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ORIGINAL ARTICLE

Safety and efficacy of catheter ablation on patients with persistent atrial fibrillation by targeting repetitive activation patterns and focal impulses

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Abstract

Background: The study is intended to evaluate the acute and long-term effectiveness and peri-procedural safety in ablation of persistent atrial fibrillation (PsAF) using the CartoFinder algorithm guided ablation (CFGA) targeting on repetitive activation patterns (RAPs) and focal impulses (FIs) identified in dynamic maps.

Methods: This is a prospective, single-arm, multicenter study. A 64-pole multielectrode basket catheter was used for intracardiac global electrogram (EGM) mapping. The RAPs or FIs were repeatedly mapped and ablated for up to five iterations by the CartoFinder algorithm to achieve sinus rhythm (SR) or organized atrial tachycardia (AT), which were followed by PVI. All patients were followed up for 12 months after procedure.

Results: Sixty-four PsAF patients (age, 60.7 ± 9.1 years; male, 76.6%; median PsAF duration, 6.0 months) underwent CFGA on RAPs/FIs. Six patients (9.4%) reported primary adverse event (PAE) including groin hematoma (2), complete heart block (1), tamponade (1), pericarditis (1), and pseudoaneurysm (1). Repeated mapping and ablation on RAPs/FIs resulted in the cycle length (CL) increase from 191.0 ± 167.6 ms at baseline to 365.7 ± 296.7 ms in the LA and from 167.8 ± 41.6 ms to 379.4 ± 293.5 ms in the RA and 30.2% (19/63) AF termination to SR or organized AT. The 12-month arrhythmia-free and symptomatic AF-free rates were 60.9% and 75.0%, respectively. Patients with acute AF termination showed a higher 12-month arrhythmia-free rate (76.9%) than those without (50.0%, $p = .04$).

Conclusions: The study demonstrated that the CartoFinder algorithm can be used for global activation mapping during PsAF ablation. Patients with acute AF termination had a lower 12-month AF recurrence rate compared to patients without.

KEYWORDS
ablation, focal impulse, mapping system, persistent atrial fibrillation, repetitive activation pattern

Abbreviations: AAD, anti-arrhythmic drug; AF, atrial fibrillation; CF Map, activation map in the CartoFinder Module; CFGA, CartoFinder guided ablation; CL, cycle length; CVA, cerebrovascular accident; FAM, fast anatomical map; FIs, focal impulses; LA, left atrium; MI, myocardial infarction; PAEs, primary adverse events; PAF, paroxysmal atrial fibrillation; PsAF, persistent atrial fibrillation; PV, pulmonary vein; PVI, pulmonary vein isolation; RA, right atrium; RAPs, repetitive activation patterns; SR, sinus rhythm; ST, ThermoCool SMARTTOUCH Catheter; TTM, Transtelephonic Monitoring.

1 | INTRODUCTION

Since the introduction of catheter ablation as a treatment option for patients with atrial fibrillation (AF), improvements in device design and procedure workflow have significantly reduced safety risk while achieving a high success rate in paroxysmal atrial fibrillation (PAF). The 1-year success rates with pulmonary vein isolation (PVI) in patients with PAF ranged from 53%–87% after a single ablation procedure with radiofrequency catheter ablation technology.[1–5] However, much lower success rates (~60%) from multicenter trials were reported in patients with persistent AF (PsAF).[6–9] Different strategies beyond PVI have been explored to increase the long-term success rate of patients with PsAF.[6,10] However, improvement of the success rate has been limited.

The underlying mechanism perpetuating fibrillation in PsAF patients is not fully understood and is believed to be a key to improve the long-term success of patients with PsAF. Repetitive activation patterns (RAPs) and focal impulses (FIs) were reported to be an important mechanism for AF.[11] Studies showed that electroanatomic mapping and catheter ablation of RAPs and FIs, which were commonly distributed outside the PV area, had advantage in reducing recurrence of atrial arrhythmias over the conventional AF ablation approach.[12,13] Therefore, further development of mapping techniques and software to identify locations that sustain arrhythmia could improve the long-term outcome of patients with PsAF.

The CartoFinder algorithm (CARTOFINDER™, Biosense Webster, Irvine, CA) was developed to analyzes multiple simultaneous electric signals acquired with a multi-electrode catheter. The processed signals can be displayed as a unipolar activation map in the CartoFinder module (CF Map) during the procedure to facilitate the identification of RAPs or FIs (Figure 1). After dynamic presentation of unipolar activation signals on CF Map, RAPs/FIs were identified by experienced electrophysiologists. The primary purpose of this study was to evaluate the capability of CF Map in identifying RAPs or FIs and outcomes associated with RAPs/FIs ablation for treatment of PsAF.

