Original Article

Midterm Follow-up Results of Transcatheter Interatrial Septal Defect Closure

Mehdi Ghaderian, Mohammad Reza Sabri, Ali Reza Ahmadi, Mohammad-Reza Alipour[1], Bahare Dehghan, Mahdie Mehrpour

Pediatric Cardiology Research Center, Isfahan Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, [1]Yazd Cardiovascular Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

ABSTRACT

Objectives: We studied immediate and midterm results of transcatheter closure of atrial septal defects (ASDs) using the Amplatzer septal device closure.

Methods: The study included one hundred and thirty-seven patients (31 men, 106 women; mean age 8 ± 7.3 years; range 1–65 years) who underwent transcatheter closure of secundum ASD between October 2014 and October 2016 in our center. All the patients were evaluated by transthoracic echocardiography before and during the procedure and in adult patients; transesophageal echocardiography was performed before the procedure. Closure of ASDs was performed under general anesthesia with transthoracic echocardiographic guidance. Follow-up controls were done on the day after procedure, 1 week, 1, 3, 6, and 12 months, and annually thereafter. The median follow-up periods of ASD was 15 months.

Results: The mean ASD and device size were 13.5 ± 2.3 and 14.3 ± 3.2 mm, respectively. The mean procedural and fluoroscopy times were 21.3 ± 4.7 and 5.1 ± 1.9 min. Immediate complications such as mortality, bleeding, fatal arrhythmia, and device embolization did not occur in any patient during and after the procedure. Cardiac arrhythmias were seen in 4 patients during the 1st month after the procedure. Late device embolization did not occur during the follow-up. No residual shunts were seen after the procedure. Transient ischemic attack was seen in one patient during the procedure and in one patient 2 days after the procedure without long-term complication.

Conclusion: Transcatheter closure of ASDs using the Amplatzer devices is an efficacious and safe therapeutic option.

Key words: Amplatzer, interatrial septal defect, transcatheter closure

INTRODUCTION

Atrial septal defect (ASD) is one of the most frequent (5%–10%) congenital heart diseases in adults.[1] Some of patients with ASD are free of symptoms although most of them will become symptomatic during their lives. Patients with ASD have a left-to-right shunt and with consequent chronic volume load of the right atrium and right ventricle and pulmonary artery causing heart failure and pulmonary hypertension.

Address for correspondence: Dr. Mehdi Ghaderian,
Pediatric Cardiology Research Center, Isfahan Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran.
E-mail: ghader_45@yahoo.co.uk

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Identification of the atrial defect is important during the life to prevent the different complications such as arrhythmias, pulmonary hypertension, paradoxical embolism, and heart failure.[2,3]

In patients with significant volume overload in right heart with a shunt ratio >1.5:1 or dilated right atrium or right ventricle during echocardiographic study, atrial septal closure is suggested. During the past decade, percutaneous ASD closure has become approach for most secundum type ASDs among interventional cardiologist, provided the defect has suitable rims.[4,5]

Compared to surgical closure transcatheter, ASD closure is associated with fewer complications and

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faster hemodynamic improvement.[6,7] Decreases in right ventricular volume overload, right ventricular dimensions, and pulmonary artery pressure (PAP) after transcatheter ASD closure result in prominent symptomatic improvement.[2] Residual shunt after ASD closure by surgical or transcatheter approaches may result in volume overload and consequently increased pulmonary circulation.

Patent foramen ovale (PFO) is a common finding in the general population. It has a prevalence of approximately 25%–30%.[8] Patients with PFO who have right-to-left shunt have increased risk of transient ischemic attack (TIA), sleep apnea, migraine, and cryptogenic stroke.[9,10] Patients without symptoms do not require therapy. Transcatheter device closure in patients with recurrent TIA or stroke has been recommended.

Between 2013 and 2016, transcather closue of secundum type ASD were closed with devices at Chamran Hospital. We investigated the efficacy and safety of transcatheter closure in these patients.

