Amplatzer Device closure of Atrial Septal Defects and Patent Ductus Arteriosus: Initial Experience

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Abstract

Surgical closure of Atrial Septal Defects (ASD) and Patent Ductus Arteriosus (PDA) can be performed successfully with low mortality. However, the morbidity associated with general anaesthesia, thoracotomy, cardiopulmonary bypass, postoperative monitoring in the intensive care unit, several days of hospital stay and the requirement of blood products is considerable. The expense associated with this morbidity, operative scar and the psychologic trauma to the patient and parents are additional disadvantages of surgery. Hence, the closure of these defects by transcatheter methods with various devices has been evaluated worldwide. We report the initial experience at our centre with closure of secundum ASDs and large PDAs with the Amplatzer Septal Occluder and Amplatzer Duct Occluder.

Key Words : Amplatzer device; Large Patent Ductus Arteriosus; Secundum Atrial Septal Defects

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Introduction

Although surgical repair of interatrial communications and PDA is a safe, widely accepted procedure with negligible mortality, it is associated with morbidity, discomfort and a thoracotomy scar [1]. As an alternative to surgery, a variety of devices for transcatheter closure of ASDs have been developed over the past 25 years, but none has gained wide acceptance. Large delivery sheaths, cumbersome implantation techniques, inability to recapture, structural failure, dislodgement and embolization of the device are some of the limitations of previously prescribed techniques [2-12]. This study describes our experience with transcatheter closure of ASDs and PDAs using a new self expanding, self-centering and repositionable device, the Amplatzer. This device was tested at the University of Minnesota and has been evaluated in animals and in vivo experimental studies [13] with promising results that support initiation of clinical trials.

Material and Methods

1. Device and Delivery System

The Amplatzer Septal Occluder (AGA Medical Corporation, Golden Valley, MN) and delivery system have been described in detail in previous reports [13]. In brief, this device consists of two self-expandable round discs made of 0.004 to 0.005 inch Nitinol wire mesh that are linked together by a short (4 mm) connecting waist, corresponding to the thickness of the atrial septum. The left atrial disc extends 7 mm radially around the connecting waist and the right disc 5 mm. The left disc is slightly larger than the right because of the higher left atrial pressure. Both discs

are angled slightly toward each other to ensure firm contact with the atrial septum. The prosthesis is filled with Dacron fabric to facilitate thrombosis. Prostheses are currently available in sizes ranging from 4 to 32 mm at increments of 1 mm. The device is attached by a microcrew mechanism onto a 0.038 inch delivery cable made of stainless steel. It is loaded into a long 6F to 9F (occluders >10 mm) introducer sheath. For introduction into the delivery sheath the device is pulled into a loader.

The Amplatzer Duct Occluder is a self-expandable, mushroom-shaped device made from a 0.004 inch thick Nitinol wire mesh (a thin retention disc, 4 mm larger in size than the diameter of the device ensures secure positioning in the mouth of PDA). The PDA is closed by the induction of thrombosis, which is accomplished by polyester fibres sewn securely into the device. Platinum marker bands are applied to the wire ends and laser welded. The shape is then formed by heat treatment. All devices are cone-shaped and 7 mm in length, with a recessed screw, sizes are given from the larger to the smaller diameter. The delivery system consists of a delivery cable, long Mullins-type sheath, loader and pin vise.

Fig. 1 : Amplatzer septal occluder

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Fig. 2 : ASD sizing balloon

Fig. 3 : Amplatzer duct occluder

2. Study Protocol

ASD Closure

From March 2001 to Dec 2001, eleven patients underwent transcatheter closure of ASD by the Amplatzer device. 13 patients were screened by transthoracic two dimensional Doppler echocardiography with multiple subxyphoid and precordial windows. Adult patients with poor transthoracic echocardiographic windows were further evaluated with biplane transesophageal echocardiography. Patient inclusion criteria were 1) the presence of an ostium secundum ASD, 2) left to right shunting across the ASD 3) a distance of >5 mm from the margins of the defect to the mitral and tricuspid valves, superior vena cava, right upper pulmonary vein and coronary sinus and 4) dilation of the right ventricle with evidence of right ventricular volume overload. All patients underwent balloon sizing to establish the stretched diameter of the ASD, which was then used to select the appropriate size of the occluding device. The device size was selected

Fig. 4 : Amplatzer septal occluder in situ

Fig. 5 : Amplatzer duct occluder in situ

to be 2 mm more than the measured stretched diameter. Two patients with a size >32 mm on balloon sizing were not taken up for device closure since the largest available size of the device was 32 mm.

PDA Closure

From March 2001 to Dec 2001, seven patients (6 females, 1 male) underwent transcatheter closure of PDA as an alternative to standard surgical ligation or the use of other devices. All patients had left atrial and ventricular volume overload documented by echocardiography.

