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Early and Mid-Term Follow-Up Results After Transcatheter Closure of Secundum Atrial Septal Defect

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What is already known on this topic?

- *Spontaneous closure of secundum atrial septal defects (ASDs) may occur. Closure of the defect is recommended in large defects that show volume overload, and spontaneous closure is not possible.*
- *In the last 2 decades, transcatheter occlusion devices have been used to close secundum ASDs.*
- *Patients treated by transcatheter method have a shorter hospital stay and less morbidity than those treated surgically.*

What this study adds on this topic?

- *In this study, early and mid-term follow-up results of 179 patients who underwent ASD closure by transcatheter method were shared and it aimed to include the experiences on this subject in the literature.*

ABSTRACT

Objective: Transcatheter secundum type atrial septal defect closure is an alternative to surgical closure in many cases when conditions are appropriate. In this study, the demographic data and follow-up results of patients with secundum atrial septal defect undergoing transcatheter closure were discussed.

Materials and Methods: Data of patients who underwent transcatheter closure of secundum atrial septal defect between 2004 and 2017 were investigated retrospectively. Gender, age at intervention, defect size, procedure duration, fluoroscopy time, periprocedural complications, residual shunt existence, and early and mid-term follow-up results were collected.

Results: A total of 179 patients [41% males; 10% adults, median age: 8.1 years (1.3-58.6); weight: 28 kg (11-90)] were admitted to catheterization for atrial septal defect closure and their median atrial septal defect size was 13 mm (6-30); 74 (41%) patients had a large atrial septal defect (≥12 mm). Suitable defects for closure were observed in 165 of 179 patients. The procedural success rate was 95.7%. No death was observed; however, minor complications occurred in 3 patients during the procedure (1.6%). The rate of residual shunt after 1 year was 1.3%, and all shunts were mild. After a median follow-up of 2.8 years (range, 6 months to 13.6 years), delayed major complications such as death, cardiac erosion, and infective endocarditis were not experienced. The delayed minor complication was supraventricular extrasystole in 1 patient.

Conclusion: Transcatheter atrial septal defect closure is safe in children and adults with a minimal rate of periprocedural and delayed complications. It has a favorable early and mid-term outcome in our study, especially with no death or major complications.

Keywords: Atrial septal defect, complication, transcatheter closure

INTRODUCTION

Atrial septal defect (ASD) is a defect that causes an abnormal shunt between the left and right atria in any area of the atrial septum.[1] According to the anatomical location of the interatrial septum, it can be classified as primum, secundum, sinus venosus, and coronary sinus types.[2] Spontaneous closure of secundum-type defects may occur. Closure of the defect is recommended in large defects that show volume overload, and spontaneous closure is not possible.[2] This treatment was performed by a surgical method for many years. In the last 2 decades, transcatheter occlusion devices have been used to close secundum ASDs and it was first performed by Mills and King in 1976.[3] Over the years, it has become the preferred method over surgery. Surgical treatment because of thoracotomy, scar formation, long hospital stay, residual shunting, and other complications is no longer a preferred option.[4] Patients treated by transcatheter method have a shorter hospital stay and less morbidity than those treated surgically .[4] In our study, the data of patients with secundum ASD who underwent transcatheter intervention in Cerrahpaşa Medical Faculty Pediatric Cardiology Department between 2004 and 2017 were

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shared. The demographic characteristics of the patients, the measurements related to the defect before and during the procedure, the types of devices used, the residual shunt rate in the follow-up after the procedure, the comparison of the patients with and without a residual shunt, complications, and problems that developed in the early and mid-term follow-up were discussed.

MATERIALS AND METHODS

Patients

This study was designed as a retrospective study at a single center. All secundum ASD patients who were processed to close ASD in the cardiac catheterization laboratory between January 2004 and December 2017 were included in the study. A total of 179 patients participated, and 18 of these patients were adults. Before this study, consent was obtained from the patients to share their information. The approval of the Ethics Committee of Cerrahpaşa Medical Faculty, numbered 83045809-604.01.02, was obtained.

