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Background—Percutaneous closure of the patent foramen ovale (PFO) is usually performed under x-ray in combination with ultrasound guidance. We tested the feasibility of applying magnetic resonance (MR) guidance for percutaneous closure of PFO in an animal model, thus avoiding the disadvantage of ionizing radiation.

Methods and Results—Real-time MRI with radial or spiral k-space filling (15 frames per second) on an interventional 1.5-T high-field whole-body system was exploited to examine the feasibility of MR-guided closure of the PFO in 7 piglets weighing ≈14 kg. A specially designed prototype nonmagnetic closure device was introduced via the femoral vein. The short bore of the magnet and in-room monitors allowed for visualization and steering of the catheter with the loaded occluder. Catheterization of the left atrium and, finally, correct placement of the device was possible in all animals. Deployment of the device was depicted by real-time MR, and initial misplacement, which occurred in 2 animals, was easily detected and corrected.

Conclusions—Real-time MR guidance of PFO closure, without the use of ionizing radiation, is feasible in an animal model. (Circulation. 2002;106:511-515.)

Key Words: magnetic resonance imaging • catheterization • defects

Percutaneous closure of patent foramen ovale or atrial septal defects is becoming an increasingly accepted alternative to surgical repair. Placement of the different available devices is usually performed under combined x-ray and transesophageal echocardiographic guidance. A reduction in the amount of radiation might be especially advantageous for pediatric patients.1,2 Consequently, atrial septal defect closure has been attempted mainly with the use of transesophageal echocardiography for guidance.3 Ewert et al4 were able to completely abandon x-ray guidance and to exploit transesophageal echocardiography in children, albeit at the cost of higher propofol doses for sedation. Because the quality of real-time magnetic resonance (MR) has improved sufficiently for application in the field of vascular interventions,5 we designed the present study to investigate the use of real-time MR guidance for the closure of patent foramen ovale in an animal model.

Methods

Animal Model

The official committee for animal affairs gave approval for the animal experiments. Experiments were performed on 7 domestic farm piglets (Germany) with an average body weight (bw) of 14 kg (ranging from 12.5 to 17.5 kg). After intramuscularly applied premedication of 0.5 mL atropine per 10 kg bw, 2 mL azaperone per 10 kg bw, and 1 mL ketamine per 10 kg bw, pentobarbital solution diluted 1:3 with saline was injected as needed via a venous access line placed in an ear vein. The animals were intubated and mechanically ventilated. General anesthesia, including mechanical ventilation, was maintained during the whole procedure, including the MR-guided placement of the septal occluder. The age of the animals was chosen to allow for easy passage through the usually patent foramen ovale.

MR Scanner and Real-Time Imaging Sequence

The interventions were performed on a dedicated interventional 1.5-T ACS-NT MR scanner (Philips Medical Systems). X-ray control of the MR-guided interventions was performed by a specially shielded C-arm unit positioned in the same room with the MR scanner. LCD screens beside the magnet enabled direct control of the MR-guided intervention. A remote control was used to change the image plane, orientation, and angulation as required during the procedure. Specially designed real-time reconstruction hardware (Philips Research Laboratories) performed the real-time gridding interpolation of the raw data, consequently allowing standard fast Fourier reconstruction of the images also in real time.6 A 5-element synergy cardiac coil was used for signal acquisition.

Real-time MR image data acquisition was achieved by applying a gradient echo sequence with either radial (repetition time [TR] 2.5 ms, echo time [TE] 1.2 ms, flip angle 45°, field of view 300 mm², matrix 128×256, slice thickness 10 mm, and 80 radials) or spiral (TR 30 ms, TE 4 ms, flip angle 40°, field of view 250 mm², matrix

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Movies I and II are available in an online-only Data Supplement at http://www.circulationaha.org.

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Atrial Septal Occluder and MR-Guided Intervention

Self-made nonmagnetic prototypes of atrial septal occluders made of nitinol were used because they were favorably depicted during in vitro experiments applying real-time MRI sequences. The occluder consists of 2 connected button halves, one or both of which can be applied with a membrane (Figure 1). The system runs over a 0.25-mm nitinol guidewire. In addition, it is fixed by one 0.15-mm nitinol guidewire, which allowed us to perform the “Minnesota wiggle” procedure and, in conjunction with a small nitinol tube (1 mm), to recapture the occluder into the delivery catheter. The whole system as described passes through a 2.7-mm (8F) delivery catheter.

