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Original Article

Utility of 3D Echocardiography for Device Sizing During Transcatheter ASD Closure: A Comparative Study

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ABSTRACT

BACKGROUND: Two-dimensional (2D) transesophageal echocardiography (TEE) is commonly used for assessing patients undergoing transcatheter atrial septal defect (ASD) device closure. 3D TEE, albeit providing high resolution en-face images of ASD, is used in only a fraction of cases. We aimed to perform a comparative analysis between 3D and 2D TEE assessment for ASD device planning.
METHODS: This was a prospective, observational study conducted over a period of one year. Patients deemed suitable for device closure underwent 2D and 3D TEE at baseline. Defect characteristics, assessed separately in both modalities, were compared. Using regression analysis, we aimed to derive an equation for predicting device size using 3D TEE parameters.
RESULTS: Thirty patients were included in the study, majority being females (83%). The mean age of the study population was 40.5 ± 12.05 years. Chest pain, dyspnea and palpitations were the common presenting complaints. All patients had suitable rims on 2D TEE. A good agreement was noted between 2D and 3D TEE for measured ASD diameters. 3D TEE showed that majority of defects were circular in shape (60%). The final device size used had high degree of correlation with 3D defect area and circumference. An equation was devised to predict device size using 3D defect area and circumference. The mean device size obtained from the equation was similar to the actual device size used in the study population (p = 0.31).
CONCLUSIONS: Device sizing based on 3D TEE parameters alone is equally effective for transcatheter ASD closure as compared to 2D TEE.

Keywords: Atrial septal defects; Transesophageal echocardiography; 3D echocardiography

INTRODUCTION

Atrial septal defects (ASDs) are one of the most common congenital heart diseases noted in the adult population. Females constitute majority of patients with ostium secundum ASD.[1] Transcatheter closure of ASD is considered as the treatment of choice in patients with significant left to right shunt.[2][3] Percutaneous ASD device closure was initially guided by fluoroscopy and two-dimensional (2D) transthoracic echocardiography (TTE). Balloon sizing of the septal defect has long been considered as the gold standard for determining device

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size. However, it is associated with its own set of limitations and complications. Balloon sizing can cause overstretching of the defect rims which increases the defect size, leading to use of an oversized device.[4] Stretching of the defect rims can lead to inadvertent tear of the atrial septum, micro-embolization causing stroke and balloon related cardiac perforation.[5] Therefore, a large number of operators have foregone balloon sizing of ASD for imaging guided ASD closure. The routine use of transesophageal echocardiography (TEE) has led to a better understanding of anatomy of ASD and plays a vital role in determining device size.[6]

2D TEE helps in assessment of defect size which can help choose the appropriate device. However, 2D TEE measurements are dependent of the plane of image obtained and may be inconsistent, especially in complex ASD. This is related to the inherent limitation of visualizing a 3D structure in a 2D plane. The advent of 3D echocardiography has improved our understanding of cardiac anatomy and associated abnormalities.[7] Real time 3D gives a better idea of the relationship of cardiac structures as compared with 2D echocardiography.[8] 3D TEE can be used to obtain enface view of ASD which can help to understand the spatial orientation of ASD as well as help in assessment of rims.[9] 3D echocardiography gives better guidance for percutaneous device closure of ASD when compared to 2D echocardiography. It can also help in determining device size based on defect shape and orientation, something which is not possible on 2D imaging. There are some studies where 3D TEE has been shown to be equally effective and safe as compared to balloon sizing of ASD.[10] Despite these encouraging results, there is some inertia in relying on only 3D TEE for device sizing and operators still tend to use 2D TEE measurements for sizing. In the current study, we aim to study defect characteristics in ASD patients using 3D TEE and compare them with 2D TEE. We also aim to correlate the 3D TEE characteristics with the final device used for defect closure. We hypothesize that device sizing based on 3D TEE alone is equally effective when compared to 2D TEE.

METHODS

This was a prospective, observational, single centre study performed over a period of one year. All patients, above 18 years of age, who were deemed suitable candidates for transcatheter ASD device closure were included in the study. Patients with very large ASD (> 30 mm), deficient rims and poor TEE windows were excluded from the study. Informed consent was obtained from all study participants at the beginning of the study. The study protocol was approved by the Institutional Ethics Committee at SCTIMST, Thiruvananthapuram (SCT/IEC/1726) on 12/02/2021, prior to start of the study.

