Percutaneous closure of Ostium Secundum Atrial Septal Defect using Amplatzer Occlusion Device

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La fermeture percutanée des communications inter-auriculaires par des prothèses d'amplatzer : Experience du service de cardiologie de l'hôpital Hedi Chaker Sfax

LA TUNISIE MEDICALE - 2013 ; Vol 91 (n°07) : 453-457

R É S U M É

But : Evaluer les résultats et la faisabilité de la technique de fermeture percutanée des communications inter-auriculaires diagnostiquées au service de cardiologie CHU Hédi Chaker SFAX.

Méthodes : Il s'agit d'une étude rétrospective descriptive, s'étalant sur une période de 5 ans (Octobre 2005 jusqu'à avril 2010) et qui a inclut 34 patients. La fermeture percutanée a été réalisée sous anesthésie générale à la salle de cathétérisme avec contrôle échographique (ETT+/-ETO). L'évaluation du résultat était réalisée dans les 24 heures suivant la procédure et quelques mois après.

Resultats : L'âge moyen des patients était de 27.5 ans avec une nette prédominance féminine (82%). Toutes les CIA étaient de type Ostium Secondum (OS) avec un diamètre moyen de 19.4 mm à l'échographie trans-thoracique ; 18.1 à l'échographie trans-oesophagienne et 23.4 à l'angiographie. La taille moyenne des prothèses était de 23.2mm [extrêmes : 10 à 34mm]. Le succès procédural était de 90.9% (30/33). Une patiente était exclue de la fermeture après avoir constaté un retour veineux anormal à l'angiographie. L'échec procédural était noté chez trois patients avec migration de la prothèse dans deux cas et persistance d'un large shunt résiduel dans un cas ce qui a nécessité le recours au traitement chirurgical. Le suivi ultérieur a montré l'absence de complications à moyen et à long termes avec maintien d'un bon résultat échographique attestant l'absence de shunt résiduel.

Conclusion : La technique de fermeture percutanée des CIA par amplatzer est efficace et à faible risque. Elle est désormais le traitement de référence des CIA ostium secondum.

M o t s - c l é s

Communication inter-auriculaire, amplatzer, fermeture percutanée

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Percutaneous closure of Ostium Secundum Atrial Septal Defect using Amplatzer Occlusion Device: Experience of cardiology department, Hedi Chaker Hospital, Sfax, Tunisia

LA TUNISIE MEDICALE - 2013 ; Vol 91 (n°07) : 453-457

S U M M A R Y

Aim: To report our clinical experience with transcatheter closure of ostium secundum atrial septal defects (OS ASDs) using Amplatzer septal occluder.

Methods: It's a retrospective study conducted between October 2005 and April 2010 and involving 34 patients. The procedures were conducted in the hemodynamic laboratory under general anesthesia with transthoracic (TTE) and transoesophageal echocardiographic (TEE) monitoring. Clinical and echocardiography assessments of the patients were conducted within 24 hours post procedure and several months after the procedure.

Results: From the 34 patients, 28 (82%) were females. The middle age was 27.5 years. The mean ASD diameter was 19.4 mm by TTE; 18.1 mm [12-38] by TEE, and 23.4 by angiography. The average size of the implanted devices was 23.2 mm ranging from 10 to 34 mm. The final success rate of the procedure was 90.9% (30/33). One patient was excluded from transcatheter occlusion and three patients (8,6%) had complications including two prosthesis migrations and one large residual shunting. A total of 4 patients (11,7%) underwent surgery. No major complication (thromboembolic events, obstruction of intracardiac structures, cardiac perforation, device embolization and endocarditis) or death has occurred during follow-up and all devices were securely anchored without any persistent residual shunts.

Conclusion: Compared to previous data of the literature, percutaneous closure of OS ASDs using Amplatzer device appears safe and effective according to our experience of the cardiology department of Hedi Chaker Hospital.

K e y - w o r d s

Atrial Septal Defect, Amplatzer, Percutaneous closure.

Atrial septal defect (ASD) is, after bicuspid aortic valve, the most common congenital heart diseases, occurring in 5 to 10% of children and in 30 to 40% of adult patients [1]. It also represents about 6 to 10% of all congenital heart defects [2]. Diagnosis has become easier with the contribution of echocardiography. Surgical closure has been considered for many years the gold standard treatment for patients with an ASD. But since 1976, when King and al [3] performed the first percutaneous (transcatheter) occlusion of an ASD in humans using a double umbrella device, a therapeutic revolution was born and raised a renewed interest. The septal closure using atrial septal occluder (ASO) and especially Amplatzer device has become the most common intervention [4]. Many studies have shown its simplicity and safety with a high success rate [5, 6].

