Sizing of Atrial Septal Defects by Intracardiac Echocardiography for Device Closures

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Background: Transcatheter closure of a secundum atrial septal defect (ASD) has become an effective method for surgical treatment. In this study, we evaluated the feasibility and accuracy of intracardiac echocardiography (ICE) for sizing ASDs compared with conventional methods.

Methods: Between January 2004 and December 2006, 270 patients underwent transcatheter closure of secundum ASD by using septal occluders. For 142 patients, the procedure was guided by transesophageal echocardiography (TEE), and for 128 patients by ICE. We compared the maximal diameters of the ASDs obtained during angiocardiography, transthoracic echocardiography (TTE), ICE, and TEE with balloon-stretched sizes ascertained by using a sizing plate.

Results: ASD diameters measured with the sizing plate were significantly correlated with those measured with ICE ($r = 0.963$), TEE ($r = 0.912$), angiography ($r = 0.88$), and TTE ($r = 0.85$). The predicted stretched diameter of the ASDs, i.e. (nonstretched diameter measured with ICE $\times$ 1.07) + 3.23 mm, agreed well with that measured by using a sizing plate ($Ri = 0.974$).

Conclusion: ASD diameters measured with ICE correlated with sizing-plate measurements better than those determined with TEE, angiography or TTE. [*J Chin Med Assoc* 2008;71(8):399–405]

Key Words: atrial septal defect, intracardiac echocardiography, transcatheter closure

Introduction

Secundum-type atrial septal defects (ASDs) account for 10% of all cases of congenital heart disease. In recent years, transcatheter device closure has become an effective and safe alternative for treating ASDs.[1–4] Accurate measurement of the size of the defect is essential for transcatheter closure. Conventional methods to measure these defects include transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), and angiocardiography. The balloon-stretched diameter measured by using a sizing plate has been considered as the criterion standard for device selection.[5,6] TEE improves assessment of the size, number and position of the defects over traditional TTE. In addition, TEE can be used to effectively evaluate the surrounding structures and septal rims. It has also been useful for monitoring and guiding device-deployment procedures.[2,5,7] However, the need for general anesthesia and endotracheal intubation creates potential discomfort and risk for patients.

Several studies have recently demonstrated that intracardiac echocardiography (ICE) using a diagnostic ultrasound catheter (AcuNav; Acuson Corp., Mountain View, CA, USA) is better than TEE for transcatheter device closure of ASDs.[8–13] Advantages of ICE include: (1) a capacity for multiplanar and high-quality, near-field imaging using a steerable quadridirectional catheter; (2) shortened fluoroscopy, procedural, and recovery times because only local anesthesia is required; (3) no patient discomfort from general anesthesia or endotracheal intubation; and (4) no risk of airway or esophageal perforation, as is associated with TEE. However, to our knowledge, the correlation between the maximal,

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nonstretched defect diameter measured with different methods and the balloon-stretched diameter based on sizing plates has not been discussed previously. Therefore, the aim of this study was to evaluate the accuracy of measuring ASDs by using ICE and to compare these measurements with those obtained with conventional methods.

Methods

Study population

Between January 2004 and December 2006, 292 patients with a secundum ASD were admitted for transcatheter device closure at 3 medical centers (Taipei, Taichung, and Kaohsiung Veterans General Hospitals). Before the procedure, all patients underwent TTE to investigate the type and size of interatrial communication. Informed consent was obtained from patients or from parents if patients were younger than 18 years.

Procedures were guided by TEE in 154 patients (group I) and by ICE in 138 (group II). The patients were not randomly distributed. Rather, TEE was performed in those treated before April 2005, and ICE was performed after April 2005, when the AcuNav catheter (Acuson Corp.) became available. All patients underwent TTE and cardiac catheterization (cineangiography and balloon sizing) to evaluate the ASD. Patients who had defects measuring ≥ 3 mm, as determined with TEE or ICE, and who were at least 2 years old and who weighed at least 12 kg were eligible for transcatheter device closure. Patients with multiple fenestrated ASDs, balloon-stretched defect diameters > 38 mm, and other clinically significant associated cardiac malformations (anomalous pulmonary venous return) were excluded from the study because they might impose difficulties in transcatheter closure, with higher risk of residual leak, distal migration and deformity of the device and a certain failure rate percentage.

