A multi-centred evaluation of high-powered ablation guided by ablation index: establishing ablation targets for pulmonary vein isolation

Gurpreet Dhillon
EP Research Fellow
Barts Heart Centre, London
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Background

• Gaps in PVI lines are associated with AF recurrence
• Better predictors of ablation lesion formation have emerged
• Weighted formulae comprising Contact Force, Time & Power
• Limited pre-clinical studies on AI available
• Impedance data suggest AI values reflect lesion formation
• Targets have yet to be defined
Background

- Single centre reports on AI guided PVI:
  - 98% first pass PVI
  - 92% Freedom from arrhythmia at 12 months
  - 73% Freedom from arrhythmia & off AADs at 12 months

- Can this be reproduced in multicentre setting?

- Higher powers may be effective and reduce procedure times

- Could use of higher power guided by AI improve outcomes?
Conventional irrigated catheter compared to Surround Flow catheter
Hypothesis

PVI utilising high power can be safely guided by AI to achieve quicker more effective procedures.
Objectives

1. Common protocol agreed across 4 centres
2. Procedure metrics, safety and efficacy assessed
3. Analysis of ablation lesions - what determines PV reconnection?
4. Follow up to assess 12 month outcome
5. Compared to retrospective controls
Methods:

Control Group
ST catheters
Conventional powers: 25W posterior wall and 30W elsewhere
Guided by Force Time Index, no specified targets
High Power AI Group

• Surround Flow Catheters

Regional Settings

40W 450 AI

PV

Posterior Wall

30W 350 AI

PV

VISITAG Module Settings

• Display 3 mm VISITAGs
• Distance measure tool <6mm (from centre to centre)
PVI Work Flow: HPAI and Controls

- Complete WACA line
- Transparent Mesh
- Target Gaps between VISITAGs
- Repeat lesions below target (HPAI only)
- Only then EGM guided ablation

Once isolation achieved:
- 30 minute wait time
- 18mg of Adenosine
- Further ablation if reconnected
Offline Analysis of Ablation Lesions

- Lesion data exported for analysis in Matlab
- Lesions allocated in 10 Segment model of WACA line
- Segments with acute PVR compared to those without
- Factors analysed:
  - AI value (% of regional target)
  - Contact Force
  - Inter-lesion distance (ILD)
  - Impedance drop
- Analysed as mean per segment and min/max
End points

Primary end point
Rate of acute PV reconnection

Secondary End Points:
RF time and Procedure times
Rates of 1st pass PVI & need for ablation on ridge
12 month outcome data
Predictors of PVR from VISITAG analysis
# Results: Demographics

<table>
<thead>
<tr>
<th></th>
<th>HPAI Group</th>
<th>Control Group</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. Patients</strong></td>
<td>50</td>
<td>50</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Age years Mean ± SD</strong></td>
<td>60.1 ± 11.8</td>
<td>59.9 ± 10.8</td>
<td>0.92</td>
</tr>
<tr>
<td><strong>Male n (%)</strong></td>
<td>35 (70)</td>
<td>24 (48)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Hypertension n (%)</strong></td>
<td>19 (38)</td>
<td>17 (34)</td>
<td>0.84</td>
</tr>
<tr>
<td><strong>Diabetes Mellitus n (%)</strong></td>
<td>6 (12)</td>
<td>3 (6)</td>
<td>0.49</td>
</tr>
<tr>
<td><strong>Ischaemic Heart Disease n (%)</strong></td>
<td>2 (4)</td>
<td>1 (2)</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>CHA2DS2VASC Score mean ±SD</strong></td>
<td>1.3 ± 1.2</td>
<td>1.68 ± 1.6</td>
<td>0.18</td>
</tr>
<tr>
<td><strong>LA Diameter (mm)</strong></td>
<td>37 ± 5</td>
<td>38 ± 4</td>
<td>0.15</td>
</tr>
</tbody>
</table>
Results: Procedural Factors

- No acute complications in the HPAI group vs 3 in Controls Group

<table>
<thead>
<tr>
<th></th>
<th>High Power AI</th>
<th>Control Group</th>
<th>Reduction (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial PVI RF Time</td>
<td>23.6 (19.4 – 28.9)</td>
<td>40.7 (34.2 – 47.6)</td>
<td>42%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total RF Time</td>
<td>27.2 (21.5 – 35.8)</td>
<td>43.2 (35.1 – 52.1)</td>
<td>37%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Procedure Time</td>
<td>156 (133 – 179)</td>
<td>199 (178 – 227)</td>
<td>22%</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
First Pass Isolation and Ablation on PV Ridge

