Usefulness of Transesophageal Echocardiography for Transcatheter Closure of Ostium Secundum Atrial Septum Defect with the Amplatzer Septal Occluder

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Background: Transcatheter closure of ostium secundum atrial septum defect (ASDII) using the new self-centering occluder, Amplatzer Septal Occluder (ASO), has been well developed in recent years. We describe the importance and role of transesophageal echocardiography (TEE) in the selection and closure of such defects.

Methods: Thirty patients referred for transcatheter closure of ASD_{II} by ASO were enrolled in this study. During catheterization, two-dimensional TEE was performed on all patients during and after transcatheter closure. ASD size and morphology were assessed by TEE before catheterization. The ASD stretched diameter was also measured by TEE and fluoroscopy.

Results: With the aid of TEE, transcatheter closure of an ASD was successfully, safely and effectively performed on 29 patients. The mean ASD diameter determined by TEE was 17.4 $\pm$ 4.8 mm. The mean stretched diameters measured by TEE and fluoroscopy were 18.7 $\pm$ 5.6 mm and 17.9 $\pm$ 5.5 mm, respectively. The mean device diameter was 19 $\pm$ 5.6 mm. Immediate complete closure was documented by color Doppler TEE in 29 patients. Complications were encountered in one patient, with the device becoming dislodged into the main pulmonary artery. The device was retrieved by surgery and the defect was repaired in the operating room.

Conclusions: Transcatheter closure of ASDs using an Amplatzer device is feasible, safe and effective. Two-dimensional TEE can provide useful information before, during and after transcatheter closure of ASDs.

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Key words: amplatzer septal occluder, ostium secundum atrial septum defect, transesophageal echocardiography.

The atrial septal defect (ASD) represents about 10% of all congenital cardiac anomalies.[1] The *ostium secundum* type atrial septal defect (ASD_{II}) is the fourth most common congenital heart disease (CHD), with an incidence of 3.78 per 10,000 live births,[2] corresponding to 5.9% of diagnosed CHDs in children.[3] Although surgical repair of ASDs is a safe, widely-accepted procedure with negligible mortality, it is associated with morbidity, discomfort and a thoracotomy scar.[4] As an alternative to

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surgery, a variety of devices for transcatheter closure have been developed over the past 20 years. The Amplatzer Septal Occluder (ASO) (AGA Medical Corporation, Golden Valley, Minnesota, USA), has been well described as an innovative self-centering, self-expanding device that is repositional and is effective for closure of ASDs.[5-8]

Advancements in transducer technology and the continued miniaturization of transesophageal echocardiography (TEE) probes have led to a rapid increase in the use of intraoperative TEE for monitoring and diagnosis of CHDs and repairs.[9] The use of TEE for guidance and monitoring to facilitate proper device placement during transcatheter closure of ASDs is becoming a routine procedure.[5,6,10,11] TEE provides the detailed cardiac anatomy and physiology in real-time by 2-dimentional (2-D) and Doppler techniques. In this study, we report our experience in using real-time 2-D TEE to demonstrate the efficacy of the transcatheter closure of ASDs by ASO devices in our hospital.

METHODS

From October 2004 to July 2005, 30 patients (8 male and 22 female) with clinical and transthoracic echocardiography (TEE) evidence of an ASD were referred for transcatheter closure using the ASO. Inclusion criteria were single ASD_{II}, significant left to right shunt, and maximal ASD diameter of 30 mm with right ventricular overload and circumferential rim of at least 5 mm on 2-D TEE. Patients ranged in age from 2.6 to 41 years (mean age 17.2 $\pm$ 12.7 years), and their weights ranged from 13.5 to 81.0 kg (median 34.9 $\pm$ 19 kg). Patients with preoperative unstable hemodynamic status, intermittent dysrhythmia, history of dyaphagia, esophageal pathology and recent upper gastrointestinal bleeding or surgery were excluded from this study. Informed consents were obtained from all patients or their guardians. Preoperative clinical variables including pulse pressure, cardiothoracic ratio on chest radiography and electrocardiography were documented. Preoperative conventional TEE was performed on all patients to locate the position of the septal defect.

All patients were taken to the laboratory catheterization room without premedication. Routine monitors included electrocardiogram (ECG), invasive arterial blood pressure, pulse oximetry and capnography. Following preoxygenation, intravenous anesthesia was administered: thiamylal (5 mg/kg), fentanyl (3 μg/kg) and rocuronium (0.6 mg/kg), to facilitate endotracheal intubation. Anesthesia was then maintained with sevoflurane or desflurane.

