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Outcomes Of Transcatheter Device Closure of Atrial Septal Defect Cases in Pediatric Cardiology Center of Combined Military Hospital, Dhaka, Bangladesh

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Abstract
In Bangladesh, ASD Device Closure Has Been Started In Various Centers For About A Decade. Still, To Date, Few Studies Concern The Complications Associated With Transcatheter Device Closure Of ASD.
From January 2016 To December 2016, Patients With Suspected And Confirmed ASD Cases Reported To The Department Of Paediatric Cardiology Center Of Combined Military Hospital Dhaka, Bangladesh, Were Evaluated. Osteum Second ASD Cases That Were Suitable For Device Closure Were Selected. Data Of Patients Who Underwent Device Closure Were Recorded In A Predesigned Data Collection Sheet.
During The Study Period, A Total Of 48 Patients Were Found With Second ASD And Tried For Transcatheter Device Closure, And 46 (95.83%) Were Successfully Closed. There Were 6/46 (13.04%) Complications, Of Which 2 Were Major, And 4 Were Minor. The Only Major Complication Was Device Embolization Occurring In 2/46 (4.37%) Cases; 1 (2.1%) Required Surgical Retrieval, While In The Remaining Case, The Device Was Retrieved By Catheter Technique. Another Important Complication Is The Formation Of A Thrombus On The Device. Among Minor Complications, Arrhythmia Was Most Common And Occurred In 2/46 (4.34%) Of Cases. In One Of These 2, Atrial Fibrillation Required Electrical Cardioversion, And The Other One Recovered Spontaneously. Post-Procedural Lower Respiratory Tract Infection Occurred In 1/46 (2.17%) Patients, For Which No Apparent Reason Was Found. Transient Hypoxemia Occurred In One Case, 1/46 (2.17%), Which Also Recovered Spontaneously.
In Summary, It Is Stated That Transcatheter ASD Device Closure Is A Safe And Effective Procedure
Keywords: *Atrial Septal Defect (ASD), Congenital Heart Disease, Transcatheter ASD Device Closure, Paediatrics.*

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I. Introduction

Atrial septal defects (ASDs) can occur in any portion of the atrial septum (secundum, primum, or sinus venosus), depending on which embryonic septal structure has failed to develop normally. [19] Secundum Atrial septal defect (ASD) is one of the most common congenital heart defects with an incidence of 3.78 per 1000 live birth, accounting for approximately 5.9% of all CHD having female predominance.[19] Male female ratio is 1:2.[19] The secundum atrial septal defect usually arises from an enlarged foramen ovale, inadequate growth of the septum secundum, or excessive absorption of the septum primum. Ten to twenty percent of individuals with ostium secundum ASDs also have mitral valve prolapse. [19]

It is one of the most common CHD found in adolescent and adulthood.[35] This defect causes shunting of blood between the systemic and pulmonary circulations. Patients with an isolated ASD secondum often remain asymptomatic during childhood and adolescence. If the defect remains untreated, however, the rates of exercise intolerance, supraventricular arrhythmias, right ventricular dysfunction and pulmonary arterial hypertension (PAH) increase with patient age, and life expectancy is reduced. [36]

Until the early 1990s, surgery was the usual method for closing all ASDs. King and Mills attempted the first transcatheter closure of secundum ASD in 1976.[22] In our country 1st transcatheter ASD device closure was performed in CMH Dhaka on April 2001[32]. It is gaining popularity because of the cosmetic benefits, reduced pain

and reduced hospital stay and less complications. However, some procedure related early and late complications may arise.

Most centers around the world perform this procedure under general anaesthesia in children. This then adds the risks of general anaesthesia to the procedure. Transcatheter closure is associated with all the general risks inherent in any interventional cardiac catheterisation procedure such as the risk of contrast reactions, vessel or cardiac perforation and the introduction of infection.[5]

Complications of femoral vein access include haematomas that may rarely require blood transfusions and, even more rarely, surgical repair when retroperitoneal haematomas have developed. [12] Chessa *et al* have reported on a large series of 417 patients who had catheter closure of secundum ASDs of whom 159 received Cardioseal starflex and 258 Amplatzer septal occluder devices. Overall, there were 36/417 (8.65%) complications, of which 11 were major and 25 minor.[25]

The most common complication was device embolisation/malposition occurring in 3.5% of cases. Of the 15 patients in whom devices embolised or malpositioned, 10 required surgical retrieval while in the remaining device were retrieved by catheter technique. The next most common complication was arrhythmia, which occurred in 11/417 (2.6%) of cases.[25] Pericardial effusion occurred in two patients, in one case due to cardiac perforation, and for no obvious reason in another.[25]

