Clinical Results of Large Secundum Atrial Septal Defect Closure in Adult Using Percutaneous Transcatheter Cocoon™ Atrial Septal Occluder

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Background: *Atrial septal defect (ASD) is a common congenital heart disease in adults. Amplatzer septal occluder is one of the most common devices used for transcatheter closure due to its high success rate and ease to implant. Cocoon™ atrial septal occluder is a new nitinol-based device, its shape resembles Amplatzer septal occluder but coated with platinum to prevent nickel release. Little is known about clinical outcomes of large ASD closure using Cocoon™ atrial septal occluder.*
Objective: *To review our experience in closure of secundum ASD in adults by Cocoon™ septal occluder and to compare the clinical outcomes and results of the patients who had ASD closure with a device greater than or equal to 30 mm and less than 30 mm.*
Material and Method: *Between November 2005 and October 2008, 63 consecutive patients underwent transesophageal echocardiography (TEE) - guided transcatheter closure of secundum ASD. The patients were divided into two groups (Groups' 1 and 2) according to device diameter that is greater than or equal to 30 mm (n = 31) and less than 30 mm (n = 32), respectively. Clinical outcomes, complications, and transthoracic echocardiography (TTE) before hospital discharge, one to three months, and one-year were analyzed.*
Results: *Device implantations were successful in 27 patients (87.1%) in group 1 and 31 patients (96.9%) in group 2 (p = 0.196). The maximum size of secundum ASD in group 1 determined by TTE, TEE, and balloon sizing diameter (BSD) were 22.6±5.0 mm (range 15-32), 28.1±4.8 mm (range 19-39), and 31±3.5 mm (range 23-38) respectively. The maximum size of secundum ASD in group 2 determined by TTE, TEE, and BSD were 19.7±4.4 mm (range 12-31), 20.4±3.4 mm (range 13-26), and 23.1±2.9 mm (range 15-30) respectively. The mean device size in groups 1 and 2 were 33.5±3.1 mm and 24.6±3.3 mm, respectively. Four patients (12.9%) in group 1 had unsuccessful implantations. All of them were in the first 15 cases of using large device and two of them had device embolization requiring surgical removal. One patient (3.1%) in group 2 had an unsuccessful implantation and had device embolization requiring surgical removal. The patients in both groups gradually improved in clinical symptoms with decreased RV systolic pressure and decreased RV size with complete ASD closure at one year.*
Conclusion: *Transcatheter closure of large secundum ASD by Cocoon™ septal occluder is feasible with hemodynamic benefit. However, complication rates are higher with large ASD closure with device size greater than or equal to 30 mm especially during the early "learning curve" period. With experience, the complication rate declines and the success rate is no different from the group with smaller device size.*

Keywords: *Secundum atrial septal defect, Cocoon™ atrial septal occluder*

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Atrial septal defect (ASD) is a common form of congenital heart disease, accounting for approximately 10% of all congenital cardiac defects[1]. The closure of ASD with large left to right shunt is considered necessary to prevent development of reduced exercise tolerance, pulmonary vascular disease, atrial arrhythmia, and congestive heart failure[2]. The benefits of this procedure have been shown, even in patients older than 40 years[3]. The Amplatzer septal occluder (ASO; AGA Medical, Golden Valley, MN, USA) has a high successful rate with simple implantation. Transcatheter closure of secundum ASD with this device has become an

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accepted alternative to surgical repair[4,5]. Studies comparing ASO device closure to surgical closure have shown decreased complication rates, shorter hospital stays, low morbidity, and greater cost-effectiveness[6].

Previous reports have demonstrated that transcatheter ASD closure is safe and easy to use with a high successful rate in small and moderate-sized defects[7-10]. Closure of large ASD with device size more than 30 mm is difficult and technically challenging. Cocoon™ atrial septal occluder (Vascular Innovations Co. Ltd., Thailand) is a new self-expanding nitinol-based device, which resembles ASO but coated with platinum to prevent nickel release[11]. Therefore, the purpose of this study was to review our experience in closure of secundum ASD in adults by Cocoon™ atrial septal occluder, and to evaluate its effectiveness, and results in large ASD closure with a device larger than 30 mm.