Pre-procedure Evaluation

The patients with ASD were evaluated by 2-dimensional transthoracic echocardiography (TTE) and color Doppler echocardiography with images taken from the subxiphoid, precordial, and short-axis positions before the procedure. The distance of the defect to the atrioventricular (AV) valves, coronary sinus, pulmonary vein, superior vena cava (SVC), and inferior vena cava (IVC) was evaluated. The length of the superior and inferior rims, the largest diameter of the defect, and the total septum length were recorded. If any rim around the defect was 5 mm or less, it was accepted as a "deficient rim."

Transcatheter closure was decided according to TTE findings and clinical findings. Transthoracic echocardiography findings of the patients scheduled for closure treatment were as follows:

1) presence of secundum ASD with the left to right shunt,
2) dilatation of the right heart chambers,
3) $\geq$5 mm rim between defect and SVC, IVC, pulmonary vein, AV valves, and coronary sinus(CS), and
4) patients who had minimal shunt but had symptoms (arrhythmia, transient ischemic attack, etc.).

After deciding which patients were to be treated, anesthesia examinations of the patients were performed.

Procedure

Informed consent was obtained from the patients and parents before the procedure. The procedure was performed under general anesthesia with intubation. Antibiotic prophylaxis (cefazolin 50 mg/kg, maximum 1000 mg, single dose) was administered 30 minutes before the procedure. Transesophageal echocardiography (TEE) and TTE were used in 177 cases, and only TTE was used in 2 cases.

The parameters measured in the TEE study were as follows:

1) a minimum distance of 5 mm to the vital cardiac structures around the defect (AV valves, SVC, IVC, right upper pulmonary vein, and CS),
2) maximum defect diameter < 38 mm,
3) evaluation of rims <5 mm in length and sufficient interatrial septum length, and
4) device diameter suitability.

The transverse, bicaval, and aortic positions were evaluated using TEE. The diameter of the defect and septum was evaluated. Angiographic and echocardiographic measurements were performed using 24 or 34 mm size balloon catheters (AGA, Golden Valley, Minn, USA) to assess the stretched diameter of ASDs in all patients (Figure 1).

Three types of devices (Amplatzer Septal Occluder (ASO) of Jude Medical, Figulla Occlutech Septal Occluder of R&D, and Biostar Septal Occluder of NMT Medical) were used for transcatheter ASD closure. When the device was selected, a device equal to or close to the diameter of the defect was preferred. In patients with multiple defects, if the distance from the other defect to the central defect was less than 5 mm, one of the devices suitable for the central defect was used. All devices were chosen to be smaller than the total septum diameter. After device selection, device placement was performed by following the protocols described previously[3] (Figure 2).

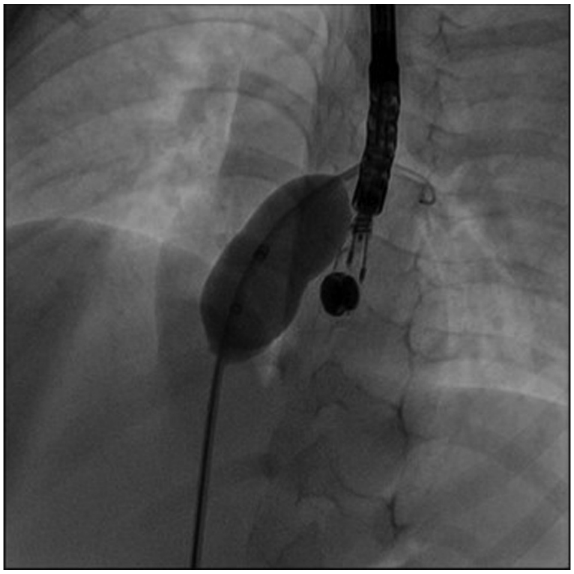

Figure 1. Measurement of the stretched diameter of the defect with a balloon-sizing catheter.