The maximal diameter of the nonstretched defects and the stretched defects measured by using the different techniques were compared with the criterion standard of the sizing-plate diameter.

TTE evaluation

Two-dimensional and color Doppler echocardiograms were recorded using a Sonos 7500 ultrasound system (Hewlett-Packard, Andover, MA, USA) with a 4- or 8-MHz transducer. Conventional short-axis, 4-chamber, and subcostal views of the atrial septum were obtained to measure the diameter of the ASD. The largest diameter obtained from the different views was recorded as the TTE measurement of the ASD diameter. The surrounding rims of the defect were also measured, including the relation to superior and inferior vena cava inflow (superoposterior and inferoposterior rim) aspects of the interatrial septum, the right pulmonary vein, the retroaortic region (superoanterior rim), and the atrioventricular valves (inferoanterior rim).

Echocardiographic guidance

Patients in group I received general anesthesia with endotracheal intubation. TEE images were obtained by using a multiplanar TEE probe with a 5-MHz phased-array transducer and the ultrasonography system Sonos 7500 (Hewlett-Packard) in the standard transverse (0–60°) and longitudinal (90–120°) views. The maximal diameter of the defect was measured and recorded.

Group II patients received conscious sedation without endotracheal intubation. ICE images were obtained by using a 10F (3.2 mm), 5.5-MHz to 10-MHz ultrasound-tipped AcuNav catheter (Acuson Corp.). The catheter tip contained a 64-element, vector phased-array transducer that scanned in the longitudinal plane to provide a 90-sector image with tissue penetration of 12 cm. The catheter was connected to an ultrasonography unit (Sequoia 256; Acuson Corp.) that was equipped with special software for ICE. The ICE catheter was introduced through a separate 11F sheath in the same femoral vein in patients weighing more than 35 kg or from the left femoral vein in patients weighing less than 35 kg. The catheter was advanced through the inferior vena cava into the right atrium under fluoroscopic guidance. By using 4-way articulation, the catheter was flexed posteriorly (posterior/anterior knob rotated counterclockwise) and rotated rightward (right-left knob rotated clockwise). This view corresponded to the long-axis view and delineated the atrial septum from the entry of the superior vena cava to the inferior portion of the septum, the entire left atrium, and the entry of the left pulmonary vein. To demonstrate the aortic root and the relationship of the ASD to the aortic valve, the entire catheter was rotated clockwise until the ultrasonographic array was near the opening of the tricuspid valve. This view corresponded to the short-axis view. Standard long-axis and short-axis views were acquired to best see the ASD and device deployment, as well as to assess results of the closure.

The largest ASD diameter measured from these views was recorded as the ICE measurement.

Closure protocol

The Amplatzer septal occluder (AGA Medical Corp., Golden Valley, MN, USA) was used in all patients. The device-closure protocol and techniques have been previously described.[1,7,14] In brief, the device was selected

Table 1. Demographic, hemodynamic and echocardiographic data of the 270 patients*

	Group I ($n=142$)	Group II ($n=128$)	p
Age (yr)	15.3±14.9 (2.0–72)	20.9±16.8 (3.2–66)	0.002†
Body weight (kg)	35.1±18.6 (12–86)	45.3±17.3 (13–79)	0.001†
Qp/Qs	2.2±1.0 (1.1–5.4)	2.1±1.1 (1.0–5.6)	0.700
Defect size (mm)			0.120
TTE	12.9±5.6 (3.3–30)	14.0±5.9 (2.5–30)	
ICE		14.3±7.3 (3.0–31.7)	
TEE	14.2±6.4 (3.0–30)		
Angiography	15.2±6.6 (4.5–35.7)	15.4±7.3 (2.7–35.1)	0.770
Stretched balloon diameter (mm)			
ICE		19.4±7.4 (5.9–37.8)	
TEE	19.1±6.9 (8.2–37)		
Angiography	19.3±7.5 (4.3–37.6)	19.5±7.8 (6.2–37.9)	0.820
Sizing-plate diameter (mm)	18.9±7.1 (5.0–38)	19.4±7.4 (5.0–38)	0.560
Device size (mm)	19.5±7.6 (7.0–38)	19.4±8.4 (5.0–38)	0.930
Fluoroscopy time (min)	18.4±7.9 (3.8–40)	14.14±5.8 (3.7–25.8)	0.001†
Procedure time (min)	70.6±22.2 (31–120)	60.6±13.8 (22–88)	0.001†

