Outcomes of Defibrillator Lead Implants Performed by High Volume Operators vs. Low Volume Operators: 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).

What is the original PAIDLESS study?

- Retrospective analysis at a large-volume implanting hospital
- Includes all patients at Winthrop University Hospital that underwent defibrillator lead implantation between February 1, 1996 and December 31, 2011
  - A total of 4078 leads were implanted in 3802 patients
- The study compared patient characteristics, implant approach, lead construction, recall status, lead survival, and patient mortality

Lead failure

Defined by the Medtronic System Longevity Study:

- Failure to capture
- Failure to sense
- Abnormal pacing impedance (< 400 ohms or > 2000 ohms)
- Abnormal defibrillation impedance (< 20 ohms or > 200 ohms)
- Insulation defect
- Lead fracture
- Extracardiac stimulation
- Cardiac perforation
- Tricuspid valve entrapment
- Lead tip fracture
- Lead dislodgement
Recall status

- Three lead manufacturers: Boston Scientific (537), Medtronic (1834), St. Jude Medical (1707)
- October 2007: Medtronic Sprint Fidelis was recalled due to lead fracture (801 PAIDLESS leads)
- November 2011: St. Jude Medical Riata and Riata ST were recalled due to insulation failure (703 PAIDLESS leads)
PAIDLESS results

- Boston Scientific and St. Jude leads performed better than Medtronic leads ($p<0.001$ and $p=0.01$, respectively)
- Recalled leads were associated with earlier lead failure ($p=0.0126$) and more patient mortality ($p=0.006$)
- Multivariable Cox regression model: factors contributing to lead failure
  - Younger age
  - History of percutaneous coronary intervention
  - Baseline rhythm (sinus vs. atrial fibrillation vs. flutter)
  - Lead insulation coating (combination vs. silicone)
  - Number of coils (one vs two)
  - Recalled lead status
Purpose of this sub-study:

- To investigate the effects of operator volume on defibrillator lead failure
Methods

- Between February 1, 1996 and December 31, 2011 at Winthrop University Hospital:
  - High volume operators: performed $\geq 500$ implants
  - Low volume operators: performed $< 500$ implants
- These two groups were analyzed based on patient characteristics and lead failure
- Statistical analyses included: T-tests, Chi-Square tests, and Kaplan-Meier analysis
## Results

<table>
<thead>
<tr>
<th>Operator group</th>
<th>Number of operators</th>
<th>Type of operator</th>
<th>Number of patients N=3802 (%)</th>
<th>Number of implants N=4078 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>4</td>
<td>Electrophysiologists</td>
<td>3150 (83)</td>
<td>3375 (83)</td>
</tr>
<tr>
<td>Low</td>
<td>4</td>
<td>Electrophysiologists and a cardiothoracic surgeon</td>
<td>652 (17)</td>
<td>703 (17)</td>
</tr>
</tbody>
</table>
Results

- Patient characteristics:
  - High volume operators group
    - More men (75% versus 69%; p=0.0006)
    - Older patients (71+12 years versus 68+13 years; p<0.0001)
    - Longer follow up (4+3 years versus 2+2 years; p<0.0001)
    - Implanted mostly with Medtronic leads (52% versus 10%)
    - Implanted more with recalled leads (42% versus 12%; p<0.0001)
Results

- Lead failure:
  - More lead failures occurred in patients operated on by high versus low volume operators (136 failures (4%) versus 17 failures (2%); p=0.0408)
  - Kaplan Meier analysis: time to lead failure was not significant (p=0.0806)
Conclusions

- Contrary to previous studies, high volume operators used more recalled leads and had more lead failures than low volume operators.
- This may be attributed to lead selection and differences in patient characteristics.
- Further research is needed to better understand the impact of operator volume on lead failure and patient outcomes.