3. Procedure

ASD

After percutaneous puncture of the femoral vein, a 6F Courmand catheter was passed across the ASD and contrast medium was injected at the junction of the left atrium with the right upper pulmonary vein to delineate the anatomy of the ASD. Using an exchange 260 cm, J-tipped guidewire, a balloon catheter was introduced into the left atrium. The balloon catheter was inflated with various increments of contrast medium and pulled across the ASD under fluoroscopic and transesophageal echocardiographic

Table 1

Clinical and closure data for patients of ASD

Patient No/ Age (yrs)	Sex	Wt (Kg)	ASD diameter		Device size (mm)	Outcome	
			TTE/TEE (mm)	Stretched (mm)		Immediate	24 hrs
1/50	M	60	08	10	12	TS	TS
2/05	M	17	10	12	14	Closed	Closed
3/10	M	21	26	> 32		Not closed	Not closed
4/13	F	20	20	28	30	Closed	Closed
5/32	F	40	18	22	24	Closed	Closed
6/2½	F	10	14	20	22	Closed	Closed
7/26	F	40	28	33		Not closed	Not closed
8/09	F	18	20	22	26	Closed	Closed
9/36	F	56	26	30	32	Closed	Closed
10/25	F	43	12	16	18	Closed	Closed
11/53	M	65	24	30	32	Closed	Closed
12/53	F	56	20	24	26	Closed	Closed
13/27	F	40	22	26	28		Embolised to MPA

Table 2

Clinical and closure data for patients of PDA

Patient no./ Age	Sex	PDA diam (mm)	Device size (mm)	Sheath size	Results	
					Immediate	1 day
6 ½ months	F	06	10/8	7F	TS	Closed
2/06 yrs	F	05	8/6	6F	TS	Closed
3/15 yrs	F	05	8/6	6F	TS	Closed
4/25 yrs	F	07	10/8	7F	TS	Closed
5/15 yrs	F	08	10/8	7F	TS	Closed
6/08 yrs	M	06	10/8	7F	TS	Closed
7/02 yrs	F	03	6/4	6F	TS	Closed

TS - Trivial shunt, PA - Main pulmonary artery

observation. Formation of a waist of the sizing balloon was used to determine the stretched diameter. The sizing balloon was then removed, reinflated with the same amount of contrast medium and passed through calibrated openings in a sizing plate to determine the stretched diameter. The occluding device was selected to be 2 mm larger than the stretched diameter. The device size refers to the diameter of the connecting waist. The device was screwed to the tip of the delivery cable, immersed in normal saline and drawn into the loader. A 8F-10F (depending on the size of the device used), long guiding sheath and dilator were advanced over the guidewire through the communication into the left atrium. The correct position of the delivery sheath was verified by a test injection of contrast medium. The loader with the collapsed device was then advanced into the guiding catheter by pushing the delivery cable. Under fluoroscopic and echocardiographic guidance, the left atrial disc was deployed and pulled gently against the atrial septum, which was both felt and observed by transesophageal echocardiography. Using gentle tension on the delivery cable, the sheath was pulled back and the right atrial disc was deployed. To and fro motion of the delivery cable ensured a secure position across the ASD. This was also observed by two dimensional Doppler echocardiography and fluoroscopy. Biplane transesophageal colour Doppler echocardiography was performed in the two adult patients after device deployment to check for the presence of residual

shunt, possible obstruction to systemic or pulmonary venous return and impairment of the atrioventricular valves. Once its position was optimal, the device was released by counterclockwise rotation of the delivery cable. After release of the Amplatzer, both colour Doppler echocardiography and pulmonary angiography were performed to detect any residual shunt. Intravenous antibiotics (Cefotaxime 100 mg/kg body weight and Gentamycin 5mg/kg) were delivered immediately after placement of the prosthesis and repeated at 8 and 16 h, for a total of three doses. All patients were discharged on the day after the procedure with instructions to take aspirin 3 to 5 mg/kg daily for 6 months.

PDA

All patients underwent routine right and left heart catheterization using a 4F or 5F sheath in the femoral artery and a 6F sheath in the femoral vein. Heparin was used according to operator preferences. A biplane anteroposterior and lateral descending aortogram was performed to evaluate the size, position and shape of the ductus. A 5F or 6F multipurpose catheter was advanced from the venous side into the PDA and placed in the descending aorta. This catheter was exchanged for the delivery sheath (6/7F) over a 0.035 inch exchange guidewire and the dilator was removed, leaving the sheath in the descending aorta.

The delivery cable was passed through the loader and the proper size occlusion device (≥ 1 to 2 mm larger than

the narrowest size of the PDA) was screwed clockwise into the tip of the delivery cable. The device and the loader were immersed in saline solution as the ADO was pulled into the loader. The loader was introduced into the delivery sheath and without rotation the device was advanced into the descending aorta. The sheath was retracted until the retention disc was opened in the proximal descending aorta. The sheath with the delivery cable in it were pulled back as one unit until the retention disc was snug against the aortic end of the ampulla. While maintaining tension on the delivery cable, the introducing sheath was withdrawn into the pulmonary artery to deploy the tubular frame of the prosthesis into the PDA, similar in a way to deployment of a self-expandable stent. With the device still attached to the cable, a descending aortogram was performed in the lateral projection to confirm device position. If there was device malposition, the device could be retracted back inside the delivery sheath. Once proper device position was confirmed, the device was released by turning the cable counter-clockwise using the pin vise. A repeat descending aortogram was performed 10 minutes after the release to assess the degree of residual shunt.

