Addis Ababa University

College of Health Sciences

Department of Internal Medicine

Procedural success rate and its associated factors of transcatheter atrial septal defect device closure among adolescent and adult patients in Ethiopia, 2024

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ACRONYMS AND ABBREVIATIONS

ASD ……..…Atrial septal defect
ASO ……..Amplatzer septal occluder
CCE……Cardiac center Ethiopia
CHD……..Congenital heart disease
CKD……..Chronic kidney disease
Dr……...Doctor
FDA…….…. Food and drug administration
G.C ……Gregorian Calender
IAS……Interatrial septum
IHD……Ischemic Heart Disease
LVEF ……Left ventricular ejection fraction
NYHA.....New York Heart Association
PASP.....Pulmonary artery systolic pressure
QP:Qs .....Pulmonary to systemic flow ratio
Sr. .....Sister
UK ……..United Kingdom
US……United States
USA ……..…..United states of America
WHO ……..…World Health Organization

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ABSTRACT

Background – Atrial septal defect (ASD) is the leading congenital heart disease(CHD) in adults and its prevalence is increasing. Secundum ASD is the most common type of ASD, and it results in different complications if left untreated. Surgery has been the only option to close ASD for several decades. Transcatheter ASD device closure has revolutionized and replaced surgery due to its lower complication rate, avoidance of cardiopulmonary bypass, lower comorbidity, lower cost, avoidance of sternotomy scar and shorter hospital stay. But the efficacy and safety of this noninvasive procedure is not well known in East Africa, including Ethiopia. Therefore, the aim of the study is to assess the success rate and its predictors of transcatheter ASD device closure in Ethiopia.

Method – Institution-based retrospective study was conducted at Cardiac Center Ethiopia(CCE) from May 2024 to December 2024. Consecutive adolescent and adult patients who underwent transcatheter ASD device closure from September 2009 to August 2024 were included. The data on sociodemographic characteristics, clinical factors, comorbidities and procedural variables were collected from patient medical records using a structured data abstraction checklist. The data was analyzed with SPSS version 26.

Result – A total of 71 patients were included in the study. About 80% of the patients were adults whereas the remaining 20% were adolescents and females accounted for 63.4% of the patients. Transcatheter device closure of ASD was successful in 66 of 71 patients (93%). Absence of a prominent eustachian valve was significantly associated with success rate of transcatheter ASD device closure. Device embolization was the most common complication.

Conclusion – Success rate of transcatheter ASD device closure among adolescent and adult patients is effective and safe in Ethiopia. Procedural complications are rare and device embolization is the most common complication. Prominent eustachian valve is an independent predictor of procedural success rate of transcatheter ASD device closure.

Keywords: Atrial septal defect, transcatheter device closure, success rate, Ethiopia

1. INTRODUCTION

1.1 Background

Congenital heart disease is the most common cardiac disorder in children worldwide. The prevalence of congenital heart disease continues to increase globally. Congenital heart disease is also a problem for adults. Atrial septal defect (ASD) is the commonest congenital heart disease in adults. The estimated birth prevalence of ASD is around 1.6 per 1000 live births and the probability of survival to adulthood is 97% (1). It has a female predominance of a 2:1 ratio. There are four types of atrial septal defects. These include secundum ASD, primum ASD, sinus venosus defect and unroofed coronary sinus. Secundum ASD is the most common type in children, adolescents and adults, accounting for 80% of all atral septal defects. Small secundum ASD can close spontaneously during early childhood. But in most patients, spontaneous closure doesn't occur (2-4). Individuals with secundum ASD can be asymptomatic, but the rest will develop heart failure due to right side cardiac chamber volume overload, arrhythmia, infective endocarditis, paradoxical embolism or pulmonary hypertension (4). To prevent these complications, secundum ASD should be closed when indicated. ASD closure results in regression of pulmonary hypertension, reverse of right ventricular remodeling, improved cardiac output, exercise capacity as well as functional status regardless of age at closure (5, 6).

Surgical closure was the standard management and only option of closure for all ASD types for several years. However, for the past few decades, transcatheter device closure has been done for secundum ASD. Transcatheter device closure of ASD is the closure of atrial septal defect and avoidance of shunt by a specially made device through a transvenous catheter. Transcatheter device closure has comparable efficacy with surgical closure (7). Due to its lower complication rate, avoidance of cardiopulmonary bypass, comorbidities, cost, avoidance of sternotomy scar, less adverse psychosocial effect and shorter hospital stay, transcatheter device closure is the preferred method of secundum ASD closure whenever feasible (8, 9).

