Mechanism of Lead Failure

Results from the Pacemaker and Implantable Defibrillator Leads Survival Study (‘‘PAIDLESS’’)

Partially funded through Winthrop University Hospital investigator initiated grants from Medtronic, Inc. (Minneapolis, MN) and Boston Scientific (Marlborough, MA).

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To examine the mechanisms of lead failure among three manufacturers:

- Boston Scientific (BSC)
- Medtronic (MDT)
- St. Jude Medical (SJM)
A Comparative Study of Defibrillator Leads at a Large-Volume Implanting Hospital: Results from the Pacemaker and Implantable Defibrillator Lead Survival Study (“PAIDLESS”)
Kaplan Meier survival estimates comparing Medtronic to St. Jude Medical recalled leads only

Logrank p < .0001

Survival Probability

Implant Age

Manufacturer 1: Medtronic 2: St. Jude Medical

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>No. of Subjects</th>
<th>Event</th>
<th>Censored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td>801</td>
<td>56</td>
<td>745</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>703</td>
<td>20</td>
<td>683</td>
</tr>
</tbody>
</table>
Methods

- This study analyzed all leads implanted at Winthrop University Hospital between February 1, 1996 and December 31, 2011

- Lead failure was defined by Medtronic Systems Longevity criteria: failure to capture, failure to sense, abnormal pacing impedance, abnormal defibrillation impedance, insulation defect, lead fracture, extracardiac stimulation, cardiac perforation, tricuspid valve entrapment, lead tip fracture, and/or lead dislodgement

- Statistical analyses included Chi-Square and Fisher’s Exact Tests
FAILURE POINTS ACROSS MANUFACTURERS

- Erosion
- BSC
- Lead Fracture
- MDT
- Externalized Conductor
- SJM
## Results

- Total failures = 153

- Significant differences between manufacturers:

<table>
<thead>
<tr>
<th>Lead type</th>
<th>Number of failures (N=153)</th>
<th>Causes of lead failure</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>High impedance</td>
<td>Insulation defects</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>18 (12%)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Medtronic</td>
<td>99 (65%)</td>
<td>36</td>
<td>6</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>36 (23%)</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td><strong>p-value</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results

- Failure in non-recalled leads: 77 (3% of non-recalled leads)
- Failures in recalled leads: 76 (5% of all recalled leads)
  - Medtronic’s Sprint Fidelis: 56
  - St. Jude Medical’s Riata and Riata ST: 20

Significant differences based on recall status:

<table>
<thead>
<tr>
<th>Recall status</th>
<th>Causes of lead failure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensing</td>
</tr>
<tr>
<td>Recalled</td>
<td>14 (18%)</td>
</tr>
<tr>
<td>Non-recalled</td>
<td>4 (5%)</td>
</tr>
<tr>
<td>p-value</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Results

- Recalled leads: Medtronic vs. St. Jude Medical

- Abnormal impedance – low only:
  - Recalled Medtronic: 0 (0%)
  - Recalled St. Jude Medical: 3 (15%) (p=0.003)
Conclusions

- Lead failure mechanisms differ amongst manufacturers as well as between recalled and non-recalled leads.
- Lead failure mechanisms also differ by manufacturer within the recalled group.
- Limitation: Recall of the St. Jude Medical Riata and Riata ST leads occurred in 2011, the same year the PAIDLESS study ended.
- Future research in this field would help determine the importance of understanding the mechanism behind lead failures.