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EARLY AND MIDTERM OUTCOME OF TRANS CATHETER DEVICE CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT-SINGLE CENTER EXPERIENCE

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ABSTRACT

Trans-catheter atrial septal defect (ASD) closure is becoming mainstay of therapy for secundum type ASD for the past few decades. **Aims:** This research evaluated the early and mid-term outcome of trans-catheter device closure for secundum atrial septal defect. **Methods:** Retrospective single center study from January 1997 to December 2019. All patients who underwent trans-catheter closure of secundum atrial septal defect during the study period were included. Those patients with incomplete data were excluded. The Patients files were checked, Gender, age at intervention, defect size, procedure duration, and early and midterm follow-up results were collected, All statistical analysis tests were performed using IBM SPSS version 25 (IBM crop, Armonk, N.Y.). **Results**: A total of 385 patients were included, 44% males; median age: 8 years (3-65), 77.7% children less than 18 years age, mean ASD defect diameter as measured by Trans Esophageal Echocardiography (TEE) was 16.2 ± 6 mm. Successful closure of ASD was achieved in all patients. *Early complication*: device embolized in 2 patients after 24 hour, 29 patients had small residual shunt ,8 of them closed within 2 years follow up, two patients have pericardial effusion Twelve (3.1%) patients had mitral valve regurgitation (MR) before ASD device closure. After a median 4 years follow-up, 9 (2.3%) patients had no change in severity of MR (mild plus to moderate MR), 3 patient improved from moderate to mild MR. Six (1.6%) patients had moderate tricuspid regurgitation (TR) pre-procedure and at the last follow-up 2 (0.5) patients improved to mild TR. *Late complication*: one patient has device embolization after 18 months, one patient has atrial fibrillation No death, cardiac erosion, decreased left ventricular function or thromboembolism recorded. **Conclusion**: Trans catheter closure of secundum atrial septal defect is safe in children and adults. It has a favorable early and mid-term outcome in our study, especially no death or major complications. Regular follow up for monitoring complication is crucial

KEYWORDS: Atrial septal defect, Trans-catheter device closure, Device embolization, arrhythmia, Congenital heart defects.

INTRODUCTION

Atrial septal defect (ASD) is second common congenital heart disease with birth prevalence of 2.9/1000. ASD secundum type (ASDII) has prevalence of 1.64 /1000 live births.[1] and accounting 18% of congenital heart disease in Saudi Arabia.[2]

Moderate to large atrial septal defect increases right ventricular volume, through left to right shunt, necessitating closure either by open heart surgery or trans-catheter device occluder.[3]

Trans catheter device stands as an alternative option to surgical closure as it avoids cardiopulmonary bypass, shortening hospital stay, as well as is cost effective.[4,5,6] First case of ASD device closure was performed in 1976 by King and Mills, nowadays 85-90% of cases can be closed by device in suitable patients.[8,9] Safety and outcome of trans catheter ASD closure has been reported

in both pediatric and adult patients 4 In this study we report early and midterm outcomes of ASD device closure in on our institution from 1997 to 2019.

METHODS

Study design and patient population

This is a retrospective review of all patients diagnosed with ASDII who underwent percutaneous ASD device closure at our institution from January 1997 to December 2019.

Those patients with incomplete records were excluded from the study. Demographic data, clinical presentations, echocardiographic characteristics, hemodynamics, intra-procedural data and pre discharge in-hospital events were collected. The intervention was performed in a total of 475 patients during the study period. After thorough medical records review, 90 cases were excluded from the study due to incomplete record. Three hundred eighty-five (385) patients were included in the analysis. The study has been approved by our institution's Research Ethics Committee (approval no. IR19014).

Study outcomes

Events were a composite endpoint of: (1) embolization (2) arrhythmia (3) pericardial effusion (4) major procedure related complications like bleeding, embolism (5) residual ASD shunt (6) impaired ventricular function (7) aortic erosion 8) surgical device retrieval and redo closure.

