Atrial Fibrillation Ablation Strategies for Paroxysmal Patients
Randomized Comparison Between Different Techniques

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Background—Whether different ablation strategies affect paroxysmal atrial fibrillation (AF) long-term freedom from AF/atrial tachyarrhythmia is unclear. We sought to compare the effect of 3 different ablation approaches on the long-term success in patients with paroxysmal AF.

Methods and Results—One hundred three consecutive patients with paroxysmal AF scheduled for ablation and presenting in the electrophysiology laboratory in AF were selected for this study. Patients were randomized to pulmonary vein antrum isolation (PVAI; n=35) versus biatrial ablation of the complex fractionated atrial electrograms (CFAEs; n=34) versus PVAI followed by CFAEs (n=34). Patients were given event recorders and followed up at 3, 6, 9, 12, and 15 months postablation. There was no statistical significant difference between the groups in term of sex, age, AF duration, left atrial size, and ejection fraction. At 1 year follow-up, freedom from AF/atrial tachyarrhythmia was documented in 89% of patients in the PVAI group, 91% in the PVAI plus CFAEs group, and 23% in the CFAEs group (P<0.001) after a single procedure and with antiarrhythmic drugs.

Conclusion—No difference in terms of success rate was seen between PVAI alone and PVAI associated with defragmentation. CFAEs ablation alone had the smallest impact on AF recurrences at 1-year follow-up. These results suggest that atrial isolation is sufficient to treat most patients with paroxysmal AF. (Circ Arrhythmia Electrophysiol. 2009;2:113-119.)

Key Words: catheter ablation ■ paroxysmal atrial fibrillation ■ pulmonary vein antrum isolation ■ radiofrequency ■ randomized study ■ complex fractionated atrial electrograms or defragmentation

Catheter ablation has been shown to be a successful and effective therapy for the treatment of atrial fibrillation (AF). Although the pulmonary veins (PVs) have been shown to play a major role in the initiation of AF, different ablation strategies, including isolation of the pulmonary veins and ablation of sites outside the pulmonary veins, have been proposed. However, the relative benefit and success of each approach alone and in combination has not been evaluated in randomized studies.

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We sought to compare the effect of different ablation strategies on the AF termination mode and the long-term success of patients with paroxysmal AF presenting to the...
electrophysiology laboratory (EP laboratory) in AF. We compared pulmonary vein antrum isolation (PVAI) alone, ablation of complex fractionated atrial electrograms (CFAEs), and a hybrid strategy that combines PVAI followed by ablation of complex fractionated atrial electrograms.

**Methods**

**Study Population**

We enrolled 103 consecutive patients with paroxysmal AF presenting to the EP laboratory with spontaneous AF. The definition of paroxysmal AF followed the guidelines suggested by the American College of Cardiology/American Heart Association/European Society of Cardiology.

Patients included in this study were enrolled for their first AF ablation by 6 different Institutions in the period between November 2004 and January 2007. Patients were assigned a treatment based on the permuted block strategy. The treatments were balanced within a block size of 3, with the block randomly assigned to each center using a web-based centralized control program. Patients underwent PVAI only (group I, n = 35), ablation of CFAEs only (group II, n = 34), or a hybrid approach including PVAI plus CFAEs (group III, n = 34).

Patients were enrolled if (1) they had a history for at least 1 year of paroxysmal AF, (2) they were refractory to at least 2 antiarrhythmic drugs (AADs), and (3) they presented to the EP laboratory in AF. We enrolled 103 consecutive patients with paroxysmal AF presenting to the EP laboratory. The definition of paroxysmal AF followed the guidelines suggested by the American College of Cardiology/American Heart Association/European Society of Cardiology.

All patients signed an informed written consent before the procedure. The Institutional Ethical Committees approved the study. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

**Ablation Procedure**

All patients discontinued AADs at least 5 half-lives before ablation. Amiodarone therapy was discontinued 6 months before the procedure.

