

## Short and Mid-Term Outcome of Percutaneous Atrial Septal Defect Closure in Adults

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Received: 05<sup>th</sup> May 2018, Accepted: 11<sup>th</sup> May 2018, Published: 31<sup>st</sup> August 2018

### Abstract

**Introduction:** Percutaneous closure is considered to be the first treatment approach for a vast majority of secundum atrial septal defect (ASD) patients. Despite the frequent usage of closure devices for these treatments, there is a little level of evidences about their outcomes. The aim of our study was to determine the short and mid-term treatment outcome of patients undergoing percutaneous ASD closure with devices.

**Method:** This cross-sectional study was conducted on patients with secondary ASD admitted to the Department of Cardiac Surgery of Shahid Madani Hospital in Tabriz, Iran during 2011 to 2014. All surgeries were performed without general anesthesia with the guidance of fluoroscopy and transthoracic echocardiography (TEE). Eight French (Fr) venous access was obtained and Initial right heart catheterization was done. A sizing balloon catheter was used for measuring the diameter of the defect, and closure device was loaded using the standard and venous sheath. Follow up at 24 hours and 6 months after surgery was completed with physical examination and TEE.

**Results:** Eighty-seven patients (33 male/ 54 female) with a mean age of  $39.1 \pm 15.4$  years (range 22-71 years) were studied. Device closure was done successfully in most of the patients (98.8%). One patient (1.1%) needed surgical intervention because of embolization of device. At 6 month follow up, complete closure was documented in 98.3%, of ASD patients and in 88.7% of patients with PFO.

**Conclusion:** It seems that percutaneous closure of secundum ASD with devices is an optimal approach for treatment of adults with a very low incidence of complications.

**Keywords:** Percutaneous Closure, Atrial Septal Defect, Patent Foramen Ovale, Device, Cardiac Intervention.

### Introduction

The ostium secundum atrial septal defect (ASD) is the most common form of ASD that increases the volume

overload of right ventricle and pulmonary arteries, resulting in dilatation in long run and finally the right ventricular failure and increased pulmonary arterial pressure (1-3). The treatment of ASD is open heart surgery in large defects and the use of septal occlude devices such as Amplatzer in relatively small defects (less than 13 mm) (4, 5). Angiography via femoral artery is employed to implement it (5).

A meta-analysis of 28,142 patients across 203 studies concluded that short- and long-term septal occlude device-related mortality rates are low, at 0.01% and 0.1% respectively (6). Although the preliminary research findings of studies that have evaluated these devices were promising, their increased use has been associated with some major complications including atrial arrhythmias, cardiac erosion, conduction abnormalities, device endocarditis, nickel allergy, thromboembolic events, and valvular damage (6-9). As ASD closure is frequently performed, there is a requirement to identify the device-related complications that may have a direct impact on mortality to assist physicians to make informed decisions as to the most appropriate methods by which to treat patients; for example, choosing surgery as opposed to percutaneous intervention and selecting which devices to use (10-12). Research of this nature will also address the lack of data that is currently available relating to the adult patient population (13). The aim of the present study was to evaluate the findings, short-term and mid-term complications in the patients with the secondary atrial septal defect following the closure with cardiac catheterization.

### Material and Methods

#### 1. Study Setting

This cross-sectional study was conducted on patients with secondary atrial septal defects treated with catheterization technique admitted to the Department of Cardiac Surgery of Shahdi Madani Hospital in Tabriz, Iran during 2011 to 2014.

#### 2. Participants

All the patients were assessed by transthoracic (TTE) and transesophageal (TEE) echocardiography before the procedure. Echocardiographic assessment of the

size and morphology of the ASD or PFO and the correct positioning of the device was performed using a multiplane TEE probe. A diameter of less than 36 mm with the rims of the septum facing toward the mitral valve, coronary sinus, and superior and inferior vena cava were required for inclusion, with a minimum rim of 5 mm, except of the aortic rim. The procedure was also indicated in patients with transient cerebrovascular attacks (TIA), with ASD and non-significant left-right short circuit or with a patent foramen oval (PFO) with right-left short circuit evident during performance of the Valsalva maneuver. Exclusion criteria were the primary types or sinus venous ASD, the presence of other heart diseases requiring surgery, the patient's insistence on general anesthesia and allergy to contrast agents. In this study, all patients underwent surgery were assessed by census analysis during the study period.

