

Prospective Randomized Trial of Transthoracic Echocardiography Versus Transesophageal Echocardiography for Assessment and Guidance of Transcatheter Closure of Atrial Septal Defects in Children Using the Amplatzer Septal Occluder

Sergio Bartakian, MD, Howaida G. El-Said, MD, PhD, Beth Printz, MD, PhD, John W. Moore, MD, MPH

San Diego, California

Objectives This study sought to determine whether transthoracic echocardiography (TTE) can provide safety and efficacy equivalent to transesophageal echocardiography (TEE) for assessment and guidance of transcatheter atrial septal defect (ASD) closure in pediatric patients.

Methods We performed a prospective randomized trial of ASD closure using the Amplatzer septal occluder (ASO) from March 2008 to April 2012. Inclusion criteria were isolated secundum ASD, age 2 to 18 years, and adequate TTE windows. Forty patients were enrolled and randomized to either TEE or TTE. In the TEE group, we used “stop flow” balloon sizing to determine device size. In the TTE group, we used the average ASD diameter times 1.2 (scaled). Patients were followed up to 1 year.

Results Patient general and hemodynamic characteristics were similar in both groups. Procedural success was 100% in both groups. The average TEE stop flow diameter was similar to the scaled TTE diameter (15.35 ± 4.62 mm vs. 16.57 ± 5.47 mm; $p = 0.46$). Device size (16.0 ± 4.94 mm vs. 16.37 ± 5.05 mm, $p = 0.82$) and ratio of device to defect size (1.0 ± 0.06 vs. 0.99 ± 0.03 , $p = 0.52$) were also similar. Total procedure (70.6 ± 22.98 min vs. 51.1 ± 17.61 min, $p = 0.005$), room (126.8 ± 28.41 min vs. 95.7 ± 20.53 min, $p = 0.0004$), and fluoroscopy (13.6 ± 6.17 min vs. 8.9 ± 8.45 min, $p = 0.007$) times were all significantly shorter in the TTE group. Neither group had significant complications during the procedure nor in follow-up. Rates of shunt resolution were similar between groups.

Conclusions This study suggests that in selected pediatric patients, use of TTE is as efficacious and safe as TEE for assessment and guidance of ASD occlusion using the ASO. TTE also may offer the additional safety benefit of reduced fluoroscopy exposure. (J Am Coll Cardiol Intv 2013;6:974–80)

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Successful nonsurgical closure of atrial septal defect (ASD) was first reported in 1974 by King and Mills (1). Recent studies have demonstrated the safety and efficacy of percutaneous ASD occlusion, making it the preferred method of treatment at most centers (2-4).

Soon after it received U.S. Food and Drug Administration approval in 2001, the Amplatzer septal occluder (ASO) became the most widely used device for percutaneous ASD closure. Transesophageal echocardiography (TEE) was required in the pivotal trial of the ASO, and continues to be the most common ultrasound technology used for definitive ASD assessment, device selection, and device guidance during implantation (2,5).

We have previously reported experience implanting the ASO using transthoracic echocardiography (TTE) (6). Because there have been no studies directly comparing TEE with TTE, we undertook this study to determine whether TTE can provide safety and efficacy equivalent to TEE for assessment, device selection, and guidance of transcatheter ASD occlusion, using the ASO in children.

Methods

Study design. This study was approved by the Rady Children's Hospital/University of California-San Diego institutional review board. All patients between 2 and 18 years of age, discovered to have an isolated secundum ASD amenable to device closure, were considered eligible. All patients were initially evaluated using TTE at the time of diagnosis. We excluded patients not meeting age criteria as well as those who had multiple ASDs, or had other hemodynamically significant cardiac lesions. This was simply to ensure uniformity between groups and to exclude any potential confounders. We excluded any patient with previously diagnosed coagulation defects and those with any history of esophageal varices, esophageal obstruction, or past radiation therapy to the area. We also excluded any patient who was deemed not to have adequate TTE windows on initial screening exam, defined as the ability to see the defect well from 3 perpendicular planes of imaging. Between March 2008 and April 2012, 40 patients met the criteria, were enrolled, and were then randomized to 1 of 2 groups: TEE versus TTE.

