



## Original article

# Clinical impact of contact force and its regional variability on efficiency and effectiveness of pulmonary vein isolation for atrial fibrillation



Yohei Sotomi (MD)<sup>a</sup>, Koichi Inoue (MD, PhD)<sup>a,\*</sup>, Takayuki Kikkawa<sup>b</sup>, Koji Tanaka (MD)<sup>a</sup>, Yuko Toyoshima (MD)<sup>a</sup>, Takafumi Oka (MD, PhD)<sup>a</sup>, Nobuaki Tanaka (MD)<sup>a</sup>, Yoshiyuki Orihara (MD)<sup>a</sup>, Katsuomi Iwakura (MD, PhD, FJCC)<sup>a</sup>, Yasushi Sakata (MD, PhD, FJCC)<sup>c</sup>, Kenshi Fujii (MD, PhD, FJCC)<sup>a</sup>

<sup>a</sup> Cardiovascular Center, Sakurabashi Watanabe Hospital, Osaka, Japan

<sup>b</sup> Department of Medical Engineering, Sakurabashi Watanabe Hospital, Osaka, Japan

<sup>c</sup> Department of Cardiovascular Medicine, Osaka University Graduate School of Medicine, Osaka, Japan

## ARTICLE INFO

## Article history:

Received 11 July 2015

Received in revised form 5 October 2015

Accepted 13 October 2015

Available online 19 November 2015

## Keywords:

Atrial fibrillation

Catheter ablation

Pulmonary vein isolation

Contact force

Recurrence

## ABSTRACT

**Background:** The purpose of this study is to analyze the impact of average contact force (CF) and its regional variability during pulmonary vein isolation (PVI) for atrial fibrillation (AF) on periprocedural parameters and midterm outcome.

**Methods:** This retrospective cohort study enrolled 57 drug-refractory AF patients who underwent initial PVI for AF using an open-irrigated CF catheter (SmartTouch Thermocool, Biosense Webster, Diamond Bar, CA, USA). Thirty patients were assigned to a lower CF (LCF) group (average CF  $\leq 10$  g) and 27 patients to a higher CF (HCF) group (average CF  $> 10$  g). The relationship between CF and clinical outcome was analyzed.

**Results:** Patients were followed-up for  $317 \pm 57$  days after PVI. The CF was  $8.1 \pm 1.3$  g in the LCF group and  $12.4 \pm 1.5$  g in the HCF group. Higher average CF was associated with shorter ablation time ( $28 \pm 6$  min vs.  $36 \pm 9$  min,  $p = 0.0002$ ) and lower radiofrequency energy delivery ( $79 \pm 18$  vs.  $99 \pm 26$ ,  $p = 0.0016$ ) for PVI. The rate of acute PV reconnection (APVR) was similar in both groups (LCF group 60% vs. HCF group 44%,  $p = 0.36$ ). Four patients (13%) in the LCF group and nine patients (33%) in the HCF group experienced AF-recurrence. Average CF did not impact on AF-recurrence during midterm clinical outcome ( $p = 0.09$  by log-rank test). In the non-recurrence group ( $n = 44$ ), average CF was higher at left posteriosuperior PV and right anteroinferior PV than that in the recurrence group ( $n = 13$ ) ( $p = 0.012$  and  $p = 0.004$ , respectively).

**Conclusions:** Higher average CF decreased ablation time and radiofrequency energy delivery for PVI, but did not decrease APVR rate or improve midterm clinical outcome.

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## Introduction

Pulmonary vein isolation (PVI) is the cornerstone of catheter ablation procedures for both paroxysmal and persistent atrial fibrillation (AF) and has evolved into an increasingly safe and efficacious procedure [1]. However, despite the significant improvements made in catheter ablation strategies to treat AF in recent years, recurrent arrhythmia remains a concern. Insufficient radiofrequency (RF) ablation of lesions can result in electrical

pulmonary vein (PV) reconnection, which is the primary cause of recurrent arrhythmia after ablation for AF [2–4].

