FULL LENGTH ARTICLE

ASD device closure in pediatrics: 3-Dimensional transthoracic echocardiography perspective

Sonia A. El-Saiedi [a,*], Hala M. Agha [a], Mohamed F. Shaltoot [a], Hayat H. Nassar [a], Amal M. El Sisi [a], Wael A. Attia [a], Yasser M. Sedky [a]

[a] Pediatric Cardiology Division, Department of Pediatrics, Cairo University Children Hospital, Cairo

[a] Egypt

Objective: **Real-time three-dimensional echocardiography, using both reconstruction methods and RT3D, has been used as an extra helping tool in several forms of congenital heart diseases. Our aim was to understand the relation of the ASD device to all surrounding structures by 3-dimensional echocardiography (3D).**

Methods: **This prospective study included 37 patients diagnosed as ASD secundum by transthoracic (TTE) and transesophageal echocardiography (TEE) referred for transcatheter closure from October 2013 to July 2016. Follow-up for 1 year using 2D and 3D-echocardiography was performed to assess the relations of the device to the surrounding structures.**

Results: **Transcatheter ASD closure and echocardiographic examinations were successfully performed for all patients. By 3D echocardiography, 16 patients (43.24%) had their ASD device close to the aortico-mitral continuity plane without apparent regurgitation, while the rest of our patients (56.75%) the devices were away from this plane. The following variables were significantly different between the two groups; body surface area, atrioventricular rim (AV), device size, left disc size and ratio of left disc to interatrial septum. A cut-off AV rim length not less than 8 mm was found optimal to avoid device encroachment on the sensitive surrounding structures. New Formula was constructed to aid in device choice.**

Conclusion: **Use of 3D before and after ASD closure is of value to determine the device relation to the surrounding structures. AV rim by TEE is an important rim to avoid eventual encroachment on the mitral valve and aorta.**

Keywords: 3-Dimensional echocardiography, Atrioventricular rim, Mitral regurgitation

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* Corresponding author at: Pediatric Cardiology Division, Department of Pediatrics, Cairo University Children's Hospital, PO Box 11111, 2 Aly Basha Ibrahim Street, Mounira, Cairo, Egypt.
E-mail address: myheartclinic@windowslive.com (S.A. El-Saiedi).

P.O. Box 2925 Riyadh – 11461KSA
Tel: +966 1 2520088 ext 40151
Fax: +966 1 2520718
Email: sha@sha.org.sa
URL: www.sha.org.sa

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Introduction

The use of trans-catheter device techniques has become widely accepted as an alternative therapy to surgery. Device closure is much safer and advantageous compared to surgery [1]. For safe percutaneous ASD device closure, the rims surrounding the defect should be appropriate to allow the device to firmly hang onto the atrial septum. The device should not be deployed if there were concerns about drainage from coronary sinus, vena cava or pulmonary veins, or if there was interference with the function of the atrioventricular valve [2]. In children, the indication for percutaneous treatment is based on the defect diameter/septal length ratio regardless of the device type used. The AV valve rim plus the average size of the ASD (measured in at least two orthogonal views) plus the superior rim equals total atrial septal length. A device where the left atrial disc of the septal occluder is equal to or smaller than the total atrial septal length can be used. To avoid oversizing, a recommendation was not to use devices larger than 1.5 ASD diameter [3]. The device was chosen according to the TEE maximum ASD diameter. The device stent diameter is 4–6 mm and 5–8 mm larger than the TEE maximal diameter, if the defect was <14 mm and ≥14 mm, respectively or 1.2–1.5 times the maximal defect diameter provided that the left atrial disc should be always less than the total interatrial septal length [4]. The stop-flow technique should be used when balloon sizing of the ASD was done [5]. However, it is conceded that in some patients who have thin flailing septum primum, balloon sizing may not be easy because the septum is stretched even by gentle inflation of the balloon. Reported erosion of the aortic wall by the Amplatzer device with development of aorta-to right atrium [6] or aorta-to-left atrium [7] fistulae was the basis of the idea of oversizing the device (4 mm larger than the measured stretched diameter) in large defects with deficient aortic rim This is meant to ensure that the device disks straddle and remain flared around the ascending aorta to prevent discrete areas of pressure where erosion may occur. Obviously, when over-sizing the device, care must be taken not to interfere with valve function and/or venous return [8]. The ability to record, to analyze the entire cardiac structure and to display complex spatial relationships are potential advantages of 3D imaging over 2D echocardiography. 3D examination is a potential useful tool in studying the ASD device and its points of contact or pressure. Accordingly, the aim of this current work is to focus on the relation of the ASD devices to the aorta and aortic-mitral plane using three-dimensional echocardiography.

