Remote-controlled catheter ablation of accessory pathways: results from the magnetic laboratory

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Aims This study evaluates feasibility, safety, and efficacy of magnetic remote-controlled accessory pathway (AP) ablation.

Methods and results The novel magnetic navigation system (MNS) (Niobe, Stereotaxis) creates a steerable magnetic field (0.08 T) controlling the distal magnetic tip of an ablation catheter. In conjunction with a catheter advancer system (Cardiodrive, Stereotaxis) remote catheter ablation is enabled. Conventional electrophysiology study identified AP conduction in 59 patients (37 males, 36 ± 14 years, 60 APs). First generation 1-magnet tip (1-M) (group I, n = 18), second generation bipolar 3-magnet tip (3-M) (group II, n = 27), and third generation quadripolar 3-magnet tip catheters (3-M quad.) (group III, n = 14) were used for magnetic remote-controlled ablation. Successful AP ablation was achieved in 67% (group I), 85% (group II), and 92% (group III). A significant decrease of median [IQR: Q1–Q3] fluoroscopy time and dosage was observed: 21.2 [12.1–33.8] min, 1110 [395–3234] mGy² (group I); 6.5 [4.4–15.4] min, 290 [129–489] mGy² (group II), and 4.9 [3.4–8.0] min, 129 [74–270] mGy² (group III). Mean procedure time (217 ± 67 min; 182 ± 68 min, and 172 ± 90 min) significantly decreased in group III. Median number [Q1–Q3] of radiofrequency current applications in groups I, II, and III was 4 [2–9], 4 [2–6], and 2 [2–4], respectively. No complications occurred.

Conclusion Remote AP ablation is safe and feasible using the novel MNS. Introduction of the 3-magnet quadripolar ablation catheter significantly improved the efficacy of the procedure.

Introduction Curative catheter ablation has become the therapy of choice for symptomatic atrioventricular reentry tachycardia (AVRT). Conventional ablation of accessory pathways (APs) can be performed with a high success and low complication rate. However, complications may include pneumothorax, hematoma, thrombotic events, AV block, etc. and rarely cardiac perforation due to manipulation with the relatively stiff manually deflectable catheter. In addition, both the patient and the investigator are exposed to fluoroscopic radiation. The magnetic navigation system (MNS) (Niobe, Stereotaxis) in conjunction with a motor drive catheter advancer unit allows complete remote-controlled catheter mapping from the control room. Therefore, the operator’s exposure to scattered radiation is markedly reduced. Whether the MNS also allows a further reduction of radiation exposure for the patient due to the option to store and reapply once visited sites or due to a reduced numbers of required diagnostic catheters is still unclear. Furthermore, the soft catheter tip makes tissue damage including perforation almost impossible. Based on the experience of remote-controlled ablation in atrioventricular nodal reentry tachycardia in humans, this present study was designed to investigate remote-controlled ablation in patients with APs using the MNS.

Methods Patient population Between May 2003 and August 2005, a total of 59 patients (37 male, mean age 36 ± 14 years) were included in this study for AP ablation using the novel MNS. After exclusion of contraindications for MNS such as ICD or pacemaker devices, metallic implants, claustrophobia, age <18 years, body weight >150 kg, patients were studied in a fasting state under continuous intravenous propofol sedation and intermittent 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 (PerryHis, Biosense Webster) was advanced through the femoral vein and a multipolar catheter (PerryHis, Biosense Webster) was positioned in the distal coronary sinus through the left subclavian
vein. Two non-deflectable catheters (Soloist, Medtronic) were positioned in the right ventricular apex (RVA) and the high right atrium (HRA).