- WACAs: HPAI 82% vs Controls 34% (P < 0.001)
- R&L WACAs: HPAI 68% vs Controls 14% (P < 0.001)
- Ablation PV Ridge: HPAI 16% vs Controls 41% (P < 0.001)
Primary End Point: Acute PV Reconnection

- PV Reconnection: 14 (HPAI) vs 24 (Controls) with P = 0.015
- WACA Reconnection: 22 (HPAI) vs 36 (Controls) with P = 0.042

Barts Health NHS Trust
PV Reconnection by Vein

P = 0.015
HPAI 28/200
Controls 48/200

RSPV: HPAI 11, Controls 10
RIPV: HPAI 8, Controls 11
LSPV: HPAI 4, Controls 13
LIPV: HPAI 5, Controls 14
Regional Analysis of Reconnection

- 4569 ablation lesions were analysed from 49/50 patients
- 3.9% (38/980) segments acutely reconnected (55% Right vs 45% left WACAs)
Largest ILD AUC 0.755 (95% CI 0.678 – 0.833), p < 0.001

Mean ILD AUC 0.478 (95% CI 0.393 - 0.646), p = 0.563

Max ILD cut off of 6.0: Sensitivity 78.9 and Specificity of 61.4.
ROC Curve of Mean and Minimum AI achieved as Percentage of Target

Minimum AI (% of regional target) AUC 0.710 (95% CI 0.632 – 0.788) p < 0.001

Mean AI (% of regional target) AUC 0.543 (95% CI 0.447 – 0.640) p = 0.366

Min AI of 68.4: Sensitivity 69.3 and Specificity 68.4.
ROC Curve of Mean and Minimum Impedance

Minimum Impedance drop AUC 0.747 (95% CI 0.685 – 0.809), p < 0.001

Mean Impedance drop AUC 0.637 (95% CI 0.565 – 0.709), p < 0.004

Min Imp cut off 2.5: Sensitivity 78.9 and Specificity 63.1
ROC Curve of Mean and Minimum Contact Force

Minimum Contact Force AUC 0.728 (95% CI 0.665 – 0.791), p < 0.001.

Mean Contact Force AUC 0.454 (95% CI 0.390 – 0.521) p = 0.351.

Min CF cut off 5.8: Sensitivity 65.8 and Specificity 71
## Predicting segmental PV reconnection

<table>
<thead>
<tr>
<th></th>
<th>&lt;6mm</th>
<th>6-7mm</th>
<th>&gt;7mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max ILD</td>
<td>1.4%</td>
<td>5.4%</td>
<td>10.4%</td>
</tr>
<tr>
<td>Min Imp Change</td>
<td>&lt;3 Ω</td>
<td>3-5 Ω</td>
<td>&gt;5 Ω</td>
</tr>
<tr>
<td></td>
<td>7.5%</td>
<td>1.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Min Contact Force</td>
<td>&lt;5g</td>
<td>5-8g</td>
<td>&gt;8g</td>
</tr>
<tr>
<td></td>
<td>8.6%</td>
<td>5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Min AI (% of reg)</td>
<td>&lt;65%</td>
<td>65-75%</td>
<td>&gt;75%</td>
</tr>
<tr>
<td></td>
<td>7.7%</td>
<td>4.1%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Effective Ablation targets

Achieving Min AI > 70% (regional target) and Max ILD < 6mm:

< 1% of segment reconnection

Failing to achieve either Min AI > 70% and Max ILD < 6mm of target

= 6% of segment reconnection
## Twelve Month Outcome Data

<table>
<thead>
<tr>
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<th>Controls</th>
<th>P Value</th>
</tr>
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<tbody>
<tr>
<td>Freedom from AF/AT at 12 months</td>
<td>94% (47/50)</td>
<td>66% (33/50)</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td>Freedom from AF/AT and AADs at 12 months</td>
<td>78% (39/50)</td>
<td>64% (32/50)</td>
<td>P = 0.186</td>
</tr>
<tr>
<td>Repeat AF ablation within 12 months</td>
<td>2% (1/50)</td>
<td>30% (15/50)</td>
<td>P &lt; 0.001</td>
</tr>
</tbody>
</table>
Conclusion

• High powered ablation with STSF guided safely by AI
  → Pilot data in terms of safety.
• Reduced RF time & procedure time
• Markedly higher rates 1st pass PVI
• Less likely to require ablation between PVs
• Markedly reduced acute PVR - is waiting period necessary?
• Improved outcomes & reduced redo rate versus controls
Conclusion

