Transcatheter Closure of Secundum Atrial Septal Defects with Complex Anatomy

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ABSTRACT: The aim of this study was to evaluate the feasibility, safety and efficacy of transcatheter closure of secundum atrial septal defects (ASD) in patients with complex anatomy. From September 1997 to July 2003, a total of 40 patients (median age, 34 years; 65% female) with complex ASDs, defined as the presence of a large defect (stretched diameter > 26 mm) associated with a deficient rim (n = 23); multiple defects (n = 8); a multi-fenestrated septum (n = 5); and defects associated with an aneurysmal septum irrespective of their size (n = 4) underwent closure. The Helex device was used in 4 patients and the Amplatzer in the remaining. Two devices were implanted in 2 patients each. Implantation was unsuccessful in 5 patients, with 4 having large defects associated with a deficient anterior rim and a floppy posterior septum. Occlusion was observed in 22/35 patients (63%) immediately after implantation and in 31 (89%) at a mean follow-up of 18 ± 9 months. No major complications occurred. Right ventricular end-diastolic dimensions (indexed for body surface area) decreased from 135 ± 25% before closure to 124 ± 15% 24 hours after closure, and to 92 ± 12% after 12 months. Two patients with 2 giant defects and 2 patients with large defects remained with shunts (< 4 mm) at the latest visit. Transcatheter closure of complex secundum ASDs was feasible, safe and effective; however, large defects associated with a deficient anterior rim and a floppy posterior septum may not be suitable for this approach.


Key words: atrial septal defect, septal occluder device

Transcatheter closure of secundum atrial septal defects (ASDs) has evolved over the last 2–3 decades since its first description by King and Mills in 1976.1,10 Classically, selection criteria for adequate device placement included a single and centrally located defect with sufficient (> 4–5 mm) and firm surrounding rims. However, anatomical suitability for transcatheter closure has also evolved due to the versatile designs of some devices, especially the Amplatzer septal occluder (ASO; AGA Medical Corporation, Golden Valley, Minnesota), and refinements in implantation techniques. The aim of this study was to evaluate the feasibility, safety and efficacy of transcatheter closure of secundum ASDs with complex anatomy.

Methods

Definitions. For transcatheter purposes, secundum ASD with complex anatomy was arbitrarily defined as the presence of a large (stretched diameter > 26 mm) ASD associated with a deficient (< 4 mm) rim located at the anterior, inferior or posterior portion of the atrial septum; two separate ASDs within the septum (distant or close to each other); and a multi-fenestrated septum. Defects associated with a floppy, redundant and hyper-mobile atrial septum (excursion > 10 mm), considered to be aneurysmal, were also regarded as ASDs with complex anatomy, irrespective of their size.

Study subjects. From September 1997 to July 2003, a total of 143 patients with hemodynamically significant secundum ASDs with increased right ventricular end-diastolic dimensions (indexed for body surface area) and abnormalities in ventricular septal motion by transthoracic echocardiography (TTE) underwent an attempt of transcatheter closure mainly at our institutions (n = 104), but also at other centers in our country (n = 39). All attempts were performed or supervised by one of the operators (CACP, CAE, SLNB, VFF). Selection of patients with regard to transcatheter closure suitability was carried out by ambulatory transesophageal echocardiography (TEE) days to months prior to the procedure. Out of the 143 patients, forty (28%) were considered to have complex anatomy as defined above. Two patients with significant associated lesions. A 9-year-old girl had a 2.5 mm patent ductus arteriosus, which was occluded in the same catheterization session with a coil.11 A 51-year-old patient with a large defect (26 mm on TEE) had impaired left ventricular function (ejection fraction, 38%) due to an old anterior infarct. He was admitted to the hospital 24 hours before the procedure to receive intravenous diuretics and dobutamine in order to improve left ventricular diastolic function and prevent pulmonary edema after ASD closure.12,13 Patients with complex ASD anatomy ranged in age from 5–60 years (median age, 34 years) and weighed from 18–90 kg (median weight, 65 kg). Twenty-six patients (65%) were female. Informed consent for the procedure was obtained from all patients or guardians.

