FULL LENGTH ARTICLE

Spectrum of morphological abnormalities and treatment outcomes in ostium secundum type of atrial septal defects: Single center experience in >500 cases

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Background: **Transcatheter closure (TCC) has emerged as the first line treatment option for secundum type of atrial septal defects (ASD). Outcomes of TCC depend upon proper delineation of defect anatomy by transesophageal echocardiography (TEE). Stability and proper placement of the device mandates adequate rims and proper alignment to the septum. Failed or unfavorable morphology for TCC requires referral for surgical repair.**

Methods: **We prospectively analyzed the ASD patients who were referred for treatment. The morphological features of the defect were evaluated and the outcomes of TCC studied. Patients who undergo TCC and surgical repair were followed for immediate and long-term outcome comparison.**

Results: **Of the 512 patients who underwent treatment, TCC was attempted in 430/512 (83.2%) patients. It was successful in 393/430 (91.3%) patients. The remaining 119 patients underwent surgical patch closure. Twenty patients had failure of device alignment and device embolization occurred in 17 patients. Very large defect size ≥35 mm, absent or deficient posterior rim, absent/deficient inferior naval rim showed high chances for failure and formed major reasons for surgical referral. The surgical group had higher success (100%) across all anatomic variables. However, they had longer intensive care unit (ICU) and hospital stay ($p < 0.001$).**

Conclusion: **TCC offered a success rate of 91% in complex defects after TEE selection. Very large size and deficient inferior, posterior rims predicted failure of TCC. Surgery offered 100% success and it involved a longer hospital and ICU stay. The long-term clinical results were identical with both treatment modalities.**

Keywords: Complex atrial septal defect, Device closure, Inter atrial septum, Morphology, Surgical repair

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1. Introduction

Transcatheter closure (TCC) has emerged as the first line treatment for the majority of secundum type of atrial septal defects (ASD) [1–3]. The spectrum of anatomic variation is relatively high in ASD which may challenge the success and even complicate an attempt with TCC with risk of device embolization [3–5]. Hence case selection becomes important for TCC, and it is largely based on transesophageal echocardiographic (TEE) findings [4–7]. Many morphologic abnormalities such as deficient rims, altered septal geometry in the form of aneurysm, malalignment, etc. can influence the outcome and failed TCC patients will eventually get referred for surgical repair [7,8]. We have previously published our initial experience and outcomes of catheter closure of complex ASD [1,9]. Catheter intervention in complex defects are plagued by issues such as device embolization and device erosion. Surgical approach is definitely more invasive but is devoid of the device-related issues mentioned before. Both forms of therapies have established their role in the clinical practice. Both techniques have evolved with time as well. Modified TCC techniques offer improved closure rates reduce surgical referrals. Surgical incisions have become minimal reducing postoperative morbidity. In this study we sought to examine the pattern of morphological abnormalities that exist in ASD in a large unselected group of patients and to compare the clinical outcomes of TCC and open surgical repair in contemporary clinical practice.

2. Materials and methods

Prospective single center observational registry data on 512 patients with ASD who were referred for treatment to Department of Cardiology at JIPMER Hospital, Puducherry, India, an institute of national importance under the Ministry of Health, Government of India were studied. This is a university level referral center offering treatment for ASD by TCC as well as by open surgical repair. Patients subsequently underwent TCC or open surgical closure. The study was conducted during the 10-year period from January 2006 to December 2016 after getting approval from the institute scientific and ethics committee. We looked at the various morphological abnormalities detected by TEE and the subsequent treatment outcome.

Patients in whom ASD was the predominant disease or in whom associated shunts/valve disease for which a catheter-based therapy/surgery was available were included in the study. Patients in whom the pulmonary artery hemodynamics were indicative for inoperability or in whom ASD was part of complex congenital cardiac disease (cyanotic/acyanotic) such as (tetralogy of Fallot, transposition of great vessels, single ventricle physiology) were excluded in the study. All patients with ASD who were deemed fit for closure, were included. All patients were initially evaluated by the structural heart team (interventional cardiology, echocardiography, and cardiac surgery) to determine if a transcatheter option was feasible based on size and morphology. Those patients deemed appropriate were planned for transcatheter device closure. In those patients unable to undergo device closure, or in those who failed device closure, a surgical referral was made to undergo ASD pericardial patch repair by either a conventional median sternotomy approach or by a 3–4-cm right anterolateral mini-thoracotomy/lower mini-sternotomy.

Abbreviations

ASA	atrial septal aneurysm
Echo	echocardiography
ICU	intensive care unit
OS-ASD	ostium secundum atrial septal defect
TCC	trans catheter closure
TEE	trans esophageal echocardiography
TTE	Trans thoracic echocardiography

2.1. Echocardiographic assessment

All patients referred for ASD closure were initially evaluated with transthoracic echocardiography (TTE) and then with TEE. In very small children and infants, TEE was avoided if the TTE provided satisfactory delineation of the anatomical details. General anesthesia was used for all pediatric patients who required TEE. Right ventricular systolic pressure was estimated and documented in patients with tricuspid regurgitation. TEE imaging was done in the standard sweep imaging angles from 0° to 120° [2]. The mitral and aortic valves were also profiled in the 120° sweep. The parameters assessed in the TEE included size of the defect, shape of the defect (elliptical or round), adequacy of rims, the number of defects, and location with regard to the aortic and mitral valve. Long axis measurement $\geq$30 mm was defined as large and $\geq$35 mm as very large [1,2]. Presence of septal malalignment and septal aneurysm were also documented. The various rims were described according to TEE findings as follows [2]. The aortic rim was measured at 45° short axis. The mitral valve rim was measured at 0° sagittal four-chamber view. The posterior rim was measured at 120–130° adjacent to the right upper pulmonary vein. The inferior vena caval or inferior rim was measured at 90° bicaval view and the superior vena caval rim was measured at 90° bicaval view.

