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Research Article

Transcatheter Closure of Complex Secundum Atrial Septal Defects

Khalid Ahmed Khalid[1]* and Zayir Hashim Khalid[2]

[1]*Interventional Pediatric Cardiology, Basrah Medical Collage, Iraq*

[2]*Consultant Interventional Pediatric Cardiologist, Ibn Al-Bitar Specialized Center for Cardiac Surgery, Iraq*

***Corresponding Author:** Khalid Ahmed Khalid, Interventional Pediatric Cardiology, Basrah Medical Collage, Basrah, Iraq.

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Abstract

Introduction: Atrial septal defects (ASD) are congenital cardiac defects, that result in a communication between the left and right atria, and account for 6 - 10% of all congenital hearts disease (CHD). Transcatheter closure of secundum ASD now widely used with global acceptance, closure of atrial septal defect with complex anatomy remain the challenging issue required careful planning and special technique.

Aim of the Study: To prospectively study the outcomes and techniques of transcatheter closure of complex Atrial septal defects.

Methods: An eighty-eight patients with complex atrial septal defects included in a prospective single-center study, from January 2018 till February 2019, at Ibn Albitar center for cardiac surgery, Baghdad, Iraq. Complex atrial septal defect was predefined and inclusion and exclusion criteria are included. All the patients had meticulous echocardiography imaging beforehand. Modifications of the conventional techniques were allowed on a case per case basis according to operator preference.

Results: Out of the 88 patients enrolled, 80 patients had successful device closure (success rate 90.9%) despite challenging anatomy. The closure was failed in 8 cases (9.1%), all of them had a deficient/absent rim, most commonly inferior rim. The most common method used was a conventional technique with or without modifications, followed by dilator assisted method. With no recorded major complication.

Conclusion: Transcatheter closure is safe and feasible in anatomically complex Secundum atrial septal defect. Careful case selection, scrupulous imaging protocol, and expertise in modified techniques are mandatory for successful outcomes.

Keyword: *Congenital Heart Disease; Echocardiography; Device Closure of Septal Defect*

Introduction

Atrial septal defects (ASD) are congenital cardiac defects that result in a communication between the left and right atria and account for 6 - 10% of all congenital heart disease (CHD) [1,2]. The secundum ASD is the most common type, account for about 75% of all ASDs [1]. ASD is one of the most common forms of CHD, with an incidence of 0.2 to 0.5 per 1000 live births. ASD accounts for 6 - 10% of all CHD, with male to female ratio 1:2 [2].

Closure of an ASD if indicated can be done by transcatheter or surgical closure. Although surgical closure of ASD is safe, effective, and time tested, it still requires open-heart surgery and hospitalization. Transcatheter closure of secundum ASD was first described in 1976 by Mills and King [3]. When conditions are favorable, transcatheter secundum ASD closure has become the treatment of choice rather than surgery in many institutions [4].

A full TTE or TEE assessment before catheterization is the initial step in planning the transcatheter closure of an ASD secundum. The goal behind this detailed assessment include [2]:

1. To determine whether the defect is amenable for transcatheter closure.
2. To identify the number of defects.
3. To confirm the absence of other structural heart diseases.
4. To obtain a baseline assessment of cardiac structures that may be affected by the transcatheter procedure.

Atrial septal rims and ASD morphology

To close the ASD using transcatheter techniques, it is important for the interventional cardiologist to have sound knowledge of the atrial septal rims and the structures that surround the ASD. In the past, the rims of the atrial septum have been named according to their physical location (anterior, inferior, etc.) in reference to the patient. For example, the atrial septal rim that is close to the anterior chest wall was called the anterior or anterior/superior rim. When the orientation of the patient changes (for example, from upright to lying down position) the description of the rims may become confusing. To avoid any confusion, a modified classification of the atrial septal rims based upon adjacent structures. This simplified classification was initially proposed by Shrivastava and Radhakrishnan [5]. With minor modification to their classification, Z. Amin suggests the following [6]:

1. Aortic rim, the atrial septal rim that is adjacent to the aortic valve.
2. Superior vena cava (SVC) rim, the rim adjacent to the SVC.
3. Superior (anterosuperior) rim, the rim between the SVC rim and the aortic rim.
4. Posterior rim, the rim opposite to the aortic rim.
5. Inferior vena cava (IVC) rim, the rim adjacent to the IVC.
6. Atrioventricular valve (AV) rim, the rim adjacent to the AV valve rim.