Devices and implantation procedure. The Helex device (William Gore and Associates, Flagstaff, Arizona) was used in 4 patients and the ASO device was used in all others. Device description and the basic implantation techniques for both devices have been previously reported.14,15 Modifications in the implantation technique for the ASO were required in some patients and are described below. All procedures were performed under general endotracheal anesthesia and TEE guidance.16 From September 1997 to November 1999, balloon sizing of the defect was performed using the dynamic method, as previously reported. A Meditech sizing balloon (Boston Scientific/SciMed, Inc., Maple Grove, Minnesota) was inflated

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with diluted contrast in the left atrium and brought toward the atrial septum until the defect was occluded, as documented by TEE. The balloon was gradually deflated, with gentle traction applied to the catheter. This was recorded on cine and TEE, and the diameter of the balloon at the moment it popped to the right atrium was considered to be the stretched diameter. A sizing plate was also employed to further assess the balloon diameter at that time. Since November 1999, the stationary method has been employed using a 24 or 34 mm sizing balloon (AGA Medical Corporation). The balloon was inflated with diluted contrast media until the appearance of a waist and disappearance of left-to-right shunting across the defect (‘stop-flow’). This was recorded on cine and TEE, and the size of the waist, which was considered to be the stretched diameter, was measured by both methods. In some patients, a second and smaller defect was only demonstrated after balloon occlusion of the larger one. When present, the size and location of the smaller defect was recorded, as well as the distance between both defects. When the defects were close to each other (< 6–7 mm), the sizing balloon was slightly overinflated to overstretched the atrial septum and possibly close the adjacent smaller hole. In the setting of 2 distant defects (> 7–8 mm), both were crossed with different catheters and 2 sizing balloons were positioned across the atrial septum to estimate the stretched diameter of each hole. In patients with multi-fenestrated septums, the most centrally located defect was crossed with a catheter and the stretched diameter was determined in the usual way. Defects associated with an aneurysmal septum were stretched using the least amount of diluted contrast medium in the balloon (static method) needed to generate a waist.

In general, ASO size was selected to be 0–2 mm larger than the stretched diameter. Oversizing the ASO up to 2–4 mm larger than the stretched diameter was employed in patients with large defects (stretched diameter > 26 mm) and a deficient (< 4 mm) or absent anterior rim behind the aorta. According to previously published protocols, the size of the Helix device was chosen to be at least 80–100% larger than the stretched diameter (max, 20–22 mm), with care taken not to overstretch the defect with the sizing balloon. The choice between ASO or Helix device was based on the availability of the device and the underlying anatomy. The Helix device was introduced in our country only in March 2002. From then on, it was primarily employed in patients with a fenestrated septum and with a small to moderate ASD associated with an aneurysmal septum, such as seen in 2 patients in this series. In patients with 2 defects close to each other (< 7 mm), a single device (either ASO or Helix, depending on the local availability) was implanted in the larger defect, with the smaller defect covered by the left and right atrial discs. In patients with 2 distant defects (> 7–8 mm), two separate devices (either ASO or Helix) were implanted in each defect according to previously published protocols. The smaller defect was the first to have a device deployed and not released. This was followed by implantation of a second device in the larger defect. After satisfactory positioning of both devices was confirmed by TEE, release from the delivery cable was carried out starting with the first implanted device.

The implantation technique of the ASO has evolved since the beginning of this experience and was modified according to the underlying anatomy and failure to implant the device at the first attempts using the standard technique. In patients with large defects and deficient anterior rims, the left atrial disc of the Amplatz device would often prolapse through the defect during deployment of the connecting waist, coming in at a perpendicular angle toward the atrial septum. To overcome this problem, some maneuvers were employed according to operator preference. First, the left atrial disc was initially deployed in the mouth of the left upper pulmonary vein, assuming a “bubble” appearance. The sheath was retracted to deploy part of the device in the left atrium and part in the right atrium. While retracting the sheath, gentle traction was applied to the delivery cable. This generally enabled the device to “catch” the atrial septum after both discs were reconfigured. Second, the left atrial disc was initially deployed at the mouth of the right upper pulmonary vein, allowing proper alignment of the left atrial disc with the atrial septum. The latter option was also employed in a patient with borderline (6–7 mm) posteroseptal rim (toward the superior vena cava). Third, a slight curve (30°) was manually shaped onto the distal segment of the delivery cable so that during deployment of the waist and the right atrial disc, the left disc would come parallel to the atrial septum. However, by doing so, in order to unscrew the device, the long sheath had to be re-advanced to rectify the delivery cable. After the sheath was gently touching and securing the device, the delivery cable was rotated in a counterclockwise fashion to unscrew and release the device. Sometimes, depending on its availability, instead of remodeling the delivery cable, the long sheath was changed for one with a very sharp curve (Cook Cardiology, Bloomington, Indiana) to achieve the same angle to attack the atrial septum. We did not cut the tip of the long sheath in an oblique fashion to enable the device to exit at an angle from the delivery sheath.

