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Can 3-Dimensional Transesophageal Echocardiography Replace Balloon Sizing for Transcatheter Atrial Septal Defect Closure? Insights from a Prospective Registry

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Abstract

Background: Achieving optimal results in transcatheter closure of Atrial Septal Defect (ASD) necessitates the careful selection of device size. Balloon sizing is traditionally used for sizing, but it may stretch the ASD and cause trauma. Three-dimensional (3D) Transesophageal Echocardiography (TEE) could potentially prove similarly accurate for sizing, while reducing the risk of complications.

Methods: We prospectively recruited a cohort of 30 patients with an indication to transcatheter closure of ASD. Intraprocedural TEE was utilized to create a 3D reconstruction of the ASD, aiding in the determination of the appropriate device size. Following this, Balloon Sizing (BS) was performed to confirm device selection. Then, ASD occlusion was performed using Amplatzer Septal Occluder (Abbott Vascular, Santa Clara, CA, USA). Descriptive, inferential and predictive analyses were performed to appraise the association between 3DTEE, BS and device dimensions.

Results: Out of the 30 included patients, 24 (80.0%) presented an elliptical ASD. Diameter was underestimated by 3DTEE by -0.20 (95% confidence interval; -0.09; 0.09) in comparison to BS, and by -0.97 (-1.73; -0.27) in comparison to device diameter. Yet, linear regression analysis using an appropriate equation enabled to predict BS diameter from 3DTEE diameter with great accuracy (R^2=94% using y=-0.04+1.01*3DTEE). The only other predictor of BS diameter was a history of ischemic events (albeit with only 1% increase in R^2). Cross-validation using 10,000 samples

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and N=20:10 splitting confirmed the satisfactory predicting accuracy of 3DTEE for BS diameter (R^2=93.0% [92.6%; 93.4%]). Similar results were obtained when aiming to predict device size using 3DTEE diameter (R^2=93.9% [93.5%-94.2%]).

Conclusion: In patients undergoing transcatheter ASD occlusion, 3DTEE provides accurate imaging details and can be used to precisely measure the size of the ASD, thus guiding device choice, obviating the need to routine BS.

Introduction

Atrial Septal Defects (ASD) are among the most common congenital heart anomalies, with the ostium secundum subtype accounting for approximately 75% of all cases [1]. This specific variant is uniquely suited for percutaneous transcatheter closure, provided that patients meet the necessary anatomical and clinical criteria [2,3]. Successful closure of an ASD has been associated with long-term improvements in cardiac function, enhanced exercise capacity, and better cardiopulmonary performance, even in asymptomatic individuals [4]. The key to optimizing procedural outcomes lies in the accurate selection of device size, which traditionally relies on Transesophageal Echocardiography (TEE) and Balloon Sizing (BS). However, ASD dimensions fluctuate due to TEE imaging angles and cardiac cycle variations, necessitating meticulous image acquisition by experienced operators to ensure proper defect assessment [5,6].

Despite its advantages, percutaneous ASD closure carries inherent risks, particularly device embolization and structural erosion, which can lead to serious complications. Notably, oversizing the closure device—often a result of balloon sizing-induced defect stretching—has been implicated in erosion of the atrial wall and adjacent structures such as the aortic root [7,8]. These concerns underscore the need for a more precise, minimally invasive sizing strategy that avoids artificial distortion of the defect while still ensuring appropriate device selection. Three-dimensional TEE (3DTEE) has emerged as a promising alternative, offering high-resolution spatial imaging that allows for direct visualization of ASD morphology and rim sufficiency without overstretching the septal tissue.

This study aims to evaluate whether 3DTEE-derived ASD measurements can accurately predict the diameter obtained via balloon sizing, thus eliminating the need for BS during device selection. By conducting a comparative analysis, we seek to determine if 3D TEE alone can provide the necessary precision for guiding transcatheter ASD closure without compromising procedural success. If validated, this approach could potentially reduce procedural risks, enhance patient safety, and streamline the decision-making process for percutaneous ASD interventions.

