

Added value of three dimensional transesophageal echocardiography in percutaneous closure of atrial septal defect.

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Abstract

Unrepaired secundum ASD (atrial septal defect) is the commonest congenital heart disease encountered in adulthood. In this study we try to correlate the three-dimensional size of a secundum ASD to the device size. We did a retrospective analysis to 36 patients who underwent successful transcatheter closure of atrial septal defect guided by balloon sizing and correlated this to the device size. The device size was correlated significantly with all the maximal ASD diameter by 2D-TTE, 2D-TEE and 3D-TEE. However, the most significant correlation was between three-dimensional maximal diameter and device. 3D TEE is a promising and reliable tool that can be used to determine the size, number and shape of ASD and to accurately select the suitable device size during percutaneous closure.

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Abstract:

Unrepaired secundum ASD (atrial septal defect) is the commonest congenital heart disease encountered in adulthood. In this study we try to correlate the three-dimensional size of a secundum ASD to the device size. We did a retrospective analysis to 36 patients who underwent successful transcatheter closure of atrial septal defect guided by balloon sizing and correlated this to the device size. The device size was correlated significantly with all the maximal ASD diameter by 2D-TTE, 2D-TEE and 3D-TEE. However, the most significant correlation was between three-dimensional maximal diameter and device. 3D TEE is a promising and reliable tool that can be used to determine the size, number and shape of ASD and to accurately select the suitable device size during percutaneous closure.

Introduction

Unrepaired secundum ASD is the commonest congenital defect seen in adult congenital heart disease population. Transcatheter closure of secundum ASD has been proven safe, very effective and become preferred method of choice for the treatment. It avoids the prolonged hospital stay and the unpreferred sternotomy that are associated with surgical closure. Accurate assessment of the ASD shape and size is the cornerstone of a successful transcatheter closure of an ASD. Both under sizing and oversizing the defect could lead to serious complications. At present balloon sizing is the preferable technique adopted by most of the cardiac interventionists to assess the defect size and select the device. Although it proved to be a reliable method, balloon sizing prolongs exposure to fluoroscopy and adds cost. Some authors have mentioned that an overstretched balloon can lead to distortion of the defect margins leading to enlarging the defect size and probably losing a pre-existing tiny rim (Ooi et al., 2016).

Three dimensional transesophageal echocardiography (3D-TEE) is a promising tool to guide different cardiac interventional procedures. It is widely available, easy and reproducible imaging modality that has the ability to overcome geometric assumption which is considered one of the major limitations of the two dimensional echocardiography.(Balzer et al., 2013)

Nowadays, image acquisition and processing using the 3D TEE have become more applicable during different cardiac interventional procedures (references) (Balzer et al., 2013)The 3D TEE obtained en face view of interatrial septum provides accurate information about the number, shape and size of the defect. Moreover, it provides additional valuable information about the relation between the defect and the surrounding structures and confirms the adequacy of the surrounding rims. (Balzer et al., 2013)

We conducted this retrospective analysis to assess the efficacy and reliability of 3D TEE as a reproducible imaging modality to accurately determine the size of ASD and selection of the device.

Patients and methods:

We retrospectively reviewed thirty-eight patients who underwent a transcatheter closure of atrial septal defect from November 2018 to December 2019. In this study 28 patients were done at The Royal Brompton Hospital in London and 10 patients were done at The Children Hospital, Mansoura University, Egypt. There was no patients with significant residual shunts. However, we excluded two patients one of them had a major complication (device dislodgement) and the other one had multiple defects. A total of 36 patients composed study group.

All our patients had a percutaneous ASD closure under 3D TOE guidance as the presence of haemodynamically significant ASD and suitable anatomic characters. The device selection was done according to balloon sizing using the flow stopping technique.

We considered a procedure to be successful in all patients with no residual shunt or with residual shunt of less than 2 mm and without encroachment on the surrounding structures or other major complications

(device dislodgement) Subsequently, we assumed that the device size was appropriate among those patients. Echocardiographic assessment was conducted in all patients, using an IE 33 Philips machine and TEE probe X7-2t.

From transthoracic echocardiogram both color and 2D images of ASD were obtained in the standard subcostal view and the modified apical four chamber view, maximal dimensions of the ASD were measured.

