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Simultaneous pace-ablate during CARTO-guided pulmonary vein isolation with a contact-force sensing radiofrequency ablation catheter

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Abstract

Purpose Elimination of pace-capture along pulmonary vein isolation (PVI) lesion sets reduces atrial fibrillation (AF) recurrence in catheter ablation of paroxysmal AF. Pacing from the RF ablation electrode during RF application is prevented within the CARTO electroanatomic mapping system (Biosense Webster, Inc.) due to theoretical safety considerations. We evaluated a method of pacing the distal ablation electrode during RF application in the CARTO system, thus avoiding repeated activation and inactivation of the pacing channel and facilitating immediate recognition of pace-capture loss. We investigated the safety, feasibility, and utility of simultaneous pace-ablate (SPA) during AF ablation with the CARTO-3 system and a contact-force sensing RF ablation catheter.

Methods Safety of feasibility of SPA was evaluated in 250 patients undergoing first-time AF ablation. Frequency and regional distribution of pace-capture following PVI was evaluated in a cohort of 50 consecutive patients undergoing catheter ablation of paroxysmal AF.

Results SPA was successfully performed in all 250 patients without adverse event. At least one pace-capture site was noted in 22 of 50 PAF patients (44%), and pace-capture following PVI was most common at anterior and superior left atrial sites. There were 2.0 ± 3.3 RF applications during pacing via the distal ablation electrode per patient, and all lesions sets were successfully rendered unexcitable.

Conclusions Pace-capture along the completed PVI lesion set remains common despite utilization of contact-force sensing RF ablation catheters and automated lesion annotation. Simultaneous pace-ablate in AF ablation using the CARTO system may be safely used to render atrial lesion sets unexcitable.

Keywords Atrial fibrillation · Catheter ablation · Contact-force sensing · Radiofrequency ablation · Pacing · Electroanatomic mapping

1 Introduction

Pulmonary vein ectopy is primarily responsible for initiation and maintenance of atrial fibrillation (AF) [1], and pulmonary vein isolation (PVI) remains foundational to catheter ablation procedures for prevention of AF [2]. Conduction recovery of pulmonary veins is seen in nearly all patients who undergo repeat ablation [3–5]. Radiofrequency (RF) application guided by atrial tissue excitability has been shown to be helpful to identify potential conduction gaps in atrial myocardium [6, 7], and ensuring unexcitability along the PVI lesion set has been shown to markedly improve arrhythmia-free survival, compared with demonstration of bidirectional block alone [8]; however, the applicability of these findings to catheter ablation using a contact-force sensing RF ablation catheter is unclear.

RF application during pacing from the distal ablation catheter electrode allows immediate recognition of loss of pace-capture, thereby allowing limitation of RF application. Additionally, disabling the pacing channel for each RF application can be a cumbersome process that can increase procedure time. Pacing from the distal ablation electrode during RF application, however, has been disabled within the CARTO electroanatomic mapping system (Biosense Webster, Inc.) due to the theoretical risk of inducing ventricular fibrillation and microbubble formation [9]. We created a simultaneous pace-

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and-ablate (SPA) pacing channel that bypasses the RF generator disconnect mechanism in order to allow pacing from the distal bipolar ablation catheter electrode during RF application within the CARTO system. Of note, SPA in NAVx-guided (St. Jude Medical, Inc.) AF ablation procedures has been previously reported [6]. We sought to evaluate the safety, feasibility, and utility of SPA in CARTO-guided catheter ablation of AF using a contact-force sensing RF ablation catheter.

2 Methods

Safety outcomes were evaluated in 250 patients from two cohorts of patients undergoing first-time left atrial ablation using a contact-force sensing RF ablation catheter at our medical center: (1) 200 consecutive patients undergoing catheter ablation of persistent AF between May 16, 2014, and March 9, 2016, and (2) 50 consecutive patients undergoing catheter ablation of paroxysmal AF between October 4, 2015, and March 9, 2015.

2.1 Safety outcomes

Incidence of major complications within 3 months of catheter ablation was assessed in all patients. A major complication was defined as a complication that results in permanent injury or death, requires intervention for treatment, or prolongs or requires hospitalization for more than 48 h [2].