Many different types of secundum ASD closure devices have been developed since the introduction of the first ASD device closure in 1976 by King and Mills (10). Food and Drug Administration (FDA)- approved atrial septal defect closure devices in the United States (US) include Gore cardioform septal occluder, Amplatzer septal occluder (ASO) and Amplatzer cribriform occluder. ASO is the most commonly used self-centering double disc ASD closure device. There is excellent experience with ASO for a long period of time. These devices have different efficacy and limitations (11). There has been marked improvement and refinement of ASD closure devices over time.

1.2 Statement of Problem

Atrial septal defect is the leading congenital heart disease following bicuspid aortic valve in adults. The prevalence of congenital heart disease, including atrial septal defect, is recently increasing worldwide due to better care and advanced interventions. Secundum type ASD is the commonest atrial septal defect both in children and adults (12). There is still a severe unmet diagnostic need in Africa (13). Morbidity and mortality effects of congenital heart disease, including secundum ASD are not limited only to children, but it is also health problem for adults (1).

In developing countries, including Ethiopia, cardiac surgery is not easily available due to different reasons, including cost, absence of sufficient cardiac surgery centers, presence of limited number of cardiac surgeons and other cardiac team members. Additionally, its lower complications and other benefits mentioned above makes transcatheter device closure the treatment of choice for secundum ASD whenever feasible.

With the revolutionized technology of atrial septal defect closure devices, secundum ASD is effectively closed with reduced complications (11). But still there are a few complications that occur during and after transcatheter secundum ASD device closure, specially in morphologically and hemodynamically complex atrial septal defect. Complications can be major or minor and their frequency varies due to different factors. Device dislodgment and embolization, cerebrovascular event, death, residual shunt, mitral regurgitation, pericardial effusion, clot on the device, cardiac tissue erosion and arrhythmia are among the complications. But data on success rate of percutaneous transcatheter ASD closure is scarce in developing countries, including Ethiopia. And experience on this noninvasive procedure is limited in adults. To the best of our knowledge, there is no study in Ethiopia on success rate and its predictors of percutaneous transcatheter secundum ASD device closure. Therefore, this study aimed to answer this question, and became the first study in the country and the basis for further studies in the area.

1.3 Justification

Transcatheter device closure of ASD has now become the first line and preferred method for secundum ASD closure. Studies showed comparable efficacy with surgical closure but has lower morbidity and mortality. Many of these studies were done in developed countries and in children. But evidence is lacking of this noninvasive procedure in developing countries and in adults.

To the best of our knowledge, there is no study on transcatheter ASD device closure in Ethiopia. So, the aim of this study was to evaluate the success rate of transcatheter device closure of ASD in Ethiopia and to determine its influencing factors. Therefore, this study could fill this gap and become the first trial in the country on percutaneous ASD device closure.

1.4 Literature Review

1.4.1 Success rate of transcatheter ASD device closure

The efficacy and safety of transcatheter secundum ASD device closure has been studied in the past several years. A worldwide study of the efficacy of transcatheter ASD device closure showed an immediate success rate of 97.4% and the success rate increased with time during short term, medium and long term follow-up, respectively (14). A prospective multicenter study done in the US including patients aged from 0.3 years to 83.6 years revealed that transcatheter ASD closure was safe and effective (97.9%) (15).

A prospective multicenter post-approval study on transcatheter closure of ASD was done with good immediate outcome, and it was safe for both adolescents and adults in underdeveloped countries (16, 17). Similarly, the procedural success rate was excellent (98.5%) in Africa even without using multiple devices for multiple defects and without balloon sizing, which was recommended in previous studies (18). On the contrary, a study conducted in Indonesia including both children and adults revealed that the failure rate of transcatheter ASD closure was high (12.5%) (19).

Even though complication rates are low in transcatheter device closure of ASD, there are a few major and minor complications that can occur during and after the procedure. According to the US FDA manufacturer and user facility device experience database, the most common adverse events associated with ASO were device embolization, cardiac perforation, rupture and erosion. Similarly, device embolization was the major adverse event in a prospective study conducted in Pakistan (16, 20).

