Transcatheter Closure of Secundum Atrial Septal Defects with the Amplatzer Septal Occluder: Early Experience

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Abstract

Background: Secundum atrial septal defect is a common congenital heart defect that causes right heart volume overload and produces symptoms usually after the third decade of life. Treatment until the last few years has been open heart surgery.

Objectives: To review our early experience with transcatheter closure of ASD2 using the Amplatzer septal occluder.

Methods: Between November 1999 and February 2000, 20 children and young adults with a median age of 9.1 years (4.2-35.1 years) were referred for transcatheter closure of ASD2. Diagnosis was established by transthoracic echocardiography. Implantation was performed under general anesthesia through the femoral vein with the guidance of transesophageal echocardiography and fluoroscopy. Femoral arterial puncture was performed for blood pressure monitoring during the procedure. The device size chosen was similar to the balloon-stretched diameter of the ASD2.

Results: Implantation was completed successfully in 18 patients. Two patients were referred for elective surgery: one had an unsuitable anatomy for transcatheter closure by TEE in the catheterization laboratory, and the device could not be implanted properly, the other patient had a large multi-perforated septal aneurysm that was retrieved. Mean ASD2 diameter by TTE and TEE was similar (13.9 $\pm$ 3 mm, 13.4 $\pm$ 3.5 mm) and mean stretched diameter was 18.3 $\pm$ 4.3 mm. Mean Qp:Qs (pulmonary flow: systemic flow) was 2.2 $\pm$ 0.6. Mean fluoroscopy time for the procedure was 14.8 $\pm$ 4.8 minutes. The patients were discharged the day after the procedure. Four patients had a tiny leak immediately post-procedure, and none had a leak at one month follow-up. The only complication was a small pseudoaneurysm of the femoral artery in one patient, that resolved spontaneously.

Conclusions: Transcatheter closure of ASD2 with the Amplatzer septal occluder is a safe and effective alternative to surgical closure. Long-term outcome has to be evaluated.

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ASD2 = secundum atrial septal defect
TEE = transesophageal echocardiography
TTE = transcatherer echocardiography

The development of interventional cardiac catheterization techniques and devices presents an alternative therapeutic approach to surgery for various congenital heart defects. In this article we review our initial experience with transcatheter closure of atrial septal defects of the secundum type.

ASD2 is a common form of congenital heart disease. It allows for an intracardiac shunt, whose direction and volume depend on a combination of defect size, right and left ventricular diastolic function and pulmonary and systemic vascular resistances [1]. In the otherwise normal heart, ASD2 causes a constant flow of blood from left to right across the defect, particularly in diastole [1]. The shunt imparts a volume load on the right ventricle causing dilation and progressive myocardial changes [2]. This may contribute to the development of right heart failure later in life [3]. Chronic right atrial enlargement may cause atrial arrhythmias, usually atrial flutter or fibrillation, which are more common after the third decade of life and become more frequent with increasing age [3]. The increased pulmonary blood flow exerts increased shear stress forces on the pulmonary vascular bed, with subsequent dysfunction and morphological changes leading to pulmonary vascular disease [4].

Closure of an ASD2 eliminates the hemodynamic disturbance and is beneficial to most patients in all age groups. The indications for closure include the clinical or echocardiographic presence of right ventricular dilatation or a pulmonary/systemic blood flow ratio greater than 1.5:1. [1,3,5]. Surgery for ASD2 entails general anesthesia, sternotomy, cardiopulmonary bypass, cardioplegia, right atrial incision, primary or patch closure of the defect, and 5–7 days recovery depending on the age of the patient. Recovery is usually uneventful, but approximately 18% of the patients develop post-pericardiotomy syndrome in the early postoperative period [6].

Due to the anatomic characteristics of the lesion and its accessibility at cardiac catheterization, transcatheter techniques for ASD2 closure have been developed. We report on our initial experience with the Amplatzer septal occluder device (AGA Medical Corporation, USA). The device is made of nitinol (a shape-memory nickel-titanium alloy), which returns to its original preformed shape when extruded from the small delivery catheter into which it has been collapsed. The expanded device

consists of two discs connected by a central tube woven from nitinol wire with pieces of Dacron filling them. The discs lie on either side of the atrial septum, while the central part fills the defect itself. The device size is chosen to match the balloon-stretched diameter of the ASD2 as measured at cardiac catheterization.

Patients and Methods

Between November 1999 and January 2000, a total of 20 patients (6 males and 14 females) with a median age of 9.1 years (4.2–35.1) were referred for transcatheter closure of ASD2 following evaluation by transthoracic echocardiography. Patients were selected if a circumferential rim of septal tissue was present around the ASD2. A narrow rim or the absence of a rim adjacent to the aortic aspect was not a reason for exclusion. All patients or parents of young patients signed an informed consent after a thorough discussion about the options of surgery and device closure of the ASD2.