Material and Method

Patients

The authors reviewed records from 63 consecutive patients who underwent transcatheter closure ASD at King Chulalongkorn Memorial Hospital by using Cocoon™ atrial septal occluder between November 2005 and October 2008. Patients with secundum ASD were screened for suitability for transcatheter closure by transthoracic echocardiography (TTE) and then by transesophageal echocardiography (TEE) for complete assessment of the defect, its margins, pulmonary venous drainage, and for additional defects. The indication for closure was an increased right ventricular end-diastolic diameter (right atrial enlargement and right ventricular volume overload) with left to right shunt and adequate rim grater or equal than 5 mm from any surrounding structures except retroaortic rim.

Patients were assigned to one of two groups. Group 1 and 2 included ASD closure patients using device diameter grater or equal than 30 mm and less to 30 mm, respectively.

Cocoon™ atrial septal occluder (Fig. 1) is a new nitinol-based device, its shape resembles Amplatzer septal occluder but coated with platinum to prevent nickel release. The device is self-expanding, self-centering, fully retrievable, and can be repositioned. The size of the device is determined by the diameter of the waist. The device stents the actual defect and occlusion is achieved partly by thin polypropylene sheaths inserted inside, but mainly by in situ thrombosis and subsequent endothelialization. The retension rims extend the device by 6 to 7 mm and retains the device in position. The device is attached to a delivery cable by a microscrew and can be loaded into a long introducing sheath.

Interventional procedure

All procedures were done with local anesthesia with or without conscious sedation. Infective endocarditis was prophylactically treated with intravenous 1 gm-cefazolin and heparin 70 to 100 U/kg administered at the time of the procedure.

Defect sizing and device selection

The size of the ASD was measured by TEE and balloon sizing with 24 mm and 34 mm (Vascular Innovations Co. Ltd., Thailand). A 50 ml syringe with 1:4 solution of contrast agent to water was prepared for balloon infusion. Under the guidance of multipurpose catheter placed distally, the balloon was placed into the left upper pulmonary vein, a 260 cm, 0.035-inch J-tipped guidewire was advanced into the distal pulmonary vein for exchange with a balloon occlusion. The balloon was guided in to place where it straddled the defect. It was then inflated until the waist could be demonstrated on the fluoroscopic image and no color flow was shown by TEE. The balloon sizing diameter (BSD) was measured by TEE and radiology using calibration markers on the balloon catheter. Devices selected were 1 to 2 mm larger than the stretched diameter.

Device deployment

After the authors selected the device, an appropriate long delivery sheath was placed over the guidewire in the left upper pulmonary vein. Air was completely removed from the sheath before it was advanced through the left atrium.

Fig. 1 The Cocoon™ atrial septal closure device. Frontal view (left) of the left atrial disc; Side view (right) with the left atrial disc on the left and the right atrial disc on the right (the right atrial disc is connected to the delivery cable).

The device was carefully screwed into place with the delivery cable and loaded into the loader; then vigorously flushed with saline before its introduction into the long delivery sheath. The device was deployed to the left atrium under fluoroscopy and TEE guidance[11]. For ASD with deficient retroaortic rim, the device was aligned to straddle the aortic margin for successful implantation. After TEE image confirmed both disks were in the appropriate chamber with no or trivial color flow, the device was gently wiggled back and forth to confirm its stability. If the finding were adequate, the device was released from the cable (Fig. 2).

Discharge and follow-up

All patients were discharged home after TTE evaluation on the day after the procedure. Patients were prescribed aspirin 325 mg per day for six months and clopidogrel 75 mg per day for one month to prevent thromboembolic complications. Clinical follow-up visits and repeat TTE evaluations were scheduled for one visit within the first one to three months, and one year after the procedure, followed by yearly interval visits thereafter.

Data and statistical analysis

Clinical outcomes, complications and TTE before hospital discharge, during the first one to three months, and one year after the procedure were assessed. The data was expressed as the mean ± standard deviation, range, and percentage. An independent t-test was applied to compare variables between group 1 and 2. Categorical variables were analyzed by using the Fisher's exact test, as appropriate. $P<0.05$ was considered statistically significant.