Abbreviations

RT3D	Real time 3 dimension
ASD	Atrial septal defect
TTE	Trans thoracic echocardiography
AV	Atrio ventricular
TEE	Trans esophageal echocardiography
2D	2 dimension
3D	3 dimension
SVC	Superior vena cava
IVC	Inferior vena cava
MV	Mitral Valve
MVP	Mitral valve prolapse
ICE	Intra cardiac echocardiography
FC	Fixed curvature
BSA	Body surface area
RA	Right atrium
RV	Right ventricle
Qp/Qs	Pulmonary to systemic flow ratio

Patients & methods

This prospective study included 37 consecutive patients diagnosed as ASD secundum by transthoracic echocardiography who were referred to Pediatric Cardiac Catheterization Laboratory at Cairo University Specialized Pediatric Hospital from October 2013 to July 2016. Then they were examined by 2D and 3D echocardiography to determine the shape of the defect and visualize the surrounding structures before catheterization, the examination was done with commercially available Vivid 7 ultrasound machine (GE Vingmed, Ultrasound AS, Horten, Norway). For all patients, TEE ultrasound was performed 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°. Two crucial parameters were measured to select patients for trans-catheter ASD closure. First; the maximal defect diameter was chosen and the selected device was usually 2 mm larger than the largest ASD diameter if there is no aortic rim deficiency, while it was at least 4 mm larger in aortic rim deficiency. The second was the tissue rim dimensions all around the defect to optimize the placement of the device. In the absence of gold

standards, the balloon sizing technique measuring the stretched diameter was used as a reference to size the large defect. Follow-up using 2D and 3D echocardiography performed 1 year after the trans-catheter ASD closure.

3D Echocardiography was performed before ASD closure to describe the shape of the defect. After ASD closure, the relation of the device to the valves and vessels and if any residual flow were described.

To achieve the highest resolution of the atrial septum and adjacent structures, a ''full-volume'' 3 dimensional (3D) dataset is obtained over 4 to 7 cardiac cycles. For transthoracic 3D images, the subcostal view is the preferred view because its projection is en face to the atrial septum; in patients with suboptimal windows the low parasternal 4-chamber view may be used. The parasternal long axis views for the left side enface view of the interatrial septum.

Real-time 3D imaging demonstrates the changing shape of the ASD during a cardiac cycle, with maximum size in diastole. Once acquired, these Full volume data sets can be analyzed immediately at the bedside in our study and stored for later analysis.

To adjust the full volume, the echocardiography machine displays two adjacent 2D images showing two perpendicular planes of the data about to be acquired.

The left plane is the coronal plane of the data which corresponds to the 2D echocardiography image when using the same probe position. The full volume was named after this coronal plane. The right plane is the sagittal plane showing the antero-posterior display of the data in the full volume. This plane was used to ensure the inclusion of all the data needed from a specific full volume.

Analyzing the volume rendered data using cropping to show the structure of interest was the main method of describing the segmental approach of each patient.

Analysis was done off line using the Q-lab software and quantification system mostly on the echocardiography machine.

The data collected to: Visualize the ASD. Identify its relation to the surrounding structures. Assessment of ASD regarding the shape and the dimensions, the surrounding rims. The number of ASDs or multiple fenestrations. The relation of the device to the surrounding structures.

Statistical analysis: The analysis was performed by SPSS for Windows release 11.0. All statistical data were interpreted. Mean/median (as measure of central tendency) standard deviation, minimum/maximum (as measure of variability) were used for quantitative variables. Frequency and percentages were used for qualitative variables. Correlation to estimate association between quantitative variables was presented in the form of correlation coefficient and its significance. P value is significant if ≤ 0.05.

Table 1. Demographic and baseline clinical and hemodynamic data.