All patients underwent general anesthesia and transesophageal echocardiography prior to catheter insertion. TEE evaluation included the size and position of the defect and its anatomic relationship to the vena cavae, aorta and atrioventricular valves, presence of additional defects, and identification of all pulmonary veins. Access of femoral vessels was performed by the Seldinger technique, and a 7–8Fr sheath was placed in the vein and a 4Fr sheath in the artery for continuous blood pressure recording. Patients received 100 IU/kg of heparin and 25 mg/kg of cefonicid intravenously. A right-sided hemodynamic study was performed including shunt calculation. An end-hole catheter was then advanced into a left pulmonary vein via the ASD2. In the cases of fenestrated ASD2, caution was taken to pass through the largest of the defects using TEE guidance. A stiff exchange wire was inserted into the pulmonary vein and both catheter and sheath were removed. A sizing balloon was advanced into the defect and inflated with diluted contrast fluid until a waist was clearly seen. The presence of a waist was also noted on TEE and the balloon was inflated until no evidence of leak on color Doppler was present. The waist diameter was measured on TEE and fluoroscopy, usually in the right and left anterior oblique projections. The balloon was then removed and a device similar in size to the stretched diameter was screwed onto the loader of the delivery system. (By convention, the device size is defined as the diameter of the waist between the two discs, and this size is chosen to match the balloon stretched diameter of the ASD2.)

A long sheath and dilator were advanced over the wire to the left atrium/pulmonary vein, and the dilator and wire were removed with care to prevent air embolism. The device was then collapsed into the sheath and advanced to the left atrium. Under TEE and fluoroscopic guidance the left atrial disc was extruded into the left atrium and the whole system withdrawn so that the disc engaged the septum [Figure 1]. When the position seemed satisfactory, the right atrial disc was extruded by pulling back the sheath, taking care not to move the device. When the position was satisfactory on TEE, stability of the device was assessed by pushing and pulling. The device was then released by unscrewing it from the loader [Figure 2]. The delivery system and sheath were removed and pressure applied to the groin until bleeding stopped.

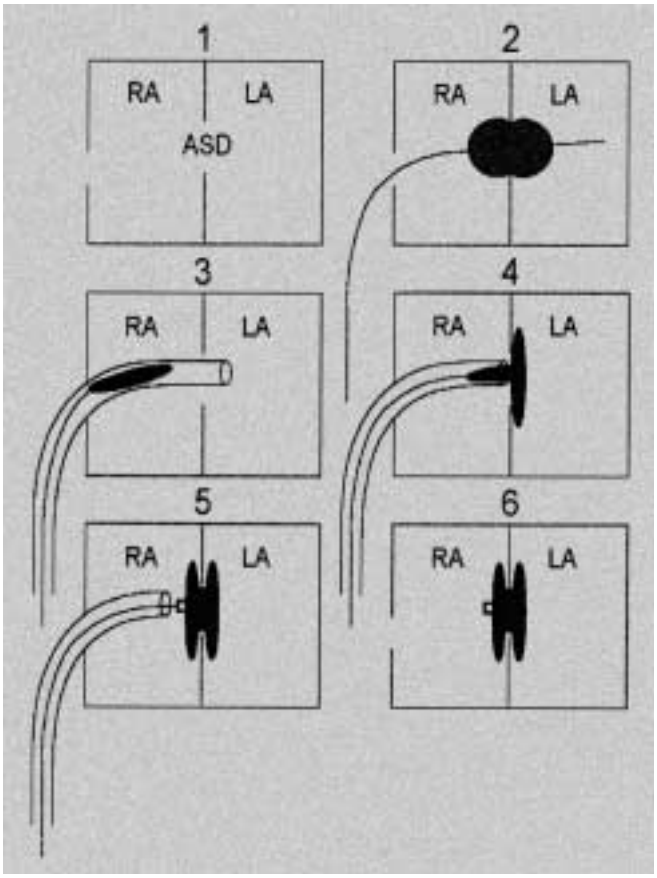

Figure 1.
RA = right atrium, LA = left atrium, ASD = secundum atrial septal defect.
1. Atrial septal defect secundum (ASD)
2. Balloon sizing of ASD to determine the stretched diameter
3. Device is loaded into a long sheath placed in LA
4. The distal disc of the device is opened in LA
5. The proximal disc is opened in RA by pulling the sheath back. The device is still retrievable by the wire.
6. The device is released by unscrewing the wire.

The patients stayed overnight and were discharged home the following day on aspirin 5 mg/kg daily and sub-acute bacterial endocarditis prophylaxis for a period of 6 months. A follow-up appointment was scheduled for 2 weeks later.

