Trans-catheter closure of atrial septal defect: Balloon sizing or no balloon sizing – single centre experience

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ABSTRACT

Background	:	Selecting the device size using a sizing balloon could oversize the ostium secundum atrial septal defect (OSASD) with floppy margins and at times may lead to complications. Identifying the firm margins using trans-esophageal echocardiography (TEE) and selecting appropriate-sized device optimizes ASD device closure. This retrospective study was undertaken to document the safety and feasibility of device closure without balloon sizing the defect.
Methods	:	Sixty-one consecutive patients who underwent trans-catheter closure of OSASD guided by balloon sizing of the defect and intra procedural fluoroscopy (group I) and 67 consecutive patients in whom TEE was used for defect sizing and as intraprocedural imaging during device deployment (group II) were compared. The procedural success rate, device characteristics, and complications were compared between the two groups.
Results	:	The procedure was successful in 79.7 % patients. The success rate in group II (60 of 67, 89.6%) was significantly higher than in group I (41 of 61, 67.2 %) ($P = 0.002$). Mean upsizing of ASD device was significantly lower in group II ($P < 0.001$). TEE also provided better success rate with smaller device in subjects with large ASD (>25 mm) and in those who were younger than 14 years of age. There were four cases of device embolization (two in each group); of which one died in group II despite successful surgical retrieval.
Conclusion	:	Balloon sizing may not be essential for successful ASD device closure. TEE-guided sizing of ASD and device deployment provides better success rate with relatively smaller sized device.
Keywords	:	Atrial septal defect, trans-catheter closure, balloon sizing, trans-esophageal echocardiography

INTRODUCTION

Trans-catheter closure has been accepted as an alternative to surgery in the treatment of ostium secundum atrial septal defect (OSASD). The Amplatzer septal occluder is the most popular device for trans-catheter closure of atrial septal defect (ASD), because of a high success rate and low incidence of complications.[1-5] The size of the defect, adequacy of rims and its relation with surrounding structures are the major factors determining suitability for nonsurgical closure of ASD.[6] Balloon sizing of the defect has been regarded as an integral part of trans-catheter closure of ASD.[7,8] The selected device is usually identical to or 2 mm larger than the stretched balloon diameter (SBD) of the defect.[9,10] However, ASD device closure is increasingly being done without balloon sizing using various imaging modalities.[11,12] We retrospectively reviewed our experience with respect to the feasibility and safety of device closure of ASDs both with and without balloon sizing.

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METHODS

During a 32 month period between January 2005 and August 2007, 128 consecutive patients with hemodynamically significant (clinically or echocardiographically documented left to right shunt ≥1.5:1) single OSASD underwent trans-catheter closure of the septal defect using Heartr™ atrial septal occluder device (Lifetech Scientific Inc., Shenzhen, China) in our institute. Heartr™ is a self-centering device, made of 0.004 inch nitinol wire mesh and shaped similar to Amplatzer septal occluder device (AGA Medical, Golden Valley, Minnesota). The technique of deployment of the Heartr™ septal occluder was similar to that described in the literature for Amplatzer septal occluder.[3-5] Patients with multiple ASDs and patent foramen ovale (PFO) were not included in the analysis. All patients underwent screening for suitability of device closure by TTE using Vivid 7 ultrasound system (GE Medical systems, Horton, Norway). Twelve patients required TEE to confirm suitability for the study due to poor acoustic trans-thoracic window, deficient rims, etc. The selected patients made up the study population.

Before September 2006 standard practice in our institute was to assess defect size using sizing balloon followed by closure under fluoroscopy guidance (group I) which was gradually shifted to ASD sizing as well as device deployment under TEE guidance (group II) in view of lesser procedural time, radiation, cost constrains, and possibility of oversizing of defect by balloon in defects with floppy rims. The results of ASD closure in the 61 patients with balloon sizing (January 2005 to September 2006, group I) were compared with those of 67 patients (October 2006 to august 2007, group II) who underwent ASD closure without balloon sizing.

In group I, defect sizing was done using AGA sizing balloons (AGA Medical Corporation, Golden Valley, MN). Measurement of the waist of the balloon was performed with quantitative fluoroscopic analysis. The device size selected was at least 2 mm more than the waist measured. Final device size selection was at operator's discretion. After device selection, device was deployed under fluoroscopy and trans-thoracic echocardiography guidance. Device was further upsized if the device prolapsed at multiple attempts provided there was adequate septal length and the device did not impinge on adjacent structures like the mitral valve.

