

Transcatheter closure of secundum atrial septal defects with the Amplatzer occluder in adult patients

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Atrial septal defect;
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Background. Secundum atrial septal defect (ASD) is a common congenital heart disease diagnosed in adulthood. Data regarding the use of the percutaneous occluder device in adult populations are very limited and few studies including the use of the Amplatzer septal occluder (ASO) device in such populations are available. The aim of this study was to evaluate the immediate and mid-term outcomes of the percutaneous ASD closure with the ASO device in an adult population.

Methods. Between May 1999 and December 2000, 21 adult patients (8 males, 13 females) with a mean age of 44.6 ± 15.1 years were enrolled for an attempt at ASD closure with the ASO device.

Results. Only 18 of the 21 patients underwent implantation of the ASO device, whereas the other 3 patients were submitted to cardiac surgery. The ASO device was successfully implanted in 17 patients (94.4%). The mean maximal ASD transesophageal echocardiography diameter was 14.4 ± 7.2 mm (range 4-23 mm). The mean stretched defect diameter measured 19.5 ± 8.4 mm (range 8-34 mm) and the ASO implanted stalk size was 19.8 ± 8.2 mm (range 8-34 mm). In 2 (11.1%) of the 18 patients a percutaneous transcatheter coronary angioplasty was successfully performed before implantation of the ASO device because of coronary artery disease. At 6 months of follow-up, transesophageal echo examination showed that the device was correctly positioned in all cases.

Conclusions. In adults, transcatheter closure of ASDs with the ASO device is a safe and effective alternative to surgical closure. The immediate and mid-term outcomes are excellent. However, a combined procedure may be necessary.

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Introduction

The secundum atrial septal defect (ASD) is the second most common congenital heart disease diagnosed in adulthood and accounts for 22% of all congenital heart lesions in adults¹. Until the last few years, the treatment of choice has been open-heart surgery. Since 1974, when a percutaneous occluder device was, for the first time, used to successfully treat ASD, several efforts have been made to improve the technical characteristics of ASD percutaneous occluder devices². Several transcatheter closure devices have been developed during the past three decades³⁻⁷. The Amplatzer septal occluder (ASO) (AGA Medical Corporation, Golden Valley, MN, USA) is the most recent of the devices which have been investigated. In several studies the reported series have included mostly children and adolescents³⁻⁷. The ASD and atrial dimensions in adult patients are larger than in children and the atrial septum is often pliable and thin or aneurysmatic because of the effects of the shunt. The left ventricle is less compliant

and mitral and tricuspid regurgitation are often present. Data from studies including adults who have been submitted to ASD closure using a percutaneous occluder device are limited to a small group of patients^{8,9}. The aim of this study was to evaluate the immediate and mid-term outcomes in a population of adults who had undergone, in a single center, percutaneous closure of an ASD using the ASO device.

Methods

From May 1999 to December 2000, 21 patients underwent attempted transvenous closure of a secundum ASD using the ASO device in our catheterization laboratory. All patients had been previously studied at two-dimensional transthoracic (TTE) and transesophageal echocardiography (TEE). The criteria for inclusion in the study were the presence of a secundum ASD with a maximal ASD diameter ≤ 30 mm and with a postero-superior rim ≥ 5 mm as assessed at TEE.

Device. The device is constructed of a nitinol mesh and is a self-expanding and self-centering prosthesis. Two disks joined by a central stalk form the device when it is expanded. The stalk occludes the defect and the disks adhere to the residual septum. Available sizes of the ASD range from 4 mm to the current largest diameter of 38 mm with 1 mm increment from 4 to 20 mm and with 2 mm increments for larger devices. The advantages are that the ASD is retrievable, that it may be repositioned and even used for the closure of very large defects.

