Role of Remote Navigation Systems in AF Ablation

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Abstract

During the past decade atrial fibrillation (AF) ablation has developed from being an experimental treatment option to an evidence based therapy implemented in current guidelines. Irrigated radiofrequency current guided ablations remain the golden standard of pulmonary vein isolation (PVI) procedures. Although practiced more frequently, it remains a demanding procedure requiring skilful operators. Novel technologies such as balloon based catheters or remote navigation (RN) systems have been developed to overcome the pitfalls of manual ablation procedures.

Introduction

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Introduction of RN Systems

To date, two different RN systems are commercially available: 1) magnetic navigation (Niobe II™, Stereotaxis, St. Louis, USA) and 2) robotic navigation (Sensei™, Hansen Medical, Mountain View, CA, USA). Both systems and their technical specifications have been introduced in detail elsewhere but the major concepts will be described briefly.

Magnetic Navigation

In brief, the MNS (Niobe II™, Stereotaxis) consists of 2 computer controlled permanent magnets located on either side of the fluoroscopy table which create a steerable, uniform magnetic field (0.08 T) approximately 15 cm inside the patient’s chest. The mapping and ablation catheter is equipped with 3 permanent magnets within the distal shaft of the soft catheter and aligns parallel to the externally controlled magnetic field. The orientation of the magnetic field is manipulated by changing the orientation of the outer magnets relative to each other. All magnetic field vectors can be stored and, if necessary reapplied for automatic naviga-
tion of the magnetic catheter. To enable remote controlled catheter navigation, a computer controlled catheter advancer system (Cardiodrive™, Stereotaxis, Inc.) is required. The video workstation (Navigator 3.0, Stereotaxis, Inc.) allows for precise catheter manipulations and moreover, for an integrated display of the magnetic catheter tip within the 3D electroanatomic (EA) LA map on standard fluoroscopy [Figure 1]. The second generation Niobe II™ system enables tilting both permanent magnets thus allowing increased C-arm angulations to RAO 30° and LAO 40°.

Robotic Navigation

The electromechanical system achieves catheter navigation by two steerable sheathes (Artisan™, Hansen Medical, USA) incorporating an ablation catheter. Outer (14F) and inner sheath (10.5F) are both manipulated via a pull-wire mechanism by a sheath carrying roboter arm (“slave”) that is fixed at the patient’s table. The roboter arm is controlled by the commands of the central workstation (“master”) positioned in the control room. Catheter navigation is accomplished using a three dimensional joystick (Instinctive motion control™, Hansen Medical, USA) and allows a broad range of motion in virtually any direction. In general, all catheters < 8.5F and all electroanatomical mapping systems may be used. A customized software (CoHesion™) allows for integration of NavX™ (St. Jude Medical, St. Paul, MN, USA) 3D mapping data into the workstation allowing for instinctive navigation in the 3D map.

Since the operator is deprived of any tactile feedback during catheter manipulation the system is equipped with a proximal contact force sensor (IntelliSense™) for online display of calculated contact force values. An optical and a vibrant alarm can be set at an individual contact force level to increase operator’s awareness towards exaggerated forces.

Rationale to Use RN Systems for AF Ablation

The current consensus document on catheter ablation of AF states that electrical pulmonary vein isolation should be the cornerstone of any ablation procedure.2 It was shown that circumferential PVI

Figure 1: Screenshot of the Stereotaxis workstation with the novel Navigant software (Version 3.0). It allows for integration of fluoroscopic and 3D electroanatomic reconstruction information (right upper panel RAO 30°; right lower panel LAO 40°). The yellow arrow indicates the direction of the designed magnetic field vector. All magnetic vectors can be stored and re-applied during the procedure. Moreover, the option to apply predefined vectors may allow for semi-automatic catheter navigation.
is more efficient than a segmental PVI approach. However, deploying permanently transmural circumferential lesion is still a challenging task, requiring a skilled operator who is able to achieve stable catheter positions and to perform precise catheter navigation. For patients with paroxysmal AF mid-term single procedure success reported from single centre trials range between 70-80% and decline to 50-60% over time during long-term follow-up. The major determinant for recurrences is PV to LA reconduction across initially complete circumferential ablation lines following non-transmural ablation lesions. The reasons may be multi-factorial, but recent trials suggest that insufficient contact between the catheter tip and ablated tissue may play a dominant role for incomplete ablations. During TOCCATA multicenter study a novel contact force sensing catheter was evaluated and it was shown that 12% of all ablations during PVI procedures were carried out with a contact force of as low as 5g. Furthermore, there was a clear pattern of low-contact predilection sites namely the myocardial ridge between the lateral PVs and the LA appendage being the most critical region. In sub-analyses it was demonstrated that mean contact force during AF ablation was directly related to success during follow-up.

Similarly, contact force determines the safety of an AF ablation procedure. The two most feared mechanical complications of AF ablation are pericardial tamponade and thermal esophageal injury. The incidence as reported in a recent survey is relatively low (1% for tamponade and 0.04% for atrioesophageal fistula, respectively). Nonetheless, the low complication rate is the benchmark for novel technologies and should not be exceeded. Moreover, despite the use of 3D mapping systems both, the patient and the physician are still exposed to scattered X-ray bearing the potential risk for adverse effects during a long professional career.

Clinical Experience of AF Ablation Using Magnetic Navigation

Published data on AF ablation using MN is scarce. This might partly be explained by the lack of an irrigated tip catheter that had been unavailable until late 2007. The initial feasibility study reported on circumferential PV ablation in 40 patients performed with a 4mm solid tip ablation catheter with the endpoint of voltage abatement >90%. The endpoint could be achieved in 38/40 patients and no major complications occurred. However, the procedure times were significantly longer than in a non-randomized control group.

