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Contact Force-Guided Ablation Reduced Poor Contact Segments and Improved Acute Reconnection in Patients with Atrial Fibrillation

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Abstract

Background: There is a paucity of information regarding whether contact force (CF)-guided ablation improves the outcomes of pulmonary vein isolation (PVI) in patients with atrial fibrillation (AF) by achieving more optimal contact. We sought to assess whether real time CF-guided ablation has an impact on ablation parameters and acute pulmonary vein reconnection (PVR).

Methods: Left or right PVs were randomized to either CF-guided or blinded groups, and the order of CF blindness: CF-guided left PV/CF-blinded right PV, CF-blinded left PV/CF-guided right PV, CF-guided right PV/CF-blinded left PV, and CF-blinded right PV/CF-guided left PV groups. We compared CF parameters and acute PVR between segments ablated by CF-guided and CF-blinded strategies.

Results: Sixty patients with drug refractory symptomatic AF were included (paroxysmal AF 73%). CF-guided segments did not show significant differences in CF parameters compared to CF-blinded segments. However, CF-guided segments showed fewer segments with mean CF value <5 g than CF-blinded segments (4.3% vs. 12.4%, p<0.001). Forty-two patients showed acute PVR in 92 segments (8.5%). CF-guided PV segments showed lower acute PVR rate than CF-blinded segments (5.9% vs. 11.1%, p=0.011).

Conclusions: CF-guided ablation could reduce acute PVR after PVI by decreasing the number of segments with poor contact rather than increasing the mean CF during ablation. Better contact guided by CF information might help in improving the results of PVI. Further investigation will be needed to identify the association between the difference in acute reconnection and the long-term outcomes.

Introduction

Pulmonary vein isolation (PVI) is a fundamental procedure in atrial fibrillation (AF) ablation.[1] Permanent PVI is an important goal to improve outcomes after AF ablation and is related to the quality of energy delivery and transmural lesion formation. Contact between the tissue and ablation catheter is important when creating a transmural lesion, and ultimately creating a durable lesion.[2-4] Recent advancements in technology that can measure the contact between tissue and ablation catheter, represented as contact force (CF), could provide the operator with an accurate quantitative assessment of tissue contact in real time.[2,3]

Recent clinical studies using the CF reported that low contact force predicted PV reconnection (PVR).[5,6] These randomized clinical trials have been conducted to compare PVI using CF sensing catheters with PVI using non-CF sensing catheters.[7,8] These studies showed less AF recurrence or lower PVR rate and more optimal CF parameters in the CF-guided group. However, non-CF sensing catheters used in control group might have different catheter profiles compared to CF-sensing catheters, and there is no information of CF in the control group. Several studies used CF-sensing catheter to compare CF-blinded and CF-guided ablation.[9-11] CF-guided ablation showed a lower acute PVR rate, shorter procedure time, and additional touch-up ablation. Although the patients were randomized to either CF-guided or blinded group, there is still a possibility of patient bias. To avoid the patient bias, we randomized PVs, instead of patients, to CF-guided or CF-blinded ablation. We also randomized the order of

Key Words

Contact Force; Acute Pulmonary Vein Reconnection; Pulmonary Vein Isolation; Atrial Fibrillation

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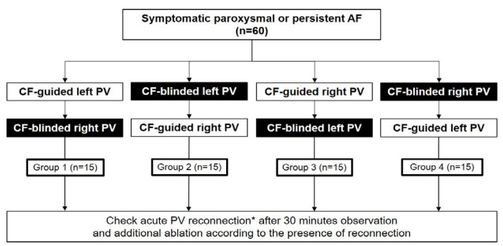

Figure 1: Study flow.

