Original Article

# Short- and Mid-term Results of Atrial Septal Defect and Patent Foramen Ovale Occlusion with Starway Septal Occluder Device

J Kojuri, MA Ostovan, M Rezaee

*Cardiovascular Research Center , Shiraz University of Medical Sciences, Shiraz, Iran*

## Abstract

**Background:** With a prevalence of almost 7% of all congenital heart diseases, atrial septal defect (ASD) is a common condition. Patent foramen ovale (PFO) is also a congenital heart disease which is frequently sustained into adulthood.

**Objective:** To study the feasibility of closure of ASD and PFU by Starway septal occluder device and the incidence of its inherent complications and procedural failure in 62 patients referred to our center.

**Methods:** Starway septal occluder device was used for closure of ASD and PFO in 62 patients. After left and right heart catheterization, transesophageal echocardiography-guided closure was done for the patients with immediate recording of the results. Patients were followed for 6 months by transesophageal echocardiography for observing short- and mid-term complications.

**Results:** The 62 studied patients were categorized into 2 groups. Group 1 included 31 patients (64% females) with ASD (mean±SD age: 26.7±7.6 years). Group 2 consisted of 31 patients (35.6% females) with PFO (mean±SD age: 53.5±12.4 years). Size of the right ventricle (RV) annulus was significantly (P=0.005) decreased after the intervention in the ASD group. Overall 5 (8%) patients developed post-intervention complications (transient ischemic attack, leg edema, and residual shunt) and procedural failure—4 (13%) in ASD group and 1 (3%) in PFO group. None of the patients developed device-related thrombosis, significant arrhythmia, aortic regurgitation and pericardial effusion after intervention.

**Conclusion:** Starway occluder device is effective and safe with very low short- and mid-term complication rates.

**Keywords:** Atrial Septal Defect; Patent Foramen Ovale; Congenital Heart Disease; Septal Occluder Device

*Manuscript received: June 20, 2011; Accepted: August 7, 2011*

**Iran Cardiovasc Res J 2011;5(3):82-86**

## Introduction

With a prevalence of almost 7% of all congenital heart diseases, atrial septal defect (ASD) is a common condition.[1] The defect is usually closed spontaneously or at least decreased in size when its diameter is <7 mm and in patients with younger age at diagnosis.[2] In these patients, two-thirds of the defects are closed by the age of 18 months. In patients with left to right shunt, right atrial enlargement or right ventricular enlargement, regardless of their symptoms, intervention is necessary for closure of the defect.[2]

Correspondence: Javad Kojuri, Cardiologist, Interventionist, Iran, Shiraz, Zand Blvd, Namazi Hospital, Department of Cardiology.
Tel: +98-711-631-8032
Fax: +98-711-233-3064
E-mail: kojurij@yahoo.com

Patent foramen ovale (PFO) is also a congenital heart disease which frequently persists to adulthood. Since no septal tissue is missing in PFO, it is not considered as a real ASD, thus the right-to-left inter-atrial shunt cannot occur until the right atrial pressure exceeds that of the left.[3] Despite its benign course and asymptomatic nature, some clinical manifestations such as cryptogenic strokes are attributed to this pathology.[4]

The prevalence of PFO is significantly higher in patients with cryptogenic strokes compared to those presenting with stroke and who had known stroke risk factors.[5] PFO is a possible pathway for atrial transit of emboli (paradoxical emboli) with right-to-left shunt when the pressure in the right atrium is higher than that in the left atrium.[6]

There are several therapeutic modalities for

**Table 1:** Epidemiologic data of the patients

| Disease | Mean±SD Age (yrs) | Female Sex | Size of Device Median (Range) | Mean±SD EF (%) |
|---|---|---|---|---|
| ASD (n=31) | 26.7±7.6 | 64% | 24 (18–34) | 58.4±5.2 |
| PFO (n=31) | 53.5±12.4 | 35.6% | 25 (25–30) | 52.4±4.6 |

