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Efficacy and Safety of a Zero-Fluoroscopic Technique for Ablation of Right Atrial Arrhythmias Guided By Three-Dimensional Electro-Anatomy Mapping System Compared With Fluoroscopic Method

ALselmi Fadhle[1], Wang Yan[1]

Abstract

[Objective]: This study was performed in order to compare the safety, efficacy as well as benefits of zero-fluoroscopy (ZF) ablation of right atrial arrhythmias guided only by Ensite-NavXTMnon-fluoroscopic mapping system, with conventional fluoroscopic catheter ablation method, which is two-dimensional. While Ensite-NavXTM system is a three-dimensional navigation system.

[Methods]: Patients were enrolled if right atrial arrhythmias were diagnosed after initial screening by history and ECG and then were randomly assigned into Zero-Fluoroscopic (ZF) or Fluoroscopic(F) approach. The procedure time, fluoroscopic time, success rate, recurrence rate, and complications were studied.

[Results]: Among the 324 consecutively enrolled patients, patients were assigned to either the ZF or F group at a ratio of 1:2 based on the operator's preference, generally without any special selection.

Out of 324 patients, 108 patients were assigned into the zero-fluoroscopy (ZF) group, while 162 patients were assigned to the fluoroscopic (F) group. Out of 108 cases, 4 cases switched to F approach due to the need of trans-septal puncture and were not included in the analysis. Finally, 104 cases out of 108 (96.3%) completed the ablation without fluoroscopic guidance. There was not any compelling variation between the ZF group and F group in the operation time (52.33±33.2 vs. 53.8±37.6 min), immediate success rate (100.0% vs. 99.5%), recurrence rate (1.9% vs. 1.4%), total success rate (96.3% vs. 98.3%) and the severe complications (0% vs. 0%).

[Conclusion]: The efficiency and safety of the zero-fluoroscopy approach guided by Ensite-NavXTM is similar to the fluoroscopy approach of ablation of the right atrial arrhythmia. It can leave the medical staff and patients free of radiation risk.

Keywords: Fluoroscopy; radiofrequency catheter ablation; atrial flutter; atrial premature beat; atrial tachycardia; right atrial arrhythmia; three-dimensional

I. INTRODUCTION

Atrial arrhythmias result from defective Heart's electrical system or inappropriate response of heart muscles to their electrical stimuli. It can cause an accelerated and uneven heart rate which does not let the atria pump blood efficiently to the ventricles. Arrhythmias are categorized according to their rhythm, rate and where they are located in the heart.

They are always associated with several kinds of non-cardiac or cardiac risk factors, such as ischemic heart disease (IHD), heart failure, high blood pressure, diabetes, hyperlipidemia, alcohol abuse, overweigh. They are associated with ageing and usually happen more frequently during middle age. Generally10 to 15 percent of people older than 70 years experiences arrhythmias.

Atrial fibrillation (AF), atrial flutter (AFT),premature atrial contraction (PAC or premature atrial impulses), atrial tachycardia (AT), etcetera are various type of atrial arrhythmias.

Clinicians often fail to detect atrial arrhythmia, which is more difficult to detect than ventricular arrhythmias. In addition, it is also known that the patients may develop tachycardia-induced cardiomyopathy, if the ventricular response, during atrial arrhythmia, is not well controlled.

It has frequently been said that Catheter Ablation is a "cure" for atrial arrhythmias. In contrast, medicines can only control the atrial arrhythmias but cannot cure them. In the ablation process an energy source is directed to the heart tissue. In radio ablation process heat is produced via the use of energy to burn the heart tissue at the origin of the arrhythmias. Our goal is to eliminate the malfunctioning pathways by developing a collection of scar tissue. These procedures are traditionally performed using fluoroscopic navigation which can be associated with considerable X-ray direct exposure that is potentially hazardous to the patients and the medical personnel.[1-3]

Over the past decades, three-dimensional mapping and navigation system has been widely adopted in interventional electrophysiology. Despite the fact that application of three-dimensional systems can further decrease the fluoroscopic time, the conventional approach guided by fluoroscopy is still the main approach for RFCA in most hospitals, and three-dimensional mapping systems primarily act as a supplemental navigation, which means medical care personnel still has to be exposed to radiation.

Nevertheless, the use of a zero-fluoroscopy approach guided exclusively by Ensite-NavX^{TM} has been extensively reported in the literature, although its efficacy and safety has not been yet tested in a randomized trial versus conventional methods. Here-in, the results of a randomized trial that compared the two techniques for ablation of arrhythmias originating from the right atrium are reported.

II. METHODS

Study design

A randomized, multi-center study was carried out in four centres on patients with right atrial arrhythmias after initial screening by history and ECG characteristics. Eligible participants were assigned to either the ZF or F group based upon a computer-based randomization. Using ZF approach, the medical staff did not wear any lead protective facilities, and EnsiteNavX^{TM} was takenas the only navigation system, and fluoroscopy was not used. The F approach used fluoroscopic guidance plus any three-dimensional navigation systems. Prior to the procedure written informed consents were collected from all patients. The Ethics Committee of Tongji Medical College approved this study by the Declaration of Helsinki.

