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Initial Experience With Remote Catheter Ablation Using a Novel Magnetic Navigation System

Magnetic Remote Catheter Ablation

Sabine Ernst, MD; Feifan Ouyang, MD; Christian Linder, MD; Klaus Hertting, MD; Fabian Stahl, MD; Julian Chun, MD; Hitoshi Hachiya, MD; Dietmar Bänsch, MD; Matthias Antz, MD; Karl-Heinz Kuck, MD

Background—Catheters are typically stiff and incorporate a pull-wire mechanism to allow tip deflection. While standing at the patient's side, the operator manually navigates the catheter in the heart using fluoroscopic guidance.

Methods and Results—A total of 42 patients (32 female; mean age, 55 ± 15 years) underwent ablation of common-type (slow/fast) or uncommon-type (slow/slow) atrioventricular nodal reentrant tachycardia (AVNRT) with the use of the magnetic navigation system Niobe (Stereotaxis, Inc). It consists of 2 computer-controlled permanent magnets located on opposite sides of the patient, which create a steerable external magnetic field (0.08 T). A small magnet embedded in the catheter tip causes the catheter to align and to be steered by the external magnetic field. A motor drive advances or retracts the catheter, enabling complete remote navigation. Radiofrequency current was applied with the use of a remote-controlled 4-mm, solid-tip, magnetic navigation-enabled catheter (55°C , maximum 40 W, 60 seconds) in all patients. The investigators, who were situated in the control room, performed the ablation using a mean of 7.2 ± 4.7 radiofrequency current applications (mean fluoroscopy time, 8.9 ± 6.2 minutes; procedure duration, 145 ± 43 minutes). Slow pathway ablation was achieved in 15 patients, whereas slow pathway modulation was the end point in the remaining patients. There were no complications.

Conclusions—The Niobe magnetic navigation system is a new platform technology allowing remote-controlled navigation of an ablation catheter. In conjunction with a motor drive unit, this system was used successfully to perform completely remote-controlled mapping and ablation in patients with AVNRT. (*Circulation*. 2004;109:1472-1475.)

Key Words: catheter ablation ■ tachycardia, supraventricular ■ mapping

Catheter ablation of supraventricular tachycardia, such as atrioventricular nodal reentrant tachycardia (AVNRT), has been established with a high procedural success rate and long-term effectiveness, yet a very low risk of associated complications.¹⁻⁵ Mapping of the cardiac chambers is performed with relatively stiff manually deflectable catheters with unidirectional or bidirectional deflection radius. Steering of those electrodes is performed via a pull-wire mechanism integrated in the handle of the catheter, allowing a reliable and reproducible deflection. While standing at the patient's side, the operator navigates the catheter to the desired position guided by fluoroscopy. Recently, a novel magnetic navigation system (MNS) was introduced that allows the use of a soft ablation catheter that can be guided and positioned precisely by magnetic fields to any desired site within the cardiac chambers in an animal model.⁶

We report our initial experience using the MNS for completely remote-controlled catheter ablation in the right atrium in patients with documented AVNRT.

Methods

Patient Population

Between May 15, 2003, and October 2003, a total of 42 patients (32 female; mean age, 55 ± 15 years) underwent an ablation attempt for common-type (slow/fast) or uncommon-type (slow/slow) AVNRT with the use of the MNS. After exclusion of contraindications for magnetic navigation (eg, pacemaker or implanted cardioverter/defibrillator device, metallic implants, claustrophobia), patients were studied in a fasting state under continuous sedation by intravenous propofol infusion (1 to 4 mg/kg body wt per hour) and/or intravenous bolus of midazolam. This study was part of the initial safety and feasibility protocol approved by the ethics board of the Hamburg Chamber of Physicians. All patients gave their written permission after informed consent was obtained.

Electrophysiological Study

Four standard catheters were positioned for the diagnostic electrophysiological study. A His bundle recording catheter (Parahis, Biosense Webster) advanced via femoral venous access, and a multipolar catheter (Parahis, Biosense Webster) advanced in the distal coronary sinus via the left subclavian vein (Figure 1). Two

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From the Second Department of Medicine, Allgemeines Krankenhaus St Georg, Hamburg, Germany.

