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Evaluation of short-term consequences of atrial septal defect closure in adults referred to Shahid Chamran heart center in Isfahan

Payam Ebrahimifar[1], Houman Dehghan[2], Alireza Khosravi Farsani[3]

Abstract

BACKGROUND: Secundum Atrial Septal Defects (ASDs) are the most common type of atrial septal defects. Today, using different types of occluders, transcatheter closure is widely used to treat ASD and has replaced the surgical procedure in anatomically suitable patients. This study was performed to evaluate the short-term clinical outcomes of treatment of adult patients requiring an ASD device closure referred to Shahid Chamran Cardiovascular Center in Isfahan, Iran.

METHODS: All patients who underwent ASD treatment using transcatheter closure at Shahid Chamran Cardiovascular Center in 2020 and 2021 were recruited in this retrospective descriptive study. The characteristics of the treated lesion and the cardiovascular complications during treatment were recorded immediately and one month after treatment.

RESULTS: A total of 70 patients (47 females and 23 males) with a mean age of 39.81±12.56 years were investigated in this study. The number of difficult anomalies was 46 (65.7%), and the most common type was the deficient aortic rim. In terms of the incidence of vascular complications, hematoma, bleeding, and pseudoaneurysm were observed in 8 patients. The most common cardiac complication was atrial fibrillation, which occurred in 12 patients. No cardiovascular complications were observed during the one-month follow-up.

CONCLUSION: The results of this single-institute study showed that ASD treatment by the transcatheter procedure using an ASO device at Shahid Chamran Cardiovascular Center was performed safely and successfully with very few complications. The short-term analysis of the outcomes indicated no major complications, deaths, or device malposition.

Keywords: Atrial Septal Defect; Transcatheter Closure; ASD Devices; Complications

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Introduction

Atrial Septal Defect (ASD) is a common form of congenital heart disease that accounts for about 10% of congenital heart defects. Secundum ASDs are the most common type of atrial septal defect. The survival rate in people with this defect up to the age of 18 is about 97%[1].

Patients with isolated ASD may not show any symptoms in infancy and childhood, so diagnosis may be delayed until adolescence and adulthood. Treatment of these defects is generally recommended because an increase in pulmonary artery flow, in the long run, can lead to an increase in pulmonary artery pressure[2].

Adults with ASD are also more likely to have complications such as atrial arrhythmia, pulmonary hypertension, and atrioventricular valve dysfunction associated with chronic ventricular enlargement. These patients also have comorbidities such as diabetes, systemic hypertension, a history of stroke, chronic cardiovascular disease, and atherosclerosis. The long-term left-to-right atrial shunt can lead to atrial fibrillation and increased ventricular volume, resulting in tricuspid regurgitation. The left side of the heart may also be affected[3].

1- Interventional Cardiology Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
2- Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
3- Hypertension Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran
Address for correspondence: Alireza Khosravi Farsani; Hypertension Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran; Email: payame1383@yahoo.com

ASD surgery is performed as a standard treatment through cardiopulmonary bypass. Today, using different types of occluders, transcatheter closure is widely used to treat ASD and has replaced the surgical procedure in anatomically suitable patients[2].

Closure of ASD using a percutaneous device was introduced in 1970. Since then, various devices have been used for this purpose. The most common occluder used is the Amplatzer™ Septal Occluder (ASO) (AGA Medical Corp Golden Valley, MN, USA)[4].

Numerous studies have shown that the treatment of ASD by transcatheter is as safe and effective as the surgical procedure and has similar results[5-7]. The benefits reported for this procedure include aesthetic advantages by avoiding sternotomy scarring, avoidance of cardiopulmonary bypass, less postoperative discomfort, and shorter hospital stay. This method is currently considered a standard treatment for ASD in adults[8].

