



Intracardiac echocardiography: an ideal guiding tool for device closure of interatrial communications

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Received 12 December 2003; received in revised form 22 July 2004; accepted 27 July 2004

Available online 17 September 2004

KEYWORDS

Intracardiac echo;
Interatrial
communications;
Device closure

Abstract Background This study sought to evaluate safety and radiation exposure when using intracardiac echocardiography (ICE) in comparison to transesophageal echocardiography (TEE) in order to guide transcatheter closure of interatrial communications.

Methods Eighty patients (44 males, 36 females, mean age 46, SD 13 years) undergoing device closure of atrial septal defect ($n = 12$) or patent foramen ovale ($n = 68$) had the procedure guided by ICE ($n = 50$, group 1) or TEE ($n = 30$, group 2). In group 1, all procedural stages were completely guided by ICE, including imaging of the interatrial communication during balloon sizing, device unfolding and release, and during the final check for adequate positioning. In group 2, exclusive implantation of devices was guided by use of TEE.

Results Especially, the spatial relationship between device and cardiac structures (e.g. the ascending aorta, the interatrial septum and the superior vena cava) was accurately demonstrated in group 1. Image resolution provided by ICE was superior to that of TEE. No severe complications, including any related to ICE, were seen. Fluoroscopy time (FT) and procedure time (PT) were shorter in group 1 than in group 2 (FT: 5.5 ± 1.5 min vs. 9.3 ± 1.6 min, $P < 0.0001$; PT: 31.9 ± 4.6 min vs. 38.8 ± 5.8 min, $P < 0.01$). Neither sedation nor anesthesia was required in group 1. **Conclusions** ICE is a safe tool to guide device closure of interatrial communications. For the patient, procedural stress and radiation exposure are negligible.

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ICE can be considered the guiding tool of choice for device closure, particularly when long or repeated echocardiographic viewing is required.

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Introduction

During the last decade, device closure of interatrial communication has become a well established technique in order to prevent paradoxical embolism in patients with patent foramen ovale (PFO) and to adequately treat severe left-to-right shunt associated with atrial septal defect (ASD).^{1,2} Specific severe complications of transcatheter closure, the rate of which was reported to range between 1 and 4% depending on the device and the experience of the center,^{2–5} can possibly be avoided by improved echocardiographic monitoring of interventional device closure. Transesophageal echocardiography (TEE) is considered the standard approach to guide those interventions,⁶ but supine patients do not tolerate the transesophageal probe well, so that most centers use more or less extensive fluoroscopic imaging when performing device closure, although fluoroscopy cannot sufficiently depict the spatial relation between occluder device and cardiac structures next to the interatrial communication. Rapidly growing clots on the device are not shown either.

The aim of the present investigation was to evaluate if intracardiac echocardiography (ICE) is superior to TEE as a safe guiding tool for transcatheter closure of interatrial communications.

Methods

A total of 80 patients (44 male, 36 female, mean age 46, SD 13 years) with PFO ($n = 68$) or ASD ($n = 12$) were randomly selected for either continuous guidance by ICE (group 1; $n = 50$) or TEE guidance (group 2; $n = 30$). An 11 F sheath was required to introduce the 10.5 F AcuNav-catheter (Acuson–Siemens Inc.) for ICE. After venous puncture and introduction of an 11 F access sheath into the left femoral vein, the catheter was advanced into the right atrium and the probe aimed at the interatrial septum (Fig. 1). Two standardised views were used to get a sufficient overview of the complete defect including its rims and its spatial relation to the aorta and the superior vena cava as well as the right-sided pulmonary veins: longitudinal view showing the extent of the interatrial septum (IAS) from cranial to its distal margins and a perpendicular short-axis view to visualise the

anterior part of the IAS and the transition to the ascending aorta.⁷ Group 2 patients were sedated with 5 mg of midazolam and continuous intravenous administration of propofol at 5–10 mg/h. Patients who did not tolerate the probe under this regimen were intubated. A Sequoia 256 ultrasound unit (Acuson–Siemens Inc.) was employed for ICE and TEE. Amplatzer and Starflex occluder systems (AGA Medical Corp. and NMT Medical Inc.) were implanted as previously described.⁸ In group 1 patients, the procedure was primarily guided by ICE and was supplemented by fluoroscopy, whereas in group 2, the procedure was primarily guided by fluoroscopy and additionally monitored by TEE. Fluoroscopic time (FT), procedure time (PT) and image resolution were comparatively assessed.