All patients underwent a pre-procedure evaluation and their baseline demographics were recorded using a structured questionnaire. 2D TEE was done at baseline to evaluate the anatomy of the ASD and determine feasibility of device closure. The degree of pulmonary hypertension was also assessed in each case. All device sizing was done using defect diameters measured on TEE. We do not use balloon sizing for ASD at our centre owing to its well-defined complications. Currently, device sizing using TEE is the standard for ASD closure at our centre. The final device size chosen is 2–4 mm larger than the maximal ASD diameter measured on TEE. In defects with floppy rims, the floppy segment is also taken into consideration while determining appropriate device size. This is to ensure safety and prevent device embolization.

All transcatheter ASD closures were performed under general anesthesia as TEE guidance was required during the procedure. During procedure, TEE was done using a Phillips EPIQ 7C ultrasound machine and 5 MHz TEE probe. ASD assessment was done at 0°, 45°, 90° and 120° views (**Figure 1**). In each view, ASD rims were assessed for length, thickness and stability. The maximum and minimum ASD diameter was recorded. Presence of floppy rims were also recorded. After 2D TEE images

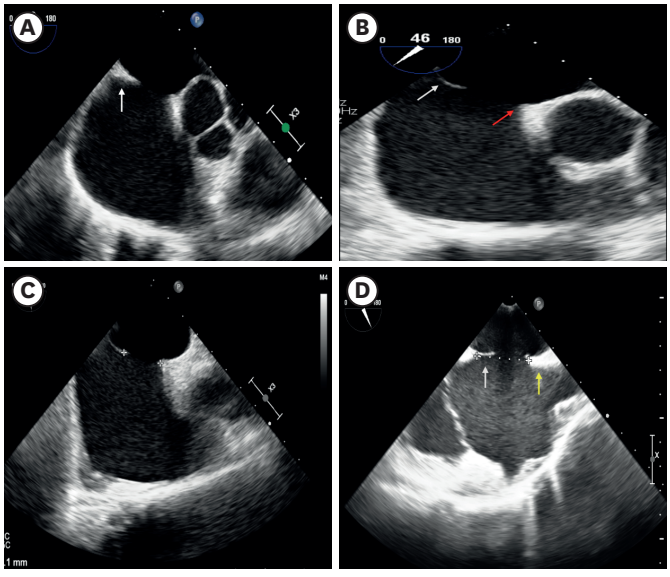

Figure 1. Two-dimensional transesophageal echocardiography assessment of ASD in different views. (A) The 0° view showing pulmonary vein rim (white arrow). (B) The 45° view showing posterior rim (white arrow) and aortic rim (red arrow). (C) The 90° view showing inferior vena cava and SVC rim in a malaligned ASD. (D) The 120° view showing SVC (yellow arrow) and coronary sinus rim (white arrow).
ASD: atrial septal defect, SVC: superior vena cava.

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were obtained, 3D imaging was performed using dedicated 3D imaging software. 3D images were acquired over consecutive beats with patient's breath hold which helps to increase the temporal resolution. 3D zoom modality was used for generating high resolution en-face views of the ASD. Optimal gain and compression settings were used to Defect characteristics like defect shape, defect area and defect circumference were recorded (**Figure 2**). Circular index was defined as the ratio of maximal diameter to minimal ASD. Defects with circular index > 1.5 were considered to be oval in shape. 3D imaging also gave an idea about the relation of defect with the surrounding structures. Using 3D defect area and circumference, an equation was devised to predict the appropriate device size for each defect.

Patients underwent ASD device closure under both fluoroscopy and TEE guidance. Device sizing was done during procedure on the basis of 2D TEE measurements. 3D images were also obtained. After initial deployment, device position and stability were checked using TEE. Amplatzer septal occluder (AGA Medical, Golden Valley, MN, USA) was used for device closure in all patients. Any device impingement on surrounding structures was also looked for. Procedural time, defined as the time period from start of the procedure (after obtaining vascular access) to final deployment and release of device, was noted for each case. Any intraprocedural events like rhythm disturbances, hemodynamic instability was noted. Procedural complications like vascular access issues, cardiac perforation/tamponade, device embolization was recorded. All patients underwent 2D TTE prior to discharge for evaluating device stability, residual ASD flow and ventricular function.

