Remote Magnetic Navigation With Irrigated Tip Catheter for Ablation of Paroxysmal Atrial Fibrillation

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Background—The remote magnetic navigation system (MNS) has been used with a nonirrigated magnetic catheter for atrial fibrillation (AF) ablation. The objective of this study was to evaluate the feasibility and efficiency of the newly available irrigated tip magnetic catheter for index pulmonary vein isolation (PVI) in patients with paroxysmal AF (PAF).

Methods and Results—Between January 2008 and June 2009, 30 consecutive patients with drug-resistant PAF underwent circular mapping catheter-guided PVI with MNS (MNS group). The outcomes were compared retrospectively with those of a conventional hand-controlled ablation technique during the same period in 44 consecutive patients (manual group). All 4 pulmonary veins were successfully isolated in both groups except in 4 patients in the MNS group. Radiofrequency and procedure duration were higher in the MNS group (60±27 versus 43±16 minutes; P=0.0019) than in the manual group (24±50 versus 153±51 minutes; P<0.0001). In the patients who underwent only PVI, total fluoroscopic time also was longer in the MNS group than in the manual group (58±24 versus 40±14 minutes; P=0.0002). At 12-month follow-up after a single procedure, 69.0% of the patients in MNS group and 61.8% of patients in manual group were free of atrial tachyarrhythmia without antiarrhythmic drugs. There was no significant difference in the atrial tachyarrhythmia-free survival between the 2 groups (P=0.961). Cardiac tamponade occurred in 1 patient in the manual group.

Conclusions—In patients with PAF, MNS-guided PVI with the newly available irrigated tip magnetic catheter backed up with manual ablation whenever required is feasible. However, it requires longer ablation, fluoroscopy, and procedural times than the conventional approach in the early experience stage. (Circ Arrhythm Electrophysiol. 2010;3:585-589.)

Key Words: atrial fibrillation • catheter ablation • robotics • irrigation

Over the past decade, radiofrequency (RF) catheter ablation of atrial fibrillation (AF) has become an important therapy with good procedural success rates. The remote magnetic navigation system (MNS) has been introduced recently into clinical practice, which allows the use of a soft-tipped ablation catheter that can be guided to and positioned at the desired site by directional magnetic fields. On the other hand, the MNS is available and has been used with a nonirrigated magnetic tip catheter for RF ablation. Furthermore, a previous report showed that MNS with a nonirrigated 4-mm magnetic catheter could not achieve pulmonary vein isolation (PVI) in most of the cases, and charring of the catheter tip was frequently observed during the procedure. The purpose of the present study was to investigate whether AF ablation using the newly available irrigated tip catheter and MNS is feasible and effective in patients with paroxysmal AF (PAF) when compared with the widely established manually steerable catheter approach.

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Methods

Between January 2008 and June 2009, among 50 patients who underwent AF ablation using MNS and a new irrigated tip magnetic catheter at our center, 30 consecutive patients fulfilling the inclusion criteria mentioned herein were enrolled in this study (MNS group) of electric PVI for drug-resistant PAF as an index procedure without inducibility testing. Over the defined time period, 139 patients underwent catheter ablation for PAF as an index procedure. Among them, the procedural and clinical outcomes in the MNS group were compared with those of the conventional, hand-controlled catheter ablation in all consecutive patients who underwent PVI (manual group, n=44). The patients who received hand-controlled catheter ablation therapy as a part of simultaneously running other investigational protocols using novel tools (n=68) and those who received hand-controlled catheter ablation therapy with inducibility testing (n=27) were not included in this study.

AF was defined as paroxysmal when AF terminated spontaneously and lasted <7 days according to the “HRS/EHRA/ECAS 2007
Consensus Statement on Catheter and Surgical Ablation of AF. All patients gave written informed consent before the procedure.

Electrophysiological Study
All antiarrhythmic medications, with the exception of amiodarone, were discontinued at least for 5 half-lives before the ablation procedure. All patients received antiocoagulation therapy with warfarin for at least 1 month before the procedure (target international normalized ratio, 2 to 3), and therapeutic antiocoagulation was maintained with intravenous or low-molecular-weight heparin following warfarin discontinuation starting 3 days before the intervention. Transeosophageal echocardiography was performed within 48 hours before the procedure to exclude left atrial thrombus. Warfarin was resumed on the day of the procedure, and effective anticoagulation was maintained with heparin until the international normalized ratio was >2.0.