This study describes our experience with transcatheter closure of ASDs using Amplatzer. Our aim was to evaluate the feasibility, efficacy and safety of transcatheter ASD closure using Amplatzer according to our experience of the cardiology department of Hedi Chaker Hospital.

PATIENTS AND METHODS

The study population consisted of a total of 34 consecutive patients with a definite diagnosis of secundum type ASD who underwent attempted percutaneous closure of OS ASD using Amplatzer device from October 2005 to April 2010 in the cardiology department of Hedi Chaker Hospital (Sfax-Tunisia).

1. Device system:

The Amplatzer device is a new self-centering septal occluder that consists of two self-expandable round disks made of Nitinol wire mesh that are linked together by a short connecting waist, corresponding to the thickness of the atrial septum. The left atrial disk extends 7 mm radially around the connecting waist and the right disk 5 mm. The left disk is slightly larger than the right because of the higher left atrial pressure. Both disks are angled slightly toward each other to ensure firm contact with the atrial septum [7].

The ASO employs the concept of closing the ASD by stenting the defect with its conjoint waist. The device is therefore truly self centering and achieves fixation and stability by stenting the defect. Extra stability is provided by the two atrial discs. The polyester inserts in the atrial disc and the conjoint waist facilitate closure by promoting thrombosis and subsequent neoendothelium formation. The device was designed to be easily retrievable until it is released from the delivery wire, thereby allowing removal in the event of malpositioning.

2. Selection of suitable patients for percutaneous closure:

The selection was based on the determination of morphological characteristics of the ASD. Before interventional therapy, all patients underwent TTE (± TEE) for determination of ASD number, size, position and spatial relations with adjacent cardiac structures (the margins of the defect to the mitral and tricuspid valves, the superior and inferior vena cava, the right upper pulmonary vein, the orifice of the coronary sinus and the aorta rim were whenever possible specified in order to define the spatial anatomy of the ASD); but also the measurement of the atrial and ventricular diameters, the total length of the atrial septum and estimation of pulmonary artery systolic pressure.

3. Implantation technique:

The ASD was sized with a sizing balloon catheter. The stretch diameter of the atrial septal defect was measured using a 24 or 34 millimeter sizing balloon [8]. The right upper pulmonary venous deployment technique was preferably used. The device and the adjacent structures were examined by TEE to ensure that there was no encroachment of the device on the atrio-ventricular valves or the right pulmonary vein. After releasing the device from the cable by unscrewing it, a final TEE examination was undertaken to demonstrate the position of the device and any residual shunting. The procedures were performed under general anesthesia in all patients and under ultrasound guidance (TTE ± TEE) [9]. Heparin was administered in all patients. Intravenous antibiotics prophylaxis was delivered just before the procedure and repeated at 8 and 16 h, for a total of three doses.

4. Follow-up:

All patients were discharged on aspirin 5mg/kg per day for 6 months. Acenocoumarol (Sintrom) was added in patients with history of atrial fibrillation. Before discharge, an electrocardiogram, a biplane chest X-Ray, an echocardiogram was performed. After successful ASD closure the patients remained in the hospital for one night. They were discharged on the day after the procedure with regular follow-up in our consultations.

RESULTS

1. Patients' characteristics:

The basic characteristics of the patients are outlined in Table 1.

Table 1: Baseline characteristics of patients

Characteristics	Number	Percentage
Sex (F/M)	28/6	82/18
Average age (years)	27.5	-
Cardiac symptoms	16	47
Dyspnea	9	26.4
Chest pain	2	5.8
Palpitations	3	8.8
Others	2	5.8
Atrial fibrillation	1	2.9
Right heart failure	1	2.9
Cardiomegaly	19	55.8
Total of patients	34	-

The average patient age was 27.5 years (range 4-66 years). There were 28 women (82%) and 6 men (18%) (sex ratio=¼). Overall, 16 patients in the study population (47%) reported

cardiac symptoms at presentation, but the chance discovery after auscultation of a systolic murmur during a routine examination was the common cause of revelation (18 patients; 54.3%). Physical examination showed signs of right heart failure in only one patient with an hydrops related to the combination of a wide OS ASD, a ductus arteriosus and a severe valvar pulmonary stenosis. The maintenance of sinus rhythm was observed in 33 patients (97%) and atrial fibrillation was noted in only 1 patient. The chest radiography showed cardiomegaly in 19 patients (55%).

