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The feasibility of using remote magnetic navigation system as the primary technological training tool for novice cardiac electrophysiology operators in the catheter ablation of left-sided accessory pathway

Guanhua Wu et al., LSAP ablation using RMN as a training tool for novice

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#### Abstract

Background: For novice operators, mastering catheter ablation of left-sided accessory pathway (LSAP) in a short duration of time without compromising efficacy and safety remains a challenge. In this study an attempt to shorten the learning curve by using robotics via a remote magnetic navigation (RMN) system was performed. Methods: Novice physician fellows without prior catheter ablation experience initiated their process of learning LSAP ablation using the Niobe™ RMN system. Their procedure parameters were recorded and compared with experienced operators using RMN and manual catheter navigation (MCN).

**Results:** Novice operators quickly shortened the total procedure time after their first five procedures. In subsequent procedures, no significant difference in procedure time, fluoroscopy exposure or ablation time was observed between novice and experienced RMN operators. When compared to MCN operators, novice operators

avoided excessive radiation exposure beginning with their first RMN procedure, while lower fluoroscopy doses were noted after five procedures. It was observed that procedure parameters did not differ significantly according to LSAP location. **Conclusion:** The RMN system is a practical and easy to use tool for novice electrophysiology operators to quickly master LSAP ablation, without compromising efficacy or safety. Additionally, when compared to MCN it also protects the operators and patients from excessive radiation exposure during the procedure.

Key words: catheter ablation, remote magnetic navigation, left-sided accessory pathway

#### Introduction

Catheter ablation has become the standard therapy for symptomatic atrioventricular reentry tachycardia (AVRT) [1, 2]. As a curative method, the ablation of accessary pathways (AP) is considered to have both high efficacy and safety, and continues to improve due to an increased understanding of cardiac electrophysiology (EP) and technological advances [3].

With a relatively uniform maneuver and stable contact, the catheter ablation of left-sided AP (LSAP) is generally considered to be easier than catheter ablation of right-sided AP. Therefore, LSAP ablation can often be one of the first procedures selected for novice EP fellows to practice. However, novice operator inexperience with catheter manipulation could lead to an increased probability of disease recurrence and serious complications like cardiac tamponade [4]. Additionally, radiation exposure to both operator and patient could be elevated during the learning process.

The remote magnetic navigation (RMN) system facilitates catheter navigation in the cardiac cavities with superior stability and safety [5, 6]. As a practical tool for the ablation of various cardiac arrhythmias including supraventricular tachycardia [7, 8], the system is routinely used in more than 100 hospitals worldwide including our center [9, 10]. During the last 2 years, the present center has begun to use the RMN system as the initial tool for new EP fellows to perform LSAP ablation, to shorten the learning period and to ensure safety. This study aims to evaluate the feasibility of applying the RMN system in EP procedures for completely new operators.

# Method

### **Patient characteristics**

A total of 153 consecutive patients who underwent catheter ablation of LSAP in the present center from January 2018 to December 2020 were included in this prospective study. Patients presented with either overt pre-excitation which was indicative of being left-sided through resting electrocardiogram (ECG), or several episodes of supraventricular tachycardia that were determined to be caused by LSAP through EP study. All patients enrolled signed an informed consent before the procedure, while patients with structural heart diseases including ischemic, valvular or congenital heart disease were excluded. This study was approved by the Ethics Committee of Ruijin Hospital, Shanghai Jiao Tong University School of Medicine.

# Electrophysiological procedure and ablation strategy

For all of the procedures, three catheters were introduced: 1) A deca-polar coronary sinus catheter from right intra-jugular vein, 2) A quadri-polar, and 3) A bipolar catheter from left femoral vein for His bundle and right ventricle signals respectively (St. Jude Medical, Inc., St. Paul, MN). The 12-lead surface ECG and the intracardiac electrograms were recorded simultaneously using a digital multichannel system (LABSYSTEM PRO, Bard Electrophysiology, Lowell, MA). Intravenous heparin was administered to maintain an activated clotting time of > 250 s.

After the presence of LSAP was confirmed, a trans-septal puncture was performed using an 8.5 F sheath (SL1, St. Jude Medical, Inc., St. Paul, MN) and needle, with the assistance of fluoroscopic landmarks. As soon as the successful puncture was confirmed, the sheath was advanced into the left atrium and the dilator as well as the needle were withdrawn. The ablation catheter was then placed at the atrial side of the mitral annulus through the sheath.

The choice of ablation catheter was according to the preference of operators. For operators using the RMN system, a magnetic ablation catheter (NaviStar<sup>™</sup> RMT ThermoCool<sup>™</sup>, Biosense Webster Inc., Irvine, CA) was connected to the CARTO<sup>™</sup> three-dimensional mapping system (Biosense Webster Inc., Irvine, CA) and the RMN Niobe<sup>™</sup> system (Stereotaxis Inc., St. Louis, MO) to perform electro-anatomic mapping and ablation. A non-irrigated 4-mm tip ablation catheter (Celsius<sup>™</sup>, Biosense Webster Inc., Irvine, CA) was used by other conventional operators in the manual catheter navigation arm.