The rims were measured and documented both in terms of length and strength. The absent and floppy rims were clubbed together as "deficient" for analysis. In TTE, the anterior (aortic) and posterior rims were identified in parasternal short axis and apical four-chamber views. The inferior caval rim was identified in the subcostal vertical 90°-plane (the subcostal bicaval view). Septal malalignment was defined to exist when the aortic rim tends to deviate away from the plane of attachment of noncoronary cusp. It was identified in the short axis 45° of the TEE/TTE. Atrial septal malalignment is a morphological characteristic frequently encountered in cases with a deficient aortic rim. Surfaces arising from septum primum and septum secundum are different in a defect with malaligned atrial septum resulting in vertical displacement. This often poses challenge in TCC, and modified techniques are often required for proper device alignment. An atrial septal aneurysm (ASA) was described as a redundancy or saccular deformity of the atrial septum with increased mobility of the atrial septal tissue [2,5]. ASA was defined as excursion of the septal tissue (typically the fossa ovalis) of >10 mm from the plane of the atrial septum into the right or left atrium or a combined total excursion toward right and left of 15 mm [2,5]. Multiple ASD was defined as presence of two or more defects separated by a thick ridge of tissue [2,5].

Three-dimensional echo imaging was started to be used in some of the cases in the latter half of the study period and data on three-dimensional imaging were added if available.

2.2. Catheter Intervention

Local anesthesia with sedation and TEE guidance were used for all adult patients. General anesthesia was used for all pediatric patients and TEE was done in selective pediatric cases according to the discretion of the physician. Femoral venous access was used for transcatheter closure in all cases. Anticoagulation was achieved using 100 units/kg unfractionated heparin and ACT (activated clotting time) was maintained between 250 seconds and 300 seconds. Right heart study and hemodynamics were documented for all patients. Patients with pulmonary hypertension underwent vasodilator challenge after regular oximetry and hemodynamic data. Crossing the ASD was done using 5F/6F Cournand or multipurpose catheter with 0.035" hydrophilic glide wire (Terumo Inc. Osaka, Japan). Balloon sizing with stop flow technique was used if there was a septal aneurysm and or if there were any sizing discrepancies with TEE. After crossing the defect, the Cournand catheter was parked in the left or right upper pulmonary vein. This catheter was exchanged for 0.9652-mm super stiff wire for supporting the long device delivery sheath (Mullin's sheath). Our choice of devices was random as per shelf availability of the particular size and did not follow any particular order. The devices used in this study include the double umbrella type discs [Amplatzer Septal Occluder (St. Jude), Cocoon Septal Occluder (Vascular Innovations) and Heart R Septal Occluders (Lifetech) Shenzen, China].

Successful deployment of device depends upon orientation of left atrial disc parallel to the defect. Standard deployment technique where after advancement of sheath to left atrium, the left atrial disc is deployed, and the entire assembly is pulled back to against the septum to release the subsequent components of the device such as the waist and the right atrial disc which is expected to fan out on to the right atrial side of the septum. If this fails, the technique was declared failed. A modified deployment technique such as balloon assisted technique, pulmonary vein technique, A dilator or catheter-assisted technique was used when the standard technique was not successful. In cases with failed TCC, surgical repair was carried out.

2.3. Surgical closure

In patients with defects not suitable for or failed device intervention, surgical closure was carried out. ASD was conventionally closed through a median sternotomy. Alternative approaches for closure were right anterolateral (periareolar) thoracotomy, lower mini-sternotomy. The technique chosen was either direct or patch (autologous pericardium, Dacron, Poly tetrafluro ethelene, bovine pericardium) closure depending upon the size, shape, and location of the defect. In cases of septal aneurysm with fossa ovalis ASD, the aneurysmal septum was excised due to risk of thrombogenicity if plicated. In case of fenestrations associated with defect, the fenestrated septum was also excised to make it a single defect so that the margins of the defect are strong enough to hold the suture. The triangle of Koch, which is the location of AV (atrioventricular) node, was identified and the suture bites are taken closer on the antero-inferior rim so as to avoid the AV node. In a deficient inferior rim and selective inferior vena cava (IVC) cannulation, suture bites are taken onto the floor of the left atrium and the Eustachian valve should not be mistaken for the inferior rim, as suturing the patch to the Eustachian valve will result in directing the IVC blood to the left atrium. The patch is seated to the inferior rim first using running proline sutures and then the suturing is carried on to the anterior and posterior rim and then finally to the superior rim. Additional valve repair procedures were carried out if planned.

2.4. Post procedure

Successful or failed intervention was documented. Morphological feature for failure if any was noted. Total procedure time and total fluoroscopic time was noted. All patients underwent TTE at 24 hours and monthly for 6 months. All patients were discharged on oral aspirin and infective endocarditis prophylaxis for 6 months. Follow up included clinical and echocardiographic assessment until 6 months.

Patients who underwent surgical repair, had echocardiogram predischarge, then every 6 months for the initial year, and then every 3 years thereafter. Patients who had concomitant valve issues were followed up more closely according to physician discretion.

