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Erişkin ve çocuklardaki sekundum tip atriyal septal defektlerin perkütan yaklaşım ile kapatılması: Kısa-orta dönem izlem sonuçlarımız

Percutaneous closure of secundum atrial septal defects in pediatric and adult patients: short- ,and mid-term follow-up results

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ÖZET

Amaç: Perkütan yolla atriyal septal defekt (ASD) kapatma işlemi yapılan hastaların kısa ve orta dönem takip sonuçları değerlendirildi.

Çalışma planı: Çalışmaya sekundum tip ASD tanısı konan 79 hasta (54 kadın, 25 erkek; ortalama yaş 26.2±17.2; dağılım 3-71) alındı. Tüm hastalar transtorasik ekokardiyografi (TTE) ve/veya transözefageal ekokardiyografi (TÖE) ile değerlendirildi. Perkütan kapatma için Amplatzer septal oklüder (ASO) cihazı kullanıldı. İşlem, 76 hastada lokal anestezi altında ve TTE eşliğinde yapılırken, kalan üç hastada ise genel anestezi altında TÖE eşliğinde yapıldı. Hastalar birinci, altıncı, 12. aylarda ve sonrasında yıllık olarak takip edildi. Ortalama takip süresi 13.5±6.6 ay idi.

Bulgular: Ortalama defekt çapı (TTE) 18.2±7.5 mm, ortalama balon ile gerilmiş çapı 20.7±8.04 mm, ortalama ASO cihaz çapı 22.7±8.5 mm idi. Ortalama işlem süresi 40.2±12.6 dakika, ortalama floroskopi süresi

ABSTRACT

Objectives: We aimed to evaluate the short- and mid-term results of patients with atrial septal defect (ASD) who were treated with percutaneous closure.

Study design: Seventy-nine patients with a diagnosis of secundum ASD (54 female and 25 male; mean age 26.2±17.2; range 3 to 71] years) were included in this study. All patients were evaluated by transthoracic (TTE) and/or transesophageal echocardiography (TEE). Amplatzer septal occluder (ASO) was used for percutaneous closure in all patients. In 76 patients, the procedure was performed under local anesthesia with TTE, while in the other 3 patients, it was performed with general anesthesia under the guidance of TEE. Patients were followed up at the 1st, 3rd, 6th and 12th months and annually thereafter. Mean follow-up period was 13.6±6.6 months.

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10.9±4.1 dakika idi. İşlem, tüm hastalarda %100 başarıyla uygulandı. Başarılı işlem sonrası kalp tamponadı gelişen bir hasta acil ameliyata verildi. Ameliyat sonrası yedinci günde hasta kaybedildi. İki hastada işlem sonrası cerrahi girişim gerektiren cihaz embolizasyonu gözlendi. İşlemden hemen sonraki TTE incelemesinde; üç hastada minimal kalıntı geçiş izlenirken bir ay sonraki kontrollerde izlenmedi. Bir hastada bir ay sonraki kontrolde hafif perikart sıvısı, bir hastada ise altı ay sonraki kontrolde cihazın kötü yerleşimi (malpozisyonu) ve önemli kalıntı geçiş görüldü.
Sonuç: Çalışmamızın bulguları, ASD'nin perkütan yolla kapatılmasının düşük komplikasyon ve yüksek bir başarı oranı ile uygulanabileceğini ve takiplerde olguların çoğunda kısa ve orta dönemde kalıntı geçiş olmadığını göstermektedir.

Results: Mean diameter of ASDs was 18.2±7.5 mm and stretched diameter was 20.7±8.04 mm during balloon dilatation, and mean diameter of implanted devices was 22.7±8.5 mm. Procedural time was 40.2±12.6, and fluoroscopy time was 10.9±4.1 minutes. The procedure was successfully performed in all patients (100%). One patient with cardiac tamponade died seven days after cardiac surgery. In two patients, the implanted devices embolized to the pulmonary circulation. Residual flow was found in three patients immediately after the procedure, without residual shunts one month after closure. Mild pericardial effusion in one patient and significant residual shunt due to device malposition in another were discovered at 1 and 6 months of the postprocedural follow-up period, respectively.
Conclusion: Our findings showed that percutaneous closure of ASDs is successful in most patients with a low complication rate, and demonstrated that residual shunts do not develop in the majority of patients in the short- and mid-term.

