Feasibility of Real-Time MRI With a Novel Carbon Catheter for Interventional Electrophysiology

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Background—Cardiac MRI offers 3D real-time imaging with unsurpassed soft tissue contrast without x-ray exposure. To minimize safety concerns and imaging artifacts in MR-guided interventional electrophysiology (EP), we aimed at developing a setup including catheters for ablation therapy based on carbon technology.

Methods and Results—The setup, including a steerable carbon catheter, was tested for safety, image distortion, and feasibility of diagnostic EP studies and radiofrequency ablation at 1.5 T. MRI was performed in 3 different 1.5-T whole-body scanners using various receive coils and pulse sequences. To assess unintentional heating of the catheters by radiofrequency pulses of the MR scanner in vitro, a fluoroptic thermometry system was used to record heating at the catheter tip. Programmed stimulation and ablation therapy was performed in 8 pigs. There was no significant heating of the carbon catheters while using short, repetitive radiofrequency pulses from the MR system. Because there was no image distortion when using the carbon catheters, exact targeting of the lesion sites was possible. Both atrial and ventricular radiofrequency ablation procedures including atrioventricular node modulation were performed successfully in the scanner. Potential complications such as pericardial effusion after intentional perforation of the right ventricular free wall during ablation could be monitored in real time as well.

Conclusion—We describe a newly developed EP technology for interventional electrophysiology based on carbon catheters. The feasibility of this approach was demonstrated by safety testing and performing EP studies and ablation therapy with carbon catheters in the MRI environment. (Circ Arrhythmia Electrophysiol. 2009;2:258-267.)

Key Words: ablation ■ electrophysiology ■ MRI

Although interventional therapy of complex arrhythmias is becoming more and more common, these approaches are still accompanied by a substantial risk of procedural complications.1 Therefore, real-time imaging of the surrounding anatomy, lesion mapping, and early detection of complications seem to be crucial for the further development of these interventional approaches.

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In this context, MRI has been proposed as an alternative imaging modality for guiding and monitoring electrophysiological (EP) procedures.2 MR technology combines various strengths—providing excellent 3D information on anatomy, cardiac function and size, and the location of ablation lesions—with the benefit of examinations without ionizing radiation or iodized contrast agents. Furthermore, an assessment of the extent of the ablation lesions and identification of possible remaining gaps could be possible in the future.3,4

However, to perform EP interventions with MRI guidance, a special setup must be established, and the catheters used must fulfill many requirements. There are concerns related to magnetic field–induced movement and substantial radiofrequency (RF)-induced heating at device-to-tissue interfaces, potentially resulting in thermal tissue damage around the lead. The electrically conductive lead may pick up electromagnetic interference from the MR system, which can translate into heat or produce a life-threatening tachycardia in the patient.5–7 Additionally, image distortion by the metallic intracardiac lead can reduce the advantage of high-resolution imaging.8

MRI-compatible devices and strategies would open new avenues for treatment options in the field of invasive

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electrophysiology. The objectives of this study were (1) developing carbon catheters and a compatible setup for interventional EP in the MR environment, (2) subsequent demonstration of the feasibility of diagnostic EP procedures, and (3) ablation therapy under real-time MRI guidance.

Methods

Catheter Design
A custom EP ablation catheter with carbon fiber conductors was designed for use in the MRI environment. In this steerable catheter, unlike standard EP ablation catheters, the steel elements such as wires, coils, crimping hubs, and bearing surfaces were replaced by plastic or ceramic alternatives. This was done to eliminate potential imaging artifacts and to prevent interactions with the static field. The catheter body was made of 7F Pebax tubing reinforced with nonconductive fibers and a 7F steerable tip. The catheter’s usable length was approximately 85 cm, and the 8 cm steerable tip could be deflected from straight position to 120° to achieve precise electrode placement. The large carbon fiber bundle (approximately 30 000 fibers) used for the distal electrode yielded a low resistance of 3.8 ohms, whereas the smaller carbon bundle (approximately 3000 fibers) had a higher resistance of 126 ohms. The platinum/iridium electrodes were connected to the carbon bundles by means of silver conductive epoxy, crimp rings, and connector copper wires soldered to the electrodes. The catheter had a 4-mm-long ablation electrode, a 2-mm-long ring electrode, and 2-mm spacing. These carbon-based circuits were designed to allow for high-energy RF ablations through the distal electrode and low-energy sensing/pacing through the bipolar pair made from the distal and proximal electrodes. The catheter was connected to the RF generator and to the external pacer (ERA 300, Biotronik GmbH, Berlin, Germany) through customized long cables and a filter box that allowed the equipment to remain in the scanner room. A custom-made neutral electrode with a large skin contact patch (100×200 mm) and a carbon lead was used for RF delivery to avoid adverse effects in the MRI environment.