2 | METHODS

2.1 | Study design and patients

This was a prospective, non-randomized, single-arm, open-label, multicenter study on patients with PsAF undergoing clinically indicated catheter ablations. The objective was to evaluate the acute and long-term effectiveness and peri-procedural safety using CartoFinder guided ablation (CFGA) of RAPs and FIs. The study was conducted in four centers in Belgium and the Czech Republic. Subjects aged ≥18 years and scheduled for clinically-indicated catheter ablation for treatment of drug-refractory PsAF were eligible for enrollment irrespective of prior ablation experience. Drug-refractory PsAF was defined as continuous AF that failed ≥1 class I or III anti-arrhythmic drugs (AADs) and sustained >7 days. Subjects with paroxysmal AF, long-standing PsAF (continuous AF for >12 months duration), or AF refractory to cardioversion (inability to restore to SR for ≥30 s) were excluded from the study.

The study was approved by the institutional review board and/or ethics committee at each participating center and was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonized Tripartite Guidelines for Good Clinical Practice (E4). All patients provided written informed consent prior to enrollment.

2.2 | Mapping and ablation procedure

Eligible subjects were prepared for ablation according to the hospital's standard protocol at the investigator's discretion. Anticoagulation therapy was recommended for 30 days before the ablation procedure. On the day or one day before the ablation procedure, all the patients were examined for left atrium (LA) thrombus using approved imaging modalities.

Eligible subjects were required to be in spontaneous or induced AF at the beginning of the procedure. The procedure began with the acquisition of a fast anatomical map (FAM) in the right atrium (RA) with the operator's choice of diagnostic catheter, where the multi-electrode basket-shaped mapping catheter (Constellation™, Boston Scientific) then was deployed. After optimal contact with the RA wall was confirmed, two sequences of 30-second intracardiac signals were recorded. Subsequently, the LA was accessed by transseptal puncture, and FAM and intracardiac signals were acquired in a similar fashion. Intracardiac signals acquired in the RA and LA were processed and analyzed to generate a dynamic CF Map. If RAPs/FIs in RA or LA were identified in the dynamic CF Map per physician's discretion, they were targeted for ablations with a contact-force radiofrequency catheter (THERMOCOOL SMARTTOUCH™ Catheter [ST], Biosense Webster, Irvine, CA). After RAPs/FIs ablations, if AF was converted into sinus rhythm (SR) or organized arrhythmia such as atrial flutter and atrial tachycardia (AT), no additional multi-electrode mapping was performed; instead, the subjects were treated for the organized arrhythmia.

If AF did not terminate or organize after all the RAPs/FIs were ablated, a new CF Map was generated by re-acquiring intracardiac signals in the RA and LA to identify and ablate additional RAPs/FIs. This mapping and ablation processes were repeated until AF was terminated or organized per operator's discretion, but not more than a total of five iterations (Figure 2). After completion of the CFGA session, all the patients underwent standard PVI and extra-PV ablations per physician's standard practice. Confirmation of complete entrance block was required for all ablated PVs. If a subject was still in AF after all these steps, cardioversion was allowed.

2.3 | Follow-up and rhythm monitoring

During the 3-month blanking period following the procedure, anticoagulation was strongly recommended and AAD management was

