TRANSVENOUS LEAD EXTRACTION ON UNINTERRUPTED ANTICOAGULATION: A MULTICENTRE REGISTRY ANALYSES

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Background

• 1.2 to 1.4 million CIED implants annually worldwide

• Transvenous lead extraction (TLE) is an integral part of the management of patients with CIED

• TLE procedures on the rise, estimated 10,000 – 15,000 leads/yr worldwide
Background

- TLE is associated with a risk of potentially life threatening haemorrhagic events

- Consensus is to review peri-procedural anticoagulation on an individual case basis

- Limited evidence on safety of patients undergoing lead extraction on uninterrupted anticoagulation
Hypothesis

- Transvenous lead extraction on uninterrupted warfarin (with therapeutic INRs) is safe
Objectives

Aimed to assess

- Procedural metrics
- Safety
- MVA to assess factors predicting failure
Methods

• Consecutive patients undergoing TLE over 18 months from 2 centres

• Study Cohort
  - Cases: TLE on uninterrupted warfarin
  - Controls: TLE on no anticoagulation

• Retrospective, Case-control study

• Medical and device records reviewed, telephone contact with patients for follow-up where possible
Methods: Extraction Procedure

- Under sedation or GA
- Invasive arterial monitoring
- Extraction Kit: Telescoping sheaths/Evolution/Tightrail
- Oncall cardiothoracics on site
- Patients monitored for at least 24 hrs as inpatient
- Post-procedure
  - TTE, Uninterrupted Warfarin
End Points

Primary End Point
• Composite of (a) successful lead removal in its entirety (b) major and minor procedural complications

Secondary End Points
• Procedure/fluoroscopy times, multivariate analyses of factors predicting success
End Points

Major Complications
- death
- ≥ 2g/dL drop in Hb/blood transfusion
- cardiac tamponade
- need for surgical intervention

Minor Complications
- haematoma
- pericardial effusion
Results: Study Cohort

N = 44
(22 Cases and 22 Controls)

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Results: Study Cohort

- 119 TLEs over 18 months
- 2 operators, 2 Centres
- 22 (18%) TLEs done on uninterrupted anticoagulation (Cases)
- Controls
  - n = 22
  - age and sex matched
  - TLE on no anticoagulation over the same time period
### Baseline Demographics

<table>
<thead>
<tr>
<th></th>
<th>CASES</th>
<th>CONTROLS</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N = 44</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age, years, (mean ± SD)</strong></td>
<td>66±15</td>
<td>65±17</td>
<td>0.83</td>
</tr>
<tr>
<td><strong>Sex, M, n (%)</strong></td>
<td>81</td>
<td>76</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>Background heart disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal heart, n (%)</td>
<td>23</td>
<td>19</td>
<td>0.74</td>
</tr>
<tr>
<td>Ischemic heart disease, n (%)</td>
<td>36</td>
<td>38</td>
<td>0.89</td>
</tr>
<tr>
<td>Dilated cardiomyopathy, n (%)</td>
<td>32</td>
<td>29</td>
<td>0.83</td>
</tr>
<tr>
<td>Other, n (%)</td>
<td>9</td>
<td>14</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>AF, (%)</strong></td>
<td>55</td>
<td>35</td>
<td>0.18</td>
</tr>
<tr>
<td><strong>LVEF, %, (mean±SD)</strong></td>
<td>38±14</td>
<td>36±16</td>
<td>0.66</td>
</tr>
<tr>
<td><strong>INR at procedure, (mean ± SD)</strong></td>
<td>2.2±0.6</td>
<td>1.1±0.6</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Creat (mean ± SD)</strong></td>
<td>101±22</td>
<td>95±20</td>
<td>0.34</td>
</tr>
<tr>
<td><strong>Type of Device</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPM (%)</td>
<td>32</td>
<td>30</td>
<td>0.88</td>
</tr>
<tr>
<td>ICD (%)</td>
<td>41</td>
<td>37</td>
<td>0.78</td>
</tr>
<tr>
<td>CRTP (%)</td>
<td>9</td>
<td>16</td>
<td>0.48</td>
</tr>
<tr>
<td>CRTD (%)</td>
<td>18</td>
<td>17</td>
<td>0.93</td>
</tr>
</tbody>
</table>
Cases