Device and Procedure

The procedure of percutaneous device closure of ASD was performed under general anesthesia and Trans Esophageal Echocardiography (TEE) guidance. ASD size was determined by TEE or intracardiac echocardiography (ICE). Sizing for the device was performed by balloon 128 sizing in some patients. The devices used were Amplatzer septal occluder (ASO), Multifenestrated Septal Occluder (Cribriform) and Occlutech ASD occluder. Amplatzer ASO is a nitinol device intended for secundum ASD. Cribriform is a self-expanding double-disc nitinol mesh occlusion device. Occlutech ASD occluder is a titanium oxide-covered nitinol with a unique ball-connection between pusher and occlude for safer locking.

Procedural success was defined as successful implantation of transcatheter closure device in proper position, without embolization and free from re-intervention at 30 days.

Follow-up

Patients were follow-up at the pediatric cardiac OPD clinic at 6 weeks, 6 months, and annually.

Statistical Analysis

Descriptive statistics were used to illustrate the population. Categorical variables were expressed as frequencies and percentages. Continuous variables as means ± standard deviation or median with the 25^{th} – 75^{th} percentile as applicable. Normality distribution was assessed by shapiro-wilk test. Changes in pre-procedure and post procedure atrioventricular valve regurgitation was assessed by Friedman's test being ordinal data. Kaplan-Meier method was used for time to event analysis. All statistical analysis test was performed using IBM SPSS version 25 (IBM crop, Armonk, N.Y.).

RESULTS

Patients Characteristics

The median age of patients was 8 years at the time of procedure (range: 3-65 years), 299 (77.7%) were of pediatric age group (<18 years old) and 86 (22.3%) were adult (≥18 years old). Patients' characteristics are summarized in table 1.

Table 1: Demographic and clinical characteristics of ASD patients for percutaneous closure.

Variable	n = 385 / Value
Age, years	8 (6, 15)
Gender	
Female	226 (58.7)
Male	158 (44.1)
Weight, Kg	24 (17.5, 52.8)
Clinical presentation	
Asymptomatic	214 (55.6)
Palpitation	31 (13.2)
Shortness of breath	20 (5.2)
Shortness of breath and palpitation	6 (1.6)
Chest pain	3 (0.8)
Transient ischemic attack	1 (0.3)
Multiple atrial septal defects	15 (3.9)
Two ASD	13 (3.4)
Three ASD	2 (0.5)
Deficient rim	78 (20.3)
Aortic rim	53 (13.8)
Pulmonary vein rim	3 (0.8)
IVC rim	8 (2.1)
SVC rim	10 (2.6)
Aortic and SVC rim	4 (1.0)
Fenestrated septum	6 (1.6)

Table 2: Associated Cardiac Anomalies.

Cardiac Anomaly	Counts (%)
Congenitally corrected transposition of the great arteries	1 (0.3)
Chari mal formation	1 (0.3)
Ebstein's anomaly	2 (0.5)
Left superior vena cava	1 (0.3)
Mitral Valve Prolapse	6 (1.6)
Partial anomalous pulmonary venous drainage	5 (1.0)
Patent Ductus Arteriosus	8 (2.1)
Pulmonary Stenosis	21 (5.5)
RHD	8 (2.1)
Ventricular Septal Defect	1 (0.3)

Changes in mitral valve and tricuspid valve regurgitation after procedure:
Twelve (3.1%) patients had mild to moderate mitral valve regurgitation before ASD closure device. After a median 4 years' follow-up 9 (2.3%) patients had no change in severity, 2 (0.5%) patients worsened (became moderate MR) and 1 (0.3) patient improved from moderate MR to mild MR.

Six (1.6%) patients had moderate tricuspid regurgitation pre-procedure and at the last follow-up 2 (0.5) patients improved to mild TR.