Results

Patients

Of the 20 patients admitted for transcatheter ASD2 closure, 18 underwent successful Amplatzer device implantation. In one of the 18 patients the device was retrieved prior to release due to

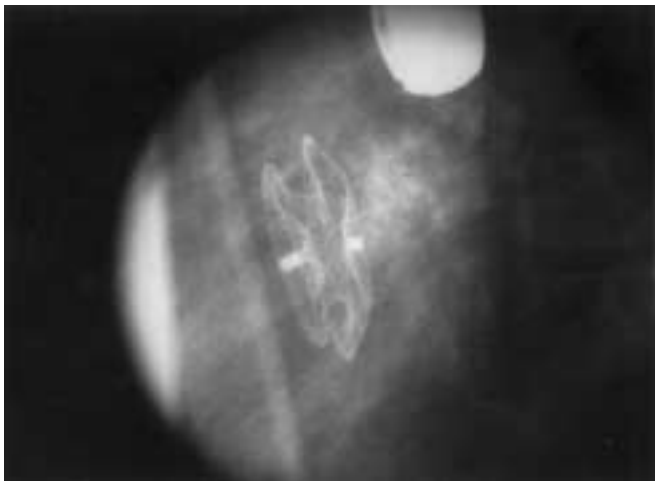

Figure 2. Amplatzer septal occluder, a fluoroscopic view.

protrusion into the right atrium and replaced with a device one size larger, with no complications. Another patient had had critical pulmonic stenosis in infancy and had undergone a Rashkind atrial septostomy, surgical valvotomy and subsequent balloon pulmonary valvuloplasty. He remained with an atrio-septal defect with bi-directional flow. Successful transcatheter closure of the ASD was performed after a trial of temporary balloon occlusion of the ASD failed to reduce cardiac output.

Two patients were referred to surgery. In one patient TEE in the catheterization laboratory revealed an unfavorable anatomy for device closure (large ASD2 and absence of inferior rim). In a second patient with a large ASD2 and additional smaller ASD2 and large septal aneurysm between the two defects, repeated implantation attempts were unsuccessful since the left atrial disc would not align to the interatrial septum. Eventually the device was withdrawn and the patient underwent an elective surgical closure of the defect with an uneventful recovery. All implantations were performed without angiography with a mean fluoroscopy time of 14.84.8 minutes per case.

Defect and device measurements

Mean ASD2 diameter was similar on TTE and TEE evaluation (13.9 ± 3 and 13.4 ± 3.5 mm respectively) and significantly smaller than the balloon-stretched diameter (18.34.3 mm) ($P < 0.01$). The balloon:TEE diameter ratio was 1.4 ± 0.2. Mean device:stretched diameter ratio was 1.0 ± 0.1.

Hemodynamic data

All patients had a detectable left-to-right shunt at catheterization with a Qp:Qs of 2.2 ± 0.6. None of the patients had evidence of pulmonary hypertension, with a mean pulmonary arterial pressure of 15.3 ± 2.1 mmHg.

Defect closure

TEE showed small leaks through the device in four patients immediately after implantation. All patients are well and with no residual leaks at one month follow-up.