**TEE monitoring.** A complete TEE study was performed under general anesthesia just before the procedure. For complete assessment of the defect and the atrial septum, standard echocardiographic views such as four-chamber, short and long axis were employed. Generally, the superior and inferior rims were measured using the long-axis view, which demonstrated the superior and inferior vena cava in the same plane. The anterior and posterior rims were assessed using the short axis view at the level of the aortic root. Patients with a distance of < 5 mm from the margin of the defect to the coronary sinus, antroventricular valve (mainly the mitral valve) and the right upper pulmonary vein were excluded as candidates for transcatheter closure of the secundum ASD. TEE was employed throughout the procedure to assess device deployment and position, as well as the presence and magnitude of potential residual shunting after device release. Residual shunt was classified as trivial (jet width < 1 mm), small (1–2 mm), moderate (2–4 mm) or large (> 4 mm) according to the Toronto protocol.

**Post-procedure care and follow-up.** Cephalazin (20 mg/kg, max, 1 gram) was given during the procedure and at 8-hour intervals (total, 3 doses). Hemostasis was achieved by manual compression. The patients were awakened in the catheterization
laboratory and transferred to the recovery room for routine clinical observation. They were discharged home the following day and instructed to receive aspirin (2–5 mg/kg/day; max, 100 mg) for 6 months, to avoid contact sports for 2–3 months and to observe the recommendations for endocarditis prophylaxis for 6 months or until complete closure was documented. Chest radiograph, electrocardiogram and TTE were obtained before discharge. Right ventricular end-diastolic dimension measured by TTE was indexed for body surface area according to previously published protocols. TTE and TEE were performed after 6–12 months to assess chamber sizes, ventricular septal motion, device position and potential residual shunting. In the presence of residual shunting, TEE was repeated after 12 months.

Statistical analysis. Values are expressed as means and standard deviations or medians and ranges, as appropriate. Chi-square or Fisher's exact tests were used to assess changes in interventricular septal motion. ANOVA tests were employed to assess changes in the right ventricular end-diastolic dimensions with time. The level of significance was set at $p < 0.05$.

Results

**ASD features.** Of the 40 patients considered to have complex ASD, twenty-three had single and large defects associated with a deficient anterior rim ($n = 21$), posteroinferior rim ($n = 1$) or posteroinferior rim ($n = 1$), and an aneurysm of the interatrial septum ($n = 2$). In these patients, ASDs ranged in size from 20–30 mm (mean, 25.3 ± 2.7 mm; median, 25 mm), and the stretched diameter ranged from 26–36 mm (mean, 29.7 ± 3.4 mm; median, 30 mm). Six patients had 2 defects close to each other (1 associated with an aneurysmal septum), with the larger defect ranging from 14–25 mm (mean, 18.8 ± 3.6 mm; median, 18 mm) and a stretched diameter ranging from 18–31 mm (mean, 24.2 ± 4.8 mm; median, 23.5 mm). In these patients, the smaller defects were all located in the posteroinferior region of the interatrial septum and ranged in size from 2–5 mm. Five patients had a multifenestrated septum (2 associated with an aneurysmal septum), with the most centrally located defect having a stretched diameter ranging from 12–24 mm (mean, 16.4 ± 5.0 mm; median, 14 mm). Four patients had small to moderate defects associated with an aneurysm of the interatrial septum, ranging in size from 10–15 mm (mean, 12.5 ± 2.4 mm; median, 12.5 mm), and a stretched diameter ranging from 13–26 mm (mean, 21.2 ± 5.7 mm; median, 23 mm). Finally, two patients had 2 distinct defects (1 associated with a floppy posterior septum) with ASD diameters measured by TEE of 5 and 13 mm, and 3.5 and 5 mm, respectively, and stretched diameters of 8 and 21 mm, and 12 and 14 mm, respectively. The distances between the defects were 8 mm and 14 mm, respectively. No patient had more than 1 deficient rim.