METHODS

Patient selection

Between October 2014 and October 2016, one hundred and thirty-seven patients (31 men, 106 women) with a significant ASD, as demonstrated by initial transthoracic echocardiography (TTE) or transesophageal echocardiography (TEE) before the procedure, were considered for transcatheter closure with the atrial septal occluder (ASO) at our Cardiology Department. Inclusion criteria in our patients with ASD detected by echocardiography for percutaneous device closure were significant left-to-right shunt (Qp/Qs >1.5, measured during catheterization or in echocardiography), right heart dilatation, and increased right ventricular volume load. These patients had symptoms of reduced exercise capacity, dyspnea, tachypnea or paradoxical embolism in physical exam. The defects must have good rims in evaluation before procedure and provided that the defect was at least 5 mm far away from the atrioventricular valves, coronary sinus, right superior and inferior veins, and had not partial anomalous pulmonary vein connection from right superior pulmonary vein to superior vena cava. In patients with good rims and had aortic rim <5 mm percutaneous closure was performed. Patients were excluded from the study if they had sinus venosus or primum-type ASD, coexistent congenital heart disease that need surgical correction, pulmonary vascular resistance >8 Wood units with, or significant mitral or tricuspid regurgitation. Three patients were excluded from our study because of pulmonary hypertension (pulmonary artery systolic pressure >70 mmHg and pulmonary artery resistance >8 woods). Five patients had not good rims (floppy rims) in procedure during using of sizing balloon. Before the procedure, all the patients were evaluated through transthoracic (TTE). Patients over 30 kg that had suspicious anatomy for ASD referred for TEE. For patients who underwent ASD closure, evaluation of left-to-right shunt by color Doppler echocardiography was performed.

All the procedures were performed in adult patients under local anesthesia and in small patients under deep sedation, with transthoracic guidance throughout. Standard right-heart evaluation and catheterization were done through the right femoral vein for calculation of QP/QS ratio and measurement of PAP and resistance. Main pulmonary artery and right upper pulmonary vein angiography were performed to evaluate of anomalous pulmonary vein connection and atrial septum.

A sizing balloon was inflated at the level of the defect until the waist in the middle of the balloon was seen, but in patients with clear septum in echocardiography, sizing balloon was not used. A device with a waist diameter similar to the stretched ASD diameter in sizing balloon, or 2–3 mm larger than defect by color echocardiography, was chosen. The right femoral vein was used for procedure as the access site. After insertion of sheath into the right femoral vein, 80–100 IU/kg heparin was administered intravenously and for endocarditis prophylaxis, the patients received cefazolin (50–100 mg/kg intravenous [IV]) during the procedure, followed by 100 mg/kg/day IV divided 8 h for an additional 1 day. The selected ASO was deployed at atrial septum through standard protocol. After deployment of device residual shunt was studied by color Doppler echocardiography and right atrium angiography in left anterior oblique position. Pull and pushing maneuver was done and after confidence of stability of ADO, the device was released [Figure 1].

All patients were monitored for 24 h and discharged the day after the procedure. Evaluation of patients was done in hospital with chest X-ray, electrocardiogram, and echocardiography. To prevent thrombus formation on the device, the patients were discharged on ticlopidine (1 mg/kg/day to maximum dose of 75 mg/day) for 1 month and aspirin (3–5 mg/kg/day to maximum dose of 80 mg/day) for 6 months. Follow-up TTE was performed 1 week, 1, 3, 6 and 12 months after the procedure and annually thereafter. Patients were told to inform us in case of any suspicion of chest discomfort, TIA, stroke, other thromboembolic events, magnetic resonance study, or any hospitalization during their follow-up.

All the data were collected on a set data sheet, collated by a single coordinator. The data were expressed as mean ± standard deviation, median, range, and categorical variables were expressed as percentages. Independent samples *t*-test used for comparisons of continuous variables between the