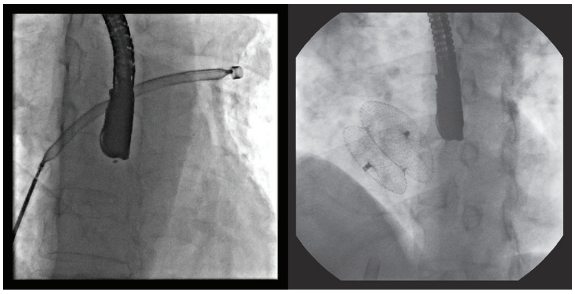

Fig. 2 Fluoroscopic images of self-expandible platinum-coated nitinol device (Cocoon™ atrial septal occluder) before (left) and after (right) device deployment under transesophageal echocardiographic guidance.

Results

Sixty-three consecutive patients who underwent transcatheter closure ASD by using Cocoon™ atrial septal occluder between November 2005 and October 2008 were enrolled. The total patient's mean age was 43.6±15.2 years (range 15-80 years) and female to male ratio was 3.5:1. Group 1 included 31 patients (49.2%) and group 2 had 32 patients (50.8%). Table 1 shows baseline clinical characteristics of the two groups. Age, sex, weight, height, clinical symptoms, right ventricular systolic pressure (RVSP), and main pulmonary artery (MPA) size were not significantly different between the groups. The patients in group 1 had significantly larger right ventricular (RV) size than group 2 ($p = 0.011$).

Defect and device sizes

The ASD size measured by TTE, TEE, and balloon sizing were larger in group 1 than group 2 significantly. The maximum size of secundum ASD in group 1 determined by TTE, TEE, and BSD were 22.6±5.0 mm (range 15-32), 28.1±4.8 mm (range 19-39), and 31±3.5 mm (range 23-38), respectively. The maximum size of secundum ASD in group 2 determined by TTE, TEE, and BSD were 19.7±4.4 mm (range 12-31), 20.4±3.4 mm (range 13-26), and 23.1±2.9 mm (range 15-30), respectively. The mean device size in group 1 and 2 were 33.5±3.1 (range 30-42) and 24.6±3.3 mm (range 14-28), respectively. Device was significantly larger in group 1 than in group 2 (Table 1).

Device implantation

Device implantations were successful in 27 patients (87.1%) in group 1 and 31 patients (96.9%) in group 2 ($p = 0.196$). Four patients (12.9%) in group 1 had unsuccessful implantation. All of them were in the first 15 cases of using large device (≥30 mm); two of them had device embolization that required surgical removal. The first one had the delivery cable break off from the device where it was attached to the device leaving it to embolize to LA. The second one had device embolization to IVC. The other two patients had inadequate rim for stabilization of device. One patient in group 2 had unsuccessful implantation due to device embolization that required surgical removal. There was no differentiation in TEE time, procedure time, and fluoroscopy time between the two groups (Table 1).

Table 1. Comparison of baseline data and clinical outcomes between groups of secundum ASD patients using Cocoon™ atrial septal occluder

	Group 1 (n = 31)	Group 2 (n = 32)	p-value
Age (year)	42.7±14.9	44.4±15.7	0.669
Gender (male:female)	9:22	5:27	0.669
Weight (kg)	54.4±12.6	58.4±11.0	0.182
Height (cm)	158.1±7.3	159.4±6.2	0.436
NYHAFC			0.496
FC I	29.0% (9)	40.6% (13)	
FC II	45.2% (14)	43.8% (14)	
FC III	25.8% (8)	15.6% (5)	
Palpitation	6.5% (2)	6.3% (2)	1.000
History of CHF	3.2% (1)	6.3% (2)	1.000
TTE ASD size (mm)	22.6±5.0	19.7±4.4	0.023
RVSP (mmHg)	53.0±18.6	45.7±13.9	0.116
RV size (mm)	38.6±6.7	33.9±6.6	0.011
MPA size (mm)	32.5±7.9	29.2±5.5	0.081
TEE ASD size (mm)	28.1±4.8	20.4±3.4	<0.001
Balloon ASD size (mm)	31.0±3.5	23.1±2.9	<0.001
Device size (mm)	33.6±3.1	24.8±3.3	<0.001
TEE time (min)	49.1±27.0	41.5±21.0	0.225
Procedure time (min)	87.5±43.2	70.4±30.0	0.072
Fluoroscopy time (min)	17.3±15.6	13.3±7.7	0.198
Successful implantation	87.1% (27)	100.0% (32)	0.196
Complication	26.7% (8)	21.9% (7)	0.660
Cardiac arrhythmia	13.8% (4)	12.5% (4)	1.000
Device embolization requiring surgical removal	6.7% (2)	3.1% (1)	0.607
Cardiac tamponade	3.4% (1)	6.3% (2)	1.000
Groin complication	3.4% (1)	3.1% (1)	1.000