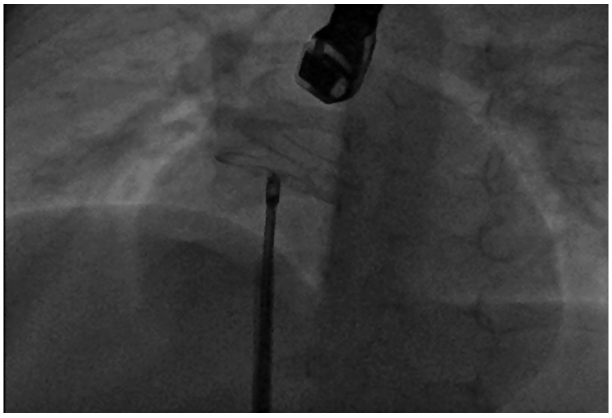

Figure 2. Device placement for transcatheter ASD closure. ASD, atrial septal defect.

Follow-up

Patients who were followed up in the hospital for 24 hours after the procedure were discharged following TTE and electrocardiograpy (ECG) evaluations. Then, they were checked by physical examination, TTE, and ECG at 1, 6, and 12 months. The presence of residual shunt and possible complications were evaluated by TTE. Arrhythmias were evaluated by ECG. A 24-hour Holter ECG monitoring was performed in patients with ECG pathology or clinical findings. The patients were treated with acetylsalicylic acid at a dose of 3-5 mg/kg for the first 6 months after the procedure. In addition, patients were administered bacterial endocarditis prophylaxis for the first 6 months after the procedure. After the first year, follow-up was performed once a year.

Statistical Analysis

The data processed in the digital database were transferred to the "Minitab 17 statistical software" program. Categorical variables were presented as percentage and frequency and numerical variables as median (range) and median (minimum-maximum) in the descriptive statistics. The Anderson–Darling normality test was used to determine whether the quantitative variables were normally distributed in the descriptive statistics, and the 2-sample *t*-test was used to compare 2 groups containing quantitative variables. In cases where the *P*-value was less than .05, the statistical difference was accepted as significant.

RESULTS

Demographic Characteristics and Preoperative Findings

This study included 179 patients who underwent transcatheter ASD closure in our center; 106 patients were female (59%), and 73 were male (41%). Female to male ratio was 1.45. The median age at the time of the intervention was 8.1 years (1.3-58.6 years), and 18 (10%) were adult patients. The median of their weight was 28 kg (11-90), and 10% weighed less than 15 kg. Demographic data of the patients during the intervention are summarized in Table 1.

Additional cardiologic pathology was present in 23% of the patients. Mild pulmonary stenosis (because of thickened valves) followed by mitral regurgitation (MR) and mitral valve prolapse (MVP) were the most commonly associated pathologies. There was a 16-month-old girl with Down syndrome and chronic lung disease and a 58-year-old woman with pulmonary hypertension. It was evaluated that 95% of the right heart cavities were wide in the heart cavities examination. Interventricular septum (IVS) movements were impaired in 76% of the patients. In 74% of patients, both right heart chambers were dilated, and IVS movements were impaired.

Table 1. Demographic data of the patients (179 patients)

Data	Median (Range), Number of Patients (%)
Sex (F: M)	106:73 (59:41%)
Age (year)	8.1(1.3-58.6)
0-5	36 (20%)
5-10	72 (40%)
10-18	53 (30%)
>18	18 (10%)
Weight (kg)	28 (11-90)
>15	161(90%)
<15	18 (10%)

The diameters of the defect and septum measured by TTE before the procedure are shown in Table 2. Wide ASD (≥12 mm) was present in 74 patients (41%). There were multiple defects in 9 patients and a fenestrated septum in 4 patients. Aneurysm of the interatrial septum was evaluated in 8 patients. Four of these patients (50%) had fenestrated septum walls, and 68 patients (38%) had a missing rim (<5 mm). The most common rim deficiency was the superior rim of the aortic window (89%).