*acute pulmonary reconnection was defined as having spontaneous early reconnection (ER) of the left atrium to PV or dormant conduction (DC). If there was ER, additional ablation was performed. In the absence of ER, DC was assessed by intravenous adenosine bolus injection

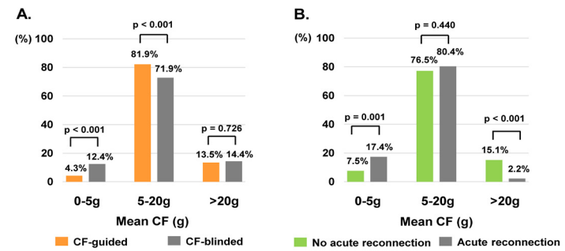

Figure 2: Distribution of mean CF of segments based on CF-guided strategies (A) and acute PV reconnection (B) .

*Denotes statistical significance p <0.05. All values are absolute.

CF blindness to avoid the effect of prerequisite learning of CF. The aim of this study, therefore, was to evaluate in a randomized fashion within the same patient with AF, the relationship between CF and acute PVR during catheter ablation.

Methods

This study is a multicenter prospective randomized controlled trial (NCT02924181). Four experienced electrophysiologists in 3 tertiary hospitals performed the procedure. Drug refractory symptomatic AF patients aged between 20 and 80 years were consecutively enrolled. Patients who had undergone previous PVI for AF were excluded. Patients with left atrium (LA) diameter > 50 mm were also excluded. The study protocol was approved by the institutional review boards at each institution (1505-020-669), and informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments (as revised in Fortaleza, Brazil, October 2013) or comparable ethical standards.

Pulmonary vein isolation procedure

Under conscious sedation, we performed double transseptal puncture and introduced two non-steerable long sheaths (SL1) into the LA Steerable sheath was not used in this study. Three-dimensional electroanatomic mapping of the LA and PVs was performed using the CARTO 3 system (BiosenseWebster, Inc., Diamond Bar, CA, USA). Using a Thermocool SmartTough irrigated CF-sensing RF ablation catheter (BiosenseWebster, Inc., Diamond Bar, CA, USA), a circumferential lesion set was created for PVI. Power was limited to 25 to 35 W at anterior and 20 to 30 W at posterior sites, and minimum ablation time per point was 20 seconds. Among different centers and operators, general procedure characteristics were applied in the same manner. Steerable sheath was not used in this study.

Study design and primary outcomes

To compare the CF-guided and CF-blinded ablation purer, we randomized two different strategies within each patient. Left or right PVs were randomized to either CF-guided or blinded, and the order of CF blindness was also randomized. Therefore, 4 different PVI protocols were identified: CF-guided left PV/CF-blinded right PV, CF-blinded left PV/CF-guided right PV, CF-guided right PV/CF-blinded left PV, and CF-blinded right PV/CF-guided left PV (Figure 1). Each patient received PVI according to the order of randomization. After 30 minutes observation after PVI, spontaneous early reconnection (ER) of the LA to PV was evaluated. If there was ER, additional ablation was performed. In the absence of ER, dormant conduction (DC) was assessed by intravenous adenosine bolus injection (6 to 12 mg intravenous bolus). If there was DC, additional ablation was performed. The site of ER and DC was identified by 18 predefined segments (Supplementary Figure 1). Then, we performed an AF induction test with high-dose isoproterenol and ended the procedure or performed additional linear ablation in patients with persistent AF. The primary outcome was acute PVR including ER or DC in each segment.

Safety outcome and long-term success during follow-up

The safety endpoint was defined as any procedure-related serious adverse events (e.g., tamponade, pericarditis, pericardial effusion, and perforation), which occurred during procedure or within 7 days following the index procedure or PV stenosis or atrioesophageal fistula which occurred >7 days post-procedure. Patients were followed up and evaluated with outpatient visits at 1, 3, 6, 9, and 12 months after the index ablation. Long-term ablation success was defined as freedom from recurrence of AF, atrial tachycardia (AT), or atrial flutter (AFL) at 12 months after the index procedure with the exclusion of the 3-month blanking period.