MR Systems
MR examinations were performed on 3 different 1.5-T whole-body scanners: a Magnetom Vision (hereafter referred to as Scanner 1), a Magnetom Avanto (Scanner 2; both Siemens Medical Solutions, Erlangen, Germany), and a Gyroscan ACS NT Intera R12 (Scanner 3, Philips Medical, Best, The Netherlands), using the integrated body coil for radiofrequency excitation. Signal reception was performed using either the body coil or additional receiver coils, depending on the scanner and experiment. For in vivo MRI experiments on pigs, fast, non–ECG-triggered scout images (ie, using fast low-angle shot [FLASH] pulse sequences) were used to position the imaging slice in the region of interest, for example, the midventricular short-axis plane of the heart. Cine movies and high-resolution images of specific heart phases were acquired using an ECG trigger module. Detailed descriptions on the various pulse sequences implemented on the 3 scanners can be found below.

MR Compatibility/Safety Testing
For testing of heat development caused by RF pickup during MRI, various in vitro investigations of conventional (metallic) and custom-made (carbon) EP catheters were performed in Scanners 1 and 2. In Scanner 1, heating tests of the catheters were performed in a gelatin-casted block containing a fresh pig heart. The gelatin contained 0.9% NaCl solution and the size of the phantom was 300×230×130 mm. This phantom was centered inside the transmit coil. RF-related catheter heating during MRI was evaluated by temperature measurements using an external fluoroptic thermometry system (Labkit m3000 with connected STF-10 probes, Luxtron, Santa Clara, Calif). Temperature probes were attached to different segments of the catheters, and the temperature distribution was continuously recorded while performing MRI.

Additional heating tests were performed in Scanner 2 within a gel-filled head and torso phantom as previously described. Water doped with 0.15% NaCl and 3% hydroxyethylcellulose (volume, 45 L) was used as phantom filling, providing conductivity values comparable to that of body tissue (0.47 S/m) while preventing convective heat transport. Ten representative catheter configurations were tested for each catheter, including straight, curved, half circle, and full circle configurations, with the catheter always crossing from air to gel at the lower right phantom side. All investigations were performed with temperature probes at the tip, 200 mm behind the tip, at the crossing from air to gel, and apart from the catheter in the gel (reference). Catheter positions and orientations were tested for RF-related heating using the fluoroptic thermometry system while running an SSFP imaging sequence, with the following imaging parameters: echo time, 1.65 ms; repetition time, 3.29 ms; bandwidth, 543; field of view, 500 mm; slice thickness, 10 mm; matrix, 64×64. Total acquisition time was set to 5 minutes. Transmit power of the MR system was adjusted by variation of the flip angle between 2 W and 131 W, relating to a specific absorption rate between <0.1 and 2.8 W/kg.

In addition to the experiments on MRI safety, in vitro investigations of the custom-made catheter on MRI compatibility were performed at 1.5 T in the phantoms described above to prepare for the in vivo experiments. Various pulse sequences were tested for determination of possible artifacts and visualization properties of the catheter.

In Vivo Imaging Protocol
As a result of the safety and compatibility investigations, short FLASH and TrueFISP (echo time, 1.35 ms; repetition time, 2.69 ms; flip angle, 80°; field of view, 400 mm; slice thickness, 8 mm; matrix, 168×256; total acquisition time, 0.7 s) imaging sequences for in vivo catheter tracking purposes were developed. These sequences were adapted for low RF transmit power/SAR (lowest value still accounting for admissible image quality <4 W/0.1 W/kg), while enabling detection of the carbon catheters in vivo and guidance to the ablation sites as demonstrated later.

