

## A Minimalistic Approach of Device Closure of Atrial Septal Defect: Analysis of Cases Over Five Years.

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**ABSTRACT:-** Transcatheter device closure of atrial septal defect (ASD) secundum type has become an alternative treatment option to surgery since late 1990. The aim of this study was to analyze five years' outcome of minimalistic approach of ASD device closure using transthoracic echo guide under conscious sedation. This retrospective study was conducted in a tertiary care cardiac hospital in Dhaka, Bangladesh, from December 2014 to 2019. Cases planned for device closure using minimalistic approach were included in the study. Out of 351 cases, 320 cases fulfilled the criteria for device closure. The patients were aged  $13.97 \pm 14.82$  years, weighed  $27.48 \pm 20.11$  kg, with a male: female ratio of 0.58:1. The mean ASD diameter was  $18.24 \pm 8.63$  mm, balloon occlusion diameter was  $21.00 \pm 7.16$  mm and mean device diameter was  $21.05 \pm 7.49$  mm. Mean fluoroscopy and procedure time was  $7.63 \pm 2.05$  and  $32.44 \pm 8.17$  minutes. The QP: QS was 2.80:1. The device was successfully implanted in 99.05% cases and embolized in 0.95% cases. There were no major complications in follow up of 6 months to 5 years (median 28 months). In conclusion, minimalistic approach of ASD device closure is safe, effective and can simplify the procedure without adding any major complications and risk.

**Keywords:** atrial septal defect, transcatheter, closure, device

### I. INTRODUCTION

The technique of transcatheter closure of atrial septal defect (ASD) was first reported by King and Mills in 1976 [1]. The technique has been in evolution since then for the last four decades with improvement in the design of devices which are safer and more user-friendly with less chance of complications. Thus, it has become the first choice of therapy in suitable cases [2,3]. This technique is now widely used for closing isolated secundum ASD in children and adults [4,5]. Despite good outcome, rare complications may occur in less than 2% cases e.g. perforation of heart, embolization of device and arrhythmia [3,6,7]. Usually transcatheter ASD closure procedure is performed under general anesthesia (GA) using transoesophageal echocardiography (TEE) guide [2]. It has been observed from some study experiences that prolong procedure and excessive manipulation of device across ASD lead to complications like arrhythmia, cardiac perforation, thromboembolic manifestations etc. [1,8]. In the current study, cases were performed under awake condition in adults or conscious sedation with monitored anesthesia care in children. GA was at stand by for all cases. Transthoracic echo guide (TTE) and fluoroscopy guide were availed. As transesophageal echo guide was avoided in most cases, with exceptions such as in cases with poor echo window, GA was not required. The aim of this study was to show the outcome of cases using minimalistic approach in procedure steps by avoiding GA and TEE in a resource constraint set up.

### II. METHODS

A retrospective analysis of patients from December 2014 to December 2019 was performed. A total of 351 cases were admitted for ASD device closure in Lab Aid Cardiac Hospital, Dhaka, Bangladesh, in this period. They fulfilled the criteria for any kind of closure, either surgical or with devices, based on previous diagnostic work up and were planned for device closure. Some young children were included as their ASD size were increasing progressively in every subsequent follow up and parents were interested in device closure before ASD became too large for transcatheter closure. Among those included, 35 cases had very large ASD (>35mm) and were planned for trial. All the cases were evaluated thoroughly by chest X Ray (CXR), 12 leads electrocardiogram (ECG) and transthoracic echocardiography (TTE). Adult patients were evaluated for comorbidities like coronary artery disease, arrhythmia, renal disease, diabetes etc. Routine blood tests (CBC, PT, APTT, grouping, urea, creatinine, electrolytes, HBsAg) were performed in all cases along with lipid profile,