Study outcomes and definitions. The primary outcome was procedural success, defined as successful implantation of the device without embolization or malposition. The study tested the hypothesis that TTE was noninferior to TEE for device selection, guidance, and assessment in select patients with isolated secundum ASD. Sample size estimates were based on published statistics formulae (7), and we determined that 20 patients per study arm would result in the needed power of 0.80 at an alpha of 0.05.

Secondary outcomes included procedure time, fluoroscopy time, complications, and correlation of device size to "scaled"

TTE ASD diameter. The procedure time was defined as the time from initial skin puncture to hemostasis being achieved at case end. The room time was defined as the time from patient entry into and exit from the catheterization lab.

Informed consent was obtained for all patients. Patients in both study groups underwent our routine catheterization protocol for ASD occlusion. This included use of general anesthesia, administration of heparin and monitoring of activated coagulation time, femoral venous access, right and left heart catheterization, and measurement of intracardiac pressures and saturations. All patients had an ASO implanted using standard catheterization techniques by 1 of 2 senior interventional cardiologists (J.W.M. and H.E.S.). All patients received intravenous antibiotics during the procedure. **Procedure. TTE GROUP.** While the patient was being prepared in the catheterization laboratory, the TTE previously performed in clinic was reviewed, and measurements of the ASD were obtained from 3 standard views: parasternal short axis, apical 4 chamber, and subcostal sagittal (6) (Fig. 1).

These 3 measurements were averaged, and this average diameter was then multiplied by a factor of 1.2 to derive a "scaled" ASD diameter. A device equal to (or just larger in the case of a half size or odd number) to the scaled diameter was selected for implantation. If the images from the initial diagnostic TTE were not considered to be adequate, additional TTE imaging was performed as needed in the catheterization laboratory. This was carried out following induction with general anesthesia and before the patient was prepped. The implant procedure was guided using fluoroscopy. Once the device was in place and felt to be in good position, the drape was pulled back, allowing the echocardiographers access to the chest to perform a brief assessment of the device. If TTE imaging was reassuring and confirmatory of adequate positioning, the patient was re-draped, and the device released under fluoroscopic observation.

For device assessment, before release, the 3 views described in the previous text were used to ensure the septum was captured between the left and right atrial discs (Fig. 2). In the parasternal short-axis view, the retroaortic rim was evaluated. If this rim was deficient, splaying around the aorta was considered to confirm adequate device position. In the 4-chamber view, capture of the mitral (anterior-inferior) rim was evaluated, as was the pulmonary venous (posterior-superior) rim. Finally, in the subcostal sagittal (bicaval) view, capture of the superior vena cava (superior) rim was evaluated, as was the appropriate inferior device rim capture or device alignment (suggesting capture) of the

Abbreviations and Acronyms

ASD = atrial septal defect

ASO = Amplatzer septal occluder

ECG = electrocardiogram

ICE = intracardiac echocardiography

TEE = transesophageal echocardiography

TTE = transthoracic echocardiography

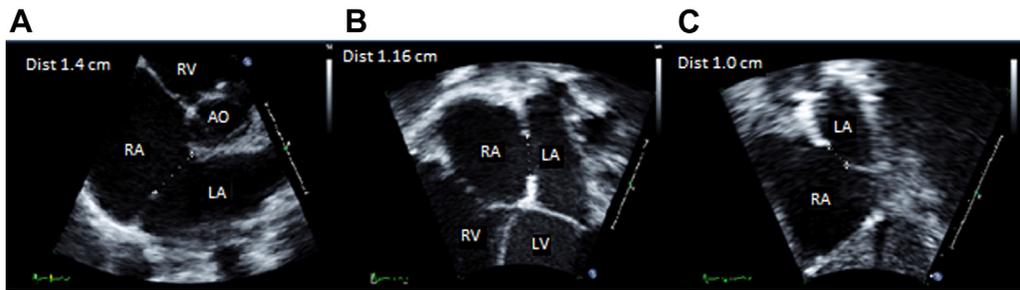


Figure 1. Pre-Procedure ASD Assessment

(A) The parasternal short-axis view, (B) apical 4-chamber view, and (C) subcostal sagittal view. Scaled formula: $((1.4 + 1.16 + 1.0)/3) \times 1.2 = 1.42$ cm; therefore, a size 14 device. Ao = cross section of the aortic valve; ASD = atrial septal defect; LA = left atrium; LV = left ventricle; RA = right atrium; RV = right ventricle.

inferior vena cava (posterior-inferior) rim. The sagittal view is the most complicated because the device does not acquire its final configuration until release of the delivery cable, as seen in Figures 2C and 2D. The operator may pull on the device cable gently to separate the right and left discs, facilitating visualization of rim capture in all views.

