Intermediate Term Follow-up on Transcatheter Closure of Atrial Septal Defects by Amplatzer™ Septal Occluder

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Abstract

Background : Surgical repair of secundum atrial septal defect (ASD) is a safe, widely accepted procedure with negligible mortality. However, 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.

Objectives : We report our clinical experience with transcatheter closure of ASD using the Amplatzer™ Septal Occluder, a new occlusion device with intermediate term follow-up.

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

Results : There were 26 patients with a mean age of 17.2±15.9 years old (2 to 60) and a mean weight of 22±37.5 kg. (10.7 to 62.5). The mean ASD diameter measured by TEE was 18.3±5.2 mm. and by stretched diameter was 22±7.5 mm. Four patients who had ASD stretched diameter over 32 mm were excluded because a larger device was not available. Devices were deployed in 22 patients with sizes from 9 to 30 mm (median = 22mm). Immediately after closure a tiny residual shunt was observed at the core of the device in each case. At 24 hours only two patients had a small (< 2 mm) shunt. One patient with fenestrated ASD had a device embolized into the right ventricle with successful removal and surgical closure. Patients were followed-up for a mean duration of 8±3.5 months (from 3 to 12 months). Complete occlusion was found in 20 out of 21 patients (95%).

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Conclusion : The Amplatzer™ Septal Occluder is a new device designed for closure of different sizes of ASD and can be easily and safely deployed. Our experience showed that this device could be used to close an ASD as large as 30 mm. The intermediate term follow-up also demonstrated an excellent closure result. Caution should be undertaken with patients who have a fenestrated atrial septal defect particularly at the septal rim.

Key word : Transcatheter Closure, Atrial Septal Defect, Septal Occluder, Intermediate Term Follow-up

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J Med Assoc Thai 2000; 83: 1045-1053

BACKGROUND

Secundum atrial septal defect (ASD) accounts for 10 per cent of congenital heart disease at birth and 30-40 per cent of cases seen in adults[1]. Many patients do not have symptoms until they reach adulthood. However, reports of the natural history of ASD and results of surgery suggested that this group of patients become increasingly symptomatic with advancing age. It is generally agreed that ASD associated with a large left-to-right shunt and either symptom or significant cardiomegaly should be electively closed in childhood. Long-term follow-up after atrial septal defect closure was reported by Murphy et al[2]. It appeared that survival of patients who had surgical closure at a older age was lower than patients who had surgery done before the age of 25. Closure of ASD at a later age can result in late morbidity, which includes 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 [3-12]. We initially reported our first experience of using the Amplatzer™ Septal Occluder in five patients for closure of ASD ranging from 15 to 24 mm[13]. This study was to report an intermediate term follow-up for a larger group of patients who had ASD closure.

METHOD

Device and Delivery system. The Amplatzer™ Septal Occluder[11-13] (AGA Medical Corp., Golden Valley, MN, U.S.A.) is constructed from 0.004-0.005 inches Nitinol (nickel and titanium) wires, tightly woven into two flat buttons (discs) with 4-mm connection waists (Fig. 1). The device diameter (size) is the same as the diameter of the waist joining each disc. The devices are different in size with a 1 mm increment for size below 20 mm and 2 mm increment for size above 20 mm. Currently the sizes of devices that are available in Thailand are from 4 mm to 30 mm. A larger sized device will be available in the near future. However, a device up to 34 mm was successfully deployed in a report from a phase II US multicen-

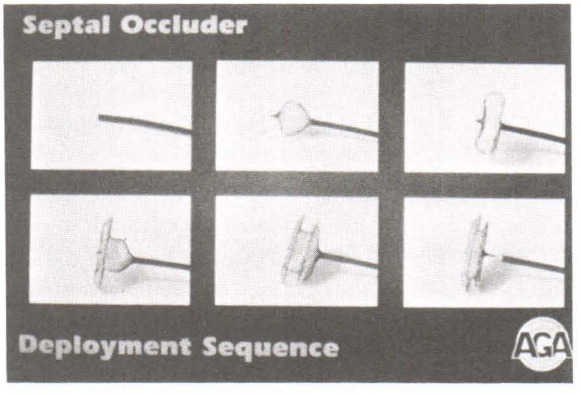

Fig. 1. The Amplatzer™ Septal Occluder with its deploying sequence from top left to bottom right; the device was loaded in the sheath; left atrial disc was delivered, fully deployed left atrial disc; the connecting waist was deployed; right atrial disc was deployed; device recoiled to the initial shape.