Variables	Patients (n = 37)
Age (years)	4.95 ± 2.46
Weight (kg)	16.64 ± 5.80
BSA (m^2)	0.67 ± 0.16
Gender: Male/Female	19/18
Dyspnea on exertion	13 (35.14%)
Recurrent chest infection	29 (78.38%)
Increased CT ratio	17 (54.84%)
RA dilatation	17 (54.84%)
RV dilatation	20 (64.52%)
ASD size by 2D TTE (mm)	15.50 ± 5.57 (5–26)
ASD size by 2D TEE (mm)	14.73 ± 5.28 (6–28)
Qp/Qs Ratio	2.2 ± 0.8 (1.5–5.1)
Systolic pulmonary artery Pressure (mmHg)	40 ± 10 (26–70)
Total septum diameter (mm)	42.2 ± 10.8 (26–62)
Occluder device diameter/ total septum diameter ratio	0.44 ± 0.11 (0.13–0.63)

BSA = body surface area, RA = right atrium, RV = right ventricle, ASD = atrial septal defect, Qp/Qs = pulmonary-to-systemic flow ratio.

Results

Trans-catheter ASD closure and echocardiographic examinations were successfully performed for all patients. Patient's demographic data and ASD measurements are presented in Table 1. Complications such as arrhythmia (1st degree heart block) were reported in one patient. All the patients had single implanted device; Amplatzer septal occluder in 21 patient (56.75%) and Occlutech device in 16 patients (43.25%).

Table 2. 2D TTE& 2DTEE measurements of ASD rims.

Parameters	TEE	TTE	Paired t-test	
	Mean ± SD	Mean ± SD	t	P-value
IVC rim	9.13 ± 4.48	10.71 ± 5.12	−1.62	0.11
SVC rim	11.78 ± 4.4	12.98 ± 5.08	−1.16	0.25
Aortic rim	5.21 ± 1.79	6.3 ± 2.18	−2.42	0.02
AV rim	9.32 ± 3.76	10.37 ± 4.04	−1.13	0.26
Posterior rim	8.49 ± 3.11	9.41 ± 4.32	−1.08	0.29

IVC = inferior vena cava, SVC: superior vena cava, AV: atrioventricular.

Table 3. Comparison of ASD size by 2DTTE, 2DTEE and 3DTTE.

Modalities	ASD Size	Comparison	Paired t-test	
	Mean ± SD		t	P-value
3DTTE	16.67 ± 3.68	3DTTE–2DTTE	0.86	0.41
2D TTE	14.73 ± 5.28	3DTTE–2DTEE	1.13	0.28
2D TEE	15.50 ± 5.57	2DTTE–2DTEE	−1.24	0.22

Table 4. The relation of the ASD device proximity to aortic mitral continuity plane by 3DTTE and the device/ defect size ratio by 2DTEE.

ASD device/Defect size by 2DTEE		ASD device away from aortic mitral continuity plane by 3DTTE	ASD device close to aortic mitral continuity plane by 3DTTE	Total
No < 1.5	N	19	14	33
	%	51.35	37.84	89.19
Yes > 1.5	N	2	2	4
	%	5.41	5.41	10.81
Total	N	21	16	37
	%	56.76	43.24	100.00
Chi-square	X2	0.083		
	P-value	0.774		
Sensitivity	Specificity	PPV	NPV	Accuracy
12.50	90.48	50.00	57.58	56.76

The sizes of the occluder device ranged from 10.5-26 mm. There was significant correlation between the ASD diameter measured by TTE and that by TEE (r = 0.759, p = 0.001).

Echocardiographic assessment techniques prior to ASD device closure

1-2D transthoracic echocardiography and transesophageal echocardiography: no significant difference between the sizes of different rim by the two techniques except for the aortic rim (P = 0.02) (Table 2).

2- 3D transthoracic echocardiography

The ASD shape was well delineated by the 3D echo performed after full volume data acquisition and cropping. All the defects were rounded except eight patients had oval ASDs. There was no statistically significant difference in the ASD shape assessed by 2D and 3D (P = 0.78). The ASD size by 3D TTE ranged from 10-23 mm with a mean of 16.67 ± 3.68 mm and the ASD size by 2D TTE ranged from 6-28 mm with a mean of 14.73 ± 5.28 mm. While ASD size by 2D TEE ranged from 5–26 mm with a mean of 15.50 ± 5.57 mm. There was no significant difference between these measurements by the three techniques.

