Extraction for Class II Indications
- Strategic Management of Recalled CIEDs
- HRS Satellite Symposium

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Disclosures

◆ Consultant:
  ◆ Spectranetics, St Jude Medical, Boston Scientific, Medtronic, Sorin

◆ Research:
  ◆ Boston Scientific, Medtronic, Sorin, Biotronik
Do you ever abandon leads?

- A. Yes
- B. No
- C. Sometimes
Background

- Of the nearly 500,000 pacemaker & ICD devices implanted yearly throughout the world, many of these implants involve the need for new or additional leads, due to…

  - Patient Issues
    - Younger patients receiving devices
    - Patients living longer with their existing devices
  
  - Lead Issues
    - Lead Failure
    - Device Upgrade
Background
Abandon vs. Extract

◆ Lead Abandonment vs. Extraction is a Risk – Benefit Assessment

◆ Risk
  ▶ Of leaving leads in place
  ▶ Of Extracting leads

◆ Benefit
  ▶ Of leaving leads in place
  ▶ Of extracting leads
Lead Extraction Risks

- Lead extraction risks:
  - Rupture of SVC
  - Cardiac tamponade
  - Failure to extract an infected lead
  - Venous thrombosis
  - Lead breakage and migration
  - Avulsion of veins and myocardial tissue
  - Death
Extraction Risks Increase

- BMI < 25
- SVC coil of ICD lead
  - Especially non-back filled
- Increased lead implant duration
  - Especially ICD leads
- Elderly female with multiple leads
# Summary of Significant Indications

**HRS 2009**

<table>
<thead>
<tr>
<th>FUNCTIONAL LEAD</th>
<th>Due to design or failure, may pose immediate threat</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Leads causing life threatening arrhythmias</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Leads interfering with treatment of a malignancy</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Risk of interference with device operation</td>
<td>I or 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>Need MRI with no other imaging options</td>
<td>IIb</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON FUNCTIONAL LEAD</th>
<th>Due to design or failure, may pose immediate threat</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Leads causing life threatening arrhythmias</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Leads interfering with treatment of a malignancy</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Risk of interference with device operation</td>
<td>I or IIa</td>
</tr>
<tr>
<td></td>
<td>If implant would require &gt;4 leads one side or 5 leads via SVC</td>
<td>IIa</td>
</tr>
<tr>
<td></td>
<td>Need MRI with no other imaging options</td>
<td>I or IIa</td>
</tr>
<tr>
<td></td>
<td>Non functional lead at device/lead procedure</td>
<td>IIb</td>
</tr>
</tbody>
</table>
What are the Issues?

- Features of Lead Abandonment
- Data regarding Lead Abandonment
- Risk of Future Lead Extraction
- Are there any special patient populations?
- Are there any specific lead issues?
How Many Leads re Too Many?

  - 3 or more abandoned leads
  - 4 leads total

- **HRS Guidelines (2009)**
  - 4 Leads too many in either subclavian
  - 5 Leads too many in the SVC
Risks of Abandoning Leads

- Older leads are more difficult to remove
Risks of Abandoning Leads

- Older leads are more difficult to remove
- More pocket bulk means a greater likelihood for erosion
Lead Fracture Rates

- Increase over time
- Are greater in younger patients
Sprint Fidelis® Model 6949 Lead Performance
(Medtronic Report as of December 2014)

Sprint Fidelis® Model 6949 Lead Age Data
(Medtronic Report as of December 2014)

Infection Rates relative to Lead Abandonment

- Lead infection likelihood increases with each generator change or lead addition
  - Indwelling abandoned leads get older and more fibrosed
  - This makes them more difficult to remove chronically if they eventually do become infected, which is more likely to occur with repeated operations
Replace Registry

- Prospective, observational study of 713 patients at 62 centers
- Patients undergoing generator change without lead addition or revision
  - 4.2% major complication rate and a 0.6% mortality rate
- Patients undergoing device generator change with planned lead addition or revision
  - 15.3% major complication rate with a 1.1% mortality rate at 6 months
- These results demonstrate an increased complication rate with device system upgrade with lead abandonment