The novice operators (NO) always used magnetic ablation catheters in this study. Prior to this study, all of the NOs had studied EP basics and worked as assistants during EP procedures for at least one year. These young physician fellows were all well-adept in deep vein puncture, mapping catheter placement and trans-septal puncture before this study, but had no experience in ablation catheter manipulation.

Radiofrequency energy was delivered after the target site was identified, using a power setting of 30 W for 60 s to 120 s for both groups. In the manual catheter group, temperature mode was applied while the maximum temperature was set at 55°C. In the RMN group, energy was delivered in power mode. Baseline irrigation rate for the magnetic ablation catheter was set to 2 mL/min, which increased to 17 mL/min during ablation. Radiofrequency delivery was terminated within 10 s if AP conduction was not blocked.

# Assessment of ablation and follow-up

Successful LSAP ablation was defined by conventional EP criteria [4]: 1) A complete elimination of AP conduction after a 30-min waiting period, 2) Failure to subsequently induce any AVRT, and 3) Lack of recurrence of overt pre-excitation or tachycardia during the pre-discharge period of 24–48 h. Total procedure time was recorded from deep vein puncture to sheath removal. Total ablation time and

fluoroscopy dosage were also noted for further comparison. Patients received aspirin for a period of 4 weeks after the procedure. A follow-up time of 6 months was scheduled for all patients in this study. They were contacted via telephone interview or by their referring physician.

#### Statistical analysis

Continuous variables were expressed as mean  $\pm$  standard deviation, and categorical variables as a percentage. An unpaired Student t-test was used to compare the continuous variables between two groups. For comparison among the three groups, an ANOVA test was performed, with Tamhane's T2 test for further post hoc study. A value of p < 0.05 was considered statistically significant. SPSS 26.0 software was used for all statistical analysis.

#### Results

## Patient characteristics

Baseline characteristics of all enrolled patients are listed in Table 1. Among 153 patients enrolled, 80 patients were treated with RMN. When comparing patients in manual catheter navigation (MCN) and RMN groups, there was no significant difference in average age, gender proportion or parameters of ultrasound cardiogram.

#### Learning period of the novice operator with RMN

For the 3 novel operators in our center, the procedure parameters beginning with their first procedure were recorded and compared to the data of the 3 experienced operators (EO) who routinely perform catheter ablation with RMN. As shown in Figure 1A, the NOs encountered difficulties in catheter manipulation in the beginning, but rapidly mastered robotic catheter manipulation and the procedure time curve flattened after several procedures. To clarify the learning period duration for the young fellows, their procedure parameters were compared before and after the first 5 procedures. Total procedure time was significantly reduced for NOs after 5 procedures (Fig. 1B), and the total radiation exposure and ablation time decreased in the same manner (Fig. 1C, D). Surprisingly, all parameters had no differences with those of EOs, indicating a short learning period for NOs achieving parameters of EOs when using the RMN system.

#### Procedure data compared to conventional operators

Procedure data was then compared with MCN operators (Fig. 2). As no difference was noted between the data of experienced RMN operators and the NOs after the initial phase, their data was combined into the RMN group. While the procedure time and ablation time were comparable to those of the MCN group, the fluoroscopy dose was significantly reduced in RMN-guided procedures. For the young operators, the total ablation time was initially higher than that of MCN operators. However, compared to MCN group, the radiation exposure was not elevated for NOs in their first 5 procedures, suggesting a protective effect of RMN-guided LSAP ablation against radiation for both operators and patients even during the learning period.

### Procedure data according to LSAP location

To eliminate the possible interference of the AP location to the procedure data, the parameters of both the RMN and MCN groups were further evaluated according to LSAP position (Fig. 3). In the RMN group, 78.5% (51/65) of the patients had a free-wall LSAP, which was similar to 82.2% (60/73) in MCN group. For each procedure method, the performance parameters were comparable for free wall and non-free wall LSAPs. RMN-guided procedures had a particular advantage for freewall LSAP ablation in terms of time savings, while fluoroscopy dose was consistently reduced in RMN group regardless of AP location.

## Complications and follow-up

No procedure-related complications such as cardiac tamponade occurred during or after ablation. Two patients who were treated by NOs during the learning period and one patient in the MCN group had documented recurrence, and all later received a repeat ablation procedure by MCN. In all other procedures, no recurrences were observed.

#### Discussion

## Major findings

The novice operators in the present center successfully mastered the technique of LSAP ablation using the RMN system in a rapid learning curve, with remarkable assurance of efficacy and safety. After the first 5 procedures, the NOs significantly improved their procedure performance, with their procedure parameters comparable to those of experienced RMN or MCN operators. The RMN system also protected the NOs and patients from excessive fluoroscopy exposure during the learning period.

