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Experience with Intracardiac Echocardiography for Guiding Transcatheter Device Closure of Atrial Septal Defects

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ABSTRACT

Background and Objectives : Phased-array intracardiac echocardiography (ICE) is a novel method for monitoring intracardiac procedures. We report our initial experience with ICE for guiding transcatheter device closure of atrial septal defects (ASD). **Subjects and Methods :** From April 2004 to March 2005, ICE was performed in 27 consecutive patients during percutaneous device closure of ASDs. The procedural feasibility, the procedure time, the fluoroscopic time, and the complication rate were compared with 27 prior cases that had utilized transesophageal echocardiography. **Results :** The procedure was performed successfully in all patients. The total procedure time (PT), device deployment time (DT), and fluoroscopic time (FT) were 65.7±22.3, 30.4±23.8, and 12.1±6.4 minutes for the study group, and 73.6±23.7, 29.8±16.1, and 11.9±6.0 for the control group, respectively, with no significant difference between the groups. However, PT and DT were significantly shorter in the later 14 cases of the study group compared to the 13 initial cases (52.1±10.9 and 13.2±4.2 vs. 80.3±22.4 and 48.8±22.2, $p<0.01$, respectively). These differences were also significant compared to the control group, suggesting that there was a learning curve for the procedure. **Conclusion :** ICE is a feasible and relatively safe method for monitoring and guiding percutaneous transcatheter closure of ASDs, but a learning period can be expected to achieve better proficiency. **(Korean Circulation J 2006;36:612-616)**

KEY WORDS : Echocardiography ; Heart septal defects, atrial ; Heart catheterization.

Introduction

Since its first introduction in 1976, transcatheter device closure of atrial septal defects (ASDs) has become a widely used method that is replacing the need for surgical correction of this congenital anomaly,[1)2)] and it has taken place as one of the most important methods for ASD closure.[3)4)] The success of this procedure depends on effective measures for candidate identification and monitoring the safety and adequacy of the procedure; transesophageal echocardiography (TEE) has been used most popularly for this purpose.[5)] However, when using TEE for this purpose, general anesthesia is needed because the length of the procedure requires prolonged positioning of the transesophageal probe. This increases the procedure duration and adds additional concerns of safety with associated anesthesia and esophageal injury.[6)] Furthermore, in some cases, TEE does not allow for sufficient visualization of areas that are critical to the success of the procedure.

The development of intracardiac echocardiography (ICE) dates back to the early days of echocardiography.[7-9)] However, a technique that sufficiently enables the visualization of intracardiac structures has been introduced only recently with the introduction of phased-array transducers.[10-12)] With this method, interventional cardiologists have been able to receive guidance to provide safer and more successful transcatheter interventions.[11-14)] This report presents our initial experience in Korea with the ICE technique for guiding transcatheter device closure of ASDs.

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Subjects and Methods

The subjects were 27 consecutive patients with the dia-

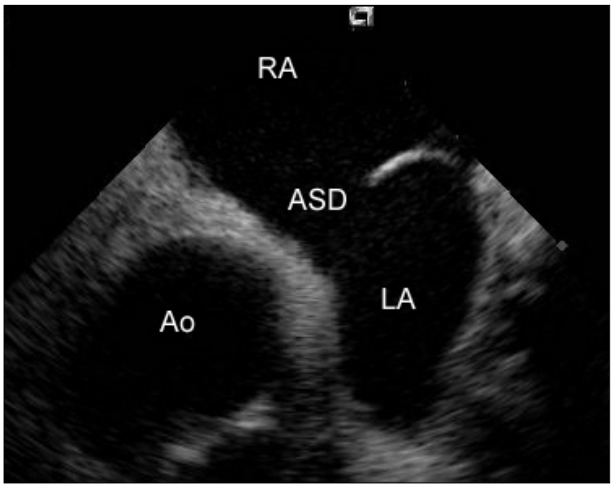

Fig. 1. View of the ASD as visualized by intracardiac echocardiography. RA: right atrium, LA: left atrium, Ao: aorta, ASD: atrial septal defect.