The incidence and regional distribution of pace-capture sites following pulmonary vein isolation and clinical recurrence was evaluated in the paroxysmal AF cohort. Antiarrhythmic drugs were stopped a minimum of five half-lives prior to the procedure in all patients at the time of ablation. After the ablation procedure, in-office visits were scheduled at 3, 6, and 12 months. At each visit, a medical history was obtained, a physical examination was performed, and a 12-lead ECG was obtained. A 2-week event monitor was obtained prior to each scheduled in-office visit. Any atrial arrhythmia greater than 30 s in duration or resting 12 lead ECG with sustained atrial arrhythmia after the 90-day blanking period was considered arrhythmia recurrence.

2.1.1 Electrophysiology study

All patients provided written informed consent. Data collection and analysis were according to protocols approved by the NYU Langone Medical Center Institutional Review Board. Surface and intracardiac electrocardiograms (ECGs) were digitally recorded and stored (EP Workmate, St. Jude Medical, Inc.). Nonfluoroscopic three-dimensional mapping was performed using the Carto 3 (Biosense-Webster, Inc.) mapping system.

A 7-F 20-polar catheter (Daig DuoDeca 2-10-2, St. Jude Medical, Inc.) was used with the distal poles (poles 1 to 10) placed within the coronary sinus and the proximal electrodes (poles 11 to 20) located along the tricuspid annulus in the lateral and inferior right atrium. For left atrial mapping and recording, a 10- or 20-pole circumferential PV mapping catheter (Lasso, Biosense-Webster, Inc.), or a five-spline mapping catheter with splines in star configuration and 1 mm electrodes (PentaRay Nav, Biosense-Webster, Inc.) was utilized. Left atrial anatomy three-dimensional anatomy and voltage mapping were created with manipulation of the multielectrode mapping catheter within the LA.

Ablation was performed with an open-irrigated, 3.5-mm tip, contact-force sensing radiofrequency (RF) ablation catheter (ThermoCool SmartTouch, Biosense Webster Inc.). Ablation lesions were generated in a power-controlled mode applying 20 to 35 W for 20 to 40 s per lesion during irrigation at a rate of 17 to 30 ml/min. Wide antral ipsilateral PV isolation was performed without empiric carinal lesions. All lesion markers within the EAM were created using automated lesion annotation (VisiTag, Biosense Webster, Inc.) with lesion marker criteria at the discretion of the operator. Additional ablation was performed in the persistent AF subgroup at operator discretion. All lesions sites were rendered unexcitable using the technique described below, and all sites of adenosine elicited dormant PV conduction were ablated.

2.1.2 Simultaneous pace-and-ablate

The pacing circuit was created by inserting a pin connector cable into the emergency stimulation socket pair above the "MAP" connector on the CARTO-3 patient interface unit (Fig. 1A). The remaining pin connector electrodes are inserted into an adjacent socket pair in the pin-box—we utilize the last pair in the box by convention (Fig. 1B). An arbitrarily named pacing electrode is created corresponding to the selected pin-box electrodes (Fig. 1C), thus overriding the RF generator-disconnect mechanism. Bipolar pacing was chosen based on data from a pre-clinical study that suggested greater predictive value of bipolar versus unipolar loss of pace-capture [10], and the use of bipolar pacing in a clinical trial that demonstrated the utility of rendering PVI lesion sets unexcitable [8]. Bipolar pacing between the two distal electrode pairs of the ablation catheter was performed with a pacing output set to 10 mA at a pulse width of 2 ms.

Pacing was performed during sinus rhythm to evaluate pace-capture along the entire lesion sets encircling the ipsilateral PVs. Catheter stability during pacing was validated by observing A contact-force consistently greater than 5 g with the contact-force vector directed orthogonally outwards from within the electroanatomic map of the LA in the three-dimensional mapping system. If atrial tissue was still excitable to pacing after PVI, additional ablation lesions were delivered until loss of PC was achieved at that location, as demonstrated in Fig. 2. In the paroxysmal AF subgroup, sites of pace-capture following PVI were marked within the EAM system.

