Phased RF Ablation for AF

Keimyung University Dongsan Medical Center
Hyoung-Seob Park
Global Cryoballoon Experience
More than 1,600 accounts worldwide

<table>
<thead>
<tr>
<th>Region</th>
<th>Accounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>&gt;30</td>
</tr>
<tr>
<td>United States</td>
<td>&gt;500</td>
</tr>
<tr>
<td>Latin America</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Asia Pacific</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Middle East &amp; Africa</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Europe</td>
<td>&gt;600</td>
</tr>
<tr>
<td>Russia, Hong Kong and China</td>
<td>&gt;130</td>
</tr>
<tr>
<td>Japan</td>
<td>&gt;130</td>
</tr>
<tr>
<td>Canada</td>
<td>&gt;20</td>
</tr>
<tr>
<td>United States</td>
<td>&gt;500</td>
</tr>
<tr>
<td>Latin America</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Asia Pacific</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Middle East &amp; Africa</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Europe</td>
<td>&gt;600</td>
</tr>
<tr>
<td>Russia, Hong Kong and China</td>
<td>&gt;130</td>
</tr>
<tr>
<td>Japan</td>
<td>&gt;130</td>
</tr>
</tbody>
</table>
Global Phased RF Experience
Over 120 Active Accounts Worldwide

Over 30,000 Patients Treated in
Over 30 countries

- Canada: >5
- United States: >15
- Latin America: >5
- Europe: >100
- Middle East & Africa: 1
- Asia Pacific: >5
Phased RF Ablation Technology

- **Pulmonary Vein Ablation Catheter (PVAC) Gold**
  - Single transseptal access with a catheter system that allows mapping, ablation, and pacing through all or selected bipolar pairs

- **GENius with ContactIQ Multichannel RF Generator**
  - ContactIQ provides a display of effective contact and ablation progress
  - 16 independent temperature-controlled channels deliver unipolar and bipolar energy simultaneously
Pulmonary Vein Ablation Catheter (PVAC)

- 9 Fr
- Over-the-wire
- Circular shaped
- Multipolar
- 3mm electrode
- 3.75mm spacing
- Mapping and Ablation
PVAC Maneuvers to Improve Tissue Contact

Steering

Pulling or Pushing

Rotating

Sliding
Energy Deployment - Phasing
Unipolar for Depth & Bipolar for Continuity

Electrode 1 (Phase 0º)  Electrode 2 (Phase 0º)

Electrode 1 (Phase 0º)  Electrode 2 (Phase 180º)

Unipolar Only

Unipolar and Bipolar
Duty-Cycling
Electrode Colling and Temperature Measurement

In conventional RF, power is continuously delivered and saline cooling is required to deliver enough power.

In Phased RF, 100W is delivered up to 10% of the time, permitting sufficient energy delivery while allowing electrodes to cool in the off period.

During the ‘off’ period, electrodes cool while tissue temperature remains close to target allowing lesion to progress.
Phased RF Ablation

Unipolar and Bipolar

Duty-Cycled RF

Voltage

One Duty-Cycle

10% ON 90% OFF 10% ON 90% OFF 10% ON 90% OFF
PVAC Ablation
**Channel Management**

- **Channel buttons** are available in Setup mode when a catheter is connected.

- Used to select or de-select ablation channels.
  - A green light appears when a channel is selected.

- **All Channels** selects or de-selects all channels with a single press.

- Channels can also be de-selected during ablation.

- **PVAC**: CH1 – CH5
- **MASC**: CH1 – CH6
- **MAAC**: CH1 – CH4
Energy Mode Buttons

- Energy modes: Bipolar, Unipolar, 1:1, 2:1 and 4:1

- The first number refers to bipolar component and second number refers to unipolar component

- Indicator is illuminated for selected energy mode (2:1 in the example)

- The default mode for PVAC is 4:1

- The default mode for MAAC and MASC is 1:1
PVAC Energy Deployment

Ablation Time: 39 sec
Mode 2:1

Max 9W
Effective Contact
CH 1 2 3 4 5
3W 6W 6W 5W 3W 3W 3W
12s 34s 32s 34s 22s 35s 35s 34s 19s

PVAC
Phased RF Ablation: Lesion Depth Control

Depth (mm)

Energy Mode

Unipolar 1:1 2:1 4:1 Bipolar

PVAC Ablations on Isolated Bovine Myocardium

Top View

Validation of Pulmonary Vein Isolation

**Entrance Block**
- Place PVAC distal to the presumed ablation line
- Check for entrance block by mapping during sinus rhythm
  - Distal CS pacing for Left PV’s
  - Proximal CS or High Right Atrial pacing for Right PV’s

