

Intermediate and long-term followup of percutaneous device closure of fossa ovalis atrial septal defect by the Amplatzer septal occluder in a cohort of 529 patients

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ABSTRACT

Objectives : The aim of present study is to analyze the intermediate and long-term follow up results of percutaneous closure of fossa ovalis atrial septal defect (ASD) with Amplatzer septal occluder (ASO) in a large cohort of patients including children and adults.

Methods : Between May 1998 and July 2008, 529 patients (age group 2-77 years, median 28 years) underwent successful device closure with an ASO at single tertiary referral cardiac center in India. This was out of an attempted 543 cases. The procedure was carried out in catheterization laboratory under transesophageal echocardiographic and fluoroscopy guidance. The mean size of ASD was 20 mm (7-40 mm) while size of septal occluder was 10-40 mm (mean 24 mm). Two devices were deployed in four patients. Three patients developed transitory pulmonary edema in immediate postprocedure period requiring ICU care for 48 hrs. All patients were advised for Aspirin (3-5 mg/kg, maximum 150 mg) once daily for 6 months. In patients with device 30 mm or larger, Clopidogril (75 mg once daily) was given for 3 months in addition to Aspirin. Clinical evaluation, echocardiogram were done on 3 months, 6 months and then at 1, 3, 5, 7 and 10 years of follow up. Transesophageal echocardiography (TEE) was performed in case of any doubt on clinical evaluation or on transthoracic echocardiography (n=10).

Results : Followup data is available for 496 patients (93.7%). Followup period is from 12 months to 120 months (median 56 months). On followup, device was in position in all patients, no residual shunt and no evidence of thrombosis. Interventricular septal motion normalized on day of procedure in 89% patients, in 6% over 3 months while flat septal motion persisted in 5% (n=25, all in age group > 40 years) of cases, though right ventricular dilatation persisted in 10% (n=50, age more than 40 years) of patients. Symptom-free survival was 96.7 % (480/496) in patients who came for followup. Only one 68 year old patient with preexistent tricuspid regurgitation developed congestive heart failure, and one patient (58 years old) had a history of hemiparesis after 1 year of device on telephonic interview. Ten patients were in atrial fibrillation (AF) before the procedure and remained in AF on followup.

Conclusions : Our study showed that percutaneous closure of fossa ovalis ASD is a safe and effective procedure on intermediate and long-term followup in both the children as well as adults. both. Technical factors during the procedure and proper follow up are important. Our single centre intermediate and long term experience in a large number of patients support the use of device closure as an alternative to surgery.

Keywords : ASD device closure, fossa ovalis ASD, long-term followup

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INTRODUCTION

Transcatheter closure of fossa ovalis ASD is an established procedure and is increasingly used as an alternative to surgical closure. Follow up data (immediate, intermediate, long term) has been published from western countries.^[1-7] We are reporting intermediate to long-term follow up

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data from a single tertiary cardiac center in India in a large number of patients.

Medical records including clinical, chest X-Ray, electrocardiography, echocardiography, cardiac catheterization and followup data of all patients who underwent attempted percutaneous device closure (ASD) were reviewed. Consent for reviewing the records of patients was obtained from the ethical committee of the institute.

PATIENT POPULATION

From May 1998 to July 2008, device closure of fossa ovalis ASD using Amplatzer septal occluder (ASO) was attempted in 543 patients and procedure was successful in 529 (97.4%) [Figure 1]. The reasons for failure (n=14) include deficient various rim(s) (n=6), unacceptable interatrial septum length in relation to balloon size of ASD (n=4), while in four patients device embolized in immediate post-procedure period. All four patients with device embolization were taken for surgery for ASD closure and device retrieval. On retrospective analysis, the causes for embolization were very large ASD (38 mm) with deficient aortic rim in one, larger ASD than measured on TEE in another, torn atrial septum during device closure attempts in third, and in one case. The device was inadvertently released in the right atrium and could not be snared.

Followup data of all 529 patients who underwent successful device closure was analyzed till July 2009. Total 496 patients (93.7%) came for followup. Mean age of patients was 28 (2-77) years and weight 52 kg (9.6-128 kg), female:male ratio was 1.34:1.

SYMPTOMATIC STATUS AT PRESENTATION

Majority of patients were asymptomatic at presentation. In age group <10 years, 14% (20/136) children had history of poor weight gain (mean weight 10th percentile), though there was no limitation of functional capacity. However, some patients of > 40 years of age were symptomatic. The main presenting feature in this age group was early fatigability (NYHA class II) in 30% (30/102) and palpitations 22% (21/102). In the rest, it was accidental detection of murmur or cardiomegaly on chest X-Ray for which echocardiography was advised.

