Original Article

Non Surgical Closure of Secundum Atrial Septal Defect by Percutaneous Transcatheter Amplatzer Septal Occluder

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Summary:

Background:
To assess the feasibility and early results of non-surgical transcatheter closure of atrial septal detect (ASD) using the Ampiatzer septal Occluder (ASO).

Patients and Methods:
From June 2003 to June 2005, i75 patients with ASD secundum, age range 3- 65 years, female to male ratio of 3:2. were evaluated for transcatheter closure using ASO at Ibn Al-Bitar Hospital for Cardiac Surgery. Transthoracic echocardiography was performed in al patients using standard suhxyphoid, apical, parasternal and suprasternal views. In all patients, the procedure was done under general anesthesia.

Results:
Based on transesophageal echocardiography (TEE) Findings, 60 patients (33.7%) did not meet the criteria for transcatheter closure (40 females and 20 males). One hundred Fifteen patients were found to have ASDs suitable for device closure. The device was successfully deployed in allpatients except 11 of them (104/115) (90.4%).

In 11 cases with failure of ASO deployment, 6 patients had small floppy inferior rims which were not able to hold the device after the Minnesota wegeal maneuver. One adult patient with a large ASD secundum and second degree AV block developed complete heart block during the procedure before the deployment of the occluder. One of them dislodged into the left atrium (LA) immediately after deployment because of a very small inferior rim and the other one dislodged into the LA because of descrewing of the cable after multiple manipulations. Both of them were referred for surgery. An other one of the 11 patients had developed a thrombus in the LA during the procedure because of delay in giving heparin after placing the guide wire in the left upper pulmonary vein. In the last patient, the procedure was abandoned and the occluder recaptured into the sheath before release from the cable because the TEE showed that the LA disc encroached on the mitral valve causing mitral stenosis.

Conclusion:
The transcatheter closure of secundum ASD is safe, efficacious with a very low rate of early and Sate complications. It is becoming an increasingly popular alternative to surgical closure.

Keywords: Non surgical closure, secundum atrial septal defect, percutaneous transcatheter, Amplatzer septal occluder.

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Introduction:

Secundum ASD is one of the most common defects occur as an isolated lesion. It represents about 6 to 10% of cardiac anomalies encountered and is more frequent in females than in males (2:1) (1). It is estimated that ASD occurs in 1 child per 1500 live births (2). Small ASDs may be clinically silent and diagnosed only by echocardiography. Data are not yet available to assess how often such small defects are encountered. Most cases of ASDs occur sporadically; however, few families have the defect as a genetic abnormality (3). Holt and Oram (4) noted the association between ASD and anomalies of the upper extremities; this also has been observed in tarn families.

In 1970 Campbell (1) reported on the natural history of ASD and found that one quarter of patients died before their 27th year, half by their 36th year, three -quarters by age 50years, and 90% by age 60 year. Death most often the result of heart failure.

Transcatheter techniques for closure of ASDs have been available for almost two decades, yet the approach has not achieved widespread usage. In 1976 King et al. (5) reported the first transcatheter closure of a secundum ASD with a double-umbrella device in humans. Since then the device has undergone several evolutionary changes in an attempt to improve the design and the technique of delivering the device. An early model was called the Raskind Atrial Septal Defect Occluder and was recommended for isolated ASDs of 18mm or less in diameter (6). Satisfactory closure was achieved in only 14 of 23 children (61%) and the delivery system for the device required a large sheath 16 Fr. Subsequently a modified double-umbrella device called the lock clamshell Occluder was developed (7). With the device, transcatheter occlusion of ASD was achieved in 32 of 34 highly selected patient with one episode, of major morbidity in high risk patient. Limitations of this device include the inability to use it when the ASDs stretched diameter is larger than 22mm, the inability to use it when there is less than a 4mm separation between the defects edges and the other important cardiac structures and the necessity of an 11 Fr delivery system. The most recently advanced model was developed by Sideris et al (8) and has been used also by Rao et al (9) the most important advantage of the last model is the fact that it can be delivered through an 8Fr sheath.

