Original Article

Comparison Between 2D Transthoracic Echocardiography, Transesophageal Echocardiography, and Balloon Sizing Methods for Device Size Selection in Pediatric Patients Undergoing Transcatheter Closure of Atrial Septal Defects

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ABSTRACT

Background: Transcatheter closure of atrial septal defects (ASDs) is considered an alternative technique to surgery, and appropriate device size selection is essential to an effective procedure. We aimed to compare 2D transesophageal echocardiography (TEE), transthoracic echocardiography (TTE), and balloon sizing methods for device size selection in pediatric patients undergoing ASD transcatheter closure and to establish an accurate and simple procedure for device size selection.

Methods: This cross-sectional study was performed on pediatric patients for 8 months in Tehran, Iran. Device size was identified by balloon sizing, 2D TEE, and TTE.

Results: This study enrolled 39 children (64.1% female, average age= 7.1±3.1 y) who underwent successful ASD transcatheter closure. The mean defect size by balloon-stretched diameter measurement was significantly greater than the ASD size measured by 2D TEE and TTE. There was a strong, highly significant positive correlation (P<0.001) between the device waist size and different ASD diameters measured by 2D TEE, TTE, and balloon sizing. A good linear association was found between the ASD size measured by device waist size and 2D TEE (device waist size= 0.99×TEE-derived defect size+1.678; P<0.001) as well as TTE (device waist size= 1.01×TTE-derived defect size+1.17; P<0.001), respectively.

Conclusions: In this study, TEE and TTE-derived defect sizes were significantly associated with the device waist size. Additionally, the equations generated herein may provide a reliable and good prediction for appropriate device size. ***(Iranian Heart Journal 2022; 23(1): 74-84)***

KEYWORDS: ASD, TTE, TEE, Children, Iran

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Congenital heart diseases (CHDs) refer to multifarious abnormalities that have a major impact on the function or structure of the heart; they are caused by embryonic defects and constitute the important causes of early childhood mortality and disability. [1,2] CHDs are the most common birth defects that occur in 4/1000 to 50/1000 cases of live births per annum. [3] The findings of a recent systematic review showed a wide range of CHD prevalence, from 4/1000 to 16/1000 across geographical distributions in different parts of Iran. [4]

Atrial septal defects (ASD) comprise a common type of CHDs, and they are defined as an opening in the atrial septum. [5] Such defects account for nearly 10% of CHDs, over 1/1000 live births. [5] The ostium secundum type (ASD-II) is the most prevalent, representing approximately 85% of all ASDs with an incidence of 3.78/10000 live births. [6] Nevertheless, increases in ASD prevalence are due to the enhanced diagnostic echocardiography. [7]

Small ASDs usually do not have any symptoms throughout infancy and early childhood, especially those of the secundum type and normal pulmonary vascular resistance. [8] Most people may live their entire lives with small ASDs and remain unaware of any defects often until later in life. [8] Nonetheless, children with medium or large-sized defects may often have poor physical growth, recurrent chest infections, and failure to thrive. [8]

Transcatheter closure of ASDs has been extensively applied as an alternative technique to surgical closure. Appropriate device size selection is considered the cornerstone of effective ASD device closure and can prevent complications due to inappropriate devices. [6] The Amplatzer Septal Occluder is the most common device for this procedure on the strength of its low occurrence of complications and high success rates. [9]

Balloon sizing to measure ASD size and define device size for ASD transcatheter closure is regarded as the gold standard and an integral part of the procedure with the Amplatzer Septal Occluder. [10] Nevertheless, balloon sizing not only lengthens the fluoroscopy and procedure times but also causes complications. [11] The stretched-balloon diameter (SBD) measurement of ASDs throughout catheterization is a common method. [12] Device size is commonly either equal to the SBD of the defect or 2 mm larger than its measurement, bearing in mind that an accurate ASD measurement is crucial. [12,13] Be that as it may, balloon sizing has some disadvantages that may cause defect enlargement or low blood pressure; additionally, bradycardia may occur during the long inflation of the balloon. [10, 14] Further, its measurements may be inaccurate and may have a low, albeit predictable, risk of injury to the interatrial septum. [15]