**Procedure results.** We were unable to place the device across the atrial septum in 5 patients, four of whom were in the first half of our experience (the first 70 patients). These 4 patients had large defects (stretched diameters: 26 mm, 28 mm, 30 mm and 32 mm) associated with a deficient anterior rim and a thin, floppy and hypermobile posterior rim (Figure 1). In these patients, the Amplatzer devices would not anchor in the

![Figure 1. Transesophageal echocardiogram in short axis view at the level of the aortic root demonstrating a large atrial septal defect with no anterior rim behind the aorta associated with a thin and hypermobile posterior septum.](image-url)
Discussion

Initial prerequisites for device closure of secundum ASDs were strict mainly because of device and imaging limitations. As imaging modalities evolved with the advent of high-quality TEE, computer software for 3-D reconstruction, and the recently introduced intracardiac echocardiography (ICE), a better understanding of the anatomy of the atrial septum was achieved. In addition, new device designs and sizes became available, which enabled the physicians to extend the eligibility criteria. This study further confirms the feasibility, safety and efficacy of transcatheter closure of secundum ASDs with complex anatomies, especially those that are large, with deficient anterior rims and multiple defects. However, at least in our hands, there are still some anatomical features that limit device placement.

This study confirms the good outcomes of transcatheter closure of large secundum ASDs associated with deficient anterior rims using the Amplatzer device. Because of its inherent design, the Amplatzer embraces the posterior wall of the aorta in the setting of no anterior rim. Stable device position is achieved by the stenting mechanism given by the connecting waist in the defect. However, aortic wall erosion can result from this device position.

We agree with Du et al. that as long as the defect has sufficient rims around 75% of its margins, device implantation is feasible. Stable position is achieved and elimination of shunting is likely. Although in this report we had a single case of deficient inferoposterior rim, the same concept can be applied to these circumstances, as shown by the same author. Implantation of the Amplatzer in patients with large ASDs associated with a deficient anterior rim can be challenging and technically demanding.

We believe that opening the left atrial disc at the mouth of the left or right upper pulmonary vein, hand-shaping the delivery cable or using a long sheath with a tight curve can be helpful to overcome the problem of mal-alignment between the left atrial disc and the atrial septum. Also, slight oversizing of the device (2-4 mm larger than the stretched diameter) may be helpful to better anchor the device in the atrial septum and not miss the anterior aortic moud. Longer, though not prohibitive, fluoroscopic and procedural times may be required in these challenging cases. On the other hand, this experience suggests that large ASDs associated with a deficient anterior rim and a floppy, thin and hypermobile posterior rim are not good candidates for transcatheter closure using the Amplatzer device. In this scenario, although there is enough rim around 75% of the defect, the floppy posterior rim does not offer enough support for adequate stabilization of the ASO. Because our failures to implant the device in such cases occurred at the beginning of our experience, it is possible that the application of the technical modifications described above at the very start of the procedure may have enabled satisfactory device positioning. This, in turn, should limit device manipulation in the left atrium and reduce the likelihood of tearing the thin posterior septum. However, failure to implant the device in the setting of large defects and a floppy septum has also been described in other series. Some have suggested that other anatomic features may also limit transcatheter closure of secundum ASDs, including those near (< 5 mm) viral structures such as the atroventricular valve.

toward the superior vena cava, the right disc of a 28 mm ASO displayed some protrusion toward the superior vena cava, without resulting in local flow disturbance or pressure gradient.

Immediate complete closure was achieved in 22/35 patients (63%). Seven patients had trivial to small shunts, five had moderate shunts and six had a large shunt.

