

Lead extraction

The dark side of the coin

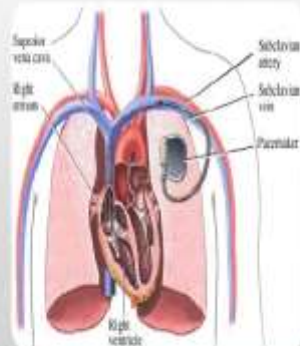
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Agenda

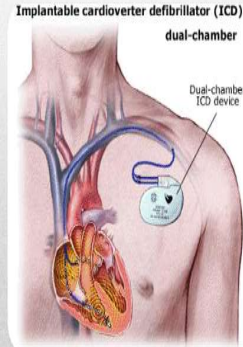
- Introduction
- History of consensus
- Definitions
- Complications
- Indications
- Lead management environment
- Extraction tools
- Current european practice in lead extraction
- Egyptian steps in lead extaction

Introduction

Pacemaker & Leads



ICD & leads



Introduction

Types of Leads



Introduction

- 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.

Introduction



History of consensus

- **NASPE Policy Conference – 1997**
Love CJ, Wilkoff BL, Byrd CL, et al. Recommendations for Extraction of Chronically Implanted Transvenous Pacing and Defibrillator Leads: Indications, Facilities, Training. Pacing Clin Electrophysiol. 2000;23:544-551.
- **HR 2008 Satellite Symposium**
Lead Extraction 2008: Critical Review and Implementation of HRS Guidelines, HR 2008 Satellite Symposium co-sponsored by CCF & HRS
- **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

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

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.**

Complication

Predictor of major complication:

- Implant duration of oldest lead
- Female gender
- ICD lead
- Use of laser

Major complication	<ol style="list-style-type: none"> 1. Death 2. Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair 3. Vascular avulsion or tear (requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair) 4. Pulmonary embolism requiring surgical intervention 5. Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization 6. Stroke 7. Pacing system related infection of a previously non-infected site
Minor complication	<ol style="list-style-type: none"> 1. Pericardial effusion not requiring pericardiocentesis or surgical intervention 2. Hemothorax not requiring a chest tube 3. Hematoma at the surgical site requiring reoperation for drainage 4. Arm swelling or thrombosis of implant veins resulting in medical intervention 5. Vascular repair near the implant site or venous entry site 6. Hemodynamically significant air embolism 7. Migrated lead fragment without sequelae 8. Blood transfusion related to blood loss during surgery 9. Pneumothorax requiring a chest tube 10. Pulmonary embolism not requiring surgical intervention

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)**

Indications

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)**

Indications

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)**

Indications

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)**

Indications

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)**

Indications

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 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)**

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

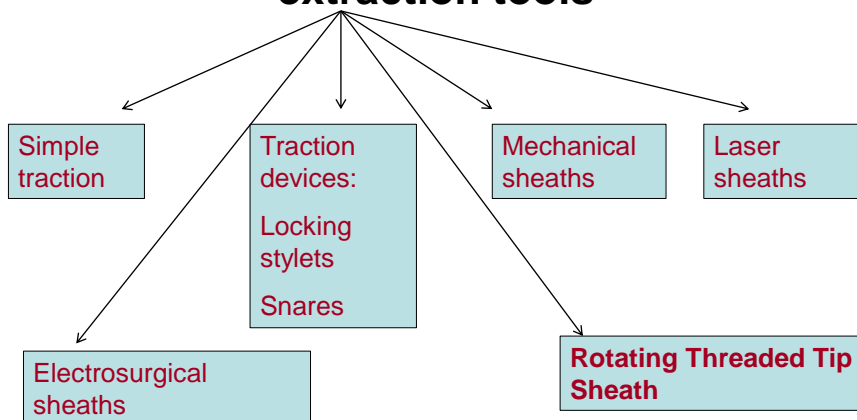
Extraction Environment

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)

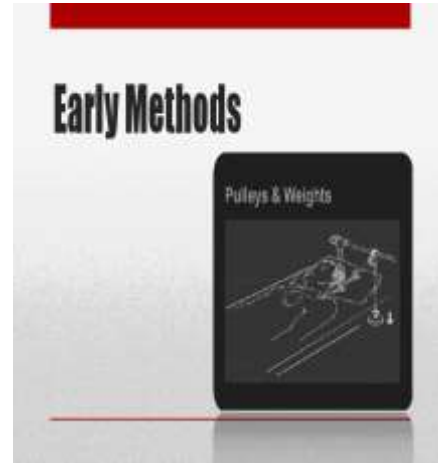
Extraction tools and techniques

extraction tools



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)