Surface ECG and bipolar endocardial electromograms (filtered from 30 to 500 Hz) were continuously monitored and stored on a computer-based digital amplifier/recorder system (LabSystem Pro; Bard EP; Lowell, Mass). Electrophysiological studies were performed in the fasting state under mild sedation. The following catheters were introduced through the right femoral vein: (1) a deflectable quadripolar catheter (5-mm interelectrode spacing [Xtrem; ELA Medical; Montrouge, France]) positioned within the coronary sinus with the distal electrode positioned at 4 to 5 o'clock along the mitral annulus in the 30° left anterior oblique radiographic projection; (2) a 10-pole, fixed-diameter (20 mm) circumferential mapping catheter to guide PVI (Lasso; Biosense-Webster; Diamond Bar, Calif) introduced with the aid of a long sheath (Preface Multipurpose; Biosense-Webster) and continuously perfused with heparinized saline; and (3) a 3.5-mm tip externally irrigated magnetic tip catheter (ThermoCool RMT; Biosense-Webster) with the aid of a second long sheath in the MNS group or 3.5-mm externally irrigated tip ablation catheter in the manual group.

A single transseptal puncture was performed in the anteroposterior radiographic position under pressure monitoring. Left atrial access was confirmed by an appropriate atrial pressure waveform and contrast injection. The circumferential mapping catheter was introduced into the left atrium through the transseptal sheath, and the sheath was withdrawn into the right atrium to facilitate the passage of the ablation catheter to the left atrium through the same, but dilated puncture site. Following the transseptal puncture, a bolus of 50 U/kg heparin was administered and repeated only if the procedure lasted >4 hours.

Catheter Ablation
PVI was performed as widely in the antrum as possible, with the end point of abolition or dissociation of activities in all the PVs and PV ostia during the sinus rhythm. PV potential and far-field potential were distinguished with pacing technique from the left atrium, left atrial appendage, or coronary sinus using the ablation or the quadripolar catheter. Cavotricuspid isthmus (CTI) ablation was added, when CTI-dependent flutter was documented on 12-lead ECG before or during the procedure, with the end point of bidirectional conduction block. In the MNS group, manual versus robotic ablation for CTI was left to the operator’s choice. PVI of all the veins was confirmed at the end of the procedure.

RF ablation was performed in the power control mode with target tissue temperature of not more than 45°C. Power of 25 to 35 W was used with manual titration of the saline perfusate from 10 to 60 mL/min to achieve the desired power. The power was limited to 30 W in the left atrium and 35 W on the CTI. A 3D electroanatomical mapping system was not used in the manual group. The Cartaphx radioprotection cabin (Lemer Pax; Carquefou, France) was used to protect the operator from radiation during all the procedures in both groups.

MNS Group
The remote MNS consists of 2 weak permanent magnets that generate a uniform magnetic field (0.08 T) and that are computer controlled and located on either side of the patient’s body. The MNS consists of 2 components: the Niobe Stereotaxis MNS (Stereotaxis Inc; St Louis, Mo) and an electroanatomical mapping system (CARTO RMT; Biosense-Webster). The CARTO RMT system sends catheter tip location and orientation data to the Stereotaxis system. It also sends target locations, points, and anatomic geometric information from the reconstructed map to the MNS. The real-time catheter location is displayed on the radiographic images, enabling continuous real-time monitoring of the catheter tip position. Remote catheter advancement and retraction from the control room are performed using a catheter-advancing system (CardioDrive; Stereotaxis Inc) positioned anteriorly on the thigh. Even fluoroscopy can be undertaken remotely from the control room. The catheter contains 3 magnets within the distal tip segment and an irrigation channel. It aligns with the field produced by the external magnets, allowing effective tip orientation.

Switching over to manual navigation was allowed for device failure, malfunction, patient anatomy, or medical necessity at the discretion of the investigator. The procedure duration was defined as the time from the start of the first venous puncture until just before the sheath withdrawal at the end of the procedure. RF duration was defined as the cumulative length of all RF applications necessary to achieve the end point. There was no difference in terms of ablation strategy and ablation condition between the study groups.