Methods

Consecutive patients with an indication to percutaneous ASD closure were recruited at participating centers (Istituto Clinico San Rocco, Ome, and Clinica Humanitas Gavazzeni, Bergamo). Notably, patient selection was based on the presence of hemodynamically significant left-to-right shunting, as demonstrated Qp/Qs ratio >1.5, as assessed by Transthoracic Echocardiography (TEE) [9].

Before the index admission, 2-dimensional echocardiography (2DTEE) was performed in all patients, followed by 3DTEE, which was repeated intraprocedurally [10]. All such imaging procedures were performed with an Omniplane-EPIQ 7C probe and a EPIQ 7C workstation (Philips Medical Systems, Milan, Italy). In particular, ASD diameters were measured using several angles (0-180°), including a 4-chamber view (0°), a short-axis one (30–60°) and a long-axis one (90–100°). Then, a real-time 3D box was applied, enabling 3D imaging of the ASD, including "en face" imaging, and volume rotation, as well as right and left sides. We considered elliptical those ASD with a difference between maximum and minimum diameter >4.0 mm, measured during the end-systolic phase of the cardiac cycle. Notably, all 3DTEE measurements were conducted offline by the same experience operator to ensure reproducibility (AML).

After 3DTEE measurements of ASD dimensions, BS was performed using a progressively (0.5 mL increments) inflated balloon (Meditech Equalizer, Boston Scientific, Natick, MA, USA) to determine the stretched ASD diameter [11]. In particular, the balloon was inflated until left-to-right shunting ceased, and the diameter at that point was recorded, using the pullthrough technique. Color Doppler imaging was used to confirm complete occlusion of the ASD during balloon inflation, and balloon diameter was measured using both TEE and balloon inflation volume.

All patients then underwent percutaneous ASD closure with Amplatzer Septal Occluder (Abbott Vascular, Santa Clara, CA, USA) using the most appropriately sized device [12]. Notably, the size was based on both 3DTEE and BS measurements, with the increment in size of 2/3 mm in case of septum softness. Patients received aspirin and clopidogrel for thrombotic prophylaxis as per standard of care [13].

Descriptive analysis was based on computing mean, standard deviation, minimum and maximum for continuous variables, and count (%) for categorical variables. We then computed differences between different measurements, providing again mean, standard deviation, minimum and maximum, as well as 95% confidence intervals (95% CI) based on 1000 bootstrap samples, using the percentile method. Then, we conducted a series of linear regression analyses were performed to explore the association between maximum diameter at 3DTEE and diameter at BS, as well as the eventual device diameter. Such analyses provided R2 values, as well as actual constant, and point estimate of effect for the independent variable. Finally, repeated 10,000-fold cross-validation procedures were performed to assess the predictive accuracy of analogous linear regression models using maximum diameter at 3DTEE as the independent variable and first diameter at BS and then device diameter as the dependent variable. In each iteration, 20 cases were randomly selected as the training set, and the remaining 10 cases were used for validation. Model performance was evaluated using Mean Squared Error (MSE), mean Absolute Error (MAE), and R^2, with accompanying 95% CI. Results were illustrated with scatterplots, Bland-Altman plots, fit plots, and histograms of MSE, MAE and R2.

Computations were performed with Stata 18 (StataCorp, College Station, TX, USA), and R 4.4.1 (R 4.4.1 (R Project for Statistical Computing, Vienna, Austria). The study was approved by the competed ethics committees and all patients provided written informed consent.

Results

Patient characteristics are provided in Table 1. In particular, age 47.6±15.7 years, and we included 19 (63.3%) women.

Significant differences were found in diameters measured with 3DTEE and BS, as well as device diameter (Table 2). In particular, diameter was underestimated by 3DTEE by -0.20 (95% confidence interval; -0.09; 0.09) in comparison to BS, and by -0.97 (-1.73; -0.27) in comparison to device diameter. Irrespectively, there was strong association between 3DTEE, BS and device diameters (Figure 1 & Figure 2). Accordingly, linear regression analysis using an appropriate equation enabled to predict BS diameter from 3DTEE diameter with great accuracy (R^2=94% using y=-0.04+1.01*3DTEE) (Figure 3; Figure 1S & Figure 2S). Similar findings, were obtained when aiming at predicting device diameter (R^2=95% using y=-0.64+1.10*3DTEE) (Figure 3S & Figure 4S). The only other predictor of BS diameter was a history of ischemic events (albeit with only 1% increase in R^2), with a similarly weak impact for predicting device diameter (1% increase in R^2) (Figure 5S & Figure 6S).

