Novel, Magnetically Guided Catheter for Endocardial Mapping and Radiofrequency Catheter Ablation

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Background—Ablation of complex arrhythmias would be greatly facilitated by more precise control of ablation catheters. A feasibility study was performed in animals to evaluate a novel magnetic guidance system (MGS) that generates a magnetic field to control the movement and position of a magnetic ablation catheter.

Methods and Results—The MGS is composed of a digital biplanar fluoroscope within an array of superconducting electromagnets that surround the torso of the experimental animal and a computer control system that generates a composite magnetic field for directional catheter deflection. Magnetic catheter navigation was performed in dogs and pigs (20 to 30 kg). A 7F magnetic ablation catheter was used for intracardiac navigation and radiofrequency ablation. The performance of a standard 7F deflectable catheter was not affected by the MGS. The magnetic catheter was navigated successfully to 51 predefined targets throughout the heart in 6 animals. In 5 animals, the magnetic catheter, guided by a 3D computed tomogram, was successfully navigated to all pulmonary veins. Navigation accuracy was estimated as <1 mm displacement from the target. The magnetic catheter was used to ablate the atrioventricular node in 4 animals and to perform linear ablations across the endocardial surface underlying an epicardial multielectrode recording plaque in 4 animals.

Conclusions—These results demonstrate that the MGS can navigate and stabilize an ablation catheter at endocardial targets. Linear or focal radiofrequency ablation with the magnetic catheter is not compromised by the magnetic field. This technology provides precise control of endocardial catheters. (Circulation. 2002;106:2980-2985.)

Key Words: mapping ablation catheters

The success of arrhythmia ablation procedures has redefined the treatment of simple supraventricular arrhythmias, and catheter ablation techniques have an evolving role in the management of atrial fibrillation and ventricular arrhythmias.1-10 Conventional, manually deflected ablation catheters have several inherent limitations. Catheter deflection occurs with a fixed radius in a single plane restricting the freedom of movement. Side-to-side catheter motion is achieved by torque transmission that may be limited by tortuosity of blood vessels and the orientation of the catheter within the heart. In addition, stable endocardial contact with the catheter can be compromised by a lack of catheter compliance coupled with cardiopulmonary motion. These limitations may be particularly important for ablation of complex arrhythmias, such as atrial fibrillation, that depend on extremely accurate control of the catheter for development of focal or linear lesions. Advances in catheter design are needed to improve the efficacy of these difficult procedures. The purpose of this feasibility study in animals was to evaluate a novel magnetic guidance system (MGS) that generates magnetic fields to control the movement and position of a magnetic ablation catheter within the heart. We tested the ability of the MGS to move the magnetic catheter through all 4 cardiac chambers and perform radiofrequency ablation. We compared electrical recordings, pacing thresholds, and navigability with those of a conventional ablation catheter.

Methods

Magnetic Guidance System

Experiments were performed with the MGS shown in Figure 1A. The MGS (Telstar; Stereotaxis, Inc) is composed of a housing containing 3 orthogonal electromagnets cooled by liquid helium, biplanar digital fluoroscopic imaging plates, and a conventional fluoroscopy table. Directional catheter navigation is accomplished by drawing a desired magnetic field vector on orthogonal fluoroscopic views with a digitization tablet as shown in Figure 1B. A control computer then calculates the appropriate currents to each of the superconducting electromagnets. The resultant composite magnetic field interacts with a permanent magnet in the tip of the magnetic ablation catheter (AC0; Stereotaxis, Inc) and deflects the

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catheter to align parallel to the magnetic field. Navigation to a particular target often requires 2 or 3 manipulations of the magnetic field to refine the catheter position. Each magnetic field manipulation requires <20 seconds to activate. The position of the magnetic catheter within the heart is also controlled by manual advancement or retraction of the catheter through the vascular sheath.

Catheter Navigation

Navigation targets within the heart were a combination of broad regions, such as the high right atrium; spatially restricted regions, such as the His bundle; and electrode targets on a decapolar catheter. Navigation success with the MGS or a standard ablation catheter was judged subjectively by a combination of electrogram analysis and analysis of the biplanar fluoroscopic images. For example, an appropriate His bundle recording made at the anteroseptal tricuspid valve annulus was judged a successful navigation to the His bundle. Navigation failure was judged if the catheter had not reached the intended target within 10 minutes of attempted navigation.