The Amplatzer Septal Occluder is a device named after Kurt Amplatz of Minnesota University Hospital in 1997 (10). The Occluder is a self expandable double disc device made from Nitinol wire mesh. The two discs are linked together by a short connecting waist corresponding to the size of the ASD. In order to increase its closing ability, the discs and the waist are filled with polyester fabric. The polyester fabric is securely sewn to disc by polyester thread. The Amplatzer delivery system was designed specifically to facilitate attachment, loading, delivery and deployment of the Amplatzer Septal Occluder and is comprised of a delivery sheath, dilator. loading device, plastic vise and delivery cable (11).

The aim of this study is to assess feasibility and early results of non surgical closure of atrial septal defect using this Amplatzer occluder device.

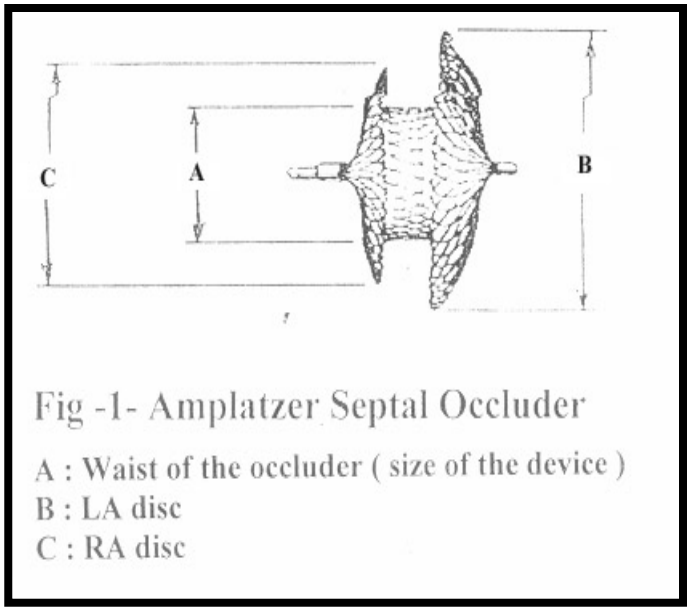

Fig -1- Amplatzer Septal Occluder

A : Waist of the occluder (size of the device)
B : LA disc
C : RA disc

Patients and Methods:

From June 2003 to June 2005, 175 patients with ASD secundum, age range from 3 - 65 years, female to male ratio of 3:2, were evaluated for transcatheter closure using Atrial Septal Occluder (ASO). Transthoracic echocardiography (TTE) was performed in all patients, using standard subxyphoid, apical, parasternal and suprasternal views. In our study all patients also underwent Transesophageal echocardiography (TEE). TEE was used for accurate determination of the defect size and morphology of ASDs. In addition, partial anomalous pulmonary venous connection was excluded with TEE. The maximal longitudinal diameter of the defect was measured in the longitudinal view (bicaval view or the plane of the ascending aorta was used). The maximal horizontal defect diameter was obtained by the 4-chamber view.

The rims of defect was measured using standard TEE views .The superior anterior rim was measured in the horizontal plane as the maximal distance between the anterior defect margin and the Aorta. The posterior rims represent the maximal distance from the posterior defect margin to the posterior atrial wall. The inferior anterior rim was measured in the 4 -chamber view as the maximal distance from the defect to the atrio -ventricular valve (mitral and tricuspid valve). The bicaval views were used to determine the superior posterior rim as the maximal distance from the defect to the opening of the superior vena cava (SVC) and the inferior posterior rim as the maximal distance from the defect to the opening of inferior .vena cava (IVC).The total interatrial septal length was obtained using either the 4-chamber view or the plane of the caval veins.

Patient selection and criteria for transcatheter closure were:

1- ASD secundlim with maximal TEE defect diameter < 38mm.

2- Defect rims except the superior anterior rim are :

a-More than 5mm distance from coronary sinus.

b-More than 5mm distance from AV valve.

c-More than 5mm distance form IVC, SVC. Even so, rims smaller than 5mm were included in this study.

3- The total length of the interatrial septum greater than the occluder size (more than 14mm

for device size from 4-32 mm and more than 16 mm for device size From 34-40).

In all cases it was carefully explained to the patients and the parents about the possibility of being referred for surgical closure in case of device failure. A signed consent was taken for every patient.

