PVI with multielectrode RF catheter: long term outcome of the PVAC GOLD catheter

Dr Giovanni Rovaris
Chief of Electrophysiology
San Gerardo, Monza (MB)
PHASED RF TECHNOLOGY

ContactIQ
effective contact = f (power + temperature)

Next Generation
PVAC®
• **ContactIQ®** provides precise management of power and temperature to simplify decision-making and ablation effectiveness assessment

• **Effective contact** displayed by target temperature and power >3W - Green bars

• **Only effective contact** (heating time) per electrode **displayed**
New User Interface Enhances Decision Making

- *De Greef et al* have demonstrated that good power and good temperature produces effective lesions\(^1\)
- New ContactIQ user interface highlights electrodes with both good power and good temperature
- Users’ impressions of the new user interface have been strong. According to a recent survey,

New User Interface Enhances Decision Making

Scenario 3: INEFFECTIVE Lesion Creation: Low/No Contact

- Yellow bars < 45 °C suggest tissue contact is minimal
- Max power delivery of 8 W suggests Limited Tissue Contact
- Gently INCREASING contact pressure may increase temperature to green range
GENius Contact IQ®

Temp. > 48°C + power > 3W = enhance long term outcome (LESION)

Effective contact = green bar

99% ppv for making lesion with 30 sds. of effective contact

¹ De Greef Y et al. Impact of radiofrequency characteristics on acute pulmonary vein reconnection and clinical outcome following PVAC ablation. doi:10.1111/jce.12021
Contact Recognition Improves Outcomes
Combination of power and temperature is predictive of outcomes

Contact Recognition & Outcome

PV Isolation after 1hr & Adenosine Challenge

<table>
<thead>
<tr>
<th>Reconnection</th>
<th>% Low Power RF apps (&gt;48°, &lt;3W)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27% ± 13%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No Reconnection</th>
<th>% Low Power RF apps (&gt;48°, &lt;3W)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13% ± 15%</td>
</tr>
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Patient Outcome @ 12 months (n=80)

<table>
<thead>
<tr>
<th>AF recurrence</th>
<th>% Low Power RF apps (&gt;48°, &lt;3W)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>28% ± 18%</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Free from AF</th>
<th>% Low Power RF apps (&gt;48°, &lt;3W)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11% ± 11%</td>
</tr>
</tbody>
</table>

AF recurrence

Free from AF

Patients

PVs

Reconnection

No Reconnect

\[ p < 0.0001 \]

De Greef Y; Tavernier R; Schwagten B; De Keulenaer G; Stockman D; Duytschaever. Impact of Radio-Frequency Characteristics on Acute Pulmonary Vein Reconnection and Clinical Outcome after PVAC Ablation. O007. PACE, 2011; Vol 34: 1309-1310.

* Note: data shown is the average Temp & Power during ablation duration
Duty-Cycled RF

Heats tissue when ON

RF ‘ON’ – Electrode Delivers Current, Tissue Heats
RF ‘OFF’ – Electrode Cooling Pulls Heat from Surface, Tissue at Depth Holds and Conducts Heat

Duty-Cycled RF Cools electrode when OFF
RF Power Delivery
Duty-Cycled vs. Conventional

Conventional RF

Duty-Cycled RF
Power delivery independently controlled for each electrode

Electrode 1 – 8W
Electrode 2 – 4W
Electrode 3 – 4W
Duty-Cycled Energy Creates Deeper, More Homogenous Lesions

- Myocardial tissue has a high thermic storage capacity requiring 3 times as much time to cool the electrode-tissue interface.
- Electrodes can be OFF without tissue losing enough heat to affect lesion size and shape.

Score 1: Smooth, borderline to tissue without fluctuation in depth
Score 4: Lack of continuity with gaps

Adapted from Erdogan A et al. Homogeneity and diameter of linear lesions induced with multipolar ablation catheters: In vitro and in vivo comparison of Pulsed vs continuous radiofrequency energy delivery. JICE 4, 655-661 (2000)
PVAC GOLD

- Eliminate 1:10 electrode interaction
- Gold thermal conductivity (4x greater than platinum) allows more uniform heating and faster cooling than platinum providing precise temperature control across the electrode
- Improved uniformity of electrode contact force
- Over-the-wire design provides stability in all anatomies
Next Generation PVAC®

PVAC

New PVAC Gold

20° Tilted Array

Platinum PVAC

Gold PVAC

Poor contact and more force applied

Good overall contact and less force applied
Comparison of Gold Versus Platinum Electrodes on Myocardial Lesion Size Using Radiofrequency Energy

WALTER N. SIMMONS, SEAN MACKEY, DING SHENG HE, and FRANK I. MARCUS

From the Cardiology Section, Department of Medicine, and the Department of Electrical and Computer Engineering, University of Arizona, College of Medicine, Tucson, Arizona

(PACE 1996; 19[Pt. 1]:398–402)

Gold has 4 times greater thermal conductivity

Platinum

71 \frac{W}{mK} \times 4

Gold

318 \frac{W}{mK}
Temperature Control
Temperature differential across the electrode is less with gold than platinum in the in-vitro perfusion test set-up

