

# A Comparative Study of Outcomes after Transcatheter Closure of Secundum-Type Atrial Septum Defect in Adults Younger than 60 Years and the Older Ones

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**Objective:** To compare the results of transcatheter atrial septal defect (ASD) closure between adults younger than 60 years and the older ones in terms of the clinical and echocardiographic outcomes.

**Material and Method:** The cohort study consisted of 333 adult patients who underwent device closure of secundum ASD at Central Chest Institute of Thailand between January 2007 and June 2012. They were divided into two groups, group 1 were patients with age younger than 60 years, and group 2 were patients with age equal or older than 60 years. Clinical and echocardiographic outcomes were collected and analyzed.

**Results:** There were 274 patients in group 1 with mean age of  $38.7 \pm 12.1$  years and 59 patients in group 2 with mean age of  $66 \pm 4.9$  years. One year after ASD closure, functional class improvement  $\geq 1$  class was observed in both groups but there was no significant difference between group (64% in group 1 vs. 71.4% in group 2,  $p = 0.308$ ). A decrease in systolic pulmonary arterial pressure (PAP) and right ventricular systolic pressure (RVSP) were observed in both groups. The absolute changes of RVSP at baseline and one year post procedure were not significantly different between groups ( $15.8 \pm 9.9$  mmHg in group 1 vs.  $12.3 \pm 12.2$  mmHg in group 2,  $p = 0.067$ ). Procedural time and minor complications were comparable.

**Conclusion:** Transcatheter ASD closure can be effectively and safely performed in patients older than 60 years as compared with the younger ones. Symptomatic improvement and reduction of PAP and RVSP were observed at any age. ASD closure should be recommended irrespective of symptoms, even in adults with advanced age.

**Keywords:** Transcatheter closure of secundum atrial septum defect, Over 60 years of age, Elderly

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Atrial septal defect (ASD) is one of the common congenital heart disease that are diagnosed in adult. Chronic right heart volume overload leads to chronic right heart failure, pulmonary hypertension, and atrial arrhythmias<sup>(1,2)</sup>. Closure of ASD in children and young adults result in an improvement in symptoms, right heart remodeling, and reduction in pulmonary artery pressures<sup>(3-6)</sup>. However, the benefits of ASD closure in patients with advanced age are less clear and remained uncertain<sup>(7,8)</sup>.

Transcatheter closure of secundum type atrial septum defect is widely accepted as an alternative to surgical closure. This procedure is less invasive, lower complication rate and shorter length of hospital stay as compared with surgery<sup>(9-11)</sup>. The aim of the present study was to compare the effects of transcatheter ASD closure on functional status and echocardiographic

parameters between patients over and under the age of 60 years.

## Material and Method

### Patient recruitment

This cohort study enrolled 333 consecutive patients age over 20 years old who underwent device closure of secundum ASD at Central Chest Institute of Thailand, Nonthaburi between January 2007 and June 2012. The indication for closure included significant left to right shunt defined by calculated Qp/Qs ratio over 1.5 and the presence of right heart dilatation on echocardiogram, irrespective of symptoms. Transesophageal echocardiography (TEE) was routinely performed in all patients prior to scheduled device closure to assess ASD morphology and to exclude additional lesions such as anomalous pulmonary venous connection. Transcatheter ASD closure was not performed in patients who had ASD size  $>36$  mm or inadequate morphology (multiple defects, insufficient rim except anterior rim, interatrial septum aneurysm, and significant additional lesions).

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Invasive evaluation was routinely performed prior to the intervention. During study period, transcatheter ASD closure was attempted in 338 patients, but five patients (1.5%) required surgery because of device migration immediately after deployment.

#### **Device closure**

Transcatheter closure of ASD was conducted under local anesthesia with fluoroscopic and/or transesophageal echocardiographic guidance, after obtaining written informed consent. The Amplatzer septal occluder (AGA Medical Corporation) was used in all patients and device size was selected by intraprocedural transthoracic or transesophageal echocardiogram. The size of device was chosen based on maximal diameter plus 2 mm. Oral aspirin (162-325 mg/day) was administered one day before the procedure and continued for six months. Clopidogrel was given orally 300 mg loading one day prior to the procedure and then 75 mg once daily for one month.

#### **Echocardiography**

Transthoracic echocardiographic evaluation was performed the day following the procedure, three to six months and one year to evaluate for residual shunt and complications. Comprehensive echocardiographic data was measured by M-mode, two-dimensional, continuous-wave, pulsed-wave, and color Doppler echocardiography. Right ventricular systolic pressure (RVSP) was estimated using the maximum velocity of the tricuspid regurgitant jet. Right atrial pressure was estimated by inferior vena cava (IVC) diameter.