Cross-validation using 10,000 samples and N=20:10 splitting confirmed the satisfactory predicting accuracy of 3DTEE for BS diameter (MAE=2.51 [2.42-2.59], MSE=1.02 [1.00-1.04], R^2=93.0% [92.6%; 93.4%]) (Figure 7S & Figure 8S & Figure 9S). Similar results were obtained when aiming to predict device size using 3DTEE diameter (MAE=2.65 [2.59-2.72], MSE=1.24 [1.23-1.26], R^2=93.9% [93.5%; 94.2%]) (Figure 10S & Figure 11S & Figure 12S).

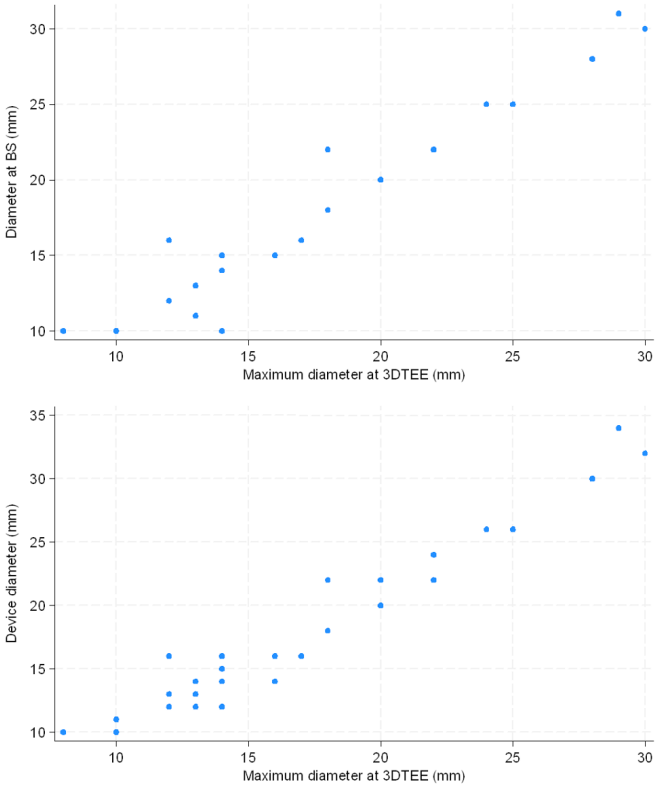

Figure 1: Scatterplots of maximum diameter at 3-Dimensional Transesophageal Echocardiography (3DTEE) and diameter at Balloon Sizing (BS) (top panel) and device diameter (bottom panel).