Two-dimensional transesophageal echocardiography (2D TEE) is the gold standard for all transcatheter occlusion techniques and a reliable imaging procedure for the real-time monitoring of SBD measurements. [16] Not only can 2D TEE provide useful data regarding the position, size, and number of defects but also it can evaluate the surrounding structures. [17] It is also effective in guiding device deployment in proper opening and positioning. [17,18]

Two-dimensional transthoracic echocardiography (2D TTE) is utilized to assess patients with CHDs. It is noninvasive and readily available and needs less cooperation from the patient, while it does not rely on harmful radiation. [19,20]

Transcatheter device closure of ASDs has been increasingly applied through the use of several imaging techniques without balloon sizing. [21] Thus, the present study aimed to

compare 2D TTE, TEE, and balloon sizing methods for device size selection in pediatric patients undergoing ASD transcatheter closure and to establish a precise and simple procedure for device size selection.

METHODS

This cross-sectional study, conducted between April 2019 and November 2019, recruited 44 pediatric patients with ASD-II admitted to the catheterization laboratory for elective transcatheter device closure of ASD in Rajaie Cardiovascular Medical and Research Center, Tehran, Iran. Convenience sampling was used to recruit patients. Thirty-nine pediatric patients fulfilled the initial inclusion criteria and were enrolled in this study.

Patients were excluded from the study based on the following criteria: Eisenmenger syndrome, primum ASDs, ASD-II with inappropriate anatomy for closure caused by floppy or defective rims detected by echocardiography, associated congenital defects requiring surgical intervention, maximum ASD diameters greater than 30 mm, ASD rims equal to or less than 5 mm (except the anterosuperior rim), and fenestrated septa with multiple defects or interatrial septal aneurysms. The Ethics Committee of Iran University of Medical Sciences (IUMS) approved the study protocol (IR.IUMS.FMD.REC.1398.500). The parents or guardians of children provided written informed consent before study commencement. Clinical and sociodemographic data of the patients were collected. Defect size was measured via 3 techniques: 2D TEE, TTE, and balloon sizing under TEE guidance during catheterization.

2D TTE

TTE was performed with a Philips iE33 Machine (Philips Medical Systems, Andover, MA) with phased-array transducers of various frequencies based on the patient's weight, age, and body build for the entire study population. The patients were examined by an experienced operator following a standard echocardiographic protocol. In addition, 2D, color flow Doppler, and M-mode from all standard echocardiographic views (viz, parasternal, apical, suprasternal, and subcostal) were drawn upon via sequential analysis to identify any related defects. Color flow mapping (CFM) and 2D were applied to assess the diameter and position of the ASD in the 4 views. [22] The maximum TTE diameter of the ASD was the maximum diameter of the mentioned views.

2D TEE

On the day of the procedure, 2D TEE was applied with a multiplane 7.0 MHz TEE probe (Vivid 3, GE) inside the catheterization laboratory. The rims surrounding the defect were assessed. CFM and 2D were applied to assess the diameter and position of the ASD in the 4 views of parasternal, apical, suprasternal, and subcostal. The largest TEE diameter of the ASD was considered the maximum diameter assessed between 2 stable rims in the 4 views. The fact that 2D TEE provides superior views of ASDs may help determine the precise size of the defect.

Transcatheter Closure of ASDs

The procedures were performed under general anesthesia. The Seldinger method was used to recognize right femoral vein access. A multipurpose catheter was positioned into the upper left pulmonary vein when crossing the defect, and a 0.35/260 stiff guidewire was placed in that vein. SBD was carried out in the defects and was assessed by cine recording and TEE. Then, the delivery sheath was advanced through the wire. The standard method was

applied, and the device was advanced into the tip of the sheath.

For the second time throughout device implantation and balloon sizing, TEE was applied. This SBD was considered to be the largest balloon passing across the ASD in catheterization. Device size was selected 1 to 4 mm larger than the maximum diameter assessed by TEE depending on whether or not balloon sizing was applied and the stability of the ASD rims. During catheterization, a proper device size was predicted by the Amplatzer SBD (PTS-X, NuMED Inc). TEE was performed to confirm that the balloon was perpendicular to the septum throughout the balloon sizing of the ASD. After the deployment of the device from the cable, a final TEE inspection was performed to establish any residual shunting and the position of the device.

