CLINICAL RESEARCH

Robotic magnetic navigation for ablation of human arrhythmias: Initial experience

Navigation magnétique robotique pour l’ablation par cathéter des arythmies humaines : expérience initiale

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KEYWORDS
Arrhythmia; Radiofrequency ablation; Magnetic navigation

Summary
Background. — Magnetic navigation system (MNS) (Niobe, Stereotaxis, Saint-Louis, Missouri, USA) allows remote control of a radiofrequency ablation catheter using a steerable magnetic field and a catheter advancement system.

Aims. — We report our initial experience of ablation of human arrhythmias using the MNS.

Methods. — Eighty-four patients (mean age 54 ± 17 years; 39 women) had an electrophysiologic study followed by ablation with the MNS using non-irrigated 4, 8 and 3.5 mm-tip catheters with three distal magnets. All patients were symptomatic, with commonly-accepted indications for ablation: atrioventricular nodal re-entrant tachycardia (AVNRT; n = 37); typical atrial flutter (n = 15); accessory pathway (n = 12); atypical atrial flutter (n = 7); ventricular tachycardia (n = 7); atrial tachycardia (n = 3); paroxysmal atrial fibrillation (n = 3). Electroanatomical mapping was used for atrial flutter, atrial fibrillation, atrial tachycardia and ventricular tachycardia procedures (29 patients, 34%).

Results. — Ablation was performed successfully in 69 (82%) patients. In 15 patients (18%), MNS technique was unsuccessful: seven typical atrial flutters, four accessory pathways, two left atrial flutters after atrial fibrillation ablation, one ventricular tachycardia and one AVNRT; in all these cases except one typical atrial flutter and two left atrial flutters, success was obtained by switching to the manual technique by means of an irrigated catheter. Total fluoroscopy time was 14 ± 11 minutes; operator exposure fluoroscopy time was 1.5 ± 0.6 minutes; procedure time was 169 ± 72 minutes.

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Conclusion. — MNS ablation is a feasible treatment for various human arrhythmias, with a high success rate. Mapping with a magnetic catheter is safe. However, magnetic ablation of typical atrial flutter remains challenging, probably because of insufficient pressure for cavotricuspid isthmus ablation.

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Abbreviations

AF = atrial fibrillation
AP = accessory pathway
AT = atrial tachycardia
AVNRT = atrioventricular nodal re-entrant tachycardia
MNS = magnetic navigation system
VT = ventricular tachycardia

Background

Developments in information technology have found a vast field of application in health sciences. Techniques such as virtual reality, image fusion and robotics have been applied recently to the diagnosis and treatment of human arrhythmias [1,2]. Two robotic systems exist for the manipulation of catheters inside the human heart: the first is based on a MNS [3] and the second on a steerable sheath, which is remote-controlled mechanically [4].

The MNS (Niobe, Stereotaxis, Saint-Louis, Missouri, USA) uses a steerable magnetic field that guides a soft magnetic catheter within the heart chambers for mapping and ablation. Since its first published use in humans in 2002 [3], several small series have proved its efficacy in the treatment of various arrhythmias. Nevertheless, literature is sparse and availability is still largely limited. We report our initial experience using the MNS for completely remote-controlled catheter ablation of human arrhythmias.

Methods

Study design

Between April 2006 and June 2008, patients with various arrhythmias, who were symptomatic and had a commonly accepted indication for ablation, underwent an electrophysiological examination followed by an ablation attempt using the MNS (Niobe, Stereotaxis, Saint-Louis, MO, USA). Contraindications for magnetic navigation were excluded before the study (implanted pacemaker or defibrillator, various metallic implants) and all patients gave written informed consent. Interventions were performed in a fasting state under local anaesthesia and mild sedation with midazolam (intravenous bolus from 0.5 mg to a total of 3 mg per patient). Analgesia comprised intravenous administration of nalbuphin (10 mg to a maximum of 20 mg).
Magnetic navigation for electrophysiological examination and catheter ablation

