Transcatheter closure of secundum atrial septal defects, a ventricular septal defect, and a patent arterial duct

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We report our clinical experience with the newly developed Amplatzer device in transcatheter closure of nine atrial septal defects (ASDs), one ventricular septal defect (VSD), and one patent arterial duct (PDA).

Eleven patients with ASD (age range 2.5-18 years) selected according to the location and size of the defect by transesophageal echocardiography (TEE), a five-year-old patient with muscular VSD and a one-year-old patient with PDA were considered for transcatheter closure with Amplatzer devices. All procedures were performed under general anesthesia with fluoroscopic and TEE guidance, following a routine hemodynamic evaluation in the catheter laboratory. The optimal device size was selected after the balloon sizing of the ASDs. The sizes of the VSD and PDA were measured on TEE and angiography. The patients were discharged at 24 hours, after an evaluation with x-ray, electrocardiogram (ECG), and echocardiography; they were on 3-5 mg/kg/day aspirin and infective endocarditis prophylaxis for six months after the procedure. They were reassessed at six to eight weeks and Holter monitoring was done in addition.

Devices were used for nine ASD patients, and for the VSD and the PDA patients. Mean ASD size was 14.3 ± 5.3 mm at TEE and 18.3 ± 4.3 mm at balloon sizing ($p=0.02$). The mean size of the device was 18.7 ± 4.2 mm. The procedure time and the fluoroscopy time were 46.1 ± 12.3 and 12.9 ± 1.6 minutes, respectively. Immediately after the procedure, four patients (44%) had trivial shunts (TS). TS remained in only two during discharge, and no shunt was observed at second evaluation. The devices were similarly applied to VSD (12-7 mm) and PDA (8-6 mm) patients. Both cases had TS immediately, which disappeared at 24 hours. None of the patients had major complications. Junctional rhythm developed in one patient, and another patient had frequent supraventricular extrasystoles.

Amplatzer is an effective and safe device for transcatheter closure of ASD, VSD, or PDA, especially in pediatric patients.

Key words: Amplatzer septal occluder, transcatheter closure, atrial septal defect, ventricular septal defect, patent ductus arteriosus.

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 a longer stay in hospital[1]. Therefore, transcatheter closure of atrial septal defects (ASD) has been developed as an alternative to surgery. William Rashkind[3] did the first studies about transcatheter closure of intracardiac defects in the late 1960's. "Single hooked umbrella" was the initial device created for this purpose (Fig. 1). This device was implanted in the dog heart (left ventricular posterior wall) via thoracotomy, and the endothelization of the device was observed with serial autopsies. In 1970, in Philadelphia Children's Hospital, Bilgiç used this device, which was produced in the catheter laboratory using transatrial needle,

basket and balloon catheters, on 15 dogs with ASDs (unpublished data) (Figs. 2 and 3). The first reports of transcatheter device closure of secundum ASDs in humans were published in 1976 by King and Mills[2]; and in 1983 by Rashkind[3]. Since 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, structural failure causing damage to neighboring structures, dislodgment, and embolization[5-13]. In 1997, Sharafuddin et al.[14] reported an animal study using a different approach to defect occlusion by stenting the inter-atrial communication with a Nitinol prosthesis, tightly woven into two flat buttons with a short connecting waist[15]. There is clinical evidence that the Amplatzer is a preferable choice among the other devices. It produces significantly higher occlusion rates and is much easier to apply[16,17]. The Amplatzer ventricular septal occluder and ductal occluder are new devices especially designed for transcatheter closure of muscular ventricular septal defects (VSDs), and patent arterial ductus (PDAs), an they have been successfully tested in animal and in vivo experimental studies[18,19]. We report our clinical experience with the Amplatzer device in transcatheter closure of nine ASDs, one VSD, and one PDA.