1.4.2 Associated factors of success rate of transcatheter ASD device closure

1.4.2.1. Sociodemographic factors

Transcatheter ASD closure can be done in a wide range of age groups (21). Functional impairment, right ventricular remodeling and pulmonary artery hypertension increase with age. However, early closure of ASD is still safe and effective with improvement of functional status, right ventricular remodeling as well as pulmonary hypertension in older adults even at more than 75years of age (22). But the degree of improvement in pulmonary hypertension, tricuspid regurgitation and right ventricular remodeling is not marked in older age (5). According to a study done in the United Kingdom(UK), the success rate of transcatheter ASD closure with ASO was high (94%) and major complications were rare in adults, including large ASD up to 38mm (23). A study conducted in Thailand revealed that transcatheter ASD closure can be done safely and effectively for patients older

than 60 years. In these individuals, the decrement in the right ventricular systolic pressure and pulmonary arterial systolic pressure (PASP) was also comparable with younger ones (<60years) (24). Similarly, a study done in Chicago, United States of America (USA), indicated that transcatheter ASD closure was effective and safe in those adults with ≥40 years of age (25).

At the other extreme, the effectiveness of transcatheter ASD closure was studied and found to be effective and safe in children between one and eight years of age. Regarding gender, in most studies conducted, women are more common than men with a F:M ratio of 2:1 (16).

1.4.2.2. Clinical, echocardiographic and procedural factors

Different clinical, echocardiographic and procedural factors affect the outcome of transcatheter ASD closure. According to a study which evaluated echocardiographic predictors for successful transcatheter ASD closure, ASD size and device to defect ratio were significantly associated with transcatheter ASD closure outcome (21). In other studies, rim deficit is an important factor in determining the success of transcatheter ASD closure (16, 19). On the hand, floppiness of interatrial septum (IAS), pulmonary to systemic flow (Qp:Qs) ratio > 3.13 and post-implantation interatrial septal erosion were predictors of atrial septal occluder dislodgement in both children and adults (10, 26, 27).

Deploying a large ASD closure device (>26mm) was not associated with increased complications, radiation dose or length of procedures as compared to smaller devices (<26mm) (23). Similarly, a study comparing small (≤24mm) and large (≥25mm) devices for ASD closure demonstrated similar efficacy, safety and effect in symptom improvement between the two different sizes (28). On the other hand, device size was significantly associated with successful ASD device closure ($p=0.044$) in a study performed in UK. But in the same study patient weight ($p=0.031$), diameter of the defect ($p=0.030$), aortic rim size ($p=0.002$) and device/defect ratio ($p<0.001$) were significantly associated with successful transcatheter ASD device closure. Moreover, the device to defect ratio was found to be a significant predictor of complications of transcatheter ASD closure (26).

1.4.2.3. Comorbidities

Although transcatheter ASD closure is safe and effective in older individuals, comorbidities including hypertension, ischemic heart disease, chronic obstructive airway disease and stroke are the challenges in this group of patients (29). Airway responsiveness is highly prevalent in patients with secundum ASD and complicates evaluation and closure of the ASD (30). Atrial fibrillation can be a complication as well as a predictor of ASD device closure. Atrial fibrillation management is similar to that in non-ASD patients. ASD can be effectively closed in the presence of permanent atrial

fibrillation with attainment of symptomatic improvement as well as reversal of ventricular remodeling (31).

