Full-Color Direct Visualization of the Atrial Septum to Guide Transseptal Puncture

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Transseptal Puncture Using Direct Visualization. Introduction: Transseptal puncture is required for many interventional procedures but has a serious complication rate of ∼1%—primarily related to misidentification of the fossa ovalis resulting in inadvertent puncture of other cardiac structures. We investigated the utility of a full color visualization catheter to correctly position and guide transseptal puncture of the fossa ovalis.

Methods and Results: Transseptal puncture and left atrial cannulation were performed after visualization of the atrial septum and fossa ovalis with the visualization catheter (IRIS, Voyage Medical Inc.) on six swine. For each animal, the transseptal puncture was performed twice and the catheter was examined for clot after each puncture. The 12 transseptal punctures required 6.8 ± 3.6 minutes procedural time and 300 ± 94 mL of fluid administered per procedure (i.e., two punctures). IRIS visualization of the atrial septum correlated well with postmortem examination of the atrial septum. In the three animals in which a patent foramen ovale was present (as confirmed by pathological examination), it was also correctly identified by in vivo visualization using the IRIS catheter.

Conclusion: The IRIS catheter allows direct in vivo visualization of the interatrial septum to guide transseptal puncture of previous punctures. (J Cardiovasc Electrophysiol, Vol. pp. 1-6)

atrial fibrillation, atrium, catheter ablation, electrophysiology, valvuloplasty

Introduction

Transseptal puncture is an important technique that allows catheterization of the left atrium and left ventricle. Transseptal puncture was initially introduced by Cope and Ross1,2 in 1959 for diagnostic left heart catheterization. The technique was largely neglected for many years with the advent of floating pulmonary artery catheters that enable indirect left atrial pressure measurement with a lower risk of serious complications.3 However, the development of numerous therapeutic techniques that require left heart catheterization has increased the need for transseptal puncture. Transseptal puncture is now widely performed during procedures in pediatric cardiology, interventional cardiology, and cardiac electrophysiology.4

The risks associated with transseptal puncture have been well recognized, with a complication rate of approximately 1% even when performed in high-volume institutions.5 The most serious complications are related to inadvertent puncture of structures other than the atrial septum, particularly the aortic root, coronary sinus, and the posterior wall of the right atrium. Transseptal puncture is generally performed under fluoroscopic guidance, which provides excellent spatial resolution and visualization of the catheter/needle assembly, but has a limited ability to resolve soft tissue. The safety of transseptal puncture can be improved by (i) the use of biplane fluoroscopy,5 (ii) positioning catheters to mark important locations such as the aortic root or coronary sinus os,6,7 (iii) right atrial angiography,8 or (iv) the use of echocardiography (transthoracic, transesophageal, or intracardiac).9,11

The IRIS catheter is a novel visualization catheter that incorporates a 12 mm diameter hood with an integrated camera and working lumen through which a transseptal needle can be deployed. We investigated the utility of full color direct visualization of the atrial septum to identify anatomical landmarks and enable safe deployment of the transseptal needle.

Methods

This study was approved by the Massachusetts General Hospital Subcommittee on Research Animal Care and was performed according to institutional guidelines. Experiments were performed on six female pigs (weight 56.5 ± 2.6 kg) in the Massachusetts General Hospital animal research facility. This study did not include an initial eight swine that were used for the operators to gain experience
using early prototypes of the IRIS catheter. After an overnight fast and premedication with Telazol (4.4 mg/kg Tiletamine and zolazepam intramuscular) and Antipine (0.04 mg/kg intramuscular), animals were anesthetized with inhaled 5% Isoflurane and then intubated with a 6.5 endotracheal tube. The animals were then mechanically ventilated and general anesthesia was maintained with Isoflurane 1.5–3% in 100% oxygen.

Vascular access was obtained with standard angiography sheaths in the femoral artery (8-Fr, Fast Cath, St. Jude Medical, Minnetonka, MN, USA) and right internal jugular vein (10-Fr). Invasive arterial pressure was monitored during the procedure via the side arm of the femoral arterial sheath. A 12-French Sheath (Cook P/N RCFW-12.0-38-45-RB, Cook Medical, Bloomington, IN, USA) was then inserted in the right femoral vein. Anesthetic and hemodynamic monitoring parameters (degree of sedation, invasive arterial pressure, pulse rate, end tidal CO₂, oral temperature, and oxygen saturation) were recorded at 10-minute intervals throughout the procedure. Electrophysiological and hemodynamic data were monitored and recorded on a GE Prucka 7000 electrophysiology recording system (GE Healthcare Technologies, Wisconsin, WI, USA). Heparin was administered (10,000 U i.v.) after all sheaths had been placed. Catheters were manipulated under fluoroscopic guidance using a digital fluoroscopy system (GE OEC GSP 9800 1024 × 1024 pixels, GE Healthcare Technologies).

