First clinical use of INTELLANAV MIFI OI catheter incorporating local impedance data

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Introduction

• Successful RF ablation is dependent on:
  1. Good spatial resolution of abnormal local signals to determine critical ablation sites
  2. Ability to deliver effective lesion with good tissue contact

• Contact force catheters - surrogate for electrical coupling to the myocardium

• Electrical impedance may provide a more accurate indication of electrical coupling
INTELLANAV MIFI OI catheter

- 3 equally spaced mini-electrodes (MEs) (2.5mm centre-to-centre) incorporated into tip
- Ultra-high density mapping
- Incorporate ‘DirectSense’ algorithm to measure local tissue impedance (LI) at distal electrode
- Distortions in local potential field generated between neighbouring regions of myocardium can be measured by the MEs (similar to active electrolocation used by some weakly electric fish)
Methods

- 31 patients, 3 centres (Bordeaux, Toulouse, Newcastle)
- Mapping and ablation of a range of complex arrhythmias
- Intellamap Orion mapping catheter and Intellanav MiFI OI ablation catheter
Measurements before ablation

- Generator impedance (GI) - Stockert between dome electrode & cutaneous patch
- Local impedance (LI) - micro-electrodes
- Impedance recorded in SR
  - Blood pool
  - In contact with range of tissue scar levels
• Good tissue contact determined by:
  • Presence of nearfield electrogram signals
  • Capture during pacing
  • Fluoroscopy
Measurements during ablation

- Initial impedance and max impedance drop measured both from micro-electrodes and from Stockert
- Electrode amplitude measured from micro-electrode bipolar recordings just prior to ablation onset
- For a subset of lesions, lesion quality was assessed by bipolar pacing directly following the end of the ablation lesion from a micro-electrode at 10V output, 2 ms duration
- Successful: loss of >50% nearfield signal, inability to capture local tissue
<table>
<thead>
<tr>
<th>Procedure type</th>
<th>Number</th>
<th>Age (yrs)</th>
<th>Gender (M)</th>
<th>Procedure time (min)</th>
<th>Ablation time (min)</th>
<th>Fluoroscopy time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Typical flutter</td>
<td>2</td>
<td>71 ± 1</td>
<td>1 (50%)</td>
<td>48 ± 23</td>
<td>3 ± 0</td>
<td>10 ± 0</td>
</tr>
<tr>
<td>Redo AF</td>
<td>3</td>
<td>67 ± 4</td>
<td>2 (67%)</td>
<td>92 ± 51</td>
<td>24 ± 51</td>
<td>43 ± 34</td>
</tr>
<tr>
<td>Focal right AT</td>
<td>2</td>
<td>65 ± 2</td>
<td>1 (50%)</td>
<td>120 ± 75</td>
<td>21 ± 17</td>
<td>85 ± 65</td>
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<tr>
<td>Atypical flutter</td>
<td>11</td>
<td>65 ± 4</td>
<td>6 (55%)</td>
<td>244 ± 97</td>
<td>16 ± 10</td>
<td>110 ± 58</td>
</tr>
<tr>
<td>Focal VT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVOT</td>
<td>2</td>
<td>64 ± 5</td>
<td>1 (50%)</td>
<td>150 ± 30</td>
<td>16 ± 1</td>
<td>60 ± 40</td>
</tr>
<tr>
<td>RVOT</td>
<td>2</td>
<td>67 ± 2</td>
<td>1 (50%)</td>
<td>85 ± 35</td>
<td>7 ± 2</td>
<td>65 ± 15</td>
</tr>
<tr>
<td>Re-entrant VT</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischaemic</td>
<td>8</td>
<td>67 ± 3</td>
<td>7 (88%)</td>
<td>201 ± 103</td>
<td>32 ± 10</td>
<td>98 ± 68</td>
</tr>
<tr>
<td>Tetralogy of Fallot</td>
<td>1</td>
<td>33</td>
<td>1 (100%)</td>
<td>190</td>
<td>10</td>
<td>21</td>
</tr>
<tr>
<td>TOTAL</td>
<td>31</td>
<td>65 ± 6</td>
<td>20 (65%)</td>
<td>179 ± 106</td>
<td>19 ± 13</td>
<td>83 ± 62</td>
</tr>
</tbody>
</table>
Results