In a subset of 5 animals, an ECG-gated, contrast-enhanced computed tomogram of the heart (Plus 4 Volume Zoom CT scanner; Siemens Medical) was performed before the procedure to identify the location of the pulmonary vein ostia. Navigation to the pulmonary vein ostia with either a standard catheter or the magnetic catheter was guided by “real-time” biplanar fluoroscopic images adjacent to a 3D rendering of the computed tomogram. Once in the pulmonary vein ostium, the catheter was advanced beyond the cardiac silhouette to identify which pulmonary vein the catheter had entered. Transseptal and retrograde aortic approaches were used for pulmonary vein ostial navigation.

Catheter Deflection Force

Deflection of the magnetic catheter in the direction of the magnetic field vector occurs because of force exerted on the permanent magnet as described by the equations in Figure 2A. Preliminary work with 7F catheter prototypes demonstrated that a full range of catheter deflection is possible with a magnetic field strength of 0.15 T. An estimate of the maximum endocardial force applied by the catheter in the presence of a 0.15-T magnetic field was made to assess the risk of cardiac perforation. To measure deflection force, nonmagnetic weights and a balance were used to equalize the magnetic force exerted on the catheter. The nonmagnetic weights were then transferred to a balance connected to a force gauge (Chatillon, Inc) to estimate the magnetic force exerted on the catheter for a particular deflection angle. For comparison, force measurements were made with 10 conventional, manually deflectable catheters from a variety of manufacturers. Catheter deflection force was measured directly by catheter deflection against a T-bar connected to a force gauge.
To assess the possibility of endocardial injury or perforation, the magnetic catheter was deflected toward a target outside the cardiac silhouette at the lateral right atrium in 3 animals. Gross inspection of the endocardial surface at the site of the navigation attempt did not demonstrate any significant abnormality resulting from this maneuver.

Animal Studies
All animal experiments were performed in accordance with institutional and National Institutes of Health guidelines. Studies were performed on healthy dogs (Covance, Inc, Princeton, NJ) and pigs (Oak Hill Genetics, Inc, Ewing, II) weighing 20 to 30 kg. Animals were premedicated with atropine (0.04 mg/kg IM) and a Telazol/ketamine/xylazine cocktail (1 mL/50 lb body wt IM), intubated, mechanically ventilated, and maintained with isoflurane (1% to 5%) inhalational general anesthesia. The right and left femoral neurovascular bundles were then exposed by cutdown, and arterial and venous endovascular access sheaths were placed. In 4 animals, a right lateral thoracotomy was performed to expose the pericardium overlying the right atrium. The pericardium was incised, and a multielectrode recording plaque was sutured in place over the right atrial appendage and anterolateral right atrium. The pericardium and thoracotomy were closed with surgical tape. At the conclusion of the study, animals were euthanized with 150 mg/kg pentobarbital IV. The heart was explanted and fixed in formalin for gross and histological tissue analysis.

Electrogram Recordings
A standard multichannel amplifier/digital recording system was used for all experiments (Prucka, Inc). Intracardiac and surface ECG signals were digitized at 1 kHz for recording. Intracardiac signals were filtered with a bandpass of 30 to 400 Hz. Surface ECG signals were recorded with a bandpass of 0.05 to 120 Hz. Stored electrograms were analyzed and measured with the analysis package provided with the recording system (Prucka). Frequency-domain analysis of recorded signals was performed by Fourier transformation using a Blackman window function (Origin; Microcal, Inc).

Radiofrequency Energy Application
Radiofrequency energy was applied between the magnetic catheter tip and a cutaneous ground patch with a conventional radiofrequency current generator (Radionics, Inc). The progress of ablation was followed by impedance monitoring. Radiofrequency power was increased until a significant impedance reduction (>5 Ω) was observed. With this protocol, radiofrequency energy applications of 5 to 20 W for 60 seconds typically produced transmural lesions visible on gross inspection of the heart at the conclusion of the procedure, and impedance increases were not observed.

Statistical Analysis
Sample means, SDs, and Student’s t tests were performed with a standard statistical analysis program.

Results
Comparison of Force Applied by Magnetic and Conventional Catheters
Measurements of the applied magnetic force, shown in Figure 2B, conform closely to the calculated force. The maximum force applied to the tip of the magnet catheter was 26.8 g. The range of force measurements from the conventional catheters was 19.7 to 45.4 g, with an average force measurement of 31.4 g (117% of the measured magnetic catheter force).

Surface ECG Recordings in the Presence of a Magnetic Field
Standard surface ECGs were recorded in the presence and absence of a 0.15-T magnetic field. In the presence of the constant magnetic field, some distortion of the recorded electrogram was present. Figure 3A demonstrates typical surface lead III recordings from a single animal in the presence and absence of an applied magnetic field of 0.15 T. Distortion is noted predominantly in the T wave. Fourier analysis of the waveform revealed a dominant interference frequency of between 10 and 20 Hz. The ratio of the recorded QRS amplitude to interference amplitude is maximal for lead III and minimal for lead I. The average power spectra ratio from 4 animals for surface ECGs in the presence and absence of the magnetic field was 5.75±8.7 (mean±SD).