### 3. Data Collection

Initially, age, gender, height and weight of patients were recorded. Heparin 75unit/KG and antibiotic prophylaxis was given. Eight French (Fr) venous access was obtained and Initial right heart catheterization was done. The diameter of the defect was measured with a sizing balloon, locating the interatrial defect as precisely as possible, closure device was loaded using the standard and venous sheath was exchanged with the delivery sheath. The device was placed in the left upper pulmonary vein (LUPV) with part of left atrial disk in LUPV. First the right atrial disk was delivered following which the left atrial disk fell into its place completely occluding the shunt. In this study, four different devices were used including, 1) Cocoon, 2) Amplatzer, (AGA Medical Corp., Golden Valley, Minne sota), 3) Occlutech Figulla, and 4) BioSTAR. Device placement was checked with TEE, which showed no residual shunt and unobstructed flow across both the atrioventricular valves and systemic and pulmonary veins. Midazolam and morphine was used for conscious sedation.

After intervention, the patients were monitored for 24 hours, and short-term complications (aspiration in the catheter room, rhythm disorder, heart block and clotting embolism, air or device) were recorded. In addition, TTE was performed prior to hospital discharge.

### 4. Follow up

After the surgery, the patients were followed up for six months in terms of the success rate of surgery, device-related embolism, pneumonia, death, need for unplanned mechanical ventilation. Furthermore, another TEE event was also performed at the end of the 6th month after reoperation to evaluate the success rate of the surgery.

### 5. Statistical Analysis

Data were analyzed by SPSS V.18 software.

### 6. Ethics

The patient's information was encoded and inserted into the statistical software, and the patients could leave the study at any phase. Moreover, the patients signed informed consent from before participating in the study. In all steps we followed the ethical committee principles of Tabriz University of Medical Sciences.

### Results

#### 1. Baseline Characteristics

Eighty-seven consecutive patients (33 male/ 54 female) with a mean age of  $39.1 \pm 15.4$  years (range 22-71 years) and a mean BMI of  $25.4 \pm 3.7$  kg/m<sup>2</sup> were studied. Seventy five patients were diagnosed with secundum ASD, less than 36mm, and 12 others with patent foramen ovale (PFO). Mean fluoroscopy time was reported to be  $30.6 \pm 2.0$  minutes and mean sheet size was  $11.3 \pm 1.7$  French. Most of the patients underwent Amplatzer placement (50 patients, 57.5%), followed by Occlutech Figulla in 23 (26.4%), and 14 patients (16.1%) with Cocoon and BioSTAR. The diameter of the devices was ranged between 11-30 mm with a mean size of  $23.1 \pm 4.4$  mm.

#### 2. Concomitant Diseases

Pulmonary hypertension (4 patients, 4.5%) was the most prevalent concomitant disease presented in the ASD patients. Atrial fibrillation (AF) in 1 (1.1%), coronary artery disease in 2 (2.3%) patients, and embolic events (stroke, transient ischemic attack (TIA) in 5 cases (5.7%) were observed.

#### 3. Short-Term Outcomes

Device closure was done successfully in most of the patients (98.8%). Severe procedure related complications occurred only in one patient (1.1%) who needed surgical intervention because of embolization of device to the RVOT, where the defect was closed and the embolized devices was removed. No thrombi were detected on the devices, one patient (1.1%) developed AF which converted to normal sinus rhythm spontaneously.

#### 4. Mid-Term Outcomes

At 6 month follow up, complete closure was documented in 98.3%, of ASD patients and in 88.7% of patients with PFO. Because of non-significant residual right to left shunt in three of PFO patients, they were followed medically. No pneumonia, requirement to mechanical ventilation, thrombo-embolic events, and death was reported during the follow-up.

