Transcatheter Closure of Atrial Septal Defects by Amplatzer™ Septal Occluder Instead of Open Heart Surgery

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Abstract : **Although surgical repair of secundum atrial septal defect (ASD) is a safe, widely accepted procedure with negligible mortality, it is associated with morbidity, discomfort and a thoracotomy scar. As an alternative to surgery, a variety of devices for transcatheter closure of ASD have been developed. Large delivery sheath, difficult implantation technique, inability to capture, and structural failure are some of the limitations of previous devices.**

Objectives : **This study reports our clinical experience with transcatheter closure of ASD using the Amplatzer™ Septal Occluder , a new occlusion device.**

Patients & Methods : **Patients with ASD met established two-dimensional echocardiographic criteria for transcatheter closure. ASD size was measured by transesophageal echocardiogram (TEE) and balloon occlusion catheter (stretched diameter). The Amplatzer™ 's size was chosen to be equal to stretched diameter (± 1 mm). The device was advanced transvenously into a guiding sheath and deployed under fluoroscopic and TEE guidance. Once its position was optimal, it was released. Right atrial atriogram and TEE were undertaken to demonstrate the residual shunt.**

Results : **There were 5 patients with mean age of 9.6±8.4 years and mean weight of 24.7 ±14.9 kg. The mean ASD diameter measured by TEE was 16.1±2 mm and by stretched diameter was 18.5 ±3.5 mm. The mean device diameter was 19.2 ±4 mm (range 15 to 24 mm). Immediately after the deployment, a tiny residual shunt was observed at the core of the device in each case. However, at 24 hours only one patient who had a 24 mm device placed had a small (<2 mm) residual shunt. No complication was encountered during the procedure.**

Conclusions: **The Amplatzer™ Septal Occluder is a prosthesis that can be easily deployed in patients with secundum ASD. The result of closure was excellent. This device could be used to close large ASD (particularly with diameter > 20 mm) safely in our patients.**

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เรื่องย่อ : **การปิดรูรั่วผนังกั้นหัวใจห้องบนทางสายสวนหัวใจโดยใช้ Amplatzer™ Septal Occluder แทนการผ่าตัด**

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ถึงแม้ว่าการผ่าตัดปิดรูรั่วผนังกั้นหัวใจห้องบน หรือ secundum atrial septal defects นี้จะได้ผลดี แต่ก็ยังมีอัตราเสี่ยงในการทำผ่าตัดเปิดหัวใจ และผู้ป่วยยังจะมีแผลผ่าตัดบริเวณหน้าอก ในระยะเวลากว่า 20 ปีที่ผ่านมาได้มีการพัฒนาอุปกรณ์สำหรับปิดรูรั่วผนังกั้นหัวใจห้องบน แต่อุปกรณ์เหล่านี้ก็ยังมีข้อบกพร่องอยู่

วัตถุประสงค์ : เพื่อรายงานผลการปิดรูรั่วผนังกั้นหัวใจห้องบนทางการสวนหัวใจ ด้วยอุปกรณ์ชนิดใหม่ Amplatzer™ Septal Occluder แทนการผ่าตัดเป็นครั้งแรกในประเทศไทย ที่โรงพยาบาลศิริราช

ผู้ป่วยและวิธีการ : ผู้ป่วยที่ได้รับการวินิจฉัยว่ามีรูรั่วผนังกั้นหัวใจห้องบนชนิด secundum และมีปริมาณเลือดไปปอดมากจะได้รับการตรวจหัวใจทางสายสวนหัวใจ และวัดขนาดของรูรั่วด้วยสายสวนที่มีลูกโป่ง (balloon occlusion catheter) ร่วมกับการตรวจคลื่นเสียงสะท้อนความถี่สูงทางหลอดอาหาร (transesophageal echocardiogram ; TEE) หลังจากนั้น Amplatzer™ จะถูกสอดผ่านสายสวนหัวใจ เพื่อปิดรูรั่ว โดยอาศัยแผ่นจาน 2 แผ่นที่มีแกนกลางยึด ทำด้วยโครงร่างตาข่ายของลวด Nitinol ประกบผนังกั้นหัวใจทั้งสองข้าง และทดสอบการปิดรูรั่วด้วยการฉีดสารทึบรังสีหัวใจและ TEE ภายหลังการปิดรูรั่ว และตรวจวันรุ่งขึ้นด้วยคลื่นเสียงสะท้อนความถี่สูงทางผนังหน้าอก และภาพถ่ายรังสีทรวงอกและหัวใจ