TEE GROUP. TEE was performed in the catheterization laboratory after general anesthesia was initiated. ASD

dimensions were obtained from the bicaval, aortic short-axis, and modified 4-chamber views. During the diagnostic portion of the catheterization, “stop flow” balloon sizing of the ASD was performed using TEE (8,9) (Fig. 3). A device equal to (or just larger in the case of a fraction or odd number) the stop flow diameter was selected for implantation. The implant procedure was guided using TEE and fluoroscopy.

After catheterization, all patients were treated with low-dose aspirin therapy and remained in the hospital overnight

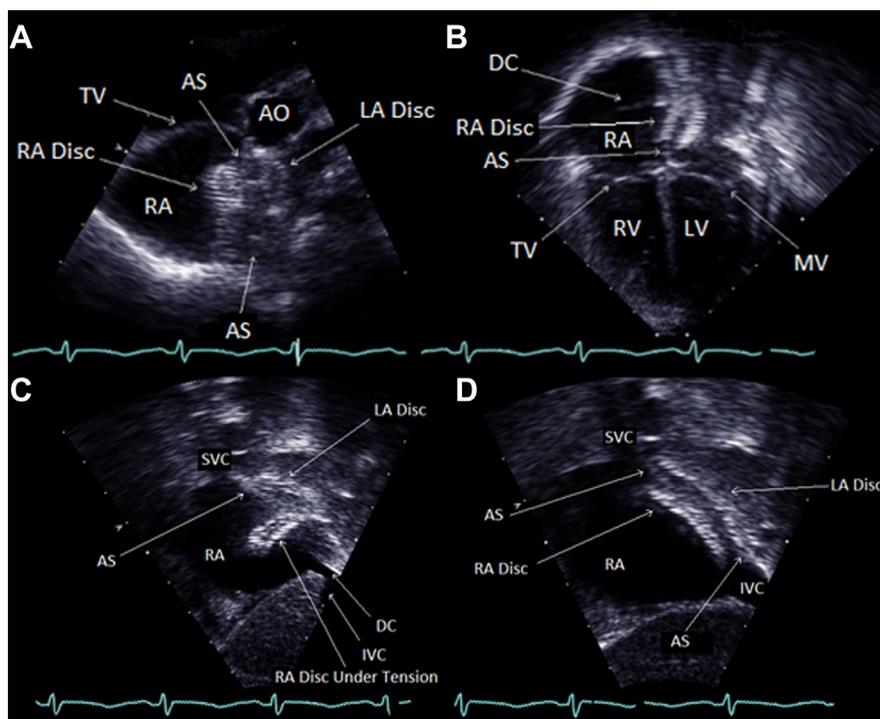


Figure 2. Device Guidance

Parasternal short-axis (A), apical 4-chamber (B), and subcostal sagittal (C) transthoracic echocardiogram views during device positioning with cable attached. Comparison of panels C and D shows the drastic change in conformation of the device after release in the subcostal sagittal view. AO = aorta; AS = atrial septum; DC = delivery cable; IVC = inferior vena cava; MV = mitral valve; SVC = superior vena cava; TV = tricuspid valve; other abbreviations as in Figure 1.

