Intracardiac Echocardiography Guided Device Closure of Atrial Septal Defects

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OBJECTIVES
This study was designed to determine the feasibility and accuracy of intracardiac echocardiography (ICE) in guiding percutaneous closure of atrial septal defects (ASD).

BACKGROUND
Intracardiac echocardiography is a novel imaging technique that might be used to guide interventional procedures. The sensitivity and specificity of ICE, compared to standard imaging techniques, in detecting potentially adverse procedural events and guiding remedial action will be an important consideration in its use.

METHODS
In a prospective study, 24 patients underwent device closure of ASD using ICE as the primary echocardiographic imaging modality. Feasibility was expressed as proportion of cases in which complete diagnostic ICE imaging was achieved. Accuracy was expressed as the percent agreement between ICE and simultaneously performed transesophageal echocardiography (TEE).

RESULTS
High-quality ICE images were acquired in all patients, though images were limited in two patients with aneurysmal septa. Intracardiac echocardiography successfully guided closure of 24 out of 25 ASDs (96%) in 23 patients. There was close agreement between ICE and TEE in their assessment of device position and the adequacy of septal capture before device release (98%) and in identifying the presence of significant residual shunts. Intracardiac echocardiography detected all potentially adverse events, including four malpositions, and guided appropriate remedial action.

CONCLUSIONS
Intracardiac echocardiography guided device closure of secundum ASDs is feasible in the majority of patients and provides diagnostic data comparable to TEE. These data indicate that ICE may be used to guide routine closure of ASDs in adults without the need for TEE and general anesthesia. (J Am Coll Cardiol 2003;41:285–92) © 2003 by the American College of Cardiology Foundation

Transcatheter closure of atrial septal defects (ASD) has been established as a safe and effective treatment modality, with excellent short- and medium-term results (1–3). During the procedure transesophageal echocardiography (TEE) is used to assess the defect with reference to size and position, adequacy of the septal rim, and proximity to surrounding structures, and to ensure satisfactory deployment of the device before its release from the delivery system. Because of the discomfort associated with TEE and the need for adequate airway protection in the supine patient, the procedure is usually performed under general anesthesia with endotracheal intubation, which adds additional time, complexity, and cost to the procedure.

The recent development of intracardiac echocardiography (ICE) has added a further dimension to the imaging modalities available to cardiologists (4). With the transducer positioned in the right heart, ICE accurately delineates cardiac anatomy and has been used to guide transseptal needle punctures (5). Advantages of currently available ICE transducers include high-quality near-field imaging, the ability to achieve multiple image planes using a steerable quadrudirectional catheter, and full-color flow and Doppler capabilities. Early reports in a small number of patients have suggested that ICE may be useful in guiding the percutaneous closure of ASDs, avoiding the need for TEE and general anesthesia (6). However, no systematic assessment of the utility of ICE in this capacity has been reported. We therefore prospectively assessed the feasibility and accuracy of ICE in guiding the percutaneous closure of secundum ASD and assessing the success of device deployment.

METHODS
Consecutive patients referred to the University of Toronto Congenital Cardiac Centre for Adults for device closure of a secundum ASD were eligible for the study. Before the procedure all patients had undergone a TEE examination to determine the number, position, and size of the defect(s). Patients with a secundum ASD (diameter <40 mm) with an adequate circumferential rim were considered suitable for device closure. Defects were classified on the basis of their size and their proximity to the aorta (central defects aortic rim >5 mm, anterosuperior defects aortic rim <5 mm). The septum was deemed to be aneurysmal if the total excursion throughout the cardiac cycle was >15 mm. The study was approved by the University Health Network research ethics committee and all patients gave informed written consent.

Study protocol. The procedure was performed under general anesthesia, with the image intensifier positioned with a 30° left anterior oblique and 30° cranial tilt throughout the
procedure. All patients were administered heparin 3,000 IU/kg and antibiotic prophylaxis (1 g Cephalexin) during the procedure. Intracardiac echocardiography was used as the primary echocardiographic imaging modality to assess the anatomy of the intraatrial septum and surrounding structures before attempted closure of the defect, to guide deployment of the occluding device, and to assess its position after release. The feasibility and accuracy of ICE in assessing the salient features of the procedure and determining a successful outcome were assessed by sequential independent TEE examinations performed during the procedure. Both the ICE and TEE operators were blind to the findings of the other modality.