The device

The ASO and delivery system (AGA Medical, Golden Valley, MN) have been described in detail in other reports.^[8,9]

PREPROCEDURE ASSESSMENT

A physical examination, a standard 12-lead electrocardiogram (ECG), chest radiograph and transthoracic echocardiography (TTE) were performed

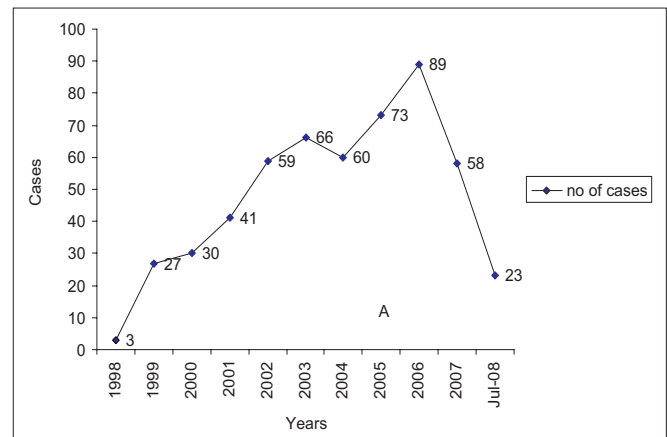


Figure 1: Annual number of patients (from 1998 - 2008) with ASD Device closure

in all patients. In patients with poor echocardiographic windows (adolescents and adults), TEE was also done for detailed definition of the defect. Written informed consent was taken from parents or patient before the procedure.

Patient's selection for transcatheter closure

Selection of patients suitable for device closure was based on measurement of maximal defect diameter and morphological characteristics of the defect.^[10,11]

The initial assessment of the size of ASD by TTE in all patients. In almost all adolescents/ adults a TEE was performed to assess size of defect and margins. The only exception to this rule was those patients in whom a central defect was seen on TTE. Even in these patients a TEE was performed in the cardiac catheterization laboratory prior to venous access.

Coronary angiogram was performed in all patients beyond 40 years of age and in those with suspected history of coronary artery disease before this age. If there was evidence of coronary artery disease opinion was sought from the adult team before proceeding for the device closure.

A complete right heart study for right-sided pressures and shunt was performed in all.

Implantation procedure

The procedure was done in catheterization laboratory under general anesthesia with TEE and fluoroscopy guidance. The protocol for device implantation is same as described in literature.^[12,13] In period prior to November 2003, our institute policy was to use balloon stretch diameter (Equalizer™ Occlusion Balloon Catheter, Boston Scientific) for selecting the device size. With this technique, ASD size and device size ratio was 1.5-1.7. Since December 2003 till 2006, we were taking balloon occlusion diameter (Amplatzer sizing balloon) to select the device and ASD size and device ratio was 1.2:1.4. Since 2007, our policy is to take device 2 mm larger than defect

if all the rims are adequate or 2-4 mm larger than defect if 1 or more rim(s) is deficient. The ASD size and device ratio remained between 1.2 and 1.4 with this policy. The mean diameter of ASD was 20 mm (range 7-40 mm) and required device sized 24 (range 10-40mm) [Figure 2a-b].

Immediate results of successful patients

Postdevice deployment there was minimal flow through the device fabrics in all patients, no abnormality in flow across pulmonary vein(s), superior and inferior vena cava and atrioventricular (AV) valves. Fifty-four patients were having multiple defects, in four additional defect(s) was large or in different plane requiring use of two devices to occlude the defects. Rest 50 patients had tiny or small defect adjacent to the main defect and complete closure was achieved in all except one.

Combined procedure: Combined procedure was done in eight patients, balloon pulmonary valvotomy (n=4), PDA device closure (n=2), PDA coil closure (n=1) and balloon mitral valvotomy (n=1). Additional procedure was successful in all.