Complications. One patient with a 28 mm ASD (stretched diameter) associated with a deficient posterior rim received a 30 mm Amplatzer device. Soon after its release, TEE showed that the device, although stable, was positioned in an oblique fashion across the atrial septum, with the superior portion of the left atrial disc prolapsing into the right atrium at the superior vena cava level. The centrally located screw of the device was snared via the femoral vein and the device was recaptured into a 14 French sheath with no complications. A 32 mm ASO was subsequently and successfully implanted in the usual fashion.

One patient had signs and symptoms of acute arterial occlusion in the left leg despite the use of the right femoral vein for the procedure. Retrospective inspection of the equipment used during the procedure revealed that the Meditech sizing balloon was ruptured and a fragment was missing. Surgical retrieval of the embolized fragment was carried out with no complications.

Two patients had transient episodes of supraventricular tachycardia during device deployment, controlled with adenosine administration. One patient (ASD, 20 mm; stretched diameter, 28 mm; ASO device, 32 mm) had transient junctional rhythm with good ventricular response after the procedure. After a 3-day course of corticosteroids, sinus rhythm was restored.

Follow-up results. TTE before discharge revealed that 26/35 patients (74%) had complete closure. Interventricular septal motion normalized in 31/35 patients (89%; p < 0.001). Twelve-month follow-up data were available in 25 patients (71%). At a mean follow-up of 18 ± 9 months, all patients were asymptomatic and 31 patients had complete closure (89%). The right ventricular end-diastolic dimensions (indexed for body surface area) decreased from 135 ± 25% to 124 ± 15% at 24 hours after closure, to 105 ± 16% at 3-month follow-up and to 92 ± 12% at 12-month follow-up (p < 0.001). Both patients with 2 separate and distant defects, and 2 patients with large and single defects (1 with left ventricular dysfunction post-infarct), remained with shunts at the latest follow-up visit (11%), being trivial to small in 2, and moderate to large in 2. However, right ventricular end-diastolic dimensions normalized in these patients. All patients with 2 close defects, small to moderate defects associated with an aneurysm of the interatrial septum and multifenestrated septum, had complete closure of their defects. Interventricular septal motion was normal in all patients at the latest follow-up visit.

There was no flow abnormality in the inferior or superior vena cava and no de novo mitral regurgitation at the latest echocardiographic evaluation. Reduction of the profile of the ASO device was observed in the patient with limited superior rim toward the superior vena cava. No new arrhythmias or other complications were observed during follow-up.
coronary sinus and right upper pulmonary veins. In this regard, we believe that a borderline (6–7 mm) superior rim near the superior vena cava is not per se a contraindication for transcatheter closure. In this setting, the device should be implanted using the right upper pulmonary vein approach and as long as there is no major flow abnormality in the superior vena cava and in the right upper pulmonary vein, device release can be performed despite slight protrusion toward the superior vena cava. Reduction of the device profile with time will result in a satisfactory cosmetic result, as seen in one of our patients.

This study has also shown that transcatheter closure of fenestrated septums and multiple ASDs is feasible using some technical variations. We were able to close ASDs associated with a fenestrated septum using a single standard ASO device implanted in the most centrally located hole. The stenting mechanism within the central defect helps to “smash” the adjacent holes, providing effective occlusion. Some may argue that if the central defect is too small, it may limit the size of the ASO to be used. Consequently, the adjacent holes may not be effectively covered. Although we believe that this scenario is extremely uncommon, performing a Rashkind septostomy to implant a larger device can be an option in such cases. Using a “patch” type of device, such as the CardioSEAL or Helex device, or the new modified Amplatzer ASD device (Cribiform), may be a more reasonable alternative in this setting; however, the standard ASO worked well and closed all such defects in this series. When there are 2 separate ASDs, the distance between them will dictate the management strategy. Because the standard ASO has a self-centering mechanism and the left atrial disc is 12–16 mm larger than the connecting waist, close defects (6–7 mm) can be occluded with a single device implanted in the larger hole, with the smaller hole covered by the left atrial disc. This was observed in all patients with this anatomical arrangement in our series. When the distance between the defects is > 8 mm, the use of 2 separate ASO devices becomes mandatory. In contrast, the use of a single device without a self-centering mechanism, such as Helex or CardioSEAL, may provide coverage for a distant defect in some cases. However, too distant defects do require 2 different devices, as seen in 1 patient in this series. It is important to note that multiple defects may be diagnosed only after balloon occlusion of the larger hole. Leaving a too distant defect of 1–2 mm of diameter uncovered may also be acceptable from the clinical efficacy viewpoint in some cases. Although we did not achieve complete closure in both patients with 2 distant defects in this experience, better rates have been seen in larger series of such patient.