**ICE.** An 11-F valved sheath was inserted percutaneously into the right femoral vein and a 3.3 mm (10F) diameter Acuson ICE transducer interfaced with a Sequoia ultrasound system (both Acuson, Mountainview, California) was advanced into the right atrium (RA). The catheter has a quadridirectional steerable tip that houses a side-fringing, multiple-frequency (5 to 10 MHz) phased-array transducer, with two-dimensional and color Doppler imaging modes. The scan plane is along the axis of the catheter with a range of tissue penetration from 2 to 120 mm. Intracardiac echo images, similar to those derived from TEE, were obtained in the following sequence. On entering the RA the transducer was rotated anteriorly to obtain an image of the tricuspid valve (TV) and right ventricular (RV) inlet (Fig. 1A). The transducer tip was then flexed posteriorly and rotated clockwise to view the aorta and atrial septum in the long axis (Fig. 1B). Movement of the catheter cranially and caudally afforded excellent views of the superior and inferior aspects of the atrial septum (Fig. 1C). The course of the right-sided pulmonary veins could be easily imaged from the junction of the RA and superior vena cava by rotating the catheter clockwise. A short-axis image of the aortic valve and atrial septum was achieved by further posterior flexion and clockwise rotation of the transducer, such that the catheter tip was directed toward the TV (Fig. 1D).

**TEE.** Transesophageal echocardiography was performed using a multiplane TEE probe (3.5 to 5 MHz) and a Hewlett-Packard Sonos 2500 ultrasound system. Standard transverse (0° to 60°) and longitudinal (90° to 20°) views were acquired as previously described (7).

**ASD closure protocol.** Defects were closed percutaneously using an Amplatzer Septal Occluder (AGA Medical, Golden Valley, Minnesota) or Cardioseal device (NMT Medical, Boston, Massachusetts), using techniques previously described (1,8).

After the initial assessment of ASD anatomy, confirming its suitability for device closure, the stretched diameter of the defect was determined by fluoroscopy, using a 34-mm diameter contrast-filled sizing balloon (AGA Medical) inflated across the defect until a clear waist was visible. A long sheath was advanced over the guide wire to the left upper pulmonary vein and the distal disk of an occluding device of the appropriate size was deployed in the left atrium by withdrawal of the sheath. With a combination of ICE and fluoroscopy to guide the operator, the device was withdrawn until it abutted the atrial septum, and the right atrial disk was deployed by further withdrawal of the sheath. Once deployed, but before release, the device position was again assessed by ICE imaging (Fig. 2). Long- and short-axis views were used to assess adequacy of capture of the aortic, posterior, and caval rims of the defect. Color flow Doppler mapping was used to assess the presence of residual leaks and additional unrecognized defects. Devices that were deemed to be malpositioned were withdrawn within the sheath and redeployed. Once the operators were satisfied with device position, a further confirmatory TEE examination was performed. The interventional cardiologist remained blind to the results and images of the TEE study, other than receiving a verbal confirmation of the satisfactory position of the device before its release after corresponding ICE and TEE data were collected. After confirmation of a satisfactory device position, the device was released and further independent ICE and TEE examinations were performed. All adverse events that might affect the success of the interventional procedure were logged. In the event that the TEE indicated an unsatisfactory device position, a further assessment of the device position was made using ICE to ascertain the source of the conflicting results. A further attempt was made to redeploy the device if deemed appropriate using ICE, fluoroscopy, and TEE in an open fashion.

Patients were discharged taking aspirin 325 mg once per day to protect against thrombosis formation on the device. All patients were reviewed at six to eight weeks after device implantation with a clinical examination, transthoracic echocardiogram, and 12-lead ECG.