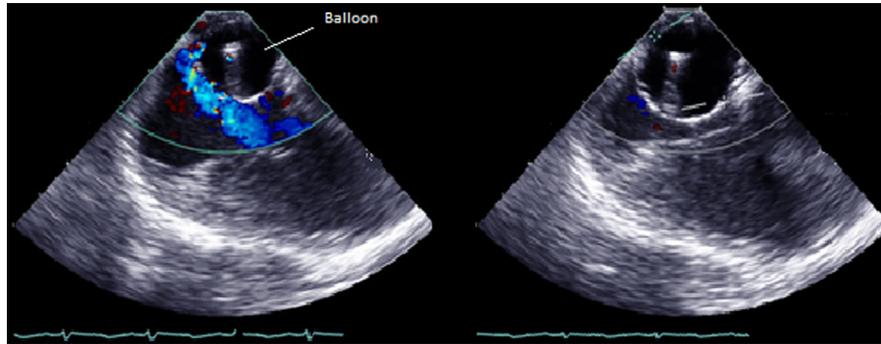


Figure 3. Balloon Stop Flow Measurement

Atrial septal defect during transesophageal echocardiography.

for recovery and observation. Patients received a chest x-ray, electrocardiogram (ECG), and TTE before hospital discharge. All patients had a 1-month as well as a 6- to 12-month outpatient follow-up evaluation. At these evaluations, each patient received a chest x-ray, ECG, and TTE. Additional studies and follow-up evaluations were performed as deemed clinically appropriate.

Data collection. Demographic information was collected including age, sex, height, and weight at the time of the procedure. Experienced echocardiographers interpreted all echocardiograms (procedural and follow-up points). Reports and images of TTEs and TEEs were reviewed to collect data pertaining to the defect diameters, stop flow balloon diameters, residual ASD shunting, as well as information regarding potential negative effects of device placement (pericardial effusion, new or changes in valvar insufficiency, and so on). Catheterization reports were used to collect hemodynamic data (total pulmonary to systemic output ratio [Q_p/Q_s ratio] and pulmonary vascular resistance), times (room, procedural, fluoroscopy), scaled diameters, device sizes, stop flow measurements, as well as information regarding complications. Follow-up ECGs, Holter reports, and clinic notes were reviewed.

Statistical analysis. For all patient and procedural data, continuous variables are presented as mean \pm SD or median (range), depending on whether or not they were normally distributed. For all variables, a Grubb's test was performed to detect the presence of any outliers. Where there was missing data, the number of nonmissing values is reported for that variable. Percentages are provided for categorical variables.

For comparisons of continuous variables (e.g., procedure time) between 2 groups, an unpaired Student *t* test or Wilcoxon rank sum test for related samples was used for normally distributed or skewed data, respectively. For comparison of categorical variables (presence of residual) at different time points, a Fisher exact test was used with 2-tailed *p* values. A 2-tailed *p* value <0.05 was considered

statistically significant. Pearson's correlation was performed as a measure of assessing the relationships between measurements and device size. All statistical analyses were performed using GraphPad Software (GraphPad Software, La Jolla, California).

Results

During the study period, there were a total of 84 ASD device closures using the ASO. Forty patients met study criteria and were initially enrolled. Of the 44 not enrolled, 14 refused consent and 18 met exclusion criteria. Of these 18, 5 patients required multiple devices, 5 had significant coexisting cardiac diagnoses, 5 failed to meet age criteria, and 3 had procedures performed by a private cardiologist not taking part in the study. The remaining 12 patients were not enrolled due to poor TTE imaging windows. The ages for these 12 patients ranged from 3 to 18 years, with a median of 10 years. We later excluded 2 additional patients, leaving a final population of 38 patients (19 in each group). The 2 patients were excluded due to the discovery of additional or disqualifying cardiac defects during their procedural echocardiograms. In the TEE group, 1 patient was found to have a sinus venosus ASD (deficient superior vena cava rim), and in the TTE group, 1 patient was discovered to have moderate right pulmonary vein stenosis in addition to an ASD; both patients were referred for surgery.

General patient characteristics showed no differences between the 2 groups (Table 1). Hemodynamic and echocardiographic data are depicted in Table 2. Hemodynamic variables, including Q_p/Q_s and pulmonary vascular resistance were similar between groups.