Statistical Analysis

The Statistical Package for Social Sciences, version 25 (SPSS Inc, Illinois, USA), was applied for data analysis. The normality of data was evaluated by using the Shapiro–Wilk test. Descriptive data were explained as the median (the interquartile range), the percentage, and the mean (the standard deviation).

The defect sizing methods (continuous variables) were compared by using the paired *t* test. The association and correlation between the final device waist size and the maximal defect size of the ASD measured by 2D TTE, TEE, and balloon sizing were assessed through the linear regression analysis and the Pearson correlation test, respectively. For the prediction of optimal device size for the closure of ASDs based on different methods, several equations were generated by linear regression analysis. A *P*-value of less than 0.05 was considered statistically significant. The Bland–Altman plot was implemented to assess the agreement between the methods of defect measurement.

RESULTS

The study comprised 39 children who underwent successful ASD device closure. The procedural success was defined as appropriate device position, hospital discharge on the second postprocedural day, and successful device implantation without complications. The study population consisted of 39 patients: 25 female (64.1%) and 14 male (35.9%) patients. The average age of the participants was 7.1±3.1 years (range= 2–14 y), and their mean weight was 24.2±11.1 kg. The average TTE- and TEE-derived maximum defect diameter was significantly lower than the mean waist size of the implanted device (11.72±4.91 mm vs 13.39±5.10 mm; $P<0.001$) and (12.05±4.95 mm vs 13.39±5.10 mm; $P<0.001$). The mean maximum defect size by SBD was significantly higher than the waist size of the implanted device (14.57±4.52 mm vs 13.39±5.10 mm; $P<0.001$). The average ASD size measurements by the different methods are displayed in Table 1.

There were strong and highly significant positive correlations ($P<0.001$) between device waist size and ASD diameters assessed by 2D TEE ($r=0.935$), CFM TEE ($r=0.939$), 2D TTE ($r=0.976$), CFM TTE ($r=0.946$), and SBD ($r=0.943$).

The linear regression analysis of the measurements highlighted a significant association between the final device waist size and the parameters measured by TEE, the TTE-derived defect size, and SBD ($P<0.001$). In addition, several formulas were generated that could be applicable to the estimation of device size in ASD size measurement procedures. Moreover, the Bland–Altman plot displayed agreement between the 3 methods and device waist size (Fig. 1–5).

Device waist size = (2D TEE-derived defect size × 0.99) + 1.678 (r=0.962)
Device waist size= (CFM TEE-derived defect size × 0.95) + 1.08 (r=0.939)
Device waist size = (2D TTE-derived defect size × 1.01) + 1.17 (r=0.983)
Device waist size = (CFM TTE-derived defect size × 1.07) − 0.12 (r=0.946)
Device waist size = (balloon diameter of the defect × 1.06) − 2.12 (r=0.943)

Table 1. ASD size measured by TEE, TTE, balloon sizing, and device

Measurement Methods	Maximum ASD Size (mm)	
	Mean ± SD	Range
2D TEE	11.72±4.91	4.63-24
CFM TEE	12.87±5.01	6-24.6
2D TTE	12.05±4.95	4.5-23.5
CFM TTE	12.55±4.48	5-22
SBD	14.57±4.52	8-25.5
Device size	15.85±5.53	7.50-27
Device waist size	13.39±5.10	4-24

ASD, Atrial septal defect; 2D TEE, Two-dimensional transesophageal echocardiography; 2D TTE, Two-dimensional transthoracic echocardiography; CFM, Color flow mapping; SBD, Stretched-balloon diameter