Although the standard ASO has been used to close ASDs associated with aneurysmal and hypermorphic septum (as seen in 7 cases in this series), such anatomy is probably more suitable for devices that do not rely on a stenting mechanism within the defect to achieve stabilization in the septum. This may be particularly true in small to moderate defects. The relatively larger area of each disc on each side of the septum provides septal stability in “patch” type devices, such as Helex or CardioSEAL, which are also lighter and have a lower profile than the standard ASO. This was the rationale to use a Helex device in 2 subsequent patients with small ASDs associated with an aneurysmal septum in this series. However, large defects associated with an aneurysm of the interatrial septum (as seen in 2 patients) may well require a large ASO device or may not even be amenable to transcatheter closure. Failure to implant a Helex device in a patient in this series might have been related to our initial learning curve or even to a technical problem with the locking mechanism of the device rather than the underlying anatomy. Further developments by the company have been made to correct this problem in the latest version of the Helex device. Unfortunately, device removal resulted in a septal tear, which precluded implantation of a new device. In this regard, the finding of tears in the floppy portion of the atrial septum in 3 patients in this series is worrisome and suggests that extreme care should be taken during manipulation of devices and delivery systems in patients with this anatomical feature.

The rate of complete closure in this series was 89%, which is slightly lower than the classically reported 94–96% overall occlusion rate observed with the use of the ASO and Helex devices. Lower overall closure rates have also been reported for patients with large defects. In addition, patients with deficient rims may have lower rates of complete closure compared to those with sufficient rims, although this was not statistically significant in a previous published report. More importantly, the procedure corrects the hemodynamic burden to the right ventricle, reflected by the significant and progressive reduction of the right ventricular end-diastolic diameter associated with normalization of the septal motion in the whole population in this series. Moreover, right ventricular dimensions returned to normal in all patients with residual shunting, providing clinical cure even in a patient with a 4 mm residual shunt. The risk of endocarditis and paradoxical embolization in patients with residual shunts after device closure remains unknown. Interestingly, the presence of a residual shunt in the patient with impaired left ventricular function, although not deliberate, may have been helpful to decompress the left ventricle. It has even been suggested that fenestrated devices should be used in this clinical scenario.

In conclusion, this report shows the feasibility, safety, and efficacy of transcatheter closure of large secundum ASDs associated with a deficient anterior rim and a firm posterior rim, multiple ASDs, ASDs with fenestrated septum, and ASDs associated with an aneurysmal septum. In our hands, patients with large ASDs associated with a deficient posterior rim (< 4 mm) and a floppy and hypermorphic posterior septum were not good candidates for the transcatheter approach. Surgery should be considered in these patients.

Disclosure. This paper was presented, in part, at the XIV Brazilian Congress of Echocardiography and received an award for Best Abstract in Congenital Heart Disease.

Addendum. After this paper was accepted for publication, we performed transcatheter closure of complex ASDs in 8 additional patients. One had 2 distant holes, requiring 2 ASOs, with immediate occlusion and no complications. Five had large defects, four associated with a deficient anterior rim and 1 with a deficient posterior rim. All had ASOs implanted with immediate occlusion and no complications. One patient had 2 defects close to each other associated with an aneurysmal septum. A single
ASO was implanted; however, a 2 mm immediate residual shunt was observed in the posterior inferior portion of the septum where the second smaller hole was located. The remaining patient had a moderate ASD associated with an aneurysm of the interatrial septum, completely closed with a Helex device. This further experience corroborates our previous observations.

References