A 20 or 22 gauge catheter was placed in the right or left radial artery for continuous monitoring of arterial pressure and end-tidal carbon dioxide tension, during the operation. A Philips SONOS 7500 system with pediatric and adult multiplane TEE transducer was inserted into the patients' esophagus after induction of anesthesia. Before catheterization, comprehensive TEE examination was performed using a sequence of transducer positions. Transducer positioning was selected at mid esophageal or basal bicaval view to provide optimum imaging of the interatrial septum, which is best visualized in multiplane TEE. TEE monitoring and guidance of atrial defect closure involved identification and localization of atrial defects as well as careful measurement of defect diameter, proximity to surrounding structures and adequacy of septal rim, including anterior superior (SA) rim, posterior superior (SP) rim, anterior inferior (IA) rim and posterior inferior (IP) rim (Fig. 1). Two-dimensional TEE with color Doppler imaging was performed to monitor the whole catheterization process and to ensure that the balloon was perpendicular to the septum during balloon sizing ASD measurement.

After percutaneous puncture of the femoral vein, a complete hemodynamic evaluation was performed with pressure and saturation measurements taken in all cardiac chambers. A balloon-tipped end-hole catheter was manipulated through the ASD into the left upper or lower pulmonary vein. The catheter balloon was inflated with various increments of contrast medium and pulled across the ASD under fluoroscopic and TEE observation. TEE was used to guide the measurement of ASD balloon stretched diameter (BSD), i.e. the diameter of the ASD after balloon sizing to ensure no residual color flow through the balloon (Fig. 2). The BSD of the ASD was also measured using fluoroscopy (Fig. 3). 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 or 1-2 mm bigger than the stretched diameter.