1.5 Conceptual Framework

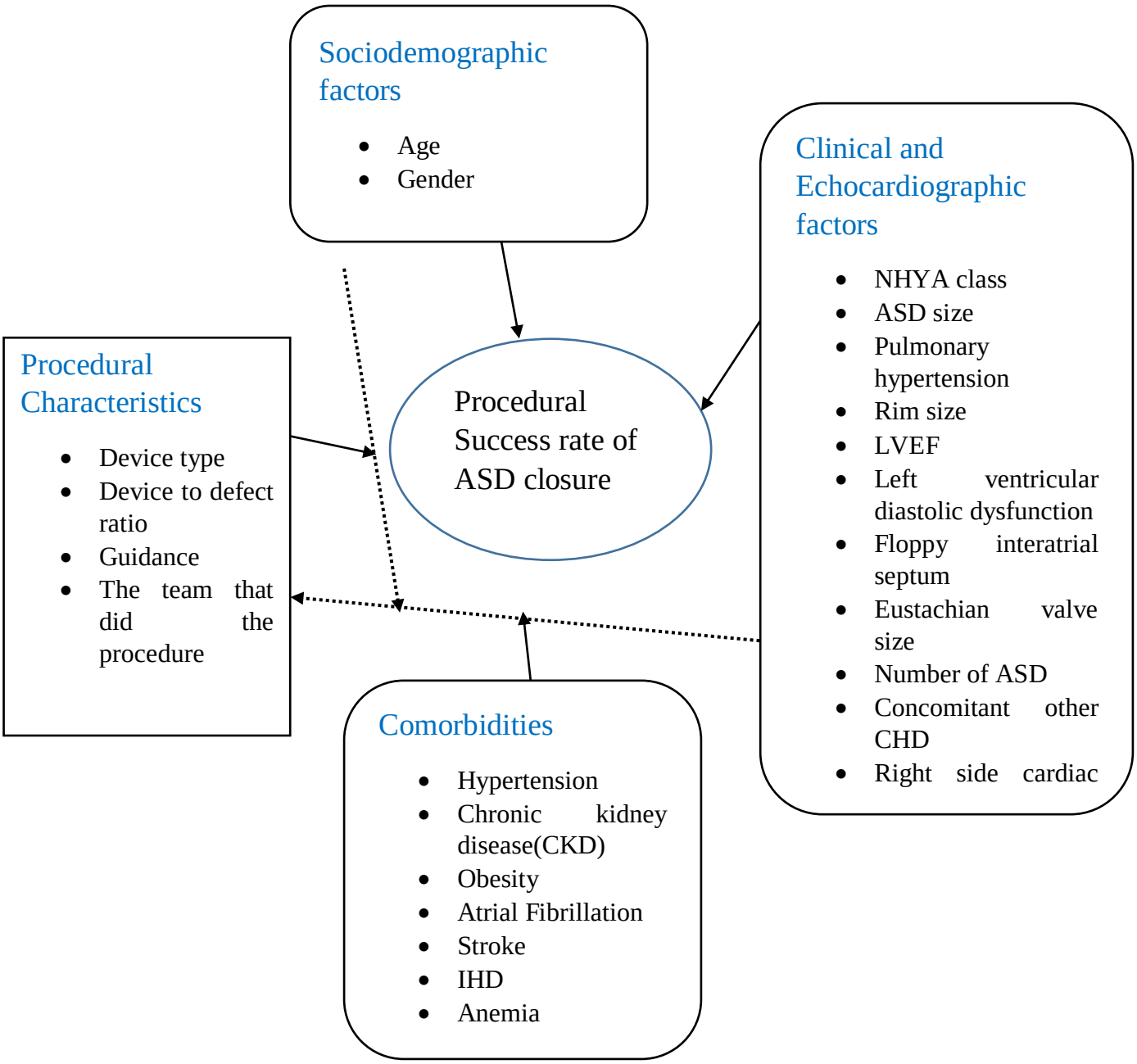

Figure 2:Factors associated with success rate of transcatheter ASD device closure among patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

2. OBJECTIVES

2.1 General Objective

-To assess procedural success rate and its associated factors of transcatheter atrial septal defect device closure among adolescents and adults in Ethiopia, 2024

2.2 Specific Objectives

-To determine procedural success rate of transcatheter atrial septal defect device closure among adolescents and adults in Ethiopia, 2024

-To identify associated factors of procedural success rate of transcatheter atrial septal defect device closure among adolescents and adults in Ethiopia, 2024

3. STUDY METHODS AND MATERIALS

3.1 Study Design, Setting and Study Period

Institution-based retrospective study design was used to assess the procedural success rate of transcatheter ASD closure in adolescent and adult patients. It was conducted at Cardiac Center Ethiopia from May 2024 to December 2024.

Cardiac Center Ethiopia, also called the Children's Heart Fund of Ethiopia, was established in 1989 G.C. It is a nongovernmental and nonprofit making humanitarian cardiac center in Ethiopia. The founder of the center is Dr. Belay Abegaz, is an Ethiopian pediatric cardiologist. Cardiac Center Ethiopia has delivered cardiac services, including cardiac surgery and transcatheter interventions in the past 15 years for patients referred to all over the country.

The service was initially given by missions from different countries of the world, but then after routine scheduled, continuous procedures are being done by local cardiac team including cardiac surgeons, adult and pediatric interventional cardiologists, cardiac anesthesiologists and nurses for more than a decade.

The center has 11 subspecialist doctors, 56 high-level trained nurses and allied health professionals. The center has 15,000 cardiac patients on outpatient follow-up and thousands of patients have undergone surgeries and catheterization laboratory interventions.

