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ARTICLE

Safety and Efficacy of Transcatheter Closure of Atrial Septal Defects in Everyday Practice: A Multicenter Study in a Developing Country

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ABSTRACT

Background: Transcatheter closure of secudum atrial septal defect (ASD) has gained wide acceptance since its introduction more than 3 decades ago. Safety and efficacy of the procedure in everyday practice needs continuous update. **Objective:** The aim of the study is to determine the incidence of complications and identify everyday management protocols. **Methods:** This is a prospective nonrandomized study including all the patients with Secundum ASD or fenestrated IAS referred to two different congenital heart diseases centers in Ain Shams university and sohag university in Egypt over 2 years with an indication for closure according to American and European guidelines. A custom-made sheet was made to include all relevant demographic and procedural data as well as any intra or periprocedural complications. **Results:** This study evaluated 330 patients over a period of 2 years. Most of the patients were in pediatric age group where the mean age was 12 +/– 13 years, mean weight of 40 +/– 15 kg, the mean device diameter used was 20 +/– 7.7 mm. The procedure was successful in 326, four patients required 2 simultaneous devices, and another three adult patients underwent simultaneous percutaneous coronary intervention (PCI). There were 26/330 (7.7%) complications, only one was life threating complication (0.3%); a LA appendage perforation which was managed surgically. The remaining complications were either major or minor, the most common was arrhythmia in 7 patients (2.3%), followed by device embolization in 5 patients (1.5%) all of them were retrieved percutaneously except one which was removed surgically. Four patients (1.2%) developed thrombus either on the right atrial side or LA side or both, managed successfully by anticoagulation, similarly another four patients (1.2%) had pericardial effusion +/– hemopericardium, one of which was due to erosion of the left atrial roof while none of our patients had residual shunts. Two patients had anesthesia related complications, one patient developed nickel allergy and one patient had vascular complication. **Conclusion:** Although transcatheter ASD closure is a safe and effective procedure, but a wide range of complications should be anticipated and managed properly. In high volume centers with proper patient selection, complications could be significantly reduced but not completely abolished.

KEYWORDS

ASD transcatheter closure; complications; safety and efficacy

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1 Introduction

Percutaneous ASD closure has gained wide acceptance over surgical option for both patients and parents [1]. As the procedure is minimally invasive with less hospital stay, it has been increasingly introduced over the last three decades. Starting from simple defects with adequate rims up to defects with more complex anatomy and relatively deficient rims [2]. Two defects are amenable for closure, firstly the Secundum ASD which is the most common type of ASD and the PFO which accounts for 20% of the population however only 2% with interatrial septal aneurysm who develops paradoxical embolization are indicated for closure [3]. Lately there are innovative techniques for sinus Venosus ASD transcatheter closure.

Nowadays as most of the Secundum ASD (85 to 90%) are percutaneously closed, the safety and efficacy of the procedure is of utmost importance in the structural and congenital heart disease centers [4]. Although many different devices and techniques for percutaneous ASD closure are used, reporting the outcome data, complications and long term follow up for those patients is mandatory to ensure continuous safety and efficacy of the procedure [5].

The Aim of our study is to determine the incidence of complications and identify everyday management protocols.

2 Methods

The current study was approved by the relevant institutional review board of each center and informed consent was obtained from the enrolled patients or their guardians.

This is a prospective nonrandomized study done in Ain Shams university hospitals in conjunction with Sohag university hospital, both are tertiary referral centers with well-established congenital and structural heart disease service.

The inclusion criteria included all the patients either children or adults with Secundum ASD or fenestrated IAS amenable for transcatheter closure and have an indication for transcatheter closure according to American and European guidelines over a period of two years were included.

While exclusion criteria included those with large secundum ASD stretched diameter >38 mm and deficient any of the following rims (SVC rim, IVC rim, Av valve rim, posterior rim) except for the aortic rims (A rim less than 5 mm when assessed by transesophageal echocardiography was considered deficient), we also excluded patients with small non hemodynamically significant Secundum ASD (normal RV dimensions, shunt fraction <1.5), with no history of pervious paradoxical embolization.