CARTO Visitag module

During CF-guided ablation, the CARTO Visitag module (Biosense Webster, Diamond Bar, CA, USA) displayed real time ablation parameters including power, impedance, ablation time, and CF at each ablation location, and operators targeted the CF from 10 to 20 g. Only CF information was not provided during CF-blinded ablation. Each ablation point was marked automatically on the 3-dimensional LA map with the following configuration: in the CF-guided PVs, a minimum of 7 seconds, stability of 2.5 mm, and 50% of ablation time higher than 7 g of force, in the CF-blinded PVs, only the stability and time criteria were applied. The maximal interlesion

Table 1: Baseline characteristics of the study patients and procedural parameters

	Total (n=60)	Group 1 (n=15)	Group 2 (n=15)	Group 3 (n=15)	Group 4 (n=15)	p-value
Age (years)	58.1±8.6	56.2±7.9	58.8±10.5	56.4±8.3	61.1±6.9	0.216
Gender (men)	37 (61.7)	8 (53.3)	13 (86.7)	11 (73.3)	5 (33.3)	0.014
Body mass index (kg/m²)	25.1±2.7	24.7±3.2	25.1±2.4	24.3±2.4	26.3±2.7	0.273
Paroxysmal AF	44 (73.3)	11 (73.3)	11 (73.3)	8 (53.3)	14 (93.3)	0.154
Hypertension	19 (31.7)	5 (33.3)	5 (33.3)	6 (40.0)	3 (20.0)	0.644
Diabetes	8 (13.3)	3 (20.0)	1 (6.7)	0 (0)	4 (26.7)	0.120
History of stroke	2 (3.3)	0 (0)	0 (0)	2 (13.3)	0 (0)	NA*
CHA_2DS_2-VASc score	0.9±0.9	0.8±1.0	0.7±0.7	0.9±1.1	1.0±0.9	0.796
LVEF (%)	61.0±5.9	61.1±6.4	61.1±7.5	61.7±4.2	60.0±5.5	0.941
LA size (mm)	42.2±4.4	41.1±3.6	43.2±4.0	41.5±5.6	43.0±4.1	0.353
Number of ablation points for PVAI	180.0±42.7	182.7±47.6	192.0±47.1	179.2±41.3	166.1±33.8	0.552
Additional ablation						
Cavo-tricuspid isthmus	16 (26.7)	4 (26.7)	5 (33.3)	4 (26.7)	3 (20.0)	0.958
LA roof line	9 (15.0)	3 (20.0)	3 (20.0)	2 (13.3)	1 (6.7)	0.808
LA anterior line	1 (1.7)	0 (0)	0 (0)	1 (6.7)	0 (0)	NA*
RA superolateral focal	1 (1.7)	0 (0)	0 (0)	0 (0)	1 (6.7)	NA*
Total procedure time (minutes)	237.0±67.6	251.6±63.0	268.0±87.1	200.7±40.1	227.9±57.7	0.082
Ablation time (minutes)	81.5±28.2	89.8±35.6	85.5±25.9	76.6±23.2	74.0±26.1	0.606
Fluoroscopic time (minutes)	28.3±12.3	31.1±17.8	30.5±12.4	28.2±8.5	23.5±7.3	0.239

Continuous variables, mean ± standard deviation, Categorical variables, n (%)
* P-value calculation was not available due to small number.
Abbreviation: AF, atrial fibrillation; LA, left atrium; LVEF, left ventricular ejection fraction; NA, not applicable; PVAI, pulmonary vein antrum isolation; RA, right atrium.

Table 2: Comparison of ablation parameters between CF-guided and CF-blinded segments

Ablation parameters	CF-guided segments (n=540)	CF-blinded segments (n=540)	p-value †
Number of ablation points	10.4±6.6	9.6±5.8	0.120
Minimum force (g)	7.4±4.8	7.3±5.4	0.812
Maximum force (g)	20.5±9.3	21.4±14.2	0.313
Mean force (g)	12.7±6.0	12.7±7.1	0.942
5g>	23 (4.3%)	67 (12.4%)	
5-20g	442 (81.9%)	388 (71.9%)	<0.001
20g<	73 (13.5%)	78 (14.4%)	
Minimum FTI (gs)	98.4±85.1	100.3±86.2	0.829
Maximum FTI (gs)	456.9±307.9	457.5±337.8	0.995
Mean FTI (gs)	228.5±139.0	224.9±149.1	0.804
Impedance drop (ohm)	8.5±4.1	8.4±4.2	0.687
Temperature (°C)	37.8±2.4	37.9±2.5	0.484
Ablation time by each point (sec)	18.2±7.1	18.2±6.7	0.983
Total ablation time (sec)	186.9±142.9	174.9±115.9	0.215

