

# Single transseptal puncture technique and contact force catheter: A simplified ablation strategy for paroxysmal atrial fibrillation

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**Abstract.** The present study aimed to evaluate the safety and efficacy of an optimized single transseptal puncture technique and contact force sensing atrial fibrillation (AF) radiofrequency catheter ablation (RFCA) strategy within a clinical setting. Fast anatomic mapping and contact force sensing ablation was applied to patients with paroxysmal AF (PAF) ablation between September 2014 and December 2016 using a single trans-septal sheath. Pulmonary vein isolation (PVI) and linear ablation were performed in PAF individually with a 10-20 g contact force with minimal fluoroscopy. Stimulation with 10 mA outputs on the lesions without capture was used as endpoint. A total of 419 consecutive patients who underwent first-time RFCA were enrolled in the current study, and acute PVI was achieved in all patients. The average procedure time was  $74.5 \pm 9.7$  min, with an average ablation time of  $27.3 \pm 7.8$  min. The average fluoroscopy time was  $4.7 \pm 3.3$  min and the average radiation dose was  $24.3 \pm 25.2$  mGy. At a mean follow-up time of  $14.5 \pm 4.1$  months, sinus rhythm was maintained at 85.0%. Cardiac tamponade occurred in one case. The results indicated that this simplified technique was a simple, safe and effective approach for PAF ablation therapy.

## Introduction

Radiofrequency catheter ablation (RFCA) is used as first-line therapy in selected patients with drug-refractory symptomatic atrial fibrillation (AF) (1,2). Ablation strategies that target the pulmonary vein antra are the cornerstone for the majority of AF ablation procedures (3-5). Twice transseptal punctures with

ablating and monitoring pulmonary venous potential simultaneously are commonly applied in the vast majority of cardiac electrophysiology centers (6,7). However, the traditional mapping and ablation techniques without real-time contact force sensing show poor efficiency on permanent transmural lesion formation and may lead to excessive X-ray exposure and procedure time. Persistent iatrogenic atrial septal defect after transseptal puncture has been observed and complications associated with septal puncture may also be increased, as this technique punctures more than one site in fossa ovalis, particularly in complicated cases (8).

To improve the effectiveness and safety with reducing fluoroscopy of the AF ablation procedure, a simplified ablation strategy was developed that combines the single transseptal puncture technique, fast anatomical mapping (FAM) of the left atrium (LA), a contact force (CF) sensing catheter, and the high output stimulation verification technique (9). The present study aimed to demonstrate the value of this ablation strategy for patients with paroxysmal AF (PAF).

## Patients and methods

**Patient selection.** A total of 419 PAF patients with non-valvular, antiarrhythmic drug refractory PAF who underwent *de novo* RFCA at Fuwai Hospital between September 2014 and December 2016 were prospectively enrolled in the present study. These patients were diagnosed with PAF according to the standard clinical guidelines (10). The present study was approved by the Institutional Ethics Committee for Biomedical Research of Fuwai Hospital and registered at Chinese Clinical Trial Registry (Unique identifier: ChiCTR2000033663). Written informed consent was obtained from each patient. Patients with non-valvular, antiarrhythmic drug refractory PAF diagnosed according to the standard clinical guidelines were included in the present study. Patients who exhibited a previous AF ablation history, LA size  $>55$  mm measured by echocardiogram, documented LA thrombus, severe pulmonary diseases, or previous cardiac surgical history were excluded from the present study. The details of their clinical characteristics are presented in Table I. There were 275 male patients (65.6%) and the average age was  $58.7 \pm 10.9$  years old.

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**Key words:** atrial fibrillation, catheter ablation, contact-force sensing, fast anatomical mapping

Table I. Baseline characteristics of patients (n=419).

Characteristics	Value (%)
Age (years)	58.7±10.9
Sex	
Male	275 (65.6%)
Duration of AF (years)	4.1±4.3
Patients with >1 year of AF	267(63.7 %)
CHA2DS2-VASc score	
0	90 (21.5%)
1	131 (31.3%)
2	107 (25.5%)
3	54 (12.9%)
4	23 (5.5%)
5	12(2.9%)
6	2 (0.5%)
Diabetes	56 (13.4%)
Heart failure	1 (0.2%)
Hypertension	199 (47.5%)
Myocardial infarction	10 (2.4%)
Peripheral vascular disease	9 (2.0%)
History of stroke	26 (6.2%)
LVEF (%)	63.9±6.6
LA size (mm)	36.5±4.8

AF, atrial fibrillation; LVEF, left ventricular ejection fraction; LA, left atrial.