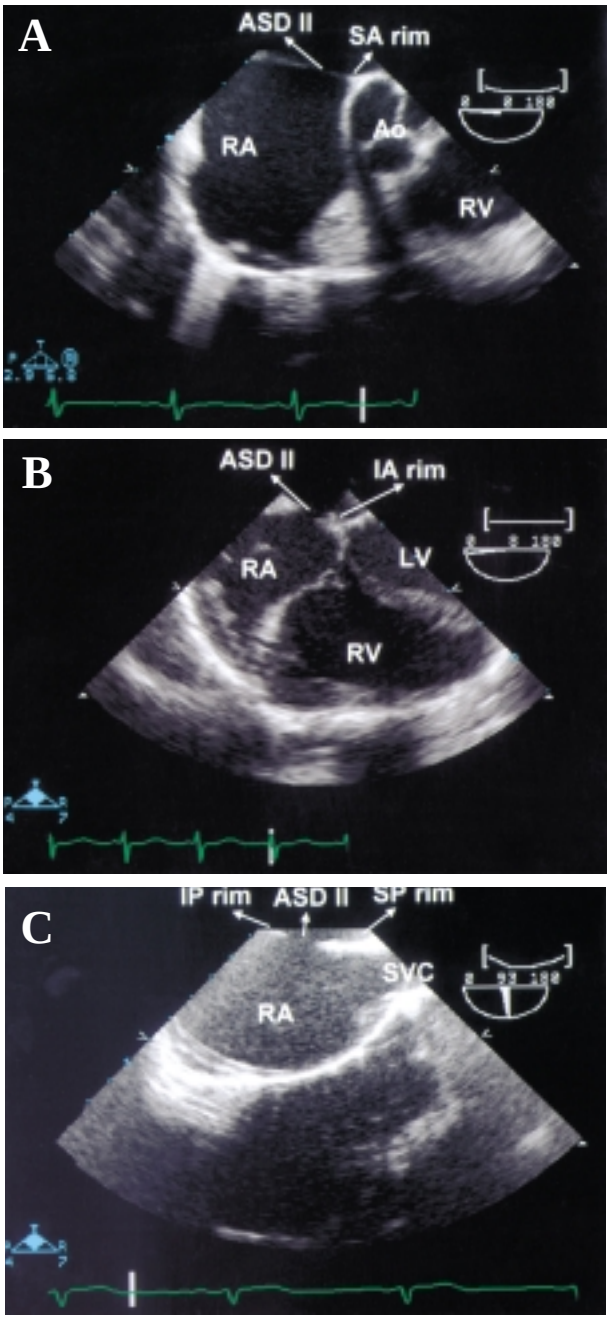

Fig. 1 (A) TEE image from mid-esophageal aortic valve short axis demonstrating anterior superior (SA) rim of defect. (B) Mid-esophageal four-chamber view at 0° of TEE showing anterior-inferior (IA) rim. (C) Mid-esophageal bicaval view at 90° of TEE showing superior-posterior (SP) rim and inferior-posterior (IP) rim.
RA: right atrium, RV: right ventricle, LV left ventricle, AO: aorta, SVC: superior vena cava, ASDII: secundum-type atrial septal defect.

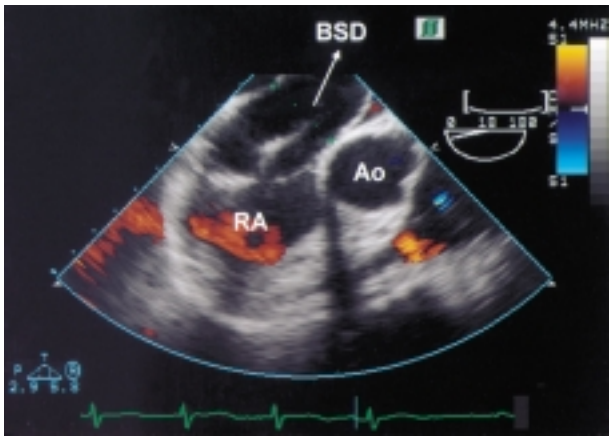

Fig. 2 TEE measurement of the balloon stretched diameter of the atrial septal defect (ASD). RA: right atrium, AO: aorta, BSD: balloon stretched diameter.

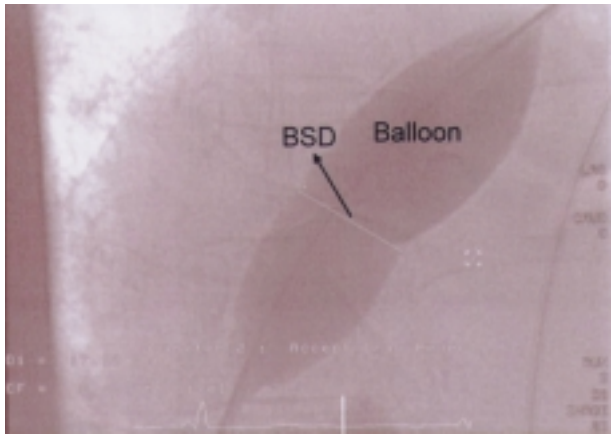

Fig. 3 Fluoroscopic measurement of balloon stretched diameter of ASD. BSD: balloon stretched diameter.

During placement of the occluder device, TEE provided visualization of the ASD's size and location and also the surrounding rims, between the superior vena cava and inferior vena cava, right pulmonary vein, aortic root, atrioventricular valves and coronary sinus. It was used to ascertain that multiple arms of the device were properly aligned and well-seated on both sides of interatrial septum (Fig. 4). After release of the properly placed occluder device, the device and adjacent structures were examined by TEE to ensure that there was no encroachment on the aortic valve, atrioventricular valves, right pulmonary veins or superior or inferior caval vein. Any obstruction of flow from the occluder device to the pulmonary vein and the superior or inferior caval vein can be evaluat-

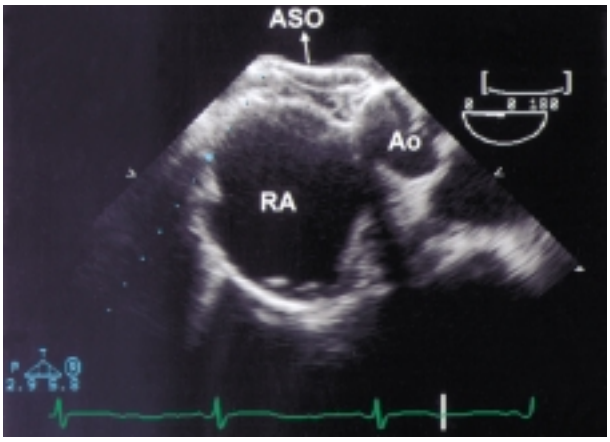

Fig. 4 TEE view after device deployment, demonstrating both disc and waist covering the defect.
RA: right atrium, AO: aorta, ASO: Amplatzer Septal occluder.