**Data analysis.** Identical analysis protocols were used for the TEE and ICE images. For each device the position was assessed in orthogonal transverse and longitudinal planes similar to the standard transverse (0 to 60°) and longitudinal (90° to 120°) TEE views. Satisfactory septal capture was assessed for both rims in each view using a combination of two-dimensional echocardiography and color flow Doppler. Before release of the device, septal capture was classified as satisfactory (septum visible between the right and left atrial discs and absence of color flow lateral to device margin) or unsatisfactory (device malposition with no obvious septum between discs or presence of residual leak with a color flow signal seen lateral to device in both the atria). A dichotomous variable was chosen, as this best represents the

### Abbreviations and Acronyms

- **ASD** = atrial septal defect
- **ICE** = intracardiac echocardiography
- **RA** = right atrium
- **RV** = right ventricle
- **TEE** = transesophageal echocardiography
- **TV** = tricuspid valve
Figure 1. Fluoroscopic position of the intracardiac transducer with corresponding echocardiographic images. (A) Long-axis view of the tricuspid valve (TV), right ventricle (RV), and right ventricular outflow tract viewed from the right atrium (RA). (B) Rotation of the catheter clockwise reveals a long-axis view of atrial septum and the left atrium (LA); color Doppler demonstrates an atrial septal defect. (C) Advancing the transducer cranially with slight posterior flexion reveals the sinus venosus septum, superior vena cava (SVC), and origin of the right upper pulmonary vein (RUPV). (D) Further posterior flexion and rotation of the transducer towards the TV provides a short-axis image of the aorta (Ao), atrial septum, and atrial septal defect.
decision-making process taken by the operator, in which information from a number of sources was integrated (position of the device, presence of visible septum between the discs, presence of color flow through or round the device) before a decision on device release or redeployment. After device release a similar detailed assessment was performed in two orthogonal planes using each modality, and assessed as no leak, residual leak (trivial, <4 mm; moderate, >4 mm), or device malposition (failure of septal capture).

The primary end point for this study was the agreement of ICE and TEE imaging in assessing the position of the occluding device before release, expressed as the percent agreement. Secondary end points were the agreement between ICE and TEE in the predeployment assessment of ASD anatomy with respect to the number of defects, their position and size, the adequacy of septal rims, postrelease assessment of device position, and the presence of residual leaks. Feasibility of ICE-guided device closure of ASDs was expressed as the proportion of cases in which complete diagnostic ICE imaging was achieved.

RESULTS

Twenty-four patients were entered in the study (6 men, 17 women, median age 43 [18 to 74] years). Individual patient demographics and characteristics of their ASD are given in Table 1. In one patient with significant right heart dilation but a poor-quality preprocedural TEE performed in an outlying hospital, only a small patent foramen ovale was found. Further assessment by ICE demonstrated anomalous drainage of the right-sided pulmonary veins to the RA. This finding was confirmed by angiography and TEE, and the patient was referred for surgery. In the remaining 23 patients, five (20%) had multiple defects, though in only two were the additional defects of sufficient size to warrant closure. Six patients (26%) had an aneurysmal intraatrial septum. Of the 25 ASDs considered for closure, the median (range) ASD size was 14 mm (range 4 to 24 mm); stretched diameter 22 mm (range 6 to 29 mm). Eleven ASDs (44%) were anterosuperior with a deficient aortic rim.

Twenty-four ASDs were closed using the Amplatzer Septal Occluder (median size 24 mm; range 6 to 26 mm). In one patient with a grossly aneurysmal septum and two small ASDs, a 40-mm Cardioseal device was deployed covering both defects. The median (range) procedure time, fluoroscopy time, and radiation dose were 79 (31 to 140) min, 9 (2 to 50) min and 2,768 (648-13,060) cGy/cm², respectively. Feasibility. High-quality ICE images of the atrial septum were achieved, with multiple views in transverse and longi-
tudinal planes, defining the anatomy of the posterior wall, the sinus venosus septum, and pulmonary venous drainage in all the patients (Table 2). Intracardiac echocardiography was used as the primary imaging modality to close 24 of the 25 (96%) ASDs where closure was attempted. In two patients with grossly aneurysmal atrial septa, there was some limitation in imaging the complete septum owing to its prolapse into the RA. In one case, early in the series (Patient 6), this necessitated use of TEE to monitor the device closure of a second defect, which was not well visualized with ICE. In a second patient (Patient 12), a second small defect identified by TEE was not seen with ICE. Despite this ICE was used to guide closure of a larger defect using a 40 mm Cardioseal device covering both defects and reducing aneurysmal movement of the atrial septum.

**Concordance of ICE and TEE.** There was a close agreement between ICE and TEE in the assessment of the number of defects in each patient (86%) and their position with respect to the aorta and vena cavae. The mean difference in the maximum diameter measured by ICE and TEE was 0.14 mm (range 7 to 6 mm).