Correspondence to Karl-Heinz Kuck, MD, Allgemeines Krankenhaus St Georg, 2 Med. Abteilung (Kardiologie), Lohmühlenstrasse 5, 20099 Hamburg, Germany. E-mail: sernst1708@aol.com

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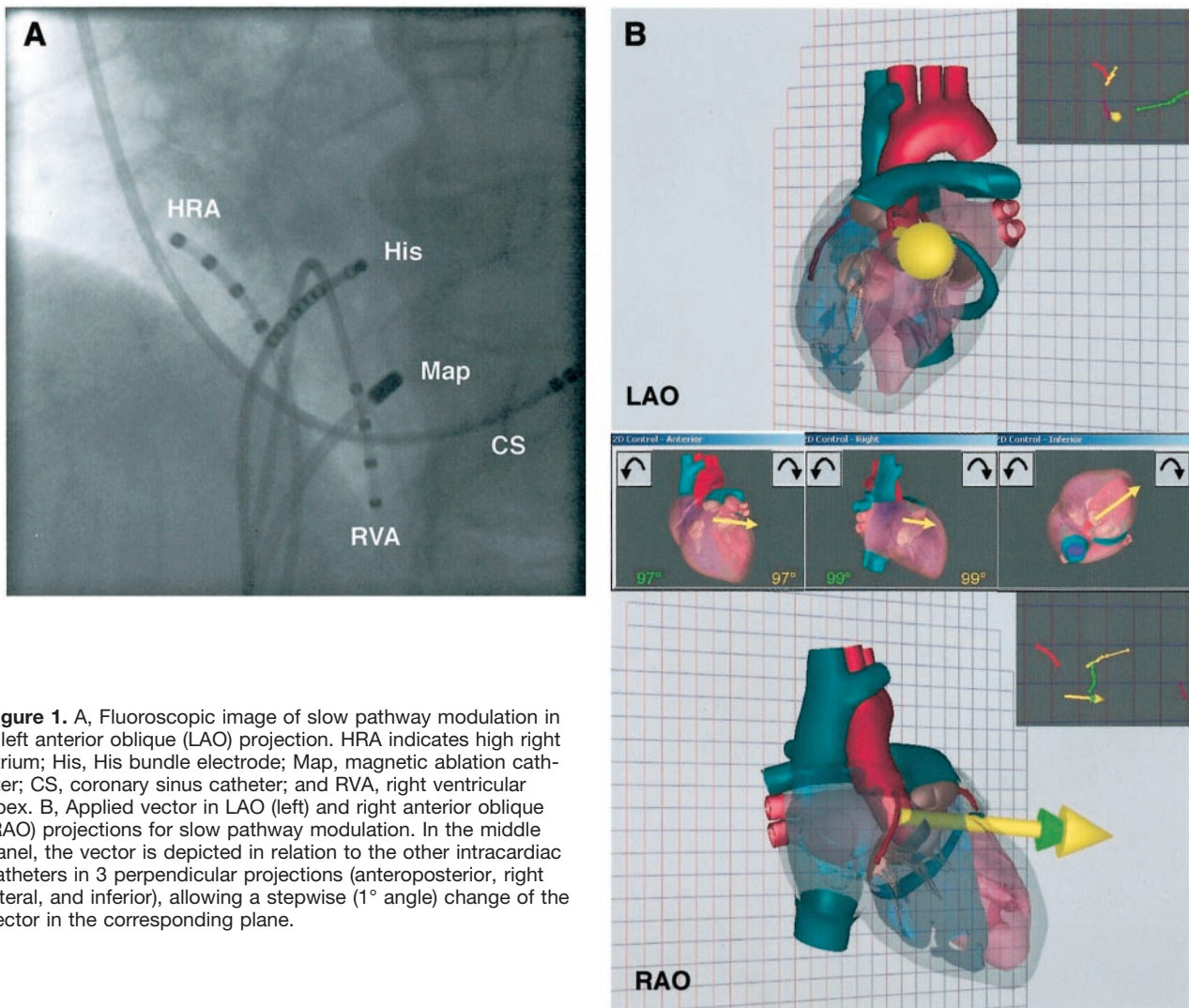


Figure 1. A, Fluoroscopic image of slow pathway modulation in a left anterior oblique (LAO) projection. HRA indicates high right atrium; His, His bundle electrode; Map, magnetic ablation catheter; CS, coronary sinus catheter; and RVA, right ventricular apex. B, Applied vector in LAO (left) and right anterior oblique (RAO) projections for slow pathway modulation. In the middle panel, the vector is depicted in relation to the other intracardiac catheters in 3 perpendicular projections (anteroposterior, right lateral, and inferior), allowing a stepwise (1° angle) change of the vector in the corresponding plane.

nondeflectable catheters (Soloist, Medtronic) were positioned in the right ventricular apex and the high right atrium.

In the beginning, a standard electrophysiological study was performed to identify the underlying tachycardia mechanism. Orciprenaline was administered intravenously to facilitate tachycardia induction if necessary. After AVNRT was confirmed as the underlying tachycardia mechanism according to standard criteria,¹⁻⁴ the magnetic mapping and ablation catheter (Helios, Stereotaxis, Inc) was introduced manually into the right atrium (Figure 1).