**Exit Block**
- Place PVAC array within the targeted vein
- Pace at high output from each of the PVAC pairs checking for effect on PV and atrial activations
Case. 63 Y.O. Female, Paroxysmal AF
After 1\textsuperscript{st} RSPV ablation
Post RSPV
RIPV Baseline
RIPV 1\textsuperscript{st} Ablation
Post RIPV
After 4\textsuperscript{th} LSPV Ablation
LIPV: 1st Ablaton
LAA Pacing after LIPV ablation
Conventional Circular vs. PVAC Catheter
Differences in Electrogram Waveforms

Circular Mapping

PVAC Catheter

Parallell Wavefront

1mm ↑

UEGM     BEGM

3mm

UEGM     BEGM

Uni EGM: less amplitude and less steep
Bip EGM: less amplitude and smoothened
Differential Pacing with Diagnostic Catheter
PV Potentials in LSPV?
Confirm Exit Block: Pacing from LSPV
5 Year FU with PVAC vs. Irrigated RF

**Procedure Success off Drugs**
- cPVI group 45%, MER group 48%, P=0.777

**Major Complication Rate at 60 months**
- PVAC: 1.30%
- Irrigated RF: 4.80%
  *Statistically significant*

**Procedure Time**
- PVAC: 134 minutes
- Irrigated RF: 178 minutes
  *Statistically significant*

* cPVI = PVI with conventional RF using IRF
* MER = Multi-electrode Radiofrequency using phased RF

Effectiveness : PVAC vs. Irrigated RF

Effectiveness at follow-up

- PVAC
- Irrigated RF

*Statistically significant
Procedure Time: PVAC vs. Irrigated RF

Average Procedure Time

- PVAC
- Irrigated RF

*Statistically significant
Safety: PVAC vs. Irrigated RF

Scharf Survey Results

- Total reported complications: 3.90% (Scharf) vs. 4.54% (Cappato)
- Neurologic events: 1.10% (Scharf) vs. 0.94% (Cappato)
- Tamponade: 0.76% (Scharf) vs. 1.31% (Cappato)
- PV Stenosis: 0.07% (Scharf) vs. 0.29% (Cappato)

Andrade Meta-Analysis Results

- Total reported complications: 2.00% (Andrade) vs. 4.90% (Calkins)
- Neurologic events: 0.63% (Andrade) vs. 0.50% (Calkins)
- Tamponade: 0.35% (Andrade) vs. 0.80% (Calkins)
- PV Stenosis: 0.11% (Andrade) vs. 1.60% (Calkins)
PVAC vs. Cryoballoon: Meta-analysis
Freedom from AF

C PRF vs. CBA

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>log(Odds Ratio)</th>
<th>SE</th>
<th>Weight</th>
<th>Odds Ratio</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IV, Random, 95% CI</td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>Traditional analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malmborg</td>
<td>-0.51083</td>
<td>0.402274</td>
<td>100.0%</td>
<td>0.60 [0.27, 1.32]</td>
<td>0.60 [0.27, 1.32]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.27 (P = 0.20)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayesian analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRF vs CBA (NMA)</td>
<td>1.31</td>
<td>0.326531</td>
<td>100.0%</td>
<td>3.71 [1.95, 7.03]</td>
<td>3.71 [1.95, 7.03]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 4.01 (P &lt; 0.0001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PVAC vs. Cryoballoon: Meta-analysis

Procedural Duration

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>SE</th>
<th>Weight</th>
<th>Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malmborg</td>
<td>2</td>
<td>7.627551</td>
<td>100.0%</td>
<td>2.00</td>
<td>[-12.95, 16.95]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>100.0%</td>
<td>2.00</td>
<td>[-12.95, 16.95]</td>
</tr>
<tr>
<td>Heterogeneity: Not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.26 (P = 0.79)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayesian analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRF vs CBA (NMA)</td>
<td>-20.26</td>
<td>16.76276</td>
<td>100.0%</td>
<td>-20.26</td>
<td>[-53.11, 12.59]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>100.0%</td>
<td>-20.26</td>
<td>[-53.11, 12.59]</td>
</tr>
<tr>
<td>Heterogeneity: Not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.21 (P = 0.23)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Kabunga P et al., JACC Clin Electrophysiol 2016
Comparison of Ablation Techniques for AF

