

Comparing the Performance of Amplatzer® and Occlutech® Figulla® Septal Occluders: The Pediatric Point of View. A Retrospective Study

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ABSTRACT: **Background:** The closure of an atrial septal defect is procedure that is frequently performed in both adults and children. Currently, the most commonly used devices are the Amplatzer® and Occlutech® Figulla® atrial septal occluders. Studies conducted in adults have shown that these devices all have similar performance efficiency for the closure of secundum atrial septal defects. No study to date has examined their performance in the pediatric population.

Objectives: To evaluate and compare the performance of Amplatzer® and Occlutech® Figulla® atrial septal occluders in the pediatric population.

Methods: A consecutive retrospective study of exclusively pediatric patients who underwent percutaneous closure of atrial septal defect with these devices was conducted at our institute.

Results: The study comprised 110 children, 50 in the Amplatzer® device group and 60 in the Occlutech® Figulla® device group. The groups had similar demographic and defect characteristics, except for defect size per transesophageal echocardiography (TEE), which was 2.1 mm larger in the Amplatzer® device group ($P = 0.02$). No adverse events were recorded in either of the study groups. Complete defect closure at 12 months follow-up (procedural success) was achieved in all but one of the patients in the Amplatzer® group and all but two in the Figulla® group ($P = 1$). The residual shunt rates of fenestrated defects were similar in the two groups.

Conclusions: For children with an isolated secundum atrial septal defect, percutaneous closure is equally safe and effective with either Amplatzer® or Occlutech® Figulla® devices.

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usually close spontaneously by the age of 2 years [5-7]. Larger defects (> 10 mm), however, do not have that tendency, and can even increase in size if left untreated [6,7]. The symptoms of unresolved ASD usually appear after the third decade of life [3,4]. In asymptomatic children, the indications for intervention are the presence of right ventricular volume overload due to a significant ASD (> 5 mm) without evidence of spontaneous closure and a defect that causes a hemodynamically significant shunt ($Q_p/Q_s > 1.5$) [4].

Today, most secundum ASDs are closed percutaneously. The superiority of the percutaneous approach over surgical repair, from the points of view of peri- and post-procedure morbidity, hospital stay, and hemodynamic improvement, has been demonstrated in several studies [8-10]. ASD closure initiates a chain of physiological events with immediate and long term remodeling, leading to improved mechanics and hemodynamics of the heart [11,12]. The most frequently used devices today are the Amplatzer® Septal Occluder (ASO, St. Jude Medical Inc., St. Paul, Minnesota, USA) and the Figulla® ASD Occluder (FSO, Occlutech® GmbH, Jena, Germany).

Several studies have been published recently about the equality in safety and efficacy of these devices for percutaneous ASD closure [13-15]. These studies were conducted on adults or on mixed-age groups without distinguishing between adult and pediatric age groups. In our study, we aimed to examine the performance of these devices solely in the pediatric population, which is the main target group of this procedure.

PATIENTS AND METHODS

AIM OF THE STUDY

The aim of the study was to evaluate and compare the safety and efficacy of the ASO and the FSO for the percutaneous closure of ostium secundum ASD in the pediatric population.

STUDY DESIGN

A consecutive retrospective study was conducted on pediatric patients who underwent percutaneous closure of isolated

Atrial septal defect (ASD) is the second most common congenital heart disease (CHD), accounting for about 10% of congenital malformations of the heart [1,2]. Of all ASDs, 75% are ostium secundum ASD [3,4]. Small defects (4-5 mm)

ostium secundum ASD in our institute, using either the ASO (May 2006–June 2009) or the FSO (July 2009–July 2013) devices. All procedures took place in our specialized catheterization laboratory and were conducted by the same senior cardiologist, who was assisted by the department's residents. Exclusion criteria were identical for both devices and included the presence of concurrent cardiac defects or significant comorbidities not related to the ASD and its hemodynamic effects. We collected demographic, clinical, and catheterization data from the hospital's database. The study protocol was approved by the institution's ethics committee.