Mean ± standard deviation
†P-value by generalized linear mixed model

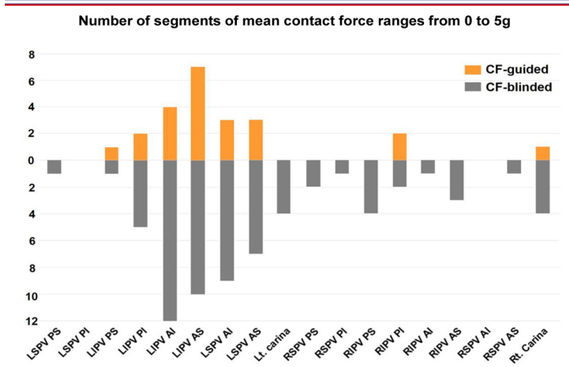

Figure 3: Distribution of segments with mean CF value less than 5 g according to CF-guided or CF-blinded ablation

distance between neighboring lesion was ≤4 mm. Retrospectively, the ablation parameters were extracted for analysis at each ablation point, including average CF, force time integral (FTI), ablation time, temperature, power, and delta impedance. Ablation parameters were analyzed by each predefined PV segment.

Statistical analysis

Categorical variables were presented as proportions and compared using Fisher's exact chi-square test. The Kolmogorov-Smirnoff test was performed to evaluate normal distribution for continuous variables. Normally distributed continuous variables were presented as mean ± standard deviation (SD) and compared using the independent t-test. Variables with non-normal distributions were compared with the Kruskal-Wallis test. We applied generalized linear mixed models for binary outcome (reconnected and non-reconnected) to compare the effect of ablation strategies (CF-guided and CF-blinded) and ablation parameters.[9] A two-tailed P<0.05 was considered statistically significant. All statistical analyses were performed using SPSS (version 20, IBM SPSS Statistics, IBM Corp, Armonk, NY).

Results

Baseline characteristics of study populations and procedural parameters

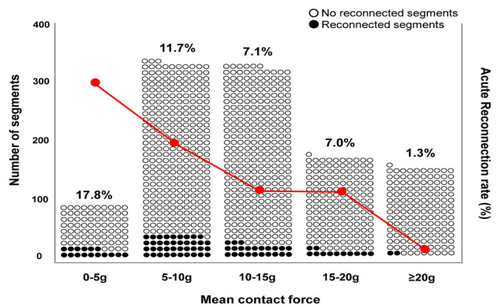

Figure 4: Distribution of segments according to mean CF and acute reconnection

From September 2015 to October 2016, a total of 60 patients (62% men; mean age 58 ± 9 years) were included in the analysis. Thirty patients were allocated to left PVs CF-guided and right PVs CF-blinded groups and 30 patients were allocated to right PVs CF-guided and left PVs CF-blinded groups. Baseline characteristics are summarized in Table 1. All PVs were completely isolated during the procedures.

Comparison of the ablation parameters, differences in contact force-guided versus contact force-blinded segments

Overall, CF-guided segments did not show significant differences in the CF parameters, the impedance drop, and total ablation time compared to CF-blinded segments (Table 2). However, CF-guided segments showed fewer segments with mean CF value less than 5 g than CF-blinded segments (4.3% vs. 12.4%, p<0.001) (Figure 2A). The distribution of segments with mean CF value less than 5 g according to CF-guided or CF-blinded ablation is summarized in Figure 3. Left inferior PV (LIPV) anterior and left superior PV (LSPV) anterior showed higher incidence of segments with mean CF value less than 5 g in CF-blinded group compared to CF-guided group (16.7% vs. 6.7%, p=0.016). For each segment, the mean and minimum CF, mean FTI, and ablation time are shown in Supplementary Figures 2 and 3.