In group II, multiplane TEE using Vivid 7 ultrasound systems (GE Medical systems, Horton, Norway) was performed in each patient after endotracheal intubation and assisted ventilation under general anesthesia. Dimensions of the defect were measured in various imaging planes. The maximal diameter of the defect was measured using atrial end-diastolic frames in 0°, 45, 90°, and 135°. A minimum diameter was also obtained from other imaging planes. In the presence of a very floppy and mobile rim, measurement of defect diameter was made between steadier and firm rims and the color flow jet width across the defect was also measured to provide supplementary information. The largest dimension was used to select device size. If there was more than 6 mm difference between the largest measurements on two orthogonal planes then the defect was presumed to be oval in shape and the average size was considered to be the appropriate circular size.

Immediate procedural success, failures and major complications (device embolization and death) were noted and compared between the groups. Procedural success was defined as ability to close ASD percutaneously with no or insignificant residual shunt on echocardiography. Failure was defined as inability to close ASD percutaneously with atrial septal occluder.

Deployment of atrial septal occluder

After obtaining a written informed consent, trans-catheter closure of ASD was planned using Heartr™ septal occluder device (Lifetech Scientific Inc., Shenzhen, China). All patients received intravenous ceftriaxone injection (50 mg/kg) 30 min before the procedure. Intravenous heparin was injected to achieve therapeutic level of anticoagulation [activated clotting time (ACT) > 250 s]. Mullin's sheath at least one size larger than the size recommended for the device size was used for delivery of the device. In several patients with a large defect and/or deficient rims, deployment of the device from the upper pulmonary vein (left or right) was generally performed. In group II, the procedure from sheath introduction to device deployment was done with positive pressure ventilation (PEEP 5 cm of H_2O) which has possible benefit of avoiding air being sucked in during removing the dilator and device delivery. When the position of the device was not well visualized on TEE images, particularly the posterior inferior rim, transthoracic and subcostal echocardiography was used as adjunct to TEE to monitor device position especially during deployment.

Following the procedure, patients were monitored for 24 h and echocardiographic evaluation was done after 24 h. Patients were discharged 48 h after the procedure. Low dose of aspirin (3–5 mg/kg/day) and clopidogrel (2 mg/kg) were given for 6 months. Infective endocarditis prophylaxis was advised for 6 months after the device implantation.

Statistical analysis

Statistical analysis was done with the standard SPSS software (version 15, Chicago, IL, USA). Categorical data were presented as frequencies and compared using the Fisher exact and chi square test. Continuous variables were presented as mean ± SD and compared using

the two-tailed Student's *t*-test. A *P* value < 0.05 was considered statistically significant.

RESULTS

Acute results

One hundred twenty eight patients were analyzed, 61 patients in Group I and 67 in Group II. Mean age of the patients was 22.6 ± 15 years. The basic demographic profile and baseline characteristics are shown in Table 1. Among the 61 patients in group I, trans-catheter closure was not attempted after balloon sizing in 12 patients due to relatively large SBD of the defect with respect to total septal length (i.e., waist size plus 14 mm retention rims exceeded the best available total septal length). Among 49 cases in which ASD device closure was finally attempted, six cases underwent surgical closure of ASD due to multiple failed attempts. Two patients developed device embolization despite demonstrating stability during the "push pull" manoeuver. The devices were retrieved successfully with surgical closure of ASD in both patients. Upsizing from the initially selected device became necessary in six patients in group I due to significant residual flow after placement of intended device size. In 41 patients in whom procedure was successful, mean ASD size by pre procedure TTE was 16.4 ± 4.4 mm while SBD was 19.9 ± 4.3 (median 20 mm).

The mean diameter of the device used was 23.7 ± 4.5 mm, with a mean device upsizing of 7.39 ± 2.72 mm from ASD size by TTE and 3.76 ± 1.26 mm (median 4 mm) from defect size by balloon sizing.

In group II, 67 cases underwent attempted trans-catheter closure of ASD of which 3 were not considered suitable after preprocedure TEE due to significantly floppy rims or large ASD with respect to available total septal length. Among 64 cases who underwent attempted device closure, 60 procedures were successful (overall success 60 of 67, 89.6 %). Among four unsuccessful cases; two cases procedure failed despite multiple attempts while two cases had device embolization. The embolized device was successfully retrieved and septal defect closed surgically. However, one of these patients died in postoperative period on day 10 due to uncontrolled sepsis. The ASD in 60 patients with successful deployment of device measured 17.4 ± 5.2 mm by TTE and 20.1 ± 5.8 mm by TEE. The mean diameter of the device deployed was 22.3 ± 5.8 mm with a mean upsizing of 4.7 ± 3.3 mm and 2.1 ± 1.7 mm (median 2 mm) beyond the measured size by TTE and TEE respectively. Only two patients required upsizing from the initially selected device size in group II. The number of patients with measured ASD diameter >25 mm, i.e., large ASD was higher in group II; however, the difference was not significant (21% in group I versus 25% in group II, p 0.44) [Table 2].