**Magnetic navigation**

The basic concept of MNS has been previously described by Faddis et al.\(^5\) In brief, it consists of two permanent outer magnets creating a uniform magnetic field (0.08 T) inside the chest of the patient steering small permanent magnets embedded in the distal tip of the ablation catheter. Three types of magnetic ablation catheters were consecutively available: The first generation mapping and ablation bipolar catheter had a single magnet in the distal tip (Helios I, Stereotaxis, 1-M, 8F, May 2003–April 2004) which aligned parallel to the direction of the externally created magnetic field. The second generation **bipolar** catheter with 3 magnets integrated in the tip, lead to an increased deflection force (Helios II, Stereotaxis, 3-M, 8F, May 2004–June 2005) followed by the third generation **quadripolar** 3 magnet catheter (Celsius RMT, Biosense Webster, 3-M quad, 7F, since July 2005) (**Figure 1**). Changing the orientation of the outer magnets creates a new magnetic vector resulting in new parallel alignment of the mapping catheter. This reorientation process requires ~1.5 s. All magnetic field vectors could be stored and, if needed, reapplied navigating the catheter back to its previous position. Therefore, in combination with the catheter advancer system (Cardiodrive Unit, Stereotaxis), remote-controlled catheter navigation without manual manipulation is possible. Precise catheter orientation is achieved by \(^1\) increments in all spatial dimensions and by \(^1\) mm steps advancing or retracting the ablation catheter. The system is controlled from the control room and therefore allows complete remote-controlled navigation. To reach left-sided APs, either retrograde passage of the aortic valve using complete remote-controlled magnetic navigation from the control room or conventional transseptal puncture with subsequent magnetic navigation was performed (**Figure 2**). After transseptal puncture, a single bolus of 5000 IU heparin was intravenously administered.

**Magnetic ablation catheters**

In group I \((n = 18\) patients), the first generation 1-M ablation catheter \((8\)F) was used. Group II \((n = 27\) patients) were treated with the second generation 3-M catheter \((8\)F) with an increased deflection force. Both catheters had a 4 mm solid tip and a single ring electrode \((2\) mm) with an interelectrode spacing of \(1.8\) mm allowing single bipolar recording (**Figure 1**). In group III \((n = 14\) patients) were treated with the third generation 3-M quadriplanar catheter \((7\)F), which consisted of a 4 mm solid tip with three additional ring electrodes \((2, 5,\) and \(2\) mm)

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**Figure 1** On the left side, the first generation 1-magnet map (1-M) catheter is shown. The second generation magnetic catheter (middle) has 3 magnets (3-M) embedded in the tip (arrows). Both catheters have a 4 mm solid tip and a single ring electrode. To the right, the third generation, quadriplanar 3-magnet catheter (3-M quad), also 4 mm solid tip with 2 additional ring electrodes (*) allowing the simultaneous recording of a distal and proximal signal is shown (* small panel shows magnification). All catheters are extremely soft and flexible, lacking the pull wire mechanism of conventional steerable catheters.

**Figure 2** Transseptal magnetic mapping sequence approaching a left-sided AP: remote-controlled magnetic navigation to a left posterior AP using different magnetic vectors (green arrow) and the Cardiodrive unit for catheter advancing (dashed line). (CS, coronary sinus; LAO, left anterior oblique).
interelectrode spacing) allowing the simultaneous recording of a distal and proximal bipolar signal. Due to the evolving MNS technology the three different magnetic catheter generations have been chronologically introduced.

Ablation
Ablation was performed in a temperature controlled mode with a maximum temperature of 55°C for right and 65°C for left-sided APs, (maximum duration: 60-120 s, maximum energy: 40 W) using a Stockert RF generator (Biosense Webster, Europe).

Endpoints for successful catheter ablation
Successful AP ablation was proven by conventional electrophysiology criteria.1,2

Follow-up
A follow-up time of three months had been intended to monitor clinical success besides the primarily successful ablation itself. All patients were seen in the arrhythmia ambulance 3 months after the ablation procedure or were contacted via telephone interview or their referring physicians.