Catheters were inserted through the femoral vein. Classic manual ablation catheters are relatively stiff and are steerable via a pull-wire mechanism, whereas magnetic catheters are very soft and, in our study, were all equipped with three small magnets at their distal end. We used four magnetic catheters: Helios II (pure bipolar, Stereotaxis, Saint-Louis, MO, USA) for AVNRT and AP ablation; Celsius RMT (quadripolar, Biosense-Webster, Diamond Bar, CA, USA) for most of the AVNRT cases, AP and typical atrial flutter cases and one VT; Navistar RMT 4 mm tip (Biosense-Webster) for electroanatomical mapping and ablation of most flutters and cases of AT and VT; Navistar RMT DS 8 mm tip (Biosense-Webster) for electroanatomical mapping and ablation of some flutters and one case of AT. The only irrigated magnetic catheter available temporarily for clinical evaluation purposes (Navistar Thermocool RMT, Biosense-Webster; 3.5 mm tip) was used in nine cases: the three AF cases, four atypical atrial flutters (three post-AF ablation left atrial flutters and one occasional right atrial flutter), one typical atrial flutter and one VT. Sheaths (Swartz, Saint-Jude Medical, Minnetonka, MN, USA) were used only in cases where left atrial access was needed.

Other bipolar or quadripolar catheters were also used for stimulation and mapping purposes, depending on the target arrhythmia. For typical flutters, a decapolar ‘halo’ catheter was positioned on the tricuspid ring. For left atrial procedures, transoesophageal echocardiography was performed to exclude left atrial thrombi and to guide the transseptal puncture; a circular ‘lasso-type’ catheter was used for mapping the pulmonary veins.

The MNS consists of two permanent giant magnets, each weighing 1.8 tons, positioned on either side of the fluoroscopy table (Axiom Artis, Siemens, Germany; Fig. 1). They create a steerable computer-controlled magnetic field of an intensity of 0.08 tesla. The soft magnetic catheters equipped with three magnets at their distal tip tend to be aligned in the direction of the magnetic field. A catheter advancement system (Cardiodrive, Stereotaxis; Fig. 2) allows remote push and pull movements of the catheter.

The operator, sitting in the control room (Fig. 3) away from radiation exposure, uses a computer interface (Navigant, Stereotaxis; Fig. 4) to change the orientation of the magnetic field (which is realized by the system by changing the position of the permanent magnets relative to each other) and may advance and retract the catheter. Thus, by controlling advancement, deflection and rotation, the catheter’s position, which also depends on the anatomical constraints, may be fine-tuned. Software automation tools are available for simplifying navigation: storage of a field direction; use of constellations (points groups of catheter positions). Integration with the electroanatomical mapping system (Carto RMT, Biosense-Webster) allows automatic target navigation (‘Click-and-Go’) and automated creation of user-defined ablation lines (‘Naviline’).

Ablation

Radiofrequency catheter ablation was performed in a classic manner in a temperature-controlled mode with programmed temperature, energy and pulse duration (we used the standard parameters used for manual ablation according to our centre’s protocols). A Stockert (Biosense-Webster) radiofrequency generator was used for all procedures. The endpoint for all procedures was the same as the widely-accepted
Figure 4. Navigant software — example from an AVNRT ablation procedure; note the anatomical model of the right atrium, the magnetic field direction and (top, centre) the list of available presets for field direction.

endpoint for manual technique ablation for the respective arrhythmia. Procedures were performed by two operators with considerable experience of manual catheter ablation.

Statistical analysis

Continuous variables are expressed as mean plus or minus standard deviation. Fisher’s exact test was used for comparing two categorical variables. A p-value less than 0.05 was considered to be significant.

Results

Patient characteristics

A total of 84 patients (age range 12 to 90 years, mean age 54 ± 17 years; 39 women) with various arrhythmias were included in the study. Thirty-seven (44%) patients had AVNRT, 15 (18%) had typical atrial flutter, 12 (14%) had an AP, seven (8%) had an atypical atrial flutter, seven (8%) had VT, three (4%) had AT and three (4%) had paroxysmal AF.