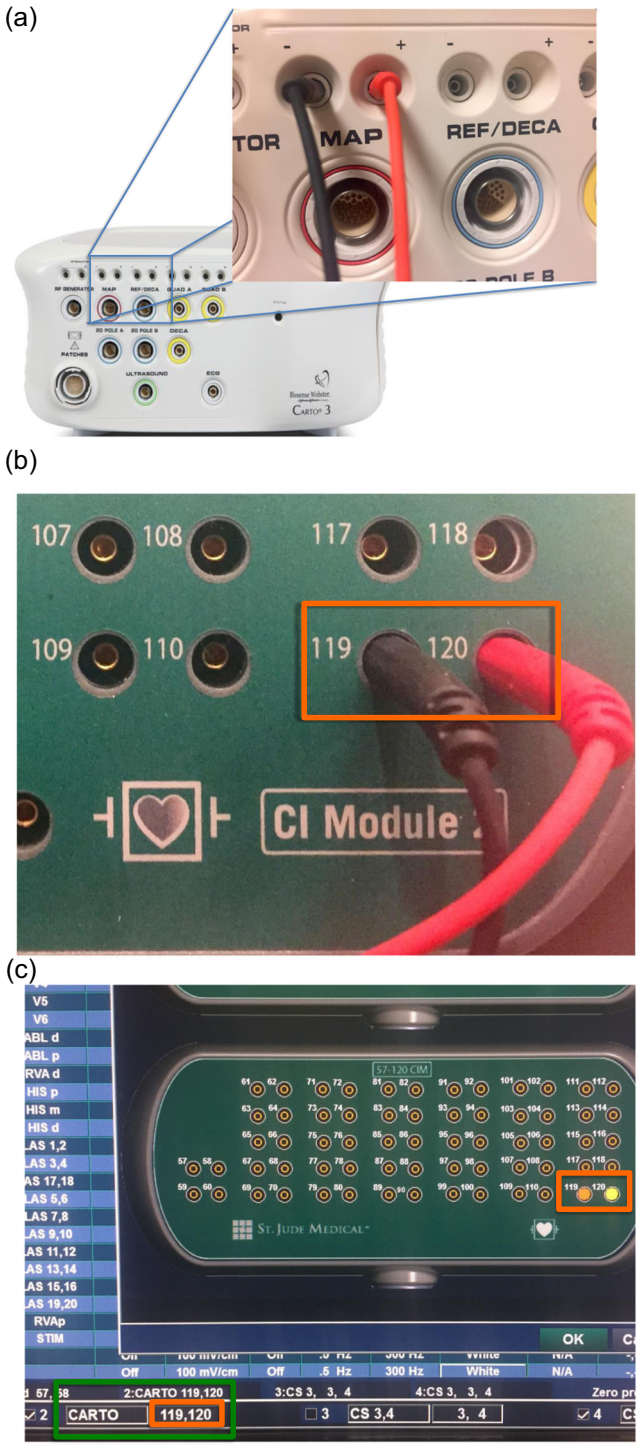

Fig. 1 Creation of simultaneous pace-and-ablate circuit. A pin connector cable is inserted into the emergency stimulation socket pair above the "MAP" connector on the CARTO-3 patient interface unit (**A**) and connected to an adjacent socket pair in the recording system pin-box (**B**, orange box). An arbitrarily named pacing electrode is created (**C**, green box) and assigned to the selected pin-box socket pair (**C**, orange boxes), thus overriding the RF generator-disconnect mechanism

The location of pace-capture sites was recorded and analyzed according the schema in Fig. 3.

2.2 Statistical methods

Continuous variables are expressed as the mean value ± SD. Continuous variables were analyzed using the Student's *t* test. A two-tailed *P* value < .05 was considered statistically significant.

3 Results

3.1 Safety outcomes

Major complications occurred in 3 of 250 patients (1.2%) and consisted of pericardial tamponade ($n = 1$), post-procedure complete heart block ($n = 1$), and femoral pseudoaneurym ($n = 1$). There was no incidence of SPA-related ventricular fibrillation or atrial fibrillation. There was no symptomatic cerebral embolism within 3 months of any procedure.

3.2 Pace-capture after pulmonary vein isolation

At least one pace-capture site was noted in 22 patients (44%), and in 27 lesion sets (27%) after PVI was achieved. Pace-capture was present more frequently at right PV sites than left PV sites (5.8% vs. 2.3%, $p < 0.001$). There were 2.0 ± 3.3 pace-and-ablate sites per patient (range 0–11), and all lesions sets were successfully rendered unexcitable. Pace-capture sites following PVI were most frequently seen at anterior and superior LA sites (Fig. 4). One year following ablation, 4 patients were lost to follow-up, 2 patients had recurrent AF, and the remaining 44 patients had no evidence of recurrent arrhythmia. Kaplan-Meier estimated arrhythmia-free survival at 1 year was 95.5%. Sites of pace-capture after PVI were present in both patients who developed recurrent atrial arrhythmia during follow-up, and neither patient has undergone repeat ablation.