Procedure. The procedure was performed with the patient under general anesthesia. Having gained femoral venous and arterial access, a coronary angiography was performed if the patient was > 50 years old or if multiple coronary artery disease risk factors were present. The pulmonary and right heart pressures were measured by means of the Swan-Ganz catheter after coronary angiography. The oxygen saturations of the femoral artery, pulmonary artery, right ventricle, right atrium and superior and inferior vena cava were determined in the blood sample collected during right catheterization in order to obtain the pulmonary to systemic blood flow ratio (Qp/Qs). After cardiac catheterization, a guide wire was positioned in the left atrium using the femoral venous access and then a spherical balloon was passed over the guide wire into the left atrium. The spherical balloon was inflated in the left atrium and then pulled back against the ASD. It was progressively deflated until it could just be pulled through the defect and into the right atrium. The balloon stretched diameter was defined as the smallest balloon size that completely occluded the ASD as confirmed at TEE and was measured either during TEE or using fluoroscopic techniques. All of these steps were performed under both multiplane TEE and fluoroscopic guidance. Multiplane TEE was performed before and during the procedure. Images displaying the anatomical structures of interest were recorded on videotape and the measurements were taken by means of an electronic caliper. The most useful views were the mid-esophageal 4-chamber view at 0°, the short-axis view at 45° to 60° and the biatrial long-axis view at 90° to 110°. We measured the maximal ASD diameter and the rim length: antero-superior (distance from the aorta), antero-inferior (distance from the tricuspid valve annulus), postero-superior (distance from the superior vena cava) and postero-inferior (distance from the inferior vena cava). The correlations between the ASD and the mitral valve, coronary sinus, right upper pulmonary vein flow and superior vena cava were assessed. TEE was particularly important to confirm the presence of the inflated balloon in the left atrium and to demonstrate at which size the balloon occluded the defect in such a way that no residual shunt was visible at color Doppler (balloon stretched diameter). The balloon was re-inflated after

removal from the patient and the size was confirmed with a sizing plate. Having determined the balloon stretched diameter, an Amplatzer device in which the occluding stalk diameter equaled or exceeded by 1-2 mm the ASD stretched diameter was utilized. The delivery catheter was passed over the guide wire and introduced into the left atrium. The left atrial disk and waist were opened and positioned against the interatrial septum before the deployment of the right atrial disk. Before releasing the device, careful pull and push movement tests were performed so as to exclude the presence of any device instability. Once adequate stability was achieved the ASD device was released. All of these phases were performed under TEE guidance. Having deployed the device, the presence of any residual shunt through and around the ASD was evaluated by means of multiplane TEE color-flow Doppler. A very small residual jet was considered insignificant. Primary success was defined as an uneventful procedure without any significant residual shunt as evaluated during TEE color-flow Doppler.

On the day following the procedure, the patient was submitted to physical examination in order to check for any complications (peripheral or rhythm). A TTE examination was also performed so as to ensure that the device was still in the correct position. Moreover, the dimensions of the right ventricle and the right atrium were also determined during TEE. On the parasternal long-axis view, the right ventricular outflow diameter was taken to be the widest right ventricular diameter at the end-diastolic phase. Four-chamber views were obtained to measure the right ventricular inlet diameter (tricuspid plane-right ventricular tip length) at end-diastole and the right atrial width (medio-lateral diameter) and length (supero-inferior diameter) during the end-systolic phase.

All patients were discharged within 2-3 days of the procedure.

Medication. The day before the procedure all patients received a combination of aspirin (160 mg) and ticlopidine (500 mg). A bolus of heparin (2500 to 5000 IU) was administered to maintain the activated clotting time ≥ 200 s during the procedure. At the time of discharge, the patients received a combination of aspirin (160 mg) and ticlopidine (500 mg) daily for 4 weeks and then aspirin alone for 6 months, so as to prevent thromboembolic complications. Prophylactic antibiotics were administered to prevent endocarditis during the invasive procedure.

Follow-up. A clinical and TTE examination were performed at 6 months of follow-up.

Statistical analysis. Parametric data are expressed as means \pm SD and were compared using the paired Student's t test. A p value < 0.05 was considered statistically significant.

Results

Twenty-one patients (8 males, 13 females) were enrolled for attempt at closure of the ASD using the device. The clinical characteristics are shown in table I. The mean age was 44.6 ± 15.1 years (range 26-84 years). All patients were symptomatic at the time of enrollment. Eleven patients (52.4%) had a supraventricular arrhythmia. One of them underwent atrial flutter ablation before the procedure, whereas 5 other patients needed medical treatment. Six patients (28.6%) had heart failure and 1 of them needed an atrio-biventricular pacemaker because of dilated cardiomyopathy. Four patients (19.0%) had a previous cerebral ischemic attack consequent to paradoxical embolism.

The anatomical characteristics are shown in table II. An antero-superior rim ≤ 5 mm was present in 3 patients (14.3%). Another patient presented with a pliable postero-superior rim (< 5 mm) which was considered

unsuitable for closure using the ASO under TEE guidance. This patient was referred for surgical ASD closure. Out of 21 patients, only 18 (85.7%) underwent ASO device implantation (Fig. 1). Two other patients had a maximal ASD-TEE diameter of 28 and 30 mm respectively with a stretched diameter > 38 mm. They underwent surgical closure because implantation of the ASO device was not possible.

