The Riata® Implantable Cardioverter Defibrillator Lead: Extraction Experience for Conductor Exteriorization and Electrical Malfunction

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Disclosures

• H. Saltzman – none
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Introduction

• St. Jude Medical Riata® Implantable Cardioverter-Defibrillator (ICD) Leads have been found susceptible to a characteristic defect where internal conductors wear through the silicone insulation.

• The defect was first reported in 2008 but has been found, in fluoroscopic studies, to occur in 12% - 33% \(^1,2\) of Riata leads.

• While not all leads with conductor exteriorization (CE) experience electrical malfunction, the presence of CE has been hypothesized to increase the incidence of electrical malfunction.\(^2\)

• While the scope of the lead defect and its future implications are not clear, the presence of electrical malfunction should prompt further lead management (placement of a new lead or extraction and re-implantation.)³

• Prior reported attempts at endovascular extraction of Riata® leads have led to a need for conversion to an open thoracotomomy for extraction⁴ and death in some cases.⁵

3. Riata Lead Webinar, HRS website 12/2011
4. Richards et al, Europace 2010
Methods

• Our center’s device extraction records were reviewed from January 2009 through March 2012 and patients who had extraction of a St. Jude Medical Riata® lead (1500 and 7000 series) were included

• Standard extraction techniques were used
The Riata® Lead

Silicone lead body

Ethylene tetrafluoroethylene (ETFE) coating around outer conductors and Polytetrafluoroethylene (PTFE) around inner coils

Single coil has three lumens, dual coil has four (on 1500 series)

Shock coils have round wires with no silicone back filling (on 1500 series)

Images c/o St Jude Medical
# Baseline Characteristics

<table>
<thead>
<tr>
<th>Patients = 27</th>
<th>Riata leads = 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>65 ± 16</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28 ± 5</td>
</tr>
<tr>
<td>Male (%)</td>
<td>64</td>
</tr>
</tbody>
</table>

## Primary Explant Indication

<table>
<thead>
<tr>
<th>Conductor Exeriorization (%)</th>
<th>4 (14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical Malfunction (%)</td>
<td>9 (32)</td>
</tr>
<tr>
<td>Infection (%)</td>
<td>15 (54)</td>
</tr>
<tr>
<td>Total leads with CE (%)</td>
<td>11 (39)</td>
</tr>
</tbody>
</table>

## ICD Implant indications

- Ischemic CM - 20 (71%)
- Non ischemic CM - 4 (14%)
- Hypertrophic CM - 2 (7%)
- Long QT syndrome - 1 (4%)
- Arrhythmogenic RV dysplasia - 1 (4%)
# Device and Lead Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
<th>Single chamber (%)</th>
<th>Dual chamber (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age of lead (months)</td>
<td>$71 \pm 28$ (4-119)</td>
<td>7 (25)</td>
<td></td>
</tr>
<tr>
<td>Average extraction time (min)</td>
<td>$21 \pm 22$ (6-90)</td>
<td></td>
<td>12 (43)</td>
</tr>
<tr>
<td>Active fixation (%)</td>
<td>26 (93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dual coil (%)</td>
<td>25 (90)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1500 series Riata (%)</td>
<td>22 (79)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7000 series Riata (%)</td>
<td>6 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural Complications</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Total leads extracted/case</td>
<td></td>
<td></td>
<td>$2.1 \pm 1.2$</td>
</tr>
</tbody>
</table>
Extraction Tools

# of cases

16F Laser
14F Laser
13F
10F
11.5 F

Manual Traction
Byrd Dilator (Cook)
Laser Sheath (Spectranetics)
Liberator locking stylet
LLD locking stylet

1
3
2
9
1
12
12
16
Age of lead vs Extraction time

Red = 1500 series        Green = 7000 series            r = 0.44
Conductor Exteriorization (CE) vs Extraction Time

- CE-YES (n=11) 35.8 min
- CE-NO (n=16) 12.5 min

p value = 0.004
65 y/o with NICM – 1581, lead age – 119 months
Appropriate shock for VT with 9 ohm HV impedance
16 F Laser Extraction
Tips for Riata® Extractions

• Conductor cables should be tied-off and held separately (i.e. not tied to the locking stylet)
• Anticipate snow-plowing (from exteriorized conductors and damaged insulation)
• An outer sheath is helpful in dealing with externalized conductors, tissue ingrowth into the shock coils, and for counter-traction
Conclusions

• Riata leads can be extracted safely at experienced centers with standard extraction tools.

• A 14 French laser sheath, when used with an outer sheath can be safely used in most cases, even with extensive CE

• The difficulty of lead extraction, as measured by extraction time, is associated with lead age and the presence of CE
Bibliography


3. HRS Riata Lead webinar 12/2010

4. Richards MV et al. Late failure of a single-coil transvenous implantable cardioverter-defibrillator lead associated with conductor separation. Europace. 2010, 12 (8) 1191-1192