### Summary of Significant Indications

**HRS 2009**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INDICATION</th>
<th>CLASS</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFECTION</td>
<td>Pocket infection, erosion, skin adherence, or draining fistula</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Occult gram-Positive Bacteremia</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Valvular endocarditis with or without definitive lead involvement</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 not manageable medically or surgically</td>
<td>IIa</td>
</tr>
</tbody>
</table>

Risks of Abandoning Leads

- Older leads are more difficult to remove
- More pocket bulk means a greater likelihood for erosion
- Lead malfunction increases over time
- Infection risk increases with each generator change with retained material
- Risk of occlusion and stenosis increases
  - Subclavian / axillary vein
  - SVC
  - TV
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>INDICATION</th>
<th>CLASS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCCLUSION</td>
<td>Bilateral subclavian or SVC occlusion precluding implant</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Planned stent deployment</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>SVC stenosis or occlusion with symptoms</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Ipsilateral occlusion with contraindication to opposite side</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Significant thromboembolic events with lead thrombus</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Ipsilateral occlusion w/o contralateral contraindication</td>
<td>IIa</td>
</tr>
</tbody>
</table>
Venous Occlusion in ICD Patients

- Venography at the time of ICD generator replacement
  - 9% of patients had complete occlusion of the access vessel
  - 25% had some degree of stenosis

- 67 % risk of some obstruction in pts with a pacemaker before placement of the ICD

- 17 % risk of obstruction in pts with just single leads

Superior Vena Cava Syndrome Induced by Endocardial Defibrillator and Pacemaker Leads

Arash Aryana, MS, MDa,*, Kristi D. Sobota, MD b, Dennis J. Esterbrooks, MD c, and Andrew I. Gelbman, DO, PhD d

Am J Cardiol 2007;99:1765–1767
Severe tricuspid valve stenosis secondary to pacemaker leads presenting as ascites and liver dysfunction: a complex problem requiring a multidisciplinary therapeutic approach


Pacemaker lead related tricuspid stenosis: a report of two cases
D J Heaven, M Y Henein, R Sutton
Heart 2000; 83:351–352
Abandoned Pacing Leads

- Of 1,207 leads, 611 became non-functional
  - 531 non-functional leads were abandoned

- Reasons for abandonment
  - capture and/or sensing failure (243)
  - lead recall (177)
  - lead fracture (86)
  - pacing system replacement to the contralateral side (11)
  - accommodating patient growth (5)
  - pacemaker function upgrade (5)
  - replacement with ICD (2)
  - interference with ICD (1)
  - unknown (1)

Suga C, Hayes DL, Hyberger LK, Lloyd MA
Abandoned Pacing Leads

- 5.5% total pacemaker related complications
- Of 24 complications
  - 8 device infections
  - 16 vascular occlusions complicating device revisions
- No interactions between the abandoned lead and the active leads or other complications

Suga C, Hayes DL, Hyberger LK, Lloyd MA
Abandoned Pacing Leads

- Complication rates were higher in patients with
  - Three or more Abandoned leads
  - Four or more Total leads
  - Three or more Procedures of new lead placement
  - Younger Age at initial pacemaker implantation

Suga C, Hayes DL, Hyberger LK, Lloyd MA
Abandoned Pacing Leads

- 60 patients with abandoned leads (“cut and snap” technique)

- Complications in 12 patients (20%)
  - 5 lead migration (with the cut proximal end of the lead retracted into the vascular space and ending up looped in the heart or vasculature)
  - 3 skin erosion
  - 2 subclavian vein thrombosis
  - 2 extracardiac stimulation

Abandoned ICD Leads

- 78 ICD patients with 101 abandoned leads
- Mean follow-up of $3.1 \pm 2.0$ years
- No complications that could be attributed to the abandoned leads
Abandoned Pacing Leads

- 399 pacemakers in pediatric patients
  - 18 patients with abandoned leads
  - Follow-up mean of 4 years

- No reports of venous occlusion or electrical problems

- 2 patients developed endocarditis (at 5 and 10 years after abandonment)

- No other complications related to the leads

Risk of Future Lead Extraction

- > 3500 leads in 266 centers
  - 2-fold increase in the risk of extraction failure with every 3 years of implant duration

- 212 consecutive patients
  - 3.5-fold increase in TLE complications per additional right ventricular lead extracted
  - 50% increase in the need for powered sheath assistance per year increase in implant duration of the oldest lead


