Device Closure of Atrial Septal Defect in Patients of Age More than 40 Years: Immediate and Intermediate Out Come

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Abstract

Background: Transcatheter closure of atrial septal defect (ASD) is an established procedure in children and young adults, but the benefit of this procedure in older patients is still controversial. This study was performed to evaluate the immediate and intermediate outcome of transcatheter closure of ASD in patients over 40 years of age.

Materials and Methods: Between January 2009 and March 2013, 23 consecutive patients aged more than 40 years treated with percutaneous closure of ASD were evaluated. Statistical analysis was performed using Statistical Package for the Social Sciences version 16 to detect significance by applying paired *t*-test.

Results: Mean age at procedure was 46.56 ± 6.66 years (range: 40-58 years). Majority of them were having New York Heart Association (NYHA) functional Class II symptoms (2 in NYHA III) before the closure of ASD, and mean ASD diameter was 21.6 ± 4.26 mm (range 14-30 mm). ASD closure was successfully performed in all 23 patients without any major complications. During the follow-up period of 16.19 ± 5.69 months (3-23 months), there was an improvement in NYHA functional class in all patients. Right ventricular end-diastolic dimension (RVEDD) decreased from 25.52 ± 4.56 mm to 15.14 ± 5.1 mm, left ventricular end diastolic dimension (LVEDD) increased from 38.52 ± 5.96 mm to 42.6 ± 4.04 mm, RVEDD/LVEDD from 0.68 ± 0.17 to 0.36 ± 0.10 . There was a fall in systolic pulmonary artery systolic pressure from 48 ± 14.79 mmHg to 31.13 ± 12.73 mmHg (P < 0.05). There was a decrease in tricuspid regurgitation in 19 of 21 patients and improvement in mitral regurgitation in 2 patients.

Conclusion: Transcatheter closure of ASD in patients aged more than 40 years is safe and causes significant improvement of NYHA functional class and positive cardiac remodeling. An long-term follow-up is necessary for the detection of the occurrence of arrhythmia and RV dysfunction.

Key words: Atrial septal defect, Congenital heart defects, Patients

INTRODUCTION

Atrial septal defects (ASD) account for 25-30% of newly diagnosed congenital heart defects in adults.¹ The



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left-to-right shunt through an ASD results in chronic volume overload of the right heart and, if untreated, may lead to atrial arrhythmias, right heart failure, pulmonary hypertension (HTN) (PH) and/or systemic embolism,² atrioventricular (AV) valve regurgitation.³ Increased arterial stiffness,⁴ may cause acute congestive heart failure after ASD closure.⁵ Although some patients are asymptomatic or mildly symptomatic, they may have significant reduction in cardiopulmonary function during formal exercise testing.⁶⁻⁸ Left ventricular (LV) diastolic dysfunction, which is also seen as part of normal aging and frequently occurs in

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elderly individuals with HTN will further increase the atrial shunt. Hence, ASD closure has become an established therapy, being performed increasingly in adult patients. There are conflicting reports, however, that ASD closure alone is sometimes insufficient for the improvement of symptoms and heart failure in older individuals. Available literature of outcome on ASD device closure in adults is from the Western population, with no reported studies with respect to the immediate, intermediate and long-term outcome from the Indian population, to the best of our knowledge. Hence, this study was undertaken to know the immediate and short-term outcome of transcatheter closure of ASD in terms of improvement in New York Heart Association (NYHA) functional class and echocardiographic parameters.

MATERIALS AND METHODS

We studied 23 consecutive patients aged more than 40 years who underwent device closure of ostium secundum ASD at Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bangalore, between January 2009 and April 2013. The study was approved by the institutional ethics committee, and patients were followed up personally for the status of clinical symptoms. Serial echocardiographic reports were retrieved from the institutional database.

Inclusion Criteria

- 1. Symptoms of dyspnoea, fatigability, palpitations or giddiness
- 2. Right ventricular (RV) enlargement on echocardiogram as defined by RV end diastolic dimension (RVEDD) >2.1 cm on M-mode measurement in parasternal long
- 3. Significant left-to-right shunt with Qp: Qs >1.5.