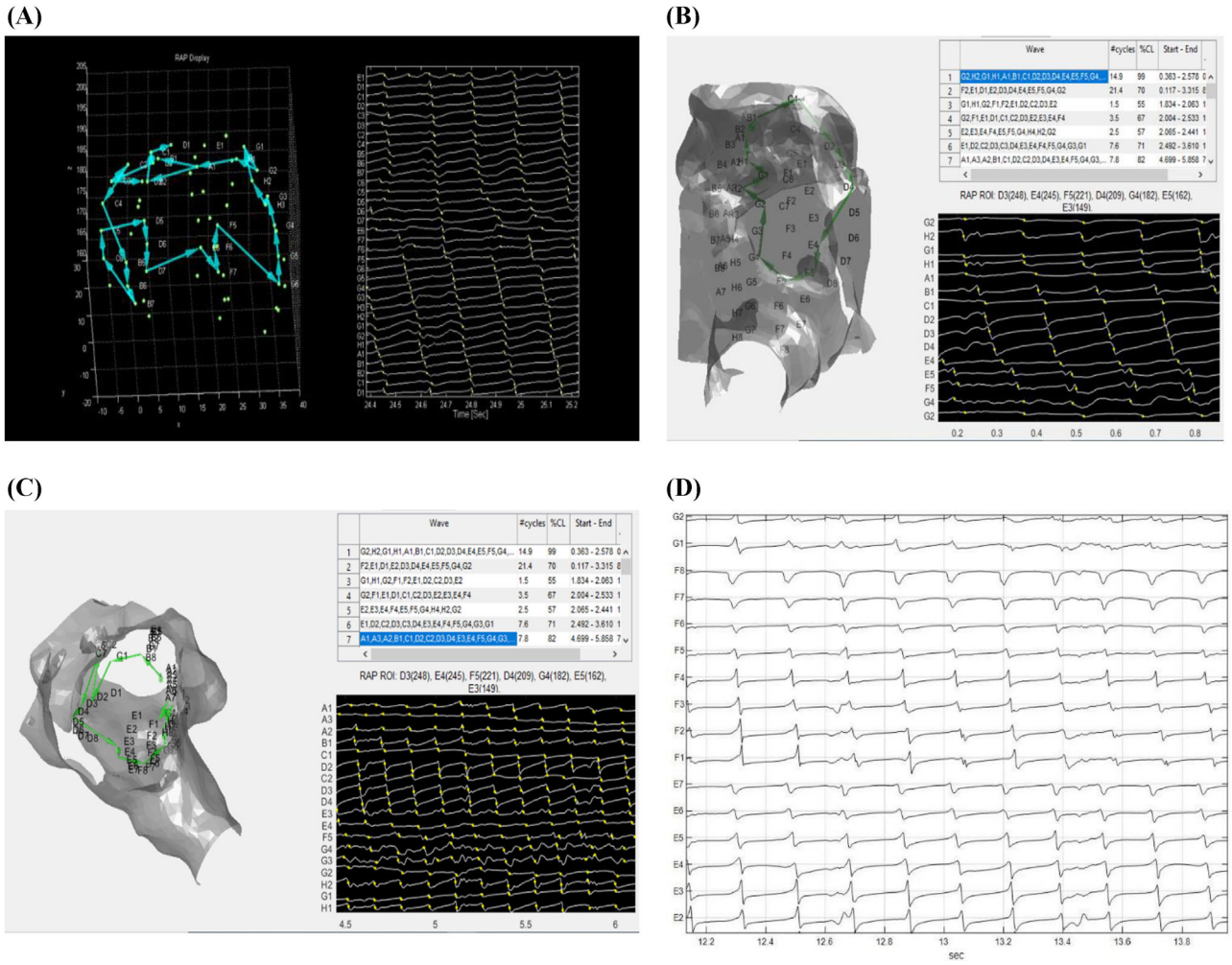


FIGURE 1 Electrograms (EGMs) showing RAPs and FIs. Panels A–C. EGMs during pansystolic RAPs with arrow plots representing the wave propagation along the catheter's electrodes. Panel D. Focal impulse, showing repetitive QS morphology on electrodes F7 and F8. FI, focal impulse; RAP, repetitive activation pattern. [Color figure can be viewed at wileyonlinelibrary.com]

conducted at physician's discretion. On the 7th day of the ablation procedure, all patients were contacted via telephone or in-clinic visits for assessment of any adverse events and medication changes. Thereafter, all subjects were scheduled for 3-, 6-, and 12-month followed up visits. Arrhythmia was monitored via 7-day Transtelephonic Monitoring (TTM) devices or Holter at the 3-month visit and before 6- and 12-month visits. Repeat ablation was performed as clinically indicated.

2.4 | Study endpoints

The primary effectiveness endpoint was the slowing of the overall mean AF cycle length (CL) achieved by CFGA. The primary safety endpoint was freedom from procedure-related primary adverse events (PAEs) at 7 days post-procedure including death, cardiac tamponade/perforation, myocardial infarction (MI), stroke/cerebrovascular accident (CVA), thromboembolism, transient ischemic attack, diaphragmatic paralysis, pneumothorax, heart block, pulmonary edema, pericarditis, and major vascular access complication/bleeding. Atrio-esophageal fistula and PV stenosis that occurred beyond 7 days post-procedure were also considered PAEs. The secondary endpoints included the proportion of patients with identified RAPs/FIs and the number of areas and locations of RAPs/FIs, acute success with AF termination into SR or organized arrhythmia following CFGA, and freedom from documented AF recurrence at 12 months post-procedure, which is defined as any occurrence of documented AF episodes ≥30 s during the post-blanking period (Day 91–365).

2.5 | Statistical analysis

The safety cohort comprised all enrolled patients who had the multi-electrode catheter inserted. The evaluable cohort consists of all enrolled subjects who underwent the CFGA. There was no formal hypothesis testing on the endpoint data. Descriptive statistics were used to summarize the baseline results and the endpoints. The 95% confidence intervals are presented using the t-distribution for continuous variables and the exact binomial distribution for categorical

