Original Article

Observation of Immediate and Short Term Results of Percutaneous Trans-Catheter Device Closure of Atrial Septal Defect in a Paediatric Cardiac Centre, Bangladesh

DOI: dx.doi.org

Md Ashfaque Ahemmed Khan[1*], Mohammad Nazmul Islam Bhuiyan[1], Nurun Nahar Fatema[2], Md Ferdousur Rahman Sarkar[1], Sultana Yesmin[3]

Received: 18 January 2024
Accepted: 27 January 2024
Published: 10 February 2024

Published by:
Sher-E-Bangla Medical College, Barishal, Bangladesh

*Corresponding Author

Editor: Prof. Dr. HN Sarker

Available Online:
https://bdjournals.org/index.php/planet/article/view/435

ABSTRACT

Introduction: *Atrial Septal Defect (ASD) is a common congenital heart defect that can lead to various complications if left untreated. Percutaneous trans-catheter device closure has emerged as a viable alternative to surgical closure, especially for secundum ASDs. However, data on its effectiveness and safety in a resource-constrained setting like Bangladesh are limited.* ***Methods and materials:*** *This prospective observational study was conducted at Pediatric Cardiac Centre, Combined Military Hospital Dhaka, a tertiary care center in Bangladesh. Fifty patients with secundum ASD were enrolled and underwent percutaneous trans-catheter ASD device closure. Various parameters like age, gender, comorbidities, presenting symptoms, and investigation findings were analyzed. Immediate and short-term outcomes following intervention were assessed through clinical examination and follow-up investigations.* ***Result:*** *The device was successfully implanted in 48 out of 50 patients (96%). No residual shunts were observed in any of the successful cases during the follow-up period. Right Ventricular (RV) size normalization was observed in 81.25% of the patients by the third follow-up. Incomplete Right Bundle Branch Block (RBBB) with or without Right Ventricular Hypertrophy (RVH)*

(The Planet 2023; 7(1): 323-333)

1. *Classified Child Specialist & Interventional Paediatric Cardiologist, Department of Paediatric Cardiology, Combined Military Hospital, Dhaka, Bangladesh*
2. *Paediatric & Structural Interventional Cardiologist, Department of Paediatrics & Paediatric Cardiology, Combined Military Hospital Dhaka & Armed Forces Medical College, Dhaka, Bangladesh*
3. *Associate Professor, Department of Pharmacology, Dhaka Dental College, Dhaka, Bangladesh*

decreased from 66.67% immediately post-procedure to 35.42% at the third follow-up. ***Conclusion:*** *The study confirms the safety and efficacy of percutaneous trans-catheter ASD device closure in a resource-constrained setting. It also emphasizes the importance of thorough pre-procedure evaluation for optimal patient selection and outcome.*

Keywords: *Atrial Septal Defect, Percutaneous Trans-Catheter Device Closure, Resource-Constrained Setting, Safety, Efficacy.*

INTRODUCTION

Atrial Septal Defects (ASDs) are one of the most common congenital heart defects, accounting for 10-15% of all cases. They occur due to abnormal development of the septum separating the left and right atria during embryogenesis [1]. Based on anatomical location, ASDs are classified into ostium secundum, ostium primum, and sinus venosus defects. Ostium secundum ASD is the most frequent type, representing approximately 70-80% of cases [2]. While small ASDs may remain asymptomatic, larger defects can lead to volume overload of the right heart chambers and pulmonary arteries over time. This results in symptoms such as effort intolerance, dyspnea, and palpitations as the pulmonary vascular pressures and resistance increase [3]. Untreated large ASDs are associated with increased risk of atrial arrhythmias, pulmonary hypertension, right ventricular dysfunction, and heart failure in the long term. Surgical closure through median sternotomy was previously the standard treatment for ASDs. However, advancements in interventional cardiology have paved the way for less invasive methods, such as percutaneous trans-catheter device closure [4,5]. Since the introduction of the Amplatzer septal occluder (ASO) in 1995, percutaneous device closure has become the treatment of choice for ostium secundum ASDs with suitable anatomy [6,7]. It offers several advantages over surgery, such as avoidance of cardiopulmonary bypass, shorter hospital stay and recovery time, and superior cosmetic results [8,9]. Multiple studies have demonstrated the safety and efficacy of ASO device closure for ASDs in both adult and pediatric populations. Success rates of over 95% are routinely reported, with major complication rates of 1-2% [10]. Residual shunts occur in less than 5% of cases and usually close spontaneously. Long-term follow-up studies show significant and sustained improvements in symptoms, exercise capacity, and normalization of right heart dimensions and pressures post-closure [11-13]. Despite its advantages, percutaneous trans-catheter device closure is not without limitations. Physicians must be well-versed in the potential risks and complications associated with the procedure, ranging from device embolization and transient arrhythmia to more severe post-interventional complications [12,14]. While device closure is now accepted worldwide as the treatment of choice for most secundum ASDs, its use in resource-limited settings remains limited due to high equipment costs. In such contexts, the procedure's success can have significant implications for healthcare delivery and patient outcomes [15-17]. This study aims to provide a comprehensive observation of the

immediate and short-term results of percutaneous trans-catheter device closure of ASD. By focusing on a specific demographic and geographic context, this research seeks to contribute to the existing body of knowledge by offering data on the procedure's efficacy, safety, and outcomes.

