How to Manage the Faulty ICD Lead

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Manchester Heart Centre
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Not All Implants Work Well Long-Term
Inappropriate Shocks Occur Frequently and Lead Failure is a Common Cause

Cumulative lead malfunction incidence is 4.6% at 10 years across manufacturers

Lead malfunction resulted in inappropriate shocks in 76% of the cases

Surprisingly High Failure Rate in Some Series

Single Centre Study (n=990)
Failure Rate Increases With Time (unsurprisingly)

Causes of ICD Lead Failure

- Subclavian crush
- Exit block
- Insulation attrition
- Twiddler’s syndrome
- Excessively tight coiling of lead in pocket
- Intrinsic lead design flaw
Sprint Fidelis 6949 Lead

6.6F bipolar lead

2 areas prone to fracture:

1) the ring electrode
2) near the anchor sleeve predominantly affecting the cathode (helix tip electrode)

<10% of fractures affect the HV conductor
Sprint Fidelis 6949 Lead Performance

- CareLink PLUS (72 mos): 89.0% [+0.5/-0.5], 91.3% [+2.7/-3.8]
- SLS (66 mos): 89.7% [+0.1/-0.1], 91.3% [+0.1/-0.2]

<table>
<thead>
<tr>
<th>Model 6949</th>
<th>0 yr</th>
<th>1 yr</th>
<th>2 yr</th>
<th>3 yr</th>
<th>4 yr</th>
<th>5 yr</th>
<th>Last Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareLink PLUS</td>
<td>21,500</td>
<td>21,218</td>
<td>20,059</td>
<td>17,796</td>
<td>15,542</td>
<td>12,709</td>
<td>at 6 yrs: 2,663</td>
</tr>
<tr>
<td></td>
<td>99.7% [+0.1/-0.1]</td>
<td>98.7% [+1.1/-1.5]</td>
<td>98.7% [+0.3/-0.3]</td>
<td>96.2% [+1.4/-2.0]</td>
<td>93.8% [+1.7/-2.2]</td>
<td>92.5% [+2.0/-2.7]</td>
<td>89.0% [+0.5/-0.5]</td>
</tr>
<tr>
<td>SLS</td>
<td>795</td>
<td>716</td>
<td>625</td>
<td>513</td>
<td>321</td>
<td>130</td>
<td>at 66 mos: 50</td>
</tr>
<tr>
<td></td>
<td>98.8% [+0.6/-1.1]</td>
<td>96.9% [+1.1/-1.5]</td>
<td>96.2% [+1.1/-1.5]</td>
<td>94.9% [+1.4/-2.0]</td>
<td>93.8% [+1.7/-2.2]</td>
<td>92.5% [+2.0/-2.7]</td>
<td>91.3% [+2.7/-3.8]</td>
</tr>
</tbody>
</table>

[Graph showing lead survival probability over years with data points for CareLink PLUS and SLS.]
Sprint Fidelis 6949 Lead Performance
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It’s Not Only the Fidelis....
Effects of ICD Lead Failure

Inappropriate shocks

High pacing/shock impedance leading to failure to pace or failure to shock

Noise/short V-V intervals
Effects of ICD Lead Failure - Noise
Effects of ICD Lead Failure – Sudden Rise in Impedance

RV pacing impedance
At implant 872 ohms
Last 1,552 ohms

Highest >2,500 ohms
Lowest 606 ohms

Last 80 weeks (minutes/max per week)
Horse Hospitals
Short-term Management of Failing ICD Lead

- Admit to monitored bed
- Suspend tachycardia therapy using ring magnet
- Urgent device interrogation
Long-term Management of Failing ICD lead
Options

Reprogramming of device

New P/S lead

New HV coil

New lead with abandonment of defective lead

Extraction of failed lead with implantation of new lead
Long-term Management of Failing ICD Lead

Device-Related Factors

Mechanism of lead failure
Type of lead
Lead advisory/recall guidelines
Age of lead
Number of chronic leads
Long-term Management of Failing ICD lead