- Targets for ablation using STSF catheters should include:
  - contact force > 6g
  - ILD < 6mm
  - Impedance drop > 2.5 Ω
  - AI value > 68% of the regional target
- These targets not independent
- May be sufficient to observe ILD & AI targets alone
- Lower AI values still may be sufficient for PVI
  - $68\%$ of target = 306 anteriorly and 240 posteriorly
Thank you
Additional Slides
## Results: Procedural Factors

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<td>Procedure Time, (Mins)</td>
<td>156 (133.8 – 179.3)</td>
<td>199 (178.6 – 227)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Transeptal to PVI Time, (Mins)</td>
<td>62 (50 – 73.7)</td>
<td>78 (62.8 – 98.5)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Initial PVI Radiofrequency (RF) Ablation Time, (Mins)</td>
<td>23.6 (19.4 – 28.9)</td>
<td>40.7 (34.2 – 47.6)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Redo PVI RF Time, (Mins)</td>
<td>2.3 (1.7 - 3.7)</td>
<td>4.5 (1.8 – 9)</td>
<td>0.21</td>
</tr>
<tr>
<td>Non PVI RF Time, (Mins)</td>
<td>10.6 (3.3 - 15)</td>
<td>10.4 (9.8 - 11.2)</td>
<td>0.74</td>
</tr>
<tr>
<td>Total RF Ablation Time, (Mins)</td>
<td>27.2 (21.5 - 35.8)</td>
<td>43.2 (35.1 – 52.1)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Acute Reconnection of PV</td>
<td>28/200 (14%)</td>
<td>48/200 (24%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Acute reconnection of WACAs</td>
<td>22/100</td>
<td>36/100</td>
<td>0.04</td>
</tr>
<tr>
<td>Acute reconnection in patients</td>
<td>18/50</td>
<td>26/50</td>
<td>0.16</td>
</tr>
<tr>
<td>1st Pass Isolation of WACAs (Circles)</td>
<td>82 (82%)</td>
<td>64 (64%)</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Regional Analysis of Reconnection

Right WACAs
- 38%
- 10%
- 5%
- 10%
- 14%
- 6%
- 12%
- 0%
- 0%
- 0%

Left WACAs
- 12%
- 6%
- 12%
- 0%
- 10%
- 10%
- 12%
- 12%
- 12%
- 12%
Results: Procedure Times

- Left WACA Time
- Right WACA Time
- Initial WACA Time
- Initial PVI RF Time
- Total RF Ablation Time
- Procedure Time

Controls vs. HPAI
## Optimal Statistical cut off for predicting PV Reconnection

<table>
<thead>
<tr>
<th></th>
<th>Value of Best Fit</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Hazard ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Inter-lesion distance</td>
<td>6.0</td>
<td>76.9</td>
<td>61.7</td>
<td>7.9</td>
<td>98.7</td>
<td>6.30 (2.86 – 13.90)</td>
</tr>
<tr>
<td>Minimum Impedance drop</td>
<td>2.5</td>
<td>78.9</td>
<td>63.1</td>
<td>7.9</td>
<td>98.7</td>
<td>6.40 (2.90 - 14.12)</td>
</tr>
<tr>
<td>Minimum Contact Force</td>
<td>5.8</td>
<td>65.8</td>
<td>71.3</td>
<td>8.5</td>
<td>98</td>
<td>4.80 (2.42 - 9.52)</td>
</tr>
<tr>
<td>Percent of AI Target</td>
<td>68.4</td>
<td>69.3</td>
<td>68.4</td>
<td>8.3</td>
<td>98.2</td>
<td>4.88 (2.43 – 9.81)</td>
</tr>
</tbody>
</table>
Minimum and Mean AI ROC Curve

Minimum AI AUC 0.689 (95% CI 0.601 – 0.744) p < 0.001

Mean AI AUC 0.516
(95% CI 0.426 – 0.606) p = 0.366
Duration of Ablation Lesion

AI 450, 40W: Median lesion time 15.1 seconds

AI 350, 30W: Median lesion time 13.2 seconds
Relationship between factors

• Comparing Min AI and Contact Force:
  - Min AI < 70%: 44% (146/335) achieved CF > 6 g.
  - Min AI > 70%: 81% (519/642) achieved CF > 6, p < 0.001

• Comparing Min AI and Impedance:
  - Min AI < 70%: 30% (102/336) achieved a imp > 3 Ω
  - Min AI > 70%: 70% (452/642) achieved a imp > 3 Ω, p < 0.001