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ORIGINAL PAPER

# Treatment of left accessory cardiac pathway conduction disorders using radiofrequency catheter ablation under the guidance of the Ensite NavX 3D mapping system: a retrospective study

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**Abstract**
To investigate the effectiveness and safety of using the Ensite NavX three-dimensional (3D) mapping system during Radiofrequency catheter ablation (RFCA) of left accessory pathway (AP) disorders. A total of 227 patients having their left AP treated by RFCA, were classified into study group (n = 112) and the control group (n = 115). X-ray irradiation time and exposure doses during the course of the operations were recorded. Time taken to place the mapping catheter along with total duration of operations and procedural complications were compared. The X-ray irradiation time and exposure doses in the course of manipulating the ablation catheters were significantly lower in the study group compared to control (5.1 ± 2.3 min vs. 13.1 ± 3.1 min; $P < 0.05$ and 5.7 ± 2.6 mGy vs. 17.8 ± 4.3 mGy; $P < 0.05$, respectively). The total duration of operation was also significantly shorter in the study group compared to control (53.1 ± 18.8 min vs. 62.3 ± 20.6 min; $P < 0.05$). No procedural complications were reported in both groups. The irradiation time and exposure dose along with total operation duration was significantly reduced when the Ensite NavX mapping system was used during RFCA in comparison with traditional X-ray fluoroscopy method.

**Keywords** Three-dimensional mapping system · Radiofrequency catheter ablation · Left accessory pathway · X-ray irradiation

## Introduction

Supraventricular tachycardia (SVT) is a serious cardiac condition that results from structural abnormalities or electrophysiological disorders within the conduction system of the heart [1]. In general, pharmacotherapy can be used to control the accelerated heart rate and alleviate symptoms [2–4], but in case of persistent uncomplicated SVT, radiofrequency catheter ablation (RFCA) technology is the only successful procedure performed without evoking rhythmic disturbances permanently [5, 6]. However, RFCA operations result in excessive X-ray exposure for both, patients as well as operating surgeons due to increased X-ray fluoroscopy times and exposure doses, with a high risk of potential tissue damage [7]. The use of the Ensite NavX three-dimensional (3D) electrophysiology mapping system is common in the treatment of paroxysmal supraventricular tachycardia (PSVT) using RFCA and constitutes a novel technology that provides real time, accurate, 3D views of the heart chambers. Moreover, studies suggest that RFCA under the guidance of Ensite NavX mapping system affords "Near-Zero" fluoroscopic exposure in PSVT ablation, which is safe and effective in a relatively younger population and those who are at higher radiation risk [8]. Atrioventricular reciprocating tachycardia (AVRT) is the second most common type of PSVT with a higher prevalence among children (~ 30%) [9, 10] caused due to circuit re-entry mediated by accessory pathways (AP) [11]. So far, reports on the effectiveness of Ensite NavX based RFCA in specifically treating disorders of left AP conduction are scarce. In addition, the preparatory stage and the therapy stage of ablation along with the exposure time and doses of X-rays in the course of therapy stage that may reflect the unique advantages of 3D mapping system were not studied in patients treated with RFCA for left accessory pathway. In this study, we estimated the X-ray

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irradiation time and exposure dose while placing the mapping catheter, the X-ray irradiation time and the exposure dose while operating the ablation catheter, the total duration of operation and complications in the left AP radiofrequency catheter ablation (RFCA) treatment under the guidance of the Ensite NavX 3D mapping system and compared the efficacy and safety with the X-ray fluoroscopy mapping system.

## Methods

### Study design and patients

This was a retrospective, single centre study conducted in The Affiliated Hospital of Traditional Chinese Medicine, China to evaluate the effectiveness and safety of RFCA performed for the treatment of left AP conduction under the guidance of Ensite NavX navigation system compared with traditional transient X-ray fluoroscopy mapping techniques. Paroxysmal supraventricular tachycardia (PSVT) patients who underwent RFCA operations between July 2010 and August 2016, with no change in anti-arrhythmia medication for more than five half-life periods were selected from the medical records of the hospital. Of these, only patients who were conclusively diagnosed with left AP disorders in the electrophysiological examination was included and assigned to study group (Ensite NavX mapping system) and the control group (traditional transient X-ray fluoroscopy), respectively. During the study period, cases were continuously enrolled in the observation group and the control group. All techniques were performed by experienced doctors who have engaged in the RFCA operations independently for more than 10 years. The choice of mapping system was patient dependent. Preoperatively, the physician conducted a detailed informed consent conversation briefing the patients and their families about the procedure, intra- and post-operative attention, advantages and disadvantages of different mapping strategies, after which the decision was made them one day prior to surgery.