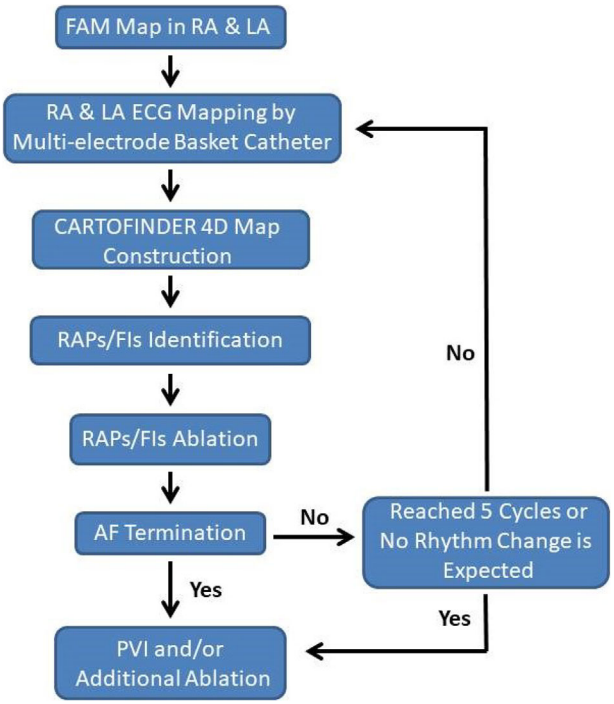


FIGURE 2 Study design: mapping/ablation procedure. AF, atrial fibrillation; FAM, fast anatomical mapping; FI, focus impulse; LA, left atrium; PVI, pulmonary vein isolation; RA, right atrium; RAP, repetitive activation pattern. [Color figure can be viewed at wileyonlinelibrary.com]

variables. The primary effectiveness endpoint was evaluated in the evaluable cohort. CL at baseline and after each cycle of CFGA were summarized descriptively. Freedom from documented AF recurrence at 12 months was determined using Kaplan–Meier estimates. All statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC).

3 | RESULTS

3.1 | Study population

The enrollment initiated in July 2015 and completed in January 2017. The study enrolled 70 patients in a sequential manner at each site, 6 of whom were excluded from the study before the mapping catheter was inserted due to consent withdrawal or failure to meet inclusion/exclusion criteria. In total, 64 patients had the mapping catheter inserted and underwent CFGA. All these patients completed the 12-month follow-up and comprised the safety and effectiveness cohort (evaluation cohort).

The baseline characteristics and medical history of the study population are presented in Table 1. The study subjects consisted mainly of male patients (76.6%, 49/64) with a mean age of 60.7 ± 9.1 years. On average, the evaluation cohort had 34.3 ± 43.0 months of symptomatic AF. The mean duration of PsAF was 11.4 ± 19.4 months. The mean duration of PsAF episode in the past 12 months was 10.3 ± 38.5 days. Sixteen patients (25.0%) had undergone PVI previously.

TABLE 1 Baseline patient characteristics.

Characteristics	Evaluation cohort ($N = 64$)
Age (years), mean ± SD	60.7 ± 9.1
Male, *n* (%)	49 (76.6)
Comorbidity, *n* (%)	
Atrial flutter	6 (9.4)
Congestive heart failure	2 (3.1)
Coronary disease	3 (4.7)
Myocardial infarction	1 (1.6)
Hypertension	36 (56.3)
Diabetes	6 (9.4)
Cerebrovascular accident/TIA	1 (1.6)
Past thromboembolic events	7 (10.9)
Other clinically significant medical history	36 (56.2)
NYHA class, *n* (%)	
I	34 (53.1)
II	21 (32.8)
III	8 (12.5)
IV	1 (1.6)
Baseline AAD medications, *n* (%)	
I/III at baseline	29 (45.3)
II/IV at baseline	37 (57.8)
Duration of symptomatic AF (months), mean (SD)	34.3 (43.0)
Duration of PsAF (months), mean (SD)	11.4 (19.4)
Duration of PsAF episode in past 12 months (days), mean (SD)	10.3 (38.5)
Previous PVI catheter ablation for AF, *n* (%)	16 (25.0)
LA dimension (mm), mean (SD)[a]	46.3 (5.1)
LVEF (%), mean (SD)[a]	57.8 (11.0)

Abbreviations: LA, left atrium; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PsAF, persistent atrial fibrillation; SD, standard deviation; TIA, transient ischemic attack.
[a]Transthoracic echocardiogram was only performed in 63/64 patients.

3.2 | Procedural characteristics

The mean procedure time was 272.6 ± 68.7 min, with a mean fluoroscopy time of 21.0 ± 9.6 min. The mean mapping time, ablation time, and RF application time were 64.0 ± 43.3 min, 85.2 ± 42.2 min, and 51.2 ± 19.8 min, respectively. Entrance block was confirmed in 96.9% (62/64) of subjects following PVI. Additional procedural data are shown in Table 2.

TABLE 2 Acute success and procedure characteristics.