The device sizes used were similar in both groups as was the average defect size as measured by TEE or TTE. There was no difference when we compared the stop flow diameter in the TEE group with the scaled diameter in the TTE group. The ratio of device size to the scaled diameter in the

Table 1. General Patient Characteristics

	TEE (n = 19)	TTE (n = 19)	p Value
Age, yrs	6.5 ± 4.8	5.5 ± 3.4	0.47
Weight, kg	25 ± 17.4	20.8 ± 12.2	0.4
Height, cm	112.8 ± 28.53	109.8 ± 23.34	0.72
Male	9 (47)	12 (63)	

Values are mean ± SD or n (%).
TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

TTE group (0.99 ± 0.03) was also not different from the ratio of device size to stop flow diameter in the TEE group (1.0 ± 0.06; p = 0.52), further suggesting the 2 methods are equally efficacious in determining the device size needed for closure. The Pearson correlation for the scaled diameter to the final deployed device size in the TTE group was slightly better than the correlation of stop flow balloon diameter to the final deployed device size in the TEE group (Fig. 4). To test our scaled formula further, we retrospectively evaluated the initial screening TTE of a subset of 13 patients in the TEE group who had adequate imaging windows to make our required measurements. When we applied our scaled formula to this subset and compared it with either the TTE group’s mean scaled diameter (Table 2), or the balloon stop flow measurement we had used in the procedure, there was no significant difference (scaled TTE in TEE group, 14.82 ± 4.59 mm vs. stop flow 15.35 ± 4.62 mm; p = 0.72), implying no benefit to having used TEE in these patients. We also compared the individual scaled diameters of this subset of patients against their balloon stop flow diameters and again found a strong correlation (Fig. 5).

Procedural success was 100% (19 of 19) in both study groups. There were no major complications in either group. There were a total of 5 minor complications, 1 in the TTE group (5%) and 4 in the TEE group (21%; p = 0.35), as described in Table 3.

In the TTE group, 1 patient experienced a brief episode of accelerated junctional rhythm while in recovery. He

Table 2. Hemodynamic and Echocardiographic Data

	TEE Group	TTE Group	p Value
Qp/Qs	1.79 ± 0.59	1.87 ± 0.49	0.65
PVR, Wood units × m ²	1.03 ± 0.43	0.95 ± 0.47	0.57
Device size, mm	16.0 ± 4.94	16.37 ± 5.05	0.82
Mean defect size (2D imaging), mm	14.11 ± 5.07	13.81 ± 4.56	0.85
TEE stop flow vs. TTE scaled, mm	15.35 ± 4.62	16.57 ± 5.47	0.46
Scaled TTE diameter, mm	14.82 ± 4.6 (n = 13)	16.57 ± 5.47	0.35

Values are mean ± SD.
2D = 2-dimensional; PVR = pulmonary vascular resistance; Qp/Qs = total pulmonary to systemic output ratio; other abbreviations as in Table 1.

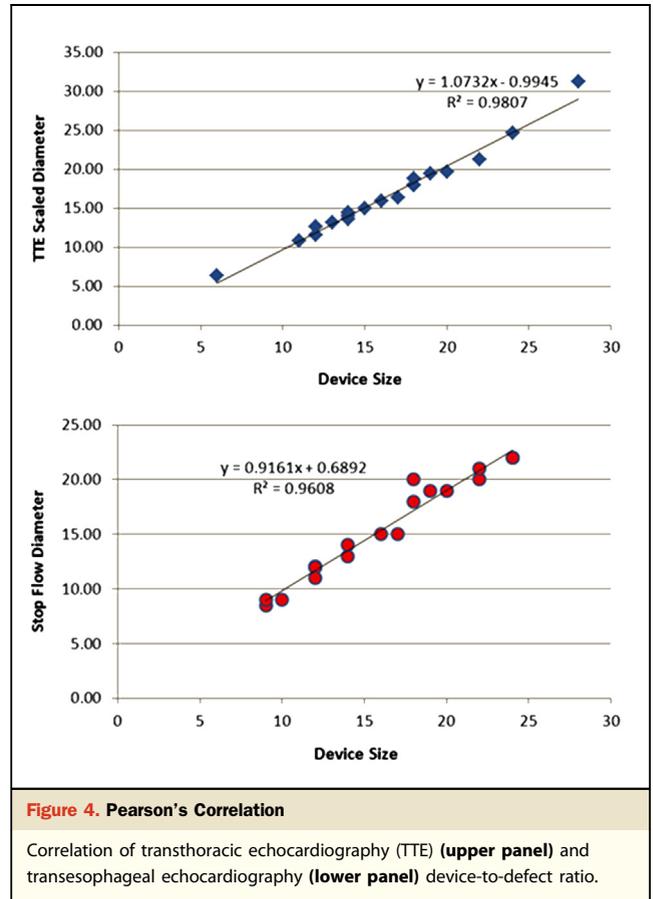


Figure 4. Pearson's Correlation

Correlation of transthoracic echocardiography (TTE) (upper panel) and transesophageal echocardiography (lower panel) device-to-defect ratio.