In contrary, in a second feasibility trial true PVI demonstrated with a spiral catheter within the PVs could not be achieved in the vast majority (92%) of patients using the non-irrigated magnetic ablation catheter. Moreover, in one third of the cases significant charring on the tip of the ablation catheter was observed, underscoring the need for an irrigated ablation technology. If the PVs were disconnected at a more distal level, the solid tip catheter demonstrated efficacy in smaller patient series. While fluoroscopy times were consistently lower using MN as compared to a manual ablation strategy, data on procedure times are controversial. However, no data from prospective randomized trials are available yet.

Chun and co-workers recently demonstrated the feasibility of MN based PVI using the novel irrigated tip catheter. In a prospective fashion 56 patients were treated with the first (n=28; Thermocool NaviStar RMT I) or second (n=28; Thermocool NaviStar RMT II) generation irrigated tip catheter. In total the primary endpoint of complete PVI was achieved in 93% of all patients in both groups. The major improvements of the novel catheter were the higher effectiveness as documented by a significantly reduced procedure time (370 versus 243 min; p ≤ 0.0001) and the decreased incidence of charring on the catheter tip following the ablation procedure (61% versus 0%; p ≤ 0.0001). Notably, two patients treated with the first generation catheter and an evidence of charring experienced embolic events 7 and 14 days after the procedure. No complications occurred with the second generation irrigated tip catheter. During an average follow-up of 426 ± 213 days 70% of all patients remained in sinus rhythm after a single procedure off antiarrhythmic drugs.
Clinical Experience of AF Ablation Using Robotic Navigation

The initial results on AF ablation of a multi-centre feasibility trial using the first generation RN device were published in 2008. In total 40 patients underwent PV antrum isolation with an irrigated tip catheter using a 3D mapping system. In all patients the acute endpoint was achieved leading to a chronic success rate of 86% at one year follow-up off antiarrhythmic drugs. However, the complication rate of 5% (2 patients developed cardiac tamponade requiring pericardiocentesis) raised safety concerns among the electrophysiologic community.

It became evident that most of the severe complications occurred during an initial learning phase and modification of procedural techniques contributed to improve safety [20]. This included the use of a long femoral sheath for introduction of the Artisan catheter to prevent mechanical venous wall stress and vascular access complications. Second, ablation power needs to be lowered and adapted to the improved wall contact in order to avoid steam popping leading to cardiac perforation. The latter also holds true for thermal esophageal complications as recently demonstrated.

The excess contact force and relative stiffness of the Artisan sheath may lead to distortion of the cardiac anatomy, thereby decreasing the distance between the map catheter and the esophageal tissue [Figure 2]. The improved heat transfer may lead to an increased incidence of thermal esophageal lesions. According to our experience, ablation power at the posterior wall should therefore not exceed 20 W

Figure 2: Mechanical distortion of the posterior left atrial wall during an AF ablation using robotic navigation. Left panel: Screenshot from the Sensei workstation showing a NavX map in a left lateral (LL) view. The map catheter pokes out of the LA geometry at a contact force of 10-20g towards the esophageal temperature probe (ESO). Right panel: Corresponding fluoroscopic image in LAO 40° demonstrating the map catheter is situated distant from the left PVs on top of the temperature probe (ESO). CS: multipolar catheter in the coronary sinus. Lasso: spiral catheter in the left superior PV.
ever is the relative reduction in the operator’s fluoroscopy exposure by 35%.

Moreover, in a prospectively randomized trial operator’s fluoroscopy exposure was significantly reduced using robotic navigation for AF ablation (7 ± 2.1 versus 22 ± 6.5 minutes; p < 0.001). 25

It is noteworthy, that despite the availability of contact force information only 22.5% of patients who had undergone a segmental PVI procedure using RN demonstrated chronic PVI at 3 months follow-up assessed by an invasive repeat EP study. 28

Summary

In summary, feasibility of AF ablation using remote navigation systems has been demonstrated in multiple independent clinical trials. In comparison to manual ablation procedures similar acute and chronic success rates were reported, however data on safety and efficacy from prospectively randomized clinical trials (“man and machine”) have not been available yet. Therefore, the question whether the use of RN translates into a better clinical outcome remains unanswered.

It became evident that the use of remote navigation systems requires modifications of the standard manual ablation approach to prevent serious complications. This includes in particular esophageal temperature monitoring and a decrease in ablation power in robotic navigation procedures.

Unfortunately, recent trials could not provide

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<th>Author</th>
<th>Study cohort (n)</th>
<th>Success rate</th>
<th>Follow-up [months]</th>
<th>Complication rate RN (%)</th>
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Table 1: Clinical trials on AF ablation using robotic navigation.
compelling data that the use of robotic navigation will overcome the problem of catheter stability at particular LA regions such as the myocardial ridge sbetween the left atrial appendage and the left PVs or will improve the chronic PV isolation rate. 25

The major demerit of MN is the extensive procedure time of approximately 4 hours.

Nonetheless, both systems help to reduce the operator’s exposure to scattered X-ray by ~35% during AF ablation procedures.

**Future Directions**

It remains the electrophysiologist’s dream to perform a completely automated AF ablation procedure from a workstation within the control room. The magnetic navigation system software contains features (NaviLine) to store vectors and to navigate the catheter to and on pre-defined lines. One day, this might enable the operator to perform a circumferential ablation just by clicking the mouse. However, there is still a long road to travel.

In times of limited economical resources novel technologies should prove at least non-inferiority to conventional treatment options. Besides the reduced X-ray burden to the operator, the theoretical advantages of RN still need to be proven in clinical trials.

**References**

virtual catheter tip/tissue surface contact during cardiac mapping