The procedure was done under general anesthesia under guidance of TEE. The femoral artery was cannulated for monitoring of systemic pressure. The right femoral vein was cannulated and right upper pulmonary vein was engaged by side hole catheter and an angiogram was done in 35 LAO and 35 cranial angulations to define the location of defects and also use this as a road map for subsequent procedure. The ASD was then balloon sized in order to determine the stretched diameter of the defect. The size of the device chosen was I to 4 mm more than the stretched diameter of the defects.

The stiff guide wire 0.035 is advanced through the end-hole catheter crossing the defect to be fixed in the left upper pulmonary vein. Meanwhile, heparin is given in a dose of 100 iu/kg. The sizing balloon is advanced over the stiff guide wire to place it across the defect when it is inflated with diluted contrast media, under guidance of the TTE and the fluoroscopy. The balloon size is determined and measured when no residual shunt detected by continuous flow Doppler, the stretched diameter of defect is measured using an Amplatzer sizing balloon.

There are two size of balloon 24, 34 mm, where the maximum inflated balloon diameter for them are 30-31mm, 42-43mm respectively while the maximum inflated balloon volume are 30 ml and 90ml for both balloons. Maximum lesion stretch diameter is $\leq$ 22 mm for balloon size 24 and $\leq$ 40rnm for balloon size 30mm. Thus, the stretch defect diameter was obtained and used for selection of the proper size of the device. The device was Fixed to the delivery cable and introduced through the loader into delivery sheath. Under simultaneous TEE and Fluoroscopic guidance the left atrial disc and the waist were deployed in the left atrium. Then the whole system was then pulled back against the interatrial septum resulting in the self-centering of the device in the defect.

The right atrial disc was then deployed in the right atrium and pushed against the right atrial aspect of the interatrial septum. Adequate device position was confirmed using TEE by demonstrating unobstructed flow from the coronary sinus, right pulmonary vein, SVC and IVC. In particular, normal functions of both atrioventricular valves were confirmed. Aspirin therapy started in a dose of 3-5 mg/kg for all patients two day before and 6 months after the procedure except two patients who are hypersensitive to aspirin, given clopidogrel (Plavix) in a dose 75mg/day for 6 months after occlusion. 25 patients who have had large defects, especially those with deficient rims less than 5 mm, faced problem of prolapsing of the left atrial disc through the defect into the RA. The LA disc becomes perpendicular to the atrial septum. In these patients the detect closure is possible but very challenging. The device was recaptured and multiple attempts at repositioning the LA disc to be parallel to the septum failed. At the time the 9 Fr dilator of delivery sheath was advanced from the left femoral vein to the RA. The stiff end of a 0.035 guide wire was reshaped and curved to 45^{O}, this wire was advanced inside the dilator until it reached the tip. The dilator was maneuvered inside the LA to hold the superior/anterior aspect of the LA disc while deploying the waist and the right atrial disc in the defect and the right atrium. The dilator was withdrawn back to the RA. The TEE confirmed good device position and no residual shunt. This referred to as H.A. Wahab maneuver to prevent prolapse of the ASO through large ASD (12).

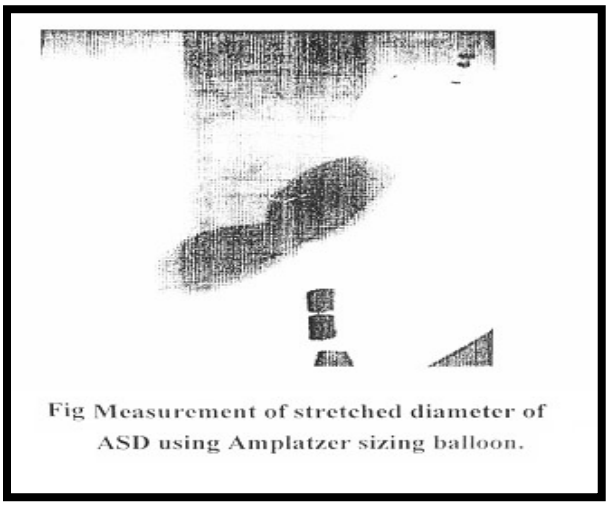

Fig Measurement of stretched diameter of ASD using Amplatzer sizing balloon.