Fig. 5 Color Doppler flow interrogation demonstrating trivial residual shunting.
RA: right atrium, ASO: Amplatzer Septal occluder, RS: residual shunting.

ed immediately via TEE image. In addition, a final TEE examination was performed to demonstrate the position of the device and any residual left to right interatrial shunting (Fig. 5).

All the patients regained consciousness promptly after the procedure. The endotracheal tube was removed after complete reversal of the neuromuscular blocking agent. All the patients were transferred to the intensive care unit for further observation. None of the patients required narcotic medication for postoperative pain. There were no arrhythmias during the postoperative course, which was uneventful overall.

RESULTS

Clinical data of all patients are listed in Table 1. Twenty-nine (97%) of 30 consecutive patients were treated successfully with the ASO. All the patients had pulmonary/systemic flow ratio (Qp/Qs) ranging from 1.3 to 2.7 (mean 2.11 $\pm$ 0.51). No anomalous pulmonary venous drainage was observed. The mean ASD diameter determined by TEE was 17.4 $\pm$ 4.8 mm. The mean BSD measured by TEE and fluoroscopy was 18.7 $\pm$ 5.6 mm and 17.9 $\pm$ 5.5 mm, respectively. Occluder devices ranging from 10 to 38 mm (mean 19 $\pm$ 5.6 mm) were implanted into 29 patients. Two patients had deficient anterior rims of $<$ 5 mm. The average procedure time was 38.1 $\pm$ 11.7 minutes and the fluoroscopy time was 18.5 $\pm$ 5.1 minutes.

Eight patients had BSDs over 22 mm (22 to 34 mm) and were successfully treated. Several attempts were made to deploy the ASO in patient no. 4 who had a large ASD, with a BSD greater than 24 mm and small left atrium (LA 30 mm). Initial attempts at device deployment were made using a delivery sheath positioned in the left upper pulmonary vein but were unsuccessful due to failure of the left atrial disk to align in the small atrial septum plane. After a further attempt was made to deploy the delivery sheath via the right upper pulmonary vein, the left atrial disc and the waist of the device were deployed in the left atrium and pulled against the septum, which resulted in self-centering of the device within the defect. A bulgy appearance of the retention buttons occurred in patient no. 22 due to an overestimation of the defect size. In this case, we replaced a 22 mm device with an 18 mm device and obtained a satisfactory result. In patient no. 14 who had a 32 mm defect with deficient anterior rim ($<$ 5 mm), the stretched diameter was found to be 36 mm. A 38 mm device was successfully implanted via the right upper pulmonary vein without any complications or residual shunt.

The only complication encountered occurred in patient no. 30 when the occluder device dislodged into the main pulmonary artery immediately after release of the ASO from the connecting waist. This patient was sent to the operating room for surgical

Table 1. Clinical Data for Patients Who Underwent Catheter Closure with ASO

Patient No.	Gender	Age (yr)	Wt (kg)	ASD Diameter (mm)			ΔBSD	Device size (mm)
				TEE	BSD			
					By TEE	By Fluoroscopy		
1	F	8	21	21.1	25.9	25.1	0.9	26
2	M	6	15	17.6	18.4	18.3	0.3	20
3	F	4	15	17.7	18.2	19.4	0.4	20
4	F	5	17	20.1	23.8	22.8	0.4	24
5	F	15	35	13.5	14.6	13.6	0.2	16
6	F	4	15	13.2	14.5	13.5	0.9	14
7	F	8	22	20.0	21.4	21.3	-0.1	22
8	F	18	41	14.1	16.3	14.4	1.2	16
9	F	10	25	10.1	11.9	10.3	0.2	12
10	F	8	21	17.9	20.1	18.4	1	20
11	M	3	15	11.1	12.8	11.5	0.3	12
12	F	5	15	9.8	9.1	10.1	0.5	10
13	M	16	46	14.3	15.7	15.3	0.4	16
14	F	41	42	31.0	36.8	33.6	0.7	38
15	F	32	45	21.2	24.2	21.0	2.2	24
16	M	25	81	14.9	16.0	14.9	0.4	17
17	F	38	65	14.2	16.8	14.5	1.7	17
18	F	31	54	15.2	15.7	15.2	0.1	17
19	F	22	45	13.2	13.3	12.5	0.6	16
20	F	25	46	15.5	16.5	14.8	2.2	18
21	F	37	51	13.9	14.5	12.5	0.7	16
22	M	28	38	18.3	19.3	19.5	0.2	22
23	F	2	13	14.0	14.2	11.9	-0.9	14
24	F	29	58	22.0	22.5	22.5	1.5	22
25	F	5	16	20.0	20.9	20.9	1.4	22
26	M	22	47	20.0	20.4	20.4	1	20
27	F	12	19	23.4	23.9	23.9	2	24
28	M	41	56	23.6	23.1	23.0	0.8	22
29	F	3	15	14.0	13.7	13.7	1.3	12
30	M	15	55	25.5	25.0	24.4	1.1	24
Mean		17.2	34.9	17.4	18.7	17.9	0.8	19.1
SD		12.7	19	4.8	5.6	5.5	0.7	5.6