Study population

Consecutive patients for this study were enlisted between January 2012 and December 2015 if the patients were diagnosed with right atrial arrhythmia, including atrial premature complex (APC), atrial tachycardia (AT), atrial flutter (AFL). The exemption criteria consisted of: (1) unstable and multifocal atrial premature beat and tachycardia; (2) atrial tachycardia occurred after atrial fibrillation ablation; (3) atrial tachycardia occurred after mitral or aortic valve replacement; (4) atrial tachycardia occurred after surgical therapy of congenital heart disease; (5) Medical history and ECG suggested a left atrial origination.[4,5]

All patients had ECG evidence of the onset of arrhythmia, and trans-esophageal atrial pacing was applied to make a definitive diagnose if necessary. Medicines for arrhythmias were ceased for at the very least 5 half-life prior to electrophysiological studies (EPS). Blood tests, electrolyte analysis, electrocardiography, chest X-ray imaging, Holter recordings, and cardiac echocardiography were consistently carried out before the procedure. For the ablation of the atrial premature beat, wireless telemetry monitors were applied for a minimum of two days after the procedure.

1. Zero-fluoroscopy (ZF) approach

Fluoroscopy was not used for the ZF approach, and the X-ray machine was set in standby status. None of the staff wore any kind of lead apparel throughout the procedure

Catheter Implantation

After local anaesthesia with 1% lidocaine, two venous accesses were established from the femoral vein by Seldinger technique. Then an initial optimisation and respiratory compensation were performed. Under the guidance of Ensite-NavX^{TM} system, a tetrapolar electrode and a controllable bending electrode were inserted in the right ventricle and coronary sinus (CS) respectively, with external skin patch set as the reference. The interscapular area can be used for pasting the body reference, specifically in those patients who are quite fat and with intense abdominal respiration.

After the catheter had been placed in the target chamber, optimisation and respiratory compensation were conducted once again. As soon as the three-dimensional model of the target chamber was constructed (generally just the interested area), the tricuspid annulus and the position of His bundle were labelled both in right anterior oblique (RAO) view and in left anterior oblique (LAO) view. Here are two of those cases procedures describe in detail.

(A) Atrial premature beat/tachycardia

Figure 1 and figure 2 showed a frequent atrial tachycardia arising from the bottom of the right atrium, with a ventricular rate of 130 bpm (beats per minute). The geometry of both vessels and cardiac chambers was reconstructed accurately using annular electrode and the His bundle potential was marked in the model.

The electrophysiological study revealed that the origin of the premature beat was at the lower crista terminals. The patient went through a successful single point ablation set in temperature control mode (35 watts and 50 centigrade) (Figure 1-2).

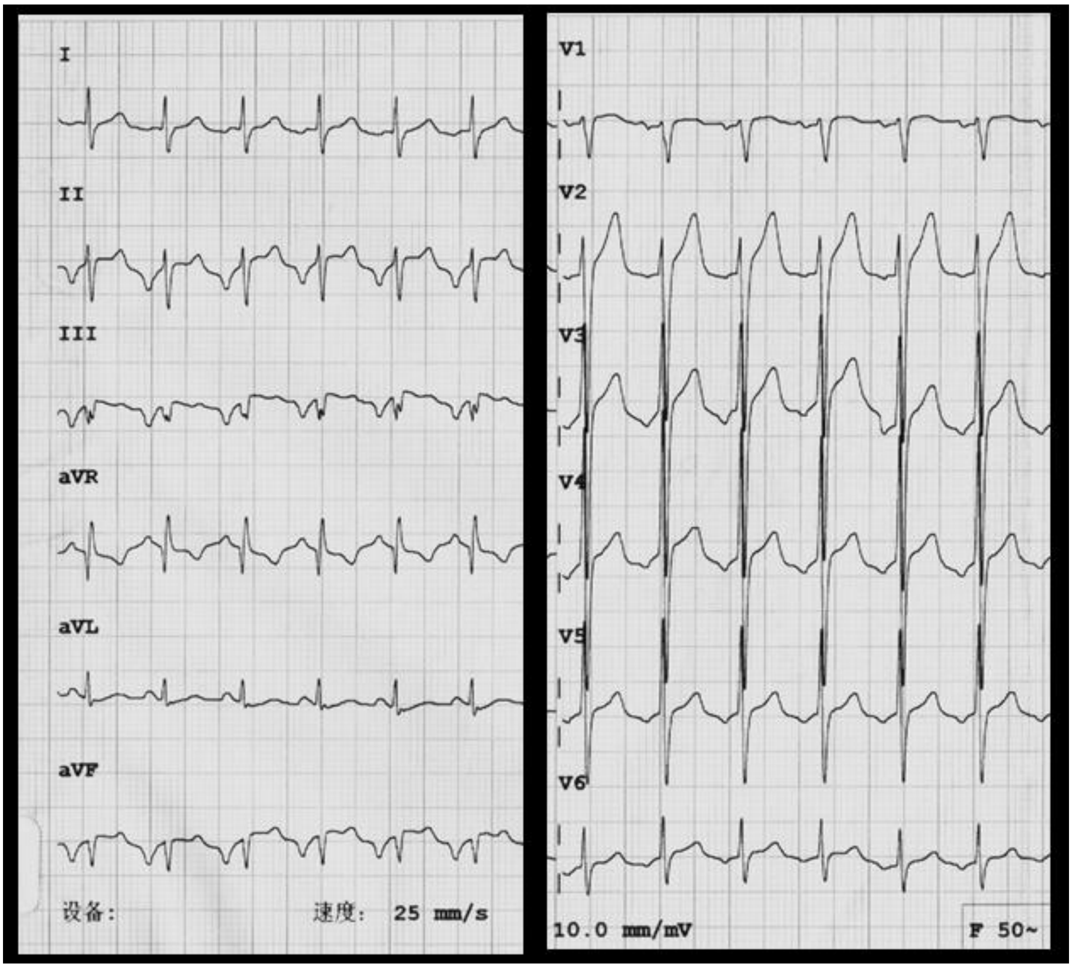

Figure 1 Diagram showed surface ECG focal atrial tachycardia arising from the lower right atrium. The left panel showed surface leads I, II, III, avL, avF, and avR; and the right panel showed precordial leads V1to V6.

