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Vasovagal responses during cryoballoon pulmonary vein isolation in paroxysmal atrial fibrillation predict favorable mid-term outcomes

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ABSTRACT

Background: Vasovagal responses (VR) encountered during radiofrequency pulmonary vein isolation (PVI) in paroxysmal atrial fibrillation (PAF) suggest ablation of the atrial tissue subjacent to the ganglionic plexi (GP) and confer durability of PVI.
Objective: We hypothesized that VR during cryoballoon PVI (CB-PVI) in PAF can predict mid-term AF recurrence.
Methods: We enrolled 39 patients who underwent PVI using 2nd generation cryoballoon for PAF from November 2014 to July 2016. We evaluated the long term outcomes for those who had VR during index procedure.
Results: A total of 39 patients (76% male, mean age 57 ± 9 years) underwent CB-PVI for PAF and 66.67% (26/39) had VR. VR was frequently observed in the LSPV (100%), followed by RSPV (64%), LIPV (60%), and less frequently, RIPV (28%). Overall, the mean difference in the HR and SBP, and the relative differences in the HR and SBP were observed during CB-PVI in the LSPV (mean difference in HR, $p < 0.001$; mean difference in SBP, $p < 0.001$; relative difference in HR, $p < 0.001$); relative difference in SBP, $p < 0.001$). After PVI, 22/26 (84.62%) and 5/13 (38.46%) of patients in the VR and NVR group, respectively, maintained SR at 14 ± 6 months follow-up. The Kaplan-Meier analysis showed statistical difference in favor of patients with VR during CB-PVI (log rank $p < 0.01$) with a better mid-term outcome.
Conclusion: In a small cohort of patients, VR during CB-PVI in PAF is a surrogate marker for ablation of atrial tissue subjacent to the GP and predicts a favorable mid-term outcome for AF recurrence.
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1. Introduction

Circumferential pulmonary vein isolation (PVI) has become the cornerstone for radiofrequency catheter ablation (RFCA) of drug-refractory paroxysmal atrial fibrillation (PAF) [1]. The durability of pulmonary vein (PV) lesions is one of the most important goals during catheter ablation of AF, as PV electrical reconduction frequently results in atrial fibrillation (AF) recurrence [2]. In recent years, the second-generation cryoballoon (CB) has emerged as a valid alternative to RFCA and has been released with technical developments resulting in a larger and more homogeneous zone of freezing on the balloon surface, leading to significant improvements in procedural and clinical outcomes as compared to the first-generation CB [3,4].

While RFCA or CB techniques are an effective therapeutic option for the elimination of triggers and atrial substrate, recurrences can still occur because of several external modifiers [5]. Clinical studies have underscored the critical role of the intrinsic cardiac autonomic nervous system (ICANS) in the dynamics of AF initiation and maintenance [6,7]. Structural and functional evidences indicate that ICANS forms a complex neural network composed of ganglionated plexi (GP) concentrated within epicardial fat pads and the interconnecting ganglia and axons [8]. Stimulation of the GP results in rapid, repetitive discharges from the PVs, and the inadvertent injury to the GP tissue, manifested by overt vagal reaction, is thought to be an important determinant of procedural success, recurrences, and sinus rhythm maintenance [9,10]. Studies on vasovagal responses (VR) during CB-PVI and AF recurrence are still lacking. We hypothesized that VR during CB-PVI in PAF can predict mid-term atrial arrhythmia recurrence.

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2. Methods

2.1. Study population

A total of 39 patients with drug-refractory symptomatic PAF, defined as AF whose episodes self-terminated within 7 days [11], who were referred for cryo-ablation from November 2015 to July 2016 were included in the study. All patients received 12 lead ECG, 24-hour Holter, 2D echocardiography, and CT angiography of the LA and PVs prior to the procedure. The patients with persistent and long-standing AF, moderate to severe valvular heart disease, uncontrolled thyroid function, pre-procedural significant coronary artery disease, and LA diameter > 55 mm were excluded from this study. Baseline characteristics of the patients were assessed in detail.