3.2 Source Population and Study Population

Source population

All adolescent and adult patients with secundum atrial septal defect at Cardiac Center Ethiopia

Study population

Adolescent and adult patients with secundum atrial septal defect who underwent transcatheter device closure from September 2009 to August 2024 at Cardiac Center Ethiopia

3.3 Inclusion and Exclusion Criteria

3.3.1 Inclusion Criteria

All adolescent and adult patients with secundum atrial septal defect underwent transcatheter device closure at Cardiac Center Ethiopia from September 2009 to August 2024G.C

3.3.2 Exclusion Criteria

Patients whose important information is missed

3.4 Sample Size Determination and Sampling Procedures

Sample size was calculated using single population proportion formula

n= (Z α/2) 2 p (1-p) / d2

Where: -

- ✓ n = is the calculated sample size
- ✓ Z = Confidence interval [95%]
- ✓ p = success rate of 98.5% from a study in Egypt (18)
- ✓ d2 = marginal error [5%]

n = ((1.96) 2 x 0.985 [1-0.985])/ (0.05)2 = 23

Based on this calculation, sample size is 23+10% nonresponse rate = 25. To increase the power of identifying associated factors affecting success rate, all consecutive patients (71) who underwent ASD device closure in the past 15 years were included.

Patients with secundum ASD who underwent transcatheter device closure were extracted from the logbook and the folder was traced from the record office.

3.5 Study Variables

3.5.1 Dependent variable:

- Procedural success rate of transcatheter ASD closure

3.5.2 Independent variables:

- Socio-demographic variables: age and gender
- Clinical and echocardiographic variables: NYHA class, LVEF, left ventricular diastolic dysfunction, ASD size, rim size, pulmonary hypertension, floppiness of IAS, eustachian valve size, number of ASD defects, concomitant other CHD and right side cardiac chamber dilatation
- Procedural variables: device to defect ratio, device type, team that did the procedure and guidance
- Comorbidities : hypertension, CKD, obesity, atrial fibrillation, IHD, stroke and anemia

3.6 Operational definition

Procedural success: Complete occlusion or clinically insignificant residual shunt (<3mm width of color jet) as determined by echocardiogram immediately after the procedure or the next morning

Residual shunt: the flow across the defect after device closure

Moderate ASD size: atrial septal defect of 6-11mm

Large ASD size: atrial septal defect of ≥12mm

Rim deficit : defect rim size <5mm (32)

Floppy IAS: defined as a bulge in the atrial septum, which moves to and fro.

Prominent eustachian valve- as described prominent in echocardiography.

Adolescent: Age group between 10-18 years according to WHO classification.

Adult: Age group is more than 18 years old according to WHO classification.

3.7 Data Collection and Data Entry

A structured data abstraction checklist was prepared by the principal investigator, pretested, and filled out by a trained data collector. The questioner included sociodemographic information (age, gender), clinical and echocardiographic factors (NYHA class, LVEF, left ventricular diastolic dysfunction, ASD size, rim size**,** pulmonary hypertension, number of ASD defect, floppiness of atrial septum, eustachian valve size, concomitant other CHD, right side cardiac chanber dilatation), comorbidities (hypertension, CKD, obesity, atrial fibrillation, stroke, ischemic heart disease and anemia) and procedural factors (device to defect ratio, device type, the team that did the procedure and guidance) from the patient medical record or hospital database.

Then the data was entered using Epi-data and imported to SPSS version 26 and analyzed.

3.8 Data Quality Assurance

Training was given to data collectors and supervisors for two days. And the completeness of the questioner was reviewed by the principal investigator. The standard operating process was followed during data collection, storage and analysis.

3.9 Data Processing and Analysis

Collected data was checked for completeness and consistency and coded manually. The data was analyzed using SPSS version 26. Descriptive analysis was done for the success rate of transcatheter atrial septal defect and associated factors using frequency and percent. Bivariate and multivariate logistic regression were performed to analyze the independent effect of sociodemographic, procedural, clinical and echocardiographic variables on the outcome variable.

All variables with a P-value of less than 0.25 were included in the multivariate analysis. All possible 2-way interactions were checked, and those significant variables were included in the model. The independent variables were fitted into multiple logistic regressions and multicollinearity was checked. The result was presented with odds ratio. The P value of <0.05 was taken as significant. The fitness of the model was tested by the Hosmer Lemeshow Goodness of Fit test, the classification table, and the receiver operator characteristic curve.