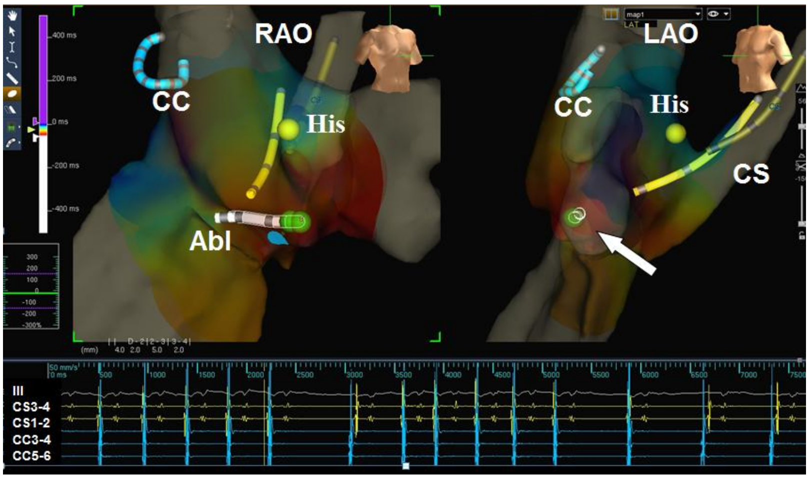

Figure 2 Three-dimensional geometry was reconstructed during the zero-fluoroscopy ablation of the focal atrial tachycardia arising from the lower right atrium. The geometry was presented in RAO and LAO view. The yellow dot referred to His bundle location, and the green dot referred to the targeted origin site for ablation. 3-5 seconds of single power delivery stopped the atrial tachycardia with a maximum power at 35 watts set in the temperature-control mode in 53 centigrade. RAO, right anterior oblique view; LAO, left anterior oblique view; CC, circular mapping electrode; CS, coronary sinus electrode; Abl, ablation catheter.

(B) Right atrial flutter

Figure 3 and 4 showed zero-fluoroscopy ablation of a case with right atrial flutter. The geometry was shown in RAO and LAO view. The arrhythmia was terminated during the linear ablation at 35 watts set in the temperature-control mode in 43 centigrade using saline irrigation catheter.

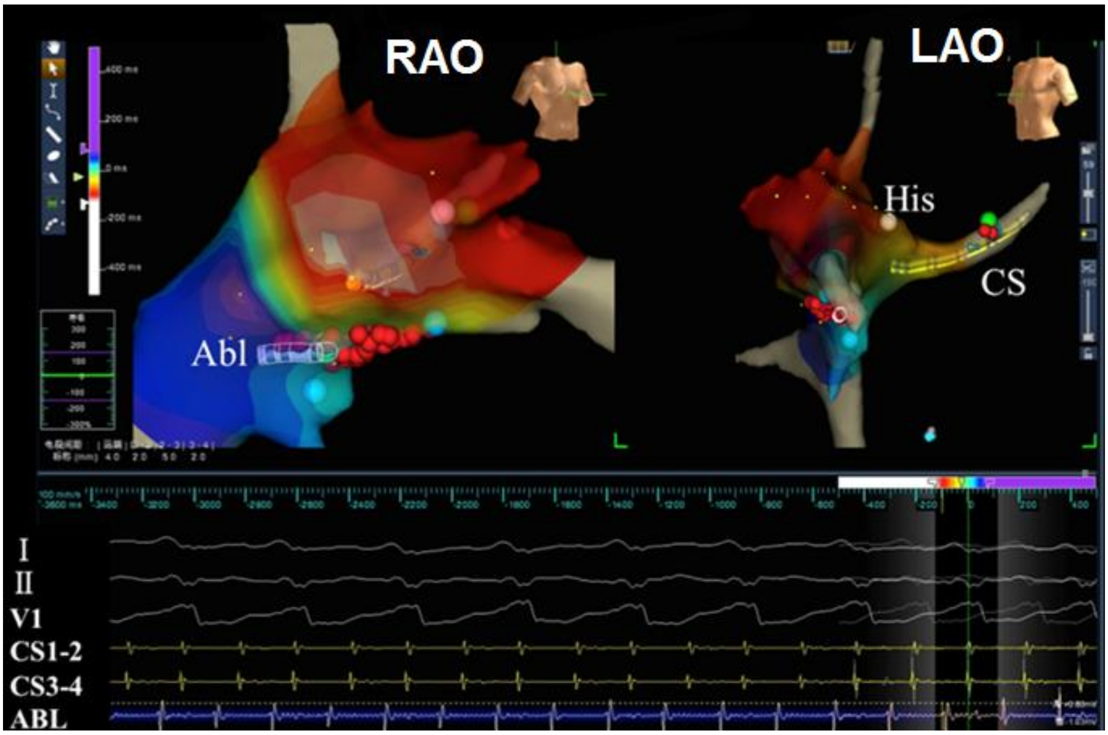

Figure 3 Three-dimensional geometry demonstrated the clockwise sequential reentrant activation along cavotricuspid isthmus. The conduction interval between two sides of the cavotricuspid isthmus was relatively long. The abbreviations are same as they were seen in figure 2.