Periprocedural data and early events
Mean defect diameter as measured by trans esophageal echocardiography 16.2 ± 6 mm. ICE was used in 16 (4.2%) patients and mean defect diameter was 20.7 ± 9.2 mm.

Closure of ASD was achieved in all patients. Procedural success was achieved in 99.5% of the patients.
Two (0.5%) patients had device embolization after 24 hours. Both patients went for retrieval in cath lab, then surgical ASD closure.

There was no in-hospital mortality and no major cardiac or cerebrovascular complications post-percutaneous ASD closure.

Table 3: Periprocedural characteristics.

Variable	Value
ASD diameter by TEE, mm (n=368)	16.2 ± 6
ASD diameter by ICE, mm (n=16)	20.7 ± 9.2
Large ASD (≥30 mm)	13 (3.8)
ASD balloon sizing, mm (n=126)	19.4 ± 6.3
Hemodynamics	
Qp / Qs ratio	2.1 ± 0.5
Systolic PAP	25.7 ± 6.4
Diastolic PAP	11.2 ± 3.5
Mean pulmonary artery pressure, mmHg	16.8 ± 4.3
LVEDP measured	51 (13.2)
LVEDP, mmHg	10.7 ± 2.6
Devices	
Amplatzer ASO	321 (83.4)
Amplatzer Cribriform	7 (1.8)
Occlutech ASD occluder	57 (14.8)
Device implanted size ≥30 mm	29 (7.5)
Concomitant procedure	
PS ballooning	4 (1)
PDA closure	2 (0.5)
VSD closure	1 (0.3)
In-hospital event	
Embolization	2 (0.5)
Arrhythmias	1 (0.3)
Pericardial effusion	2 (0.5)
Major bleeding thrombosis	0
Impaired ventricular function	0
Residual shunt	29 (7.5)

Values are presented as mean ± standard deviation or cou nts and percentages
ASD atrial septal defect; TEE transesophageal echocardiography; ICE intracardiac echography.
Qp/Qs; pulmonary to systemic blood flow ratio; LVEDP left ventricular end diastolic pressure
ASO atrial septal occlude, PS pulmonary stenosis, PDA patent ductus arteriosus,
VSD ventricular septal defect,
PAP pulmonary artery pressure

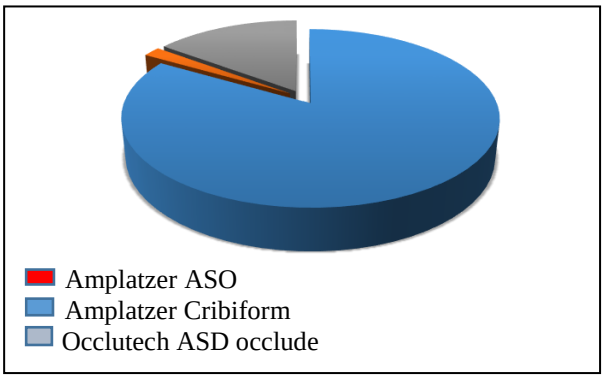

Figure 1: Type of device used in percutaneous closure.

Follow Up and Late events
All patients had clinical follow-up at our pediatric cardiology outpatient clinic and had TTE and 12 lead ECG on each visit. Median clinic follow-up was 4 years (2, 8 years); the range was 1 year to 20 years. Mean survival time was 18 [95% CI (17.7, 18.8)] years.

Freedom from any event (embolization, ASD re-intervention, arrhythmia, pericardial effusion, bleeding and residual shunt) at 18 years was 91 ± 1.4 %.

One (0.3%) patient had late embolization, 18 months after ASD device closure which was successfully removed by surgery and had surgical ASD closure. One (0.3%) patient had arrhythmia at 6 weeks follow- up.

Twenty-nine patients had small residual shunts at the time of discharge after the procedure. Among them, 8 (2.1%) of patients had spontaneous shunt closure at follow-up (2 patients 6 weeks after procedure, 3 patients after 6 months, 2 patients after 1 year, 1 patient after 2 years).

