

## IMMEDIATE OUTCOME AFTER PERCUTANEOUS DEVICE CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT

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### Contribution

MY conceived the idea and designed the study. Data collection and manuscript writing was done by MY, AB, and TAC. All the authors contributed equally to the submitted manuscript.

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## ABSTRACT

**Objective:** To determine immediate outcome after percutaneous device closure of secundum atrial septal defect in children and adults.

**Methodology:** This descriptive study was conducted at Paediatric Cardiology department, Ch. Pervaiz Elahi Institute of Cardiology, Multan from 2011 to 2019. Patients with moderate to large ASD secundum with RV volume overload were selected. Patients below 10 Kg and with severe pulmonary hypertension were excluded. Procedures were performed either under general anaesthesia or deep sedation. Immediate outcome after procedure was studied.

**Results:** A total of 86 patients underwent ASD device closure. Mean age was  $25 \pm 1.4$  (4-54 years) and male to female ratio 1:2. Mean defect was  $20.57 \pm 0.57$  (09 to 32 mm). Pulmonary valvuloplasty was performed in 03 patients (3.5 %). Device size was selected on the basis of echo measurement + 2-5 mm. Balloon sizing was performed only in 4 (4.6 %) cases. Septal occluders from different companies were used with equal good results. Balloon assisted technique was used in 09 (10 %) patients. Two devices (2.3 %) were embolized. In both cases IVC margin was deficient. Transient arrhythmias were observed in 07 (8%). One patient each of pericardial effusion and clot on left atrial disc were observed and treated conservatively. There was no mortality.

**Conclusion:** Percutaneous closure of moderate to large ASD secundum in children and adults is a safe procedure with good immediate outcome. IVC margin is crucial to prevent device embolization. The most of the complications are uncommon, transient and can be managed.

**Keywords:** ASD secundum, Device Closure, immediate outcome

## INTRODUCTION

Atrial septal defects (ASDs) constitute 8 % to 10 % of congenital heart defects.<sup>1</sup> Secundum ASD constitutes approximately 75 % of ASDs followed by ostium primum ASD (20 %) and sinus venosus ASD (5%). Presentation is usually asymptomatic or dyspnoea on exertion. Age of diagnosis varies from childhood to adults. Device closure of ASD secundum was tried in 1976 by King and Mills.<sup>2</sup> A numbers of devices were used in the past. Common devices are CardioSeal, StarFlex, button device, Helex and Amplatzer septal occluder.<sup>3</sup> AGA Amplatzer device has revolutionized the ASD device closure and is the most commonly used device now a days.<sup>4</sup> Even large defects can be closed by this device. Results of device closure are comparable with surgical closure with short hospital stay and no complications related to thoracotomy or bypass.<sup>5</sup> In this study, we will study immediate outcome after device closure of secundum ASD in our centre.

## METHODOLOGY

This was a descriptive study, performed at Chaudhry Pevai Elahi Institute of Cardiology Multan. Study duration was from 2011 to 2019. Total 86 patients were studied. Informed consent was taken from patients or their parents. Study was approved by ethical committee of the Institution. Diagnosis of ASD was based on history, examination and echo. Suitability for device closure was assessed by Transthoracic as well as Trans-Oesophageal Echo (TOE). Patients with small ASD secundum (4-5 mm defect with no RV volume overload), children below 10 Kg and patients with severe pulmonary hypertension were excluded from the study. Moderate to large secundum ASDs with RV volume overload were included in this study. On the basis of age, patients were divided into two groups (Group-I = < 15 years of age and Group -II > 15 years). In Group I, moderate ASD secundum was defined as ASD size between 5-15 mm with RV volume overload and large ASD was defined as ASD size > 15 mm with significant RV volume overload. In Group II, moderate ASD secundum was defined as ASD size between 5- 20 mm with RV volume overload, moderately large ASD between 21-25 mm and large ASD was defined as ASD size 26 mm or more with significant RV volume overload. Total absence of surrounding margins except aortic margin was considered as contraindication. Margin of 5 mm or more was considered adequate and less than that was considered as deficient margin. Disposables were mostly provided by the Institute. Patients were admitted to the hospital one day before procedure. Screening for infection, anaemia, bleeding tendency and hepatitis were done . Fitness from pulmonologist and anaesthetist were obtained. Deep sedation with ketamine and propofol was used for children with simple ASDs. General anaesthesia with ETT was used