Statistical analysis
Continuous data are presented as mean values ± SD. In case of non-Gaussian distribution of measured variables, the median and interquartile range is given. For overall comparisons of the three groups, the Kruskal-Wallis test is used whereas the Mann-Whitney U test is calculated for comparing two treatments. Categorical data was described by absolute and relative frequencies and compared among the three groups by the Pearson χ² test. All data is analysed exploratory, i.e. P-values are nominally interpreted and no further adjustment for multiple tests is made. The P-values were calculated asymptotically and two-tailed and a P-value <0.05 were considered as significant finding. Statistics are calculated using SPSS for Windows 11.5.2.1 (SPSS Inc.).

Results
General characteristics
A total of 59 patients (37 male, age 36 ± 14 years, 60 APs) were included in this study. Thirty-three patients had overt anterograde AP conduction. In 36/59 patients, AVRT was induced with a mean cycle length of 342 ± 144 ms. Anatomical distribution of all APs insertion sites is shown in Figure 3. In one pt, two left-sided APs (1 AP: posteroinferior, 2. AP superior) were present. In brief, 19 right-sided APs and 41 left-sided APs were identified, which were either mapped retrograde after passage of the aortic valve (n = 7) or anterograde after trans-septal puncture (n = 33). Patients in groups I, II, and III did not differ in baseline characteristics which are given in Table 1.

Ablation results
Successful remote-controlled AP ablation was achieved in 67% in group I (12/18 patients), 85% in group II (23/27 patients), and 92% in group III (13/14 patients) using the

Figure 3 Schematic distribution of all AP insertions in an LAO view according to the current nomenclature.11,12 Further on, overall success and group specific success rates using MNS are given. (S, success; F, failure).
3-M quadripolar catheter, respectively (Figure 4). In the single pt, who failed successful ablation in group III (3-M quad.), a left superior AP insertion site was identified using the MNS. However, due to an epicardial AP insertion, only temporary AP block was achieved and finally switch to conventional cooled tip ablation was required to abolish AP conduction. All other APs in group III, including 2 infero-paraseptal APs were successfully ablated.

Fluoroscopy exposure and procedure parameters

A summary of all procedural parameters (groups I, II, and III) is given in Table 2. Significant reduction of median fluoroscopy time could be demonstrated: 4.9 [3.4–8.0] min, \( P < 0.001 \) in group III, 6.5 [4.4–15.4] min in group II \( (P = 0.004) \) compared to 21.2 [12.1–33.8] in group I. The median [Q1–Q3] fluoroscopy dosage was also significantly reduced in group III (129 [74–270] \( \mu \)Gym\(^2\), \( P < 0.001 \)) and group II (290 [129–489] \( \mu \)Gym\(^2\); \( P < 0.001 \)) in comparison to group I (1100 [395–3234] \( \mu \)Gym\(^2\)). Mean procedure time was significantly decreased using the 3-M quad. catheter (group III: 172 ± 90 min, \( P = 0.038 \); group II: 182 ± 68 min; group I: 217 ± 67 min). Median [Q1–Q3] number of radio-frequency current applications in groups I, II, and III was 4 [2–9], 4 [2–6], and 2 [2–4], respectively.

Left-sided APs

A total of 41 left-sided APs were identified in 40 patients. Retrograde access \( (n = 7) \) was associated with a low ablation success rate \( (3/7, 43\%) \) compared to the anterograde access using standard transseptal puncture \( (n = 33) \) and subsequent magnetic navigation and remote-controlled ablation \( (29/33, 88\%) \) (Figure 5). As a consequence of these results, left-sided APs were primarily approached using the anterograde approach.

MNS failures

MNS failures \( (n = 11) \) were associated with: (a) the use of the first generation 1-M catheter (group I, \( n = 6 \)), (b) an infero-paraseptal AP insertion site \( (n = 7) \), and (c) the retrograde access for left-sided APs \( (n = 4) \) as summarized in Table 3.