During the transesophageal Echocardiography the ASD diameters were assessed using the standard views including a mid-oesophageal four-chamber view (0), a short-axis view (35 – 60) and a long-axis view (90 – 130). Continuous rotation was performed to track the maximal diameter and both colour and 2D pictures were obtained.

The 3D images were obtained in the mid-oesophageal bicaval view at around 90 degrees, the 3D zoom mode was activated and the zoom box was optimized in the lateral plane to include the opening of the SVC and IVC. The whole septum was included by optimizing the depth settings. A full volume for the IAS was obtained and then rotated anticlockwise for 90 degrees and turn the image leftwards, the SVC opening is directed upwards. This was considered anatomically oriented en face view of ASD from the RA perspective. Gain optimization was done to remove all blood shadows and optimise the image for accurate identification of defect border then the image was acquired.

An offline MPR was performed moving each axis to obtain an image, which included the whole ASD. Measurements of the minimal and maximal diameters were performed using two axes on the 2D images obtained by MPR (figure 1)

The maximal diameters were all compared with the device size. Three types of devices were encountered in this study which were Occlutech, Hyperion and Amplatzer according to the availability of the selected size.

Statistical analysis:

Data were analysed using the Statistical Package of Social Science (SPSS) program for Windows (Standard version 24). The normality of data was first tested with one-sample Kolmogorov-Smirnov test.

Continuous variables were presented as mean $\pm$ SD (standard deviation) while qualitative data were described using number and percent. Pearson correlation was used to correlate continuous variables.

Significant variables in correlation entered into linear regression models using the enter statistical technique to predict the most significant determinants and to control for possible interactions and confounding effects.

Level of significance:

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p-value). The results were considered:

Non-significant when the probability of error is more than 5% ($p > 0.05$).

Significant when the probability of error is less than 5% ($p \leq 0.05$).

The smaller the p-value obtained, the more significant are the results.

Results:

Study population:

Thirty-six patients (18 males and 18 females) who underwent successful transcatheter closure of atrial septal defect from November 2017 to December 2019 were studied. Mean age of the patients was 31.5 $\pm$ 19.1 (min 3, max 74). The demographic data of our study population are shown in Table (1).

Echocardiographic measurements

The device size was correlated significantly with all the maximal ASD diameter by 2D-TTE (R 0.64, P [?] $\leq$ 0.001), by 2D-TEE (R 0.78, P [?] $\leq$ 0.001) and 3D-TEE (R 0.80 P [?] $\leq$ 0.001). The correlations between maximal ASD diameters by echocardiography and device size are reported in Table (2). The strongest correlation was noted with 3D TEE maximal diameter R 0.80. Mean device size 24.04 $\pm$ 6.53, Mean 3D TEE maximal diameter 19.52 $\pm$ 6.01, and mean TEE maximal diameter 17.42 $\pm$ 5.86. Maximal ASD diameters by 3D-TEE were larger than maximal ASD diameters by 2D-TEE and by 2D-TTE The mean difference was 2 mm P [?] $\leq$ 0.001 , and 2.25 mm , P 0.008).

The device size was larger than all echocardiographic ASD diameters. The mean difference between Device size and 3D-TEE maximal diameter, 2D-TEE maximal diameter, and 2D-TTE maximal diameter was 4.0 mm P [?] $\leq$ 0.001, 6 mm, P [?] $\leq$ 0.001- and 6.5-mm P [?] $\leq$ 0.001 respectively. (Table 4).

With multiple linear regression analysis, one formula was suggested to predict device size using the different echocardiographic measurements. The suggested formula was $y = c + b \cdot x$ where y = estimated dependent variable score (device size) c = constant, b = beta coefficient, and x = score on the independent variable .This model was more predictive with 3D maximal diameter with R 72%.The values for this suggested formula are presented in (Table 3) Using the 3D maximal diameter (Device size = $6.9 + 0.87 \times 3D \text{ max diameter}$) $R^2 = 0.72$ P [?] $\leq$ 0.001.Using 2D TEE maximal diameter (Device size = $8.9 + 0.87 \times 2D \text{ TEE max diameters}$) $R^2=0.69$ P [?] $\leq$ 0.001.However, all these formulas needs to be validated on a larger number of patients.

Using the first and second formulas there was no significant difference between the suggested device and the actual device. Mean difference was 23.97 $\pm$ 5.31 for equation 1 and 24.03 $\pm$ 5.08 for equation 2 with P 0.919 and 0.984 respectively.