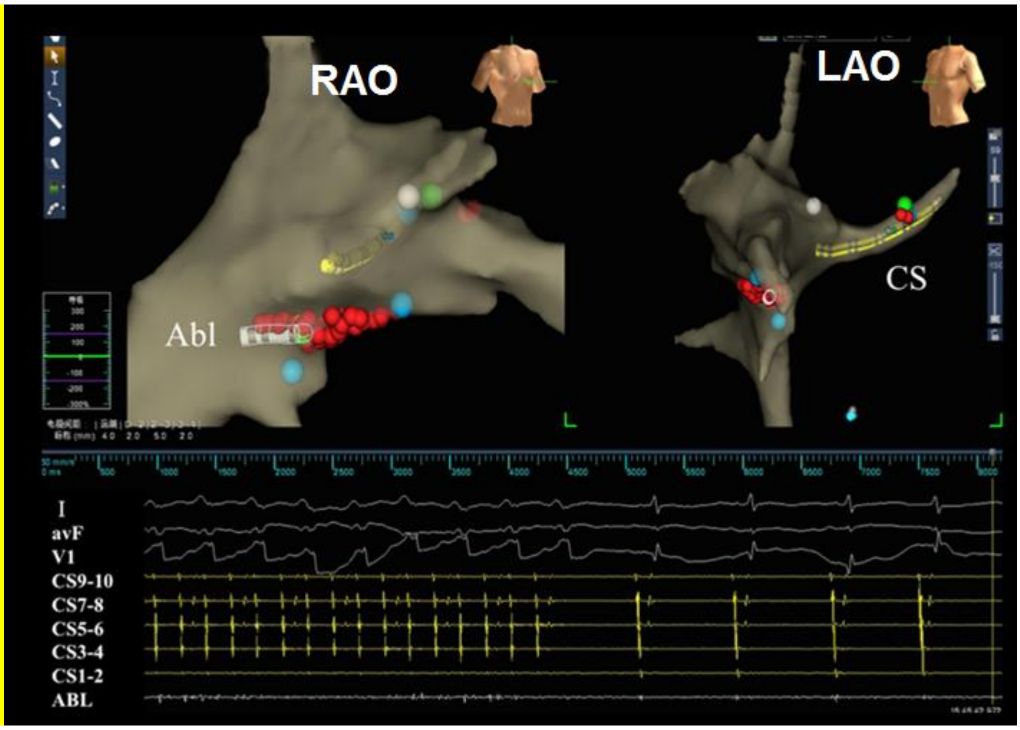

Figure 4 Three-dimensional geometry demonstrated the termination of right atrial flutter. The atrial flutter was terminated during the linear ablation at 35 watts set in the temperature-control mode in 43 centigrades using saline irrigation catheter. The abbreviations are same as they were seen in figure 2.

2. Conventional Fluoroscopy approach

When it comes to the fluoroscopy group undergoing the conventional ablation, catheter implantation was guided by X-ray plus any three-dimensional mapping system. Fluoroscopy had been used throughout the procedure, including catheter implantation, EPS, mapping, and ablation.

When a long sheath (SR0) was required in some cases with atrial flutter, it was introduced into the vein 2-3 centimetres deep via the guide wire; then the guide wire was removed and replaced by an ablation catheter. The ablation catheter was progressed into the right ventricle and was made a sharp curve guided by Ensite-NavX^{TM}. Finally, the sheath was imported into the desired position in right atrium along the ablation catheter.

Electrophysiological Study

The routine electrophysiological study was accomplished in all the cases in the ZF group (100%) and F group (100%). [6-7] Isoproterenol was administered by intravenously in some cases as recommended.[8-9]

Mapping and ablation

Once the diagnosis was clear by the electrophysiological study, a bidirectional large-curve catheter (Safire, St. Jude Medical) or D-curve catheter (Celsius^{TM}) was introduced to the target site via the right femoral vein (Table 1). Reconstruct the model of the right atrium then mapping the tricuspid annulus. A decadal-polar annular electrode was used when high-density anatomical mapping was required. The origin or critical reentrant circuits of the arrhythmia was mapped. Ablation end points results were as follows: (1) no spontaneous arrhythmia; (2) multiple-site programmed atrial stimulation (S1S1\S1S2\S1S2S3) cannot induce arrhythmia; (3) intravenous infusion of adrenaline and other kinds of stimulations cannot induce arrhythmia.

Table 1 Navigation systems and catheters used for right atrial ablation.

Approach	Navigation System	Ablation Catheter
Fluoroscopy (F)	NavX^{TM} Carto 3^{TM} Multielectrode Array^{TM}	Celsius^{TM}, IBI^{TM}, Safire^{TM}
Zero-fluoroscopy (ZF)	NavX^{TM}	Celsius^{TM}, IBI^{TM}, Safire^{TM}

Study variables

All preoperative, operative and follow-up data were gathered and stored in Excel spreadsheets by independent technicians. The study variables consisted of: (1) the electrophysiological study time and the procedure time: the duration from the first puncture of the skin to the complete removal of the catheter.; (2) immediate success rate: 24-hour ECG wireless telemetry monitoring system or 24-hour Holter monitoring showed no onset of atrial flutter, atrial tachycardia, and atrial premature beat in 24 hours after procedure; (3)recurrence: symptoms, ECG, and Holter monitoring showed any evidence of recurrence during follow-up; (4) total success rate: after redo procedure, 24-hour Holter monitoring revealed no onset of arrhythmia; (5) complications: general complications included pseudoaneurysm, arteriovenous fistula, first degree atrioventricular block (AVB), and severe complications included sinoatrial node damage, second or third degrees atrioventricular block, severe valve damage, cardiac rupture, pericardial tamponade, myocardial infarction, stroke, and other injuries requiring thoracotomy; (6) Fluoroscopic time: the cumulative time under the radiation exposure from puncture to the end of procedure.