Experimental Setup for Animal Experiments
All animal protocols were approved by the governmental animal care and use committee (Regierung von Unterfranken, approval No. 54 to 2531.01 to 63/04). One dead minipig was used to establish the setup; a total of 8 minipigs weighing 30 to 54 kg were then sedated with a 10-mg intramuscular injection of ketamine and maintained on 1% isoflurane at the initial preparation of the jugular veins and placing of the catheters. Further experiments were performed under intravenous sedation/analgesia (midazolam/fentanyl/rocuroniumbromide). For ventilation during the MR procedures, an Oxylog ventilator (Dräger Medical, Luebeck, Germany) was located outside the scanner room and the animals were ventilated using a 4-m extension tube. 8F introducer sheaths were placed in the jugular veins for catheter access. The pigs were positioned supine, feet first, inside the scanner, allowing access to the sheaths. Signal reception in Scanner 1 was performed using a 4-element body array. In Scanner 2, various setups were tested, including signal reception with the body coil, a multiple flex coil assembly, and an experimental 16-channel surface coil. In Scanner 3, a 5-channel cardiac array was used. A broad spectrum of diagnostic and interventional EP procedures was performed in the animals. Detailed descriptions on some of the test components are given below.

EP/Ablation Protocol
For diagnostic EP studies including programmed stimulation, different anatomic regions were targeted in each animal including the right atrium (lateral free wall), right ventricular apex, the His bundle
approach has been described earlier. IEGM tracings were acquired via the carbon catheters and directed outside the scanner room through the filter system. Recordings were performed with automated data acquisition software (LabSystem Duo, BARD Electrophysiology, Lowell, Mass).

One ablation target was chosen in each animal, including sites in the right atrium, right ventricle, atrioventricular (AV) node, and coronary sinus, to simulate different interventional EP approaches. Ablation was performed in cycles for 60 seconds with maximum power of 75 W and temperature cutoff at 65°C. After baseline images were acquired for the optimal slice selection, RF ablation was performed at the site between the distal electrodes and the custom neutral electrode patch, which was adhered to the skin of the lower abdomen; ideal contact was secured using commercial contact gel. The primary endpoint of RF delivery was a significant reduction (>80%) of IEGM voltage. RF delivery was interrupted when bradycardia or tachycardia occurred. Although lesion mapping was beyond the scope of this study, we assessed lesion size during the procedure to gain intraprocedural information of whether there was successful creation of lesions. For this purpose, gadolinium-enhanced MRI was used according to previously published protocols.

After the MR experiments, the animals were euthanized by intravenous administration of T61 (Intervet, Unterschleisheim, Germany): 1 mL contains Tetracain-HCL 5.00 mg; Mebezoniumiodid 50.00 mg; Embutramid 200.00 mg. The hearts were excised and sectioned to identify the thermal lesions. Extent and location of the respective lesion was recorded by gross examination.

**Statistical Analysis**

Changes in pacing and sensing threshold levels were analyzed during the time course and were considered significant at a level of \( P<0.05 \) in a paired \( t \) test (ANOVA). Comparisons of ablation lesions in MRI and in pathological specimens were performed by a paired \( t \) test (ANOVA). Unless noted otherwise, results measurements are reported as arithmetic mean±SD. Statistical analysis was performed using SPSS 14.0.1.

