Circumferential Pulmonary Vein Ablation with Additional Linear Ablation Results in an Increased Incidence of Left Atrial Flutter Compared with Segmental Pulmonary Vein Isolation as an Initial Approach to Ablation of Paroxysmal Atrial Fibrillation

Running Title: Sawhney et al; CPVA is associated with LAFL

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This single center clinical trial was not registered on a publicly accessible website.
Abstract

**Background:** There has been growing concern that linear ablation is associated with an increased risk of iatrogenic arrhythmias in patients undergoing ablation for atrial fibrillation (AF). Therefore, we compared circumferential pulmonary vein ablation plus left atrial linear ablation (CPVA + LALA) to segmental pulmonary vein isolation (PVI) in patients with paroxysmal AF. **Methods and Results:** 66 consecutive patients with paroxysmal AF were prospectively randomized to PVI vs. CPVA + LALA (consisting of encircling lesions around the pulmonary veins, a roof line, and a mitral isthmus (MI) line with documentation of bi-directional MI block. All patients were seen at 1, 3, 6 and every 12 months after ablation, with 14-day continuous ECG monitoring every 6 months. At 16.4±6.3 months after one ablation procedure, 19 patients (58%) remained free of atrial arrhythmias after PVI vs. 17 patients (51%) after CPVA + LALA (p=0.62). After PVI, 14 patients had recurrent paroxysmal AF, whereas after CPVA + LALA, 8 patients had recurrent AF, 6 had atypical left atrial flutter (LAFL), and 2 had both AF and LAFL (p=0.32 between PVI vs. CPVA + LALA for AF, but p=0.002 for LAFL). 28 patients (85%) remained arrhythmia free after 1.3±0.5 PVI procedures vs. 28 patients (85%) after 1.4±0.6 CPVA + LALA procedures (p=NS). Fluoroscopy time was longer after CPVA + LALA vs. PVI (91 vs. 73 minutes, p= 0.04). **Conclusions:** As an initial ablation approach in patients with paroxysmal AF, more LAFL occurred after CPVA + LALA and fluoroscopy times were longer compared to segmental PVI.

**Key words:** atrial fibrillation, pulmonary vein isolation, circumferential pulmonary vein ablation, linear ablation, left atrial flutter
Introduction

Although circumferential pulmonary vein ablation (CPVA) is commonly preformed as an initial approach to atrial fibrillation (AF) ablation, and randomized trials have shown an improvement in AF ablation success rates with additional left atrial linear ablation (LALA) at the LA roof or mitral isthmus (MI)\(^1,2\), there has been a growing concern about the potential proarrhythmic effect of additional ablation,\(^3,4\) particularly with regard to the occurrence of atypical left atrial flutter (LAFL).

Therefore, we conducted a randomized, prospective study comparing the efficacy of segmental pulmonary vein isolation (PVI) vs. CPVA + LALA at the LA roof and MI (with documented bidirectional MI block), as an initial approach to ablation in selected patients with paroxysmal AF.

Methods

**Patient population:** There were 66 consecutive patients enrolled in this study with symptomatic, medically refractory paroxysmal AF, who underwent catheter ablation for the treatment of their AF, and agreed to be prospectively randomized with regard to the initial ablation strategy. For the purpose of this study, paroxysmal AF was defined as self-terminating AF of < 48 hours duration. Exclusion criteria included a previous ablation procedure, permanent or persistent AF, refusal to provide informed consent, contraindication to anticoagulation, myocardial infarction or cardiac surgery within 3 months of enrollment, and intracardiac thrombus identified on trans-esophageal echocardiogram. In those patients already on warfarin, it was held for five days before ablation, and patients were bridged with enoxaparin 1mg/kg SQ bid up to the night before the ablation procedure. All antiarrhythmic drugs were held for five half-lives before...
ablation. The Human Studies Committee at the University of California, San Diego approved the study protocol, and all patients provided written and informed consent.

**Catheter placement for ablation:** Transseptal catheterization was performed using standard Brokenbrough needle technique with intracardiac ultrasound (ICE) and fluoroscopic guidance. Two 8 French SL1 sheaths were placed in the left atrium, through which an 8 mm tip (standard curve) ablation catheter (Blazer, Boston Scientific, Inc., Natick MA, or Navistar, Biosense-Webster, Inc., Diamond Bar, CA) and a circular twenty-pole Lasso™ catheter (Biosense Webster, Inc) were placed for mapping the PVs. Prior to transseptal puncture, unfractionated heparin (10,000-15,000 Units) was administered as a bolus followed by a continuous intravenous infusion to maintain an ACT >350 seconds throughout the procedure, as measured every 15 minutes.