ASD = atrial septal defect; NYHAFC = New York Heart Association Functional Classification; CHF = congestive heart failure; TTE = transthoracic echocardiography; TEE = transesophageal echocardiography; RVSP = right ventricular systolic pressure; RV = right ventricle; MPA = main pulmonary artery

Complication

Device embolization occurred in two patients of group 1. The first one had the screw break off from the device where it was attached to the device leaving it to embolized to LA. The second patient had device embolization to IVC. Group 2 had one device embolization that occurred 24 hours after a successful procedure and was detected by TTE. One patient (3.4%) in group 1 and two patients (6.3%) in group 2 had cardiac tamponade that required pericardiocentesis to be performed on all of them, which was resolved after symptomatic treatment. The cause of tamponade was not exactly identified. This might cause minimal tearing of atrium during deployment in the situation of fully anticoagulation.

Cardiac arrhythmias were found in four patients (13.8%) in group 1 and four patients (12.5%) in group 2 (p = 1.000). All four patients in group 1 had atrial fibrillation (AF), which was controlled by medication. Group 2 had two patients with AF and 1 patient with atrial flutter. One patient in group 2 had second degree AV block requiring a temporary pacemaker and transient ST-elevation in inferior lead, which had normal coronary angiography that disappeared within 10 minutes.

Table 2. Echocardiagraphic data before, In-hospital before discharge, 3 months and 1 year after transcatheter closure of ASDs

	Device group	Before	In-hospital	3 months	1 year
RVSP (mmHg)	≥30 mm	53.0±18.6	43.4±21.3	43.8±15.9	34.1±25.0
	<30 mm	45.7±13.9	32.6±11.2	37.2±19.2	35.2±16.4
RV size (mm)	≥30 mm	38.6±6.7	33.1±7.3	30.1±6.6	28.6±6.2
	<30 mm	33.9±6.6	27.9±4.9	28.3±7.7	26.7±5.2
Complete closure	≥30 mm		92.0%	95.7%	100.0%
	<30 mm		100.0%	100.0%	100.0%

There were no groin complication differences between the groups. One patient (3.4%) in group 1 had a groin hematoma and the one patient (3.1%) in group 2 had femoral AV-fistula.

Closure rate

There was no difference in the complete closure rate between either groups during hospital discharge, three months and one year after procedure ($p>0.05$). A slightly lower percentage of complete closure was demonstrated in group 1 before hospital discharge and three months after procedure but 100% complete closure rate was shown in both groups after one year (Table 2).

Discussion

Transcatheter closure of secundum ASD has been shown to be a safe and effective alternative to the surgical repair. It decreases the morbidity, hospital stay, and cost when compared to surgical closure[6,12-14]. Device closure of small to moderate ASD is well established and its safety has been well documented even in children[7-10]. The size of ASD in adults is usually larger than ASD size in children[21]. The large ASD mostly means BSD size greater than 25 mm, which is difficult to close and technically challenging[15,17]. A variety of devices has been developed for transcatheter closure of ASD. The simple deployment technique and self-centering design of Cocoon™ atrial septal occluder that resembles to Amplatzer septal occluder makes it the device of choice for closing large defects[18-20]. The largest device available was 42 mm and was implanted into one of the patients who took part in the present study.