3-The required parameters for ASD device size selection

The mean value of the whole interatrial septal length was 42.2 ± 10.8 mm, ranging from 26 to 62 mm while the mean value of the left atrial device disc size was 33.51 ± 6.27 mm ranging from 22–42 mm. According to the Review Board and AGA Medical, the oversized device is defined if its size exceeds 1.5 times the TEE/ICE diameter of ASD [3]. It was previously published that the device should be visualized by 3D echo after one month of deployment and its relation to the aortic-mitral continuity plane was noted [9]. No significant oversized device was observed and the accuracy of this ratio was only 56.76% (Table 3). So, other parameters were used to compare the device relation and its proximity to aortic mitral continuity plane. The ASD device proximity to the aortic mitral plane was affected by BSA, AV rim size by TEE, device size, left atrial device disc, the ratio of the device to the interatrial septum length (Tables 4 and 5, Figs. 1 and 2). By a multivariate analysis a significant correlation was found between these variables; BSA, AV rim by TEE, device size and left disc of the device and the mitral valve assessed by 3DTTE. The AV rim size by TEE and the left disc size directly influenced the selection of the device size to avoid the oversizing and the encroachment on the aortic mitral

Table 5. Demographic and echocardiography parameters of the ASD device relation to aortic-mitral continuity plane.

Parameters	ASD device away from aortic mitral plane Mean ± SD	ASD device close to aortic mitral plane Mean ± SD	T-test	
			t	P-value
Age (years	4.548 ± 2.449	5.500 ± 2.449	−1.172	0.249
Weight (Kg)	15.333 ± 6.560	18.375 ± 4.225	−1.614	0.115
BSA (m^2)	0.608 ± 0.130	0.753 ± 0.180	−2.832	0.008
IVC rim (mm) (2DTEE)	10.171 ± 4.272	7.780 ± 4.301	1.682	0.101
IVC rim (mm) (2DTTE)	10.479 ± 4.389	10.988 ± 6.009	−0.289	0.774
SVC rim (mm) (2DTEE)	11.143 ± 4.170	12.200 ± 4.921	−0.707	0.484
SVC rim (mm) (2DTTE)	12.080 ± 5.013	14.100 ± 5.086	−1.194	0.241
Aortic rim (mm) (2DTEE)	5.081 ± 1.526	5.150 ± 1.862	−0.124	0.902
Aortic rim (mm) (2DTTE)	6.495 ± 2.667	6.000 ± 1.103	0.608	0.548
AV rim (mm) (2DTEE)	11.090 ± 3.882	7.013 ± 1.476	3.978	0.000
AV rim (mm) (2DTTE)	10.253 ± 4.409	10.536 ± 3.642	−0.196	0.846
Posterior rim (mm) (2DTEE)	8.490 ± 3.081	7.300 ± 3.152	1.132	0.265
Posterior rim (mm) (2DTTE)	9.897 ± 4.322	8.846 ± 4.433	0.634	0.532
Device size (mm)	16.524 ± 5.616	20.781 ± 3.834	−2.602	0.014
Device/ASD Size	1.208 ± 0.181	1.237 ± 0.204	−0.441	0.662
Device/BSA	37.789 ± 23.464	35.357 ± 10.524	0.363	0.719
Device/Weight	1.230 ± 0.562	1.278 ± 0.342	−0.286	0.777
Total septal length (2DTTE) (mm)	37.757 ± 5.544	40.763 ± 3.963	−1.837	0.075
Left disc size (mm)	30.714 ± 6.206	37.188 ± 4.215	−3.584	0.001
Left disc/total septum	0.813 ± 0.110	0.914 ± 0.080	−3.103	0.004
ASD size (3DTTE) (mm)	16.250 ± 4.062	17.500 ± 3.109	−0.537	0.603
ASD size (2DTTE) (mm)	13.381 ± 5.463	16.500 ± 4.619	−1.836	0.075
ASD size (2DTEE) (mm)	14.267 ± 6.066	17.113 ± 4.521	−1.571	0.125

continuity. The cut-off value of the AV rim to avoid the encroachment was 8.3 mm with an accuracy of 83.3% more than the previously published ratio (1.5 × ASD) (Figs. 3 and 4). Accordingly, the new Formula that was constructed for device choice: ½ the defect size + AV rim length (not ≤ 8 mm) = ½ the left disc size of the device.

4-Follow-up of the patients by 2D and 3D transthoracic echocardiography

The assessment of the device relation to the aortic-mitral continuity, superior vena cava (SVC) and inferior vena cava (IVC) by 2D and 3D echocardiography was done at one and twelve months. Three patients had mitral regurgitation; two of them had mitral valve prolapse (MVP) before closure. After the ASD closure, two devices were close to the SVC and one device was close to the IVC. Sixteen devices were close to the MV with significant regurgitation in three of them; two were newly detected and one with previous mitral regurgitation. Seventeen devices were close to the aortic rim without regurgitation.