**Data presented as mean±standard deviation (range); †$p<0.05$ was regarded as statistical significance. Qp/Qs = pulmonary-to-systemic blood flow ratio; TTE = transthoracic echocardiography; ICE = intracardiac echocardiography; TEE = transesophageal echocardiography.*

on the basis of the type and size of the interatrial septal defect we measured. Patients were given systemic anticoagulation at the time of the procedure with intravenous heparin 50–100 U/kg to attain an activated clotting time of longer than 200 seconds. Routine cardiac catheterization and hemodynamic measurements were performed from the femoral vein to assess the degree of shunting and evaluate pulmonary vascular resistance. The ratio of pulmonary-to-systemic blood flow (Qp/Qs ratio) was calculated by applying the Fick principle. We performed right upper pulmonary venography with 20–70° left anterior oblique and 20–35° cranial views to define the location and size of the ASD. The maximal diameters of the defects and surrounding rims were completely evaluated, and the balloon-stretched diameters of the defects were measured and compared with those observed during ICE, TEE and quantitative fluoroscopy.

A 24-mm or 34-mm balloon catheter (AGA Medical Corp.) was used to measure the stretched diameter of the defect. After it was filled with contrast medium diluted 1:4, the balloon was pulled through the defect and inflated until shunting was eliminated on TEE or ICE images or until a waist was visible on fluoroscopic images to prevent oversizing the defect. Using the waist of the balloon measurements, we chose the size of the sizing plate and selected an adequate device for closure. Device deployment was guided by continuous ICE or TEE and by fluoroscopy as needed. Venous sheaths were removed once the activated clotting time was less than 150 seconds.

Statistical analysis

Data are expressed as mean±standard deviation. The clinical parameters of the 2 groups were compared by applying unpaired Student's t test. Measurements of the maximal nonstretched and balloon-stretched diameters of the defects were compared with a sizing plate by using regression lines and plotting scattergrams (SigmaPlot 9.0). Pearson's correlation coefficients were calculated. A p value of less than 0.05 indicated statistical significance. Intraclass correlation coefficients were calculated for balloon-stretched diameters determined with ICE and with the sizing plate and for predicted and measured sizing-plate sizes by using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

Results

Demographic, hemodynamic, and echocardiographic data for both patient groups are summarized in Table 1. In group I, 142 patients successfully underwent sizing and transcatheter device closure of their ASDs under TEE guidance. Four patients were excluded because of multiple ASDs, 4 because of excessively large defects

and deficient rims, 3 because of an associated partial anomalous pulmonary venous return, and 1 because of an excessively small ASD. TEE-derived ASD diameters correlated well with diameters measured with other methods, both before and during balloon stretching.

In group II, 128 patients successfully underwent sizing and transcatheter device closure of their ASDs under ICE guidance. Five patients were excluded because of an unexpectedly large defect and deficient rims, 3 because of multiple ASDs, and 2 because of an associated partial anomalous pulmonary venous return. ICE-derived ASD diameters were significantly correlated with diameters measured with other methods, both before and during balloon stretching. Balloon-stretched diameters measured with ICE significantly agreed with sizing-plate sizes ($Ri = 0.975$; 95% confidence interval, 0.965, 0.983; $p < 0.001$).

The 2 groups did not significantly differ in terms of the Qp/Qs ratio ($p = 0.7$), ASD diameters measured with TTE ($p = 0.119$) or angiography ($p = 0.769$), balloon-stretched diameters measured with angiography ($p = 0.82$), sizing-plate diameters ($p = 0.56$), or device selection ($p = 0.93$). However, a significant difference was found for patients' age ($p < 0.002$) and body weight ($p < 0.001$).

The sizing-plate diameter of the ASD could be estimated as follows: (ICE diameter × 1.07) + 3.23 mm ($r = 0.96$, $p < 0.001$), (TEE diameter × 1.05) + 4.08 mm ($r = 0.91$, $p < 0.001$), (angiographic diameter × 0.94) + 4.50 mm ($r = 0.88$, $p < 0.001$), and (TTE diameter × 1.07) + 4.43 mm ($r = 0.85$, $p < 0.001$).

Correlation was better between sizing-plate diameters and ICE-measured ASDs than with ASDs measured with the other methods (Figure 1). Also, good correlation ($r = 0.975$; $p < 0.001$) and significant agreement ($Ri = 0.974$; 95% confidence interval, 0.963, 0.982; $p < 0.001$) were observed between the predicted and measured sizing-plate diameters (Figure 2).