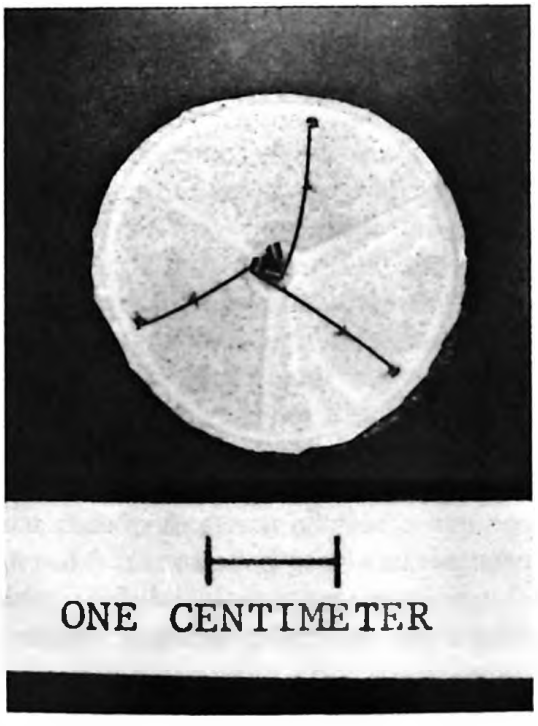

Fig. 1. Single hooked umbrella device (courtesy of Arman Bilgiç, MD).

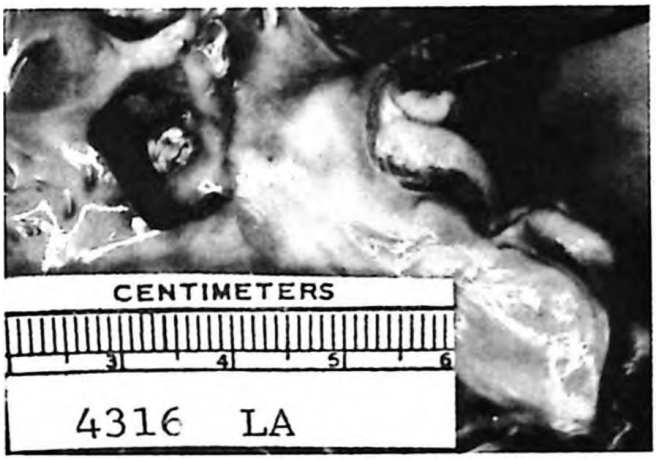

Fig. 2. Transcatheter device closure of atrial septal defects in dogs: two weeks after the procedure (courtesy of Arman Bilgç, MD).

Fig. 3. Transcatheter device closure of atrial septal defects in dogs: six months after the procedure (courtesy of Arman Bilgiç, MD).

Material and Methods

Patients

Eleven patients between 2½-18 years of age (mean 7.8 years) with secundum ASD, a five-year-old patient with mid-muscular VSD, and a one-year-old patient with PDA met echocardiographic criteria for transcatheter closure with Amplatzer device (AGA Medical Corporation, Golden Valley, MN). All patients were evaluated at our institution with two-dimensional and color Doppler echocardiography with multiple subxyphoid and precordial windows. All patients with ASD were further evaluated with biplane transesophageal echocardiography (TEE). Patient inclusion criteria were 1) the presence of an ostium secundum ASD with left to right shunt across the ASD, 2) a distance of >4 mm from margins of the defect to the mitral and tricuspid valves, superior vena

cava, right upper pulmonary vein, and coronary sinus, and 3) dilation of right atrium and right ventricle indicating right ventricular overload. One of the patients with ASD had reentrant ventricular tachycardia originating from the right ventricle, which was successfully ablated one month before the procedure. Another patient had dilated cardiomyopathy complicating a past viral myocarditis. Transcatheter closure was preferred for this patient due to the relative safety of this procedure over open-heart surgery.

The echocardiographic examination revealed a 3 mm mid-muscular VSD and 70 mmHg pressure gradient across the defect with continuous wave Doppler in a five-year-old patient, and a 3 mm PDA in a one-year-old patient. These two patients were also included in the group.

Routine examination before the procedure included electrocardiography (ECG), chest x-ray, and transthoracic echocardiography. Informed parental consent was obtained for each patient. All were discharged the next day. Before discharge, ECG, a biplane chest x-ray, and transthoracic echocardiography were repeated. Six to eight weeks later a follow-up transthoracic echocardiography and a Holter monitoring were done, and six months later a TEE was planned. The patients received prophylactic antibiotics to cover the implant procedure and any intervention for six months following the implantation. They also received 3-5 mg/kg/day acetylsalicylic acid after the procedure for six months.