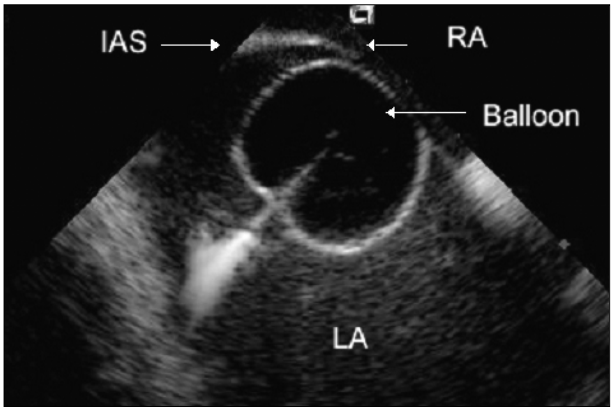

Fig. 2. Balloon sizing of the ASD guided by intracardiac echocardiography. The sizing balloon is placed in the left atrium, pulled against the inter-atrial septum and gradually deflated until the balloon is pulled through the defect into the right atrium. The size of the balloon at the moment of passing is measured. RA: right atrium, LA: left atrium, IAS: interatrial septum, ASD: atrial septal defect.

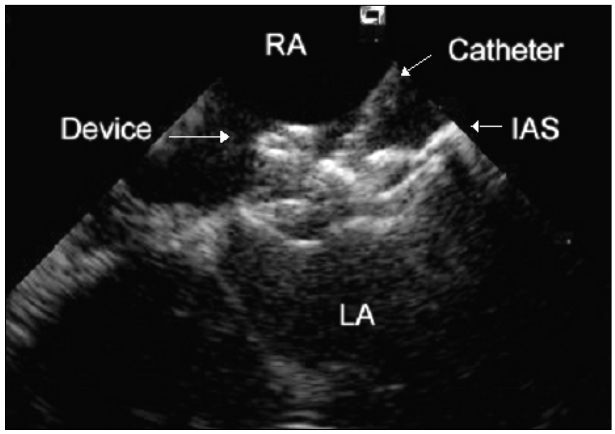

Fig. 3. Monitoring of the closure device deployment with intracardiac echocardiography. RA: right atrium, LA: left atrium, IAS: interatrial septum.

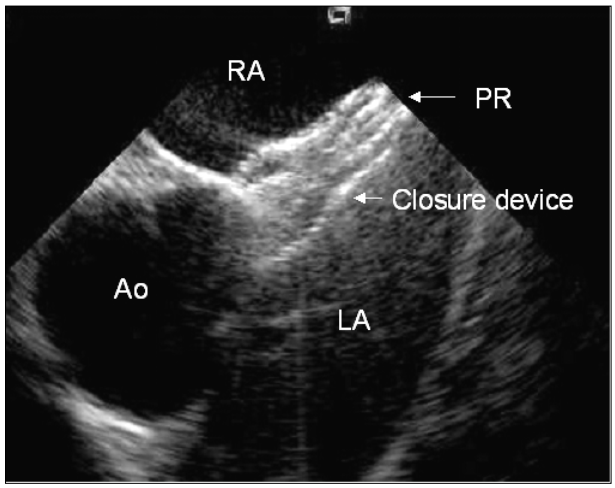

Fig. 4. ICE view of the closure device immediately after deployment, showing the device placed stably with the posterior rim of the defect set between the two arms of the device. RA: right atrium, LA: left atrium, Ao: aorta, PR: posterior rim of the interatrial septum, ICE: intracardiac echocardiography.

gnosis of ASD or patent foramen ovale (PFO) who visited Samsung Medical Center between April 2004 and March 2005 and received transcatheter device closure with ICE guidance. For comparison, 27 patients who received the same intervention but with the use of TEE between April 2003 and March 2004 were selected as controls. We followed the guidelines set by the ethical committee for human research at our institution and all subjects provided informed written consents.