Patients with defect size >38 mm on transesophageal echocardiography (TEE), other concomitant congenital heart disease, and PH with pulmonary vascular resistance (PVR) >8 wood units were excluded.³

The transthoracic echocardiographic evaluation was performed before ASD closure, 1 day and 6-12 months after the procedure, and annually thereafter. Both RVEDD and LV end diastolic dimension (LVEDD) were measured from using M-mode in parasternal long-axis views. Pulmonary artery systolic pressure (PASP) was estimated by tricuspid regurgitation (TR) velocity and dimensions of the inferior vena cava. The degree of TR and mitral regurgitation (MR) were quantified by color Doppler imaging as per the recommendations in the guidelines laid down by the American Society of Echocardiography. The degree of TR and mitral down by the American Society of Echocardiography.

Catheter Intervention

All procedures were carried out under local anesthesia and guided by fluoroscopy and TEE. Aspirin therapy (150 mg/day) was initiated at least 2 days prior to and maintained for at least 6 months after the intervention. Intravenous heparin was administered at the start of the procedure at a dose of 5000 U and additional doses as required to maintain an activated clotting time of 200-300 s during the procedure. The invasive evaluation was performed prior to intervention when patients presented with a non-invasively estimated PASP of >50% of systemic pressure or an absolute PASP of >60 mmHg. In these patients, PVR was carefully assessed. Only patients with PVR ≤5 wood units either at baseline or after vasoreactivity testing with 100% oxygen for 10 min were considered for ASD closure.

Device Closure

Transcatheter ASD closure was performed through right femoral vein approach as described. The ASD was crossed using a multi-purpose catheter over a terumo wire, and the left upper or lower pulmonary vein was engaged. The terumo wire was then exchanged for a 0.035" exchange length wire. The multipurpose catheter was then exchanged for a delivery sheath after ensuring that there was no air within the delivery sheath. Devices were chosen to exceed the measured defect size by 3-4 mm. Lifetech ASD devices (Lifetech Scientific Inc., Schenzen, China) were used in 21 cases, Amplatzer septal occlude (AGA Medical, Plymouth, Minnesota) in one case and Cocoon device (Vascular innovations Co. Ltd., Thailand) in one patient.

Follow-up

The patients underwent serial follow-up examinations at 1 day, 3-6 months, 12 months, and then yearly after the procedure. ECG and echocardiograms were obtained during follow-up and patients were asked questions regarding their functional class.

Statistical Analysis

Statistical analysis was done using SPSS version 16. Continuous variables were expressed as mean \pm standard deviation, or median with range, as appropriate. Pre device closure and post device closure parameters were compared using paired *t*-test in Statistical Package for the Social Sciences (SPSS) Version 16.0 by IBM Corporation, USA. A P < 0.05 was considered statistically significant.

RESULTS

Patient's baseline characteristics have been summarized in Table 1. A total of 23 patients (17 women and six men) with a mean age of 46 years (range: 40-58 years) underwent ASD

closure. Mean weight was 58.47 ± 1.39 kg, and height was 159 ± 7 cm (range: 149-170 cm). 4 (17.4%) patients were diabetic, and four patients were hypertensive. Dyslipidemia was present in 6 (26.7%) patients. Hypothyroidism and a history of recurrent respiratory tract infections in early childhood were present in one each. The mean ASD size was 18 mm (range 14-30 mm) and device sizes ranged from 20 to 36 mm. Median Qp/Qs ratio was 2.6 (1.5-3.5). Duration of follow-up was 16.19 ± 5.69 months (3-23 months).

Patient's symptoms before and after ASD device closure were analyzed and are summarized in Table 2 and Graph 1. Fatigability was the most common symptom in 14 of 23 patients followed by dyspnoea (13 of 23 patients), palpitations (8 of 23 patients), and atypical chest pain (4 of 23 patients). Exertional chest pain was present in one patient which disappeared after device closure. The giddiness was present in two cases before closure, and this disappeared following the procedure.

All patients were in sinus rhythm with right axis deviation in two patients and left axis deviation in one case. The mean PR interval was 0.20 s (0.16-0.22 s) and mean QRS duration was 0.10 s (0.08-0.12 s). The incomplete right bundle branch block (rsR') pattern was present in 19 patients and

Table 1: Baseline characteristics of study population

Parameter	(Mean±SD)/frequency	
Age	46.5652±6.66	
Females	17 (74%)	
DM	4 (17.4%)	
HTN	4 (17.4%)	
Dyslipidemia	6 (26.1%)	
Hypothyroidism	1 (4.3%)	
RRTI	1 (4.3%)	
Weight (kg)	58.4783±1.39280 E1	
Height	159±7 cm (max-170 cm, min-149 cm)	
Hemoglobin	13.26±1.15 g/dL (range; 10.7-15 g/dL)	
ASD defect	21.6±4.26 mm (max-30 mm, min-14 mm)	
ASD device size	28.52±4.69 mm (max-36 mm, min-20 mm)	
Follow-up	16.19±5.69 (3-23 mo)	