#### **Follow-up**

Patients underwent serial physical examination, 12-lead ECG and chest X-ray 1 day, 3-6 months, 12 months and yearly after the intervention to determine the functional status and any complications.

#### **Statistical analysis**

The results were reported as percentages for categorical variables and means with standard deviations or median (minimum-maximum) for continuous variables. The differences between two groups were compared using Chi-square or Fisher's exact test for categorical variables and Independent t-test or Mann-Whitney U test for continuous variables. Two-way repeated measures ANOVA was used for testing the mean difference between two groups. All data were analyzed by SPSS software version 15.0.

A *p*-value of less than 0.05 was considered to indicate statistical significance, and all tests were two-sided.

## **Results**

### **Baseline characteristics**

Baseline clinical characteristics and echocardiographic data were shown in Table 1. Three hundred and thirty three patients were enrolled in the study, 274 were younger than 60 years and 59 were older than 60 years. The ASD size and shunt ratio were not significantly different between two groups. However, the older group had more co-morbid diseases with higher prevalence of persistent atrial fibrillation (AF), history of heart failure, and admission from heart failure as compared with the younger group. All patients in the older group were symptomatic, 91.5% in New York Heart Association (NYHA) class II and 8.5% in NYHA class III. Age was slightly correlated with NYHA ( $r = 0.30, p < 0.001$ ) and baseline RVSP ( $r = 0.28, p < 0.001$ ). There was no correlation between age and ASD size. Left atrium size, main pulmonary artery (MPA) size, and moderate tricuspid regurgitation (TR) were significantly higher in the older group. Functional class was significantly related to RVSP with NYHA class I ( $38.5 \pm 12.8$  mmHg), class II ( $45.6 \pm 13.5$  mmHg) and class III ( $58.8 \pm 29.6$  mmHg),  $p < 0.001$ .

### **Intervention results and complications**

Cardiac catheterization data were shown in Table 2. The systolic and mean pulmonary arterial pressure (PAP) significantly increased with age. There was no significant difference in shunt ratio and pulmonary vascular resistance. The device size, fluoroscopy time and procedure time did not significantly differ between age groups. After the procedure, systolic pulmonary arterial pressure (PAP) immediately decreased in both age groups but absolute changes did not differ between groups ( $10.3 \pm 13.8$  mmHg for older group vs.  $8.5 \pm 8.8$  mmHg for younger group,  $p = 0.308$ ). No major procedural complication occurred. Subcutaneous hematoma was observed in four patients and two patients had femoral AV fistula. No residual shunt was observed.

### **Follow-up**

In the younger group, one patient was lost to follow-up in early period (3 months) and two patients died from non-cardiac event after two years of follow-up. In the older group, two patients with persistent AF died from cerebrovascular events and

**Table 1.** Baseline characteristics of patients

	All patients (n = 333)	<60 years (n = 274)	≥60 years (n = 59)	p-value
Age at time of procedure (year)	43.5±15.3	38.7±12.1	66.0±4.9	
Female, n (%)	272 (81.7%)	226 (82.5%)	46 (78.0%)	0.416
BMI (kg/m <sup>2</sup> )	22.4±4.8	22.2±4.9	23.6±4.3	0.049
Fn class (NYHA)				<0.001
NYHA I, n (%)	89 (26.7%)	89 (32.5%)	0	
NYHA II, n (%)	224 (67.3%)	170 (62.0%)	54 (91.5%)	
NYHA III, n (%)	20 (6.0%)	15 (5.5%)	5 (8.5%)	
History of heart failure, n (%)	23 (7.0%)	12 (4.4%)	11 (18.6%)	<0.001*
Diabetes, n (%)	20 (6.0%)	8 (2.9%)	12 (20.3%)	<0.001*
Hypertension, n (%)	58 (17.4%)	27 (9.9%)	31 (52.5%)	<0.001
Respiratory disease, n (%)	10 (3.0%)	2 (0.7%)	8 (13.6%)	<0.001
Ischemic stroke, n (%)	1 (0.3%)	0	1 (1.7%)	0.177*
Persistent AF, n (%)	21 (6.3%)	8 (2.9%)	13 (22.0%)	<0.001*
Paroxysmal AF, n (%)	10 (3.0%)	6 (2.2%)	4 (6.8%)	0.082*
History of admission from CHF, n (%)	18 (5.4%)	10 (3.7%)	8 (13.6%)	0.006*
Echocardiographic data <sup>+</sup>				
ASD size from TTE (mm)	21.1±6.8	21.1±6.6	20.6±7.5	0.657
ASD size from TEE (mm)	20.9±6.0	21.1±5.7	19.9±7.0	0.194
Shunt ratio Qp/Qs	3.4 (1.05, 75)	3.3 (1.1, 75.0)	3.8 (1.2, 12.0)	0.093 <sup>#</sup>
MPA size (mm)	28.9±5.8	28.3±5.6	31.4±6.2	<0.001
Left atrium size (mm)	35.7±7.8	34.1±6.9	43.0±7.4	<0.001
LVEF%	65.2±10.9	65.0±10.4	66.0±12.9	0.607
LVEDD (mm)	37.3±5.8	37.0±5.5	38.6±7.1	0.051
LVESD (mm)	24.0±5.2	23.7±4.4	25.1±7.7	0.2
RVOT diameter (mm)	29.9±5.7	29.1±5.2	31.4±6.2	0.029
RVSP (mmHg)	43.8±15.4	42.2±15.6	51.1±12.3	<0.001
Moderate TR, n (%)	73 (22.1%)	53 (19.5%)	20 (33.9%)	0.023*
Severe TR, n (%)	27 (8.2%)	19 (7.0%)	8 (13.6%)	0.113*