SD: Standard deviation, EF: Ejection fraction

prevention of stroke in such patients namely antiplatelet agents, anticoagulants and surgical or percutaneous closure of the defect.[7] Overall, it was demonstrated that surgical interventions are significantly more effective than medical treatment especially in those with recurrent stroke.[8]

Transesophageal echocardiography during valsalva maneuver is a sensitive method for the diagnosis of PFO with right-to-left shunt.[7]

In this study, we investigated the prevalence of complications such as residual shunt, device-related thrombosis, aortic regurgitation, arrhythmia and embolic events after closure of the ASD and PFO using Starway septal occluder device in 62 patients referred to our center.

## Patients and Methods

This study was conducted from July 2009 to July 2011. It comprised patients referred to our center with the final diagnosis of septum secondum, ASD and large PFO with left-to-right shunt or inter-atrial septal aneurysm referred by neurologist for transesophageal echocardiography as a part of routine investigations for evaluation of stroke or transient ischemic attacks. Those patients with other congenital heart diseases were excluded from the study.

All the studied patients gave written informed consent for inclusion in this study and were medically cleared to participate in this investigation.

The patients were treated using Starway septal occluder device (Starway Medical Technology, Inc., Beijing, China) for closure of the defect. The patients then underwent successive angiography and transesophageal echocardiography followed by another follow-up transesophageal echocardiography after six months. Short- and mid-term complications of the procedure were followed and recorded in a questionnaire. The patients were put on dual antiplatelet therapy of aspirin (160 mg) and Plavix (75 mg) for one month. It followed by taking aspirin (80 mg) for at least one year.

All patients aged more than 40 years underwent diagnostic coronary angiography prior to the procedure. In PFO group, six (19%) patients had coronary artery disorders of whom one for having significant coronary artery disease (CAD), underwent coronary stenting. Coronary artery disease was not significant in other patients.

Detection of arrhythmia was based on a 12-lead ECG. Patients were readmitted if they had significant arrhythmias.

Residual shunt was defined as "significant color flow through the device or passage of more than five bubbles of contrast (shaked saline) during contrast transesophageal echocardiography."

Based on NACET (North American Symptomatic Carotid Endarterectomy Trial) criteria, transient ischemic attack (TIA) was considered as any significant transient neurologic deficit and cerebrovascular accident (CVA) proved by MRI. All cases of TIA and CVA were referred to neurologist for further follow-up.

The data obtained were analyzed using the SPSS® ver. 15.0. Descriptive methods were used for statistical analysis of the results. Independent *Student's t* test was used to compare means of two normally distributed variables. A p value $<0.05$ was considered statistically significant.

## Results

Overall, we studied 62 patients who were divided into two groups (Table 1). Group 1 included 31 patients (64% females) with a mean±SD age of 26.7±7.6 years who had ASD. Group 2 consisted of 31 patients (35.6% females) with a mean±SD age of 53.5±12.4 years who had PFO.

The patients with PFO were significantly older than those with ASD (P=0.005). Also male to female ratio for patients with PFO was significantly higher than that for ASD (P=0.005). CAD was seen in six (19%) patients with PFO, whereas it could not be found in any of patients with ASD. Moreover, all of the patients with PFO had history of TIA or CVA.

Size of the right ventricle (RV) annulus was significantly decreased after intervention in ASD group (Before intervention: 12.8±2.1, After intervention9.5±2.2, P=0.005).

Five (8%) patients developed post-intervention complications and procedural failure; 4 (13%) were in ASD and one (3%) in PFO group (Table 2).