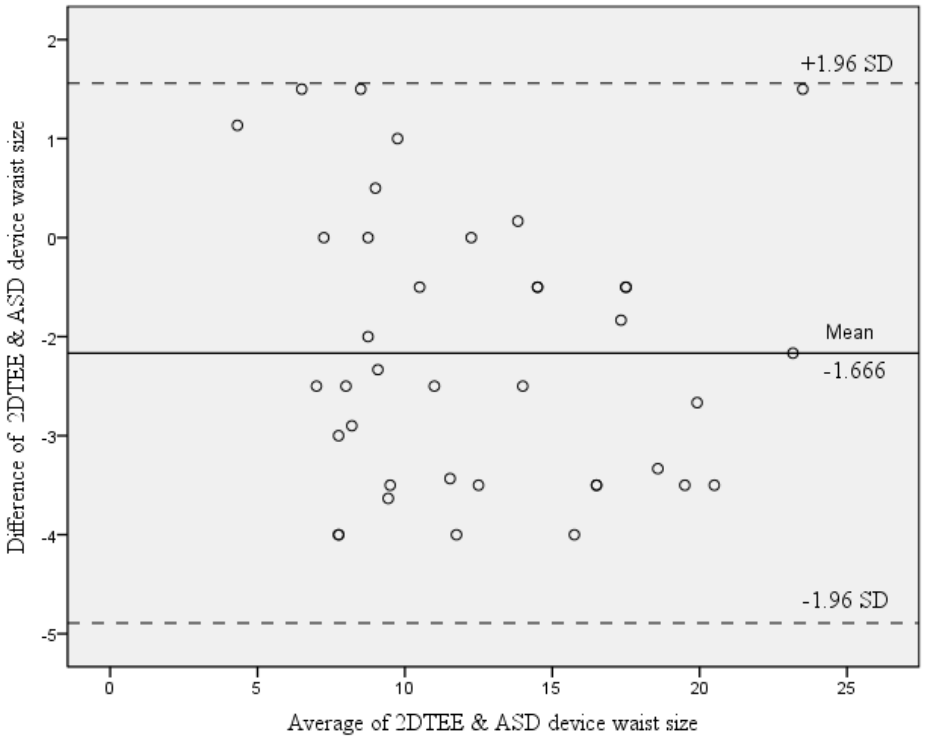

Figure 1. The image depicts the Bland–Altman plot for assessing the agreement between ASD size measured by 2D TEE and device waist size.

ASD, Atrial septal defect; 2D TEE, Two-dimensional esophageal echocardiography

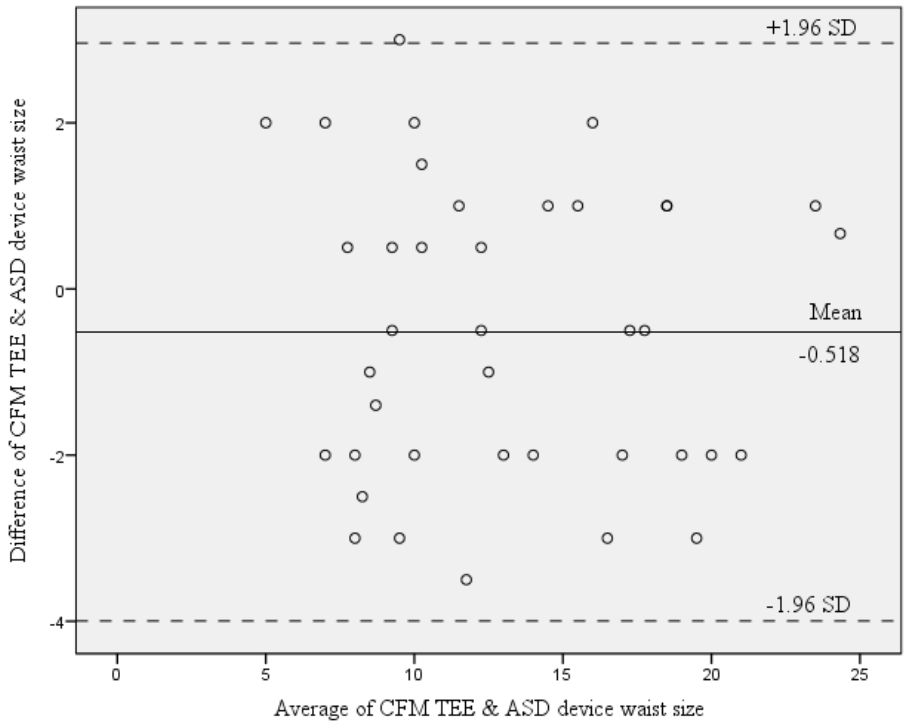

Figure 2. The image depicts the Bland–Altman plot for assessing the agreement between ASD size measured by CFM TEE and device waist size.

