Cavo-tricuspid isthmus radiofrequency ablation using a novel remote navigation catheter system in patients with typical atrial flutter

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Aims
A new remote catheter system (AMIGOTM Remote Catheter System) compatible with conventional ablation catheters is now commercially available but no data about its performance in clinical use during ablation have been reported. This study evaluates the feasibility, efficacy, and safety of cavo-tricuspid isthmus (CTI) ablation with this system in patients with typical atrial flutter (AFl).

Methods and results
Sixty patients with typical AFl underwent CTI ablation using the new remote catheter navigation system with 8 mm tip or irrigated catheters in three centres following each centre’s routine practice. The endpoint was stable bidirectional CTI block. CTI ablation was successful in 98% of patients. Ablation was completed manually in one patient. The overall procedure, fluoroscopy, and radiofrequency times (median + standard deviation, range) were 123 ± 42 (50–250), 24 ± 13 (3–82), and 10 ± 8 (1.17–43.3) min, respectively. Three patients had vascular complications not requiring surgical intervention. There were no complications related to the remote catheter manipulation system.

Conclusion
Cavo-tricuspid isthmus ablation for typical AFl can be safely and effectively performed with the AMIGOTM. The learning curve seems to be short even for physicians with limited ablation experience.

Keywords
Atrial flutter • Ablation • Remote navigation

Introduction
Catheter ablation is nowadays the standard treatment for most arrhythmias. The use of remote navigation catheter systems offers lower radiation exposure and less fatigue to the operator, and more precise catheter manipulation.¹–⁴ Two remote navigation systems are commercially available: the NiobeTM magnetic navigation system (Stereotaxis Inc.) and the Sensei® robotic navigation system (Hansen Medical). However, electrophysiology (EP) laboratories have not widely incorporated these available systems because of some important limitations. NiobeTM requires a dedicated and expensive installation, not affordable for many EP laboratories, along with use of a specific ablation catheter. Furthermore, it is necessary to pair use with the Carto® (Biosense Webster) electroanatomical mapping system. The Sensei® system, although compatible with all ablation catheters and electroanatomical mapping systems, requires a 14F diameter steerable long sheath (Artisan®, Hansen Medical) to operate.

The AMIGOTM Remote Catheter System (Catheter Robotics Inc.) is a new robotic system for catheter navigation that does not require a dedicated installation neither long nor large sheaths. In addition, it can be used with conventional ablation catheters. No report has been published about its efficacy and safety for ablation of cardiac arrhythmias so far.

Radiofrequency (RF) ablation of cavo-tricuspid isthmus (CTI) is widely accepted as a first-line therapy for typical atrial flutter (AFl), with high acute and long-term success rates when bidirectional isthmus block is achieved.⁵–⁸ The aim of this multicentric prospective observational study was to assess the feasibility, acute efficacy, and safety of AMIGOTM for CTI ablation in patients with typical AFL.
CTI radiofrequency ablation using AMIGO™ in patients with AFl

What’s new?

- Most electrophysiology (EP) laboratories have not incorporated any of the available remote navigation catheter systems (Niobe™ magnetic navigation system and Sensei® robotic navigation system) due to technical and/or economic limitations.
- A new simpler remote navigation catheter system (AMIGO™ Remote Catheter System) is now commercially available.
- This is the first study assessing the feasibility and the success and complication rates of catheter ablation with this system.
- Ablation of CTI using AMIGO™ offers comparable acute results with past reported conventional case series.
- This system can be easily incorporated in most EP labs to increase comfort and reduce the fluoroscopic exposure of the operator.

Methods

Patients

Between April 2012 and March 2013, 60 patients (47 men) underwent CTI catheter ablation using AMIGO™ in three different centres. The patients were eligible for enrolment if at least one episode of typical AFl had been documented in a 12-lead electrocardiogram (ECG) recording and a procedure of CTI ablation had been clinically indicated. Patients with previous CTI ablation or considered amenable to concomitant ablation of a different substrate were excluded from the study. All the patients provided written informed consent for RF catheter ablation.