- Mean INR $2.3 \pm 0.4$ (range $2 - 3.5$)

- $\text{CHA}_2\text{DS}_2\text{Vasc Score} \ 3.2 \pm 1.8$

- Indication for anticoagulation
  - Prosthetic Valve 7 (50%)
  - AF 6 (43%)
  - Multiple PEs 1 (7%)
## Procedural Characteristics

<table>
<thead>
<tr>
<th>Extraction Indication</th>
<th>CASES</th>
<th>CONTROLS</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection [%]</td>
<td>46</td>
<td>50</td>
<td>0.79</td>
</tr>
<tr>
<td>Lead Malfunction [%]</td>
<td>45</td>
<td>36</td>
<td>0.54</td>
</tr>
<tr>
<td>Other [%]</td>
<td>9</td>
<td>14</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Elective Procedure, n (%)</strong></td>
<td>22 (50)</td>
<td>9 (41)</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Procedure Time, n (%)</strong></td>
<td>229±149</td>
<td>194±100</td>
<td>0.36</td>
</tr>
<tr>
<td><strong>Fluoroscopy Time, n (%)</strong></td>
<td>33±18</td>
<td>30±20</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Number of leads Extracted, n</strong></td>
<td>26</td>
<td>23</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Lead Age, yrs, (mean ± SD)</strong></td>
<td>7.35±2.12</td>
<td>8.21±3.11</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>Drop in Hb (mean ± SD)</strong></td>
<td>0.96±0.47</td>
<td>0.7±0.7</td>
<td>0.15</td>
</tr>
</tbody>
</table>
Results: Primary End Point

- 26/29 (90%) removed in their entirety
- 52% defibrillator, 34% pace-sense, 14% CS leads
- Mean Lead Age: 7yrs
Results: Primary End Point(2)

• No deaths or need for surgical intervention

• Cases
  - 24 hr inotropic support (n=1)

• Controls
  - extraction site haematoma (n=2)
## Predictors of Success

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N = 44</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>1.83</td>
<td>0.87 – 1.94</td>
<td>0.97</td>
</tr>
<tr>
<td>Age</td>
<td>0.84</td>
<td>0.02 – 0.88</td>
<td>0.93</td>
</tr>
<tr>
<td>Gender</td>
<td>0.17</td>
<td>0.44 – 0.68</td>
<td>0.57</td>
</tr>
<tr>
<td>Infection</td>
<td>0.89</td>
<td>0.07 – 1.13</td>
<td>0.03</td>
</tr>
<tr>
<td>Defib Leads</td>
<td>0.11</td>
<td>0.61 – 0.75</td>
<td>0.79</td>
</tr>
<tr>
<td>No. of leads explanted</td>
<td>2.01</td>
<td>0.08 – 2.21</td>
<td>0.04</td>
</tr>
<tr>
<td>Procedure Time</td>
<td>1.05</td>
<td>0.01 – 1.07</td>
<td>0.14</td>
</tr>
<tr>
<td>Time since implant</td>
<td>0.21</td>
<td>0.11 – 0.17</td>
<td>0.63</td>
</tr>
<tr>
<td>LVEF</td>
<td>0.34</td>
<td>0.01 – 0.44</td>
<td>0.21</td>
</tr>
<tr>
<td>Creatinine</td>
<td>2.01</td>
<td>0.01 – 2.3</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Six Month Follow-up

• Of those with infected devices, all had a re-implant

• Cases
  - lead displacement (n=1)
  - mortality (n=2), cause – end stage heart failure, small cell CA

• Controls
  - infection of the new device (n=1)
  - mortality (n=1), cause – end stage heart failure
Study Limitations

• Small cohort, 2 centres

• Extraction on uninterrupted anticoagulation not first line approach

• Safety of extraction on DOACs unknown
Conclusions

• Transvenous lead extraction can be carried out on uninterrupted Warfarin without a significantly increased risk

• Lead age, renal failure and infected devices have a poor prognosis

• Larger multicentre studies/RCT are required to confirm these findings
Acknowledgements


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THANK YOU