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Complications Associated with Transcatheter Device Closure of Atrial Septal Defect Cases in Pediatric Cardiology Center of Combined Military Hospital Dhaka, Bangladesh

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Abstract

Background: 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. **Material & Methods:** 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. **Results:** 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. **Conclusion:** 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.

INTRODUCTION

Congenital heart disease (CHD) represents one of the major groups of birth defects and affects around 8-10/1000 live birth. 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 diagnosed CHD.[1,2,3,4,5]

ASD secondum as large as 5 to 8 mm may close spontaneously in a significant portion of subjects as old as 2 to 3 years of age.[6,7,8] Although recognized as a relatively benign form of cardiac disease, if left untreated can

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eventually contribute to significant morbidity and mortality. ASD can cause volume overload of the right side of the heart with the potential for subsequent development of right heart failure, systemic embolism, elevated pulmonary vascular resistance, or atrial arrhythmias.[9,10,11,12] Surgical or transcatheter device closure is advised for all symptomatic patients and also for asymptomatic patients with a Qp: Qs ratio of at least 2: 1 or those with right ventricular enlargement. The timing for elective closure is usually after the 1st year and before entry into school.[13,14,15]

Surgical repair of an ASD is a low-risk and widely accepted procedure.[15] Conventional surgical closure through midline sternotomy is considered the gold standard in the treatment of children with atrial septal defect (ASD) due to meager mortality rates among these children. However, it is associated with morbidity, discomfort, a longer period of hospital stays, and a thoracotomy scar.[15] Operative mortality is low (0% to 3%), and long-term survival is high (25-year survival of 92%).[16,17] Recent advances in the use of minimally invasive surgical techniques (characterized by very small incisions with minimal exposure to the operative field) and of interventional percutaneous device applications are now challenging the role of the conventional approach.[18,19,20,21]

As an alternative to surgery, the first transcatheter closure of ASD was described in 1976 by King et al.. Then ASD transcatheter occlusion techniques have become an alternative to surgical procedures.[22,23,24] A series of patients with ASD treated with transcatheter occlusion shows that the method is safe, with a low rate of early and late complications.[25,26] Echocardiography is an excellent investigation to select the cases for device closure and follow-up of the cases after closure.[27,28]

There are some well-known ASD closure devices such as Amplatzer Septal Occluder, Figulla Flexible Occlutech Septal Occluder, Gore Helex Septal Occluder, Gore Cardioform Septal Occluder, The Gore Cardioform ASD Occluder.[29,30,31] In our country, 1st transcatheter ASD device closure was performed in April 2001.[32] Since then, several hundreds of transcatheter ASD closures have been done in CMH Dhaka and other pediatric cardiac centers in Bangladesh.[32] Aim of this study is to evaluate early and late complications associated with transcatheter device closure of Atrial Septal Defect cases as well as major and minor complications related to the procedure.

Rationality of research

Although the worldwide incidence of CHD is 0.8% of live-born infants but an epidemiological study carried out in the department of pediatrics, CMH Dhaka, established the incidence of CHD is 25/1000 live births in our country and among the most common congenital heart lesion was ASD (26%).[3] Transcatheter closure of ASD is gaining popularity day by day. The procedure-related complications are less. There is a scarcity of study in documenting complications associated with transcatheter device closure of Atrial Septal Defect cases. Therefore, this study will help determine the rate of complications associated with transcatheter device closure of ASD cases.

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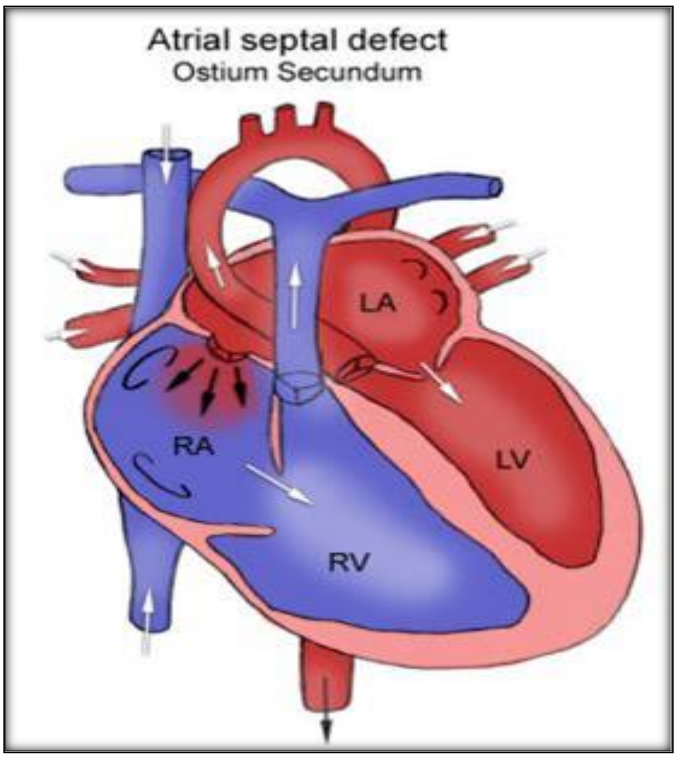