Times for both fluoroscopy (14.1 ± 5.8 *vs.* 18.4 ± 7.9 min, $p < 0.001$) and the procedure were shorter in group II than in group I (60.6 ± 13.8 *vs.* 70.6 ± 22.2 min, $p < 0.001$) (Table 1). After the device was released, TEE revealed 6 trivial and 2 mild immediate residual leaks, and ICE revealed 2 trivial and 1 mild leaks.

Arrhythmias affected fewer patients in group II than in group I. In group I, 8 patients developed a transient heart block, and 4 developed transient supraventricular tachycardia secondary to TEE manipulation. In group II, 2 patients developed transient heart block, and 2 developed transient supraventricular tachycardia secondary to ICE manipulation. No embolization or migration of the septal occluder occurred after the ASD was closed.

Discussion

Accurate measurement of the size of an ASD is essential for successful transcatheter device closure. Until now, interatrial septal defect sizing and appropriate device selection with ICE versus conventional methods have not been compared in published large series. Our data confirm improvements in the accuracy, efficacy, and safety of ICE for sizing interatrial septal defects and for guiding transcatheter device closure of ASDs (Figure 1).

Conventional TTE can normally detect the ASD, but it does not achieve optimal imaging in some adults with obesity, chest deformities, or previous surgical trauma. TTE is limited by progressive beam attenuation and scattering as ultrasound waves pass through tissues.[15] Sometimes, TTE may lead to underestimation of the actual size and number of defects, or it may suggest false-positive interatrial shunting shadows, especially when the interatrial septum is not seen perpendicularly in the subcostal view[16,17] and traced in the oblique or modified 4-chamber view. Angiocardiography cannot provide a well-defined shape or detailed endocardiac characterization of the defect and its surrounding structures.

A balloon-sizing maneuver and 2-dimensional TEE have long been regarded as the criterion standard for measuring ASDs and for guiding selection of the size of the occluder. In addition, it is a helpful imaging technique for real-time monitoring of transcatheter closure, and is widely accepted.[5,6] Although few authors have questioned whether the size of a defect can be accurately measured with balloon sizing, avoidance of overstretching of the defect could prevent overestimating the size of the ASD and choosing an occluder of improper size.[18,19] Today, our institution and most medical centers still use the balloon-sizing maneuver as the standard for measuring moderate or large ASDs.

TEE imaging is superior to traditional TTE and angiocardiography because it provides more information regarding the anatomy of the defect, the surrounding structures, and the relationship between the device and septum.[5,7] However, TEE has some disadvantages because general anesthesia and endotracheal intubation are typically required, because it increases the risk for aspiration, and because airway obstruction is a potential complication. Other risks are pharyngeal injury, esophageal injury, and gastric perforation during TEE manipulation. An additional expert echocardiographer is needed to interpret the TEE images. Although TEE offers multiple imaging planes, the point of its imaging source is relatively fixed with respect to the interatrial septum. Although TEE can be moved by means of insertion, withdrawal, flexion, anteflexion, or rotation,