*Simplified electrophysiological procedures.* All procedures were conducted under conscious sedation, and catheters were typically inserted via the right femoral vein. After positioning the coronary sinus catheter as an anatomical landmark, the transseptal puncture was performed under fluoroscopy using a single 8.5 Fr sheath only (11). FAM of the LA was guided by the CARTO® 3 system (Biosense Webster, Inc.) using a PentaRay catheter (Biosense Webster, Inc.). At this stage, a CF catheter (THERMOCOOL SMARTTOUCH® Catheter; Biosense Webster, Inc.) was out of the body but with the tip placed at the cardiac silhouette of the chest (Fig. 1).

The PentaRay catheter was taken off the sheath when FAM of LA was accomplished and the CF catheter was inserted into the LA. Circumferential pulmonary vein isolation (CPVI) was performed in the present study. The maximal power and temperature were set as 40 W and 43°C, respectively. The catheter was continuously irrigated with saline at a speed of 17 ml/min and the CF was maintained between 10 and 20 g during the ablation procedure. Ablation tags were annotated with the CARTO VISITAG™ Module (Biosense Webster, Inc.).

To verify PVI, stimulation with 10 mA outputs along the ablation lesions was delivered through the distal electrode of the ablation catheter. Additional ablation was performed if conduction gaps were identified. A successful procedure was defined by the absence of LA capture at all pacing sites (Fig. 2).



Figure 1. Placement of ablation catheter during left atrial mapping.

*Post-ablation follow-up.* Antiarrhythmic medications, including propafenone and amiodarone, were administered for 3 months after ablation in all patients, then terminated if no AF recurred. An electrocardiogram (ECG) and 24 h Holter were obtained at 1, 3, 6, 9 and 12 months post-ablation during the follow-up. An additional ECG and Holter were also performed if symptoms suggestive of AF recurrence occurred. After the 3 month blanking period, arrhythmia recurrence was defined as any episode (>30 sec duration) of AF or atrial tachycardia (AT).

*Study endpoints.* The primary effectiveness endpoint was freedom from any documented episode of AF/AT, which sustained for >30 sec during the 12 month follow up and outside a blanking period of 3 months. Secondary endpoints included procedure time and ablation time, procedure-related complications, and repeated ablation procedure during follow-up.

*Statistical analysis.* Continuous data were summarized as mean ± standard deviation. Categorical data were summarized as counts and percentages. Comparisons of categorical variables were performed using  $\chi^2$  tests. Rates of survival from atrial arrhythmia recurrence following the 3 month blanking period were estimated with a Kaplan-Meier model. Cox regression models were used to test for the significance of patient baseline characteristics and procedural detail in predicting atrial arrhythmia recurrence rates, as well as for calculating hazard ratios (HRs) to compare recurrence risks. All statistical analyses were performed using SPSS v23.0 software (IBM Corp.).

## Results

*Procedural parameters.* The procedural parameters are summarized in Table II. Entrance/exit block in all PVs during the procedure were achieved in 415 (99.0%) patients. The average procedure time was 74.5±9.7 min and the average ablation time was 27.3±7.8 min. In addition, the average radiation dose was 24.3±25.2 mGy.

*Follow-up for effectiveness.* At a mean follow-up time of 14.5 ± 4.1 months, 18 (4.3%) patients were unable to be contacted, including one patient who died due to pulmonary



Figure 2. Verification of pulmonary vein isolation with high output stimulation. Stimulation with 10 mA outputs along the ablation lesions (red point) was delivered through the distal electrode of the ablation catheter. Due to successful pulmonary vein isolation, the atrial rhythm was not related to pacing rhythm.

Table II. Procedural and complication data.

