CLINICAL RESEARCH

Remote-controlled magnetic pulmonary vein isolation using a new three-dimensional non-fluoroscopic navigation system: A single-centre prospective study

Isolation des veines pulmonaires par robot magnétique couplé à la cartographie 3-D : étude prospective monocentrique

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KEYWORDS
Atrial fibrillation; X-ray; Pulmonary vein; Remote magnetic navigation

Summary

Background. — Catheter ablation of atrial fibrillation (AF) focuses on pulmonary vein isolation (PVI), but the procedure is associated with significant X-ray exposure. Few data exist concerning the combination of remote magnetic navigation (RMN) and a new three-dimensional non-fluoroscopic navigation system (Carto® 3), which facilitates precise catheter navigation and limits X-ray exposure.

Aims. — To assess the efficacy and extent of fluoroscopic exposure associated with the combination of RMN and the Carto 3 system in patients requiring AF ablation.

Methods. — Between January and September 2011, catheter ablation was performed remotely using the Carto 3 system in 81 consecutive patients who underwent PVI for symptomatic drug-refractory AF. The radiofrequency generator was set to a fixed power ≤ 35 W. The primary endpoint was wide-area circumferential PVI confirmed by spiral catheter recording during ablation and including additional lesion lines (left atrial roof and coronary sinus defragmentation) or complex fractionated atrial electrograms for persistent AF. Secondary endpoints included procedural data, complications and freedom from atrial tachycardia (AT)/AF.

Abbreviations: 3D, three-dimensional; AF, atrial fibrillation; AT, atrial tachycardia; RF, radiofrequency; RMN, remote magnetic navigation; VKA, vitamin K antagonist.

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Background

Over the past few years, radiofrequency (RF) therapy has had a decisive place in the treatment of complex arrhythmias and, more particularly, atrial fibrillation (AF) [1–5]. This technology requires experienced operators with special skills in manipulating catheters in difficult clinical situations, so this intervention may involve long, tedious and potentially risky procedures [1,3–5]. Catheter technology is a major limitation to the manual method, as catheter mobility is limited by the transmission of the torque, which depends on vessel tortuosity, catheter orientation in the heart and catheter rigidity or instability. During these procedures, the operator is exposed not only to X-rays, but also to abnormal fatigue, which may lead to a loss of concentration.

This decreased concentration may result in delayed analysis, a lengthened procedure and an increased risk of complications. AF treatment is increasingly used in electrophysiological laboratories due to the prevalence of AF (2–3% of the population aged > 60 years) and the low benefit/risk ratio of antiarrhythmic drugs compared with RF techniques, as shown in several randomized studies [1,6–8]. The current trend favours technology that is similar to or more effective than manual RF techniques, but is safer in terms of potential complications and other variables such as X-ray exposure for patient and operator. Such technology should eventually allow the management of more patients without adverse effects on the operators’ health. The remote magnetic navigation (RMN) system appears to be a futuristic technology benefiting from a very favourable benefit/risk.
Remote magnetic navigation system

The RMN system (Niobe II; Stereotaxis, Inc., St. Louis, MO, USA) is a technological platform that uses a steerable magnetic field to remotely guide a supple catheter inside the

Radiofrequency catheter ablation procedures

Regardless of the study group, the endpoints of ablation were isolation of the pulmonary veins, defined by complete elimination or dissociation of pulmonary potentials validated with a circumferential mapping catheter in all cases (paroxysmal and persistent AF), and the creation of linear lesions interconnecting the upper pulmonary vein ostia (roof line).

RF was applied using an open irrigated-tip catheter with a power output $\leq 35$ W close to the pulmonary vein ostia and 30 W for the roofline or while creating coronary sinus disconnection. Irrigation with sodium chloride 0.9% at a rate of 20–35 mL/min was employed to maintain a tip temperature of $< 43^\circ$C.

Electrophysiological procedures

All patients received anticoagulation therapy with vitamin K antagonists (VKAs) for at least 2 months prior to the procedure (target international normalized ratio, 2–3). Therapeutic anticoagulation was maintained with intravenous or low-molecular-weight heparin following VKA discontinuation, starting 3 days before the intervention. Transoesophageal echocardiography was performed within 48 hours before the procedure to exclude left atrial thrombus. VKAs were resumed the day after the procedure and effective anticoagulation was maintained with heparin until the international normalized ratio was $> 2.0$. Surface electrocardiograms and bipolar endocardial electrograms (filtered from 30 to 500 Hz) were continuously monitored and stored on a computer-based digital amplifier/recorder system. A deflectable quadripolar catheter (5 mm interelectrode spacing; Xtrem; ELA Medical, Montrouge, France) was positioned in the coronary sinus for pacing and recording. The left atrium was accessed by a patent foramen ovale, when present, or by transseptal puncture. A guidewire was introduced into the left atrium using an 8F long sheath. The sheath was perfused during the procedure with heparinized solution (3000 U of heparin in 500 mL of sodium chloride 0.9% at a rate of 150 mL/h).