Discussion

With progressive experience with trans-catheter device closure, device size is gaining more attention rather than success alone, as too large devices are prone for mushroom deformities, encroaching cardiac structures and possible serious complications as cardiac erosions. [10]. 2D-transesophageal echocardiography is currently the standard method to assess the atrial septal defect size [11,12]. Balloon sizing stretches septal tissues and thus overestimate round defects, furthermore, in multiple defects it underestimate the defect as it only measures one of the holes. Three-dimensional echocardiography is currently being used to show the morphology of the defect, this questioned the accuracy of 2D-transesophageal echocardiography in shape determination. In Amplatzer septal occluder the recommended device selected should be 1 to 2 mm larger than the largest diameter of the ASD [8]. Similarly, Occlutech device company recommended that the device size chosen would usually be the same, ±2 mm of the stretched diameter, as this would ensure an optimal fitting of the occluder [13]. And in a recent report, for Occlutech device it was recommended that the device size should not exceed the defect size more than 5 mm and the ratio of device size to the defect size should not be more than 1.5 at TEE [14].

The ASD size by 2D transesophageal (TEE) examination ranged from 5–28 mm with a mean of 15.50 ± 5.57 mm while ASD size by 2D TTE ranged from 5–24 mm, with a mean of 14.73 ± 5.28 m m. There was significant correlation between

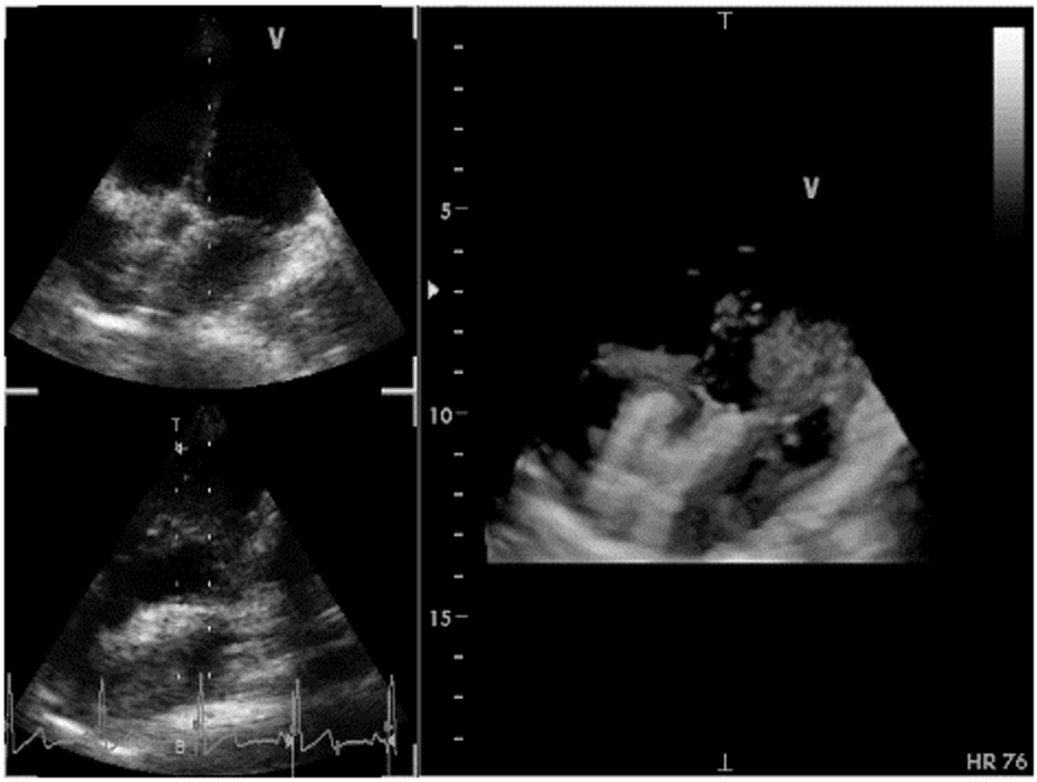

Figure 1. ASD Amplatzer device touching mitral valve with no mitral regurge.