Parametric data were given as mean \pm 1 SD and tested with the unpaired 2-tailed Student's *t* test for group distinction. Nonparametric data were tested employing the χ^2 test with one degree of freedom. A value $P < 0.05$ was considered significant.

Results

Age and sex ratio were not different between both groups. Group 1 included 8 ASDs and 42 PFOs and group 2 included 4 ASDs and 26 PFOs. In group 1, ICE depicted one early thrombus growing on the occluder device. Immediate treatment with

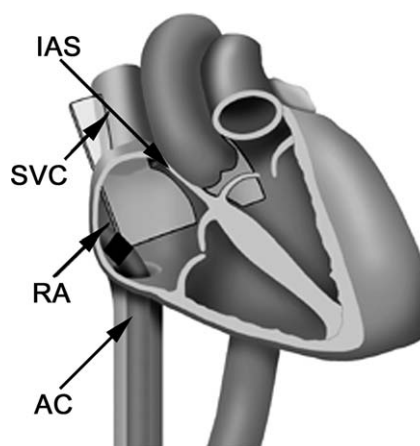


Figure 1 The AcuNav-catheter is introduced into the right atrium. AC = AcuNav-catheter, IAS = interatrial septum, RA = right atrium, SVC = superior vena cava.

10,000 U of heparin became therefore possible. Further complications, especially cerebral embolization could be prevented in this patient. No severe complications, including any related to ICE, were seen.

In group 2, 4 patients did not tolerate TEE and had to be intubated. The other 26 individuals tolerated the TEE probe for 3–18 min during device implantation. Neither sedation nor general anesthesia was required in any group 1 patient, and all procedural stages were completely guided by ICE (Figs. 2 and 3), including imaging of the interatrial communication during balloon sizing, device unfolding and release, and during the final check for adequate positioning. Other procedural steps were partially guided, e.g. catheter passage of the communication, placement of a wire into the left upper pulmonary vein, and placement of the long sheath with its distal opening inside the left atrium (Fig. 4). Especially, the spatial relationship between device and cardiac structures (i.e. the ascending aorta, the IAS and the superior vena cava) was accurately demonstrated. In addition, it was shown that the counterclaspers of the device had really engaged the IAS (Fig. 5).

FT and PT were found to be shorter in group 1 than in group 2 (FT: 5.5 ± 1.5 min vs. 9.3 ± 1.6 min, $P < 0.0001$; PT: 31.9 ± 4.6 min vs. 38.8 ± 5.8 min, $P < 0.01$). Compared to TEE, ICE reduced patient stress and improved compliance. With respect to the image resolution, particular details, e.g. the guide wire inside the long sheath or the membrane inside the counterclaspers of an Amplatzer closure device, could be clearly depicted by ICE, but not by TEE. All patients underwent a follow-up TEE 6 months after device

