Transcatheter closure of interatrial communications with Amplatzer device: results, unfulfilled attempts and special considerations in children and adolescents

Çocuklarda ve adolesanlarda atriyumlar arası ilişkilerin Amplatzer cihazı ile kapatılması: sonuçlar, başarısız girişimler ve özel noktalar

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ABSTRACT

Objective: We report our clinical experience with the Amplatzer device in transcatheter closure of 80 atrial septal defects (ASD) in children.

Methods: Among 99 patients (mean age: 7.2±3.8 years) with ASD selected by transthoracic echocardiography, procedures were performed in 80 patients under general anesthesia with fluoroscopic and transesophageal echocardiographic (TEE) guidance. Optimal device size was selected after stretched balloon sizing of the ASD's. The patients were discharged at 24 hours after an evaluation with X-ray, electrocardiography and echocardiography.

Results: The mean follow-up period (FUP) was 38±14 months. Mean ASD size was 11.5± 3.7 mm at TEE (stretched size: 17.6±3.9 mm). The mean size of the device was 18.6±4.0 mm. Procedure and fluoroscopy time were 52.1±17.8 minutes and 11±4.9 minutes respectively. Immediately after the procedure 35 patients (43.8%) had residual shunts. Trivial shunt remained in only 2 of them (2.5%) after FUP. None of the patients had major complications. Minor and transient rhythm abnormalities were observed in 5 patients and trivial mitral regurgitation was seen in 6 patients.

Conclusion: Amplatzer is an effective and safe device for transcatheter closure of ASD especially in pediatric patients. *(Anadolu Kardiyol Derg 2005; 5:159-64)*

Key words: Amplatzer septal occluder, atrial septal defect, children

ÖZET

Amaç: Çalışmanın amacı, Amplatzer cihazı kullanılarak transkateter yöntemle kapatılmış 80 atriyal septal defekt vakası (ASD) (ortalama yaş: 7.2±3.8 yıl) ile ilişkili klinik deneyimlerimizin sunulmasıdır.

Yöntemler: Transtorasik ekokardiyografik çalışma ile seçilmiş 99 hasta arasından seçilen 80 atriyal septal defektli hastada genel anestezi altında transözofajiyal ekokardiyografi ve floroskopi kılavuzluğunda transkateter ASD kapatılması işlemi uygulandı. Optimum cihaz çapı balon ile gerilmiş ASD çapı ölçülerek belirlendi. Hastalar işlemden 24 saat sonra göğüs grafisi, elektrokardiyografi ve ekokardiyografi ile değerlendirildikten sonra taburcu edildiler.

Bulgular: Ortalama izlem süresi 38±14 aydı. Transözofajiyal ekokardiyografi ile ölçülen ortalama ASD çapı 11.5± 3.7 mm (gerilmiş çap: 17.6±3.9 mm) idi. Ortalama cihaz çapı 18.6±4.0 mm idi. İşlem ve floroskopi zamanı sırasıyla 52.1±17.8 ve 11±4.9 dakika bulundu. İşlemden hemen sonra 35 hastada (43.8%) rezidüel şant saptanırken, izlem süresi sonrasında sadece 2 (2.5%) hastada eser şant gözlendi. Hastaların hiçbirinde majör bir komplikasyon gözlenmedi. Beş hastada minör ya da geçici ritm anormallikleri, 6 hastada da eser mitral yetmezliği gözlendi.

Sonuç: Çocuk ve adolesan hastalarda transkateter ASD kapatılması için Amplatzer etkili ve güvenli bir cihazdır. *(Anadolu Kardiyol Derg 2005; 5:159-64)*

Anahtar kelimeler: Amplatzer cihazı, atriyal septal defekt, çocuklar

Introduction

Surgical repair of interatrial communications has negligible mortality, and is widely accepted as a safe procedure; however it is associated with morbidity, discomfort after thoracotomy, and longer stay in hospital (1). Therefore transcatheter closure of atrial septal defects (ASD) has been developed as an alternative to surgery. The first reports of transcatheter device closure of secundum atrial septal defects in humans were published in 1976 by King and Mills (2) and in 1983 by Rashkind (3). Since

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then, a variety of devices have been developed, but none has gained wide acceptance (4). Previous techniques had some limitations like large delivery sheaths, difficult implantation techniques, inability to recapture, and structural failure causing damage to neighboring structures, dislodgment, and embolization (5-13). There is clinical evidence that the Amplatzer is a preferable choice among the other devices. It produces significantly higher occlusion rates and is much easy to apply (14, 15). We report our clinical experience with Amplatzer device in transcatheter closure of interatrial communications in children and adolescents.