Abbreviations: ASO: amplatzer septal occluder; ASD: atrial septal defect; TEE: transesophageal echocardiography; BSD: balloon stretched diameter; Wt: weight; ΔBSD: BSD measured by TEE-by fluoroscope.

retrieval and the defect was repaired with a patch closure. The ASD of this patient had a stretched diameter of 24 mm and was located in an extremely inferior and posterior position next to the orifice of the inferior vena cava, which caused unstable positioning of the device. This anatomy was confirmed by the cardiac surgeon. One patient had transient supraventricular tachycardia during the procedure. No anti-arrhythmia agents were given. Insignificant trivial residual shunt was demonstrated on TEE in nine cases immediately after implantation of the device. Immediate TEE examination revealed no disturbance or obstruction in the blood flow of the superior and inferior vena cava, the coronary sinus or the right upper pulmonary vein. The retention disk was not in contact with the two atrioventricular valves and no valve regurgitation was observed. No thrombus was noticed immediately after device deployment.

All patients were discharged from the hospital within two days of the ASD occlusion procedure. There were no complications related either to the

catheterization or anesthesia procedures.

DISCUSSION

Surgical repair of congenital ASDs can be performed successfully with low mortality. However, the morbidity associated with postpericardiotomy syndrome, cardiopulmonary bypass, postoperative monitoring in the intensive care unit and prolonged hospital stay is considerable. The associated expense, surgical scarring and psychological stress on the patient and parents are additional disadvantages of surgical treatment.[12]

Since the first attempt in 1976 by King and Mills,[13] transcatheter closure of ASDs is currently offered in many countries as an accepted alternative to cardiac surgery. According to the study of Du et al,[14] the success rates for device closure versus surgical closure of ASDs are not statistically different; however, the overall complication rate is much lower for the device closure patients than the surgical patients. Surgical closure of ASDs is characterized by a reduction of right ventricular volume overload status and complete resolution to normal size, if the procedure is performed in children.[15] However, similar results with transcatheter closure of ASDs using the ASO have been confirmed by Yew et al.[16]

With the extensive use of echocardiography for patient selection and intervention, and the development of new occluder systems, the transcatheter closure of ASDs has become a standard technique.[7] The miniaturization of TEE probes, together with the development of the capability for multiplane imaging from the esophagus, has increased the use of TEE in cardiology, especially in the pediatric population. Two-dimensional TEE was used in this study for monitoring and guidance of transcatheter closure of ASDs. TEE imaging is superior to fluoroscopy as it allows better visualization and delineation of the posterior structures of the heart, provides more information regarding the anatomy of the defect to assist in the selection of appropriately sized occluder devices, and shows the position of the device across the atrial septum and its relationship to adjacent cardiac structures.[10,17] Our study demonstrated that the addition of TEE imaging to fluroscopic imaging during catheterization closure of ASDs enhances the ability of the operator to visualize the defect. It also affords direct visualization of the atrial septum surrounding the defect, providing important information and allowing a safer and more effective application of this non-surgical technique.

Our cardiology department began transcatheter closure of ASDs with the new self-centering occluder ASO in October 2004. Complete occlusion was achieved in 29 (97%) out of 30 patients, with no complications during the procedures. Our imaging techniques and continuous TEE monitoring evolved over the course of this study. TEE provides excellent procedure guidance, adequate assessment of closure, reduced procedure time and greater patient comfort. With increasing operator experience and technical skill, x-ray exposure time is minimized, particularly if TEE is used.[18] It appears that the efficacy and safety of the technique predominantly relied on TEE monitoring and increasing operator experience and technical skill.