The study was approved by the institutional ethics committee of the Traditional Chinese Medicine Hospital (Approval No. 200965), affiliated to Xinjiang medical university and the protocol conformed to the principles of the declaration of Helsinki and subsequent revisions. A written informed consent was obtained from all patients enrolled in the study.

### Catheter placement and electrophysiological examination

The catheters were inserted percutaneously in the sites of vascular access. The coronary electrode catheters were introduced into the coronary sinus via the left subclavian vein or right jugular vein and the ventriculus dexter electrode catheter was introduced into the right ventricular apex via the femoral vein. The catheters were moved via the veins and introduced into the heart chambers under fluoroscopic guidance (pre-set voltage of 80 kV, critical threshold of 110 kV, dose per frame of 10 nGy/P and frame rate of 6 P/s at a window width of 15 cm × 15 cm). Stabilization of pacing and the type of arrhythmia were assessed using intracardiac electrograms. Wherever necessary, isoprenaline was used to induce arrhythmia and refine the ablation strategy after the diagnosis of arrhythmia type was confirmed. The position of mapping catheters was adjusted in X-ray fluoroscopy during electrophysiological examination.

### Lesion mapping and ablation

All patients underwent successful interatrial septal puncture using transesophageal echocardiography and the catheter electrodes were sent to the left atrium along the sheathing canals. Due to high chances of damage to aortic valve and complications of lower extremity arterial or retroperitoneal hematomas, retrograde approach was not followed. For patients in the study group, electrical models of corresponding cardiac chambers were set up via the Ensite NavX 3D (St Jude, MN, USA) mapping system (low-current 350 μA at 5.7 kHz) and patients in the control group received conventional pace mapping using X-ray fluoroscopy. The procedure of electrophysiological study, mapping and ablation was done in the standard manner [12]. After the ablation process was completed successfully, the electrophysiological examination was repeated.

### Study outcomes

X-ray irradiation time and exposure doses while placing mapping catheters were compared between both groups. These parameters were estimated between the points at which the mapping catheter was sent via the coronary sinus to the heart chamber until the electrophysiological examination of the heart was completed.

X-ray irradiation times and exposure doses while operating ablation catheters were also compared between both groups. These parameters were estimated between the point at which atrial septum puncture occurred, until the withdrawal of ablation catheter. In addition, total duration of the operation (defined as the entire length of time for which the procedure lasted, from blood vessel puncture until the withdrawal of the ablation catheter) was estimated. Further, during the mapping and ablation phase, the conventional fluoroscopy and 3D mapping systems were completed by the same surgeon for each individual patient to avoid the difference in the skill and experience of different surgeons affecting the study outcomes.

The X-ray exposure time and total exposure dose were recorded by the X-ray machine. Since the precise X-ray radiation dose received by the patient and the physician depends on the distance and the body surface area, radiation dose recorded by the instrument reflecting the individual effective dose was used in the study.

### Statistical analysis

All analyses were performed using the SPSS 17.0 software. Results are presented as mean ± standard deviation (SD). The student 't' and Chi square test ($\chi^2$) were used to compare the means of two independent samples respectively. $P < 0.05$ was considered statistically significant.

## Results

### Baseline characteristics

A total of 227 patients were enrolled in the study (study group, n = 112; control group, n = 115). The study group patients had a mean age of 50.2 ± 18.9 years with 65 male patients. Most frequent comorbidities observed were coronary heart disease (n = 27), hypertension (n = 25) and diabetes mellitus (n = 10). On the other hand, mean age of patients in the control group was 55.6 ± 17.9 years, of which 70 were male. The proportion of patients with comorbid coronary heart diseases, hypertension and diabetes mellitus was 31, 30 and 12 respectively. There were no significant differences in demographic characteristics between the two groups. Further, there were no significant differences in the type of left AP between the two groups. (Table 1).