Holter ECG, and blood sugar in high risk adult cases. Transthoracic echocardiography was performed thoroughly on the day before examination in GE vivid 7 (Probo Medical, USA) and Philips EPIQ 7C (Philips, USA) machine to plan the strategy and possible device size. Cases with good rims and normal pulmonary artery pressure or mild pulmonary artery hypertension were planned for direct closure without any haemodynamic study. Patients with significant pulmonary hypertension and very large ASD were planned for haemodynamic study in detail. All cases were performed under fluoroscopy and TTE guidance except two cases. In those two adult cases, transoesophageal echocardiography guide was taken under GA for poor echo window. All patients over the age of 18 years were considered as adult patients and were operated in awake condition. Patients were monitored closely by the nurse intensivist and in some cases by anesthesiologist. All the children below 18 years were performed under conscious sedation with injection Midazolam, Injection Ketamine and Injection Phenobarbitone either alone or as cocktail. In our institution, we prefer cocktail of these three drugs in lowest therapeutic dose to avoid complications from maximum dose of a single drug. Femoral vein was cannulated in majority of the cases but in cases with severe pulmonary hypertension, femoral artery was cannulated for proper haemodynamic calculations. Left ventricle sample was considered as femoral artery sample for QP:QS calculation in cases with mild or moderate pulmonary hypertension. Balloon sizing was performed in all except three cases in young children, where rims were thick and supportive and maximum diameter was taken from transthoracic echo excluding thinner part of rim. During measuring balloon occlusion diameter (BOD), waist of balloon was measured in cases with good rims and stop flow technique was followed in cases with floppy rims. In two cases, left atrium (LA) was small, and LA disc was opened partially inside right atrium and was forwarded to left atrium. For large ASD cases, left atrial disc was deployed by left pulmonary vein engagement technique. All the patients were heparinized with 100 unit/kg body weight. Activated clotting time was kept above 200. Injection Ceftriaxone 50mg/kg body weight was given, and another dose repeated after 24 hours. Two more doses of heparin 50 unit/kg were repeated after six hours and 12 hours and ECG recorded after 12 hours and 24 hours. Tablet Aspirin 5mg/kg body weight was advised for all patients up to six months. All patients were discharged after 24 hours of close monitoring. CXR and TTE were performed before discharge. Follow up was planned at 1, 3, 6, 9, 12, 18, 24 months and yearly thereafter. CXR, ECG and TTE were performed in each follow up.

a. **Devices used:**

Cera ASD Occluder (Lifetech scientific, (Schenzen) Co limited), Amplatzer septal occlude (St Jude Medical, St Paul, MN, USA), Cookon Septal occluder (Vascular innovations company limited, Nonthaburi, Thailand), Figulla flex device (Occlutech, Switzerland).

Ethical committee of the hospital permitted this study as per their guideline. Informed consent was taken from patients and guardians as required.

b. **Statistical calculations:**

Numerical variables are expressed as mean  $\pm$  standard deviation and categorical variables are expressed as frequency and percentage. As it is a single variant study, comparative analysis was not done. Results were calculated from MS Excel spread sheet.

### III. RESULTS

A total of 351 cases were included in the cohort, eight (2.28%) cases were postponed for severe pulmonary hypertension and high pulmonary vascular resistance (PVR), 23 (6.55%) cases were postponed after balloon sizing for excessively large ASD size and unachievable stop flow after balloon inflation, four (1.14%) cases were postponed for malposition and mushrooming deformity of device. Three cases (0.85%) were embolized and 313 (89.17%, n= 351) had successful closure (Fig.1).

Table I showed demographic data. The mean age of the patients was  $13.97 \pm 14.82$  years (range 12 months to 65 years). Male:female ratio was 0.58:1, mean weight was  $27.48 \pm 20.11$  kg and range were eight to 72.5 kg. Pre-intervention ASD diameter was  $18.24 \pm 8.63$  mm. Associated defects were pulmonary stenosis (PS) in 10 (2.85%) patients, VSD in six (1.71%) case, PDA in four (1.39%) and additional small ASD in five (1.43%) cases.