Procedural complications

Major complications were encountered in five patients. Three patients (aged 18, 35 and 52 years) developed pulmonary edema after device deployment requiring positive pressure ventilation for 24 hrs along with intravenous diuretics. One 35 years old lady had LV diastolic dysfunction on echocardiography on preprocedural evaluation and device closure was attempted after balloon occlusion test. In cath lab, baseline LVED pressure was 16 mmHg which increased to 18 mmHg on balloon occlusion. wAfter device deployment LVED pressure was 18 mmHg .Despite adequate perioperative precaution (intravenous frusemide and elective extubation after 1 hour) ,she developed pulmonary edema requiring ventilation support for next 24 hrs. Diastolic dysfunction was found on tissue Doppler examination after the event. Now we give intravenous diuretics after device deployment and delay the extubation (8-12 hours) in all patients who are hypertensive or over 40 years. In one patient, left atrial appendage (LAA) was perforated during catheter manipulation. Pericardial effusion was noted immediately after device deployment and she was managed with pericardial drainage, autotransfusion and was taken for emergency surgery. Operative findings showed perforation in LAA which was sutured. In one patient (4 years, 12 kg), there was loss of femoral pulse on the side of venous sheath. Doppler study showed wall edema. She was given intravenous heparin infusion for 5 days till pulses restored.

Electrocardiographic abnormalities: Electrocardiographic changes during the procedure or within 24 hours of device deployment were seen in 55 patients (10.3 %). ST segment elevation was the commonest ECG change,

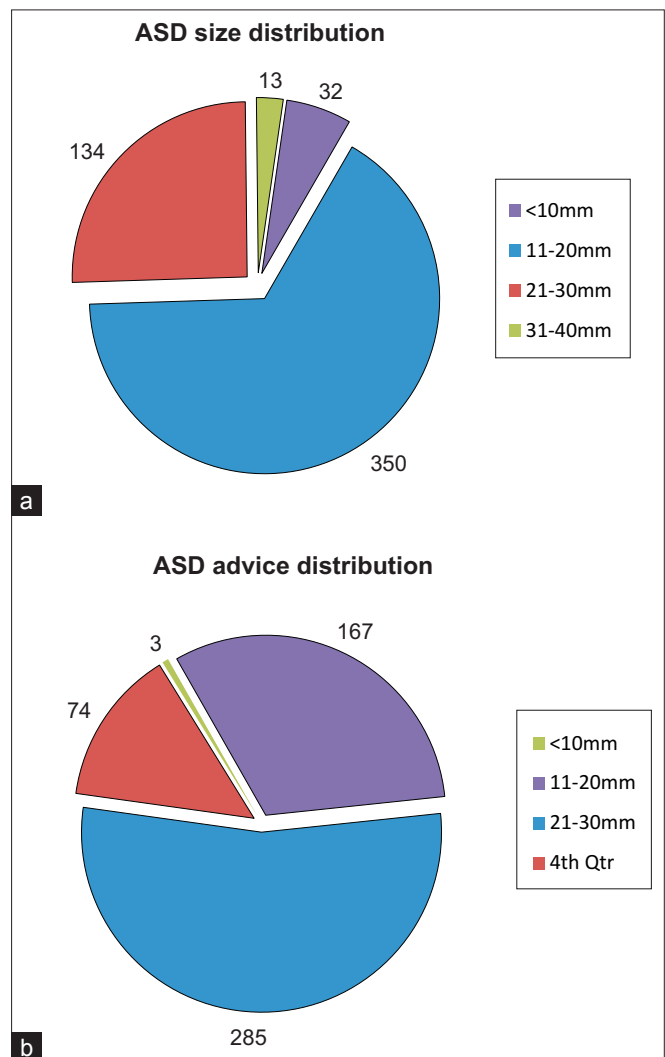


Figure 2: The distribution of ASD size (2a), and the device size (2b), in the patient population

seen in 24 patients which was transient in all except one in whom there was significant fall in blood pressure requiring intravenous fluid administration though on echocardiography there was no wall motion abnormality. In rest 31 patients, there was rhythm abnormalities including supraventricular tachycardia (SVT) (n=22), atrial fibrillation (AF) (n=4), junctional rhythm (n=4) and wandering pacemaker(n=1). For SVT, long-term treatment (1-3 years) (metoprolol n=1, amiodarone n=6) was required in 7 patients. In two patients AF was transient, while in rest two it was persistent requiring antiarrhythmic treatment (Amiodarone). Patients with junctional rhythm and wandering pacemaker did not require any treatment.

