

The Ampatzter Septal Occluder as a Standard for Therapy of Secundum-Type Atrial Septal Defect

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Atrial septal defect (ASD) accounts for 5-10% of congenital heart malformations. An uncorrected ASD may lead to congestive heart failure, severe pulmonary hypertension, or paradoxical arterial embolism with stroke. Transthoracic echocardiography is often diagnostic in the pediatric population, but transesophageal echocardiography may be required in adults. Closure of an ASD traditionally has been performed surgically, but the most common type (secundum ASD) can now be closed with a percutaneously deployed device. We briefly describe the types of ASDs and their diagnosis. Results of percutaneous closure in 74 children and adults are then presented.

Atrial septal defect (ASD) is a congenital anomaly in which a defect is present between the right atrium (RA) and left atrium (LA). Accounting for 5-10% of congenital heart malformations, ASD occurs in four general types (Figure 1), the most common being the ostium secundum or fossa ovalis type.

A secundum ASD allows left-to-right shunting of blood from the LA to the RA. The volume of the shunt is determined by the size of the anatomic defect and by the relative compliances of the two ventricles. An increased blood flow to the right heart and pulmonary vascular bed, as a result of left-to-right shunting, may lead to car-

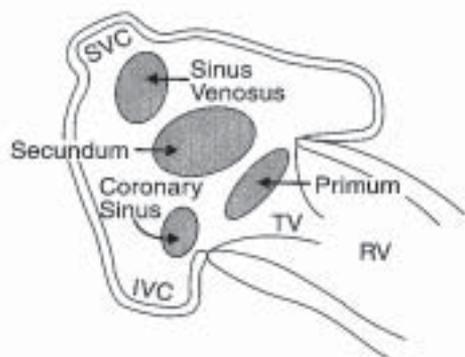


Figure 1. Schematic representation of the four types of atrial septal defect (ASD). The *sinus venosus* type usually involves the posterosuperior atrial septum, just inferior to the right atrium (RA) – superior vena cava (SVC) junction. Rarely the defect may occur near the inferior vena cava (IVC). A *primum* defect lies in contact with the tricuspid valve (TV) ring, and the *coronary sinus* type defect at the site of the orifice of the coronary sinus, in the posteroinferior aspect of the atrial septum. A *secundum* ASD lies in the fossa ovalis. (Reprinted with permission from Kerut EK, McIlwain EF, Plotnick GD. *Handbook of Echo-Doppler Interpretation 1996*; Futura Publishing Company, Inc.; Armonk, New York)

diac failure, pulmonary vascular disease and pulmonary hypertension, and atrial arrhythmias.

An ASD is usually diagnosed by early adolescence. Symptoms are based upon the volume of the shunt. Adults usually present with exercise intolerance, shortness of breath, or arrhythmias, but some are asymptomatic until symptoms of pulmonary hypertension develop.

Abnormalities usually present on physical examination include of a widely split fixed second heart sound, a palpable right ventricular impulse to the left of the sternum, and a systolic ejection murmur at the left upper sternal border. Electrocardiographic findings typically reveal a right ventricular conduction delay, and RA and right ventricular enlargement may be present. Radiographic signs include an increased pulmonary vascularity, as well as an enlarged right heart, particularly the right ventricle. When the defect is small, many or all of these physical, electrocardiographic, and radiographic findings may be absent.

Transthoracic echocardiography (TTE) may prove diagnostic for secundum ASD, especially in the pediatric population. RA and right ventricular volume overload is evident with a sizable left-to-right shunt. In adults, a transesophageal echocardiogram (TEE) may be needed to confirm the diagnosis. Peripheral injection of “agitated” saline (introduces microscopic air bubbles into the injectate for ultrasonic visualization) and color flow Doppler imaging help visualize an atrial-level shunt. Rarely is cardiac catheterization needed for diagnosis; however, it may be useful for determination of pulmonary vascular resistance and to evaluate coronary anatomy in the adult patient.