<table>
<thead>
<tr>
<th>Lead characteristics</th>
<th>(n= 2463)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead location</td>
<td></td>
</tr>
<tr>
<td>RA</td>
<td>34.8%</td>
</tr>
<tr>
<td>RV</td>
<td>53.8%</td>
</tr>
<tr>
<td>CS</td>
<td>11.2%</td>
</tr>
<tr>
<td>Others</td>
<td>0.2%</td>
</tr>
<tr>
<td>Lead duration</td>
<td>61.95± 55.24 months</td>
</tr>
<tr>
<td></td>
<td>(Range 0-331)</td>
</tr>
<tr>
<td>Lead fixation</td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>67.9%</td>
</tr>
<tr>
<td>Passive</td>
<td>32.1%</td>
</tr>
<tr>
<td>Abandoned leads</td>
<td>10.2%</td>
</tr>
<tr>
<td>Lead polarity</td>
<td></td>
</tr>
<tr>
<td>Unipolar</td>
<td>95.3%</td>
</tr>
<tr>
<td>Bipolar</td>
<td>4.7%</td>
</tr>
</tbody>
</table>
## Abandoned leads

<table>
<thead>
<tr>
<th></th>
<th>Abandoned leads</th>
<th>Non-abandoned leads</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implant duration</strong></td>
<td>118.35 ± 69.15 months</td>
<td>55.78 ± 45.8 months</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Unipolar leads</strong></td>
<td>5.9%</td>
<td>4.6%</td>
<td>0.380</td>
</tr>
<tr>
<td><strong>Passive leads</strong></td>
<td>50.7%</td>
<td>30.1%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>RV location</strong></td>
<td>76.2%</td>
<td>51.2%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>ICD leads</strong></td>
<td>35%</td>
<td>29.2%</td>
<td>0.066</td>
</tr>
<tr>
<td><strong>Dual coil among ICD leads</strong></td>
<td>90.9%</td>
<td>87.1%</td>
<td>0.520</td>
</tr>
</tbody>
</table>

Hahnemann Data 2015
## Extraction tools for abandoned leads

<table>
<thead>
<tr>
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<th>Abandoned leads</th>
<th>Non-abandoned leads</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction time</td>
<td>18.8 ±21.2 minutes</td>
<td>10.7 ±7.6 minutes</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Manual traction only</td>
<td>14%</td>
<td>42.8%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Adjunct tools</td>
<td>86%</td>
<td>57.2%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Locking stylets</td>
<td>81%</td>
<td>56%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Dilator sheaths</td>
<td>48.1%</td>
<td>37.2%</td>
<td>0.001</td>
</tr>
<tr>
<td>Excimer laser</td>
<td>38.3%</td>
<td>20.6%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Electrosurgical dissection sheath</td>
<td>5.5%</td>
<td>2.7%</td>
<td>0.023</td>
</tr>
<tr>
<td>Femoral work station</td>
<td>4.7%</td>
<td>1.5%</td>
<td>0.002</td>
</tr>
<tr>
<td>Evolution sheath</td>
<td>1.3%</td>
<td>0.9%</td>
<td>0.494</td>
</tr>
<tr>
<td>Snare</td>
<td>6.8%</td>
<td>2.2%</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
## Patient outcomes with abandoned leads