ผลการรักษา: ผู้ป่วยจำนวน 5 ราย อายุตั้งแต่ 2 ปี ถึง 24 ปี (อายุเฉลี่ย 9.6 $\pm$ 8.4 ปี) น้ำหนักโดยเฉลี่ย 24.7 $\pm$ 14.9 กิโลกรัม ขนาดเฉลี่ยของรูรั่วที่วัดได้จาก TEE 16.1 $\pm$ 2 มม. และจากสายสวนที่มีลูกโป่ง 18.5 $\pm$ 3.5 มม. ขนาดเฉลี่ยของอุปกรณ์ที่ใช้ปิด 19.2 $\pm$ 4 มม. (15 ถึง 24 มม.) ภายหลังการปิดมีเพียง 1 รายที่ยังเหลือรูรั่ว (ขนาดเล็ก 2 มม.) ในวันรุ่งขึ้นด้วยการตรวจคลื่นเสียงสะท้อนความถี่สูงทางผนังหน้าอก ไม่พบภาวะแทรกซ้อนในการทำ

สรุป: Amplatzer™ Septal Occluder เป็นอุปกรณ์ปิดรูรั่วผนังกั้นหัวใจห้องบนชนิดใหม่ทางสายสวนหัวใจที่มีความปลอดภัยและสะดวกในการใช้เมื่อเทียบกับอุปกรณ์รุ่นก่อน ผลการรักษาเบื้องต้นพบว่าสามารถใช้ปิดรูรั่วเพื่อทดแทนการผ่าตัดปิดรูรั่วได้

Background

Secundum atrial septal defect (ASD) accounts for 10% of congenital heart disease at birth and for 30-40% of cases seen in adults.[1] Reports of the natural history of ASD and results of surgery imply that patients become increasingly symptomatic with advancing years. It is generally agreed that ASD associated with large left-to-right shunt and either symptoms or significant cardiomegaly should be electively closed in childhood. Long-term follow up 27 to 32 years after atrial septal defect closure was

reported by Murphy et al.[2] It appeared that the survival of patients who were operated on before 25 years old with normal pulmonary artery pressure was not significantly different from a normal population of age-matched controls. Closure of ASD at a later age resulted in late morbidity. This morbidity included persistent pulmonary hypertension, atrial tachyarrhythmia or paradoxical emboli. Although surgical repair of ASD is a safe and widely accepted procedure with negligible mortality, it is associated with morbidity, discomfort and a thoracotomy scar. As an alternative to surgery, a variety of devices for transcatheter closure of ASD have been developed over the past 20 years.[3-10] None has gained wide acceptance. Large delivery sheaths, cumbersome implantation techniques, inability to recapture, structural failure, dislodgement and embolization of the device are some of the limitations of previously prescribed techniques. This study describes our experience with transcatheter closure of ASD in patients using a new self-expanding, self-centering and repositioning device, the Amplatzer™ Septal Occluder.

MATERIALS AND METHODS

Device and Delivery system.

The Amplatzer™ Septal Occluder (AGA Medical Corp., Golden Valley, MN, U.S.A.) is constructed from 0.004-0.005 inch Nitinol (nickel and titanium) wires, tightly woven into two flat buttons (discs) with a 4 mm connection waist (Figure 1). The device diameter is dictated by the diameter of the waist, and is available in 4- 32 mm sizes with a 1 mm increment for sizes below 20mm and 2 mm increment for sizes above 20 mm. The left atrial disc extends 7 mm radially around the connecting waist and the right disc 5 mm. The left disc is slightly larger than the right because of the higher left atrial pressure. Both discs are angled slightly toward each other to ensure firm contact with the atrial septum. The prosthesis is filled with Dacron fabric to facilitate thrombosis. The device is attached by a microscrew mechanism onto a 0.038 inch delivery cable made of stainless steel. It is loaded into a long 6 French (F; one French is equal to 0.33mm) to 9 F diameter sized sheath. For introduction into the delivery sheath the device is pulled into a loader (Figure 1).