2.5. Statistical analysis

Data were analyzed by using both descriptive and inferential statistics. The distribution of the clinical characteristics, morphological profiles, comorbidity conditions, sex, social status, clinical/treatment outcome, etc. was expressed as frequency and percentages. The distribution of continuous data such as age, size of defect, anatomic parameters, etc. was expressed as mean with standard deviation or median with range whichever is appropriate. Fisher's exact test was done to find association of morphological parameters with outcome. Independent sample t test was used to compare the ASD size with outcome. A forward conditional (stepwise) univariate logistic regression analysis was used to identify the risk factors predicting the success and failure of TCC. The unadjusted relationship between closure method and presence of any residual shunt was modelled using Kaplan–Meier time-to-event methods, with the two curves compared using the log–rank test statistics. Hazard function between groups was done to find the difference between outcomes in surgery and TCC. A propensity score analysis was done for variables that showed differences, if any, between TCC and surgery. The adjusted Cox proportional hazard model was used to differentiate the risk of residual shunt between treatment groups. The proportional hazard assumption was tested by generation of log–log plots and by use of Schoenfeld residuals. Confidence intervals were set at 95%; all p values were two-sided and considered statistically significant if $p < 0.05$. When possible, exact p values have been reported. All statistical analyses were carried out by 5% level of significance and $p < 0.05$ was considered as significant. The analysis was performed by SPSS software version 20.0 by IBM for Windows 2015.

3. Results

A total of 548 patients were evaluated for ASD intervention (Fig. 1). Thirty-six patients had severe pulmonary artery hypertension and inoperable hemodynamics after vasodilator challenge testing during cardiac catheterization. The mean pulmonary pressure in these patients was 59.36 ± 13.56 mmHg and mean Qp/Qs was 1.04 ± 0.23. The mean pulmonary vascular resistance (PVR) (postvasodilator) was 6.38 ± 1.34 wood units and the mean systemic vascular resistance was 13.45 ± 0.67 wood units. The mean pulmonary to systemic vascular resistance (PVR/SVR) ratio was 0.47 ± 0.03. Data on 512 patients were included in the study. TCC was attempted in 430/512 (83.2%) patients and was successful in 393/430 patients (91.3%). The remaining 119 (23.3%) patients underwent surgical patch closure.

Baseline clinical characteristics are given in Table 1. Twenty patients had failure of device alignment and device embolization occurred in 17 patients. All embolized devices were retrieved percutaneously. The results did not find any specific difference with respect to the type of device used. In patients in whom all techniques of TCC failed, elective surgical repair was performed.

3.1. Anatomic complexities in transcatheter intervention

The majority of patients (476/512) had regular two-dimensional TEE imaging. Three-dimensional echo was only used in 36 patients. The various anatomic complexities are listed in Table 2. Fig. 2 shows pictorial representation of various morphological substrates in ASD. Absent

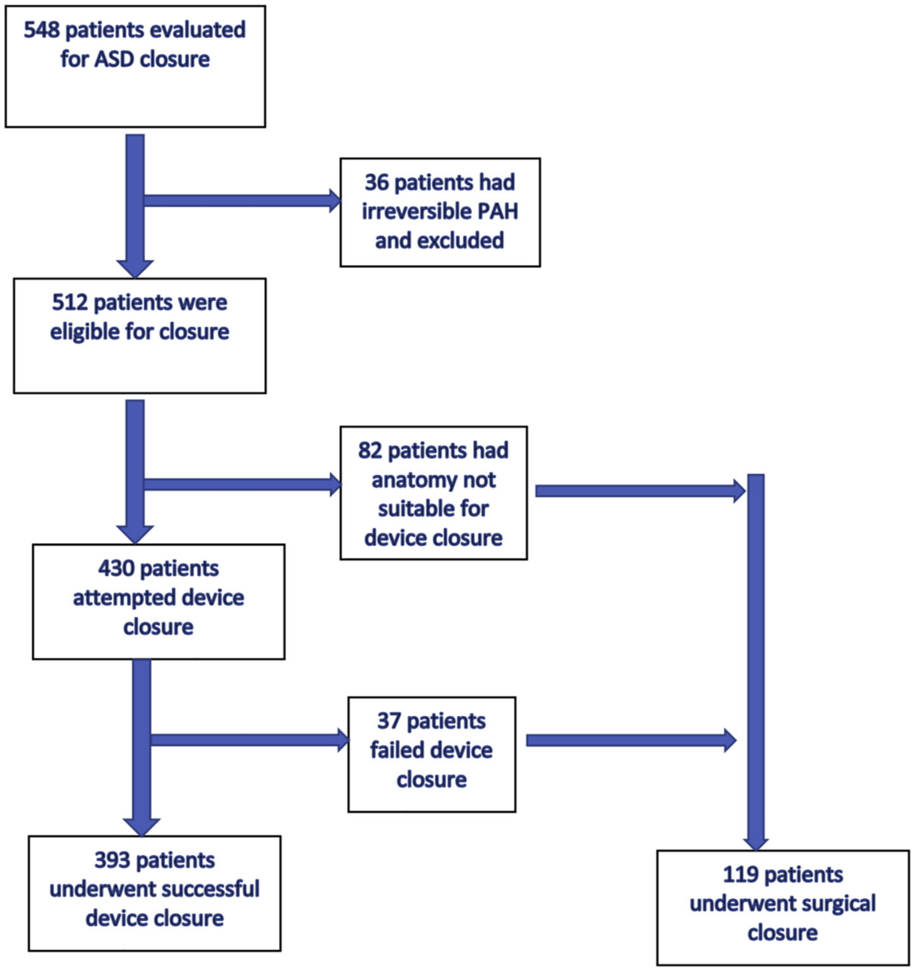

Figure 1. Flow chart depicting patient evaluation and treatment. ASD = atrial septal defects; PAH = pulmonary artery hypertension.

Table 1. Baseline characteristics.