Materials and Methods

Patients

Ninety nine patients between 2-21 years of age (mean 7.3±3.9 years) with secundum ASD were eligible for transcatheter closure with Amplatzer device (AGA Medical Corporation, Golden Valley, MN). All patients were evaluated at our institution with transthoracic two-dimensional and color Doppler echocardiography with multiple subxyphoid and precordial windows. Inclusion criteria for patient with ASD were 1) the presence of an ostium secundum ASD with left to right shunt, 2) a distance of >5 mm from margins of the defect to the mitral and tricuspid valves, superior vena cava, right upper pulmonary vein, and coronary sinus, 3) dilation of right atrium and right ventricle indicating right ventricular overload, 4) stretched ASD size < 26 mm (measured by inflating a balloon catheter at the level of the defect). Multiplane transesophageal echocardiography (TEE) was performed just before the transcatheter intervention for those patients who met the first three inclusion criteria, in order to confirm the transthoracic measurements and to have a better three-dimensional view of the defect. Later, the stretched diameter of the defect was measured after insertion of the balloon catheter. If the fourth criterion was met, the transcatheter closure was carried out, if it was not met; only the hemodynamic work-up was done.

Associated Pathologies

One of the patients with ASD had left fascicular ventricular tachycardia, which was successfully ablated before the procedure one month ago. Two patients had ductus arteriosus. One of these was too small (1.5 mm) and was not closed at the time of ASD closure, and the other was embolized with a 6.5 mm X 5 loop detachable coil at the time of ASD closure. Two patients had pulmonary stenosis creating 20 mmHg and 50 mmHg pressure gradient across the pulmonary valve. Balloon valvuloplasty was successfully performed to the patient with 50 mmHg pressure gradient simultaneously with ASD closure. One patient had three small muscular ventricular septal defects and another had mitral valve prolapsus with mild mitral insufficiency. These two patients are being followed for their associated pathologies.

Routine examination before the procedure included thorough physical examination, ECG, chest x-ray, and transthoracic echocardiography. Informed parental consent was obtained for each patient.

Device

The Amplatzer ASD Occluder is a self-expanding, self-centering, retractable, and repositionable double disc device constructed of a dense mesh of Nitinol wires. A 3-4 mm short, cylindrical waist connects the two discs. The left atrial disk extends 7 mm and the right disk extends 5 mm radially around the connecting waist. The left disk is slightly larger than the right, because of the higher left atrial pressure. The prosthesis is filled with Dacron fabric to facilitate thrombosis. The waist of the device is designed to stent the ASD. In order to stent, the diameter of the waist has to correspond to the stretched diameter of the defect. The device is connected to a delivery cable by a microscrew fixed to the right atrial disc and loaded into a 6-10 French long sheath (4). Currently, devices with waist diameters from 4-30 mm are available in Turkey.

Procedure

All procedures were performed under general anesthesia to allow continuous multiplane TEE imaging of the atrial septum and the neighboring structures (Fig. 1). In all patients, after the hemodynamic work-up (including the pulmonary artery pressure measurement, calculation of the amount of the left-right shunt through the ASD, and the angiograms) a sizing balloon catheter (AGA Medical, Golden Valley, MN) was inflated at the level of the defect until the waist in the middle of the balloon was seen (Fig. 2). The waist was measured and calibrated on the sine-angiographic frame as well as by TEE. These measurements were used to determine the diameter of the ASD occluding device. Identical with the stretched ASD diameter or 2 mm larger devices in patients with borderline ASD rims were selected. The devices were deployed under fluoroscopic and TEE guidance. Special care was given to detect the residual shunt or any obstruction of the caval veins, pulmonary veins, or the atrioventricular valves by TEE. In addition, gentle pulling and pushing of the delivery cable (Minnesota Wiggle) was done to ensure the stable position. If the device was satisfactorily well positioned and no or trivial shunt was observed through the stented defect, the device was unscrewed from the cable.