Devices

The Amplatzer Septal Occluder (Fig. 4) is a self-expanding, self-centering, retractable, and repositionable double disk device constructed of a dense mesh of Nitinol wires. A 3-4 mm short, cylindrical waist connects the two disks. The left atrial disk extends 7 mm and the right disk 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. Currently, devices with waist diameters from 4-26 mm are available. The device is connected to a delivery cable by a microscrew fixed to the right atrial disk and loaded into a 6-7 French (F) long sheath[4,15].

Fig. 4. (From right to left) Amplatzer septal occluder, ductal occluder, and ventricular septal defect occluder.

The VSD device (Fig. 4) is similar to the ASD device. The length of the central stent has been increased from 3 to 7 mm to allow for the thicker interventricular septum compared to the interatrial septum. The retention disks are smaller and project only 4 mm on each side of the device. A microscrew is fixed to the right ventricular disk[20].

The Amplatzer ductal occluder (Fig. 4) is a self-expanding mushroom-shaped device with a thin aortic retention disk designed to secure positioning in the aortic ampulla[21].

Procedure

ASD : All procedures were performed under general anesthesia to allow continuous biplane TEE imaging of the atrial septum and neighboring structures. A 7F sheath was placed in the right femoral vein and a 4F sheath in the left femoral artery for pressure monitoring. Right and left heart catheterization was performed to measure the pulmonary artery pressure and to compute the amount of the left-right shunt through the ASD. A left atriogram in a 45° left anterior oblique position and a 35° cranial angulation, with the catheter pointing towards the right upper pulmonary vein, was done to illustrate the angiographic morphology of the left to right shunt. A sizing balloon catheter (AGA Medical, Golden Valley, MN) was passed over an exchange length guidewire and was inflated at the level of the defect until the waist in the middle of the balloon was seen. The waist was measured on the sine-angiographic frame and was calibrated using the radiopaque markers on the shaft of the catheter. The waist of the sizing balloon was used as the stretched diameter of the defect and an occluding device of similar diameter was chosen. A 7F long sheath and a dilator were passed over the exchange guidewire. The selected device was screwed on to the delivery system and was loaded under water. The dilator and the

exchange guidewire were then withdrawn, replaced by the device and the delivery system. The left atrial disk and the waist of the device were deployed under fluoroscopic and TEE guidance. The device was pulled against the septum to enable self-centering and, then the right atrial disk was deployed. At this instant special care was given to detect the residual shunt, or any obstruction of the caval veins, right pulmonary veins, or the atrioventricular valves by TEE. In addition, gentle pulling and pushing of the delivery cable (Minnesota Wiggle) was done to ensure a stable position. If the device was satisfactorily well positioned and no or only a trivial shunt was observed through the stented defect, the device was unscrewed from the cable. A right atriogram was performed to demonstrate the position of the device and any residual shunts.

PDA : The procedure was done under general anesthesia. A multipurpose catheter and an exchange guidewire were placed in the pulmonary artery via the right femoral vein, right atrium and ventricle and were then advanced into the aorta. A 8-6 mm ductal occluder was used. After preparing the device in a similar way to the septal occluder, it was placed across the PDA. The retention disk was deployed at the aortic edge of the ductus. Any residual shunt was detected with repeated contrast injection in the arcus aortae, which is reached via the left femoral artery.

VSD : The procedure was done under general anesthesia and transesophageal guidance. After confirming the place and distance of the defect to the atrioventricular valves and aorta by left ventriculogram, a cobra catheter and an exchange guidewire were advanced to left ventricle via the right femoral artery and arcus aortae. With repeated hand injection of a small amount of contrast through a second catheter introduced from the opposite femoral artery, the catheter and the guide were passed through the ventricular septal defect to the right ventricle and the pulmonary artery. The guidewire was then snared from a percutaneous jugular vein approach. The long sheath was advanced over the guidewire from the jugular vein to the left ventricle. The size of the VSD was measured as 10 mm with TEE. A 12-7 mm ventricular septal occluder was deployed in a manner similar to that used for the septal occluder.