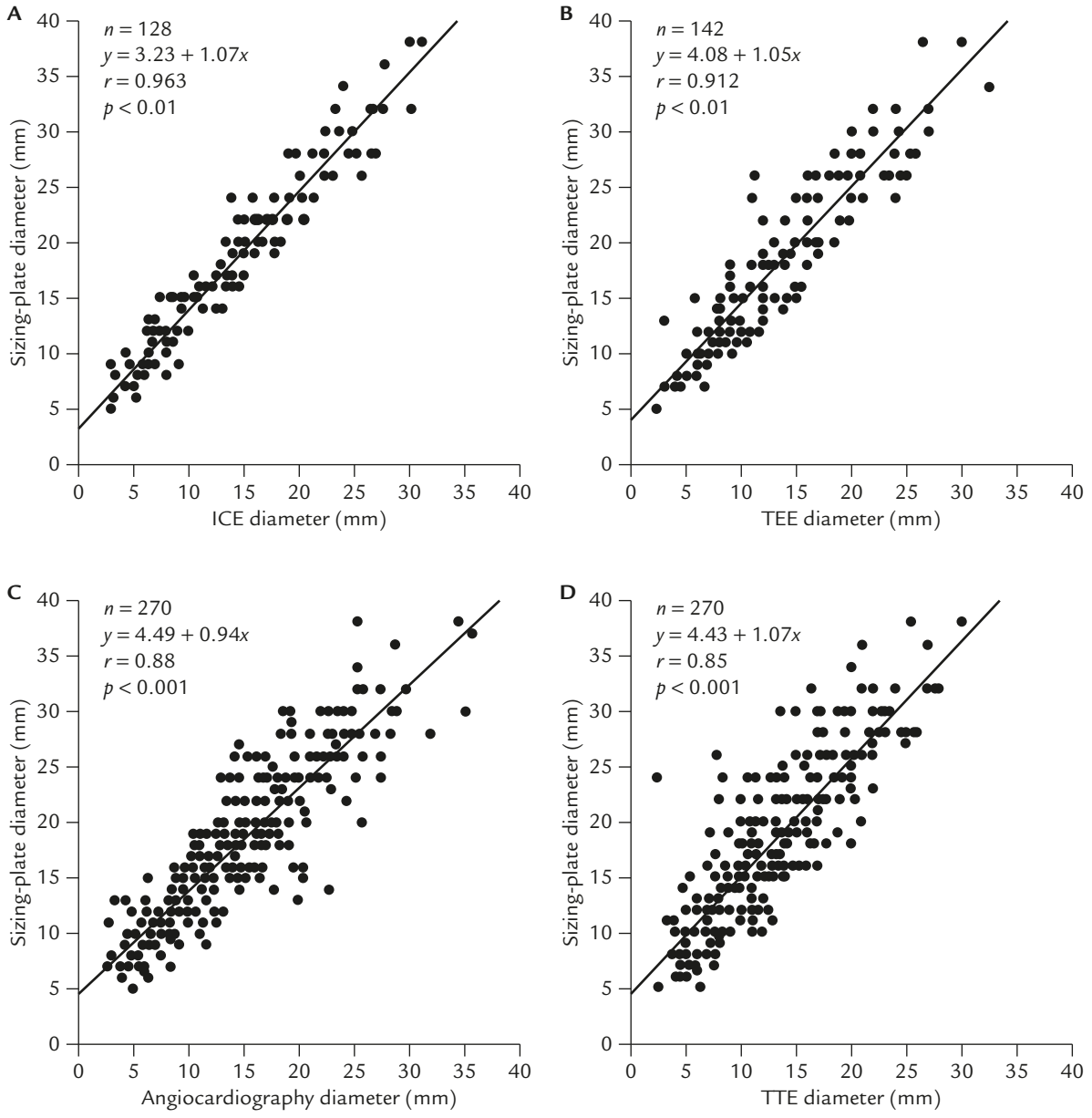

Figure 1. Comparison of the different atrial septal defect sizing methods with sizing-plate diameter. (A) Intracardiac echocardiography (ICE) versus sizing-plate diameter. (B) Transesophageal echocardiography (TEE) versus sizing-plate diameter. (C) Angiocardiography versus sizing-plate diameter. (D) Transthoracic echocardiography (TTE) versus sizing-plate diameter.

the resultant locations do not typically permit imaging of the complete interatrial septum in the near field or in the inferior septum.[11]

At present, ICE is increasingly used in interventional electrophysiology and catheterization.[20] It is a relatively new method for evaluating intracardiac lesions, and it substantially improves imaging resolution of the atrial septal morphology over that of TTE and TEE.[21–25] ICE imaging from the right atrium can be used to determine the location of the ASD, to estimate the size and number of defects, to accurately assess the entire atrial septum (including the superior and inferior fatty limbus and fossa ovalis membrane), and to directly visualize the surrounding structures and drainage of the pulmonary veins. For investigating atrial defects in the inferior portion of the septum, ICE is much better than TEE.[24,25] In contrast to TEE, the point of the ICE imaging source can be moved to different parts of the right atrium to allow imaging of the atrial septum from different angles; therefore, it is proven to be superior to TTE and TEE in detecting additional ASDs. ICE enables us to select an appropriately sized