4 Discussion

There were no complications related to simultaneous atrial pace-ablate in the 250 analyzed patients undergoing first-time RF ablation of atrial fibrillation. Atrial simultaneous pace-and-ablate was successfully performed in all patients in whom it was attempted, and all PVI lesion sets were rendered acutely unexcitable. Simultaneous bipolar pacing of the distal ablation electrode during atrial RF ablation within the CARTO-3 system using the technique presently described is easily implemented and appears to be safe.

The incidence of pace-capture after PVI in our cohort of PAF ablation using a contact-force sensing RF ablation catheter was only slightly lower than that reported by Steven et al. using an RF ablation catheter without contact-force sensing

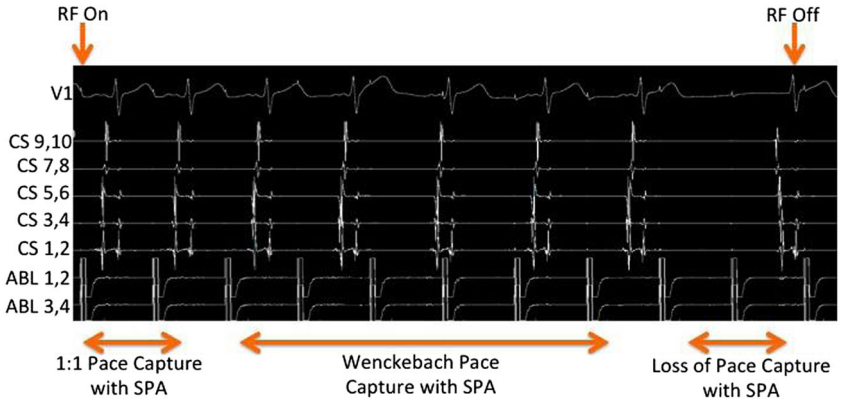

Fig. 2 Simultaneous pace-ablate along lesion set following pulmonary vein isolation. Capture at posterior aspect of left pulmonary vein isolation lesion set pacing at a cycle length of 500 ms. After RF application conduction time from pacing stimulus to CS catheter prolongs until capture is lost and sinus rhythm is re-established

[7] (44% vs. 50%); thus, assessment of excitability along the PVI lesion set remains relevant despite the utilization of contact-force sensing ablation catheters and automatic lesion annotation. In that prior study, pacing was discontinued during RF ablation "to avoid any interference with loss of pace-capture assessment along the encircling line" [7]. In the present study, with SPA, there was no difficulty assessing loss of pace-capture during RF application along the lesion set, and thus RF application could be limited accordingly. Pace-capture following PVI was most frequently seen at anterior and superior left atrial sites. Freedom from recurrent AT/AF at 1 year compared in our PAF cohort compared favorably to a reported pace-capture-guided cohort without contact-force sensing ablation catheters [8] (95.5% vs. 83%). Avoidance of repeated activation and inactivation of the pacing channel may improve operator willingness to assess lesion set excitability.

4.1 Limitations

The present study evaluated the use of atrial SPA in the context of identifying regions of pace-capture along a complete, contact-force and automated lesion annotation-guided lesion set. It is unclear if similar clinical outcomes could be achieved using SPA to render lesion sets unexcitable during initial lesion set creation. Further study is required to determine the optimal use of SPA in AF ablation.

The present study was performed using the EP Workmate stimulator and recording system, and the applicability of our findings using other stimulator and recording systems in conjunction with the CARTO mapping system is unclear. Based on the experience presented in this manuscript, we have implemented SPA with CARTO in conjunction with the Prucka, CadioLab recording system (GE Healthcare, Waukesha, WI) and EPS320 stimulator (MicroPace, Inc., Santa Ana, CA) in