In 2012, a panel of Food and Drug Administration (FDA) experts gathered to evaluate the effectiveness and safety of using the device in the treatment of ASD. They reported that the available information was insufficient to determine the risk of specific complications in patients treated with the device. They also recommended that the follow-up of patients with serial echocardiography be performed one week, one month, and six months postoperatively, and then annually[9]. Therefore, national and international studies have evaluated the safety and success of transcatheter ASD treatment in adults[1,3,10,11-14]). They have reported the effect of different factors on treatment outcomes in various treatment centers. However, so far, there has been no report on the success and treatment results of patients referred to Shahid Chamran Cardiovascular Center in Isfahan.

Therefore, this study was conducted to evaluate the short-term clinical outcomes of the treatment of adult patients in need of ASD device closure referred to Shahid Chamran Cardiovascular Center in Isfahan in the second half of 2020-2021. The obtained results will be used to create a system to record the treatment outcomes at Shahid Chamran Cardiovascular Center.

Methods

All patients who underwent ASD treatment using transcatheter closure at Shahid Chamran Cardiovascular Center in 2020 and 2021 were investigated in this retrospective descriptive study. The inclusion criteria consisted of patients aged ≥18 years with confirmed ASD <38 mm in size, and rims (except aortic rims) of at least 5 mm[10]. Informed consent was obtained from all patients and their relatives. The study protocol was designed based on standard percutaneous ASD closure and was approved by the ethics committee of Isfahan University of Medical Sciences.

The exclusion criteria included patients with defects >38 mm, severe pulmonary artery hypertension >80 mmHg, insufficiency of upper, lower, and posterior rims around ASD based on Transesophageal Echocardiography (TEE) findings, patients' unwillingness to participate in the study, patients who were candidates for heart surgery for other reasons, and incomplete information recorded in the file[10].

The suitability of patients for the transcatheter method and the inclusion criteria were assessed by echocardiography. All echocardiographic assessments were done by a single operator (an echocardiology fellowship). The size of the lesion and the adequacy of the surrounding rims were measured and recorded by TEE. Although patients with rim deficiencies and those with large defects are generally contraindicated[15], we consider them for transcatheter closure in our institution based on previous studies and our experience of successful closure in such complex cases. Furthermore, all patients over 45 years underwent angiography before the procedure. First, patients' information, including age, sex, height, weight, and comorbidities such as diabetes, hypertension, and chronic lung disease, were evaluated and recorded. Moreover, the characteristics of the lesion, including ASD size, rims around the lesion, the presence of multiple defects, and septal aneurysm examined in the initial echocardiography, were recorded.

Patients were treated under local anesthesia and sedation. For this purpose, conduction was used with the help of TTE, TEE, and fluoroscopy. First, the ASD type (shunt size and rim size) was determined by TEE. The size of the lesion was also determined by balloon sizing. The balloon was inflated until the transseptal shunt was stopped, following which its size was recorded. An appropriate device was selected and positioned. The type of device used in all patients

was the ASO device (AGA Medical Corp., Golden Valley, MN). The device placement technique was similar to that of previous studies[16,17]. All patients were fully heparinized before the procedure. To evaluate the complications and position of the device, ECG and TTE were performed after the procedure. Aspirin (100-300 mg/qd) was also prescribed for all patients. All the ASD closure procedures were done by a single operator who was an interventional cardiologist, accompanied by an assistant who was a postgraduate student of interventional cardiology.

The duration of the procedure in each patient and complications during the procedure were recorded. After treatment, short-term cardiovascular outcomes were recorded during the patients' hospital stay and one month after discharge. Patients' clinical symptoms, along with ECG and TTE findings, were used to record the outcomes.

Statistical Analysis

The frequency of complications in patients was reported as a percentage. Quantitative variables (height, weight, PAP, EF, time of procedure, hospital stay) of patients were reported as mean ± SD. In addition, mean lesion size in TEE, balloon sizing, and selected device size were reported, and their correlation was measured using SPSS software version 26.0 (SPSS Inc., Chicago, IL, USA) with the Intraclass Correlation Coefficient (ICC) test (P value <0.001).