METHODS & MATERIALS

This prospective observational study was conducted at the Department of Paediatric Cardiology, Combined Military Hospital Dhaka, Bangladesh, between March and December 2021. The study enrolled 50 consecutive patients, including children over 2 years and adults, diagnosed with secundum Atrial Septal Defect (ASD) and eligible for percutaneous ASD device closure. Purposive sampling was used to select participants. Inclusion criteria consisted of patients with secundum ASD confirmed by echocardiography, showing significant left-to-right shunt and right ventricular volume overload. Exclusion criteria ruled out patients with Patent Foramen Ovale, insignificant secundum ASD, or complex congenital heart diseases. The study variables included the success of device implantation, residual ASD, and post-intervention complications such as device embolization and transient arrhythmia. Ethical clearance was obtained from the Ethics Review Committee of CMH, and informed consent was acquired from all participants. Data were collected using a pre-designed sheet and included clinical findings and investigation results. Tools employed for data collection were ECG, X-ray, and 2D color Doppler echocardiography. Patients were monitored for 24 hours post-procedure and followed up at one, three, and six months. Clinical outcomes were recorded and analyzed from July to December 2021 using SPSS Version 23.0.

RESULTS

In the study, a total of 50 participants were included. The age distribution was as follows: 15 participants (30.00%) were under 5 years of age, 16 participants (32.00%) were between 5 and 11 years, 9 participants (18.00%) were between 12 and 18 years, and 10 participants (20.00%) were above 18 years. The gender distribution was evenly split, with 25 males (50.00%) and 25 females (50.00%). Regarding comorbidities, the majority of the participants (94.00%) had no comorbidities. Only one participant (2.00%) had hypothyroidism, one (2.00%) had Down syndrome, and one (2.00%) had Noonan syndrome. In terms of presenting symptoms, feeding difficulties in infancy were reported by 26 participants (52.00%), repeated respiratory tract infections by 30 participants (60.00%), and failure to gain weight by 20 participants (40.00%). Delayed milestones of development were noted in 4 participants (8.00%), palpitations in 9 participants (18.00%), and exertional dyspnea (NYHA-II) in 13 participants (26.00%). Incidental diagnosis was observed in 11 participants (22.00%) **[Table-I].**

Table I: Distribution of participants by baseline characteristics (n=50)

Variable	Frequency	Percentage
Age		

<5 years	15	30.00%
5-11 years	16	32.00%
12-18 years	9	18.00%
>18 years	10	20.00%
Gender		
Male	25	50.00%
Female	25	50.00%
Comorbidities		
Hypothyroidism	1	2.00%
Down syndrome	1	2.00%
Noonan syndrome	1	2.00%
No Comorbidities	47	94.00%
Presenting Symptoms		
Feeding difficulties in infancy	26	52.00%
Repeated respiratory tract infection	30	60.00%
Not gaining weight	20	40.00%
Delayed milestones of development	4	8.00%
Palpitations	9	18.00%
Exertional dyspnea (NYHA-II)	13	26.00%
Incidental	11	22.00%

All 50 participants in the study exhibited a Normal Sinus Rhythm (NSR) on their Electrocardiogram (ECG), accounting for 100.00% of the sample. Right Ventricular Hypertrophy was observed in 32 participants (64.00%), and Incomplete Right Bundle Branch Block (RBBB) was found in 29 participants (58.00%). In the Chest X-ray findings, Cardiomegaly was present in 45 participants (90.00%), and a Plethoric lung field was also observed in 45 participants (90.00%). Echocardiographic (Echo) findings revealed that all patients had dilated RA, RV and 22 participants (44.00%) had Pulmonary Hypertension. Aneurysmal tissue was noted in 10 participants (20.00%) **[Table-II].**

Table II: Investigation findings of participants by (n=50)

