Duty-cycled multi-electrode radiofrequency vs. conventional irrigated point-by-point radiofrequency ablation for recurrent atrial fibrillation: comparative 3-year data

Y. De Greef1*, I. Buysschaert1, B. Schwagten1, D. Stockman1, R. Tavernier2, and M. Duytschaever2,3

1Department of Cardiology, Antwerp Cardiovascular Institute Middelheim, Lindendreef 1, 2020 Antwerpen, Belgium; 2Department of Cardiology, Sint Jan Hospital Bruges, Belgium; and 3Department of Cardiology, University Hospital of Ghent, Belgium

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Aims Pulmonary vein isolation (PVI) is an accepted treatment to relieve symptoms in patients with atrial fibrillation (AF). We studied 3 year outcome after PVI guided by duty-cycled multi-electrode radiofrequency (RF) ablation (pulmonary vein ablation catheter, PVAC) and provided comparative data to outcome after conventional PVI (CPVI) using mapping with irrigated, point-per-point RF ablation.

Methods and results One hundred and sixty-one consecutive patients with symptomatic paroxysmal or persistent AF and minimal heart disease underwent PVI (PVAC, n = 79 vs. CPVI, n = 82). Follow-up (with symptom-guided rhythm monitoring) was truncated at 3 years in all patients. Success was defined as freedom of documented arrhythmia after a single procedure and without antiarrhythmic drug treatment (ADT). Baseline characteristics did not differ between both groups. At 3 years follow-up, single-procedure success without ADT was comparable between PVAC and CPVI (65% vs. 55%, P = NS). The majority of recurrences occurred during the first year (PVAC 79% vs. CPVI 70%, P = NS). The annual rate of very late recurrence (i.e. beyond 1 year) was similar in both groups (10.5% vs. 15%, P = NS).

Conclusion At 3 years follow-up, outcome after PVAC-guided PVI is comparable to conventional isolation by irrigated point-by-point RF ablation. In both strategies, the majority of recurrences occurred in the first year of ablation.

Keywords Atrial fibrillation • Pulmonary vein isolation • Pulmonary vein ablation catheter • Electro-anatomical mapping system

Introduction In the last years, different so-called ‘single-shot’ ablation devices and alternative energy sources (cryoballoon ablation, high-intensity focused ultrasound, laser ablation, and multi-electrode ablation) have been developed in an attempt to facilitate pulmonary vein isolation (PVI).1–5 The pulmonary vein ablation catheter (PVAC, Medtronic, Inc) uses a multi-electrode, over-the-wire design to deliver duty-cycled bipolar and unipolar non-irrigated radiofrequency (RF) energy. Single-centre, non-controlled reports have repeatedly demonstrated good clinical outcome at 6 months,1,2 1 year,3,4 and 2 years.5 In comparative studies, PVAC-guided PVI proved to have a similar clinical efficacy at 6 months and 1 year compared with conventional point-by-point approaches.6–12

Controlled and long-term data (>3 years follow-up) after PVAC ablation are lacking. We report 3 year outcome after PVAC ablation and provide comparative data to a control group undergoing conventional PVI (CPVI, electroanatomical mapping with point-per-point irrigated RF).
What’s new?

- There are no comparative, long-term outcome data after duty-cycled multi-electrode RF ablation for atrial fibrillation.
- The present comparative study shows that 3 years outcome of pulmonary vein isolation using PVAC is similar to a conventional approach of irrigated point-by-point RF ablation.