**PVAI**

PVAI has been described in detail elsewhere. Briefly, we used a circular mapping catheter (Lasso, Biosense Webster) and a 3.5-mm irrigated tip catheter (ThermoCool) to ablate the antrum of the pulmonary veins (PVs) and to achieve abolition of all electrograms. Intracardiac echocardiogram (ICE) was used to monitor the coronary sinus (CS) was limited to 30 W, and energy was delivered for 20 seconds. The maximum power over the esophagus and within the coronary sinus (CS) was limited to 30 W, and energy delivery was discontinued when the esophageal temperature probe reached 39°C.

A 3D geometry of the left atrium (LA) was reconstructed with the CARTO system (Biosense Webster) or the NavX system (St Jude Medical) (Figure 1A through 1D). The procedural end point for this ablation strategy was the local elimination of all the pulmonary vein potentials along the antra or inside the veins (entry and exit block). The antrum included the entire posterior wall and extended anteriorly to the right PVs along the left septum. Further ablation of the superior vena cava (SVC) along the right atrium/SVC junction was also performed if mapping revealed PV-like potentials around this region and when high output (30 mA) pacing did not capture the phrenic nerve.

**CFAEs-Only Group (Group II)**

CFAEs were defined as (1) atrial electrograms with 2 deflections or more or with fractionated baseline complexes with continuous
activity over a 10-second recording time or (2) atrial electrograms with a cycle length \( \leq 120 \text{ ms} \) over a 10-second recording time. The ablation catheter was required to be in a stable position when recording these electrograms.\(^3\)\(^,\)\(^4\) All operators assessed a sample of CFAEs electrograms to ensure uniformity in selecting ablation sites (Figure 2).

The left and right atria (including the CS) were mapped to identify areas with electric fractionation. These areas were ablated with the open irrigation ablation catheter (same settings parameters as described above for the PVAI group) until the CFAEs were completely eliminated. The CFAEs were first ablated in the LA, then CS and right atrium, respectively. The procedural end point of this ablation strategy was complete elimination of the CFAEs potentials. If AF terminated before elimination of all CFAEs, induction of AF was attempted with pacing on and off isoproterenol (up to 20 \( \mu \text{g/min} \)). The categories of AF termination considered have been described above (secondary end point). If AF persisted after elimination of all CFAEs’s sites, cardioversion was used to restore sinus rhythm.

### Hybrid Approach: PVAI Followed by Ablation of CFAEs (Group III)

This ablation strategy was a combination of the 2 previously described approaches. PVAI was followed by CFAEs ablation; therefore patients underwent antrum isolation of all pulmonary veins and subsequently the elimination of CFAEs in both atria.

The procedural end point for this strategy was the complete elimination of CFAEs areas and electric isolation of all the PV antra defined by entrance and exit block. If AF terminated before CFAEs ablation or before all CFAEs were ablated, induction of AF was performed with pacing on and off isoproterenol (up to 20 \( \mu \text{g/min} \)). Modes of AF termination were the same as in Group I and II (secondary end point). If AF persisted after PVAI plus CFAEs, cardioversion was used to restore sinus rhythm.

### Primary End Point

The primary end point of this study for all the ablation strategies was freedom from AF defined as no episodes of AF/AT with or without AADs that lasted more than 1 minute at the 1 year follow-up. Episodes that occurred during the first 2 months (blanking period) after the procedure were not considered as recurrences.

AADs were discontinued in all patients 2 months after the ablation when no recurrences were present. In cases of recurrences, patients were given their previously ineffective AADs. Patients with arrhythmia recurrence 6 months beyond the first procedure and on AADs were offered a repeat ablation.

### Postablation Management and Follow-Up

All patients were discharged on warfarin with a target international normalized ratio of 2 to 3 and on AADs previously ineffective, except for amiodarone. Warfarin was continued for a minimum of 6 months after the ablation procedure. They were followed in the outpatient clinic at 3 months after the procedure and then every 3 months. Patients were also given an event recorder for 5 months. They were asked to record 4 times a week even if asymptomatic and anytime they experienced symptoms. A 48-hour Holter monitor was obtained at 3, 6, 9, 12, and 15 months postablation.