ter clinical trial[14]. The left atrial disc extends 7 mm radially around the connecting waist and the right disc 5 mm. The prosthesis is filled with Dacron fabric to facilitate thrombosis. The device is attached by a microscrew mechanism onto 0.038 inches of delivery cable made of stainless steel. It is loaded into a long sheath varying in size from 6 to 10 French (F). For introduction into the delivery sheath the device is pulled into a loader (Fig. 1)

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[11-13]. were selected. This criteria generally included isolated secundum ASD with a 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 patients who had had associated congenital heart defect (s) which required cardiac surgery, had other types 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 research protocol approved by the Ethical Committee on Clinical Investigation of the 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. Detailed procedure is described elsewhere [11-13]. A complete hemodynamic evaluation was performed with pressure and saturation measurements taken in all cardiac chambers. An angiographic picture was taken in the right pulmonary vein to delineate the anatomy of the ASD. An exchange 260 cm, J-tipped guidewire was placed into the end hole catheter in the left upper pulmonary vein for exchange with a balloon occlusion catheter. This balloon catheter was inflated and pulled across the ASD under fluoroscopic and transesophageal echocardiographic (TEE) guides. A slight deformity of the sizing balloon or disappearence of the left to right shunt seen by TEE were used to determine the stretched diameter (Fig. 2). The occluding device was selected to be the same size or 1 mm smaller than the stretched diameter. A long (7 to 10 F) guiding sheath and dilator were advanced over the guidewire through the commu-

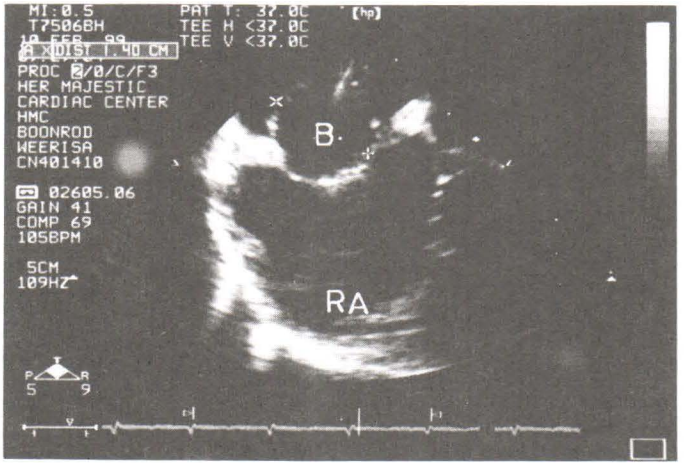

Fig. 2. Transesophageal echocardiogram (TEE) short-axis view showing balloon sizing method: RA right atrium, B balloon.

nication into the left atrium. 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. Then the sheath was pulled with the right atrial disc deployed. This was also observed by TEE and fluoroscopy. Once its position was optimal, the device was released by counterclockwise rotation of the delivery cable. The device position and residual shunt were checked again by TEE (Fig. 3).