Immediate success rate

The overall success rate was 81%. The immediate success rate by arrhythmia is detailed in Table 1. The immediate success rate was excellent for slow pathway ablation in AVNRT, for VT, for AT and for left-sided AP. A good success rate was achieved for atypical atrial flutter. Disconnection of pulmonary veins was achieved successfully for the three patients with paroxysmal AF. Nevertheless, success rate was poor for cavitricuspid isthmus ablation for patients with typical atrial flutter.

VT cases concerned both ventricles. Three originated in the right ventricular outflow tract, one occurred on an arrhythmogenic right ventricular dysplasia and three were left ventricular VT: one fascicular VT (treated successfully by ablation of the posterior hemibranch of the His-Purkinje system), one scar-related VT ablated successfully and one idiopathic focal VT arising in the anterior part of the mitral annulus (which required the switch to a manual irrigated catheter to achieve success).

AT cases also concerned both atria: two sinonodal re-entrant tachycardias and one focal left septal AT, all of which were ablated successfully.

<table>
<thead>
<tr>
<th>Arrhythmia</th>
<th>Successful MNS ablation/total cases, n/n</th>
<th>Success rate of MNS ablation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrophic ventricular nodal re-entrant tachycardia</td>
<td>36/37</td>
<td>97</td>
</tr>
<tr>
<td>Atrial tachycardia</td>
<td>3/3</td>
<td>100</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>6/7</td>
<td>85</td>
</tr>
<tr>
<td>Accessory pathways</td>
<td>8/12</td>
<td>67</td>
</tr>
<tr>
<td>Typical atrial flutter</td>
<td>8/15</td>
<td>53</td>
</tr>
<tr>
<td>Atypical atrial flutter</td>
<td>4/7</td>
<td>57</td>
</tr>
<tr>
<td>Paroxysmal atrial fibrillation</td>
<td>3/3</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>68/84</td>
<td>81</td>
</tr>
</tbody>
</table>
AP cases were all fast-conducting atrioventricular, with the exception of one where decremental retrograde conduction was observed. There were 10 left-sided AP (of which eight were ablated successfully with MNS) and two right-sided AP (none of which were ablated successfully with MNS).

Six of the atypical atrial flutters were left atrial post AF ablation flutters (three of which were ablated successfully using MNS) and there was one right atrial scar-related incisional flutter, which was ablated successfully with MNS.

Follow-up

All patients were followed up prospectively. After a mean of 2.5 months, 64 of the 68 patients who were ablated successfully initially were free of symptoms, with no documented recurrence. Arrhythmias recurred in three patients: one perimital left atrial flutter (reablated successfully), one AVNRT and one VT in the arrhythmogenic right ventricular dysplasia patient. In one patient, who had been ablated for a left-sided AP, the pre-excitation pattern recurred without any inducible arrhythmia and a long anterograde refractory period of the AP; reablation was not performed.

Unsuccessful MNS procedures

MNS ablation failed in 16 patients (19% of cases). In one AVNRT patient with a left-sided extension of the AV node, ablation was discontinued after interruption of the right-sided conduction. Another failure was noted in a case of left atrial flutter after AF ablation; this procedure was performed with a magnetic irrigated catheter. In one patient with typical atrial flutter, AF occurred after failure of MNS ablation. After electrical cardioversion, cavotricuspid isthmus block was later obtained with a manual catheter. In another atypical atrial flutter, cavotricuspid isthmus block was later obtained with a magnetic irrigated catheter and the procedure was successful.

Four AP cases could not be ablated with MNS. Two were anterolateral left-sided AP (posterosuperior in the current nomenclature [5]) and the use of irrigation (by means of a manual catheter) allowed successful ablation. The other two were right lateral AP (anterosuperior [5]) and the MNS procedure was unsuccessful because of the lack of catheter stability. Manual catheters (irrigated in one case, nonirrigated in the other) were better stabilized on the AP site and ablation was performed successfully.

The other procedures where irrigation (by means of a manual catheter) allowed successful ablation after an MNS failure involved ablation sites with thick tissue: one left focal VT originating near the anterior mitral ring and a left atrial flutter (perimital) where the ablation target was the mitral isthmus. In the perimital flutter, mitral isthmus block was obtained by delivering radiofrequency energy inside the distal coronary sinus with the manual irrigated catheter.