Table 1: Baseline demographic characteristics and procedural outcome

	All (*n* = 128)	Gp I (*n* = 61)	GpII (*n* = 67)	*P* value
Age (years)	22.6 ± 15	22.9 ± 14.5	22.3 ± 15.6	0.65
Age < 14 year	48 (38)	22(36)	26 (39)	0.78
≥ 14 year	80 (62)	39 (64)	41 (61)	0.92
Female: Male	2.2	2.6	2.1	0.5
ASD (TTE)				
Size (mm)	17 ± 4.9	17.6 ± 4.9	17.7 ± 5.2	0.89
Floppy rims	15 (12)	2 (3)	13 (13)	<0.005
ASD size				
TEE	29 (23)	22.4 ± 5.9	20.6 ± 6.0	0.98
SBD	-	12 (20)	17 (25)	<0.001
Large ASD#				
Procedural success	101 (79)	41 (67)	60 (90)	0.02
Failed procedure	27 (21)	12 (19)	7 (10)	0.02
Large ASD/inadequate rims	15 (11.7)	12 (19)	3 (5.9)	0.01
Failed multiple attempts	8 (6.3)	6 (9.8)	2 (2.9)	0.157
Device embolization	3 (3.1)	2 (4.9)	1 (1.5)	0.97
Death	1 (0.78)	-	1 (1.5)	-

*P between group I and II. #>25 mm in diameter. Figures in parenthesis are in percentage. SBD: Stretched balloon diameter

Table 2: Demographic and procedure related characteristics of successful procedures

	All (*n* = 101)	Gp I (*n* = 41)	Gp II (*n* = 60)	*P* value
Age (year) mean ± SD	24 ± 15	25.5 ± 13.3	22.9 ± 16.2	0.58
Female: Male	2.67	2.9	2.2	0.76
ASD size TTE (mm)	17 ± 4.9	16.4 ± 4.4	17.4 ± 5.2	0.34
SBD (mm)		19.9 ± 4.34		
ASD size by TEE (mm)			20.1 ± 5.8	0.89
ASD device size (mm)	22.9 ± 5.3	23.7 ± 4.55	22.3 ± 5.8	0.18
Device upsizing (mm) from TTE size	5.8 ± 3.3	7.4 ± 2.7	4.7 ± 3.3	0.0001
Device upsizing (mm) from SBD or TEE size	2.8 ± 1.7	3.76 ± 1.26	2.15 ± 1.72	<0.001

*P between group I and II. SBD: Stretched balloon diameter

Complications

Four patients, described above, developed device embolization of which three cases had early embolization (within minutes of deployment) while in one device embolized after approximately 6 h after the procedure. All of four patients had successful retrieval of the device and surgical closure of ASD. However, one patient in group II expired in postoperative period (postoperative day 10) from uncontrolled septicaemia. During cardiac catheterization, two patients had transient atrial flutter/fibrillation with spontaneous recovery. There were no instances of serious pericardial effusion or tachy/bradyarrhythymia. There were no instances of pulmonary venous drainage obstruction or obstruction to the mitral apparatus after the procedure.

Comparison of outcome parameters between group I and II

The procedural success in group II was better than in group I (60/67 vs 41/61, *P* = 0.002). The incidence of major complications was similar in two groups. The mean maximal diameter of the defect was similar in both groups with respective measurement techniques, 19.9 ± 4.38 vs 20.1 ± 5.79 (*P* = 0.89) as well as by screening TTE imaging, i.e., 16.4 ± 4.4 mm vs 17.4 ± 5.2 mm (*P* = 0.34). The mean diameter of device used was similar in group I and group II (23.7 ± 4.5 mm vs 22.3 ± 5.8 mm, *P* = 0.183). In addition, when groups were compared with respect to mean upsizing of device size from basal measured size of the ASD ,the mean upsizing in group I was significantly higher than in group II (3.76 ± 1.26 mm vs 2.1 ± 1.7 mm, *P* < 0.001). Despite similar defect size by screening TTE and balloon sizing or TEE, upsizing of device deployed was higher in group I. The mean device upsizing from TTE defect size was 7.4 ± 2.72 mm in group I compared to 4.7 ± 3.3 mm in group II (*P* < 0.001). Analysis based on defect size from SBD versus TEE also demonstrated higher upsizing in group I (3.76 ± 1.26 mm vs 2.1 ± 1.7 mm, *P* < 0.001).