Factor	Value
Procedure time (min)	74.5±9.7
Ablation time (min)	27.3±7.8
Fluoroscopy time (min)	4.7±3.3
PVI ablation (%)	419 (100.0)
Acute procedural success (%)	415 (99.0)
AF persisted after ablation (%)	0 (0.0)
Acute PVI reconnection (%)	0 (0.0)
Complications	5 (1.2)
Pericardial effusion	1 (0.2)
Arteriovenous fistulas	2 (0.5)
Femoral artery pseudoaneurysm	2 (0.5)

PVI, pulmonary vein isolation; AF, atrial fibrillation.

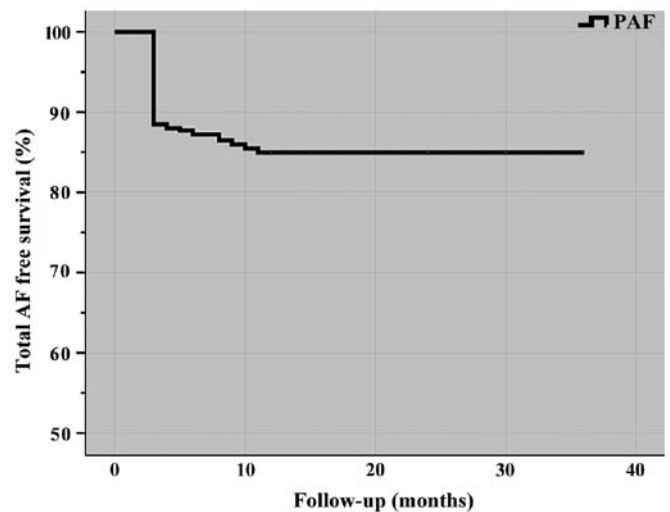


Figure 3. Follow-up outcomes of AF free survival. PAF, paroxysmal atrial fibrillation; AF, atrial fibrillation.

carcinoma without AF recurrence. Kaplan-Meier analysis estimated that 341 (85.0%) patients were free from AF/AT during follow-up (Fig. 3). A total of 7 patients underwent repeat ablation procedures during follow-up. Electric reconnection of PVI was demonstrated during the repeat procedures, and re-ablation at gaps were performed.

Multivariable Cox regression modeling demonstrated that the duration of AF was a significant predictor of recurrence (Table III). The greatest risk was an AF duration >1 year, relative to a duration of ≤1 year [HR, 2.0; 95% confidence interval (CI), 1.2-3.2]. A history of hypertension resulted in a reduced risk, as evidenced by a HR of <1 (HR, 0.6; 95% CI, 0.4-0.9).

**Complications.** The overall procedure-related complication rate was 1.2%, including 1 (0.2%) case of pericardial effusion and 4 (1.0%) cases of vascular access complications. A total of 2 cases of arteriovenous fistulas were resolved with

only conservative medical therapy. In addition, 1 case of pericardial effusion required pericardiocentesis and 2 cases of femoral artery pseudoaneurysm required puncture, suction and compression. There were no strokes during the ablation visit or follow-ups (Table II).

## Discussion

The present study demonstrated the advantages of a simplified ablation procedure for PAF of combined single transseptal puncture, FAM of LA, CF-sensing ablation and the high output stimulation verification technique among a large number of patients with PAF. In the current study, the 12 month AF/AT-free survival rate was improved compared with previous studies (12,13), while the average procedure time was just  $74.5 \pm 9.7$  min and the complication rate was controlled at a considerably lower level, which suggests this

Table III. Cox regression predictors of recurrence after a 3 month blanking period.

Parameter comparison	Hazard Ratio	
	(95% CI)	$\chi^2$ P-value
Duration of AF (>1 year vs. $\leq$ 1 year)	3.0 (1.5, 5.9)	0.002
History of hypertension (Yes vs. no)	0.7 (0.4, 1.2)	0.264
History of diabetes (Yes vs. no)	1.6 (0.8, 3.1)	0.145
Left atrial size (per mm increase)	1.0 (1.0, 1.1)	0.935

n=415 patients with non-missing values for all included variables. AF, atrial fibrillation; CI, confidence interval.

simplified and practical strategy is beneficial in a clinical setting. The multiple-factor analysis demonstrated that the duration of AF and left atrial size were significant predictors of recurrence, whereas the history of hypertension resulted in a reduced risk. Although this finding may initially appear counter-intuitive, it is supported by a prior study and is likely due to the protective effect of medications used to treat hypertension (14).