All data obtained using a structured questionnaire was recorded in a tabular format. Categorical variables were expressed as proportions and continuous variables were expressed as mean and standard deviations. Bland Altman analysis was used to determine agreement between ASD diameters measured on 2D vs. 3D TEE. Correlation analysis was used to determine degree of correlation between device size and 3D TEE parameters. Regression analysis was used to derive an equation for predicting device size based on 3D defect characteristics. A p-value of < 0.05 was considered as statistically significant. All analysis was done using R v4.2.1 (R Foundation, Vienna, Austria).

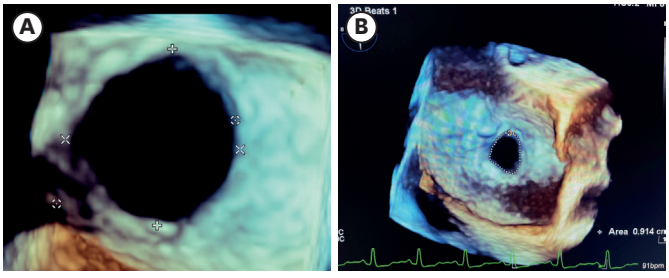

Figure 2. (A) 3D transesophageal echocardiography showing en-face view of atrial septal defect with all rims. (B) 3D defect characteristics like defect area and circumference can be measured along with determination of defect shape.
3D: 3-dimensional.

RESULTS

Thirty patients were included in the study over a period of one year. The average age of the study population was 40.5 ± 12.05 years. Majority of patients in the study cohort were females (83.3%). Patients with ASD commonly presented with complaints of chest pain, dyspnea and palpitations (**Table 1**). None of the patients in the study cohort had history of coronary artery disease or right heart failure. Electrocardiogram analysis

Table 1. Baseline demographic characteristics of the study population

Characteristics	Value (n = 30)
Age (years)	40.50 ± 12.05
Females	25 (83.3)
Clinical presentation	
Chest pain	9 (30)
Dyspnea	17 (56.6)
Palpitations	12 (40)
Syncope	1 (3.3)
Diabetes	5 (16.6)
Hypertension	3 (10)
Dyslipidemia	1 (3.3)
Hypothyroidism	4 (13.3)
Known CAD	0 (0)
History of right heart failure	0 (0)
ECG	
Sinus rhythm	29 (96.7)
Atrial fibrillation	1 (3.3)
Axis (degrees)	61.0 ± 32.6
RBBB	19 (63.3)
CTR	0.52 ± 0.06
2D TTE	
LVEF (%)	65.9 ± 6.8
MR	3 (10)
TR	
Mild	29 (96.7)
Moderate	1 (3.3)
RVSP (mmHg)	31.9 ± 11.5
TAPSE (mm)	20.2 ± 2.3
RV internal diameter (mm)	27.5 ± 3.4
RA diameter (mm)	38 ± 7
ASD maximum diameter (mm)	19.8 ± 5.3

All values are expressed as number (%) or mean ± standard deviation.
ASD: atrial septal defect, CAD: coronary artery disease, CTR: cardiothoracic ratio on chest X-ray, ECG: electrocardiogram, LVEF: left ventricular ejection fraction, MR: mitral regurgitation, TAPSE: tricuspid annular plane systolic excursion, TR: tricuspid regurgitation, TTE: transthoracic echocardiography, RA: right atrial, RBBB: right bundle branch block, RV: right ventricular, RVSP: right ventricular systolic pressure, 2D: 2-dimensional.

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revealed that majority of patients were in sinus rhythm (96.7%). Right bundle branch block pattern was noted in 63.3% patients. Mean cardiothoracic ratio on chest X-ray was 0.52 ± 0.06. TTE revealed normal left ventricular (LV) function in all study participants with a mean LV ejection fraction (LVEF) of 65.9 ± 6.8%. Mitral regurgitation was noted in 10% of the patients. Tricuspid regurgitation was mild in majority of the patients (96.7%). All patients had dilated right atrial and right ventricular (RV) whereas RV systolic function, denoted by tricuspid annular plane systolic excursion, was normal in all patients. Mean RV systolic pressure noted was 31.9 ± 11.5 mmHg, signifying mild pulmonary hypertension. The mean ASD diameter noted on TTE was 19.8 ± 5.3 mm.

