

## Durability of cryothermal pulmonary vein isolation – Creating contiguous lesions is necessary for persistent isolation



Shinsuke Miyazaki <sup>\*</sup>, Hiroshi Taniguchi, Hitoshi Hachiya, Hiroaki Nakamura, Takamitsu Takagi, Kenzo Hirao <sup>1</sup>, Yoshito Iesaka

Cardiovascular Center, Tsuchiura Kyodo Hospital, Tsuchiura, Ibaraki, Japan

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### ABSTRACT

**Background:** Electrical reconnections after pulmonary vein isolation (PVI) are common in catheter ablation. This study aimed to evaluate the impact of the ablation method on the durability of cryothermal PVI.

**Methods:** One hundred thirty-two consecutive paroxysmal atrial fibrillation patients undergoing cryothermal PVI were enrolled. PVI was performed with one 28-mm second-generation balloon using 3-minute freeze techniques, and touch-up lesions were created by focal cryothermal applications.

**Results:** Out of 520 PVs, 503 (96.7%) were isolated using exclusively cryoballoons, and 17 required additional focal ablation. Adenosine testing was performed in 111 patients for 439 PVs including 427 isolated with cryoballoons and 12 isolated by focal ablation. The incidence of dormant conduction was significantly higher in PVs isolated by focal ablation than by cryoballoons (4/12 vs. 3/427 PVs,  $p < 0.0001$ ). All latent conduction was successfully eliminated by additional cryoapplications. In 36 patients, 142 PVs were re-evaluated during repeat procedures a median of 6 [4.3–9.0] months after the initial procedure. Late reconnections were detected in 32 (22.5%) PVs. The incidence of late reconnections was significantly higher in PVs isolated by focal ablation than by cryoballoons (5/6 vs. 27/136 PVs,  $p = 0.0003$ ). Among the PVs requiring touch-up ablation, both the acute dormant conduction and late reconnection sites were identical to sites requiring touch-up ablation.

**Conclusions:** The incidence of both acute latent and late PV reconnections was significantly higher when PVI was achieved by focal cryoablation than by cryoballoon ablation despite using the same energy source. These data suggest that creating contiguous lesions is essential for achieving a durable PVI.

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## 1. Introduction

Pulmonary vein isolation (PVI) has become an established therapy for drug-resistant paroxysmal atrial fibrillation (AF) [1,2]. Although point-by-point radiofrequency (RF) ablation has been the standard method for PVI, data available in the literature has suggested that a recently developed second-generation cryoballoon (CB) is effective in terms of the procedural safety and efficacy with a simple ablation procedure [3–6]. Indeed, the reported incidence of dormant pulmonary vein

(PV) conduction during the acute phase after PVI [7] and late PV reconnections during repeat procedures [8] was significantly lower after second-generation CB ablation than point-by-point RF ablation. However, it remains unknown whether or not this difference was produced by the difference in the energy source (cryo and RF) or manner of ablation (balloon and point-by-point ablation). In this regard, this study set out to investigate the rate of acute dormant PV conduction and late PV reconnections after cryothermal PVI to evaluate the impact of the method of ablation on the durability.

## 2. Methods

### 2.1. Study population

This prospective study consisted of 132 consecutive patients with drug-refractory paroxysmal AF who underwent their first PVI using cryothermal energy in our institute. PVI was performed with a single balloon 3-minute freeze technique using a 28-mm second-generation CB (Arctic Front Advance, Medtronic, Minneapolis, MN), and touch-up lesions were created with an 8-mm tip conventional cryocatheter (Freezor MAX, Medtronic). AF

**Abbreviations:** AF, atrial fibrillation; PVI, pulmonary vein isolation; PV, pulmonary vein; CB, cryoballoon; ATP, adenosine triphosphate; RF, radiofrequency; LSPV, left superior PV; LIPV, left inferior PV; LCPV, left common PV; RSPV, right superior PV; RIPV, right inferior PV.

<sup>\*</sup> Corresponding author at: Cardiology Division, Cardiovascular Center, Tsuchiura Kyodo Hospital, 11-7 Manabeshin-machi, Tsuchiura, Ibaraki 300-0053, Japan.

E-mail address: [mshinsuke@k3.dion.ne.jp](mailto:mshinsuke@k3.dion.ne.jp) (S. Miyazaki).