Abbreviations:

ASD Atrial septal defect
ASO Amplatzer septal occluder
LA Left atrium
PAP Pulmonary artery pressure
RA Right atrium
RAP Right atrial pressure
TAPSE Tricuspid annular plane systolic excursion
TEE Transesophageal echocardiography
TTE Transthoracic echocardiography

Atrial septal defect (ASD) constitutes nearly 10 % of relatively prevalent congenital heart diseases.[1-3] Surgical treatment of secundum type ASDs has evolved since its first introduction in 1953, and nowadays, it is performed with higher success, and lower mortality rates (1 %) both all over the world, and in our country.[4,5] However higher morbidity rates have urged investigators to develop catheter –assisted treatment modalities. Today, important developments have been made concerning catheter-assisted treatment modalities, and they have become the preferred first-line treatment alternatives to surgery in cases with secundum type ASD with appropriate morphological features amenable to catheter-assisted interventions. In 80 % of the indicated cases, this method has been applied using different devices.[6]

In this study our experience in transcatheter closure of secundum type ASDs using Amplatzer septal occluder (ASO) device, and our mid-, and long-term follow-up results have been evaluated.

PATIENTS AND METHOD

Seventy-nine patients with secundum type ASDs (54 women, and 25 men; mean age 26.2±17.2 yrs; range 3 – 71 yrs) who had undergone percutaneous closure of secundum type ASD between May 2010, and February 2013 using an

ASO in two different centers were included in the study.

All patients were informed about the intervention, before the procedure, and a consent form was obtained from themselves and/or their intimates. The study was approved by the ethics committee

Echocardiographic examination

Echocardiographic examinations were performed using Vivid -7 device with adult, and pediatric transducers (GE Vivid 7, GE Healthcare Systems, Piscataway, New Jersey, USA). Routine transthoracic echocardiography (TTE) was applied to all patients. Monitorization before, and after the procedure was performed using M-mode, 2D, and Doppler examinations was performed from standard parasternal, and apical views. Parasternal long-axis images were analyzed to estimate right ventricular diameter. Measurement of tricuspid annular plane systolic excursion (TAPSE) distance is a method used to evaluate right ventricular function, and it was measured from apical 4-chamber view using M-mode echocardiography.[7] Pulmonary artery pressure was estimated by measuring tricuspid regurgitant flow velocity from apical 4-chamber view. Its value was calculated based on the equation: PAP= RAP+4V2 (PAP=pulmonary artery pressure, RAP= right atrial pressure, V= maximal velocity of the tricuspid regurgitant flow.[8] Qp/Qs ratio was calculated based on cross-sectional areas of the left ventricular outflow tract, right ventricular outflow tract, and velocity –time integral derived from these measurements.[9] In symptomatic patients with increased right ventricular workload, and Qp/Qs ratio equal or more than 1.5, transcatheter ASD closure procedure was applied. Patients with ASDs apart from secundum type ASD (ie.sinus venosus, primum type ASD), concomitant pathologies requiring cardiac surgery or those with significant mitral and/or tricuspid regurgitation, and cases who developed Eisenmenger syndrome were excluded from the study.