SD: Standard deviation, DM: Diabetes mellitus, HTN: Hypertension, RRTI: Recurrent respiratory tract infection, ASD: Atrial septal defect

Table 2: Symptoms before and after device closure of ASD

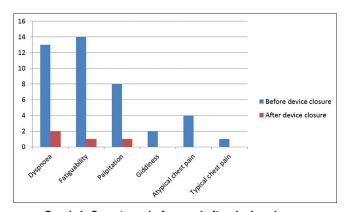
Symptoms	Before device closure (%)	6-12 months after closure (%)
Dyspnoea	13 (55.5)	2 (8.6)
Fatigability	14 (61)	1 (4.3)
Palpitation	8 (35)	1 (4.3)
Giddiness	2 (8.6)	0 (0)
Atypical chest pain	4 (17.2)	0 (0)
Typical chest pain	1 (4.3)	0 (0)

RS pattern was observed in two cases. Device delivery and implantation were successful without procedure-related complications in all patients.

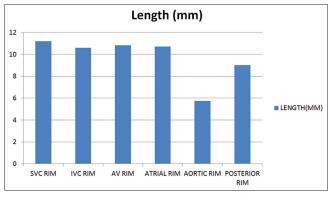
One patient aged 50 years who underwent closure using a 30 mm Lifetech Device developed 2:1 AV block, 12 months after the procedure and underwent permanent pacemaker implantation. A 48-year-old lady developed leg pain after the procedure which subsided over the next 6 months. This might have been due to injury to the branches of femoral nerve at the time of obtaining transvenous access. None had hematoma at the puncture site. No patient died during the follow-up period.

Assessment of size of ASD and rims adequacy was done by using TEE in 13 out of 23 patients in whom transthoracic echocardiography was not able to delineate the rims adequately. TEE findings have been summarized in Table 3 and Graph 2. The aortic rim was deficient (<5 mm) in four patients and absent in four patients.

Various transthoracic echocardiographic parameters assessed before and after device closure have been summarized in Table 4 and Graph 3. LV internal dimensions end diastole (LVIDD), LV dimensions end systole, left atrial (LA) size and LV ejection fraction



Graph 1: Symptoms before and after device closure



Graph 2: Lengths of various rims as assessed by transesophageal echocardiography

Table 3: TEE findings of before ASD closure

ASD rims adequacy in those who underwent device closure done (13 of 23 patients)

SVC rim

11.2±3.12 mm (max-16 mm, min-5 mm)

IVC rim

10.58±3.40 mm (max-16 mm, min-6 mm)

AV rim

10.83±3.74 mm (max-18 mm, min-6 mm)

Atrial rim

10.7±3.24 mm (max-16 mm, min-6 mm)

Aortic rim

5.75±10.03 (max-35 mm, min-0)

Posterior rim

(5 of 23 patients)

Sufficient rim All SVC rims, IVC rims, AV rims, atrial rim, posterior rims

Aortic rim deficient Deficient in 4 of 13 patients, absent in 4 of

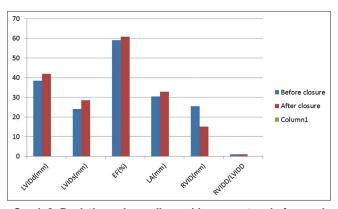
13 patients

ASD: Atrial septal defect, SVC: Superior vena cava, IVC: Inferior vena cava, AV: Atrioventricular, TEE: Transesophageal echocardiography

Table 4: Transthoracic echocardiography parameters of study population before and after device closure

Parameter	Before closure	6-12 months after closure
LVIDD (mm)	38.52±5.96 mm	42.60±4.04 mm
LVIDS (mm)	24.10±4.13 mm	28.5±3.05 mm
EF (%)	59±2.45	60.83±1.23
LA (mm)	30.5±4.8 mm	32.79±3.9 mm
RV dimension (mm)	25.52±4.56 mm	15.14±51 mm³
RVIDd/LVIDd	0.68±0.17	0.36±0.10
TR	21 (91.4%)	2 (8.6%)
TR jet	31.90±19.42 mmHg	24.25±6.3 mmHg
PASP	48±14.79 mmHg	31.13±12.73 mmHg
MVP	5	3
MR	1	0

