, the FSO seems to be a real alternative to the classic ASO for ASD closure. However, further studies with more patients and a longer follow-up are necessary to confirm these preliminary results.

**Disclosure of interest**

The authors declare that they have no conflicts of interest concerning this article.

**References**


