Fluoroscopic Grading Scale and Correlation to Lead Extraction in Failed St. Jude Medical Riata Family ICD Leads

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Disclosures

• Sunthosh V Parvathaneni MD
  – None

• Christopher R Ellis MD
  – Speaking Fees/Honoraria < $10,000/yr – Boston Scientific
  – Equity Holder > $50,000 – Johnson and Johnson

• Jason A Rytlewski MD
  – None

• Jeffrey N Rottman
  – None
Background

• Kodoth et al in 2011 quoted their experience in Northern Ireland with the Riata® lead and noted a 15% incidence of externalized conductors in 212 patients

• After this abstract appeared, St. Jude Medical issued the following letter:

Dear Doctor,

The purpose of this letter is to provide updated estimates of failures associated with all cause insulation failure on our Riata® (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads, with a specific emphasis on externalized conductors. The information provided is based on updates to worldwide complaints and returns analysis as well as new peer reviewed publications. Out of over 227,000 Riata and Riata ST silicone leads sold worldwide over the past 9 years, the incidence rate based on returns and complaints (reports from the field with no product returned) is now estimated to be 0.63% for all cause abrasion versus the prior rate of 0.47% communicated in December 2010 (attached for your reference), with approximately 15% of those exhibiting externalized conductors.
Background

MEDICAL DEVICE ADVISORY
IMPORTANT PRODUCT INFORMATION UPDATE

St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads
Riata (8Fr): Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592
Riata ST (7Fr): Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042

The table below summarizes the incidence rate of externalized conductors for the Riata and Riata ST family of silicone leads based on worldwide complaints and returns, along with estimated remaining active U.S. implants.

<table>
<thead>
<tr>
<th>Riata Family</th>
<th>Shock Coil Configuration</th>
<th>Model Numbers</th>
<th>Worldwide Complaint and Returns Rate of Externalized Conductors</th>
<th>Estimated Remaining Active U.S. implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riata (8Fr)</td>
<td>Single</td>
<td>1562, 1572, 1582, 1592</td>
<td>0.64%</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Dual</td>
<td>1560, 1561, 1570, 1571, 1580, 1581, 1590, 1591</td>
<td>0.096%</td>
<td>48,000</td>
</tr>
<tr>
<td>Riata ST (7Fr)</td>
<td>Single</td>
<td>7002, 7042</td>
<td>0.081%</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>Dual</td>
<td>7000, 7001, 7010, 7011, 7040, 7041</td>
<td>0.024%</td>
<td>27,000</td>
</tr>
</tbody>
</table>
Methods

- The true incidence of externalized conductors remained uncertain

- We conducted this study to:
  - Determine the incidence of externalized conductors in our patient population using fluoroscopy
  - Evaluate a straightforward classification scheme for the fluoroscopic findings to facilitate longer-term evaluation
  - Study correlates of externalized conductors in our patients
Methods

• Cine-fluoroscopic assessment was completed of 52 implanted St. Jude Riata® leads over a mean follow up of 5.67 years since time of implant
  – Images were obtained using 15 fps and 15 cm magnification in the RAO 30° and LAO 45° projections

• Riata® leads: 1570, 1580, 1590, 7000, 7020
  – Both Riata® and Riata ST® leads were evaluated
  – No Durata® leads were evaluated
Methods

- Cine-fluoroscopy was performed based on these clinical findings:
  - Abnormal sensing or noise
  - Abnormal lead impedance trends with greater than 20% fluctuation in RV pace-sense or HV impedance
  - Suspected lead fractures
  - Infected leads
  - Devices nearing Elective Replacement Indicator
  - Any patient that elected for fluoroscopy after a detailed discussion
Methods

• A simple grading scale was employed to characterize the degree of conductor externalization
  – Type 0 (T0) → Normal or no extrusion
  – Type 1 (T1) → Abnormal cable spacing without breech
  – Type 2 (T2) → Evidence of gross extrusion of ≤ 1 cm in longitudinal length
  – Type 3 (T3) → Evidence of gross extrusion of > 1 cm in longitudinal length

• Two independent electrophysiologists reviewed and graded each lead
Methods

Methods
Methods

Methods

Results

- 34.6% (18/52) of Riata® leads demonstrated abnormal findings consistent with loss of structural integrity

- 22.2% (4/18) of leads had electrical abnormalities
  - Abrupt changes in HV impedances
  - An increase in RV pacing impedance indicating fracture
  - A decrease in RV pacing impedance possibly indicating insulation compromise
  - Inappropriate shocks from over-sensing of noise
## Results

<table>
<thead>
<tr>
<th>Lead Model</th>
<th>Class</th>
<th>Diam (Fr)</th>
<th>Tip Press. (psi)</th>
<th>Thick (inch)</th>
<th>Total</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1570</td>
<td>Riata</td>
<td>7.6</td>
<td>4.9</td>
<td>0.012</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>R1580</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70</td>
<td>33</td>
</tr>
<tr>
<td>R1581</td>
<td></td>
<td>2</td>
<td>2</td>
<td></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>R1590</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>R7000</td>
<td>Riata ST</td>
<td>6.3</td>
<td>4.1</td>
<td>0.008</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>R7020</td>
<td>Riata ST Optim</td>
<td>6.3</td>
<td>4.1</td>
<td>0.008</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>87</strong></td>
<td><strong>37</strong></td>
</tr>
</tbody>
</table>

**Fluoroscopically abnormal**

- 43%

**Structurally abnormal**

- 33%

Results

• Serious Electrical Abnormality: lead noise, high threshold, lead fracture, or high voltage short

<table>
<thead>
<tr>
<th></th>
<th>Serious Electrical Abnormality</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>2</td>
<td>48</td>
</tr>
<tr>
<td>T1-T3</td>
<td>10 (83%)</td>
<td>27 (36%)</td>
</tr>
</tbody>
</table>

\( p = 0.003 \)
Results
Results

Fluoroscopic Observations

Regression model

Conclusions

• High resolution Cine-fluoroscopic imaging using a simple grading scale closely correlated with extracted ICD Riata® leads in assessment of structural integrity

• True incidence of mechanical failure is unknown but the occurrence of electrical failure is apparent and thusly impact clinical care
Conclusions

• Time related failure mechanisms have important implications for designing appropriate post-market surveillance

• Fluoroscopic mechanical failure in this abstract was 34.6% and warrants a large multi-center study to determine the true incidence of mechanical as well as electrical failure
References

- Henrikson C. The Riata story – where are we now? Heart Rhythm 2012; In Press.
- Parvathaneni S, Ellis C, and Rottman J. High prevalence of insulation failure with externalized cables in St. Jude Medical Riata family of ICD leads; fluoroscopic grading scale and correlation to extracted leads. Heart Rhythm 2012; In Press.
- Chan C and Chiang C. An ICD lead with failure of outer insulation goes undetected by regular measurements. PACE 2011; 1-2.


St. Jude Medical Device Advisory Statement. 11/2011.