Table II showed catheterization laboratory data. The mean balloon occlusion diameter was  $21 \pm 7.16$  mm, mean ASD device size was  $21.05 \pm 7.49$ mm (range 12 mm- 40 mm), mean fluoroscopy time was  $7.63 \pm 2.05$  minutes and procedure time was  $32.44 \pm 8.17$  minutes. Mean QP: QS ratio was  $2.80 \pm 0.64:1$ . Eight (2.28%) cases were postponed for high PVR ( $>10$  wood units). Twenty-three (6.55%) cases were postponed for large size evident from balloon occlusion of sizing balloon and stop flow was not achieved. All rims were collapsed with balloon occlusion. In first attempt 320 (91.17%) cases had successful device implantation, but four (1.25%) cases had malposition of device which could not be corrected and was removed before release. Device was embolized in cath lab in one (0.31%) case and in post cath area within 24 hours in two cases (0.57%). Cera flex

device was used in 66.25% cases, Cookon in 15.94 % cases, Amplatzer Septal occluder in 16.25% and Figulla flex in 1.36% cases.

Table III showed outcome and late events. Out of 316 cases of device implantation, 313 (99.05%) had successful implantation, 312 (98.73%) cases had complete occlusion, one (0.31%) had mild residual shunt and three (0.95%) had embolization of device. No cardiac erosion or mortality was recorded in long term follow up. Ventricular tachycardia was noticed in one (0.31%) case, allergic reaction to Nickel in one (0.31%) case and new onset migraine was noticed in two (0.63%) cases.

Fig. II and III showed balloon sizing of ASD from waist and stop flow diameters.

Fig. III showed checking of fully deployed device by fluoroscopy and TTE.

Fig. IV showed device after release from delivery cable.

#### IV. DISCUSSION

Percutaneous closure of ASD has become an attractive procedure because of its short learning curve, cosmetic benefit, short hospital stay, less work day loss and good outcome [9]. The reported prevalence of secundum ASD was 3.2 per 1000 live birth [10]. Indications for closure are hemodynamically significant ASD secundum with QP:QS $\geq$ 1.5:1, history of stroke or transient ischemic attack (TIA) and cyanosis due to transient right to left shunt (11). Small secundum ASD without hemodynamic significance are excluded unless there is history of stroke. In this cohort, ASD with advanced pulmonary hypertension were excluded from device closure after catheterization study (Figure I). Many studies were conducted to compare surgical and transcatheter technique of closure and the outcome was better in the transcatheter group [12,13]. In this study, age of the patients ranged from 12 months to 65 years (Table I). In other studies, specific age groups (children, adult) were included. The average age was 37.19 $\pm$  13.30 years in one study and 28.3 $\pm$ 6.6 years in another study [14,15]. In our series, we observed that ASD rapidly increases in size with increasing age in infants in subsequent follow up. These cases were included for device closure. So, the lowest age was 12 months and the lowest weight was eight kg which were considered safe for passage of delivery system up to 7 French size. In our series, there was no age or weight related complications. But some studies showed low procedural success rate in young children with high complications [16,17]. Due to its asymptomatic nature, ASD is the most common congenital heart disease (CHD) present in adult [18,19]. In our study, significant number of cases were more than 18 years of age (mean age 13.97 $\pm$  14.82 years). The male female ratio of 0.58:1 correlates with a study by Yangyang Han et al [15] but not with Ata Firouzi et al [14]. In this cohort, many female cases were detected during their pregnancy which led to a higher number of female patients (63.2%). The mean preintervention ASD size was 18.24 $\pm$ 8.63 mm as measured by color doppler echocardiography. The actual assessment of ASD size prior to device implantation was based on measurement of balloon occlusion diameter and matching with sizing plate. This is in contrast with majority of the studies where ASD size was measured by TEE or intracardiac echocardiography (ICE) [5,14]. We preferred balloon sizing because it was the best option as it can be done by a single operator and can take proper stretched diameter especially in cases with floppy rims. Waist formation and stop flow of blood across ASD after inflation of balloons gives exact idea about its size so we can plan the smallest possible device which is equal to or up to two mm more than balloon occlusion diameter (BOD) (Table 2) [1,9]. In our series, the patients' age varied from one year to 65 years so even though all the ASDs were large, there is a wide variation of balloon occlusion diameter (mean BOD was 21 $\pm$ 7.16 mm (range 11mm- 36mm)).