### Statistical Analysis

A permuted block randomization schedule with block size of 3 was generated using a random number generator. Each permuted block was assigned a number and each block was randomly assigned to a center.

Although Nadamanee et al\(^1\) had reported high success with CFAEs, our initial experience did not agree with his published results. We expected a 50% success rate using a CFAEs-only approach and, based on published results from our experience, we expected an 80% success rate with a PVAI-only approach. Under these assumptions, using a 1-tailed \( \alpha \) of 5% and 80% power, a total of 32 patients would be required.

All continuous data are presented as mean \( \pm \text{SD} \) and were compared by Student \( t \)-test or by ANOVA. Tukey-Kramer method for multiple comparisons was used to compare the efficacy of the three procedures. The analysis used the intention-to-treat principle. Categorical variables comparison used \( \chi^2 \) analysis. A probability value \( <0.05 \) was considered statistically significant. (SPSS software version 11.0).

### Results

#### Patients Characteristics

Baseline characteristics of the 3 groups are presented in Table 1. No significant difference between groups in terms of sex, age, AF duration, LA size, and ejection fraction (EF) was present. Previously ineffective AADs are also reported in Table 1.

#### Procedural Results

The procedural end point was achieved in all patients (100%) in each group. The total fluoroscopy times of the groups were 65.6\( \pm \)22.6 for group I, 59.9\( \pm \)24.7 for group II, and 76.8\( \pm \)21.8 for group III (\( P=0.8 \)). The duration of radiofrequency applications were 54\( \pm \)11 minutes for group I, 48\( \pm \)9 minutes for group II, and 68\( \pm \)14 minutes for group III (\( P=0.04 \)). The total number of patients with CFAEs ablated and the median number of radiofrequency applications necessary to abolish CFAEs at each right and LA sites are reported in Table 2 (see also Figure 1).

#### Secondary End Point: AF Termination During Ablation

Organization into atrial tachyarrhythmia was 34% in group I, 16% in group II, and 29% in group III (\( P=0.158 \)), with a mean cycle length 236.8\( \pm \)32.9 ms. Conversion to sinus rhythm was seen in 60% (group I), 17% (group II), and 65%
(group III) of patients, respectively \((P<0.001)\). Persistence of AF requiring cardioversion was observed in 6\% of group I, 67\% of group II, and 6\% of group III \((P<0.001); \text{Table 3}\).

When AF organized into AT, an attempt to map and terminate the AT during ablation was performed each time. Conversion from an organized flutter/tachycardia to SR was observed in 7 patients in group I, 2 patients in group II, and 6 patients in group III \((P=0.2)\). The majority of these ATs were located at the mitral valve level (16 patients) and in the posterior wall (11 patients) as demonstrated by mapping/entrainment around the PVs.

### Chronic Follow-Up/Primary End Point
The primary end point of the study is reported in Tables 4 and 5 as freedom from AF/AT after a single procedure with or without AADs at 1-year follow-up. In group I and group III, freedom from AF/AT after 6 months was observed in 94\% of patients (14\% requiring AADs), whereas in group II it was 59\% (11\% requiring AADs; \(P<0.001\)).

After 1 year follow-up \((13.7\pm2.2\text{ months})\), in group I and group III, freedom from AF/AT was seen in 89\% (15\% requiring AADs) and 91\% (15\% requiring AADs) of patients, respectively, whereas in group II was achieved in 23\% (11\% requiring AADs) of patients \((P<0.001); \text{Tables 4 and 5}\).

The timing for a second procedure was at least 6 months after the first procedure. All 7 patients belonging to group I and III and with primary end point failure accepted a second procedure after 7.1 \(\pm\) 1.1 months from the first procedure. Six of the 7 patients (86\%) demonstrated no further AF/AT at 9 \(\pm\) 7 months follow-up from the second procedure without any AADs.