Results of the Procedure

All patients were processed with general anesthesia and intubation. Transesophageal echocardiography was performed in all patients except for 2 patients. Defect diameter and interatrial septum were evaluated by TEE. Measurements by TEE, the hemodynamic study data recorded during cardiac catheterization, duration of the procedure, and scope are summarized in Table 2. The minimum Qp/Qs ratio was 0.83. This patient had 2 small defects, an interatrial aneurysm and an enlargement of the right heart cavities, and it was closed. During catheterization, the mean pulmonary artery pressure (PAP) of 7 patients (3%) was 25 mmHg and above. Four of these patients underwent transcatheter closure, and 3 of them were referred for surgery. The pulmonary to systemic flow ratio of patients whose ASD was closed with the transcatheter method was suitable for closure.

A total of 179 patients were admitted to the catheterization laboratory for transcatheter ASD closure. Fourteen of these patients were not suitable for transcatheter closure, and the procedure was discontinued. Thirteen of them were referred for surgery, and 1 was followed up without treatment. The procedure was unsuccessful in 7 patients. The remaining 158 patients underwent successful ASD closure with the device. The success

Table 2. Data About the Defect and the Procedure

Data	Median (Range), Number of Patients (%)
Procedure time (minutes)	60 (10.5-180)
Fluoroscopy time (minutes)	7.5 (2-32)
Measurements by TTE in short axis view	
ASD diameter (mm)	12 (7-27)
IAS length (mm)	31 (17-57)
Measurements by TEE in short axis view	
ASD diameter (mm)	13 (5-32)
IAS length (mm)	31 (18-54)
Measurements by "Balloon-sizing"	
ASD diameter (mm)	16 (6.5-33)
Device diameter (mm)	16 (6-33)
Defect/device diameter	1 (0.8-1.4)
Device type	
Amplatz	104 (65%)
Occlutech Flex II	46 (30%)
Biostar	8 (5%)
Qp/Qs	2.1 (0.83-8.3)

ASD, atrial septal defect; IAS, interatrial septum; TEE, transesophageal echocardiography; Qp/Qs, pulmonary to systemic flow ratio.

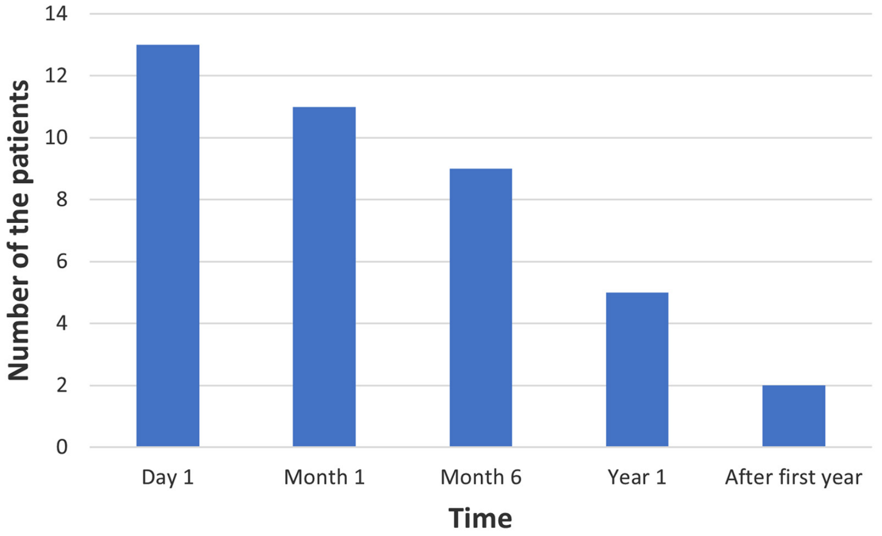

Figure 3. Time distribution of patients with residual shunt.

rate was 95.7% in the patients who underwent closure. The most common reasons for discontinuation were device-diameter incompatibility and multiple large defects. In addition, septum diameter insufficiency, proximity to vital structures, and other pathologies were among these reasons. When the reasons leading to procedure failure were examined, it was determined that the most common cause was rim deficiency and septum diameter insufficiency.

Successful closure of secundum ASD was performed using 3 kinds of devices. These devices were ASO (St Jude Medical, Inc. Saint Paul, Minn, USA), Occlutech Flex-II ASD occluder (Occlutech GmbH, Jena, Germany), and Biostar (NMT Medical, Boston, Mass, USA) (Table 2). Amplatzer septal occluder (65%) was used most frequently. Nine patients had multiple defects and 6 patients had aneurysmatic defects. Sixty-two (40%) patients had large defects. The defect size of 10 patients (6%) was ≥20 mm.