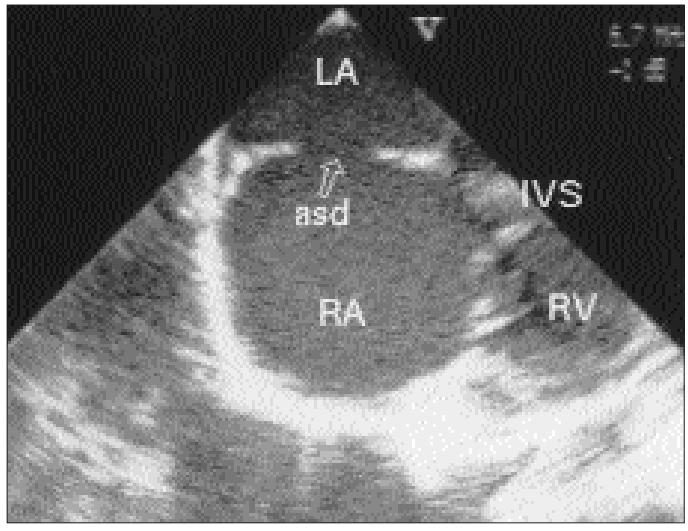

Figure 1. Transesophageal echocardiographic view of a secundum atrial septal defect

Follow-up

The patients received 24-hour heparin infusion and were discharged at 24 hours, after an evaluation with chest X-ray, ECG, and transthoracic echocardiography (Fig 3). Reassessment was done at first month and every 6 months thereafter with transthoracic echocardiography and Holter monitoring. The patients received prophylactic antibiotics to cover the implant procedure and for any intervention within six months after the implantation. Patients received 3-5mg/kg/day acetylsalicylic acid after the procedure for 6 months.

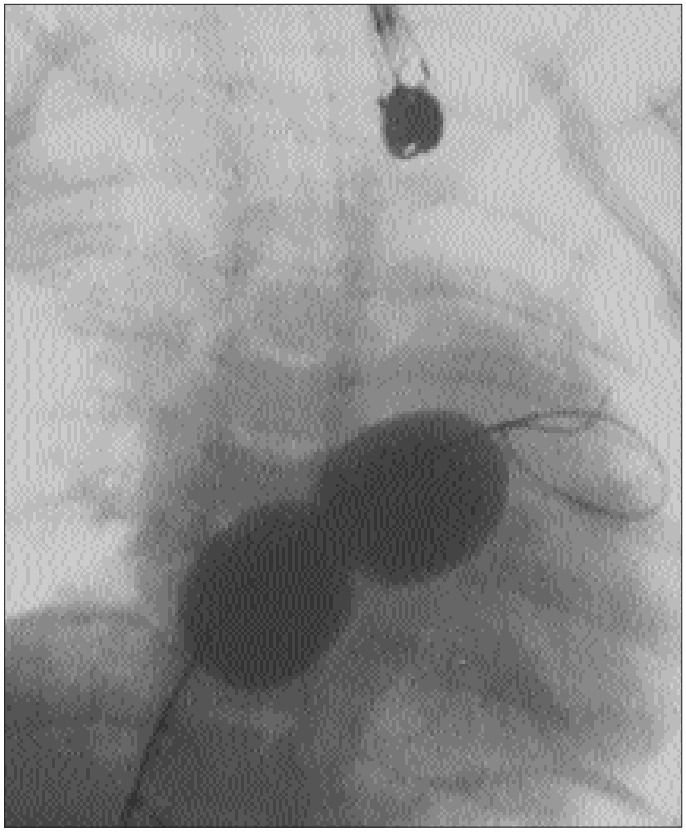

Figure 2. Measurement of stretched diameter of an atrial septal defect by a sizing balloon catheter