A custom made sheet was made to include all relevant demographic data which included age at first presentation, age on the day of procedure, body weight, height, ASD size by intraprocedural TEE, ASD device size, intraprocedural method to confirm the size of defects (TEE or balloon sizing), Qp/Qs, pulmonary artery pressure (measured by right heart catheterization), fluoroscopy time, and procedural time. Success of implantation was defined as the device being properly placed and deployed without malposition or embolization in the catheterization lab. Following the procedure, all major events were recorded to gather information about in-hospital complications. These included anesthesia related complications, device related complications as device embolization, thrombus formation, and nickel allergy. Procedure related complications as cardiac tamponade, cardiac arrhythmia, hypotension, bleeding and vascular complications. Complications has also been classified into life threating and non-life-threatening complications.

All patients were subjected to proper history taking, physical examination, chest radiography (CXR), electrocardiograms (ECG), echocardiography before the procedure and Transesophageal echocardiography intraprocedural (TEE). Standard transthoracic echocardiographic studies were used to assess ASD morphology, right ventricular systolic pressure (RVSP), and cardiac function to determine the feasibility for transcatheter-based ASD closure. After being informed and giving their consent, patients were scheduled for

transcatheter closure of ASD under general anesthesia. Right heart catheterization was performed for all cases to measure pulmonary pressure. Unfractionated heparin (100 unit/kg) and antibiotics were administered intravenously to all patients after establishing femoral access and prior to the procedure.

The procedure was performed under general anesthesia and TEE guidance, assessment of adequacy of all rims except for the aortic rim was carried on all patients, in some patients with IAS aneurysm or floppy rims or mal-aligned septum balloon sizing as a s top flow technique was used to measure the stretch diameter of the ASD. The ASD device was delivered by an appropriate delivery system and deployed after confirming a satisfactory device position by TEE. The size of device was determined to have 2 increments more than size of the defect or equal to the stretched diameter in case of balloon sizing.

Following the procedure, patients routinely received six-months of aspirin therapy. All had repeated physical examinations, ECG, and CXR, to determine echocardiographic parameters at 24 hours. A residual shunt was considered if the color Doppler echocardiography revealed left to right shunt across the interatrial septum. Patients, who attended the interventional clinic, were evaluated with physical examinations and echocardiography at: one month, three months, six months, and one year after discharge, and at regular intervals thereafter, according to guidelines.

The outcomes of interest for the study included acute complications at the time of the procedure, and during follow up at one month, 3 months, 6 months and one year after discharge.

3 Results

3.1 Demographic Data

This study evaluated 330 patients,305 patients with secundum ASD and 25 patients with fenestrated IAS +/– aneurysm formation with mean age of 12 +/– 13 years with age range from (4–45 years), mean weight of 40 +/– 15 kg, mean shunt fraction of 1.8 +/– 0.2, pulmonary artery systolic pressure 38.6 +/– 10.5, mean pulmonary artery pressure 17.8 +/– 5.6 mmHg, mean procedural time 49 min +/– 12 min (Tab. 1).

Table 1: Demographic data

Age	Mean = 12.6 +/– 13.6 years (4–45 years)
Gender	Males: n = 146 (44.4%); Females: n = 184 (55.6%)
Weight	Mean = 40.5 +/– 15.4 kg
Pulmonary artery systolic pressure	Mean = 38.6 +/– 10.5 mmHg
Mean pulmonary artery pressure	Mean = 17.8 +/– 5.2 mmHg
QP: Qs	Mean = 1.8 +/– 0.2
Procedural time	Mean = 49 +/– 12.1 min
Fluoro time	Mean = 14.6 +/– 9.3 min
ASD diameter	Mean = 22.1+/– 7.3 mm
Device size	Mean = 26.2 +/– 7.5mm
Device/ASD diameter ratio	Mean = 1.31 +/– 0.3
ASD sizing balloons	n = 61 (18.5%)
Device type	Amplatzer: n = 192 (58%); others: n = 138 (42%)
Complications	n = 26 (7.7%)

The ASD diameter as assessed by TEE in all patients was 22.1 +/– 7.3 mm, device size 26.2 +/– 7.5 mm, device/ASD diameter ratio 1.31 +/– 0.3. Several types of devices were used for percutaneous closure, the most common device used was ASD Amplatzer device (58% of the cases), followed by Occlutech, Hyperion, the least common device was Cocoon, in addition to 7.6% who had a cribriform ASD device for fenestrated IAS, we used ASD sizing balloon in 18.5% of the patients, 95% of them had defects more than 25 mm. (Tab. 1).