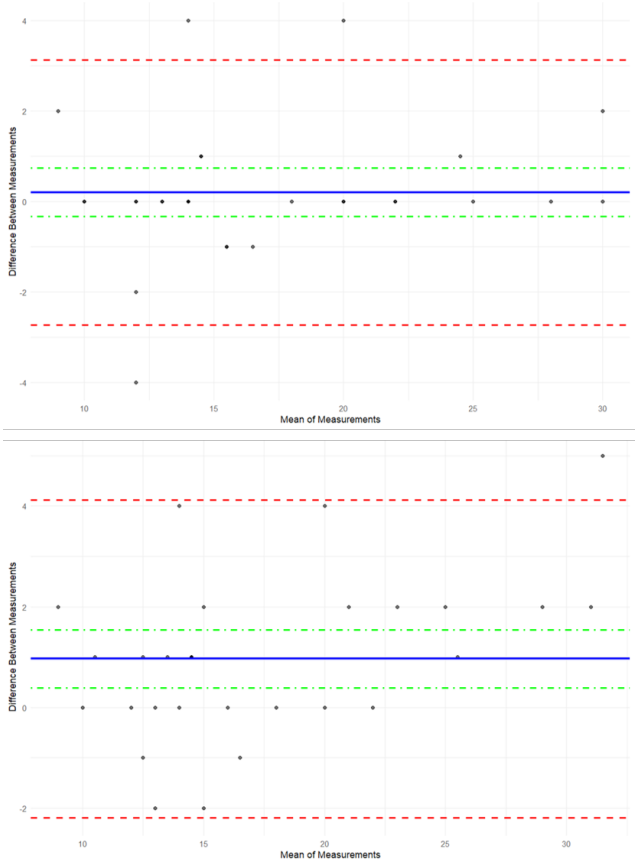

Figure 2: Bland-Altman plot for maximum diameter at 3-dimensional transesophageal echocardiography and diameter at balloon sizing (bottom panel) and device diameter (bottom panel). Notably, green lines represent the 95% confidence interval of bias, and red lines represent the limits of agreement.

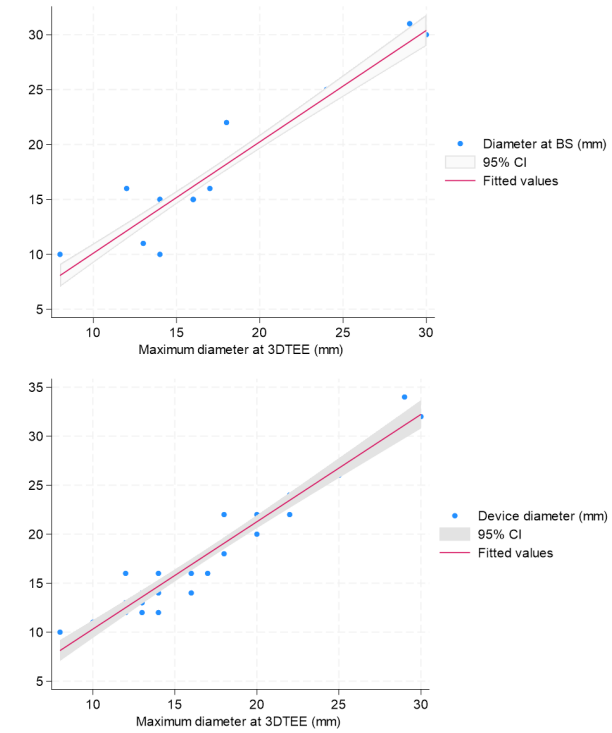

Figure 3: Regression plot with maximum diameter at 3-Dimensional Transesophageal Echocardiography (3DTEE) as independent variable and diameter at Balloon Size (BS) (top panel) and device diameter (bottom panel) as dependent variable.

Table 1: Descriptive statistics. SD: Standard Deviation.

Patients (N=30)	Count or mean	% or SD	Minimum	Maximum
Age (years)	47.6	15.7	18	68
Female sex	19	63.3%	-	-
History of transient ischemic attack or stroke	17	56.7%	-	-
Ischemic lesions at cerebral magnetic resonance	16	53.3%	-	-
Right ventricular overload	6	20.0%	-	-
Three-dimensional transesophageal echocardiography				
Intraprocedural	3	10.0%		
Maximum diameter (mm)	16.87	5.82	8	30
Minimum diameter (mm)	14.37	5.35	7	26
Maximum – minimum diameter (mm)	2.50	1.92	0	6
Eccentricity index*	0.17	0.13	0	0.48
Area (cm^2)	2.13	1.56	0.50	5.71
Balloon sizing				
Diameter (mm)	17.07	6.09	10	31
Area (cm2)	2.57	1.89	0.79	7.55
Device				
Size				
10	2	6.7%	-	-
11	1	3.3%	-	-
12	3	10.0%	-	-
13	2	6.7%	-	-
14	3	10.0%	-	-
15	4	13.3%	-	-
16	4	13.3%	-	-
18	1	3.3%	-	-
20	1	3.3%	-	-
22	3	10.0%	-	-
24	1	3.3%	-	-
26	2	6.7%	-	-
30	1	3.3%	-	-
32	1	3.3%	-	-
34	1	3.3%	-	-
Diameter (mm)	17,83	6.56	10	34
Area (cm^2)	2.82	2.19	0.79	9.09

*Difference between maximum and minimum diameter divided by their average

Table 2: Inferential analysis. 3DTEE: 3-dimensional transesophageal echocardiography; BS: balloon sizing; CI: confidence interval; SD: standard deviation.