4. ETHICAL CONSIDERATIONS

The proposal was submitted to the Department of Internal Medicine, Faculty of Medicine, Addis Ababa University for ethical clearance from the ethical review committee. The proposal got permission to access patients' medical records and a waiver of the requirement for informed consent was granted. The study was conducted after research ethical approval was obtained. A permission letter was obtained from the Cardiac Center Ethiopia administration. Confidentiality of participants was kept by assigning codes rather than writing their name or other personal identifiers.

5. RESULT

5.1 Sociodemographic characteristics of participants

A total of 71 participants were included in this study. More than 80% of patients were adults, whereas the remaining 20% were adolescents. Two thirds of the patients were in the age group between 19-40 years and all the patients were 60 years old and below. Females accounted for 63.4% of the participants (Table 1).

Table 4: Sociodemographic characteristics of patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

Variable	Category	Frequency	Percent
Age	10-18 years	14	19.7
	19-40 years	47	66.2
	41-60 years	10	14.1
	>60 years	0	0
Sex	Male	26	36.6
	Female	45	63.4

Table 5: Clinical and echocardiographic characteristics of patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

Variable	Category	Frequency	Percent
NHYA Class	Class I	1	1.4
	Class II	42	59.2
	Class III	28	39.4
	Class IV	0	0.0
Size of ASD	Small	0	0.0
	Moderate	3	4.2
	Large	68	95.8
ASD defect number	Single defect	65	91.5
	Multifenestrated	6	8.5
Pulmonary artery systolic pressure	<50mmHg	55	77.5
	≥50mmHg	16	22.5
Dilated right side cardiac chambers	Yes	65	91.5
	No	6	8.5
Left Ventricular ejection fraction	≥50%	69	97.2
	<50%	2	2.8
Left ventricular diastolic dysfunction	Yes	5	7.0
	No	66	93.0
Floppy Interatrial septum	Yes	17	23.9
	No	54	76.1
At least one rim deficit	Yes	33	46.5
	No	38	53.5
Prominent Eustachian valve	Yes	8	11.3
	No	63	88.7
Other concomitant congenital heart disease	Yes	8	11.3
	No	63	88.7

5.2 Clinical and Echocardiographic characteristics of participants

Regarding clinical characteristics of participants, most participants had NYHA class II HF and a large ASD size was found in 95.8% of the participants. More than ninety percent of participants had only a single ASD defect and a similar percent of participants developed dilated right side cardiac chambers. At least one ASD rim deficit was found in a significant number of patients and isolated retro-aortic rim deficit was the most common, accounting for 93.9% of all rim deficits. Eustachian valve was prominent in 11.3% of the patients and a similar percent of the participants had other concomitant congenital heart disease (Table 2).

Table 3: Procedural characteristics of patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

Variable	Category	Frequency	Percent
Occluder Device type	Amplatzer	65	91.5
	Other device types	6	8.5
Device to defect ratio	<1.125	30	42.3
	1.125-1.333	36	50.7
	>1.333	5	7.0
Guidance for the procedure	TTE guided	57	80.3
	TEE guided	14	19.7
The team that did the procedure	Local Team	58	81.7
	Mission Team	13	18.3

5.3 Procedural Characteristics and Comorbidities

Nearly eighty percent of ASD device closure procedures were done with TTE guidance in addition to fluoroscopy and in a similar percent of patients, ASD closure was performed by a local team. Amplatzer septal occluder was the commonest ASD occluder device used in 91.5% of procedures. Among the remaining six devices, LifeTech Ceraflex TM ASD Occluder was used in 5 of the procedures whereas Cocoon Septal Occluder was implanted in one of the patients. In half of the patients, device-to-defect ratio was between 1.125 and 1.333 (Table 3).

5.4 Success rate of ASD device closure and associated factors

The procedural success rate of transcatheter secundum ASD device closure was 93% (66 of 71 patients). Device closure was not successful in 5 patients. Device embolization occurred in 3 patients. In two of the patients, the device was retrieved percutaneously, whereas in the other patient surgery was required for device retrieval. There was significant access site bleeding and hematoma in one of the patients and the patient was transfused multiple bags of whole blood and the procedure was aborted. The same patient also developed pericardial effusion without tamponade effect.