### X-Ray exposure time and doses during catheter placement

An example of the three-dimensional mapping obtained from the Ensite NavX system is shown in Fig. 1. There was no significant difference between the two groups in terms of X-ray fluoroscopy exposure times or doses while placing mapping catheters ($P > 0.05$), which also accounts for isoprenaline induction, wherever necessary. However, while puncturing the atrial septum and operating the ablation catheters, the X-ray fluoroscopy exposure time was 61% significantly shorter in the study group compared with the control group (5.1 ± 2.3 vs. 13.1 ± 3.1; $P < 0.05$). Similarly, the average X-ray exposure doses were significantly reduced by 68% in the study group when compared with the control group during the process of atrial puncture and ablation catheter operation (5.7 ± 2.6 vs. 17.8 ± 4.3; $P < 0.05$), (Table 2).

### X-Ray exposure time and doses during RFCA procedure

Over the entire course of the operation, the average X-ray irradiation time was reduced significantly by 52% for patients in the study group when compared to the control group (7.5 ± 3.3 vs. 15.6 ± 4.1; $P < 0.05$). A significant reduction in the total X-ray exposure dose of 56% over the control group was also observed in the study group (8.3 ± 3.5 vs. 19.3 ± 4.6; $P < 0.05$). In addition, a statistically significant reduction of 13.8% in the total time taken to complete the surgical procedure was also observed in the study group when compared to the control group ($P < 0.05$), (Table 3).

### RFCA success rate and procedural complications

Patients in both groups received ablation operations successfully, and no procedure related serious complications were observed. Overall success rate was 98.2% in the study group and 97.4% in the control group as accessory cardiac conduction recurred in two and three patients in the study group and control group, respectively at a follow up visit of 3 months. There was no significant difference in the long-term efficacy between the two groups ($P > 0.05$).

**Table 1** Baseline patient characteristics

| Variable | Study group N = 112, n (%) | Control group N = 115, n (%) | *P* value |
|---|---|---|---|
| Age (years) | 50.2 ± 18.9 | 55.6 ± 17.9 | 0.1 |
| Sex (male) | 65 (58.03) | 70 (60.86) | 0.66 |
| Cases with hypertension | 25 (22.32) | 30 (26.08) | 0.51 |
| Cases with diabetes mellitus | 10 (8.92) | 12 (13.63) | 0.70 |
| Cases with coronary heart diseases | 27 (24.10) | 31 (26.95) | 0.62 |
| Types of arrhythmia (origin) | | | |
| Left anterior free wall | 20 | 22 | > 0.05 |
| Left posterior free wall | 22 | 28 | > 0.05 |
| Left posterior septum | 70 | 65 | > 0.05 |