Complications

Complications were sparse. In one left atrial procedure, a minimal pericardial effusion appeared after septal puncture; this was managed conservatively and the procedure was continued successfully. In one case, a puncture site haematoma was noted; this was also managed conservatively. We do not consider these complications to be related to the specificities of MNS ablation. In two AVNRT procedures, a lengthening of atrioventricular nodal conduction (PR segment in sinus rhythm increased by a mean of 26%) was recorded after successful ablation of the slow pathway. In both cases, alteration of the fast pathway conduction was considered to be responsible for this phenomenon. The two patients remained asymptomatic during follow-up.

Procedure data

Mean total procedure time was 169 ± 72 minutes (calculated from puncture to introducer withdrawal). Mean fluoroscopy time was 14 ± 11 minutes per procedure. Operator exposure to fluoroscopy (during the initial phase of the procedure

### Table 2 Failure rate of typical atrial flutter magnetic navigation system (MNS) ablation classified by catheter type.

<table>
<thead>
<tr>
<th>Catheter type</th>
<th>Number of cases, n</th>
<th>MNS failure, n</th>
<th>p</th>
<th>Conversion to manual irrigated catheter, n</th>
<th>Success with manual catheter, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navistar RMT (4 mm)</td>
<td>9</td>
<td>4</td>
<td>1.0</td>
<td>4</td>
<td>4 (100)</td>
</tr>
<tr>
<td>Navistar RMT DS (8 mm)</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3 (100)</td>
</tr>
<tr>
<td>Navistar Thermocool RMT (3.5 mm)</td>
<td>1</td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7 (100)</td>
</tr>
</tbody>
</table>
before moving into the control room) was 1.5 ± 0.6 minutes (which represents 17 ± 12% of the total fluoroscopy time).

Electroanatomical mapping (Carto RMT, Biosense-Webster) was used for all atrial flutter, AF, AT and VT procedures (29 patients, 34%). Presets available in the Navigant software were often used to facilitate mapping. Automation tools were sometimes used for mapping (Automap, Click-and-Go) or ablation (Naviline).

**Discussion**

We report here our initial experience of using the MNS for ablation of human arrhythmias. Our centre was the first Stereotaxis centre in Europe, opened in April 2006. This new technology has all the general advantages of robotics; it is extremely comfortable to use, with the operator seated in the control room, away from fluoroscopy exposure. Another specific advantage of the MNS is the safety of the procedure; as the pressure applied by the magnetic catheter is small (less than 15 g [6]), mechanical cardiac perforation is highly unlikely and indeed has never been reported.

Our series concerns all type of arrhythmias, arising in all four heart chambers. Although AF ablation is the procedure performed most frequently in our centre, there were only three AF cases treated using the MNS; these were performed during the initial short clinical evaluation phase of the first generation of Navistar Thermocool RMT catheter. This evaluation was suspended and resumed in the end 2008. More generally, the lack of irrigation with commercially-available magnetic catheters prevented us from using this technology in the left atrium, other than for left AP. It is worth noting that circumferential pulmonary vein ablation for AF using the MNS (with a 4 mm-tip nonirrigated catheter using CARTO RMT) was achieved in the series reported by Pappone et al. [7], with good results, but data on long-term effectiveness are lacking. The series reported by Di Biase et al. [8] does not confirm the results reported by Pappone et al.; significant charring (33% of patients) is one possible explanation for the failure to achieve effective lesions.

In our experience, AVNRT is the arrhythmia where MNS can be ideally exemplified. Slow pathway ablation effectiveness and safety have also been reported in other series [9–11]. The MNS allows very fine mapping of the low right atrial septum next to the coronary sinus (the slow pathway area) with catheter advancement and retraction in steps of 1 mm and direction changes by one degree. Furthermore, there are reasons to believe that magnetic catheters provide better tissue contact [12], their movement being synchronous to the movement of the tissue (in-vitro Stereotaxis data, unpublished). We found that there were fewer junctional beats during successful MNS AVNRT ablation (66 junctional beats in a consecutive 26-patient subseries) compared with manual AVNRT ablation (200 junctional beats in a consecutive 11-patient control group, \( p = 0.01 \)), which allows us to argue in favour of better magnetic catheter-tissue contact [13]. Junctional rhythm during radiofrequency delivery did not alter magnetic catheter stability, as shown in previously published data [9,11]. In our series, the mean procedure time for AVNRT ablation using the MNS was 124 ± 29 minutes, which is similar to that in the first published series [9] (145 ± 43 minutes). At the moment, procedure times are likely to be long because of the learning curve, but these times should diminish, becoming similar to those for the conventional technique in the series reported by Thornton et al. [11]. Thus, AVNRT represents a perfect indication for MNS ablation, with outstanding results being achieved; in our series, all patients (other than the patient with left atrioventricular node extension) were ablated successfully without serious complications.