3.2 Procedural Success and Complication Rate

The procedure was successful in 326 patients, 4 patients required two simultaneous devices, another 3 patients were ischemic and had simultaneous PCI with heparin dose adjusted according to activated clotting time (ACT), with their age range from 40–45 years, actually they were complaining of anginal symptoms and ASD was discovered accidently.

The overall complication rate was 7.8%, (26 out of 330 patients), we had only one patient (0.3%) with life threating complication which was left atrial appendage perforation while using the sizing balloon leading to acute left atrial collapse which was managed surgically on time.

The most common complication was arrhythmia which occurred in 7/330 (2.3%) of cases, five patients developed transient 2nd degree heart block and 1 patient developed Atrial fibrillation and 1 patient developed supraventricular tachycardia. Device embolization occurred in 5 patients either immediately after the release, up to 6 days post procedural, the device was successfully retrieved percutaneously in four patients and only one patient had to remove it surgically, most of those patients had absent aortic rim and relatively small posterosuperior rim. We had 4 patients who developed either pericardial effusion or hemopericardium, all where managed conservatively, only one case had repeated accumulation of effusion and the device was removed surgically, also this patient had absent aortic rim and relatively small posterosuperior rim, however more than 5 mm. Four patients (1.2%) developed thrombus formation immediately after device deployment despite full heparinization, one on the LA side and two on the RA side managed successfully by anticoagulation. We had one reported case of nickel allergy, one reported case of vascular complication and two patient had anesthesia related complication. To sum up we had 14 patients with procedure related complications, 2 patients with anesthesia related complications, 11 patients with device related complications (Tab. 2).

Table 2: Incidence and types of complications

Category	Complication	N	Percentage	Total
Anesthesia related complications	Vocal cord hempotysis	1	0.3%	0.6%
	Pneumothorax	1	0.3%	
Procedure related complications	Arrhythmia	7	2.3%	4.0%
	Pericardial effusion + hemopericarduim	4	1.2%	
	LAA perforation with LA collapse	1	0.3%	
	Vascular complications	1	0.3%	
Device related complication	Device embolization	5	1.5%	3.2%
	Thrombus on device	4	1.2%	
	Nickel Allergy	1	0.3%	
	COBRA formation	1	0.3%	
Total		26	7.8%	7.8%

4 Discussion

Although successful, trans-catheter ASD closure is not complication free. Complications can occur during the procedure, during immediate follow-up and in the long term. The overall complication rate in our multicenter study was 7.7% when compared to the overall complication rate in literature which was 8% carried in experienced centers in Europe [6].

Complications has many classifications in literature, however, we classified it into minor and major complications. Major complication can be further divided into life threating and non-life threating complication [7].

In our series we had 330 patients, more than half of them (58%) received ASD Amplatzer device, 7.6% of the cases received the ASD cribriform device, 18.5% of the cases underwent balloon sizing, major complications were reported in 2.3% (7 cases) and minor complications 5.4% (19 cases) compared to the globally reported rates of major complications 1–3% and minor complications 5–6% in the developed countries [8]. Despite Comparison of complication rates is difficult since literature reports deal with different devices, indications, age groups, length of follow up, focus and definition of complications, however our reported rates are close to those experienced centers in Europe which depends on the experience of the operators, optimum selection of the patients and the ability to manage the complications.

In comparison to our study Chessa et al. [9] have reported 417 patients who had catheter closure of secundum ASDs in which 258 Amplatzer septal occluder devices were used, Overall, there were 36/417 (8.65%) complications, of which 11 were major and 25 minors in an Italian study. In another large study, Fisher et al. [10] included 236 patients considered for closure with the Amplatzer septal occluder, of these, 200 had successful transcatheter closure and two had a serious procedural related complication consequently there was no statistically significant difference between the incidence of complications post transcatheter ASD closure between developing and developed countries.

4.1 Anesthesia Related Complication

We had two cases of anesthesia related complications. One complication with limited pneumothorax due to tube insertion and another rare complication which was minimal hemoptysis due to vocal cord injury due to tube insertion. Most centers around the world perform this procedure under general anesthesia which adds the risks of general anesthesia to the procedure. So, A balanced anesthetic technique with short-acting drugs is indicated; direct arterial pressure monitoring is reserved only for high-risk cases. Muscle relaxation and endotracheal intubation is required and maintenance can be via an inhalation technique or total intravenous Anesthesia [11].