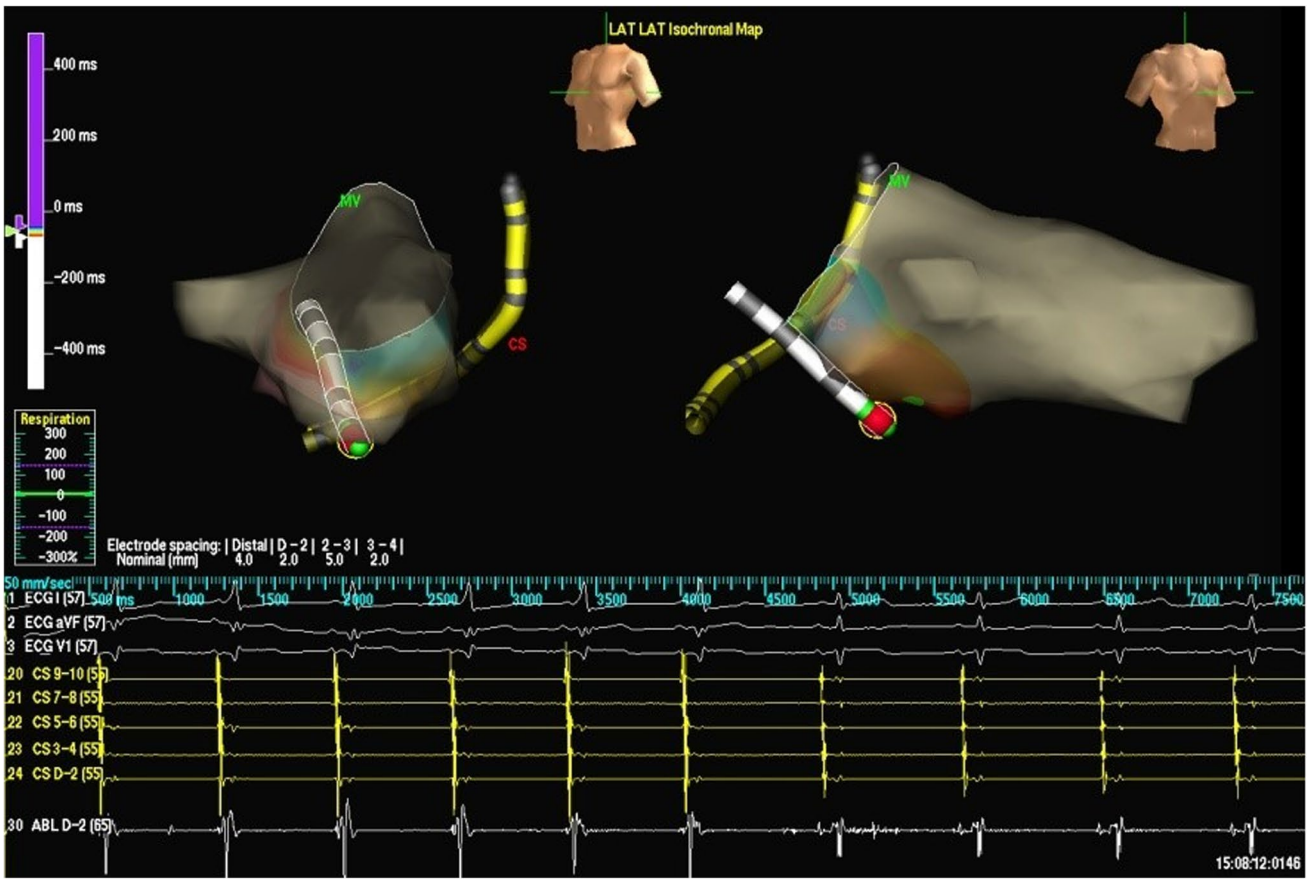


**Fig. 1** Ensite NavX mapping system guided RFCA. Figure 1 showing the use of the Ensite NavX system for the treatment of a 52-year old male patient with a history of tachycardia spanning 15 years. Electrocardiograms showed significant pre-excitation syndrome and the IECG showed a dominant bypass of the sinus rhythm by the atrial septal pathway. The ablation catheter was activated after the earliest advance of the V wave, AV fusion, ablation discharge was carried out for 4 s before the bypass block, and consolidation discharge for 120 s. The operation was successful and no recurrence was found within 6 months of the operation

**Table 2** Comparison of variables during RFCA between groups

| Variable | Study group | Control group | *P* value |
|---|---|---|---|
| $T_1$ (min) | 2.4 ± 1.4 | 2.5 ± 1.2 | 0.45 |
| $CD_1$ (uGy) | 1.6 ± 1.1 | 1.5 ± 1.0 | 0.62 |
| $T_2$ (min) | 5.1 ± 2.3 | 13.1 ± 3.1 | < 0.001 |
| $CD_2$ (uGy) | 5.7 ± 2.6 | 17.8 ± 4.3 | < 0.001 |
| Success ratio (%) | 98.2 | 97.4 | > 0.05 |
| No. of cases with complications | 0 | 0 | – |

*$T_1$* X-ray irradiation time in the course of putting the mapping catheters; *$CD_1$* X-ray irradiation doses in the course of putting the mapping catheters; *$T_2$* X-ray irradiation time in the course of operating the ablation mapping catheter; *$CD_2$* X-ray irradiation dose in the course of operating the ablation mapping catheter; $P < 0.05$ bears the statistical significance

## Discussion

RFCA operations have become the primary choice for the management of PSVT patient's due to several advantages such as fewer wounds, higher success rates and fewer procedure-related complications. In addition, the efficacy and cost-effectiveness of RFCA technology in the treatment of PVST have been established in comparison with pharmacotherapies [13, 14]. However, traditional RFCA operations cause damage to the human body due to increased X-ray exposure times [7], adversely affecting both, operating physicians as well as patients. Although precautionary steps have provided some relief from the hazards of X-ray exposure [8], there still remains a chance of radiation related complications. Moreover, the effectiveness and safety of operations under short X-ray exposure time and low doses remains to be explored in the X-ray fluoroscopy guided RFCA or in the 3D mapping guided RFCA in the course of puncture, placing the mapping catheters and the ablation treatment. It is hard for the RFCA operations to be completely devoid of X-ray