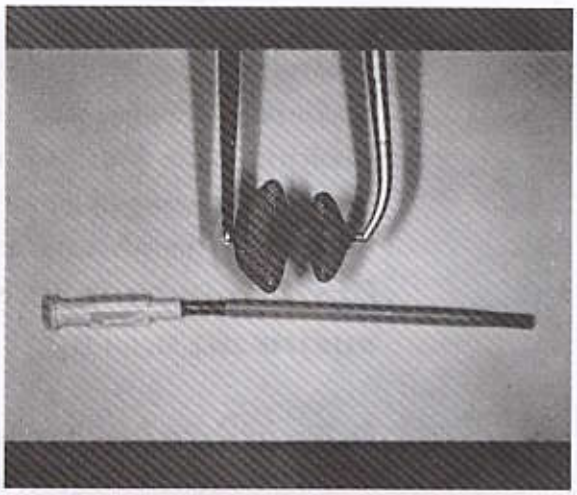

Figure 1. The Amplatzer™ Septal Occluder held by needle holder on each side with the loader.

Patients

Patients with a secundum ASD awaiting surgical closure were evaluated with transthoracic or transesophageal two-dimensional color Doppler echocardiography. Patients who met the criteria for transcatheter closure by Amplatzer™ Septal Occluder[11-12] were selected. This criteria generally included isolated secundum ASD with diameter less than 32 mm, large left to right shunt (ratio of pulmonary to systemic blood flow or Qp:Qs > 1.5:1), a distance of > 5 mm from the margins of the defect (s) to the coronary sinus, atrioventricular valves and right upper pulmonary vein. Patients who were excluded were those who had associated cardiac anomalies which required cardiac surgery, other type of ASD (sinus venosus or ostium primum), partial anomalous pulmonary venous drainage, or pulmonary vascular resistance above seven Wood units.

All devices were implanted under a research protocol approved by the Ethical Committee on Clinical Investigation of Faculty of Medicine Siriraj Hospital. The Amplatzer™ Septal Occluder was approved by the Office of Compliance, Center for Devices and Radiological Health of the U.S. Food and Drug Administration for export and investigational use. Informed parental or patient consent was obtained for each patient.

Procedure

The patients were intubated and placed under general anesthesia. Cefazolin (50 mg/kg) was given intravenously before the procedure was started. After percutaneous puncture of the femoral vein, 100 units per kg of heparin were given intravenously. A complete hemodynamic evaluation was performed with pressure and saturation measurements taken in all cardiac chambers. An angiographic catheter was placed in the right pulmonary vein. Contrast media was injected in the right upper pulmonary vein with X-ray tube in a 35° left axial oblique with 20° cranial angulation to delineate the anatomy of the ASD. A 7 F balloon-tipped end-hole catheter (Arrow International Inc., Reading, PA, U.S.A.) was manipulated through the ASD into the left upper or lower pulmonary vein. Using an exchange 260 cm, J-tipped guidewire, a 27 mm, 100 cm occlusion balloon catheter (Meditech, Watertown, MA) was introduced into the left atrium. The balloon catheter was inflated with various increments of contrast medium and pulled across the ASD under fluoroscopic and transesophageal echocardiographic (TEE) observation. A slight deformity of the sizing balloon was used to determine the stretched diameter (Figure 2). The sizing balloon was then removed, reinflated with the same amount of contrast medium and passed through calibrated openings in a sizing plate to determine the stretched diameter. The occluding device was selected to be the same size as the stretched diameter (± 1 mm). The device size refers to the diameter of the connection waist.