For ICE, the 10-french, 90-cm long AcuNav catheter (Acuson-Siemens, Mountain View, CA, USA) was used, and the images were visualized and collected with the Cypress system at 7 MHz (Acuson-Siemens, Mountain View, CA, USA). Venous puncture was performed at the left femoral vein, and an 11 F access sheath was introduced. The ICE catheter was introduced through the sheath and the transducer was placed in the right atrium. Views of various angles of the ASDs were obtained (Fig. 1) and the catheter was fixed to obtain sufficient visualization of the defect and its relationship to adjacent structures such as the aorta and the superior vena cava. The Amplatzer occluder device (AGA Medical Co., Golden Valley, USA) was implanted as previously described,[4] and ICE was used to guide the defect size estimation via a balloon catheter (Fig. 2), the device deployment procedure (Fig. 3), and adequate device positioning (Fig. 4). The total procedure time (PT: The total duration of the procedure beginning from patient preparation until the removal of all intravascular catheters), the device deployment time (DT: The duration between sizing of the defect and the end of the device deployment), and the fluoroscopic time (FT: the total duration of exposure to fluoroscopy) were assessed and compared with those of the control group. In the control group, all patients received general anesthesia with propofol-fentanyl induction/maintenance and endotracheal intubation. TEE was performed with a 7-MHz multiplane

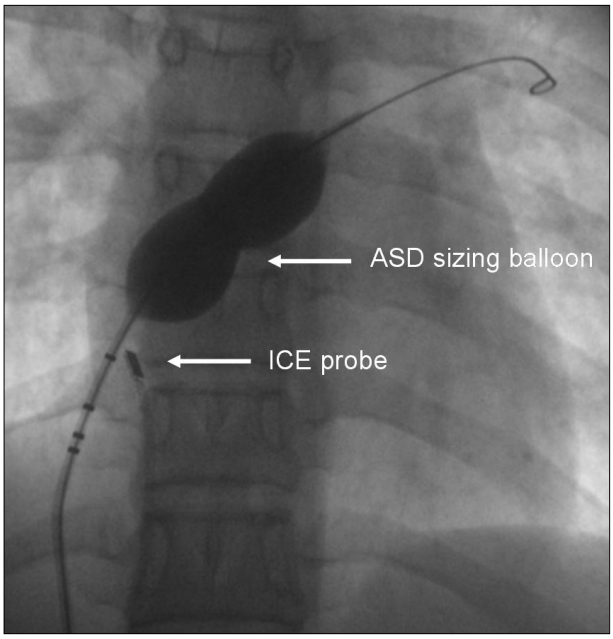

Fig. 5. Fluoroscopic view of the intracardiac echocardiographic catheter and the sizing balloon for the closure device relative to each other. ICE: intracardiac echocardiography, ASD: atrial septal defect.

TEE transducer connected to the Phillips 5500 echocardiographic system (Philips Medical Systems, Andover, MA, USA). The parametric data are presented as mean±standard deviation and tested with the Student's T-test for group distinction; a p of below 0.05 was considered significant.

Results

The mean age of the subjects who received ICE was 29±20 years (range: 3-59), and the gender ratio was M : F=8 : 19; there was no significant difference compared to the control group (mean age 32±20, M : F=6 : 14, p=NS).

The PT, DT, and FT were 65.7±22.3, 30.4±23.8, and 12.1±6.4 minutes, respectively, for the group who received ICE, and 79.4±25.4, 32.4±16.7, and 14.3±5.5 for the control group. Overall, the PT was significantly shorter for the ICE group, but no significant difference was found for the DT or FT. We divided the group that received ICE into two halves: The earlier cases, which were cases that were performed from April to September 2004 (N=13), and later cases, which were performed from October 2004 to March 2005 (N=14). When the same data were compared separately, the PT and DT for the later group were significantly shorter than for the earlier group (Table 1). Furthermore, these durations were significantly shorter for the later group compared to those of the control group; this included the FT that was also significantly shorter for the later cases as compared to the control group (Table 1). In fact, the DT was significantly longer in the earlier group compared to that of the control group, suggesting that a learning curve for the procedure that improved with the duration of the procedure was present due to improvement in operator proficiency in the later group.