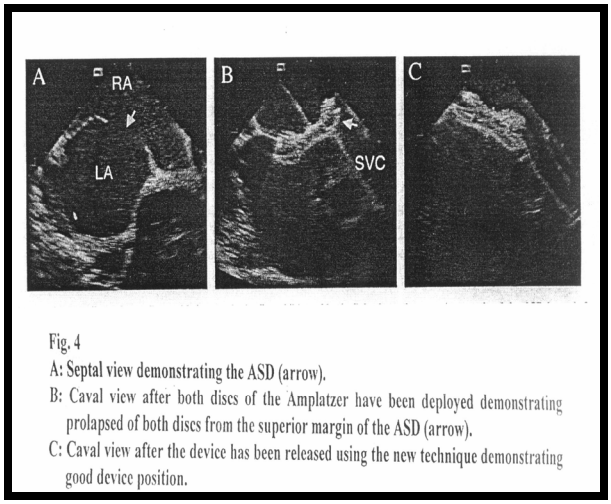

Fig. 4
A: Septal view demonstrating the ASD (arrow).
B: Caval view after both discs of the Amplatzer have been deployed demonstrating prolapsed of both discs from the superior margin of the ASD (arrow).
C: Caval view after the device has been released using the new technique demonstrating good device position.

Follow up examinations were scheduled at I min, 24 hours, 1 month 6 months and l year. Clinical examination and TTE were performed at each follow up visit, with particular attention being focused on residual shunt, right ventricular diameters and late complications. Residual shunt, after transcatheter closures were studied according to the Following classification (11):

a: Trivial (< 1mm).
b:.Small (1-2 mm).
c: Moderate (3-4 mm)
d: Large (> 4mm).

Results:

Based on the TEE Finding 60 patients (34.2%) did not meet the criteria for transcatheter closure, 40 patients were female, 20 patients were male, their ages ranged between 6-40 years, ASD size ranged between 14-38m. They were referred for surgical closure.

Table 1: Patients referred for surgical closure after TEE

1.	Defects with deficient inferior rim	30
2.	Defects with deficient superior rim	2
3.	Defects with deficient posterior rim	2
4.	Sinus venosus ASD	5
5.	Large size of ASD > 38 mm	14
6.	Multiple ASDs with septal aneurysm	5
7.	Anomalous upper right pulmonary veins	2
Total		60

Of these 175 patients, 1 15 patients were found to have ASD suitable for device closure. All patients had right ventricular volume overload by TEE examination .The patients ages ranged from 3 years to 65 years, their weights ranged from 12 kg to 78 kg .there were 72 females (62.6%) and 43 males (37.4%) (Table2).

Table 2: Patients baseline demographic variables

Gender	Number and %
Female	72 (62.6%)
Male	43 (37.4%)
Weight range	12-78 kg
Age range	3-65 years
Clinical Presentation	
CHF	3/115 (2.6%)
FTT/Failure to thrive (pediatric ages)	5/115 (4.3%)
Recurrent respiratory infection	4/115 (3.4%)
Asthma	2/115 (1.7%)
Hypertension	3/115 (2.6%)
Abnormal heart rate and/or rhythm	5/115 (4.3%)

Three of those who had dysrhythmia were found to have atrial fibrillation and all of them are adult patients. 112 patients had an isolated ASD-secundum while only 3 patients had an associated congenital heart disease. Of them; two had pulmonary valvular stenosis with pressure gradient more than 80 mmHg and one patient had PDA. There were 3 patients with multiple ASDs, 2 patients with distance between defects 3 and 4mm respectively. A single ASO device was used in each of these two patients with no residual shunt. The third one, the distance between ASDs was 10 mm and 2 ASO devices applied in this patient with no residual shunt. The device were successfully deployed in all patients except 11 patients (104/115) (90.4%). Correct placement of the device was achieved in 75 of 104 patients (75.96%) at one or more attempts, while in 25 patients recapturing of the ASO with the use of a novel technique with successful closure of the ASD by occluder (24.04%). 50 patients (48%) had defects with a deficient anterior rim underwent successful implantation of ASO without complications.

The diameter of the ASD secundum measured by TEE ranged from 9-30 mm. Measuring stretch defect diameter ranged from 10-38 mm. the ranged implanted ASO were between 12 and 40 mm. the procedure time ranged from 25-90 min, and the fluoroscopy time ranged from 7 to 30 min. The size of the device ranged from 12-40 mm.