Parameters	Evaluation cohort ($N = 64$)
Total procedure time (min), mean (SD)	272.6 (68.7)
Total fluoroscopy time (min), mean (SD)	21.0 (9.6)
Total mapping time (min), mean (SD)	64.0 (43.3)
CFGA mapping time (min), mean (SD)	52.7 (39.5)
Total average ablation time (min), mean (SD)	85.2 (42.2)
CFGA ablation time (min), mean (SD)	50.5 (24.8)
Total RF duration (min), mean (SD)	51.2 (19.8)
CFGA RF duration (min), mean (SD)	31.8 (17.7)
Acute procedure success, *n* (%)	26 (40.6)
Post-CFGA, *n/N* (%)	19/63 (30.2)
Post-PVI, *n/N* (%)	5/52 (9.6)
Post-further ablation, *n/N* (%)	2/36 (5.6)
Termination to NSR, *n* (%)	13 (20.3)
Termination to organized arrhythmia, *n* (%)	13 (20.3)

3.3 | RAPs/FIs identification and ablation

During the 1st CFGA cycle, an average of 2.8 ± 1.7 RAPs/FIs was identified per subject. The number of subjects with RAPs/FIs decreased following each CFGA cycle, from $n = 64$ at the 1st cycle to $n = 16$ at the 5th cycle. Overall, each patient had an average of 7.0 ± 4.5 RAPs/FIs mapped, 3.1 ± 1.9 in the RA ($n = 56$), and 4.4 ± 3.1 in the LA ($n = 61$). The RAPs/FIs in the RA were most often located on the lateral free wall (16.7% [29/174]), followed by the septal wall (12.1%, 21/174), posterior wall (10.9%, 19/174), and superior vena cava (10.3%, 18/174) (Table 3). In the LA, RAPs/FIs were most often located on the roof (14.8%, 40/271), followed by the posterior wall (11.1%, 30/271), left superior pulmonary vein (PV) (6.3%, 17/271), and anterior wall (5.9%, 16/271).

RAPs/FIs were ablated by creation of focal lesions (50.9%, 224/440), linear lesions (24.3%, 107/440), circumferential lesions (14.8%, 65/440), box lesions (0.5%, 2/440) or other miscellaneous lesions per operators' discretion (9.5%, 42/440).

3.4 | Acute procedural success

RAPs/FIs were identified in all 64 patients. In one patient, RAPs/FIs were ablated during PVI due to protocol deviation. The other 63 patients had 1–5 cycles of CFGA. Acute procedural success defined as conversion into SR or organized arrhythmia (AT or AFL) following CFGA was achieved in 19 of the 63 (30.2%) patients, with 11 in SR and 8 in organized arrhythmia. Additional ablations through PVI (5/64) and post-PVI ablations (2/64) resulted in overall AF termination in 26 out of 64 (40.6%) patients, 13 in SR, and 13 in organized arrhythmia (Table 2).

TABLE 3 RAPs/FIs identification, ablation, and distribution

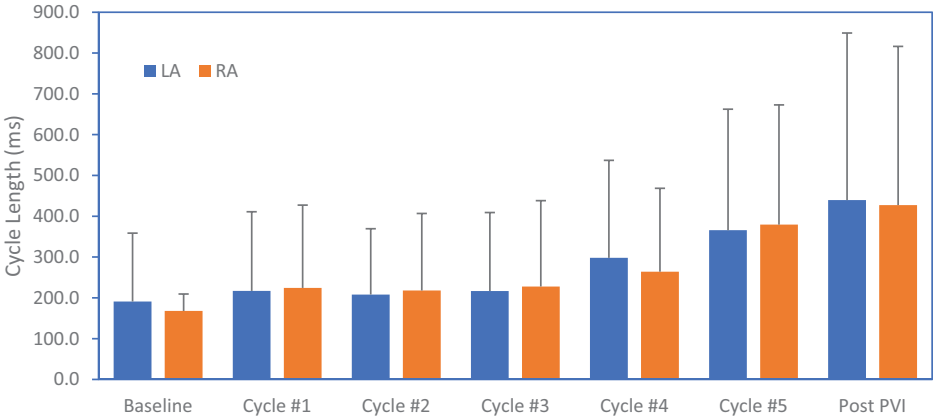
	RA	LA	Total
No. identified RAPs/FIs, mean (SD)			
Cycle #1, $n = 63$			2.8 (1.7)
Cycle #2, $n = 45$			2.3 (1.2)
Cycle #3, $n = 28$			2.3 (1.3)
Cycle #4, $n = 23$			2.2 (1.4)
Cycle #5, $n = 16$			2.8 (2.0)
No. RAPs/FIs ablated, mean (SD)			
Cycle #1, $n = 63$			2.8 (1.6)
Cycle #2, $n = 45$			2.3 (1.2)
Cycle #3, $n = 28$			2.3 (1.3)
Cycle #4, $n = 23$			2.2 (1.4)
Cycle #5, $n = 16$			2.8 (2.0)
Distribution of RAPs/FIs, *N*	174	271	445
Anterior wall, *n* (%)	10 (5.7)	16 (5.9)	26 (5.8)
CTI, *n* (%)	2 (1.1)		2 (0.4)
Mitral annulus, *n* (%)	1 (0.6)	10 (3.7)	11 (2.5)
Tricuspid annulus, *n* (%)	1 (0.6)		1 (0.2)
IVC, *n* (%)	1 (0.6)		1 (0.2)
SVC, *n* (%)	18 (10.3)		18 (4.0)
LCPV, *n* (%)		1 (0.4)	1 (0.2)
LIPV, *n* (%)		15 (5.5)	15 (3.4)
LSPV, *n* (%)		17 (6.3)	17 (3.8)
RIPV, *n* (%)		2 (0.7)	2 (0.4)
RSPV, *n* (%)		5 (1.8)	5 (1.1)
Lateral free wall	29 (16.7)	5 (1.8)	34 (7.6)
Lateral wall	10 (5.7)	4 (1.5)	14 (3.1)
Posterior wall	19 (10.9)	30 (11.1)	49 (11.0)
Roof		40 (14.8)	40 (9.0)
Septal wall	21 (12.1)	8 (3.0)	29 (6.5)
Other	62 (35.6)	118 (43.5)	180 (40.4)

