Comparison of Intracardiac Echocardiography Versus Transesophageal Echocardiography Guidance for Percutaneous Transcatheter Closure of Atrial Septal Defect

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Transcatheter closure of interatrial septal defects is guided by transesophageal echocardiography (TEE), which requires general anesthesia in most cases. Using a new intracardiac echocardiographic (ICE) catheter may avoid endotracheal and esophageal intubation while using only local anesthesia. Forty-two patients underwent transcatheter interatrial septal defect closure; half of them underwent TEE guidance with general anesthesia and the other half underwent ICE guidance with local anesthesia. Device deployment success rate, adequate 2-dimensional and Doppler visualization of the defect and deployment steps, interatrial communication closure at 24 hours, and at 3 and 6 months, procedure time length, complications, fluoroscopic time, and length of hospitalization were compared between both methods. All interventions were completed successfully with no complications, except for 1 patient in the TEE group who had a minor oral trauma. Echocardiographic visualization of the septal defect and deployment was adequate by both methods. Catheterization laboratory time (92 ± 18 vs 50 ± 12 minutes, p <0.001) and interventional procedure length (47 ± 8 vs 35 ± 6 minutes, p <0.001) were shortened using ICE. There was no difference in the rate of closure after 6-month follow-up by either method. ICE guidance offers equivalent echocardiographic views compared with TEE and similar rates of closure. ICE is associated with decreased procedure length while eliminating the risks of endotracheal or esophageal intubation and general anesthesia.

Methods

Study population: Forty-two consecutive adult patients referred for percutaneous interatrial defect closure were prospectively included in the study (37 patients with patent foramen ovale with cryptogenic stroke and 5 patients with atrial septal defects with hemodynamically significant shunts, QP/QS >1.5). Twenty-one of the defects were closed using TEE guidance and the other 21 were closed with ICE guidance. All patients had a preprocedural TEE to document their type of interatrial communication and in the selection of an adequate closure device. It also plays an important role during the procedure, assisting in device positioning, deployment, and assessment of immediate closure results.

Due to the length of the procedure, continuous TEE monitoring usually requires general anesthesia with endotracheal intubation. A new FDA-approved intracardiac echocardiographic (ICE) catheter with complete 2-dimensional imaging and Doppler capabilities has been successfully used to direct transseptal punctures and electrophysiologic studies in humans. This catheter can be used to evaluate cardiac anatomy and for hemodynamic studies; it has great potential for interventional procedures that require echocardiographic guidance. ICE may also shorten the procedure and recovery times because it requires only local anesthesia, and importantly, it may eliminate the risk and discomfort of endotracheal intubation, esophageal intubation, and general anesthesia associated with TEE. This study compares the use of ICE versus TEE as guiding tools for transcatheter interatrial closure in adults.
atrial septal defects. The devices were deployed ac-

Medical, Golden Valley, Minnesota) for patients with

ovale closure and Amplatzer Septal Occluders (AGA

Massachusetts) devices were used for patent foramen

closure was selected based on the type and size of the inter-

atrial defect. Catheterization laboratory time was intro-

duced through a 14Fr, 10-cm hemostatic valve sheath from the right common femoral vein through a transseptal sheath. The device de-

ployment was guided by continuous echocardiography and by fluoroscopy as needed over the transseptal sheath. Patients were anticoagulated using intravenous heparin for a target activated coagulation time of 250 to 280 seconds.

**Study end points:** Device deployment success rates and adequate 2-dimensional visualization of the interatrial septum, defined as a clear defini-
tion of the defect size and its surrounding rims, were assessed in short-axis and 4-chamber views. Adequate visualization of the di-

ferent deployment steps were performed by echocardiography. Adequate Doppler and color Doppler visualization of interatrial communication, the interatrial communication closure rate at 24 hours, and at 3 and 6 months, procedure time, general complications, venous access site complications, fluoroscopic time, and length of hospitalization were compared between the ICE- and TEE-guided groups.

**Statistical analysis:** Categorical variables were summarized as frequencies with percentages and continuous variables as means ± SD. The differences be-
tween groups were analyzed with a chi-square test for categorical variables and a Wilcoxon-Mann-Whitney nonparametric test for continuous variables. A level of p = 0.05 was used for hypothesis testing. Statistica for windows 5.1 (Statsoft Inc., Tulsa, Oklahoma) was used for the statistical analysis.