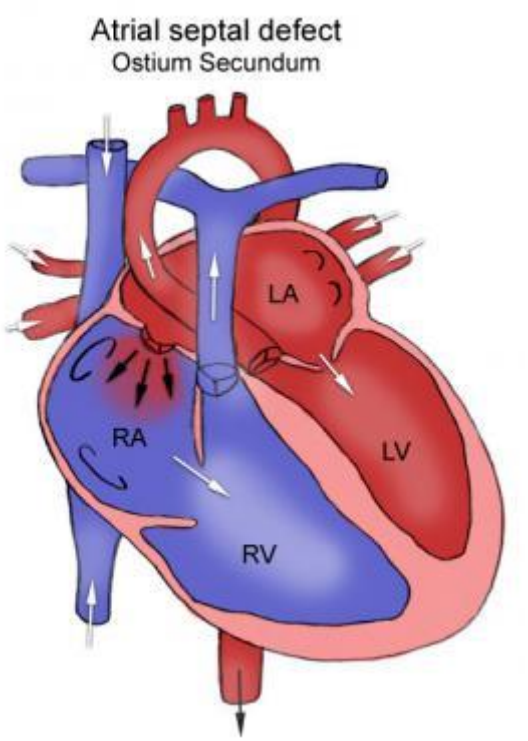

Figure 1- Secundum ASD

There have been many other reports of procedure related complications. These include a report on 236 patients considered for closure with the Amplatzer septal occluder.[5] Of these, 200 had a successful transcatheter closure and two had a serious procedural related complication (one retroperitoneal hematoma requiring surgery and one air embolism to the right heart after device implantation with no apparent sequel). Among intermediate and long-term complications erosions, wire fracture has been reported. Even though introduction of new devices like atrial septal defect occlusion system (ASDOS) and Amplatzer septal occluder (ASO) decreases the chance of embolization.[5]

II. Materials & Methodology

Study place, period and population

We designed a prospective cross-sectional interventional study, and the place of all the cases was the Department of Pediatric Cardiology, CMH Dhaka. The study period was from January 2016 to December 2016. Our targeted population was children up to 12 years of age who were diagnosed as secondum ASD cases and have

been treated by transcatheter device closure and followed up in the Pediatric Cardiology Department of Combined Military Hospital Dhaka within 12 months.

Procedure of data collection and Equipment

Data were collected with a predesigned standard data collection sheet with a Questionnaire for history taking, physical examination, and laboratory investigation. We used X-ray, ECG, and Color Doppler Echocardiography as required equipment.

Sample size

The sample size was determined by following formula, $n = \frac{z^2 pq}{d^2}$

Here,

n= the desired sample size
p= the prevalence rate of ASD is 37.8% = 0.378
q= 1- 0.378 = 0.622
z= the standard normal variant 1.96 which correspond to 95% confidence
d= the acceptable standard error (0.05)

$n = \frac{z^2 pq}{d^2}$ = $(1.96)^2$x0.378x0.622/ $(0.05)^2$ =361.28 [Due to time limitation the sample size has been taken as 46]

Selection criteria

Our inclusion criteria were – **a)** Secondum ASD cases **b)** Age from 1-12 years **c)** Underwent transcatheter device closure.

Besides, the exclusion criteria were determined as **a)** Patient with other variety of ASD **b)** Managed by surgical closure **c)** ASD associated with other CHD **d)** ASD with complications.

Study procedure

The study was carried out in the Department of pediatric cardiology of CMH Dhaka. Firstly, parents were explained about the study, and informed written consent was taken. Then detailed clinical history & physical examination were undertaken. Necessary investigation (X-ray, ECG, ECHO) had been done. Osteum secondum ASD cases were selected. For patients who underwent transcatheter device closure, data were collected and recorded in a predesigned data collection sheet. After recording all information, data were analyzed & results were expressed with discussion.

All data had been entered, checked, rechecked & scrutinized by the principal investigator following standard procedure and analyzed by the SPSS program, version 22.0.

Ethical implication during study process

Written informed consent was obtained after a brief of the study in Bengali to all responders for their better understanding and their participation was voluntary. Interview had been taken in a suitable time and place that was convenient to the responder and they were ensured to have the right to withdraw from this study at any point of time. All answers will be kept confidential as well as their identity.

Scheme of study procedure

Selection of topic

↓

Review of literature, books and publications

↓

Discussion with guide

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Permission from respective department and ethical clearance from ethical review committee

↓

Submission of protocol

↓

Protocol accepted

↓

Case selection and data collection

↓

Data analysis and interpretation

↓

Discussion with guide about expected and unexpected result

↓

Presentation of results, dissemination of findings & submission of dissertation

Figure 2: Illustration of Study plan

III. Results & Discussion

In our study successful closure of ASD device achieved in 46 (95.83%) of 48 patients and 2(4.16%) patients in the device closure group had failed procedural attempts due to anomalous pulmonary drainage.