**IRIS Catheter Imaging System**

The IRIS catheter visualization system consists of a (i) transseptal visualization catheter incorporating a fiberscope, (ii) a camera head to digitize the images from the fiberscope, and (iii) a 19° flat panel monitor to display the images from the system. The IRIS catheter is a 70 cm length, 12-Fr device with a distal 12 mm diameter collapsible hood (see Fig. 1).

![Figure 1. IRIS direct visualization catheter system setup.](image-url)

The catheter handle incorporated a (i) flexion activator (0° to 90°), (ii) controls to axially position the fiberscope (thereby varying the magnification and field of view of the final image), and (iii) a proximal entry port for the working lumen through which the transseptal puncture needle was advanced. The transseptal needle is a sharpened, flexible, 21 gauge stainless steel needle that was located in a separate needle sheath that had an internal diameter of 0.033". Intracardiac images were captured using a custom 10,000 pixel fiberscope. The images from the fiberscope were digitized with a Stryker 988 video endoscopy system (Stryker Endoscopy, San Jose, CA, USA).

The visualization hood had a 3 mm eccentric opening with eight 1 mm-diameter holes located circumferentially around the hood perimeter (see Fig. 2). The IRIS catheter was flushed through a dedicated irrigation lumen and the needle lumen using a peristaltic pump at a flow rate of 33 mL/min with a pressurized infusion of heparinized saline (1,000 I.U. in 1,000 mL).

The initial IRIS catheter assembly was prepared by inserting the fiberscope, needle sheath, and needle into the respective lumens. The camera orientation was calibrated outside the animal (with "up" on the visualization monitor corresponding to cranial movement of the IRIS catheter within the animal). The IRIS catheter was deaired by flushing the catheter while pointing the distal hood upward. The IRIS catheter was then introduced through the hemostatic valve of the 12-French sheath using a split cone to compress the IRIS hood.

The IRIS catheter was then advanced into the right atrium through the 12-French sheath. Under fluoroscopic guidance, the catheter was advanced medially from the inferior vena cava until it formed a seal on the septal wall of the right atrium to allow direct visualization. The catheter was then panned over the atrial septum to visualize as large a portion of the region as possible. If present, the location of a patent foramen ovale was also noted. Once the atrial septal region had been visually mapped, the catheter was steered to the fossa ovalis and the needle was advanced 2 mm across the septum. The needle sheath was then advanced over the needle until it protruded approximately 5 mm into the left atrium. The needle was then withdrawn and an exchange length (250 cm) 0.032" guidewire was passed through the needle sheath into the left atrium. The IRIS catheter was then removed while maintaining the location of the guidewire within the left atrium under fluoroscopic guidance (Fig. 3). The IRIS catheter was visually inspected for the presence of thrombus.

After the second transseptal puncture was performed, the 0.032" guidewire was withdrawn from the left atrium and the needle was replaced within the needle sheath. The IRIS catheter was reinserted into the swine and the atrial septum was visualized again to confirm the location of the previous transseptal punctures. A repeat transseptal puncture was then performed using the technique described in the previous section. After the transseptal puncture had been performed, the guidewire was removed and the atrial septum was again visualized to confirm the location of the two transseptal punctures.

**Examination for Thrombus Formation**

After the second transseptal puncture, the IRIS catheter was kept within the right atrium to exclude the possibility that removal of the catheter through the hemostatic valve
Figure 2. IRIS visualization catheter. Shown in panel A is the distal hood of the IRIS catheter. The hood is kept open with nitinol struts that are gold plated to improve radio-opacity. The 5 mm diameter central aperture can be seen. In panel B, the needle sheath (brown and white striped exterior) and needle have been extended through the central aperture. In panel C, the catheter has been flexed back over the catheter handle. The flexion mechanism (uppermost blue lever) and flexion lock (lowermost blue lever) can be seen on the IRIS catheter handle. The 10,000 pixel fiberscope can be seen exiting from the upper port and the central port contains the needle and needle sheath assembly.

dislodged any adherent thrombus. The IRIS catheter was kept within the vasculature for twice the time required to perform the first transseptal puncture (approximately 20 minutes) to test the sensitivity of the catheter to the formation of thrombus under an extended period of time.

