Remote magnetic navigation and arrhythmia ablation

Navigation magnétique robotisée et traitement de l’arythmie

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Summary Radiofrequency treatment is the first-choice treatment for arrhythmias, in particular complex arrhythmias and especially atrial fibrillation, due to the greater benefit/risk ratio compared with antiarrhythmic drugs. However, complex arrhythmias such as atrial fibrillation require long procedures with additional risks such as X-ray exposure or serious complications including tamponade. Given this context, robotic magnetic navigation is a technique well suited to the treatment of complex arrhythmias, on account of its efficacy and reliability, the significant reduction in X-ray exposure for both patient and operator, and the very low risk of perforation. As ongoing developments will likely improve results and procedure times, this technology will become one of the most advanced for treating arrhythmias.

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Résumé Le traitement par radiofréquence constitue le traitement de choix des arythmies notamment des arythmies complexes avec au premier plan la fibrillation auriculaire du fait d’un bénéfice/risque supérieur à celui des médicaments antiarythmiques. Cependant, les arythmies complexes comme la fibrillation atriale nécessitent des temps de procédures longs d’où des risques supplémentaires comme l’exposition aux rayons X ou les risques de complications graves comme la tamponnade. Dans ce contexte, le système de traitement des troubles du rythme par navigation magnétique robotisée s’impose comme une technique parfaitement adaptée aux arythmies complexes du fait de son efficacité, de sa fiabilité, de la réduction significative de

Abbreviations: 3D, three-dimensional; AF, atrial fibrillation; MNS, magnetic navigation system; RF, radiofrequency; RFA, radiofrequency ablation.

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Background

Radiofrequency (RF) treatment is the first-choice therapy for simple arrhythmias, considering the numerous secondary effects and low efficacy of antiarrhythmic drugs in this indication [1]. Over the past few years, RF treatment has taken a decisive place in the treatment of complex arrhythmias and, more particularly, in the treatment of atrial fibrillation (AF) [1—5]. For these particular indications, operators must be experienced, especially in manipulating catheters in difficult clinical situations, which may lead to long, tedious and potentially risky procedures [2—5]. A major limitation of this manual method is caused by the catheter technology, as catheter mobility is limited by the transmission of the torque, depending on vessel tortuosity, orientation of the catheter in the heart and its 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 and, thus, a lengthened procedure or greater risk of complications. In addition, AF treatment is increasingly used in electrophysiological laboratories, owing to the prevalence of AF (2—3% of the population aged more than 60 years) and the low benefit/risk ratio of antiarrhythmic drugs compared with RF techniques, as shown in randomized studies [2,6–8].

The future is therefore in favour of a technology that is at least as effective as the manual RF technique but has an improved safety profile regarding potential complications and other variables, such as X-ray exposure for the patient and operator. Such technology should eventually allow for the management of more patients without affecting operator health. The magnetic navigation system (MNS) appears to be a futuristic technology that benefits from a very favourable benefit/risk ratio for both the patient and operator [6–8]. This article aims to present an overview of this modern technology, which seems particularly adapted to the treatment of complex arrhythmias using RF.

Description of the system

The MNS (Niobe II; Stereotaxis, Inc., St. Louis, MO, USA) is a technological platform using a steerable magnetic field, which remotely guides a supple catheter inside the heart [9]. The steerable magnetic field contains two giant computer-controlled 1.8-ton magnets positioned on opposite sides of the fluoroscopy table (Fig. 1). A magnetic field of 0.08—0.1 Tesla is generated (according to the initial choice), such that the three small magnets incorporated in parallel with the tip of the RF catheter permit three-dimensional (3D) navigation (Fig. 2). The magnetic field is applied to a theoretical cardiac volume of 20 × 20 cm. The catheter tip may be directed very precisely by using a vector-based computer system (Navigant; Stereotaxis, Inc., St. Louis, MO, USA) (Fig. 3). This system operates by aligning the catheter relative to the magnetic field generated, whereby the movements of the catheter depend on changes in the direction of the two magnets in relation to each other. Advancing or retracting the catheter is controlled by a computerized motor drive system (Cardiodrive; Stereotaxis, Inc., St. Louis, MO, USA) (Fig. 4), while its orientation in space requires a computerized workstation (Navigant 2.1; Stereotaxis, Inc., St. Louis, MO, USA) (Figs. 3 and 4). Using a keypad (arrows...
Figure 3. ‘QuickCAS’ Cardiodrive system positioned in the patient’s groin, permitting the catheter to be advanced by means of a keypad or joystick, as shown above.