BMI = body mass index; NYHA = New York Heart Association; AF = atrial fibrillation; CHF = Congestive heart failure; ASD = atrial septal defect; TTE = transthoracic echocardiogram; TEE = transesophageal echocardiography; MPA = main pulmonary artery; LVEF = left ventricular ejection fraction; LVEDD = left ventricular end-diastolic diameter; LVESD = left ventricular end-systolic diameter; RVOT = right ventricular outflow tract; RVSP = right ventricular systolic pressure; TR = tricuspid regurgitation

\* Fisher's exact test, <sup>#</sup> Mann-Whitney U test

<sup>+</sup> Data were presented as mean (SD) or median (min, max) as appropriate

one patient died from lung cancer two year after the procedure. One elderly patient died one month after discharge from unknown cause.

### Functional status

Functional class improvement ≥1 class was observed in both age groups but there was no significant difference between groups (64.3% in younger group vs. 71.4% in older group,  $p = 0.308$ ). As shown in Fig. 1, one year after the procedure, 95.2% of younger group were asymptomatic. In the older group, 37.5% of patients remained in NYHA class II, whereas

62.5% were asymptomatic. Patients who had history of admission from heart failure prior to ASD closure had a significant reduction in readmission rate from heart failure; one patient in younger group and none in the elder group had to be readmitted due to heart failure in the first year after the procedure.

### Echocardiographic results and arrhythmias

As shown in Fig. 2, a decrease in RVSP was observed in both age groups. The absolute changes of RVSP at baseline and one year post ASD closure were not significant difference among groups

**Table 2.** Cardiac catheterization data<sup>+</sup>

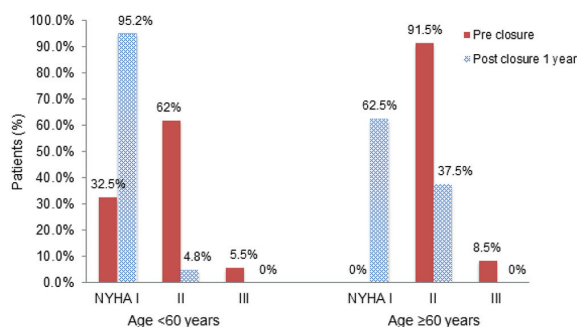
	All patients (n = 333)	<60 years (n = 274)	≥60 years (n = 59)	p-value
Systolic PA pressure (mmHg)	38.7±16.4	36.8±15.5	47.5±17.8	<0.001
Mean PA pressure (mmHg)	24.2±9.6	23.4±9.9	27.7±7.5	0.002
Shunt ratio Qp/Qs	2.6 (0.5, 28.0)	2.6 (0.50, 23.0)	2.6 (1.4, 28.0)	0.493 <sup>#</sup>
Pulmonary vascular resistance (wood unit)	2.23 (0.01, 27.6)	2.2 (0.01, 27.6)	2.5 (0.95, 5.03)	0.080 <sup>#</sup>
Device size (mm)	27.4±5.1	27.4±5.0	27.1±5.6	0.673
Fluoroscopic time, min	11.0±5.3	10.7±5.3	12.2±5.0	0.053
Procedure time, min	46.8±16.8	46.1±16.3	50.2±18.4	0.087