Follow-Up

All patients went through continuous wireless telemetry, monitoring for at least 24 hours prior to their discharge. Independent technicians performed follow-up at one month, three months, and six months after the ablation procedure. Echocardiography, 12-lead ECG, 24-hour Holter were included in the assessment.

Statistical Analysis

Commercially available computer software SPSS13.0 (IBM Inc., Armonk, NY, U.S.A.) was used to perform the statistical analysis. Continuous data are defined as the mean ± standard deviation, whereas absolute data are expressed as percentages and numbers. were used to compare The differences among groups were compared using Student’s t-tests, one-way analysis of variance, Fisher’s exact tests and Chi-square tests . All of the tests were two-sided, and a *P*-value of 0.05 was considered statistically significant.

III. RESULTS

Baseline characteristics

After preliminary screening by medical history, surface ECG, and transesophageal recording, 324 patients were detected with the right atrial arrhythmia and were signed up in the study; The mean age of patients was 44.9±15.1 years old. There was no considerable variation between the two groups as to the baseline characteristics (*P*>0.05). The study group assignment was as follows: A total of 108 cases received zero-fluoroscopy approach; among them, 35 cases were an atrial flutter, and 73 cases were atrial premature beat and atrial tachycardia; (Table 2). The average follow-up duration was 5.8 ± 2.9 months.

Table 2 Baseline Characteristics and Atrial Arrhythmia Types

	ZF (*n*=108)	F (*n*=216)	Total (*n*=324)
1. Arrhythmia Type			
APC/AT	73 (67.6%)	142 (65.7%)	215 (66.4%)
● APC only	5 (4.6%)	14 (6.5%)	19 (5.9%)
● AT	68 (63.0%)	128 (59.3%)	196 (60.5%)
Right atrial flutter	35 (32.4%)	74 (34.3%)	109 (33.6%)
2. Baseline Characteristics			
Female (*n*, %)	53 (49.1%)	101 (46.8%)	154 (47.5%)
Age (years)	44.8±15.6	45.0±14.8	44.9±15.1
Height (cm)	162.7±8.2	164.7±8.1	164.0±8.2
Weight (kg)	62.7±11.9	63.5±11.8	63.2±11.8

(1) Success rate and safety

All the cases in the fluoroscopy group (F) (100%) and zero-fluoroscopy group (ZF) (100%) completed the electrophysiological study. There were no significance difference between two groups as to intra-procedural success rate (99.5% vs. 97.2%), recurrence rate (1.4% vs. 1.9%) and total success rate (98.3% vs. 96.3%). The fluoroscopy group had slightly better result than Zero- fluoroscopy group and also lower recurrence rate. Both group had no severe complications (Table 3)

In the zero-fluoroscopy (ZF) group, four cases were finally detected as left atrial tachycardia after electrophysiological study. Among the four cases, three cases switched over to fluoroscopy approach due to the need of transseptal puncture; whereas one case with patent fossa ovalis still completed the procedure without fluoroscopic guidance. One patient with atrial flutter failed to gain bidirectional block of the cavotricuspid isthmus during redo ablation. He was recommended for an epicardial ablation. In the fluoroscopy group, one patient failed during the primary procedure, and two cases failed during the redo procedure.

(2) Fluoroscopic time and efficiency

Considerable variation in fluoroscopic time (0 vs. 9.6±10.8 min) (*P*< 0.05) was noted between zero-fluoroscopy (ZF) group and fluoroscopy (F) group; whereas there were no considerable variation between the ZF group and F group as to electrophysiological study time (24.5±6.6 vs. 23.6±8.0 min) and procedure time (52.3±33.2 vs. 53.8±37.6 min) (*P*> 0.05) (Table 3).

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Table 3 Success rate, complications, and efficiency of the two approaches

	ZF (n=108)	F (n=216)
Electrophysiological study	108 (100%)	216 (100%)
Switch to F	3 (2.8%)	NA
Immediate success rate (n, %)	105 (97.2%)	215 (99.5%)
Recurrence (n, %)	2 (1.9%)	3 (1.4 %)
Redo procedure (n, %)	2 (1.9%)	3 (1.4 %)
Final success rate (n, %)	104 (96.3%)	213 (98.3%)
General complications (n, %)	2(1.9%)	2(0.9%)

Severe complications (n, %)	0 (0%)	0 (0%)
EP study time (minute)	24.5±6.6	23.6±8.0
Procedure time (minute)	52.3±33.2	53.8±37.6
Fluoroscopy time (minute)	0.0	9.6±10.8

3 cases finally switched to fluoroscopy approach due to the need of trans-septal puncture under fluoroscopic guidance because of left origination.

IV. DISCUSSION

This study reveals thatthe expediency of zero-fluoroscopic ablation of right atrial arrhythmias, which gained a satisfactory and nearly complete success rate. All the medical staffs including the operators, nurses, and technicians did not put on any kind of lead facilities for safety during the procedures. With initial selection by surface ECG and medical history before electrophysiology study, 97% of the patients had a success, and only less than 3% had to switch to fluoroscopy approach due to the need of left atrial mapping.