Main outcome variable

Age and Sex	Thrombus formation
Heart block	Atrioventricular valve regurgitation
Aortic erosion	Arrythmia
Vessel or cardiac perforation	Infective endocarditis
Device malposition	Pericardial effusion
Embolization	Stroke

Table 1-Outcome Variables for the study

Among early complications, 2 developed arrhythmia, 2 developed device embolization and 1 developed hypoxemia.

Device Malposition/Embolization: Device embolization is a potential complication of every attempted ASD closure, and the causative factors can be undersized device, inadequate or floppy rim, operatorrelated technical issues such as malposition during the "push-pull" maneuver, or excessive tension on delivery cable during device deployment. A survey of AGA proctors carried out in 2003 revealed that there were 21 embolizations out of 3,824 ASO implants (0.55%); of those, 15 were retrieved using a transcatheter approach (71.4%) and 6 were retrieved surgically (28.5%).[37] An analysis of the device embolizations reported to the MAUDE database found it to be the most prevalent adverse event and the device was retrieved surgically in 77.2% of cases and using a transcatheter approach in 16.7% of cases.

There were 2 deaths related to embolization. The AGA survey showed that experienced operators were able to successfully retrieve the embolized device using a transcatheter approach. All operators who use the septal occluders should be prepared to perform percutaneous device retrieval in the event of a device embolization. After device embolization, the first objective is simply to get the device into a position in which it will not cause harm. The device may then be stabilized and moved or removed from the body.[1]

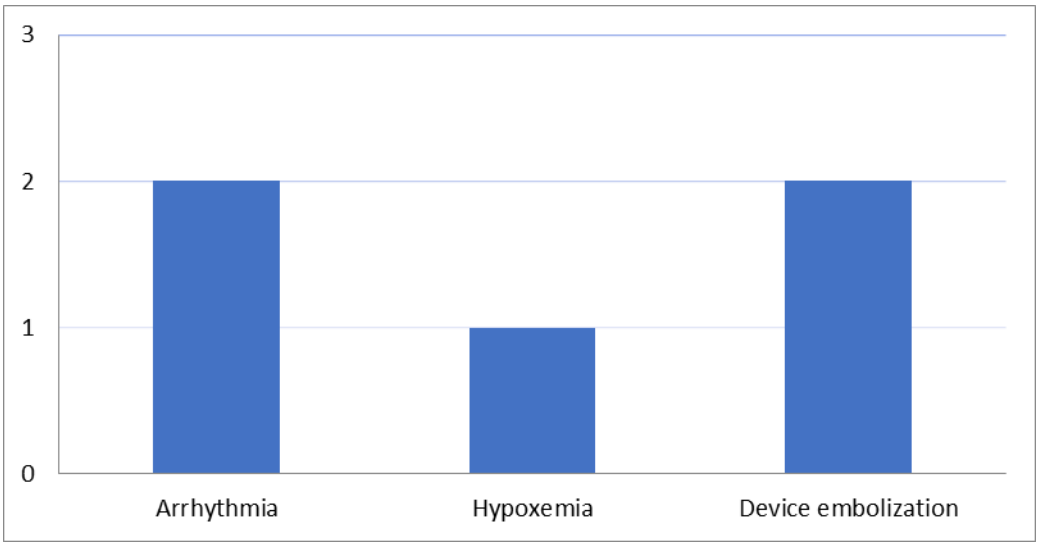

Figure 3- Early complications associated with ASD device closure

Arrhythmias: The reported complications from device closure of ASD include development of atrial tachyarrhythmias or heart block, both transient and permanent. The risk of bundle branch block in patients with large ASD, particularly those with deficient rims, may be increased, although the true risk is unknown. A retrospective study of 610 device patients (585 ASO), who underwent device closure of ASD, showed a low overall risk of arrhythmias with clinically significant heart block occurring in 0.3% of patients. A tendency toward atrial arrhythmias appears to increase with device closure. [39] In the MAUDE analysis, 5% of the MDR were arrhythmias.[11] There is a concern that device closure of ASD may preclude future electrophysiology procedures that require transseptal access.[1]

Thromboembolic Complication: An analysis of the MAUDE database showed that 2.5% (18 of 705) of the MDR were related to device thrombus, and 1 death was attributed to thrombus.11 In one report, 1,000 patients were studied to investigate the incidence and clinical course of thrombus formation following device closure of ASD. This study showed that the incidence of thrombus on closure devices is low. However, significant differences were noted between different devices with the Amplatzer nitinol wire frame filled with polyester fabric and the Helex nitinol wire covered by an ultra-thin membrane of expanded polytetrafluoroethylene to be least thrombogenic. Atrial fibrillation and persistent atrial septal aneurysm after transcatheter closure are significant risk factors for thrombus formation. In most of the patients, the thrombus resolved under medical therapy without clinical consequences.[40]

Only one patient developed post-procedural lower respiratory tract infection. Transient arrhythmia developed in 2 patients among them 1 recovered spontaneously and another required electrical cardioversion. Two developed device embolization of which one required surgical retrieval and in another case device was retrieved by catheter technique. One developed transient hypoxemia which recovered spontaneously and one developed post-procedural LRTI which required treatment with antibiotic.

