A Contemporary Approach to Lead Management

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Overview – What we are Focusing on

- Definitions & History
- Indications/Management
- Technique
- Applications
  - Complications
  - Safety
Definitions

• **Lead removal**
  • Removal of a pacing or defibrillator lead using any technique.
  • It includes two completely different procedures

• **Lead explant**
  • Removal of a lead using simple traction techniques, which is usually possible for leads implanted for less than 1 year

• **Lead extraction**
  • Removal of:
  • Lead/s implanted for more than 1 year or
  • that require the assistance of *specialized equipment* in order to be removed.

From Guidelines: Definitions, Indications, Facilities, and Outcomes of Transvenous Lead Extraction R. Verlato et al.
Historical Perspective

- Initial options
  - Traction vs open thoracotomy

- Late 1980’s – Early 1990’s
  - Locking stylet
  - Telescoping sheaths

- 1999 – PLEXES
  - Excimer laser sheath
Traction with Weights

Image provided by Spectranetics Corporation, 2008
Expanding Indications: Pool of Patients

- 7 million CIEDs worldwide
- 13 million leads
- 700,000 new devices annually
- 1.4 million new leads annually

Patients and Devices

- ICD patients are younger and live longer
- 35% of new implants are ICDs and CRT-Ds
- CRT-Ds have more leads per device
- 7 million CRM devices worldwide
- 700,000 new devices annually
- 14 million leads worldwide
- 1.4 million new leads annually

EXPANDING INDICATIONS…

5% Estimated Annual Incidence and Growing

1% Infection
- 6 in 10 patients may be undertreated
- 2-7% infection rate for replacements/upgrades

5.0% Malfunction
- 1.65%-20% annual ICD lead failure based on age

5.0% Occlusion
- 9-35% of device replacement or upgrade

1% Redundant
- +Advisory Leads
- +MRI Conditional
65% of Infection Patients Are Undertreated

More than 6 in 10 patients suffering from cardiac device infections are treated with antibiotics only or not treated at all.

Pocket and systemic infection are a Class I indication for complete removal of hardware, including leads.
Infection
Lead Failure

1. Dislodgement
2. Fracture of conductor elements
3. Insulation breach
Lead Malfunction

Figure 1. Kaplan-Meier curves of event-free lead function of all lead models (n=990).

Figure 2. Annual rate of defibrillation lead defects versus time after lead implantation. The annual rate of ICD lead defects increases with time (P<0.001, Cochran-Armitage test). *Failures per number at risk.

Kleemann et. al. Circulation 2007;115:2474
Lead
Malfunction/Recall/Advisories
Redundant leads

Venous Occlusion
Redundant Leads

Abandoned leads can be a risk factor:

• As a source for infection

• Venous and tricuspid lead burden

• For venous occlusion due to compromised vascular space

Venous Occlusion

Oclusions may pose a significant challenge during a device upgrade or a malfunctioning lead replacement

Oclusion Management Options

• Laser lead extraction
• Implant a new system on contralateral side
• Tunnel leads from contralateral side
• Implant and tunnel an epicardial lead
• Venoplasty to gain access
Growing Need for Lead Management

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INDICATION</th>
<th>CLASS</th>
</tr>
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<tbody>
<tr>
<td>Infection</td>
<td>Pocket infection</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Occult gram-positive bacteremia</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Occult gram-negative bacteremia</td>
<td>IIa</td>
</tr>
<tr>
<td>Chronic Pain</td>
<td>Severe chronic pain</td>
<td>IIa</td>
</tr>
<tr>
<td>Occlusion</td>
<td>Ipsilateral occlusion w/o contralateral contraindication</td>
<td>IIa</td>
</tr>
<tr>
<td>Functional Lead</td>
<td>Due to design or failure, may pose immediate threat</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Risk of interference with device operation</td>
<td>IIb</td>
</tr>
<tr>
<td></td>
<td>Due to design or failure poses potential future threat</td>
<td>IIb</td>
</tr>
<tr>
<td></td>
<td>Functional leads not being used (ICD upgrade)</td>
<td>IIb</td>
</tr>
<tr>
<td></td>
<td>To permit the implantation of an MRI conditional CIED system</td>
<td>IIb</td>
</tr>
<tr>
<td></td>
<td>Need MRI with no other imaging options for diagnosis</td>
<td>IIb</td>
</tr>
<tr>
<td>Non Functional Lead</td>
<td>Implant would require &gt; 4 leads on one side or &gt;5 leads through SVC</td>
<td>IIa</td>
</tr>
<tr>
<td></td>
<td>Need MRI with no other imaging options for diagnosis</td>
<td>IIa</td>
</tr>
<tr>
<td></td>
<td>To permit the implantation of an MRI conditional CIED system</td>
<td>IIb</td>
</tr>
<tr>
<td></td>
<td>Non functional lead at device/lead procedure</td>
<td>IIb</td>
</tr>
</tbody>
</table>
Techniques and Tools
Technique: Counter-traction
Techniques

• Manual Traction – “pulling” on lead

• Counter traction – “pulling” on lead while advancing laser/mechanical rotating blade

• Reverse “sweet tip” - manual counterclockwise “unscrewing” of lead
What is known

• Fibrous adhesions
  • Non uniform
  • Form at ICD coils and tip of the lead
• More advanced methodologies beyond simple traction are needed when the degree of fibrosis occurs at the vasculature
• At times when the only tip of the lead remains fibroserd the standard of care is application of manual traction which can result in laceration of the right ventricle if performed with excess force.
• Preparation should include:
  • OR staff with CV surgeon on standby
  • Readily available and accessible equipment is accessible and in/outside room (Saw, Redo Saw, Perfusion machine, TEE)
  • Making sure staff is consistent and knowledgeable about the procedure
  • Thorough patient informed consent
Complications

- Complications include but are not limited to
  - Pulmonary embolism
  - Venous laceration (SVC, IVC, Subclavian)
  - Myocardial Perforation (Atrial or Ventricular)
  - Cardiac Tamponade
  - Hematoma, Pain, Reinfection
  - Death
Lead Extraction in the Contemporary Setting

Factors associated with higher complications or lower success*

• Body mass index <25 kg/m²
• Leads implanted ≥10 years
• Low volume centers with ≤60 lase
• Lead extraction cases over 4 years
• Higher all-cause in-hospital mortality associated with endocarditis (4.3%), endocarditis and diabetes (7.9%), or endocarditis and renal insufficiency** (12.4%)

* Procedural and/or clinical success
** Creatinine ≥2.0 mg/dl
Safe Lead Management

• While the risk of an adverse event occurring during lead extraction procedures is low, it is important to be prepared for them if they do occur.

• Rarely a patient undergoing lead extraction may require urgent surgical treatment for a complication; therefore, patients should not undergo lead extraction with a laser sheath in centers where emergency surgical procedures cannot be performed. (i.e. tear to blood vessel, tear to heart structure, bleeding at surgical site)

• Having the appropriate protocols and the right team in place are vital to having a safe lead management program.
Conclusions

• Evolving technology and patient needs facilitate a need for lead management

• Expanded indications by the Heart Rhythm Society addressed the evolution process

• Treatment decisions should be patient focused with thorough consent, risk benefit analysis and preparation
Thank you!