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

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Abstract

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-NavXTM non-fluoroscopic mapping system, with conventional fluoroscopic catheter ablation method, which is two-dimensional. While Ensite-NavXTM system is a three-dimensional navigation system. 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. 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%). 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

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1 INTRODUCTION

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-NavXTM 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.

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 EnsiteNavXTM was taken as 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.

**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™ 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. 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 V1 to V6.](image-url)
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.

(A) 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.

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.

Electrophysiological Study
The routine electrophysiological study was accomplished in all the cases in the ZF group (100%) and F group (100%). Isoproterenol was administered by intravenously in some cases as recommended.

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™) was introduced to the target site via the right femoral vein (Table 1).

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.

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

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

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).

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

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

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 |
DISCUSSION
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.[10-11].
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] 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.
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. A few studies reported the usefulness of zero-fluoroscopic ablation of supra ventricular arrhythmias using three-dimensional electric-field navigation systems. Nevertheless, the success rate, efficiency, and safety of zero-fluoroscopy approach to right atrial arrhythmias compared with conventional fluoroscopy approach are not known.
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. Finally, we used two types of three-dimensional mapping systems in fluoroscopy group; however, this was the scenario in the real world.

REFERENCE
Near-Zero Fluoroscopy Use During Ablation of Cardiac Arrhythmias.