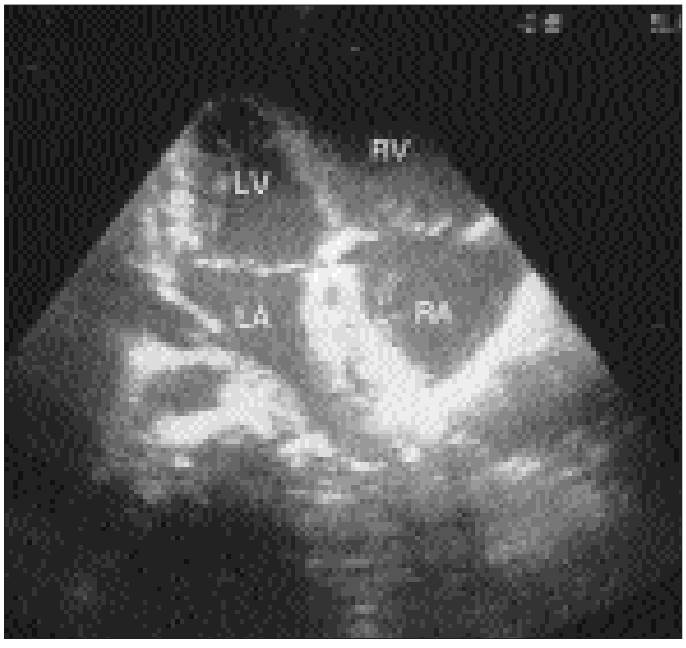

Figure 3. Transthoracic four-chamber view of an Amplatzer atrial septal defect occluder device at 24 hours after implantation indicated by arrow

Results

Transcatheter closure was attempted for ASD's in 99 patients aged between 2 to 21 years old (mean 7.3±3.9 years). The procedure was not carried out in 18 patients (18.2%) because the superior, inferior, anterior or posterior rims of the ASD were < 5 mm during TEE examination, total device diameter necessary for occlusion (waist + the atrial discs) was larger than the total atrial septum, or stretched ASD size was >26 mm (Table 1). Closure was carried out in 80 patients with ASD (44 female/36 male) from June 1999 to September 2003. The mean age of these patients was 7.2±3.8 years (median: 6.0 years, range 2-21 years). Body weight was 24.2±12.4 kg (12-68 kg) in these patients. The pulmonary/systemic flow ratio (Qp/Qs) in patients with ASD varied between 1.2 and 5.8 (mean: 2.3±0.9), and the mean pulmonary artery pressure varied between 11 and 38 mmHg (mean: 19.5±5.7 mm Hg). The mean ASD diameter determined by TEE was 11.5±3.7 mm (range 5 to 22 mm) the stretched diameter of ASD was 17.6±3.9 mm (range 10 to 26 mm). Total septal diameter was 33.8±5.8 mm (range 22 to 55 mm), the mean device diameter and the ratio of total septal diameter / device diameter were 18.6± 4 mm (range 10 to 26 mm) and 1.8±0.4 (range 1.1 to 3.5) respectively (Table 2).

The mean total procedure time was 52.1±17.8 minutes (range 25-120 minutes) and the mean fluoroscopy time was 11±4.9 minutes (range 5-33.2 minutes). Mean follow-up period was 38±14 months (range 6-60 months) (Table 2). Immediately after release of the device, 8 patients (10%) had small residual shunt (shunt reaching 1-2 mm beyond the device by color Doppler), and 30 patients (37.5%) had trivial shunts (shunt <1 mm by color Doppler) with TEE. Trivial shunt remained in only 5 of them (6.3%) during discharge, and at the end of the follow-up period, trivial shunt was observed only in 2 patients (2.5%). No shunt greater than trivial shunt was observed at this time.

Table 1. Characteristics of the patients in whom ASD closure was not carried out

Characteristic	Number of patients
ASD size >26 mm	8 patients
Distance of ASD to superior vena cava <5 mm	1 patient
Distance of ASD to inferior vena cava <5 mm	3 patients*
Distance of ASD's to inferior and superior vena cava <5 mm	1 patient**
Distance to the atrioventricular valves <5 mm	1 patient
Distance to posterior wall <5 mm	1 patient
Total device diameter (waist + the atrial discs) > total atrial septum	3 patients

*One patient had two ASD's, **Patient had three ASD's, ASD –atrial septal defect

In a patient whose stretched ASD diameter was measured 20 mm, a 19-mm device was initially used to occlude the defect, however obvious residual shunt was observed with TEE. This device was successfully retrieved and replaced with a 24-mm device; only trivial shunt was then observed with TEE. At the time of discharge no residual shunt was observed on echocardiogram. Two patients had two ASD's situated very close to each other, but were away from the surrounding tissues (AV valves, pulmonary veins, and both vena cava`s). In one of these patients, a single device of 26-mm diameter was placed through the larger defect, which also occluded the small defect close to it. Similarly in the other patient, a 24-mm device placed through one of the defects also occluded the second defect. No residual shunt was observed in these patients at the time of discharge.