DEVICE AND PROCEDURE

ASD closure was performed under general anesthesia. Delivery deployment and release was guided by fluoroscopy and transesophageal echocardiography (TEE). Two different devices were used: the ASO and the FSO. During the first years of percutaneous ASD closure (2006–2009) we used the ASO device, later shifting to the FSO device (2009–2013), which at that time had a substantially lower cost but similar performance reports. There was no overlap period between the two devices. The technical aspects relating to device deployment were similar for both devices, thus a very short adjustment period was required. During the procedure, the defect's size was measured by either balloon sizing (a technique in which a balloon is inserted on the guide and inflated across the defect until a "waist" appears in the balloon and the waist is measured in a fluoroscopy image to represent the defects size) or by the 'stop flow' technique, in which the size of the defect is measured by color Doppler echocardiography. We maintained an activated clotting time of more than 200 seconds during the procedure. All patients were treated with antibiotics during and 24 hours following the procedure as well as oral aspirin (5 mg/kg with or after a meal), which was maintained for 6 months.

All patients underwent clinical examination, electrocardiogram (ECG) and transthoracic echocardiography (TTE) before discharge. Post-procedural follow-up visits were documented equally for the two groups.

OUTCOME MEASURES

The primary outcome of this study was procedural safety. We assessed the device-related and procedure-related adverse events throughout the follow-up period including device embolization, arrhythmia, conduction defects, cardiac perforation, stroke, or transient ischemic attack (TIA) and the need for surgical removal of the device. The secondary outcome of our study was defined as procedural efficacy assessed by defect closure or residual shunt size at the follow-up examination during the first year after the procedure. Follow-up meetings were conducted at outpatient cardiology clinics, and the defect was assessed by TTE, a less accurate but more readily available technique in the outpatient setting. Residual shunt was classified

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).

STATISTICAL ANALYSIS

Baseline patient characteristics, procedural findings, and results were compared in the two study groups using chi-square, Student's *t*-test, or Fisher's exact test when sample sizes were small. Results are expressed by frequency or percentage for nominal variables and as the mean \pm standard deviation for continuous variables. A *P* value of < 0.05 was considered to be statistically significant.

RESULTS

DEMOGRAPHIC AND CLINICAL CHARACTERISTICS

A total of 110 pediatric patients were included in the study, 50 in the Amplatzer® ASO device group and 60 in the Occlutech® Figulla® FSO device group. Pre-procedural data including patient demographics, clinical data, and defect characteristics are shown in Table 1. There was no statistically significant difference between the two groups in terms of average age or ECG findings prior to the procedure. The most common finding indicating the need for ASD closure in both groups was right heart enlargement. The second most common indication was the presence of a large shunt ($Q_p/Q_s > 1.5$), which was more common in the ASO group ($P = 0.04$). Pre-procedural average defect size, measured by TEE, was 2.1 mm larger in the ASO group (12.6 ± 5.9 vs. 10.5 ± 3.8 in the FSO group, $P = 0.02$). There was no statistically significant difference between the

Table 1. Baseline characteristics

	ASO device (n=50)	FSO device (n=60)	<i>P</i> *
Demographic data			
Female	26 (52%)	38 (63.3%)	NS
Age in years, mean (range)	7 (2–17)	7.6 (2–16)	NS
ECG before procedure			
Sinus rhythm	50 (100%)	60 (100%)	NS
RBBB pattern	35 (70%)	33 (55%)	NS
Indication for closure			
CVA/TIA	0	1 (1.6%)	NS
Large shunt ($Q_p/Q_s \geq 1.5$)	8 (16%)	2 (3.3%)	0.04
Pulmonary hypertension	0	1 (1.6%)	NS
Right chamber enlargement	45 (90%)	56 (93.3%)	NS
Defect characteristics			
Average size TEE (mm \pm SD)	12.6 \pm 5.9	10.5 \pm 3.8	0.02
Antero-superior rim deficient (< 4 mm)	12 (24%)	11 (18.33%)	NS
Septal aneurysm	11 (22%)	9 (15%)	NS
Fenestrated defect	12 (24%)	7 (11.6%)	NS

ASO = Amplatzer® septal occluder, CVA = cerebrovascular accident, ECG = electrocardiogram, FSO = Figulla® septal occluder, NS = not significant, RBBB = right bundle branch block, TIA = transient ischemic attack, TEE = transesophageal echocardiography

**P* values for continuous measures based on Student's *t*-test for categorical variables on chi-square or Fisher's exact test.