Average Temperature Differential Across Electrode
4E PVAC - 60°C/60s at 1.8LPM with 90° TC Misalignment (n=9)

<table>
<thead>
<tr>
<th>Energy Mode</th>
<th>Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:1 (8W Power Limit)</td>
<td>9.99 ± 2.27</td>
</tr>
<tr>
<td>2:1 (9W Power Limit)</td>
<td>9.43 ± 2.74</td>
</tr>
</tbody>
</table>

- □ Platinum (3mm)
- ■ Gold (3.75mm)
Temperature Control

Thermocouple placement

- Placed at electrode-tissue interface to improve accuracy of temperature measurement
- Temperature control using precise tissue interface temperature eliminates possibility of steam pops

ΔT < 5°C
Better Lesions Under Low-Flow Conditions

PVAC GOLD produced deeper lesions versus PVAC under low flow conditions due to the improved cooling ability of gold\(^1\)

- **Coagulum**: no evidence was observed on catheter or thigh muscle.

PVAC GOLD is More Efficient than PVAC
Procedures were performed with 30% fewer RF applications with PVAC GOLD

<table>
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<tr>
<th>Procedure</th>
<th>ERACE</th>
<th>PRECISION GOLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Time</td>
<td>100 ± 35 min</td>
<td>92 ± 25 min</td>
</tr>
<tr>
<td>LA Dwell Time</td>
<td>64 ± 27 min</td>
<td>59 ± 17 min</td>
</tr>
<tr>
<td>Fluoroscopy Time</td>
<td>-</td>
<td>16 ± 6 min</td>
</tr>
<tr>
<td>Average Effective Contact</td>
<td>32 secs</td>
<td>36 secs</td>
</tr>
</tbody>
</table>

Gas Production with Gold is the Same

Gold and platinum produce the same volume of microbubbles in both normal and misuse conditions.

- Misuse conditions include thermocouple misalignment and intermittent tissue contact
- Coagulum: non-adherent solid particles were not observed in any of the filters post ablation

ContactIQ Sensitivity and Specificity Results

Sensitivity
- Correctly identified a lesion was present at >30s and >45s

Specificity
- Correctly identified a lesion was not present at <30s and <45s

Positive Predictive Value (PPV)
- Percent of time a lesion is predicted and one is present
Conclusions - Applying procedural changes to MER ablation significantly reduces the ACE incidence to 1.7%, which is on the low end of reported ACE rates of any technology.
Caution: Clinical results across studies/protocols may not be comparable.
All studies included used 1.5T MRI scanner and used a consistent lesion definition as per Gaita/Herrera-Siklódy (DWI + ADC + FLAIR)

PVAC GOLD ACE Rate is Consistent with Previously-Reported Microembolism Reductions

- PVAC
- PVAC GOLD
- Irrigated RF
- Cryoballoon
- nMARQ
PVAC GOLD May Be More Efficient than PVAC

Comparing data from PRECISION GOLD (PVAC GOLD) and ERACE (PVAC) shows more Effective Contact and less RF applications with PVAC GOLD.

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</tr>
<tr>
<td>Fluoroscopy time</td>
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<td>-</td>
</tr>
<tr>
<td>Effective contact</td>
<td>36s</td>
<td>32s</td>
</tr>
</tbody>
</table>

![Total RF Applications Graph](image)

Azienda Ospedaliera San Gerardo
**PVAC vs point by point PVI: follow up**

<table>
<thead>
<tr>
<th>Technique</th>
<th>Patients (N)</th>
<th>Success %</th>
<th>FU duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paroxysmal atrial fibrillation (PAF)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulava et al.⁶</td>
<td>PVAC</td>
<td>51</td>
<td>71</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>96</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>49</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>
</tr>
<tr>
<td></td>
<td>Point by point</td>
<td>47</td>
<td>68</td>
</tr>
<tr>
<td><strong>Persistant atrial fibrillation (PERS) AF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Choo et al.⁸</td>
<td>PVAC</td>
<td>8</td>
<td>50</td>
</tr>
<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><strong>PAF + PERS AF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bittner et al.⁹</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.
Conventional radiofrequency catheter ablation compared to multi-electrode ablation for atrial fibrillation

Pim Gal, Alissa E.S.M. Aarntzen, Jaap Jan J. Smit, Ahmet Adiyaman, Anand R. Ramdat Misier, Peter Paul H.M. Delnoy, Arif Elvan*

Department of Cardiology, Isala Klinieken, Zwolle, The Netherlands

<table>
<thead>
<tr>
<th></th>
<th>Total group</th>
<th>cPVI</th>
<th>MER</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>n = 460</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender men (%)</td>
<td>0.347</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.6</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>LA size in PPLAX (mm)</td>
<td>41.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHA²DS²VASc score</td>
<td>0.178</td>
<td>0.160</td>
<td>0.160</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
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</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-morbidity (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.161</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous TIA/stroke</td>
<td>0.25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structural heart disease</td>
<td>0.53</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type AF: paroxysmal</td>
<td>0.375</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failed AADs (range)</td>
<td>1.58</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>0.282 (63.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>0.329 (71.5%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AF duration (years)</td>
<td>8.3 (±1.5)</td>
<td>8.6 (±1.8)</td>
<td>7.9 (±1.5)</td>
<td></td>
</tr>
</tbody>
</table>

Safety Profile

Procedure Time

AF free survival (%)

Follow up (months)

P = 0.777
5 year Follow-Up with PVAC vs. Irrigated RF

Very long-term follow-up shows improved efficiency, improved safety and similar effectiveness with first-generation PVAC vs. Irrigated RF.