• 31 patients - 65 ± 6 years, 20 male
• For ischaemic LV cases, LV ejection fraction was 39 ± 11 %.
• For LA cases, LA volume was 215 ± 65 ml.
• No significant complications.
• All cases were completed successfully, except for 2 atypical flutters, which could not be terminated by ablation and underwent external cardioversion.
• Mean procedure time 179 ± 106 min,
• RF time 19 ± 13 min
• Fluoroscopy time 83 ± 62 min.
Signal from Intellanav MiFi OI catheter

- Bipolar signals demonstrated nearfield electrograms; standard bipolar recordings recorded both local signal and farfield electrograms.
- Nearfield signal could be differentiated from farfield signal at a line of block by moving the catheter from one side to the other.
• Micro-electrodes show solely nearfield signal on either side of a line of block in the RV of a patient with ToF

• Bipolar electrode recordings show double potentials representing both local nearfield signal on the ipsilateral side of the line of block and farfield signal from the other side.
Nearfield recordings can aid identification of PV isolation

- Atypical flutter ablation,
- Catheter at ostium of RSPV,
- Bipolar electrodes record ongoing atrial flutter waves, whilst micro-electrodes record isolated PV potentials, demonstrating vein isolation.

All three micro-electrode recordings show no signal, whilst bipolar electrograms do show signal, which may therefore represent farfield signal from the LA appendage.
Impedance values prior to ablation

• LI values in blood pool not different between cardiac chambers (ANOVA: p = 0.76)

• When catheter was in contact with healthy tissue:
  • LI values higher than in blood pool
  • no difference between chambers (ANOVA: p = 0.83)

• LI values were taken from different levels of scar
  • 8 ischaemic LV cases (total number of points = 104, mean number of points per case = 13.0 ± 9.4)
  • 14 LA cases (total number of points = 170, mean number of points per case = 12.1 ± 3.6).

• LI values were significantly lower in dense scar in both LV and LA than in healthy tissue, and also lower in dense scar than in the blood pool
<table>
<thead>
<tr>
<th>Cardiac chamber</th>
<th>LI values (Ω)</th>
<th>Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood pool</td>
<td>Healthy tissue</td>
</tr>
<tr>
<td>LV</td>
<td>93 ± 13 (c = 9, n= 18)</td>
<td>141 ± 13 (c = 10, n = 25)</td>
</tr>
<tr>
<td>LA</td>
<td>95 ± 6 (c = 9, n = 18)</td>
<td>132 ± 12 (c = 12, n = 25)</td>
</tr>
<tr>
<td>RV</td>
<td>98 ± 6 (c = 4, n = 8)</td>
<td>137 ± 7 (c = 4, n = 8)</td>
</tr>
<tr>
<td>RA</td>
<td>97 ± 7 (c = 4, n = 8)</td>
<td>141 ± 7 (c = 4, n = 8)</td>
</tr>
</tbody>
</table>
Blood pool values not significantly different in a given chamber in each patient between the start and end of each case

<table>
<thead>
<tr>
<th>Cardiac chamber</th>
<th>Initial LI bloodpool values (Ω)</th>
<th>Final LI bloodpool values (Ω)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV</td>
<td>96 ± 13 (n = 9)</td>
<td>91 ± 13 (n = 9)</td>
<td>0.35</td>
</tr>
<tr>
<td>LA</td>
<td>97 ± 5 (n = 9)</td>
<td>93 ± 6 (n = 9)</td>
<td>0.12</td>
</tr>
<tr>
<td>RV</td>
<td>97 ± 3 (n = 4)</td>
<td>98 ± 8 (n = 4)</td>
<td>0.91</td>
</tr>
<tr>
<td>RA</td>
<td>98 ± 6 (n = 4)</td>
<td>96 ± 9 (n = 4)</td>
<td>0.71</td>
</tr>
</tbody>
</table>
Voltage maps of LA roof during an AT case, with LI measurements.

White and blue tags indicate fractionated signal; red and pink tags indicate ablation lesions.