A 3.3-mm (10F) introducer sheath was placed in the right femoral vein by the Seldinger technique. Next, the left atrium was catheterized through the foramen ovale. In the first animal, a 17.5-kg piglet, the foramen was not patent, and an artificial opening had to be created by use of a transjugular portosystemic shunt needle (Cook) and dilation with a 12-mm balloon catheter. In all other animals, it was easily possible to pass the atrial septum through the patent foramen ovale with a 1.6-mm (5F) multipurpose catheter and to secure the path with a 0.9-mm (0.035-in) nitinol guidewire. These procedures were performed under x-ray guidance in the first 4 animals and purely under MR guidance in the last 3 animals. The general imaging plane for the intervention was chosen on a parasagittal plane along the orientation of the catheter to contain the inferior vena cava and the right and the left atria (Figure 2). In the first 4 animals, the mounted occluder was advanced under MR guidance over a guidewire previously positioned under x-ray guidance into the left atrium. In the last 3 animals, catheterization of the left atrium was performed under MR guidance, steering the catheter with a loaded occluder through the foramen ovale (Figure 3, Movie I [representative image quality for all experiments]). All occluders were deployed and positioned over the foramen ovale solely under MR guidance (Figure 4, Movie I). The position of each device as determined by real-time MR was confirmed by x-ray. Correct positioning of the device was tested under MR by wiggling the still connected occluder. Free movement in the right or left atrium without movement of the septum was considered as misplacement, with both halves of the occluder either in the right or left atrium. This was proved by the same wiggle maneuver as performed under x-ray guidance (Figure 5). If misplacement occurred, the occluder was recaptured and replaced.

MR images of the occluder were obtained by applying a fast, navigator-gated, free-breathing, segmented k-space, cardiac-triggered, 3D, true fast imaging with steady state precession (FISP) sequence (TR 3.9 ms, TE 1.9 ms, flip angle 75°, resolution 1.2×1.2 mm², slice thickness 1.5 mm, 16 slices, and acquisition time <2 minutes [triggering included]) (Figure 6). Finally, the animals were euthanized, and their hearts were removed and opened to macroscopically inspect the occluder position.

Results

Correct occluder placement with closure of the foramen ovale was achieved in all cases. MRI time for occluder deployment ranged from 8 minutes to 17 minutes (mean 10 minutes). This does not include the time needed for x-ray control during the interventional procedure. Susceptibility artifacts on the real-time MR images caused by the mounted occluder allowed visualization of the delivery catheter and, thereby, catheterization of the left atrium (Figure 3). Deployment of the occluder could be depicted as well (Figure 4), enabling correct occluder placement in all cases. Both halves of the occluder could be discerned on the real-time images, because the artifacts caused by the occluder were small enough (Figure 4c). Correct positioning of the occluder was tested by wiggling the occluder (Movie II). This wiggling maneuver revealed initial misplacement in 2 cases, once in the right and once in the left atrium (Figure 5, Movie II). Incorrect placement was suspected but not clearly visible on the real-time MR images, because the interatrial septum could not be macroscopically inspected.

Figure 1. Self-made occluder consisting of 2 connected halves, which can be individually covered with a membrane. Delivery can be accomplished with 0.9-mm guidewire. Eyellets (arrow) allow for fixation of 2 small nitinol wires, enabling wiggling maneuver after occluder placement as well as recapture of device.

Figure 2. a, Diagram of a parasagittal real-time MR image after occluder placement (white arrow), indicating planning of slice orientation generally used for control of intervention yielding para-axial image (b). Orientation in panel a results in para-axial image showing part of vena cava inferior (curved arrow), atrial septum (white arrow), aortic valve (star), and both ventricles. Catheter tip is located in right ventricle (RV). LV indicates left ventricle; LA, left atrium.
not be clearly visualized in relation to the occluder. Real-time MR observation of the wiggle maneuver clearly demonstrated the misplacements in either atrium, and it was easily possible to recapture the occluder and replace it correctly. After each deployment, the occluder position as seen by real-time MR was controlled by x-ray and proved to be correct. Finally, the correct occluder position and its relation to the pulmonary veins and mitral valve was certified in all cases by fast 3D MRI (Figure 6) and macroscopic examination of the ex vivo heart.