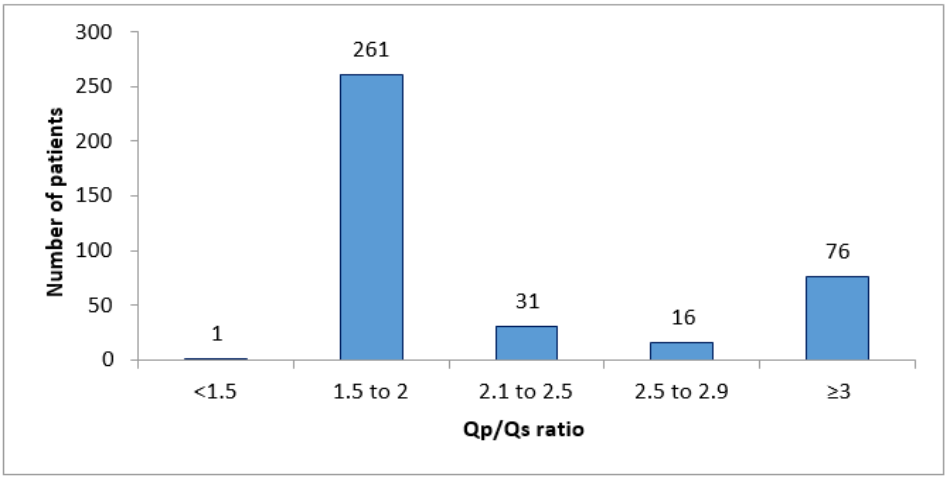

Figure 2: Pulmonary to systemic blood flow ratio.

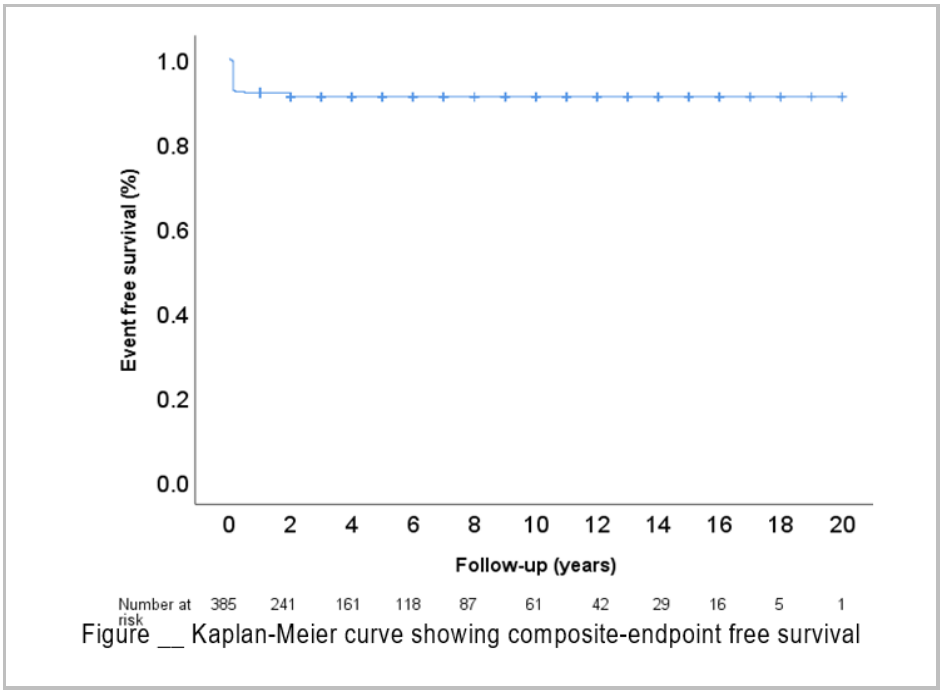

Figure __ Kaplan-Meier curve showing composite-endpoint free survival

Composite endpoint free survival probabilities

Number at risk	Time	Number of events	Survival estimate ± standard error
354	6 months	29	92.4 ± 1.4
353	1 year	30	92.2 ± 1.4
291	2 year	34	91.0 ± 1.5
No more events reported	—	—	—

