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Robot-assisted navigation in atrial fibrillation ablation – of any benefits?

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ABSTRACT

In recent years, catheter ablation has established itself as a safe and effective treatment for atrial fibrillation (AF). The benefits of robotic catheter navigation technology and techniques for AF ablation are currently a frequent topic of discussion. Most clinical trials have suggested that robotic ablation is (at least) as effective as the manual approach. The most important potential advantages of robotic ablation include excellent catheter stability and accuracy of its movement, reduced fluoroscopic time, catheter contact monitoring, improved comfort of the operator during the procedure as they can sit most of the time unexposed to radiation and, last but not least, a very short learning curve potentially allowing for more complicated procedures (persistent forms of AF, structural ventricular tachycardias, congenital heart disease).

SOUHRN

Katetrizační ablace se za poslední roky stala zcela standardní a efektivní léčbou fibrilace síní. Přínos robotizačních technik a postupů v ablaci fibrilace síní je v současnosti často diskutován. Z většiny provedených studií vyplývá, že v porovnání s manuální ablací je ta robotická stejně efektivní. Výhody, které robotická navigace přináší, jsou např. dobrá stabilita katetru a preciznost jeho pohybu, zkrácení skiaskopického času, monitorace přítlaku katetru na srdeční tkáň, komfort operatéra, který v průběhu skoro celého výkonu může sedět u pracovní stanice mimo dosah rentgenového záření, a v neposlední řadě krátká učební křivka s potenciálem řešení i složitějších výkonů více operatéry (chronické formy fibrilace síní, strukturální komorové tachykardie, vrozené srdeční vady).

Introduction

The ultimate aims of robot-assisted technologies establishing in branches of medicine include increased efficacy, accuracy, and safety of the procedure and, also, standardization of the course of the procedure. However, use of these procedures in clinical practice is often hampered by lack of funds. Robotic systems were marketed several years ago and are currently used for catheter navigation in an effort to enhance patient safety and increase the efficacy of the procedure also in catheter ablation and, hence, catheter-based management of AF [1]. Despite initial enthusiasm, operators continue to consider manual catheter ablation the gold standard.

Catheter ablation of atrial fibrillation

The number of catheter ablation procedures for paroxysmal or chronic AF has been substantially increasing in recent years. The reasons include increasing numbers

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of patients who develop this arrhythmia (a prevalence of 1.5–2%) [2,3] and, also, the outcomes of recent clinical trials clearly favoring catheter-based treatment over pharmacotherapy. Their results have been incorporated into the current guidelines of the European Society of Cardiology (last updated in August 2012) [3].

Although the success rate of catheter-based treatment of AF is high (65–90% absence of AF at 12 months post-ablation [4–6,25]), the procedure is still plagued by numerous pitfalls for the patient and operator alike. The procedure is a complex and not only time-consuming one (overall duration 2-4-6 hours) and always based on so-called electrical isolation of all pulmonary veins. The success of ablation is dependent on a variety of factors such as the type of the arrhythmia to be managed (paroxysmal versus persistent or long-lasting persistent ones), left atrial anatomy and size, the ablation strategy chosen (pulmonary vein isolation and/or, alternatively, the connecting lines in left and right atria), source of ablation energy (radiofrequency current, laser, cryothermia, etc.) and, also importantly, on the center's/operator's experience [7]. Although various types of imaging techniques are available to the physician performing ablation to manipulate with catheters in the left ventricle (three-dimensional [3D] mapping systems, intracardiac ultrasound, integrated CT/MR scan and, most recently, also rotational CT angiography), fluoroscopy continues to be an absolutely irreplaceable technique for a number of reasons. Exposure times of about 10-30-50 minutes represent a non-negligible radiation load for the operator and patient, and are more than three times longer compared with those of common procedures such as atrial flutter ablation [8,9]. On top of this, the patient may experience various side effects with complications reported in up to 5% of cases! [2].

In light of the above, ideal ablation procedures would be short, 100% effective both acutely and particularly in the long term, devoid of risk and, not requiring the use of X-ray radiation. Admittedly, despite the impressive technological advances and advent of robot-assisted ablation procedures, discussed in more detail below, we are still a long way to the above ideal.

Current robotic technologies

Currently, the two most widely used robotic navigation systems in clinical practice operate on completely different principles of catheter navigation. These are Niobe (I, II, Epoch upgrade) developed by Stereotaxis, Inc. (St. Louis, Missouri, USA) using the magnetic field to navigate the catheter, and the Sensei system (Hansen Medical Inc., Mountain View, CA, USA) operating on the electromechanical principle (see below). Another two devices put recently on the market include the robotic navigation CGCI system (Magnetecs, Inc., Inglewood, CA, USA) and Amigo (Catheter Robotics, Inc., New Jersey, USA); however, the body of clinical data currently available for the latter two systems is not large enough to allow for their critical evaluation.