Magnetic Navigation

The MNS (Niobe, Stereotaxis, Inc) consists of 2 permanent magnets the positions of which, relative to each other, are computer controlled inside a fixed housing and positioned on either side of the fluoroscopy table (AXIOM Artis, Siemens). While positioned in “navigate” position, they create a relatively uniform magnetic field (0.08 T) of approximately 15 cm inside the chest of the patient. The mapping and ablation catheter is equipped with a small permanent magnet positioned at the tip that aligns itself with the direction of the externally controlled magnetic field to enable it to be steered effectively. By changing the orientation of the outer magnets relative to each other, the orientation of the magnetic field changes and thereby leads to deflection of the catheter (Figure 1). All magnetic field vectors can be stored and, if necessary, reapplied while the magnetic catheter is navigated automatically. In addition, a computer-controlled catheter advancer system (Cardiodrive unit,

Stereotaxis, Inc) is used to allow truly remote catheter navigation without the need for manual manipulation. The video workstation (Navigant II, Stereotaxis, Inc) in conjunction with the Cardiodrive unit allows precise orientation of the catheter by 1° increments and by 1-mm steps in advancement or retraction. The system is controlled by joystick or mouse and allows remote control of the ablation catheter from inside the control room (Figure 2). When the external magnet housing is in navigation position (close to the patient), the angulation of the C-arm is limited to approximately 28° for both right anterior oblique and left anterior oblique projections.

Ablation

Radiofrequency current (RFC) catheter ablation was performed with the 4-mm, solid-tip, magnetic ablation catheter in a temperature-controlled mode (maximum temperature 55°C , maximum duration 60 seconds, maximum 40 W) with the use of a Stockert RF generator (Biosense Webster).

End Point for Catheter Ablation

End point for catheter ablation was evidence of slow pathway ablation or modulation and failure to induce clinical tachycardia, as proven by conventional electrophysiological pacing maneuvers.¹⁻⁵

Statistical Analysis

Continuous variables are expressed as mean \pm 1 SD.

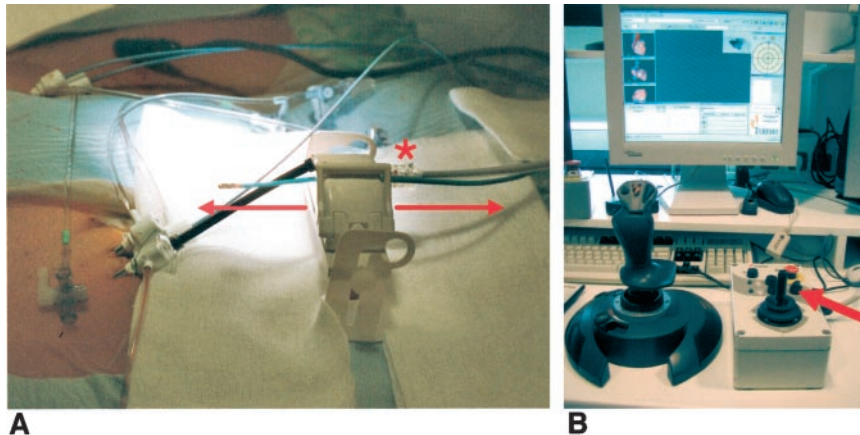


Figure 2. A, Cardiodrive unit fixed to the patient's right groin. An arrow is inserted to demonstrate the possible remote-controlled movements of the catheter. The star depicts a sterile connection with an inner metal rotating shaft that transfers the motor drive actions to the catheter. B, Cardiac advancer system in which the smaller right joystick inside the control room is used with either stepwise or continuous movement. The left joystick allows change in orientation of the tip of the ablation catheter by magnetic navigation.

Results

Procedural Data

A total of 42 patients with documented supraventricular tachycardia suggesting typical AVNRT as the underlying tachycardia substrate amenable to catheter ablation were included in this study (Table 1).

Catheter Positioning

Sheath insertion and positioning of the diagnostic catheters, including the magnetic catheter, required a mean total of 12 ± 5 minutes, with a radiation exposure of 3.4 ± 2.7 minutes for the patient and the physician. In 1 patient, contrast injection in the left subclavian vein depicted a persistent left superior caval vein resulting in a giant coronary sinus ostium.⁷ Thereafter, the physician left the interventional room and performed the entire electrophysiological study and ablation procedure from within the control room without wearing lead protection.