Follow-up studies. A chest radiograph and transthoracic color Doppler echocardiographic study were performed on all patients 24 hours after the procedure. Each patient took an anti-platelet dose of aspirin up to six months or longer in some cases if the investigator felt the device was not well endothelized from the echocardiographic examination. Patients were scheduled for chest radiograph to compare the position of the device one week after the procedure. Repeat visit for each patient was done at one month, three months, six months and one year. Echocardiogram was per-

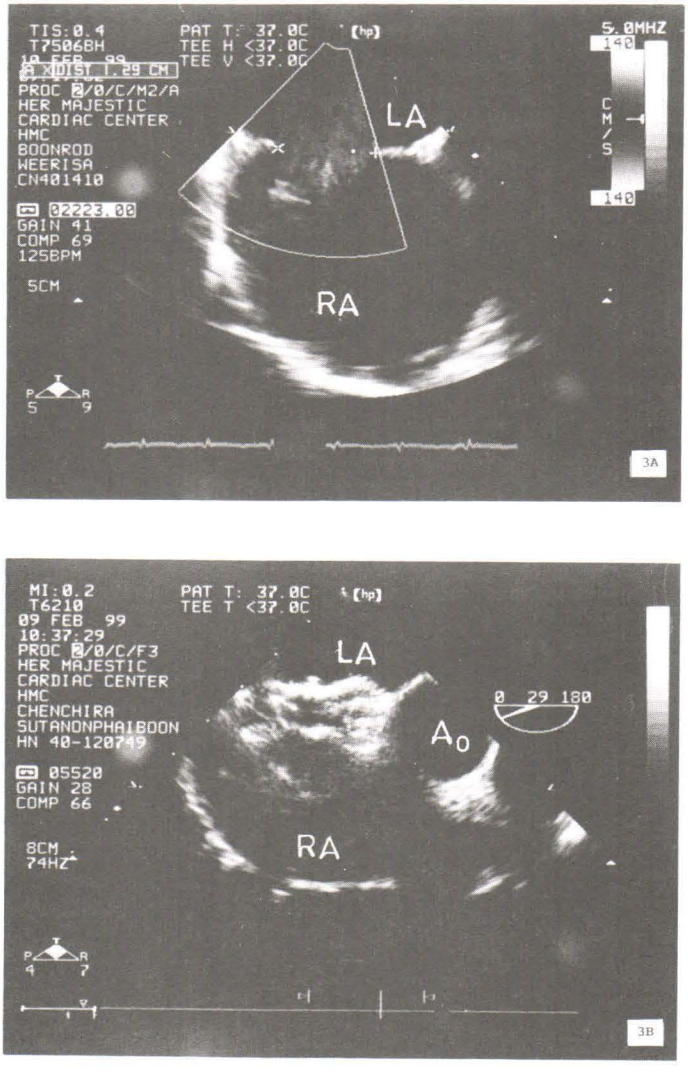

Fig. 3. Transesophageal echocardiogram (TEE) short axis view showing the ASD before (3A) and after (3B) device placement: RA right atrium, LA left atrium, Ao aorta.

formed to identify any residual shunt or possible device malposition.

RESULTS

1. Immediate results

There were 26 patients who met the established criteria. Their mean age was 17.2±15.9 years old (2 to 60) and the mean weight was 22± 37.5 kg. (10.7 to 62.5). The mean ASD diameter measured by TEE was 18.3±5.2 mm. and by stretched diameter was 22±7.5 mm (from 9 to 38 mm). The average ratio of the measurement of the defect size by stretched diameter by TEE was 1.2± 0.2 (from 1 to 1.44). Four patients who originally had ASD diameter measured by TEE ranging from 25 to 28 mm had a stretched diameter of over 32 mm (34, 34, 36 and 38 mm). This group of patients was excluded from further study because a larger device was not available. Two patients were found to have fenestrated ASD. The pulmonary to systemic flow ratio (Qp:Qs) was 3.1±1.5 to 1. Devices were successfully deployed in 22 patients. The size of the devices used ranged from 9 to 30 mm (median = 22 mm). In both patients with fenestrated ASD the device was placed through the larger ASD with measurements according to the stretched diameter of the larger defect. Average fluoroscopy time was 22.5±8.6 min (11 to 40). The average procedure time was 79.1±19.3 min (50 to 120). Immediately after closure, the TEE examination showed that all of the devices were in good position. A tiny residual shunt was observed at the core of the device in 19 cases. Three patients had a small shunt (<2 mm) and two of them had fenestrated ASD. After 24 hours only two patients were found to have a small (< 2mm) shunt by echocardiographic examination.