Within 24 h, chest radiographs in the posteroanterior and lateral positions were obtained to assess device position, and each patient underwent a complete two-dimensional echocardiographic study and colour flow mapping and Doppler interrogation using commercially available machines. The same antibiotics were used as for patients with ASD and all patients were discharged on the day after the procedure.

Results

One ASD device embolised following deployment which was due to an inadequate anterior rim of the atrial septum. This patient was immediately heparinised and operated with successful removal of the device without a pulmonary arteriotomy and the ASD was closed by direct suture. Immediate TTE revealed no evidence of obstruction to the superior or inferior venae cavae, coronary sinus, right upper pulmonary vein. Neither retention disc was in contact with the mitral or tricuspid valve and no AV valve regurgitation was observed. After release of the prosthesis, angiography and colour Doppler echocardiography revealed no residual shunt in all except the first patient of ASD who had a trivial shunt (TS).

Patients with PDA had a transient shunt immediately after device release but this closed within 24 h of follow up in all seven cases. There was no evidence of obstruction of the left pulmonary artery or descending aorta confirmed by Doppler interrogation. Patient No. 2 had a failed coil embolisation to the PDA (migrated to the right pulmonary artery with no adverse effects) and later underwent Amplatzer device closure successfully. No patient had haemolysis or required blood transfusion and no femoral arterial or venous complications. All patients were discharged 2 days after the procedure and will be followed up at 6 months and 1 year after the procedure.

Discussion

Several reports of successful transcatheter closure of ASDs have appeared since the first report by King et al [2]. However, the procedure has not yet achieved widespread clinical use and is still investigational. Previous devices include the clamshell septal occluders [3,4], Sideris prosthesis (buttoned device) [5-7], the atrial septal defect occlusion system (ASDOS) [8,9], the Das Angel Wing [10,11] and the Pavenik monodisc [12]. All these were bulky devices, requiring larger sheaths for introduction which make their application difficult in small children. The Amplatzer ASD device with its novel self centering design, smaller size, simplicity of deployment, retrievability, and delivery through a small sheath overcomes the drawbacks of the previously used devices. It uses a short waist to stent the defect, forcing blood through a network of highly thrombogenic polyester material. The inward inclination of both retention discs allows firm contact with the atrial septum, enhances endothelialisation and reduces the risk of residual shunting. In our study, only one patient had trivial residual shunt and one patient could not undergo device closure due to the large size (32 mm) of the ASD and failure of the device to centre across the defect. The balloon sizing has proved most reliable in selecting the appropriate device size. Thanopoulos et al [14] reported residual shunting in 3 of their 16 patients using a device 1 mm less than the measured balloon stretched ASD diameter. One case of device embolisation has been reported by Losay et al [15] in a patient with deficient anterior rim out of their series of 44 cases.

The feasibility of nonsurgical closure of the PDA was demonstrated when Porstmann et al [16] in 1967 reported closing a PDA with an Ivalon plug in a 17 year old boy without thoracotomy. Subsequently, a number of devices and coils have been used for catheter closure of PDA with varying degrees of success [17-25]. The major drawbacks of these devices and coils are the high incidence of residual shunt, the sometimes complex delivery systems and their unsuitability for larger PDAs.

In this study, we report our initial human experience using a different new device to close large (>4mm) PDAs. We performed the closures from the venous side in all patients, using 6/7F delivery sheaths. The venous route has several advantages, including confirmation of PDA position before device release because the arterial catheter can be used for injection of contrast, avoidance of a large sheath in the femoral artery and the potential application of this technique to the very young infant who has PDA. Although we did not encounter all the angiographic types of PDA [26], we believe that such PDAs will be easily amenable to closure with this device. Further clinical testing is necessary to determine any

potential size and angiographic shape limitations of this device. Although most patients had a residual shunt at the end of the procedure, none had a detectable residual shunt by color flow mapping within 24 h of implantation, stressing the advantage of the plug type of design of the device for closing PDAs. Although procedures in children were performed under anaesthesia and patients were admitted to the hospital for one night, we believe that because of the small size sheath, the closure can be safely performed as an outpatient procedure under local anaesthesia and heavy sedation. All procedures in adults were performed under local anaesthesia.

To conclude, the ASD Amplatzer is an efficient prosthesis that can be safely used for closure of secundum ASDs. It is simple in construction, easy to deploy and can be withdrawn and repositioned, if required. Further studies are required to establish its value in a larger number of patients, for closure of larger ASDs. Long term follow up is required to exclude possible adverse side effects and future research is required to develop innovative methods to nonsurgically close defects with deficient septal rims.

The Amplatzer Ductal Occluder is safe and effective in closing PDAs in most patients with a large PDA. Small PDAs of 4mm diameter or less are being closed by transcatheter method at our centre using the 0.32 in Gianturco coils.

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