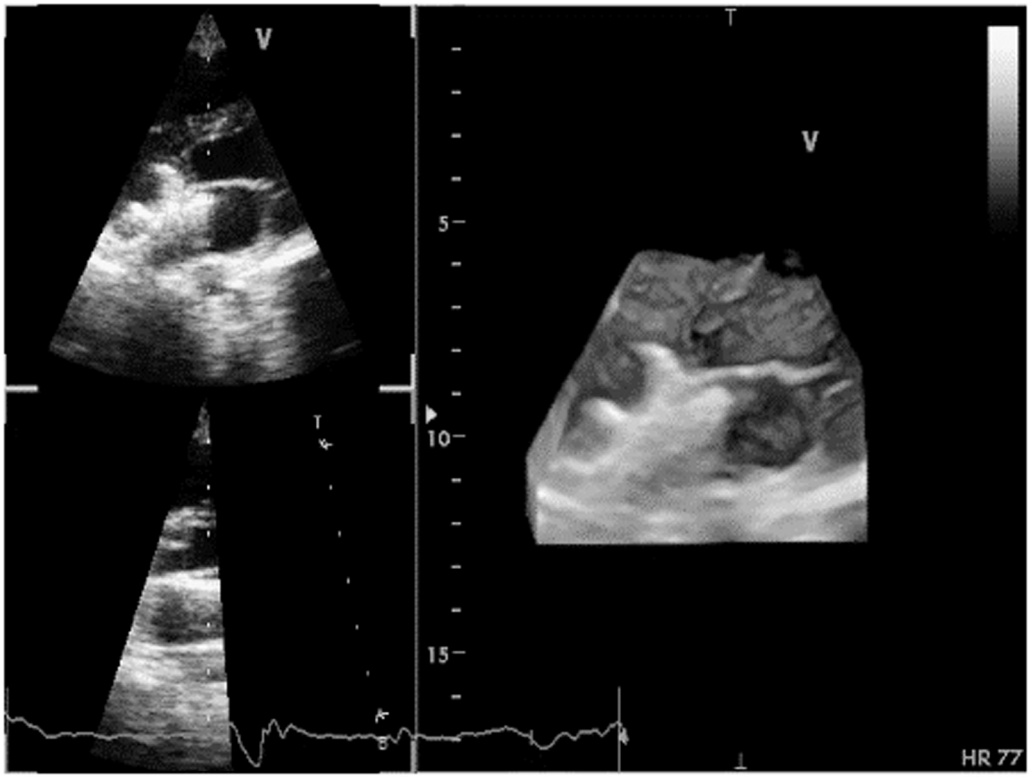

Figure 2. Large ASD Amplatzer occluder encroaching on the mitral valve causing minimal mitral regurge.

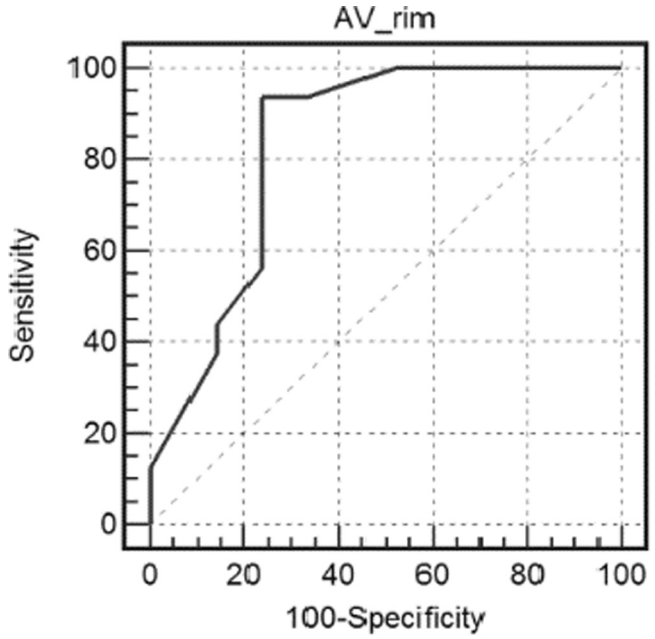

Figure 3. Roc curve graph showing the sensitivity and specificity of AV rim size by 2DTEE.

