Lead extraction

The dark side of the coin

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Agenda

• Introduction
• History of consensus
• Definitions
• Complications
• Indications
• Lead management environment
• Extraction tools
• Current European practice in lead extraction
• Egyptian steps in lead extraction
Introduction

Pacemaker & Leads

ICD & Leads

Implantable cardioverter defibrillator (ICD) dual-chamber

Introduction

Types of Leads

Active fixation lead

Passive fixation lead
since the first implantable pacemaker was placed in 1958, conductors, insulation materials, lead construction, implantation techniques, infection and venous occlusion have been the source of significant clinical problems.

However, not until the late 1980s was a serious attempt made to develop tools and techniques to safely remove problematic leads.

The penetration of transvenous lead extraction techniques into general use was slow due to the potential for fatal complications and the limited training in the tools and techniques.
**History of consensus**

- **NASPE Policy Conference – 1997**

- **HR 2008 Satellite Symposium**

- **Expert Consensus Task Force Formed**
  Symposium feedback, literature, new research, face-to-face, tele-conference, email

- **HRS Consensus Document**
  HR BOT Approval May 2009
  Online available, full publication July 2009 in Heart Rhythm

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**Definitions**

- **Lead removal**: removal of a pacing or defibrillator lead using any technique

- **Lead explant**: lead removal using simple traction techniques (no locking stylet, telescoping sheaths, or femoral extraction tools)

- **Lead extraction**: removal of a lead that has been implanted for more than 1 year, or a lead regardless of duration of implant requiring the assistance of specialized equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than via the implant vein. ICD leads may require specialized extraction equipment even when implantation duration is less than 1 year

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Definitions

• **Complete Procedural Success:** Removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death.

• **Clinical Success:** Removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that does not negatively impact the outcome goals of the procedure.

• **Failure:** Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure related death.

Complication

**Intra-procedural complication:** Any event related to the performance of a procedure that occurs or becomes evident from the time the patient enters the operating room until the time the patient leaves the operating room. This includes complications related to the preparation of the patient, the delivery of anesthesia, and opening and closing the incision.

**Post-procedural complication:** Any event related to the procedure that occurs or becomes evident within 30 days following the intra-procedural period.

**Major complication:** Any of the outcomes related to the procedure which is life threatening or results in death. In addition, any unexpected event that causes persistent or significant disability, or any event that requires significant surgical intervention to prevent any of outcomes listed above.

**Minor complication:** Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy, and does not limit persistently or significantly the patient’s function, nor does it threaten life or cause death.
Predictor of major complication:
- Implant duration of oldest lead
- Female gender
- ICD lead
- Use of laser

<table>
<thead>
<tr>
<th>Major complication</th>
<th>Minor complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Death</td>
<td>1. Pericardial effusion not requiring pericardiocentesis or surgical intervention</td>
</tr>
<tr>
<td>2. Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair</td>
<td>2. Hemorrhage not requiring a chest tube</td>
</tr>
<tr>
<td>3. Vascular avulsion or tear (requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair)</td>
<td>3. Hematoma at the surgical site requiring reoperation for drainage</td>
</tr>
<tr>
<td>4. Pulmonary embolism requiring surgical intervention</td>
<td>4. Arm swelling or thrombosis of implant veins resulting in medical intervention</td>
</tr>
<tr>
<td>5. Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization</td>
<td>5. Vascular repair near the implant site or venous entry site</td>
</tr>
<tr>
<td>6. Stroke</td>
<td>6. Hemodynamically significant air embolism</td>
</tr>
<tr>
<td>7. Pacing system related infection of a previously non-infected site</td>
<td>7. Migrated lead fragment without sequelae</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor complication</th>
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<tbody>
<tr>
<td>8. Blood transfusion related to blood loss during surgery</td>
</tr>
<tr>
<td>9. Pneumothorax requiring a chest tube</td>
</tr>
<tr>
<td>10. Pulmonary embolism not requiring surgical intervention</td>
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</tbody>
</table>
**Indications**

Recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes.