Methods

Study population

One-hundred sixty-one consecutive patients with symptomatic, drug-resistant paroxysmal or persistent AF with no or limited structural heart disease undergoing first PVI at our institution from January 2009 till April 2010 were prospectively enrolled in a database. Patients underwent at random multi-electrode ablation (PVAC group, n = 79) or point-by-point RF ablation with an irrigated-tip catheter guided by 3D electroanatomical navigation (CPVI group, n = 82). The choice of the technique was chosen at the discretion of the operator. In both groups, procedures were performed by the same three operators with an equal distribution in both groups (YDG: 42 PVAC [47%]/48 CPVI [53%]. DS: 39 PVAC [52%]/29 CPVI [48%]. BS: 6 PVAC [55%]/5 CPVI [45%]). Atrial fibrillation (AF) was classified as persistent if the patient had undergone ≥1 electrical or chemical cardioversion within 1 year. In the PVAC patients with persistent AF, 20/27 (74%) underwent cardioversion within 48 h. A total of 65 cardioversions were performed with a mean of 2 ± 2 (range 1–9) per patient and 56% underwent >1 cardioversion. In the CPVI patients 28/37 (76%) underwent cardioversion within 48 h. A total of 86 cardioversions were performed with a mean of 2.3 ± 2.0 (range 1–8) and 41% underwent >1 cardioversion. This study was approved by the local ethics committee.

Ablation procedure

All ablation procedures were performed under therapeutic anticoagulation (uninterrupted warfarin or bridging with LMWH) and general anaesthesia. A 6F decapolar catheter was positioned in the coronary sinus (CS). Immediately prior to transseptal puncture an intravenous loading dose of 10 000 IU heparin was administered. Transseptal sheath(s) were invariably stopped.

Conventional pulmonary vein isolation

A double transseptal puncture was performed to position two 8F non-steerable sheaths (SL0, St Jude Medical) in the LA. A 3.5 mm irrigated tip ablation catheter (Navistar ThermoCool, Biosense-Webster) was used to reconstruct the LA (CARTO, Biosense-Webster). A steerable multipolar CMC (Lasso, Biosense Webster or Optima, St Jude Medical) was placed 0.5 cm within the PV to record baseline electrograms during sinus rhythm and differential pacing. The endpoint for ablation was LA-PV entry block with elimination of the PV potentials during sinus rhythm and differential pacing. If PVI was not obtained after encircling the ipsilateral veins, residual conduction gaps at the circumference were identified by the aid of the CMC and subsequently closed by selective RF lesions. Pulmonary vein isolation was rechecked after 30 min.

Post-procedural management and follow-up

After the procedure, subcutaneous low-molecular weight heparin was administered to all patients, as well as oral anticoagulation therapy (OAT) to achieve a target INR between 2.0 and 3.0. Antiarrhythmic drug treatment (ADT) was reinstituted in all patients. After the 3 months blanking period, OATs were continued (unless if a CHA2DS2-VASc score of 0) whereas all ADT (except for beta-blocking agents) were invariably stopped.

Data are presented as mean ± SD or as percentages. Differences between groups were determined by t-test, Mann–Whitney U or χ² test, where appropriate. Univariate and multivariate analysis was performed using Cox-regression analysis. A P value of < 0.05 was considered significant. IBM SPSS version 20.0 was used for statistical analysis.

Results

Baseline clinical characteristics were not different between both groups (Table 1).
Procedural data
All targeted PVs (PVAC: n = 308, CPVI: n = 321) were isolated in both groups. In neither groups additional left atrial substrate ablation was performed. A left common PV was present in eight PVAC and seven CPVI patients. In the PVAC group, mean N of PVAC applications was 23 ± 8 per patient and 6 ± 3 per vein, with more frequent use of 2:1 vs. 4:1 mode (4 ± 3 vs. 2 ± 2 per vein). In the CPVI group, mean number of RF applications was 91 ± 21. Procedure (skin-to-skin) time was significantly shorter in the PVAC group compared with CPVI (121 ± 41 vs. 169 ± 43 min, P < 0.001) with similar fluoroscopy times (33 ± 11 vs. 32 ± 15 min, P = NS).