**Table 3** Comparison of variables in the whole course of RFCA between the groups

| Variable | Study group | Control group | *t* statistics | *P* value |
|---|---|---|---|---|
| Total exposure time (min) | 7.5 ± 3.3 | 15.6 ± 4.1 | 9.8 | < 0.001 |
| Total exposure doses (mGy) | 8.3 ± 3.5 | 19.3 ± 4.6 | 12.4 | < 0.001 |
| Duration of operations (min) | 53.1 ± 18.8 | 62.3 ± 20.6 | 3.5 | < 0.001 |

fluoroscopy, but it is feasible to reduce the exposure time and doses of X-rays remarkably using non-fluoroscopic mapping.

The Ensite NavX three-dimensional electrophysiological mapping system has been used widely for various kinds of RFCA operations of complicated arrhythmia as a novel mapping approach due to its unique safety and effectiveness, with its advantages widely acknowledged [15, 16]. It has also been used successfully in the treatment of PSVT [17–20], however, there is little available information on its use for the treatment of left AP disorders. Although ablation procedures for accessory pathway are safe, anatomical variants and the anatomical approach required might be challenging [21]. This might increase the overall radiation exposure time and the radiation dose which is hazardous especially in children. A recent case report utilized the Ensite NavX three-dimensional electrophysiological mapping system for the ablation of left AP using the retrograde approach with near zero radiation exposure [22].

Previous studies [12, 18, 23] have evaluated the total time and dose reduction that occurs while using the Ensite NavX 3D mapping system. They indicate that the X-ray exposure time is significantly curtailed in RFCA operations performed under the guidance of the Ensite NavX 3D mapping system, thus reducing the X-ray exposure dose as well [24], We obtained similar results from our work, which indicated that the duration and dose of X-ray exposure was reduced due to an increased efficiency in the operating surgeon's ability to manoeuvre and control the ablating catheter while treating left AP. We also show that this increase in efficiency led to a favourable reduction in the total time taken for the procedure. Recently, Ma et al. performed 3D mapping for catheter ablation of right-sided accessory pathways and reported that there were no differences in the preparation or geometry time between the two approaches; however, use of the 3D system significantly reduced the total procedure time, EP study, and fluoroscopy times, as well as the cumulative radiation doses, especially in cases with a large right AP. Similar to our study, the success rates in the both mapping systems guided RFCA did not significantly vary in right AP [25]. Enhanced guidance enables the operator to pinpoint critical sites for ablation more accurately. Moreover, Jason et al. reported that the location of the accessory pathway can be marked on the reconstructed geometry using the Ensite 3D mapping system. Subsequent radiofrequency pulses can then be delivered in a precise manner, even if pre-excitation is minimized or transiently disappears after the initial RFCA delivery [26]. Although, compared to conventional X-ray fluoroscopy, Ensite NavX 3D mapping system is expensive with increased disposable cost [27], the procedure has proven to be beneficial to the patients as well as the operators.

This study has some limitations and hence the readers should interpret the findings with caution. The main limitation was that the study was non-randomized and the decision to use the mapping systems was left entirely to the patients. However, this can be taken as strength of the study as the findings reflect the real-world effectiveness of the 3D mapping system unlike the findings from studies controlled for various exclusion and inclusion criteria. Nevertheless, a prospective randomized trial is warranted to further validate the advantages of 3D mapping systems over X-ray mapping of RFCA for left AP. The findings are also limited by a short follow up duration of 6 months; hence the recurrence of arrhythmias and long-term complications could not be recorded, and however, the duration was sufficient to conclude the findings as most recurrences reportedly occur within the first 2 months after ablation [28].

## Conclusion

Based on the results obtained from this study and previous work, we conclude that compared to traditional X-ray fluoroscopy procedures, the Ensite NavX 3D mapping system provides efficient and safe alternative that allows the accurate mapping of the chambers of the heart and their characteristic anatomical structures. This advantage allows surgeons to accurately locate the target ablation spots and to place and operate the ablation catheter within a shorter time frame, thus significantly reducing the X-ray exposure time and dose, for both, operating physicians and surgeons, and enhancing the overall safety of the procedure.

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### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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