Complication: We found three complications in our patients.

1) One 12 year old girl with fenestrated ASD who had a 22 mm device, was found to have the device embolized into the right ventricle the next morning from the chest X-ray and echocardiogram. The patient did not experience any symptom. The device was found straddled through the tricuspid valve creating mild tricuspid regurgitation. It was noted that the posterior inferior rim of the fenestrated atrial septum was quite small. We decided to remove the device and close the ASD surgically. During the surgery, it was noted that the posterior-inferior rim of the atrial septum (close to IVC) was small (< 4 mm). Three defects were found. Two smaller defects were at the posterior inferior rim of the septum. The larger defect was located at the position of foramen ovale. This part of the septum was excised before patch closure of ASD was performed. The patient recovered well from the procedure.

2) One 8 year old girl with a 20 mm device who also had fenestrated ASD was found to have a second degree atrioventricular (AV) block (Mobitz type I) alternating with junctional rhythm immediately after the procedure. The abnormal rhythm lasted 8 hours before turning into first degree AV block. Retrospectively it appeared that the lower edge of the left atrial disc was slightly tilted to the left atrium. This edge was seen pushing at the anterior leaflet of the mitral valve and atrioventricular septum. Mild mitral regurgitation was noted. She was observed for four days in the hospital. Holter monitor was done which revealed her rhythm of first degree AV block with a heart rate varying from 65 to 130 BPM. No evidence of hemodynamic compromise was found.

3) One 24 year old women with 22 mm device was found to have transient brachial plexus injury. She stayed four days in the hospital, and had complete recovery of symptoms after two weeks of physical therapy.

No evidence of obstruction to the superior and inferior vena cava, the coronary sinus or the right upper pulmonary vein was seen in any patient. Neither retention disc was in contact with the mitral or the tricuspid valve and no evidence of valve regurgitation was observed other than one patient mentioned earlier. Nineteen patients were discharged from the hospital the day after the procedure. Chest radiograph was taken one week later in each patient which revealed that all of the devices deployed were in good position.

2. Intermediate term follow-up

All 21 patients were followed from 3 months to 12 months (mean = 8±3.5 months). 16 of 21 patients were followed beyond 6 months. Each patient had an echocardiogram done according to the protocol. Complete occlusion was found in 20 of 21 patients (95% occlusion rate). The patient who did not have complete occlusion was the eight year old girl with fenestrated ASD and had a small shunt through the small hole. She still has first degree AV block. Her maximal heart rate was noted

to be 150 BPM at the exercise test three months after the procedure.

One further complication was found in a 37 year old woman who experienced atrial fibrillation at the one month follow-up period. She experienced some palpitation before being admitted to the CCU for cardioversion. She was placed on propafenone for 3 months with no further symptoms. Aspirin was discontinued in 14 of the 16 patients who had the procedure done more than six months previously. Two patients (2 and 3 year old girls) were felt to have incomplete endothelized atrial disc from the echocardiographic examination. Both of them were scheduled for follow-up at the three months period.

DISCUSSION

Several successful transcatheter closures of the secundum ASD by a variety of devices has been reported in the literature[3-13]. These procedures are becoming more available in many institutes. Currently the Amplatzer Septal occluder has been used in more than 1400 patients world wide [11-18]. It appears that the efficacy and safety of this device are predominantly due to the simplicity of the deployment technique and design. Moreover, the successful closure of a defect as large as 34 mm was reported recently[14]. We reported our initial experience of using the Amplatzer^{TM} Septal Occluder to close defects ranging from 15 to 24 mm in five patients[13]. From our initial result there was a 100 per cent occlusion rate at 6 months follow-up with only one complication from brachial plexus injury.