BOD reduced procedure time by providing the exact size of ASD, so there was less chance of mismatching and repeated trial with inaccurate sized devices. Use of TEE or ICE could be avoided for accurate sizing especially in resource constraint (manpower and equipment) setups. General anesthesia was not required which also reduces the risk and overall procedure time. This approach was successfully used in another study conducted in 2015 [1]. In this series, only two cases were performed with TEE guide because of very poor echo window. In some cases, combined intervention was done. The most common was pulmonary valvuloplasty which correlates with other studies [20]. Additional small ASDs were covered with a single device. The mean size of ASD devices used was 21 $\pm$ 7.16 mm which correlates with other studies [5,14]. Currently devices up to 40 mm is available. In our study, we used devices ranging from 12 mm to 40 mm. Although there is no comparative study available between outcome of small and large devices (large $>$ 30mm waist diameter), concern remains about use of large devices [21]. Most frequent complications with large devices are device embolization, perforation of heart etc. [6,21]. Guan et al found a relationship between small surrounding rims of large defect and embolization (Table II) [22]. Traditionally, defect  $>$ 38 mm size are extremely challenging for device closure [10].

Fluoroscopy time and procedure time was much less in this study in comparison with others [2,14]. In those studies, procedure time was 60.5 $\pm$  12.4 minutes and 68.65 $\pm$ 19.26 minutes compared to this series, where the time was 32.44 $\pm$  8.17 minutes. Air embolism was noticed in three (0.91%) cases which correlates with another study [14]. Major complication related to ASD device closure are new onset atrial arrhythmia,

atrioventricular block, thromboembolism etc [10]. The rate of embolization reported by AGA in 2004 was 21 out of 3824 which was 0.55% [23]. Many meta-analyses of transcatheter closure of ASD showed 0.2-0.43% embolization [24,25]. In our series device embolization was 0.95% (three cases). One patient had embolization in catheterization laboratory and two more within 24 hours of intervention. All three patients were referred to cardiac surgeon for retrieval and closure. One of them had deficient aortic rim and the rest two had deficient posterior and inferior rims.

A retrospective review of all adverse events reported to the food and drug administration (FDA) manufacturer and user facility device experience (MAUDE database) published in the literature included a review of institutional cases by Divekar et al in 2005 found 24 cases of cardiac perforation (26). We have not experienced any perforation (Table III). A survey conducted in 2004 by congenital cardiovascular interventional study consortiums (CCISE) recommends following points to avoid aortic erosion: a) deficient aortic rims is a cause of erosion in 90% cases, b) device which straddle the aorta has low risk of erosion, and c) device with protruding left atrial disc on aortic root has greater chance of erosion. In our series, we postponed cases with deficient aortic rims and oversizing of device was avoided by measuring BOD [6].

Figure II to figure V showed balloon sizing of ASD from waist diameter and stop flow diameter inside ASD, deployment after checking in long axis oblique (LAO) view (fluoroscopy) and with TTE, release of device by unscrewing. In our series 99.05% cases had successful device implantation, 98.73% had complete occlusion and 0.31% had residual shunt. These findings correlate with other studies [6,10,27]. A study conducted by Se Yong Jung et al showed 99.1 % success rate for large ASD and 100% for very large ASD group [2].

Baruteau et al conducted the largest study on feasibility and safety of ASD device closure in both pediatric and adult age group. Their success rate on large ASD ( $\geq 34$  mm BOD) was 89.7% [28]. Success rate was 97% in a study conducted by Romanelli et al on large and very large ASD cases [29].

The frequency of residual shunt was 4.2%, device erosion was 0.9%, atrial fibrillation was 4.9% and atrial arrhythmia was 6.55% in a meta-analysis conducted by Alnasser et al in 2018 [30]. We had a patient of 33 years of age who had ischemic cardiomyopathy from coronary artery disease. Afterward he was referred for ASD device closure. After one month he had on and off attacks of ventricular tachycardia. After observing closely for another three months, an implanted cardioverter defibrillator (ICD) was deployed.

In our median follow up period of 28 months (range six to 60 months), no major complications like device migration, perforation, complete heart block, cardiac erosion, unexplained death was noted. Two cases (0.63%) had new onset migraine headache in follow up and were treated. Up to 4.4% migraine was reported in another study [2]. Nickel allergy was experienced in one case (0.31%) in the form of skin rash and was treated. Allergy from Nickel prosthesis may cause dyspnea, chest pain, pericarditis, migraine, palpitations etc. [31, 32]. Both migraine and allergic rashes were cured after treatment.