An adequate rim is 7 mm and longer. However, a minimum of a 5 mm rim of atrial septum around the defect has been suggested as a requisite for device closure with an occluder [7]. A deficient or absent rim is anything less than 3 mm. A questionable or inadequate rim is between 3 and 5 mm [2].

Criteria of complex ASD

Definition of complex ASD includes satisfying one of the following criteria [8]:

1. Large ASD measuring ≥ 25 mm.
2. Malaligned septum.

3. Multiple ASD.
4. ASD with a septal aneurysm.
5. ASD with deficiency/absence of one rim.
6. ASD with associated lesions like mitral/pulmonic stenosis, post-tricuspid shunts, coronary anomalies.
7. Small left atrium
8. Combination of any of the above.

Aim of the Study

- To assess the feasibility and safety of transcatheter closure of complex atrial septal defects.
- To determine which method is more suitable for closure of a specific type of ASD complexity.

Patients and Methods

Out of 195 patients who underwent transcatheter closure of ASD, 88 patients with complex ASDs included in a prospective study, from January 2018 till February 2019, at Ibn Albitar center for cardiac surgery, Baghdad, Iraq.

All patients have attended the out-patient clinic of Congenital and Structural Heart Diseases and evaluated clinically and by transthoracic echocardiography, and they met the criteria of complex ASD.

After a full anatomic evaluation of the defect, the decision of transcatheter closure was discussed with the patient/parents and written consent was taken. Every patient was sent for blood testing, chest x-ray, and electrocardiography. 3 - 5 mg/kg/day of oral aspirin was prescribed 24hr before the catheterization day.

On the day of catheterization patients were attended to the catheterization laboratory, all underwent reassessment using TTE/TEE for anatomy and proper sizing.

The procedures were done under general anesthesia using for those patients younger than 18 years and those required TEE, while for older patients, only local anesthesia was used, the femoral artery and vein were cannulated.

Complete right heart hemodynamic study was done to assess the pulmonary artery pressure, right ventricle pressure. The ASD then crossed and a multipurpose catheter was placed in a proper position in the upper left pulmonary vein, an extra stiff guide wire 0.035" was advanced and fixed well in the pulmonary vein, meanwhile, intravenous heparin bolus 100 unit/kg was administered. Then in 14 patients, the ASD balloon stretched diameter was determined using appropriate sizing balloon catheters (AGA Medical Corporation, Plymouth, MN, USA), a device 1 - 4 mm larger than the measured diameter was used. The device size was chosen according to 2D/color echocardiography estimation in the other patients (74 patients), the selected device was 20 - 25% of the measured ASD. TTE was used in 84 patients, while TEE used in 4 patients to guide the transcatheter closure of ASD.

Once the device size was selected. The delivery sheath was advanced over the guidewire to the left upper pulmonary vein. Both dilator and wire were removed, keeping the tip of the sheath inside the left upper pulmonary vein.

The device was then loaded and advanced into the pulmonary vein. The LA disk was deployed first under fluoroscopic and/or echocardiographic guidance then the waist and RA disk. Proper device position then verified using one of the following maneuvers:

- Fluoroscopy in the hepatoclavicular projection (35° LAO/35° cranial), a good device position was evident by the presence of two disks that are parallel to each other and separated from each other by the atrial septum. In the same view and under echocardiography the 'Minnesota wiggle' (the cable is pushed gently forward and pulled backward) was performed to check the stability of the device. A stable device position manifests by the lack of movement of the device in either direction.
- Angiography using the sidearm of the delivery sheath, good device position manifests by opacification of the right atrial disk alone when the contrast was in the right atrium and opacification of the left atrial disk alone on pulmonary levophase.

Once the device position was verified, the device was released.