**Method for Segmental PVI:** Each pulmonary vein (PV) was mapped using the Lasso™ catheter placed at the ostium using fluoroscopic, 3D mapping (ESI NavX, St. Jude Medical, Inc.) and ICE guidance, to record PV potentials (during distal coronary sinus pacing for the left PVs and during sinus rhythm for the right PVs). PVI was performed by sequential application of radiofrequency energy at sites proximal to the Lasso™ catheter (Figure 1), where the earliest bipolar PV potentials were recorded, until all PV potentials were eliminated. Radiofrequency energy was delivered in a temperature controlled manner (EPT-1000 or Maestro, Boston Scientific, Inc., Natick, MA, or Stockert 70 RF, Biosense-Webster, Inc., Diamond Bar, CA, radiofrequency generators, respectively) at a maximum power of 50 Watts, with a target temperature of 55°C, for up to 30 seconds at each location. The end point of ablation was elimination of all PV potentials and demonstration of entrance and exit block into and out of the pulmonary
veins by pacing. Ablation of the cavo-tricuspid isthmus (CTI) was performed in all patients after PVI, using the 8 mm tip catheter at a maximum power of 100 watts and maximum temperature of 60°C, with documentation of bidirectional CTI block. After ablation, isoproterenol was infused intravenously at 20 mcg per minute to elicit any non-pulmonary vein triggers and confirm persistent PVI. Persistent PVI was also confirmed 30 minutes after initial documentation of PVI. Ablation was repeated as described above in the event of any evidence of PV reconnection during this waiting period.

**Method for CPVA + LALA:** A 3D geometry of the LA was either constructed using an electroanatomical mapping system (CARTO, Biosense Webster Inc., Diamond Bar, CA or ESI NavX, St. Jude Medical, St. Paul, MN), or a 3D CT image of the LA and PVs was imported and registered in the mapping system prior to ablation (CartoMerge™, Biosense Webster, Inc. or Fusion™, St. Jude, Inc. software). Radiofrequency energy was applied at a maximum power of 50 watts and maximum temperature of 55°C for up to 30 seconds at each location (EPT-1000 or Maestro, Boston Scientific, Inc., Natick, MA, or Stockert 70 RF, Biosense-Webster, Inc., Diamond Bar, CA, radiofrequency generators, respectively) to encircle the left and right PVs at least 10 mm proximal to the PV ostia. Radiofrequency energy was applied at each location around the PVs until the maximum local electrogram amplitude was < 0.5 mV. Linear ablation was then performed at the LA roof connecting the two encircling lesions until maximum local electrogram amplitude was < 0.5 mV along the entire line, and at the MI, from the mitral valve annulus up to the left encircling lesion (Figure 2). Following ablation, pacing from the left atrial appendage and the proximal coronary sinus was preformed to document bidirectional MI block. If block was not achieved, ablation was performed within the
coronary sinus with an 8 mm tip catheter at a maximum power of 50 watts and maximum
temperature of 55ºC, with the catheter tip deflected toward the atrium, as the catheter was
gradually withdrawn from the distal to proximal coronary sinus, until bidirectional MI
block was achieved. The Lasso™ catheter was then placed in all four PVs to confirm
PVI. If PVI was not complete, ablation was performed around the antrum along the
CPVA lines or at the carina between the PVs until all PV potentials were eliminated.
Isoproterenol was infused intravenously at 20 mcg per minute to elicit any non-
pulmonary vein triggers and confirm persistent PVI. Persistent PVI was also confirmed
30 minutes after initial documentation of PVI. CTI ablation was then performed in all
patients with documentation of bidirectional isthmus block.

**Monitoring During Ablation:** Esophageal position and temperature were
monitored during all left atrial ablations using a nasogastric tube containing a temperature
probe continually repositioned in the esophagus at the level of the ablation catheter in
order to avoid any temperature rise above 38ºC. Pacing was performed through the
ablation catheter at all locations prior to ablation in the anterior right PVs at 10 mA
output and 10 msec pulse duration to ensure lack of phrenic nerve capture.