Twenty-two patients of the 26 patients of group II failing the primary end point accepted a second procedure after 7.3 \(\pm\) 1.1 months. These procedures were performed using the PVAI-only approach. After a mean follow-up of 9 \(\pm\) 7 months from the second procedure, 20 patients (91\%) were free from AF/AT without AADs.

### Complications
No major complications have been observed in these groups of patients during or after the procedures.

### Discussion

#### Main Findings
This is the first prospective multicenter randomized study comparing 3 ablation techniques in patients with paroxysmal AF. CFAEs ablation alone had the smallest impact on both acute AF termination and freedom from AF/AT at 1-year follow-up. The hybrid strategy, which combines isolation of the PV antra and ablation of CFAEs, was not associated with a better acute success rate (defined as conversion to sinus rhythm) or chronic success rate (defined as event freedom from AF or AT at 6-month and 1-year follow-up), when compared to PVAI alone.

#### Previous Studies
The pulmonary veins are known for their preponderant role in triggering and maintaining AF.\(^2\) Segmental ostial pulmonary vein isolation maintains sinus rhythm in approximately 2/3 of the patients with paroxysmal AF.\(^{12,13}\) Additional lesions such as mitral isthmus ablation\(^3\) or antrum isolation\(^4\) have been reported to increase this success to approximately 90\%.

### Table 1. Baseline Characteristics and Previous Ineffective AADs

<table>
<thead>
<tr>
<th>Clinical Characteristic</th>
<th>PVAI Only (n=35)</th>
<th>CFAEs Only (n=34)</th>
<th>PVAI+CFAEs (n=34)</th>
<th>(P) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>57(\pm)8.1</td>
<td>59.9(\pm)8.6</td>
<td>58.4(\pm)7.5</td>
<td>0.43</td>
</tr>
<tr>
<td>Male, %</td>
<td>83</td>
<td>76</td>
<td>88</td>
<td>0.44</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>34</td>
<td>38</td>
<td>35</td>
<td>0.51</td>
</tr>
<tr>
<td>AF duration, years</td>
<td>5.3(\pm)5.7</td>
<td>5.1(\pm)4.1</td>
<td>5.3(\pm)5</td>
<td>0.61</td>
</tr>
<tr>
<td>LA size, cm</td>
<td>4.3(\pm)0.6</td>
<td>4.1(\pm)0.5</td>
<td>4.4(\pm)0.6</td>
<td>0.38</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>55(\pm)8</td>
<td>55.5(\pm)6</td>
<td>54.6(\pm)6</td>
<td>0.89</td>
</tr>
</tbody>
</table>

### Table 2. Total Number of Patients With CFAEs and Median Number of RF Applications Necessary to Abolish CFAEs at Each Right and Left Atrial Sites

<table>
<thead>
<tr>
<th>CFAEs Sites</th>
<th>Group II (CFAEs Only)</th>
<th>Group III (PVAI+CFAEs)</th>
<th>RA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior wall</td>
<td>33/11</td>
<td>28/10</td>
<td>9/10</td>
</tr>
<tr>
<td>Posterior wall</td>
<td>34/14</td>
<td>21/7</td>
<td></td>
</tr>
<tr>
<td>Mitral isthmus</td>
<td>9/6</td>
<td>8/5</td>
<td></td>
</tr>
<tr>
<td>Posterior annulus</td>
<td>10/7</td>
<td>5/6</td>
<td></td>
</tr>
<tr>
<td>Appendage</td>
<td>8/6</td>
<td>4/6</td>
<td>9/5</td>
</tr>
<tr>
<td>Roof</td>
<td>34/12</td>
<td>20/10</td>
<td></td>
</tr>
<tr>
<td>Septum</td>
<td>32/9</td>
<td>24/7</td>
<td>15/10</td>
</tr>
<tr>
<td>CS</td>
<td>22/11</td>
<td>18/10</td>
<td>17/6</td>
</tr>
<tr>
<td>Crista terminalis</td>
<td>/</td>
<td>32/20</td>
<td>27/19</td>
</tr>
<tr>
<td>Cavo tricuspid isthmus</td>
<td>/</td>
<td>2/7</td>
<td>2/6</td>
</tr>
<tr>
<td>SVC</td>
<td>/</td>
<td>11/3</td>
<td>9/3</td>
</tr>
</tbody>
</table>