Follow-Up
Patients routinely were hospitalized for 2 days postprocedure and again for 1 day at 1, 3, 6, and 12 months for clinical interview and ambulatory monitoring in addition to the routine follow-up by the referring cardiologist, which included Holter monitoring in the event of symptoms. A blanking period of 3 months was applied. Antiarrhythmic medication was stopped following the index procedure or after 3 months in case of early recurrence of atrial arrhythmia. Warfarin anticoagulation was continued for at least 3 months. Success was defined as the absence of all documented arrhythmia or symptoms suggestive of an arrhythmia recurrence off drugs.

Statistical Analysis
Continuous variables are reported as mean ± SD or as median and interquartile range (IQR), depending on the normality of distribution. Comparison between the 2 groups was performed with the Student t test or the Wilcoxon rank sum test (nonnormally distributed data). Categorical variables are reported as number and percentage and were compared using the Fisher exact test. Cumulative event rates were calculated according to the Kaplan-Meier method, and any differences in the arrhythmia-free survival were evaluated using the log-rank test. All tests were 2-tailed, and statistical significance was established at P < 0.05.

Results
Study Patients
There was no significant difference in patient characteristics between the 2 groups (Table).

PVI
In the MNS group, 114 (95%) of 120 veins could be isolated with MNS only. In the manual group, all veins were successfully isolated. A total of 6 veins among 4 patients in the MNS group required the conventional catheter approach to ablate ostial PV potentials (right inferior PV, 2 patients; right PVs, 1 patient; left PVs, 1 patient). RF duration for PVI was higher in the MNS group than in the manual group (60 ± 27 versus 43 ± 16 minutes; P = 0.0019). The procedural duration from first femoral puncture to the end of PVI also was higher in the MNS group than in the manual group (246 ± 50 versus 153 ± 51 minutes; P < 0.0001). In the patients who underwent...
only PVI, the total fluoroscopic time was longer in the MNS group than in the manual group (58±24 versus 40±14 minutes; \( P=0.0002 \)).

### CTI Ablation

CTI ablation was added in 6 (20.0%) and 15 (34.1%) patients in the MNS and manual groups, respectively \( (P=0.187) \). In the MNS group, CTI ablation was started with MNS in all the patients, and it was completed in 3 (50%) patients with an RF time of 14±11 minutes. In the remaining 3 patients, CTI line was created by switching over to the conventional ablation in 1 (16%) patient, and it could not be created in 2 (33%) patients. In the manual group, CTI line was completed in 14 (93%) patients with an RF time of 11±8 minutes and was not completed in 1 (7%) patient.

### Total Fluoroscopy, Procedural, and RF Times

Total fluoroscopy (63±18 versus 45±16 minutes; \( P=0.0002 \)), procedural (263±72 versus 165±52 minutes; \( P<0.0001 \)), and RF (67±33 versus 47±17 minutes; \( P=0.0016 \)) times were significantly longer in the MNS group than in the manual group.

### Clinical Outcome

The follow-up period was 14±5 months in the MNS group and 15±5 months in the manual group. At 12-month follow-up after a single procedure, 69.0% of patients in the MNS group and 61.8% in the manual group were free of atrial tachyarrhythmia without antiarrhythmic drugs. There was no significant difference in terms of atrial tachyarrhythmia-free survival between the 2 groups (log–rank test \( P=0.961 \)) (Figure). In total, 11 (14%) patients, including 4 (13%) in the MNS group and 7 (16%) in the manual group \( (P=0.498) \), underwent a second procedure 12.3±2.5 and 12.7±5.2 months, respectively, after the index procedure \( (P=0.874) \). Electric PV reconnection was observed in at least 1 vein in all patients except for 1 patient in the MNS group. The average number of reconnected PVs was 1.5 (IQR, 0.25 to 3.5) and 2.0 (IQR, 1.0 to 3.0) in the MNS and manual groups, respectively. There was no significant difference between the 2 groups in terms of PV reconnection \( (P=0.777) \).

