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Evaluation of a Strategy Aiming to Enclose the Pulmonary Veins With Contiguous and Optimized Radiofrequency Lesions in Paroxysmal Atrial Fibrillation

A Pilot Study

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ABSTRACT

OBJECTIVES This study sought to evaluate the safety and the acute and 1 year outcomes of an ablation protocol aiming to enclose the PV with a contiguous and optimized RF circle by targeting region-specific criteria for lesion depth assessed by ablation index and interlesion distance.

BACKGROUND Reconnections after pulmonary vein (PV) isolation are explained by insufficient lesion depth and/or discontiguity of radiofrequency (RF) lesions.

METHODS A total of 130 consecutive patients with paroxysmal atrial fibrillation (AF) underwent PV encircling using a contact force-sensing catheter. RF was delivered targeting interlesion distance ≤6 mm and ablation index ≥400 at posterior wall and ≥550 at anterior wall. Recurrence was defined as any AF, atrial tachycardia (AT), or atrial flutter (AFL) (AF/AT/AFL >30 s) on Holter electrocardiographs at 3, 6, and 12 months.

RESULTS Procedure and RF time per circle were 155 ± 28 min and 17 ± 5 min, respectively. Incidence of first-pass and adenosine-proof isolation were 98% and 98%, respectively. One short-lived transient ischemic attack was observed. At 12 months, single-procedure freedom from AF/AT/AFL was 91.3% in those 104 patients off antiarrhythmic drug therapy and 96.2% in those 26 patients on antiarrhythmic drug therapy. Single-procedure freedom from both AF/AT/AFL and antiarrhythmic drug therapy was 73.1%.

CONCLUSIONS This study suggests that an ablation protocol respecting strict criteria for lesion depth and contiguity results in acute durable PV isolation followed by a high single-procedure arrhythmia-free survival at 1 year. A prospective, multicenter trial is ongoing. (J Am Coll Cardiol EP 2018;4:99–108) © 2018 by the American College of Cardiology Foundation.

Single-procedure freedom from atrial fibrillation (AF) after radiofrequency (RF) pulmonary vein isolation (PVI) is ≈70% in patients with paroxysmal AF (1–3). PV reconnection (PVR) is the major determinant of AF recurrence during follow-up (4–6). The use of contact force (CF)-sensing catheters, allowing better control over energy delivery during point-by-point pulmonary vein (PV)

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ABBREVIATIONS AND ACRONYMS

ADT = antiarrhythmic drug therapy

AF = atrial fibrillation

AFL = atrial flutter

AI = ablation index

ALCI = ablation line contiguity index

AT = atrial tachycardia

AU = arbitrary unit

CF = contact force

FTI = force-time integral

ILD = interlesion distance

IQR = interquartile range

PV = pulmonary vein

PVI = pulmonary vein isolation

PVR = pulmonary vein reconnection

RF = radiofrequency

encircling, seems to improve freedom from AF to ≈80% (7–10). Nevertheless, acute and late PVR still occur, and data on 1-year outcome are not consistent across studies (11,12).

We recently showed that acute and late PVR after CF-guided PVI are explained by lack of contiguity and insufficient lesion depth, as assessed by ablation index, within the deployed RF circle (13–15). Ablation index is based on the experimental work of Nakagawa et al. (14). This index, incorporating CF, power, and time in a weighted formula, predicted lesion depth in the canine ventricle with high accuracy.

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The CLOSE protocol is a new approach aiming to enclose the PV with contiguous and optimized RF lesions by targeting an interlesion distance (ILD) ≤6 mm and ablation index (AI) ≥400 at the posterior wall and ≥550 at the anterior wall. We evaluated 1) the safety; and 2) the acute and 1-year single-procedure outcomes after CLOSE-guided PVI in 130 patients with paroxysmal AF.

METHODS

STUDY SUBJECTS. From August 2013, all patients undergoing CF-guided ablation for AF at the St. Jan Hospital Bruges are followed in a prospective database approved by the local institutional review committee. This database implies collecting patients' written informed consent, a detailed case report form of the procedure, and follow-up with Holter electrocardiographs (ECG) at 3, 6, and 12 months. In this paper, we present the analysis of 130 consecutive cases of PVI for paroxysmal AF using the CLOSE protocol.

CLOSE-GUIDED PVI. PVI was performed by 4 operators under conscious sedation or general anesthesia. In anesthetized patients, esophageal temperature monitoring (SensiTherm, St. Jude Medical, St. Paul, Minnesota) was performed. After transseptal puncture (SL0, St. Jude Medical), a Lasso catheter and CF catheter (Thermocool SmartTouch, Biosense-Webster, Diamond Bar, California) were positioned in the left atrium and calibration of CF and respiratory gating were performed. Then we predefined the RF circle around the PV (nephroid shape) on the 3-dimensional geometry (Carto System, Biosense Webster). Point-by-point RF delivery was performed during sinus rhythm aiming for a contiguous circle enclosing the veins. Real-time automated display of RF applications (Visitag, Biosense Webster) was used with predefined settings of catheter stability (3 mm for 8 s) and minimum CF (30% of time >4 *g*). RF was delivered (EP Shuttle ST-3077, Stockert, Freiburg, Germany) in power-controlled mode (without ramping) with 25 to 35 W (irrigation flow up to 30 cc/min). RF was delivered until an AI of ≥400 at the posterior wall/roof and ≥550 at the anterior wall (**Figure 1**). In case of dislocation, a new RF application reaching the AI target was applied. Maximal ILD between 2 neighboring lesions was ≤6 mm. In case of chest pain or intraesophageal T° rise >38.5°C during posterior wall ablation, RF delivery was stopped at an AI of 300. In the absence of first-pass isolation (i.e., no isolation after completing the circle), touch-up ablation was delivered until PVI. After PVI, we waited for 20 min, after which time, adenosine (dose resulting in atrioventricular block) was given 4 times (with the Lasso in its corresponding position). In case of reconnection during waiting time or during adenosine, the site of reconnection was located and treated with touch-up ablation until PVI was resistant to subsequent adenosine challenge. In case of (pre-) procedural documentation of typical flutter, cavotricuspid isthmus ablation was performed.

OFFLINE ANALYSIS OF CRITERIA TO ASSESS INTEGRITY OF THE DEPLOYED RF CIRCLE. Each procedure was analyzed offline. For each RF tag within the circle, we determined time of application (s), median delivered power (W), impedance drop (Δ-Imp, Ω), average CF (*g*), force-time integral (FTI) (*g*/s), and AI (arbitrary unit [AU]). Custom-made software was used to automatically determine the path of encircling, perimeter of the RF circle, ILD (center-to-center distance, mm), and ablation line contiguity index (ALCI). ALCI was developed as a criterion to algorithmically score the combination of contiguity and lesion depth (13).

To describe the overall quality for a given circle, we determined for each circle the median value of all analyzed ablation parameters. Four circles from 2 patients were not available for offline analysis.

To describe the weakest link in a given circle, we determined for each circle the minimal value for AI and the maximal value for ILD.

Follow-up. Complications were reported on the case report form and collected during follow-up. After ablation, anticoagulation and antiarrhythmic drug therapy (ADT) were continued. At 3 months, anticoagulation was continued according to stroke risk, whereas ADT was continued at the discretion of the treating physician. Clinical evaluation and ECG were performed at 1, 3, 6, and 12 months. Holter ECG was performed at 3 and 6 months (24 h) and 12 months (7 days) or in case of symptoms. Freedom from recurrence was defined as 1-year absence from