**RESULTS**

The study included 42 patients. Both groups had comparable clinical characteristics (Table 1). Proce-
dural variables are listed in Table 2. The device was suc-

cessfully deployed in all patients, and visualization for device guidance and deployment was adequate for all deployed devices regardless of the echocardiographic method, including 2-dimensional and Doppler evaluation before and after deployment (Figure 1). In general, the Amplatzer septal occluder was better visualized than the CardioSeal device by both methods during deployment. Catheterization laboratory time was significantly shorter for the ICE-guided group (92 ± 18 vs 50 ± 12 minutes, p <0.001). This difference was mainly due to the lack of administration of anesthesia, endotracheal intubation, anesthetic recovery,
and extubation. There was also a decrease in the interventional procedure length in the ICE group (47 ± 8 vs 35 ± 6 minutes, p < 0.001). Fluoroscopy time and hospitalization length were similar for both groups as well as the rate of defect closure during follow-up (Figure 2). There were no major complications; 3 patients developed minor groin hematomas (2 in the ICE group and 1 in the TEE group) and 1 patient in the TEE group developed an oral trauma.

DISCUSSION

In the present study, we found that using an ICE catheter (AcuNav) was comparable with TEE for guiding percutaneous closure of atrial septal defects. ICE had similar deployment success rates and defect closure at 24 hours, and at 3 and 6 months, without increasing complications. However, ICE significantly reduced catheterization laboratory time and the length of the intervention. Using ICE did not affect patients’ overall hospitalization length. This may become an important advantage of ICE in the near future as the current technology evolves toward simplified and smaller devices with a great potential for same-day hospital discharge. Patients’ defects that were closed using ICE guidance remained awake during the procedure; thus, they required minimal sedation, and, afterwards, only the bed rest necessary for a safe venous sheath removal, with a recovery time not much longer than that needed a regular right-sided cardiac catheterization. The patient being awake during the procedure is also advantageous in evaluating the effects of Valsalva maneuvers and coughing on shunt hemodynamics. Using ICE avoids the need for another physician to maneuver the TEE probe because the operator doing the closure manages the ICE catheter simultaneously. This allows precise and more rapid determination of the views needed for closure by the primary operator, in addition to reducing the need for the availability of another cardiologist during the procedure.

Although all the necessary views were obtained by both imaging methods, in our experience, ICE offered better quality images and required less manipulation due to its favorable position in the right atrium with respect to the interatrial septum and the possibility of a wider range of motion in the atrium. Due to these technical advantages, ICE can overcome some of the important near-field limitations of TEE, especially in patients with small left atriums.

The cost of the ICE catheter may be an important limitation ($2,500.00 for each disposable probe) to its use. However, it is likely that its use will still be a cost-effective strategy considering that it eliminates the cost and risk of anesthesia, the need for an anesthesiologist and another cardiologist to operate the

FIGURE 1. Transcatheter interatrial closure device guidance by ICE. (A) Patent foramen ovale (PFO) with large right to left shunt by agitated saline (1). (B) Sizing balloon with a waist (1) across the PFO with a maximum diameter of 1.74 cm. (C) Transseptal sheath (1) across the interatrial septum (2) with the device exiting the pulmonary vein (3). (D) Device in the left atrium (LA) (1) across the interatrial septum. (2) (E) Device against the interatrial septum (1) attached to the delivery system. (2) (F) Left atrial occluder (1) and right atrial (RA) contraoccluder (2) in good apposition against the septum right before release from the delivery system. (3) (G) Device closing the PFO (1) with no interatrial shunt by agitated saline. (H) and (I) Color Doppler and continuous Doppler respectively by ICE of another patient with a PFO and a bidirectional shunt showing a predominantly left to right shunt at rest.
TEE probe, and also reduces catheterization laboratory time and procedure length. Additionally, although not proved or approved at the present time, it might be possible to safely resterilize these probes which will greatly improve their cost effectiveness. The potential risks in our experience using ICE seems to be low, although the device is not advanced over the wire and its large profile may cause serious complications if is not advanced with caution. The need of 2 venous punctures may also increase the risk of venous thrombosis in a population susceptible to paradoxic embolization. We acknowledge that the difficulty of blinding the echocardiographic procedure may be a limitation in the present study; however, the follow-up echocardiograms after closure were all blinded and therefore without bias regarding the mode of closure.

Hijazi et al.12 showed that using ICE was feasible in humans to guide atrial septal defects closure. The present study demonstrates that ICE safely offers equivalent echocardiographic views compared with TEE, with similar success rates of closure after 6 months of follow-up. ICE was associated with a significant decrease in the procedural time, while eliminating the risks and discomforts of endotracheal and esophageal intubation and the risk of general anesthesia needed for continuous TEE guidance.