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## Intracardiac Echocardiography Is Superior to Conventional Monitoring for Guiding Device Closure of Interatrial Communications

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**Background**—This study sought to test whether intracardiac echocardiography (ICE) is superior to conventional monitoring in guiding device closure of interatrial communications (atrial septal defect [ASD] and patent foramen ovale [PFO]).

**Methods and Results**—Forty-four patients undergoing device closure of ASD (n=6) or PFO (n=38) were randomized to have the procedure guided by either ICE (group 1; n=22) or by transesophageal echocardiography (TEE) (group 2; n=22). All interventions were completed successfully. In 1 patient from group 2, atrial fibrillation occurred 1 day after device implantation; the patient was successfully cardioverted on the next day. There were no other complications. Fluoroscopy time (FT) ( $6.0 \pm 1.7$  minutes versus  $9.5 \pm 1.6$  minutes;  $P < 0.0001$ ) as well as procedure time (PT) ( $33.4 \pm 4.7$  minutes versus  $37.8 \pm 5.6$  minutes;  $P < 0.01$ ) were shorter in group 1 than in group 2. Group 2 patients required general anesthesia without (n=19) or with endotracheal intubation (n=3). In contrast, ICE allowed continuous monitoring of the whole procedure, including balloon sizing before device closure, without sedation.

**Conclusions**—ICE is a safe tool to guide device closure of PFO and ASD. Supine patients tolerate ICE better than TEE. ICE reduces FT and PT. ICE seems to be advantageous, especially when long continuous or repeated echocardiographic viewing is required. (*Circulation*. 2003;107:795-797.)

**Key Words:** heart septal defects ■ catheterization ■ echocardiography ■ imaging

Transcatheter closure of interatrial communications is an alternative to anticoagulant or antiaggregant therapy and surgical closure.<sup>1-4</sup> Since this method was first introduced, its safety has been improved, and the risk of recurrent embolic events is now lower.<sup>1,2,5-7</sup> Nevertheless, a certain risk of severe complications remains.<sup>8-11</sup> Some complications are the result of suboptimal device performance,<sup>6</sup> but they may also be related to discontinuous echocardiographic monitoring. Supine patients do not tolerate continuous monitoring with transesophageal echocardiography (TEE) well unless they are sedated or under general anesthesia. Intracardiac echocardiography (ICE) was proposed as an alternative method to guide percutaneous device closure.<sup>12,13</sup> Hypothesizing that ICE is superior to TEE, both techniques were compared with respect to their safety, fluoroscopy time (FT), procedure time (PT), and image quality.

### Methods

#### Patients

A total of 44 consecutive patients with patent foramen ovale (PFO) (n=38) or secundum atrial septal defect (ASD) (n=6) and a history of at least 1 thromboembolic event or a left-to-right shunt with a

$Q_p/Q_s$  ratio of  $\geq 1.5/1$  were scheduled for transcatheter closure. All patients were randomized to either continuous guidance by ICE (group 1; n=22) or guidance using brief episodes of TEE monitoring (group 2; n=22).

#### Echocardiographic Guidance

For ICE, the 10 F AcuNav-catheter (Acuson-Siemens Inc) was inserted via an 11 F sheath and advanced through the inferior vena cava into the right atrium (RA).<sup>14,15</sup> To permit adequate imaging of the interatrial septum (IAS) and its neighboring structures,<sup>16</sup> 2 standardized views were used: a longitudinal view showing the extent of the IAS from cranial to its distal margins (Figure 1a) and a perpendicular short-axis view to visualize the anterior part of the IAS and the transition to the ascending aorta (Figure 1b).

Group 2 patients received 5 mg of midazolam intravenously before introduction of the TEE-probe and continuous intravenous propofol at a rate of 5 to 10 mg/h to maintain general anesthesia without endotracheal intubation. Patients who did not tolerate the probe under this regime were intubated. ICE and TEE were performed with a Sequoia 256 ultrasound unit (Acuson-Siemens Inc).