PA = pulmonary artery

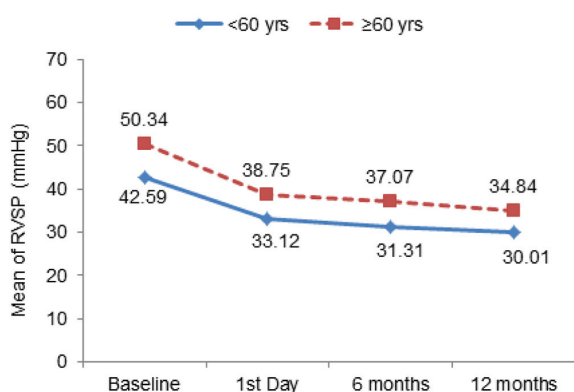
\* Fisher's exact test, <sup>#</sup> Mann-Whitney U test

<sup>+</sup> Data were presented as mean (SD) or median (min, max) as appropriate

(15.8±9.9 mmHg in older group vs. 12.3±12.2 mmHg in younger group,  $p = 0.067$ ). There were no significant changes in left ventricular dimensions and ejection fraction. Patients with persistent atrial fibrillation were remained in this rhythm at follow-up.



**Fig. 1** Functional status before and after ASD closure for patients younger and older than 60 years old.



**Fig. 2** Right ventricular systolic pressure (RVSP) before, 1 day, 6 months and 1 year after atrial septal defect closure for patients over and younger than 60 years.

## Discussion

Current guideline recommends all hemodynamically significant ASD patients should undergo ASD closure, regardless of symptoms<sup>(12)</sup>. Transcatheter ASD closure is much less invasive than surgery and has been reported as safe and effective treatment<sup>(13-15)</sup>. This procedure can relieve the symptom, improve exercise capacity, and right heart remodeling<sup>(5,16)</sup>. Elderly patients have a prolonged left to right shunt resulting in chronic right ventricular volume overload and subsequent pulmonary hypertension and atrial arrhythmia. Furthermore, elderly patients have high prevalence of co-morbid conditions such as hypertension, diabetes, ischemic heart disease that concern benefits of ASD closure in these patients. Surgical closure of ASD in the elderly can result in significant mortality and morbidity<sup>(17,18)</sup>. There were limited studies regarding safety and efficacy of transcatheter ASD closure in patients over 60 years of age. However, previous small studies revealed that this procedure not only can be performed safely, but also results in improvement of functional capacity and regression of RV dimension<sup>(19-22)</sup>.

The present study showed that transcatheter ASD closure was associated with very low rate of complications and particularly no mortality even though it was performed in patients older than 60 years. High success rate of closure was found in both age groups (97%). Procedural time, fluoroscopy time and complication rate were similar in both age groups. Vijarnsorn et al<sup>(23)</sup> reported that this procedure was safe and had low rate of complications, regardless of age. The major concern about acute transient pulmonary edema after ASD closure was described in elderly patients<sup>(22,24)</sup>. However, it did not occur in our patients. Significant improvement of functional class was

observed in all age particularly in the elderly because all patients in the older groups were symptomatic and had higher baseline RVSP. Moreover, elderly patients with history of hospitalization from heart failure did not require additional admission from heart failure during one-year follow-up.

The risk of atrial arrhythmia is closely related to age. Previous studies reported that the new onset of atrial arrhythmias occur more frequently in patients older than 40 years at time of surgery<sup>(3)</sup>. Furthermore, the likelihood of remaining no arrhythmia after transcatheter ASD closure was highest in patients younger than 40 years without a history of atrial arrhythmia<sup>(25)</sup>. The present study showed that the incidence of atrial fibrillation after ASD closure was higher in the older group than in the younger group. Atrial fibrillation persisted in all patients who had this rhythm before the procedure.

RVSP and PAP increased continuously with age. A reduction in RVSP and PA pressure has been documented in younger patients after ASD closure<sup>(26,27)</sup>. Several authors have suggested that these beneficial effect may be blunted or disappear with advancing years<sup>(9,26)</sup>. Humenberger et al<sup>(27)</sup> reported regression of PA pressure and RV size with symptomatic improvement in three months after ASD closure even in patients with advanced age. Nevertheless, the present study showed that the RVSP and PA pressure decreased in both groups at one year after the procedure but the absolute changes did not significantly differ between age groups. Future study is required to demonstrate whether long-term follow-up of RVSP can show further reduction.