Results

A total of 70 patients (47 females and 23 males) with a mean age of 39.81±12.56 years were recruited for this study. There was no concomitant coronary artery disease in these patients.

Patients' conditions in terms of height, weight, Ejection Fraction (EF), Systolic Pulmonary Artery Pressure (SPAP), the duration of the procedure, and the length of hospital stay are presented in Table 1. Most patients were normal in terms of RV function, while only six patients were normal in terms of RV size. The frequency distribution of patients in terms of RV function and size is shown in Table 2.

The estimated mean lesion size in TEE and balloon sizing, as well as the mean device size, are presented in Table 2. The ICC test was used to determine the consistency of the measurements, which showed a significant correlation between the sizes obtained by TEE and balloon sizing and the size of the selected device (p <0.000) (Table 3). The number of difficult anomalies was 46 (65.7%), and the most common defect was the deficient aortic rim. Its types and the frequency of each are listed in Table 4.

In terms of the incidence of vascular complications during the procedure and hospital stay, hematoma occurred in 5 patients (7.14%), bleeding occurred in one patient (1.4%), and pseudoaneurysm occurred in 2 patients (2.85%). No patient suffered from fistula, Cerebrovascular Accident (CVA), Transient Ischemic Attack (TIA), air embolism, or Pulmonary Thromboembolism (PTE). Furthermore, no complications were observed in any of the patients during the one-month follow-up.

As for cardiac complications after the procedure and during the hospital stay, the most common complication was Atrial Fibrillation (AF) (12 patients, 17.1%). Other complications included Paroxysmal Supraventricular Arrhythmia (PSVT) in 8 patients (11.4%), frequent Premature Ventricular Contraction (PVC) in 2 patients (2.9%), pericardial effusion in one patient (1.4%), and residual shunt in one patient (1.4%). No cases of death, ST elevation, cardiac perforation, intracardiac thrombosis, or

Table 1. Patients' characteristics

Patients' characteristics (n=70)	Mean ± SD
Age (yrs)	39.81±12.56
Height (cm)	168.35± 7.87
Weight (kg)	72.04± 6.93
EF	51.71± 5.44
PAP	31.90± 4.67
Time of procedure (minutes)	50.40 ± 11.26
Hospital stay (days)	2.04±0.43

Abbreviations; EF: Ejection Fraction; PAP: Pulmonary Artery Pressure

Table 2. Frequency of patients in terms of performance and size of RV

n=70	Normal	Mild	Moderate	Severe
RV enlargement	6 (8.6%)	24 (34.3%)	32 (45.7%)	8 (11.4%)
RV dysfunction	31 (44.3%)	24 (34.3%)	15 (21.4%)	0 (0.00%)

Abbreviations; RV: Right Ventricle

Table 3. Mean lesion size in TEE, balloon sizing, and selected device size

Technique (n=70)	Mean ± SD
TEE (mm)[a]	20.63±4.95
Balloon sizing (mm)[b]	21.71±5.08
Device size (mm)[c]	23.57±5.63

Interclass Correlation Coefficient (ICC) : [a] and [b] : 0.94 – [a] and [c] : 0.82 – [b] and [c] : 0.85 (p<0.001)

Table 4. Difficult anatomies

Difficult anatomies (n=70)	Number (%)
Deficient aortic rim	34 (48.6%)
Deficient IVC rim	1 (1.4%)
Multi-fenestrated ASD	5 (7.1%)
Large ASD (>30mm)	4 (5.7%)
Multiple defects	1 (1.4%)
Aneurysmal septum	1 (1.4%)

Abbreviations; ASD: Atrial Septal Defect; IVC: Inferior Venna Cava

Table 5. Frequency of cardiac complications

Type of complication (n=70)	Immediately after procedure or during hospital stay	After one month follow up
Atrial Fibrillation	17.1% 12 patients	1.4% 1 patient
PSVT	11.4% 8 patients	
PVC	2.9% 2 patients	
Residual shunt	1.4% 1 patient	None of these were observed
Pericardial effusion	1.4% 1 patient	
death, ST elevation, cardiac perforation, intracardiac thrombosis, device malposition	None of these were observed	

device malposition were observed. Moreover, AF was observed in only one patient during the one-month follow-up, and no other complications were found. The remaining shunt in one patient was also resolved. The frequencies are presented in Table 5.