The device was screwed to the tip of the delivery cable, immersed in normal saline and drawn into the loader. A long (7 to 9 F) guiding sheath and dilator were advanced over the guidewire through the communication into the left atrium. The dilator was removed when sheath was advanced into the inferior vena cava to prevent air embolization. The correct position of the delivery sheath was verified by a test injection of contrast medium. The loader with the collapsed device was then advanced into the sheath by pushing the delivery cable. Under fluoroscopic and TEE guidance, the left atrial disc was deployed and pulled gently against the atrial septum which were both felt and observed by TEE. Using gentle tension on the delivery cable, the sheath was pulled and the right atrial disc was deployed. The deploying sequence is shown in Figure 3. To and fro motion of the delivery cable ensured a secure position across ASD. This was also observed by TEE and fluoroscopy. The TEE was performed to check residual shunt, possible obstruction to systemic or pulmonary venous return and impairment of the atrioventricular valves. Once its position was optimal, the device was released by counterclockwise rotation of the delivery cable. The device position was checked again by TEE (Figure 4). Contrast media was injected in the right atrium at the end of procedure to verify residual atrial shunt.

Follow-up studies

A chest radiograph and a transthoracic color Doppler echocardiographic study were performed on all patients 24 hour after the procedure. Aspirin (5 mg/kg) was given orally in each patient for 3 months. At one week patients were scheduled for chest radiograph to compare the position of the device. Persistent atrial shunts were angiographically (immediately after the procedure) and echocardiographically defined as "foaming" (minor diffuse leak through Dacron fabric), trivial (faint left atrial opacification or jet < 1mm in diameter), small (jet 1 to 2 mm), moderate (obvious left atrial opacification and jet 3 to 4 mm) and large (intense left atrial opacification and jet > 4 mm in diameter).

RESULTS

Transcatheter closure of secundum ASD was carried out in five patients. Descriptive statistics and outcome are shown in Table 1. Delivery of the device was successful in all patients. The mean age of the patients was 9.6±8.4 years old (2 to 24 years old). Their mean weight was 24.7±14.9 kg (10.7 to 50 kg). The mean ASD diameter determined by TEE was 16.1±2 mm (14 to 18 mm) compared with the stretched diameter from the sizing balloon of 18.5±3.5 mm (15 to 23 mm). One patient (no.3) had two ASDs; 2 and 18 mm. The mean pulmonary to systemic flow ratio (Qp:Qs) was 3.8±1.7 to 1. The device sizes was selected from 15 to 24 mm. Average fluoroscopy time was 20±7.5 min (13 to 32 min) and the procedure time was 75±22 min (50 to 100 min). Misplacement of the device occurred in patient no. 3 because the larger defect was stretched against the smaller one and the device was placed in a position which straddled the atrial septum close to the smaller defect. However, the device was pulled back inside

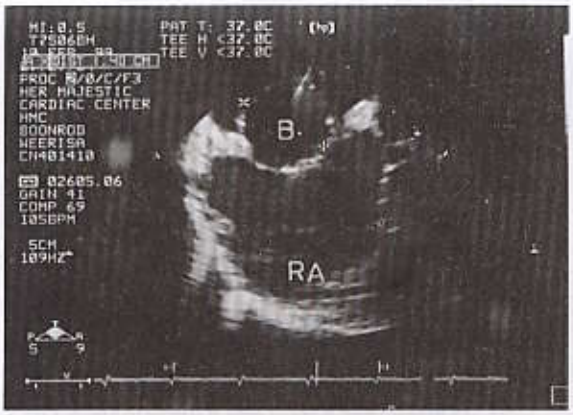

Figure 2. Transesophageal echocardiogram (TEE) short-axis view showing balloon sizing method : RA right atrium, B balloon.