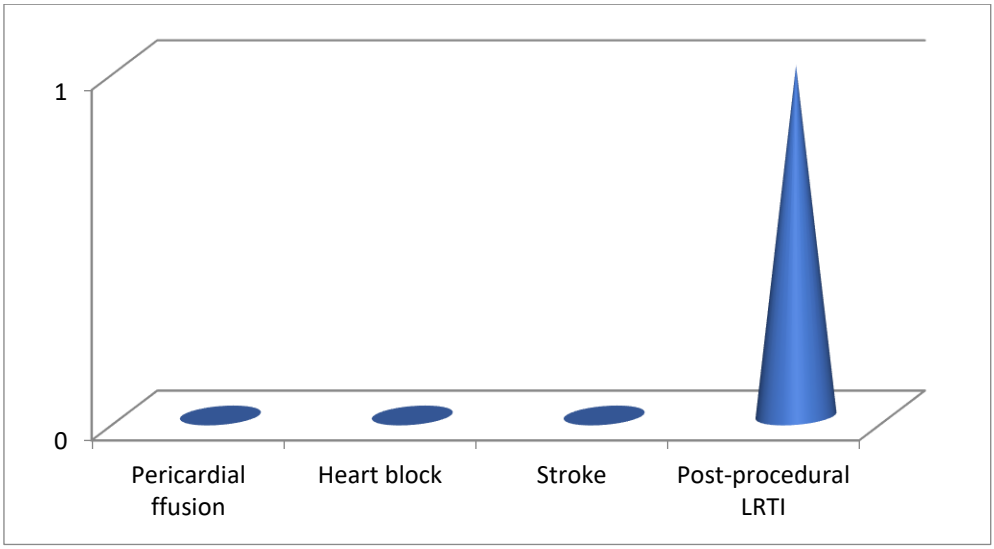

Figure 4- Late complications of ASD device closure

Complications	Number of cases	Treatment required		Spontaneous recovery	
		Number	%	Number	%
Transient Arrhythmia	2	1	50%	1	50%
Transient Hypoxemia	1	0	0	1	100%
Post-procedural LRTI	1	1	100%	0	0
Device Embolization	2	2	100%	0	0

Table 2- Management of complications

Sergio et al reported 128 patients were 12 short-term minor complications (9.4%), including: transient arrhythmia resolving spontaneously or with only catheter manipulation (2 cases); rebleeding from access site (1 case); transient hypoxemia (2 cases); trivial/small pericardial effusions that resolved spontaneously (4 cases); deployment malfunctions (2 cases); and development of post-procedural lower respiratory tract infection (1 case). There have been no minor complications reported to date beyond day 7 following the procedure. There were 7 short-term major complications (5.5%) in 5 patients. No medium- or long-term major complications have been reported. [41]

Complications	Number of cases	Recover		Mortality	
		Number	%	Number	%
Transient Arrhythmia	2	2	100%	0	0
Transient Hypoxemia	1	1	100%	0	0
Post-procedural LRTI	1	1	100%	0	0
Device Embolization	2	2	100%	0	0

Table 3- Outcome of complications

One thousand and twenty patients with secundum ASD, age 8 months to 18 years (median 11 years) from December 2000 to December 2013 were included in a study at Combined Military Hospital Dhaka, Bangladesh. Device implanted on 1020 patients but tried on 1075 patients. Forty one cases postponed after balloon sizing and 12 for unstable position of device or mash rooming deformity of device. Immediate complications were ST change (n=12), transient arrhythmia (n=4), residual shunt (n=7) etc. Immediate major complication was embolization of device (n=2). There was no late embolization, thromboembolic events, erosion, pericardial effusion, aortic regurgitation in follow up. The study recommended that device closure of ASD is safe and effective in short and long term follow up without any major late complication.[32]

IV. Limitations

There were some limitations in our study. Firstly, the design was not a randomized trial. Secondly, the sample size was small due to the limitation of time. Last but not least, there were variable lengths of time between ASD device closure and follow-up examination, but our study didn't include enough patients.

V. Conclusion

Despite of limitations of this study, our study demonstrates that transcatheter device closure of secondum ASD is safe and effective. The procedure-related complications are very low, and the only major complication in our study was device embolization. From this study's results and observation, further research should be done with a larger sample size and a longer duration of follow-up.

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