Baseline characteristics	*N* = 512
Age (y)	23 ± 5.6 (11–56)
Sex, female: male	1.8:1
Sinus rhythm	484 (94.5)
Atrial fibrillation	28 (5.4)
Left to right shunt & right ventricle (RV) volume overload RV systolic pressure ≥50 mmHg	98 (19.14)
Previous stroke	12 (2.3)
Congestive heart failure	84 (16.4)
Hypertension	23 (4.4)
Coronary artery disease	16 (3.1)
RV systolic dysfunction	81 (1.58)
ASD with mitral stenosis (Lutembacher's syndrome)	6 (1.1)
ASD with valvular pulmonary stenosis (PS)	8 (1.5)
ASD with patent ductus arteriosus (PDA)	11 (2.1)
ASD with ventricular septal defect (VSD)	27 (5.2)
ASD with partial ALCAPA	1 (0.1)

Data are presented as mean ± SD (range) or *n* (%).
ASD = atrial septal defects.

aortic rim was the most common abnormality found. Approximately 20% of patients had very large defects of ≥35 mm and about 25% had maligned septum and absent or deficient posterior rim. Fig. 3 shows appearance of different anatomical variations in the septum. The complex defects

Table 2. Anatomic complexities N = 512.

Anatomic complexity	Total (*N* = 512)[*]	TCC success (*N* = 393)	Surgical repair (*N* = 119)	*p*
Large ASD (≥25 mm)	247 (48.2)	212 (84.8)	35 (14.2)	<0.001
Very large ASD (≥35 mm)	106 (20.7)	65 (61.3)	41 (38.7)	0.02
Malaligned septum	123 (24)	89 (72.3)	34 (27.6)	<0.001
Multiple/Fenestrated ASD	45 (8.7)	45 (100)	0	<0.001
Septal aneurysm	36 (7)	32 (88.8)	4 (11.1)	<0.001
Deficient/floppy posterior rim	138 (26.9)	64 (46.3)	74 (53.6)	0.5
Deficient/floppy inferior vena caval rim	78 (15.2)	29 (37.1)	49 (62.8)	0.6

Data are presented as *n* (%).
TCC = transcatheter closure.
[*] Individual patients had multiple coexistent morphological abnormalities.

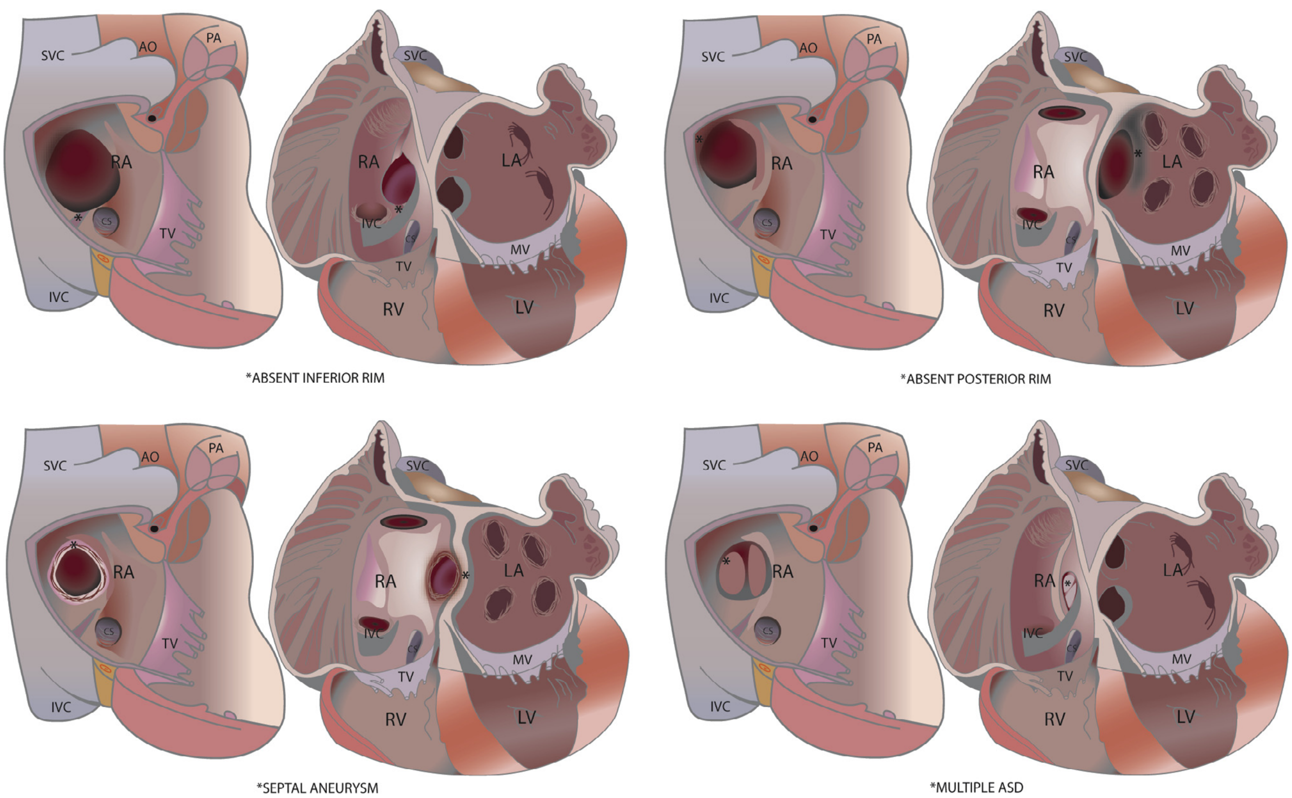

Figure 2. Pictorial representation of different anatomic complexities in ASD from right atrial and left atrial views. (A) Absent inferior rim; (B) absent posterior rim; (C) septal aneurysm; and (D) multiple defects. ASD = atrial septal defects; IVC = inferior vena cava; SVC = superior vena cava; AO = Aorta; PA = pulmonary artery; RA = right atrium; TV = tricuspid valve; MV = mitral valve; LV = left ventricle.

required longer procedure and fluoroscopic time. The mean fluoroscopic time was 28 minutes and procedure time was 52 minutes. More than 60% of patients with successful device placement required a modified technique (Table 3). Balloon assisted technique was more commonly used (40%, Fig. 4). On univariate analysis, very large defect size ≥35 mm, absent or deficient posterior rim, and absent/deficient inferior naval rim indicated a high chance for failed TCC. The odds ratio for failed TCC was highest for deficient IVC rim. Table 4 depicts the various anatomical features and outcome of TCC.