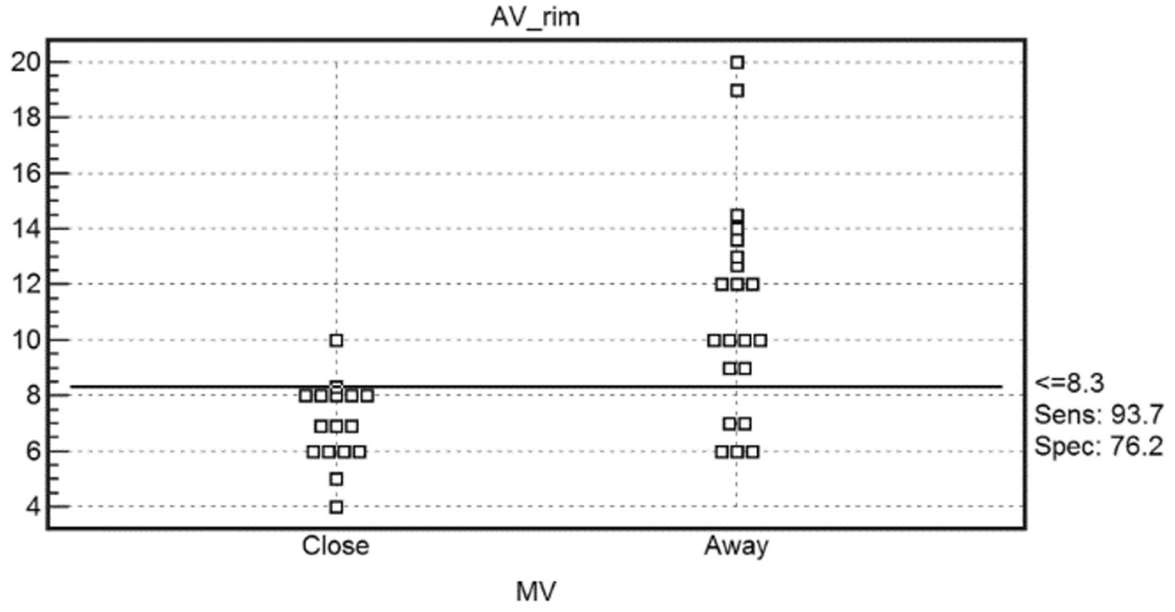

Figure 4. Cut-off point of the AV rim size by 2D TEE to avoid encroachment on the mitral valve by the chosen device.

these measurements by both techniques (r = 0.759, P = 0.001). In the current study, 2D TEE was used for the selection of the appropriate device size with addition of 2 or 4 mm depending on the presence or the absence of aortic rim. The balloon sizing method was done in ten patients with the large defects with flimsy rims and/or deficient rims. A survey was done in 2004 showed that patients with deficient aortic rims were noted in 90% of patients with erosion. The devices with lower risk of erosion are those that straddle the aorta, are somewhat oversized and don't move relative to the heart, while the devices with higher risk are those with protruding left atrial disk into the aortic root, are somewhat undersized and may have motion relative to adjacent heart structures [15]. The definition of an oval shaped atrial septal defect was used when the ratio of the shortest diameter to the longest diameter $\leq$0.75 [16]. In our cohort, there was no significant difference