Niobe I, II, and Epoch (Stereotaxis, Inc.)

The Niobe system features two giant permanent magnets creating around and within the patient's body on the operating table a magnetic field of 0.08–0.1 Tesla (Fig. 1). The direction and movement of a custom-made catheter,

Fig. 1 – Stereotaxis system featuring two permanent magnets generating a magnetic field in the patient's body for remote-control catheter navigation.

equipped with a miniature magnet on its tip, are determined by the magnetic field vector. The vector is changed by the operator moving a computer mouse thus advancing the catheter as necessary to the point in the cardiac chambers. Forward and backward movement of the catheter is controlled by a miniature motor (V CAS). Catheter contact with tissue is visualized indirectly, through a continuous curve showing catheter deviation from the direction relative to the pre-defined vector. The Stereotaxis device is compatible with both basic 3D imaging systems (CARTO, NavX). Apart from ablation in all cardiac chambers and the pericardial space, it can also be used to implant left ventricular leads and perform percutaneous coronary interventions [10]. The latest upgrade, the Epoch, has dramatically improved the speed of catheter navigation (a response time of 0.125 s), which means virtually real-time visualization of the catheter movement on the computer display as the catheter is being deployed in the heart. In addition to the ablation catheter, mechanical movement, rotation, and flexion of a 13F supporting sheath in the left atrium (and, if needed, also the diagnostic spiral "lasso" catheter inserted into the individual pulmonary veins to document their electrical isolation) can also be controlled by an integrated joystick potentially affording increased ablation catheter contact (see below).

The only health care facility in the Czech Republic with a magnetic remote control navigation system currently in clinical use is Prague, Na Homolce Hospital.

Sensei (Hansen Medical, Inc.)

The Sensei system, operating on the electromechanical principle, consists of three main components: 1. a robotic arm, 2. a system of two telescopic and flexible sheaths with a catheter inside, and 3. a workstation with monitors and a special lever controller (Fig. 2). The system is again compatible with both 3D imaging systems. Throughout the procedure, the operator is seated and intuitively manipulates with the lever controller within space; the controller movements are transmitted via the robotic arm to a sheath and/or a catheter. While originally developed primarily for AF ablation, the device has been in recent years also employed for ventricular arrhythmia ablation procedures. As the system of sheaths with the ablation