At the end of the waiting period, the animal was euthanized with an intravenous injection of Euthasol 20 mL (390 mg pentobarbital sodium and 50 mg phenytoin sodium per mL, Delmarva Laboratory, Midlothian, VA, USA). The heart was examined in situ for the presence of pericardial bleeding. The IRIS catheter was photographed with a macro camera (Nikon D50, Micro Nikkor 60 mm f2.8, Nikon Corporation, Melville, NY, USA) to examine for the presence of small thrombi not detected by visual examination alone.

Figure 3. In vivo direct visualization image comparison with postmortem examination and fluoroscopic views of the IRIS catheter. Fluoroscopic images taken during a direct visualization-guided transseptal puncture are shown. The IRIS catheter is positioned at the fossa ovalis (panels A to C show fluoroscopic images in the left anterior oblique projection) after mapping of the atrial septal region is complete. The transseptal puncture needle (marked with arrow) is then used to puncture the atrial septum (panel B) and the needle sheath is introduced into the left atrium. The transseptal needle is then withdrawn and 0.032" guide wire (marked with arrow) is advanced within the left atrium (panel C). Images of the atrial septum from postmortem examination (panel D with scale in millimeters) and the IRIS direct visualization catheter (panel E) are shown for comparison. The color difference between myocardial and fibrous tissue can be appreciated using direct visualization. In both images three atrial septal punctures can be seen proximal to the location of a patent foramen ovale (PFO).
TABLE 1
Procedural Details from the 12 Transseptal Punctures

<table>
<thead>
<tr>
<th>Transseptal Puncture Number</th>
<th>Animal</th>
<th>Operator</th>
<th>Fossa Ovalis Size</th>
<th>Time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>47 mm²</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>2</td>
<td>96 mm²</td>
<td>8.3</td>
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<tr>
<td>4</td>
<td>2</td>
<td>1</td>
<td>121 mm²</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>1</td>
<td>42 mm²</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>1</td>
<td>79 mm²</td>
<td>14</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>1</td>
<td>108 mm²</td>
<td>6</td>
</tr>
</tbody>
</table>

Pathological Examination

The endocardial surface of the excised heart was then examined by creating an incision in the left atrium to allow inspection and photography of the left atrial aspect of the atrial septum. The right atrial appendage was then opened and the right atrium was inspected for the location of the transseptal puncture sites, the presence of a patent foramen ovale, and any indication of complications. The size and shape of the fossa ovalis were measured with digital photography.

Statistical Methods

Results are expressed as mean ± standard deviation. For comparison of transseptal puncture times, a paired sample t-test was used (two tailed). Statistics were performed using R for Macintosh OS X (R version 2.5.1, R Foundation for Statistical Computing). A significance level of 0.05 was used.

Results

The fossa ovalis was a mean of 82.0 ± 32.3 mm². A patent foramen ovale was present in three of the six specimens. The fossa ovalis could be identified during in vivo direct visualization as a noncontracting region surrounded by fibrous (white) tissue. In some animals, the thinnest part of the fossa ovalis was red because blood in the left atrium was visible through this thin fibrous tissue.

A total of 12 transseptal punctures were performed on six swine by three operators (see Table 1, Figs. 3 and 4). The 12 transseptal punctures required 6.8 ± 3.6 minutes: when stratified by first or second puncture per animal, the punctures required 9.5 ± 2.6 minutes for the first puncture per animal and 4.1 ± 1.6 for the second puncture (P = 0.014). A total of 299 ± 94 mL of fluid were administered per animal (i.e., for two punctures). No pericardial blood was seen in any of the cases. All of the transseptal punctures were located in the fossa ovalis on pathological examination (see Fig. 3). In the first animal there was a very small (120 × 200 μm) potential thrombus attached to one of the hood struts. This was only visible as an area of discoloration on the magnified macro photographs and was not visible to the naked eye.

Discussion

The major findings of this study include: (i) direct visualization can be used to differentiate the fossa ovalis from other parts of the atrial septum and (ii) transseptal puncture can be performed using direct visualization within a relatively short period of time (2–10 minutes).

These results may have important clinical implications. The technique of performing a transseptal puncture requires a fundamentally different approach to most other cardiac procedures that generally require gentle movement of relatively atraumatic instruments within the heart. In contrast, transseptal puncture is performed using a sharp intracardiac instrument, which sometimes requires application of significant force to penetrate a fibrosed septum. For these reasons, transseptal puncture represents a practical barrier to the clinical adoption of some procedures requiring access to the left heart. A technique that can provide additional confirmation of correct catheter location before deploying the transseptal needle may allow less experienced operators to perform these interventional procedures.
Transseptal puncture has become an increasingly important technique due to the rapid growth in the number of interventional procedures that require access to the left atrium or left ventricle. Locating a relatively small structure such as the fossa ovalis (176 ± 107 mm²) using only fluoroscopy, which does not provide detailed tissue imaging, requires further information in the form of distinctive movements of the catheter as it is being withdrawn in a caudal direction along the septal wall. However, this technique is not effective in all cases, and performing a transseptal puncture in patients with structural heart disease or previous transseptal punctures can be more challenging. One method to provide further information during the transseptal puncture is to place catheters in important anatomical locations, such as the aortic root, HIS bundle, coronary sinus, and high right atrium. However, this strategy still requires a high enough level of clinical expertise that many physicians are not comfortable with the technique. In addition, it is only practical when a transseptal is being performed as part of a procedure in which these catheters would be useful during the rest of the procedure.