Acute pulmonary vein reconnection

Forty-two patients (70%) demonstrated at least one ER or DC. Acute reconnection was observed in 92 segments of total 1080 segments (8.5%): ER in 55 segments (5.1%), DC in 28 segments (2.6%) and both ER and DC in 9 segments (0.8%). CF-guided segments showed a significantly lower acute reconnection rate compared to CF-blinded segments (5.9% vs. 11.1%, p=0.011). The CF-blinded group showed higher acute reconnection in RIPV PS segment compared to CF-guided group (20% vs. 0%, p=0.024). Acute PVR was more frequently observed in superior ridge (LSPV AI and LSPV AS) and left carina compared to other segments (16.7% vs. 6.9%, p<0.001). The distribution of acute reconnection by different regions according to CF-guided or CF-blinded is presented in Supplementary Figure 4.

Effect of contact force learning and the order of PV antrum isolation on contact force parameters and acute reconnection

We analyzed the segments ablated by CF-blinded according to CF learning: group A with CF-blinded ablation after CF-guided ablation (groups 1 and 3), and group B with CF-blinded ablation before CF-guided ablation (groups 2 and 4). There was no significant difference in CF parameters between the two groups except for ablation time (Supplementary Table 2). The mean ablation time per point in group A was longer than that in group B (18.8 vs. 17.5 sec, p=0.032). The proportion of segments with less than 5 g was not different between two groups (14.1% vs. 10.7%, p=0.296). There was no significant difference in acute reconnection rate during CF-blinded ablation between CF experienced and non-experienced group (13.3% vs. 8.9%, p=0.100).

We analyzed the effect of the order of PVI on CF parameters and acute reconnection. Groups 1 and 2 had started PV ablation from left

sided PV, whereas groups 3 and 4 had started from right sided PV ablation first. There was no significant difference in CF parameters between right side first and left side first groups. Also, there was no significant difference in the acute reconnection between right side first and left side first groups (7.4% vs. 9.6%, p=0.230).

Determinants of acute pulmonary vein reconnection, differences between "non- reconnected" and "reconnected" segments

We compared the ablation parameters between segments with and without reconnection (Supplementary Table 1). The mean CF was significantly lower in segments with acute reconnection compared to those without reconnection (9.7 ± 4.9 vs. 13.0 ± 6.6 g, p<0.001). Reconnected segments showed lower mean impedance drop and longer total ablation time compared to those without reconnection. Reconnected segments showed a higher incidence of segments with mean CF values less than 5 g than those without reconnection (17.4% vs. 7.5%, p=0.001, Figure 2B). The distribution of segments according to mean CF are depicted in Figure 4. Also, the acute reconnection rate according to the mean CF of each segment is summarized. The most common mean CF was 5 to 10 g (333 segments, 31%), followed by a mean CF of 10 to 15 g (326 segments, 30 %). Segments with a mean CF less than 5 g were least common, but the acute reconnection rate in this group was the highest (17.8%), whereas the segments with mean CF more than 20 g showed the lowest acute reconnection rate (1.3%). We found that there was an inverse relationship between the mean CF and acute reconnection rate.

Safety outcome and long-term success during follow-up

There were no procedure-related adverse events during study period. There was no pericardial effusion, cardiac tamponade, deaths, cerebrovascular accident, thromboembolism, atrioesophageal fistula, myocardial infarction, or PV stenosis that occurred within the study period. Overall, the 1-year freedom from AF/AT/AFL after a single procedure was 68.3%. Nineteen patients (32%) showed late recurrence after the 3-month blanking period. Group 1 showed the highest recurrence of AF/AT/AFL, but there was no significant difference in late recurrence among the 4 groups (46.7% in group 1, 33.3% in group 2, 13.3% in group 3, and 33.3% in group 4, log-rank