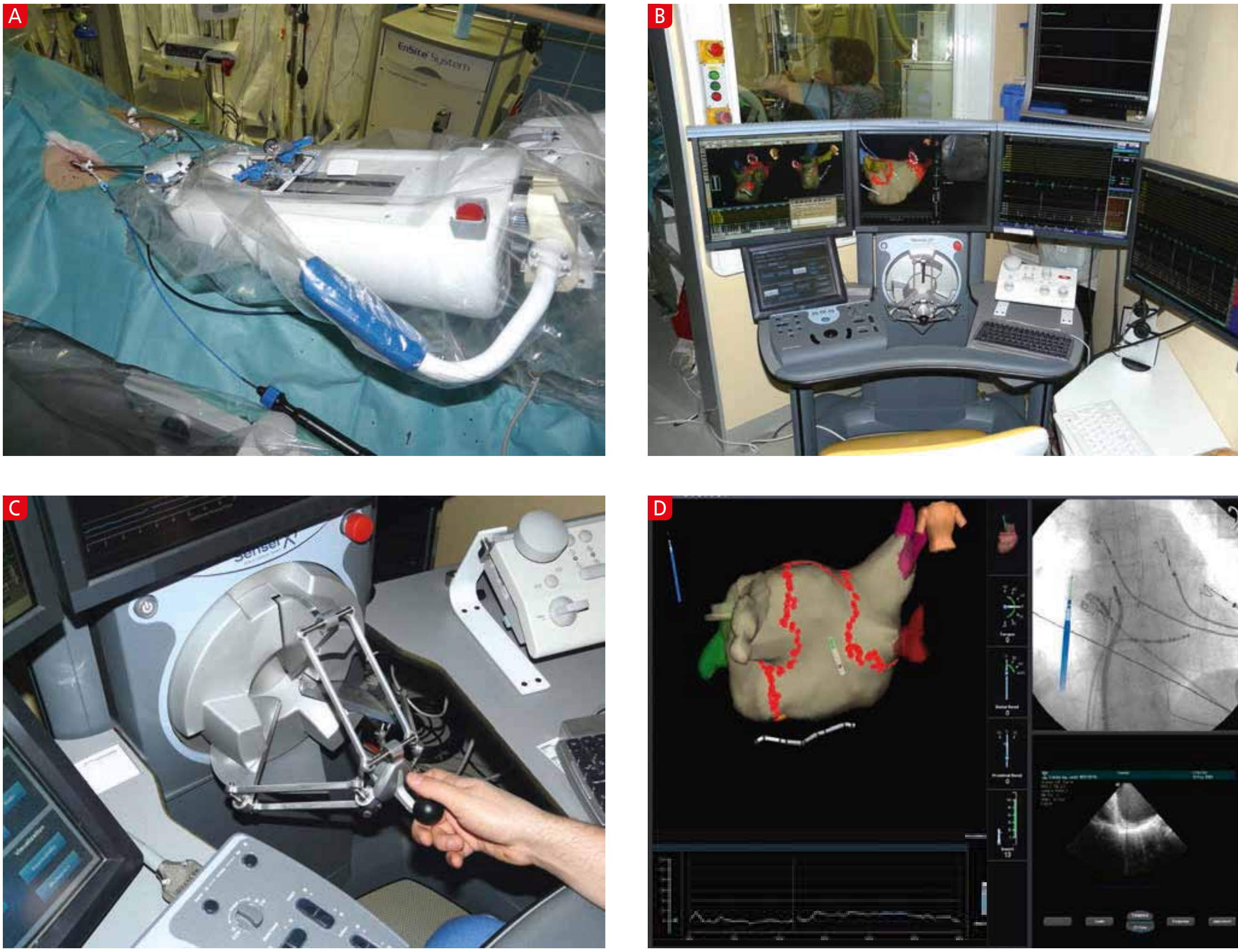

Fig. 2 – Sensei system (Hansen Medical): (A) robotic arm with catheter sheath in the right femoral vein, (B) workstation with several monitors and an intuitively controlled lever joystick, (C) joystick for catheter movement control, (D) a NavX map of the left atrium with ablations performed in the left atrium.

catheter is fairly rigid, several cases of cardiac tamponade have been reported before adding a system measuring contact of the catheter tip with the cardiac wall (IntelliSense) [8]. The degree of contact is shown both visually in graphic form on the display and, in a tactile manner, as vibrations of the lever mechanism when the preset level of contact has been exceeded.

By the end of 2011, over 8,000 procedures were performed using this remote-control navigation system all over the world! By March 2012, a total of 93 robotic systems have been installed worldwide, of this number, three are in use in the Czech Republic (Institute for Clinical and Experimental Medicine, Prague; Na Homolce Hospital, Prague, and České Budějovice Hospital).

CGCI – Catheter Guidance Control and Imaging system (Magnetecs)

This device again operates on the magnetic field principle. It is composed by a system of 8 electromagnets generating a variable magnetic field of 0.1–0.2 Tesla (Fig. 3). The advantage of the variable electromagnetic field is that it allows not only to bend the catheter; the catheter can also be rotated along its longitudinal axis; the type of contact with the cardiac wall can also be chosen. The catheter moves faster than with the Stereotaxis device and allows to perform what is called "automated" ablation at sites predefined in a 3D electroanatomical map (NavX). Initial

Fig. 3 – CGCI – catheter guidance control and imaging system (Magnetecs) – a schematic drawing.

clinical experience was reported already in 2010 after the device had been put into service in Hospital Universitario la Paz in Madrid, Spain; plans are for the installation of additional devices throughout the world including, again, the Czech Republic (Na Homolce Hospital).

Amigo (Cardiac Robotics, Inc.)

Another robotic system operating, similarly to the Sensei device, on the electromechanical principle is the Amigo. Using this device, a standard ablation catheter is advanced into a custom-made steerable sheath remotely and intuitively manipulated via a manual controller out of reach of X-ray radiation. The system is very simple and, again, fully compatible with 3D imaging software. The first ablation procedure was performed in Leicester, UK, in 2010.

Are there then any obvious benefits of robot-assisted ablation over manual ablation?

Yes, there are; at least some of them will be highlighted in the paragraphs below.