or joystick, the catheter may be continuously advanced or retracted, or even adjusted (from 1–9 mm). The second-generation Niobe II allows the magnets to be tilted in directions 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 delivery of the RF current. The flexibility and weak force (15–20 g) exerted by the magnetic field result in reliable navigation inside the heart, with a near-zero risk of perforation [6–8]. The system is able to memorize certain data, such as the position of veins, and reutilize these vectors during the examination to facilitate the navigation of the catheter 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.

The main progress made over the past months has been to integrate a platform with the 3D mapping systems Cardo XP, Cartomerge and Carto 3 (Biosense Webster, Diamond Bar, CA, USA) (Fig. 5). With the development of the 3.5-mm tip irrigated magnetic catheter, this technology is being used for the treatment of complex left atrial arrhythmias. In this platform, the advantage of Carto 3 is the visualization of all the catheters and the possibility of rapid reconstruction of the anatomical structures using the magnetic lasso tool (Lasso NAV; Biosense Webster, Diamond Bar, CA, USA).

Experimental studies

The first experimental studies using a magnetic field to test the displacement of catheters were carried out by Tillander et al. and then by Ram et al., but the attempts of these authors were limited by the weak force of the magnetic field, the size of the catheters and the absence of precise control in three dimensions [9,10]. Subsequent developments incorporated the use of stereotactic localization and vector control using dedicated software [11].

Figure 4. Screenshot of the Navigant system, which allows for real-time navigation in the different parts of the heart using simple vector orientation from the keyboard, where the physician works remotely on the patient.
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The first feasibility study carried out in animals was published by Faddis et al. in 2002. The authors studied MNS technology in the laboratory [12]. The precision of the navigation system was tested and shown to be viable in six animals undergoing an RF procedure, for which 51 anatomical targets were tested, including the pulmonary veins [12]. Several variables were evaluated, including navigation, deflection force of the catheter, interference of the electrocardiogram signal analysed during the procedure and RF efficacy [12]. The authors showed that the maximal force applied on the catheter was 26.8 g versus 31.4 g using the manual method (limits of 19.7–45.4 g), while navigation precision was possible in 46/51 of the targets tested (90%). The only failure occurred in an animal in which the aortic arch could not be crossed. To overcome this difficulty, the magnetic catheter was modified by improving the profile of the two catheter segments (flexible section and section more rigid). For the 30 targets tested following modification of the catheter, the success rate of lesion completion was 29/30 (i.e. 97% of the cases tested). During the course of the same procedures, the variation measured for the position of the catheter with respect to the target was only 0.73 mm. Navigation at the level of the pulmonary veins was tested in five animals, including 30 veins, and was found to be possible in 100% of cases versus 70% using the manual method [12]. The feasibility of the technology in terms of obtaining an efficacious lesion was validated as excellent. Interference of the signals studied via the signal/noise ratio was very small, despite the distortion exerted on the catheter and, above all, was non-significant compared with the manual method. A certain number of limitations exist for this study, such as the lack of a randomized study design as well as the absence of evaluation of microscopic lesions caused by RF treatment [12].