ASD, Atrial septal defect; CFM, Color flow mapping; 2D TEE, Two-dimensional esophageal echocardiography

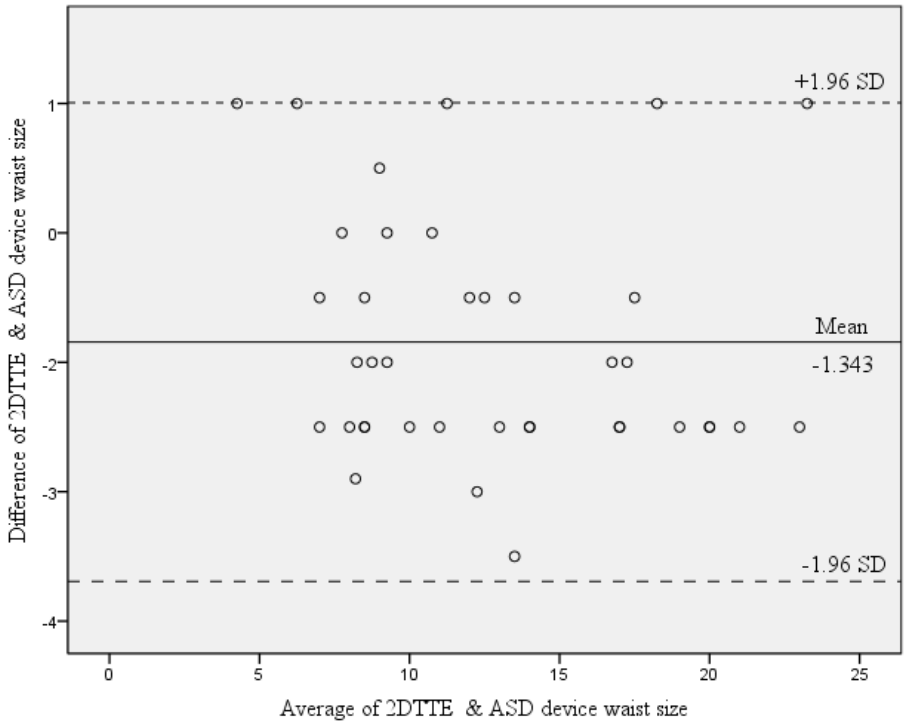

Figure 3. The image depicts the Bland–Altman plot for assessing the agreement between ASD size measured by 2D TTE and device waist size.

ASD, Atrial septal defect; CFM, Color flow mapping; 2D TTE, Two-dimensional transthoracic echocardiography

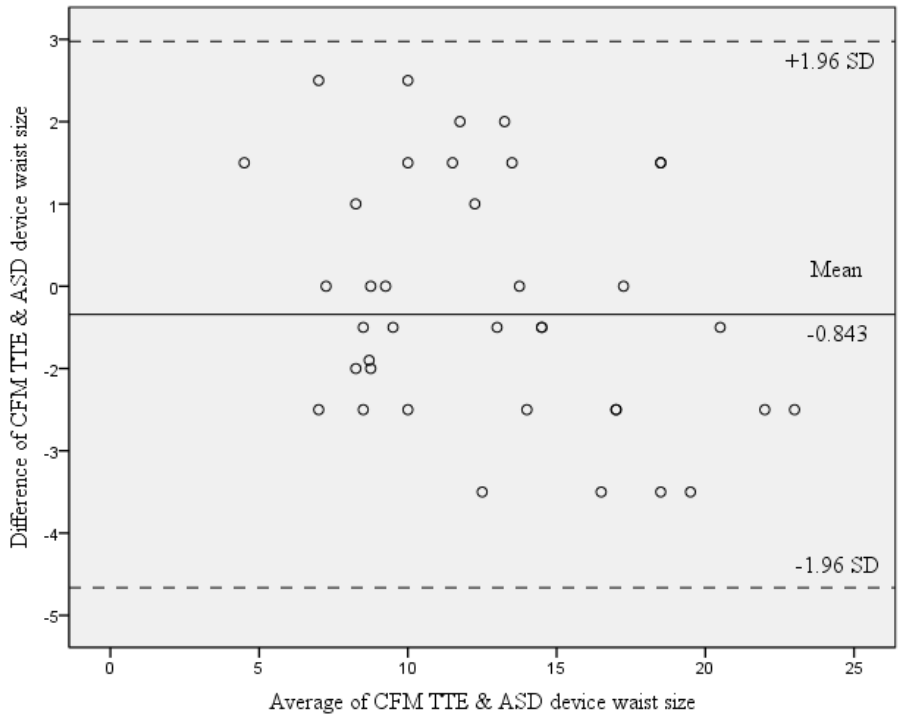

Figure 4. The image depicts the Bland–Altman plot for assessing the agreement between ASD size measured by CFM TTE and device waist size.