Followup protocol

ECG, chest X-ray (Deep penetrating, frontal and lateral views) and TTE were performed at 24 hours. On TTE, device position, stability, any evidence of encroachment over AV valves, pulmonary veins, and vena cava was looked for. Patients were discharged on Aspirin 5 mg/kg

(max 150 mg) for 6 months and in case of large device (≥ 30 mm) or double device Clopidogrel (300 mg stat, 75 mg once daily) was given in addition to Aspirin for 3 months. Bacterial endocarditis prophylaxis was advised for 6 months postprocedure. Thereafter, followup was done at 3 months, 1 year and then annual with clinical evaluation, ECG (if there is rhythm abnormality) and TTE. TEE was done if there is any doubt on TTE. Additional visit at 1 month was advised where device is larger >30 mm or when two devices were deployed.

Followup data

Followup data is available for 496 (93.7%) patients [Figure 3], period 12 months -120 months (median 56 months). Of these 496 patients, 10 patients did not come for followup but were evaluated at local center and details were available on phone/fax. Clinically all patients were in NYHA class 1 except two. This 68-year-old lady with fossa ovalis ASD (18 mm), left to right and moderate tricuspid regurgitation underwent device closure (24 mm) after balloon occlusion test to look for any rise in right atrial pressure. She was discharged on diuretics and was stable on 1 month followup. On 3 months followup she was in right-sided failure with respiratory distress, hepatomegaly and pedal edema. She was stabilized after increasing the dose of diuretics. Twenty patients developed headache after device deployment, nine were having pre-existing migraine while in 11 patients headache developed *de novo*. On followup headache was not persistent and also there was no further worsening of migraine episodes. A 58-year-old female patient (ASD 17 mm, device 24 mm) developed hemiparesis 1 year after the procedure. At the time of discharge she was in normal sinus rhythm and was discharged on aspirin. As she did not come for followup, she was contacted telephonically. No cardiology or neurologic evaluation was done to look for the cause of hemiparesis.

Fourteen patients who were discharged with arrhythmia (tachy or brady), remained stable. With tachyarrhythmia who were discharged on antiarrhythmic medication (n=9), there was recurrence of SVT in two patients and were stabilized with increasing dose of medication. Patients with junctional rhythm (n=4) and wandering pacemaker (n=1) did not require any treatment and recovered over 2-6 weeks. Two patients develop atrial flutter 1-4 weeks after device deployment and were controlled with medication (Amiodarone).

Ten patients (age group >50 years) were in AF before the procedure. They were discharged on oral antiarrhythmic (Amiodarone) but remained in AF with controlled ventricular rate.

TTE was done in all patients on followup. Device was *in situ* with no residual flow in all except one with small residual flow. Ventricular function was normal on followup.

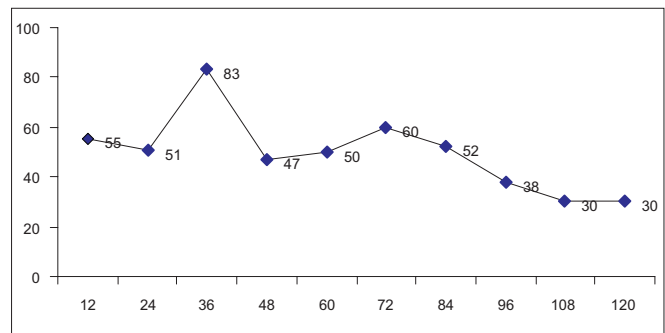


Figure 3: Number of patients and their maximum follow up period

Interventricular septal motion normalized on same day of procedure in 89% patients, in 6% over 3 months while flat septal motion persisted in 5% (n=25) of cases. Right ventricular end-diastolic dimension normalized over 3-6 months period in 90% cases while RV dilatation persisted in rest 10%. Right ventricular dilatation and flat septal motion persisted in age group more than 40 years.

There was no evidence of new appearance of valve leak (mitral, tricuspid or aortic), cardiac perforation and erosion of aorta by device, device embolization or device distortion/fracture.

DISCUSSION

Although surgical closure of ASDs has been the traditional method of treatment, as long as in 1976, King *et al* first documented successful device closure of fossa ovalis ASD.^[14] It is after 1990s, the technique became a widely accepted and practiced approach, such that it has now largely replaced surgical closure of fossa ovalis ASD in most centers.^[10,11,13,15,16] Recently, device closure of fossa ovalis ASD in infants has also been reported.^[17]

Since the launch of transcatheter closure of septal defects, there have been many devices introduced over the period. ASO is the commonest occluder used for closure of septal defects with excellent results and very low risk of complication.