Right coronary sinus refers to the ostium of the coronary sinus. RF indicates radiofrequency; RA, right atrium.
More recently, ablation targeting CFAEs has been shown to result in sinus rhythm maintenance in approximately 80% of patients with paroxysmal and persistent AF. However, these results originated from a single center. To date, CFAEs ablation for paroxysmal AF has only been reported in another publication during the tailored approach described by Oral et al., but CFAEs ablation was never performed alone and was not performed in all patients.

Our results are different from the data published by Nadamanee et al., who reported a success rate of 82% at 1-year follow-up in paroxysmal patients who underwent CFAEs ablation alone (2 of them with amiodarone) and 100% conversion to SR in paroxysmal patients, including 8 patients (14%) who required concomitant ibutilide administration during ablation.

The results of this study also indicate that CFAEs ablation alone has a minimal impact on AF termination during ablation of patients with paroxysmal AF and should not be considered as an alternative strategy unless a better identification of critical CFAEs zones becomes widely available and proven effective. In this respect, although we believe that the technique used in this series of patients was really similar to the one described by Nadamanee, it is possible that a difference exists in the technique and extent of ablation used in our study.

**General Comments**

Of note, after a short follow-up (≤6 months), CFAEs ablation alone appeared to lead to an improvement in a significant number of patients; however, most of this effect was lost by 12 months (Tables 4 and 5). This suggests that a longer follow-up is required to assess the real impact on AF recurrences after any ablation procedures.

The presence of sites other than the PVs that are able to initiate and maintain AF is probably responsible for the inability to treat all patients with PV isolation alone and has prompted the use of different strategies adjunctive to PV isolation. These strategies include: creation of various ablation lines such as the mitral isthmus, roof line, posterior LA wall lines, antrum isolation, and cardiac autonomic denervation. Our results demonstrate a reduced efficacy of the CFAEs ablation alone when compared to PVAI alone and PVAI plus CFAEs in the treatment of the paroxysmal AF. In fact, the success rate of the PVAI approached 90% at 13.7±2.2 months of follow-up with a single procedure with AADs, whereas the success rate of CFAEs ablation alone was 23%.

In our study, all patients had paroxysmal AF, which was present for at least 1 year before ablation. The lack of differences between PVAI and PVAI plus CFAEs and the small impact on success rate reached by CFAEs alone suggest that electric isolation of the PVs remains a cornerstone for catheter ablation of paroxysmal AF.

Our results are consistent with the revised strategy reported by Morady et al in a recent viewpoint. The authors state that they do not limit the ablation to the arrhythmogenic veins as in their previous tailored approach, but they perform an antral ablation of all the pulmonary veins. CFAEs ablation did not have a statistically significant additive effect when combined with PVAI on AF termination mode (CFAEs terminated AF during ablation in 17% of cases, PVAI in 60%, and the combination of both in 65% of cases). This suggests that extraantral CFAEs areas may be less relevant in maintaining AF and that isolation of the antrum is necessary in nearly all cases of paroxysmal AF to achieve long-term success. Of note, it is important to recognize that isolation of the antrum eliminates many areas associated with fragmented electrograms. However, the poor chronic success obtained with defragmentation alone reinforces the importance of PV isolation.

In agreement with our results, Morady et al. found that many CFAEs, which appeared critical for the maintenance of the AF, were in the antral region, suggesting that CFAEs present in other areas (coronary sinus, LA roof, and mitral annulus) should be considered as “innocent bystanders,” at least in the paroxysmal AF patients.