Greenberg et al. were the first researchers to test the MNS on the electrical disconnection of the pulmonary veins in animals (seven healthy dogs) [13]. They showed that electrical disconnection of the veins was possible in 100% of the cases without the risk of pulmonary vein stenosis at 80 days, as analysed via necropsy and computed tomography scan [13].

Faddis et al. subsequently conducted a clinical feasibility and safety study in 31 patients requiring ablation of complex arrhythmias, including three patients with AF [14]. In this study, blinded analysis showed that there was no qualitative difference in the signal compared with the manual method [14]. Navigation in the cardiac cavities was possible in 213/215 sites tested on the right (99%) and in 13/13 sites tested on the left, while the levels of pacing thresholds were not significantly different between the manual method and the MNS [14]. No complication was noted in this study and arrhythmia ablation was possible in the seven patients tested (100% of cases) [14].

Ernst et al. subsequently investigated the feasibility and efficacy of the MNS in patients with intranodal re-entry reciprocating tachycardia [15]. In the 42 patients tested, analysis of the slow potentials was possible in 100% of cases, as was ablation of the slow path in 100% of cases [15]. The advantages of this technique were underscored by the authors, who highlighted the absence of the risk of perforation, the excellent stability of the catheter and the possibility of navigating in complex anatomical structures, such as was described for a patient with persistence of the superior vena cava associated with a giant ostium of the coronary sinus and a junctional tachycardia, who was efficaciously treated with the MNS [16].

Clinical studies

During the past 10 years, ablation of AF has become the dominant indication in centres of excellence and may account for up to 60% of interventions. The problem with these procedures is essentially due to the duration (at times more than 4 hours) and length of exposure to X-rays for both operator and patient. The notably severe complications are a major limitation of these techniques, as was shown by Cappato et al. in their registry of AF ablation procedures undertaken in 521 centres in 24 countries [17]. Although AF ablation was shown to be efficacious in approximately 80% of cases, with an average of 1.3–1.7 procedures per patient, the rate of reported major complications was 4.5% of cases, with 1% vascular accidents and 1.3% tamponade [17]. It is also necessary to take into account the number of procedures to be performed by each operator, due to the long-term risk of exposure to X-rays.

Clinical studies evaluating the use of the MNS in AF are now numerous [18–20]. In the initial phase, Pappone et al. evaluated the feasibility of the MNS in 40 patients with AF prior to RF treatment [19]. This was the first human study conducted in the AF setting [19]. In addition to feasibility, the authors demonstrated the substantial efficacy of the robotic technique, associated with a significantly decreased application time compared with the control group; however, this was a case-control study [19]. The operator underlined the extreme stability of the magnetic catheter, which was particularly useful for approaching straight veins [19]. Success was obtained in this study for 38 of the 40 patients tested (i.e. 95% of cases).

Di Biase et al. reported contradictory results in a non-randomized study on 45 patients, while testing the MNS
using a non-irrigated 4-mm catheter [18]. Although navigation was possible in most cases, the attainment of vein disconnection was low (< 90% of cases), mainly due to the use of the non-irrigated catheter [18]. Since March 2008, the irrigated magnetic catheter has been commercialized and utilized, allowing ablation results to be compared with those achieved using the conventional method [18]. Schmidt et al. also showed that the concept functions in AF patients, highlighting the quality of the navigation and stability of the catheter [20].

The issue raised by these authors refers to the learning curve, which means that the initial procedures were longer than those using the conventional method [20]. We have had the same experience, as one needs to get over the learning curve to obtain the large benefits associated with the technology. The first 100 patient procedures performed in our centre in 2010 allowed us to achieve AF ablation in a constant and reproducible manner. Currently, all our RF AF procedures are performed via stereotaxis (MNS) and there was no need to resort to the manual method in the 150 patient procedures performed in 2011.

Katsiyiannis et al. reported on their RF experience using the MNS in AF patients in a non-randomized case-control study [21]. The authors presented very promising results compared with the manual technique by showing a significant reduction in procedure time and X-ray exposure, but the catheter used was also non-irrigated, thus resulting in a risk of clot formation or ‘char’ formation [21].

