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Prevalence and Pre-Procedural Predictors Associated With Right Phrenic Nerve Injury in Electromyography-Guided, Second-Generation Cryoballoon Ablation

Single Large Balloon and Single 3-Minute Freeze Techniques

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ABSTRACT

OBJECTIVES This study aimed to evaluate the incidence and pre-procedural predictors of right phrenic nerve injury (PNI) in electromyography-guided, second-generation cryoballoon (CB) ablation.

BACKGROUND Second-generation CBs perform better pulmonary vein isolation (PVI) than first-generation CBs; however, right PNI remains a concern.

METHODS One hundred consecutive patients with paroxysmal atrial fibrillation who underwent cryoablation were prospectively enrolled. Contrast-enhanced cardiac multidetector computed tomography (MDCT) was obtained pre-procedurally. PVI was performed with one 28-mm second-generation balloon using a 3-min freeze technique under electromyography guidance.

RESULTS In all, 377 of 392 (96.2%) PVs were isolated using a CB. In 9 (9.0%) patients, right PNI was observed during the ablation of the right superior PV (RSPV). All events occurred during freezing, except for 1 that occurred during thawing. Right peri-cardiophrenic bundles (RPCBs) were identified at the level of the RSPV on MDCT in 97 patients. In the logistic regression analysis, the distance from the RSPV ostium to the RPCBs (hazard ratio: 0.263; 95% confidence interval [CI]: 0.110 to 0.630; $p = 0.003$) was the sole predictor of PNI. The optimal cutoff point for the distance for predicting right PNI was 12.4 mm (sensitivity 96.6%, specificity 88.9%) with an area under the curve of 0.968 (95% CI: 0.922 to 1.000). The PNI resolved spontaneously within 1 day and 2 months in 6 and 2 patients, respectively, and at 8 months in the remaining patient, with delayed recognition of an electromyography decrease.

CONCLUSIONS Persistent right PNI is a rare complication during electromyography-guided, second-generation CB ablation. Electromyography should be monitored even during the thawing time. Pre-procedural MDCT might be useful for risk stratification of right PNI. (J Am Coll Cardiol EP 2016;2:508–14) © 2016 by the American College of Cardiology Foundation.

Radiofrequency (RF) catheter ablation is an established therapy for drug-resistant paroxysmal atrial fibrillation (AF) (1-3). However, point-by-point ablation is time consuming, and creating contiguous lesions is challenging. Balloon technologies have been introduced into AF ablation to overcome this issue, and previous studies have demonstrated that first-generation cryoballoon (CB) ablation was similarly effective as RF ablation (4) and more effective than antiarrhythmic drug therapy for paroxysmal AF (5). However, the prevalence of right phrenic nerve injury (PNI) (6) has been 11.2% (5) due to various factors, including anatomical close proximity (7). A recently introduced second-generation CB (8) had a better performance of pulmonary vein isolation (PVI) (9,10), which led to concern for a

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possible higher incidence of PNI than the first-generation balloon (9) because of the improved cooling of the distal balloon hemisphere. The high performance of the second-generation balloon enabled a single large balloon technique and shortening of the freezing time (e.g., a single 3-min freeze technique) (11). The efficacy of the 3-min ablation was not significantly different from that of the 4-min ablation technique in dogs when using the second-generation CB (12). Although electromyography-guided ablation (13,14) has been emerging as the standard technique to anticipate this complication, right PNI is still a concern of this procedure. The present study aimed to evaluate the incidence and pre-procedural predictors of any right PNI, including any transient PNI, in electromyography-guided, second-generation CB ablation.

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METHODS

STUDY POPULATION. This prospective study consisted of 100 consecutive patients with drug-refractory paroxysmal AF who underwent their first PVI using a second-generation CB (Arctic Front Advance, Medtronic, Minneapolis, Minnesota) in our institute. The PVI was performed with a single balloon technique using a 28-mm CB, and touch-up lesions were created with an 8-mm tip conventional cryocatheter (Freezor MAX, Medtronic). AF was classified according to the latest guidelines (3). 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.

MAPPING AND ABLATION PROTOCOL. All antiarrhythmic drugs were discontinued for at least 5 half-lives before the procedure. Transesophageal echocardiography was performed to exclude any atrial thrombi 1 day before the procedure. Contrast-enhanced cardiac multidetector computed tomography (MDCT) was performed to evaluate the cardiac anatomy before the procedure. The surface electrocardiogram and bipolar intracardiac electrograms were continuously monitored and stored on a computer-based digital recording system (LabSystem PRO, Bard Electrophysiology, Lowell, Massachusetts). The bipolar electrograms were filtered from 30 to 500 Hz. A 7-F, 20-pole, 3-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 using dexmedetomidine. A 100 IU/kg body weight of heparin was administered immediately following the venous access, and heparinized saline was also infused to maintain an activated clotting time of 250 to 350 s. A single transseptal puncture was performed using an RF needle (Baylis Medical, Montreal, Quebec, Canada) and 8-F long sheath (SL0, AF Division, St Jude Medical, Minneapolis, Minnesota). The transseptal sheath was exchanged over a guidewire for a 15-F steerable sheath (Flexcath Advance, Medtronic). A 20-mm circular mapping catheter (Lasso, Biosense Webster, Diamond Bar, California) 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 CB and to map the PV potentials. Complete sealing at the antral aspect of the PV was confirmed by a contrast medium injection. This was followed by a single freeze cycle of 180 s. No additional applications were performed once the isolation was achieved. The procedural endpoint was defined as the electrical PVI without dormant conduction, which was verified by the 20-mm circular mapping catheter. If electrical isolation was not achieved by a total of 3 CB applications per vein, additional touch-up freezes with an 8-mm tip conventional cryocatheter were performed within 2 min of each application.

MDCT SCANNING AND MEASUREMENT. Gated contrast-enhanced CT of the chest was performed with a 320-row MDCT scanner (Aquilion one, Toshiba, Otawara, Japan). A bolus of 50 to 100 ml of iodinated contrast media was injected intravenously at an injection rate of 3.0 to 4.5 ml/s using an automatic injector to regulate the iodine injection speed at 22.2 mgI/kg/s. Scanning was initiated with a 10-s delay after the signal density level reached a predefined threshold of 200 Hounsfield units in the left atrium. The following parameters were used for scanning: electrocardiographically-gated acquisitions; 120 kVp; 110 to 206 mAs; and 320- × 0.5-mm slice collimation. Scans were performed from the tracheal bifurcation to the diaphragm. Reconstructions were performed with a FC13 to generate 0.5-mm-thick slices, with a reconstruction interval of 0.5 mm with a workstation (SYNAPSE VINCENT, Fujifilm, Tokyo, Japan). All images were acquired in the supine position and reviewed independently by an experienced radiologist and cardiologist.

The ostium of the right superior PV (RSPV) was determined to be the point at which the vein

ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation
AUC = area under the curve
CB = cryoballoon
CI = confidential interval
CMAPs = compound motor action potentials
MDCT = multidetector computed tomography
PNI = phrenic nerve injury
PVI = pulmonary vein isolation
RF = radiofrequency
RPCB = right peri-cardiophrenic bundles
RSPV = right superior pulmonary vein