Transcatheter Closure of Secundum Atrial Septal Defect Using the Amplatzer Device: Single Center Experience in 140 Patients

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ABSTRACT

In this paper we present our experience with the Amplatzer septal occluder device, employed in 140 patients for percutaneous closure of atrial secundum defect (ASD), from October 2002 to February 2006. The age of patients ranged between 5.3 and 70 years, median 21.9 years. Procedure time ranged between 25 and 240 minutes, median 60 minutes; fluoroscopy time ranged between 3.5 and 45 minutes, median 12 minutes. Transoesophageal echocardiography was used to monitor the implantation procedure. The size of the selected device was 1 to 2 mm larger than the stretched diameter of the defect and ranged between 6-40 mm. Two devices have been implanted in two patients. Serious procedure related complications (embolization and perforation of the left atrial wall) occurred in two cases. At follow up (10 days to 3.4 years, median 2.3 years) complete closure was documented in 97% of this patient group. Unrecognized during implantation, but detected after release, small additional defect with trivial residual shunt was documented in 4 patients. A young critically ill patient, cyanotic due to right-to-left shunt, with complex congenital heart disease developed a brain abscess three months after implantation. In conclusion, percutaneous ASD closure with use of the Amplatzer device in this patient cohort was highly successful with a low complication rate.

INTRODUCTION

The first nonoperative closure of atrial secundum defect (ASD) was performed by Noel L. Mills and Terry D. King in a 17-year old female patient on April 8, 1975 [1,2]. In the following years (1983) Rashkind developed a Clamshell device [3]. There was little interest in this clinical field and the trials with the “Clamshell Device” had been discontinued because of arm fractures. From the late 1980s until the mid 1990s E. B. Sideris (“Buttoned Device”) [4] and Babic [5] (“ASDOS”) kept the ideas of King & Mills alive while G.S. Das developed the first self-centering device (“Angel Wings”) [5-7]. Clinical trials with ASDOS and AngelWings have stopped because of complicated technology and risk of perforation. Since the pioneering works of King & Mills marked improvements in devices and delivery systems have been achieved.
Device ASD closure is now widely practiced and has replaced surgical ASD closure in many centers. Improvements in design have made the devices retrievable, and reduction in the size of the introduction systems allows interventional treatment even in young patients. Different types of device are in widespread use, and new devices are being introduced. While the patch type occlusion device—represented by the Cardi oSeal, or its modification, the StarFlex [8,9] occluder (NMT Medical) and the Helex-device [7] (Gore) mimics surgery by placing a patch over the ASD, the self centering Amplatzer septal occluder [6,8], (AGA Medical Corporation) offers a different approach by stenting the interatrial communication. This unique technique makes it possible to close even up to 40 mm large defects, while the inability to close such large defects remains a limitation of the patch type devices.

Since the first clinical trials with the Amplatzer septal occluder in 1995 and 1997, there have been many reports of excellent early follow up results after ASD closure with the Amplatzer occluder [6-12]. We now report our own clinical experience and short-midterm results with this device in patients who have presented with ASDs in our center.

**PATIENTS-METHODS**

Between October 2002 and February 2006, 206 consecutive patients with a significant ASD, demonstrated by initial transthoracic echocardiography (TTE), were considered for transcatheter closure with the Amplatzer septal occluder. A total of 156 patients underwent cardiac catheterization, and 140 patients had successful transcatheter ASD closure with the Amplatzer device.

Routine examination before catheterization included a standard ECG, a chest x ray, blood tests and TTE (Figure 3A). Magnetic resonance imaging (MRI) (Figure 3B), transesophageal echocardiography (TEE), Valsalva maneuver and contrast injections were performed in selected cases.