The procedural characteristics of the 18 patients who underwent closure of the ASD using the ASO device are shown in table III. The mean systolic pulmonary pressure was 28.1 ± 10.2 mmHg; the mean diastolic pulmonary pressure was 9.4 ± 6.7 mmHg. The mean Qp/Qs ratio was 1.8 ± 0.1 . In 6 patients (33.3%) a pliable or aneurysmatic rim tissue was assessed during TEE examination. The mean maximal ASD-TEE diameter was 14.4 ± 7.2 mm. The mean stretched defect diameter measured 19.5 ± 8.4 mm and the ASO implanted stalk size was 19.8 ± 8.2 mm. The ASD-TEE

Table I. Clinical characteristics.

Age (years)	44.6 ± 15.1
Sex (M/F)	8/13
ASD closure indications	
Arrhythmia	11 (52.4%)
Heart failure	6 (28.6%)
Cerebral ischemic attack-paradoxical embolism	4 (19.0%)

ASD = atrial septal defect.

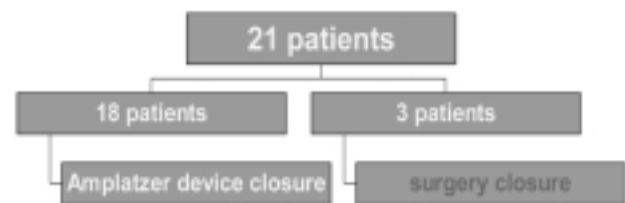


Figure 1. Atrial septal defect was treated with the Amplatzer device in 18 patients out of the total population (21 patients), whereas 3 patients underwent surgical closure.

Table II. Anatomical and procedural characteristics of 21 patients submitted to atrial septal defect closure.

No. patients	Rim ≤ 5 mm	Aneurysmatic or pliable rim	TEE diameter (mm)	Stretched diameter (mm)	ASO diameter (mm)	Residual shunt
1	No	No	16	18	18	No
2	No	Yes	4	8	8	Yes
3	No	Yes	4	8	8	Yes
4	No	No	12	15	15	No
5	Yes (A-S)	No	20	28	28	Yes
6	No	No	18	24	24	No
7	No	No	13	14	14	No
8	Yes (A-S)	No	20	34	34	Yes
9	No	No	16	20	20	No
10	No	Yes	4	16	17	No
11	No	No	23	25	26	No
12	No	Yes	5	8	8	No
13	No	Yes	23	24	24	No
14	Yes (A-S)	No	20	24	24	Yes
15	No	Yes	16	26	26	Yes*
16	No	No	23	30	30	No
17	No	No	4	5	8	No
18	No	No	18	24	24	No
19	No	No	28	> 38	–	–
20	Yes (P-S)	Yes	26	–	–	–
21	No	No	30	> 38	–	–

A-S = antero-superior rim; ASO = Amplatzer septal occluder; P-S = postero-superior rim; TEE = transesophageal echocardiography. * = residual shunt of 3 mm.

Table III. Procedural characteristics of 18 patients who underwent Amplatzer septal occluder closure.

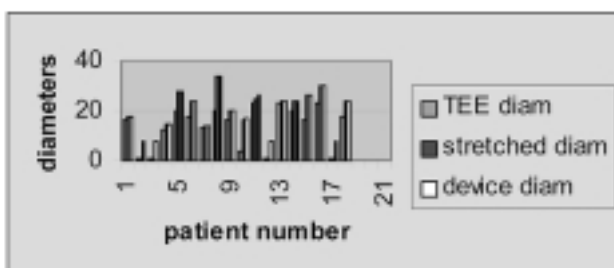
Systolic pulmonary pressure (mmHg)	28.1 ± 10.2
Diastolic pulmonary pressure (mmHg)	9.4 ± 6.7
Qp/Qs	1.8 ± 0.1
Pliable or aneurysmatic rim	6/18 (33.3%)
TEE diameter (mm)	14.4 ± 7.2
Range	4-23
Stretched diameter (mm)	19.5 ± 8.4
Range	8-34
Device diameter (mm)	19.8 ± 8.2
Range	8-34
Procedural success	94.9%

Qp/Qs = pulmonary to systemic blood flow ratio; TEE = transesophageal echocardiography.

diameter underestimated the balloon stretched diameter by 5.4 mm ($p < 0.001$). However, there was a linear correlation between the ASD-TEE diameter and the ASO size ($r = 0.89$) and between the stretched defect diameter and the ASO size ($r = 1$). Figure 2 shows a graph that compares the TEE, the stretched and the device diameter for every patient.

