When Should We Extract a Lead?

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Christopher R. Ellis, MD, FACC, FHRS Disclosures

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  – Thoratec, Boehringer Ingelheim, Boston Scientific, Heart Ware, Medtronic, Biosense-Webster.

• Consulting Fees/Advisory Board:
  – Boston Scientific, Medtronic, Sentre Heart, Atricure, Spectranetics.
Looks Bad….Is it bad? YES

CIED patients are multiplying, aging

4 leads 2 SVC coils, a Fine Line, no LV lead (LBBB).

Rule #1- If you don’t extract leads for a living, DON’T TRY TO PULL THEM OUT!!
The Indications to Extract...

- Class I indications for extraction or replacement of any pacer or ICD lead =
  - * Lead CIED related infection...INCLUDES POCKET EROSION!! (Look at every pocket)
  - ** Lead interferes with function of another intracardiac lead/device.
    - ICD or PM lead fracture or failure = Viewed as “Optional” to replace or extract (#1 reason we extract).

- HRS: All Advisory ICD lead management decisions are “controversial”? (not really).

- No guidelines suggest extraction of recalled or advisory leads, NOR for chronic venous occlusion, NOR retained leads, NOR for moving the device from XRT beam.

- In REALITY, extraction of retained leads or advisory leads is a critical skill for our patients... ↓ infection, ↓ thrombosis, ↓ sudden death (device malfunction)?
  - (WE need data to support this statement from the “masters” of CRM)
Risks of Spontaneous Injury and Extraction of an Active Fixation Pacemaker Lead
Report of the Accufix Multicenter Clinical Study and Worldwide Registry

G. Neal Kay, MD; Jeffrey A. Brinker, MD; David T. Kawanishi, MD; Charles J. Love, MD; Margaret A. Lloyd, MD; Russell C. Reeves, MD; Guy Pioger, MD; JoAnn Fee, RN, BSN; Mary K. Overland, PhD; Lisa Gamsey Ensign, MS; Gary L. Grunkemeier, PhD; for the Accufix Multicenter Clinical Study Investigators

15 YEARS AGO ! Pre-AF PVI

Circulation 1999;100:2344-2352

TABLE 5. Complications of Lead Extraction*

<table>
<thead>
<tr>
<th>Extraction Complication</th>
<th>MCS Intravascular (n=619)</th>
<th>WWR Intravascular (n=3404)</th>
<th>Primary Thoracotomy (n=116)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Major</td>
<td>20</td>
<td>3.2</td>
<td>138</td>
</tr>
<tr>
<td>Fatal</td>
<td>1</td>
<td>0.2</td>
<td>15</td>
</tr>
<tr>
<td>Life threatening</td>
<td>1</td>
<td>0.2</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td>18</td>
<td>2.9</td>
<td>103</td>
</tr>
<tr>
<td>Minor</td>
<td>26</td>
<td>4.2</td>
<td>122</td>
</tr>
<tr>
<td>Total complications</td>
<td>46</td>
<td>7.4</td>
<td>260</td>
</tr>
</tbody>
</table>

*Patients with known extraction outcome data.

TABLE 3. WWR Reported Accufix Injuries Related to J Retention Wire

<table>
<thead>
<tr>
<th>Injury</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>6</td>
</tr>
<tr>
<td>Pericardial tamponade (nonfatal)</td>
<td>19</td>
</tr>
<tr>
<td>Pericardial effusion without tamponade</td>
<td>5</td>
</tr>
<tr>
<td>Atrial perforation with pericarditis</td>
<td>3</td>
</tr>
<tr>
<td>Embolism of J-wire fragment</td>
<td>4</td>
</tr>
<tr>
<td>Tricuspid valve perforation and insufficiency</td>
<td>1</td>
</tr>
<tr>
<td>Aorta-right atrial fistula</td>
<td>1</td>
</tr>
<tr>
<td>Right atrial thrombus with pulmonary thromboembolism</td>
<td>1</td>
</tr>
</tbody>
</table>

Total injuries=40.

- 15 deaths from extraction
- 6 deaths from lead
- 4.1% Major Complications

260

40
Death- 1.86% in hospital mortality (highest for CIED related infections, or sepsis)
Cardiac Avulsion 0.6%
Vascular Tear- 0.4%

Major Complications Higher If...
<60 cases / 4yrs versus >130 cases
BMI <25
Creat >2.0 mg/dL
Failure to extract leads high > 10 yrs old

** Lead extraction volume and experience should be considered when deciding whether to pursue a LLE program

2010 Data:
- The leads are older and more complex

** Great, but 13 centers, and all data pre-Riata recall.

Many Riata are now >10yrs old.
1- CIED Related Infection: Definitions

1) Pocket Infection/Erosion

2) Device/Lead Endocarditis

3) Native Valve Endocarditis

4) Occult Gram ++ Bacteremia
   “No obvious source”

*CIED infection = 1-4 AND = complete system removal. Class I in ID, HRS Guidelines.*
Trends in CIED Infections; Increasing Mortality

• ~ 50% of patients with CIED infections don’t survive @ 3 years post procedure.