AMIGO™ remote catheter system

The system consists of a robotic arm installed on the patient’s table and a remote controller connected to the robot through a cable. A standard ablation catheter is introduced into the patient’s right or left femoral vein through a conventional 7F sheath and advanced manually up to the inferior vena cava; then, the catheter steering mechanism is attached to the system and the operator controls catheter navigation with the remote controller from the control room, away from the fluoroscopy field (Figure 1). The remote controller imitates the operation of the catheter by the conventional handle: forward and backward, deflection, and torque. At any point during the procedure, the catheter can be removed from the robotic arm for manual manipulation and can also be re-attached to the robot without breaking sterility.

Ablation procedure

Three experienced EP laboratories participated in the study. In each centre except one (Centre 2), two experienced operators in standard CTI ablation performed the procedures with the AMIGO™. In Centre 2, four in-training operators performed the procedures under supervision of an experienced operator. Centres 1, 2, and 3 included 34, 14, and 12 patients, respectively.

The ablation procedures were conducted in every centre according to their current practice. As a rule, two catheters were introduced via the femoral vein through standard introducer sheaths: a 7F multipolar steerable catheter (Halo, Biosense Webster or Duo-Deca Livewire, St Jude Medical Inc.) or a multipolar non-steerable catheter (Orbitr, Bard Electrophysiology) was manually placed around the tricuspid annulus and coronary sinus; a 7F ablation catheter (Blazer II XP™ 8 mm, Blazer™ Open-Irrigated, Boston-Scientific, or Termocool®, Biosense Webster) was manually advanced up to the inferior vena cava and attached to the robotic arm. Hereafter, the ablation catheter was handled from the control room through the remote controller. Cavo-tricuspid isthmus ablation was initiated either during AFl in patients with the arrhythmia or during atrial pacing from the proximal coronary sinus in patients in sinus rhythm. Entrainment manoeuvres to confirm CTI participation in the AFl reentrant circuit were performed when needed. Electrical cardioversion was performed in patients with atrial fibrillation at the beginning or during the procedure. The ablation catheter was positioned at the ventricular aspect of the CTI under fluoroscopy control (left anterior oblique view) and RF energy was delivered in a temperature-control mode with a target temperature of 60–70°C and a power limit of 60–70 W when using an 8 mm catheter. When using irrigated catheters, the RF current was delivered with a maximal power of 40–50 W and a temperature limit of 50°C.

Radiofrequency energy was administered while dragging the catheter from the tricuspid valve to the inferior vena cava until complete bidirectional CTI block was achieved. In case of CTI conduction recovery, focal applications guided by local electrograms were delivered until the CTI block endures for 30 min. Bidirectional CTI block was defined when a reversal of the atrial activation sequence was observed in the recordings of the multipolar catheter positioned around the tricuspid annulus during pacing from both sides of the CTI.

Centre 1 used 8 mm catheters for ablation in 32 patients and open irrigated in 2 patients. Centre 2 used 8 mm ablation catheters and combined the AMIGO™ with an electroanatomical mapping system (EnSite, St Jude Medical Inc.) with every patient. Centre 3 used open-irrigated catheters in 7 out of 12 patients.

Endpoints

Primary endpoints were the feasibility of robotic CTI ablation, the success rate, and the safety of the procedure. Total procedure duration, fluoroscopy time, RF time, and complications were evaluated. Total procedure duration was defined as the time between ECG monitoring in the EP lab to catheter withdrawal, including the setting up of the remote navigation system arm and the waiting period after CTI block.
Statistical analysis
Statistical analysis was performed using IBM SPSS Statistics version 2.0. Continuous variables are expressed as mean ± standard deviation with range values. Normal distribution was confirmed by Shapiro–Wilk test. Student’s t-test and analysis of variance tests were used for the statistical analysis using a statistically significant P value of < 0.05.