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### Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Male gender ((n;\ %))</th>
<th>Age (\text{years})</th>
<th>Left-sided AP location ((n;\ %))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (n = 18, 18\ APs)\</td>
<td>12; 67 (36 \pm 12)</td>
<td>9; 50 (37 \pm 15)</td>
<td></td>
</tr>
<tr>
<td>Group II (n = 27, 27\ APs)\</td>
<td>17; 63 (36 \pm 16)</td>
<td>21; 78 (37 \pm 15)</td>
<td></td>
</tr>
<tr>
<td>Group III (n = 14, 15\ APs)\</td>
<td>8; 57 (37 \pm 15)</td>
<td>10; 71 (37 \pm 15)</td>
<td></td>
</tr>
</tbody>
</table>

There are no statistically significant differences among the groups.

### Table 2 Significant improvement of procedural parameters using the MNS was observed in group II, and in particular in group III

<table>
<thead>
<tr>
<th></th>
<th>Group I (n = 18)</th>
<th>Group II (n = 27)</th>
<th>Group III (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy time (\text{min}) (\text{Median (Q1–Q3)})</td>
<td>21.2 (12.1–33.8)</td>
<td>6.5 (4.4–15.4)</td>
<td>4.9 (3.4–8.0)</td>
</tr>
<tr>
<td>\text{P-value vs. 3-M (group II)} | 0.004</td>
<td>0.001</td>
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<tr>
<td>\text{P-value vs. 3-M quad. (group III)} | &lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dosage (\text{(\mu)Gym(^2)}) (\text{Median (Q1–Q3)})</td>
<td>1110 (395–3234)</td>
<td>290 (129–489)</td>
<td>129 (74–270)</td>
</tr>
<tr>
<td>\text{P-value vs. 3-M (group II)} | &lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
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<tr>
<td>\text{P-value vs. 3-M quad. (group III)} | &lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure time (\text{min}) (\text{Mean ± SD})</td>
<td>217 ± 67</td>
<td>182 ± 68</td>
<td>172 ± 90</td>
</tr>
<tr>
<td>\text{P-value vs. 3-M (group II)} | 0.071</td>
<td>0.038</td>
<td></td>
<td></td>
</tr>
<tr>
<td>\text{P-value vs. 3-M quad. (group III)} | 0.240</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RFC applications (\text{Median (Q1–Q3)})</td>
<td>4 (2–9)</td>
<td>4 (2–6)</td>
<td>2 (2–4)</td>
</tr>
</tbody>
</table>

\text{P-value <0.05 was considered statistically significant.}
Complications and follow-up

No complication or documented recurrence of the treated arrhythmia occurred during a median [Q1–Q3] follow-up time of 351 [180; 735] days.

Discussion

This present study reports the first human experience of complete remote-controlled AP ablation using the novel MNS.

General aspects

The principle advantages of MNS catheter ablation (no risk of perforation, reduced fluoroscopy exposure and lead wearing time for the investigator) have been recently reported.4–6

Ablation results

In our series, only moderate AP ablation success (67%) was observed in group I (1-M catheter) using the novel MNS. This was improved to 85% in group II (3-M) and 92% in group III using the 3-M quad. catheter with an increased deflection force due to three magnets embedded in the distal tip. In addition, simultaneous recording of a distal and proximal bipolar signal facilitated AP mapping (group III). Therefore, using magnetic navigation and the 3-M quad catheter, remote-controlled AP ablation can be at least as successful as previously published conventional AP ablation2,3 but lacking the risk of manually manoeuvring a stiff ablation catheter.

Fluoroscopy exposure and procedure parameters

Although this study reports first human experience using MNS for AP ablation, overall procedural parameters, including procedure time and number of RFC applications are in agreement with recently published data.7–9 Since the whole mapping and ablation process are performed from the control room, the investigator saves fluoroscopy and leads wearing time. In addition, we could also demonstrate in groups II and III a further significant improvement of radiation exposure for both, the investigator and the patient (reduction of fluoroscopy time and dosage). When compared with conventional AP ablation data,7–9 our patients were exposed to less radiation when using the MNS (groups II and III). This can partially be explained by magnetic catheter improvements (three magnets, quadrupolar electrodes), but also by the MNS itself, with the option to store once visited sites allowing to reapply the previously created magnetic vector.4,10 However, one has to note that our MNS experience reflects a sequential approach and is not a randomized trial.