Investigation Findings	**Frequency**	**Percentage**
ECG		
Normal sinus rhythm (NSR)	50	100.00%
Right Ventricular Hypertrophy	32	64.00%
Incomplete RBBB	29	58.00%
Chest X-ray		
Cardiomegaly	45	90.00%
Plethoric lung field	45	90.00%
Echo		
Dilated RA, RV	50	100%
Pulmonary Hypertension	22	44.00%
Aneurysmal	10	20.00%

Tissue		

The size of the Atrial Septal Defect (ASD) varied among the participants. A total of 21 participants (42.00%) had an ASD size ranging from 6 mm to less than 12 mm. The majority, 27 participants (54.00%), had an ASD size ranging from 12 mm to less than 30 mm. Only 2 participants (4.00%) had an ASD size greater than 30 mm. In terms of Pulmonary Artery Pressure, 28 participants (56.00%) had normal levels. Mild Pulmonary Hypertension was observed in 20 participants (40.00%), and Moderate Pulmonary Hypertension was found in 2 participants (4.00%) **[Table-III].**

Table III: Pulmonary artery pressure and ASD diameter measurements (n=50)

Variables	Frequency	Percentage
Size of ASD		
6-<12 mm	21	42.00%
12-<30 mm	27	54.00%
>30 mm	2	4.00%
Pulmonary artery pressure		
Normal	28	56.00%
Mild Pulmonary hypertension	20	40.00%
Moderate Pulmonary hypertension	2	4.00%

The study employed two methods for measuring the size of the Atrial Septal Defect (ASD) in the 50 participants. Transthoracic echocardiography was used in 18 participants, accounting for 36.00% of the sample. The majority of the participants, 32 in total (64.00%), had their ASD size measured using the balloon sizing with stop-flow technique **[Figure 1].**

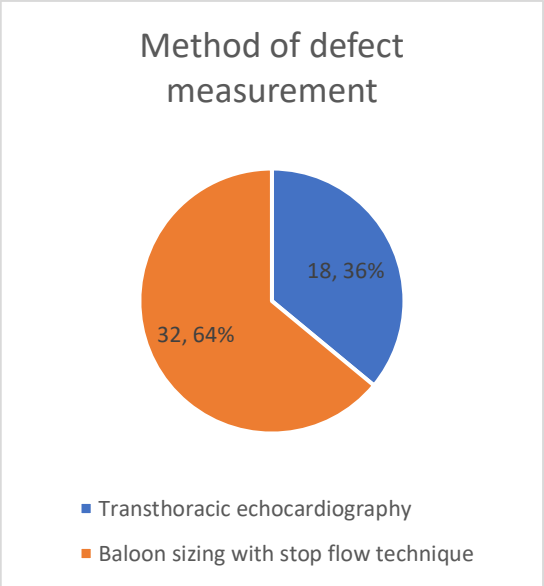

Figure 1: Distribution of participants by method of defect measurement (n=50)

In terms of immediate outcomes after Atrial Septal Defect (ASD) closure, the device was successfully implanted in 48 participants, making up 96.00% of the sample. There was one instance (2.00%) of failure in device placement; the device was not implanted because it became unstable during the Minnesota wiggle and was displaced. Additionally, there was one case (2.00%) where the device embolized post-deployment, specifically to the Right Atrium. Transient arrhythmia and transient ST changes noted in three case (6.00%) and one case respectively **[Table-IV].**

Table IV: Immediate outcome after ASD closure (n=50)

Immediate Outcome	Frequency	Percentage
Device successfully implanted	48	96.00%
Failure of device placement	1	2.00%
Transient arrhythmia	3	6.00%
Transient ST change	1	2.00%
Device embolized post deployment	1	2.00%

Among the 48 participants who had successful Atrial Septal Defect (ASD) device closure and were included in the follow-up, the device position was confirmed to be normal in all cases (100.00%) through echocardiography (Echo) at each follow-up point (Immediately within 24 hours, D30, D90, and D180). No residual shunt was observed in any of the participants at any follow-up time. In terms of Right Ventricular (RV) size normalization, only 1 participant (2.08%) showed normal RV size immediately within 24 hours of the procedure. This number increased to 16 participants (33.33%) at the first follow-up (D30), 34 participants (70.83%) at the second follow-up (D90), and 39 participants (81.25%) at the third follow-up (D180). The device position was also confirmed to be normal in all cases (100.00%) through X-ray at each follow-up point. Electrocardiogram (ECG) findings revealed that Incomplete Right Bundle Branch Block (RBBB) with or without Right Ventricular Hypertrophy (RVH) was present in 32 participants (66.67%) immediately and at the first follow-up (D30). This number decreased to 29 participants (60.42%) at the second follow-up (D90) and further decreased to 17 participants (35.42%) at the third follow-up (D180). No instances of Heart Block or Arrhythmia were observed at any follow-up point **[Table-V].**