We followed the manufacturer’s recommendation for echocardiographic exclusion criteria if the patient presented in TTE or TEE a distance of less than 5 mm from the rim of the defect to the atrioventricular valves, the coronary sinus, or the right upper pulmonary vein. After ASD closure the patients remained in the hospital for one night, and received heparin (partial thromboplastin time ≥50-60 seconds) for 14-18 hours, followed by aspirin 2-3 mg/kg/d or clopidogrel 75 mg/d for six months. In the stroke group and in cases with coagulation disorders warfarin or acenocoumarol were given for six to twelve months. Before discharge an ECG, a biplane chest x ray, and a TTE examination were performed. Follow up examinations including ECG were scheduled at 1, 3, 12, 24, and 48 months after the procedure. The 3 and 12 month follow-up examination also included a 24 hour Holter ECG recording. In order to study the right ventricular-remodeling, MRI studies were performed in 32 patient 3-12 months before and after transcatheter closure.

The initial TTE (Figure 4) showed the location of the ASD, its septal rim, and its diameter and also enabled us to measure the length of the interatrial septum in the four chamber view. These measurements were used to assess the feasibility of transcatheter closure with the Amplatzer septal occluder. The Amplatzer septal occluder is a self expanding, self centering, and repositionable double disc device constructed of a mesh of 72 nitinol wires. A 3-4 mm short cylindrical waist connects...
the two round discs. Basically, the Amplatzer septal occluder stretches and stents the ASD. Thus the diameter of the waist has to correspond to the so called “stretched” diameter of the ASD, determined by a balloon sizing catheter. Additionally, polyester fibers are sewn into the device promoting thrombosis and complete defect occlusion. Twenty seven different sizes with waist diameters from 4-40 mm are available. For devices between 4-10 mm, the left atrial disc is 12 mm larger than the waist and the right atrial disc is 8 mm larger. For bigger devices the left atrial disc is either 14 mm larger than the waist (waist diameter 11-30 mm) or 16 mm larger than the waist (waist diameter 32-40 mm).

For transvenous implantation of the Amplatzer occluder, the manufacturer provides a loader, a delivery cable, and a 6-12 French long sheath. Before loading the device into the long sheath it is connected to the delivery cable by a micoscrew fixed to the right atrial disc. In the catheterization laboratory a biplane transesophageal echocardiogram (TEE) was done under general anesthesia (in all except one) to evaluate the size and location of the defect and its margins. Vascular access was obtained from the femoral vein, and heparin (100 IU/kg max 9000 IU, ACT ≥250), and antibiotics (cefazolin) were given; two cases with coagulation disorders received danaparoid sodium (Orgaran). After making a complete haemodynamic evaluation, an anomalous pulmonary vein connection was excluded by angiocardiography in the pulmonary artery. The

“stretched” diameter of the ASD (Figure 5A, 5B and 5C, 5D, 5E: 2 defects, 2 balloons) was measured using a Numed or Amplatzer sizing balloon. A device with a waist diameter similar to, or in large defects up to 2 mm bigger than, the stretched ASD diameter was chosen. After introducing the long sheath over the exchange guide wire into the left upper pulmonary vein, the device was inserted and deployed under fluoroscopic and TEE guidance, as described in previous publications. A secure and stable position of the occluder within the defect was checked by a push-pull maneuver (Minnesota wiggle). The device and adjacent structures were then examined by TEE to ensure that there was no encroachment of the device on the atrioventricular valves or the right pulmonary veins. After releasing the device from the cable by unscrewing it (Figure 7), a final TEE examination was undertaken to demonstrate the position of the device and any residual shunting (Figure 8).

**RESULTS**

Between October 2002 and February 2006, 156 patients underwent cardiac catheterization, and 140 patients had successful transcatheter ASD closure with the Amplatzer device. Their ages ranged from 5.3 to 70 years (median 21.9 years), 49, 35%, were male, 91, 65% female (Figure 1 and 2 for age and gender distribution). The majority (85%) of the patient group showed a simple, single centrally located fossa ovalis ASD on echocardiographic examination, while 15% of the cases had multiple or fenestrated defects, an additional septal aneurysm, inferior extension of the defect towards the atrioventricular valves or coronary sinus. Nine patients suffered from stroke. One patient had a significant residual ASD after previous
CardioSeal implantation, two devices were implanted in two patients, one during the same session.