The echocardiographic characteristics are summarized in Table 2. Patients were screened by transthoracic two-dimensional Doppler echocardiography. A number of parasternal, apical and subcostal cross sectional views were imaged for different measurements. Eleven patients (32.3%) with poor transthoracic echocardiographic windows were further evaluated with biplane trans esophageal echocardiography. All the patients (34) had ostium secundum defect and met echocardiographic criteria for trans catheter closure with the Amplatzer device but only 33 patients (97%) had ASD with a suitable septal rim (of at least 5-7 mm from adjacent cardiac structures) and 2 patients (5.8%) had no sufficient rims at the ascending aorta side.

Table 2: Echocardiographic characteristics

Characteristics	Average	Extreme
ASD size (mm)		
TTE	19.4	10-34
TEE	18.1	12-38
Septal length (mm)	33.8	22-55
Septal rims (mm)		
Ascending aorta	9	2-12
Mitral and tricuspid valves	14.6	8-19
Superior vena cava	12.6	12-14
Right upper pulmonary vein	11.5	5-16
	Number	**Percentage**
Aneurysm of inter atrial septum	0	0
Congenital heart disease associated	6	17.6
Pulmonary stenosis	5	14.7
Ductus arteriosus	1	2.9
Ebstein's anomaly	1	2.9
Total of patients	**34**	**-**

The study patients had predominant left-to-right interatrial shunt. The dilation of the right ventricle with evidence of right ventricular volume overload was noted in all cases. Mild pulmonary arterial hypertension was found in 20 cases (57.1%). A good correlation was found between transthoracic and trans esophageal echocardiographic measurements of the atrial septal defect diameters. The mean ASD diameter determined by TTE was 19.4 mm (range 10 to 34) and by TEE was 18.1 mm (range 12 to 38). Echocardiography revealed the association with other congenital heart disease in 6 patients.

There were 5 patients with combined pulmonary stenosis including one with a ductus arteriosus, one patient had Ebstein's anomaly.

2. Procedural characteristics:

Table 3 demonstrates the closure results and complications at procedure. The procedures were performed under general anesthesia in 34 patients. TTE was applied to guide ASO positioning and assess residual shunt, the use of a complement by TEE was necessary in 25 patients (71.4%). The balloon stretched diameter was 23.4 mm (range 10-34 mm). The mean device size placed was 23.2 mm (range 10-34 mm). The difference between the diameter of ASO and that of ASD (ASO-ASD) was 3.8 mm. Thirty-one (91.1%) of 34 consecutive patients were treated successfully, as documented by color Doppler flow imaging, with a single Amplatzer Septal Occluder. One patient was excluded from transcatheter occlusion after the initial angiography when we discovered an anomalous pulmonary venous drainage. Two failures to implant occurred early during the procedure: migration of ASO into the left atrium then left ventricle occurred in one patient and the other had various ASD with large residual shunting after ASO deployment and which were located in an extremely superior and posterior position with no sufficient rims at the superior vena cava side. Thus the use of surgical repair was necessary for these three situations.

Table 3: Primary closure results and complications at procedure

Characteristics	Number	Percentage
Balloon stretched diameter (mm)	23.4	Range 10-34
Device size (mm)	23.2	Range 10-34
Primary success	31	88.6%
Excluded procedures	1	2.9%
Failed procedures	2	6%
Total of patients	34	-

3. Immediate and medium term outcome:

No major complication (thromboembolic events, obstruction of intracardiac structures, cardiac perforation leading to tamponade, device embolization and endocarditis) or death has occurred during the hospital phase. There was one complication of secondary prosthesis migration into the left ventricle outflow occurring in one patient with a 22 mm device that appeared to be stable at the time of implantation. The device was immediately retrieved at surgery and the ASD closed at the same time without any further complication. Color-flow Doppler performed in the follow-up after the procedure showed complete closure in all patients. After discharge from the hospital, treated patients were followed for 38 ±14 months (range 6-60 months). During this period, no further complications occurred and 32 patients (94%) performed TTE to demonstrate the maintenance of a good result without residual shunting.