Safety of ablation
In the PVAC group, we observed one major complication and three minor complications. One patient developed a symptomatic PV stenosis with hemoptoe 5 months post-ablation, which has been previously reported. Minor complications consisted of a transient gastropaesis in one patient and a groin haematoma (without prolonged hospital stay and without the need for surgery or transfusion) in two other patients. In the CPVI group, we observed one major complication and four minor complications. One pericardial tamponade occurred requiring surgical drainage. Whereas two patients suffered from pericarditis post-ablation, one patient developed a ‘fluid retention syndrome’ necessitating intake of diuretics and one patient had a groin haematoma (without prolonged hospital stay and without the need for surgery or transfusion).

Three years outcome after ablation: single-procedure success without antiarrhythmic drug treatment
The survival curve is given in Figure 1. At 3 years follow-up, single-procedural success without ADT was 65% for the PVAC group compared with 55% in the CPVI group (P = NS). In the PVAC group, 39 patients experienced symptoms suggestive for arrhythmia. Electrocardiogram, Holter or event recording revealed AF in 28 patients (35%) and premature beats or short runs of ectopic beats (<30 s) in 11 patients. In the CPVI group, 43 patients experienced symptoms suggestive for arrhythmia. Electrocardiogram, Holter, or event recording revealed AF in 37 patients (45%) and premature beats or short runs of ectopic beats (<30 s) in six patients.

Time to first AF recurrence was similar as well (10 ± 8 vs. 12 ± 11 months in the PVAC and CPVI group respectively, P = NS). The majority of recurrences occurred during the first year in both groups (PVAC: 22 of 28, 79% vs. CPVI: 26 of 37, 70%, P = NS). The annual rate of late recurrence (i.e. beyond 1 year) was 10.5% in the PVAC vs. 15% in the CPVI group (P = NS).

No clinical or procedural factors were associated with AF recurrence. In both groups, success rates for patients with persistent or paroxysmal AF were similar (63% vs. 65% for the PVAC group, P = NS and 49% vs. 60% for the CPVI group, P = NS). No clinical or procedural parameter was predictive for early (≤1 year) or late recurrences (>1 year).

Management of patients with atrial fibrillation recurrence
A repeat ablation using point-by-point irrigated RF was performed in 17/28 (61%) patients in the PVAC group and 28/37 (76%) in the CPVI group (P = NS). One patient refused a repeat ablation, in the remaining patients re-initiation of antiarrhythmic drugs resulted in sufficient symptomatic improvement.
Discussion

The main finding of this study is that at 3 years follow-up, single-procedure outcome without ADT after duty-cycled multi-electrode RF ablation is comparable to outcome after irrigated point-by-point RF ablation. The majority of recurrences occurred during the first year after ablation.

Prior comparative studies on the efficacy of pulmonary vein ablation catheter-guided pulmonary vein isolation

In Table 2, studies comparing the short-term outcome after PVAC and point-by-point RF ablation are listed.6–12 The success rate after a single procedure in short-term follow-up studies (< 1 year) in predominantly paroxysmal patients ranged from 67% to 82% in the PVAC group and from 49% to 80% in the point-by-point RF group. Beukema et al.10 report in exclusively paroxysmal patients a success rate of 82 and 80% respectively after a follow-up of 367 ± 139 days.10 Comparative data on patients with persistent AF are very scanty. Choo et al.8 observed a lower success rate in patients with persistent AF irrespective of the technique used. Tivig et al.12 also reported a lower success rate in patients with persistent AF treated with PVI and substrate modification with a follow-up of at least 12 months after a single procedure compared with paroxysmal patients only treated with PVI. However, the outcome after PVAC or point-by-point ablation was not different in each group (paroxysmal patients 74% vs. 68%, persistent patients 46% vs. 61%). These data are in line with our 1 year data and suggest that PVAC is as effective as other single shot devices. Likewise, in a randomized, comparative study the cryoballoon and the PVAC showed a similar clinical outcome at 12 months.15