ASD, Atrial septal defect; CFM, Color flow mapping; 2D TTE, Two-dimensional transthoracic echocardiography

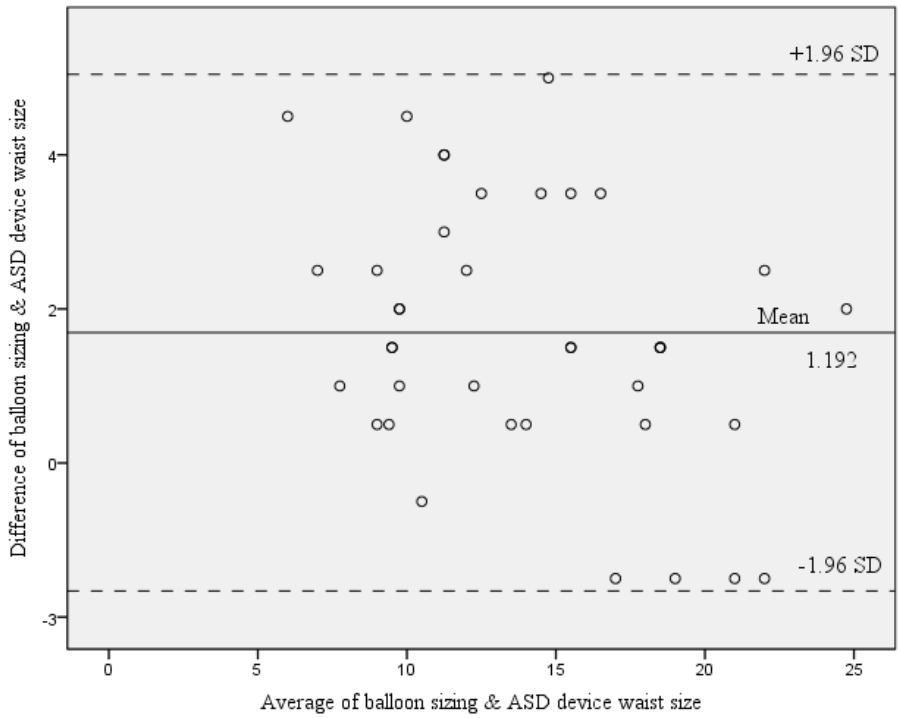

Figure 5. The image depicts the Bland–Altman plot for assessing the agreement between ASD size measured by balloon sizing and device waist size.

ASD, Atrial septal defect

DISCUSSION

In this study, we evaluated the size and position of ASDs, along with the feasibility of ASD transcatheter closure, by 2 imaging methods and balloon sizing to ensure successful closure with the appropriate size and fewer complications. Recent years have witnessed a rise in the implementation of ASD transcatheter closure. In addition, technical progress in the production of more appropriate devices, especially in the pediatric age group, has resulted in the conduct of many studies on the different aspects of the procedure. [23-26] Large-sized devices will lead to the risk of impingement on cardiovascular structures, device malformation, and further severe complications such as cardiac erosion; nonetheless, smaller devices may have the risk of residual shunting, distal embolization, and device instability. [15, 27]

Researchers have tried to correlate SBD with ASD diameter assessed by TEE or TTE. [10] A good linear correlation has been reported between the echocardiographic assessment of ASDs and SBD in previous studies. [17,28] In recent years, device size measurement has been progressively implemented by using non-balloon imaging methods. [29] Many pediatric cardiac interventionists deem balloon sizing unnecessary and close ASDs successfully with transcatheter closure techniques. [28, 30]

In the current study, we enrolled 39 pediatric patients (64.1% female, mean age =7.1±3.1 y) who underwent successful transcatheter closure of ASDs. The mean TTE- and TEE-derived maximal diameter of the defect was significantly lower than the mean waist size of the implanted device, and the mean maximum defect size measured by SBD was significantly higher than the waist size of the device. The defect size measured by balloon sizing was larger than that through TEE and TTE. There was a good linear association between ASD size measurement by device waist size and TEE (device waist size =0.99 × TEE-derived defect size + 1.678; $P<0.001$) as well as TTE (device waist size = 1.01× TTE-derived defect size + 1.17; $P<0.001$), respectively.