Follow-Up and Complications

Information about the follow-up of the patients was obtained from their files. Five out of 158 patients with secundum ASD treated with the transcatheter method did not participate in the follow-up study. The median follow-up period was 2.8 years (6 months-13.6 years).

The presence of residual defects detected after the first day, first month, sixth month, 1 year, and after the first year of intervention is shown in Figure 3. On the first day of the patients, residual shunts were present in 13 patients (8%), and shunts were not detected in the follow-up of 5 of them. Shunt status could not be detected in 6 of them, because they did not come for follow-up after 6 months. There were 2 patients (1.3%) whose shunts continued until the last follow-up. The shunts were all trivial and very small. Patients with residual passage were compared with those without; there was no significant difference in terms of age, body weight, procedure duration, defect diameter, and mean device size.

Complications were observed in 4 patients during and after transcatheter closure. These complications are summarized in Table 3. Complications developed in 3 patients during the closure procedure. In 1 patient, Mobitz type 2 AV block developed after the device was released, and heart rate was around 55-60/min. The rhythm returned to normal during follow-up. One patient developed atrial flutter during catheter manipulations at the beginning of the procedure. It was returned to a normal rhythm by cardioversion. One patient had brachial plexus palsy in the right arm. The procedure had failed, and the patient was referred for surgical closure. After 1 month of physical therapy, the patients' paralysis regressed.

During the follow-up of patients with ASD closure, none of them developed complications such as death, cardiac erosion, transient ischemic attack, or infective endocarditis (IE). Complications developed in only 1 patient during mid-term

Table 3. Characteristics of Patients with Complications During and After the Procedure

	During Procedure			Follow-Up
Complications	**Mobitz Type 2 AV Block**	**Atrial Flutter**	**Brachial Plexus Palsy**	**Supraventricular Extrasystole**
Age (years)	23	14.3	13.4	4.5
Weight (kg)	68	76	55	15
Defect diameter (TEE) (mm)	31	10	21	14
Device diameter (mm)	30	10		13
Fluoroscopy duration (minutes)	23	17	17	10.5
Device type	Amplatz	Amplatz	Procedure failed	Occlutech flex II

AV, atrioventricular; TEE, transesophageal echocardiography.

follow-up. It was supraventricular extrasystole detected after 1 year after closure. It did not require any treatment.

Pulmonary valve stenosis in patients was related to right ventricular hypertrophy and muscular overgrowth of the right ventricular outflow tract. Two of 13 patients' pulmonary stenosis (PS) had regressed after ASD closure; it had disappeared in 10 and had remained unchanged in 1. Mitral valve prolapse in all 6 patients was regressed. In 7 patients with MR, it improved in 5, decreased in 1, and remained unchanged in 1. Pulmonary arterial pressure was normalized in 4 patients with pulmonary hypertension after defect closure. Cardiac cavities and septum movements normalized on the first day after device closure. Three of the patients with ASD closure had a pregnancy in the post-closure period. There were no complications/problems during pregnancy.

DISCUSSION

Transcatheter closure of the secundum ASD was first described in 1976 by Mills and King, who successfully treated 5 patients with a large defect of up to 26 mm with a double umbrella device.[3] In the last 30 years, with the development of devices, their use has become widespread and has started to be applied as an alternative to surgical treatment. This method has been used safely and successfully in Cerrahpaşa Pediatric Cardiology Department since 2004. In our study, the aim was to share early and mid-term follow-up results of secundum ASD patients who underwent transcatheter closure in our center.