for complex cases and for adults with poor chest windows. Device was selected on the basis of 2-D Echo size and adding 2-5 mm. Balloon sizing was performed only if there was any doubt about size of the ASD. From femoral vein, multipurpose catheter was placed in right or left upper pulmonary vein and 0.35 "extra stiff exchange wire was anchored. Appropriate sized ASD delivery sheath was selected, prepared and taken to pulmonary vein. Left atrial (LA) disc was opened partially in pulmonary vein or along LA roof, later waist and RA (right atrium) disc were released slowly. If position on Echo was satisfactory then gentle push and pull (Wiggle maneuver) was performed to check stability of the device. Patients were observed in ward for 24 hours. Transthoracic Echo was performed after 24 hours and then patient was discharged if stable. Aspirin once a day (75 mg for < 30 Kg, 150 mg for > 30 Kg) was started a day before intervention. Procedure was considered successful if there is no residual shunt or residual shunt of < 2 mm. Data about success, immediate complications (mortality, device embolization, pericardial effusion, thromboembolism and arrhythmia) was entered in SPSS software and analyzed.

## RESULTS

Out of total 86 patients, 60 (70%) were more than 15 years of age. Mean age was  $25 \pm 1.4$  (4 -54 years). Male to female ratio was 1:2. Patient data about age and sex is given in Table 1. Severity of lesions is described in Table 2 and separated according to age. Mean defect as a whole was  $20.57 \pm 0.57$  (09 to 32 mm). Complex ASDs were defined as having two or more margins deficiency, multiple ASDs, defects with malaligned or floppy margins and ASD associated with aneurysm of fossa ovalis. Complex ASDs were found only in six patients (7%). Two margins deficiency was observed in four (4.6%) patients. Two patients (2.3%) had IVC and aortic margins deficiencies and two (2.3%) had SVC and aortic margins deficiencies. One patient (1.16%) had floppy rims. ASD closed successfully in this patient after balloon sizing. One patient had two ASDs secundum (one was moderate, second was small and close to IVC). Only moderate ASD was closed with device.

**Table 1: Patients characteristics (n=86)**

Characteristics	Frequency (%)
<b>Age</b>	-
1-5 yrs	1.2% (1)
6-10 yrs	12.8% (11)
11-15ys	16.3% (14)
> 15ys	69.7% (60)
<b>Sex</b>	-
Male	33.7% (29)
Female	66.3% (57)

**Table 2: Severity of lesions**

Total	Group I < 15 years N=26	Group II > 15 years N=60
<b>Severity</b>		
Moderate	34.6% (9)	41.7% (25)
Mod- large	-	38.3% (23)
Large	65.4% (17)	20% (12)
<b>Complexity</b>		
Simple	88.5% (23)	95% (57)
Complex	11.5% (3)	5% (3)
Two or more margins deficiency	66.7% (2/3)	66.7% (2/3)
ASD with floppy	0 (0/3)	33.3% (1/3)
Two ASDs	33.3% (1/3)	0 (0/3)

fix the device across defect. Second patient was 15 years

Deficiency of surrounding margins is described in Table 3. Aortic margin was deficient or absent in 61 (71%) patients. Assessment of patients for suitability of device occlusion, severity of pulmonary stenosis and level of pulmonary hypertension were performed totally with transthoracic and /or trans-oesophageal echocardiography. All the patients on echocardiography had mild to moderate pulmonary hypertension. Haemodynamics were not assessed during cardiac cath. Pulmonary valvuloplasty was performed in 03 (3.5%) patients due to moderate pulmonary stenosis. Coronary angiography was performed and LV end diastolic pressure was recorded in only 09 patients (10.5%). These patients were > 45 years of age. Among them, only one patient had large ASD secundum. LV end diastolic pressure was < 15 mm Hg in these patients and no rise was observed after device placement. We used different techniques for device deployment like right upper/ left upper pulmonary veins or left atrial roof. Right upper pulmonary vein approach was used in 52 patients (60%). Balloon assisted technique was used in 09 (10%) patients to align device along interatrial septum. We used ASD devices of different sizes ranging from 12 to 36 mm. The most commonly used devices were 22, 24 and 26 mm. ASD devices from AGA Amplatzer, Life Tech Cera and Occlutech Figulla were used. Mean procedure time was 50 min (Range = 35 to 125 min) and mean fluoroscopy time was 12 min (Range= 4 to 35 min). The procedure was uneventful in most of the patients with small insignificant residual leak (< 2 mm) in 11 (12.8%) patients. These residual leaks disappeared within 24 hours. Post procedure immediate outcome is given in Table 4. Arrhythmia requiring medication during procedure was observed in 7 patients (8%). Two devices were embolized in our study. One was 10 years old boy with 20 mm defect. Device unscrewed accidentally and embolized into right ventricle while trying to