Before the procedure all patients aged >15 years underwent transesophageal echocardiography (TEE). With TEE, at the midesophageal level, images were obtained in four-chamber view at 0 degree, short-axis view of aorta at 45^{o} degree, and bicaval, and interatrial septum images at 120^{o} (Figure 1). From these projections, estimates of superior, and atrioventricular, aortic, and posterior, vena cava superior, and inferior rims of ASDs were obtained, and their sizes were determined. If rims other than the aortic rim were less than 5 cm in length, then transcatheter ASD closure was given up. Besides diameter of the defect was confirmed by TEE. In patients with indeterminate defect diameters, measurements were performed using balloon catheter in the angiography laboratory. Defect diameters were measured at least twice using TTE and/or TEE, and balloon catheter, and 1-2 mm was added to this estimate in order to decide on the size of the ASO device.

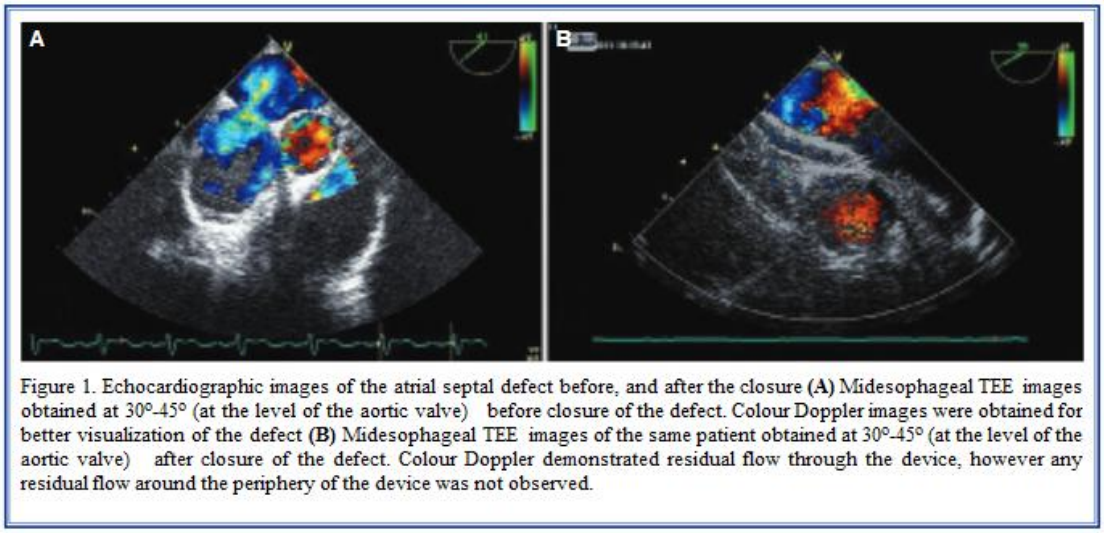

Figure 1. Echocardiographic images of the atrial septal defect before, and after the closure **(A)** Midesophageal TEE images obtained at 30º-45º (at the level of the aortic valve) before closure of the defect. Colour Doppler images were obtained for better visualization of the defect **(B)** Midesophageal TEE images of the same patient obtained at 30º-45º (at the level of the aortic valve) after closure of the defect. Colour Doppler demonstrated residual flow through the device, however any residual flow around the periphery of the device was not observed.

Amplatzer septal occluder

Amplatzer septal occluder devices (AGA Medical Corporation, Golden Valley, USA) are one of the most frequently used occluder for ASD closure (Figure 2). The main body of the device is made from 0.004-0.0075 inch nitinol (55 % nickel and 45% titanium alloy) wire mesh into which polyester fibers are sewn. It has a 3-4 mm thick cylindrical main body, and right, and left atrial retention disc attached to it. The device is a self-expanding occluder which takes the shape of the cavity it enters. Dacron fibers provides the device the ability to form thrombus so as to occlude the defect completely. In our country various occluder types with * a waist diameter varying between 4-42 mm are available. For device with a waist diameter of 4-10 mm left atrial disc is 12 mm, and right atrial disc 8 mm larger than the waist. Left atrial disc is 14 mm, and 16 mm larger than the waist of the device, in occluders with a waist diameter of 11-30, and 32-42 mm, respectively. Right atrial disc is 10 mm larger than the waist in occluders with a waist diameter of 11-42 mm. Since left atrial (LA) BP is higher than the right atrial (RA) BP, diameter of the left atrial disc is larger than the right atrial disc.