Radiofrequency ablation for patients with AF generally requires two transseptal punctures to deliver a multipolar mapping catheter and an ablation catheter into the left atrium, respectively. However, this procedure requires a skilled operator to perform it, and in most cases intracardiac echocardiography is required (8). Puncture-related complications and iatrogenic atrial septal defects are increased followed by an increase in the number of punctures (8). In a previous study, a modified transseptal puncture protocol was developed that used only a coronary sinus catheter as the landmark under fluoroscopy (11). In the present study, all transseptal procedures were overwhelmingly accomplished by fellows and guided only by fluoroscopy.

A number of different parameters are known to affect the transmural ablation lesions, including catheter tip temperature, power output, ablation time and CF. It has previously been demonstrated that real-time electrogram amplitude and impedance are poor predictors of the true CF applied (6). It is important to have an accurate measure of CF because a higher CF may increase the risk of blood charring (15). CF-guided catheters can provide stable and moderate CF, allowing for improvements in ablation safety and effectiveness, while simultaneously reducing procedure and fluoroscopy times (16). The improved catheter stability leads to faster transmural lesion formation (17), particularly in the right side PV (18). Procedures have been shortened due to faster assessment of appropriate catheter contact, resulting in the reduction of radiation (14,19-21). In CF-guided PV isolation, pulmonary vein reconnection remains primarily attributable to insufficient lesion depth and contiguity (17). Additionally, since the achievement of ideal ablation lesions depends on a combination of CF, power and duration parameters, the integration of these parameters via an automated algorithm, such as the Visitag with Ablation Index, may

provide a valuable solution to this complex optimization problem (22-24).

FAM, which is guided by a three-dimensional (3D) mapping system and a circular or multi-electrode mapping catheter, also serve a role in CF-guided ablation (25). Traditional point-to-point modeling cannot rapidly and accurately map the true LA geometry; therefore, it typically leads to increased fluoroscopy usage in order to reduce the complication risk (25). Alternatively, FAM can provide precise LA modeling and electronic substrate mapping information, leading to fewer manipulation difficulties and lower radiation (8,26). FAM guidance has been indicated to allow procedures with nearly zero fluoroscopy and without compromising the procedure duration, effectiveness or safety (25,27).

High output stimulation provides a convenient and reliable approach for the verification of ablation lesions. The traditional endpoint of PVI is antral disconnection detected by a circular mapping catheter, which requires complex catheter manipulation to ensure sufficient contact (22). High output stimulation along the encircling lesion line without LA capture could also effectively vivificate the conduction block between all PVs and LA (28). Guided with 3D mapping and CF monitoring, an operator can ensure ablation line integrity without concerns regarding poor contact or inaccurate location (9,29). Supplementary ablation to touch up any residual gaps (LA capture during high output stimulation along the lesion line) can be performed immediately, thus decreasing the procedure and fluoroscopy times.

There are some limitations of the present study. Firstly, the current study reflects the experience of a single center in China, and thus may not be representative of results across sites with differing workflows, levels of operator experience or patient populations. Secondly, the current study did not set a control group with the twice transseptal puncture. Giving the low complication rates and acceptable sinus rhythm maintenance during follow-up, the choice of this simplified strategy is also a reasonable option. Additionally, atrial arrhythmia recurrence estimates could potentially be biased due to patients with an incomplete follow-up, although the magnitude of this bias could not be significant due to the low number of these patients with <12 months of follow-up.

In conclusion, the present study demonstrated that this simplified technique was a simple, safe and effective approach for PAF ablation therapy. This strategy is a reasonable alternative for patients experiencing difficulty undergoing twice septal puncture.

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## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.



## Authors' contributions

YY conceived and designed the study. ZD, LZ, LD, EL and GC conducted the research and acquired the data. FH and LW analyzed and interpreted the data. ZD drafted the manuscript. All authors substantially contributed to the revision of the manuscript, and approved the final version.

## Ethics approval and consent to participate

The current study was approved by the Institutional Ethics Committee for Biomedical Research of Fuwai Hospital and registered at Chinese Clinical Trial Registry (Unique identifier: ChiCTR2000033663).

## Patient consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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