Our intermediate term follow-up on a larger group of patients demonstrated the efficacy of 95 per cent (complete closure of 20 of 21 patients) in six months. Two valuable pieces of information were observed from the study. First, the size of the ASD still varied from the size measured by transthoracic or transesophageal echocardiogram to the stretched diameter. We had four patients with defects measured in the range of 25 to 28 mm echocardio- graphically. However, during the procedure the stretched diameters measured from 34 to 36 mm. The procedure was terminated in this group of patients. Our study demonstrated a larger stretched diameter size with a ratio of 1.2±0.2. This ratio made us try to enroll patients with defects measured by echocardiogram no larger than 25 mm in order to have a successful chance of closure until larger devices are available. Exclusion of patients was also reported in many studies[15-17].

Secondly, two of our patients were found to have a fenestrated ASD. One of them was incidentally found to have the device embolized to the right ventricle. We found that the posterior-inferior septal rim around the ASD was very small and fenestrated by itself. Surgically, this part of the septum was excised before patch closure of ASD was performed. The device was probably embolized because of the very weak structure of this part of the septum. In the other patient, the device was found tilted to the left atrium because the upper rim of both discs were coapting against the fenestrated septum which probably was a weak structure and caused the device to rotate. Although reports of closure of the fenestrated ASD have been seen in the past[18], we found that caution should be undertaken in the presence of the fenestrated ASD. We should anticipate that the device position could change after the delivery cable become detached.

Comparison with other devices[19-22], the Amplatzer^{TM} Septal Occluder was designed to overcome many of the drawbacks of previously used devices. Previous devices included the clamshell septal occluder[3-6] and Cardioseal with starflex system[23], the Sideris button device[7,8], the atrial septal defect occlusion system[9], and the Das Angel Wing[10]. 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 makes their application difficult or impossible in small children. Our smallest patient was 2 years old and weighed 10.7 kg. The Amplatzer^{TM} Septal Occluder was reported to be successfully deployed in a child as small as 6.3 kg[14].

The Amplatzer^{TM} 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 the starflex system had the self-centering mechanism, however, both of them required a large device/ASD diameter ratio and consequently the retention disk had to remain oversize.

In contrast to other occluders that accomplish closure of the ASD by retention flanges (patches) which still leave an opening through the ASD, the Amplatzer^{TM} Septal Occluder use a short (4 mm) communicating waist to stent to 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 enhanced endothelialization and reduced the risk of residual shunting. In fact we discontinued aspirin in 14 of 16 patients in our study who were followed-up for more than 6 months.

A very important property of the Amplatzer^{TM} 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. We found this technique gave us more opportunity to readjust the device position resulting in a higher rate of success occlusion. Most of the devices, with the exception of the clamshell or Cardioseal, are not retrievable. Even if successfully retrieved, it is unlikely the device will be used again. A recent study[24] showed identical complete closure rates and complications of surgical and Amplatzer^{TM} device closure of atrial septal defect. However, compared with the surgical closure, patients will benefit from less morbidity, a shorter stay in hospital (2 to 3 days) and no thoracotomy scar. The patient could return to school or work within 3 to 4 days after the procedure.

SUMMARY

We demonstrated the capability of the Amplatzer^{TM} Septal Occluder that could be effectively and safely deployed to close an ASD as large as 30 mm. Intermediate term follow-up revealed an excellent closure rate (95%). However, caution should be undertaken in patients who have fenestrated ASD. Benefit to individual patients was clearly demonstrated. Further studies with long term follow-up are required to establish its value in a larger number of patients.

(Received for publication on February 7, 2000)

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การปิดรูรั่วผนังกั้นหัวใจด้านบนด้วยการใช้อุปกรณ์สวนหัวใจ Amplatzer™ Septal Occluder รายงานผลการติดตามการรักษาผู้ป่วยในระยะปานกลาง

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วัตถุประสงค์ : การศึกษานี้รายงานผลการติดตามการรักษารูรั่วผนังกั้นห้องหัวใจด้านบนโดยการสวนหัวใจด้วยอุปกรณ์ Amplatzer™ Septal Occluder (ASO)