Results
Sixty patients were enrolled for CTI ablation with AMIGOTM. Baseline characteristics are shown in Table 1. Stable, bidirectional CTI block was achieved in 59 patients (98%). In one patient, stable CTI block was not reached after 43 min of RF energy and was only achieved with additional RF applications switching to manual handling.

Procedural data
The mean total procedure duration was 123 ± 42 (50–250), fluoroscopy time 24 ± 13 (3–82), and RF time 10 ± 8 (1.17–43.3) min. Robotic arm arrangement took a mean of 8 min after the first case in each centre. Ablation details are shown in Table 2. The 14 procedures performed with EnSite (Centre 2) showed significantly lower fluoroscopy time compared with those performed without it (14 ± 6.9 vs. 27 ± 13 min, P < 0.01), but longer total duration (162 ± 42 vs. 111 ± 34 min, P < 0.001).

Ablation was performed using an 8 mm tip catheter in 51 patients and an irrigated catheter in the remaining 9 patients. Radiofrequency time was lower with irrigated catheters (6.6 ± 4.5 min) compared with 8 mm tip catheters (10.7 ± 8.5 min), although this difference was not statistically significant.

No correlation between RF time and any of the pre-specified clinical characteristics of the patients (sex, age, cardiopathy, left ventricle ejection fraction, baseline rhythm, and body mass index, BMI) was found. However, RF time was longer in patients with a BMI > 30 (n = 19, 32%) than in those with a BMI < 30 (14 ± 10 vs. 8 ± 7, P = 0.018).

We compared the data between the first 10 and the following 24 procedures in Centre 1 to analyse the effect of the learning curve. Total procedure, fluoroscopy, and RF time were similar in both groups (Table 3). The only failure in achieving CTI block occurred in the second group.

Complications
No major complication occurred during the procedures related to the use of the remote system. There were two minor acute vascular complications resolved spontaneously in both cases. A third patient suffered a right groin haematoma and pseudoaneurysm 1 week after the procedure, requiring transfusion and direct ultrasound-guided injection of thrombin. In this patient, the catheters had been introduced through the left femoral vein because right femoral vein canalization was not possible due to a vascular malformation.

Follow-up
Follow-up (FU) visits were scheduled at outpatient clinics 3 and 6 months after the procedure. Thirty-eight patients completed at least 6 months of FU. Recurrence of typical AFI was recorded in one patient (1.7%). No additional complications were seen during FU.

Discussion
To the best of our knowledge, this is the first report describing the feasibility, efficacy, and safety of the AMIGOTM in clinical practice. It is remarkable that in our study, several operators, including in-training operators, performed the procedures in three different centres, according to their usual practice. Although the sample size is too

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**Table 1** Baseline characteristics of patients (n = 60)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (60)</th>
<th>Centre 1 (34)</th>
<th>Centre 2 (14)</th>
<th>Centre 3 (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age years, mean ± SD, range</td>
<td>64 ± 14</td>
<td>47 ± 13</td>
<td>34</td>
<td>30</td>
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<tr>
<td>Sex (male/female), n, %</td>
<td>78/22</td>
<td>78/13</td>
<td>56</td>
<td>56</td>
</tr>
<tr>
<td>Structural heart disease, n, %</td>
<td>30 ± 7%</td>
<td>23–56%</td>
<td>30–70%</td>
<td>32–56%</td>
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<td>Ejection fraction, % mean ± SD, range</td>
<td>28.6 ± 4</td>
<td>19.2–40.4</td>
<td>19 ± 4</td>
<td>32</td>
</tr>
<tr>
<td>BMI mean ± SD, range</td>
<td>19 ± 26</td>
<td>14 ± 18</td>
<td>23 ± 14</td>
<td>33 ± 16</td>
</tr>
<tr>
<td>BMI &gt; 30, n, %</td>
<td>30</td>
<td>14</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Baseline rhythm, n, %</td>
<td>Sinus</td>
<td>35</td>
<td>35</td>
<td>35</td>
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<tr>
<td>Atrial flutter</td>
<td>36</td>
<td>24</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Atrial fibrillation, n</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1C atrial flutter, n, %</td>
<td>14</td>
<td>23</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Pacemaker/ICD, n, %</td>
<td>1/1</td>
<td>3.3</td>
<td>3.3</td>
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</table>

ICD, implantable cardioverter defibrillator; SD, standard deviation.