### Conclusion

Transcatheter ASD closure can be effectively and safely performed in patients older than 60 years as compared with the younger ones. The symptomatic improvement as well as reduction of RVSP and pulmonary arterial pressure can be noticed at any age. However, the absolute changes of RVSP did not significantly differ between age groups and not reach the normal level after one year follow-up.

### Limitations

First, the improvement of functional class in the present study was based on the patients' subjective, not on other functional measurement such as six-minute walk test or cardiopulmonary exercise test. However, it is a practical and easy way to assess patients during outpatient visit. Second, this study did

not monitor patient's rhythm with 24 hour ECG monitoring, so it could underestimate the incidence of arrhythmias.

### What is already known on this topic?

The benefits of ASD closure in patients with advanced age are less clear. The previous studies showed that transcatheter ASD closure in patients over 60 years of age not only can be performed safely, but also results in symptomatic improvement, reduction of RVSP and regression of RV dimension.

### What this study adds?

This study confirmed the benefit of transcatheter ASD closure in the elderly in terms of functional class improvement, reduction of RVSP and pulmonary arterial pressures. There was no additional heart failure hospitalization during one-year follow-up in elderly patients with history of previous hospitalization. This procedure is safe so it should be recommended even in the elderly patients.

### Acknowledgements

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### Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบผลการปิดผนังหัวใจห้องบนรั่วแต่กำเนิดชนิด *secundum* ผ่านทางสายสวนหัวใจ ในผู้ป่วยที่อายุมากกว่าและน้อยกว่า 60 ปี

สมรรถันต์ จำปาเทศ, เกรียงไกร เสงรัมย์

**วัตถุประสงค์:** ศึกษาเปรียบเทียบผลการรักษาในแง่อาการและผลการตรวจคลื่นเสียงสะท้อนหัวใจหลังจากการปิดรูรั่วที่ผนังกันห้องหัวใจห้องบนโดยใช้วิธีสวนหัวใจ ระหว่างผู้ป่วยอายุมากกว่าและน้อยกว่า 60 ปี

**วัสดุและวิธีการ:** ศึกษาข้อมูลในผู้ป่วยอายุ 20 ปีขึ้นไป จำนวน 333 ราย ที่ได้รับการรักษาปิดรูรั่วที่ผนังกันห้องหัวใจห้องบนโดยใช้วิธีสวนหัวใจที่สถาบันโรคทรวงอก ในช่วง เดือนมกราคม พ.ศ. 2550 ถึง มิถุนายน พ.ศ. 2555 แบ่งผู้ป่วยเป็น 2 กลุ่มอายุ ได้แก่ อายุน้อยกว่า 60 ปี จำนวน 274 ราย (อายุเฉลี่ย  $38.7 \pm 12.1$  ปี) และอายุ 60 ปีขึ้นไป จำนวน 59 ราย (อายุเฉลี่ย  $66 \pm 4.9$  ปี)

**ผลการศึกษา:** หลังการรักษา 1 ปี พบว่าอาการเหนื่อยลดลงอย่างชัดเจนในผู้ป่วยทั้งสองกลุ่มอายุ โดยไม่พบความแตกต่างระหว่างกลุ่มอย่างมีนัยสำคัญ (64% ในคนอายุน้อย และ 71.4% ในคนสูงอายุ,  $p = 0.308$ ) พบการลดลงของความดันหลอดเลือดปอดและความดันหัวใจห้องขวาล่างทั้งสองกลุ่ม โดยระดับการลดลงของความดันหัวใจห้องขวาล่างหลังการรักษาที่ 1 ปี ไม่แตกต่างระหว่างกลุ่มอย่างมีนัยสำคัญ ( $12.3 \pm 12.2$  mmHg ในคนอายุน้อย และ  $15.8 \pm 9.9$  mmHg ในคนสูงอายุ,  $p = 0.067$ ) รวมถึงไม่พบความแตกต่างในแง่ระยะเวลาและผลแทรกซ้อนจากการรักษาในทุกกลุ่มอายุ

**สรุป:** การปิดรูรั่วที่ผนังกันห้องหัวใจห้องบนโดยใช้วิธีสวนหัวใจมีความปลอดภัยสูง และทำให้อาการผู้ป่วยดีขึ้น รวมถึงมีผลลดความดันหลอดเลือดปอดและความดันหัวใจห้องขวาล่างในผู้ป่วยทุกกลุ่มอายุ ดังนั้นการรักษาวิธีนี้จึงควรแนะนำในผู้ป่วยทุกรายแม้ในคนสูงอายุก็ตาม