Patient-Related Factors

- Age of patient
- Co-morbidities
- Ease of implant of additional hardware
- Initial indication for ICD
- Patient choice
Integrated Bipolar Lead

The distal defibrillation coil also serves as the ring electrode - failure of the conductor to the RV coil will necessitate replacement of the entire lead.
The ring electrode and defibrillation coil have independent conductors
Long-term Management of Failing ICD lead

Reprogramming of Device

Reduce HV impedance alarm from 200 to 100 ohms
(1 week extra notice for 26% of patients)

Set RV pacing impedance alert at 1000 ohms
(47% of patients would have 4 or more extra days notice)
Long-term Management of Failing ICD lead
Sensing Integrity Counter

<table>
<thead>
<tr>
<th>Battery Voltage</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>3.38 V</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Last Capacitor Formation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Charge Time</td>
<td>13.0 sec</td>
</tr>
<tr>
<td>Energy</td>
<td>1.9 - 30 J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Last Charge</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Charge Time</td>
<td>9.4 sec</td>
</tr>
<tr>
<td>Energy</td>
<td>0.0 - 20 J</td>
</tr>
</tbody>
</table>

**Sensing Integrity Counter**
(if >300 counts, check for sensing issues)

Since 13-Jan-1994 22:41:21
Short V-V Intervals 17

| Atrial Lead Position Check | No measurement since reset. |

**Battery and Lead Measurements Report**

**Date of Visit:** 04-Apr-2003 08:00:02

**Device:** D1AT930
**Serial Number:** DAT012SIMR

**Lead Impedance**

<table>
<thead>
<tr>
<th>Lead Impedance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Pacing</td>
<td>257 ohms</td>
</tr>
<tr>
<td>RV Pacing</td>
<td>256 ohms</td>
</tr>
<tr>
<td>RV Defib</td>
<td>128 ohms</td>
</tr>
<tr>
<td>SVC Defib</td>
<td>129 ohms</td>
</tr>
</tbody>
</table>

**Sensing**

<table>
<thead>
<tr>
<th>Sensing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>P-Wave Amplitude</td>
<td>5.3 mV</td>
</tr>
<tr>
<td>R-Wave Amplitude</td>
<td>9.4 mV</td>
</tr>
</tbody>
</table>

**Last High Voltage Therapy**

<table>
<thead>
<tr>
<th>Last High Voltage Therapy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>05-Jan-1997 08:34:50</td>
<td></td>
</tr>
<tr>
<td>Measured Impedance</td>
<td>&lt;20 ohms</td>
</tr>
<tr>
<td>Delivered Energy</td>
<td>28 J</td>
</tr>
<tr>
<td>Waveform</td>
<td>Biphasic</td>
</tr>
<tr>
<td>Pathway</td>
<td>AX&gt;B</td>
</tr>
</tbody>
</table>
Lead Integrity Suite

Combines two algorithms that detect, alert, and withhold inappropriate therapy for lead failure:

Lead Integrity Alert
Provides advance warning for lead fracture and extends the VF detection time

Lead Noise Discriminator + Alert
Identifies oversensing due to noise artifacts and provides ability to withhold therapy delivery
No compromise of VT/VF detection sensitivity
Notifies clinician of potential lead noise

Medtronic Protecta™ and Protecta™ XT system reference guides
Shock Avoidance in Lead Failure

LIA is based on lead impedance and an oversensing trigger. When triggered, it extends the NID to 30 out of 40. LIA provided at least a 3-day warning of inappropriate shocks in 76% of patients.