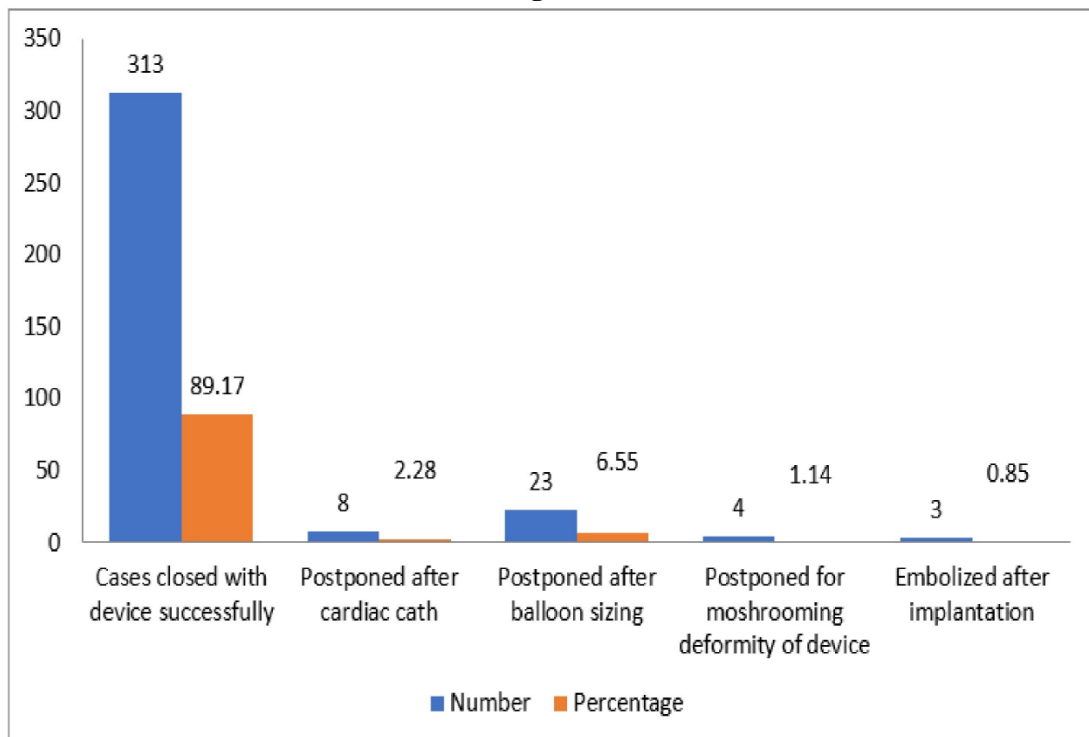
a. **Limitations of study**

As it was a retrospective study, patients' clinical status and symptomatic improvement after device closure could not be evaluated specifically other than those found in the records. Growth chart of young children could not be evaluated.

## V. CONCLUSION:

Transcatheter closure of ASD is already accepted as an established technique in most of the cardiac centers. Success rate is excellent, and complications are less if cases are selected judiciously. It is not necessary to close very large ASDs with deficient rims risking complications, rather it is better to refer them to surgical colleagues as surgeons also have good options for closing ASDs in minimally invasive technique. Our study showed that routine procedure of device closure of ASD can be simplified by taking TTE guide and avoiding GA in suitable cases especially in resource constraint countries where there is scarcity of trained manpower and equipment. The outcome of the cases following this minimalistic approach is comparable with other studies which used the traditional approach. However, this study recommends long term follow up using minimally invasive technique by skilled, experienced teams.