Discussion

Previously, the slow data acquisition of MR has been a major disadvantage. For diagnostic imaging of the constantly moving heart, this has been overcome by special imaging techniques combined with cardiac and respiratory triggering. Furthermore, real-time imaging capabilities have been developed, thus enabling MR guidance of vascular and cardiac interventions in animals. The present study was designed to test the applicability of real-time MRI techniques to guide the transcatheter placement of atrial septal occluders. We used self-made prototypes of nonmagnetic devices, including the delivery system. This was achieved by manufacturing all metallic parts from nitinol and using an introducer catheter without any metallic braiding (Figure 1). The occluder device was well visible on both real-time MRI sequences. While it was mounted in the deployment catheter, it created an artifact, which enabled depiction and guidance of the catheter (Figure 3). The imaging speed of 15 frames per second was sufficient for direct control of the instruments under MR guidance. Deployment of the 2 occluder halves was also clearly visible (Figure 4), but the button size of the occluder prototype, which was available with a fixed diameter of 20 mm only, usually obscured the anatomy of the atrial septum. Although this was of no negative consequences in the present study, the use of relatively large occluders for patients with large atrial septal defects could cause difficulties in depiction of the adjacent anatomic structures with the current occluder device. However, the size of susceptibility artifacts caused by the occluder could be further reduced by using different metal alloys. Nonetheless, in consideration of the given artifacts of the occluder, it can be expected that residual leakage through the atrial septum after occluder placement can be detected. A disadvantage of our animal model is the lack of a real septal defect and the fact that no shunt was to be expected because of the lack of any pressure gradient between the atria. Therefore, we neither tried to depict the atrial septal defect or shunt directly on anatomic or flow images by MR nor did we look for a remaining shunt after occluder placement.
Correct occluder placement was determined by a wiggle procedure identical to that (Minnesota wiggle) carried out under x-ray fluoroscopy (Figure 5, Movie II). If misplacement occurred, the occluder was recaptured into the delivery catheter and reinserted successfully under MR guidance and confirmed by wiggle procedures performed under x-ray fluoroscopy and macroscopically in the ex vivo heart specimens.

The tomographic nature of MR made it important to choose a suitable imaging plane for control of the procedure. Because we wanted to visualize the advancing catheter as well as the atrial septum, we planned an imaging plane including the inferior vena cava and both atria. Planning was performed on a parasagittal slice, as shown in Figure 2. The resulting para-axial image contained parts of all heart chambers and the aortic valve. Slight adjustments of this imaging plane were made during the procedure by moving the imaging plane parallel to the originally planned slice. Because of the interactive abilities of the interventional MR scanner, this was possible as required, without any significant time delay. The fully anesthetized animals did not inadvertently move, but the interactive abilities can be expected to be sufficient for quick slice repositioning in a clinical setting, where patient motion might occur.

The present study demonstrates the general feasibility of artifact-free real-time MRI of the heart, enabling MR-guided placement of an atrial septal occluder. Neither cardiac nor respiratory triggering nor breath-holding was necessary to achieve high-contrast images of the heart chambers. The occluder was depicted passively by susceptibility artifacts, which are due to the different magnetization of the metal nitinol compared with tissue. An advantage of MR compared with x-ray fluoroscopy is the lack of exposure of the patient and technician to ionizing radiation. Furthermore, the depiction of the heart anatomy shows the relation of the occluder to the atrial septum, pulmonary veins, and atrioventricular valves. The value of MR compared with echocardiography, which already has been shown to be applicable to the procedure in clinical studies, remains to be examined. The high costs of an MR scanner, the ability to deal with complications such as loss of the occluder, and use of a cardioverter close to the MR scanner have to be considered. Furthermore, the use of metallic nitinol instruments, which can at least in theory act as antennas and consequently heat up during the MR experiment, has to be thoroughly examined in septal occluder systems before clinical trials can be undertaken. Nonetheless, the experiments show the general feasibility of real-time MR guidance for cardiac interventions with a sufficient imaging speed and contrast.

In conclusion, high quality real-time MRI of the heart allows MR guidance of transcatheter patent foramen ovale occlusion in an animal model.
References


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