In the present study, the authors did not use balloon sizing in every case. We found that sizing large ASD with balloon often "melon-seeds" between left and right atrium[21] making it difficult to occlude flow across ASD and measure waist on radiologically image that lead to incorrect balloon ASD size when choosing the device size. Thus, maximum TEE ASD size was instead used and adding 4 to 6 mm for choosing corrected device size.

The procedure requires a high level of technical experience and extended learning curve. This was evident in four patients whose unsuccessful implantation occurred in the first 15 cases of using large device size (grater or equal to 30 mm). Two of them had device embolization requiring surgical removal. One patient in group 2 had unsuccessful implantation and also had device embolization requiring surgical removal. This patient in group 2 had severe PS and secundum ASD. After successful percutaneous balloon pulmonic valvuloplasty (PBPV), the Cocoon™ atrial septal occluder was successfully implanted in the same procedural period. The device was embolized to LA and compressed mitral valve 24-hours after post procedure when the patient was routinely echocardiography before discharge. The authors propose that suicide of the right ventricle (RV) occurred after PBPV and high pressure from vigorous RV contraction, which made the device embolization to LA. Emergency surgical removal was performed and the defect was uneventfully closed with infundibulectomy.

The proper size of long delivery sheath was also important. In group 1, one patient with unsuccessful implantation due to device embolization required surgical removal was due to breakage of the delivery cable where it was attached to the device. The authors used 12 Fr long delivery sheath with device size 34 mm as the instruction recommendation. The actual mechanism that caused the failure is unknown. There was some unexpected resistance as the larger device size passed over the small long delivery sheath, this could have made the screw break off from the device. In our experience, the authors recommend using 14 Fr long delivery sheath for device size grater or equal than 30 mm and 12 Fr long delivery sheath for device size less than 30 mm.

The complication was not statistically different between groups. Most common complications in both groups were cardiac arrhythmia especially atrial fibrillation which mostly occurred in the 1-2 weeks after the procedure and was well-controlled by medication.

Before the patient was discharged from hospital, after the procedure, the complete closure was lower in group 1 than in group 2 without statistical significance. This was due to acceptable small amount of the shunting at the edge of the device in the large ASD group. At 1-year follow-up, 100% complete closure was demonstrated as endothelialization and fibrosis around the device occurred.

The present study had some limitations, retrospective study with incomplete data collection in some patients and too small of the populations in both groups to clearly demonstrate statistical significance. Transcatheter closure of large secundum ASD by Cocoon™ septal occluder is feasible with hemodynamic benefit. However, complication rates are higher with large ASD closures with device size greater or equal to 30 mm especially during the early "learning curve" period. With experience, the complication rate declines and the success rate was similar between the groups with smaller device size.

Potential conflicts of interest

None.

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การศึกษาผลทางคลินิกของการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนขนาดใหญ่ด้วย Cocoon™ atrial septal occluder

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ภูมิหลัง: โรครูรั่วระหว่างผนังกั้นหัวใจห้องบน (atrial septal defect) พบได้บ่อยในกลุ่มโรคหัวใจพิการแต่กำเนิดที่พบในผู้ใหญ่ amplatzer septal occluder (ASO) เป็นอุปกรณ์ที่ใช้บ่อยในการปิดรูรั่วดังกล่าวผ่านทางสายสวน ซึ่งทำได้ง่ายและให้ผลสำเร็จในการรักษาสูง Cocoon™ atrial septal occluder เป็นอุปกรณ์ชนิดใหม่ที่ทำจากนิกเกิล และมีลักษณะคล้าย ASO แต่เคลือบด้วยพลาตินัมเพื่อป้องกันการปล่อยสารนิกเกิลออกมาในร่างกาย

วัตถุประสงค์: ทบทวนการใช้ Cocoon™ atrial septal occluder ในการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนและศึกษาเปรียบเทียบประสิทธิภาพและผลการรักษาในการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนขนาดใหญ่ด้วยอุปกรณ์ขนาดมากกว่าหรือเท่ากับ 30 มม. และขนาดน้อยกว่า 30 มม.