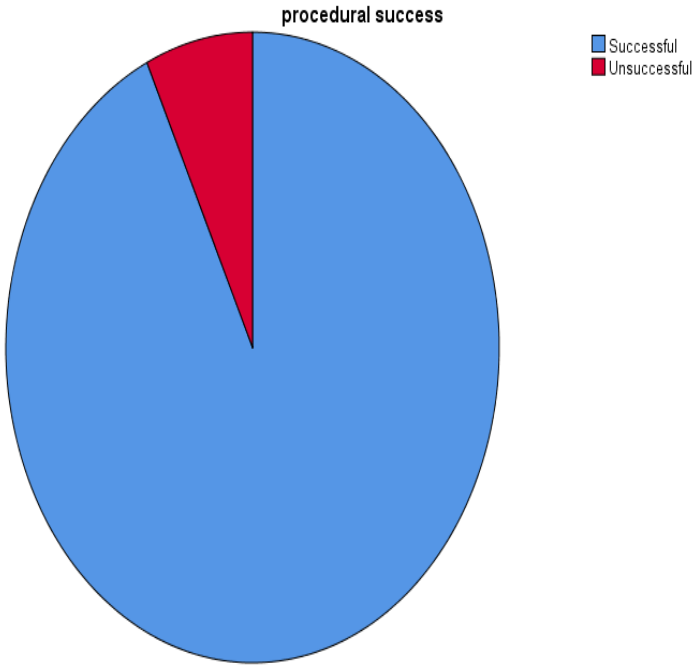

Figure 3:Success rate of transcatheter ASD device closure among patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

Statistical analysis was done with SPSS version 26. Binary logistic regression was performed to determine the effect of independent variables on the outcome variable. Those variables with a P valve less than 0.25 were included in the multivariate analysis. Right side chamber dilatation, eustachian valve size and concomitant other congenital heart disease were the factors which had p valve of less than 0.25 and were included in the multivariate analysis. Age and sex were not important predictors of the success rate of ASD device closure. Regarding clinical and echocardiographic variables, NYHA class, pulmonary hypertension, size of ASD, floppiness of interatrial septum or rim deficit were not important predictors of the outcome variable. Right-side chamber size and the presence of other congenital heart valves were not predictors of the success rate of ASD device closure, with P valve of 0.19 and 0.62 respectively on multivariate analysis.

But the absence of a prominent eustachian valve significantly affected the success rate of transcatheter ASD device closure with an AOR of 4.53 (CI=2.23,6.37 P=0.005. Procedural factors including ASD occluder type, device to defect ratio and procedural guidance were not significant factors affecting the outcome variable. The effect of comorbidities on success rate was not analyzed due to rare risk occurrence (Table 4).

Table 6:Bivariate and multivariate analysis of factors affecting success rate of transcatheter ASD device closure among patients undergoing transcatheter ASD device closure in Ethiopia between September 2009 to August 2024 (N=71)

Variable	Category	Successful		COR (95%CI)	P value	AOR (95%CI)	P valve
		Yes N (%)	No N(%)				
Sex	Male	24(36.4)	2(40)				
	Female	42(63.6)	3(60)	1.17(0.18,7.48	0.87		
Number of defects	Single	61(92.4)	4(80)				
	Multi fenestrated	5(7.6)	1(20)	0.33(0.03,3.52)	0.36		
Pulmonary artery systolic pressure	<50mmHg	51(77.3)	4(80)				
	≥50mmHg	15(22.7)	1(20)	0.85(0.09,8.19)	0.89		
Dilated right side cardiac chambers	Yes	62(93.9)	3(60)				
	No	4(6.1)	2(40)	10.33(1.32,80.68)	0.03	7.95(0.39,16.27)	0.19
Floppy interatrial septum	Yes	15(22.7)	2(40				
	No	51(77.3)	3(60)	2.27(0.35,14.85)	0.39		
Rim deficit	Yes	31(47)	3(60)				
	No	35(53)	2(40)	1.33(0.21,8.48)	0.76		
Prominent e eustachian valve	Yes	4(6.1)	4(80)				
	No	62(93.9)	1(20)	6.2(5.55, 6.93)	0.001	4.53(2.23,6.37)	0.005
Other congenital heart disease	Yes	6 (9.1)	2(40)				
	No	60(90.9)	3(60)	6.67(0.92,48.1)	0.06	2.06(0.12, 35.5)	0.62
Guidance of the procedure	TTE	53(80.3)	4(80)				
	TEE	13(19.7)	1(20)	0.98(0.1,9.53)	0.99		

6. DISCUSSION

This study showed that transcatheter ASD device closure was effective and safe. And the complication rate of the procedure was only 7%. Many of the factors identified in the study did not affect the success rate. But the prominent eustachian valve was the most important predictor of procedural success rate.