#### Device Closure Protocol

In group 1, access for the ICE catheter was from the left femoral vein. Stretch size of the PFO or ASD was measured using balloon catheters (Arrow Corp and AGA Medical Corp) and an Amplatzer

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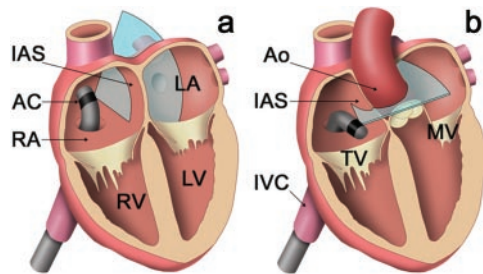
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**Figure 1.** Schematic drawing of the intracardiac echocardiographic approach to the interatrial septum: (a) longitudinal view of the IAS; (b) short-axis view, imaging the anterior part of the IAS and the transition to the ascending aorta. AC indicates transducer-tipped AcuNav catheter; Ao, aorta; IAS, interatrial septum; IVC, inferior vena cava; LV, left ventricle; MV, mitral valve; RA, right atrium; RV, right ventricle; and TV, tricuspid valve.

closure device (AGA Medical Corp) deployed as reported.<sup>1,17</sup> In group 1 patients, the procedure was primarily guided by ICE and was supplemented by fluoroscopy as needed. In group 2 patients, the procedure was primarily guided by fluoroscopy. To avoid endotracheal intubation, TEE was not employed in most patients until the ultimate phase of device closure. FT and PT were measured.

### Statistical Analyses

Parametric data were expressed as mean $\pm$ SD and tested with the unpaired 2-tailed Student's *t* test for group distinction. Nonparametric data were tested employing the  $\chi^2$  test with one degree of freedom. A value  $P<0.05$  was considered significant.

### Results

Between groups 1 and 2, there were no differences in age, sex ratio (data not given), and stretch size of the defects ( $9.3\pm 4.2$  mm versus  $9.0\pm 4.5$  mm, not significant). Group 1 included 4 ASDs and 18 PFOs, whereas group 2 included 2 ASDs and 20 PFOs. In group 1, ICE depicted 1 asymptomatic thrombus on the device. The patient received an additional 10 000 U of heparin. One group 2 patient developed atrial fibrillation 10 hours after device implantation. On the following day, the patient underwent successful cardioversion. No other complications, including any related to the ICE catheter or the 11 F sheath, were observed.

### Fluoroscopy and Procedure Times in Group 1 Over the Study Period

Parameters	No. of Cases			
	1 through 5	6 through 10	11 through 15	16 through 22
FT	$7.3\pm 1.9$	$6.9\pm 2.0$	$5.3\pm 1.1$	$4.8\pm 1.0$
PT	$38.8\pm 3.9$	$34.6\pm 3.5$	$32.4\pm 3.3$	$28.7\pm 4.3$

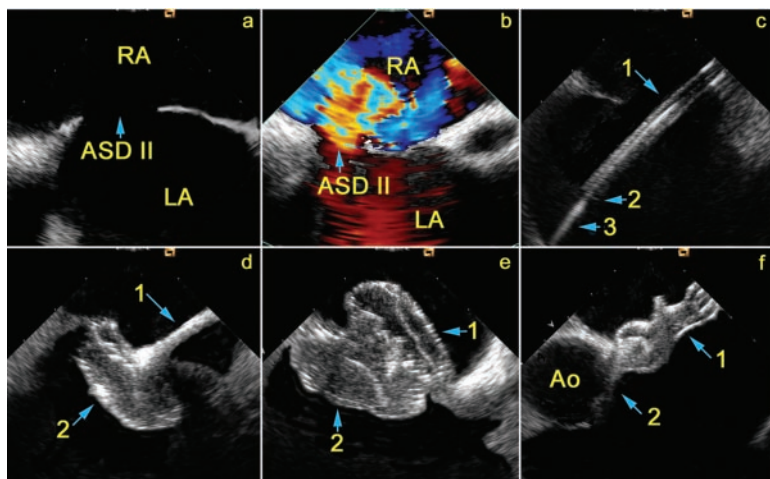
Values are presented as mean $\pm$ SD. FT indicates fluoroscopy time; PT, procedure time.