On the second day, the patient discharged after echocardiography confirming the position of the device. The patient kept on Aspirin 100 mg/day for 6 months and to be followed up at 1, 3, 6 months then annually for the first 2 years, then every 3 - 5 years. The patient informed to resume full activity after 4 weeks.

The above-described method is the conventional technique used to close ASD in 46 patients, if this method was failed to deploy the device successfully, then other special techniques were used as the following.

Dilator assisted technique

Used in (16) patients, in which a second femoral vein line and sheath was required. The stiff end of a 0.035 guidewire was pre-shaped and curved to 45°. This wire was advanced inside the dilator until it reached to the tip. The dilator was maneuvered inside the left atrium. The left atrial disc was deployed inside the left atrium. The dilator was maneuvered to hold the LA disc inside the LA while deploying the waist and the right atrium disc in the defect and right atrium respectively. The dilator was withdrawn back to the right atrium and out of the patient. This technique used for ASD with deficient/absent rim or floppy rim, especially for superior and inferior rims and according to the preference of the operator.

Balloon-assisted technique

Used in (7) patients, in which a second femoral vein line and sheath was required, A2 multipurpose catheter was stationed in the left upper pulmonary vein. This was exchanged for the sizing balloon catheter that was initially used for sizing the defect (or any sizing balloon). The left atrial disc was released well within the LA just outside the opening of the left or right superior pulmonary veins. The sizing balloon then inflated in the right atrium and pushed over the guidewire to about the IAS from the RA side with the assistance of another operator. The LA disc along with the delivery sheath was pulled back towards the IAS so that the inflated balloon could support the LA disc. The waist and the RA disc were then released in succession. The LA disc that tended to prolapse through the ASD and lies horizontally across the defect when not supported was found to cuddle the aortic root with the balloon support. The balloon was gradually deflated. During the balloon deflation, the RA disc was moved toward the LA disc by pushing the loading cable. The balloon, along with the guidewire, was brought down into the inferior vena cava. Again this technique used for ASD with deficient/absent rim or floppy rim, especially for superior and inferior rims and according to the preference of the operator.

Pulmonary vein methods

This method used in (15) patients, in which the delivery sheath was placed into the left/right upper pulmonary vein; the depth of the sheath should be enough to ensure that the left atrial disc will temporarily stay in the pulmonary vein when the sheath was withdrawn. The sheath then withdrew swiftly into the right atrium to deploy both discs simultaneously, while the delivery cable was kept taut and stable in one location. The device resembles an American football at initial deployment. The left disc springs out of the pulmonary vein

and slaps onto the atrial septum. This maneuver keeps the left disc parallel to the atrial septum, which prevents the aortic edge of the device from protruding into the right atrium. If the device does not spring out of the pulmonary vein, gentle traction on the cable helps in withdrawing the device. This method used for a defect with deficient or floppy rim with small size left atrium.

Multiple ASD

If the intervening tissue was less than 7 mm then the defects were closed using a single device. But if the intervening tissue was more than 7 mm then the defects were closed using two separated devices, first to close the smaller one then the larger defects.

Oversizing

If the inferior rim was deficient, closure the defect using a device that was larger than expected to ensure stenting the deficient rim (2 patients) [9].

Results

Eighty-Eight patients with complex ASD secundum were included, 67 females and 21 males with a female to male ratio about 3.2:1. Their age ranged from 4 - 67 years (26.8 ± 18.4) and weight 13 - 129 kg (55.3 ± 25.8).

The most common category of the complex defect was ASD with deficient/absent rim seen in 26 (29.5%) patients (Table 1). In eighty patients (90.9%) the defect was successfully closed (significant correlation to complexity with P-value 0.001) and failed in 8 patients (9.1%) all of them were with deficient/absent rim (Table 2).