Intracardiac Recording and Pacing
In 3 animals, distal-pair, bipolar recordings were made with a standard 4-mm-tip deflectable catheter at the His bundle, right atrium, and right ventricle. These recordings were compared with those obtained by the magnetic catheter in the same animal in the presence of a 0.15-T magnetic field. Representative recordings from a single animal are shown in Figure 3A. Despite some distortion noted in the surface ECG as described above, there was no qualitative difference in the fidelity of the intracardiac recordings at any of the sites. A signal-to-noise ratio was calculated at the His bundle site.
using the amplitude of the His electrogram and the amplitude of the baseline noise envelope recorded during the diastolic interval. The signal-to-noise ratio recorded by the magnetic catheter at the His bundle location was 11.8±6.1 (mean±SD) compared with 9.1±1.8 recorded by the standard deflectable catheter. The difference was not significant.

In 3 animals, stimulation thresholds were measured in the right atrium and ventricle with both the standard deflectable catheter and the magnetic catheter. Representative recordings of pacing in the right atrium and right ventricle from a single animal are shown in Figure 3B. In the right atrium, a stimulation threshold of 2.1±0.9 mA (mean±SD) was measured with the standard catheter compared with 1.2±0.5 mA measured with the magnetic catheter. In the right ventricle, a stimulation threshold of 0.9±0.8 mA (mean±SD) was measured with the standard catheter compared with 1.2±0.6 mA measured with the magnetic catheter. The differences in stimulation thresholds between the magnetic and standard catheters were not significant.

**Directional Navigation**

The ability of the magnetic catheter to navigate to 10 predefined targets was compared in 3 animals with the performance of a conventional, manually deflectable catheter to reach the same targets. Navigation targets included the high right atrium, the right atrial appendage, the His bundle, the right ventricular apex, the left ventricular apex, the left ventricular free wall, and the posterior and lateral mitral valve annulus. The magnetic catheter was navigated to 7 predefined targets in 3 additional animals. Navigation targets were a subset of the targets defined for the first 3 animals. Of 51 navigation targets in 6 animals, magnetic catheter navigation was successful to 46 targets (success rate, 0.90; CI, 0.79 to 0.97). All navigation failures occurred in 1 animal in which the magnetic catheter could not be passed around the aortic arch and therefore could not reach the navigation targets within the left ventricle and mitral annulus. In this animal, an atypical aortic arch promoted prolapse of the magnetic catheter into the subclavian artery at the catheter transition point between the distal floppy segment and the more rigid proximal segment. On the basis of this observation, a new catheter design was implemented to modify the transition between the 2 catheter segments, and this problem was not encountered subsequently. The conventional catheter was successfully navigated to 29 of 30 navigation targets (success rate, 0.97; 95% CI, 0.83 to 1.00). The navigation success rates were not significantly different between the standard and magnetic catheters.

Navigation precision was assessed by measurement of the maximum displacement between the magnetic catheter and navigation targets visualized in orthogonal fluoroscopic views. In 3 animals, a decapolar catheter was deployed into the right atrium. The magnetic catheter was directed to each electrode pair of the decapolar catheter in sequence. The average maximum displacement of the magnetic catheter to the navigation target was 0.73 mm (95% CI, 0.23 to 1.34 mm).

**Navigation to Pulmonary Vein Ostia**

In 5 animals, a 3D rendering of the computed tomogram was used to guide navigation to the pulmonary vein ostia with the magnetic catheter. In 5 animals, the magnetic catheter was successfully advanced into a total of 30 of 30 pulmonary veins. A representative experiment from a single animal is shown in Figure 4. In the figure, the catheter is introduced into the left atrium by the retrograde aortic approach and navigated to each of 6 pulmonary vein ostia. Navigation to Pulmonary Vein Ostia

In 5 animals, the magnetic catheter was also navigated by a transseptal approach to 1 of 6 pulmonary veins.