With stable contact, the LI value plateaus at 134 Ω in healthy tissue (A) and 88 Ω in scar tissue (B) on the roof.
• Exponential relationship between LI value and maximum electrogram amplitude

• Conversely, the correlation between impedance values measured from the Stockert generator (GI) and electrogram amplitude was very weak
• For 9 LV cases, LI values were compared
  • Atrial pacing from the proximal coronary sinus (CS),
  • Pacing from the RV apex and
  • Pacing from an LV branch of the CS
• No difference in LI values (mean difference between atrial, RV and LV pacing for each point = 4.0 ± 3.2 Ω, n = 20, p = 0.09)
• Difference between maximum electrogram amplitudes (but did not reach statistical significance in this limited sample - mean difference between atrial, RV and LV pacing for each point = 0.24 ± 0.16 mV, n = 20, p = 0.06).
Impedance values during ablation

• Values of initial micro-electrode electrogram amplitude, initial LI, LI drop on ablation, initial GI and GI drop on ablation were recorded
  • LV ischaemic VT cases (total number of points = 74, mean number of points per case = 13.0 ± 9.4)
  • LA cases (total number of points = 119, mean number of points per case = 12.1 ± 3.6).

• Ablation lesions were delivered at 30-35 W in the atria and 40-45 W in the ventricles for 30s duration
• (C) With good catheter contact with the myocardium, on onset of ablation LI drops to a plateau with a 30 Ω drop

• After 30 s application, the signal had attenuated and there was no local capture.

• (D) Catheter has poor stability and potentially lacked good contact; the impedance drop was only 6.8 Ω and local tissue capture remained
Left ventricle:

- (A,B) Max LI drop on ablation linearly correlated with the initial LI value
- (C,D) Conversely, there was no relationship between the initial GI and the subsequent drop in GI on ablation for the LV

Left atrium:

- B
  - $y = 0.22x - 6.29$; $r_m = 0.64$, $p<0.001$
  - D
  - $y = 0.11x - 6.36$; $r_m = 0.31$, $p=0.001$
• There was relatively weak correlation between maximum LI drop and maximum GI drop.
• The LI drop on ablation correlated with the initial maximum electrogram amplitude (LV: \( r_m = 0.66, p<0.001 \); LA: \( r_m = 0.64, p<0.001 \)),

• No strong relationship between maximum GI drop and electrogram amplitude (LV: \( r_m = 0.27, p =0.03 \) LA; \( r_m = 0.11, p=0.26 \))
• Column scatterplots of absolute LI drop and LI drop as a percentage of initial LI value for successful and unsuccessful lesions.

• The median LI drop was significantly larger for successful than unsuccessful lesions (LV: p = 0.001, LA: p = 0.049).

• We also calculated LI drop as a percentage of initial LI.

• Successful lesions were significantly larger than for unsuccessful lesions (LV: p = 0.002, LA: p = 0.005).
<table>
<thead>
<tr>
<th></th>
<th>Successful lesions</th>
<th>Unsuccessful lesions</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV</td>
<td>Absolute LI drop (Ω)</td>
<td>16.0 (12.1-19.8), c = 6, n = 37</td>
<td>9.4 (5.4-15.6), c = 6, n = 19</td>
</tr>
<tr>
<td></td>
<td>% LI drop</td>
<td>17.1 (14.0-19.6), c = 6, n = 37</td>
<td>10.6 (7.1-16.5), c = 6, n = 19</td>
</tr>
<tr>
<td>LA</td>
<td>Absolute LI drop (Ω)</td>
<td>14.6 (10.0-18.3), c = 13, n = 33</td>
<td>6.8 (4.7-13.0), c = 13, n = 33</td>
</tr>
<tr>
<td></td>
<td>% LI drop</td>
<td>14.2 (10.8-19.5), c = 13, n = 33</td>
<td>7.5 (5.1-11.0), c = 13, n = 33</td>
</tr>
</tbody>
</table>
Comments: Nearfield signal

- Maps generated with mini-electrodes on INTELLANAV MIFI OI catheter had excellent electrogram spatial resolution
- Could provide us with accurate information of tip location in relation to line of block
- Highly localized signal from catheter aided distinction between viable & non-viable tissue types and identification of critical isthmuses and gaps in lines of block
Comments: LI measurement

- LI measurements from INTELLANAV MIFI OI catheter useful
  - To establish that we had good contact with the myocardium
  - To help us produce an effective lesion.
- Contact force catheters = standard of care
  - Electrical impedance - more accurate indication of electrical coupling?
- Explanted and in-vivo swine tissue models
- Further studies in humans needed to establish normal range of impedance values and provide framework of target impedance drops to guide successful lesion formation
- Impedance metric could be used as an alternative to contact force sensing to guide ablation procedures
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