3.5 | Primary effectiveness endpoint

Figure 3 shows the average AF CL in the LA and RA at baseline, after each CFGA cycle, and after PVI. The CL in both the LA and RA increased with the proceeding CFGA cycle. The major increases were observed after 4th and 5th CFGA cycles. In the LA, the average CL at baseline was 191.0 ± 167.6 ms, which increased by 175 ms to 365.7 ± 296.7 ms after five cycles of CFGA. In the RA, the average CL at baseline was 167.8 ± 41.6 ms, which increased by 211 ms to 379.4 ± 293.5 ms after five cycles of CGFA.

3.6 | Safety

PAEs occurred in six patients. One patient had pericardial effusion/cardiac tamponade during the ablation of mitral isthmus.



Mean Cycle Length (ms):

LA	191	217	208	217	298	366	440
RA	168	224	218	228	264	379	427

FIGURE 3 Mean cycle length of left and right atria at baseline, after each cycle of CFGA and after PVI ($n = 64$). The error bar above each column stands for standard deviation. CFGA, CartoFinder algorithm guided ablation; LA, left atrium; PVI, pulmonary vein isolation; RA, right atrium. [Color figure can be viewed at wileyonlinelibrary.com]

Following epicardial drainage, the subject fully recovered. Another patient had a complete atrioventricular conduction block requiring implantation of pacemaker. One other patient developed pericarditis the day after ablation and fully recovered in 5 days. The remaining three patients had vascular access complications including one groin hematoma requiring surgical intervention, one pseudoaneurysm requiring a stent placement, and one bleeding requiring blood transfusion.

3.7 | Clinical outcome at 12 months

Kaplan–Meier analysis indicated that 60.9% (39/64; 95% CI 49.3–72.6) and 75.0% (48/64; 95% CI 64.5–85.5) of subjects were free from all documented AF and symptomatic AF, respectively, at 12 months follow-up after a single procedure (Figure 4). Subjects with acute success had higher 12-month freedom from documented AF (76.9%; 95% CI 60.7–93.1) compared with those who did not achieve acute success (50.0%; 95% CI 34.9–65.1, $p = .04$) (Figure 5).

4 | DISCUSSION

This study assessed the utility of CF Map-guided ablation in PsAF patients by targeting RAPs/FIs. Acute AF termination was achieved in 40.6% of patients after beginning with CFGA, followed by PVI and extra-PV ablations. At 12 month, 60.9% and 75.0% of subjects were free from all documented AF/AT and symptomatic AF/AT, respectively, after a single procedure. Additional analysis showed that subjects with acute AF termination had 76.9% of 12-month AF-freedom rate, which was significantly higher than those without (50%). These results confirmed the findings from other studies that RAPs and FIs may be important extra PV drivers perpetuating the AF and can be effectively mapped with CartoFinder module.[11,14–17]

This study was conducted with an earlier version of the CartoFinder algorithm where RAPs/FIs were not automatically tagged as they currently are with the commercialized module today. Instead, they were identified by the operator based on unipolar activation map displayed on the Carto Shell. In order to maximally eliminate RAPs/FIs, the operators were allowed to perform up to five iterations of global mapping and ablation. On average, a total of 7.0 ± 4.5 RAPs/FIs per patient was identified and ablated with a mean procedure time of 272 min. In two other similar studies, ablation was performed after mapping 2.1 ± 1.0 and 1.3 ± 0.4 global AF drivers, respectively, with the basket catheter, which was slightly lower than the drivers identified in one cycle of mapping and ablation in the current study (2.8 ± 1.7 RAPs/FIs) and a similar study published earlier (2.8 RAPs).[11,15,18] Since the long-term arrhythmia-free rate achieved in the current study was similar to the other studies (70.6%,[15] 82.4%[18]), 1–2 cycle of mapping and ablation might be sufficient to achieve the same success rate, which might in turn reduce the procedure time.