Serum natriuretic peptide measurement

Blood samples were collected at early hours (between 08:00, and 10:00 AM) of the day of the echocardiographic examination, and frozen at -20º. Serum N-terminal B-type natriuretic peptide (NT-pro-BNP) levels were measured using ELISA method (bioMérieux SA, F-69280 Marcy l'Etoile, France).

Application of the procedure

The procedure was performed under local anesthesia, and mild sedation with the aid of TTE in 76 patients, and in 3 patients it was applied under general anesthesia with the aid of TEE. After application of local anesthesia on the right femoral region, a 6 F sheath was inserted into the right femoral vein. With the aid of a 0.035 inch guidewire, a 6F Judkins catheter was inserted into the right femoral vein, and advanced through vena cava inferior, right atrium, ASD, and LA, then engaged in the left upper pulmonary vein. Afterwards, rigid exchange guidewire was placed in the left upper pulmonary vein. Diameter of ASD was measured using TTE and/or TEE at various positions, and compared with angiographic balloon diameter at left anterior oblique position (Figure 3). In the measurement of the

defect diameter using balloon catheter technique, a sizing balloon catheter was advanced over a 0.035 inch-rigid exchange guidewire, and implanted on the area of defect. After measurement of the defect diameter, ASO delivery system was advanced over the guidewire, and LA was entered. Then the appropriate position of the device was confirmed by TTE and/or TEE, and firstly the left atrial disc, subsequently right atrial disc were opened to close the defect. After engagement of the device on the defect, and before its release, TTE/TEE, and fluoroscopic methods were used to decide whether it is positioned correctly or it pressed on the right pulmonary vein, coronary sinus, bicaval veins, mitral, and aortic valves. Using Minnesota maneuver, stable position of the device was checked, and then it is released.

Figure 2. Appearance of the Amplatzer septal occluder on the tip of the catheter.Amplatzer septal occluders are made of a main body (shaft), and two inteconnected discs. Upper disc is larger, and it is left atrial side of the defect.

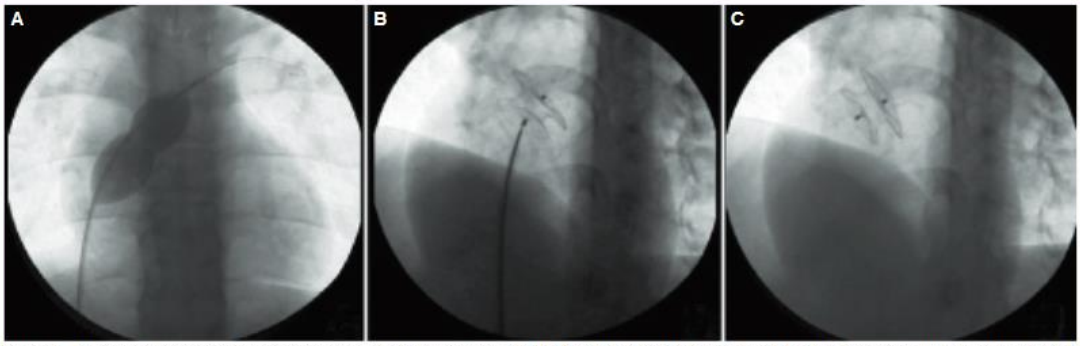

Figure 3. Fluoroscopic images of a patient before, and after closure of the defect **(A)** Ballon was inflated for the measurement of the atrial septal defect diameter. In the middle of the balloon, images of indentations formed by the edges of the defect are seen **(B)** immediately before release of the Amplatzer septal occluder, its appearance on the tip of the catheter **(C)** Fluoroscopic image obtained after release of the device.