2D TEE was performed for all study participants. The average maximum ASD diameter noted on 2D TEE was 20.9 ± 4.87 mm whereas the average minimum diameter was 17.1 ± 4.6 mm. All ASD rims were deemed suitable for device closure on 2D TEE (**Table 2**). Aortic rim was deficient in all patients, with a mean length of 1.5 ± 2.3 mm. However, this was not considered as a contraindication for device closure. A significant proportion of defects were malaligned (63%) whereas one or more rims were mildly floppy in half of the study population.

3D imaging was performed in 83.3% (n = 25) patients in the study cohort. 3D rendering could not be done in the remaining 5 patients predominantly due to floppy rims and poor 2D image quality. The average maximum ASD diameter on 3D TEE was 19.04 ± 4.6 mm whereas the average minimum ASD diameter was 15.3 ± 4.3 mm (**Table 3**). The mean ASD area measured was 214.3 ± 104 mm^2 whereas mean ASD circumference was 50.4 ± 13.2 mm. The average circular index in the study group was 1.27 ± 0.17 and majority of defects were circular in shape (92%).

Table 2. Characteristics of atrial septal defect on 2-dimensional transesophageal echocardiography

Characteristics	Value (n = 30)
ASD maximum diameter (mm)	20.90 ± 4.87
ASD minimum diameter (mm)	17.1 ± 4.6
ASD rims (mm)	
PV rim	11.3 ± 2.9
Mitral rim	11.4 ± 2.2
Aortic rim	1.5 ± 2.3
Posterior rim	12 ± 2.7
IVC rim	13.5 ± 3.1
SVC rim	10.10 ± 1.99
CS rim	12.6 ± 4.3
Floppy rims	15 (50)
Malaligned defect	19 (63.3)

All values are expressed as mean ± standard deviation or number (%).
ASD: atrial septal defect, CS: coronary sinus, IVC: inferior vena cava, PV: pulmonary vein, SVC: superior vena cava.

Table 3. Characteristics of ASD on 3-dimensional transesophageal echocardiography

Characteristics	Value (n = 25)
ASD maximum diameter (mm)	19.04 ± 4.6
ASD minimum diameter (mm)	15.3 ± 4.3
ASD area (mm^2)	214.3 ± 104.0
ASD circumference (mm)	50.4 ± 13.2
Circular index	1.27 ± 0.17
Shape of defect	
Circular	23 (92)
Oval	2 (8)

All values are expressed as mean ± standard deviation or number (%).
ASD: atrial septal defect.

ASD device closure was done in all patients under fluoroscopy and TEE guidance. The average device size used was 25.8 ± 4.9 mm. The average surface area of device used was 549.9 ± 202.7 mm^2 whereas device circumference was 81 ± 15.4 mm. The mean procedural time in the study cohort was 25.4 ± 8.9 min. Three patients had arrhythmia during device closure. Two patients had atrial arrhythmias which subsided spontaneously at the end of the procedure whereas the 3rd patient had accelerated junctional rhythm during the procedure which spontaneously reverted to sinus rhythm. None of the patients had any access site complications or device related complications like cardiac tamponade or device embolization (**Table 4**). Post procedure, all patients had stable device position with no residual flow on TTE. The mean post-implant LVEF was 64.2 ± 5.3%. None of the patients had RV dysfunction on pre-discharge TTE.

Bland Altman analysis showed good agreement between 2D and 3D TEE for measured maximum and minimum ASD diameters (measurement bias 1.12 mm and 1.44 mm, respectively) (**Figure 3**). A significant difference was noted in 3D defect area between oval and circular septal defects, with oval defects having significantly larger 3D area on TEE than circular defects (270.5 ± 108.3 vs. 176.8

Table 4. Intra-procedural and post-procedural characteristics of study population

Characteristics	Value (n = 30)
Intra-procedural	
Device size (mm)	25.8 ± 4.9
Device area (mm^2)	549.9 ± 202.7
Device perimeter (mm)	81.0 ± 15.4
Procedural time (minute)	25.4 ± 8.9
Arrhythmia	3 (10)
Access site complications	0 (0)
Cardiac tamponade/device embolization	0 (0)
Post procedure	
Post implant LVEF (%)	64.2 ± 5.3
Residual flow	0 (0)
RV dysfunction	0 (0)

All values are mentioned as mean ± standard deviation or number (%).
LVEF: left ventricular ejection fraction, RV: right ventricle.