At 1, 3, 6, and 12 months after the procedure for the MNS and manual groups, respectively, 56 (22 [73%] versus 34 [77%]), 53 (21 [70%] versus 32 [73%]), 49 (19 [63%] versus 30 [68%]), and 48 (19 [63%] versus 29 [66%]) patients were hospitalized and monitored at our center. There was no significant difference between the 2 groups. However, all patients who could not be hospitalized at our center were followed by the referring cardiologist and were subjected to Holter monitoring at each follow-up period.

### Complications

Access-site hematoma was observed in 2 patients in each of the 2 groups (MSN group, 6.7%; manual group, 4.6%; \( P=0.692 \)). Cardiac tamponade with audible pop requiring percutaneous drainage occurred in 1 (2.3%) patient in the manual group.

### Discussion

We report our initial experience with PVI using MNS and irrigated tip magnetic ablation catheter. To our knowledge, these data are the first published that evaluate feasibility and efficacy of ablation using a novel irrigated tip ablation catheter and MNS in PVI.

### Potential Advantage of MNS

The magnetic catheter has a flexible shaft and limited maximal force exerted by the magnetic vector. Several advantages have been mentioned for the MNS-compatible RMT catheter versus the conventional catheter during cardiac mapping. First, it is possible that less endocardial trauma (compared with manual mapping) would result from the MNS. Therefore, the risk of procedure-related cardiac perforation is low. Second, the “lighter” tissue touch of the remote magnetic mapping catheter is likely to cause less deformation of the cardiac chamber and thereby result in a more accurate

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**Table. Patient Clinical Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>MNS Group</th>
<th>Manual Group</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients</td>
<td>30</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>60.2±9.4</td>
<td>57.6±11.3</td>
<td>0.290</td>
</tr>
<tr>
<td>Male/female sex</td>
<td>23/7</td>
<td>37/7</td>
<td>0.423</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>3 (10)</td>
<td>5 (11)</td>
<td>0.853</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Duration of AF, mo</td>
<td>60 (40–96)</td>
<td>48 (29–84)</td>
<td>0.670</td>
</tr>
<tr>
<td>Ineffective AADs</td>
<td>2 (2–3)</td>
<td>2 (1–3)</td>
<td>0.444</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>10 (33)</td>
<td>14 (32)</td>
<td>0.891</td>
</tr>
<tr>
<td>LAD, mm</td>
<td>42.0±6.3</td>
<td>40.7±6.0</td>
<td>0.286</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>65.4±9.0</td>
<td>64.4±9.5</td>
<td>0.675</td>
</tr>
</tbody>
</table>

Data are presented as mean±SD, median (IQR), or no. (%), unless otherwise indicated. AADs indicate antiarrhythmic drugs; LAD, left atrial diameter; LVEF, left ventricular ejection fraction.
mapping than the manual mapping. Third, this method has the potential to reduce fluoroscopic exposure for both the patient and the operator, especially the latter.

Wood et al. reported reduction in fluoroscopic time and RF lesion deliveries for the ablation of supraventricular arrhythmias with MNS compared with manual catheter navigation, although there were no significant differences in procedural time and success rate. Arya et al. reported that CTI block was successfully completed in 24 (96%) of 25 patients with an 8-mm tip magnetic catheter with high RF delivery settings (70°C with a maximum power of 70 W); however, there are no data in comparison with manual ablation. In patients with congenital heart disease and anatomic variants, MNS can be a useful tool for reaching the areas otherwise inaccessible with conventional catheters.

Potential Disadvantages
On the other hand, MNS has several potential disadvantages. It needs a longer time to set up. The operator must commute frequently between the remote control room and operation room to change the circular mapping catheter position when it is unstable and the sheath position to facilitate accessing the target with the magnetic catheter. These processes would lead to longer total procedural duration but will be overcome by remote control of the new driving device. The limited contact force also may limit the lesion size, which might lead to more-frequent PV reconnection after PVI. The necessity of a second long sheath for the ablation catheter leads to a higher procedural cost. Observation and evaluation of the patient’s state are relatively difficult because the operator stays in the remote room. During conventional ablation procedure, the operator can estimate the force of the tissue contact by the tactile feedback during catheter manipulation. In contrast, no tactile feedback of the catheter tip contacting the atrial wall can be perceived by the operator using MNS.