## Considerations of LSAP ablation method

Left-sided accessory pathway can be approached by trans-septal puncture or by trans-aortic retrograde pathway. No clear recommendation has been proposed on the ideal approach for LSAP ablation. Currently, the choice of procedure method is largely according to the operator's judgement and preference, as is in the present center. Anselmino et al. [11] performed a systemic review in an attempt to assess the optimal approach for LSAP ablation through MCN. However, both approaches have a similar success rate and safety performance. For RMN-guided ablation, although Schwagten et al. [12] reported similar outcomes of both approaches, Chun et al. [13] found that retrograde access was associated with a low ablation success rate as ventricular contractions complicated the navigation and stability of the very soft magnetic ablation catheter. Therefore, in the present center and in this study, all RMN-guided LSAP ablation were through antegrade access, while MCN operators using a trans-aortic approach were not included to ensure the concordance of comparison between RMN and MCN group.

Total ablation time may also be an important factor of long-term success in LSAP ablation. Although a successful ablation attempt should always eliminate the AP within 10 s, consolidation ablation is usually applied by operators. It was recently

reported by Dionne et al. [14] that consolidation time < 90 s after AP ablation was associated with an increased incidence of early recurrence. In the present center, both RMN and MCN operators tend to consolidate the lesion after the primary ablation. The consolidation lesion could be directly on the initial site, or in a cluster around it, which is dependent on the operator's preference.

### RMN as the primary tool for novice EP operators?

With the superior reachability of the soft-tipped catheter, catheter navigation through remote computer control is thought to be easily mastered. For instance, it is reported that after 12–30 procedures, total time of RMN-guided ablation for atrial fibrillation could be remarkably reduced [15, 16]. However, in those studies, the operators were all well-trained for MCN procedures. Data to demonstrate whether RMN is suitable as the primary technological tool for the training of new EP fellows is currently very limited. As robotic technology has now been applied in many medical procedures, the learning curve of the robotic tool like Intuitive's DaVinci system is always an important topic. Many studies have demonstrated that the learning curve of robotic surgery could be quite short in high-volume centers [17]. But like other RMN system studies, no study has investigated the potential of using robotic surgical tool as the primary training tool for the novice up till now.

In this study, it was proven that novice operators with no prior catheter ablation experience could quickly master RMN-guided LSAP ablation. The RMN system has potential advantages for novice operators. For an MCN novice, their focus can often be distracted by excess attention to catheter handling, the inherent instability of a manual ablation catheter could cause young fellows to falter and increase the probability of serious complications. With the RMN system, the operators could instead 'liberate' their hands and increase their focus on the identification of local potentials, of which the understanding is pivotal for a young EP fellows' learning and even with experienced physicians. Additionally, the fine-positioning of the ablation catheter could be readily achieved by the incremental change of magnetic vector, especially for the LSAP mapping and ablation process through the trans-septal approach [13].

From very limited data, it is reported that flattening the learning curve of AP ablation by MCN takes many more procedures [4, 18]. However, those studies cannot be directly compared to the present one as they also included right-sided AP ablation, which is more complex in stabilizing the catheter and is generally associated with a higher recurrence rate [19]. Notwithstanding, the current study proved that the RMN system could be a practical tool for the EP novice and has the potential to be applied in the learning of other EP procedures.

#### Limitations of the study

There are several limitations in the current study. First, it is a single-center, nonrandomized study. The feasibility of using RMN system in the training of EP procedures should be fully demonstrated in a head-to-head comparison with the MCN novice. Also, the learning period duration of young EP fellows is largely dependent on their training mode. Each center has its unique training protocol, and the time required before allowing the fellows to practice delivering ablation differs. As a result, the data in the present study may be different when applied to other centers' training scenarios.

#### Conclusions

The RMN system is a practical tool for novice EP operators to quickly master LSAP ablation, without compromised efficacy or safety. Compared to MCN, it also protects the operators and patients from excessive radiation exposure during the procedure.

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#### Conflict of interest: None declared

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	RMN	MCN	Р
Number	80	73	
Age [years]	$50.0 \pm 14.0$	47.4 ± 15.1	NS
Male	61.2%	67.1%	NS
LA diameter [mm]	35.1 ± 3.8	34.7 ± 4.2	NS
Ejection fraction [%]	$66.0\pm6.0$	$66.5 \pm 6.1$	NS

**Table 1.** Baseline characteristics of the patients.

LA — left atrial; MCN — manual catheter navigation; NS — not significant; RMN — remote magnetic navigation

**Figure 1.** Learning period of the novice operators; **A.** Procedure time of all the leftsided accessory pathway (LSAP) ablation using remote magnetic navigation (RMN) system of all the novice operators (NOs) and experienced operators (EOs); **B.**  Procedure time; **C.** Fluoroscopy dose; **D.** Ablation time comparison among the first 5 procedures of EOs, the procedures afterwards and those of Eos; \*p < 0.05.

Figure 2. Comparison between remote magnetic navigation (RMN) and manual catheter navigation (MCN) group of procedure parameters including procedure time (A), fluoroscopy dose (B) and ablation time (C); \*p < 0.05.</li>

**Figure 3.** The impact of left-sided accessory pathway (LSAP) location to procedure time (**A**), fluoroscopy dose (**B**) and ablation time (**C**) for remote magnetic navigation (RMN) and manual catheter navigation (MCN) operators; \*p < 0.05.