Results

Transcatheter closure was attempted for ASDs in 11 patients aged 2.5 to 18 years old (mean: 7.8 years). Body weight ranged from 14-64 kg (mean: 26.9 kg). The mean ASD diameter determined by TEE was 14.2 ± 5.3 (range 6 to 25) which was significantly smaller (mean: -4.93 ± 3.2; p=0.02) than the stretched diameter of ASD measured by balloon sizing, 18.3 ± 4.3 (range 11 to 26). The pulmonary/systemic flow ratio (Qp/Qs) varied between 1.4 and 3.9 (mean: 2.3 ± 0.8), and the mean pulmonary artery pressure varied between 13 and 24 mmHg (mean: 17.8 ± 3.3). Nine of them were successfully treated with this method. The mean device diameter was 18.7 ± 4.2 (range 12 to 26) and the interatrial septum/device ratio was 1.7 ± 0.4 (range 1.1-2.3).

The procedure was not carried out in two patients. The ASD distance to the superior vena cava was initially measured as 4.3 mm with TEE in one patient; however, on the day of the procedure the repeated measurement was 1 mm. The other patient had 4 mm of superior rim and 26 mm stretched ASD diameter. The superior rim of the ASD was to small in both patients to carry out this procedure. The latter patient, had a large ASD as well. In another patient whose stretched ASD diameter was 20 mm, a 19 mm device was initially used to occlude the defect; however, an obvious residual shunt was observed with TEE. This device was successfully retrieved and replaced with a 24 mm device; only a trivial shunt was then observed with TEE.

The mean total procedure time was 46.1 ± 12.3 (range 27-65 minutes) and the mean fluoroscopy time was 12.9±1.6 (range 11.9-17 minutes). Immediately following the procedure the TEE, and at the time of discharge, the transthoracic echocardiography, revealed no obstruction of superior or inferior vena cava, coronary sinus, or of the right upper pulmonary vein. There was also no atrioventricular valve regurgitation. Immediately after release of the device, four of the patients (44%) had residual trivial shunt with TEE; at the time of discharge this rate was reduced to 22 percent (2 patients). Figure 5 demonstrates the echocardiographic image of the Amplatzer atrial septal occluder.

There were no major complications. Only one patient had a very short duration of junctional rhythm, which returned to normal immediately

after the procedure. Follow-up echocardiographic data revealed no evidence of residual shunt in any of the patients. In one of the patients, frequent isolated supraventricular extrasystoles were present in the follow-up Holter record and there were complaints of palpitation. Because of previously experienced ventricular tachycardia and the radiofrequency ablation procedure, the sense of palpitation caused panic attacks in this patient. Therefore this patient was treated with propranolol. Another patient had junctional rhythm with two short asymptomatic junctional ectopic tachycardia runs (maximum heart rate 170/min). This patient has been followed clinically without medication. All the other Holter records were normal.

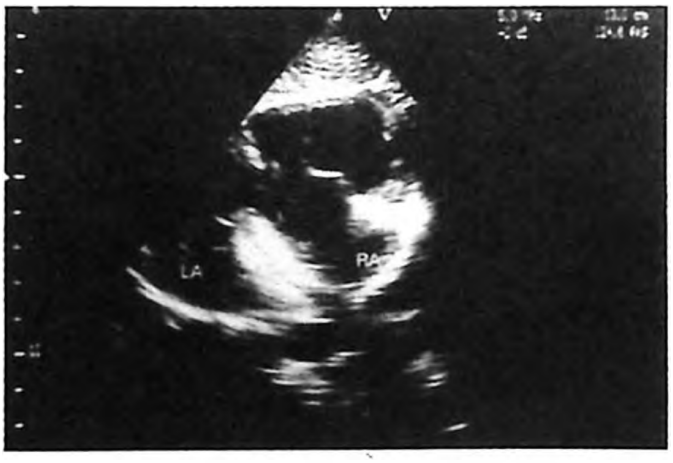

Fig. 5. Echocardiographic image of the Amplatzer septal occluder device (indicated with arrows).

The patients with VSD and PDA were successfully treated with transcatheter closure of the defect. Although both patients had trivial shunt with TEE immediately after the procedure, the shunt had disappeared by discharge the next day. The total procedure time and the fluoroscopy time, respectively, were 150 minutes and, 61 minutes for VSD closure, and 50 minutes and, 15 minutes for PDA closure. A 12-7 mm device was used for closure of VSD, and a 8-6 mm device for PDA. The mean pulmonary artery pressure and the Qp/Qs ratios for these patients with VSD and PDA were 17 mmHg/1.5, and 18 mmHg/1.8, respectively. The patient with VSD had a coil embolization for his PDA a year before the present procedure. No complications, including no arrhythmias, were observed during short-term follow-up. Figure 6 demonstrates the echocardiographic image of the Amplatzer ventricular septal occluder.