Two cases of TIA were diagnosed. The first one was a 21-year-old man who developed two

**Table 2:** Complications and procedural failure after intervention

| Disease | Complications |
|---|---|
| ASD | Residual shunt*<br>TIA†<br>Failed procedure‡<br>Transient leg edema |
| PFO | TIA |

*Residual shunt with QP/QS less than 1.5, followed on medical treatment.
†Transesophageal echo of all patients with TIA in ASD and PFO groups was unrevealing; no source for emboli was detected, so patients were put on life-long and dual antiplatelet regimen without further event.
‡ASD could not be occluded due to its large size. The device could not be inserted in place. So we stopped the procedure and removed the device.

episodes of transient speech deficit three and six months after the procedure—both were associated with discontinuation of aspirin due to gastrointestinal upset. Neurological review, transesophageal echo and MRI were performed, but no clot was seen and the patient was put on long-term aspirin and Plavix without any further events. The second case of TIA was a 56-year-old woman who developed left facial paresthesia six months after the procedure when she used aspirin. Transesophageal echo and MRI were all normal and the patient was put on long-term aspirin and Plavix without any further events.

Transient leg edema, which resolved spontaneously, was seen in a 41-year-old woman in ASD group, one month after the procedure with normal flow of hepatic vein and inferior vena cava.

None of the patients developed device-related thrombosis, significant arrhythmia, aortic regurgitation, and pericardial effusion after the intervention.

## Discussion

This study was conducted to evaluate the feasibility, safety, and efficacy of Starway occluder for treatment of PFO and ASD. Transcatheter closure of PFO has rapidly accepted as the preferred strategy for the management of recurrent CVA and paradoxical emboli.[10] Several studies have shown that this type of closure had very few complications in short- and long-term follow-up.[9] It has recently been demonstrated that transcatheter PFO closure is a safe procedure even in the selected and high risk patients.[10] Kefer, *et al*, in 2011 showed the effectiveness of this method in both PFO and ASD, and demonstrated that transcatheter interatrial septal shunt closure is an effective treatment in patients even in cases with thrombophilia or pulmonary hypertension.[11]

Kazmi, *et al*, showed that device closure of secundum ASD using Amplatzer septal occluder is safe and effective in mid- and long-term follow-ups with low mortality rate, and very low risk of developing aortic regurgitation and atrial fibrillation.[8]

In a cohort study on 529 patients, in 2011, Tomar, *et al*, showed no residual shunt or thrombosis using Amplatzer septal occluder. However, 10% of the patients had the right ventricular dilation in follow-up and 10 patient had atrial fibrillation before and after the procedure.[12,13]

A study reported in 2003 revealed more supraventricular arrhythmia and complication rates (28%) in patients whose ASD was closed surgically than those who underwent transcatheter closure; there was also more hospital stay in ASD surgical closure.[14]

Zhong-Dong Du, *et al*, showed that the early success rate of transcatheter closure was more than surgical closure and that the complication rate of surgical group was 24% compared with 7% in transcatheter procedure. In addition, hospital stay in surgical group was longer than transcatheter closure.[15]

Based on various studies, it seems that both surgical and transcatheter closure of ASD are similarly effective but due to risk of anesthesia, thoracotomy and cardiopulmonary bypass and longer hospital stay in surgical closure group, transcatheter method is preferable if it is feasible. The surgical treatment should be reserved for those who are not suitable anatomically for transcatheter closure.[14,15]

According to Thaman, *et al*, Amplatzer AGA (USA) was an alternative device used for transcatheter occlusion of ASD. They reported that the rate of residual shunting was almost 11%, which was significantly higher than the results of our study with Starway occluder.[12]

Surgery is still the gold standard therapy for ASD patients. However, it has many post-operative complications and is also very expensive and time consuming, so transcatheter occlusion of ASD seems to be safe and feasible method in selected patients.[15]