The ability of echocardiography to guide transseptal puncture has been extensively investigated. Transesophageal and intracardiac echocardiography can be performed concurrently with fluoroscopy and are, therefore, more practical than transthoracic echocardiography. Echocardiography has some important advantages in comparison with direct visualization including the ability to visualize structures beyond the atrial septum (i.e., determine the distance of the needle tip from the posterior left atrial wall), define the degree of tenting of the atrial septum, and assist in detecting complications such as pericardial effusions. However, intracardiac echocardiography does have some limitations including the requirement for (i) relatively costly ultrasound equipment, (ii) an experienced operator, and (iii) separate vascular access for the ultrasound catheter.

**Direct Visualization of Intracardiac Structures**

Kuo et al. performed direct endocardial visualization in 10 dogs using a flexible 14-Fr endoscope with a distal fluid filled balloon to exclude blood from the image. Using direct visualization they were able to guide cannulation of the coronary sinus, visualize ablation lesion formation, and identify ablation lesion locations. Nazarian et al. used a 7-Fr fiberoptic endoscope that used infrared imaging (1,620 nm wavelength) to guide placement of coronary sinus catheters. They found that the infrared catheter could visualize structures approximately 1–2 cm from the tip of the catheter and were able to successfully cannulate the coronary sinus in all 10 dogs. One disadvantage of these systems is that they do not incorporate a therapeutic lumen—that is, a separate catheter needs to be manipulated to the same location as the visualization catheter to deliver therapy or cannulate the desired structure. In contrast, Anh et al. reported preliminary clinical results from 58 patients undergoing coronary sinus cannulation with an 8-Fr deflectable endoscope that incorporated a 0.035” lumen to allow cannulation of the coronary sinus directly. The catheter was equipped with a compliant distal balloon to exclude blood from the imaging field and allow full color imaging. They were able to visualize the coronary sinus in all patients a mean of 6 ± 5 minutes after insertion of the catheter and proceeded to cannulate the CS successfully in 55 of 59 of the patients. Alternatively, an endoscopic balloon ablation catheter has been used to both visualize PV ostia and place laser ablation lesions to electrically isolate the veins.

In this porcine study, we found that in the majority of cases the fossa ovalis had a distinctive (white) visual appearance and was not covered with myocardium enabling visual mapping. Ho et al. have reported that in humans the valve of the fossa ovalis was usually fibrous with relatively few myocytes, suggesting that these results should be reproducible clinically. These results are encouraging and suggest that direct visualization of the endocardial surface allows relatively rapid recognition of important cardiac structures.

**Limitations**

These experiments were performed using a swine model in which there are some recognized differences from humans including differences in cardiac anatomy, body proportion (i.e., a long trunk relative to the limbs), and myocardial appearance (the swine myocardium is relatively pale in comparison with human myocardium). Some of these differences may make the procedure more difficult than it would be clinically; for example, the size of the porcine fossa ovalis observed in this study was approximately half that reported in patients. However, other factors such as the absence of structural heart disease or previous cardiac instrumentation may have made the transseptal puncture easier in this model than the clinical situation. All of the animals used in this study were in sinus rhythm during the transseptal puncture, and it was therefore possible to recognize the fossa ovalis as an contractile region within the heart. However, this criterion for recognition of the fossa would not be useful in clinical cases if transseptal puncture was attempted while the patient was in atrial fibrillation.

It is unknown how effective this approach would be in patients with highly fibrous atrial septa—either spontaneously or as a result of a prior transseptal procedure. However, since this procedure is performed under direct visualization, the needle employed in the IRIS catheter is sharper than the standard Brockenbrough needle used clinically. But ultimately, clinical human experience with this device is required to fully assess its safety and efficacy.

**Conclusion**

Direct full color visualization of the interatrial septum using a catheter with a saline flushed hood can be used to guide de novo transseptal puncture or cannulation of previous punctures.

**References**

5. Roelke M, Smith AJ, Palacios IF: The technique and safety of transseptal left heart catheterization: The Massachusetts General Hospital