MNS ablation for left-sided AP was also highly effective in our series. Ablation was performed on the atrial side of the mitral ring after a transseptal puncture in all but one case (an epicardial AP, which was ablated successfully in the proximal coronary sinus); our findings confirm those of a previous study [14], in which last generation quadrupolar three-magnet tip catheters were found to be the most effective for AP ablation. The fine mapping possibilities provided by the MNS are valuable for localizing AP and the use of software tools such as field direction storage may help to regain access to a previous site [15], potentially diminishing procedure time. MNS ablation was unsuccessful, however, for both of the right-sided AP, which were of superior localization. In both cases, it was impossible to stabilize the magnetic catheter on the AP site (with significant beat-to-beat changes in the local electrogram) and success was obtained only after switching to a conventional manually-guided catheter. Stability on the superior tricuspid ring is difficult to obtain by the femoral approach; sometimes a superior caval vein approach may resolve the problem [16]. The youngest patient of our series (a 12-year-old boy) had a successful left AP ablation; innocuity of MNS ablation in an even younger child has been reported [17].

One procedure with a high failure rate in our series was cavotricuspid isthmus ablation. Complete bidirectional isthmus block was obtained in only eight of the 15 typical atrial flutter patients. This poor success rate was noted for both 4 mm- and 8 mm-tip magnetic catheters. One possible explanation is the particularly thick and anfractuous anatomy of the cavotricuspid isthmus [18]. The low pressure exerted by the magnetic catheters may therefore be insufficient, but this hypothesis still needs to be proved in a clinical setting. All our MNS failure patients were ablated successfully with a conventional (manually-controlled) irrigated catheter. On the contrary, Arya et al. [19] reported a high success rate for cavotricuspid isthmus ablation with the 8 mm-tip magnetic catheter; in their series, only one patient in 25 needed the use of a conventional catheter to complete lesions. Nevertheless, our poor success rate and the long procedure time (mean 177 minutes for typical atrial flutter) for an otherwise reputedly easily-ablatable arrhythmia led us to prefer the conventional technique for cavotricuspid isthmus ablation.

Some limitations of our series should be noted. Although the two main operators were extremely experienced in manual catheter ablation [20], these procedures represent our centre’s initial experience with the MNS, starting with the very first robotic ablation. Thus, all data must be interpreted with caution, as they were acquired during the learning curve of this new technique. This explains in part the somewhat lengthy procedure time, but no matched comparison was made versus conventional ablation. In addition, our version of the MNS allows only limited oblique fluoroscopic views at 28-degree angulations, which may impair...
localization in selected cases. The latest (Niobe II) version overcomes this limitation by allowing increased magnet movement. Economic issues may also raise concern. Once the initial investment has been realized, magnetic catheters are similar in price to manual catheters, thus keeping the cost of the procedure competitive. In the near future, one may imagine that centres performing complex ablations (especially AF) on a daily basis might find that this technology makes long procedures safer and more comfortable.

Conclusion

MNS ablation is a new technology with great advantages in terms of safety and comfort for the physician. It seems to be highly effective in the treatment of almost all types of human arrhythmias. However, magnetic ablation of typical atrial flutter remains challenging. Irrigated magnetic catheters have just become available and it is anticipated that they will increase success rates further. Irrigation will also allow this technology to be used for AF ablation which, given the long procedure time, high irradiation level and sophisticated built-in software tools, seems to be particularly suited to this technique.

Conflicts of interests

None.

References