Cumulative Incidence of events

Events	6 weeks	6 months	1 year	2 years
Residual Shunt	27 (7.0)	25 (6.5)	23 (6.0%)	20 (5.2)
Arrhythmia	0	1 (0.3)	0	3 (0.8)
Embolization	0	0	0	1 (0.3)

DISCUSSION

In 1976 Mills and King succeed to treat five patients of atrial septal defect using trans-catheter device. They closed the defect using double umbrella device.[7]

In the last decade trans-catheter device closure became an alternative for surgical treatment for ASDII (4) Trans-catheter ASD device closure has been used safely in our center since 1997.

Our study is aimed at looking for early and mid-term outcome after the procedure Early and late complications of ASD device closure are not very common.

One meta-analysis by Abaci in 1923 looking for co-morbidities and mortalities involving 28142 patients from 203 studies, they found mortalities 0.01 % and co-morbidity 0.1%. This is also reflected in our study as we have no mortalities, also we are looking for morbidities in form of aortic erosion, arrhythmia, bleeding and thrombosis, precordial effusion, device embolization, transient ischemic attack and atrioventricular regurgitation or decreased left ventricular systolic function.[10]

Our study shows no patients developed erosion thrombosis or decreased left ventricular systolic function.

Device embolization occurred in three patients, first one 6 years old girl her weight is 15.9 kg, TEE showed ASD size of 15 mm, deficient aortic rim QP: QS was 2.4:1.The TTE after 24 hours from successful procedure showed device in RA, so device snared in cath lab but unfortunately there was a mitral valve tear which needed repair, therefore she underwent surgical ASD closure as well as MV repair. Patient was discharged in good condition with mild mitral regurgitation on the last follow-up.

Second one is 3 years' boy weighing 15 kg has pulmonary valvuloplasty at age of 2 months. ASD was 14 mm, Flimsy IVC rim closed by Amplatzer size 14 mm. After 24 hours' echocardiography showed device in transverse aortic arch, so device snared in cath lab and ASD closed later by device at 6 years age. During follow-up no complication.

Third one is 47 years old female patient had two atrial septal defects 18 and 13mm with aneurismal atrial septum, so these defects were closed by two devices Amplatzer 14 and 18 mm adjacent to each other. On the 6 months follow up, the small device noticed to be protruding in the LA, then after one year it took a perpendicular shape on the bigger one so patient was admitted and devices removed surgically. ASD closed with no complication.

Device embolization is a well-known complication after ASD device closure.
Levi DS reviewed 3824 patients after ASD device closure and found that 21 patients developed device embolization.[11]

Their claim was deficient rim and under sizing of the defect. In our study one patient has deficient aortic rim and the other has flimsy IVC rim. This patient had embolization due to technical problem of hypermobile aneurysmal septum, which made the device unstable in the course of time, ending with protruding in to left atrium.

Also, two of our patients their weight is 15 kg which is mentioned as risk factor for device complications.[12]
We have two patients has atrial Arrhythmia: the first one is 45 years old male develops brief atrial fibrillation after procedure; he was observed for 24 hours no more arrhythmia during follow-up.

The second one is 28 years old developed atrial fibrillation after 6 weeks started on amiodarone for 6 months. During follow up for two years no more arrhythmia.

Arrhythmia mentioned as complication of ASD device closure usually transient less than 1%.[13]

Tariq Abu Tair Reviewed arrhythmia in children post ASD device closure, out of 161 patients, 4 (1.9%) of them have atrial arrhythmia.[14]

Jonathan et.al studied 610 patients post ASD device closure, 22 of them developed atrial fibrillation and 7 developed atrial flutter.[15]

In our study there is no complete heart block and atrial fibrillation in adult patients as in our study there are adult as well as pediatric patients.