วัสดุและวิธีการ: ตั้งแต่เดือนพฤศจิกายน พ.ศ. 2548 ถึง เดือนตุลาคม พ.ศ. 2551 มีผู้ป่วยเข้าร่วมการศึกษา 63 ราย ทั้งหมดได้รับการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนผ่านทางสายสวนและใช้ transesophageal echocardiography (TEE) โดยแบ่งผู้ป่วยเป็น 2 กลุ่ม กลุ่มที่ 1 ใช้ขนาดอุปกรณ์ขนาดอย่างน้อย 30 มม. ขึ้นไป มีจำนวน 31 ราย กลุ่มที่ 2 ใช้ขนาดอุปกรณ์น้อยกว่า 30 มม. มีจำนวน 32 ราย โดยวิเคราะห์ผลการรักษาภาวะแทรกซ้อนและผล transthoracic echocardiography (TTE) ก่อนออกจากโรงพยาบาล, 1-3 เดือน และ 1 ปี

ผลการศึกษา: กลุ่มที่ 1 จำนวน 27 ราย (ร้อยละ 87.1) และกลุ่มที่ 2 จำนวน 31 ราย (ร้อยละ 96.9) ได้รับการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนด้วยอุปกรณ์เป็นผลสำเร็จ ($p = 0.196$) กลุ่มที่ 1 มีขนาดรูรั่วระหว่างผนังกั้นหัวใจห้องบนเฉลี่ยซึ่งวัดด้วย TTE, TEE และ balloon sizing diameter (BSD) 22.6±5.0 มม. (พิสัย 15-32), 28.1±4.8 มม. (พิสัย 19-39) และ 31±3.5 มม. (พิสัย 23-38) ตามลำดับ กลุ่มที่ 2 มีขนาดรูรั่วระหว่างผนังกั้นหัวใจห้องบนเฉลี่ยซึ่งวัดด้วย TTE, TEE และ BSD 19.7±4.4 มม. (พิสัย 12-31), 20.4±3.4 มม. (พิสัย 13-26) และ 23.1±2.9 มม. (พิสัย 15-30) ตามลำดับ ในกลุ่มที่ 1 และ 2 มีขนาดอุปกรณ์โดยเฉลี่ย 33.5±3.1 มม. และ 24.6±3.3 มม. ตามลำดับ ($p<0.001$) ผู้ป่วย 4 ราย ในกลุ่มที่ 1 (ร้อยละ 12.9) ปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนด้วยอุปกรณ์ไม่สำเร็จ โดยทั้งหมดอยู่ใน 15 รายแรก ที่ใช้อุปกรณ์ขนาดอย่างน้อย 30 มม. ขึ้นไป และมีผู้ป่วย 2 ราย ที่ต้องผ่าตัดเอาอุปกรณ์ออกเนื่องจากอุปกรณ์หลุดจากผนังกั้นหัวใจห้องบน ในกลุ่มที่ 2 มีผู้ป่วย 1 ราย ที่ปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนด้วยอุปกรณ์ไม่สำเร็จ และต้องผ่าตัดเอาอุปกรณ์ออกเนื่องจากอุปกรณ์หลุดจากผนังกั้นหัวใจห้องบน ผู้ป่วยทั้งหมดมีอาการดีขึ้น right ventricular systolic function (RVSP) และขนาดหัวใจห้องขวาล่าง (RV) ค่อย ๆ ลดลง และมีการปิดสนิทของผนังกั้นหัวใจห้องบนร้อยละ 100 ใน 1 ปี

สรุป: การปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบนขนาดใหญ่ด้วย Cocoon™ atrial septal occluder สามารถทำได้ และมีประโยชน์ในการลดการทำงานของหัวใจ อย่างไรก็ตามการใช้อุปกรณ์ขนาดมากกว่า 30 มม. มีอัตราการเกิดผลแทรกซ้อนสูงโดยเฉพาะในช่วงแรก ทั้งนี้เมื่อมีประสบการณ์มากขึ้น อัตราการปิดสำเร็จและอัตราการเกิดภาวะแทรกซ้อนไม่แตกต่างกันกับการใช้อุปกรณ์ขนาดเล็กในการปิดรูรั่วระหว่างผนังกั้นหัวใจห้องบน