DISCUSSION

Several reports of successful transcatheter closure of secundum ASDs have come into sight in literature in the past 20 years. However this procedure still has not achieved widespread use. A large variety of devices (at least 6) have been developed to occlude ASDs. Most of these devices have either been withdrawn or are under clinical investigation [4, 10-12]. The results with the newest of the devices, the Amplatzer, described in Thanopoulos and al [13] are encouraging and it seems to overcome many of the disadvantages of previously used devices.

The transcatheter closure of ASD using Amplatzer septal occluder has become the procedure of reference given its simplicity, its safety and high success rate regardless of age. In 34 consecutive patients recruited in our study, the final success rate for ASO deployment and ASD closure was 88.2% (30/34). One patient was excluded from transcatheter occlusion and two patients (5.8%) had their ASO migrated into either the left ventricular outflow tract, and one patient (2.9%) had various ASD with large residual shunting after ASO deployment. Thus, a total of 4 patients (11.7%) underwent surgery. The success rate and complications of transcatheter ASD closure found in this study were comparable to previous reports using TTE and TEE to guide transcatheter ASD closure [14-16]. The complications reported in the literature are possible but rare. They were quite early in most studies [10, 17], exceptionally, coming so late [10, 18].

Another finding of the present study was that with multiple parasternal, apical and subcostal views, TTE offers a reliable technique for determination of the echocardiographic characteristics of the ASD, selection of optimal ASO size, guidance of ASO positioning and deployment and evaluation of residual shunts. Indeed, the ASD size, position, number and spatial relations with adjacent cardiac structures are the key factors for deciding whether an ASD can be occluded through a catheter. The method used for evaluating whether an ASD is suitable for interventional therapy should be convenient and accurate. The generally used imaging techniques include TTE and TEE, which are able to provide 2-D images and color flow mapping of an ASD. The major problem with TEE, however, is that general anesthesia is required [19]. From our group of 34 patients, who were brought to the catheterization laboratory for interventional ASD closure, 33 (97%) were suitable for placement of the device. Echocardiography revealed also the association with other congenital heart disease in 6 patients (17.6%) and specific treatment was proposed for each cases. With previous devices, the maximum defect size for non-surgical atrial septal defect closure was limited to a stretched diameter of 20 mm, according to the respective study protocols, and this measurement was exceeded only occasionally [20, 21]. This limitation is due to the severely oversized patches for non self-centering systems. In contrast, the Amplatzer Septal Occluder allows closure of defects up to 26 mm and in our study group devices larger than 20 mm were used on 22 occasions (64.7%) and the largest ASD closed was 34 mm, which was 34 mm with balloon sizing, and the smallest rim was 5 mm.

In our study, the Amplatzer was systematically used for ASD closure. The high success rate of this device, which is also reported by other investigators [5, 9, 22] is due to its functional design; the self-centering mechanism stenting the potential ASD, forcing blood through a highly thrombogenic Dacron network, a simple application procedure and ability to recapture before and after release.

Thus, patients can benefit from the advantages of percutaneous occlusion over surgical closure, as shown by some studies [23-26]: including the avoidance of complications related to cardioplegia and cardiopulmonary bypass and its potential adverse sequelae, decreased need for blood transfusion, a lower incidence of postoperative complications, a shorter hospital stay, less discomfort with superior cosmetic results and more cost-effective.

There are some limitations in our study. First, it's a retrospective cohort study explaining some of the gaps expected in terms of data collection. Second, this study involved only one medical center with a relative small number of patients; a randomized Tunisian multicenter study involving a larger population with ASD is clearly needed. Finally, longer term results are necessary to determine the long term safety of percutaneous closure of ASD in these patients. Indeed, development of aortic regurgitation is an important concern in the long term. Schoen et al [27] reported on the long term follow up of 240 consecutive patients. Newly developed or increasing aortic regurgitation was observed in 9% of patients with atrial septal defect and 10% of patients with persistent foramen ovale closure.

CONCLUSION

Compared to previous reports of the literature, percutaneous closure of ostium secundum atrial septal defects using Amplatzer device has a high success rate and a low complication incidence and thus appears safe and effective according to our experience of the cardiology department of Hedi Chaker Hospital. Experience with larger groups of patients and longer follow-up are needed. Future research should focus on innovative methods to non-surgically close large defects with deficient septal rims.

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