LVIDd: Left ventricular internal dimensions end diastole, LVIDs: Left ventricular internal dimensions end systole, EF: Ejection fraction, LA: Left atrial, RVIDd: Right ventricular internal dimensions end diastole, TR: Tricuspid regurgitation, PASP: Pulmonary artery systolic pressure, MVP: Mitral valve prolapse, MR: Mitral regurgitation



Graph 3: Depicting echocardiographic parameters before and after device closure

(LVEF) improved after device closure whereas RV size, TR, TR jet, PASP, and MR decreased. TR was present in 21 of 23 patients before the procedure and in only 2 of 23 patients 6-12 months following device closure. PASP was 48 ± 14.79 mmHg. PH was present in 20 patients, with a maximum of 97 mmHg in a 40-year-old female whose ASD defect size was 24 mm. Four of the patients continued

to have PASP more than 36 mmHg, 6-12 months post procedure as measured on transthoracic echocardiogram. Ventricular size regression: There was a significant decrease in RV dimensions 6-12 months post procedure (25.52 \pm 4.56-15.14 \pm 3.51 mm) and also a significant decrease in LV dimensions (LVIDD) 6-12 months post procedure (38.52 \pm 5.96-42.60 \pm 4.04 mm).

Statistical Analysis

Paired *t*-test analysis done to analyze variables before and after device closure, which have been summarized in Table 5, showed statistically significant differences with regards to symptoms of dyspnoea, palpitation, fatigability, and echocardiographic parameters such as TR, tricuspid jet velocity, PASP, RV dimension, LVEDD, LA dimension, ejection fraction. There was no statistical reduction in giddiness following device closure, and this could be explained by the small number of patients who had it.

DISCUSSION

Treatment of ostium secundum ASD after 40 years of age has evolved over time from medical treatment to surgical treatment to transcatheter treatment. Earlier studies showed the adjusted 10-year survival rate of surgically treated patients was 95%, as compared with 84% for the medically treated patients, although arrhythmia were the problem in both group in patients aged 40 years or more when they were followed up.14 During the follow-up for 1-17 years (mean 6.9 years), of 88 largely symptomatic sinus venosus and ostium secundum defect patients aged 40-62 years who underwent surgical correction, improvement in NYHA present in functional Class III and IV in 62% of patients pre-operatively to 82% NYHA Class I and II post-operatively was observed.¹⁵ This is again reflective that closure of ASD irrespective age results in symptomatic improvement. In comparison between surgery and device closure. The success rate was 95.7-100% for the device group and 100% for the surgical group. 16,17 Mean age was 38 and 40 years for surgical and catheter closure respectively. 16 No statistically significant difference in the early, primary and secondary efficacy rates between the transcatheter group and surgical group (P > 0.05) has been reported.¹⁷ Despite claim of 0% mortality in both transcatheter closure and surgical closure, 16,17 complication rate report has been 7.2-13% for device group and 24-28% for surgical group, values are highly significant statistical terms $(P \le 0.001)$. Atrial flutter and fibrillation continued to be troublesome after surgical correction of defects after 40 years even when symptoms decrease with correction. 15 This problem of arrhythmias caused by scarring could be overcome transcatheter closure of defects as evidenced

Table 5: Paired *t*-test values of different parameters before and after device closure

Parameter	P value	Significance
Fatigability before closure	0.000	S
and 6-12 months after closure		
Palpitation before closure and	0.005	S
6-12 months after closure		
Giddiness before closure and	0.171	Ns
6-12 months after closure		
TR before closure and	0.000	S
6-12 months after closure		
RVD before closure and	0.000	S
6-12 months after closure		
Dyspnoea before closure and	0.000	S
6-12 months after closure		
TR jet before closure and	0.016	S
6-12 months after closure		
PASP before closure and	0.002	S
6-12 months after closure		
LVID before closure and	0.002	S
6-12 months after closure		
LA before closure and	0.012	S
6-12 months after closure		
EF before closure and	0.001	S
6-12 months after closure		

TR: Tricuspid regurgitation, RVD: Right ventricle diameter, PASP: Pulmonary artery systolic pressure, LVID: Left ventricular internal dimensions, LA: Left atrial, EF: Ejection fraction

our observation and other studies. Reported duration of hospital stay was longer by almost 2.4-4 days in surgical group difference is statistically significant (P < 0.001). ^{16,17}