One patient had dextrocardia with situs inversus who had a large ASD as part of Kartagener's syndrome underwent successful intervention. Fifty patients had severe pulmonary artery hypertension (PAH) with systolic pressures >70 mmHg. Systolic pulmonary artery pressures came <40 mmHg in 33 patients following intervention and in one patient during follow up. Twenty-seven patients had persistent pulmonary hypertension on follow up.

Procedural data are given in Table 5. Six patients underwent balloon mitral valvuloplasty before device closure. Mean mitral valve area improved

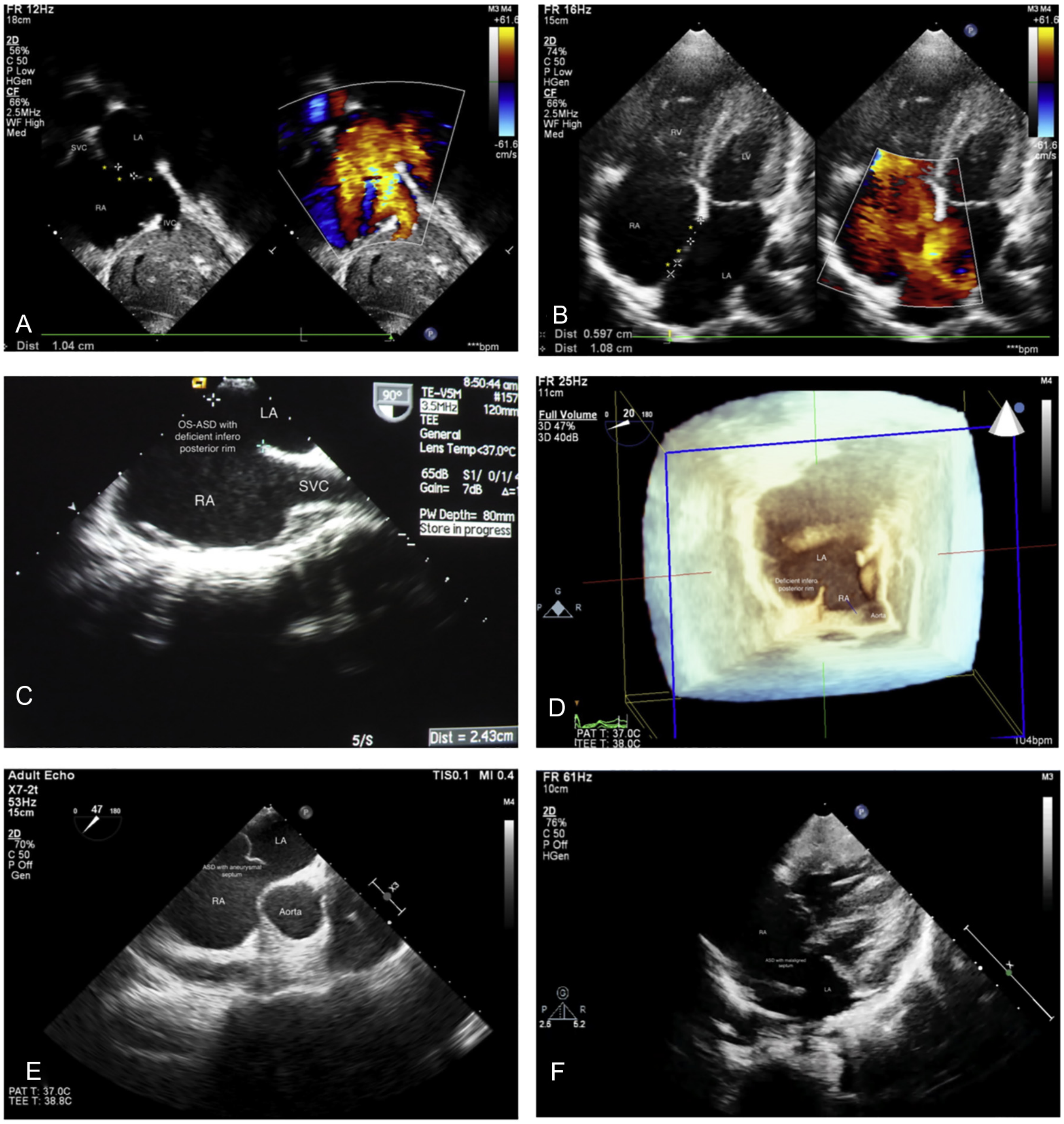

*Figure 3. The echocardiographic images of various morphologies. (A) Bicaval view with * showing multiple ASDs with left to right shunt; (B) apical four-chamber view with * showing multiple ASDs with left to right shunt; (C) transesophageal echo image showing ASD with deficient inferior vena caval rim; (D) three-dimensional echo image showing ASD with deficient inferior vena caval rim; (E) transesophageal echo image showing aneurysmal interatrial septum with ASD; and (F) apical four-chamber view showing ASD with malaligned septum. ASD = atrial septal defects.*

Table 3. Techniques used for device placement.