A multipolar deflectable catheter (Lasso; Biosense Webster, Diamond Bar, CA, USA) was inserted through the long sheath to map the pulmonary vein ostia for all ablation procedures. RF ablation was performed using a 3.5 mm open irrigated-tip magnetic ablation catheter (NaviStar<sup>®</sup> RMT ThermoCool<sup>®</sup>; Biosense Webster, Diamond Bar, CA, USA). The catheter was advanced into the left atrium through a second transseptal puncture. The venous sheath was then withdrawn in the right atrium and continuously perfused. Following transseptal puncture, intravenous unfractionated heparin was administered as a bolus (7500 units); additional boluses were given throughout the procedure to maintain an activated clotting time of $\geq 300$ seconds. Activated clotting time was determined 30 minutes after transseptal puncture and every 30 minutes thereafter. When the activate clotting time was $< 300$ seconds, an additional bolus of 2500 units was administered. Deep sedation was achieved using intravenousnalbuphine and midalzolam.

Methods

Catheter ablation was performed remotely using the Niobe II RMN system (Stereotaxis; St. Louis, MO, USA) combined with a new 3D non-fluoroscopic navigation system (Carto 3 system) in 81 consecutive patients who underwent pulmonary vein disconnection for symptomatic drug-refractory AF.

Electrophysiological procedures

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The Carto 3 system allows for real-time Advanced Catheter Location™ and visualization of both ablation and circular mapping catheters (NaviStar RMT and Lasso; Biosense Webster, Diamond Bar, CA, USA).

Figure 2. Left atrial reconstruction was obtained using a fast anatomical map algorithm. This method takes a continuous (non-gated) record of the movements of the NaviStar catheter (Biosense Webster, Diamond Bar, CA, USA). Based on this volume sampling, a surface reconstruction was built in accordance with the set resolution level. Once the map was completed, a three-dimensional computed tomography scan was performed to optimize the left atrial reconstruction.

The steerable magnetic field contains two giant computer-controlled 1.8-tonne magnets that are positioned on opposite sides of the fluoroscopy table (Fig. 3). A magnetic field of 0.08–0.1 Tesla is generated (according to the initial choice), such that the three small magnets that are incorporated parallel to the tip of the RF catheter allow for 3D navigation (Fig. 4). The magnetic field is applied to a theoretical cardiac volume of 20 cm × 20 cm. The catheter tip may be directed very precisely using a vector-based computer system (Navigant system; Stereotaxis Inc., St. Louis, MO, USA) (Fig. 5). This system operates by aligning the catheter relative to the magnetic field generated so that the movement of the catheter depends on changes in the direction of the two magnets in relation to each other. A computerized motor drive system (Cardiodrive; Stereotaxis Inc., St. Louis, MO, USA) advances or retracts the catheters, while its orientation in space requires a computerized work station (Navigant 2.1; Stereotaxis Inc., St. Louis, MO, USA). Using a keypad (arrows) or joystick, the catheter can be continuously advanced, retracted or even adjusted (from...
Remote magnetic navigation and atrial fibrillation

The steerable magnetic field contains two giant computer-controlled 1.8-tonne magnets that are positioned on opposite sides of the fluoroscopy table.

A magnetic field of 0.08—0.1 Tesla is generated (according to the initial choice), such that the three small magnets that are incorporated parallel to the tip of the radiofrequency catheter allow for three-dimensional navigation.

The second Niobe II generation allows for the magnets to be tilted at angles ranging from 40° left anterior oblique to 30° right anterior oblique. The constant application of the magnetic field during the ablation procedure keeps the catheter tip in permanent contact with the endocardial tissue throughout the cardiac cycle, thus improving the delivery of the RF current. Because the magnetic field exerts a weak force (15—20 g) and the catheter is very flexible, navigation inside the heart is very reliable, with a near-zero risk of perforation [9—14]. The system is able to memorize certain data, such as the position of veins, and reutilize these vectors during the examination to facilitate catheter navigation or improve procedure times. In addition, automatic navigation is possible using NaviLine (Stereotaxis Inc., St. Louis, MO, USA), which allows for automatic processing by producing a line or surrounding veins.