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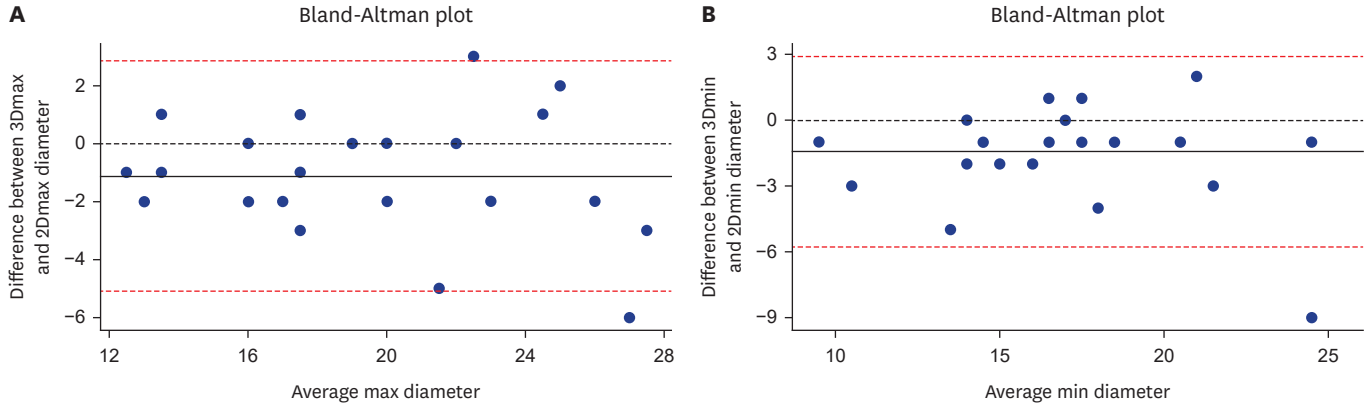

Figure 3. Bland Altman plot for agreement between measured ASD diameters on 2D and 3D transesophageal echocardiography. (A) Good agreement was noted between measured ASD maximum diameter. Measurement bias was 1.12 mm whereas upper and lower limits of agreement were 2.85 mm and −5.09 mm, respectively. (B) Good agreement was noted between measured ASD minimum diameter. Measurement bias was 1.44 mm whereas upper and lower limits of agreement were 2.9 mm and −5.78 mm, respectively.
ASD: atrial septal defect, 2D: 2-dimensional, 3D: 3-dimensional.

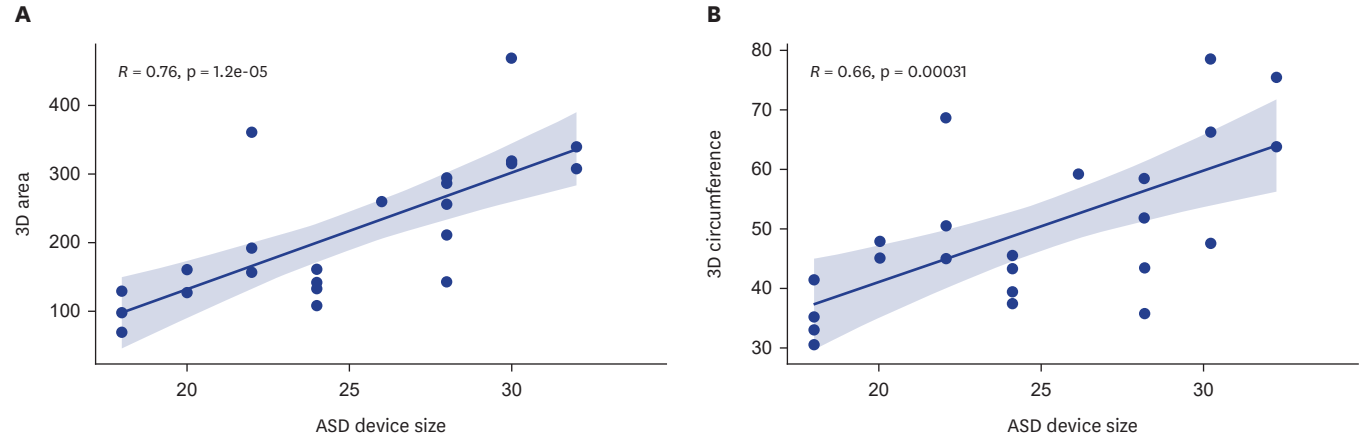

Figure 4. Correlation analysis between device size and 3D defect area (A) and 3D defect circumference (B).
ASD: atrial septal defect, 3D: 3-dimensional.