Based on our findings, additional sites of ablation should be reserved for selected patients, and probably should not be

### Table 3. AF Termination Mode During Ablation

<table>
<thead>
<tr>
<th></th>
<th>PVAI Only (n=35)</th>
<th>CFAEs Only (n=34)</th>
<th>PVAI+CFAEs (n=34)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SR</td>
<td>21 (60%)</td>
<td>6 (17%)</td>
<td>22 (65%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AT</td>
<td>12 (34%)</td>
<td>5 (16%)</td>
<td>10 (29%)</td>
<td>0.158</td>
</tr>
<tr>
<td>No AF termination</td>
<td>2 (6%)</td>
<td>23 (67%)</td>
<td>2 (6%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

AT, atrial tachyarrhythmia, including atrial flutter.

### Table 4. Freedom From AF/AT at 6-Month and 1-Year Follow-Up (13.7±2.2 Months)

<table>
<thead>
<tr>
<th></th>
<th>PVAI Only (n=35)</th>
<th>CFAEs Only (n=34)</th>
<th>PVAI+CFAEs (n=34)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from AF/AT after 6-month follow-up*</td>
<td>33 (94)</td>
<td>20 (59)</td>
<td>32 (94)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Freedom from AF/AT after 1-year follow-up*</td>
<td>31 (89)</td>
<td>8 (23)</td>
<td>31 (91)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Freedom from AF/AT after 1-year follow-up without AADs</td>
<td>26 (74)</td>
<td>4 (12)</td>
<td>26 (76)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data are presented as n (%).

*With or without AADs.
Study Limitations

Methods to identify CFAEs, although similar to the ones described by Nademanee,\(^{3}\) may be operator-dependent because they are based on visual evaluation. Software analysis tools to identify CFAEs were not used in our study. However, Scherr et al\(^{13}\) demonstrated a high correlation between software and visual identification of the CFAEs areas. In addition, the initial description of defragmentation relied on visual identification of fragmented electrogroms.

Using a fixed block size of 3, it is possible to determine the assignment of the third patient in the block before randomization. However, in a study such as this, the operators cannot be blinded to the procedural end points, because they had to know the type of procedure to perform. In addition, the physicians performing the procedures were not involved in patient’s recruitment and the outcome at follow-up was based on the objective documentation of freedom from AF/AT.

Finally, the study was underpowered to detect a difference between PVAI alone versus CFAEs plus PVAI; taking into account the adjustment for multiple comparisons with a family-wise error rate \(\leq 0.05\), the sample size required to provide 80% power to detect a difference of 5% (comparing 85% to 90%) between any 2 groups is 353 patients per group. Although we acknowledge the statistical limitations, we deem that the data presented in this study would serve as an important reference point for future studies comparing the efficacy of PVAI plus CFAEs procedures.

Conclusions

Ablation of the CFAEs alone had the smallest impact on both acute AF termination and 1-year follow-up success rate in patients with paroxysmal AF. No difference in terms of acute and chronic success rates was observed between PVAI alone and PVAI associated with defragmentation (CFAEs) ablation. These results suggest that antral isolation or equivalent strategies are sufficient to treat most patients with paroxysmal AF.

References

Whether different ablation strategies affect paroxysmal atrial fibrillation (AF) long-term freedom from AF/atrial tachyarrhythmia (AT) is unclear. This study compared 3 different ablation approaches on the long-term success rate in patients with paroxysmal AF. This is the first prospective study comparing 3 ablation techniques in patients with paroxysmal AF. Complex fractionated atrial electrogram (CFAEs) ablation alone had the smallest impact on the freedom from AF/AT at 1-year follow-up. The hybrid strategy, which combines isolation of the pulmonary vein antrum and ablation of CFAEs, was not associated with a better success rate, defined as event freedom from AF or AT at 6-month and 1-year follow-up when compared with pulmonary vein antrum isolation alone. This study reinforces the concept that electric isolation of all the pulmonary veins remains a cornerstone for catheter ablation of paroxysmal AF. The results of this study also indicate that CFAEs ablation alone should not be considered as an alternative strategy for paroxysmal patients but should be reserved only for selected patients, unless a better identification of critical CFAEs zones becomes widely available and proven effective.
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