In addition, the effectiveness and safety of our zero-fluoroscopy approach were not substandard to those of conventional fluoroscopy approach, despite of people only used three-dimensional electric field or magnetic field navigation system simultaneously as an auxiliary tool for mapping.

As all of us understand, from the preliminary radiofrequency ablation, the problem of radiation direct exposure has actually long galvanized medical professionals, individuals, and also whoever has the possibility of X-ray radiation direct exposure. Radiation produces numerous opportunities of fatal malignancies, congenital diseases, cataracts. The significant risks associated with the radiation are cancer and genetic abnormality [10], especially for those who are pregnant or are intending to become pregnant. The advancing damage of radiation exposure is much more significant. Advancing exposure contributes to a lifetime attributable risk of cancer for the catheter ablation staffs and patient undergoing procedure. [11] Also, a pregnant an patient could shed the possibility to treat her arrhythmia in the very best means, for her infant's wellness, woman may lose the chance to treat her arrhythmia in the best way, for the sake of her baby’s health, which is much more vulnerable to the radiation exposure.

Radiofrequency ablation is conventionally guided by X-ray, which needs the medical staffs to put on cumbersome, heavy lead clothing and collar, which can only partially decrease the radiation exposure in the covered area; head, feet, arms, and hands are usually still exposed to radiation. In addition, the heavy burden and poorness in heat dissipation often make the staffs feel exhausted. As a result, electrophysiologists are more likely to struggle against cervical and lumbar spondylosis. [12] Nevertheless, those measures still leave the patients at radiation risk. Electrophysiologists feel distressed, the same goes for the patients, and they are worrisome considering that radiation doses from imaging procedure can cumulate over time.[13,14] Therefore, it is meaningful to develop techniques and measures which can minimize the radiation exposure time and eliminates the requirement for wearing cumbersome lead facilities.

Just recently, three-dimensional navigation systems are commonly made use of for mapping throughout arrhythmia ablation and greatly decrease the radiation exposure not only for the medical personnels but also for the patients. Ensite-NavX™ is one of these three-dimensional navigation systems. It has been efficiently used to some much less facility ablation, such as Atrioventricular Reentrant Tachycardia or Atrioventricular Reentrant Tachycardia , because it's fairly time-consuming and costly when regarded as a newly development technique.[15] A few studies reported the usefulness of zero-fluoroscopic ablation of supra ventricular arrhythmias using three-dimensional electric-field navigation systems.[16-18] Nevertheless, the success rate, efficiency, and safety of zero-fluoroscopy approach to right atrial arrhythmias compared with conventional fluoroscopy approach are not known.

Fluoroscopy will still be used as a routine imaging modality in many centers, especially in some complex cases undergoing ablation. Anyway, this study revealed in a randomized trial the possibility of zero-fluoroscopic ablation in patients with right atrial arrhythmia judged by surface ECG and medical history before electrophysiology study.

Study limitations

First of all, left atrial arrhythmias were omitted as a result of the requirement of doing transseptal leak directed by fluoroscopy given that the intracardiac echocardiography was not made use of in zero-fluoroscopy strategy. Anyhow, below we simply intend to show zero-fluoroscopy could attain success in 97% of the patients after initial screening by the patients' history and ECG. We only used fluoroscopy for transseptal puncture during the procedure in those three switched cases; the fluoroscopic time of those three cases was much shorter that of the patients in fluoroscopy group. Second of all, this was a randomised study. Finaly, we used two types of three-dimensional mapping systems in fluoroscopy group; however, this was the scenario in the real world.

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Review

Efficacy and safety of a zero-fluoroscopic technique for ablation of right atrial arrhythmias guided by EnSite-NavXTM three-dimensional electro-anatomy mapping system compared with conventional method

Atrial arrhythmias result from defective Heart’s electrical system or inappropriate response of heart muscles to their electrical stimuli, It can cause an accelerated and uneven heart rate which does not let the atria pump blood efficiently to the ventricles. Arrhythmias are categorized according to their rhythm, rate and where they are located in the heart. Atrial arrhythmias are always associated with several kinds of cardiac or non-cardiac risk factors, such as ischemic heart disease (IHD), heart failure, high blood pressure, diabetes, hyperlipidemia, alcohol abuse, obesity. They are associated with ageing and usually happen more frequently during middle age.

Atrial fibrillation (AF), atrial flutter (AFL), premature atrial contraction (PAC or premature atrial impulses), atrial tachycardia (AT), etcetera are various type of atrial arrhythmias

This study compares the safety, efficacy and benefits of zero-fluoroscopy (ZF) ablation of right atrial arrhythmias guided only by Ensite-NavX™three-dimensional mapping system, with two dimensional conventional fluoroscopic catheter ablation method.

After decades of development, conventional fluoroscopic catheter ablation has frequently been addressed as "cure" for atrial arrhythmias. With further understanding of cardiac anatomy and electrophysiology, the therapeutic effect of radiofrequency ablation has increased. It can not only treat simple arrhythmias such as, atrioventricular nodal reentry tachycardia (AVNRT) or Wolff-Parkinson-white syndrome (WPWs), but also treat complex rhythm disorders such as atrial fibrillation, incisional tachycardia and others [1]. Conventional X-ray fluoroscopy method is the result of the combination of the location and the electrophysiological characteristics of the electrode catheter, with anatomical features through a fixed X-ray image. However, the accuracy and reliability of this visual judgment are limited [2].