วิธีการ : ผู้ป่วยที่ได้รับการวินิจฉัยว่ามีรูรั่วผนังกั้นห้องหัวใจด้านบน ชนิด secundum atrial septal defect (ASD) และมีขนาดของ left to right shunt มากพอจะได้รับการตรวจสวนหัวใจ ขนาดของ ASD จะถูกวัดโดย Transesophageal echocardiogram (TEE) และ balloon occlusion catheter อุปกรณ์ Amplatzer™ จะถูกสอดผ่านสายสวนหัวใจ เพื่อการปิด ASD โดยใช้ disk 2 ข้าง ประกบผนัง atrial septum ไว้ รูรั่วจะถูกตรวจดูอีกครั้ง หลังจากอุปกรณ์ได้ถูกปล่อยออกไปแล้ว

ผลการรักษา : ผู้ป่วยจำนวน 26 รายได้รับการคัดเลือก โดยมีอายุเฉลี่ย 17.2 ± 15.9 ปี (ตั้งแต่ 2 - 60 ปี) น้ำหนักโดยเฉลี่ยคือ 22 ± 37.5 กิโลกรัม (ตั้งแต่ 10.7 - 62.5 กก.) ขนาดเฉลี่ยของ ASD ที่วัดได้จาก TEE คือ 18.3 ± 5.2 มม. และจาก balloon occlusion ได้แก่ stretched diameter คือ 22 ± 7.5 มม. ผู้ป่วยจำนวน 4 รายมีขนาดของ ASD มากกว่า 32 มม. ทำให้ไม่สามารถใช้อุปกรณ์ได้เนื่องจากอุปกรณ์ที่มีขนาดใหญ่กว่านี้ยังไม่มีในประเทศไทย สามารถให้การรักษาในผู้ป่วยจำนวน 22 ราย โดยใช้อุปกรณ์ขนาดตั้งแต่ 9 - 30 มม. จากการติดตาม พบว่า ผลการรักษาเป็นที่น่าพอใจในผู้ป่วย 21 ราย โดยปิดรูรั่วได้สนิทในผู้ป่วย 19 ราย และมี 2 รายที่มีรอยรั่วขนาดเล็ก (น้อยกว่า 2 มม.) ผู้ป่วย 1 ราย มีการหลุดของอุปกรณ์ โดยพบในวันรุ่งขึ้น ขณะที่ผู้ป่วยได้รับการทำ echocardiogram โดยที่ไม่มีอาการ จากการผ่าตัดเพื่อปิดรูรั่ว ASD พบว่าผู้ป่วยมีรูรั่ว ASD ที่มีลักษณะเป็นรูพรุน (fenestrated ASD) และมีขอบเล็กมาก ได้ติดตามการรักษาผู้ป่วยเป็นเวลาเฉลี่ย 8.3 ± 5 เดือน (ตั้งแต่ 3 เดือน - 1 ปี) พบว่าสามารถปิดรูได้สนิท 20 ราย ใน 21 ราย (95%)

สรุป : Amplatzer™ Septal Occluder เป็นอุปกรณ์ปิดรูรั่วระหว่างผนังกั้นห้องหัวใจด้านบนชนิดใหม่ ที่มีความปลอดภัยและสะดวกในการใช้เมื่อเทียบกับอุปกรณ์รุ่นก่อน การติดตามผลการรักษา พบว่าอุปกรณ์นี้สามารถถูกใช้เพื่อปิดรูรั่วชนิด secundum atrial septal defect ได้ดี โดยขนาดใหญ่ที่สุดที่ปิดได้คือ 30 มม. ควรระวังการใช้อุปกรณ์ในผู้ป่วยที่มีรูรั่วลักษณะ fenestrated ASD

คำสำคัญ : การรักษารูรั่วผนังกั้นห้องหัวใจด้านบน, การสวนหัวใจ, Septal Occluder, การติดตามระยะปานกลาง

กฤตย์วิกรม ดุรงค์พิศิษฏ์กุล และคณะ
จดหมายเหตุทางแพทย์ ฯ 2543; 83: 1045-1053

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