between 3DTTE and 2DTEE in relation to the shape determination ($p = 0.78$). In the current work, no significant difference in the defect size assessed by 3DTTE, 2D TTE and 2D TEE (16.67 ± 3.68 mm, $p = 0.41$, 14.73 ± 5.28 mm, $p = 0.28$, 15.50 ± 5.57 mm, $p = 0.22$ respectively). Watanabe and his coworkers [17] studied the morphology and the defect differences by 3D TTE and 2D TTE. The right parasternal approach was obtained for 88 patients (80.0%) to assess ASD morphology. Although there was a significant difference in the maximal ASD diameter by comparing the conventional left approach to transesophageal echocardiographic measurements ($P < 0.05$). When the right parasternal approach was applied, a significant difference was not found ($P = 0.18$) [17], and the diagnostic concordance of the rim deficiency was improved from 85.2% to 90.9%. Three-dimensional TTE from the right parasternal approach improved visualization of the ASD shape and location from 65.5% to 74.5% (26). Based on the review board and AGA medical reports [3], the erosions caused by the device are related to the over-sizing, and their recommendation was not to use device more than 1.5times ASD diameter measured by TEE/ICE. Upon this recommendation, 3DTTE to 2DTTE relationship concerning 1.5 of the defect size showed an accuracy of only 56.76%. The above mentioned data directed us towards 3DTTE to find the relation of the aortico-mitral continuity plane to the selected device size through various parameters. There was a significant relation to BSA, atrioventricular (AV) rim size by TEE, device size, left disc size and the ratio of left disc to interatrial septum. These parameters should be taken in consideration when choosing the device size. Logistic regression analysis was done between aortic-mitral plane as a dependent variable and these parameters revealing that AV rim and the left atrial disc diameter measured by TEE are the most significant parameters to avoid the oversizing or the encroachment on the aortico-mitral continuity plane. A cut-off value AV rim length by TEE $\geq$8 mm is mandatory to avoid device encroachment on the aortico-mitral continuity plane, with accuracy of 83.3%. This highlight the importance of AV rim not only the postero-inferior rim length in the encroachment on the vital aortic and mitral tissues as mentioned by Mathewso et al. in 2004 [18] who presented the closure of a large ASD with deficient or absent postero-inferior rim. As the difference in radius length between the right and left atrial discs of the Amplatzer device is 2–3 mm, both discs couldn't be hanged on both sides of the rim if it is less than 3 mm. They concluded that they can deploy stable devices, but these devices are prone for complications, as pulmonary vein or inferior vena caval obstruction, encroachment onto the anterior mitral leaflet, or even embolization [18]. On the other hand, Pedra et al. 2000 [19] defined a large ASD as an ASD with stretched diameter more than 26 mm. According to both Amplatzer and Occlutech devices' recommendations for the device selection the shape of the defect was not taken in consideration whilst this ought to affect the choice of the device size. In children the indication for percutaneous treatment is based on the defect diameter septal length ratio with minimal differences according to the device type. The total atrial septum is measured in four chamber view by TTE and/or TEE. The AV valve rim plus the average size of the ASD (measured in at least two orthogonal views) plus the superior rim equals total atrial septal length. Thus, a device where the left atrial disc of the Amplatzer septal occluder is equal to or smaller than the total atrial septal length can be used [20]. In the current study, there was a direct relation between the ratio of the left disc of the device to the total septum (0.813 ± 0.110, $p = 0.004$). Also there was a direct relation between AV rim size, left disc of the device and the total septum regarding the BSA not only the defect size or body weight especially in the pediatric age. We postulated that the device tends to be displaced towards the aortico-mitral plane (direction of blood flow) due to continuous forces: 1- The gravity 2- weight of the device 3-Drag and friction drag which depend on the thickness of the device (friction drag is directly proportionate to the area of the object in the fluid and the square of the velocity of the blood), 4- movement of the interatrial septum. All of these forces are minimal but continuous, eventually leading to minimal displacement of the device downwards and towards the mitral especially in pediatric population due to relatively thinner septum [21] and small area of the atria in relation to the device thickness. Royse et al assessed the movement of the interatrial septum in 71 patients, they used TEE to categorize the septum by its shape and movement. [22] Fixed curvature (FC) was identified by bowing of the interatrial septum from left to right throughout the cardiac cycle, mid-systolic reversal (MSR) by minimal septal movement and transient reversal (right to left) during mid-systole, and mid-systolic buckling (MSB) by marked movement and bulging of the septum during mid-systole. [22]. This movement can be dampened by the

device and directed more towards the aortico-mitral continuity plane with the flow direction.

From the above suggestions, we postulated that the cut-off length of AV rim to avoid encroachment on the mitral valve and aortic mitral continuity plane will be 8 mm. While, previously published studies concluded that round defects are more common than oval defects, and the waist of the devices are rounded, so according to shape of the defect and its size and the length of the AV rim in a ratio with the left disc of the device we deducted a new calculation for choosing the device size (in rounded defects ½ the defect size + AV rim length not $\leq$ 8 mm = ½ the left disc size of the chosen device) from this calculation we can avoid oversizing and encroachment on the aortico-mitral continuity plane, e.g.: in a defect with a diameter of 26 mm, half the defect is 13 mm and the least AV rim size is 8 mm so the maximum left disc size that could be chosen is 42 mm suggesting that the safest device would be 28 mm. Accordingly, the new Formula that was constructed for device choice: ½ the defect size + AV rim length (not $\leq$ 8 mm) = ½ the left disc size of the device.

Conclusion

3DTTE is a good modality to determine the relation of the device to the surrounding structures before and after ASD closure. The AV rim is an important rim to avoid the encroachment of the device on the aortico-mitral continuity plane, and its length should be not less than 8 mm to avoid this complication.

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Ethical standards

The authors assert that all procedures contributing to this work comply with the ethical standards and were approved by the institutional committees in Cairo University Hospitals.

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