On TEE, the maximum defect diameter varied between 4-38 mm, while the balloon stretched diameter (Figure 5) varied between 6.5-40 mm. Implanted devices had a waist diameter similar to or slightly larger than the stretched diameter implanted, ranging between 6-40 mm (Figure 6). The procedure time varied between 45-175 minutes (median 60 minutes) and the fluoroscopy time between 3.5-65 minutes (median 12 minutes), with a tendency to shorter procedural and screening times after the initial learning curve. In 55% of the patients with an ASD, large devices of 20-40 mm were employed and devices <10 mm were used in only 4 patient. Two 40 mm devices were implanted.

Nine of 10 patients with multiple or fenestrated defects were treated with a single device, while in one patient two devices were implanted simultaneously through separate delivery systems. Defects with an additional septal aneurysm were successfully closed by catching the aneurysm during the process of configuring the right atrial disc (or using the cribiform occluder in two cases), resulting in a firm compression of the aneurysm towards the atrial septum.

At the time of cardiac catheterization, nine patients were excluded after TEE examination, as follows: inferior-posterior defects and no rim near the orifice of the inferior caval vein, defects that were very near the coronary sinus, large defect that was near the entrance of the superior caval vein, with only a small rim towards the right pulmonary veins, two symptomatic children had a defect diameter of more than 36 mm on TEE and interatrial septum length of only 46 mm.

Seven further patients were excluded after initial angiography, hemodynamic evaluation, balloon sizing of the defect, or trial of device placement. Three of these showed drainage of the right pulmonary veins into the superior cava vein. One symptomatic adult had additional coronary disease. After balloon sizing four patients were excluded; three of these had large inferior-posterior defects with a stretched diameter of between 26 mm and more than 36 mm and an insufficient margin towards the inferior caval vein. Despite repeated trials, device placement failed in three cases because of insufficient inferior margins (1) or large defects with a floppy septum (2).

On color flow Doppler, residual shunting—including foaming through the wire mesh of the device—was seen in about 80% of cases directly after implantation. By the time of discharge, 24 hours after ASD closure, the rate of residual leakage had decreased to 15%. During further follow up examinations (10 days to 3.4 years, median 2.3 years) the complete closure rate has reached 97-98%. A trivial residual shunt is still present in 4 patients. 2/4 patients had unrecognized small additional defects during initial TTE and implantation. The third and fourth patient of this subgroup had small defects near the superior and inferior vena cava respectively.

After transcatheter closure of the interatrial communication in adults a reduction of migraine or headache was observed. In this small group of patients (retrospectively analyzed) migraine disappeared completely in 60%, while 40% described improvement in symptoms.

There were 3 major procedure related complications at our institution. The first was an embolization in a patient with small inferior rim directly after release. In this case the device embolized just above the mitral valve. Although the child was stable and asymptomatic device transcatheter retrieval was not attempted. The device was retrieved surgically and the ASD closed by patch. The second procedure related complication was a perforation of the left atrial posterior wall with the extra stiff madrain which led to 5 mm pericardial effusion. The procedure was stopped; there were no sequelae of this event. A significant event occurred 3 months after a successful and uneventful closure of a fenestrated Fontan with an Amplatzer occluder in a young cyanotic patient with complex congenital heart disease. This 8-year old girl developed fever and headache. Computed tomography showed a brain abscess.

**FIGURE 6.** Occluder diameter: 55% of patients with an ASD were closed with large devices of 20-40 mm, 42% with devices 10-20 mm and only 3% with devices <10 mm.

**FIGURE 7.** Lateral view of an implanted Amplatzer septal occluder (16 mm) during and directly after implantation.