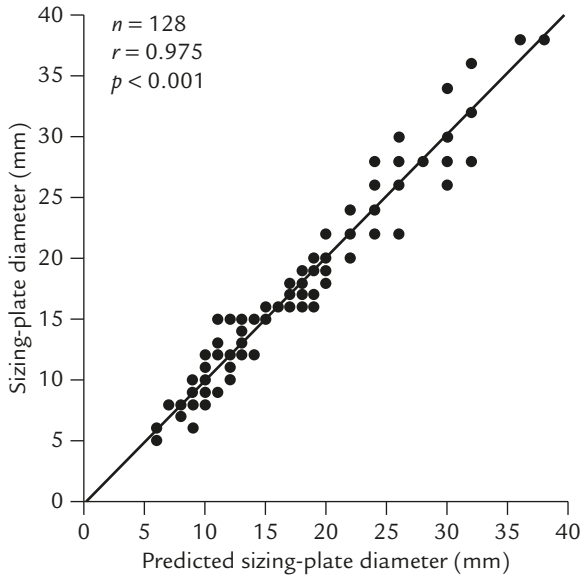

Figure 2. Correlation between predicted and measured sizing-plate diameters of the atrial septal defects. Predicted sizing-plate diameter (mm) = intracardiac echocardiography diameter (mm) × 1.07 + 3.23 mm.

device and to visualize the trans-septal passage of the catheter, sizing of the balloon, and device deployment. Moreover, ICE eliminates the need for general anesthesia and endotracheal intubation, prevents additional transesophageal echocardiographic imaging, and shortens fluoroscopy and procedure times.[8,11,13,22]

Regarding the disadvantages of ICE, the cost of the catheter may be an important limitation to its use. However, ICE is still likely to be cost-effective, as it eliminates the expense and risk of anesthesia and the need for an anesthesiologist and another cardiologist to operate the TEE probe, and it reduces catheterization laboratory time and procedure time. Limitations also include the 9F and 10F catheters, which cannot be used in children who weigh less than 12 kg. Miniaturization of this technology should overcome this problem, and the use of small puncture sheaths will lessen trauma to the femoral vein. Other limitations are monoplanar imaging and the lack of a wide field of view. These factors sometimes make visualization of the maximal diameter of the defect, catheter, and device deployment challenging. If the measured size of the defect is not its maximal diameter, the predicted sizing-plate diameter is underestimated. Future development of biplanar and multiplanar phased-array transducers—or of real-time, 3-dimensional intracardiac transducers—could replace current technologies[26] and increase the accuracy of measuring ASDs and estimating sizing-plate diameters while providing a virtual reality-type of imaging during transcatheter interventions.

From our study, the patients' ages and body weights differed significantly between the ICE and TEE groups, likely because the young patients tended to be distributed to group I. However, mean ASD, balloon-stretched, and sizing-plate diameters were similar, as were the mean diameters of the selected devices. Therefore, we could compare the characteristics of defect sizing between the ICE and TEE groups. Correlation was better between stretched sizing-plate diameters and ICE-measured nonstretched ASDs than with TTE, angiocardiographic or TEE results. We used the ICE diameter of the ASD to estimate the sizing-plate diameter, and both correlation and agreement between the predicted and measured diameters were excellent.

In patients in whom the measured balloon-stretched diameter was ≤ 20 mm, the measurement of the sizing-plate diameter was more subjective than in others because of trivial differences in the balloon waist, with increments or decrements of 1 mm. However, for those whose measured balloon-stretched diameter was > 20 mm, the equation used to predict the sizing-plate diameter with ICE was relatively objective but had certain biases. The reason may be because of an increment or decrement of 2 mm in selecting devices > 20 mm. Moreover, some defects > 20 mm had a rim deficiency or a floppy rim, and we needed a device that was 1 or 2 sizes larger than that predicted from the sizing-plate diameter calculated with the ICE equation to prevent underestimation and residual shunts. If the measured size of the defect was not its maximal diameter, the predicted sizing-plate diameter was also underestimated.

In conclusion, ASDs measured with ICE had the best correlation and agreement with the measured sizing-plate sizes. ICE facilitated all stages of device closure and monitoring of the deployment process. ICE was a relatively effective and safe alternative to TEE during transcatheter ASD closure procedures, leading to high occlusion rates similar to those with conventional methods. We recommend using ICE imaging and equation-based calculations to predict the sizing-plate diameter of ASDs. In addition, invasive balloon sizing may not be necessary for transcatheter closure of ASDs < 20 mm. Further study is necessary to demonstrate the benefit of calculations derived from ICE equation in patients with ASDs > 20 mm.

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