Although in this study a CL increase of 6 ms was considered as an acceptable response to ablation, a CL increase of 30 ms or more were considered as a preferable value to reach as a response to ablation on a driver location.[18,19] During each of initial 3 cycles of CFGA, CL increases ranged from 11 to 25 ms in the LA, and 55 to 68 ms in the RA. At the end of the 5th cycle, the mean CL increased by 175 and 211 ms as compared to the baseline at both the LA and RA, suggesting a significant change in CL occurred after elimination of all RAPs/FIs through repeated CFGA cycles. However, prolongation of CL might not a good predictor of long-term success. A substudy of STAR AF II suggested that acute AF termination, not prolongation of AF CL, was the strongest predictor of long-term freedom from AF.[20] Current

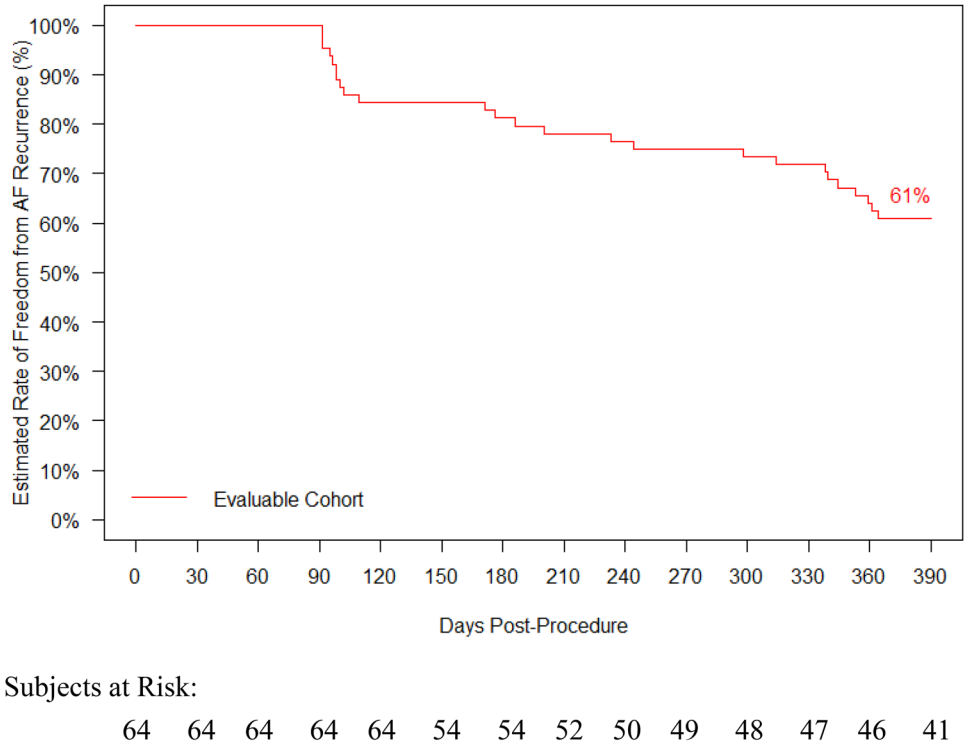


FIGURE 4 K-M analysis of time to documented AF recurrence at 12 months (evaluation cohort, $n = 64$). The percent value above the curve standards for the estimated rate of freedom from AF recurrence at 390 days post-ablation. The number of subjects at risk at each timepoint is provided below the K-M curve. AF, atrial fibrillation; K-M, Kaplan–Meier. [Color figure can be viewed at wileyonlinelibrary.com]