### Measurements: procedural and fluoroscopy variables

The following variables were recorded for all patients and compared within study groups: total duration time (skin to skin); total X-ray time and gray/cm², from needle insertion to ultimate catheter removal; skin to catheter positioning X-ray time and gray/cm², from femoral access to the end of catheter positioning in the left atrium, including transeptal access; left atrial electroanatomical mapping X-ray time and gray/cm², from catheter positioning in the left atrium to the creation of a satisfactory electroanatomical reconstruction compared with a left atrial computed tomography scan; ablation X-ray time and gray/cm², from the first to the last RF delivery.

### Endpoints

The primary endpoint was wide-area circumferential pulmonary vein isolation, as confirmed by spiral catheter recording during ablation in all patients. Pulmonary vein isolation was defined by abolition or dissociation of activities in all of the pulmonary veins. Pulmonary vein potentials and far-field potentials were distinguished with pacing technique from the left atrium, left atrial appendage or coronary sinus, using the ablation or the quadripolar catheter. An additional lesion line (left atrial roof) or coronary sinus defragmentation or complex fractionated electrograms lesions for persistent AF was possibly performed. Secondary endpoints included procedural data, complications and freedom from atrial tachycardia (AT)/AF.
Follow-up

Patients were routinely hospitalized for 3 days postprocedure and a blanking period of 2 months was applied. The blanking period was defined as a period during which early recurrences were considered transient phenomena rather than procedure failures. Antiarrhythmic medication was maintained for 6 months and then discontinued in patients with paroxysmal AF, but continued in those with persistent AF. VKAs were continued, with consideration for the CHA2DS2-VASc score. Success was defined as the absence of any documented arrhythmia or symptoms suggestive of arrhythmia recurrences; 24-hour Holter monitoring was performed each time the patient experienced palpitations. Patients were followed every 6 months by means of a clinical interview and a redo procedure was permitted > 6 months after the index procedure, if the patient so wished.

Statistical analysis

All clinical variables were assessed at the time of hospitalization and procedure. Continuous variables are presented as means ± standard deviations or medians with interquartiles as appropriate. Categorical variables are expressed as percentages. All analyses were performed using StatView® 5.0 (StatView IV; Abacus Concept, Berkeley, CA, USA).

Results

Baseline population characteristics

Baseline clinical data are summarized in Table 1. In total, 81 patients were prospectively included, with the following patient characteristics: mean age 60 ± 9 years; 20% women; mean left atrial diameter 41 ± 7 mm; and 25% with structural heart disease. The percentage of circumferential pulmonary vein isolation, as confirmed by spiral catheter recording during ablation, was 97%.

Table 1  Patient characteristics (n = 81).

<table>
<thead>
<tr>
<th>Characteristic</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>60 ± 9</td>
</tr>
<tr>
<td>Women</td>
<td>20</td>
</tr>
<tr>
<td>Hypertension</td>
<td>27</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7.5</td>
</tr>
<tr>
<td>Tobacco</td>
<td>31</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>30</td>
</tr>
<tr>
<td>Atrial fibrillation type</td>
<td></td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>73</td>
</tr>
<tr>
<td>Persistent</td>
<td>27</td>
</tr>
<tr>
<td>CHA2DS2-VASc score</td>
<td>1.2 ± 1</td>
</tr>
<tr>
<td>AF duration (months)</td>
<td>72 ± 42</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>25</td>
</tr>
<tr>
<td>History of atrial flutter</td>
<td>28.4</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>61 ± 9</td>
</tr>
<tr>
<td>TLAD (mm)</td>
<td>41 ± 7</td>
</tr>
<tr>
<td>Left atrial surface (cm²)</td>
<td>22 ± 6</td>
</tr>
<tr>
<td>Number of antiarrhythmic agents</td>
<td>2 ± 1</td>
</tr>
</tbody>
</table>

Data are mean ± standard deviation or %. AF: atrial fibrillation; LVEF: left ventricular ejection fraction; TLAD: transversal left atrial diameter.

a Median ± interquartile.
Total fluoroscopy (median ± interquartile)

Median procedure time was 3.5 ± 1 hours; total X-ray exposure time was 13 ± 7 minutes (49 ± 36 gray/cm²); dual transeptal puncture and catheter positioning time was 8 ± 4 minutes (29 ± 22 gray/cm²); left atrial electroanatomical reconstruction time was 1 ± 4 minutes (9 ± 4 gray/cm²) catheter ablation time was 3.5 ± 5 minutes (11 ± 2 gray/cm²).