In 2 (11.1%) of the 18 patients who underwent ASD closure using the ASO device, asymptomatic coronary disease was discovered during coronary angiography. The right coronary artery was occluded in 1 of the 2 patients. The other patient had a focal, very tight stenosis of the circumflex and left descending coronary arteries. A percutaneous transcatheter coronary angioplasty was successfully performed in both patients before implantation of the ASO device.

The device was successfully deployed in all patients. Among the 18 patients, an ASO device ≥ 20 mm in diameter was used in 8 patients (44.5%), whereas a device ≥ 30 mm in diameter was deployed only in 2 cases (Table II). In 1 (5.6%) of 18 patients, a 3 mm shunt was identified during TEE color-flow Doppler performed after release of the device and the procedure was considered unsuccessful. In this case, TEE revealed a maximal ASD diameter of 16 mm and a very pliable postero-superior rim. The stretched diameter was 26 mm but after deployment of an ASO sized 26 mm a residual shunt was still present. In the other 17 patients

**Figure 2.** Comparison of transesophageal echocardiography (TEE)-stretched-device diameter.

(94.4%) the ASO device was successfully implanted. Following implantation of the device, a trivial shunt was identified during TEE examination in 6 patients (33.3%). In 3 patients the trivial shunt was through the stalk device and in the other 3 patients through the device disks immediately behind the aortic root. In these cases an antero-superior rim ≤ 5 mm was revealed by TEE (Table II). The mean total procedure time was 50 ± 19 min with a mean fluoroscopy time of 15 ± 6 min. In the 2 patients in whom a coronary angioplasty was performed, the procedure time was longer (83 ± 10 min) with a fluoroscopy time of 32 ± 7 min.

Rhinopharyngeal bleeding occurred in 2 (11.1%) of the 18 patients after the ASD closure procedure, but in no case were peripheral complications (fistula, pseudoaneurysm and thrombosis) or arrhythmia observed. TTE performed the day after the procedure confirmed the trivial shunts and the residual shunt of 3 mm in the same patients in whom they were identified during TEE performed immediately after the closure procedure. However, there were no problems (stenotic effect on the superior vena cava, atrioventricular valves and coronary sinus or thrombosis, infection, and device dislocation) which could be related to the implantation of the device.

Within the 6-month follow-up period, 1 (5.6%) of the 18 patients developed a supraventricular arrhythmia and needed medical treatment. A TTE examination was performed in all 18 patients at 6 months of follow-up. No shunt was found in the patients in whom a trivial shunt was visible after the procedure and the dimensions of the larger residual shunt were found to have decreased from 3 to 2.3 mm. Moreover, at 6 months of follow-up the mean right atrial length and the mean right ventricular outflow diameter were significantly reduced compared with the dimensions measured during the post-procedural TTE (53.1 ± 6.5 vs 48.5 ± 5.2 mm, $p < 0.005$, and 41.2 ± 6.7 vs 35 ± 5.1 mm, $p < 0.005$, respectively). At 6 months a trend towards shortening was observed for the mean right ventricular inlet size but the variation was not significant (44.2 ± 4.3 vs 42.6 ± 4.5 mm, $p = 0.056$). The mean right atrial width did not change significantly (46.4 ± 4.5 vs 44.9 ± 5.1 mm, $p = 0.08$). The systolic pulmonary pressures estimated during TTE were found to have decreased during the 6-month period after the procedure but again the variation did not reach statistical significance (28.1 ± 10.2 vs 25.3 ± 8.2 mmHg, $p = 0.065$).

Discussion

Our data confirm that transcatheter closure of secundum ASDs in adult patients using the ASO device is a safe and effective alternative to surgical closure and that the immediate and mid-term outcomes are excellent.

Previous studies have assessed the outcomes following ASD closure performed using the ASO device²⁻¹¹.