During the procedure all patients received 100 IU/kg heparin, and 25 mg/kg IV cefazoline sodium for infective endocarditis prophylaxis. Procedural success was determined by confirmation of the corırect position of the device using cine/scopy and/or TTE/TEE after its proper placement on the defect, and its release.

Follow-up

Following the procedure, the patients received 200 mg aspirin daily for 6 months. All patients were monitored at postprocedural 1.,6., and 12. months with clinical evaluations, and TTE . NT-Pro-BNP values were assessed before, and one month after the procedure. Mean follow-up period was 13.5±6.6 months (range, 1-32 mos)

Statistical evaluation

For statistical evaluation SPSS 17.0 (IBM Inc.) package program was used. For the comparison of continuous variables expressed as mean ± standard deviation, paired *t*-test was used. Categorical variables were indicated as numerical values, and frequencies, and *chi*-square test was used for their comparisons. P< 0.05 was accepted as statistically significant.

Table 1. Demographic, and procedural characteristics related to the patients who underwent percutaneous ASD closure interventions

	n	%	Mean ± SD
Age (year)			26,2±17,2
Gender (male)	25	31,6	
Q P /QS ratio			1,7±0,2
Defect diameter (TTE) (mm)			18,2±7,5
Balloon diameter (mm)	79		20,7±8,0
Device diameter (mm)			22,7±8,5
Procedure time (min)			40,2±12,6
Fluoroscopy time (min)			10,9±4,1
General anesthesia	3	3,9	
Local anesthesia	76	96,1	
Follow-up period (mos)			13,5±6,6

ASD, atrial septal defect; SD, standard deviation; Q P/QS: Pulmonary blood flow/systemic blood flow; TTE, transthoracic echocardiography

RESULTS

Baseline characteristics related to the patients, and the procedure are shown in Table 1. Echocardiographic features, NT-Pro-BNP values, and functional capacities according to NHYA (New York Heart Association) classification criteria are presented in Table 2. At postprocedural first-month controls, statistically significant improvements were observed as for LA, RA, left (LVED), and right end-diastolic (RVED) diameters, left ventricular ejection fraction (LVEF), and systolic pulmonary artery pressure (SPAP) as determined by TTE. (for all, p<0.05). In patients with secundum type ASD, mean diameters of the defect (TTE) [18.2±7.5 mm (range, 6-36 mm), and the device [22.7±8.5 mm (range, 7-40 mm)], mean duration of the procedure [40.2±12.6 min (range,22-101 min)] and fluoroscopy [10.9±4.1 min, (range, 6-34 min)] were also determined as indicated in respective parentheses. Device embolization was observed in 2 patients, and these patients

were referred to the surgery. One patient died (1.3 %). LA floor perforation was observed in one patient during a surgical intervention performed with the indication of pericardial tamponade. TTE performed immediately after the procedure revealed a minimal residual flow in three patients. Disappearance of this residual flow was noted at the control visit realized one month after the procedure. Procedural success rate was detected as 100 percent. In one patient, pericardial effusion was seen one month later which was thought to be related to nitinol allergy. Priorly ibuprofen therapy was initiated without any respoınse. Then colchicine therapy was started, and complete cure was observed. Concomitancies of ASD and patent ductus arteriosus (PDA) (n=1) , and also ASD and muscular ventricular septal defect (n=1) were also detected. In both patients, other concomitant defects were also closed successfully using percutaneous interventions at the same session. In one patient device malposition and manifest left-to-right shunting were observed six months after the procedure (the defect was closed by surgical means). Arrhytmia or thrombus formation on the device was not observed in any of our patients. Mean floow-up period was 13.5±6.6 months (range, 1-32 mos).