<table>
<thead>
<tr>
<th></th>
<th>Abandoned leads</th>
<th>Non-abandoned leads</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of days inpatient after procedure</td>
<td>9.3 ± 8.6</td>
<td>7.6 ± 11.9</td>
<td>0.352</td>
</tr>
<tr>
<td>Total extraction time</td>
<td>142.4 ± 65.9</td>
<td>110.1 ± 62.2</td>
<td>0.242</td>
</tr>
<tr>
<td>Incision to 1st lead cut time</td>
<td>30.8 ± 14.2</td>
<td>25.8 ± 14.4</td>
<td>0.864</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>26.8 ± 24 minutes</td>
<td>18.4 ± 21.4 minutes</td>
<td>0.047</td>
</tr>
<tr>
<td>Total laser time</td>
<td>371.3 ± 441.7 seconds</td>
<td>198.9 ± 273.4 seconds</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Total laser pulses</td>
<td>15117 ± 17355</td>
<td>10131 ± 12338</td>
<td>0.001</td>
</tr>
<tr>
<td>Inpatient mortality</td>
<td>3.6%</td>
<td>5.3%</td>
<td>0.374</td>
</tr>
<tr>
<td>Comparison</td>
<td>Abandoned leads</td>
<td>Non-abandoned leads</td>
<td>p-value</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Any procedural complication</td>
<td>3.6%</td>
<td>2.6%</td>
<td>0.467</td>
</tr>
<tr>
<td>Major procedural complication</td>
<td>3.1%</td>
<td>1.6%</td>
<td>0.240</td>
</tr>
<tr>
<td>Minor procedural complication</td>
<td>0.5%</td>
<td>0.9%</td>
<td>0.571</td>
</tr>
<tr>
<td>Retained fragments</td>
<td>7.2%</td>
<td>2.7%</td>
<td>0.002</td>
</tr>
<tr>
<td>CCU admission</td>
<td>51.3%</td>
<td>24.9%</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Need for ionotropes</td>
<td>7.7%</td>
<td>4.2%</td>
<td>0.037</td>
</tr>
<tr>
<td>Blood transfusion during procedure</td>
<td>3.1%</td>
<td>1.3%</td>
<td>0.11</td>
</tr>
<tr>
<td>Blood transfusion during hospital stay</td>
<td>19.1%</td>
<td>12.8%</td>
<td>0.03</td>
</tr>
</tbody>
</table>
Special Patient Populations
MRI

- Need for MRI
  - Estimated need for future MRI = 50% to 85%
  - Abandoned lead(s) preclude MRI scanning

- Do we need to replace leads for MRI compatibility?
Specific Lead Issues
Recalled Leads

- **Fidelis**
  - Epstein: High failure rate even with “normal” appearing lead

- **Riata**
  - Carrillo: Thrombus formation on exteriorized cables
Medtronic Fidelis
When to Consider Removal?

- Functionally normal leads have a finite incidence of "subclinical" fracture
- 209 leads extracted from 208 pts
- Implant duration 38.9 (0.2-67.2) months
- Evident Fracture incidence = 36.9%

- 99 "Normal Leads" removed
  - 20 had fractures
    - 4 had more than one fracture site
    - 1 had 3 fracture sites
  - 17 pacing conductor fractures = 10 proximal & 7 distal
  - 6 high voltage fractures = 1 SVC & 5 RV

LEAD EXTRACTION - Conductor Exteriorization
So What’s a Person to Do?

- There are no controlled clinical trials comparing the long term effects of lead abandonment with lead extraction.
- There are risks to lead abandonment as there are risks to lead extraction.
Guidelines & Considerations (?)

**Extract**
- Young patients should be offered the option of lead removal
- Nonfunctioning leads should be removed early in their life if possible

**Abandon**
- Leads fibrose more heavily in young patients, making extraction more risky
- There are no controlled data to suggest capping has a higher long term risk
Guidelines & Considerations (?)

Abandon

- There is no need to remove leads when the vasculature is patent
- Alternative access sites exist when the vasculature is occluded

Extract

- The long term complications of leaving leads in place do exist
- Accessing an alternate site may lead to occlusion at that site also
The Decision must be Individualized

- Age of the patient
- Life expectancy
- Age & Functionality of lead
- Age & Functionality of other leads
- Vascular occlusion
- Patient’s wishes & risk tolerance
Recommendations
For Extraction

- In “young” patients, offer the option of lead removal rather than adding more leads
  - To avoid vascular overload & occlusion
  - To avoid the need to extract older leads later with an increased risk
  - To avoid lead-lead interaction, especially with ICD leads
Recommendations
For Extraction

- Additional viable indications for extraction
  - Recalled ICD leads in young patients, with or without generator replacement
  - The patient who requires an MRI safe system
  - The patient who would be excluded from MRI with abandoned leads
  - The patient who is deemed to no longer require an implantable anti-arrhythmia device
Recommendations
For Abandonment

◆ Abandon leads

- When the risk of extraction exceeds the risk of abandonment
  - Elderly diminutive patient with multiple leads
  - Reduced life expectancy
  - Unacceptable co-morbidities
  - Extra-vascular course of leads