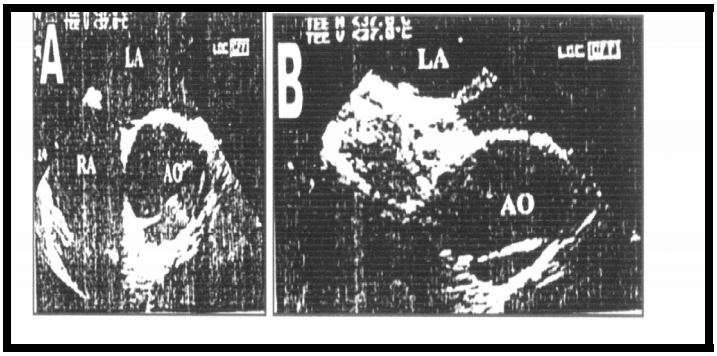

Fig. 5A: Secundum type atrial septal defect with deficient anterior rim.
Fig. 5B: Amplatzer septal occluder closing secundum-type ASD with deficient anterior rim.

Table 3: Size of the occluder

Size of the Occluder	Number of Patients
12 mm	1 (0.86%)
13 mm	1 (0.86%)
14 mm	3 (2.6%)
15 mm	1 (0.86%)
16 mm	2 (1.7%)
17 mm	2 (1.7%)
18 mm	5 (4.3%)
19 mm	6 (5.2%)
20 mm	12 (10.4%)
22 mm	14 (12.1%)
24 mm	20 (17.2%)
26 mm	16 (13.9%)
28 mm	6 (5.2%)
30 mm	5 (3.4%)
32 mm	3 (2.6%)
34 mm	10 (8.6%)
36 mm	7 (6%)
40 mm	1 (0.86)
Total	115

In the two patients with severe valvular PS:one patient, balloon dilatation was performed using balloon size 18 mm with pressure gradient decline from 80 mm Hg to 15 mm Hg: One month later a second cardiac catheterization was performed under G.A with TEE, the ASD had been closed by occluder size 26 mm with no residual shunt. In the second patient pulmonary balloon valvuloplasty and then closure of ASD by ASO was done in one setting.

In patient who had combined ASD and PDA, transcatheter closure of PDA done by Amplatzer occluder size 8/6 mm. Two months later under G.A with TEE, 22mm Amplatzer Septal occluder was implanted for ASD secundum.

The results of closure are presented in table (4).

Table 4: Results of Percutaneous closure

	Follow – up					
Residual shunt	1 min	24 hr.	1 month	3 month	6 month	12 month
	104 patients	104 patients	87 patients	72 patients	56 patients	30 patients
None	95 (91.34%)	98 (94.24%)	85 (97.7%)	71 (98.61%)	55 (98.21%)	0
Trivial	7 (6.74%)	5 (4.8%)	1 (1.15%)	1 (1.39%)	1 (1.79%)	0
Small	2 (1.92%)	1 (0.96%)	1 (1.15%)	0	0	0
Moderate	0	0	0	0	0	0

During the 12-months follow-up no symptoms have been noticed in any of these patients. Follow up by TTE revealed stable device in all patients and there was no valvular regurgitation in any patient.

In 11 cases there were failures of ASO deployment. Six patients had small floppy inferior rims which were not able to hold the device after Minnesota wegeal maneuver. One adult patient had large ASD-secundum with second degree AV block, had developed complete heart block during the procedure before deployment of the occluder. Two patients had embolization of the occluder, one of them embolized into LA immediately after deployment because there is a very small inferior rim & the other one embolized into the LA because of descrewing of the cable after multiple manipulation, both of them referred for surgery. One of the patients had developed thrombus in the LA during the procedure because of delay in giving heparin after placing of the guide wire in the left upper pulmonary vein. The last patient, the procedure was abandoned and the occluder recapture into the sheath before release from the cable because the TEE showed that the L.A disc encroached on the mitral valve causing mitral stenosis.