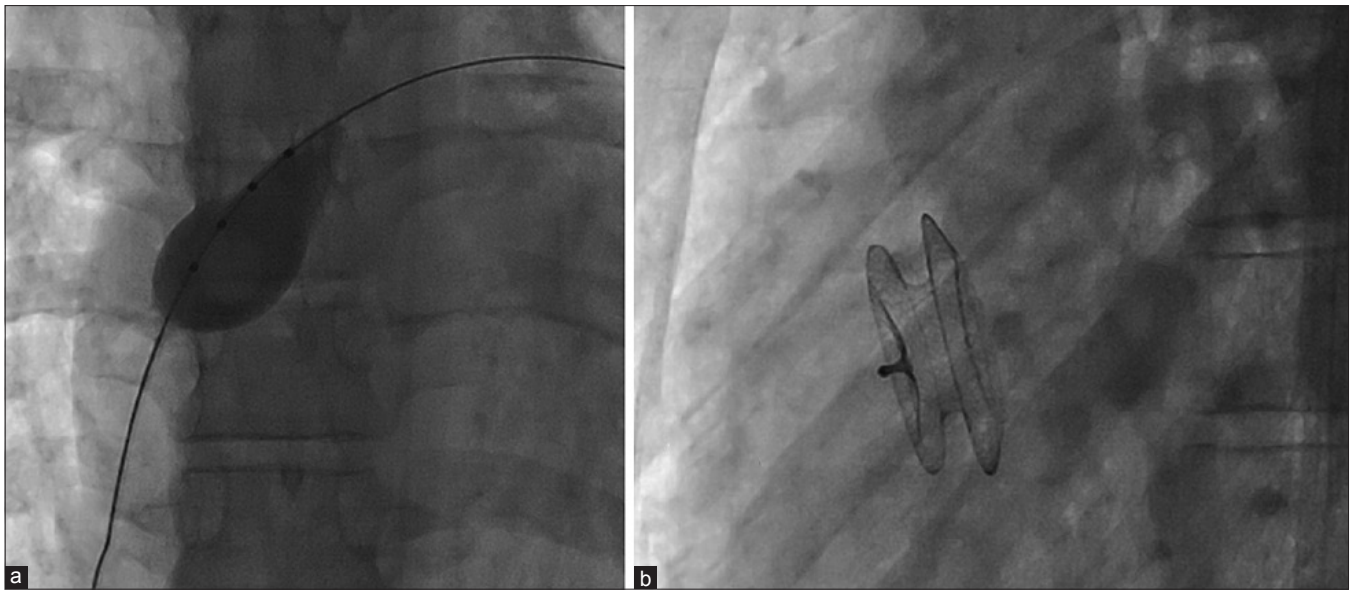

Figure 1: Atrial septal closure: Using sizing balloon for sizing of atrial septal defect diameter (a) and device closure (b)

Table 1: Demographic and periprocedural characteristics of the patients

Parameters	Patients (*n*=136)
Age (years)	8±7.3
Weight (kg)	19.9±6.5
Gender, male (%)	31 (22)
Pulmonary blood pressure (mmHg)	
Systolic	28±14
Diastolic	16±6
Mean PAP	24.4±8
Defect diameter by echo (mm)	13.5±2.3
Device diameter (mm)	14.3±3.2
Procedural time (min)	21.3±4.7
Fluoroscopy time (min)	5.1±1.9
Follow-up (months)	15±5.5

PAP: Pulmonary artery pressure

two groups. Categorical variables were analyzed by Chi-square test. Statistical analyses were performed using SPSS statistical software (version 18.0; SPSS Inc., Chicago, IL, USA). A $P < 0.5$ was considered statistically significant.

RESULTS

Patient characteristics are described in Table 1. One hundred and thirty-seven patients (31 men, 106 women; mean age 8 ± 7.3 years; range 1–65 years) underwent transcatheter ASD device closure with various devices in our department during this study. The median follow-up periods of patients were 15 months (range 1–26 m). The mean body weight was 19.9 ± 6.5 kg (range = 10–62 kg). The mean ASD and device size were 13.5 ± 2.3 and 14.3 ± 3.2 mm, respectively. The mean procedural and fluoroscopy times were 21.3 ± 4.7 and 5.1 ± 1.9 min. Mean fluoroscopy time has been decreased significantly during the time with the progress in our experience. The pulmonary to systemic shunt ratio (QP/QS) ranged from 1.6 to 3.4 (mean 2.1 ± 0.72). The mean PAP was 24.4 ± 8 mmHg (range = 13–43 mmHg). In our patients, 80% patients presenting with dilated RV and had mean RV-PA gradients (21 ± 4.2 mmHg) that from increased PA flow.

At the end of the procedure, on color flow Doppler echocardiography, residual shunting (including foaming through the device) was seen in 52 (38%) of patients and follow-up echocardiography at the day after procedure, 1 month, 3 months, 6 months, and 1 year after the procedure showed complete closure rates of 79%, 92%, 97%, and >99%, respectively. One patient had mild residual flow on echocardiographic examination after 1-year follow-up and disappeared gradually during late follow-up. Complications such as device emboli, severe bleeding, arterial or venous injuries, wire fracture, retroperitoneal hematoma, and arteriovenous fistula and mortality was not occurred during the procedures.