Our study demonstrates that ASD closure is technically feasible with 100% success rate with least complications, when they are appropriately selected and can be performed at low risk in the older population. We observed significant improvement in symptoms and functional ability with favorable cardiac remodeling in an older population after transcatheter ASD closure. The most clinically relevant finding of our study was NYHA functional class. Little data exists with respect to intermediate and long-term outcome, particularly in Indian patients, after device closure of ASD in older patients. Our study provides further evidence that transcatheter device closure of ASD in adults over the age of 40 years is not only safe and effective but also improves symptoms and NYHA functional class. Our finding is consistent with improvement in NYHA class as reported. 18

NYHA functional class is also a predictor of survival in heart failure patients in these patients.¹⁹ In one study, Functional status, the presence of arrhythmias, RV remodeling, and PAP were studied in 236 consecutive patients undergoing transcatheter ASD closure. 78 younger than 40 years (Group I), 84 between 40 and 60 years (Group II) and 74 older than 60 years (Group III) with similar defect and device characteristics. Although older age group had advanced clinical symptoms, post-interventionally.

Symptoms were present in 13, 49, and 83% of the patients before and in 3, 11, and 34% after intervention in Groups I, II, and III. Functional status was related to pulmonary artery pressure (PAP).²⁰ Khan *et al.* reported that significant improvement in functional class and echocardiographic parameters as early as 6 weeks post device closure.² There was correlation of functional class and 6-min walk test.²

We observed that despite longstanding RV dilation from volume overloading, there is still potential for improvement in RV size and possible improvement in function even in those over 40 years. Closure of ASD resulted in cardiac remodeling with a significant reversal of the right to left volumetric imbalance. There was a significant decrease in RV dimensions 6-12 months post procedure (25.52 \pm $4.56-15.14 \pm 3.51$ mm). These findings are consistent with studies by earlier authors. 2,18,20 Post-interventionally, RV size has been shown to decrease from 41 \pm 7, 43 \pm 7, and 45 \pm 6 mm to 32 ± 5 , 34 ± 5 , and 37 ± 5 mm for aged < 40 years, between 40 and 60 years and above 60 years, respectively $(P = 0.0001)^{20}$ Altinag et al. reported 58% patients with severe RV dilatation prior to intervention had no or mild dilatation at last follow-up. Reduction of RV dilatation was not related to age.18

An similar reduction in RV dimension in patients aged 40 years or more as assessed by echocardiography has been documented by echocardiography, although it was studied in in post-surgical closures patients. There was a significant decrease in LV dimensions 6-12 months post procedure $(38.52 \pm 5.96-42.60 \pm 4.04 \, \text{mm})$. Significant improvement in RV myocardial performance iondex (MPI) and LV MPI, in one study involving 25 patients with average age of 45.5 ± 16.3 years underwent transcatheter closure. The state of th

Our results are consistent with findings reported.³ Similarly, LV end-systolic dimensions increased following device closure (24.10 \pm 4.13-28.5 \pm 3.05 mm), and these are consistent with findings reported by other authors.² These changes were evident following closure and continued to alter favorably until 6-12 months after the procedure. LV systolic function also improved soon after closing the ASD. In patients with an ASD, shunting of blood into the right heart invariably affects LV filling, akin to a "steal phenomenon." Our results support the phenomenon of ventricular interdependence, associated with RV volume overload and the "reverse Bernheim's effect" in which the septum bulges into the LV cavity leading to impaired LV filling.²² ASD closure reduces the external work and total mechanical energy of the RV without influencing contractility. Reduced RV myocardial oxygen consumption preserves RV function.²³ Decreased in RA area is inversely proportional to age at the time of ASD closure.²⁴ Following device closure, left to right shunt is abolished angle filling

is improved resulting in an increase in LV dimensions and ejection fraction. A similar trend was founding a published studies.^{2,25} Improvements in LV function are likely to be a major determinant of the early improvement in NYHA functional class. Schubert *et al.* have shown that ASD closure in some elderly patients may be associated with a transient increase in LA pressure and subsequent pulmonary edema due to an underlying "stiff" LV.²⁶ It is of interest that the improvement in LV size and function appears to occur earlier than in the RV. This may suggest that LV remodeling independent of RV remodeling.^{27,28}