On subgroup analysis, TEE assisted device closure was more successful in younger patients (<14 years) (*P* < 0.001) and in patients with large defects (*P* = 0.06) [Figure 1]. The mean device size upsizing was also different in various subgroups with significantly lesser upsizing in group II [Figures 2 and 3].

DISCUSSION

Atrial septum is a three dimensional structure. A defect in the septum is difficult to image in its entire profile without three dimensional reconstruction. Location and size of ASD as well as feasibility of trans-catheter closure has been assessed by different imaging techniques to achieve- lesser complications and effective closure with smaller device size. Over the years, with increasing
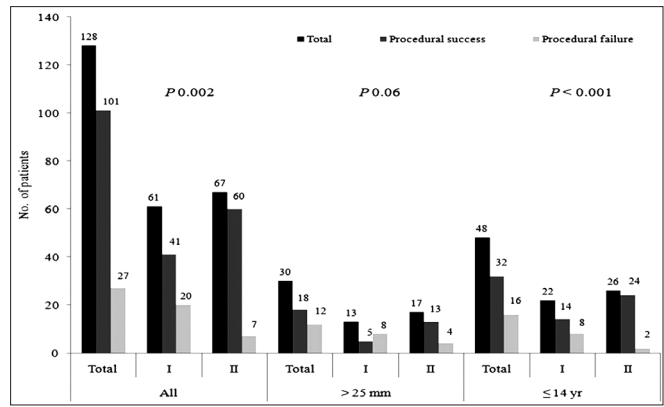
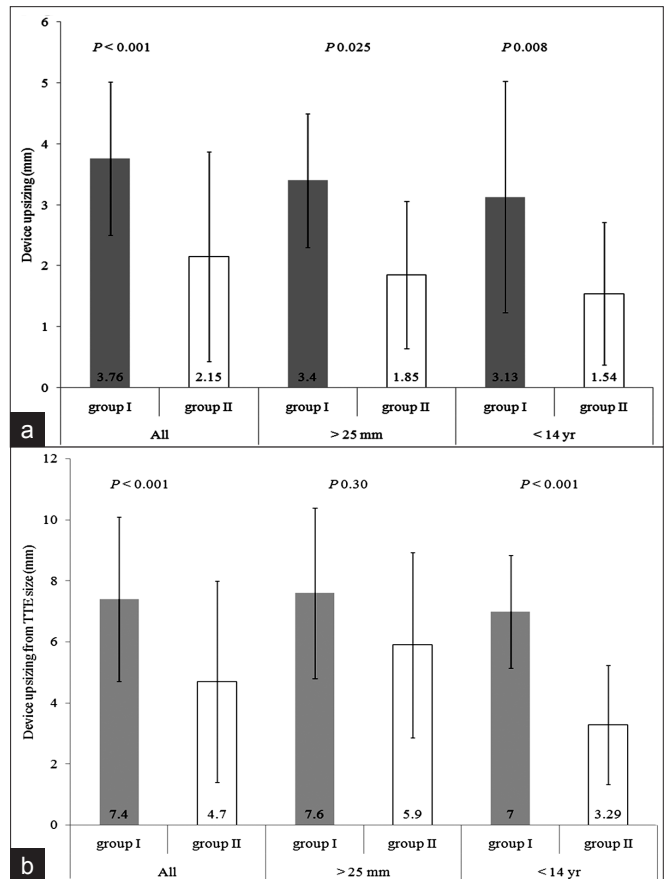**Figure 1: Procedural success in various subgroups**

Figure 2: (a) Device upsizing from defect size measured by TEE or balloon sizing. (b) Device upsizing from defect size measured by TTE

experience with trans-catheter closure, device size has gained importance apart from success alone. Too large a device carries risks of mushrooming deformity of the device, impingement on cardiovascular structures, and other serious complications, such as cardiac erosion,[13,14] while risk of device instability, distal embolization and residual shunt makes smaller devices undesirable.[15,16]

Balloon sizing has been considered as an integral part of trans-catheter closure of ASD with the Amplatzer

septal occluder, wherein the stretched diameter of the balloon measured on the cineangiography or TEE images is used to measure the ASD size and select the device. Balloon sizing was considered as the gold standard for measuring ASD size. However, there are disadvantages of balloon sizing. Balloon sizing may cause enlargement of the defect by tearing of the flap valve of the septum primum.[17] Bradycardia and hypotension may occur during prolonged inflation of the balloon due to the obstruction in diastolic filling.[18] In addition, it involves a low, but finite risk of damage to interatrial septum. Apart from associated overstretching, measurements may be inaccurate secondary to inadequate profiling of defect and the measuring balloon catheter.[14]