To our knowledge, there is no randomized study comparing the manual method with stereotaxis, particularly in the treatment of AF with RF. Recently, a study was published involving the MNS associated with an irrigated magnetic catheter (Thermocool Navistar RMT; Biosense Webster, Diamond Bar, CA, USA) [22]. A comparative study was undertaken comparing the first-generation irrigated magnetic catheter with a second-generation irrigated catheter that had been modified to increase the internal lumen to facilitate lavage [22]. The initial ablation success rate was 93% (26/28 patients) in the new-generation catheter group, with a mean procedure time of 243 minutes (limits 125–450 minutes) and a mean X-ray exposure time of 16 minutes (limits 8 to 39 minutes) [22]. During global follow-up, 70% of patients were in sinus rhythm and no complications were observed with the second-generation catheter. In addition, no ‘char’ formation was detected in this group of patients [22]. A similar case-control study was reported by Lüthje et al., involving 107 patients treated with the MNS compared with a group of 54 patients treated manually [23]. Most of the veins were electrically disconnected in the two groups (i.e. in 90% of patients). There was a similar long-term success rate for the two procedures, with 66% absence of AF in the MNS group versus 62.1% in the control group following one single procedure, while the success rate was 83% following 1.5 ± 0.6 procedures [23]. While the exposure level to X-rays was lower in the robotic group, the procedure time was longer in this study, as was the radiofrequency ablation (RFA) application time [23].

Miyazaki et al. reported a case-control study evaluating 30 consecutive patients compared with 44 consecutive patients treated manually [24]. The results were similar but the procedure time for RFA was longer in the MNS group, as was the X-ray exposure time (63 ± 18 min in the robotic group vs 47 ± 17 min in the manual group; \( P = 0.0016 \)). These contradictory results, notably with respect to X-ray exposure time, may be explained to some extent by the operators’ extensive experience with the manual technique, the absence of the use of a cartography system with an exclusive lasso technique and, finally, the non-randomized study design [24]. Pappone et al. reported their experience with 130 consecutive patients using an irrigated magnetic catheter (Thermocool Navistar RMT) and showed that ablation was possible in 118/130 patients (feasibility of 91%) with recourse to a manual catheter in only 12 cases (9%) [25]. The mean procedure time was 94.6 ± 15.3 minutes and the long-term success rate (15.3 ± 5 months) varied from 81.4% in patients with paroxysmal AF to 67.3% in patients with permanent AF [25]. No major complications were reported, with the exception of two femoral arteriovenous fistulas and an important haematoma in the fold of the groin [25].

The use of robotics in the RF treatment of complex arrhythmias constitutes one of the most interesting applications, due to the reduction in risk of X-ray exposure and potential complications. Nevertheless, this technique is applicable to other types of arrhythmia [26–42]. Latcu et al. reported on 84 patients treated with three types of magnetic catheters in different clinical situations, notably 37 intranodal re-entries, 15 right isthmus-dependent flutters, seven ventricular arrhythmias, three atrial arrhythmias and three cases of paroxysmal AF [34]. The overall success rate was 82% with a failure rate of 18% (\( n = 14 \)): seven right isthmus-dependent flutters, four accessory pathways, two left flutters after RFA of AF and one intranodal re-entry. The time of exposure to X-rays by the operator was only 1.5 ± 0.6 minutes [34].

The advantages of the MNS in the treatment of intranodal re-entry tachycardias have been demonstrated in numerous series and were related, principally, to the stability of the catheter [15,16,31,34,37]. It should be noted that during the application of the RFA current, the appearance of a junctional rhythm was more rare [15,31,34,37]. The efficacy and safety of the MNS in this indication is evident in light of the different series published from different centres, although none of the studies was randomized [15,16,31,34,37].