Discussion

Since 1974, several devices have been evaluated for the transcatheter closure of ASD secundum, and important drawbacks have been found in all of them (9). The min problems with buttoned or double umbrella / patch devices were relatively difficult implantation techniques, large delivery system, and high rate of complications including air embolism, late device failure (Fracture, unbuttoning, device embolization, heart perforating) and high rate of residual leak(9). In addition, the retrievability of device in case of malpositioning was difficult or even impossible, if the device had completely opened in the heart, resulting in the frequent need for urgent surgical removal (9). So the ideal device for transcatheter closure should allow implantation, including the possibility of complete retraction and repositioning in case of malpositioning.

The ASO is elastic and self-expandable, which makes deployment of the left atrial disc and the waist in the left atrium easy. Furthermore, self- centering of the device is crucial for its adequate positioning resulting in stenting of the defect with the waist of the occluder and complete defect closure. Positioning of the ASO can be monitored both by TFE and fluoroscopy, making the implantation procedure more precise and easier than with other devices. The high elasticity also allows easy and complete retrievability of the device in the event of malpositioning. Retrievability was demonstrated in many of our patients in whom device incorrectly implanted or their positions unstable. Therefore, urgent surgical retrieval of malpositioned devices was not necessary in tills study.

In addition, the ASO proved to be resistant to damage, despite several attempts al device positioning during the closure procedure. There were no signs of wire fractures or device damage and deformity. Late device fracture in buttoned devices caused unstable positioning of the devices, leading to a high incidence of residual leaks or even late device embolization have been reported (9).

This study shows that it is feasible to close small, moderate and large sized atrial septal defect with ASO with excel lent result. Although there is now extensive experience with this device, we have for the first time reported its feasibility and results specifically in children. It is in this age group that closure of ASD provides maximum benefit in terms of survival and freedom from atrial arrhythmia. However, device closure of ASD in children is more difficult and demands greater attention to detail as compared to adult population. The smaller size of the heart means that the larger ASDs would be difficult to close because the device size necessary to close such defects encroach on important adjacent cardiac structure (AV valve, pulmonary veins). In this study 60 (34.2%) patients with ASD secundum were found to be not suitable for device closure (table 1), this was mainly related lo deficient inferior rims and with large size ASD secundum. This is in agreement

with an Indian study (13), in which 28% of children not suitable for closure of ASDs was mainly related to the size of ASD. In this study 14 patients in whom closure was not attempted, the ASD size was > 38 mm. 5 patients had a multiple ASDs (multifenestrated) in which the defects were wide apart.

In this study two patients had embolization of device (1.92%), one patient had embolization of device during procedure before deployment of the device because of descrewing of device from the cable, the second patient had embolization of device immediately following the deployment of the device, both devices removed by cardiac surgeon as emergency cases. Compared with other study in which device embolization with surgical removal was 0.7 %(14) ,we believe that these two devices embolization occured so early after introduction of this device to our country, this is related to limited or early experience with such type of cardiac intervention. Thereafter no such cases had been reported throughout two years of work because of building experience and new technique used that prevent prolapse of the LA disc even in closure of large secundum ASDs.

In our study, successfully implanted ASO in 104 of patients (90.43), the highly successful implantation rate is due to careful patients selection, precise measurement of the stretch diameter, proper selection of the device size and precise implantation of the ASO under both TEE and fluoroscopy guidance. Recognition of defect morphology by TEE is essential for avoiding complications of closure such as device embolization, residual shunt and valve incompetence, we successfully closed defects in 50 patients (48.1 %) with deficient anterior rim, the most common morphological variation of ASD secundum, in which deficiency of anterior rim is considered a risk factor for unsuccessful closure and a significant predictor for residual leakage using the cardioseal device (10) .

All defects with deficient anterior rims were successfully closed by ASO, without any residual shunt. Both TEE and fluoroscopy demonstrated that the round and flexible disc embraced the aortic root from behind while the waist of the device stented the defect itself. This result can be compared with Slovenian result in which 23 patients (46%) had defects with deficient anterior rim (11). Twenty-five patients with closure of large defects, especially those with deficient rims (a distance less than 5mm from the defect to the wall of atrium), was possible in this study, but very challenging. In such circumstances oftentimes after deploying the left atrial disc, it becomes perpendicular to the atrial septum resulting in prolapsing into the right atrium. In this study we report a new technique via holding the left atrial disc in the left atrium by a dilator to prevent its prolapse during deployment in the large atrial septal defect. This novel technique is introduced by our colleague Dr Hussein Abdul Wahab, which had been published in American Catheterization Cardiovascular Intervention (12). This is the first description of such a novel technique to help position the Amplatzer septal occluder across a large ASD especially if one of the rims is deficient.