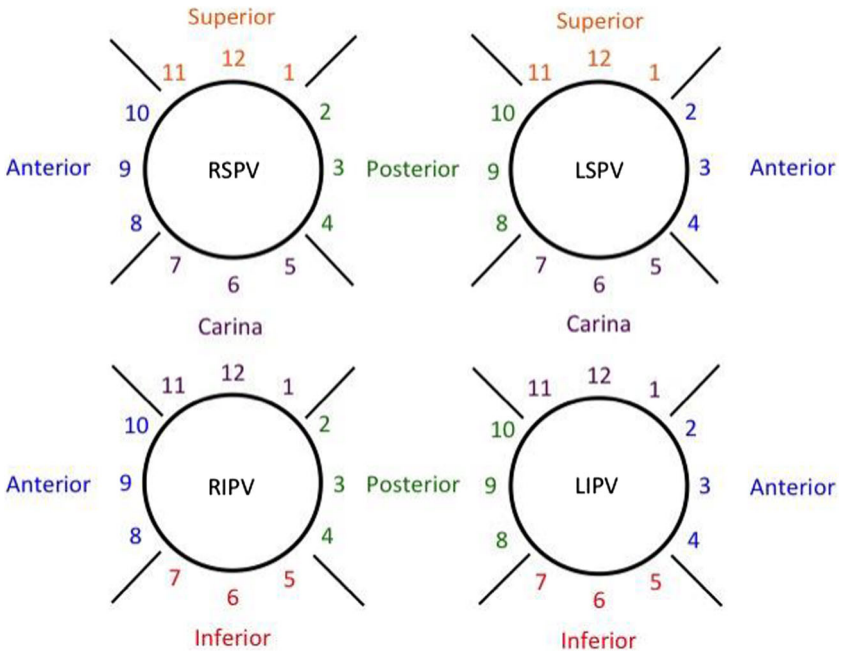

Fig. 3 Pulmonary vein schematic with location coding

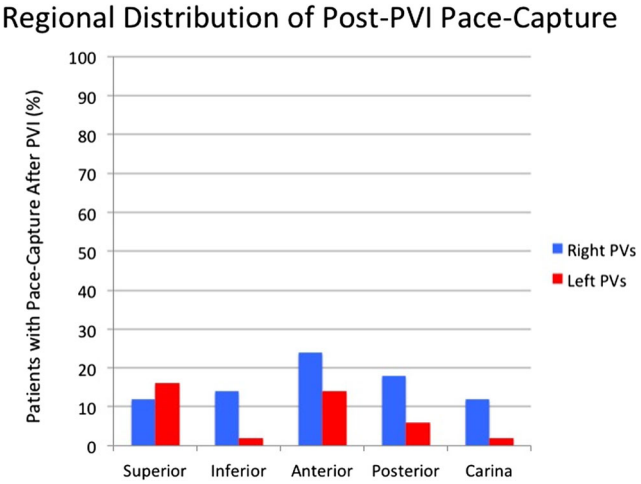

Fig. 4 Regional distribution of post-PVI pace-capture

over 20 atrial fibrillation ablation procedures at an affiliated medical center without acute adverse event. Additionally, The incidence and regional distribution of pace-capture sites following PVI were evaluated in patients in sinus rhythm with mechanical ventilation. It is unclear how measures to improve stability of catheter contact such as rapid pacing or JET ventilation would impact our findings. Finally, SPA was utilized in the present study for only atrial ablation, and thus, the safety of SPA for ventricular ablation requires further evaluation.

The manufacturers of the CARTO system issued a Field Notification concerning induction of a ventricular arrhythmia due to current leakage related to ventricular SPA in which the risk of ventricular arrhythmia related to ventricular SPA is reported to be 0.000086%, and the following recommendations are provided: "1. Do not ignore system indicators such as significant noise during ablation or an Error 7 message (a current leakage error available on some CARTO® 3 System configurations). Follow the IFU and stop using the system if current leakage is suspected. 2. Do not perform ablation while impedance readings from the ablation catheter are at extreme values beyond 250 Ω. Monitor the impedance during the procedure and avoid switching off the Impedance Cut-Off Setting on the RF generator. 3. Additionally, avoid ablation while pacing from the same electrode of the ablation catheter." [11]. In our experience of adhering closely to the first two recommendations, we were able to safely perform atrial SPA without adverse event.

Finally, the clinical outcomes reported in the present observational study require prospective evaluation relative to an appropriate comparator group. The intensity of arrhythmia monitoring in the present study compares favorably to that of recent clinical trials of AF ablation [12]; thus, the low incidence of arrhythmia recurrence in the PAF group generates a hypothesis that utilization of atrial SPA to render lesion sets unexcitable may improve clinical outcomes in AF ablation using a contract-force sensing RF ablation catheter.

5 Conclusions

Simultaneous pace-ablate in the CARTO system is safe and easily implemented. Pace-capture along the PVI lesion set remains common despite utilization of contact-force sensing RF ablation catheters, and rendering PVI lesion sets unexcitable using this technique for catheter ablation of paroxysmal AF resulted in favorable clinical outcomes in our study cohort. Further study is required to determine the optimal use of simultaneous pace-ablate and whether utilization of simultaneous pace-ablate improves procedural outcomes for catheter ablation of atrial fibrillation.

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