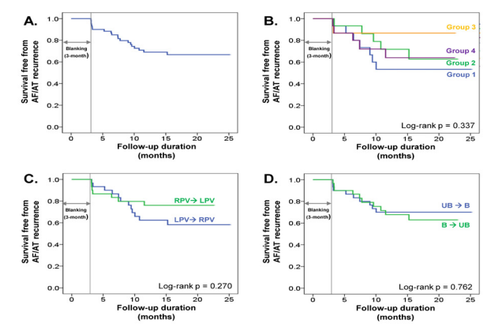

Figure 5: AF/AT free survival according to ablation strategies

A, Total population. B, 4 groups according to randomization. C, order of ablation of right-sided or left-sided PV first. D, order of ablation of CF blindness

p=0.337, Figure 5). Also, there was no significant difference in the recurrence of AF/AT/AFL according to the order of ablation (left PV first or right PV first) or the order of blindness (CF-guided first or CF-blinded first).

Discussion

This was a prospective randomized clinical study to compare the impact of CF monitoring on CF parameters and acute PVR in patients with drug-refractory AF. We found that (1) CF-guided PV isolation did not improve the average CF parameters, but showed fewer segments with mean CF less than 5 g, which resulted in having less acute reconnection than that in the CF-blinded group; (2) the prerequisite learning of real time CF did not have a significant impact on the CF-blinded ablation; and (3) there was an inverse relationship between the mean CF and the acute reconnection rate.

Previous studies reported diverse rates of acute PVR from 33 to 93%, and the importance of detecting acute PVR and re-isolation of reconnected segments to reduce AF recurrence.[12-14] The mechanism of PVR is suggested to be associated with non-permanent myocardial lesion formation, mainly related to tissue edema.[15] Therefore, it is important to deliver enough energy during the first time RF application to minimize the effect of tissue edema. Contact between the ablation catheter and tissue might be the key factor affecting the lesion size, because the passage of current into the target tissue would be influenced by this contact.[16] The real-time feedback of CF information is also important to physicians from the perspective of safety, because it could reduce the risk of perforation by avoiding involuntary overcontact.

Contact force-guide ablation strategy and acute pulmonary vein reconnection

The result of this study, that CF-guided PVAI reduced the incidence of acute PVR, is in line with that of previous clinical studies.[7,9,10,17] The reduction of acute PVR in the CF group might be due to the higher mean CF of the CF-guided group than that of the blinded group.[11] It is well known that acute PVR has an inverse correlation with the CF values.[9,18] However, the average CF of experienced operators who are blinded to real time CF values might not be lower because of the tactile feeling and movement on fluoroscopy, which could also give information related to tissue contact to the operators. In contrast to previous papers, the blindness of real time CF does not seem to affect the average of CF of the total ablation procedure. However, we found that the CF-guided ablation showed a lower incidence of segments with less than 5 grams of CF, which has close relationship with acute PVR. Although the optimal CF value to prevent acute PVR has not been standardized, recent guidelines recommend a minimal targeted CF of 5 to 10 g as reasonable, which is consistent with our study results.[19]

Learning effect on contact force parameters during contact force blinded ablation

In this study, prerequisite learning of CF values before CF-blinded ablation was not associated with lower acute PVR rate, since there was no significant difference in CF parameters between CF-blinded segments with and without CF learning. For experienced operator, CF learning immediate before CF-blinded ablation might not

affect procedure characteristics and acute outcome. Previous studies reported that the mean CF values of the right PV were usually higher than those of the left PV, so the order of ablation of the PV might have some confounding effects of next ablation of the PV on the CF parameters. However, we found that the CF parameters were not affected by the order of ablation of the PV.