Feature	Mean±SD	Minimum; maximum	95% CI*
3DTEE maximum diameter – BS diameter (mm)	-0.2±1.50	-4; 4	-0.09; 0.09
3DTEE minimum diameter – BS diameter (mm)	-2.7±2.1	-8; 1	-3.59; -1.41
3DTEE maximum diameter – device diameter (mm)	-0.97±1.61	-5; 2	-1.73; -0.27
3DTEE minimum diameter – device diameter (mm)	-3.47±2.40	-9; 0	-4.12; -1.88
BS diameter – device diameter (mm)	-0.77±0.94	-3; 1	-1.87; -0.13
3DTEE area – BS area (cm2)	-0.44±0.52	-1.85; 0.31	-0.45; -0.18
3DTEE area – device area (cm2)	-0.70±0.78	-3.39; 0.09	-0.59; -0.29
BS area – device area (cm2)	-0.25±0.38	-1.53; 0.23	-0.35; 0.00

*Based on 1000-sample bootstrap samples.

Table 3: Linear regression analysis.

Dependent variable	Independent variable(s)	Point estimate (95%CI), p value	Constant	R2
Diameter at balloon sizing	3DTEE minimum diameter	1.01 (0.92; 1.11), p<0.001	-0.04	0.94
	Prior TIA/stroke	-7.89 (-11.44; -4.35), p<0.001	21.54	0.43
	3DTEE minimum diameter Prior TIA/sroke	0.94 (0.82; 1.06), p<0.001 -1.41 (-2.75; -0.06), p=0.041	1.99	0.95
Device diameter	3DTEE minimum diameter	1.10 (1.00; 1.20), p<0.001	-0.64	0.95
	Prior TIA/stroke	-8.58 (-12.36; -4.79)	22.69	0.44
	3DTEE minimum diameter Prior TIA/sroke	1.01 (0.90; 1.13), p<0.001 -1.60 (-2.93; -0.27), p=0.020	1.65	0.96

*No other variable was significantly associated with BS diameter.

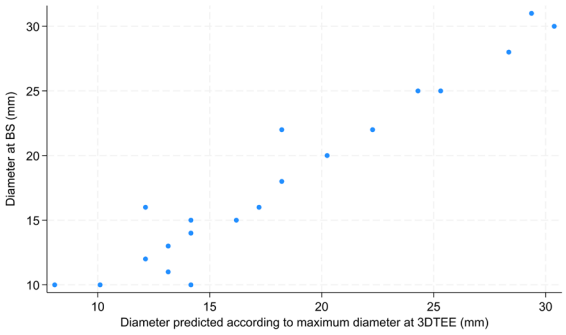

Figure S1: Scatterplot of diameter predicted according to maximum diameter at 3-dimensional transesophageal echocardiography (3DTEE) and diameter at Balloon Sizing (BS).

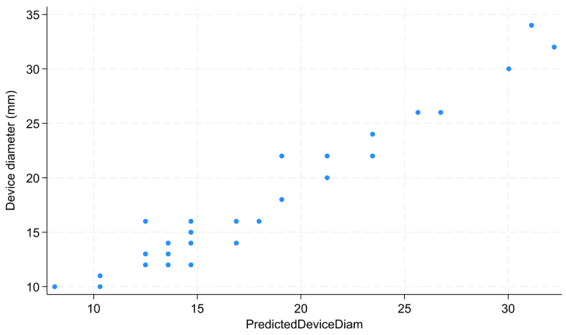

Figure S2: Scatterplot of diameter predicted according to maximum diameter at 3-Dimensional Transesophageal Echocardiography (3DTEE) and device diameter.

Figure S3: Bland-Altman plot for diameter predicted according to maximum diameter at 3-dimensional transesophageal echocardiography and diameter at balloon (green lines represent the 95% confidence interval of bias, and red lines represent the limits of agreement).