**Figures**



**Figure I: Distribution of cases accepted for device closure. (n=351)**



**Figure II: Balloon sizing of ASD showed waist formation in a two years old child**

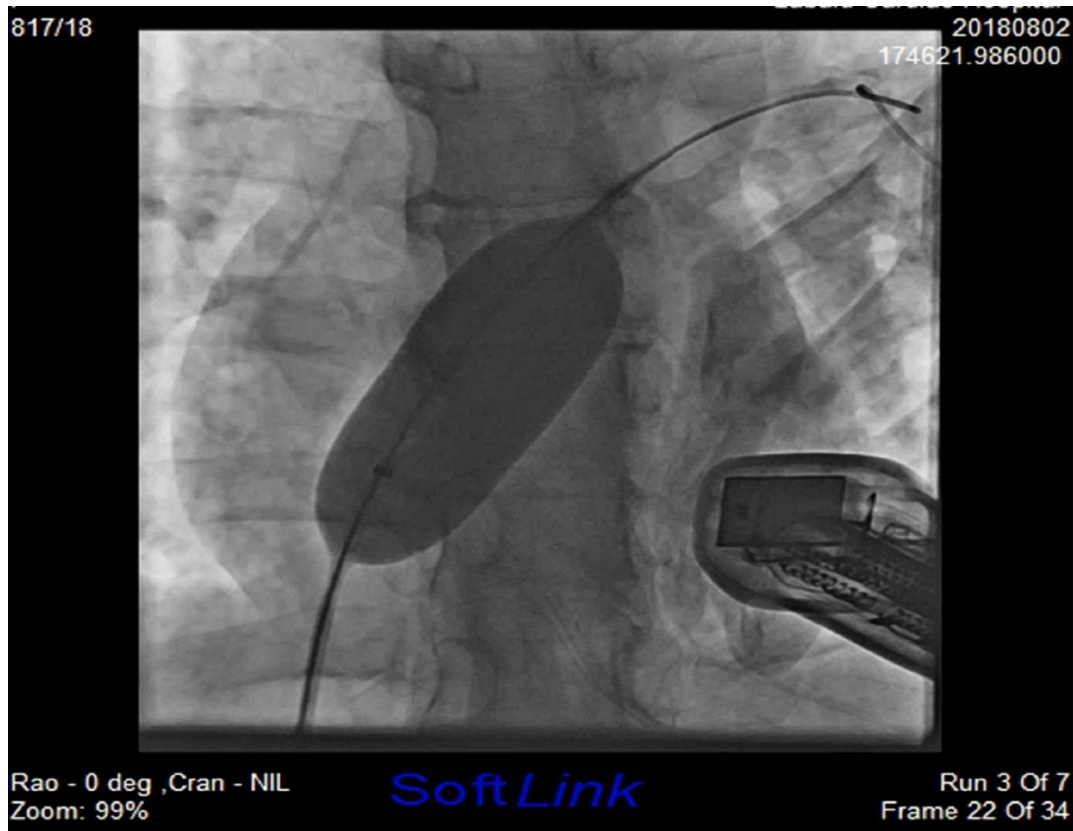


Figure III: Balloon sizing of ASD by stop flow technique in a three years old child