received a single dose of propranolol, which terminated the tachycardia without recurrence. The 3 measurements obtained of his defect were 15, 16, and 17.5 mm (average 16.17 × 1.2 = 19.4 mm), as described in the Methods section. Based on these measurements, a 19-mm ASD was successfully deployed. All follow-up ECGs, as well as a Holter study, were normal at 9 months of follow-up.

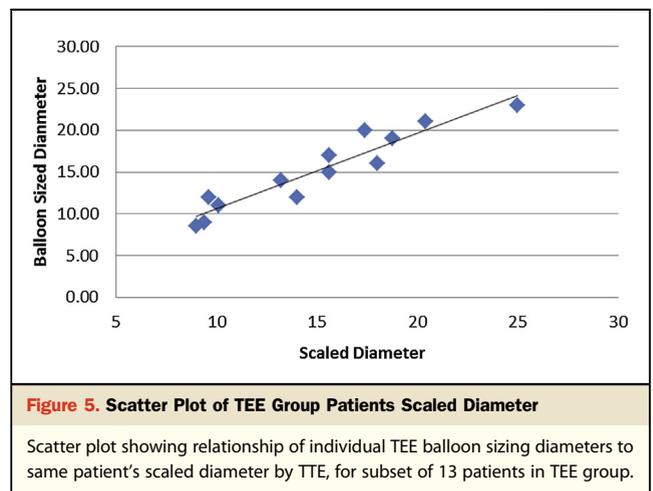


Figure 5. Scatter Plot of TEE Group Patients Scaled Diameter

Scatter plot showing relationship of individual TEE balloon sizing diameters to same patient's scaled diameter by TTE, for subset of 13 patients in TEE group.

Table 3. Complications

Patient#	Modality	Age (Years)	Weight (kg)	Complication	Device Size (mm)	ASD Average	ASD Fluoro Size (mm)	Follow-Up
1	TTE	2.5	14.2	Tachycardia in recovery	19	16.17	n/a	9 months
2	TEE	2	10	Hypotension	12	n/a	12.1	4 yrs
3	TEE	12.1	56.5	Brief atrial flutter	18	n/a	18	2 yrs 5 months
4	TEE	3.9	14.3	SVT/1° heart block	22	n/a	21	1 yr 7 months
5	TEE	3.75	15.4	Pericardial effusion	24	n/a	22	4 months

ASD = atrial septal defect; SVT = supraventricular tachycardia; other abbreviations as in Table 1.

In the TEE group, Patient #2 experienced a period of hypotension during the procedure and was started on a dopamine infusion by the anesthesiologist. He recovered with no further sequelae. Patient #3 had a brief episode of hemodynamically insignificant atrial flutter while establishing wire position. He was electrically cardioverted without further incident. Patient #4 had a very brief episode of supraventricular tachycardia during the case, which self-resolved. While the patient was in recovery, an ECG was performed that showed first-degree heart block. This was resolved by the next morning's repeat ECG. The patient was discharged and has not had a recurrence of the supraventricular tachycardia or first-degree heart block in 19 months of follow-up. Finally, Patient #5 exhibited a new, although trivial, pericardial effusion on his 1-month follow-up TTE. This was resolved, without treatment, on a repeat TTE at 2 months post-procedure.

There were statistically significant reductions in procedure time, room time, and fluoroscopy time in the TTE group (Table 4). The rates of shunt resolution were also similar in both groups at 1 day, 1 month, and long-term follow-up between 6 and 12 months (Table 5).