Since its development, the Ensite-NavX™three-dimensional mapping system has been constantly updated and improved. The Ensite-NavX™can not only be applied to atrioventricular nodal reentry tachycardia (AVNRT), paroxysmal ventricular tachycardia (PSVT), Wolff-Parkinson-white syndrome (WPWs), but also it can be used in complicated arrhythmias such as, atrial flutter(AFL), atrial fibrillation(AF), ventricular premature beat, Atrial premature beat, ventricular tachycardia, etcetera.[3,4]

The three-dimensional mapping system based on cardiac anatomy, can perform following functions:(1) It can precisely replicate the cardiac anatomy underlying an arrhythmia; (2) The catheter operation can be repeated in the same model; (3) It can quickly and continuously update the characteristics of three dimensional model through ECG phase, pacing the characteristics of continuous and rapid update of the three-dimensional model. (4) It can accurately record the ablation site in the three dimensional model.

The Ensite-NavX™three-dimensional mapping system is the world's most advanced three-dimensional electrophysiological mapping and navigation system; it works on the similar principal as the GPS global positioning system. Unlike the Ensite-Array™, which is a non-contact type system [5], Ensite-NavX™is a contact-type mapping system. While using Ensite-NavX™mapping system, three pairs of electrode films are preoperatively attached on the patients’ bodies. These electrode films are attached on the surface of the chest, the back, the right axillar midline, the left axillary midline, the posterior neck, and the medial left middle thigh, respectively. The three-dimensional orthogonal electric field along three axes (X, Y, and Z) is formed between the three pairs of electrode pads.

The Ensite-NavX™positioning system can sense a variety of electrodes based on the electric field, including ordinary electrophysiological catheters, ablation catheters, cryoablation catheters, Pacemaker electrode lead, atrial septal puncture needle, guide wire, etc. It can be displayed in the system causing interference to the electric field. The signal is processed by the signal processor. The signal processor and the computer workstation determine the position of the catheter. The system can continuously collect the movement of electrophysiological lead within the heart chamber. After processing the details, the system can construct a three-dimensional heart chamber [6].

The purpose of the Ensite-NavX™three-dimensional anatomical mapping system is shown in the following three aspects: 1, zero X-ray exposure; 2, information about the order of excitement (excitation) and voltage (voltage) in the heart cavity of the three-dimensional Display; and 3, the process of continuous movement during the collection point and synchronized display of heart cavity.

At the time of agitation mapping, the Ensite-NavX™navigation system can simultaneously obtain local anatomical sites and agitation time, which can be displayed on a three-dimensional model and distinguished by different colors.

At present, this mapping method is mainly used in easily induced, persistent, hemodynamic stable arrhythmias. For patients who are hemodynamic unstable , difficult to induce arrhythmia, discontinuous arrhythmia, a localized voltage amplitude mapping site is usually used to develop a linear ablation strategy under sinus rhythm - called voltage mapping. Another approach is directly dependent on the three-dimensional anatomy of the heart, mainly used in the atrial fibrillation ablation [6].

The outstanding benefit of this system is that it can combine the location of the lead and the anatomical information stored in the computer and the structure of the heart itself. Although, this image fusion technology is currently not widely used, over time, this technology certainly will be electrophysiologist's favorite.

The combination of two different data makes the model more accurate under the navigation of Ensite-NavX^{TM}. In the process of atrial fibrillation ablation, especially, it is more conducive to mark pulmonary vein, pulmonary vein vestibules and left atrial appendage structure. This image fusion technology can replace the selective or non-selective angiography and decrease the intraoperative radiation exposure. The objective of this system is not only to decrease the amount of radiation exposure, but also safety, reliability and effectiveness of the ablation process, the basic goal is to improve the success rate and reduce intraoperative and postoperative complications.

In this study, to implant the catheter venous entry was obtained from femoral and the left subclavian veins using standard Seldinger puncture, after an initial optimization and a respiratory compensation were performed. Under the guidance of Ensite-NavX^{TM}system, a tetrapolar electrode and a controllable bending electrode were inserted in the right ventricle and coronary sinus (CS) respectively, with external skin patch set as the reference. The interscapular area can be used for pasting the body reference. After the catheter had been placed in the target chamber, optimization and respiratory compensation were conducted once again.

While for fluoroscopy group who were undergoing the conventional ablation, catheter implantation was guided by X-ray plus three-dimensional mapping system. Fluoroscopy had been used throughout the procedure, including catheter implantation, EPS, mapping, and ablation.

When a long sheath (SR0) was required in some cases with atrial flutter, it was introduced into the vein 2-3 centimeters deep via the guide wire; then the guide wire was removed and replaced by an ablation catheter. The ablation catheter was inserted into the right ventricle and was made a sharp curve guided by Ensite-NavX^{TM}. Finally, the sheath was then introduced into the desired position in right atrium along the ablation catheter.