**Post-ablation Care:** After ablation, patients were hospitalized overnight and
administered enoxaparin 1 mg/kg SQ every twelve hours starting approximately six hours
after sheaths were pulled and hemostasis achieved. Patients were discharged on the
antiarrhythmic drug regimen they had been on prior to ablation (most commonly a class
IC drug) and were maintained on this medication for up to 90 days at the discretion of
their physician, after which it was discontinued.
Follow-Up: After discharge, all patients were seen in the University of California, San Diego outpatient arrhythmia clinic at 1, 3, 6, 12 and 24 months after ablation and at 12 month intervals thereafter. Prior to the six and twelve month follow-up visits, patients underwent 14-day continuous mobile outpatient telemetry monitoring to evaluate for recurrence of symptomatic or asymptomatic atrial arrhythmias. In addition, additional event monitors were provided to any patient reporting symptoms suggesting recurrent arrhythmia. No patients were lost to follow up. Because atrial arrhythmias that occur early after an ablation procedure may be transient, atrial arrhythmias that occurred within the first three months were excluded from the analysis as recommended by the HRS consensus guidelines. Repeat ablation was performed if the patient had recurrent symptomatic atrial arrhythmias off antiarrhythmic medications after the 90 day blanking period after their initial ablation.

Repeat Ablation in the Segmental PVI Group: In those presenting with recurrent paroxysmal AF, segmental PVI was repeated in a manner identical to that of the first procedure, but only in PVs that had reconnected. When repeat PVI was completed, isoproterenol was infused in a dose of 20mcg/minute and if ectopic atrial beats arising from non-pulmonary vein foci were induced, these were also ablated. Following left atrial ablation, the CTI was mapped to confirm persistence of bi-directional block. If conduction across the CTI had recurred, repeat ablation was performed until bi-directional block was achieved.

Repeat Ablation in the CPVA + LALA Group: In those presenting with recurrent paroxysmal AF, CPVA + LALA was repeated in a manner identical to that of the first procedure, with documentation of PVI, reduction of electrogram amplitude to...
<0.5 mV along the entire length of each line, and documentation of bidirectional MI block. In patients who developed LAFL, a combination of 3-D electroanatomical activation mapping and pacing entrainment was used to define a critical isthmus to be ablated in the reentrant circuit to eliminate all spontaneous or pacing induced macro-reentrant atrial flutters. LAFL was diagnosed by demonstrating the majority of the tachycardia cycle length within the LA during 3-D activation mapping, and pacing entrainment identifying a critical isthmus with a post-pacing interval within 20 ms of the tachycardia cycle length. Catheter ablation of all spontaneous or pacing induced LAFL was attempted until there was restoration of sinus rhythm, and LAFL could no longer be induced by rapid atrial pacing at pacing cycle lengths down to 2:1 atrial capture.

**Statistical Analysis:** All continuous variables are reported as the mean ± 1 standard deviation and were compared using student’s t-test. Categorical variables were compared by chi-square or Fisher’s exact method, as appropriate. Survival curves and event rate were calculated according to the Kaplan-Meier method, and a long-rank test was preformed to compare curves. A two-tailed p value < 0.05 was considered to be statistically significant. Statistical analysis was performed using SAS software version 9.1 (SAS Inc. USA).

**Results**

**Clinical Characteristics of the Patients Enrolled:** The study population consisted of sixty-six patients with paroxysmal AF who were prospectively randomized to undergo either segmental PVI (n=33) or CPVA + LALA (n=33), as described in the methods section above. The mean age was 58±11 years, mean duration of atrial fibrillation 5.6±5.3 years, mean ejection fraction 61±5%, and mean left atrial size 3.6±
0.4mm. Forty-eight patients were male, and 37 had a diagnosis of hypertension. The clinical characteristics of the patients were not significantly different between the two groups (Table 1).

**Follow up:** All patients were seen in the University of California, San Diego outpatient arrhythmia clinic at 1, 3, 6, 12 and 24 months after ablation and at 12 month intervals thereafter. Prior to the 6, 12, and 24 month follow-up visits, all patients underwent 14-day continuous mobile outpatient telemetry monitoring to evaluate for recurrence of symptomatic or asymptomatic atrial arrhythmias. No patients were lost to follow up. Twelve patients were followed up to 12 months, 44 patients were followed between 12-24 months and 10 patients were followed more than 24 months. There was no significant difference between two groups in the length of the follow-up (p=0.44).

**Procedural Results:** In the segmental PVI group, all PVs were isolated in all patients. In the CPVA + LALA group, PVI was achieved in all patients and bi-directional MI block was achieved in 30 of 33 patients (91%). In 97% (n=29) of patients in whom MI block was achieved, ablation was required within the coronary sinus to achieve bi-directional block. In three patients, bi-directional MI block could not be achieved.