Technique of TCC	*n* (%)
Conventional technique	75 (19)
Balloon assisted technique	162 (41.1)
Left upper/lower pulmonary vein method	87 (22)
Right upper pulmonary vein method	54 (13)
Left atrial roof method	6 (1.5)
Modified/cut sheath method	4 (1)
Catheter/dilator support	5 (1.2)
Total no. of interventions	393

TCC = transcatheter closure.

to 1.7 ± 0.06 cm^2 and then ASD was closed. Eight patients had successful balloon opening pulmonic valve before closing ASD. Patients who had post-tricuspid shunts were closed transcatheter before undertaking ASD closure. Overall 32 patients (11 with PDA and 21 with VSD) underwent device intervention before ASD intervention). One patient with anomalous left circumflex artery (partial ALCAPA, Anomalous left coronary artery from pulmonary artery) had uneventful closure of

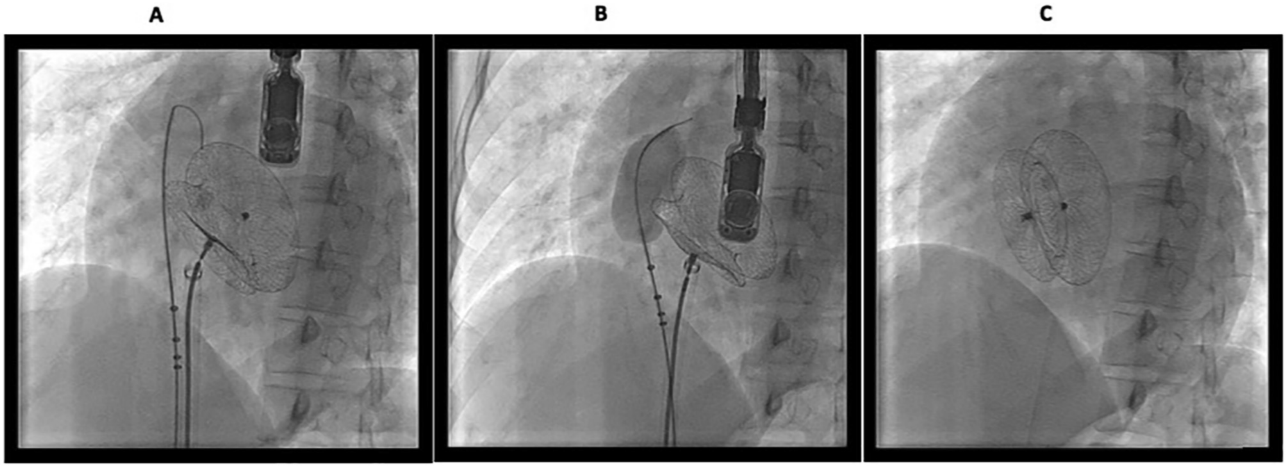

Figure 4. Images of transcatheter closure of a large ASD with balloon assisted technique. (A) Balloon assisted technique of deployment of ASD closure device; (B) successfully deployed ASD closure device under TEE guidance; and (C) final position after deployment of device in Left anterior oblique (LAO) view. ASD = atrial septal defects; TEE = transesophageal echocardiography.

Table 4. Anatomical complexity and failure of catheter intervention.

Anatomic feature	Odds ratio for failure with TCC (95% CI)*	*p*
Very large ASD (≥35 mm)	8.9 (1.4–18.5)	0.002
Malaligned septum	1.04 (0.62–1.27)	0.12
Multiple/fenestrated ASD	0.45 (0.12–0.87)	0.56
Septal aneurysm	0.56 (0.32–0.98)	0.65
Deficient/floppy posterior rim	4.1 (1.5–9.7)	0.02
Deficient/floppy inferior vena caval rim	15.6 (4.3–48.8)	<0.001

ASD = atrial septal defects; CI = confidence interval; TCC = Transcatheter closure.
* P value less than or equal to 0.05.

Table 5. Procedure data.

		Transcatheter (*n* = 393)	Surgical (*n* = 119)	*p*
Defect size (mm), median (IQR)		29.5 (25–34.5)	35.6 (32.4–39.8)	0.002
Device	Amplatzer	213 (54.1)		
	Coccon	160 (40.7)		
	Cera	20 (4.9)		
Device size (cm), median (IQR)		33.9 (2.7–3.8)		
Additional intervention				
Device closure of PDA		11 (2.1)		
Device closure of VSD		21 (4.1)		
Balloon pulmonary valvuloplasty		8 (1.5)		
Balloon mitral valvuloplasty		6 (1.1)		
Technical success		393 (76.7)	119 (100)	0.01
Additional surgery	TV repair		9 (7.5)	
	MV repair		6 (5.0)	
	VSD patch		6 (5.0)	
	Coarctoplasty		1 (0.8)	
Approach	Median sternotomy		66 (55.4)	
	Periareolar		51 (42.8)	
	Lower mini-sternotomy		2 (1.6)	
Bypass time (min), mean (SD)			122.8 (43.4)	
Cross clamp time (min), mean (SD)			69.9 (29.7)	

Data are presented as *n* (%), unless otherwise indicated.
IQR = interquartile range; SD = standard deviation.

the ASD without any device impingement on the anomalous artery.

3.2. Immediate outcomes

The surgical arm involved 119 patients. Fig. 5 shows operative image of a secundum ASD with deficient inferior vena caval margin. The immediate clinical outcomes were similar with both surgical and transcatheter methods except for the length of intensive care unit (ICU)/hospital stay ($p < 0.001$, Table 6). Otherwise, no significant periprocedural outcome differences were detected between the intervention groups. Three patients in the TCC group suffered a bleeding complication from the femoral puncture site that resolved with additional manual pressure and did not require blood product transfusion. Two patients in the surgical group received two units of packed red blood cells for an asymptomatic hemoglobin level <70 g/L during the postoperative ICU stay. No patients required transfusion of additional products such as plasma, platelets, cryoprecipitate, or recombinant activated factor VII. Table 7 shows that the independent predictors of a decision to apply surgery in the propensity score analysis. The variables included: size of the defect, presence or absence of inferior vena caval rim, presence or absence of posterior rim, posterior mal alignment, septal aneurysm and multiple defects. The adequacy of the propensity score was confirmed because the area under the receiver operating characteristics (ROC) curve was 0.91, indicating excellent discrimination. A higher propensity score in the present study indicated an increased likelihood of undergoing surgery. The mean propensity scores of patients who underwent TCC or surgery were 0.477 ± 0.312 and 0.908 ± 0.145, respectively.