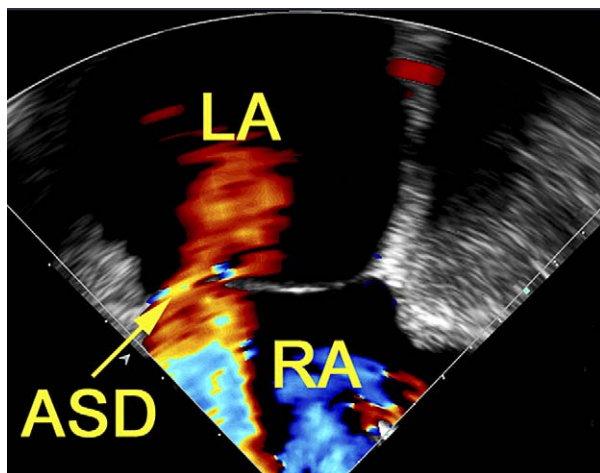


Figure 2 Atrial septal defect with characteristic left-to-right shunt. ASD = atrial septal defect and left-to-right shunt, LA = left atrium, RA = right atrium.

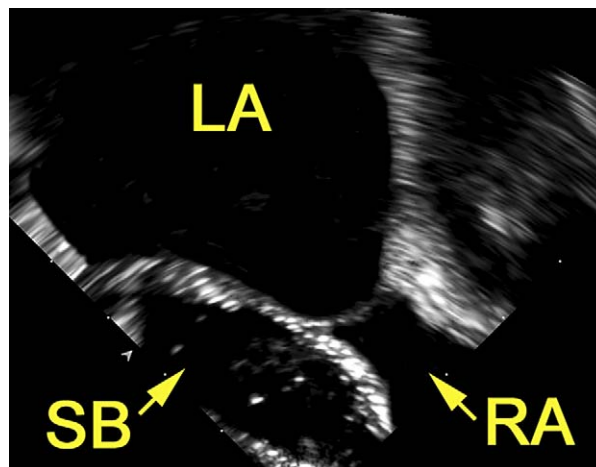


Figure 3 Balloon sizing of an atrial septal defect. LA = left atrium, RA = right atrium, SB = sizing-balloon.

closure. There was no dislocation of a device. In all cases, the septum-primum parts as well as the septum-secundum parts of the IAS were correctly engaged in between the left-sided and the right-sided umbrellas. In both groups, no residual shunt could be detected by use of colour Doppler. After administration of non-transpulmonary contrast agent, 3 patients of group 1 and 4 patients of group 2 showed slight right-to-left shunt. There was no significant difference between both groups ($P > 0.05$).

Discussion

The present results demonstrate ICE monitoring in transcatheter device closure to be superior to

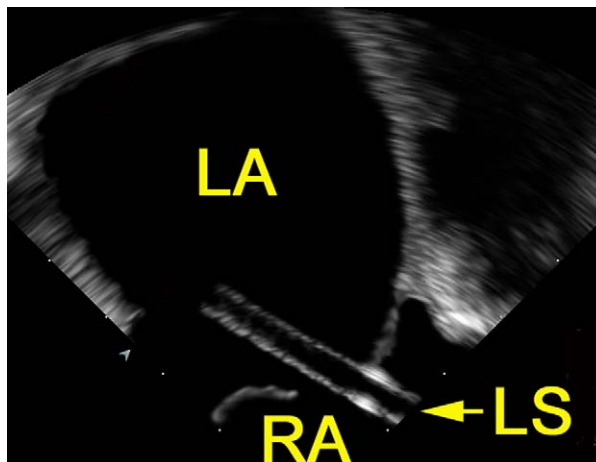


Figure 4 The long sheath does not interfere with the left atrial wall. LA = left atrium, LS = long sheath, RA = right atrium.

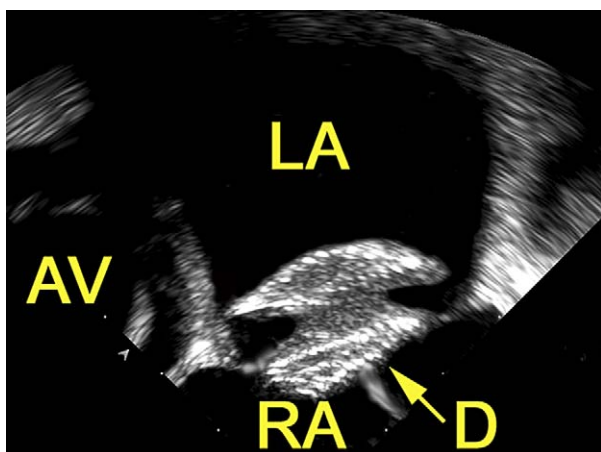


Figure 5 Occluder device connected to a delivery cable is being pushed towards the left atrium in order to make sure that it cannot embolize into the systemic circulation. AV = aortic valve, LA = left atrium, D = device, RA = right atrium.