Discussion:

In this study, 3D TEE and 2D maximal ASD diameters were found to be correlated with the device size. 3D Echocardiography has a good ability to overcome geometric assumptions and the variability in the ASD measurements.

3D Echocardiography is now widely available and validated protocols for accurate measurement of different cardiac defects are now established.

Balloon sizing is the widely used and approved technique till the moment. However, it is thought to overestimate the defect size due outstretching the defect margins. At the meantime it adds an extra cost to the procedure besides the prolonged exposure to fluoroscopy.(Zhu et al., 2000)

Underestimation of the defect size could lead to serious complications for example device dislodgment. Meanwhile, overestimation of the defect size is not appropriate too. The routine use of a bigger device has a safety concerns as it could lead to encroachment on the surrounding structures. It may result in serious complications like heart block and aortic erosion.(Zhu et al., 2000)

The main result of this study is the good correlation between the maximal ASD measurement assessed by 3D-TEE and the device size. We assumed that the device size was accurate in cases where there was no residual leak , encroachment on surrounding structures or any major complications e.g., device dislodgment. We correlated the device size with the different Echocardiographic maximal diameters.

The correlation between the device size and the Echocardiographic maximal diameters was higher with 3D TEE than other maximal diameters. R^2 0.72, P [?] $\leq$ 0.001

With multiple linear regression analysis, we suggest a formula that can predict the device size according to the 3D TEE maximal diameter: Device size = $6.9 + 0.87 \times 3D \text{ maximal diameter}$ with $R^2 = 0.72$, P [?] $\leq$ 0.001 .We can use 2D TEE maximal diameters but this could have a lower predictive value than the 3D measurement: Device size = $8.9 + 0.87 \times 2D \text{ TEE maximal diameters}$ $R^2=0.69$, P [?] $\leq$ 0.001, However, all these formulas needs to be validated on a larger number of patients.

Hajizeinali et al compared the 2D TEE maximal diameter with the device size and suggested a formula to

predict the device size using the 2D maximal diameter. They proposed the following equations to calculate a device size:

$$\text{Device size} = 2.76 + 1.16 \times \text{TEE defect size}, R^2 = 0.91$$

$$\text{Device size} = 4.08 + 1.05 \times \text{TEE defect size}, R^2 = 0.91 \text{ (Hajizeinali et al., 2013)}$$

There is some difference between this result and our results. We attribute this to the difference in sample size, and some technical aspects; for example, the variability in selecting the device size to be 1-4 mm larger than the defect size.

Hascoet et al suggested that 3D TEE maximal diameter was correlated to the balloon size. They suggested two formulas $BS = 1.07 \times 3D \text{ TEE max} - 0.1$ when the ASD shape was oval and $BS = 1.07 \times 3D \text{ TEE max} + 3$ when the ASD shape was round. (P, 0.0001). R^2 was 0.78. (Hascoet et al., 2015)

We thought that correlating the 3D maximal diameter directly to the device size would have an added benefit if the 3D proved efficacy in accurately assessing the defect size. It reduces the time of the procedure and minimize radiation exposure and more importantly decreases the cost.

Another model which was described by (Hascoet et al., 2015) is $BS = 4.5 \times \text{ASD area} + 11.5$ (P, 0.0001). R^2 was 0.74.

Roushdy et al. suggested a formula which used the 3D area and circumference to predict the device size (Roushdy et al., 2020) . The suggested formulas were:

$$\text{a-Device size} = 10.8 + 3.95 \times 3D \text{ ASD area.}$$

$$\text{b-Device size} = 3.85 \times 3D \text{ ASD circumference} - 1.02.$$

However, we used the 3D maximal diameter as it is the previously known practice and it is easier to apply.

Based upon our results we suggest that 3D TEE can be used solely to choose the suitable device without the need for balloon sizing .This will reduce the duration of the procedure, minimize the radiation exposure, avoid the defect margins distortion that is probable with the overstretched balloon and more importantly reduces the cost of the procedure. However, this needs to be validated by a larger study.

Limitations

The main limitation of this study is the small sample size. Further studies with bigger sample size are suggested to validate the 3D TEE as the appropriate method to choose the ASD device size without the use of the balloon.