PERCUTANEOUS ASD CLOSURE

First described in 1974 by two Louisiana physicians, Drs. Terry King and Noel Mills,¹ the procedure of percutaneous closure of an ASD has been increasingly performed



Figure 2. Drawing of the Amplatzer Septal Occluder. It is a double-disc device with a nitinol wire frame, having a broad waist for centering the device within the defect.

over the past several years. The Amplatzer septal occluder is presently the only device approved by the Food and Drug Administration (FDA) for use in humans. It is a double-disc device with a nitinol wire frame, having a broad waist that centers the device within the defect (Figure 2).

The FDA-approved indication for use of the Amplatzer septal occluder is a confirmed ostium secundum ASD or a patent foramen ovale (PFO).² For FDA-approved Amplatzer PFO closure, a patient must have had an embolic arterial event, and subsequently have had a recurrent event on anti-thrombotic therapy (Figure 3).

The Amplatzer septal occluder should not be used if other conditions exist that will require cardiac surgery. Intracardiac thrombus or heparin allergy are also contraindications for percutaneous closure. In patients with elevated pulmonary vascular resistance and a right-to-left shunt (Eisenmenger's syndrome), closure (surgical or percutaneous) is contraindicated.

Aspirin therapy is started at least one day prior to the procedure. The procedure is often performed with only intravenous sedation. Using TEE, one must determine that there is at least a 5mm "rim" of atrial septum around the ASD, for proper device seating. Right heart catheterization with oxygen saturation and pressure measurements is performed. Using both fluoroscopy and TEE for positioning, a guidewire is advanced across the atrial septum into the LA and the left upper pulmonary vein. A sizing balloon is advanced over the guidewire, and inflated. The "stretched diameter" of the ASD is measured, using both fluoroscopy and TEE (Figure 4).

An Amplatzer device is then selected, based on the ASD-measured diameter, and it is advanced across the ASD. The left side of the device is deployed, with TEE confirming proper seating around the rim of the ASD. The sheath is then retracted to deploy the right disc. If seating is visualized as not being satisfactory, the device, while still attached, is retracted back into the delivery sheath, and device deployment is then again performed. A counter-clockwise torque of the delivery cable then releases the device (Figure 5). Most patients are discharged from the hospital on the following day.

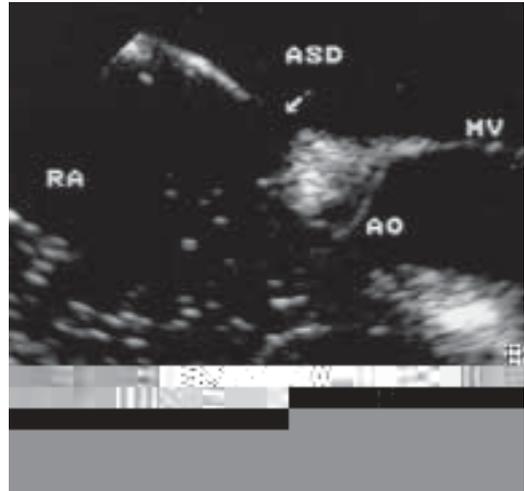


Figure 3a.

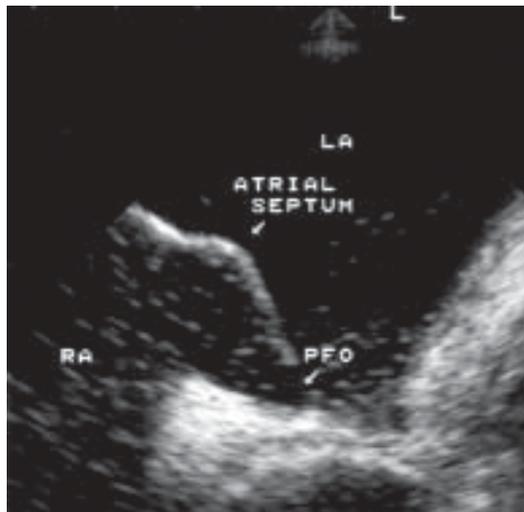


Figure 3b.