There was close agreement (98%) between ICE and TEE in the assessment of device position and adequacy of septal capture before its release from the delivery system. In only two patients did the TEE assessment contradict that of ICE. In one patient, following a satisfactory assessment of device position by ICE, the device became dislodged while still attached to the delivery system during patient movement induced by lightening of the general anesthetic. Malposition of the device was noted during the subsequent TEE assessment, with both discs on the right atrial aspect of the aortic rim and the presence of a large paraseptal residual leak. On subsequent reassessment with ICE this malposition was easily demonstrated and noted to be different from the original position. The device was redeployed using ICE, and the subsequent TEE confirmed a satisfactory position. In a separate patient with a superior

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<th>Table 2. Feasibility of Intracardiac Echocardiographic Guided Device Closure of Atrial Septal Defects</th>
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<td>Uncomplicated vascular access</td>
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*In two patients with grossly aneurysmal IAS complete imaging was not possible with ICE. †Although not used to guide closure of one ASD, ICE was able to adequately assess the device once in situ.

ASD = atrial septal defect; IAS = intraatrial septum; ICE = intracardiac echocardiography.
ASD, the initial position of the device following deployment appeared suspect, with the appearance of both discs on the right atrial aspect of the aorta. On detailed examination with ICE, however, atrial septum could clearly be seen between the discs, and it appeared that the device itself was compressed between the aorta and superior caval vein. Transesophageal echocardiographic images were similar, though the lower resolution did not demonstrate septum between the device disks. Although no significant color flow leak could be detected, the TEE operator considered the device to be malpositioned. The device was therefore redeployed using ICE, but a very similar appearance was apparent. After further assessment, septal capture was considered satisfactory on the basis of ICE images, with septum seen coursing between the discs and the absence of a significant residual leak, and the device was released. Subsequent assessment with ICE and TEE confirmed satisfactory device position and occlusion of the defect with no residual leaks or superior caval vein obstruction.

Device redeployments and adverse events. A total of eight adverse events were logged in seven patients (Fig. 3). These were classified as procedural events that required remedial action, and if undetected would alter the integrity of the device closure. Intracardiac echocardiography imaging detected device malpositions in four patients before release of the device from its delivery system and guided appropriate redeployment in all cases. In addition, in one patient ICE imaging identified a large additional ASD that had not been detected by TEE. In one patient with a grossly aneurysmal intraatrial septum and multiple fenestrations, ICE imaging did not adequately demonstrate the anatomy of a second small ASD. In this case TEE was used to guide deployment of a 6-mm Amplatzer septal occluder. No malpositions or adverse events were noted by TEE that were not initially detected using ICE, and all devices implanted remained in a satisfactory position at six weeks follow-up by transthoracic echocardiography.

Assessment after device release. Following release, the device position was confirmed as being satisfactory in all cases by ICE and TEE (100% agreement). A residual leak was detected in eight patients by TEE (6 trivial; 2 moderate), and of these, four (50%) were also detected by ICE, including both moderate leaks. In the other cases the leaks seen on TEE appeared to be related to small additional defects. In one patient with a windsock atrial septum, with at least two defects, a second defect was not seen on ICE but
was noted on TEE and transthoracic echocardiography at follow-up.

Follow-up. At six-week follow-up all devices were reported to be in a satisfactory position. Of the eight patients in whom a leak was noted immediately post deployment, this was still apparent in six patients.

Complications. The ICE transducer passed easily to the RA in all patients, generally without the use of fluoroscopy, and was not associated with additional discomfort. One patient developed atrial tachycardia on introduction of the transducer into the RA and again during manipulation of either transducer or catheter within the heart. This spontaneously reverted to sinus rhythm during the case and did not impact on the quality of ICE imaging. There were no significant vascular complications, though one patient, in whom ICE was used as the only imaging modality, developed an area of parasthesia over the lateral aspect of the right thigh two days after discharge consistent with a palsy of the lateral cutaneous nerve of the thigh. Vascular ultrasound did not demonstrate a hematoma with normal patency of the both the femoral artery and vein. Despite this, at the time of the six-week follow-up visit the symptoms had not fully resolved. One patient developed atrial fibrillation two weeks after successful implantation of a 28-mm Amplatzer septal occluder. This patient subsequently reverted to sinus rhythm and has remained stable since.