conventional TEE. They confirm and broaden the messages of previous investigations^{7,9,10} showing the suitability of ICE to safely guide interventional therapy in interatrial communications. TEE requires general anesthesia with or without endotracheal intubation, whereas ICE permits unlimited echocardiographic viewing in fully conscious and compliant patients. This is of utmost importance, since malposition and migration of the device into the systemic or pulmonary circulation as well as perforation of the cardiac wall and rapid thrombus formation on the device are known to occasionally occur.^{1,3,4,11} This new echocardiographic approach depicts the individual morphology of interatrial communications and the instrumentation needed for the closure procedure in fullest detail. It provides a much better image resolution than TEE and therefore also facilitates the procedure for the interventional cardiologist, particularly when long continuous or repeated echocardiographic viewing is required or when complications begin to develop. ICE results in much lower procedural stress to the patient, and FT as well as PT can be shortened. It also facilitates and shortens balloon sizing of interatrial communications (Fig. 3). Increasing the safety of device implantation and reducing radiation exposure and procedural stress for the patient can be considered major advantages of intra-procedural monitoring by ICE.

Employment of ICE would also be desirable in the pediatric population. Especially in young individuals, reduction of radiation exposure is of utmost importance. Beside that, the risk of

oesophageal injury from TEE probe insertion must also be considered an unresolved problem in small children. First experiences show that ICE represents a feasible and easy approach to also guide device closure in children and adolescents.¹⁰

As a result, it is likely that ICE improves the safety of interventional device closure in interatrial communications, so that this technique should replace TEE as a guiding tool not only in adults but also in adolescents and children. To our knowledge, no complications related to ICE have been reported up to now. Nevertheless, the potential risks related to ICE cannot be finally estimated at this time. Although the risk potential seems to be low, it is mandatory that the ICE-catheter is handled with caution, since it is not wire-guided what makes it generally different from conventional intravascular ultrasound catheters. Thus, fluoroscopy is recommended to safely introduce the steerable ICE-catheter into the right atrium. An even smaller version of the ICE-catheter would probably lead to more frequent use of ICE guidance. Although the expenses for the AcuNav-catheter remain an important shortcoming, certified reesterilization of the catheter is now being offered by different companies for the European Community. This way, the costs for one single application of ICE lessens to less than 1000 €, what may also improve acceptance. Nevertheless, some limitations inherent to this technique must be taken into account. That the catheter is not wire-guided makes its handling different from conventional catheter procedures. Therefore, a training including an animal experimental part offered by the manufacturer is strongly recommended in order to employ this catheter safely and effectively. In addition to that, the setting of the ultrasound unit must be particularly adjusted to optimal profit from ICE-imaging of the interatrial septum, the left atrium, and the pulmonary veins. Thus, the interventionalist handling the ICE-catheter must also be experienced in echocardiography. If this is not sufficiently the case, he should consult a colleague for interpretation of the echocardiographic images and even for adjustment of the ICE-catheter. Although large venous punctures are not necessarily expected to cause major complications, we recommend 2–6 h observation.

In conclusion, ICE can be considered a safe tool for guiding device closure of PFO and ASD. Supine patients tolerate ICE much better than TEE. ICE also reduces FT and PT and seems to be advantageous, especially when extended echocardiographic viewing is required. The

advantages of ICE seem to justify the expense for the catheter.

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