± 104.1 mm^2, respectively; p = 0.011). 3D defect area was similar between ASDs with aligned and malaligned rims (219.8 ± 104 vs. 206.1 ± 107.2 mm^2, respectively; p = 0.377) as well as between those with sturdy and floppy rims (193.4 ± 107.2 vs. 228.2 ± 104.1 mm^2, respectively; p = 0.211). The implanted device area was expectedly larger than the measured 3D defect area (512.6 ± 202.7 vs. 214.3 ± 104.1 mm^2, respectively; p < 0.0001).

There was a high degree of correlation noted between actual device size and 3D defect area (R = 0.756, p < 0.0001) as well as circumference (R = 0.662, p = 0.003) (**Figure 4**). Based on regression analysis, an equation was derived to predict device size on basis of 3D defect characteristics.

$$\text{Predicted Device Size} = 0.03199\ (\text{3D Defect Area}) + 0.01238\ (\text{3D Defect Circumference}) + 17.39961$$

Based on the above regression equation, predicted device size was calculated for each patient based on 3D defect area and circumference measured on TEE. There was no difference noted between predicted device size, calculated using 3D TEE measurements, and actual device size used in the procedure (24.88 ± 4.9 vs. 24.32 ± 3.2 mm, respectively; p = 0.31), which was based on 2D TEE measurements. No difference in accuracy of device sizing, using the predicted equation, was noted amongst both circular and oval defects.

Analysis for 10 randomly chosen patients were repeated one month after the initial analysis to look for intra-observer variability. No significant variability was noted in either 2D TEE parameters (ASD maximum diameter: intraclass correlation [ICC] = 0.88, ASD minimum diameter: ICC = 0.90) or 3D TEE parameters (ASD maximum diameter: ICC = 0.91, ASD minimum

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diameter: ICC = 0.90, ASD area = 0.89, ASD circumference = 0.93). A second observer repeated the measurements for all patients during the initial analysis. Statistical analysis showed excellent inter-observer reproducibility for 2D TEE parameters (ASD maximum diameter: ICC = 0.88, ASD minimum diameter = 0.86) and 3D TEE parameters (ASD maximum diameter: ICC = 0.89, ASD minimum diameter: ICC = 0.86, ASD area: ICC = 0.81, ASD circumference: ICC = 0.82).

DISCUSSION

The unique ability of 3D echocardiography to provide high resolution en-face images of ASD was utilized in the current study for assessment of defect characteristics. Thirty patients, majority of whom were females, were enrolled over a period of one year. All patients underwent 2D and 3D TEE prior to percutaneous device closure. Device sizing was based on 2D TEE measurements. A high degree of correlation was noted between ASD diameters measured on 2D and 3D TEE. 3D defect area and circumference also showed very good correlation with device size. The mean predicted device size, based on 3D TEE parameters, was similar to the mean device size actually used in the study population for percutaneous closure.

3D TEE is considered to have similar efficacy compared to 2D TEE for assessment of ASD characteristics. The current study demonstrated a high degree of correlation between ASD diameters measured on 2D and 3D TEE. Hascoet et al.[11] evaluated 30 ASD patients using 2D and 3D TEE and compared the ASD dimensions with balloon sizing diameters. There was a high correlation noted between 2D and 3D TEE for maximal ASD diameters in both round and oval ASD Similar findings were noted in another study performed by Seo et al.[12]

A very good correlation was noted between 3D defect area and circumference with device size in the current study. Evaluation of defect area and circumference on 3D TEE gives a better idea of ASD size as compared to diameters. Owing to good correlation noted between 2D and 3D TEE parameters, we tried to incorporate 3D defect parameters into an equation for predicting device size in the current study. The predicted device size matched well with the actual device size used in the study population, which was based on 2D TEE measurements. In our institution, 2D TEE based ASD sizing is considered as the gold standard for percutaneous closure, as we don't perform routine balloon sizing for ASD. This will help to incorporate the 3D characteristics of the defect when planning for device closure and help in better device sizing.