Follow-up time ranged from 0.6 months to 56.5 months in the TCC group and from 0.6 months to 89.0 months in the surgical groups after hospital discharge (Table 8). There was no late mortality in either groups. Late device embolization was documented in two patients (at 1 month follow up) and required reintervention for retrieval. One case of stroke occurred at the 7th month after device closure with TEE documentation of thrombus on the left atrial disc. This patient responded well to oral anticoagulation with no further recurrence of stroke. The patient median follow-up time was 9.3 months in the TCC group and 19 months in the surgical group ($p = 0.3$). All residual shunts were asymptomatic and graded as trace to mild. On Kaplan–Meier analysis, the two curves appeared divergent; however, they were not found to be significantly different by the log-rank test statistic (Fig. 6). The proportional hazard assumption was not violated. Log–log plots showed parallel curves, and the hazard function between groups was not statistically significant using Schoenfeld residuals ($p = 0.42$). The adjusted Cox proportional hazard model failed to show a significant difference in risk of residual shunt between groups [Hazard ratio (HR) 0.41, 95% confidence interval (CI): 0.03–7.30]. Similarly, there was no significant difference in late complications, defined as a composite of significant residual shunt (greater than mild on Doppler color flow), device erosion, endocarditis, device thrombosis, thromboembolism, or stroke. When subdividing the surgical group by defect

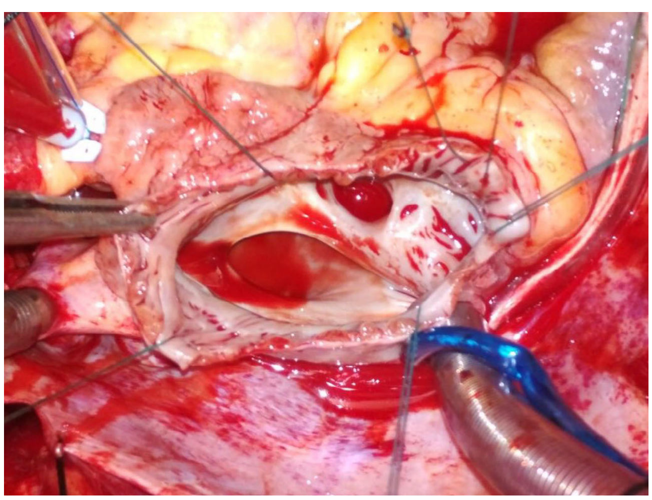

Figure 5. Operative image of a large defect with deficient inferior vena caval (IVC) margin. Note the inferior margin adjacent to the coronary sinus. See the proximity of the defect margin to the cannula placed in the IVC. IVC = inferior vena cava.

Table 6. Clinical outcomes after closure of ASD.

	Transcatheter ($n = 393$)	Surgical ($n = 119$)	p
ICU stay, median (IQR)	0 (0–0)	2 (2–3)	<0.001
Hospital stay, median (IQR)	2 (1–3)	6 (6)	<0.001
Reoperation-bleeding	0 (0)	2 (1.68)	0.68
Death	0 (0)	1 (0.8)	
Cerebrovascular accident (CVA)	1 (0)	3 (2.52)	
Air embolism	1 (0.25)	0 (0)	
Arrest	0 (0)	1 (0.8)	
Infection	0 (0)	2 (1.68)	
Device embolization immediate (<48 h)	13 (3.1)	NA	
Late (>48 h)	2 (0.5)	NA	
Atrial fibrillation	18 (4.5)	10 (8.1)	0.06
Renal failure	0 (0)	0 (0)	
Ventilator dependence (≥48 h)	0 (0)	1 (0.8)	0.06
Bleeding	3 (0.93)	2 (1.68)	0.45
Blood product use	2 (0.5)	3 (2.52)	0.36

Data are presented as n (%), unless otherwise indicated.
ASD = atrial septal defects; ICU = intensive care unit; IQR = interquartile range.

Table 7. Independent predictors of selection of surgery (propensity score analysis).

Predictors	Odds ratio (95% CI)	p
Size of the defect ≥35 mm	2.56	**0.01**
Posterior malalignment	0.64	0.22
Deficient posterior rim	7.61	**<0.001**
Deficient inferior vena caval rim	19.78	**<0.001**
Septal aneurysm	0.34	0.12
Multiple defects	0.1	0.11

complexity/additional procedures, no differences in outcomes were found ($p = 0.55$).

4. Discussion

This study involves patents with ASD who had different anatomic complexities who were subjected to treatment. We looked at the outcome of TCC and surgical repair and their follow up. The surgical group included patients with primary referral and patients in whom TCC failed. The propensity score analysis shows that lager defects >35 mm, deficient or floppy IVC and posterior rims were major reasons for surgical referral.

The success of TCC was ~91%. This is similar to our earlier experience in a smaller cohort. The main reasons for failure of TCC included large defect size ≥35 mm, deficient inferior vena caval and deficient posterior or right upper pulmonary vein rims. Modified techniques as described were used in successful delivery of the device in 79% cases. Deployment technique was modified upon discretion of the operator, to orient left atrial disc parallel to septum with some operators preferring pulmonary vein technique over balloon assisted technique and vice versa. Left atrial roof and

Table 8. Follow-up outcomes after hospital discharge.