4.2 Procedure Related Complications

In our study procedure related complications accounted for 14 cases, the most common complication was arrythmia 7 cases (2.3%), five patients had transient second degree heart block immediately after the procedure which resolved spontaneously from 12 up to 72 hours after the procedure, in some cases we had to give oral steroids, another patient had atrial fibrillation which was terminated by cardioversion, another patient developed supraventricular tachycardia during catheter closure, however terminated by IV beta blockers, while Chessa and her collogues reported the second most complication was arrhythmia, which occurred in 11/417 (2.6%) of cases. In six of these 11, atrial fibrillation required electrical cardioversion [9]. Monika et al reported that SVT occurred in 8/235 patients, 3/235 patients had atrial fibrillation which were all managed by anti-arrhythmic drugs or DC for cardioversion [12]. So arrythmia is a minor complication which occur immediately or shortly after the procedure and can be managed safely by antiarrhythmic drugs.

In our series four patients developed pericardial effusion, one was immediately during the procedure which happened after the delivery sheath was across IAS it slipped and was pushed accidentally into the coronary sinus mostly causing a minimal tear in the coronary sinus the patient developed minimal pericardial effusion which resolved spontaneously after one week. Another case developed a pericardial effusion one-month post procedure with suspected erosion of the left atrial roof as the patient had a relatively small posterosuperior rim, a deficient aortic rim and the effusion was only 5 mm posterior to LA. So, we decided to manage patient conservatively and is being followed up. Another patient with repeated accumulation of pericardial effusion yet the patient was hemodynamically stable, however the device was surgically removed. In a large study carried out on 1000 patients all over the united states, the incidence of device erosion was 0.1%, All erosions occurred at the dome of the atria, near the aortic root. Deficient aortic rim was seen in 89% and the defect described as high ASD, suggesting deficient superior rim and the device to unstretched ASD ratio was significantly larger [13], so in case of deficient aortic rim and relatively deficient superior rim if the device ratio to both stretched or unstretched ASD diameter is significantly larger procedure should be aborted and surgical option is recommended.

We reported a rare procedural complication of LAA perforation as we advanced the sizing balloon deeply in the LA, it accidently entered the LAA causing a hemodynamically significant tear with acute LA collapse, so immediately pericardiocentesis was done with autotransfusion, heparin was reversed by protamine and the patient was stabilized then transferred to the surgical operating room. In literature, a multicenter institutional study from the European congenital heart surgeon association in the surgical management of complications resulting from trans-catheter closure of ASD, they reported 9 cases of atrial or aortic perforation which was managed surgically [14]. However, this is a life threating complication and should be avoided by cautious and gentle manipulation of the delivery sheath, sizing balloon, and the device itself with meticulous TEE guidance.

We reported only one case of vascular access complication in an obese patient with massive bleeding from the puncture site after sheath removal with formation of small hematoma, managed conservatively. In comparison to Fischer et al. [10] who reported one case out of 200 patients who developed retro peroneal hematoma which was managed surgically. Another study carried on 124 patients who had ASD transcatheter closure 2 patients with vascular access complications in the form of right iliac vein dissection, and retroperitoneal hematoma, were managed surgically [15]. vascular complications too should be avoided by cautious femoral puncture without trans-fixation and minimal manipulations, in obese patients it should be done using ultrasound guidance.

4.3 Device Related Complications

In our study we had five cases (1.5%) of device embolization either immediately after or on the next day during the routine echocardiography follow up, the device embolized to different sites either into the aortic arch, left atrium (LA), right ventricle (RV), pulmonary artery (PA) and one case into the left ventricle (LV), eventually in those patients we should have used a larger device 2 increments than the one chosen as most of them had a relatively smaller and floppy posterosuperior rim or we should have used balloon sizing (stop flow) technique. In four cases the device was retrieved successfully percutaneously and in only one case in which the device embolized into the LV was removed surgically with ASD closure and MV repair. Chessa et al. [9] reported that the most common complication was device embolization/malposition occurring in 3.5% of cases. Of the 15 patients in whom devices embolized or were malposition, 10 required surgical retrieval while in the remainder the devices were retrieved by catheter techniques. Device embolization may occur in up to 1% of cases [5]. The commonest reasons for occluder dislodgement are the use of an undersized ASD device, greater defect size, left atrium too small to accommodate the device, an inadequate or floppy rim, device mobility post-implantation, and operator-related technical issues [16]. Most of dislodgement occurs within 24 hours post implantation and takes