ASD device closure is used in patients with stroke and ASD. It proves that decrease recurrence of stroke as studied by Sonergaard et al et al. They compared atrial shunt closures or with anti-platelet therapy alone. Recurrent stroke was 1.4 Vs 5.4 % respectively. Another study documented that ASD closure decreases recurrence of TIA but increases risk of new atrial arrhythmia (flutter, fibrillation).[17]

We have a patient, 27 years old with small ASD and TIA, hemodynamic QP: QS 1:1. The ASD closed successfully with the device and during follow-up of two years no more stroke, and no more arrhythmia reported.

Residual shunts after ASD device closure are well known in literature. BURCU studied 179 patients post ASD device closure, 8 % of their patients had small residual on the first day and decreased to 3 % at month follow up.[18]

Another study Cohort reported 16% of residual in the first day decreased to 2.7 % after the first year follow up.[19] In our study 29 patients (7.5 %) had small residual ASD, 8 of them (2.5 %) were found to have been closed spontaneously within two years follow up.

Tricuspid valve regurgitation (TR) is commonly found in patients with large ASD secundom .TR post ASD device closure evaluated by Fang et.al (20), they reviewed 46 patients with TR post ASD device closure, in 31 (48%) patients there was decrease in TR. In our study 6 patients have moderate TR pre-procedure, two of them TR decreased to mild, four of them TR same in degree. TR is

functional sometime due to valve abnormality one patient with CCTGA with moderate TR.

Mitral valve regurgitation after ASD device closure giving different results most of them improved due to restoration of abnormal ventricular septal configuration, but some deteriorate due to unclear mechanism, and some stay static degree.[21]

Welson et.al reviewed 194 patients for 1.2 years post ASD device closure, 88 MR same, 10 % increase and 7 %.[22]

In our study 12 patients had moderate MR, 9 of them MR stay as it is, two patients get worse, and one patient improved as in our data mitral valve regurgitation is not only functional, but it could be due to another mechanism such mitral valve prolapse.

Finding pericardial effusion on TTE after the ASD device closure is always a point of concern. This was also observed by Dailer R. Turner study of 1000 patients, only one developed pericardial effusion related to procedure treated conservatively.

In our study two patients were reported to have developed mild pericardial effusion at 24 hours TTE post ASD device. Both were observed conservatively for two days and discharged in clinically stable condition. Their follow up TTE at 6 weeks confirmed complete resolution of pericardial effusion.

The results of our study are very encouraging about the rate of immediate success after the procedure, similar to the description of Rastogi, N., Smeeton, N.C. & Qureshi, Shakeel. Ahmed.[23] The Our study shows a high immediate success rate after the procedure, aligning with findings from Rastogi, N., Smeeton, N.C., and Qureshi, Shakeel. A.[23]

Limitation

It is a retrospective single center study. We had to exclude 90 patients from data analysis due to incomplete information which might have affected the outcome of study.

CONCLUSION

The trans-catheter closure of ASD using devices is safe and has good outcome, patients should be educated for risk of atrial fibrillation even after the procedure.

Device embolization can occur even after a few years therefore a regular clinic follow up is advisable for as long as logistically possible for the patient.

Conflict of interest

All authors had no conflict of interest. This research did not receive any financial support

Ethical approval

Ethical approval for this study was approved by the ethical approval committee in PSCC research department, Approval number R19014

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Abbreviations

CHD: Congenital Heart Disease
ASD: Atrial septal defect
TTE: Transthoracic Echocardiography
TEE: Transesophageal echocardiography
ICE: Intracardiac echocardiography
ECG: Electrocardiogram
RHD: Rheumatic Heart Disease
IVC: Inferior vena cava
SVC: Superior Vena Cava
MR: Mitral valve regurgitation
TR: Tricuspid valve regurgitation
MVP: Mitral Valve Prolapse
Cath Lab: Catheterization laboratory

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