Follow-up echocardiographic data revealed no obstruction of superior or inferior vena cava, coronary sinus, or the right upper pulmonary vein. Trivial mitral regurgitation was observed in 6 patients (regurgitant flow did not reach >1.5 cm beyond the leaflets and had low velocity). The anterior rims of the ASD in these patients were >7 mm. The diameters of the implanted devices were 18, 26, 26, 26, 25 and 20 mm respectively. The mitral regurgitation observed in the patient with associated MVP did not change after the ASD closure. There were no major complications like device fracture, embolization, or migration. One patient had a very short duration of junctional rhythm (mean heart rate 68/min), which returned to normal right after the procedure. In another patient, Mobitz type II, second-degree atrioventricular (AV) block with a mean heart rate of 55/min was observed during the procedure. With application of atropine, it changed to Mobitz type I, and then to the first- degree AV block. This patient was discharged in sinus rhythm. Frequent isolated supraventricular extrasystoles were present in the follow-up Holter record of one patient and he was complaining of palpitation. Because of previously experienced ventricular tachycardia and the radiofrequency ablation procedure the sense of palpitation caused panic attacks in the patient. Therefore the patient was treated with propranolol. Another patient had junctional rhythm with two short asymptomatic junctional tachycardia runs (maximum heart rate 170/min). This patient is followed clinically without medication. One patient had coronary sinus rhythm with normal heart rate in one of the Holter records. There was no other dysrhythmia associated with this ectopic atrial rhythm. All the other Holter records were normal.

Table 2. Characteristics of the patients whose ASD's were closed with Amplatzer septal occluder

Characteristic	Mean+SD (range)
Number of patients	80 (44 female/36 male)
Age, years	7.2 ± 3.8 (2-21)
Body weight, kg	24.2 ± 12.4 (12-68)
Qp/Qs ratio	2.3 ± 0.9 (1.2-5.8)
Mean pulmonary artery pressure, mm Hg	19.5± 5.7 (11-38)
ASD diameter on TEE, mm	11.5 ± 3.7 (5-22)
Stretched ASD diameter, mm	17.6 ± 3.9 (10-26)
Total septal diameter, mm	33.8 ± 5.8 (22-55)
Device size, mm	18.6 ± 4 (10-26)
Total septum/total device diameter, mm	1.8 ± 0.4 (1.1-3.5)
Procedure time, minute	52.1 ± 17.8 (25-120)
Fluoroscopy time, minute	11 ± 4.9 (5-33.2)
Follow-up, month	38 ± 14 (6-60)

ASD – atrial septal defect, TEE – transesophageal echocardiography

Heparin infusion (dose: 25 units/kg/hour) caused bleeding from the femoral vein puncture site in 2 patients 8-10 hours after the procedure. The ages of these patients were 3 and 4.5 years respectively. Administration of protamine and application of pressure on the puncture site stopped the bleeding and transfusion was not necessary.

Long-term follow-up

Ninety percent of patients were followed-up more than two years. Except rhythm abnormalities mentioned above, no additional complications like device fracture, aortic rupture or gross thrombus formation on the device was observed during long-term follow-up.

Discussion

Several reports of successful transcatheter closure of secundum ASD's have come into sight in literature in the past 20 years. However this procedure still has not achieved widespread use, new devices are being produced or improved every day. The Amplatzer septal occluder seems to overcome many of the disadvantages of previously used devices; namely requiring large introducer sheaths, large overall device for complete closure of the defect, difficult application procedures, inability to recapture, structural failure causing damage to neighboring structures, dislodgment, embolization, and higher rates of residual shunts (5-14). The high success rate of the Amplatzer device, which is also reported by other investigators (4, 15-25) is due to its functional design; the self centering mechanism stenting the potential ASD, and forcing blood through a highly thrombogenic Dacron network. Because the potential defect is stented, there was transient left-right shunt seen in 43.8% of our cases that immediately decreased to 6% the next day, before discharge. In follow-up echocardiographic study, only trivial shunt was observed in two (2.5%) patients. The rate of residual shunt has been reported to range from 1-7% in previous studies. Compared to these reports, our rate of residual shunt is (2.5%) relatively low. It should be emphasized that our patient population has the youngest mean age among all the other reports (4, 15-25).