Swerdlow CD. *Circulation*. 2008; 118: 2122-2129
RV Lead Noise Discrimination

Noise oversensing is typically isolated to the near field sensing signal. Compare near-field sensing signal:

- Far field EGM used to confirm senses

Compared far-field cardiac activity to sensed event

Medtronic Protecta™ and Protecta™ XT system reference guides.
LIA Reduces Inappropriate Shocks

213 patients with lead fracture and LIA vs 213 patients with lead fracture but without LIA
LIA group had 46% reduction in inappropriate shocks

Swerdlow CD. *Circulation*. 2010; 122: 1449-1455
Lead Integrity Suite and Remote Monitoring

CareLink website sends a CL Notification (text message, or email) Clinic chooses whether this alert should be red, yellow, or website only up to a patient level

<table>
<thead>
<tr>
<th>Lead/Device Integrity Alerts</th>
<th>Red Alert</th>
<th>Yellow Alert</th>
<th>Website-only Alert</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RV Lead Integrity</strong></td>
<td><img src="image1" alt="Red Alert" /></td>
<td><img src="image2" alt="Yellow Alert" /></td>
<td><img src="image3" alt="Website-only Alert" /></td>
</tr>
<tr>
<td>Two of the three criteria are met within the last 60 days: two or more fast non-sustained episodes, Sensing Integrity Counter $\geq 30$ in three days and/or a right ventricular impedance variation. This could be triggered by a dislodged lead, an improperly connected lead, or a lead failure.</td>
<td><img src="image1" alt="Red Alert" /></td>
<td><img src="image2" alt="Yellow Alert" /></td>
<td><img src="image3" alt="Website-only Alert" /></td>
</tr>
</tbody>
</table>
Extract or Abandon

Wollmann et al JCE 2007;18:1172-7
Single Centre Study
Abandoned leads largely due to failed extraction or venous thrombosis

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Additional HVPS (n = 33)</th>
<th>Replaced HVPS (n = 53)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oversensing with inappropriate shocks</td>
<td>2</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>Oversensing only</td>
<td>1</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>Other P/S problems (e.g., exit block)</td>
<td>1</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>Combined defect (HV + P/S)</td>
<td>1</td>
<td>3.1</td>
<td></td>
</tr>
<tr>
<td>System infection</td>
<td>2</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>ICD recall</td>
<td>5</td>
<td>9.4</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>6</td>
<td>18.2</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>39.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>41.5</td>
<td>ns</td>
</tr>
</tbody>
</table>
Extract or Abandon

Scott et al Europace 2010;12:522–6
Single centre observational study
45 patients with isolated P/S problem
Treated with additional P/S lead

<table>
<thead>
<tr>
<th></th>
<th>Not under advisory (n = 35)</th>
<th>Under advisory (n = 10)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device infection</td>
<td>5.7 (2)</td>
<td>0 (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Rising shocking</td>
<td>0 (0)</td>
<td>10.0 (1)</td>
<td>0.499</td>
</tr>
<tr>
<td>coil impedance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death (%)</td>
<td>14.3 (5)</td>
<td>0 (0)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

87% cumulative survival from further lead defects 3 years
HV Survival After P/S Fracture

If a Fidelis lead fracture of any type has occurred, a new HV lead with or without extraction of the Fidelis lead is recommended. Implantation of a P/S lead while maintaining use of the Fidelis high voltage conductors after a Fidelis P/S fracture has occurred is no longer recommended.

<table>
<thead>
<tr>
<th>Months after a Pace-Sense Conductor Fracture</th>
<th>0</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>21</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (leads)</td>
<td>182</td>
<td>120</td>
<td>88</td>
<td>63</td>
<td>54</td>
</tr>
<tr>
<td>High Voltage Conductor Survival</td>
<td>100%</td>
<td>98.7%</td>
<td>89.0%</td>
<td>80.3%</td>
<td>77.7%</td>
</tr>
</tbody>
</table>
Long-term Management of Failing ICD lead
Advantages of Extraction + Reimplant

- Preservation of venous access
- Reduced infection risk
- Avoids lead-lead interaction
- Reduced lead burden
- Reduced risk of future extraction
Real World Practice


Data from 376 ICD-implanting physicians in 28 countries (USA 83.2%)

Implant experience:

- >10 years 61.1%
- 3-10 years 29.1%
- <3 years for 10.4%

RV coil failure: 52% abandoned, 48% explanted

P/S failure: 53.1% implanted a new P/S lead or switch sensing electrodes, using the intact lead components