place into left atrium (24.6%), aorta (18.4%), and right ventricle (16.7%) [17,18]. Most of the devices can be retrieved percutaneously after early embolization. In such cases the defect is re-evaluated and, if a misevaluation or misplacement of the device occurred during the first procedure, a correct second procedure may end up in success [19]. On the other hand, late embolization usually requires surgical treatment because of epithelization [20].

We had 4 cases (1.2%) who developed thrombus formation immediately and two weeks later after device deployment despite full heparinization, one on the LA side which was discovered two weeks later and actually this patient was discovered to have a prethrombotic disorder and three patients developed a small thrombus on the RA side immediately after the procedure , these patients were managed successfully by anticoagulation in the form of heparin infusion and warfarin and were followed up meticulously by TEE two weeks and four weeks until the thrombus resolved. Another observational study by Krumsdorf et al. [21] reported thrombus formation in 5 out of 407 ASD patients (1.2%), and in 15 out of the 593 (2.5%) PFO patients, 11 in the LA, 6 in RA and 3 in both. In 17 of the 20 patients, the thrombus resolved under anticoagulation therapy with heparin or warfarin. In three patients, the thrombus was removed surgically. Thrombus formation on the LA side is a major complication and should be avoided as it may lead to cerebrovascular accidents, so proper intraprocedural anticoagulation is recommended by giving Unfractionated heparin according to body weight and if the procedure took more than 60 minutes, activated clotting time (ACT) was measured and kept to a level of 200–300 seconds. In cases where the ACT is less than 200 seconds, another injection of 25–50 unit/kg/dose of unfractionated heparin was allowed.

We had only one female patient who had documented Nickel Allergy in the follow up proved by both patch test and Fin test, she started to complain of chest pain and left inframammary tenderness one week later till 3 months after device implantation. Medically significant Nickel allergy following ASD closure with an Amplatzer device is a rare phenomenon with few cases reported in the literature [22]. According to a survey of member of the Congenital Cardiovascular Interventional Study Consortium (CCISC), nickel allergy incidence was 2.1% after closure of congenital heart defects with nitinol-containing devices [23], similarly Roland et al reported a case of a Caucasian female with no known Nickel allergy who developed chest tightness, dyspnea and malaise immediately following percutaneous implantation of ASD Amplatzer device. She did however experience complete resolution of her symptoms with dual antiplatelet therapy (Aspirin and Clopidogrel). This case proposes a possible medically feasible therapeutic option in the form of dual antiplatelet and steroid therapy for the management of hemodynamically stable patients who develop a Nickel allergy following placement of an Amplatzer device [24], So Nickel allergy is rare but unavoidable complication , however could be managed safely in most of the cases using dual antiplatelet and steroids.

We had one case of Cobra head deformity of the device due to repeated deployment of the ASD device as it prolapsed several times in a patient with absent aortic rim and deficient posterosuperior rim. Cobra head configuration of the Amplatzer Septal Occluder (ASO) is a benign but potentially avoidable phenomenon, occurring in approximately 3% of implantations. The mechanism of deformation is thought to occur due to device rotation and twisting of the ASO nitinol wires either in the delivery catheter or following interaction with adjacent heart structures e.g., left atrial wall after delivery [25]. Three reported cobra head cases deformity in literature were due to larger than recommended delivery sheath sizes [26] so proper selection of sheath size according to the device size is mandatory.

5 Limitations and Recommendations

Long term follow-up for the patients included in the study is recommended.

6 Conclusion

Although transcatheter ASD closure is a safe and effective procedure, but a wide range of complications should be anticipated and managed properly. In high volume centers complications could be significantly reduced but not completely abolished by careful case selection, sizing of the defect, selection of the correct size of device, aseptic technique, periprocedural heparinization, testing of device stability during the procedure, meticulous attention to antiplatelet treatment, and antibiotic prophylaxis. Life threating complication occurs rarely, however the most common non-life threating complication was arrythmia, followed by device embolization.

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