Discussion

As early as 1990, the use of TEE for transcatheter guidance of ASD closure has been described and shown to be feasible (10). The fact that TEE quickly became the preferred modality employed is in large part due to the momentum garnered by its required use in the pivotal studies (2-5). As well, some believe that invasive imaging is simply better for evaluating an ASD because it may allow for improved visualization of thin membranes or other subtle structures (11).

Recently, echocardiography studies have reported on the use of intracardiac echocardiography (ICE) for procedural guidance of percutaneous ASD closure, and the use of ICE has been recommended (12-14). Although we agree TEE and ICE may provide better resolution in evaluation of cardiac structures, we have found that TTE alone is sufficient for evaluation of isolated secundum ASD and guidance of device selection and implantation in most patients with adequate windows.

Although relatively safe, TEE is a source of some additional patient risk and requires general anesthesia when used in children (15-18). ICE offers an alternative that does not require general anesthesia; however, it requires a second large venous access, which may not be possible in smaller patients, and also adds some additional risk.

Previously, we described the use of TTE for guidance of transcatheter ASD closure (6). Since that time, there have been only a few publications reporting the usefulness of TTE for this purpose (19,20). Zanjani et al. (20) recently published their experience, describing the usefulness of TTE, particularly in areas where TEE or ICE are not available. TTE is more widely available everywhere children are evaluated for ASD closure. Further, we believe that TTE use remains limited partly because of the dearth of studies demonstrating the safety and the efficacy of using it.

To date, there are no controlled, prospective, randomized studies related to the use of echocardiography in percutaneous ASD closure.

In our study, we demonstrated that using TTE images to calculate a "scaled" defect size and then using it to predict the device size needed gives similar results to use of the stop flow diameter by TEE. The 3 perpendicular imaging planes we used for making our measurements, we feel, represent an accurate circumferential diameter of the defect, similar to balloon sizing. We derived our scaled formula after review of

Table 4. Modality Characteristics

	TEE Group	TTE Group	p Value
Procedure time, min	70.63 ± 22.98	51.05 ± 17.61	0.0056
Room time, min	126.84 ± 28.41	95.74 ± 20.53	0.0004
Fluoroscopy time, min	13.57 ± 6.17	8.99 ± 8.45	0.007
Contrast, ml	2.41 ± 4.00	0.89 ± 1.45	0.12

Values are mean ± SD
 Abbreviations as in Table 1.

Table 5. Shunt Resolution

	TEE	TTE	p Value
1 day	12/19	11/19	1.0
1 month	12/18	12/18	1.0
6-9 months	15/15	16/17	1.0

Values are n/total n.
 Abbreviations as in Table 1.

previous large studies that reported device-to-defect ratios ranging from 1 to 1.4 (2,4,9) and from the long-time personal observations of the senior author.

Our study suggests that TTE may be as safe and effective as TEE in the assessment and guidance of ASO delivery for ASD device closure, in a select group of patients. TTE may also offer the added benefit of significantly reduced exposure to fluoroscopic radiation and obviates the need for an additional cardiologist in the catheterization laboratory to perform the procedure. There is also the possible benefit of eliminating the requirement for general anesthesia. This, combined with the significantly shorter room and procedure times and reduced personnel and equipment requirements, may provide significant cost reductions, which merit further study.

Study limitations. Patient selection for adequate TTE windows is subjective and may vary between operators. The small sample size of our study is also a limitation, and more research is needed to confirm these results and validate the scaled diameter. Method is limited to only isolated secundum defects and not for multiple ASDs.

Conclusions

The results of this study suggest that TTE may be as efficacious and safe as TEE for assessment and guidance of transcatheter ASD closure with the ASO in children with adequate TTE windows. In addition, use of TTE appears to have cost and safety advantages because of shorter room, procedure, and fluoroscopy times. The study results support use of less invasive, less costly TTE in selected patients undergoing ASD closure with the ASO.

Reprint requests and correspondence: Dr. Sergio Bartakian, Rady Children's Hospital/University of California, San Diego, Pediatric Cardiology, 3020 Children's Way, MC 5004, San Diego, California 92123. E-mail: nyyankeedr@yahoo.com.

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Key Words: atrial septal defect ■ defect sizing ■ device closure ■ echocardiogram.