**Radiofrequency Ablation**

The ability of the magnetic catheter to perform therapeutic radiofrequency ablation was assessed in 2 ways. In 4 animals, the magnetic catheter was directed to the His bundle record-
ing site at the conclusion of the procedure, and the atrioventricular node was successfully ablated with a single 60-second application of 15 W of radiofrequency current. In 4 animals, a multielectrode recording plaque, shown in Figure 5A, was positioned on the epicardial surface of the anterolateral right atrium. Epicardial activation was then recorded in response to pacing from the central electrode pair of the lateral edge of the recording plaque. As shown in Figure 5B, isochronal activation spread uniformly across the epicardial surface under the recording plaque. The magnetic catheter was then navigated to the endocardial surface underlying the superior middle edge of the recording plaque. Serial radiofrequency ablation lesions were applied with 60 seconds of 15 W of radiofrequency current. Between each application, the catheter was navigated along a linear trajectory across the endocardial surface underlying the middle of the recording plaque. When the catheter had reached the inferior margin of the recording plaque, epicardial activation was again measured with the recording plaque. As shown in Figure 5C, pacing from the middle electrode pair of the edge of the recording plaque demonstrated an epicardial line of conduction block overlying the line of ablation lesions. The linear lesion was visible on the epicardial surface of the heart at the conclusion of the experiment, as shown in Figure 5D. Similar results were achieved in 3 additional animals.

**Discussion**

Our results demonstrate the feasibility of magnetic control of an ablation catheter for cardiac electrophysiological procedures. The promise of this technique lies in the precision of catheter movement and the ability to steer the flexible distal portion of the catheter in any direction. In contrast to manually controlled catheters that deflect in a single plane, the tip of the magnetic catheter can be deflected toward any direction in 3D space.

We evaluated 3 questions regarding the safety and efficacy of the catheter. First, is the electrical interference induced by the magnetic field a significant limitation to the fidelity of recording standard surface ECGs or intracardiac electrograms? Second, does the magnetic catheter apply excessive endocardial force that would increase the risk of cardiac injury or perforation over that applied by a standard, manually deflectable catheter? And third, would the magnetic catheter meet the demands for accurate navigation, intracardiac recording and pacing, and radiofrequency ablation?

The magnetic field strength used for catheter manipulation in these studies induced an electrical potential that was superimposed on the ECG recorded at the body surface. The resultant distortion of the surface ECG was predominantly within the T wave and has been attributed to a potential generated by blood flow in the aorta in the presence of the
magnetic field. The temporal distribution of the interfering signal component probably would not compromise cardiac rhythm analysis or analysis of p-wave or QRS morphology. Intracardiac recordings with conventional filter settings were qualitatively unaffected by significant distortion in the presence of the magnetic field.

The maximal endocardial contact force exerted by the magnetic catheter was estimated by an assay that approximates the force applied when the catheter is intentionally deflected by a magnetic vector directed outside of the cardiac silhouette. The measured force applied by the magnetic catheter was less than that applied by a conventional, manually controlled catheter. In addition, attempts to intentionally perforate the heart with the magnetic catheter did not result in significant endocardial injury. Although further study is needed to make a definitive statement, these data indicate that the magnetic catheter is associated with a low risk of cardiac injury.

Navigation with the magnetic catheter was highly successful and precise. Navigation success to targets in all 4 cardiac chambers was comparable to that with a standard ablation catheter. In addition, navigation to the pulmonary vein ostia with the MGS by either the transseptal or retrograde aortic approach was more successful than with a conventional ablation catheter.

Our results indicate that the magnetic catheter can be used to achieve lines of conduction block by sequential, contiguous applications of radiofrequency energy. This demonstration was made on trabeculated myocardium, which is predictably the most difficult area to achieve linear conduction block. Future studies will explore the capacity of this magnetic catheter system to place lines of conduction block that may be used in curative ablation of arrhythmias.

We conclude that the MGS is safe and provides accurate navigation for an electrophysiology catheter in all 4 chambers of the heart. Its precise movement, flexibility, and ability to rotate in any direction offer potential advantages over conventional catheters. These results have important implications for advancing technology needed for ablation of complex arrhythmias.

Study Limitations
Several potential limitations are present in our study. First, the comparisons with a standard catheter were nonrandomized and unblinded; therefore, investigator bias cannot be excluded. Magnetic catheter navigation was typically performed first; therefore, some bias in favor of the standard catheter may have occurred through practice. Later studies were performed with a modified version of the magnetic catheter that minimized the transition in stiffness between the proximal catheter body and the distal tip present in the initial version of the catheter. The possibility that the modified catheter performance was substantially different from the initial catheter design is possible but unlikely. Magnetic catheter endocardial contact stability was not quantified in association with cardiopulmonary motion. As with conventional catheters, electrograms recorded on the tricuspid annulus with the magnetic catheter had some variation in amplitude that was not quantified. Finally, a detailed microscopic analysis of the radiofrequency ablation lesions was not performed. The assays of ablation efficacy were physiological in nature, with the demonstration of complete heart block or linear conduction block after radiofrequency ablation.

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References
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