**Table 2** Procedural results

<table>
<thead>
<tr>
<th>Procedures (n)</th>
<th>Overall (60)</th>
<th>Centre 1 (34)</th>
<th>Centre 2 (14)</th>
<th>Centre 3 (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navx, n</td>
<td>14</td>
<td>0</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Irrigated catheter, n</td>
<td>9</td>
<td>2</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>8 mm catheter, n</td>
<td>51</td>
<td>32</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>Procedural time, minutes (range)</td>
<td>123 ± 42 (50–250)</td>
<td>104 ± 29</td>
<td>162 ± 42</td>
<td>109.3 ± 44</td>
</tr>
<tr>
<td>RF time, minutes (range)</td>
<td>10 ± 8 (1.18–43.3)</td>
<td>12 ± 9.7</td>
<td>9.2 ± 5.4</td>
<td>5.6 ± 2.3</td>
</tr>
<tr>
<td>Fluoroscopy time, minutes (range)</td>
<td>24.5 ± 13 (3–82)</td>
<td>26.3 ± 14</td>
<td>14 ± 7**</td>
<td>31.6 ± 8.7</td>
</tr>
</tbody>
</table>

*P = 0.001 vs. Centres 1 and 3.
**P = 0.01 vs. Centre 1 and P = 0.003 vs. Centre 3.
small to detect significant differences between centres, the overall results were similar except for a shorter fluoroscopy time in Centre 2, related with the use of a non-fluoroscopic navigation system.

Cavo-tricuspid isthmus ablation is considered a standard therapy for typical AFl, with high success and low complication rates. Cavo-tricuspid isthmus block is achieved in 90–100% manually performed ablations either with 8 mm tip or irrigated catheters.6–8 Our results are in agreement with those reported in past case series, both in success and complication rates. We found a wide range of the RF amount required to achieve complete CTI block, like most reported case series of CTI ablation.6–9 This phenomenon seems to be related with the complex and variable CTI anatomy11–14 in spite of the use of the 8 mm tip or irrigated catheters. In fact, long sheaths are routinely used in some EP labs for CTI ablation to improve tissue contact.11 In our case, we reached 98% success without the use of sheaths.

Although we did not find any correlation between BMI and total procedural or RF time, the presence of BMI > 30 seemed to correlate with a longer RF time required to achieve a stable CTI block.

Remote catheter systems offer evident advantages to operators, lowering physician radiation exposure and fatigue, especially for long ablation procedures. However, some limitations and concerns about patient safety and procedure efficacy had been in question.15,16 Success rates of CTI ablation with remote magnetic navigation system have been previously reported. Vollmann et al.11 reported 84% complete bidirectional CTI block (45 patients) using remote magnetic navigation (Niobe™) and an 8 mm tip catheter (Navistar, Biosense-Webster), after a mean of 17.1 min of RF application. Ayra et al.17 obtained 96% CTI block (26 patients) using Niobe™ and a three-dimensional (3D) mapping system (Carto®) with an 8 mm tip catheter, after a mean of 10.2 min (4.2–28.8) of RF. No complications were reported. Fluoroscopy time was reduced when using 3D mapping system, as showed in our data.