A

Freedom from AF

Rank probability

Best

Intermediate

Worst

Probability

0% 20% 40% 60% 80% 100%

B

Total procedure time

Rank probability

Shortest

Intermediate

Longest

Probability

0% 20% 40% 60% 80% 100%

Kabunga P et al., JACC Clin Electrophysiol 2016
Asymptomatic Cerebral Embolism

Table 3: Characteristics of New Embolic Events in All 3 Groups

<table>
<thead>
<tr>
<th></th>
<th>Externally Irrigated RF Group (n = 27)</th>
<th>Cryoballoon Group (n = 23)</th>
<th>PVAC (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with new embolic events</td>
<td>2 (7.4)</td>
<td>1 (4.3)</td>
<td>9 (37.5)</td>
</tr>
<tr>
<td>No. of embolic lesions/patient</td>
<td>1</td>
<td>1</td>
<td>2.7 ± 1.3</td>
</tr>
<tr>
<td>Size of embolic lesions, mm</td>
<td>6</td>
<td>4</td>
<td>6.0 (4.5–8.5)</td>
</tr>
<tr>
<td>Localization of embolic lesions</td>
<td>Frontal (right): 1, cerebellar (left): 1</td>
<td>Temporo-occipital (right): 1</td>
<td>Cerebellar: 10 pariatal: 5 occipital: 4 frontal: 5 *(13 right, 11 left)</td>
</tr>
</tbody>
</table>

Values are n (%), mean ± SD, or median (25th to 75th percentile). Abbreviations as in Table 1.
PVAC GOLD Summary

- Gold thermal conductivity allows more uniform heating and faster cooling than platinum providing the potential for precise temperature control across the electrode.
- Eliminate 1:10 electrode interaction.
- Should generate equivalently deep lesions to platinum because of gold’s ability to deliver energy more efficiently and consistently.
- Potential for improved uniformity of tissue contact.
- Over-the-wire design should provide stability in various anatomies.

**Gold**
- 9 Electrodes
- 3.75mm Spacing
- 20° Forward Tilt

**Platinum**
- 10 Electrodes
- 3mm Spacing
- Perpendicular

Better Contact | Better Cooling | Better Lesions
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: 2.1%
Amongst the Lowest of any Technology

PVAC Gold: 1-Year FU Results

Spitzer SG et al., Int J Cardiol 2017
### Early Experience of Dongsan Medical Center

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>41</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63 ± 11</td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>37 (90.2%)</td>
</tr>
<tr>
<td>LA dimension (mm)</td>
<td>44.2 ± 5</td>
</tr>
<tr>
<td>LA volume (ml)</td>
<td>80.7 ± 28</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>113.6 ± 27</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>28.4 ± 12</td>
</tr>
<tr>
<td>Ablation time (min)</td>
<td>28.4 ± 11</td>
</tr>
</tbody>
</table>
## Procedure time

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-07-15</td>
<td>08:40 AM</td>
<td>Procedure start</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>08:45 AM</td>
<td>Prepare for procedure</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>08:45 AM</td>
<td>Fluoroscopy set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>08:45 AM</td>
<td>2-minute gap monitoring setup</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>08:45 AM</td>
<td>Pulse oximeter set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:00 AM</td>
<td>N/S 1000 mL heparin 10000U Mix flushing solution set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:00 AM</td>
<td>Lidocaine 2% 20 mL flushed</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:05 AM</td>
<td>Puncture set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:10 AM</td>
<td>EPS catheter by Dr., Puncture set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:20 AM</td>
<td>Septal puncture set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:30 AM</td>
<td>RFA catheter by Dr., Puncture set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>09:30 AM</td>
<td>PVAc Gold injection set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>10:08 AM</td>
<td>5% D/W 100 ml BT (dilution) + Utiva Inj 2mg V(GSK) 2%</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>10:08 AM</td>
<td>TEE (portable): free flow</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>10:10 AM</td>
<td>Ultrasound set up</td>
</tr>
<tr>
<td>2016-07-15</td>
<td>10:10 AM</td>
<td>Ultrasound set up</td>
</tr>
</tbody>
</table>

**Total Procedure time** - 65 min

**Fluoroscopic time** - 23:07 sec

**Total Ablation time** - 15:56 sec
Atrial arrhythmia free survival at 6 months

- Total 21 patients (17 PAF)
- Early recurrence: 35% in PAF, 50% in PeAF
- Clinical recurrence: 5.8% in PAF, 50% in PeAF
Gold AF Registry (NCT:02433613)

Globally, 1065 patients enrolled in 41 sites

Total enrolled patients per center as of 24th May 2017
Summary

• Phased RF ablation for AF with the PVAC catheter showed long-term safety and effectiveness with relatively short procedure times.

• Long-term data in larger populations and randomized trials will be necessary.
Thanks for your attention!!