**Results**

**Testing for Unintended Heating**

In this work, custom-made carbon EP catheters (Figure 1A) were compared with commercially available conventional metallic ablation catheters (EPT Blazer, Boston Scientific Corporation, San Jose, Calif) regarding MR safety/compatibility. Metallic and carbon catheters were tested in various phantom configurations (Figure 1B). Both of the catheter pathways in the gel and in the air strongly affected the magnitude of tip heating. The metallic catheters showed the highest MR-related temperature elevation (catheter tip heating) in a configuration as shown in Figure 1B. When performing SSFP imaging with a total acquisition time of 5 minutes and an SAR of 2.1 W/kg, the temperature at the metallic catheter tip increased from 17.3±0.4°C to a maximum of 63.5±0.2°C; maximum heating at the carbon catheter tip in all configurations (SAR 2.1 W/kg, 5 minutes) was an increase of 13°C (Figure 2). In a given configuration, heating was generally found to be proportional to the RF power applied by the MR system (Figure 2B), which is in line with previous investigations. Average temperature increase at the catheter tip was \( 22±4.1°C \) in metallic catheters and \( 4.0±1.3°C \) in carbon catheters (\( n=10; P<0.05 \)) (Figure 2C). At the point where the catheter crossed from air into gel, mean heating was 2.5°C at the conventional and 2.3°C at the
Figure 2. A, Original temperature recordings of a carbon and a metallic EP catheter. Catheters were placed in various configurations inside the described gel phantom and MRI was performed to induce heating by RF pulses. Temperature increase was measured using a fluoroptic thermometry system. Worst-case heating and heating at low RF transmit power is shown while running a pulse sequence with a total acquisition time of 5 minutes. Black line indicates temperature evolution at the catheter tip; blue line, catheter middle; green line, reference; red dots, start of pulse sequence and maximum temperature during MRI (averaged over 10 seconds). During MRI using the pulse sequences adapted for low RF transmit power (as described in the Results section), the carbon and the metallic catheters remained at room temperature. B, Dependency of catheter tip heating on RF power applied to the tissue (SAR) in 2 representative configurations. Left graph, Conventional catheter (EPT blazer); right graph, carbon catheter. Solid line indicates half-circle catheter configuration inside the phantom liquid; dotted line, straight configuration. C, Standard versus carbon catheter heating in various configurations at a SAR of 2.1 W/kg. Mean heating, SD, and maximum heating (dots with numeric data) at the catheter tip, 200 mm behind the tip, and at the point where the catheter crossed from air to gel are given for 10 configurations each as described in the Methods section. *P<0.05.
carbon catheters, whereas the middle part of the catheters showed no significant heating (Figure 2C). Comprehensive safety testing applying the low-SAR imaging sequences did not reveal a significant temperature increase of the carbon catheters in any tested configuration (room temperature, \(17.3 \pm 1.3^\circ\text{C}\); carbon catheter tip, \(17.3 \pm 0.7^\circ\text{C}\); \(n=12\); \(P=\text{NS}\)).

**Imaging of Carbon Leads**

Catheter tracking in a 1.5-T scanner is displayed using a gel phantom (Figure 3A) and in vivo in a pig heart (Figure 3B). In the phantom, the 2 carbon catheters are clearly visible with no image artifacts in the surrounding area. In contrast, the conventional metallic EP catheter caused large signal voids.

With MR-guided catheter placement, we targeted the right ventricular apex from a jugular access (Figure 3B). Images were acquired in end expiration using a breath-hold technique. The catheter did not remain in the imaging plane throughout the entire procedure but could be easily relocated with gradient echo or TrueFISP imaging. Passive visualization of the steerable carbon catheter was possible by the signal void and a small susceptibility artifact around the catheter (2.5 mm, Figure 3B and Figure 5A). Again, metallic catheters caused large image voids in the adjacent area, thus hampering precise tracking of their location.

**In Vivo Animal Studies**

For diagnostic EP studies including programmed stimulation, the catheter tip was guided to different anatomic regions including the right atrium (lateral free wall), right ventricular apex, the His bundle region, and coronary sinus. Once the catheter tip had entered the atrium, an average of 4 imaging planes had to be acquired to sufficiently identify the tip using TrueFISP pulse sequences as described in the Methods section. Subsequently, the steerable catheter was actively directed to the respective anatomic sites. For accurate placement in the right atrium, right ventricle, and coronary sinus, 3 additional real-time planes had to be used. Although identification of the His bundle ECG was possible and reproduc-
Radiofrequency and pulsed gradient fields used for MRI induce currents in the body. Recent reports have shown that concentrated in elongated, electrically conductive artificial structures. Even severe burns have been reported.

### Discussion
Radiofrequency and pulsed gradient fields used for MRI induction of currents in the body. Recent reports have shown that concentrated in elongated, electrically conductive artificial structures. Even severe burns have been reported.