Only *P* values < 0.05 are displayed

Table 2. Procedural results and complications

	ASO device (N=50)	FSO device (n=60)	P*
Intra-procedure balloon sizing, n	46 (92%)	25 (41.66%)	< 0.0001
Average balloon waist measurement (mm ± SD)	16.3 ± 5.8	14.95 ± 4.8	NS
Implanted device size: all (mm ± SD)	16.7 ± 6.2	13.1 ± 4.1	0.0003
Implanted device size: balloon sized patients	16.8 ± 5.7	15.4 ± 4.6	NS
Complications during implantation, n	0 (0%)	0 (0%)	NS
Complications at follow-up, n	0 (0%)	0 (0%)	NS
Residual shunt^a (all defects), n			
Immediately after the procedure	12 (24%)	19 (31.7%)	NS
6 month follow-up	2 (4%)	4 (6.6%)	NS
12 month follow-up	1 (2%)	2 (3.3%)	NS
Residual shunt^a (fenestrated defects), n			
Immediately after the procedure	7 (58.3%)	5 (71.4%)	NS
12 month follow-up	1 (8.3%)	1 (14.3%)	NS

^aAll residual shunts were small or trivial shunts. No moderate or large shunts were observed

ASO = Amplatzer® septal occluder, FSO = Figulla® septal occluder, NS = not significant

*P values for continuous measures based on Student's *t*-test for categorical variables on chi-square or Fisher's exact test

ASO and FSO groups in the prevalence of fenestrated defect, deficient aortic rim, or septal aneurysm.

PROCEDURE RESULTS

Procedure results are summarized in Table 2. Intra-procedure balloon sizing was more frequently used in the ASO group (92% vs. 41.6% in the FSO groups, *P* < 0.0001). Average device size was significantly larger in the ASO group, (16.7 ± 6.2 mm vs. 13.1 ± 4.1 mm, *P* = 0.0003), but when examining each patient who underwent intraprocedural balloon sizing, there was no significant difference between the two groups in the implanted device size (*P* = 0.3).

All but one fenestrated defect (12 in the ASO group and 6 in the FSO group) were closed by a single ordinary device. In the FSO device group, one 15 year old patient had his fenestrated defect closed by two FSO devices simultaneously.

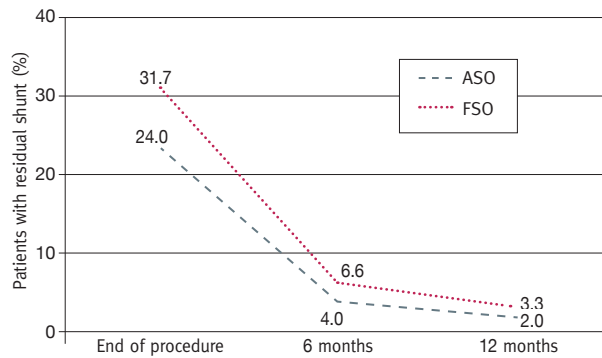
INTRA- AND POST-PROCEDURE COMPLICATIONS

The implantation procedure was successful throughout our entire cohort (N=110/110), that is, there were no intra-procedural complications in either of the device groups. Post-procedural complications, such as device embolization, thrombus formation at the device site, cardiac perforation, or erosion of mitral valve were not observed in this pediatric population.