Immediately after procedure, a 32-year-old woman had right side hemiparesis and decreased right limbs force. Computed tomography scan showed TIA and mild ischemia and in 1st h, she received TPA and symptoms dissolved during 1st day. Another 1-year-old girl with large ASD (16 mm) had right side hemiparesis and seizure 24 h after procedure and resolved during 1st month.

Major complications related to procedures were not seen. Three patients developed transient ST-elevation, which received more O_2 and cleared within a short period; these were attributed to small air emboli to coronary arteries because of their position. Five patients

Table 2: Periprocedural complications and follow-up

Complications	Patients (*n*=136)
Periprocedural (%)	
Device embolization and dislodgement	0
Severe bleeding	0
Vascular access complications	0
Atrial fibrillation	1 (0.5)
Supraventricular tachycardia	5 (3.6)
Follow-up results (%)	
Atrial arrhythmias	3 (2.2)
Transient complete heart block	2 (1.4)
Erosion of aorta	0
Wire fracture	0
CNS events	2 (1.4)
Other thromboembolic events	0

CNS: Central nervous system

presented with supraventricular tachycardia, which was spontaneously resolved in three patients and was reverted in the 2 other cases with verapamil or adenosin. Three women (range between 35 and 45 years old) had persistent atrial flutter and atrial tachycardia during the 1st month after ASD closure. In these patients, long-term maintenance of sinus rhythm was achieved with propranolol and flecainide, and then, drugs tapered to discontinued. Two patients had transient complete atrioventricular block without symptoms and find in ECG examination in follow-up that length 2 weeks and resolved spontaneously.

At a mean follow-up period of 15 ± 5.5 months (range = 1–26 months), all the defects were completely closed and remained closed afterward. No thrombus formation was seen during the follow-up period. Demographic, periprocedural clinical characteristics and complications of the patients with ASD closure were shown in Tables 1 and 2.

DISCUSSION

Transcatheter ASD closure is recommended in symptomatic patients and in the presence of increased left-to-right shunt (Qp/Qs >1.5), right ventricular dilatation, and paradoxical embolism. Transcatheter closure of ASD has become the standard of care instead of surgical closure in most experienced centers because of fewer psychological impacts, fewer hospital, and have intensive care unit stay duration. Furthermore, it does not surgical myocardial and skin scar and dysrhythmias.[11,12]

We aimed to present our single-center experience with transcatheter closure of ASD in this report.

Transcatheter closure of the ASD is a safe technique with low incidence of morbidity and mortality. During the procedure, selection of device is the most important decision for operator. An oversized device can cause to erosion of aorta, a rare but serious complication of this and procedure could be seen years after procedure during the follow-up.[13,14] In our study during the follow-up period, we did not have any cardiac erosion in our patients. We think that our patients were younger and the devices used were smaller. Undersized device selection for ASD closure may result in residual shunting after the procedure and early or even late embolization of the device.[15-17] Post *et al*. described four device embolization in their patients; skill or experience in doing the procedure was described by Aytemir *et al* to have lower device embolization. We did not have any device embolization.

After transcatheter ASD closure because of foaming through the device residual shunting is higher compared to surgical closure, but this shunt decreases during the time.[17,18] Closure rate varied over 95% during the follow-up depending on the technique used for evaluation.[19] Van de Bruaene reported 94% effective closure in their patients during 5-year follow-up and none of them required reintervention.[20]

In this study, one patient had mild residual shunt after 1-year follow-up and disappeared completely during follow-up. Small residual shunt after transcatheter ASD device closure does not seem to lead to long-term serious problems. Residual shunt after the procedure during the follow-up was seen over 99% at 6 months after the procedure and one patient had mild residual shunt that disappeared gradually during follow-up. Our results similar to other studies that reported high prevalence occlusion after ASD closure.[21,22]

CONCLUSION

In our study, transcatheter closure of ASD was effective and safe as an alternative treatment to surgery. For successful device closure, appropriate patient selection is an important factor. Although the immediate and midterm results of transcatheter interventions showed that this procedure had low complication rates and safe compared to surgical approaches, data on long-term results are limited and further studies are needed to complete our knowledge.

Our study had some limitations. The most important limitation is that our findings mainly reflect midterm results about the safety and efficacy of the devices but no long-term follow-up; thus, we could not judge about the safety and long-term complications of this procedure. Another limitation is that it is a single center experience. Multiceneter studies are needed to decrease complications.

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Conflicts of interest
There are no conflicts of interest.

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