• Delay to treatment associated with increased mortality, incomplete system removal = higher mortality.

- Average cost of care for CIED infection $72,000-$147,000 USD.


CIED Risks for Infection - PG Change
Medicare 5% LDS Data

<table>
<thead>
<tr>
<th>Effect</th>
<th>Level</th>
<th>Hazard Ratio</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>80-84 vs. 65-69</td>
<td>0.766</td>
<td>0.0172</td>
</tr>
<tr>
<td></td>
<td>&gt;85 vs. 65-69</td>
<td>0.677</td>
<td>0.0061</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>Yes vs. No</td>
<td>1.56</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No. of operation</td>
<td>2 vs. 1</td>
<td>2.886</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>3 vs. 1</td>
<td>8.15</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>4 vs. 1</td>
<td>14.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>5 vs. 1</td>
<td>16.9</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Think Ahead!!!
Anticipate High Risk,
Prevent Infection
Use SINGLE COIL
Role of TYRX-A?
Role of complete capsulectomy?
Role of post-operative antibiotics/intra-op irrigation?
Probability of CIED Infection-free Survival

High risk patients with >2 CIED infection RF’s.

135 TYRX-A 0 (0%)

353 TYRX non absorbable- 1 (0.3%)

636 Controls- 20 (3.1%)

Data presented at Heart Rhythm Society, May 14, 2015.

When to Extract a Lead?

• 1) *Lead CIED related infection...INCLUDES POCKET EROSION!!

• Preventing CIED infection (rate continues to rise)?

• MD’s say they don’t have infections
  – Medicare data and retrospective and prospective registry studies refute this.

• Referral for Rx often delayed, and when referred, we delay the extraction.
  – Some of this is logistics...need an operator, CT surgeon, perfusion, hybrid lab/OR.
  – Get the patient to an extraction center of excellence, forget PO oral antibiotics.

• 2) **Lead interferes with function of other intracardiac lead/device.
  – Optional- replace or extract ICD or PM lead fracture or “failure”.
When to Extract an ICD or PM Lead?

- Be proactive... (my practice).
- Before a patient dies from sepsis after pocket infection.
  - HRS 2015- Case Western, delay in CIED treatment = increased mortality.

- THINK AHEAD!! CRT upgrade? Secondary prevention? PM dependant?
  - Consider elective extraction to minimize abandoned hardware.

- Remove a Fidelis lead before fracture causes shocks and ICD depletion.
  - ICD generator change – 20% 1 year failure rate in 2012.

- Remove a Riata before an ICD short circuits.
  - Electrical failure appears to be higher if EC’s detected on Fluoro but normal appearing leads can fail.

- Before you cause SVC syndrome or lose ipsilateral venous access.
  - Don’t abandon a system on one side to re-implant on the opposite side.

- Or reactive... (standard).
Advisory Leads: Youngest Fidelis Now 7.5 Years Old

Risk factors for Fidelis failure:
- Female sex, younger age (< 50 yrs).
- Higher LVEF ( >40-45%).
- R sided or sub-pectoral.
- Axillary/Subclavian access.
- Prior ICD lead failure.

3-4% electrical failure rate/yr.


Riata ICD Lead FDA Recall - 4 Issues

- Externalized conductors (EC’s)
- Damage to adjacent leads
- Giant well formed thrombi

**Electric failure from HV short circuit

2% electrical failure rate/yr.

1580 > 7000
Comparative Outcomes of Transvenous Extraction of Sprint Fidelis and Riata Defibrillator Leads: A Single Center Experience

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From the Vanderbilt Heart and Vascular Institute, Nashville, Tennessee, USA

Comparison of Extraction of Recalled Defibrillator Leads. Introduction: The FDA has issued class I advisories for Medtronic Sprint Fidelis® and St. Jude Medical Riata™ ICD lead families. Transvenous Riata™ ICD lead extraction is typically considered higher risk than Fidelis® extraction, based on longer duration from implant, presence of externalized conductors and lack of silicone backfill in the SVC and RV coils. However, published data comparing procedural outcomes between these leads are limited.

Methods: Records were reviewed for all patients undergoing transvenous extraction of Sprint Fidelis® or Riata™ ICD leads at the Vanderbilt Heart and Vascular Institute from July 2006 to April 2013 to ascertain indication for extraction, procedural details, complications, and 30-day mortality.

Results: There were significant differences between those undergoing extraction of a Sprint Fidelis® (n = 145) or Riata™ lead (n = 47). In the Riata™ group, device-related endocarditis was a more common indication for extraction, the mean duration of implant was longer, and larger excimer laser sheaths were required. Lead malfunction was a more common indication in the Fidelis® group. There were no statistically significant differences in median procedure duration, procedural success (97.9% vs 95.7%, P = 0.41), median length of hospital stay (1 day vs 1 day, P = 0.23), procedural complication rate (5.5% vs 10.6%, P = 0.23) or 30-day mortality (2.1% vs 2.1%, P = 0.98). Analyses excluding patients with device infection revealed similar results.