The use of the MNS in right isthmus-dependent flutter has been investigated in several series in the form of registries, with only two randomized studies being published [36,41]. Vollman et al. randomized 45 patients with right isthmus-dependent flutter, with each group being treated with an 8-mm catheter; the authors obtained a bidirectional isthmus block in 84% using the MNS and in 91% using the manual method [41]. The authors showed that procedure times and application durations were longer with the MNS compared with the conventional method, whereas X-ray exposure time was largely and significantly lower with the MNS (median 10 vs 15 minutes; \( P < 0.05 \)) [41]. One interpretation of these data is that the force applied by the magnetic system on the cavotricuspid isthmus was insufficient with respect to the thickness and complexity of the local anatomy [28,30,38,41].

The MNS has been tested in the treatment of the accessory pathways in several studies, the most important of which was published by Chun et al., but none of the studies was randomized [28,29,32,39,42]. Three generations of magnetic catheters were tested and showed an elevated
success rate with the last generation of magnetic catheters (92% vs 85% with the second-generation catheters and only a 67% success rate with the first-generation catheters) [28]. The main difference between a first-generation catheter and the second- and third-generation catheters is the number of magnets integrated in the catheter, with three magnets for the new-generation catheters. The placement at the level of the registering electrodes was then optimized with the positioning of two proximal electrodes in the last version, permitting the simultaneous recording of proximal and distal signals [28].

A particular benefit of the MNS in the ablation of the accessory parahissian pathways has been shown in particular cases; this observation underlines the advantage of this technology based upon the stability and precision of the magnetic catheter [29,32,42].

The feasibility, efficacy and safety of the MNS have been tested in almost all indications at the auricular level and some studies were performed at the ventricular level [33,39]. Limited but efficacious experiences with RFA were reported in the treatment of benign infundibular ventricular extrasystoles, where the feasibility of the technology was similar to reported series using the conventional method [33,39].

A few studies on the efficacy of the treatment in cases of ischaemic ventricular arrhythmias have been published [26]. In addition, isolated cases have been reported in particular clinical situations, such as fascicular ventricular arrhythmia, ventricular extrasystoles localized at the level of the left anterior aortic sigmoid, left atrial arrhythmias or re-entrant arrhythmias associated with congenital cardiopathies and, finally, in the treatment of epicardial ventricular arrhythmias [27,35,40,43–45].

Advantages of the robotic magnetic navigation system

Fluoroscopy

One of the principal advantages that emerged during our review of the literature is represented by the highly significant decrease in the duration of exposure to X-rays [22,41,42]. In the short term, this observation may appear to be trivial for patients but in the case of multiple interventions using radiation it could represent a very significant decrease in X-ray exposure for the physician [22,41,42]. This analysis is even truer for electrophysiologists, who often exert multidisciplinary activities with implantation of resynchronization devices and ablation of complex arrhythmias; in the long term, this benefit becomes obvious [46]. The amplitude of the reduction in X-ray exposure was evaluated to be 50% on average [22,41,42]. Very similar results were published by Kim et al., with an average reduction of 29 minutes compared with the conventional method [46].

Procedure time

Procedure times appear to be longer than those of the conventional method but a certain number of biases exist in the studies. In fact, the studies were performed with more experienced groups, generally involving several operators, including 'fellows', and the learning curve was integrated, which makes analysis of the results difficult. Although the procedure time appears to be determinant, one should probably include operator fatigue in the evaluation. In retrospect, it appears to us that the contribution of the MNS was major concerning this variable, allowing us to significantly increase our activity, while reducing the level of fatigue at the end of the day. Di Biase et al. showed that the MNS very significantly reduced fluoroscopy time during ablation of AF and, when the learning curve was overcome, there was an additional improvement [18].