The precise measurement of the defect is very important for appropriate selection of the Amplatzer device. If the device is too bulky, the disks may protrude into the atria, if it is too small the risk of residual shunt and embolization increases (4, 26). The selected device size (18.6±4 mm) was very similar to the stretched ASD size (17.6±3.9 mm) in our population. Prominent protrusion into the atria was not observed in any patient. The patients

with residuals shunt had 23 mm stretched ASD diameter and 24 mm devices were used in both patients. One of them has been followed for 36 months; the other was followed for 42 months. We believe the identical sized device with the stretched ASD or 1-2 mm larger devices will maximize their effect without causing any bulky protrusions.

The design of the device and the method of fixation make it possible to close larger defects with smaller rims (17). In our study group the largest ASD closed was 22 mm, which was 26 mm with balloon sizing, and the smallest rim was 5 mm. The procedure was not performed in 7 of our patients with small ASD rims and in 8 patients with stretched ASD diameter >26 mm. The total septal diameter is also important. Although sufficient septal rims are present, the small total septal diameter may preclude implantation of large devices especially in small hearts, as in 3 of our patients. A total of 18 patients were found not suitable for transcatheter closure with TEE, and they now await surgery. The transthoracic echocardiography was misleading in terms of patient selection in 18.2% of our cases. Similarly, Mazic et al. (27) examined patients with secundum ASD by transthoracic echocardiography, to select those suitable for transcatheter closure with Amplatzer device. Among 240 patients 14% were later found unsuitable for this procedure by TEE examination (27). The morphologic variations of the ASD's are common and determination of the three-dimensional morphologic features of the ASD is crucial before the procedure. This is only possible with TEE. Therefore TEE is essential for proper patient selection as well as safe and effective transcatheter ASD closure (27).

The Amplatzer's loading, technical deployment and recapturing is simple, which significantly reduces the total procedure and fluoroscopy time (4, 11, 23). The longer procedure and fluoroscopy times were recorded during the initial procedures and we believe they have been improved along the learning curve.

There were no major complications like device fracture, embolization or migration. During the procedure, transient junctional rhythm and second-degree AV block were observed in two patients. Both of these patients were discharged in sinus rhythm and the follow-up Holter records were normal. They had no history of dysrhythmia and had sinus rhythm prior to ASD closure. On the other hand, asymptomatic junctional tachycardia runs, and ectopic atrial rhythm (coronary sinus rhythm) were observed in routine Holter records of two patients. Although these patients did not require a medical treatment, the asymptomatic nature of the dysrhythmia emphasizes the usefulness of routine Holter monitoring in the follow-up of these patients.

Unlike some other authors we did heparinize our patients, as well as administering low-dose (3-5 mg/kg) aspirin for 6 months in order to prevent excessive thrombus formation on the device (17, 22). Two patients bled from the femoral vein puncture site 8-10 hours after the initiation of the heparin infusion of 25 Units/kg/hour. Although the heparin dose was titrated according to partial thromboplastin time (PTT) values (PTT was kept 1.5-2 times the initial value), the PTT rapidly increased in these patients. We then modified the initial heparinization dose as 15 Units/kg/hour especially in patients <5 years and no further bleeding complication was observed in any other patient.

In conclusion, the design and the method of fixation make the Amplatzer device possible to close larger defects with smaller rims. Loading, deployment and recapturing of the device is simple, which significantly reduces the total procedure and fluoroscopy time. The device can be safely used in children since it needs smaller introducer sheaths and are easily removed or repositioned should an undesired implantation occur. We point out that this device effectively occludes ASD's in pediatric patients with very low rate of residual shunts. No major complications are observed due to this procedure among pediatric patients.

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