A large number of factors, including respiration, RF power and duration, electrode temperature and size, irrigation, local blood flow, and catheter–tissue contact, collectively interact to influence the volume of RF lesions during ablation [5–7]. Among these factors, catheter–tissue contact force (CF) is a critical determinant of RF ablation lesion size, and insufficient CF can lead to ineffective RF delivery and nonuniform lesion formation [8–10].

Recent results with CF-sensing ablation catheters showed that low catheter–tissue CF resulted in gap formation and acute PV reconnection [11–16]. According to these reports, the optimal CF to complete PVI efficiently is  $>10$ – $20$  g and varies depending on the peri-PV regions. The use of real-time CF guidance results in a significant reduction in the prevalence of dormant conduction with

\* Corresponding author at: Department of Cardiology, Sakurabashi Watanabe Hospital, 2-4-32 Umeda, Kita-ku, Osaka 530-0001, Japan. Tel.: +81 6 6341 8651; fax: +81 6 6341 0785.

E-mail address: [koichi@inoue.name](mailto:koichi@inoue.name) (K. Inoue).

improved mid-long-term freedom from recurrent arrhythmias [14,17,18]. However, it remains unclear whether the optimal CF to prevent AF recurrence during mid-term follow-up is >10–20 g, because there are limited clinical data on mid-term outcome [19,20]. In addition, the impact of regional CF difference on the mid-term clinical outcome has never been evaluated to date.

The purposes of this study are: (1) to analyze the impact of average CF during PVI on periprocedural parameters (PVI efficiency) and mid-term outcome (PVI effectiveness), and (2) to evaluate the relationship between regional CF difference and recurrence of tachyarrhythmia after PVI for AF.

## Methods

### Study design

The study design was a retrospective, single-center, cohort study. A total of 80 consecutive drug-refractory AF patients (age, 20–80 years) who underwent initial PVI for AF with the ThermoCool<sup>®</sup> SmartTouch<sup>™</sup> catheter (Biosense Webster, Diamond Bar, CA, USA) at Sakurabashi Watanabe Hospital from June to August 2013 were enrolled in this study. Written informed consent for the AF ablation was obtained from all patients. The study protocol was approved by the institution's ethics committee. Patients who underwent ablation of linear lesions in the left atrium (LA) or ablation of atrial premature complexes from non-PV origins were not enrolled. Of the 80 enrolled patients, 23 with insufficient data were excluded. The remaining 57 were divided into two groups: a lower CF group (average CF throughout the procedure  $\leq 10$  g;  $n = 30$ ) and a higher CF group (average CF throughout the procedure  $> 10$  g;  $n = 27$ ). The relationship between the peri-PV regional difference of CF distribution data and effectiveness endpoints was analyzed. The CF was defined as the average of CF values during 1.0 s just prior to location tagging using the CARTO 3 three-dimensional mapping platform (Biosense Webster). CF data for all ablation sites for PVI were analyzed offline after the procedure. Each ipsilateral pair of PV antra was divided into seven segments: roof, anterosuperior, anteroinferior, bottom, posteroinferior, posterosuperior, and carina. The details of the analyses were indicated in our previous publication [16]. The primary endpoint was freedom from recurrent AF/atrial tachycardia (AT). AF/AT episodes of  $> 30$  s were considered recurrent events. The secondary endpoints were periprocedural parameters [RF delivery, rate of acute pulmonary vein reconnection (APVR) during the procedure, ablation time for PVI, procedure time, and exposure dose]. Major adverse events were defined as procedure-related or device-related serious adverse events (e.g. tamponade, pericarditis, pericardial effusion, perforation) occurring within 7 days of the ablation procedure, and PV stenosis and atrioesophageal fistula occurring  $> 7$  days after the procedure. After 1-year follow-up, the study population was divided into two groups: patients without recurrence (non-recurrence group;  $n = 44$ ) and patients with recurrence (recurrence group;  $n = 13$ ). The regional difference of CF was evaluated retrospectively between both groups.