In group 1, no medication was required during the procedure. In 19 group 2 patients, TEE was tolerated without endotracheal intubation for 3 to 15 minutes ( $7.1\pm 3.1$ ), whereas 3 subjects needed to be intubated. In group 1, all diagnostic and most interventional stages could be completely guided by ICE (Figure 2a through 2f), including balloon sizing, unfolding of both countercluders, release of the device from the delivery cable, and the final check for adequate positioning and residual shunts. Other steps could be partially guided, eg, primary catheter passage of the interatrial communication and placement of the long sheath into the left atrium (LA). ICE image resolution was superior to that of TEE. ICE displayed specific details more clearly. The tip of the long sheath was clearly detectable when a wire was inside the sheath to facilitate adequate positioning, the occluder was observed not only during unfolding but also while being advanced through the sheath into the LA, and details of both countercluders and their spatial relation to the IAS and other structures were displayed (Figure 2f).

FT and PT were shorter in group 1 than in group 2 (FT:  $6.0\pm 1.7$  minutes versus  $9.5\pm 1.6$  minutes,  $P<0.0001$ ; PT:  $33.4\pm 4.7$  minutes versus  $37.8\pm 5.6$  minutes,  $P=0.0065$ ). In group 1, FT and PT shortened throughout the course of the study, indicating a learning curve (Table). ICE monitoring reduced patient stress significantly.

### Discussion

Many studies have shown that TEE can be used to guide closure of interatrial communications.<sup>18,19</sup> The present results show ICE to be superior to TEE: (1) Transcatheter closure, including the diagnostic part of the procedure, can be guided



**Figure 2.** Device closure of an ASD guided by ICE. A, ASD. RA indicates right atrium; ASD III, secundum atrial septal defect; and LA, left atrium. B, Significant left-to-right shunt. C, Long sheath with indwelling wire. 1 indicates long sheath crossing the septum; 2, tip of long sheath; and 3, wire. d, Unfolded left-sided countercluder. 1 indicates long sheath with folded right-sided countercluder inside; 2, unfolded left-sided countercluder. e, Unfolded countercluders with the device being pulled. 1 indicates unfolded right-sided countercluder; 2, left-sided countercluder. f, Final device position. Ao indicates aorta; 1, device after release from the delivery cable; and 2, aorta not affected.

continuously without need for general anesthesia; (2) fluoroscopy time can be shortened to less than 6 minutes, a factor of utmost importance in young patients, who are frequently candidates for device closure; (3) ICE results in much lower stress to patients than TEE; and (4) ICE depicts the individual morphology of the interatrial communication and the instrumentation needed for device closure in fullest detail. It is also likely that ICE increases the safety of device implantation. After implantation and before release, the occluder device can be pulled to make sure that the countercluders cannot tilt or slip to the contralateral side. This part of the procedure, considered the best technique to avoid unsatisfactory device position or embolization, can be displayed in detail with ICE (Figure 2e). Malposition and migration of the device into the circulation, as well as perforation and thrombus formation on the device, are known to occur at times.<sup>2,5,20</sup> Thrombus formation can be detected at a very early stage, permitting timely therapeutic decisions. Potential improvements with respect to safety and patient comfort may shed new light on the discussion of risks and benefits of device closure. The price of \$2500 US for one AcuNav catheter is a shortcoming, although the advantages of ICE seem to justify this expense.

### Limitations

The potential risks related to ICE could not be estimated at this time. In our experience, the risk potential is low and comparable to other invasive diagnostic tests. It is mandatory, however, that the ICE-catheter be handled with caution.<sup>16</sup> The fact that the catheter is not wire-guided makes it different from conventional ultrasound catheters and may present a potential risk. Thus, fluoroscopy is generally recommended to position the steerable ICE catheter into the RA. Any potential risk must also be compared with the risk associated with brief intermittent TEE monitoring, including the risk of aspiration in supine patients. The criteria defining differences in image quality between the 2 modalities are descriptive; image quality and patient tolerance were not quantitated. In group 1, device guidance was mostly accomplished with ICE, whereas fluoroscopy was the primary technique in group 2, limiting the comparability of the procedures.

### Conclusion

For guiding device closure of ASD and PFO, particularly when long continuous or repeated echocardiographic viewing is required or complications start to develop, ICE is superior to TEE. For the patient, procedural stress and radiation exposure are reduced, and the procedure is likely to become safer. Savings from shorter PT and from avoiding general anesthesia need to be weighed against the costs of the ICE catheter. After just a short learning curve, interventional cardiologists can fully benefit from the advantages of ICE.

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