## References

1. Diaconu CC. Atrial septal defect in an elderly woman-a case report. *J Med Life* 2011;**4**:91-3. [PMID: 21505579]
2. Al Hroob A. Transcatheter closure of Secundum Atrial septal defect in children and adults. *Heart view* 2002;**3**:79-83.
3. Lamy C, Giannesini C, Zuber M, Arquizan C, Meder JF, Trystram D, et al. Clinical and imaging findings in cryptogenic stroke patients with and without patent foramen ovale: the PFO-ASA Study. Atrial Septal Aneurysm. *Stroke* 2002;**33**:706-11. [PMID:11872892]
4. Homma S, Sacco RL, Di Tullio MR, Sciacca RR, Mohr JP. PFO in Cryptogenic Stroke Study (PICSS) Investiga-

tors. Effect of medical treatment in stroke patients with patent foramen ovale: patent foramen ovale in Cryptogenic Stroke Study. *Circulation* 2002;**105**:2625-31. [PMID:12045168]

5. Arquizan C, Coste J, Touboul PJ, Mas JL. Is patent foramen ovale a family trait? A transcranial Doppler sonographic study. *Stroke* 2001;**32**:1563-6. [PMID:11441202]
6. Rigatelli G, Dell'avvocata F, Braggion G, Giordan M, Chinaglia M, Cardaioli P. Persistent venous valves correlate with increased shunt and multiple preceding cryptogenic embolic events in patients with patent foramen ovale: an intracardiac echocardiographic study. *Catheter Cardiovasc Interv* 2008;**72**:973-6. [PMID:19021284]
7. Khositseth A, Cabalka AK, Sweeney JP, Fortuin FD, Reeder GS, Connolly HM, et al. Transcatheter Amplatzer device closure of atrial septal defect and patent foramen ovale in patients with presumed paradoxical embolism. *Mayo Clin Proc* 2004;**79**:35-41. [PMID:14708946]
8. Kazmi T, Sadiq M, Asif-ur-Rehman, Hyder N, Latif F. intermediate and long term outcome of patients after device closure of ASD with special reference to complications. *J Ayub Med Coll Abbottabad* 2009;**21**:117-21. [PMID:20929028]
9. Bissessor N, Wong AW, Hourigan LA, Jayasinghe RS, Scalia GS, Burstow DJ, et al. Percutaneous patent foramen ovale closure: outcomes with the Premere and Amplatzer devices. *Cardiovasc Revasc Med* 2011;**12**:164-9.[PMID:21640934]
10. Scacciatella P, Butera G, Meynet I, Giorgi M, D'Amico M, Pennone M, et al. Percutaneous Closure of Patent Foramen Ovale in Patients with Anatomical and Clinical High-Risk Characteristics: Long-Term Efficacy and Safety. *J Interv Cardiol* 2011;**24**:477-84. [PMID:21539612]
11. Kefer J, Sluysmans T, Hermans C, Khoury RE, Lambert C, Van de Wyngaert F, et al. Percutaneous transcatheter closure of interatrial septal defect in adults: Procedural outcome and long-term results. *Catheter Cardiovasc Interv* 2011 [Epub ahead of print]. [PMID:21523898]
12. Thaman R, Faganello G, Gimeno JR, Szantho GV, Nelson M, Curtis S, et al. Efficacy of percutaneous closure of patent foramen ovale: comparison among three commonly used occluders. *Heart* 2011;**97**:394-9. [PMID:21296783]
13. Tomar M, Khatris S, Radhakrishnan S, Shrivastavas S .Intermediate and long-term follow up of percutaneous device closure of fossa ovalis atrial septal defect by the amplatzer septal occlude in a cohort of 529 patients. *Ann Pediatr Cardiol* 2011;**4**:22-7. [PMID:21677800]
14. Bettencourt N, Salomé N, Carneiro F, Gonçalves M, Ribeiro J, Braga JP , et al. Atrial septal closure in adult :surgery versus amplatzer--comparison of result. *Rev Port Cardiol* 2003;**22**:1203-11. [PMID:14708334]
15. Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K. Amplatzer Investigators. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adult: results of a multicenter nonrandomized trial. *J Am Coll Cardiol* 2002;**39**:1836-44. [PMID:12039500]