DISCUSSION

In this study we have assessed the accuracy and feasibility of ICE imaging in guiding device closure of secundum ASDs. High-quality images of the intraatrial septum and surrounding structures were achieved in all patients and ICE was used to successfully guide the closure of a wide range of defects. A close agreement between ICE and TEE in their assessment of the adequacy of device position was found and ICE detected all the procedural events that might have impacted on the success of the implantation and guided appropriate remedial action. These data indicate that ICE may be used to guide routine closure of the majority of ASDs in adults without the need for TEE and general anesthesia.

The utility of ICE in guiding interventional procedures will depend on feasibility with which images of diagnostic quality are achieved in the majority of patients and the sensitivity and specificity with which adverse procedural events are detected. During device closure of ASDs, the most significant imaging issue is malposition of the device, whereby the rim of the atrial septum has not been adequately captured and, if released, can result in device embolization. In this instance surgical extraction may be necessary. Inaccurate sizing or poor device positioning might also result in residual leaks. An additional important role of periprocedural echocardiography is to demonstrate the presence of additional defects or fenestrations and to ensure that the device is free of the mitral and tricuspid valves and does not obstruct the pulmonary or systemic veins. In a small number of patients, Hijazi et al. (6) recently reported the use of ICE in the closure of ASDs and patent foramen ovales. The incidence of malpositions was not noted and therefore it is not possible to determine the accuracy of ICE in detecting such potentially adverse procedural events. In our larger study, which included unselected patients with large defects, multiple defects, and aneurysmal septa, high-quality ICE images of relevant anatomy were achieved in all patients, and ICE-guided device closure of ASDs proved feasible in all but one patient. There was a close agreement between ICE and TEE in the assessment of the device position at all stages of the procedure. Intracardiac echocardiography detected all the procedural events with potentially adverse consequences, including four malpositions, and guided appropriate remedial action. Furthermore, in two cases the ICE images proved superior to those of TEE in detecting the presence of an additional ASD and in confirming the satisfactory position of a device that appeared malpositioned on TEE.

The ICE transducer used in this study was introduced on the same side as the sheaths used for deploying the ASD occluding device, with no vascular complications in this adult population. Its high resolution and steerable tip facilitated the detailed assessment of the whole atrial septum, providing particularly good images of the sinus venosus septum and origin of the pulmonary veins. These areas are often difficult to image adequately with TEE because of its limited near field characteristics. Intracardiac echocardiography provided unobstructed views of the device, once deployed, allowed visualization of atrial septal tissue between the disks before its release, confirming the satisfactory capture of the device.

Limitations of ICE. We did not find any limitation in the use of ICE with large defects or with multiple defects. Indeed, ICE proved superior to TEE in detecting two additional ASDs located near the inferior vena cava–RA junction. Although ICE was used to successfully guide the closure of seven ASDs in patients with aneurysmal atrial septa, prolapse of the septum into the RA potentially limits a complete imaging examination. This was reflected in two patients with grossly aneurysmal septa in whom second defects, although detected by the preprocedure TEE, were not adequately imaged by ICE. In these patients the use of TEE may continue to be necessary. Further studies will be needed to ensure the accuracy and safety of ICE in patients with multiple defects or aneurysmal septa.

Study limitations. Although it was not the primary aim of this study, we found ICE proved accurate at delineating the anatomy of the atrial septum, the position and size of the defects, the adequacy of the rims, and the drainage of pulmonary veins. However, all of our patients had previously undergone TEE assessment of the suitability of their ASD for device closure, and the operators were not blind to the results of this study, which might have influenced their assessment. Furthermore, TEE itself has a number of
limitations, and further studies will be needed to assess the accuracy of ICE in assessing atrial septal anatomy compared to three-dimensional echocardiography or cardiac magnetic resonance imaging.

**Summary.** Intracardiac echocardiography is a safe technique that provides intracardiac ultrasound images of comparable quality to those derived from TEE. It facilitates the full assessment of cardiac anatomy and physiology relevant to device closure of ASDs in the majority of patients. We have demonstrated comparable accuracy and reliability of ICE and TEE in guiding device closure of ASDs. Intracardiac echocardiography detected all adverse events that were likely to affect the successful outcome of the procedure, and will facilitate the closure of ASD without the need for general anesthesia. This will increase the safety and tolerability of this procedure.

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