### Table 2. Pacing, R-Wave Amplitudes, and Capture Thresholds

<table>
<thead>
<tr>
<th>Animal No.</th>
<th>Scanner</th>
<th>Before Ablation</th>
<th>After Ablation</th>
<th>Ablation Region</th>
<th>Ablation Details</th>
<th>ECG Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Siemens Vision</td>
<td>12 mV/0.5@0.5 ms</td>
<td>2.3 mV/4.8@0.5 ms*</td>
<td>V</td>
<td>60 s/75°C/23 W</td>
<td>Asystole</td>
</tr>
<tr>
<td>1</td>
<td>Siemens Vision</td>
<td>19 mV/0.7@0.5 ms</td>
<td>0.7 mV/exit block*</td>
<td>V</td>
<td>60 s/71°C/65 W</td>
<td>SR</td>
</tr>
<tr>
<td>2</td>
<td>Siemens Vision</td>
<td>9 mV/0.9@0.5 ms</td>
<td>3.5 mV/5.2@0.5 ms*</td>
<td>V</td>
<td>60 s/72°C/48 W</td>
<td>SR</td>
</tr>
<tr>
<td>3</td>
<td>Siemens Vision</td>
<td>3 mV/0.4@0.5 ms</td>
<td>0.4 mV/3.5@0.5 ms*</td>
<td>A</td>
<td>27 s/58°C/23 W</td>
<td>AVB III</td>
</tr>
<tr>
<td>4</td>
<td>Siemens Avanto</td>
<td>4 mV/1.5@0.5 ms</td>
<td>1 mV/6.7@0.5 ms*</td>
<td>CS</td>
<td>180 s/93°C/3 W</td>
<td>SR</td>
</tr>
<tr>
<td>5</td>
<td>Philips Intera</td>
<td>12 mV/0.8@0.5 ms</td>
<td>0.5 mV/6.1@0.5 ms*</td>
<td>A</td>
<td>60 s/75°C/33 W</td>
<td>SR</td>
</tr>
<tr>
<td>6</td>
<td>Philips Intera</td>
<td>7 mV/0.7@0.5 ms</td>
<td>0.3 mV/5.1@0.5 ms*</td>
<td>CS</td>
<td>120 s/73°C/11 W</td>
<td>SR</td>
</tr>
</tbody>
</table>

Animal numbers are chronological. Animal 0 was killed before experiments to establish setup. For ablation details, the first number gives ablation times in seconds, the second number gives maximum temperature in degrees Celsius, and the third number gives maximum energy delivery in Watts. V indicates right ventricle; A, atrial; CS, coronary sinus; SR, sinus rhythm; AVB III, 3rd-degree AV block; VF, ventricular fibrillation.

*Significant worsening of pacing and sensing threshold after ablation (P<0.05).
reports, however, demonstrated feasibility of new developments in the field of interventional EP in the MRI environment. The current work further extended these studies, introducing a setup for MR-guided interventional EP and ablation therapy including MR conditional carbon fiber-based catheters.

Safety Testing
Because of the large number of factors (eg, device length, diameter, material compounds, and orientation within the MR scanner) that contribute to the amount of heating in MRI, meeting the requirements for MR safety with elongated conductive devices is extremely problematic. Therefore, this study aimed to establish a scenario for MR-guided interventional EP and ablation therapy including MR conditional carbon fiber-based catheters.

Imaging
After in vitro investigations on MRI safety of the carbon leads, they were tested for EP purposes. Typically, methods for device localization are characterized as either passive or active catheter tracking. In passive techniques, materials are chosen so that the device is visible in the MR image. Active visualization techniques use catheters that provide strong signals; however, extensive device modifications are required. It is demonstrated here that carbon catheters are sufficiently detectable in MRI without the need for active...
visualization techniques. Because the catheter components give no MR signal, the signal void of the relatively thick catheter is clearly visible in the image. At the same time, carbon catheters do not cause image voids in the surrounding area, provided that sufficient imaging techniques are used.

Diagnostic EP
Right atrial and ventricular sites and the coronary sinus were successfully targeted in living animals using steerable catheters with real-time MRI pulse sequences. The high-resolution images of cardiac anatomy considerably improved targeting and accurate lesion placement, whereas standard x-ray fluoroscopy in contrast generally delivers poor tissue contrast. The pacing threshold did not change during MRI and was identical to thresholds observed in clinical practice. With the use of differential filter system, the IEGM could be received without electromagnetic interference.