**Clinical Outcome Following the Index Ablation:** After a mean of 16.4 ± 6.3 months, after one procedure, 19 (58%) patients in the segmental PVI group were free of atrial arrhythmias off all antiarrhythmic therapy, as compared to 17 (52%) patients in the CPVA + LALA group (p=0.62) (Figure 3). After 1.3 ± 0.5 ablation procedures in the segmental PVI group, 28 patients (85%) remained free of atrial arrhythmias at the end of the follow up period, off all antiarrhythmic therapy. After 1.4 ± 0.6 ablation procedures in the CPVA + LALA group, 28 patients (85%) remained free of atrial arrhythmias at the
end of the follow up period off of all antiarrhythmic medications. There was no statistically significant difference in the efficacy of segmental PVI vs. CPVA + LALA in preventing recurrent atrial arrhythmias overall.

**Patterns of Atrial Arrhythmia Recurrence During Follow-up:** After one ablation procedure, there was recurrence of paroxysmal AF in 14 patients in the segmental PVI group vs. 8 patients in the CPVA + LALA group (p=0.32 between groups for recurrence of paroxysmal AF). In the CPVA + LALA group, two patients had both recurrence of paroxysmal AF and development of LAFL, and 6 patients had no recurrence of AF but developed LAFL (p=0.002 between groups for development of LAFL). The mean time to recurrence for AF or LAFL was similar (9.1±4.9 months vs. 9.8±4.9 (P=0.18).

**Occurrences of Left Atrial Flutter During Follow-up:** During 16.3±6.3 months of follow-up, LAFL only occurred in the CPVA + LALA group (Figure 4). Of 8 patients with LAFL, two were controlled with anti-arrhythmic medication (one with amiodarone and the other with sotalol) and six underwent repeat ablation. In the six patients undergoing repeat ablation, nine LAFLs were identified. Four were MI dependent, three originated from the ridge between the LA appendage and left upper PV (ridge-dependent) and two originated from the LA roof (roof-dependent). All LAFLs were successfully ablated, with no inducible arrhythmia at the end of the ablation procedure. One patient had a second recurrence of LAFL and underwent a third ablation that was successful.

**Fluoroscopy Times and mean duration of RF application:** Fluoroscopy time was significantly shorter in the segmental PVI group vs. the CPVA + LALA group (73 vs. 91 minutes, p=0.04). The CPVA + LALA group had more RF applications and a longer
mean duration of RF application time than the PVI group (91±24 vs. 71±26 RF applications, 45±12 vs. 35±13 minutes, P = 0.002).

Complications: There were three complications, including a femoral hematoma in one patient that required no intervention, a femoral pseudo-aneurysm in one patient that was managed medically and resolved, and a pericardial effusion with tamponade in one patient seen immediately after transeptal catheterization that required pericardiocentesis which was successful. There were no cases of symptomatic PV stenosis, although no attempt was made to identify asymptomatic PV stenosis. There were no cases of stroke, phrenic nerve injury or atrio-esophageal fistula. During mitral isthmus ablation using an 8mm tip catheter with temperature limited to 55°C and a maximum power of 50 watts, no cases of CS perforation or left circumflex coronary artery injury were noted, although neither post-ablation stress testing or angiography was routinely preformed. There was no significant difference in complications between the two groups.

Discussion

This randomized, prospective trial of catheter ablation of paroxysmal AF comparing segmental PVI vs. CPVA + LALA at the LA roof and MI showed that significantly more patients developed LAFL in the CPVA + LALA group.

Following segmental PVI, LAFL has been reported to occur rarely (in 1-2% of patients) 6-8, and there were no cases of LAFL in the segmental PVI group in this study. In contrast, when PVI is achieved by CPVA + LALA, LAFL is relatively common, occurring in 10-30% of patients during follow-up 3,4,6. The vast majority of the arrhythmias that occur after CPVA + LALA are due to gaps in the prior ablation lines 4,
and one way to potentially avoid these arrhythmias would be to limit the amount of linear ablation preformed. Creating linear lesions during ablation may result in complex geometries that promote conduction block and facilitate reentry\textsuperscript{4}, and in this study, all of the iatrogenic LAFLs were macro-reentrant. In patients with paroxysmal AF and structurally normal hearts, the LAFLs that may develop after extensive linear ablation may negate any benefit with regard to reduction in recurrence rates of AF.