**Infection**

**Class I**

1. Complete device and lead removal is recommended in all patients with definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis. *(Level of evidence: B)*

2. Complete device and lead removal is recommended in all patients with CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system. *(Level of evidence: B)*

3. Complete device and lead removal is recommended in all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. *(Level of evidence: B)*

4. Complete device and lead removal is recommended in patients with occult gram-positive bacteremia (not contaminant). *(Level of evidence: B)*

**Indications**

**Infection**

**Class IIa**

1. Complete device and lead removal is reasonable in patients with persistent occult gram-negative bacteremia. *(Level of evidence: B)*

**Class III**

1. CIED removal is not indicated for a superficial or incisional infection without involvement of the device and/or leads *(Level of evidence: C)*

2. CIED removal is not indicated to treat chronic bacteremia due to a source other than the CIED, when long-term suppressive antibiotics are required. *(Level of evidence: C)*
**Indications**

**Chronic Pain**

**Class IIa**

1. Device and/or lead removal is reasonable in patients with severe chronic pain, at the device or lead insertion site, that causes significant discomfort for the patient, is not manageable by medical or surgical techniques and for which there is no acceptable alternative. *(Level of evidence: C)*

**Indications**

**Thrombosis or Venous Stenosis**

**Class I**

1. Lead removal is recommended in patients with clinically significant thromboembolic events associated with thrombus on a lead or a lead fragment. *(Level of evidence: C)*

2. Lead removal is recommended in patients with bilateral subclavian vein or SVC occlusion precluding implantation of a needed transvenous lead. *(Level of evidence: C)*

3. Lead removal is recommended in patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. *(Level of evidence: C)*

4. Lead removal is recommended in patients with superior vena cava stenosis or occlusion with limiting symptoms. *(Level of evidence: C)*

5. Lead removal is recommended in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead when there is a contraindication for using the contralateral side (e.g. contralateral AV fistula, shunt or vascular access port, mastectomy). *(Level of evidence: C)*

**Class IIa**

1. Lead removal is reasonable in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead, when there is no contraindication for using the contralateral side. *(Level of evidence: C)*
Functional Leads

Class I
1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads. (Level of evidence: B)
2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion). (Level of evidence: B)
3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (Level of evidence: B)
4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (Level of evidence: C)

Class IIb
1. Lead removal may be considered in patients with an abandoned functional lead that poses a risk of interference with the operation of the active CIED system. (Level of evidence: C)
2. Lead removal may be considered in patients with functioning leads that due to their design or their failure pose a potential future threat to the patient if left in place. (e.g. Telectronics ACCUFIX without protrusion) (Level of evidence: C)
3. Lead removal may be considered in patients with leads that are functional but not being used. (i.e. RV pacing lead after upgrade to ICD) (Level of evidence: C)
4. Lead removal may be considered in patients who require specific imaging techniques (e.g. MRI) that can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (Level of evidence: C)
5. Lead removal may be considered in patients in order to permit the implantation of an MRI conditional CIED system. (Level of evidence: C)
## Functional Leads

### Class III

1. Lead removal is not indicated in patients with functional but redundant leads if patients have a life expectancy of less than one year. (Level of evidence: C)

2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. (Level of evidence: C)

## Non Functional Leads

### Class I

1. Lead removal is recommended in patients with life threatening arrhythmias secondary to retained leads or lead fragments. (Level of evidence: B)

2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion) (Level of evidence: B)

3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (Level of evidence: B)

4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (Level of evidence: C)
### Non Functional Leads

**Class IIa**

1. Lead removal is reasonable in patients with leads that due to their design or their failure pose a threat to the patient, that is not immediate or imminent if left in place. (e.g. Telectronics ACCUFIX without protrusion) *(Level of evidence C)*

2. Lead removal is reasonable in patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. *(Level of evidence C)*

3. Lead removal is reasonable in patients that require specific imaging techniques (e.g. MRI) and cannot be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. *(Level of evidence: C)*

### Indications

**Non Functional Leads**

**Class IIb**

1. Lead removal may be considered at the time of an indicated CIED procedure, in patients with non-functional leads, if contraindications are absent. (Level of evidence C)

2. Lead removal may be considered in order to permit the implantation of an MRI conditional CIED system. (Level of evidence: C)

**Class III**

1. Lead removal is not indicated in patients with non-functional leads if patients have a life expectancy of less than one year. *(Level of evidence C)*

2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. *(Level of evidence :C)*
Extraction Environment

- Team approach
- Spectrum of tools
- Spectrum of techniques
- Plan, train, and practice for an emergency

Extraction Environment

**Personnel:**

**Primary Operator:** A physician performing the lead extraction who is properly trained and experienced in device implantation, lead extraction and the management of complications