The Ensite-NavX^{TM}three-dimensional navigation system can display the position of the intra-cardiac catheter, construct the three-dimensional structure model of the heart, and display the location of the mapping electrode (CC, CS, HIS) and the location of the catheter to guide the operation. As soon as the three-dimensional model of the target chamber was built the tricuspid annulus and the position of His bundle were labelled both in right anterior oblique (RAO) view and in left anterior oblique (LAO) view. It is very important to determine the extent of the His bundle, His bundle is very fragile, and does not rule out anatomical variations. More importantly, an injury to His bundle revealed the characteristic on electrocardiogram of high frequency of junctional arrhythmia > 130 beats/minute, atrioventricular conduction blocks, cardiac conduction block at the junction. Even if the ablation is stopped, the injury to the ablation point continues to increase, resulting in irreversible high degree of atrioventricular block. Thus, determining the extent of the His bundle and the slow pathway and to maintain the stability of the catheter during ablation is very important.

To do the ablation, keep the catheter head down. The surgeon should not only monitor the catheter head's position, but also monitor the ablation process, heart rate and any changes in the heart rate. Intracavitary ultrasound (ICE) can be used to determine the microstructure and catheter location of the heart cavity, especially for the three-dimensional ultrasound catheter, to achieve non-contact modeling, identification of complex anatomical sites, to guide atrial septal puncture, and real-time monitoring infusion and other complications. It not only reduces operational risk, but also shortens the operation time.

Typical atrial flutter can be defined as an organized macroreentrant tachycardia restricted to the right atrium. It originates in a circuit around the tricuspid annulus restricted by anatomical blockade such as superior vena cava and inferior vena cava, the coronary sinus and crista terminalis. The current may circle around this circuit clockwise or counterclockwise, results in the clockwise atrial flutter or the counterclockwise common atrial flutter. [7]

For typical tricuspid annular atrial flutter, high-density agitation mapping in Ensite-NavX^{TM}three-dimensional navigation can show the reentry loop characteristics of the atrial flutter and the expansion of the RA, SVC and IVC. The construction of the tricuspid annulus geometrical structure is helpful for atrial flutter ablation. During the ablation process, the catheter passes through the isthmus line, and the ablation site is continuously collected. The three-dimensional model can be rotated to clarify the site has not yet been ablated; this memory function can avoid repeated ablation.

Patients who had surgery for congenital heart disease may present with incisional tachycardia after surgical repair, including typical atrial flutter (AFL) and focal atrial tachycardia. In addition, for patients who had an atrial incision or valve replacement surgery, the incision healing can form a large reentry ring. The three-dimensional anatomical mapping technique can identify the complex agitation sequence of such tachycardia and determine the centerline of the block. Due to the low voltage characteristics of the cardiac scar, the location of the atrial incision can also be determined by voltage mapping.

Ensite-NavX^{TM}three-dimensional navigation system is based on the electric field system, it can perceive a variety of electrodes, and even pacemaker electrodes can be perceived. So it is possible to implant a permanent pacemaker at a zero X-ray [8].

In this study, among the 324 consecutively enrolled patients, 108 patients with atrial arrhythmias [including typical atrial flutter(AFL) , atrial premature complex (APC), atrial tachycardia (AT)] were enrolled in to Zero-fluoroscopy approach guided by Ensite-NavX^{TM}, the immediate success rate was 97.2% (105 patients) , 2.8%(3 patients) had to switch to fluoroscopic approach guide by X-rays. The average operation time was 52.3±33.2 minutes; follow-up studies were done one month, three months and on six months after the procedure to check for any recurrences. Only 1.9% (2 patients) of the cases had recurrence. The results of this study showed that Zero-fluoroscopy ablation guided by Ensite-NavX^{TM}navigation is completely beneficial, effective and safe in ablation of atrial arrhythmias. There were no considerable variation between zero-fluoroscopy (ZF) group and fluoroscopy (F) group as to immediate success rate and recurrence rate. Both zero-fluoroscopy group and fluoroscopy group had no severe complications Fluoroscopy will still be used as a routine imaging modality in many centers, especially in some complex cases undergoing ablation.

However, there was a considerable variation between zero-fluoroscopy group and fluoroscopy group as to fluoroscopic time, which means fluoroscopic group patients and staff have to face radiation for the longer time, to avoid radiation they have to wear lead facilities for protection. They are very heavy, which makes staff fatigue. It only decreases risk partially and patients are at radiation risk [9,10]. The significant risks associated with the radiation are cancer and genetic abnormality, which can be eliminated by zero-fluoroscopic ablation [11,12]. So we can clearly say that zero-fluoroscopy ablation of right atrial arrhythmias guided only by Ensite-NavX^{TM}non-fluoroscopic mapping system is beneficiary compare to convention fluoroscopic method.

The introduction of the Ensite-NavX^{TM}three-dimensional anatomical mapping system enables the electrophysiologist to hold a sharp edge; they can eliminate patient’s arrhythmias more accurately and effectively. The three-dimensional mapping system makes it difficult for the traditional X-ray ablation to achieve the stability and intuitive. At the same time, it shows us that medicine needs to evolve and medical technology needs to improve and be safer. Currently, electrophysiological surgery-related complications are arteriovenous fistula or pseudoaneurysm caused by arterial-venous puncture, pneumothorax caused by subclavian vein puncture, aortic operation leading to aortic valve injury, pericardial effusion caused by atrial septal puncture, atrial esophageal fistula caused by atrial fibrillation ablation. Most of the complications are serious and difficult to deal with. Some more serious complications are heart rupture, acute pericardial tamponade, and even death. Therefore, we need to adopt a more secure operating plan and develop new equipment in order to avoid these risks as much as possible.

Zero-fluoroscopic catheter ablation guided by Ensite-NavX^{TM}electro-anatomical mapping system needs skilled surgeons who have rich knowledge and experience in this field. It also requires a long training.

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