The present study shows an excellent outcome on intermediate and long-term followup of patients who underwent device closure for fossa ovalis ASD in a large cohort of patients reported from a single center and with a very high rate of followup (93.7%) such as also reported from the Western world.^[1-7,15]

All patients were symptomatically better except one described above.

Three patients, who developed pulmonary edema after device closure requiring ventilator support and diuretics therapy, were discharged on oral diuretics (Frusemide and Aldactone). All three were having LV diastolic dysfunction on echocardiography after device closure. LV diastolic dysfunction normalized over 3-6 months

period time and diuretics were stopped.

Arrhythmias were reported during the procedure and in immediate postprocedure period in various reports.^[1,18,19] We have also seen ECG changes (ST elevation and arrhythmias) during procedure. ST elevation was transient and all patients were stable on followup. Nine patients developed arrhythmia after device deployment while two patients developed SVT on 1-4 weeks after device deployment. Both these were having history of palpitation before device deployment.

Various reports show effectiveness of device closure with excellent immediate, short and long-term closure rates.^[2-7] This study also showed complete closure (excluding flow through device fabrics) in 97% of patient on next day and complete closure in rest by 3 months except in one patient. On followup a large profile of device obtained immediately after deployment decreases significantly at 3 months followup.

Thrombus formation on the device, particularly on ASO, is a rare event.^[20,21] Neither thrombus nor systemic thromboembolism were detected in our study immediately and on followup; however, we have not done TEE in all cases on followup.

Device embolization or malposition is a well-known complication during the procedure which is an avoidable issue by careful evaluation of anatomy and selection of device while late embolization have also been reported.^[18,22,23] We have not experienced any case of delayed device malposition or embolization.

Cardiac perforation is a rare but serious life-threatening complication after device closure. First case reported by Amin *et al*,^[23] erosion or perforation was identified by the late development of pericardial effusion. Pooled data showed an incidence of 0.1% for device erosion with the ASO. Reports suggest that aortic rim in isolation should not be considered as a contraindication for device closure. One needs to oversize the device (2-4 mm) with deficient aortic rim to straddle the device over the aorta. We have not experienced any case of cardiac perforation after device closure on followup even in patients with deficient aortic rim.

Study by Sigler *et al*,^[24] showed that endothelialization process completes in 3 months and so bacterial endocarditis prophylaxis is advised for 3-6 months by various authors. Infective endocarditis was reported in a patient after 2 months of device closure.^[25] We have not experienced any case of infective endocarditis in our series of patients. Excellent results have been reported even in multiple defects in children and adults.^[26-28] Recently analysis of the Food and Drug Administration Manufacturer and User Facility Device Experience database^[29] for adverse events involving Amplatzer septal occluder devices and comparison with the Society

of Thoracic Surgery congenital cardiac surgery base was published. Percutaneous device deployment failure has been reported to be between 0-20%. Since July 2002, 223 adverse events in patients undergoing Amplatzer ASD closure were submitted to FDA, which included 17 death and 152 surgical rescue operations. Society of thoracic surgery data reported 1537 primary operation with 2 deaths (0.13%) and 6 reoperation (0.39%). By extrapolating on published estimates of Amplatzer implantation to provide an implant denominator (n=18,333), there was no difference between overall mortality for surgical (0.13%) and device closure (0.093%) (p=0.649). Our data shows immediate success rate of 97.4% and need of surgery as rescue in 0.9% patients (5 patients, device embolization in 4 and LAA perforation in 1 patient) during ASD device closure. On follow up we did not encounter any major complication. There is no procedure related, early or late mortality in our series.

Limitations of the study

Followup was not 100% complete but considering the fact that this study is from a single institution from a tertiary center with patients being referred from different parts of the country where communications and travel are very difficult for many patients, 93.7% followup is a very good figure.

Assessment of residual shunt and clots on the device was done by TTE for logistic reasons, and TEE was restricted to only those patients where the information from TTE was considered inadequate. It is possible that these complications might have been underestimated. However, The literature on residual shunts reported on the ASO is, however, commensurate with our data. We have not performed any objective tests to assess clinical improvement after device closure and "clinical improvement" in symptoms reported by patients was based purely on direct questioning. However, the majority of our patients were asymptomatic at presentation underscoring the difficulties in objectively documenting further improvement in symptoms status after device closure.

CONCLUSIONS

This study in a cohort of large number of patients shows that percutaneous closure of fossa ovalis ASD is a safe and effective procedure on a followup period of up to 10 years.

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