Of 115 patients treated with transcatheter method, 3 patients had multiple ASDs, the procedure was performed with a single ASO device in 2 patients, two ASO were applied in third patient with distance of 10 mm between both defects, with no residual shunt. We have demonstrated in this study that also multiple ASDs can be safely closed with a single ASO. The occluder must stent the largest hole and the left sided retention disc ideally should cover the neighboring fenestrations. The largest hole should be identified by TEE and confirmed by balloon sizing during cardiac catheterization. Meanwhile the important factor is the distance between the major and the smaller defect. The left retention disc in devices larger than 10mm has 7mm circumference around its waist (in implants 4-10 mm there is a 6mm circumference), therefore a small additional defect .which is located less than 7mm from the main defect potentially may be covered by the left sided disc. In addition the stenting mechanism of the device exert lateral compression of the atrial septum thus decreasing the distance between the two defects. This method has been reported by Marian Zembala (15). It was a transcatheter closure of multiple

atrial septal defects done by using one ASD Amplatzer septal occluder.

In this study two patients had both congenital heart disease, ASD secundum and sever pulmonary valvular stenosis, the percutaneous treatment of pulmonary valve stenosis remains the gold standard for obtaining right ventricular outflow relief.

The combination of balloon dilatation for right ventricular outflow relief and percutaneous ASD closure performed on children has not been reported in our country. In our 2 patients whether staged or combined in the same procedure these treatments were associated with effective ASD occlusion and right ventricular pressure relief. This is in agreement with study done by Alfonso Medina in Spain, which show successful combined percutaneous atrial septal occlusion and pulmonary balloon valvulplosty in adult patients (16).

In patient who had combined anomaly of both ASD and PDA Transcatheter closure of PDA by occluder as first procedure and 2 month later Amplatzer septal occluder was implanted for ASD secundum.

Immediate complete closure was achieved in95 (91.3%) of patients .Late complete closure was found in 98.3°/o of patient in this study. No patient with trivial residual shunt was observed. We believe that stenting of the defect with waist of ASO contribute to immediate closure result from thrombogenicity of the device, while epithelialisation of the implanted device contribute to the high rate of late complete closure. In comparison with Indian study in which immediate complete closure are achieved in 70% of patient and the late complete closure was found in 95% (13)

In all patients in this study the device size of the implanted ASO was 1-4 mm larger than measured stretch defect diameter in comparison with slovian study (11) in which the size of the implanted ASO was 2-4 mm larger than measured stretched defect diameter .

During follow-up, late complications, such as cardiac arrhythmias, device immobilization. thrombus events and infective endocarditis have not been detected. This is in agreement with the study done by Radhakrishnan (Indian study) which show no complications during follow up (13).

Conclusion:

The transcatheter closure of secundum ASD is safe, efficacious with a very low rate of early and late complications. It is becoming an increasingly popular alternative to surgical closure.

With the use of novel technique to help position the Amplatzer septal occluder across a large ASD, especially if one of the rims is deficient, one should be able to close a wider range of ASDs especially those associated with deficient rims. Multiple secundum -types ASDs can be effectively closed with single device occluder This depends on the size and distance between the defects and stretching capabilities of the septum.

Amplatzer Septal Occluder is not ideal device for closure of all morphological variations of secundum ASDs. Multiple small Fenestrations in the Oval Fossa are probably better managed with cardioseal device, although new cribriform amplatzer device has been introduced to close Swiss-Chess atrial septum.

Heparin should be given at correct time of the procedure and be sure that A.C.T is more than 240 Seconds throughout the procedure to avoid thrombus formation in LA.

Lastly even those patients, especially adults who had very large ASD-secundum sizing more than 35-38 mm, can be managed with diuretic and ACE inhibitor for 5 month. After that TEE shows that the cardiac and ASD sizing decline in dimension facilitating closure of ASD using ASO. This is reported in 2 patients in this study.

Recommendations:

We recommend the use of Amplatzer Septal Occluder (ASO) for non-surgical transcatheter closure of a wide varieties of secundum atrial septal defect.

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