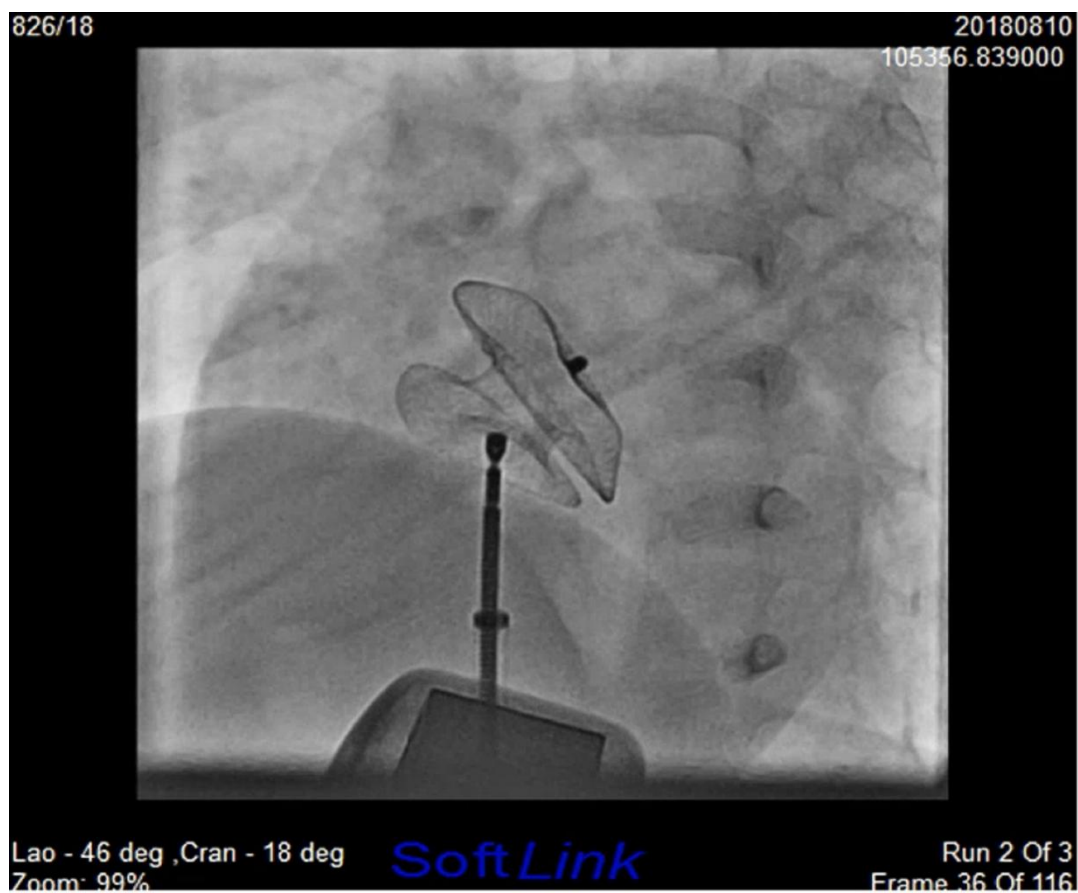
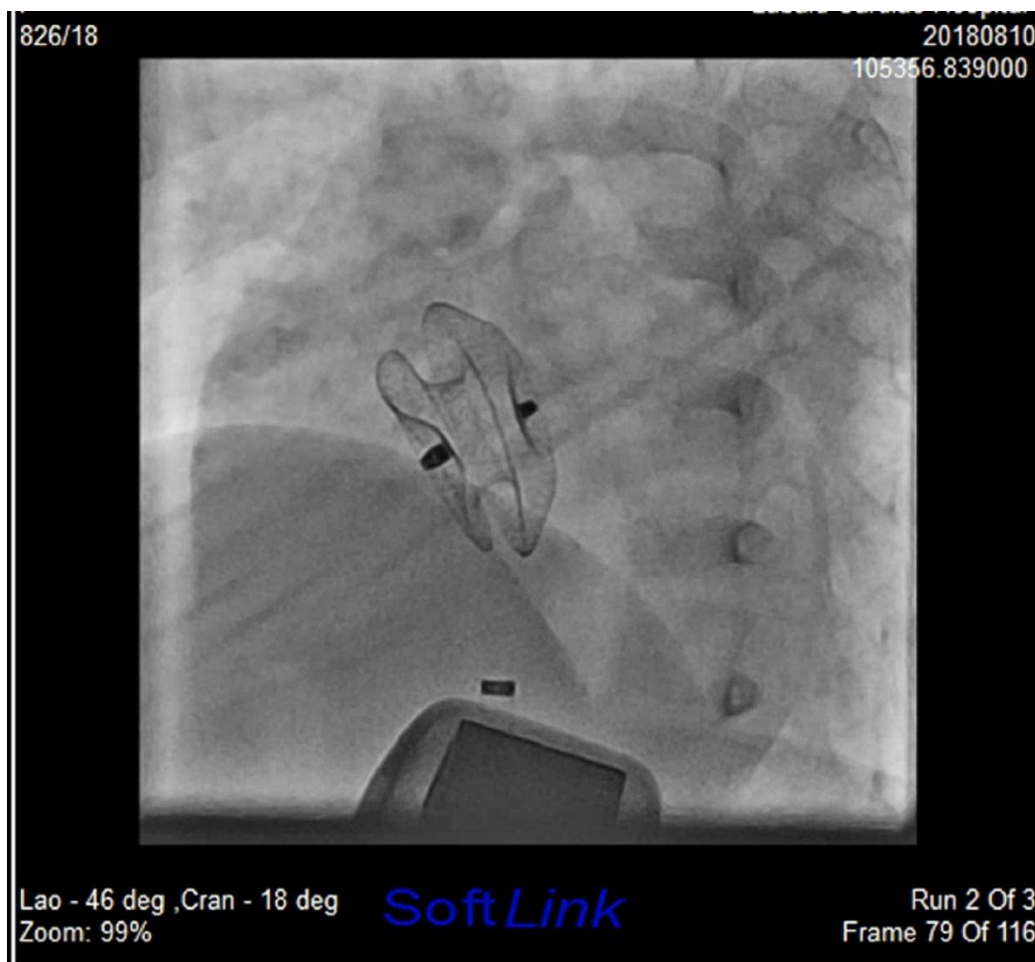