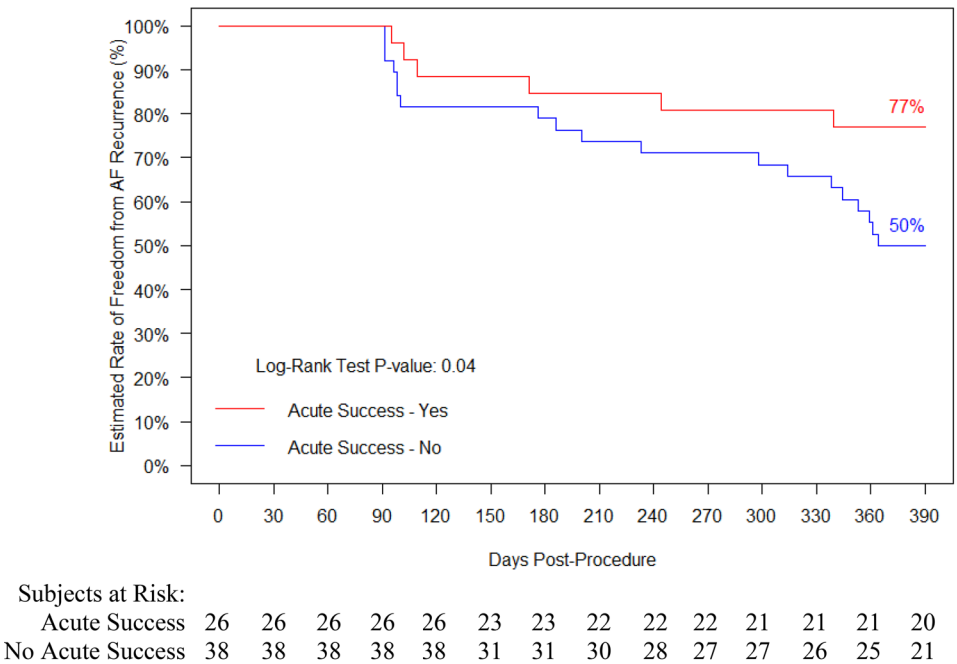


FIGURE 5 Patients with acute success had higher 12-month freedom from documented AF (evaluation cohort, $n = 64$). Log-Rand test was performed to compare the Kaplan–Meier estimated rates of freedom from AF recurrence between subjects with acute success and those without ($p = .04$). The percent values above the curves standard for estimated rates of freedom from AF recurrence at 390 days post-ablation. The number of subjects at risk at each timepoint is provided below the curve. AF, atrial fibrillation. [Color figure can be viewed at wileyonlinelibrary.com]

study also demonstrated that subjects with acute AF termination had significantly higher long-term success rate than those without.

According to a survey of in-hospital complications associated with catheter ablation of AF in the US between 2000 and 2010, the overall frequency of complication was 6.29% with a 1.53% vascular complication rate.[6,21] Considering the small sample size in the current study, the overall complication rate of 9.4% (6/64) was mainly attributable to the higher than usual vascular complication rate (4.7%). Long-procedure time requiring prolonged high ACT levels during the procedure could have contributed to the bleeding tendency. Prolonged arterial sheath placement might also have contributed to the incidence of vascular access complications.

The mechanisms perpetuating AF in subjects with PsAF are not fully understood. Many studies evaluating the benefit of additional ablation beyond PVI in PsAF patients have generated conflicting results.[8,22–27] A recent study demonstrated that tailored ablation targeting low-voltage areas is superior to PVI only for PsAF patients.[28] Another study also showed that PVI followed by ablation of regions of interests (ROIs) mapped by CartoFinder resulted in significantly lower AF recurrence rate than the control group undergoing PVI and extra-PV trigger ablations, suggesting that ROIs played important roles in perpetuating AF.[16] Current study followed a workflow by directly ablating RAPs/FIs before PVI and found that ablation of RAPs/FIs alone could lead up to 30.2% (19/64) of AF termination, suggesting that RAPs/FIs might indeed an important mechanism for AF in PsAF patients. The current study also supported the previous study that ablation of RAPs/FIs could improve the long-term rate of freedom from arrhythmia.[11] A mapping strategy based on electrogram (EGM) information and/or activation patterns during ongoing AF could potentially offer insights into mechanisms of ongoing AF and suggest targets for localized ablation.[16,17,29–31] In comparison to other panoramic mapping systems, the CartoFinder system created global activation propagation maps using local activation times obtained through annotation of atrial signals.[12,16,17,30] Combined with the use of recently developed high-density diagnostic catheters and identification of appropriate patients to avoid over-ablation, CartoFinder had the potential to provide an effective patient-specific ablation target based on high-resolution AF activation maps of the RA and LA.[11,16,17,32,33]

Study limitations included the fact that this was a non-randomized, non-blinded study. In addition, as the study was conducted with an earlier non-commercialized version of the study software, reproducibility of the identification of RAPs/FIs might have been impacted by individual operators' judgment, where the use of multiple independent operators may have potentially led to variance. Furthermore, there was potential under-sampling due to technological limitations that restricted data collection to 64-electrode samples in the LA or RA, sequentially.

5 | CONCLUSION

Our results demonstrated the feasibility of the CF mapping system for global activation mapping during PsAF ablation, with acceptable safety and 12-month success rates. Patients with acute success had significantly lower 12-month AF recurrence rate compared to patients without.

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CONFLICT OF INTEREST STATEMENT

Tom De Potter and Alan Bulava have nothing to disclose. Andrea Sarkozy has received compensation for services from Biosense Webster, Inc., and has served on the speaker's bureau for Biosense Webster, Inc., and Biotronik. Mattias Duytschaever has served on the speaker's bureau and is a consultant for Biosense Webster, Inc., and has received research support from Biosense Webster, Inc.

DATA AVAILABILITY STATEMENT

Johnson & Johnson Medical Devices Companies have an agreement with the Yale Open Data Access (YODA) Project to serve as the independent review panel for evaluation of requests for clinical study reports and patient-level data from investigators and physicians for scientific research that will advance medical knowledge and public health. Requests for access to the study data can be submitted through the YODA Project site at http://yoda.yale.edu.

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