<sup>1</sup> Heart Rhythm Center, Tokyo Medical and Dental University, Tokyo, Japan.

was classified according to the latest guidelines. All patients gave their written informed consent. The study protocol was approved by the hospital's institutional review board. The study complied with the Declaration of Helsinki.

## 2.2. Mapping and ablation protocol

All antiarrhythmic drugs were discontinued for at least five half-lives prior to the procedure. Pre-procedural cardiac enhanced computed tomography (CT) was performed to evaluate the cardiac anatomy. The surface electrocardiogram and bipolar intracardiac electrograms were continuously monitored and stored on a computer-based digital recording system (LabSystem PRO, Bard Electrophysiology, Lowell, MA, USA). The bipolar electrograms were filtered from 30 to 500 Hz. A 7Fr 20-pole three site mapping catheter (BeeAT, Japan-Life-Line, Tokyo, Japan) was inserted through the right jugular vein for pacing, recording and internal cardioversion.

The procedure was performed under moderate sedation obtained with dexmedetomidine. A 100 IU/kg body weight of heparin was administered immediately following the venous access, and heparinized saline was additionally infused to maintain the activated clotting time at 250–350 s. A single transeptal puncture was performed using an RF needle (Baylis Medical, Inc., Montreal, QC, Canada) and 8-Fr long sheath (SLO, AF Division, SJM, Minneapolis, MN). The transeptal sheath was exchanged over a guidewire for a 15-Fr steerable sheath (Flexcath Advance, Medtronic). A 20-mm circular mapping catheter (Lasso, Biosense Webster, Diamond Bar, CA) was used for mapping all the PVs before and after the cryoablation to confirm the electrical isolation. A spiral mapping catheter (Achieve, Medtronic) was used to advance the second-generation CB into the PV for support and to map the PV potentials. A 28-mm CB was inflated proximal to the PV ostium followed by a gentle push aiming for the complete sealing at the antral aspect of the PV. A 23-mm CB was not used in any cases. Contrast medium injected through the central lumen of the CB was used to verify the complete occlusion of the PV ostium. This was followed by a freeze cycle of 180 s. No additional applications were performed after the isolation. In order to avoid bilateral phrenic nerve injury [9], all CB applications were applied under monitoring the ipsilateral diaphragmatic compound motor action potentials during phrenic nerve pacing [10,11]. The procedural end point was defined as electrical PVI verified by the 20-mm circular mapping catheter (Lasso). If electrical isolation was not achieved by a total of 3 CB applications (180 s for each application) per vein, additional touch-up freezes with an 8-mm tip conventional cryocatheter were performed for 2 min for each application.

After completing the PVI, a 20-mm circular mapping catheter was placed in each vein, and a 20 mg bolus of adenosine triphosphate (ATP) was injected to unmask any dormant PV conduction [12]. If dormant conduction was provoked by ATP testing, additional touch-up freezes with an 8-mm tip conventional cryocatheter were performed until no further dormant conduction was provoked by a repeat ATP injection.

## 2.3. Follow-up

No antiarrhythmic drugs were prescribed after the procedure. The patients underwent continuous, in-hospital ECG monitoring for 2–4 days following the procedure. The first outpatient clinic visit was 3 weeks after the procedure. Subsequent follow-up visits consisted of a clinical interview, ECGs, 24 h Holter monitoring every 3 months, and 14-day consecutive monitoring using an external loop recorder (Spider Flash, Sorin, France) at our cardiology clinic. Recurrence was defined as any atrial tachyarrhythmias lasting longer than 30 s, and a 3-month of blanking period was applied. Procedural success was defined as freedom from any recurrence without any antiarrhythmic drugs administered along the latest guidelines.

## 2.4. Statistical analysis

Continuous data are expressed as the mean  $\pm$  standard deviation for normally distributed variables or as the median [25th, 75th percentiles] for non-normally distributed variables, and were compared using a Student's *t*-test or Mann–Whitney *U*-test, respectively. Categorical variables were compared using the chi-square test. A probability value of  $p < 0.05$  indicated statistical significance.

**Table 1**  
Characteristics of the study population.

N	132
Age, y	63.3 $\pm$ 10.3
Paroxysmal AF, n (%)	132 (100%)
Female, n (%)	36 (27.3%)
Structural heart disease, n (%)	9 (6.8%)
Hypertension, n (%)	64 (48.5%)
Body mass index, kg/m <sup>2</sup>	24.1 $\pm$ 3.1
LA diameter, mm	37.8 $\pm$ 5.3
LV ejection fraction, %	66.3 $\pm$ 6.7
Pro-Brain Natriuretic Peptide, pg/ml	265 $\pm$ 503
Estimated GFR, ml/min/1.73 m [2]	70.7 $\pm$ 13.6

AF: atrial fibrillation, LA: left atrial, LV: left ventricular, GFR: glomerular filtration rate.