old with a large 27 mm defect. Device of 32 mm was placed with balloon assisted technique but immediately after release, device was embolized into pulmonary artery. We tried to catch the devices with the help of goose neck snares. But due to prolonged fluoro time and considering our learning curve, decision of surgery was finalized to retrieve the devices and close the ASDs, Both ASD were closed on the same day of procedure. Post procedure, small pericardial effusion was observed in a 45 old lady with large ASD with floppy margins. We performed balloon sizing with 34 mm compliant balloon and device was aligned across interatrial septum with balloon assisted technique. Cause of pericardial effusion was not known. Pericardial effusion resolved within one month on conservative treatment. There was no procedure related mortality in our study.

**Table 3: Details of margins of ASD**

Margin	Frequency (%)
<b>Aortic</b>	
Deficient (< 5 mm)	58.1% (50)
Absent	12.8% (11)
<b>Superior vena cava</b>	
Deficient	2.3% (2)
<b>Inferior vena cava</b>	
Deficient	2.3% (2)
Posterior and atrio-ventricular valve margins were adequate in all patients	

**Table 4: Procedure outcome**

Characteristics	Frequency (%)
Residual leak	12.8% (11)
Arrhythmias	8.1% (7)
Device embolization	2.3% (2)
Clot on device (Left atrial disc)	1.2% (1)
Pericardial effusion	1.2% (1)
Mortality	0% (0)

## DISCUSSION

Atrial septal defect is the second most common cause of congenital heart defects.<sup>6</sup> Surgery had been the only treatment available for many years. Surgery is safe with no significant mortality and morbidity. Now device closure of atrial septal defect has become the treatment of choice for secundum ASD with adequate margins.<sup>7</sup> In this study we studied 86 children and adults with percutaneous device closure of secundum ASD. We evaluated their procedural characteristics and immediate outcome. This region is underdeveloped and people are non-affording. Disposables are provided by the Institute. Among the surrounding margins, aortic margin was found deficient in 61 (71 %) of patients. In another study,<sup>8</sup> aortic margin was also found deficient in 63.3 % patients. We used balloon assisted technique in 9 (10%) cases. This technique was described by Bharat Dalvi in 2005,<sup>9</sup> and used by other operators in difficult cases as well.<sup>10</sup> Successful closure was achieved in 84 (97.6 %) cases which is comparable with national<sup>11</sup> and international studies.<sup>12,13</sup> The complex ASDs were only 6 (7%). The major adverse outcomes was device embolization which was observed in two patients (2.3 %). Studies from other centers showed embolization rate from 1% to 3%.<sup>14,15</sup> Among the minor adverse outcome, atrial arrhythmia was observed in 07 (8%) patients. These transient arrhythmias were reverted to sinus rhythm with single injection of adenosine or verapamil. Clot on left atrial disc was observed in one patient immediately after deployment which was resolved in 72 hours of heparin infusion.<sup>16</sup> Post procedure pericardial effusion was observed in one patient. This patient remained asymptomatic and effusion was resolved with aspirin in four weeks. One patient with pericardial effusion was also seen in a study by Kazmi et al.<sup>10</sup> Their patient was also recovered on conservative management. There was no procedure related mortality in our study. The limitation of the study was that this was our initial experience on limited number of patients and procedures were performed by two operators in a single Institute. This study will be a base for future studies on larger number of patients and on complex atrial septal defects.

## CONCLUSION

Percutaneous closure of moderate to large ASD secundum in children and adults is a safe procedure with good immediate outcome. Device embolization is the most common major adverse outcome. Adequate IVC margin is crucial to prevent this complication. Arrhythmias are common but transient. Clot on left atrial disc and pericardial effusion are uncommon events.

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