Clinical outcome

After a median follow-up of 15 ± 6 months and the use of one procedure, 71% of patients were free of symptoms, while 84% remained asymptomatic after the use of two or three procedures. The recurrences observed were AT in three (3.7%) patients, paroxysmal AF in eight (9.9%) patients and persistent AF in four (4.9%) patients; redo ablation was performed in these 15 (19%) patients. In two patients with paroxysmal AF, three procedures were carried out without clinical success. No tamponade was observed and no char was noticed on the catheter tip upon catheter removal.

Complications

Access-site groin haematoma was observed in two patients and one patient had an arteriovenous fistula requiring surgical revision. Seven days after the procedure, a 71-year-old patient receiving low-molecular-weight heparin and a VKA presented a severe psoas haematoma requiring surgical revision. The postoperative period was unfortunately complicated by multivisceral failure and the patient died 3 weeks later.

Discussion

Major findings

This study describes the long-term outcome of consecutive patients with AF undergoing remote magnetic ablation using a new 3D non-fluoroscopic navigation system (Carto 3). The major finding was that in patients with paroxysmal or persistent AF, this new tool yielded results for AF/AT recurrence rates that were similar to those previously published for manual catheter use [24]. Our study provides evidence that AF ablation with minimal fluoroscopy use is feasible by means of technology enabling image integration with multiple catheter visualization and RMN.

Potential risks related to X-ray exposure during atrial fibrillation ablation

Guidelines have recently been modified to extend the number of indications for AF ablation [24]. As a result, the increased number of AF ablation indications has logically led to an increased number of procedures per centre. Accordingly, patients and medical staff are prone to significant radiation exposure. Moreover, many patients undergo multiple examinations and interventional procedures that increase their cumulative dose and overall radiation risks. Thus, radiation exposure to the skin in patients undergoing AF ablation or in physicians may exceed the thresholds for radiation skin injuries due to prolonged fluoroscopic times [25–27]. The additional lifetime risk for a fatal malignancy associated with a single AF ablation has been estimated to range between 0.15% and 0.21% [25–27]. The individual cancer risk (fatal and non-fatal) has been estimated to be close to 1/200 [28] and, consequently, current guidelines recommend that all physicians minimize radiation injury hazard to patients and medical or professional staff [29]. Consequently, the ability to integrate RMN and electroanatomical navigation plus catheter visualization (Carto 3 system) bears great potential for the development of quicker anatomy-specific ablation procedures and shorter fluoroscopic times.

Impact of remote magnetic navigation on atrial fibrillation procedures

One of the principal advantages reported in the literature is the highly significant decrease in X-ray exposure [9–14]. This observation may appear trivial when considering the short-term effects for patients, but in cases where multiple interventions using radiation are performed, it could represent a very significant decrease in total X-ray exposure time for the physician and patient [24–29]. This observation is even more pertinent for electrophysiologists, whose multidisciplinary activities might include implantation of resynchronization devices and ablation of complex arrhythmias, with obvious long-term benefits [9]. The amplitude of the reduction in X-ray exposure was evaluated to be 50% on average [30,31]. Similar results were published by Kim et al., who reported a mean reduction of 29 minutes compared with the conventional method [32]. Despite lacking a control group, our study findings show that the new technology allows AF procedures to be performed with a very short X-ray exposure (median 3 ± 4 minutes; 10 gray/cm²), which involves left atrial acquisition map and AF ablation times. In the scientific literature, the procedure times with this new technology were reported to be longer than those with the conventional method. However, in the reported studies, there were some biases associated with the research. Highly experienced groups performed these studies, generally involving several operators, including 'fellows', and the learning curve was integrated, which renders the analysis of the results difficult. Although the procedure time appears to be a decisive measurement, operator fatigue should also be included in the evaluation. In retrospect, it appears to us that magnetic navigation had a major impact on this latter variable, enabling us to significantly increase our activity, while reducing the level of operator fatigue at the end of the day. Di Biase et al. showed that using RMN reduced fluoroscopy time very significantly during AF ablation and when the learning curve was overcome, the amelioration was shown to be highly significant [33]. Our results confirm that RF ablation procedures can be performed with a low level of X-ray exposure and operator fatigue. Concerning safety, utilization of a flexible magnetic catheter considerably increased the safety of complex procedures such as RF ablation in AF [34–36]. The risk of perforation was almost zero and was more due to the softness of the catheter than to the constant force applied to the tissue, which did not exceed 15–20 g [9,35]. Cases of catheter-induced
tamponade have been rarely reported in the literature [9,35]. In approximately 300 AF ablation procedures carried out in our laboratory using the Stereotaxis system, only one case of tamponade was observed, which occurred during transeptal catheterization. The RMN results reported from the different studies appear to be similar to those for the conventional method, without being superior [9,35]. Based on our study results, primary success was achieved in 71% of cases and 84% of patients remained asymptomatic during long-term follow-up (median 15 months). These results should be viewed in context: the operators had considerably more experience with the manual method [9,35]. Moreover, because certain theoretical advantages, such as the stability of the catheter, access to difficult zones such as the right inferior pulmonary vein, the quality of the practiced lines and lesion homogeneity [9,35], appear to favour magnetic navigation, we must wait for the outcomes of ongoing prospective studies using both methods and conducted in experienced centres to truly answer the question.