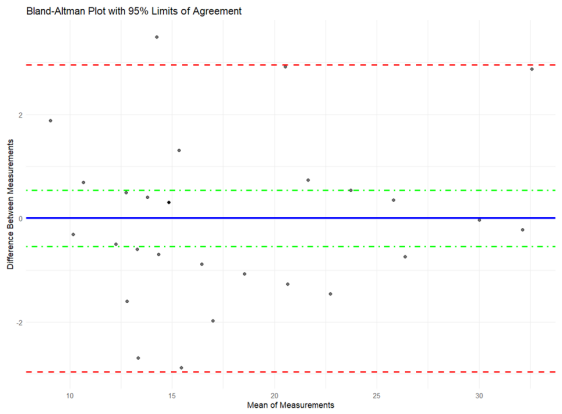

Figure S4: Bland-Altman plot for diameter predicted according to maximum diameter at 3-dimensional transesophageal echocardiography and device diameter (green lines represent the 95% confidence interval of bias, and red lines represent the limits of agreement).

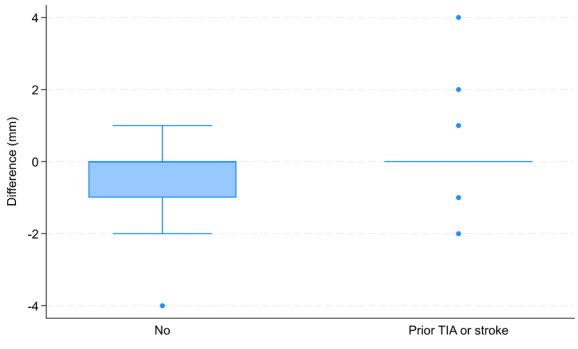

Figure S5: Impact of history of prior transient ischemic attack or stroke on the difference between maximum diameter at 3DTEE and diameter at balloon sizing (p=0.067 at t test).

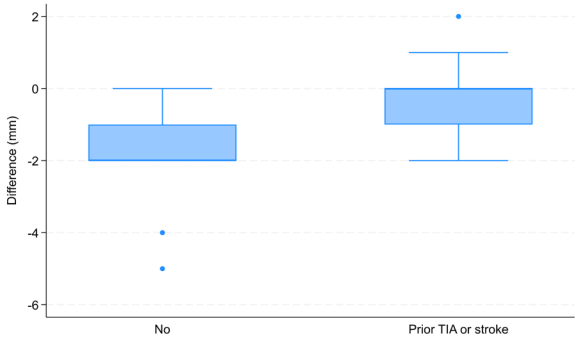

Figure S6: Impact of history of prior transient ischemic attack or stroke on the difference between maximum diameter at 3DTEE and device diameter (p=0.003 at t test).

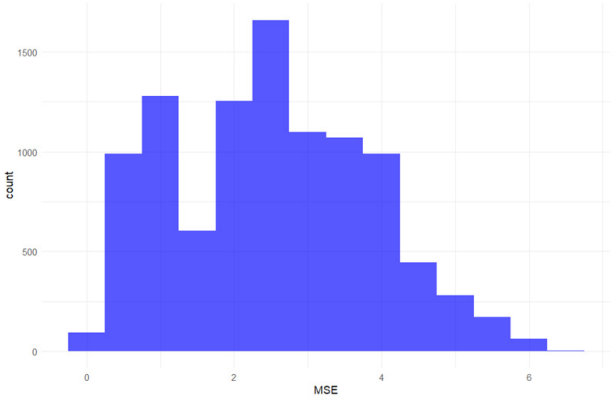

Figure S7: Histogram of Mean Squared Error (MSE) values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and diameter at balloon sizing as the dependent variable.

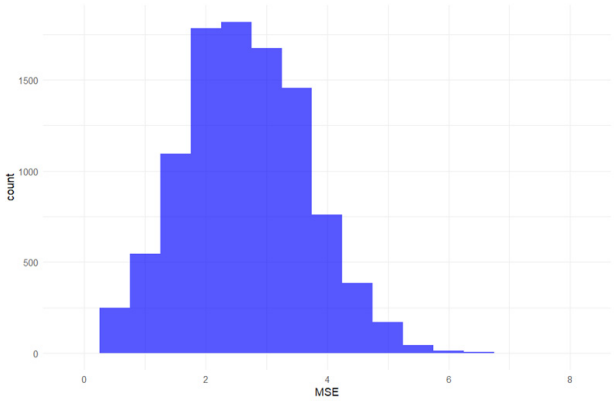

Figure S10: Histogram of Mean Squared Error (MSE) values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and device diameter as the dependent variable.