PROCEDURE OUTCOME

Immediate and complete closure was achieved in 76% (38/50) of the patients in the ASO group and in 68.3% (41/60) of patients in the FSO group (NS, *P* = 0.4). The remainder had

Figure 1. Percentage of patients with residual shunt at three time points during follow-up. Of note, only trivial and small shunts were detected at follow-up



ASO = Amplatzer® septal occluder, FSO = Figulla® septal occluder

a small or trivial residual shunt. There were no patients lost to follow-up, and all patients had documented follow-up meetings until defect closure. At 6 months of follow-up, a residual shunt was observed in two patients (4%) in the ASO group and in four patients (6.6%) in the FSO group (NS, *P* = 0.68). At 1 year of follow-up, all but one patient (2%) in the ASO group, and two patients (3.3%) in the FSO group, had a complete closure of the defect without residual shunt, *P* = 1 [Figure 1]. No moderate or severe residual shunts were reported.

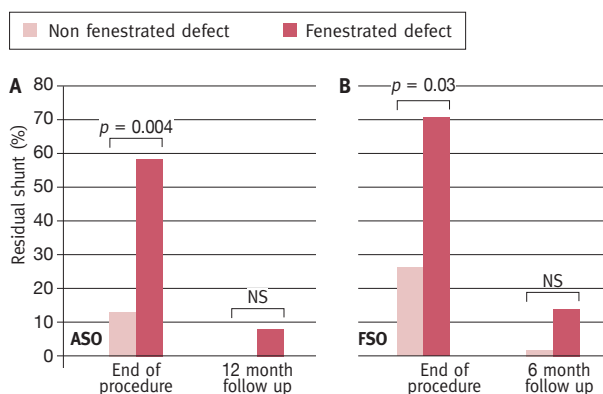
We also examined device efficacy for fenestrated defects separately. The closure rates for fenestrated defects at the end of the procedure and after 1 year follow-up were similar in both device groups [Table 2]. At 1 year follow-up two patients with fenestrated defects, one in each device group, were left with a trivial residual shunt.

When comparing fenestrated defects to non-fenestrated defects in both device groups [Figure 2], there was a statistically significant difference in the immediate closure rate. In the ASO group, immediate closure rates in the non-fenestrated defect sub-group were 86.9% vs. 41.6% in the fenestrated defect sub-group (*P* < 0.004). In the FSO group, the immediate closure rates for non-fenestrated defects were 73.6% vs. 28.6% for the fenestrated defects (*P* < 0.03). No statistically significant differences were found when comparing residual shunt rates at 1 year follow-up between the fenestrated and non-fenestrated defects in either device group.

DISCUSSION

Percutaneous closure of ostium secundum ASD is a safe and efficient procedure, performed routinely in children and adults using a variety of devices, of which the Amplatzer® septal occluder and Figulla® septal occluder were most commonly used in our department. In our series of pediatric patients who

Figure 2. Comparison of fenestrated and non-fenestrated defects and residual shunt rates in both device groups immediately after the procedure and after 12 months of follow-up. **[A]** shows the ASO group, **[B]** shows the FSO group



ASO = Amplatzer® septal occluder, FSO = Figulla® septal occluder, NS = not significant

were implanted with either ASO or FSO devices, we found no significant differences when comparing the efficacy and safety of these devices.

COMPARISON OF SAFETY

Our primary endpoint was to evaluate and compare the safety of the percutaneous introduction of these two devices, a composite evaluation of intra- and post-procedural complication rates. There were no intra- or post-procedural complications, such as device embolization, atrioventricular blocks, or symptomatic atrial arrhythmias, in the pediatric population in either device group.

Published intra- and post-procedural complication rates in studies conducted on adults have been higher. Two studies examining the rate of post-procedural arrhythmias in adults showed significantly higher rates compared to our pediatric cohort (6% and 12% vs. 0%) [16,17]. This difference may be explained by the lack of a long-standing shunt and the hemodynamic influences on a child's heart structure. It suggests that early defect closure is desirable and superior.