2.2. Ablation protocol

After informed consent was obtained, each patient underwent an electrophysiological study and CB-PVI in the fasting state with adequate pre-ablation anticoagulation and transesophageal echocardiography (TEE) to rule out LA thrombus. All antiarrhythmic drugs were discontinued for at least 5 half-lives before the procedure. A 7F decapolar catheter (St. Jude Medical (SJM), Inc., St. Paul, MN) was inserted into the coronary sinus via the right internal jugular vein. An atrial transseptal puncture by modified Brockenbrough technique (BRK™ Transseptal needle, SJM) was performed using fluoroscopic landmarks, and an 8.5 F long vascular sheath was introduced into the LA. Intravenous heparin was administered at intervals of 30 min to achieve an activated clotting time of 250 to 300 s. The transseptal sheath was exchanged over a guidewire for a 15F steerable sheath (FlexCath Advance; Medtronic Inc.). A continuous infusion of heparinized saline was connected to the transseptal sheath to avoid any thrombus formation or air embolism. A circular mapping catheter (Achieve, Medtronic) was used to advance the second-generation CB into the PV for support and mapping of PV potentials. In all patients, a 28-mm CB (Arctic Front Advance©, Medtronic) was used. The CB was inflated proximal to the PV ostium, followed by a gentle push for the complete sealing of the antrum of the PV. Assessment of complete balloon occlusion of the PV ostium was performed by injecting a 50% diluted contrast medium through the central lumen of the CB. A freeze cycle of 180 s was initially applied to the PV with good occlusion for each targeted PV. Upon the discretion of the operator, if PVI was achieved during the first freeze cycle, an additional freeze cycle of 120 or 180 s freeze cycle was performed. The procedure systematically began with the left superior PV, followed by the left inferior, right inferior, and right superior PVs, respectively. A 6-F quadripolar catheter was placed in the superior vena cava to constantly pace the right phrenic nerve (cycle length of 1200 ms, pacing output of 10–15 mV) ascertaining diaphragmatic capture, during freezing at the right-sided PVs to avoid phrenic nerve (PN) paralysis. Direct palpation of the right hemidiaphragmatic excursion and intermittent fluoroscopic visualization was performed during PN stimulation. Cryoenergy delivery was immediately stopped if weakening or loss of diaphragmatic movement was noted and no further cryoenergy was delivered along the right-sided PVs. At the end of the procedure, PVI was re-evaluated by moving the circular mapping catheter into each PV. Successful PVI or acute procedural success was defined as the elimination or dissociation of all PV potentials during CB-PVI. All identified PV reconnections that were not successfully achieved by CB isolation due to difficulty in achieving a complete seal in the PV ostium were closed by RFCA using a 4-mm irrigated tip catheter (Cool Flex™, SJM). In all patients, cavotricuspid isthmus (CTI) linear ablation was performed using the power control mode at maximal power of 35 W–40 W with a 4-mm irrigated tip catheter (Cool Flex™, SJM) or at maximal temperature of 60 °C to 70 °C using an 8-mm non-irrigated tip ablation catheter (Livewire™, SJM). Bidirectional block was confirmed by differential pacing.

2.3. Vasovagal reaction

A vasovagal reaction was defined as sinus bradycardia (<40 bpm), asystole, complete atrioventricular block, or hypotension (systolic blood pressure < 90 mm Hg, diastolic blood pressure < 60 mm Hg or a sudden drop in blood pressure from baseline by at least 20 mm Hg [12]) that occurred during the period of balloon thawing and balloon deflation following thawing at the end of CB-PVI [7]. Thawing phase was defined as the period between the end of cryoenergy delivery up to the time prior to balloon deflation when CB temperature and local tissue temperature at 35 °C was achieved. Balloon deflation phase was defined as the time when the CB was deflated and could be removed from the PV ostium.

2.4. Follow-up

The patients underwent follow-up 2 weeks after the index ablation, then every 1–3 months thereafter, at our outpatient cardiology clinic or with the referring physicians. Routine 12 lead ECGs were obtained during each follow-up, and antiarrhythmic drugs were prescribed for 8 weeks to prevent any early recurrence of AF. A 24-hour Holter monitor was also performed at 3-, 6-, and 12-month follow-ups. When the patient experienced symptoms a 24-hour Holter monitoring and/or event recording with a recording duration of 1 week were performed to define the cause of the clinical symptoms. The AF recurrence was defined as clinically documented AF, lasting for >30 s, whether symptomatic or asymptomatic, that occurred after a 90-day blanking period.