### Conclusion & Discussion

The results of this study indicate that septal occlude devices can be used to close ASDs of the secundum type in an adult patient population considered for transcatheter closure. Furthermore, beside an optimal

results of short- to mid-term follow-up, the technical success rate of ASD closure with septal occlude devices was very high in our series of patients. The results also revealed that over 90% of the patients that underwent closure based on echocardiographic findings were effectively treated with septal occlude devices. This finding is in line with that of previous studies, which have demonstrated that transcatheter closure with ASD achieves a success rate of 80% (13-17). In fact, following a study by Spies et al., (13) the current study included the second major series of adult patients undergoing ASDs closure with septal occlude devices. Spies et al. described how successful Amplatzer septal occluder implantation was achieved in 166 cases out of 200 of patients with hemodynamically significant ASD, representing a success rate of 83% (13). In our study, a procedure-related complication was observed in only one case; as such, our study identified a significantly lower percentage of complication in comparison to other studies in pediatric and adult populations. In the study by Spies et al., (13) complications occurred in 11 cases (6.5%); however, as was the case with our study, none of these events were associated with long-term sequelae.

A recent meta-analysis estimated that the rate of device thrombosis following ASD closure was 1.0% (6). A historic report from the Krumsdorf et al. study (18) found that the incidence of thrombus was 1.2% and that there was significant differences in thrombosis rate between different devices: the Amplatzer had the lowest incidence of thrombi (0%) followed by the CardioSeal (7.1%), Starflex (5.7), and Helix (0.8%) devices. Post-procedural atrial fibrillation was a significant risk factor for thrombus formation (18). In the majority of cases, thrombus was treated via a course of medical therapy and no clinical consequences were observed; however, in the current study, the patient who had an AF did not suffer from thrombus formation.

Abaci et al. specifically examined the risk of other types of thrombolytic events, such as stroke, and found that the rate of cerebrovascular events after ASD device closure was 1.1% (6). The rate at which patients suffered from a stroke was consistent with the findings of Kotowycz study (19). Kutty et al. reported a cumulative incidence of thrombolytic events of 3% after a median duration of 8.1 years following percutaneous ASD closure (20). In our study, the rate of thrombolytic events at the six-month follow-up was somehow similar to that of previous research findings in situations in which no event was reported during the study period.

Another important issue to be noted after ASD closure is conductive abnormalities; however, these have not been reported in any of the cases studied (21).

Although commonly described, conduction abnormalities, which include complete atrioventricular block (AVB), are rare following transcatheter ASD closure, with a reported prevalence of less than 1% (22). The occurrence of complete AVB is classically an acute peri-procedural complication, typically transient, and patients usually recover within a short period of time after corticosteroid therapy (23, 24). Interestingly, only five reports of late complete AVB have been described in the literature (25-29). However this was not a specific focus of our study during follow-up, we did not observe any late AVB complication either.

After percutaneous closure, atrial arrhythmias appear to be the most common complication associated with ASD in patients who do not have any pre-existent arrhythmias. In our study, AF as a postoperative complication was estimated to be around 1%, which was a much lower incidence rate than that reported in alternative studies (21). The findings indicate that pre-existing AF, the level of ASD correction and patients' age may play significant roles in the postoperative incidence rate of AF (21, 30). Previous research has concluded that, in unclosed ASD, the incidence of atrial fibrillation (AF) increases to 50% in patients who are aged over sixty years (21). Vecht et al. found that ASD closure had a beneficial effect on pre-existing AF at the mid-term follow-up; however, conversely, the recently published Danish nationwide cohort found that the rate of AF increased in patients without pre-existent arrhythmias (31, 32). Although the number of reports regarding short and midterm complications is considerable, there is currently a lack of data available pertaining to the long-term tolerance of devices that are implanted in growing children and adults; so this kind of studies is recommended.

#### Conflict of Interest

There is no conflict of interest.

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