Complications due to percutaneous ASD closure with the device are rare in the literature and have been reported in the early period after the procedure.[5,6] Some complications can be reported as an exception in the late period.[5,7-9] In the literature, long-term complications after closure of secundum ASDs are cardiac erosion, device thrombosis, atrial arrhythmias and conduction problems, valve damage, nickel allergy, transient ischemic attack, and IE. As a result of a meta-analysis of 203 studies involving 28 142 patients, device-related mortality rates in the short- and long-term were found to be 0.01% and 0.1%, respectively.[10] In a cohort study of 1326 pediatric patients, the rate of periprocedural and delayed complications was significantly higher in patients with a weight of 15 kg or less (5.2% vs. 1.5%) and patients with large ASD (3.5% vs. 1.4%). In our study, no significant difference was found in our patients with complications; this may be due to few patients with complications. There were no deaths or major complications in our study.

According to a meta-analysis, the rate of device thrombosis after ASD closure is 0.8%-1%.[10] In our study, no device thrombosis was evaluated in the mid-term follow-up. In a previous study from Frankfurt, the incidence of thrombus formation was found to be 1.2% in 407 patients after percutaneous ASD closure.[11] Abaci et al[10] found the rate of cerebrovascular events as 1.1% after ASD closure with the device and investigated the risk of stroke. This rate is consistent with other studies.[12] In a Danish study, the risk of stroke both before and after closure was found to be higher in patients with ASD compared to the general population. They evaluated that the risk of stroke after closure was related to atrial fibrillation (AF).[13] In another study, while a significantly higher rate of stroke was found before closure than after closure, AF was found in all patients who developed stroke after closure.[14] In our study, a 21-year-old patient had a history of cerebral embolism before ASD closure. After ASD closure, there was no recurrence of embolism in the 9-year follow-up.

The risk of erosion after the ASO implant has been estimated to range from 0.043% to 0.3%.[15] The specific mechanisms and risk factors for device erosion are unclear and multifactorial.[15] Deficiency of the aortic rim is a predominant relative risk factor for cardiac erosion after ASD closure with the ASO device in a case–control study.[16] In our study, no patient developed cardiac erosion during follow-up. The reason for this may be the discontinuation of the procedure in patients considered to be at risk of defect closure. In fact, in our study, the rate of patients who discontinued the procedure was high (8%).

Nickel hypersensitivity develops because nickel-containing devices cause an immune and allergic reaction. In a study of 150 patients, nickel hypersensitivity was detected in 7 patients (5%) during patent foramen ovale or ASD closure.[17] In our study, no nickel hypersensitivity was observed during follow-up. The reason for this is that the patients were not questioned in detail, and the records were not well kept.

Atrial septal defect rim being close to AV node is a risk factor for damaging the device. Conduction abnormalities (including complete AV block) have been reported in less than 1%, although they are frequently observed.[18] Complete AV block is one of the classic post-operative acute complications, and most of them are transient or improved with short-term steroid therapy. In our study, 1 patient developed a Mobitz type 2 AV block during the procedure. The patient was followed up without treatment. The following day, the rhythm returned to the sinus.

Mitral regurgitation may regress probably due to the postoperative restoration of abnormal ventricular septal configuration. In 10%-37% of patients, MR may either newly appear or may worsen after percutaneous ASD closure, but the mechanisms of these adverse developments are unclear.[19] In our study, MR improved in 5 of 7 patients, decreased in 1, and did not change in 1. Mitral valve prolapse disappeared in all 6 patients with MVP after the closure of ASD. Wilson et al[20] in a study conducted on 194 patients found that the mean degree of MR did not change in 160 (88%), progressed in 20 (10%), and decreased in 13 (7%) patients during an average follow-up of 1.2 years after ASO placement.[20] They found that a patient with severe MR had a near-normal level. In a recent study on 288 patients, similar results were obtained, and most of the patients who developed MR were reported to be women and older patients. Aortic regurgitation (AR) is also described as one of the complications after ASD closure, but published data are rare and contradictory.[21] In our study, 2 patients had AR before closure. One of these patients had Ebstein anomaly and the other had aortic stenosis. Aortic regurgitation improved in both of them after the closure of ASD.

The incidence of AF in patients with ASD increases with age, up to 50% after 60 years of age. The most common complication after percutaneous ASD closure is atrial arrhythmias. In a study by Vecht et al.[22] closure of the defect in patients with AF was found to have a beneficial effect in a 5-year follow-up. In our study, a 3-year-old patient with supraventricular tachycardia did not recur in the 1-year follow-up after ASD closure. A 14-year-old patient developed atrial flutter during the procedure, and it was resolved with cardioversion. There were no arrhythmias in the 2-year follow-up after the closure of the defect.