### Periprocedural protocol

Preoperative evaluations for all patients included transthoracic echocardiography, transesophageal echocardiography, and multi-detector computed tomography. Screening blood tests were also performed upon admission. Antiarrhythmic drugs (AADs) were discontinued more than three half-lives before the procedure. The AF ablation procedure was performed by five experienced operators using the ThermoCool<sup>®</sup> SmartTouch<sup>™</sup> catheter following standard clinical practice guidelines with conventional power

and temperature settings. Details of catheter ablation areas are mentioned below. All patients were hospitalized for 3 days after the ablation procedure with continuous rhythm monitoring. Prescription of AADs at discharge was determined by the patient's attending physician.

### Electrophysiological study and RF catheter ablation

Boluses of hydroxyzine pamoate 25 mg and pentazocine 15 mg were administered intravenously prior to the punctures. Moderate sedation using dexmedetomidine was also introduced at the beginning of the procedure (6  $\mu\text{g}/\text{kg}/\text{h}$  for 10 min) and maintained during the procedure (0.3  $\mu\text{g}/\text{kg}/\text{h}$ ). The peripheral oxygen saturation, heart rate, and blood pressure were monitored continuously. Femoral arterial access is routinely acquired for continuous arterial pressure monitoring. Noninvasive ventilation was performed with a Trilogy O<sub>2</sub> (Philips, Amsterdam, the Netherlands) in spontaneous/temporized mode. Inspiratory positive airway pressure, expiratory positive airway pressure, and respiratory rate were modified according to the clinical response, including tolerance of the patient to obtain an exhaled tidal volume of 6–8 mL/kg; FIO<sub>2</sub> requirement was 40% or less to maintain the oxygen saturation above 92%. Sedation and mechanical ventilation were discontinued at the end of the catheter ablation procedure.

A 6-Fr decapolar catheter was placed in the coronary sinus through the median antebrachial vein, whereas a 7-Fr decapolar catheter was placed in the superior vena cava and right atrium through the femoral vein. Two long sheaths were introduced into LA using a single transeptal puncture technique. An initial intravenous bolus of heparin (150 IU/kg) was followed by continuous infusion to maintain an activated clotting time of  $> 300$  s. Pulmonary angiography was performed by injecting contrast medium through the transeptal long sheaths into LA. After catheter placement, electrical cardioversion was performed in cases with persistent AF. PVI was guided by fluoroscopy or the CARTO 3 three-dimensional mapping system. We used the open irrigated-tip RF ThermoCool<sup>®</sup> SmartTouch<sup>™</sup> ablation catheter for all procedures.

Catheter ablation was basically performed using a conventional electrophysiological and anatomical approach. We monitored CF values only to avoid excessive catheter contact. All patients underwent extensive PVI using the single lasso technique. We performed point-by-point ablation, not with the dragging technique, with an interlesion distance of  $< 5$  mm. RF energy was delivered up to 30 W with a temperature limit of 43 °C using an irrigated catheter for up to 30 s at each point. At the posterior wall near the esophagus, RF delivery was limited to 15 s. Circumferential PVI (defined as abolition or dissociation of PV potentials) was performed successfully in all patients. We reconfirmed PV potential 20 min or more after initial success of PVI, and if PV potential reappeared we defined it as positive for time-dependent PV reconnection. In some patients we also checked adenosine triphosphate (ATP)-dependent PV reconnection, which was evoked by intravenous administration of ATP (0.4 mg/kg). Generally, if dormant LA–PV conduction is induced, additional RF energy is delivered to the conduction gap until ATP-induced reconnection is lost. In this study, APVR was defined as both a time-dependent and ATP-dependent PV reconnection. In this study population, neither ablation of non-PV premature atrial contraction, nor additional linear ablation of LA, nor ablation of the complex fractionated atrial electrogram was performed.

### Patient follow-up

Prescription of AADs in the outpatient clinic was determined by the patient's attending physician. We directed patients to check their pulse rate and rhythm three times a day and to visit the

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