Feature			No.	Frequency
Type of complexity	Large ASD		12	13.6%
	Multiple ASD		17	19.3%
	Malaligned septum		5	5.7%
	Septal aneurysm		18	20.5%
	Deficient/absent rim		26	29.5%
	Small LA		3	3.4%
	Large/aneurysm		3	3.4%
	Floppy rim		4	4.5%
ASD rims	Adequate rims		52	59.1%
	Deficient/absent rim	Atrioventricular	2	2.3%
		Anterosuperior	2	2.3%
		Superior (SVC)	7	8.0%
		Inferior (IVC)	17	19.3%
Method of closure	Conventional		49	55.7%
	Dilator assisted		16	18.2%
	Balloon assisted		7	8.0%
	LU/LL PV		10	11.4%
	RU PV		5	5.7%
	Intermingling		1	1.1%
Total			88	100%

Table 1: *The frequency and types of complex ASD.*

Feature			Success	Failure	P-value
Type of complexity	Large ASD		12 (100%)	0 (0%)	0.001
	Multiple ASD		17 (100%)	0 (0%)	
	Malaligned septum		5 (100%)	0 (0%)	
	Septal aneurysm		18 (100%)	0 (0%)	
	Deficient/absent rim		18 (69.2%)	8 (30.8%)	
	Small LA		3 (100%)	0 (0%)	
	Large/aneurysm		3 (100%)	0 (0%)	
	Floppy rim		4 (100%)	0 (0%)	
ASD rims	Adequate rims		52 (100%)	0 (0%)	0.001
	Deficient/absent rim	Atrioventricular	1 (50%)	1 (50%)	
		Anterosuperior	0 (0%)	2 (100%)	
		Superior (SVC)	6 (85.7%)	1 (14.3%)	
		Inferior (IVC)	13 (76.5%)	4 (23.5%)	
Method of closure	Conventional		46 (93.9%)	3 (6.1%)	0.470
	Dilator assisted		14 (87.5%)	2 (12.5%)	
	Balloon assisted		5 (71.4%)	2 (28.6%)	
	LU/LL PV		9 (90%)	1 (10%)	
	RU PV		5 (100%)	0 (0%)	
	Intermingling		1 (100%)	0 (0%)	
Total			80 (90.9%)	8 (9.1%)	

Table 2: *The success rate of closure of complex ASD.*

TTE was used in 84 patients to guide the procedure, while TEE used in 4 patients, the largest defect size measurement was taken ranged from 6 mm to 37 mm (21.5 ± 7.4), depending on the 2D/color measurement in 74 patients, and sizing balloon required in 14 patients.

The total procedure time required to complete intervention was ranged from 21 - 180 min (53.2 ± 23.2) with fluoroscopy time ranged from 4 - 53 min (13.5 ± 8). The peak systolic pulmonary artery pressure was ranged from 15 - 60 mmHg (31.6 ± 9.7). Twenty-three percent of the patients were with pulmonary hypertension (21 patients PASP > 35 mmHg, 17 patients were mild and 4 patients were moderate).

Amplatzer septal occluders were used, the device size ranged from 10 - 40 mm (27.04 ± 8.2).

Eighty (90.9%) patients of complex ASD, the defect was successfully closed (significant correlation to complexity with P-value 0.001) and failed in 8 (9.1%) patients all of them were with deficient/absent rim (Table 1).

The commonly used method for closure was the conventional method with or without simple modifications, which used in 49 (55.7%) patients, defects associated with septal aneurysm being the most commonly closed by this method 16 (32.7%) patients, followed by multiple ASDs 12 (24.5%) patients.

Dilator assisted method used to close 16 (18.2%) patients, 14 (87.5%) patients were successfully closed while 2 (12.5%) patients failed, the most commonly closed defect by this method those with deficient/absent rim (most of them were inferior rim) (Table 2 and 3).

The most challenging complexity was ASD with Deficient/absent rim, which presented in 26 patients, 18 patients were closed successfully (69.2%), 8 patients closed by using dilator assisted method, 6 cases by the conventional method (with or without oversize the device), 5 patients by balloon-assisted method, 5 patients by LUPV method and 2 patients by RUPV method (Table 3B).