Electrophysiological Study

After exclusion of an accessory pathway connection, baseline electrophysiological study reproducibly induced common-type AVNRT (slow/fast) in 35 patients and uncommon-type AVNRT (slow/slow) in 4 patients. With additional intravenous application of orciprenaline in the remaining 3 patients,

typical AVNRT was induced. The mean tachycardia cycle length was 377 ± 67 ms.

Remote Catheter Mapping Using Magnetic Navigation

With the use of the left anterior oblique plane, the septum could not be depicted in an orthogonal view in 25 patients because of the limited angulation of the C-arm (Figure 1).

With the use of the MNS in conjunction with the Cardiodrive unit, the right atrium close to the coronary sinus ostium was carefully mapped for typical slow pathway potentials. All mapping positions were stored and reviewed for the best mapping result. The vector with the best mapping result was then reapplied and navigated the ablation catheter automatically to the target site. A stable catheter position with a slow pathway potential was achieved in all patients by remote catheter navigation. The fluoroscopy system and electrophysiological stimulator were also controlled from within the control room.

Remote Catheter Ablation Using Magnetic Navigation

With the magnetic catheter at the target site, RFC energy was delivered with the use of a foot pedal from the control room. Slow pathway modulation ($n=27$ patients) or ablation ($n=15$ patients) was performed with a mean number of 7.2 ± 4.7 RFC applications (Table). Junctional rhythm was demonstrated during radiofrequency ablation in all patients without dislodgement of the ablation electrode. Overall procedure time was 145 ± 43 minutes (calculated from puncture to sheath extraction), with a mean of 8.9 ± 6.2 minutes of intermittent fluoroscopy.

Repeated control stimulation was unable to induce AVNRT in all patients, even in the presence of orciprenaline infusion, but depicted the presence of dual atrioventricular nodal conduction properties in 27 of 43 patients.

Results of Follow-Up

No recurrence was seen during a mean follow-up time of 112 ± 48 days. No complications occurred.

Discussion

We report on the initial results of catheter ablation of AVNRT by total remote control. This included not only remote control

Overview of Patient Demographics and Procedure Parameters

Total No. of pts	42
Gender, female/male, n	32/10
Mean age, y	55 ± 15
AVNRT slow/fast, No. of pts	38
AVNRT slow/slow, No. of pts	4
Tachycardia cycle length, ms	377 ± 67
Procedure duration, min	145 ± 43 (65–240)
Fluoroscopy, min	8.9 ± 6.2 (2.5–20)
RFC applications	7.2 ± 4.7 (2–16)
Median total ablation time per RFC application, s	37 (8–60)
Slow pathway modulation, No. of pts	27
Slow pathway ablation, No. of pts	15

Pts indicates patients. Values in parentheses are ranges.

of the fluoroscopy system and the RFC generator but also, most importantly, of the ablation catheter via the MNS Niobe.

From an early report in 1991 of magnetic navigation of a catheter in a neonate⁸ and further evolution of the system in the field of neurosurgery,⁹ a novel MNS system was recently introduced into interventional cardiology.⁵ Whereas the first-generation MNS (0.15 T, Telstar, Stereotaxis, Inc) consisted of electromagnets and a biplane fluoroscopic imaging system, the second-generation system Niobe consists of 2 permanent magnets (neodymium boron iron) and a single-plan fluoroscopic system (Artis, Siemens). All 42 patients underwent successful remote-controlled catheter ablation with the use of the new MNS in conjunction with the catheter advancer system. Procedural parameters such as procedure duration, fluoroscopy exposure time, and number of RFC applications (Table) were an expression of the underlying learning curve and the need to confirm catheter stability visually (eg, during RFC ablation).

Advantages for Patients

As previously reported with the first generation of magnetic navigation systems, there was no associated risk of perforation.⁶ The ablation catheter held a stable position even with changing cardiac rhythms (such as junctional beats) and complex atrial anatomy (giant coronary sinus ostium in a patient with persistent left superior caval vein).⁷ The option of reapplication of a previously applied magnetic field vector allowed renavigation to a previously visited site and thereby shortened both mapping and fluoroscopy time.

Advantages for Physicians

After the diagnostic catheters were positioned, the electrophysiological study and the ablation process were performed completely from within the control room, thereby reducing the fluoroscopic exposure time for the operator.

Limitations

The angulation of the fluoroscopic system is limited to 28° for both left anterior oblique and right anterior oblique

projections when the magnets are in “navigate” position. Although this might not be of importance in AVNRT ablation (refer to the His electrode in Figure 1A), addressing more complex substrates might be more challenging.

Conclusions

The novel MNS in conjunction with the catheter advancer system proved to be a safe and feasible tool for remote catheter ablation of AVNRT. Further technical development through the availability of additional catheter designs (eg, number of recording electrodes) is necessary to address more complex arrhythmias in the future.

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