Device closure of ASDs leads to improvement of both RV and LV function, as well as, a reduction in LA volume. These hemodynamic improvements provide insights into the symptomatic benefits gained in the closure of ASDs using the transcatheter approach. LA volume index $(25.7-21.8 \text{ ml/m}^2 (P < 0.001)$ after closure of ASD. Our study showed some increase in LA dimension as measured in M mode on parasternal long axis. This observation is in contrast to what has been observed. In our retrospective study, only M mode dimension of LA in parasternal long axis has been taken, which does not represent the true LA volume. This could also be due to small changes in LA dimension due to inter observation variation. Moreover, Khan *et al.* reported non-significant change in the LA volume after device closure.

PH was present in a significant number of patients, and mean PASP was significantly higher (48 ± 14.79 mmHg and 24.25 ± 6.3 mmHg before device closure and 6-12 months post device closure, respectively. There was statistically highly significant reduction in PASP from 48 ± 14.79 mmHg to 31.13 ± 12.13 mmHg (Table 4) in our study population. Infact, the decline was higher in contrast to other studies. Khan et al. reported median pulmonary artery pressure was 23 mmHg (range 12-27 mm Hg). Mean PAP >25 mm Hg was in three patients, and this was not seen at 1-year follow-up.² PASP decreased from 31 ± 7 , 37 ± 10 , and 53 ± 17 mmHg to 26 ± 5 , 30 ± 6 , and 43 \pm 14 mmHg (P, 0.0001), respectively in 40 years, 40-60 years, >60 years after interventions in another study.²⁰ PH was reported to present in 63% before the procedure and was reduced to 38% at follow-up. 18 In our study, 20 of 23 patients had PH before device closure and 4 of 23 patients continued to have PH at 6-12 months followup. Paired *t*-test showed a statistically significant decrease in pulmonary pressure. Even those with continued PH are on follow-up and symptomatically much better.

Atrial arrhythmias are well-known in ASDs. Fortunately, all our patients had sinus rhythm in all before device closure and immediately after device closure in contrast to 21% patients with atrial fibrillation reported in one study.²

Complications

Despite the claim of 0% mortality in both transcatheter closure and surgical closure, 16,17 complication rate report has been 7.2-13% for the device group. 16,17 In another study, report of 8.6% early complications with transcatheter closure of ostium secundum ASD in which 2.3-2.4% needed surgical intervention either for device malposition or device embolization. 18,29 6% were minor complications: Unsatisfactory device position or embolization, pericardial effusion, LA disc thrombus formation, right iliac vein dissection, groin hematoma, hemorrhage in the retro pharynx, and sizing balloon rupture. 0.4% late deaths due to peripheral embolization of device. 18,29

In our study group, there was no immediate and late complications related procedure or device. One patient developed 2:1 AV block 12 months post procedure and permanent pacemaker implantation were done. However, the arrhythmia was not a feature in any of the patients at the time of device closure. 2:1 AV block in this patient is not related to device closure as it was remote occurrence, and echocardiography revealed no abnormality with device position. No patient developed signs of diastolic dysfunction or MR following ASD closure. On the contrary, there was the disappearance of MR following device closure. This shows that catheter intervention of ASD is becoming one the safest procedures with time. It has been shown that cardiac remodeling starts very shortly after transcatheter ASD closure in relatively young populations (mean age 22 ± 18 years) and that most of the cardiac remodeling appeared within a few weeks of closure. Conversely, in our study population with a mean age of 46 years), we observed that most of the improvement in RV size was very much evident in all cases at 6-12 months post device closure.

Study Limitations

Our study was a retrospective observational study with no patient aged more than 70 years. The sample size is not very large and was done in a single institute. LA dimension was assessed in a parasternal long axis which may not reflect true LA volume. This makes it essential for the data to be further confirmed in larger multicenter studies.

Longer term follow-up might have helped to assess the effect of closure on the incidence of arrhythmia and right ventricle dysfunction which are usually delayed complications of ASD.

CONCLUSIONS

Our study demonstrated that transcatheter ASD closure is technically feasible and very safe procedure when patients with good atrial rims are chosen. Favorable cardiac remodeling in subjects aged more than 40 years as evidenced by changes in echocardiographic parameters and significant improvement in functional class on short as well intermediate-term follow-up. All ASDs should be closed irrespective of age, preferably through catheter intervention.

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