Safety

Utilization of the magnetic catheter, for which flexibility is a major asset, has considerably increased the safety of complex procedures such as RFA in AF [20,47]. The risk of perforation is almost absent, mainly due to the catheter softness rather than to the constant force applied to the tissue, evaluated as being maximally 15–20 g [12,20]. Cases of tamponade due to the catheter are very rare in the literature [20,47]. The use of this tool in daily practice in all of the AF ablation procedures has maximized safety for the patients and serenity for the operators in our centre. In approximately 250 cases of AF ablation carried out in our laboratory using the stereotaxic system, we had, unfortunately, one case of tamponade, which occurred during a transseptal catheterization. One theoretical advantage, which in not quantifiable for the moment, is the absence of iterative sheath mobilization during the procedure to prevent complications such as potential clot mobilization, which could limit the risk of emboli.

Efficacy

The results presented in the different studies appear to be similar to those for the conventional method but they are not, for the moment, superior [47]. One needs to interpret these results in the actual context, where the experience of the operators is considerably less compared with the manual method [47]. In addition, we must wait for the outcome of prospective studies using the two methods in experienced centres to really answer the question, because certain theoretical advantages appear to favour the MNS, 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 homogeneity of the lesions [47].

Limitations of the robotic magnetic navigation system

The principal inconvenience is related to the cost of the installation, which may be up to two million euros if a dedicated room is taken into account. This cost needs to be balanced with the numerous long-term advantages, namely the efficacy, safety and, once again, reduction in X-ray exposure. This is a futuristic technology that is perfectly adapted to the treatment of complex arrhythmias and, more principally, to the treatment of AF by RF. The second limitation is the initial captive nature of the system, exhibiting compatibility only with Cordis Webster...
catheters and the Carto XP, Cartomerge and Carto 3 RMT card systems. Nowadays, the system is compatible with NavX (Endocardial Solutions, St. Jude Medical, Inc., St. Paul, MN, USA) or can even use a magnetic catheter made by other companies (Biotronik and others).

Finally, the presence of a stimulation or cardiac defibrillation device makes the operator reluctant to carry out a stereotaxic procedure [48,49]. A recent study involving 121 devices showed that the risk of interference was, in reality, very small, as 95% of devices did not show any interference with the programme variables, battery status or registered data [49]. Interference was observed in six patients with pacemakers, requiring simple reprogramming [49]. A retrospective study was published on 31 patients with pacemakers (n = 5) and defibrillators (n = 36) by Eitel et al., demonstrating the safety of the system with the restrictions associated with the number of patients in the study [48]. These results are in accordance with the data, which show that the magnetic field emitted by the stereotaxic system is 20–40 times weaker than that associated with magnetic resonance imaging [49].

Other limits were evoked by Miyazaki et al. in the treatment of AF, such as the longer placement phase, the need for the operator to move for the positioning of the lasso, the restricted contact force that may limit the size of the lesion, the use of a supplementary sheath for the ablation and the cost of the procedure in relation to the manual lasso technique [24]. These disadvantages are not evident in very experienced teams and in light of the important developments made over the last months, with the release of the latest version of the Niobe ES (Epoch) system (Stereotaxis, Inc., St. Louis, MO, USA), which increases by 500% the execution speed of the magnetic catheter with respect to the earlier version, and the associated commercialization of the V-drive system, which allows the lasso to be manipulated in an automated manner at a distance.

Conclusion

The treatment of complex arrhythmias such as AF accounts for the major portion of the ablations that will be carried out by electrophysiological laboratories in the future. Over the past few years, the robotic MNS (NIOBE II) has emerged as a modern technology particularly adapted to the treatment of complex arrhythmias, exhibiting an equivalent efficacy to the manual technique in all of the clinical studies. The robotic MNS allows for a considerable reduction in X-ray exposure and risk of severe complications, essentially tamponade. The benefit is expected for the patient but also for the operator, whose level of physical constraint and ensuing fatigue is largely reduced by the system.

Disclosure of interest

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References

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