		Transcatheter ($n = 393$)	Surgical ($n = 119$)	p
Range (mo)		0.6–56.5	0.6–89	
Follow-up (mo), median		9.3	19	0.3
(IQR)		(2.5–23.25)	(2–52.5)	
Death		0	0	
Residual shunt		12 (3.05)	3 (1.6)	0.4
Residual Shunt > mild		7 (2)	2 (0.5)	0.6
NYHA	1	347 (88.5)	96 (80.6)	0.21
	2	45 (11.4)	23 (19.5)	0.32
	3	1 (0.25)	0 (0)	
	4	0 (0)	0 (0)	
Stroke		1 (0.25)	0 (0)	0.46
Endocarditis		0 (0)	0 (0)	
Device erosion		0 (0)	NA	
Device thrombosis		1 (0.25)	NA	

Data are presented as n (%), unless otherwise indicated.
IQR = interquartile range; NYHA = New York Heart Association.

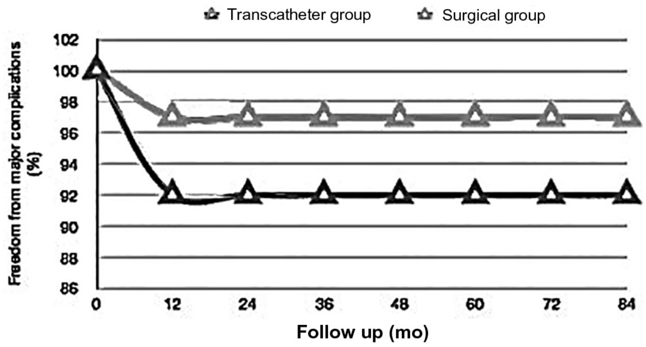

Figure 6. Kaplan–Meir curves for event-free survival comparing transcatheter technique (393) and surgical repair (119) groups.

dilator methods was chosen when balloon assisted technique failed in patients with small left atrial dimensions. The cut sheath method was used in some cases were retro aortic margin was deficient with repeated prolapse of the device in the conventional approach. Irrespective of the type of modified techniques, an absent or deficient inferior vena caval or posterior margin and a very large sized defect predicted failure. We had a large group of patients with complex morphology and surgical referral was primary and secondary after a failed TCC. The surgical approach offered 100% technical success across all anatomic complexities, it involved longer hospital and ICU stay. There was one death in the surgical arm in the early postoperative period. The long-term follow up survival and residual shunt incidence were similar in both groups.

Catheter based therapy is the less invasive option, but it is associated with issues such as device embolization and late erosions especially in complex defects with deficient margins [8,10,11]. Late embolization was noted in two patients at 1 month follow up. We did not have any incident of device erosion. Residual shunt is also a concern with TCC as many defects are ellipsoidal and malaligned which make the circular device uncovering certain parts of the defect [8,9]. Our data shows that outcomes of TCC and invasive surgical ASD repair are similar overall, with no significant difference seen in functional outcomes or amount of residual shunt. Although residual shunt in particular trended higher with TCC, these tended to be mild, clinically insignificant shunts that did not result in a difference in functional status. We found similar outcomes with different surgical approaches (conventional sternotomy and minimally invasive incisions). The number of periprocedural complications was low in both groups and it is expected to be difficult to show a significant difference between the groups. In hospital and ICU length-of-stay was much shorter for TCC. However, this immediate benefit was balanced by a trend toward higher residual shunt in TCC. Late device migration or embolization is always a concern in transcatheter patients [11], although we did not see any such events in early follow-up. Delayed device erosion and embolization remains a possibility [11,12]. Both surgical and transcatheter techniques have evolved over time [10,13–17]. Studies conducted in previous centuries have shown excellent long-term outcomes with conventional midline sternotomy approach [10]. Later on, modified approaches such as anterolateral and mini sternotomies were shown to be equally efficient less invasive strategies [13,14]. We had ~45% surgical patients who underwent one of the modified approaches. The surgical outcomes were not influenced by the defect anatomy whereas TCC had anatomical predictors for failure. The heart tram approach is important in planning the best treatment strategy in a given anatomy [18–20].

Based on the experience gained from this study we formulate the following selection criteria for catheter-based treatment for ASD. (1) Size. A long axis measurement $\geq$35 mm is a complex anatomical substrate. Approximately onefourth will have malaligned septum and absent or deficient posterior rim. Although we believe that size should not be the sole criteria for exclusion, very large size does commonly associate with deficiency of posterior or inferior vena caval margins which reduce the chance for successful device alignment. (2) Deficient inferior vena caval margin. We believe this is the most important margin for the stability of the device. As superiorly the device catches on to the retro aortic tissue, the inferior margin is key to hold the device. In the absence of proper inferior caval margin, the TCC is more likely to fail. (3) Deficient posterior margin. Posterior margin is important to align the device. In ~40–50% cases, the aortic rim is absent. Combined deficiency of aortic and posterior margins makes TCC difficult. Also, if inferior caval margin is floppy along with deficient posterior margin, the success rate comes down. (4) Posterior malalignment. This abnormality challenges the success rates. To a large extent, this can be circumvented by modified techniques such as balloon assistance which makes the device align. However, a gross malalignment with deficient inferior caval/posterior rim deficiency poses challenges. (5) Deficient coronary sinus margin is a rarity and we did not come across a situation in TCC. Most of them do have deficient IVC margin and certainly favored for surgical closure.

4.1. Limitations

This involves a single center nonrandomized observational data. The results of this study may not be generalizable and the selection criteria suggested requires external validation. Patients were subjected to surgery only of TCC fails or not considered. The event rates are low in both the groups which precluded meaningful differences in major outcomes such as death, stroke, or bleeding parameters. The morphology was assessed mainly by two-dimensional echo. Three-dimensional imaging was not regularly used in all patients. The study showed that the TCC offered a success rate of 91% and shows similar outcomes to surgery in an unselected population. Very large size and deficient inferior and posterior rims predicted failure of TCC. Although the surgery offered 100% technical success across all anatomic complexities, it involved longer hospital and ICU stay. The long-term survival and residual shunt incidence were similar in both the groups.

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