Figure IV: Device position checked by Fluoroscopy and TTE



**Figure V: ASD device after release**

**Tables**

**Table I: The demographic data of the study population (n=351)**

SI/No	Variables	Mean± SD /Number (%)	Range/Ratio
1	Age	13.97± 14.82	12 month - 65 Year
2	Sex		
	Male	129 (36.8%)	0.58:1
	Female	222 (63.2%)	
3	Weight	27.48± 20.11	8 Kg -72.5 Kg
4	Preintervention ASD diameter	18.24±8.63	8 mm – 33 mm
5	<b>Associated Heart defects</b>		
	Pulmonary stenosis	10 (2.85%)	
	Ventricular Septal defect	6 (1.71%)	
	Patent ductus arteriosus	4 (1.39%)	

**Table II: Data from catheterization laboratory of the study population (n=351)**

Variables	Mean ± SD /No (%)	Variables	No (%)
<b>Intraprocedural (Preimplantation)</b>		<b>Type of devices used</b>	
<b>Balloon Occlusion diameter</b>	21± 7.16	Cera Flex™ Septal occluder	212 (66.25%)
<b>ASD device size</b>	21.05 ± 7.49	Cookon ASD occluder	51 (15.94%)
<b>Flouroscopy time</b>	7.63 ± 2.05	Amplatzer™ Septal occluder	52(16.25%)
<b>Procedure time</b>	32.44± 8.17	Figulla flex ASD occluder	05 (1.56%)
<b>QP:QS ratio</b>	2.80 ± 0.64:1	<b>Intraprocedural complication</b>	

<b>Postponed for high pulmonary vascular resistance (PVR &gt; 10 wood units)</b>	8 (2.28%)	Device embolization	01 (0.31%)
		Air embolism	03 (0.93%)
<b>Postponed for no waist formation in balloon</b>	23 (6.55%)	Device malpositioning and mushrooming deformity thus postponed	04 (1.25%)
<b>Device Implantation</b>		Transient arrhythmia	09 (2.81%)
<b>Implanted in initial effort</b>	320 (91.17%)	Residual shunt	02 (0.62%)
<b>Combined Intervention</b>		<b>Post procedural complications in 24 hours</b>	
<b>Pulmonary valvoplasty</b>	10 (2.85%)	Device embolization	02 (0.57%)
<b>PDA device closure</b>	4 (1.14%)	Access site hematoma	02 (0.57%)
<b>VSD device closure</b>	6 (1.71%)	Rhythm disturbance	0
		Successful implantation	313 (89.17%)

**Table III: Outcome and late events in follow up (n=316)**

Sl/No	Variables	No (%)
1	Successful device implantation	313 (99.05%)
2	Complete occlusion	312 (98.73%)
3	Residual shunt	01 (0.31%)
4	Device embolization	03 (0.95%)
5	Arrhythmia	
	a. Complete heart block	0
	b. Ventricular tachycardia	01 (0.31%)
6	Allergic reaction ( Nickel related)	01 (0.31%)
7	Migraine (New onset)	02 (0.63%)
8	Death	0
9	Cardiac erosion	0
10	Follow up	06 months- 05 years (median 28 months)
11	Chest pain	04 (1.27%)

#### Disclosure

No conflict of interest

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