1. Each robot-assisted catheter movement (whether using magnetic or electromechanical navigation) is most accurate and standardized so that it is virtually independent of the operator's skills and dexterity, which explains why the learning curves for either system are mutually comparable, with the learning curves for robot-assisted navigation being much shorter than those for manual ablation, as the latter is extremely dependent on the operator's experience. Standard results have been reported after an approximate 20 procedures [11,12,14].
2. Both systems have been shown to offer very good catheter stability in otherwise difficult-to-access sites of the left atrium. The Hansen system has the clear advantage of direct mechanical monitoring of catheter contact with the cardiac wall resulting in increased efficacy in creating ablation lesions thereby increasing safety of the procedure [8,12]. Based on the above, one would expect shorter duration of ablation and the whole procedure. Still, most studies comparing manual and electromechanical robotic navigation suggest that robot-assisted procedures do not actually make ablation and procedural time shorter [8–10,12,13]. Still worse results in this respect have been reported for magnetic navigation. Despite stable contact between the catheter and cardiac tissue, the very soft ablation catheter in a relatively weak electromagnetic field (0.08–0.1 T) fails to achieve adequate contact; the result is longer ablation time and higher energy requirements [7,11,15,17]. Accordingly, total procedural time also tends to be longer as against manual ablation, partly due to the longer patient prepping (the same is true of electromagnetic navigation). A meta-analysis by Bradfield (PACE, 2012, evaluating 6 comparative studies) showed that, while the acute success rate of pulmonary vein isolation by magnetic navigation is significantly inferior (92% vs 97% for manual ablation; $p < 0.01$), their intermediate outcomes are comparable (70% and 69%, respectively). The weak correlation between acute success rates and intermediate outcomes may be due to the complexity of mechanisms of AF and the relatively frequent switch to manual ablation in the magnetic navigation group [16].
   Whether or not the recently installed new models using magnetic navigation (Epoch) with a stronger magnetic field and faster navigation, featuring a remote-control deflectable sheath for the ablation catheter (potential for increased contact, its continuity and, eventually, stability) and remote-control spiral catheter with a single joystick will improve the outcome is only to be seen.
3. Another advantage of robot-assisted navigation systems is reduction of radiation exposure both for the patient and, particularly, for the physician. Fluoroscopic times for AF ablation vary over a wide range of 5 to 50 minutes (depending on the type of arrhythmia, ablation technique, experience and routine of the center). The overwhelming majority of clinical trials with remote navigation have demonstrated a significant reduction in fluoroscopic times compared with manual ablation [7–9,11,12,15,23]. Just as an example, in a study published by Di Biase in 2009, the fluoroscopic time in the Sensei robotic navigation group was almost 10 minutes shorter (48.9 ± 24.4 vs. 58.4 ± 20.1 min; $p < 0.001$) as against manual ablation [12]. Similar results were reported by Steven with the difference in total fluoroscopic exposure being 9 ± 2.1 vs. 22 ± 6.5 min ($p < 0.001$) [9]. While no randomized trials with magnetic navigation in the treatment of AF have been published to date [16], most papers suggest a decrease in fluoroscopic time by about 50% (De Costa) [18]. This is supported by a retrospective analysis published by Arya in 2011 demonstrating a significant reduction in this parameter (34.5 ± 15.1 vs. 13.7 ± 7.8 min; $p < 0.0001$) in the group with ablation using magnetic navigation [15].
4. A definite advantage of magnetic navigation is that it is safe. The number of serious complications such as cardiac tamponade occurring as it does during AF ablation – according to Cappato – in an approx. 1% [2], is significantly lower compared with manual ablation and electromechanical robotic navigation [16,19]. The distal magnetic tip of the catheter is very soft (likened to boiled spaghetti by some), making the risk of cardiac wall perforation extremely low. There may have been only two reports of radiofrequency ablation--associated cardiac tamponade with this catheter. The safety of magnetic navigation has been highlighted by the above study of Arya reporting rates of periprocedural complications of 3.8% for manual ablation (including pericardial effusion in 2.4% of patients) versus 1.4% associated with the use of the Niobe system [15].
5. According to currently available data, the success rates of robotic techniques (acute and long-term outcomes) fully compare with those of manual ablation procedures [8,22,26–28]. This was reported in the studies assessing magnetic navigation by Katsiyiannis (20 patients in the magnetic navigation group), Arya (70 patients), Luthje (54 patients), and Di Biase (45 patients) among others, and electromagnetic navigation, e.g. studies published by Steven (30 patients) or Di Biase (193 patients; the largest published cohort published

to date; the success rates in AF termination over 14.1 ± 1.3 months in the presence of failed antiarrhythmic therapy was 85% and 81% in the robotic navigation and manual ablation groups, respectively). According to a study by Sorgente, the outcome of magnetic navigation ablation compare with that reported for cryoablation. Twelve months post-ablation, no episode of AF following antiarrhythmic discontinuation was documented in 65.5%/19 patients receiving manual ablation, 66.7%/20 patients with magnetic navigation ablation, and in 65.7%/23 patients having cryoballoon ablation. Using the above techniques, pulmonary vein isolation was invariably obtained in 100% of cases [20].