Single Procedure Success off Drugs

Safety Profile

- PVAC
- Irrigated RF

*Statistically significant

Procedure Time

- PVAC
- Irrigated RF

*Statistically significant

Gal P, et al, Conventional radiofrequency catheter ablation compared to multi-electrode ablation for atrial fibrillation. Int J Cardiol. Published online August 2014.
Phased multipolar radiofrequency pulmonary vein isolation is as effective and safe as conventional irrigated point-to-point ablation. A prospective randomised 1-year implantable cardiac monitoring device follow-up trial

S. J. Podd¹ · A. N. Sulke¹ · C. Sugihara¹ · S. S. Furniss¹

Fig. 1  AF burden pre-ablation, at 3, 6, 9, and 12 months for the PMRA and Conv groups.

Procedural times were significantly shorter for the PMRA group (PMRA 79±19 min vs Conv 139±28 min, \( p<0.001 \)).

Giovanni Rovaris¹, et al.
1 San Gerardo Hospital, Monza, Italy

Introduction

Multi-electrode radiofrequency (RF) ablation using phased, duty-cycled energy (PVAC, Medtronic, Minneapolis, USA) is a promising technique to treat atrial fibrillation that has reported equivalent freedom from AF as conventional point by point RF, with significantly reduced procedure times. Second-generation PVAC GOLD technology has recently been introduced, incorporating gold electrodes with potentially improved energy efficiency. At this point, few data are available on the acute procedural efficiency or the long-term freedom from AF with this novel device. Additionally, few data are available on freedom from AF when assessed with an implantable loop recorder, as opposed to a traditional Holter monitor. These highly sensitive devices may offer improved detection of AF at follow-up.

Methods

104 AF patients were ablated with PVAC and PVAC GOLD at our center between December 2010 and October 2014. 27% (28/104) were persistent. 71 subjects were ablated with the first-generation PVAC catheter and older versions of the GENius generator, 18 subjects were ablated with PVAC and the new GENius v15.1 generator and 15 subjects were ablated with the novel PVAC GOLD catheter and the new GENius 15.1 generator. 77% (80/104) subjects were followed with an implantable subcutaneous monitoring device to assess freedom from AF (Reveal, Medtronic, Minneapolis, USA).

Results

**Baseline characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>PVAC</th>
<th>PVAC GOLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean±std</td>
<td>58±12</td>
<td>59±12</td>
<td>57±11</td>
</tr>
<tr>
<td>Gender (male), %</td>
<td>68%</td>
<td>66%</td>
<td>76%</td>
</tr>
<tr>
<td>Left Atrial Diameter (mm), mean±std</td>
<td>40.6±4.3</td>
<td>40.4±4.7</td>
<td>41.5±2.7</td>
</tr>
</tbody>
</table>

Average procedure time was 111 ± 29 min. 115 min with PVAC and 88 min with PVAC GOLD; p=0.0004.

Average number of RF applications was 19 ± 6. 19.8 with PVAC and 14.5 with PVAC GOLD; p=0.0005.

2.9% adverse events occurred (3 vascular access complications).

At an average follow-up of 27 ± 14 months, 74% (77/104) of patients were in sinus rhythm. At an average follow-up of 5 ± 2 months, 93% (14/15) of patients treated with the novel PVAC GOLD catheter were free from AF.

Conclusions

These data demonstrate strong clinical effectiveness of Phased RF technology at long-term follow-up using a highly sensitive implantable monitor. Furthermore, they suggest improved efficiency of the second-generation PVAC GOLD device versus the predicate PVAC catheter.
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1 San Gerardo Hospital, Monza, Italy

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(3 vascular access complications)

RESULTS

- At an average follow-up of 27 ± 14 months, 74% (77/104) of patients were in sinus rhythm.
- At an average follow-up of 5 ± 2 months, 93% (14/15) of patients treated with the novel PVAC GOLD catheter were free from AF.
NEW STUDIES ONGOING

PVAC GOLD Versus Irrigated RF Single Tip Catheter With Contact FORCE Ablation of the Pulmonary Veins for Treatment of Drug Refractory Symptomatic Paroxysmal and Persistent Atrial Fibrillation (GOLD-FORCE)

GOLD AF Registry to Capture Real-World Insights Using Medtronic Phased RF Ablation to Treat Patients with Atrial Fibrillation
Conclusions

Phased RF technology demonstrate strong clinical effectiveness at long term follow up using a highly sensitive implantable monitor.

The novel catheter design of PVAC GOLD array and the Genius Contact IQ may improve:

- safety, reducing embolic events

- better tissue contact, with 20° forward tilt and the real contact with contact force

- reducing procedural time

- reducing application of energy