## 3. Results

### 3.1. Procedure results of cryothermal PVI

The patient characteristics are summarized in Table 1. In 132 patients, a total of 520 PVs including 8 left common PVs (LCPVs) were identified. Overall, 503 of 520 (96.7%) PVs were isolated successfully using exclusively a 28-mm CB. The mean number of CB applications resulting in PVI was 1.3  $\pm$  0.6, 1.2  $\pm$  0.5, 1.2  $\pm$  0.4, 1.4  $\pm$  0.7, and 3.3  $\pm$  1.3 for the left superior (LSPV), left inferior (LIPV), right superior (RSPV), right inferior (RIPV), and LCPV, respectively.

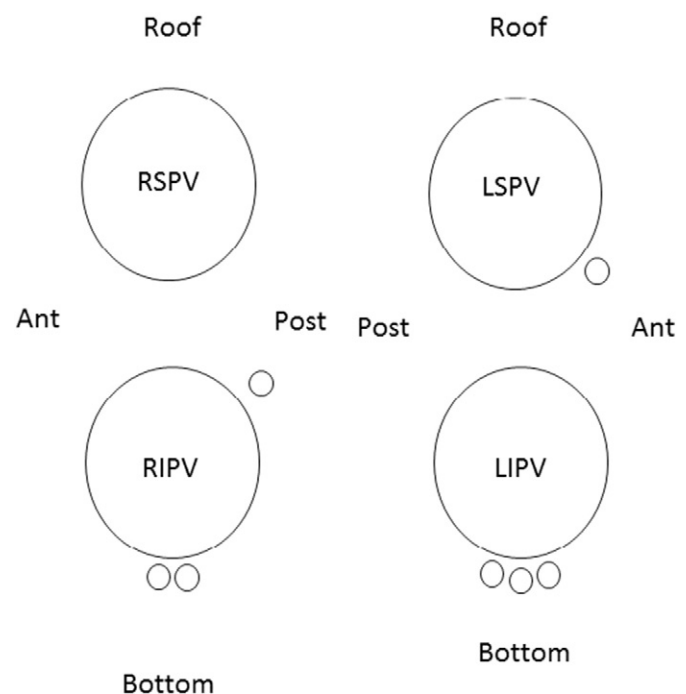
Touch-up lesions were created in the remaining 17 (3.3%) PVs including 1, 3, 1, and 12 in the LSPV, LIPV, RSPV and RIPVs, respectively. No particular anatomy was observed in those 17 PVs. The median number of additional focal applications for the achievement of the PVI was a median of 3.0 [2.0–4.0]. The bottom of the RIPV was the most common location requiring touch-up ablation. In total, all 520 PVs were successfully isolated by cryothermal ablation.

Cardiac tamponade requiring pericardiocentesis, right phrenic nerve injury, and a pneumothorax during the puncture of the right subclavian vein occurred in 1, 3, and 1 patients, respectively. The total procedure time and total fluoroscopic time were 82.1  $\pm$  26.8 and 25.5  $\pm$  14.3 min, respectively.

### 3.2. Latent PV conduction during the acute phase

ATP testing was performed in all patients except for 15 patients with a contraindication to ATP (history of bronchial asthma in 12 and glaucoma in 3) and 6 patients with sustained AF after the PVI or patient intolerance. In total, ATP testing was performed in 111 patients for 439 PVs, including 427 PVs, which were isolated with a CB, and 12 PVs (1 LSPV, 2 LIPVs, 9 RIPVs), which were isolated by focal ablation.

Dormant PV conduction was revealed during the ATP testing in a total of 7 (1.6%) (1 LSPV, 3 LIPVs, and 3 RIPVs) out of 439 PVs, and all were transient. The distribution of the location is shown in Fig. 1. Among 12 PVs, which were isolated by focal ablation, latent conduction



**Fig. 1.** The distribution of the ATP-provoked dormant PV conduction. Each small circle indicates a latent conduction gap. LSPV: left superior pulmonary vein, LIPV: left inferior PV, RSPV: right superior PV, RIPV: right inferior PV, Ant: anterior, Post: posterior.

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