Conclusion:

3D TEE is a promising and reliable tool that can be used to determine the size, number and shape of ASD and to accurately select the suitable device size during percutaneous closure. However, this needs to be validated on long-term.

Table (1): Patients' characteristics among the studied group:

Patients' characteristics	Cases group (n=36)
Age (years) Mean $\pm$ SD Median (Min-Max)	31.5 $\pm$ 19.17 27 (3-74)
Gender Male Female	18 (50%) 18 (50%)
Weight (kg) Mean $\pm$ SD	61.83 $\pm$ 21.81
Height (cm) Mean $\pm$ SD	159.8 $\pm$ 2.32

Table (2): Pearson correlation between 3D TEE maximal diameter, 2D TEE maximal diameter, TTE maximal diameter and device size.

Variables	Device size		
	r		
Maximal diameters 2D TTE Maximal diameter 2D TEE Maximal diameter 3D TEE Maximal diameter	0.640	0.780	0.80

Table (3): Linear regression analysis for different Echocardiographic diameters as independent predictors of device size:

Constant			
2D TTE Maximal diameter 2D TEE Maximal diameter 3D TEE Maximal diameter	2D TTE Maximal diameter	2D TEE	

Table (4): The difference between the device size and 3D TEE , 2D TEE and TTE maximal diameters.

		Difference Median (Min-Max)	Paired t test	P value
Device size	2D TTE maximal diameter			
24.04 ± 6.53	17.48±4.87	6.0 (-1-17)	7.76	[?]0.001*
Device size	2D TEE maximal diameter			
24.04 ± 6.53	17.42±5.86	6.5 (-1-19)	9.45	[?]0.001*
Device size	3D TEE maximal diameter			
24.04 ± 6.53	19.52±6.01	4.0 (-3-12)	6.92	[?]0.001*

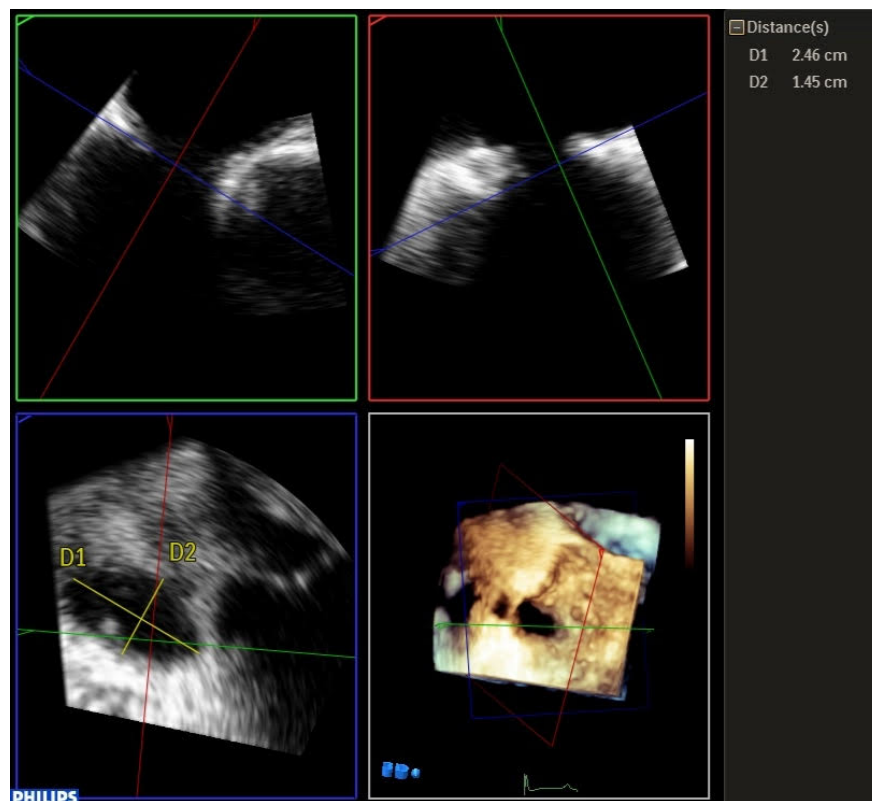


Figure (1): Measurements of the minimal and maximal diameters of ASD using offline MPR

D1 maximal diameter , D2 minimal diameter

ASD Atrial septal defect. MPR multiplanar reconstruction

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