Figure 1: Secundum ASD

MATERIAL AND METHODS

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

[Due to time limitation the sample size has been taken as 46]

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)

$$n = \frac{z^2 pq}{d^2} = (1.96)2x0.378x0.622/ (0.05)2 =361.28$$

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.

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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

Scheme of study procedure

Figure 2: Illustration of Study plan and procedure

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.

RESULTS & DISCUSSION

Our study was done to see the complications associated with transcatheter device closure of secondum ASD cases in the Pediatric Cardiac Center of CMH Dhaka. During the study period, a total of 46 patients underwent transcatheter ASD device closure. The most common age group was 4-6 years (45.65%). The mean age of ASD device closure was 4.6 years.

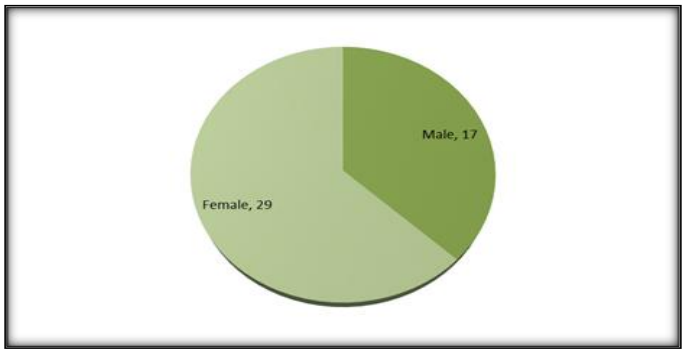

Figure 3: Distribution of sex among the study group (n=46)

In this study, 29 (63.04%) were female, and 17 (36.955%) were male. So male: female ratio is 1: 1.75, which shows female predominance and corresponds with most studies.[33,34,35]

In our study, successful closure of ASD devices was achieved in 46 (95.83%) of 48 patients, and

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2(4.16%) patients in the device closure group had failed procedural attempts due to anomalous pulmonary drainage. In a study, Jacek B et al. showed an ASD device closure success rate of 95.5%.[36,37,38,39,40,41,42] We showed transcatheter device closure success rate was 95.83% which is very similar to that study. These failures occur due to the large size of ASD, insufficient rims, and unfavorable anatomy diagnosed after the angiogram. The following table shows the distribution of the size of secondum ASD closed by the transcatheter device. The mean size of secondum ASD was 10.6 mm.

Overall, there were 6/46 (13.04%) complications, of which 2 (4.37%) were major, and 4 (8.69%) were minor. Chessa et al. reported on an extensive series of 417 patients in a study. There were 36/417 (8.65%) complications, of which 11 (2.63%) were major and 25(5.99%) were minor.[4] In our study, the complication rate is slightly higher than that, probably due to a smaller number of study population. The following table shows the age distribution of ASD device closure of secondum ASD where the common age group was 4-5 years 17 (36.95%).

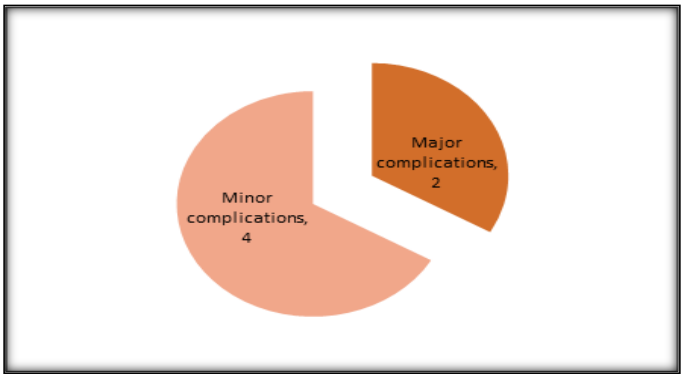

Figure 4: Major and minor complications following ASD device closure

The only major complication observed in our study was device embolization which occurred in 2/46(4.37%) cases. It is the most common and severe complication of ASD device closure. Among these 2, one (2.17%) required surgical retrieval, while in the other case, the device was retrieved by catheter technique. Cheesa et al. reported device embolization/malposition occurring in 15/417 (3.5%) cases, of which 10 (2.39%) required surgical retrieval. The remaining 5 devices were retrieved by catheter technique, which is almost similar to our study.4 In another study Sergio B et al. reported 7/347 (5.5%) major complications, which is also similar to our study.[41] No other major complications like perforation, stroke, infective endocarditis, heart block, aortic erosion, or death were observed during this study period.

