Syncope and heart block: pacemaker versus implantable loop recorder

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POST 3 - The 3rd Prevention of Syncope Trial

SYNCOPE: PACING OR RECORDING IN THE LATER YEARS (SPRITELY)
• Syncope 1.5% of ER visits
  – Bifascicular block ± complete heart block 4.9% of syncope visits
  – Suggests 74/100,000 ER visits per year

• Syncope & Bifascicular Block
  – Obvious cause:
    • intermittent complete heart block
  – Numerous competing co-morbidities:
    • carotid sinus syncope, vasovagal syncope, IOH, orthostatic hypotension, sick sinus syndrome...
Competing Strategies

Implantable Loop Recorder

Primum Non Nocere

Pacemaker

Primum Succurrere
PM for syncope and bifascicular block: IIA

ILR for syncope and bifascicular block: IIA
To determine if a strategy of empiric permanent pacing in patients with syncope and bifascicular heart block will provide a better overall reduction of adverse outcomes than a strategy of acting on the results of an implantable loop recorder.
Study Design

- **Randomized pragmatic longitudinal, prospective, parallel design, open label, clinical trial**

- Pacemaker vs. ILR

- Funded by CIHR

- Minimum 2-year observation period or until study completion
Inclusion & Exclusion

- **Inclusion Criteria**
  - ≥1 syncopal spell within 1 preceding year
  - Bifascicular block on a 12-lead ECG
  - Age > 50 years

- **Exclusion Criteria**
  - Previous ILR, pacemaker, ICD
  - Class I indication for pacing
  - LVEF <35%
  - Contraindication to permanent pacing
  - Hypertrophic cardiomyopathy
  - Sustained VT: spontaneous or induced
  - MI in <3 months
  - Epilepsy with (+) EEG
  - Definite documented other cause
Primary Outcome

- **MASRE:** Major Adverse Study-Related Events
  - Syncope
  - Symptomatic bradycardias resulting in intervention
  - Asymptomatic bradycardia resulting in intervention
  - Acute & chronic device complications
  - Cardiovascular death
SPRITELEY: Study Flow

**Allocation**
- PM Assigned (n=60)
- PM Received (n=57)

**Follow-Up**
- Lost to F/U (censored) n=8

**Analyzed**
- Analyzed (n=57)

**Excluded**
- Excluded (n=0)

**PM**

**ILR**
- ILR Assigned (n=59)
- ILR Received (n=58)

**Lost to F/U**
- (censored) n=12

**Analyzed**
- Analyzed (n=58)

**Excluded**
- Excluded (n=0)
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PM (n=57)</th>
<th>ICM (n=58)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized subjects, n</td>
<td>57</td>
<td>58</td>
</tr>
<tr>
<td>Age, y, mean ±SD</td>
<td>75 ± 9</td>
<td>78 ± 9</td>
</tr>
<tr>
<td>Female, n</td>
<td>20</td>
<td>14</td>
</tr>
<tr>
<td>Syncope history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifetime No. of spells, median (IQR)</td>
<td>2 (1-6)</td>
<td>2 (1-4)</td>
</tr>
<tr>
<td>Spells in previous year, median (IQR)</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
</tr>
<tr>
<td>Duration of symptoms, y, median (IQR)</td>
<td>1 (1-4.5)</td>
<td>1 (1-3.25)</td>
</tr>
<tr>
<td>Syncope frequency, spell/year, median (IQR)</td>
<td>1.1 (1-2.8)</td>
<td>1.2 (1-2.6)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, mean ±SD (range)</td>
<td>60±8 (38,81)</td>
<td>58±8 (39,75)</td>
</tr>
</tbody>
</table>
## Baseline Characteristics 2

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PM (n=57)</th>
<th>ICM (n=58)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Syncope Symptoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calgary Syncope Symptom Score, Mean (SD)</td>
<td>-4 ± 3.2</td>
<td>-3.9 ± 3.4</td>
</tr>
<tr>
<td>Calgary Syncope Symptom Score, Range</td>
<td>-11, 1</td>
<td>-14, 5</td>
</tr>
<tr>
<td>No prodromal symptoms</td>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>Syncope started over age of 35y</td>
<td>49</td>
<td>48</td>
</tr>
<tr>
<td><strong>Baseline ECG</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBBB</td>
<td>21</td>
<td>20</td>
</tr>
<tr>
<td>RBBB and LAFB</td>
<td>33</td>
<td>36</td>
</tr>
<tr>
<td>RBBB and LPFB</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>
Results: Primary Outcome

![Graph showing survival analysis for PPM and ICM groups](image)
Results: Syncope-Free

![Graph showing syncope-free survival over time for ICM and PPM]
## Results: Outcomes by Patient

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>PM (n=57)</th>
<th>ICM (n=58)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with primary outcomes</td>
<td>19</td>
<td>44</td>
<td>0.0001</td>
</tr>
<tr>
<td>CV Death</td>
<td>1</td>
<td>2</td>
<td>0.98</td>
</tr>
<tr>
<td>Syncope</td>
<td>13</td>
<td>14</td>
<td>0.87</td>
</tr>
<tr>
<td>Syncope causing X-over</td>
<td>0</td>
<td>11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bradycardia crossovers</td>
<td>0</td>
<td>32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Asymptomatic brady causing X-over</td>
<td>0</td>
<td>8</td>
<td>0.006</td>
</tr>
<tr>
<td>Symptomatic brady causing X-over</td>
<td>0</td>
<td>20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delayed crossover after syncope</td>
<td>0</td>
<td>4</td>
<td>0.12</td>
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<tr>
<td>Device comp requiring intervention</td>
<td>5</td>
<td>0</td>
<td>0.03</td>
</tr>
</tbody>
</table>
Results: Crossover-Free

![Graph showing crossover-free survival percentage over time.
Axes: Time (days) on the x-axis ranging from 0 to 2000, and Crossover-free survival, % on the y-axis ranging from 0 to 100.
Points marked as ICM indicating a significant event at a specific time.
]
Results: CV Death or Device Complications
Conclusions 1

- In elderly patients with bifascicular block, **Pacemaker** compared to ILR:
  - Reduced major adverse events
    - High rate of crossover from ILR to PM
  - Did not decrease syncope recurrence
- Syncope recurrence 25-30% in PM group
  - Due to vasodepression
- Crossovers may have been due to non-severe bradycardia
  - ILR group did not have more syncope
Conclusions 2

- Low Risk Group (LVEF>35%, syncope, bifascicular block)
  - No early deaths or tachyarrhythmia
  - May not require admission
  - May be able to arrange for early O/P pacemakers
Acknowledgements

- POST3 Investigators
- POST3 Patients
- POST Office
  - University of Calgary Syncope Coordinating Center
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- Canadian Institute of Health Research