2.5. Statistical analysis

The normally distributed continuous variables were presented as the mean values and standard deviation and were compared using paired *t*-test. The non-normally distributed variables were compared using the Mann-Whitney *U* test. Categorical variables were presented as proportions and percentages. Fisher's exact test was used to determine the statistical significance of AF recurrence rate 2 groups. One-way ANOVA test was performed to determine the overall statistical difference of the parameters among the groups and a post-hoc analysis using Tukey's test to determine the differences for each pair of groups. The Kaplan-Meier curve analysis with the statistical significance examined by the log-rank test was used to estimate the mid-term AF recurrence rate. The level of statistical significance was set at a p-value < 0.05. All statistical analyses were performed using commercial statistical SPSS software (version 23.0, IBM International, New York).

3. Results

3.1. Patient characteristics

In this study, 76% were male with mean age 57 ± 10 years with PAF who underwent CB-PVI. The patient's baseline characteristics are shown in Table 1. There was no significant difference in the clinical characteristics and echocardiographic parameters between the VR and NVR groups during CB-PVI.

3.2. Procedural characteristics

The procedural characteristics of CB-PVI in the study patients are shown in the graphs in Fig. 1A. The average temperature and cryoenergy delivery time achieved during the procedure were −46.73 ± −6.08 °C and 271.17 ± 54.61 s, respectively. Overall, the mean nadir temperature, mean difference in HR and SBP, and the mean and relative differences in the HR, SBP were significantly different among the 4PVs (mean nadir temperature $p = 0.007$, mean difference in HR $p < 0.001$, mean difference in SBP $p < 0.001$, relative difference in HR $p < 0.001$, relative difference in SBP $p < 0.001$). There was no overall statistical difference in the mean cryoapplication time, mean and relative difference in DBP among the 4 PVs. Fig. 1A–a shows that the LSPV mean nadir temperature achieved during CB-PVI was significantly lower than LIPV but not with other PVs (LSPV vs LIPV, $p = 0.006$; LSPV vs RSPV, $p = 0.431$; LSPV vs RIPV, $p = 0.893$). Fig. 1A-c to A-f also demonstrates that the pairwise comparison of the mean and relative differences in the HR and SBP were significantly higher in the LSPV than the other PVs during CB-PVI.

Vasovagal response was observed in 26 (66.67%) patients. In these patients (VR group), VR was frequently observed during ablation in the LSPV (26/26), followed by RSPV (17/26), LIPV (16/26), and less frequently, RIPV (7/26). In 16 of the 26 patients (61.54%), the VR occurred during the thawing phase in 9 (34.62%) patients (mean time to occurrence of VR was 22.27 ± 9.89 s), and in 7 (26.92%) patients, the VR occurred after balloon deflation (mean time to occurrence of VR was 13.07±5.16 s) (Table 2). In 10 (38.46%) patients, the exact timing of the vagal responses was not annotated in the recording system. We also found that 23 of the 26 patients in the VR group demonstrated vagal responses expressed as a hypotension with significant slowing of HR (mean HR change from baseline 16 ± 17 bpm, $p < 0.001$) with mean HR 50 ± 7 bpm, while 3 patients have vagal responses expressed as hypotension and severe sinus bradycardia (≤40 bpm). In 1 of the 3 patients, severe bradycardia (HR < 40 bpm) and hypotension (blood pressure < 90/70 mm Hg) persisted necessitating continuous temporary pacing and use of vasopressor agents until the end of procedure. There was no significant difference in the mean nadir temperature, mean cryoapplication time, procedure time and fluoroscopic time between the two groups (Fig. 1B-a and B-b). Fig. 1B-c to B-h shows the comparison between the mean and relative differences in the HR, SBP, and DBP between the 2 groups. The mean difference in the HR and SBP, and the relative difference in the HR during CB-PVI in the LSPV were significantly higher in the VR group than in the NVR group (mean difference in HR, $p = 0.001$; relative difference in

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