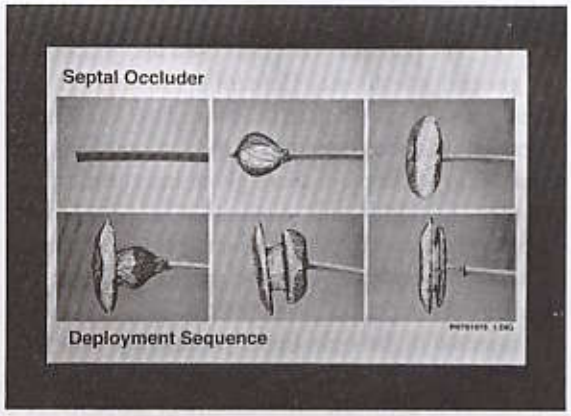

Figure 3. Deploying sequence of the Amplatzer™ Septal Occluder from top left to bottom right the device was loaded in the sheath ; left atrial disc was delivered, fully deployed left atrial disc ; the connecting waist was deployed ; right atrial disc was deployed ; device recoiled to the initial shape.

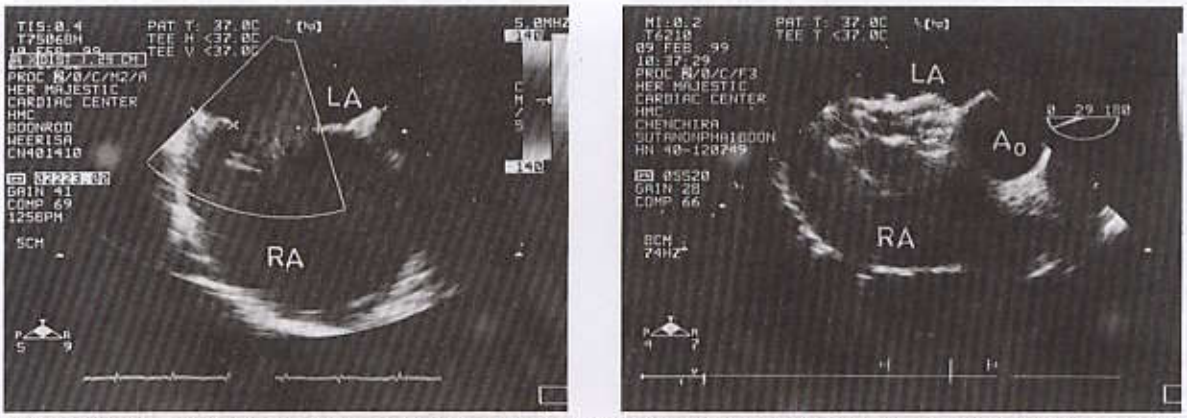

Figure 4. Transesophageal echocardiogram (TEE) short axis view showing the ASD before (4A) and after (4 B) device placement : RA right atrium, LA left atrium, Ao aorta.

the sheath and redeployed successfully at the next attempt. After release of the prosthesis, all of the patients had a tiny residual shunt at the connecting waist. One patient (no. 3) had a small shunt 1-2 mm. TEE examination revealed no obstruction to the superior and inferior vena cava, the coronary sinus or the right upper pulmonary vein. Profiles of the ASD before and after device placement by TEE were shown in figure 4. Neither retention disc was in contact with the mitral nor the tricuspid valve and valve regurgitation was not observed. At 24 hours no shunt was observed in four patients. No complication was observed during the procedure. At one week a chest radiograph was taken in each patient and this revealed that the device was in the same position when compared with the previous film in each patient.

Table 1. Pertinent patient data and outcome after transcatheter closure of ASD by the AmplatzerTM Septal Occluder.

Patient	Age (yr)	Weight (kg)	ASD size (mm)* TEE	ASD size (mm)* Balloon	Device size (mm)	Op/Qs	FT (min)	PT (min)	Results (TEE)
1	24	50.0	18.0	20.3	22.0	5:1	20.5	95.0	Complete occlusion
2	2	10.7	14.0	15.0	15.0	1.5:1	19.2	60.0	Complete occlusion
3	8	21.7	18.0	23.0	24.0	5:1	32.3	100.0	Small shunt (1-2 mm)
4	8	23.2	16.7	19.0	20.0	2.4:1	13.1	50.0	Complete occlusion
5	6	18.0	14.0	15.0	15.0	5:1	14.9	70.0	Complete occlusion

*ASD size by TEE (transesophageal echocardiogram) or Balloon (balloon sizing by balloon occlusion catheter); FT(Fluoroscopy time); PT (procedure time), Qp:Qs (ratio of pulmonary to systemic blood flow).