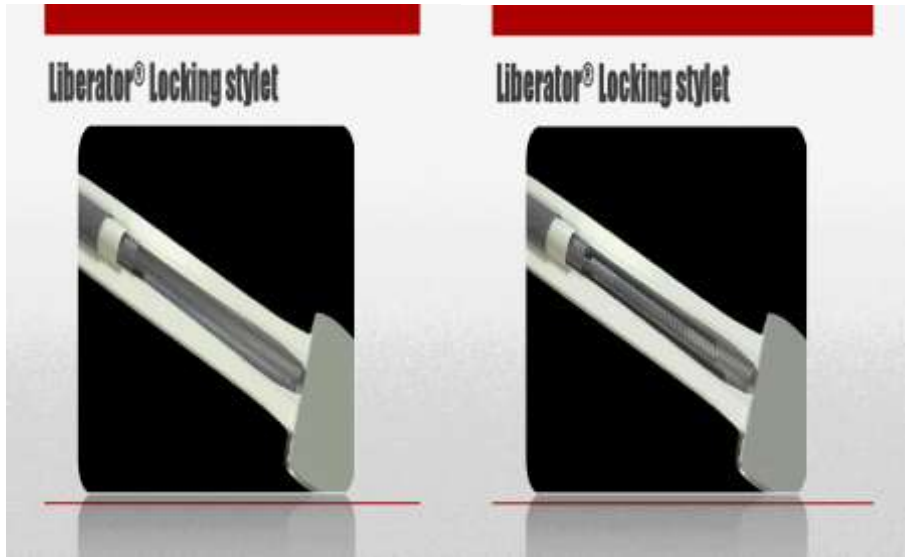
Extraction tools and techniques

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.



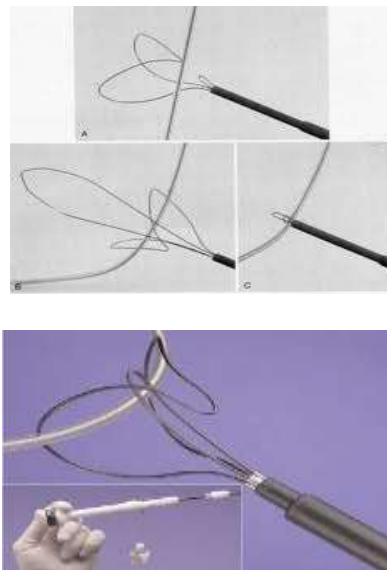
Extraction tools and techniques



Extraction tools and techniques

Traction Devices: **Snare**(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



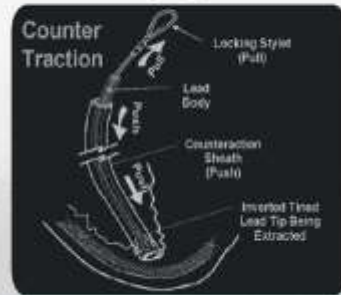
Extraction tools and techniques

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

Dilator Sheath Poly & TFE

- Manual Mechanical Telescoping Dilator Sheath Sets



Extraction tools and techniques

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.

Extraction tools and techniques

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



Extraction tools and techniques



Current european practice in lead extraction

Based on EHRA EP network survey in 2012 :(164 centers in 30 countries)

Tools of extraction :%of centers

Manual tractio	Locking stylets	Mechanical sheath s	Laser sheaths	Electrosurgical sheaths
44%	88%	79%	28%	26%

alternative transvenous approaches: %of centers

Transfemoral	Transjugular
65%	37%

Current european practice in lead extraction

Number of patient/center/year in 2011

More than 40 patients	10-40 patients	Less than 10 patients
31% of centers	46% of centers	23% of centers

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

Percentage of extracted leads

Right atrial leads	Right ventricle leads	Coronary sinus leads	ICD leads	Free floating leads
32%	31%	9.5%	24.5%	2.5%

Egypt steps in lead extraction

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:

Right atrium	Right ventricle	ICD lead	CS lead
9(34.7%)	14(53.8%)	2(7.7%)	1(3.8%)

Manual traction	Locking stylets	Mechanical sheaths	Powered sheaths evolution	Snares
8 (31%)	14(53%)	8(31%)	6(23%)	2(7.7)

Transfemoral approach	Transjugular approach
1(3.85%)	1(3.85%)