DISCUSSION

Congenital heart failure is seen in nearly 0.-1 % of the live births.[10,11] The incidence of ASD ranks fourth among these defects, and its prevalence is estimated to be nearly 10.3 in 10.000 live births.[12] After bicuspid aortic valve, and mitral valve prolapsus, it is the most frequently seen congenital heart disease.[13,14] In this age group, it represents 30 % of congenital anomalies, and 25-30 % of newly diagnosed congenital anomalies.[15-17] Early diagnosis, and treatment of atrial septal defects have a critical importance because of its serious complications as pulmonary hypertension, right heart failure, arrhytmias, and paradoxical embolism.[18] Surgical treatment has been applied with higher success, and lower mortality rates.[19] However, formation of postoperative scar tissue, wound site pain, risk of infection, post-pericardiotomy syndrome, pericardial effusion, prolonged hospital stay, development of postoperative atrial fibrillation constitute disadvantages of the surgical method.[20-23].

Bialkowski et al. [24] reported an average postoperative complication rate of 68.1 % (mild, 38.6 %; moderate 25 %, and severe 4.5 %) while the average complication rate for transcatheter closure with ASO was 6.4 % (mild, 4.3 %,and moderate, 2.1 %). In another study where the complication rates of both methods were compared, the authors found complication rates of surgical, and transcatheter closure methods as %47, and only 11 %, respectively.[25] Nowadays, lower early, and late- term complication rates of transcatheter closure procedures, relative ease of their applications, and higher success rates have made this treatment modality as the first-line alternative in the management of secundum type ASD.[24-26] Transcatheter closure of ASD was firstly performed on a 14 year-old adolescent by King et al. in 1974 with success [27] However, it was not an acceptable method with widespread use till 1990s, after that time transcatheter ASD closure has become a prevalently accepted method both in the world, and in our country thanks to the experienced surgeons, and development of innovative device models.[28-30] Currently, ASO device is one of the most frequently used armamentarium.[20] It has demonstrated 90-100 % success rates at postoperative 12

months.[31-33] Still, in compliance with literature data, our success rate was 100 percent. In our country high success rates have been reported by some investigators with various brand closure devices as follows: Ergene et al.[28] 97% (68/70), Yüce et al..[29] 92.3% (48/52), Oto et al.[30] 99.2 % (133/134), Ilkay et al.[34] 100% (28/28), and Kaya et al.[35] 91.7 % (11/12) In a study conducted by Butera et al.[23] where surgical method were compared with transcatheter closure procedure, device malposition/ embolization was reported as the most frequently observed complication in their study population of 1268 cases. The investigators detected the rate of malposition/embolization of the device in the transcatheter closure group which required or did not necessitate surgical intervention as 1.5 % (11/751), and 1.9 % (14/751), respectively. In a study performed by Chessa et al. [36] in a series of 417 cases, total complication rate was reported as 8.6 % (36/417), and the investigators emphasized malpositioning/embolization of the device as the most frequently seen complication (3.5 %). In compliance with the literature data, we also observed malpositioning/embolization of the device in 3.7 % (3/79) of the cases. In our two patients, nearly eight, and twelve hours after the procedure device embolization was observed in the right ventricle, and main pulmonary artery, respectively. Because of the risk of thromboembolism, we didn't try to pick up, and withdraw the device with a pickup forceps. The devices were removed using surgical methods, and at the same session closure of the ASD was realized. In one of our patients, malposition of the device, and marked left-to-right shunt were observed six months after the procedure. This defect was closed using surgical means.

Table 2. In patients who had undergone percutaneous ASD closure procedures, echocardiographic characteristics, functional evaluation, and laboratory results before and after closure of the defect

	Before the procedure			One month after the procedure			
	n	%	Mean ± SD	n	%	Mean ± SD	*p*
LA diameter (mm)			27,5±4,5			28,8±4,0	**<0,05**
RA diameter (mm)			32,3±5,0			29,9±4,7	**<0,05**
LVEDD (mm)			43,6±7,3			43,0±7,2	**<0,05**
RVEDD (mm)			33,5±6,3			30,9±5,9	**<0,05**
LVEF (%)			63,1±2,6			66,0±3,7	**<0,05**
SPAP (mm Hg)			38,6±9,3			26,8±7,5	**<0,05**
TAPSE (mm)			19,8±1,3			22,2±3,2	**<0,05**
NT-Pro-BNP (pg/ml)			117,2±57,6			30,7±13,4	**<0,05**
Asymptomatic	-	-		24	31,6		
NYHA							
I	10	12,6		35	46,0		
II	45	57,0		17	22,4		
III	24	30,4		-	-		