Our own experience at Na Homolce Hospital

In our hospital, both robotic navigation systems have been in use since 2007 so our body of experience is relatively large. In recent years, remote control navigation catheter ablation procedures are performed mainly in patients with persistent or long-lasting persistent AF. The implication is that the procedure involve, in the vast majority of cases, pulmonary vein isolation complemented with creating linear lesions in the left or right atrium. With these prolonged procedures, the disadvantage of longer patient prepping is outbalanced by higher comfort during ablation, safety of the procedure, and reduced radiation load. In our group of long-lasting persistent AF over the 2009–2011 period, remote control navigation catheter ablation was used exclusively as the first procedure in 68 patients. Mean duration of arrhythmia was 4.8 years (1–12 years). Regardless of the device employed (Niobe, 20 procedures; Sensei, 48 procedures), the typical set of lesions involved pulmonary vein isolation, mitral isthmus ablation, roof line, coronary sinus ablation, and tricuspid-caval isthmus ablation. Pulmonary vein isolation was accomplished in 100% of cases with sinus rhythm restored (whether by electrical cardioversion or by ablation) in all patients (13%). Atrial fibrillation termination by ablation predicted a high success rate of the primary ablation (75%). No differences in acute or long-term outcomes were observed between the two techniques of remote control navigation. In cases where the complete set of lesions with verification of bidirectional blocks in lines were made during the first procedure, the success rates at an average 11.5 months were 63% and 77% after the first and second ablation procedures, respectively. Our follow-up documented an acceptably low number of episodes of residual atrial macroreentry tachycardia in 9 (13.2%) patients.

A serious complication was experienced by two patients (both in the Sensei group). One patient developed hemopericardium requiring pericardiac puncture and drainage. The other one was a hypertensive patient dying suddenly (from full health) on day 3 post-ablation of extensive hemorrhagic stroke while receiving adequate anticoagulation. A perfusion CT scan did not document cerebral hemorrhage within the region of potential embolism so any relation with the procedure is not straightforward.

Drawbacks of robotic navigation

Last but not least, some disadvantages and "cons" of remote navigation systems should be acknowledged.

A clear con is the purchase price of robotic systems (e.g., the Stereotaxis system is priced at about 2 million euros); likewise, the cost of a single procedure compared with manual ablation is higher by tens of thousands of Czech crowns. Magnetic navigation systems (Stereotaxis, Magnetecs) are floor anchor fixed in the lab; hence, they are not portable. With robotic ablation procedures, patient prepping is somewhat longer which may reflect in prolonged overall duration of the procedure. Another disadvantage is the loss of direct communication with the patient (lying on the operating table in a room other than where the operator's workstation is placed); this lack of communication must be made up for by a third person. A drawback of the robotic Sensei system is the sheath size (outer dimension 14F), which may result in more frequent vascular complications in the groins. While a pacemaker or an implantable cardioverter-defibrillator *per se* is not a contraindication, the devices have to be reprogrammed before and after the procedure as the magnetic field activates the asynchronous mode, and there have also been reports of transient changes in the lead pacing properties [21,24].

As no comparison of the two robotic systems has been made in a randomized trial to date, they can only be evaluated using indirect parameters (see Table 1).

Table 1 – A comparison of manual vs robot-assisted navigation using the Niobe and Sensei systems.

	Manual ablation	Niobe	Sensei
Purchase price	+	+++	++
Price per ablation	+	++	++
Acute success rate	+++	+++	+++
Long-term success rate	++	++	++
System portability	+++	0	++
Fluoroscopy time reduction	+	+++	+++
Learning curve	Relatively long	Short	Short
Catheter stability	+	+++	+++
Comfort of procedure	+	+++	+++

Conclusion

The benefits of robotized techniques for catheter-based ablation procedures are unquestionable. In general, compared with manual ablation, robotic navigation in catheter-based management of atrial fibrillation makes catheter movement more accurate and standardized, is associated with a shorter learning curve, significantly reduces radiation exposure (of the patient and operator alike), and provides the physician performing a demanding procedure which takes several hours to complete with greater comfort. On the other hand, use of robotic navigation has not been conclusively shown to improve acute and long-term success rates of atrial fibrillation ablation (the outcomes are fully comparable). Major drawbacks of robot-assisted procedures include they are on average more costly and time-consuming. Nonetheless, remote-control technology is a dynamically developing field (stability of 3D imaging, increase in continuous contact, quick control) thus no doubt holding promise, particularly for complex, time-consuming procedures.

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