There are previous studies in literature which have used 3D TEE parameters to devise equations for predicting device size. Seo et al.[12] evaluated the relationship between balloon stretched ASD diameter and diameters measured using 2D and 3D TEE. They devised an equation as follows:

$$\text{Device Size} = (0.964 \times \text{3D Maximum Diameter}) - (2.622 \times \text{Circular Index}) + 7.084$$

This study did not take into account pertinent 3D TEE characteristics like defect area and defect circumference, which can provide a lot more information. The incorporation of circular index in this equation, which is an indicator of the shape of the defect, may not be as accurate as compared to direct measurement of defect area, which can be easily calculated on 3D TEE.

Hascoet and colleagues[11] also attempted to devise models for prediction of balloon stretched diameter using 3D ASD diameters They used 2 separate models, one including 3D diameter whereas other included area. The main problem of this study was use of 2 separate models which predicted the balloon stretched diameter, not the actual device size. Use of complicated models reduces the ease of use in routine clinical practice. Moreover, it has been demonstrated that routine balloon sizing is not required for ASD device closure and TEE alone can give superior results.[5][13] Similar to the current study, Roushdy et al.[14] aimed to devise a novel 3D echocardiographic method for transcatheter device closure. They used 2 separate models which predicted device size on basis of 3D area and 3D circumference of ASD.

$$\text{Device Size} = 10.8 + (3.95 \times \text{3D ASD Area})$$
$$\text{Device Size} = (3.85 \times \text{3D ASD Circumference}) - 1.02$$

Both these models were used to predict device size, which was not significantly different from the actual device size used for defect closure ($p = 0.94$). Although both models have been shown to have similar predictive value, there can be instances where the results may be discordant. Thus, it is easier to use a single model which has all the different variables incorporated together.

The equation derived by Seo et al.[12] was validated in a large study of 250 patients where initially predicted device size was compared with balloon stretched ASD diameters.[10] In the second tier of the study, 3D TEE derived data was used to calculated device size for percutaneous closure without any balloon sizing. The 99% procedural success was noted in patients who underwent device closure on basis of 3D TEE

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data alone. This shows the safety and accuracy of 3D TEE alone for device sizing during percutaneous ASD closure. In the authors opinion, balloon sizing of ASD should be avoided as it can lead to overestimation of device size and is fraught with complications.

In the current study, we used only TEE data for device sizing as per our institutional protocol. Balloon sizing for ASD has been abandoned at our centre due to its limitations, as mentioned before. We derived an equation in the current study for predicting device size using defect area and circumference measured on 3D TEE. To our knowledge, this is the first study to incorporate 3D area and circumference in a single equation for predicting device size. In our opinion, defect area and circumference are better and reliable predictors of defect size when compared to defect diameters. These parameters are expected to be more reliable in complex ASDs where measurement of diameters alone may not be suitable. Determining defect area can also help in reducing oversizing and complications associated with larger devices like mushrooming and cardiac erosion.[15] Custom made devices are currently unavailable for different ASD shapes. Evaluation of ASD shape using 3D TEE can help in development of custom devices which can reduce the risk of cardiac erosion. Further validation of this equation is needed in larger studies to determine efficacy and safety in percutaneous ASD closure. Once validated, this can serve as a simple and easy tool for device sizing during percutaneous ASD closure.

The current study has its inherent limitations. Optimal 2D images are required to generate high resolution 3D images, which may not be possible in each case. Secondly, proper optimization of 3D image plays a big role in correct assessment of defect. Improper gain settings, presence of artifacts like stitch artifacts can hamper proper interpretation of defect characteristics. Thirdly, majority of patients in the study had circular ASD. Application of the above equation to patients with oval ASD needs to be tested in another cohort. Lastly, the device prediction equation generated in the study needs to be validated in a large cohort of patients. Only after proper validation can the model be used for routine patients.

Device sizing based on 3D TEE parameters is equally effective as compared to 2D TEE based sizing for transcatheter ASD closure. Routine use of 3D TEE alone for device sizing should be encouraged and emphasized during transcatheter ASD closure.

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Conflict of Interest

The authors have no financial conflicts of interest.

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Conceptualization: Mani A, Harikrishnan S, Sasidharan B, Ganapathi S, Valaparambil AK; Data curation: Mani A; Formal analysis: Mani A, Harikrishnan S, Ganapathi S; Investigation: Mani A, Sasidharan B; Methodology: Harikrishnan S, Sasidharan B, Ganapathi S; Validation: Mani A; Writing - original draft: Mani A; Writing - review & editing: Mani A, Harikrishnan S, Sasidharan B, Ganapathi S, Valaparambil AK.

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