ASD, Atrial septal defect; SD, standard deviation; LA, left atrium; RA, Right atrium; LVEDD, Left ventricular end-diastolic diameter; RVEDD, right ventricular end-diastolic diameter; LVEF, Left ventricular ejection fraction; SPAP, Systolic pulmonary artery pressure; TAPSE, Tricuspid annular plane systolic excursion; NT-Pro-BNP, N-terminal pro-brain natriuretic peptide

Mortality rates of transcatheter closure of ASD is very close to zero (nearly 1 %). In our study our mortality rate was 1.3 % (1/79). One patient developed cardiac tamponade one hour after the procedure which necessitated urgent surgical intervention. During the operation, perforation was observed on LA floor. We thought that the perforation might be related to LA floor injury caused by catheter, guidewire, or the delivery system. The patient was lost on the seventh postoperative day. In a previous study, it was reported that soon after the procedure residual shunt could be seen in 15-20 % of the cases, and it dropped to 3.8 % at the end of the follow-up period of one year (3/79) [37] In this presentation, residual flow was seen in 3.8 % (3/79) of the cases, while it wasn't observed at control visits performed one month later.

Very rarely, thrombus is formed on the Amplatzer septal occluder devices.[38,39] Thanks to Dacron mesh of the device, formation of thrombus is an anticipated, and desirable phenomenon. However thrombus formation on the atrial discs is an unwanted event. In a study encompassing 751 cases, the incidence of thrombus formation was reported as 0.4 percent.[23] In another study, various devices were compared as for thrombus formation, and at control visits performed 6 months after the procedure, any thrombi was not detected on Rashkind, Buttoned, ASDOS, Helex, Cardio-SEAL ve StarFLEX devices, however on ASO, PFO-Star, and Angel Wings devices thrombus formation was detected in 0.3, 1.5, and 3.3 % of the cases.[38] In our study, at postprocedural echocardiographic controls any thrombus formation on discs of the device was not observed.

Atrial septal defect causes right ventricular dilatation, increased pulmonary pressure, and paradoxical excursion of the interventricular septum due to diastolic overload.[40-42] Therefore, relief of volume imbalance between higher left, and lower right atrial outputs is the most important justification for the closure of ASD.[43-46] Production of BNP is effected by pressure, and volume overload which leads to ventricular wall strain.[47] Increases in BNP have been demonstrated not only in heart failure or systolic dysfunction, but also in right ventricular dysfunction.[48] In cyanotic heart diseases, BNP might increase without any evidence of heart failure or myocardial dysfunction.[49] TAPSE is one of the assessment methods of right ventricular systolic functions.[7] Clinical, and echocardiographic follow-ups of our patients performed one month later, revealed a conspicuous improvement in their functional capacities, a significant drop in pulmonary artery systolic pressure, increase in TAPSE values, and a meaningful decrease in BNP levels. [45,46,50] All of these data demonstrate that after a successful closure, with time hemodynamic, and functional improvement is observed. Besides, increase in TAPSE, and decrease in NT-Pro-BNP might be useful for the monitorization of the procedural success.

This study revealed that percutaneous closure of ASD can be applied with a relatively lower complication, and higher success rate. Our follow-up results also disclosed that in most of the cases, residual shuntswere not observed during the short-, and mid-term follow-up period.

In conclusion, closure of secundum type ASDs using Amplatzer device has a higher success rate with marked clinical improvement.

Conflict of Interest: none declared

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