**Cardiothoracic surgeon:** well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available

**Anesthesia support**

Personnel capable of operating fluoroscopic equipment

“Scrubbed” assistant (nurse/technician/physician)

Non “scrubbed” assistant

Echocardiographer
Extraction Environment

Facilities & Equipment:

- operating rooms, or procedural laboratories ready for emergent surgical procedures
- High-quality fluroscopy
- Surgical instruments (scalpel to bypass)
- Spectrum of extraction tools
- CIED implantation tools – temporary pacing tools
- Echo (transthoracic, transesophageal)

Extraction tools and techniques

- Simple traction
- Traction devices:
  - Locking stylets
  - Snares
- Mechanical sheaths
- Laser sheaths
- Electrosurgical sheaths
- Rotating Threaded Tip Sheath
**Extraction tools and techniques**

**Simple Traction:** Manipulation of the lead so that the lead exits the vasculature via the implant vein using tools typically supplied for lead implant, such items as standard stylets (nonlocking).

**Traction Devices:**

**locking stylets**

A special type of a traction device designed to hold onto the inside of the conductor coil along its length or near the distal stimulating electrode, improve tensile properties and prevent elongation of the lead body during traction.
Traction Devices: Snares (needle ‘s eye snare):
- Used mainly for free floating or with the leads with no free end
- Can be used in jugular or femoral Approaches
Mechanical Sheaths:
- Sheaths composed of metal, Teflon™ polypropylene or other materials that require manual advancement over the lead and rely on the mechanical properties of the sheath to disrupt fibrotic attachments.

**Laser Sheaths:**
Sheaths that employ fiberoptics to transmit laser light to disrupt the fibrotic attachment.

**Electrosurgical Sheaths:**
Sheaths that use radiofrequency energy (such as found in an electrosurgical unit) emitted between two electrodes at the sheath tip to disrupt the fibrotic attachments.
Rotating Threaded Tip Sheath (evolution sheath): Sheaths that are equipped with a rotationally powered mechanism that bore through and disrupt fibrotic attachments with a threaded screw mechanism at the sheath tip.
Based on EHRA EP network survey in 2012 : (164 centers in 30 countries)

**Tools of extraction : % of centers**

<table>
<thead>
<tr>
<th>Manual traction</th>
<th>Locking stylets</th>
<th>Mechanical sheaths</th>
<th>Laser sheaths</th>
<th>Electrosurgical sheaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>44%</td>
<td>88%</td>
<td>79%</td>
<td>28%</td>
<td>26%</td>
</tr>
</tbody>
</table>

**alternative transvenous approaches: % of centers**

<table>
<thead>
<tr>
<th>Transfemoral</th>
<th>Transjugular</th>
</tr>
</thead>
<tbody>
<tr>
<td>65%</td>
<td>37%</td>
</tr>
</tbody>
</table>

**Current european practice in lead extraction**

**Number of patient/center/year in 2011**

<table>
<thead>
<tr>
<th>More than 40 patients</th>
<th>10-40 patients</th>
<th>Less than 10 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>31% of centers</td>
<td>46% of centers</td>
<td>23% of centers</td>
</tr>
</tbody>
</table>

**Total number of patients: (3081 patients, 5299 patients) in 2011**

**Percentage of extracted leads**

<table>
<thead>
<tr>
<th>Right atrial leads</th>
<th>Right ventricle leads</th>
<th>Coronary sinus leads</th>
<th>ICD leads</th>
<th>Free floating leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>32%</td>
<td>31%</td>
<td>9.5%</td>
<td>24.5%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>
Based on Ain Shams University experience in lead extraction:

**Total number of patients** (15 patients, 26 leads) in 2012.

**Percentage of leads and tools of extractions:**

<table>
<thead>
<tr>
<th>Right atrium</th>
<th>Right ventricle</th>
<th>ICD lead</th>
<th>CS lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 (34.7%)</td>
<td>14 (53.8%)</td>
<td>2 (7.7%)</td>
<td>1 (3.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manual traction</th>
<th>Locking styles</th>
<th>Mechanic al sheaths</th>
<th>Powered sheaths evolution</th>
<th>Snares</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 (31%)</td>
<td>14 (53%)</td>
<td>8 (31%)</td>
<td>6 (23%)</td>
<td>2 (7.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transfemoral approach</th>
<th>Transjugular approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (3.85%)</td>
<td>1 (3.85%)</td>
</tr>
</tbody>
</table>