<table>
<thead>
<tr>
<th>Technique</th>
<th>Patients (N)</th>
<th>Success %</th>
<th>FU duration</th>
</tr>
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<tbody>
<tr>
<td>Paroxysmal atrial fibrillation (PAF)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Bulava et al.6</td>
<td>PVAC</td>
<td>51</td>
<td>76</td>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>51</td>
<td>71</td>
</tr>
<tr>
<td>Khaykin et al.7</td>
<td>PVAC</td>
<td>31</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>19</td>
<td>54</td>
</tr>
<tr>
<td>Beukema et al.10</td>
<td>PVAC</td>
<td>89</td>
<td>82</td>
</tr>
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<td></td>
<td>Point by point</td>
<td>96</td>
<td>80</td>
</tr>
<tr>
<td>Choo et al.8</td>
<td>PVAC</td>
<td>30</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>43</td>
<td>49</td>
</tr>
<tr>
<td>Tivig et al.12</td>
<td>PVAC</td>
<td>27</td>
<td>74</td>
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<tr>
<td></td>
<td>Point by point</td>
<td>47</td>
<td>68</td>
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<tr>
<td>Persistent atrial fibrillation (PERS) AF</td>
<td></td>
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<tr>
<td>Choo et al.8</td>
<td>PVAC</td>
<td>8</td>
<td>50</td>
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<tr>
<td></td>
<td>Point by point</td>
<td>28</td>
<td>25</td>
</tr>
<tr>
<td>Tivig et al.12</td>
<td>PVAC/MAAC/MAASC</td>
<td>22</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Point by point + substrate</td>
<td>23</td>
<td>61</td>
</tr>
<tr>
<td>PAF + PERS AF</td>
<td>PVAC</td>
<td>40</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>40</td>
<td>68</td>
</tr>
</tbody>
</table>

FU, follow-up.

Long-term outcome

Long-term outcome data after PVAC are sparse. Whereas Mulder et al. reported a single-procedure success (without ADT) of 49% at 2 years, Looi et al. reported a marked and significant effect on quality of life at ≈ 2 years of follow-up.8–11 Our data on long-term success are in-line with prior studies reporting on the outcome after catheter ablation of AF over a longer time horizon.23–25 These studies reported almost exclusively on point-by-point RF ablation and are non-comparative. Depending on the ablation strategy, patient population, duration, and intensity of arrhythmia follow-up, these reports have found a range of single procedural success off-drugs from 29% to 78%.16–21 Ouyang et al.16 studied 161 paroxysmal AF patients undergoing PVI using point-by-point RF ablation with 46.6% of patients in sinus rhythm after a median of 4.8 years. Medi et al. studied 100 paroxysmal AF patients followed up for 39 ± 10 months with 49% of patients in sinus rhythm without ADT.21 A systematic review and meta-analysis on the long-term outcome of catheter ablation of atrial fibrillation by Ganesan et al.21 report an overall single-procedure success of ≈ 50%, going up to ≈ 80% with inclusion of multiple procedures. Recently, Neuman et al.23 reported long-term efficacy following cryoballoon-guided PVI with a 5 year single-procedure success rate of 53%. Comparing outcome at 3 years, 60% of cryo patients maintained sinus rhythm vs. 65% and 55% in the PVAC and CPVI group, respectively, in our study.23 Regarding the timecourse of recurrence, we observed that the majority of recurrences after PVAC ablation occurred within the first year. This timecourse was found to be comparable to the control group. The reported annual incidence of late recurrence (i.e. annual recurrence beyond 1 year of 10.5% in the PVAC group and 15% in the CPVI group) is in line with prior reports on irrigated point-by-point RF ablation (ranging from 3% to 25%).16–21 Likewise,
timecourse of AF recurrences after cryoablation displays a similar curve. Therefore, it seems that the three most commonly applied ablation techniques (cryoballoon, PVAC, and conventional CPVI) have a similar long-term outcome and timecourse of AF recurrence.