According to the percentage and type of complications observed, the short-term success rate of ASD treatment was 100% during the two-year study at Shahid Chamran Cardiovascular Center.

Discussion

Percutaneous closure is currently recognized as the first treatment option for secundum ASD[18]. The results of this single-institute study showed that ASD treatment using transcatheter with an ASO device at Shahid Chamran Cardiovascular Center was performed safely and successfully with very few complications. The short-term analysis of outcomes indicated no major complications, deaths, or device malposition.

The success rate in this study was 100%, which is comparable to other studies. In a study on the complications of this treatment method in Shiraz cardiac centers between 2003 and 2014, the success rate was estimated to be 98.7%, with 3 failures reported. The failures observed in this study are attributed to the unavailability of TEE in the past and the inadequacy of the rims around the lesion[19]. In another study in which patients treated with transcatheter were followed for 12 months, the overall success rate was 86%[20]. In this study, patients were not monitored with TEE during the procedure, which could be a reason for increased complications and a reduced success rate. In another study conducted between 2001 and 2009 at Shahid Rajaei Heart Center, three major complications were observed in 3 (4%) out of 74 patients. These complications included erosion, device malposition, and device emboli. Overall, the clinical success rate in this study was reported to be 93.2%[4]. Other studies have reported a success rate of over 90% for this treatment[15,16].

Some of the complications observed in the present study, such as groin hematoma and pericardial effusion, are associated with the aggressive nature of the procedure and have been reported in previous studies[13,21]. In the present study, cardiac arrhythmias, including PVC, PSVT, and AF, were observed in 22 patients, all of whom were successfully treated. Device closure appears to slightly increase the risk of atrial arrhythmia. However, in a study on 588 patients treated with ASO, the overall risk of arrhythmia was

reported to be very low[22]. There is a concern that device closure of ASD in the future may prevent cardiac electrophysiological procedures that require transseptal access[9]. In general, arrhythmia is a minor complication that has been reported and treated in previous studies[19,20].

In the present study, no cases of device malposition were observed, although previous studies have reported a low incidence rate for this complication[4,19]. In addition, although the death of patients was reported in one study, it was not device-related and was due to other reasons such as other diseases and systemic conditions of patients[13]. In the present study and many similar previous studies, no deaths were reported[4,19,20].

Residual shunt in the present study occurred in only 1.4% of patients, which is a small rate compared to other studies in other cardiac centers[19,20]. Furthermore, in the one-month follow-up, no trace of shunt was seen in this patient, which is because the surface of the device endothelializes over time and turns into a structure within the interatrial septum[4]. The remaining small shunt usually does not lead to long-term complications. A small residual shunt can be one of the advantages of using an ASO device over other types[23].

One of the limitations of the present study was that the ASO device was used in all patients, so the results are related to this type of device and cannot be generalized to other cases. Future studies are suggested to investigate the consequences of this treatment using other types of devices.

Conclusion

Device closure of ASD is now a standard procedure for the majority of secundum ASDs. The success rate for this technique is high at Chamran Heart Center, which can be attributed to precise transesophageal echocardiographic evaluation, familiarity with all possible complications, and the knowledge to manage them.

Conflict of interests

The authors declare no conflict of interest.

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Author's Contributions

AK conceptualized the study and developed the title. PE, HD, and AK contributed to conducting the research, drafting the manuscript, and reviewing and approving the final version.

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