DISCUSSION

Several successful transcatheter closures of secundum ASD have been reported in the literature.[3-10] However, the procedure has not yet achieved widespread clinical use. This is most likely because of difficulties related to the implantation technique and drawback in the design of the occlusion device. In the present study a new ASD occluder, the Amplatzer™ Septal Occluder was employed for transcatheter closure of ASD (ranging from 15 to 24 mm) in five patients. Complete occlusion was achieved in four and only a small left to right shunt was left at 24 hours in one patient. No complication was observed during the procedure. It appeared that the efficacy and safety of the technique are predominantly due to the simplicity of the deployment technique and design.

The Amplatzer™ Septal Occluder was designed to overcome many of the drawbacks of previously used devices. These include the clamshell septal occluder[3-5] which was changed to Cardioseal and eventually developed the starflex system (extra nitinol wire), the Sideris button device,[7-8] the atrial septal defect occlusion system,[9] the Das Angel Wing[10] and the Pavenik monodisk. Besides the Sideris device, which is delivered through an 8 F sheath, all other devices require a larger 9 F to 13 F sheath which make their application difficult or impossible in small children. Our smallest patient was 2 years old weighting 10.7 kg. Generally our device could be deployed in a child as small as 7 kg.

The Amplatzer™ Septal Occluder is a self-centering device and the round retention discs extend radially beyond the defect, resulting in a much smaller overall size than all other devices. Only the Das Angel Wing and the new Cardioseal with starflex system have the self-centering mechanism. However, both of them require a large device/ASD diameter ratio and consequently the retention disk has to remain oversized.

In contrast to other occluders[13-15] that accomplish closure of the ASD by retention flanges (patches) which still leave an opening through the ASD, the Amplatzer™ Septal Occluder uses a short (4 mm) communicating waist to stent the defect, forcing blood flow through a network of highly thrombogenic polyester material. Moreover, the inward inclination of both retention discs allows firm contact with the atrial septum, which enhances endothelialization and reduces the risk of residual shunting.

Selection of the appropriate device size is of paramount importance for effective and safe ASD closure regardless of device type. Balloon sizing to establish the stretched diameter has remained the

gold standard. The TEE may not be as reliable since many communications are not perfectly round.[16-18] A very important property of the Amplatzer™ Septal Occluder is retrievability while the device is still attached to the delivery cable, which allows repositioning in case of misplacement, thus obviating surgical removal. Most of the devices, with the exception of the clamshell or Cardioseal, are not retrievable. Even successfully retrieved, the device most likely could not be used again. The Amplatzer™ Septal Occluder can be fully recaptured into the sheath with the delivery cable. Because of the superelasticity of the nitinol frame, the device will retain its initial shape even if it is deployed several times. Indeed misplacement of the device occurred in one of our patients. As compared with other devices, the Amplatzer's loading, technical deployement and recapturing is a simple system without complicated mechanisms. This significantly reduces the procedural and fluoroscopy time. Also the Amplatzer netinol structure makes it easily visible in the short axis and longitudinal plane when using TEE during the procedure. Above all, compared with surgical closure, the patients will benefit from less morbidity, shorter stay in the hospital (2 to 3 days) and no thoracotomy scar. The patient can return to school or work within 3 to 4 days of the procedure.

CONCLUSIONS

We demonstrated the capability of the Amplatzer™ Septal Occluder that can be effectively and safely deployed to close an ASD as large as 24 mm. This device can also be used in a child as small as two years old. It is a simple in construction, easy to deploy and can be withdrawn and repositioned many times. The benefit in each individual patient was clearly demonstrated. Further studies with long term follow-up are required to establish its value in a larger number of patients.

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