Category	Methods [No. (%)]						Total [No. (%)]	P-value
	Conventional	Dilator assisted	Balloon assisted	LU/LL PV	RUPV	Intermingling		
Large ASD	8 (66.7%)	2 (16.7%)	1 (8.3%)	0 (0%)	1 (8.3%)	0 (0%)	12 (100%)	0.013
Multiple ASD	12 (70.6%)	2 (11.8%)	0 (0%)	0 (0%)	2 (11.8%)	1 (5.9%)	17 (100%)	
Malaligned septum	3 (60%)	1 (20%)	1 (20%)	0 (0%)	0 (0%)	0 (0%)	5 (100%)	
Septal aneurysm	16 (88.9%)	1 (5.6%)	0 (0%)	1 (5.6%)	0 (0%)	0 (0%)	18 (100%)	
Deficient/absent	6 (23.1%)	8 (30.8%)	5 (19.2%)	5 (19.2%)	2 (7.7%)	0 (0%)	26 (100%)	
Small LA	1 (33.3%)	0 (0%)	0 (0%)	2 (66.7%)	0 (0%)	0 (0%)	3 (100%)	
Large/aneurysm	1 (33.3%)	0 (0%)	0 (0%)	2 (66.7%)	0 (0%)	0 (0%)	3 (100%)	
Floppy rim	2 (50%)	2 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (100%)	

Table 3A: *This table shows the No and percentage of the method used for each category of complex ASD.*

Deficient/ absent rim	Methods [No. (%)]						P-value
	Conventional	Dilator assisted	Balloon assisted	LU/LL PV	RUPV	Total	
Atrioventricular	1 (50.0%)	1 (50.0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)	0.038
Anterosuperior	1 (50%)	0 (0%)	0 (0%)	1 (50%)	0 (0%)	2 (100%)	
Superior (SVC)	1 (14.3%)	2 (28.6%)	2 (28.6%)	0 (0%)	2 (28.6%)	7 (100%)	
Inferior (IVC)	4 (23.5%)	6 (35.3%)	3 (17.6%)	4 (23.5%)	0 (0%)	17 (100%)	

Table 3B: *This table shows the distribution of ASDs with Deficient/absent rim and the appropriate method of closure.*

Table 3: *The complexity of ASDs and closure methods.*

Complications occurred in 8 (7.1%) patients, 6 of them developed minor complication included: acute new-onset arrhythmia developed in 3 patients (3.4%), Three patients experienced a residual shunt (3.4%), while 2 patient developed major complication included: device embolization was complicating one patient (1.1%), one patient developed an acute pulmonary embolism (1.1%).

Discussion

Transcatheter closure of secundum ASD has become over time a widely accepted therapeutic option in many cardiac centers, with similar closure rates, fewer complications, and lower cost as compared with surgical closure. The closure of an ASD with complex anatomy is not an easy issue, the operator should understand that the success of such ASD closure mainly depends on the proper imaging techniques [10]. A thorough interpretation of the septal anatomy is paramount to success. Complex anatomical substrates like sinusoidal septum, aneurysm, and fenestrated defects require careful delineation before planning intervention [11].

Our study was a single-center experience study, out of 195 patients underwent transcatheter closure of ASD, 88 patients (45%) with complex ASD secundum were included, a female to male ratio about 3.2:1 this is higher than reported [12] that suggest a higher incidence of complex anatomy among females.

The most common category of complex ASD was deficient/absent rim which, this is a similar result to the study carried out by AA Pillai., *et al* [8]. The most common rim that met the definition of deficient/absent rim [13] was the inferior rim which comparable to the result of a recent study carried out by Marco Papa., *et al*. [9] and deferent from the result of a study carried out by Lee WC., *et al.* where the aortic rim deficiency was the most common [14].

Unlike the other studies where the transcatheter closure carried out under the guidance of TEE [8,9,14-17], in our study the closure carried out under TTE in 95% and TEE used only in 4.5%, and sizing balloon required in (15.9%), this according to the policy of closure in our center.

Total procedure time and fluoroscopy time required to complete intervention were significantly shorter than previous studies by AA Pillai., *et al*. (52 and 28 min) [8] and Santoro G., *et al*. (141 min and 28 min) [15] this may be due to improved experience in the closure of such complex ASDs or may be related to the use of TTE that may shorten the procedure time.