RF Ablation
Recent developments in the area of interventional electrophysiology demonstrated the feasibility of electroanatomic mapping and diagnostic EP studies in the MRI environment. We now added proof that RF ablation is possible in different MR scanners using carbon catheters and specific safety issues can be minimized provided adequate precautions. Ventricular fibrillation occurred in 1 animal during ablation of the right free ventricular wall. However, this adverse event is a well-known complication of RF ablation at ventricular targets and was not caused by the MRI environment. We targeted anatomic regions that are regularly addressed in clinical practice and demonstrated that imaging the catheter tip and tracking the IEGM is possible during the entire procedures. Time, temperature, and RF delivery for ablation therapy with the carbon catheters to achieve myocardial lesions were similar to those by conventional EP catheters. This approach might help to improve safety and efficacy of RF ablation, especially for ablation of complex arrhythmias, in which knowledge of the neighboring anatomy and possible gaps for conduction is crucial for success and safety.

Limitations
Although the current study presents major advances in MR-guided interventional EP, there are still limitations re-
garding investigations in certain patients. This issue has recently been reviewed in an American Heart Association scientific statement on the safety of MRI in patients with cardiovascular devices. Also, image quality is compromised because of the necessity of low SAR protocols for safety purposes. Therefore, a number of technical challenges must be resolved before its widespread clinical use can be realized. There is a need for specialized hardware for MRI-guided interventional electrophysiology studies, and further advances in imaging techniques must be established to use MR-guided electrophysiological interventions to full capacity. As an example, MR-based visualization of scar morphology was recently shown to contribute to preprocedural planning for interventional EP.

Successful assessment of ablation sites using enhanced and nonenhanced MRI protocols was recently described. Although this study was not intended to investigate lesion mapping strategies, we preliminarily investigated the possibilities to gain intraprocedural information of the lesion development. In this context, it is important to mention that assessment of the lesion size in the MRI was performed shortly after ablation to test for the clinical relevance of this procedure, whereas pathological examination followed several hours later. Clearly, more studies are warranted further extending the possibilities and clinical implications of these approaches.

Conclusion and Clinical Implications

The current study demonstrates the feasibility of interventional EP studies and targeted RF ablation under real-time MRI guidance using novel carbon catheters. Furthermore, it gives proof of improved imaging qualities and safety properties for these catheters with specific short low-SAR imaging sequences. Although the approach described here is applicable to all cardiac arrhythmias, it might be particularly well suited for more complex arrhythmias that require the accurate placement of multiple, linearly arranged lesions (eg, atrial flutter and fibrillation, ventricular tachycardia). In addition to improved anatomic targeting of critical focal sites, the ability to directly visualize the spatial extent of lesions with high spatial resolution may help to facilitate the placement of linear transmural lesions and allow for real-time detection (and possibly prevention) of complications. These advances might help to reduce the number of lesions required for conduction block, procedure time, and potential procedural risks such as perforation, all without ionizing radiation or iodized contrast agents in the future.

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Disclosures

Drs Ritter and Bauer serve as scientific advisors for Biotronik, and Dr Jakob serves as scientific advisor for Siemens. Drs Maxfield, Wurtz, and Geistert are employees of Biotronik.


**CLINICAL PERSPECTIVE**

MRI can provide detailed views of cardiac morphology and function. Real-time MR imaging during electrophysiological (EP) studies has the potential to improve visualization of anatomic detail and show ablation lesions but requires MR-compatible equipment, which is a substantial challenge. Recent work has shown feasibility of performing EP studies and electroanatomic mapping in MR scanners. The current study extends previous findings. A specialized EP setup that includes MR conditional catheters based on carbon technology is presented. This new technology allows for diagnostic EP studies and RF ablation therapy in the MR environment. We demonstrated successful targeting of different anatomic regions in the heart, with subsequent ablation in selected regions. It is hoped that further development of this technology will make real-time MR-guided EP procedures a clinical reality to facilitate complex EP interventions.
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