In most of these series, adolescent and adult patients were included. However, in adults there were particular features that have been taken into account. Owing to the fact that the shunt has been present for a longer time, the ASD and atrial dimensions are larger than in children. However, the successful ASD closure rate is similar in the two populations. Moreover, residual ASD rims may present different characteristics that could be important for a proper device deployment in adult patients. Since 1999 when the Brampton experience in ASD percutaneous closure in adult patients with the ASO device, few other experiences have been reported⁸⁻¹¹. Our experience confirms that in adult patients an ASD can be closed successfully with the ASO. Moreover, in our population ASO devices ≥ 20 mm were used in 55.6% of the patients and a device ≥ 30 mm was deployed in 2 cases (11.1%). However, a large ASD diameter is still a challenge for percutaneous closure. In our experience, 2 patients had to be referred to surgical closure because the available ASOs are not large enough for adequate repair of the defect. de Lezo et al.¹⁰ reported successful implants in 64.3% of the patients with an ASD diameter > 30 mm in whom a catheter closure was attempted with the ASO or a buttoned device. Moreover, the ASD rims and position still constitute a challenge for percutaneous closure. One of our patients needed surgical closure because of a posterior ASD with no postero-superior rim. In such cases, the risk of obstructing the superior vena cava is high and in our opinion ASD closure with the ASO is still contraindicated. Moreover, we confirm that in contrast to what applies for other devices, an antero-superior rim < 4 mm at two-dimensional TEE does not constitute a contraindication to ASO deployment⁹⁻¹¹. In 3 cases the antero-superior rim was not visible at TEE. In all of these cases the device could be successfully deployed. Owing to its round and flexible design, the ASO device can "spread-edge" to embrace the aortic root. Moreover, two-dimensional TEE may underestimate the dimensions of the antero-superior rim. Acar et al.¹² showed that, with the exception of the rim separating the defect from the aortic root (antero-superior rim), two-dimensional TEE was an adequate method for correct estimation of the rim surrounding the defect. In 3 of 28 patients who, on the basis of two-dimensional TEE suggesting insufficient tissue had been excluded, a dynamic three-dimensional reconstruction showed that the antero-superior rim was not in the same plane of the posterior rim. However, the absence of the antero-superior rim may determine technical problems while positioning the device and a trivial shunt may persist after deployment. In all of our patients with an antero-superior rim ≤ 5 mm, a trivial shunt with a jet directed through the device disks immediately behind the aortic root was observed. In such cases, it is good practice to use an oversized device 2 mm larger than the stretched diameter. However, as in the present study, a residual shunt may decrease or even disappear at fol-

low-up. These data confirm the findings of other groups and lead us to suggest that in the absence of complications, a residual shunt need not be repaired early after implantation of the device¹⁰⁻¹⁵.

In only 1 patient did a residual shunt, 3 mm in diameter, persist after device release. In this case TEE showed a maximal ASD diameter of 16 mm and a very pliable postero-superior rim. The stretched diameter was 26 mm but after deployment of an ASO sized 26 mm a residual shunt was still present. In patients with a pliable or aneurysmatic septum the stretched diameter has to be determined very accurately because it is often bigger than that measured at TEE. In these cases an oversized device, even 2-4 mm larger than the stretched diameter, should be used.

When adult patients undergo ASD closure using a percutaneous device, associated coronary disease and combined procedures of coronary revascularization have to be taken into account. For this reason, a coronary angiography is advisable before ASD closure in adult patients > 50 years of age. In our experience 2 patients had an associated coronary stenosis and needed a combined coronary angioplasty and ASD closure in the same session. As in the present study, a coronary angioplasty procedure increases the fluoroscopy time. For this reason the indication to a combined procedure has to be accurately evaluated in every single case.

ASD closure eliminates the overload volume of the right heart. In agreement with other experiences, our data show that the decrease in overload volume results in reduced dimensions of the right heart^{16,17}. In our experience, the right atrial length and right ventricular outflow diameter were significantly reduced at 6 months of follow-up. However, the right atrial and right ventricular morphology could not be considered as being completely normal. Pearlman et al.¹⁸ showed that right ventricular enlargement persists after ASD closure. This persistent right ventricular enlargement after ASD closure is the most common in patients > 40 years, suggesting, in older patients, an impaired ability of the right heart to remodel after prolonged volume overload. However, the volume overload reduction and the decrease in the dimensions of the right heart may be important to lower the risk of arrhythmia. It is interesting to note that in our series only 1 patient developed an arrhythmia at follow-up. On the other hand, arrhythmias are very common in case of adult ASD and often worsen during surgical ASD closure. However, these findings must be confirmed in studies with a longer follow-up.

Study limitations. The major limitation of the present study is the small population size that limits its statistical power. Nevertheless, the findings have clinical implications for physicians evaluating adult patients with ASD for possible transcatheter closure. Furthermore, this study assessed the Amplatzer outcome at 6 months of follow-up. A longer follow-up is necessary to evalu-

ate the real effectiveness and to assess late complications following implantation of such a device.

In conclusion, ASD transcatheter closure with the ASD device is a safe and effective alternative to surgical closure in adult populations. The immediate and mid-term outcomes are excellent. However, combined procedures may be necessary.

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