A retrospective study checked the feasibility and safety of device closure without balloon sizing of the defect among 61 consecutive patients. The procedural success rate was 79.7%. The authors concluded that balloon sizing might not be necessary for effective ASD device closure, which is similar to the results of our study. [10]

In 2013, a study was conducted in Iran to evaluate the correlation between the 2D TEE-derived size of ASDs and the exact diameter of the occlusion device among 54 patients who underwent device closure. The mean TEE-derived ASD size was significantly lower than the average size of the implanted device and the mean diameter of the ASD through balloon sizing. A good correlation was found between the TEE-derived size of the ASD and the diameter of the device, which made it feasible to generate a formula that could be applied to the estimation of device size in ASD occlusion procedures. The authors concluded that it was not adequate to estimate the actual size of the device before ASD closure through echocardiographic assessment and recommended further studies to investigate its feasibility to implement transcatheter ASD occlusion without the use of balloon sizing. [31]

In 2010, another study was conducted on 39 patients in Iran to compare the 2D TEE technique for assessing ASDs with balloon occlusive diameter (BOD) in transcatheter closure of ASD-II. The results revealed a good positive linear correlation between BOD and the TEE-derived ASD size; still, a negative correlation was observed between BOD, TEE, and TEE measurements. The defect size measured through BOD was larger than that through TEE. The investigators concluded that the TEE-derived maximal defect size was correlated with BOD and that it might provide reliable

data in device size selection for transcatheter closure of ASDs. [32]

A retrospective study in Sweden was performed on 51 patients who underwent transcatheter closure of ASDs. It examined the reliability of TEE before catheterization and compared it with balloon diameter measurement throughout catheterization. The degree of left-to-right shunting was poorly correlated with the size of the defect. The authors stated that TEE was precise for the identification of an ASD, while the assessment of its size to define the size of the closure device was imprecise. [33]

The findings of another study are in line with our results. The investigation was carried out on 16 patients in Bosnia and Herzegovina to define the reliability of TEE and TTE for the estimation of ASD size. All the patients underwent catheter-based procedures to close ASDs. The results indicated that the TTE- and TEE-derived diameter of ASDs could reliably determine the proper size required for the Amplatzer Septal Occluder. [34]

To the best of our knowledge, our study is the first of its kind in Iran to compare ASD size measured by the 3 methods of TTE, TEE, and balloon sizing for device size selection in pediatric patients undergoing ASD transcatheter closure. However, in the interpretation of the results of the present investigation, the limitations of 2D echocardiography and the small sample size of the study should be considered, which may have affected the power of its statistical tests. We recommend future studies with larger patient populations to validate the equations developed in this study and to evaluate their clinical applicability for the estimation of appropriate device selection in patients undergoing ASD transcatheter closure. An efficacy and safety study involving 2 groups of patients is also suggested. In the first group, the equation developed in the present study for the selection of device size should be used to generate a predetermined device size, while in the second group, according to the classic measurements (eg, balloon sizing, 2D TEE, and TTE), device size should be selected to compare both groups in terms of efficacy, safety, and procedure time.

CONCLUSIONS

In this study, the average ASD size assessed by balloon sizing was significantly larger than the mean ASD size measured by 2D TEE and TTE. In addition, the TTE- and TEE-derived ASD size was correlated with device waist size and a good adjunct with simple equations for appropriate device size selection in patients who underwent transcatheter device closure of ASDs. However, additional studies are required to test the clinical applicability of the equations generated in this study to estimate appropriate device selection in patients who will undergo transcatheter closure of ASDs.

Conflict of Interest

The authors declare that there is no conflict of interest.

Ethical Approval

All the procedures performed in the current study were in accordance with the guidelines laid down in the Declaration of Helsinki and approved by the Ethics Committee of Iran University of Medical Sciences (IUMS) (No. IR.IUMS.FMD.REC.1398.500). All the participants' parents or legal guardians were asked to provide written informed consent before data collection.

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