The mitral isthmus line in particular has been implicated in the development of post-ablation atrial flutters\textsuperscript{9}, and in this study 4 out of 9 LAFLs were MI dependent, despite achieving and documenting bidirectional MI block in 91\% of patients. This observation has been noted in a recent retrospective analysis as well\textsuperscript{9}, where it has been shown that the incidence of peri-mitral atrial flutter is higher in patients in whom MI ablation was performed during AF ablation, than in those who had not had MI ablation performed. These data suggest that MI ablation is a facilitating factor for the development of peri-mitral flutter and if MI ablation can be avoided, it would be prudent to do so, especially in a patient population with paroxysmal atrial fibrillation and structurally normal hearts. In this study, two LAFLs were also noted to arise from a gap in the roof line, and three were found to have a critical isthmus involving the ridge between the LA appendage and the left upper pulmonary vein which was ablated during circumferential ablation of the left pulmonary veins in the CPVA + LALA group. The anatomical and histological evaluation of the ridge between the orifices of the left upper PV and the LA appendage has revealed variable width and thickness.\textsuperscript{10-11} Like the MI, it is likely that the complex anatomy in this region, along with difficulty stabilizing the catheter along this ridge during RFCA may explain why macro-reenterant atrial
Tachycardias may arise from this region from gaps that arise after ablation, despite initial documentation of PVI.\(^{12}\)

Our results differ from those published by Oral et al.\(^{13}\) who reported better success rates with CPVA + LALA at the MI and posterior LA as compared with segmental PVI. A major difference between our study and that published by Oral, et al is that we observed a 24% incidence of LAFL when using a similar CPVA + LALA approach, which is significantly higher than the 2.5% incidence reported in that study. It is possible that the incidence of LAFL was underappreciated in the study by Oral et al. since continuous cardiac monitoring was not routinely used during follow-up in that study, and the follow-up duration was significantly shorter (164±100 days). Other more recently published manuscripts have reported a similar incidence of LAFL compared to that seen in this prospective study.\(^{3}\)

Our findings are consistent with those described in another randomized study comparing these two approaches by Karch, et al.\(^{6}\). They found no superiority of CPVA over segmental PVI and reported an 18% incidence of LAFL with the CPVA approach with additional linear ablation at the MI.

**Conclusions**

In patients with structurally normal hearts and symptomatic paroxysmal AF, CPVA + LALA is associated with a greater incidence of LAFL as compared to segmental PVI, suggesting that linear ablation should be avoided as an initial approach to ablation in this population of patients.

**Limitations**
A limitation of this study is the small number of patients enrolled. However, after an interim analysis revealed a significantly greater risk of LAFL in the CPVA + LALA group, we did not feel it was ethically appropriate to continue to randomize patients to that arm of the study, especially in light of similar results previously published by Karch et al. Another limitation of this study is that although we did confirm block across the MI line, we did not routinely assess for conduction block across the LA roof line; however, only two of the LAFLs observed in this study were found to be due to a gap at the LA roof line. Since all patients in the CPVA + LALA group received linear ablation at the LA roof and MI, it is not clear what the incidence of LAFL would have been if CPVA was preformed alone, without additional linear ablation. Lastly, we used an 8 mm tip catheter in a temperature controlled manner and not an irrigated-tip catheter as is currently used in many other electrophysiology labs. However, it is not clear that an irrigated-tip catheter produces superior results to an 8 mm catheter or greater safety.

Conflict of Interest Disclosures: None

References


**Table 1**

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*Values in parenthesis are percentages
Figure Legends:

Figure 1. ESI NavX™ 3D mapping system image of shadowed Lasso™ catheter positions in the ostium of the four PVs in a patient undergoing segmental PVI. In the segmental PVI procedure, a full geometry was not made, and a CT scan was not imported. The 3D ball markers indicate ablation locations proximal to the Lasso™ catheter that led to electrical isolation of all four PVs.

Figure 2. Carto™ 3D mapping system with imported 3D CT angiogram (postero-anterior view) showing ablation lesions for CPVA plus additional LALA at the roof and MI. White lesion markers identify locations where pacing within the right PVs stimulated the phrenic nerve. Grey lines indicate approximate location of esophagus as determined by ICE.

Figure 3. Kaplan-Meier curve showing the probability of recurrence of any atrial arrhythmia after one ablation procedure between the two groups. PVI = segmental PVI, CPVA + LALA = circumferential pulmonary vein ablation with additional left atrial linear ablation at the roof and mitral isthmus.

Figure 4. Kaplan-Meier curve showing the probability of developing LAFL between the two groups. PVI = segmental PVI, CPVA + LALA = circumferential pulmonary vein ablation with additional left atrial linear ablation at the roof and mitral isthmus.
Circulation
Arrhythmia and Electrophysiology

P-value=0.62

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Circulation Arrhythmia and Electrophysiology

Free from Left Atrial Flutter

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P-value=0.002
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