Conclusion: Despite differences in baseline characteristics, this study indicates that Medtronic Sprint Fidelis® and St. Jude Riata™ ICD leads have similar procedural outcomes with transvenous lead extraction.

(J Cardiovasc Electrophysiol, Vol. pp. 1-7)
Small Caliber ICD Lead Subacute Perforation: No Silicone Backfill

Initial fluoroscopy issue was sub-acute lead migration on CXR, with delayed perforation.
When ELSE to Extract a Lead?

- Abandoned leads? Restore access to central circulation to allow revisions/upgrades.

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<table>
<thead>
<tr>
<th>Table 3 Procedural characteristics and outcome</th>
</tr>
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<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>Obstruction crossed, n (%)</td>
</tr>
<tr>
<td>Lead successfully extracted via laser sheath, n (%)</td>
</tr>
<tr>
<td>Transvenous lead successfully sited</td>
</tr>
<tr>
<td>Procedural time (min)</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
</tr>
<tr>
<td>Radiation dose (cGycm²)</td>
</tr>
<tr>
<td>Complications</td>
</tr>
<tr>
<td>Major, n (%)</td>
</tr>
<tr>
<td>Minor, n (%)</td>
</tr>
<tr>
<td>30-day mortality, n (%)</td>
</tr>
</tbody>
</table>

*20% of non functional abandoned PM leads had late complications. (12/60).

@ICD generator change- 9% chronic total occlusion, 6% severe stenosis (>90%) and moderate stenosis in 10%.

**32% of ‘non targeted’ leads required re-intervention (U Colorado Children’s).

*Bohm A et al., Complications due to abandoned noninfected pacemaker leads. Pacing Clin Electrophysiol. 2001 Dec;24(12):1721-4.

**McCanta AC et al., The fate of nontargeted endocardial leads during the extraction of one or more targeted leads in pediatrics and congenital heart disease. Pacing Clin Electrophysiol. 2014 Jan;37(1):104-8.

Case #1

Hybrid Approach July 2015

79yr old WM PM dependant CRT-D upgrade 2014, failed endocardial CS lead, underwent EPI with pocket revision, and washout of hematoma. Initial DR PM 1996.

6 months of redness, swelling, gradual erosion, Rx ABX oral.

Referred for CIED extraction.

Off Coumadin for 5 days, bridge LMWH. Delay 7 days from office visit.
High-Risk Lead Removal by Planned Sequential Transvenous Laser Extraction And Minimally Invasive Right Thoracotomy

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From the *Vanderbilt Heart and Vascular Institute, Vanderbilt University Medical Center, Nashville, Tennessee, USA; and the †Department of Veteran Affairs, Tennessee Valley Healthcare System, Nashville, Tennessee, USA

Hybrid Lead Extraction for High-Risk Leads. **Introduction:** Transvenous pacemaker or implantable cardioverter defibrillator (ICD) lead extraction via mechanical or excimer laser sheath is typically safe and effective. Longer duration from implant, presence of large vegetations or thrombi, fractured leads, and prior failed extraction are risk factors predicting higher complication rates or incomplete or failed lead removal. Techniques developed for minimally invasive valve surgery were used in conjunction with laser extraction to refine a “hybrid” technique for lead extraction. We assessed the outcomes of high-risk lead extraction using this hybrid lead extraction technique.

**Methods and Results:** Retrospective assessment of clinical parameters and procedural outcomes in patients undergoing planned hybrid lead extraction from February 2008 to September 2012 was performed. We report 8 cases of hybrid lead extraction performed at our institution. We extracted 21 leads with average lead age of 13.8 years since implant. All leads were removed with complete clinical and radiographic success. There were no inprocedure complications. One patient died of continued sepsis and 1 other had symptoms consistent with pulmonary embolism.

**Conclusions:** Hybrid lead extraction using this technique is a safe and effective approach for removal of high-risk chronic pacemaker or ICD leads. This method extends the range of approachable leads resulting in complete removal without median sternotomy. Hybrid lead extraction can be scheduled electively facilitating complete lead removal with a low complication rate and short postoperative recovery time, mitigating the risks inherent in midline sternotomy or emergent cardiac surgical rescue. *(J Cardiovasc Electrophysiol, Vol. pp. 1-5)*
Conclusions: When to Extract a Lead

• 1- CIED infection. Avoid delays in definitive care.
• 2- Pocket erosion, or pending erosion = CIED infection.
• 3- Fidelis leads at generator change, or LIA alerts.
• 4- Leads that interfere with other leads (Riata).
• 5- Chronic total occlusion in attempt to regain intravascular access.
• 6- Abandoned leads when entering the pocket for CIED upgrade or revision.

• Consider hybrid approach to complex extractions. Measure twice, cut once.

• Be sure to review CXR or fluoroscopy on ALL referrals for extraction prior to scheduling.