Left-sided APs

Left-sided APs (n = 41) were reached either after retrograde aortic valve passage using the MNS (n = 7) or conventional anterograde transseptal puncture with subsequent remote-controlled mapping and ablation (n = 33).

The conventional movement to achieve a position at the mitral annulus using the retrograde approach consists of both a turning and advancing movement which was not easy to duplicate with the MNS. In addition, contrary to our expectations, we found that the soft catheter shaft once entangled in the papillary musculature, would only prolapse into the ventricle but not stabilize the distal catheter tip. Moreover, ventricular contractions against the soft catheter further complicated catheter stability using the retrograde approach.

In contrast, using the anterograde transseptal access, the mapping process along the smooth endocardial surface of the mitral annulus from the atrial aspect is particularly suitable for incremental changes of the magnetic vector using the MNS (Figure 2).

After the initial retrograde approach failures, we therefore changed our strategy to the anterograde access and achieved improved MNS ablation results (Figure 5).

Table 3 Overview of MNS failures for AP ablation

<table>
<thead>
<tr>
<th>MNS Failures (n = 11)</th>
<th>Group I (n = 18) (6 failures)</th>
<th>Group II (n = 27) (4 failures)</th>
<th>Group III (n = 14) (1 failure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomic location</td>
<td>Right (n = 2)</td>
<td>Right (n = 1)</td>
<td>Left (n = 1)</td>
</tr>
<tr>
<td></td>
<td>Left (n = 4)</td>
<td>Left (n = 3)</td>
<td>Left superior (n = 1)</td>
</tr>
<tr>
<td>AP insertion site</td>
<td>Infero-paraseptal (n = 4)</td>
<td>Infero-paraseptal (n = 3)</td>
<td>Left postero-inferior (n = 1)</td>
</tr>
<tr>
<td></td>
<td>Left posterior (n = 1)</td>
<td>Left posterior (n = 1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Left postero-superior (n = 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left-sided access</td>
<td>Retrograde (n = 2)</td>
<td>Retrograde (n = 1)</td>
<td>Transseptal (n = 1)</td>
</tr>
</tbody>
</table>

Figure 5 Left-sided APs: antero- or retrograde access and the corresponding remote-controlled ablation success rates.
MNS failures

MNS failures were associated with (a) the use of the 1-M catheter in group I, (b) the retrograde access for left-sided APs which is discussed above, and (c) an infero-paraseptal AP insertion (Table 3). It is well established that infero-paraseptal APs represent the most challenging anatomic localization with more ablation failures. The 3-M catheters (groups II and III) with an increased tip deflection force achieved better catheter-tissue contact, therefore improving success rates to 85% (group II) and 92% (group III). This observation is supported by successful remote ablation of the two infero-paraseptal APs identified in group III. In this group (3-M quad.), only 1 MNS ablation failure was observed, after correct magnetic mapping of the AP insertion site. This patient then required conventional cooled tip ablation which is not yet available for the MNS, emphasizing the further need of magnetic catheter improvements.

In summary, the MNS represents a novel platform technology for safe remote-controlled catheter navigation in human heart. Our experience shows feasibility, safety, and improved efficacy using the quadripolar 3-magnet catheter for AP ablation.

Limitations

Due to the stepwise introduction of the different of magnetic ablation catheters, this study is not a randomized trial but reports a chronologic experience. Further on, the C-arm angulation is restricted (LAO 28° /RAO 33°).

Conclusion

Remote-controlled catheter ablation of APs is safe and feasible using the novel MNS in humans. Introduction of the quadripolar 3-magnet ablation catheter was associated with the highest ablation success and significant reduction of radiation exposure. Further developments of magnetic catheters such as additional magnets or irrigation may further improve efficacy and enhance the ability to address more complex arrhythmias.

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Conflict of interest: none declared.

References