Sites of acute pulmonary vein reconnection

The common sites of PVR were carina of right PV and ridge of left PV.[9,13,20] These results are consistent with our study results that right and left carina, LSPV AS and AI segments were the common sites of acute PVR. The ridge is known to have a tendency of catheter instability resulting in low CF, which might explain higher incidence of acute PVR than other regions. The optimal CF values to prevent PVR would have regional difference, highest at the bottom of the right PV and posterosuperior right PV segments (22 g) and lowest in the posteroinferior right PV segment.[18] In our study, the segments with less than 5 g were distributed in the left and right carina, and the ridge of left PV. Interestingly, we found that CF-guided ablation could reduce the number of segments with mean CF values less than 5 g, which could improve the acute outcomes of AF ablation.

Effects of contact force on recurrence of atrial fibrillation

In this study, all patients achieved acute procedural success with 100% of targeted PV being successfully isolated during index ablation procedure. After the 3-month blanking period, the 1-year AF/AT free survival was 68.3%, which is in line with previous studies using CF-catheters.[8] Although the acute PVR was reduced in the CF-guided ablation group, clinical outcomes did not significantly improve in the CF-ablation group compared to the blinded group.[11] TOCCASTAR study did not show a benefit on AF-free survival following CF-guided ablation compared to non-CF ablation.[8] However, those who met optimal CF (≥90% ablations with ≥10 g) showed better AF free survival than those who do not (75.9% vs. 58.1%, p=0.018). In this study, we could not evaluate the impact of CF on the recurrence of AF but found that the order of PV isolation and prerequisite learning of CF did not have significant impact of the results of AF ablation.

Study Limitations

First, although we found that the segments with CF-guided ablation showed significantly better outcomes in acute PVR compared to those with CF-blinded ablation, this study included only a small number of patients. Further larger size studies are needed to confirm whether CF-guided PVI shows consistently better efficacy and safety than CF-blinded PVI and to find which factors mostly affect these results. Second, although we randomized the PV, not the patients, to reduce the risk of patient bias, there is still a potential bias of anatomical difference of the left and right PV. However, we also randomized the order of ablation on right-side or left-side PV, and the CF-guided or CF-blinded ablation to reduce the risk of prerequisite learning of CF and anatomical differences of right and left PV. Third, operator bias would be another limitation of this study. We found the experienced operators would be influenced less by the real-time CF feedback. Also, they tried to avoid contacting less than 5g, which did not affect the mean value of CF. We speculate that CF-guided ablation might be more beneficial in less experienced operators. Fourth, according to previous study, larger interlesion distance (≥5 mm) also influenced delete acute PVR.[20] In this study, we achieved interlesion distance less than 4 mm by study protocol. Although interlesion distance is a critical factor for acute PVR, we preemptively controlled larger interlesion distance by prespecified study protocol. Mean interlesion distance of segments with acute PVR was 2.9±0.9 mm. Fifth, the additional ablation to eliminate PVR could have affected the long-term outcomes after ablation. We tried to find the impact of CF-guided ablation on acute PVR rather than to find the long-term recurrence of AF. Sixth, the information of CF parameters can be analyzed only if the points met the criteria of Visitag setting. Therefore, our study results are more appropriate for point-by-point ablation rather than the drag ablation technique. Also, the points which did not meet the criteria of Visitag setting could not be included in this analysis, which could also have affected the results of this study. However, we tried to stabilize the catheter as much as possible to reduce the number of points which do not meet the Visitag setting. Lastly, in this study, we could not evaluate the impact of CF on the long-term recurrence of AF because of the inherent limitation of the study design: allocating unilateral PVs in a patient by ablation strategy according to CF-guided or not, rather than allocating patients who applied CF-guided or not. Also, redo procedures were performed only in selected patients (16.7% of the total study population). Thus, the results that there was no significant difference in the rates of PV reconnection between CF-guided and CF-blinded PVs should be cautiously interpreted (Supplementary Results). Despite these limitations, the difference in acute reconnection may not guarantee the long-term outcomes either AF recurrence or PV reconnection in redo procedure.

Conclusions

CF-guided ablation could reduce acute reconnection after PVI in patients with AF by decreasing the number of segments with poor contact. Better contact guided by CF information might help in improving the outcomes of PVI.

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Link for Supplementary Materials

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