Other studies we reviewed that examined the ASO and FSO devices showed similarly low complication rates [10,13-15,18-23]. These studies, however, did not examine the pediatric population separately, as in our study, thus no conclusions could be drawn regarding this special population. One small study in a pediatric population, comparing the ASO device to an older device, showed similar success and complication rates [24].

Studies have shown that using balloon sizing for the estimation of a defect's size, that is, measuring the 'waist' that is created when a balloon, placed through the defect, is inflated may lead to a longer procedure, and a longer radiation time. It may also result in an overestimation of the defect's size [25], thus caus-

ing the implantation of larger devices and an increased risk for procedural complications. In our cohort there was an average 3.84 mm increase in the estimated defect size (TEE vs. balloon waist) in patient who underwent balloon sizing. The use of intra-procedural balloon waist sizing for ASD measurement has diminished in recent years and new techniques have emerged, such as the "stop-flow" technique, in which a defect's size is estimated by color Doppler echocardiography. This technique results in the implantation of a more adequately sized occlusive device with slightly modest dimensions. The higher rate of balloon sizing in the ASO group vs. the FSO group (92% vs. 41%, respectively $P < 0.0001$) can be explained by the fact that the switch from ASO to FSO occluders was done at the time when the operators were more experienced with the technique of percutaneous ASD closure. At that time we also preferred to use the stop flow technique.

COMPARISONS OF EFFICACY

Procedural efficacy, the secondary endpoint of our study, was assessed at the follow-up meetings by TTE. No patients were lost to follow-up prior to complete defect closure in our cohort. Procedural success, defined as complete defect closure by the 12 month follow-up examination, was achieved in 97.2% of the entire cohort, 98% in the ASO group and 96.7% in the FSO group, with no significant difference in the two groups ($P = 1$). Residual shunts were estimated as minimal to mild and no clinically significant residual leaks were reported in any of the patients. Similar success rates in adult and mixed cohorts have been published in recent years [10,13-15,18-23]. The immediate closure rates in fenestrated defects were similar in both groups. In both device groups there was a higher rate of residual shunt immediately after the procedure in the fenestrated defect subgroup with no difference at the 12 month follow-up. Most of the fenestrated defects were closed with a single device covering most, but not all, of the defect surface area, explaining the larger rate of immediate residual shunt. After 12 months, when the biological reaction to the thrombogenic nitinol content of the devices and the epithelialization process was complete, no residual shunt was seen in most of the patients with either fenestrated or non-fenestrated defect in either device group. This result suggests that there was no need for a larger device for the closure of the fenestrated defects, which could have theoretically resulted in more intra- and post-procedural complications such as arrhythmias and conduction blocks.

The main limitation of our study was that it was retrospective and no patient randomization was performed; instead, to minimize bias we examined charts of all consecutive patients who underwent ASD closure at our institute. In a retrospective study, where different intervention groups are studied consecutively, the element of changes in operators, ever changing technologies, and best practice procedures need to be taken into account. In our study, the operator already had more than

20 years of experience as an interventional cardiologist thus the added experience obtained during the first 3 years of our study was important but, in our opinion, not sufficient to produce a significant advantage for the FSO group.

CONCLUSIONS

In conclusion, no significant differences were found in the performance of the ASO and FSO devices in the pediatric population. Compared to data published in recent years from studies conducted in adult and mixed-age groups, the pediatric population showed lower complication rates. This finding might indicate the superiority of early intervention and closure.

We also found that even though fenestrated defects tend to leave a residual shunt immediately after device implantation, they close completely later in the physiological process. This might encourage interventionists to avoid using a larger device with the purpose of achieving immediate defect closure, since larger devices are linked to an increased risk for adverse events.

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“Most creativity is a transition from one context into another where things are more surprising. There’s an element of surprise, and especially in science, there is often laughter that goes along with the ‘Aha’. Art also has this element. Our job is to remind us that there are more contexts than the one that we’re in – the one that we think is reality”

Alan Kay, (b. 1940), computer scientist. He is best known for his pioneering work on object-oriented programming and windowing graphical user interface design