Steven et al.18 reported 100% acute success in achieving CTI block in a randomized study comparing the Sensei® robotic system (25 patients) with the conventional approach, using an irrigated catheter. They found a lower ablation time compared with the conventional catheter ablation with no complications. The use of a steerable long sheath, as a part of the Sensei® robotic system may explain these good results, because of enhanced catheter stability and optimized tissue contact. However, the use of these long sheaths has been associated with serious complications in previous reports, especially at the beginning of the experience.15

A concern in robotic management of catheters as opposed to manual handling is the loss of tactile perception of tissue contact, since robotic movements can result in an excess of contact possibly leading to perforation. Nevertheless, no tamponade or clinically relevant pericardial effusions occurred in our case series. Tactile perception seems to be rather the result of integrating various inputs received by the operator during catheter manipulation, mainly the characteristics of the electrograms, and the shape of the catheter in fluoroscopy. The forward–backward movements with the AMIGOTM are very slow and when an excess of contact is observed it can be corrected quickly. In addition, the use of a conventional catheter without a long sheath limits somewhat the amount of force that can be provided to its tip when the catheter bends.

We did not find any significant difference in procedural parameters (total procedural, fluoroscopy, and RF time) between the first 10 and the following procedures. In our experience, the management of this remote controller and the integration with the catheter movements is easily learned by operators with previous experience in manually performed CTI ablation procedures. That this new tool could be useful in more complex ablation procedures remains to be proved. An interesting randomized study that is currently on-going, aims to compare manual vs. AMIGOTM for atrial fibrillation ablation, using contact force measure (Manual vs. AMIGOTM SmartTouch Atrial Fibrillation Study (MASTAF, ClinicalTrials.gov Identifier: NCT01583855).

Although one patient suffered a relevant vascular complication, it was not related to remote handling of the ablation catheter: Fluoroscopy time seems to be longer than some reported case series. Conceivably, fluoroscopy time may have been increased to check the catheter position more frequently.

### Limitations

This study was directed to assess the feasibility, acute success rate, and safety of the AMIGOTM in CTI ablation. No control group is included in our study.

The results of this study include the learning curve from the first patient in three different centres. Although the success rate and safety are comparable with those reported for conventional CTI ablation, the total procedure time, fluoroscopy time, and RF time might improve with experience.

These results have been obtained for CTI ablation. Feasibility, efficacy, and safety of this new tool for ablation in other substrates may include a longer learning curve and remains to be proved.

Acute results in this study are comparable with previously reported conventional procedures; however, FU data are limited to 6 months.

### Table 3  Learning curve in Centre 1

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>A First 10</th>
<th>B Last 24</th>
<th>P (A vs. B)</th>
</tr>
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<tbody>
<tr>
<td>Procedural time, min</td>
<td>123 ± 42 (50–250)</td>
<td>115 ± 23</td>
<td>102.4 ± 28.7</td>
<td>0.23</td>
</tr>
<tr>
<td>RF time, min</td>
<td>10 ± 8 (1.18–43.3)</td>
<td>9.2 ± 5.8</td>
<td>13.6 ± 10.8</td>
<td>0.23</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>24.5 ± 13 (3–82)</td>
<td>29.9 ± 10</td>
<td>25.6 ± 16</td>
<td>0.44</td>
</tr>
</tbody>
</table>
Conclusion

The use of the new AMIGO™ remote catheter system is safe and effective for CTI ablation. The learning curve seems to be short even for physicians with limited ablation experience. Owing to its compatibility with various catheters and 3D mapping systems, it can be easily incorporated for routine use in most EP laboratories. However, its usefulness for ablation of other substrates remains to be proved.

Conflict of interest: M.L.-G. has received consulting fees honoraria from Boston Scientific, St Jude Medical, Medtronic. R.S. has received fellowship support from Boston Scientific; J.L.M. has received consulting fees honoraria and speaker bureau from St Jude Medical, Sanofi, Merck, Sorin and research grants from Magnetecs. T.D. has no conflicts to declare. J.F. has received research grants from Boston scientific. E.M. has received research grants from Medtronic. R.S. has received consulting fees honoraria from Boston Scientific, St Jude Medical, Medtronic. A.F. has received consulting fees honoraria from Medtronic. A.A. has received consulting fees honoraria from Boston Scientific, Medtronic and research grant from Catheter Robotics, Boston Scientific, Medtronic. F.A. has received consulting fees honoraria from Boston Scientific, Medtronic, Sanofi Aventis and speaker bureau from Boston Scientific, St Jude Medical.

References