Figure 3. A secundum-type ASD and a patent foramen ovale (PFO) are anatomically different. **a)** Transthoracic echocardiogram (horizontal plane) of a secundum-type ASD. This involves a true defect in the fossa ovalis. **b)** A PFO is a remnant of the fetal circulation. Oxygenated blood from the placenta enters the RA via the IVC and crosses the atrial septum through the foramen ovale into the left atrium (LA). Up to 25% of the adult population may have at least a relatively small PFO, with a small population having a residual anatomically and functionally significant PFO. The PFO results from a failure of fusion of the septum primum with the septum secundum. AO – left ventricular outflow tract, MV – mitral valve, RV – right ventricle.

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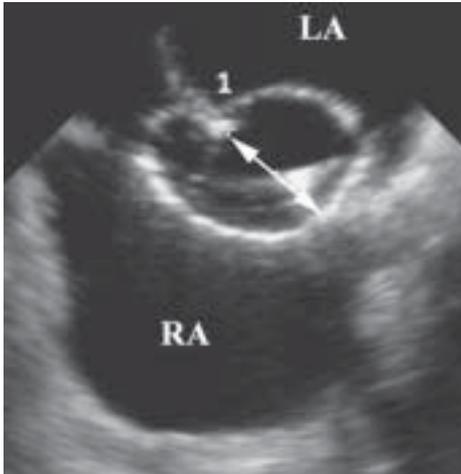


Figure 4. TEE measurement of ASD size by measurement (double arrow) of the diameter of an inflated balloon across the defect. LA – left atrium, RA – right atrium.

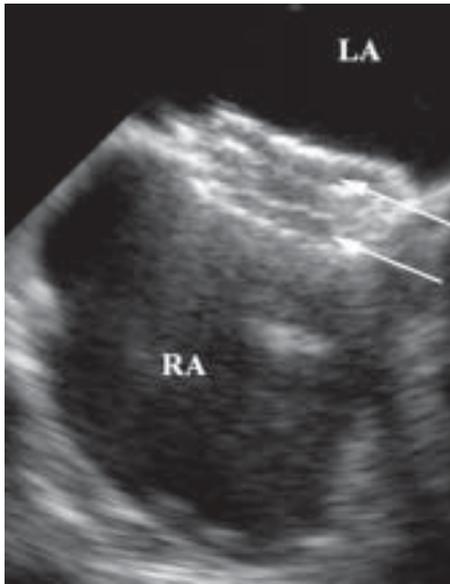


Figure 5. TEE image of the Amplatzer Septal Occluder deployed across a secundum ASD. The double disc configuration (arrows), with a disc on each side of the atrial septum, is evident. LA – left atrium, RA – right atrium.

The procedural risk and recovery time for Amplatzer percutaneous closure are significantly less than those of surgical closure.^{3,4} The post-surgical complication rate has been reported to be approximately 12%, compared to 4% for the Amplatzer device.⁴ The most common complication is post-procedural atrial arrhythmias. Other infrequent complications of Amplatzer closure include residual atrial-level shunting (most often small and physiologically insignificant) and rarely device embolization, which requires surgical correction.

PEDIATRIC AND ADULT EXPERIENCE

From December 2000 to May 2003, 74 patients (ages 9 months to 74 years) underwent percutaneous closure of a secundum ASD at our institutions (Children's Hospital, New Orleans; Heart Clinic of Louisiana, Marrero) using the Amplatzer Septal Occluder. Defect size ranged from 8 to 36mm, and fluoroscopy time from 5 to 60 minutes. Our morbidity rate was low; one patient with a multi-fenestrated ASD had a small, physiologically unimportant residual shunt. There have been no cases of device embolization or fracture, stroke, arrhythmia, or bacterial endocarditis. This morbidity rate is somewhat better than that generally reported in the literature, and better than the surgical morbidity rate for ASD closure.^{3,4}

SUMMARY

The Amplatzer Septal Occluder is the first FDA-approved device for percutaneous closure of a secundum type ASD. Its use has been increasing over the past several years, and it appears to have a low morbidity compared to traditional surgical repair. Our institutions have had success with this device in both the pediatric and adult populations, with a low morbidity rate. Percutaneous closure of a secundum ASD, as an alternative to surgical repair, appears to be safe and reliable.

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