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

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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.

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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.

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

### 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
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, mini-
mum/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.

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 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 (m²) | 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.

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

| Parameters | TEE Mean ± SD | TTE Mean ± SD | Paired t-test | 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: atriocentricular.
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.

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

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

### 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                         | 19                                                             | 14                                                            | 33    |
| %                               | 51.35                                                         | 37.84                                                         | 89.19 |
| Yes > 1.5                       | 2                                                             | 2                                                             | 4     |
| %                               | 5.41                                                          | 5.41                                                          | 10.81 |
| Total                           | 21                                                            | 16                                                            | 37    |
| %                               | 56.76                                                         | 43.24                                                         | 100.00|
| Chi-square X2                   | 0.083                                                         |                                                               |       |
| Sensitivity Specificity PPV NPV|                                                               |                                                               |       |
| 12.50                           | 50.00                                                         | 57.58                                                         | 56.76 |
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/C2 ASD) (Figs. 3 and 4). Accordingly, the new Formula that was constructed for device choice: ½ the defect size + AV rim length (not /C2) 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-transeosophageal 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-transeosophageal 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 transeosophageal (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 mm. There was significant correlation between

| Parameters | ASD device away from aortic mitral plane | ASD device close to aortic mitral plane | T-test | 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 (m²)   | 0.608 ± 0.130                           | 0.753 ± 0.180                          | −2.832 | 0.008   |
| IVC rim (mm) | 10.171 ± 4.272                         | 7.870 ± 4.301                          | 1.682  | 0.101   |
| SVC rim (mm) | 10.479 ± 4.389                         | 10.988 ± 6.009                         | −0.289 | 0.774   |
| SVC rim (mm) | 11.143 ± 4.170                         | 12.200 ± 4.921                         | −0.707 | 0.484   |
| Aortic rim (mm) | 12.080 ± 5.013                        | 14.100 ± 5.086                         | −1.194 | 0.241   |
| Aortic rim (mm) | 5.081 ± 1.526                          | 5.150 ± 1.862                          | −0.124 | 0.902   |
| Aortic rim (mm) | 6.495 ± 2.667                          | 6.000 ± 1.103                          | 0.608  | 0.548   |
| AV rim (mm) | 0.190 ± 3.882                           | 0.03 ± 1.476                           | 3.978  | 0.000   |
| AV rim (mm) | 10.253 ± 4.409                          | 10.536 ± 3.642                         | −0.196 | 0.846   |
| Posterior rim (mm) | 8.490 ± 3.081                         | 7.300 ± 3.152                          | 1.132  | 0.265   |
| Posterior rim (mm) | 9.897 ± 4.322                         | 8.846 ± 4.433                         | 0.634  | 0.532   |
| Device size (mm) | 16.524 ± 5.616                          | 20.781 ± 8.384                         | −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                        | 0.563  | 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 ± 4.109                         | −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   |
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.
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.

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.
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 1.5 times ASD diameter measured by TEE/ICE. Upon this recommendation, 3DTTE to 2DTTE relationship concerning 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 (direction of blood flow) and 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 proportional 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 ≤ 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 chosen 28 mm. 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.

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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