For stable positioning of the device, a septal rim, especially superior anterior rim, of 5 mm is needed around the ASD, where the device can be made to straddle the aorta. TEE clearly identifies the defect's proximity to surrounding structures and shows the adequacy of the septal rim and LA size. In our study, TEE monitoring demonstrated successful device implantation from the right upper pulmonary vein in two patients who had large ASDs with deficient anterior rims, small LA sizes and stretched diameters of ≥ 24 mm. Due to concerns regarding impingement of the device on neighboring structures, careful TEE monitoring is required and attempts to close large defects in younger children is not recommended.

When measuring the defect and estimating the device size, TEE provides accurate and reliable measurements of the ASD's BSD, i.e. the diameter of the ASD after balloon sizing to ensure no residual color flow through the balloon. As reported in previous literature, TEE may underestimate the ASD's BSD.[6,19-21] There was no statistical difference in our study between the TEE and fluoroscopy measurements of defect BSD. The ASO was released only when TEE showed no or only trivial residual shunt of color flow through color Doppler; otherwise repositioning the stent was required. When deploying the device, final assessment of the position was performed by TEE after its release.

We had one complication that needed surgical intervention: the device dislodged into the main pul-

monary artery and could not be retrieved. Device dislodgement is a known complication that generally occurs immediately after the procedure but can also occur later.[21,22] The possible reason for failure in this patient was location, in an extremely inferior and posterior position next to the orifice of the inferior vena cava, which caused unstable positioning and inadequate seating of the device.

Although we have demonstrated the addition of 2-D TEE imaging to fluoroscopic imaging during transcatheter closure of ASDs enhances the ability of the operator to visualize the defect, with three-dimensional (3-D) echocardiography one can truly appreciate ASDs as dynamic 3-D entities. It enables us to measure diameters throughout the cardiac cycle and gives a true representation of the cardiac pathology. It gives clinicians new insights and may have additional clinical value in appropriately selecting patients for catheter closure of defects. For optimal and widespread use of 3-D TEE, technical improvements are necessary, such as high resolution after acquisition and faster computers allowing on-line reconstruction.

In conclusion, the use of TEE for the placement of the ASO required collaboration between the cardiologist and the anesthesiologist. Transcatheter closure of ASDs using the ASO is feasible, safe and effective especially in children under general anesthesia. Two-dimensional or three-dimensional TEE can provide useful information by monitoring transcatheter closure. It is useful for confirming successful deployment in all secundum type ASDs.

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經食道超音波在經導管以中隔關閉器關閉第二型心房中隔缺損術中的應用

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背 景： 近幾年來，使用新型中隔關閉器關閉第二型心房中隔缺損已有很好的發展。我們描述使用經食道心臟超音波應用在選擇及關閉第二型心房中隔缺損的重要角色。

方 法： 共有 30 位患有第二型心房中隔缺損的病人皆使用二維經食道超音波監視並評估整個經導管關閉心房中隔缺損的過程。在置放導管前，我們以經食道超音波評估心房中隔缺損的型態及大小。而撐張開的心房中隔缺損大小也以經食道超音波和 X 光測量。

結 果： 在經食道超音波的幫助下，其中 29 位病人成功的、有效的、且安全的完成經導管關閉第二型心房中隔缺損術。以經食道超音波測量心房中隔缺損大小的平均值是 17.4 ± 4.8 mm。以經食道超音波和 X 光測量撐張開的心房中隔缺損大小的平均值分別是 18.7 ± 5.6 mm 和 17.9 ± 5.5 mm。而中隔關閉器大小的平均值是 19 ± 5.6 mm。其中 29 位病人在放置中隔關閉器後馬上以經食道都卜勒採色超音波證實無殘存心房中隔缺損血流分流。而其中一位病人發生中隔關閉器掉到主肺動脈的併發症。此位病人隨即送進開刀房以外科手術將中隔關閉器取出並關閉心房中隔缺損。

結 論： 經導管以中隔關閉器關閉第二型心房中隔缺損術是可行的、安全、且有效的。而二維經食道超音波在整個關閉心房中隔缺損術過程提供重要的資訊。

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關鍵字： 中隔關閉器，第二型心房中隔缺損，經食道心臟超音波。

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