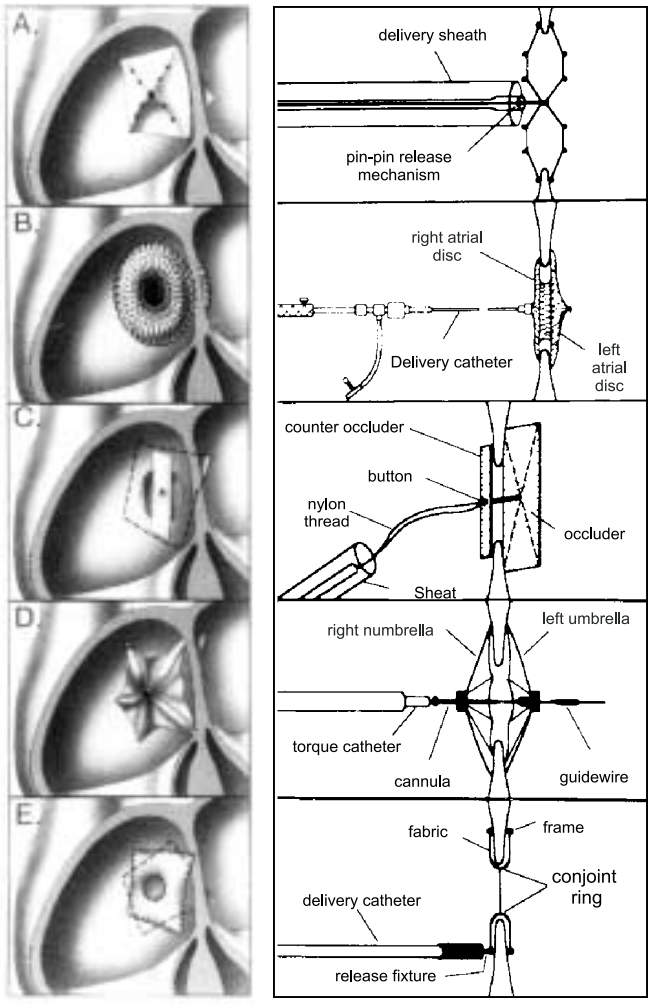

Figure 3. (Reprinted with permission from Rocchini A, Lock JE. Defect closure: Umbrella devices. In: Lock JE, Keane JF, Perry SB, eds. Diagnostic and Interventional Catheterization in Congenital Heart Disease, 2nd ed. Kluwer Academic Publishers: 2000 pp. 179–98.]

A. Cardioseal
B. Amplatzer
C. Button
D. ASDOS
E. Angel wings

Complications

All 20 patients were discharged the following day (two patients underwent elective surgery later). There were no admissions to the intensive care unit. One patient developed a small pseudoaneurysm of the femoral artery, that resolved spontaneously. Three patients complained of headaches soon after the procedure (the etiology is still unknown). Their physical examination was normal and the symptoms resolved with time.

Discussion

The ability to safely and effectively close atrial septal defects was achieved over 50 years ago by heart surgery. This procedure is now considered simple open-heart surgery with low morbidity and low mortality (1% or less) [3]. The most frequent complication is post-pericardiotomy syndrome that can usually be treated with anti-inflammatory drugs. The advent of transcatheter closure techniques for ASD2 closure has minimized the degree of invasiveness to the patient even further, with the inherent advantages of almost no pain, discharge from the hospital the day after the procedure, and rapid recovery when compared to heart surgery.

The considerable number of devices for transcatheter ASD2 closure that has been developed over the years attests to the difficulties encountered in device design and delivery. These include Cardioseal and its modification with a centering mechanism named Starflex, Amplatzer, Button, ASDOS, Angel wings [Figure 3], and the new Gore device. Essentially, most of the devices consist of conjoined discs or a disc and fixator, with the disc composed of synthetic fabrics and a metal skeleton. When extruded from the sheath, one of the discs overlies the ASD2 on the left atrial side and the second disc is extruded in the right atrium, with both discs overlying the defect and occluding it. For successful delivery of the device there needs to be a concentric rim of tissue around the defect, which will allow the device to be deployed without interfering with atrioventricular valve function, and sufficient margins to maintain position and prevent embolization [7,8]. Current devices are therefore inappropriate for sinus venosus and ostium primum defects.

Problems encountered with earlier devices included large or complex delivery systems, device breakage, irretrievability, embolization and leaks. The latter were usually due to lack of centering the device in the defect. The Amplatzer device presents a solution to some of these problems: It is retrievable even once the right atrial disc is fully extruded, and the delivery system is simple and small [7–10Fr]. The device stents the defect with its central tube, which self-centers the device to minimize embolization and leaks. Therefore exact sizing of the defect is essential. In our study we found a good correlation between the diameter of the waist of the sizing balloon measured on TEE and fluoroscopy. The advantage of TEE during balloon sizing is that color Doppler imaging clearly demonstrates the presence of additional septal defects. We found this of particular help in fenestrated ASD2 where TEE also could determine in which hole the sizing balloon had been placed.

Possible disadvantages of the Amplatzer device are that it is somewhat bulky and consists of a large amount of nitinol. This has raised the issue of possible nickel toxicity in the future, although there have been no supporting data [9,10]. Also, in case of embolization, the device may be difficult to retrieve and require surgical retrieval.

In our group of patients there was a good correlation between defect size on transthoracic and transesophageal echocardiography. Transthoracic echocardiography afforded a reliable evaluation of defect size in most patients, and although it underestimates the balloon-stretched diameter, this can be approximated by adding 4–6 mm. However, in older patients with poor echocardiographic windows it may be appropriate to perform TEE prior to a decision on transcatheter closure.

In this small and early study, we found the Amplatzer septal occluder to be "user friendly," major complications were not encountered and closure rate was excellent. The long-term effects of transcatheter ASD2 closure are unknown though its major short-term advantage is the avoidance of heart surgery. The future remains undefined at present, however it is probable that surgery for ASD2, as has been the case for patent ductus arteriosus, will become almost redundant as transcatheter techniques and devices continue to improve.

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Odi et amo
I hate and I love
Catallus, Roman poet (84-54 BC)