Investigators have tried to correlate SBD with ASD diameter measured by TEE or TTE. There is good linear correlation between echocardiographic measurement of the defect and SBD.[16,19-22] In the study using TEE, Fisher *et al.*, found a good linear correlation ($r = 0.83$) between defect diameter and SBD, SBD = 1.01 × TEE diameter + 5.28 mm.[19] El-Said *et al.* in their study found that the stretched diameter exceeded TEE and TTE diameter by an average of 13.2% and 22%, respectively.[20] Walsh and Maadi predicted stretch balloon diameter by an equation of SBD = 1.06 × TEE diameter + 4.4 mm ($r = 0.87$)[21] A recent publication by Carcagni and Presbitero showed that maximal steadier rim border (thickness ≥2.5 mm) distance on TEE images correlated well with SBD in adults.[22] TTE can also be used to predict the stretched diameter. Rao and Langhough proposed an equation of SBD = 1.05 × echocardiographic diameter + 5.49 mm.[18] A similar formula of SBD = 1.21 × echocardiographic diameter + 0.67 mm was reported in a study by Godart *et al.*[23]

More recently, assessment of device size is increasingly being performed using nonballoon imaging techniques.[24] Many pediatric cardiac interventionists have closed ASD successfully by trans-catheter closure techniques without balloon sizing. Zanchetta *et al*, did not use balloon sizing during trans-catheter closure of ASD, where waist diameter was chosen based on the r value obtained from intracardiac echocardiographic images [$r = \sqrt{(C^2 + P^2)}$, C is the foci half-distance of the fossa ovalis and P is its semi-latus rectum.[16] In another study of Zanchetta, an equation of $d = \sqrt{(a \times b)}$ was obtained, in which a and b were major axes of intracardiac echocardiography on aortic and four-chamber plane, respectively, and d was the diameter of device used.[12] In a study by Amin and Daufors, balloon sizing was considered unnecessary and a device that was 2–4 mm larger than intracardiac echocardiographic (ICE) diameter was chosen.[11] Recently, 3D TEE has been used to aid selection of device size.[25] There is good correlation between 3D TEE measurement of maximal diameter and SBD in patients with a single ASD.

In this study, the success rate in group 2 was higher despite less upsizing. This highlights the importance of the better imaging obtained by TEE which may be the most important factor influencing the outcome rather than size of the defect or the device. Sizing obtained by TEE is adequate for successful device closure and may be superior to balloon sizing as it avoids oversizing and is more physiological. Imaging the defect better rather than the actual size hold the key for successful device closure. Failed device closure was also higher in group I (12 vs 3) even though all these cases appeared suitable for trans-catheter closure by TTE. Better imaging in these patients by TEE could have resulted in successful closure in majority of these patients. The higher success rate is also likely to be contributed by improved experience.

Mean upsizing of the device was significantly lower in group II. This indicates that measurement of the defect from the firm rims by TEE provides the necessary anatomic information required for device closure and no added benefits are provided by balloon sizing of the defect, which leads to unnecessary implantation of larger sized device which may be particularly harmful in children. In a recently published study assessing feasibility and safety of trans-catheter closure of ASD without balloon, mean diameter of device used in nonballoon sizing group was larger than trans-catheter closure with balloon sizing.[26] In their study they used relatively larger devices with preplanned upsizing of 4–6 mm and also patients in that subgroup of patients were older, with larger defects. Success rate in two groups compared in that study was similar despite larger defects in non balloon sizing group, which again emphasizes the advantage of superior imaging obtained by TEE.

This retrospective study documents the safety and feasibility of trans-catheter closure of ASD without balloon sizing. It further emphasizes benefits of online TEE imaging during device deployment.

Limitation of this study

This study was not a randomized, controlled trial. It was our experience using two methods practiced at two different time frames. This retrospective analysis was based on a series of patients who underwent trans-catheter closure of ASD by the same team of operators. We accept the possible bias due to different phases of the learning curve. Furthermore, in our study "stop-flow" technique was not used for balloon sizing of the defect which may be more physiological and likely to avoid oversizing of the defect.

CONCLUSION

TEE evaluation without balloon sizing is safe and effective and may be superior to balloon sizing in trans-catheter closure of OSASD.

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