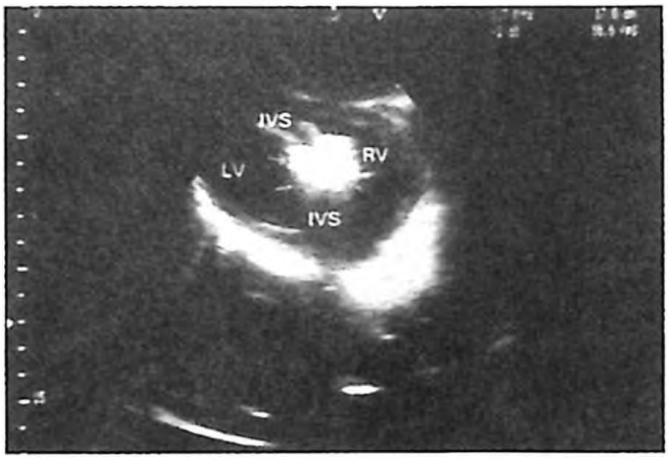

Fig. 6. Echocardiographic image of the Amplatzer ventricular septal defect occluder device (indicated with arrows).

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, and 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, requisite large introducer sheaths, a 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[5-13]. The high success rate of the present device, which has also been reported by other investigators[4, 15-17, 22], 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 trivial left-right shunt seen in 44 percent of our cases, but this immediately decreased to 22 percent the next day, before discharge. In follow-up echocardiographic study, no residual shunt was observed in any of the patients. This is the highest closure rate compared to other reports (100%)[4, 15-17, 23]. 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[4,24]. The selected device was 2 mm smaller than the measured ASD in

two patients, exactly the same size in one, 1 mm larger in two, and 2, 3, 4, and 5 mm larger in each of the remaining patients. Prominent protrusion into the atria was not observed in the latter group of patients. Three of the residual shunts were observed where a smaller or the same-sized device was used for occlusion. However, only one of these patients had shunt at the time of discharge. We believe the identical sized device with the stretched ASD or 1-2 mm larger devices will maximize effect without causing any bulky protrusions.

The design and the method of fixation make it possible to close larger defects with smaller rims[15]. In our study group the largest ASD closed was 21 mm (stretched diameter), and the smallest inferior rim was 5.2 mm. The procedure was not performed in two of our patients because of small ASD rims. One patient had dilated cardiomyopathy complicating a past viral myocarditis. Transcatheter closure of her ASD was thought to be less dangerous; however, the procedure was not performed because she had a large ASD with small rims. This patient and another one with small ASD rims now await surgery.

The Amplatzer's loading, technical deployment and recapturing are simple, which significantly reduces the total procedure and fluoroscopy time[4,11,23]. We assume the longer procedure and fluoroscopy times for VSD closure are because of the relatively more complex procedure; these should improve along the learning curve as better-designed devices are available.

There were no major complications such as device fracture, embolization, migration, or mitral regurgitation. One patient had a very short duration of junctional rhythm during the procedure, which returned to normal right after the procedure. The Holter records of two patients at six to eight weeks after the implantation revealed dysrhythmia. One of these patients was the one with reentrant ventricular tachycardia originating from the right ventricle, which was successfully ablated one month before the procedure. This patient had frequent supraventricular extrasystoles. The other patient had no history of dysrhythmia and had sinus rhythm prior to ASD closure. This patient has asymptomatic junctional ectopic tachycardias. The asymptomatic nature of the dysrhythmia in this patient emphasizes the usefulness of routine Holter monitoring in the follow-up of these patients.

Unlike some other authors, we did not heparinize our patients, but administered low-dose (3-5 mg/kg) aspirin for six months in order to prevent excessive thrombus formation on the device. We believe heparinization is not necessary and may prolong the disappearance of small residual shunts.

The Amplatzer septal, ductal and ventricular septal occluders in their current configuration are easy to implant, and provide an effective alternative for surgery, especially for those at high risk of open-heart surgery. The device can be safely used in children since it requires smaller introducer sheaths, which can be easily removed or repositioned should an undesired implantation occur.

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