Supporting this study, in most of the previous studies, ASD device closure was effective with a success rate of more than 97%. In a prospective multicenter study conducted in 50 USA sites, the success rate of ASD device closure was 97.9%, which is comparable to this study (15). The ASD device was also successfully implanted in 93% of the procedures in the study done in London, UK (23). Similarly, the success rate was 98.5% from a retrospective cohort study conducted at two centers in Egypt (18). On the contrary to the above trials and this study, the procedural failure rate of ASD device closure was unacceptably high (12.5%) in a study performed in Denpasar, Indonesia (19).

In many of the studies done previously, different predictors that affect the success rate of transcatheter ASD device closure were identified. Regarding sociodemographic factors, patient's age was not associated with success rate in a retrospective analysis of 69 patients in London, UK. The finding is consistent with this study in which the success rate was similar between adolescent and adult patients. A study in Japan also supports this study that the success rate was similar in older patients even more than 75 years, as compared to younger patients (22, 25, 29). Considering clinical and echocardiographic factors, defect size, device size, device to defect ratio and aortic rim size were important factors affecting the success rate (26). On the other hand, rim size and atrial dimension were not predictors of ASD device closure success and ASD size was the only predictor of the success rate in a study conducted in Boston, USA (21). On the contrary, ASD size was not associated with the success rate of ASD device closure based on a single center prospective registry in Switzerland (28). This finding is in favor of this study.

7. LIMITATION OF THE STUDY

This study has a number of limitations. First, the study was a retrospective study and there were patients excluded due to missing important information. Second, in this study, immediate procedural outcome was evaluated but short or long-term clinical outcomes were not assessed.

8. CONCLUSION AND RECOMMENDATION

Transcatheter atrial septal defect device closure was safe and effective. Prominent eustachian valve was an important predictor of the success rate. Detailed echocardiographic evaluation including the size of the eustachian valve is recommended before ASD device closure.

Further studies on ASD device closure with prospective study design to evaluate short and long term clinical outcomes are recommended.

9. ANNEXES

Annex I: Questionnaire - Questionnaire to assess the procedural success rate and its associated factors of transcatheter atrial septal defect device closure in adolescents and adults in Ethiopia, 2024

1- Sociodemographic profile							
101	Card number						
102	Age in years	A. 10-18 years B. 19-40 years C. 40-60 years D. >60 years					
103	Gender	A. Male B. Female					
2- Clinical and echocardiographic factors							
201	NHYA Class	.I II III IV					
202	ASD size	A. Small B. Moderate C. Large					
203	Number of ASD defects	A. Single B. Multiple					
204	PASP	A. <50mmHg B. ≥50mmHg					
205	Rt chambers dilated	A. Yes B. No					
206	Left ventricular ejection fraction	A. <50% B. ≥50%					
207	Left ventricular Diastolic dysfunction	A. Yes B. No					
208	Floppy IAS	A. Yes B. No					
209	Rim size		RA	AV	SVC	IVC	Posterior
		Deficient					
		Adequate					
210	Prominent eustachian	A. Yes					

	valve	B. No
211	Other concomitant congenital disease	A. Yes B. No
3.Procedural Factors		
301	Device type	A. Amplatzer septal occluder B. Other than ASO
302	Device to defect ratio	A. <1.125 B. 1.125-1.333 C. >1.333
303	Guidance	A. TTE guided B. TEE guided
304	The team that did the procedure	A. Local team B. Mission Team
305	Successful procedure	A. Yes B. No

4 -Complications		
401	Is there complication	A. Yes B. No
402	If yes to No. 401, which complication occurred	A. Pericardial effusion without tamponade B. Pericardial effusion with tamponade C. Heart Block D. Cerebrovascular events E. Device embolization retrieved percutaneously F. Device embolization requiring surgery G. Access site hematoma H. Access site bleeding requiring transfusion I. Others
	5. Comorbidity	
501	Hypertension	A. Yes B. No
502	Chronic Kidney Disease	A. Yes B. No
503	Obesity	A. Yes B. No
504	Atrial Fibrillation	A. Yes B. No
505	Stroke	A. Yes B. No
506	Ischemic heart disease	A. Yes B. No
507	Anemia	A. Yes B. No

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