Impact of electroanatomical mapping systems on X-ray exposure and procedure times

Even in experienced hands, conventional fluoroscopic-guided ablation is a lengthy procedure requiring extensive use of fluoroscopy. Electroanatomical maps and the integration of 3D cardiac images (magnetic resonance imaging or computed tomography scan) show great potential for reducing both procedure and X-ray exposure times [15—23]. In previous versions of the electroanatomical mapping system (Carto XP EP mapping system; Biosense Webster, CA, USA), visualization was possible only for the ablation catheter tip by means of electromagnetic technology [15—20,22,23]. The inability to visualize multiple catheters required routine validation of the Lasso catheter position by means of fluoroscopy, thereby prolonging radiation exposure [15—20,22,23]. The Carto 3 system combines the electromagnetic technology (as in the Carto XP system) with new advanced catheter location technology that enables visualization of multiple catheters without fluoroscopy [21,34,37]. Left atrial reconstruction was obtained using a fast anatomical map algorithm [37]. The theoretical advantages of old and new electroanatomical systems have not been fully proven in clinical practice [21,34,38—40]. Indeed, despite the significant reduction in fluoroscopic times, clinical studies failed to demonstrate a reduction in procedure duration or an improvement in clinical outcomes [21,34,38—40]. Our study is in accordance with previously published reports, but emphasizes the low level of X-ray exposure. The residual X-ray exposure was essentially due to the need to confirm pulmonary vein isolation by mobilizing the circumferential Lasso mapping catheter. Recently, a remote circular catheter manipulation system was developed to prevent manual catheter manipulation (Vdrive robotic system; Stereotaxis; St. Louis, MO, USA) [41].

Clinical implications

While catheter ablation to isolate pulmonary veins has become the therapy of choice for managing drug-refractory symptomatic AF, it is still considered to be a second-line treatment, according to the latest guidelines [24]. Even experienced operators can find achieving a successful outcome without unnecessary adverse events very challenging when using this procedure [24]. Given this context, our study has shown that the combination of RMN and electroanatomical technology enabling visualization of multiple catheters without fluoroscopy (Carto 3 system) is feasible with reduced X-ray exposure time and no additional complications compared with manual procedures. In our study, this strategy was shown to result in an AF/AT recurrence rate that was similar to that with the manual method, as previously reported [9,30,42—44], but with significantly reduced X-ray exposure. Accordingly, the combination of Carto 3 and RMN represents the optimal tool for performing effective AF ablation, with the ultimate aim of reducing patient and operator X-ray exposure and limiting operator fatigue. In retrospect, it appears to us that magnetic navigation has a major impact on this latter variable, allowing us to significantly increase our activity, while reducing the level of operator fatigue at the end of the day.

Study limitations

The major limitations of this study are its non-randomized design and the small sample size based on an indirect comparison with previously published results. However, randomized studies are difficult to conduct due to the low number of centres benefiting from RMN in France. To our knowledge, no prospective studies on the feasibility, safety and efficacy achieved with the combination of RMN and Carto 3 have been published to date. Despite lacking a comparative manual control group, our results appear encouraging. However, a large multicentre randomized comparative study must be performed to confirm these positive preliminary results. Even if the easier approach of sites that are difficult to reach manually is confirmed, sites such as the right inferior pulmonary vein are tackled at the expense of contact force (distal magnet only) owing to the close proximity of the transeptal puncture site, unless a curve is made by the catheter in the left atrium. Experience demonstrates that such a curve is unstable and requires the more recently introduced VCAS Deflect (Stereotaxis; St. Louis, MO, USA). The major findings are based on an indirect comparison with previously published results.

Conclusions

RMN with irrigated catheters combined with the Carto 3 system can be effectively performed in patients requiring AF ablation with minimal use of fluoroscopy, but larger randomized studies are warranted.

Disclosure of interest

Professor Da Costa is a consultant for St. Jude Medical, Medtronic, Biotronik, Boston Scientific and Stereotaxis; he has received research supports from St. Jude Medical, Medtronic, Biotronik Boston Scientific and the Sorin Group.
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