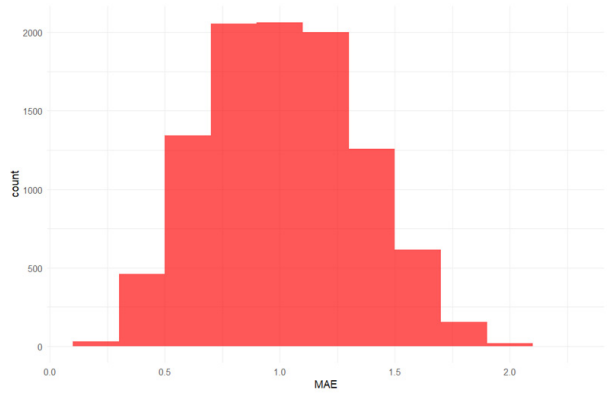

Figure S8: Histogram of Mean Absolute Error (MAE) values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and diameter at balloon sizing as the dependent variable.

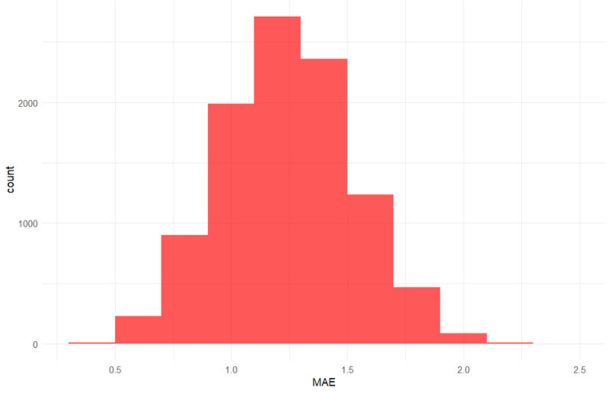

Figure S11: Histogram of Mean Absolute Error (MAE) values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and device diameter as the dependent variable.

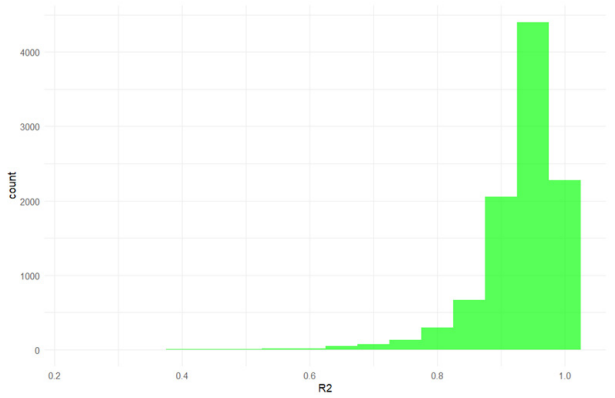

Figure S9: Histogram of R^2 values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and diameter at balloon sizing as the dependent variable.

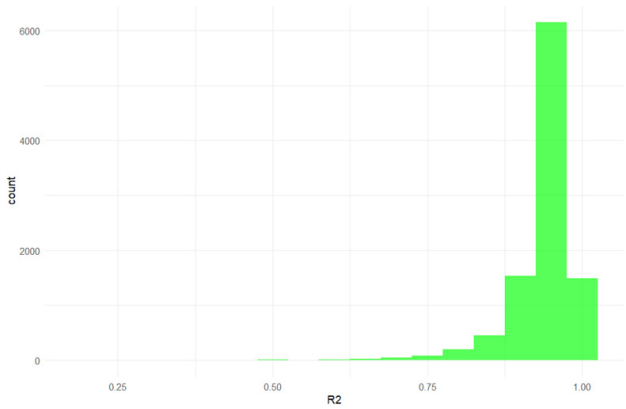

Figure S12: Histogram of R^2 values for the 10,000-fold cross-validation procedures assessing the predictive accuracy of analogous linear regression models using maximum diameter at 3-dimensional transesophageal echocardiography as the independent variable and device diameter as the dependent variable.