Among minor complications, arrhythmia was most common, occurring in 2/46 (4.34%) of cases. In one of these 2, atrial fibrillation required electrical cardioversion, and the other one recovered spontaneously. Cheesa et al. reported arrhythmia in 11/417 (2.6%) cases which is slightly less than our study, probably due to the large sample size.[4] In six (1.43%) of these 11 required electrical cardioversion. The size of the device can be a predisposing factor for arrhythmia after ASD closure. A possible explanation of arrhythmia could be the stretching of the interatrial septum by the central waist of the device. But most of the arrhythmias were transient, so they required no treatment.

Post-procedural lower respiratory tract infection occurred in 1/46 (2.17%) patients, for which no obvious reason was found. Transient hypoxemia occurred in one case, 1/46 (2.17%), which recovered spontaneously.

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In our study, there were 5 (10.86%) short-term complications occurring within 24 hours of device closure; among them, 2 (4.36%) were major, and the remaining 3 (6.36%) were minor. Only one complication arose after 24 hours. That was one patient who developed a post-procedural lower respiratory tract infection. Sergio et al. showed that minor short-term complication was 9.4% and major short-term complication was 5.5%, which is similar to our study.[41]

Most of them required to stay < 3 days in hospital following device closure. Mean period of hospital stay after ASD device closure was 2.21 days. In a study Jacek B et al showed mean period of hospital stay after surgical closure of ASD was 7.5±3 days and after device closure 2.2±1.1 days which is also almost similar to our study.[42,43,44,45]

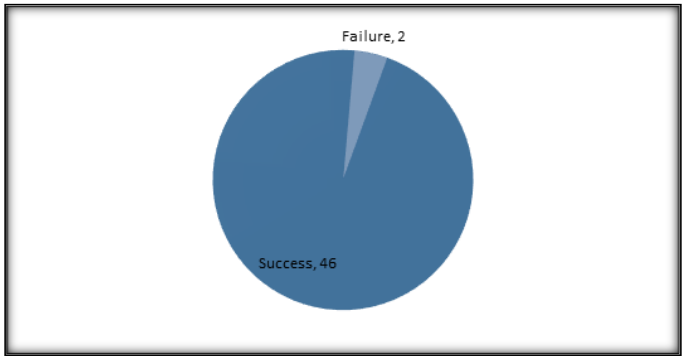

Figure 5: Success rate of transcatheter device closure procedure

The success rate of transcatheter device closure procedure was 95.83% and 46 cases were successful among total 48 cases.

Table 1: Age distribution of the study population (n=46).

Age (in years)	n	%	Mean age (years)
0-3 yrs	17	36.95%	4.6
4-6 yrs	21	45.65%	
7-12 yrs	8	17.39%	

Table 2: Distribution of size of ASD

Size of ASD	Number of cases	%	Mean size (mm)
≤8	4	8.6%	10.6
8-10	18	39.13%	
11-12	19	41.30%	
≥13	5	10.865%	

Table 3: Age of ASD device closure (n=46)

Age in year	Number of cases	%
≤1	3	6.5%
1-3	16	34.78%
4-5	17	36.95%
6-7	6	13.04%
≥7	4	8.69%

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Table 4: Major complications associated with ASD device closure (n=46)

Name of Complication	Number	%
Device embolization	2	4.34%

Table 5: Minor complications associated with ASD device closure (n=46)

Name of Complications	Number of cases	%
Transient Arrhythmia	2	4.34%
Transient Hypoxemia	1	2.17%
Post-procedural lower respiratory tract infection	1	2.17%

Table 6: Total 6 complications developed among 46 cases.

Time Duration	Within 24 Hours	After 24 Hours
Number	5	1
%	83.33%	16.66%

Table 7: Period of hospital stay after transcatheter device closure of ASD (n=46)

Period of hospital stay in days	Number of cases	Mean period of hospital stay(days)
≤ 3	42	2.21
3-7	3	
≥7	1	

Limitation of the study

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.

CONCLUSIONS

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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