Predictors of atrial fibrillation recurrence

Comparative studies have identified age, left atrial size, previous pacemaker implantation, and presence of persistent AF as potential predictors of recurrences. In our study, overall no clinical or procedural factors were associated with AF recurrence at any stage (overall, early, or late). In this study, AF was classified as persistent if the patient had undergone ≥1 electrical or chemical cardioversion for an episode of AF that lasted <1 year. This is in line with the definition of persistent AF according to the 2010 ESC guidelines. (Persistent AF is present when an AF episode either lasts longer than 7 days or requires termination by cardioversion, either with drugs or by direct current cardioversion.) The majority of persistent patients in our study, however, underwent early (within ≤48 h) cardioversion (20/27 in the PVAC group and 28/37 in the CARTO group). According to the latest consensus document by Calkins et al. these patients could have been classified as paroxysmal patients. (Paroxysmal AF is defined as “recurrent AF (≥two episodes) that terminates spontaneously within 7 days. Episodes of AF of ≤48 h” duration that are terminated with electrical or pharmacological cardioversion should also be classified as paroxysmal AF episodes.) This might explain why the outcome after PVI in persistent and paroxysmal patients in our study is similar.

Importantly, patients with persistent AF were never longstanding (continuous AF of >12 months’ duration). As such, isolation of the pulmonary veins was regarded as a sufficient procedural endpoint in both groups.

Limitations

This study enrolled consecutive patients in a single-center, case-controlled fashion. Although non-randomized, the same operators performed all procedures with the same endpoint during the study time window thus facilitating a comparative analysis. Holter monitoring or event recording was only performed in the event of symptoms. The assessment of recurrences was symptom driven. As a result, the recurrence rate of asymptomatic AF periods that could have been documented with systematic rhythm monitoring is unknown. On the other hand, symptoms are the driver for an AF patient to undergo ablation.

PV narrowing was only assessed in patients with symptoms consistent with PV stenosis, thus the true rate of PV changes cannot be determined. Cerebral diffusion-weighted magnetic resonance imaging was not performed in this study because the association between PVAC and higher incidence of asymptomatic cerebral embolism had not yet been reported. Finally, contact force sensing technology is expected to improve outcome after point-by-point PV isolation.

Conclusions

At 3 years of follow-up, clinical efficacy of PVI using the PVAC catheter is acceptable and equivalent to a conventional point-by-point approach.

Conflict of interest: none declared.

References

Catheter ablation of an anteroseptal accessory pathway guided by contact force monitoring technology and precise electroanatomical mapping

Simone Gulletta*, Dimitris Tsiachris, and Paolo Della Bella

A previously healthy 17-year-old male presented with palpitations and documented recurrent episodes of narrow QRS complex reciprocating atrioventricular (AV) tachycardia. Twelve-lead electrocardiogram was consistent with pre-excitation from an anteroseptal pathway. Detailed three-dimensional Carto™ map through a 7-Fr open-irrigated ablation contact force catheter (Thermo-cool™ SmartTouch™, D type, Biosense Webster) demonstrated earliest ventricular activation at close proximity with His bundle (Panel A). Although good catheter stability was achieved, initial radiofrequency (RF) ablation (42°C, 30 W with 17 mL/min flow, contact force of 4 g, duration of 30 s) had no effect on accessory pathway (AP) conduction (Panel B). Subsequently, a second RF pulse was applied with a contact force of 16 g (42°C, 30 W with 17 mL/min flow, duration of 120 s) and AP block occurred within <5 s of RF delivery (Panel C).

Contact between the tip electrode of the ablation catheter and the myocardial tissue affects both the accuracy of maps and the efficacy of energy delivery. Catheter ablation based on precise electroanatomical mapping and contact force technology appears to be an effective and radical treatment modality even for patients with ‘high risk’ pathways close to the AV junction (5 mm distance from the His bundle, Panel D).

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/catheter_ablation_antero septal_accessory.pdf.

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