Discussion

Transcatheter closure of ASD requires accurate appraisal of ASD morphology and size, in order to maximize the chances of effective and complete closure and minimize the risk of device-related complications (eg embolization or erosion). (1-4) We hereby demonstrate that 3DTEE is a highly accurate tool for assessing ASD dimensions and guiding transcatheter closure. Our findings indicate that 3DTEE measurements closely approximate those obtained via BS, supporting its reliability for procedural planning. Notably, 3DTEE effectively captured ASD morphology and provided measurements that aligned well with final device selection. The strong association between 3DTEE, BS, and implanted device dimensions suggests that routine BS may not be necessary in most cases, particularly when high-quality 3D imaging is available. By reducing procedural complexity and avoiding potential overstretching of the defect, 3DTEE offers a safer and more efficient approach to ASD closure without compromising accuracy.

Several previous studies have explored the comparative accuracy of 3DTEE and BS for ASD closure, with findings largely consistent with our results [13-16]. Hascoët et al. reported that 3DTEE measurements tend to be slightly smaller than BS-derived diameters but remain highly correlated, supporting its use as a reliable alternative for defect assessment [13]. Similarly, Jang et al. demonstrated that 3DTEE can accurately guide device selection without routine BS, reducing procedural time and potential risks associated with excessive septal stretching [14]. Narimani et al. further confirmed the strong concordance between 3DTEE and BS, particularly when assessing ASD area and perimeter, reinforcing the role of 3D imaging in procedural planning [15]. Our study aligns with these findings, emphasizing the predictive strength of 3DTEE for both BS diameter and final device size. However, unlike earlier reports, we incorporated rigorous cross-validation techniques to confirm the robustness of 3DTEE-based predictions, strengthening the argument for its routine use. While BS remains valuable in select cases, particularly for complex or highly compliant defects, our results contribute to a growing body of evidence suggesting that 3DTEE alone is sufficient for accurate ASD sizing in most patients.

Future research should focus on validating the use of 3DTEE across larger, more diverse patient populations to confirm its generalizability in ASD closure. Prospective multicenter trials comparing outcomes between patients undergoing device selection based solely on 3DTEE versus those incorporating BS could provide further clarity on best practices. Additionally, exploring the role of artificial intelligence and machine learning in automating 3DTEE-based measurements may enhance precision and reduce inter-operator variability. Studies assessing long-term clinical outcomes, including residual shunting, embolization risk, and structural complications, are also warranted to ensure the durability of 3DTEE-guided closure. Further refinement of standardized imaging protocols and operator training could enhance reproducibility and facilitate wider adoption of 3DTEE as a primary sizing modality. Ultimately, integrating 3DTEE into routine clinical practice has the potential to streamline ASD closure procedures while minimizing procedural risks and improving patient safety.

This study has several limitations that should be acknowledged. The relatively small sample size may limit the generalizability of our findings, particularly for patients with complex or atypical ASD. Additionally, while we employed rigorous cross-validation techniques, our analysis remains observational, and randomized comparisons between 3DTEE and BS are needed to confirm causality. Finally, operator dependency in image acquisition and measurement interpretation could introduce variability, highlighting the need for standardized protocols to optimize the accuracy and reproducibility of 3DTEE-guided ASD sizing.

In conclusion, in patients undergoing transcatheter ASD occlusion, 3DTEE provides accurate imaging details and can be used to precisely measure the size of the ASD, thus guiding device choice, obviating the need to routine BS.

Author Statements

Disclosure: Alberto M. Lanzone has consulted for Abbott Vascular. Giuseppe Biondi-Zoccai has consulted, lectured and/or served as advisory board member for Abiomed, Advanced Nanotherapies, Aleph, Amarin, AstraZeneca, Balmed, Cardionovum, Cepton, Crannmedical, Endocore Lab, Eukon, Guidotti, Innovheart, Meditrial, Menarini, Microport, Opsens Medical, Synthesa, Terumo, and Translumina, outside the present work. All other authors report no conflict of interest.

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