Twenty-three percent of the patients were with pulmonary hypertension (PASP > 35 mmHg), which is slightly higher than previously found by Suárez de Lezo J., *et al*. where they record 21.4% of their study were had pulmonary hypertension [18] as the age group in our study was older.

Amplatzer septal occluders were used. The device size ranged from 10 to 40 mm (27.04 ± 8.2) in comparison with a study carried out by Berger F., *et al*. where the defect size (28 ± 3 mm) [17].

The closure was successful in 90.9% using different methods, while the closure was failed in 9.1% all were with deficient/absent rim defects. The success rate is significantly higher than studies done by Santoro G., *et al*. [15], Assaidi A., *et al*. [16] and nearly the same for the study of AA Pillai., *et al*. [8] this increment in success rate related to improved skills with time and the variety of methods used to close complex ASDs.

The commonly used method for closure was the conventional method with or without simple modifications, which used 55.7%, this result was similar to the study carried out by Romanelli G., *et al* [19]. Defects associated with septal aneurysm being the most commonly closed by this method, followed by multiple ASDs.

Dilator assisted method used in 18.2%, the most commonly closed defect by this method those with deficient/absent rim (most of them were inferior rim). This used more frequently than other modified technique and other studies may be due to advanced experience with dilator assisted method at our center than other centers [8,20].

The balloon-assisted method used in 8% of patients, as this helps to provide a proper anchoring for stable device deployment. As its safer than dilator assisted method so it's preferred to be used by other studies as it was the most commonly used method by AA Pillai., *et al* [8].

Large ASD was present in 13.6% of patients, all were successfully closed with a success rate higher than previously recorded by Berger F., *et al*. [17] the most frequently used technique was the conventional method which is similar to Romanelli G., *et al*. [19] as these defects although large but there were enough rims for successful deployment, the next method used for ASDs not closed by the conventional method was dilator assisted method.

The success rate of closure of multiple ASDs were 100%, a single device was used in 15 patients and 2 devices used in 2 patients, this rate was higher than the study of Cao QL., *et al*. [21], the most frequently used method was the conventional method as these defects usually with favorable size and rims.

Five cases were with Malaligned septum, all were successfully closed, 3 by the conventional method, one by dilator assisted and the other by the balloon-assisted method. This success rate is similar to the results of Mullen MJ., *et al* [22].

The most challenging complexity was ASD with Deficient/absent rim, which present in 29.5% of patients, among them 69.2% were successfully closed, this rate of closure is higher than recorded previously by Marco Papa., *et al.* (50%) [9].

The small left atrial size provides a shorter distance between the left pulmonary vein and the interatrial septum (the septal defect) which provides a good opportunity to close such a category of ASD.

Acute complications occurred in 8 patients (7.1%), all were minor complications. Which comparable to other studies [2,23,24].

Acute new-onset arrhythmia developed in 3.4% which similar to the result of Zhong-Dong Du., *et al* [23]. Two patients developed supraventricular tachycardia and one case atrial fibrillation all are resolved with medical treatment.

Three patients experienced a residual shunt (3.4%), in 2 patients of aneurysmal IAS, and one patient with the floppy rim.

Device embolization was complicating one patient (1.1%) which removed percutaneously using gooseneck snare. This rate is within the range of recorded percentage by many studies (0.5 - 3%) [2,25,26].

One patient developed an acute pulmonary embolism (1.1%) that successfully treated medically (Table 4).

Complications	Frequency	Percent
Acute arrhythmias	3	3.4
Residual shunt	3	3.4
Device embolization	1	1.1
Acute pulmonary embolism	1	1.1

Table 4: *Early post catheterization complications.*

Conclusion

1. Most cases of the complex anatomy of secundum atrial septal defects can be closed successfully either by using conventional or special closure methods.
2. Defects with deficient or absent rim continue to form a challenging task for most international cardiologists, so the decision must be individualized according to the anatomy of the defect and its rims.
3. Proper imaging and sizing of the defect is the cornerstone of successful transcatheter closure of complex ASDs.

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