Table 1. Comparison of the total procedure time, the device deployment time and the fluoroscopic time between the ICE group and the TEE group. The earlier and later ICE cases are evaluated separately against the TEE group. All durations are presented in minutes

	N	PT	DT	FT
ICE group (overall)	27	65.7±22.3	30.4±23.8	12.1±6.4
Earlier cases	13	80.4±22.3	48.8±22.2*	14.2±8.4
Later cases	14	52.1±10.9*†	13.2±4.2*†	10.2±2.8*
TEE group	27	79.4±25.4	32.4±16.7	14.3±5.5

*: p<0.01 against TEE group, †: p<0.05 against earlier cases. ICE: intracardiac echocardiography, TEE: transesophageal echocardiography, PT: total procedure time, DT: device deployment time, FT: fluoroscopic time

None of the cases among the subjects on whom ICE was performed received general anesthesia, whereas all of the subjects in the control group required it. With ICE, the internal cavity of the guiding catheter could be clearly identified and the introduction of the wire and the device catheter were easily monitored. However, no such visual guidance was possible for the control group. The posterior rim of the septum could be visualized in all of the subjects in the ICE group, and we could easily identify whether the posterior rim was correctly placed between the two arms of the device. By contrast, these features could not be clearly identified in most of the cases of the control group.

There were two cases of procedure-related complications in the study group; a case of a minor dissection of the inferior vena cava by the ICE catheter, and a case of paroxysmal supraventricular tachycardia. In the first case, the procedure was stopped and the patient was monitored for 24 hours, but no surgical intervention was needed. The patient's defect was closed under ICE guidance the following week. The tachycardia that occurred during the procedure disappeared spontaneously after 2 minutes. In the study group, one case of a small thrombus was detected on the left atrial side of the closure device with ICE when the device was evaluated at the end of the procedure. The thrombus was re-evaluated after 24 hours of anticoagulation with heparin, and was found to be completely resolved.

More than 50% of the subjects in the control group complained of throat or chest discomfort after the procedure, but no such complaint was noted in any of the subjects in the study group.

Discussion

Echocardiography, and especially transesophageal echocardiography, has been widely used for patient se-

lection, device guidance, and post-procedural evaluation in transcatheter closure of ASDs.[5] The results of this study clearly show that ICE is a useful and relatively safe method that can replace TEE, which may be cumbersome and stressful for patients and can cause problems associated with general anesthesia. The superiority of the ICE procedure is not limited to improved procedure duration and reduced patient stress; in addition, we could visualize aspects of the heart and the closure device that could not be seen clearly with TEE due to the limitation of the image angles. This benefit of ICE is more important than its convenience, as malposition or migration of the device has been reported to occasionally occur.[15-17] In fact, prior to this study, we had experienced two cases of delayed device migration even with acceptable immediate post-procedural results on TEE, and these cases ultimately required surgical intervention.

Our findings are consistent with previous reports in regard to the convenience and success rate of defect closure.[18-21] Among our cases were 8 children who were below 6 years of age and received some concern about the size of the catheter, whose diameter is relatively large. The procedure was well tolerated and no complications occurred in any of these cases. Of note was that the duration of the procedure decreased significantly with time; this improved time duration was present even in comparisons with TEE. This finding shows that improved operator efficiency for this procedure can be expected with accumulating experience.

Even though the ICE technique is associated with improved efficiency and safety in a variety of interventions with intracardiac catheters, and is likely to replace TEE in most cases that require echocardiographic guidance and support, the catheter demands great care in handling. The ICE catheter is not wire-guided, like the conventional intravascular ultrasound catheters, and its diameter is quite large; as described above, we had the one case of vessel injury during the procedure. The availability of a smaller-sized catheter is anticipated; we expect a dramatic improvement in this procedure once this is available. The singularity of the imaging plane is another concern as it limits the visualization of a 3-dimensional heart to a more primitive level, and it necessitates excessive manipulation of the catheter in the heart; this increases the likelihood of catheter-related complications such as cardiac wall injury and thrombus formation. A final concern is that the procedure may be somewhat cumbersome at first and requires experience to achieve proficiency, as was demonstrated by our study results. However, we have shown that with proper training and guidance, it can surpass TEE in terms of efficiency and so become a valuable tool for this type of procedure and other related procedures.

In conclusion, even with its limitations, ICE is an efficient and relatively safe tool to guide device closure of ASDs, and it has a substantial benefit over TEE. The potential for its use is certain to grow, and it may well completely replace TEE in this field of interventional cardiology.

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