In comparison with other ablation procedures, AF ablation is much more complicated and needs many RF lesions to reach the end point. Actually, Di Biase et al. reported Lasso-guided AF ablation using MNS and the nonirrigated tip 4-mm CARTO RMT catheter. The report clarified that electric PVI was not completed in most of the PVs and needed additional manual ablation even with high RF delivery settings (55°C with a maximum power of 50 W). Furthermore, the charring of the catheter tip was observed in 33% of the patients.

MNS With Irrigated Tip Catheter
In the present study, we evaluated the feasibility and efficacy of Lasso-guided electric PVI using MNS and a newly available irrigated tip ablation catheter and drew a comparison with manual ablation with the same RF delivery settings. Our study establishes several points. First, circular mapping catheter-guided PVI using MNS is difficult in some patients, especially for the antrum of right inferior PV even after using the irrigated tip catheter and various manipulation techniques. This finding seems to be attributable to the anatomy (structural complexity, relationship between the transseptal hole and the PV ostium) and the weaker contact force compared with manual navigation. A deflectable long sheath seems to be one of the solutions for improving the manipulation.

Second, PVI using MNS needed longer RF, procedural, and fluoroscopic duration than manual ablation for the patients with PAF. Because the end point was defined as electric PVI of all the PVs, all the durations were significantly prolonged due to the difficulty in achieving the end point. The difficulty in reaching some points and soft tissue contact of the magnetic catheter may be some of the crucial factors that explain the significant difference in RF duration. Third, no charring of the catheter tip was observed during AF ablation using MNS and an irrigated tip catheter, which stands as a substantial improvement in the previous nonirrigated magnetic tip catheter. Fourth, AF ablation using MNS and an irrigated tip catheter with backup manual ablation whenever required was as effective as the conventional ablation for the index procedure with PVI as the primary end point.

Limitations
First, the study was not designed in a prospective randomized fashion, which implies the inherent limitations of the design. Nevertheless, the key patient data between the 2 groups were similar, which allowed direct comparison between the 2 different systems studied. Furthermore, we compared the results obtained using the same ablation strategy and in the similar energy delivery conditions (power, temperature setting, etc). Second, the present experience is limited to a relatively small number of patients. Therefore, we cannot comment on the safety aspect of the MNS, although no complications were noted. Our data should be confirmed in a larger randomized trial. Third, we do not have the separate data of fluoroscopic time for PVI. However, the result was not altered even after eliminating the patients who underwent CTI ablation. Fourth, the AF recurrence rate might have been underestimated because asymptomatic AF episodes would remain undetected with interval monitoring postablation. Finally, outcome procedure data may be institution specific and may be related to lack of extensive experience with MNS. The use of preprocedural anatomic imaging with CT or magnetic resonance with merging of the imaging with the electroanatomic mapping system may result in shorter procedure times and less fluoroscopy exposure with MNS.

Conclusions
The efficacy of MNS with a novel irrigated tip catheter with backup manual ablation wherever required for patients with PAF undergoing index PVI is comparable to the conventional technique in our early experience. The RF, fluoroscopy, and procedural times are significantly higher with the MNS than with the conventional approach. Technical modifications in the system, including the contact force and wider clinical experience, may help to improve these outcomes.

Disclosures
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References


CLINICAL PERSPECTIVE

Over the past decade, radiofrequency catheter ablation of paroxysmal atrial fibrillation (PAF) has become a widely accepted therapy in drug refractory cases with good procedural success rates. Electric pulmonary vein isolation (PVI) is the cornerstone of the catheter ablation procedure. Recently, the remote magnetic navigation system has been introduced into clinical practice, which allows the use of a soft-tipped ablation catheter that can be guided to and positioned at the desired site by directional magnetic fields. However, this system is available and has been used with a nonirrigated magnetic tip catheter. A previous report showed that this system with a nonirrigated magnetic catheter could not achieve PVI in most of the cases. This study compared the procedural and clinical outcomes of ablation of PAF using this system with the newly available irrigated tip catheter backed up with manual ablation wherever required for patients with PAF undergoing index PVI. In our early experience, the clinical results are comparable with the conventional technique. However, the radiofrequency, fluoroscopy, and procedural times are significantly higher with the new system than with the conventional approach. This study provides the information on the areas where further technical modifications may be helpful in the improvement of the system for future use.
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