Table V: Follow up investigation findings after successful ASD device closure (n=48)

Variables	Immediately with in 24 hour of procedure		1st Follow up (D30)		2nd Follow up (D90)		3rd Follow up (D180)	
	n	%	n	%	n	%	n	%
Normal Device position in Echo	48	100.00 %	48	100.00 %	48	100.00 %	48	100.00 %
Residual shunt in	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Echo									
Normal RV size		1	2.08%	16	33.33%	34	70.83%	39	81.25%
Normal Device position in X-ray		48	100.00 %	48	100.00 %	48	100.00 %	48	100.00 %
ECG	**Incomplete RBBB±RVH**	32	66.67%	32	66.67%	29	60.42%	17	35.42%
	Heart Block/ Arrhythmia	0	0.00%	0	0.00%	0	0.00%	0	0.00%

DISCUSSION

The present study aimed to evaluate the immediate and short-term outcomes of percutaneous trans-catheter device closure of Atrial Septal Defect (ASD) in our institution. The age distribution of participants in this study was notably diverse, with 30% under 5 years, 32% between 5 and 11 years, 18% between 12 and 18 years, and 20% above 18 years. Although ASD is generally diagnosed much earlier, this wide age range is reflective of the clinical reality that ASDs are often diagnosed across various life stages, corroborating previous studies that have reported a similar age distribution [18]. Gender distribution was evenly split at 50% for both males and females, a finding that aligns with existing literature indicating no significant gender predisposition for ASDs [19]. In terms of comorbidities, a striking 94% of participants had no associated conditions, which is consistent with the notion that ASD often occurs as an isolated cardiac anomaly [1]. Only 2% had hypothyroidism, Down syndrome, or Noonan syndrome, each of which has been previously reported in association with ASD but are relatively rare [20]. Presenting symptoms were diverse but mostly centered around feeding difficulties in infancy (52%) and repeated respiratory tract infections (60%). These symptoms are often the initial clinical manifestations leading to the diagnosis of ASD, as noted in earlier studies [21]. Notably, 40% of participants presented with failure to gain weight, a symptom that has been less frequently reported but is nonetheless significant [22]. Electrocardiographic findings were consistent across the board, with 100% of participants showing Normal Sinus Rhythm (NSR). This is in line with the general expectation for uncomplicated ASD cases [23]. However, Right Ventricular Hypertrophy was observed in 64% of participants, and Incomplete Right Bundle Branch Block in 58%. These findings are indicative of right heart strain and are often seen in larger defects [24]. Radiological findings were also significant. Cardiomegaly was present in 90% of participants, and a plethoric lung field was observed in an equal percentage. These findings are indicative of right heart volume overload and increased pulmonary blood flow, which are common in ASD [25]. Echocardiographic findings revealed that 44% of participants had Pulmonary Hypertension, a well-documented complication of ASD [26]. The size

distribution of ASDs showed that the majority (54%) had moderate-sized defects (12-30 mm), which is consistent with other studies where moderate-sized ASDs are often symptomatic and hence come to clinical attention [27]. Two methods were employed for defect measurement. Balloon sizing with stop-flow technique was used in 64% of cases, which is in line with current best practices due to its higher accuracy [28]. The immediate outcomes were overwhelmingly positive, with a 96% success rate in device implantation, slightly higher than the 90-95% commonly reported in literature [29]. In terms of follow-up, 100% of the 48 participants with successful device implantation showed no residual shunt and had a normal device position on both Echo and X-ray at all follow-up points. Right Ventricular size normalization was observed to increase over time, from 2.08% immediately post-procedure to 81.25% at the third follow-up (D180). This is a significant finding and aligns with existing literature that suggests significant improvements in cardiac dimensions post-closure [30]. In conclusion, the study provides valuable insights into the immediate and short-term outcomes of percutaneous trans-catheter device closure of ASDs. The findings suggest that this procedure is a viable and effective treatment option, warranting further investigation and broader application.

LIMITATIONS OF THE STUDY

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In conclusion, this study provides valuable insights into the immediate and short-term outcomes of percutaneous trans-catheter ASD device closure in a diverse patient population. The findings underscore the high rate of successful device implantation and the significant improvements in cardiac dimensions and symptoms post-closure. These results are consistent with existing literature and affirm the safety and efficacy of this minimally invasive technique. The study also highlights the importance of comprehensive pre-procedure evaluation, including echocardiography and other imaging modalities, for optimal patient selection and outcome. As percutaneous device closure gains more traction as a first-line treatment option for ASDs, especially in resource-constrained settings, the data from this study can serve as a foundational reference for future research and clinical practice.

FUNDING

No funding sources

CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

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