In a Danish cohort study, the incidence of AF after closure was increased in patients without previous arrhythmias.[13] In that study of 1167 patients, 300 patients underwent percutaneous ASD closure and were followed up for an average of 5.2 years. These authors found that ASD closure increases the risk of developing atrial arrhythmias. In our study, a 4½-year-old patient developed supraventricular extrasystole, and treatment was not required during a 1-year follow-up.

Infective endocarditis after ASD closure is extremely rare in patients.[23] It is published in the literature in the form of case reports and is often detected within a few months after the procedure. In our study, no IE was observed during follow-up.

A successful closure is defined as a minimal (<1-2 mm) or no residual shunt.[24] In a cohort study of 1315 patients including all age groups, the residual shunt rate was observed to be 16.9% on the first day, 3.6% during the next six months, and 2.7% during the first year.[25] In a prospective single-center study of 213 adult patients, the residual shunt rate was found to be 14% during the 1-year and was most commonly evaluated with CardioSEAL/STARFlex (40%) and the lowest rate with amplatzer device closure (5%).[26] There was no relationship between age, sex, concomitant cardiac comorbid diseases, and residual shunt development. In our study, the shunt rate of the patients was 8% on the first day, 7% during the first month, 6% during the sixth month, 3% during the first year, and 1.3% after the 1-year follow-up. The shunts were all minor and very small. There was no significant difference between patients with and without shunts in terms of age, body weight, procedure time, defect, and device diameters (2-sample t-test, $P > .05$).

Closure of ASD, regardless of technique, reduces morbidity and mortality after the age of 40 compared to follow-up with medical therapy alone.[27,28] Hemodynamic consequences of defect closure include a reduction in right atrial and right ventricular dimensions.[29,30] This usually occurs immediately. In some patients, it may occur up to 6 months after closure.[30] In our study, it was observed that the dilatation of the right heart cavities regressed and IVS movements returned to normal on the first day after the defect closure. Pulmonary stenosis (PS) may develop due to right ventricular volume load and increasing flow through the pulmonary valve in patients with ASD. The treatment of ASD provides relief of right ventricular pressure and PS regression.[31] In our study, PS decreased in 2 of 13 patients with PS, disappeared in 10, and did not change in 1. The mean PAP generally decreases after the defect is closed except for some patients with moderate and severe pulmonary hypertension.[32] The PAP pressure was 25 mmHg and above in 4 of the patients who underwent ASD closure, and their pulmonary hypertension regressed after the treatment.

Complications are not common during pregnancy unless there is pulmonary hypertension in isolated ASD patients.[33] Yap et al[34] found a low rate of maternal complications during pregnancy in women with repaired or unrepaired ASD. Three of our patients had 4 pregnancies in total and had no maternal complications.

Our study has some limitations. Some of our patients did not come for follow-up visits; therefore, some of the records could not be reached. Some information was obtained through telephone. The study included patients treated until 2017 and our study finished in 2019. We did not add information after 2019. We used 3 kinds of devices for closure, but it did not affect the study. Data for retrospective analysis were collected and the experience of a single center was shared. Prospective and multicenter studies with a large number of patients are needed.

CONCLUSION

The percutaneous ASD closure has proven to be a safe and effective method with high rates of use. The early complication rate is very low compared to surgery. The most important late complications after ASD device closure are device thrombosis and cardiac erosion. The most common are atrial arrhythmias. Although there is no or very rare mid-term complication rate, some of these can be sudden and potentially fatal. Long-term follow-up is obligatory for patients whose ASDs are closed because of the potential for serious late complications. It has a favorable early and mid-term outcome in our study, especially with no death or major complications.

Ethics Committee Approval: This study was approved by Ethics committee of Istanbul University-Cerrahpasa, (Approval No:11480, Date: 20/06/2018).

Informed Consent: Verbal informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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