Lead Abandonment or Extraction?

Jinhee Ahn, MD.
Pusan National University Hospital
Lead extraction – obviously needed

Pocket site infection

*Arrhythm Electrophysiol Rev* 2016:5;65-71.

After several revisions of PM
What about this situation?

AAI $\rightarrow$ DDD upgrade is planned. **Remove broken A lead or not??**
Management of “wrong” lead

Lead abandonment vs. Lead extraction
Definitions of “wrong” lead

• **Unnecessary lead**
  - Atrial lead in AF
  - PM lead after upgrading to ICD, ICD lead after downgrading to PM
  - After device moved to contralateral side

• **Failed lead (or potential failure)**
  - fracture, insulation break
  - High threshold, poor sensing, diaphragmatic stimulation
  - Recalled lead

• **Wrongly positioned lead**
  - Displaced in the wrong chamber (LA or LV)

• **Nonfunctional lead**
  - A lead that is not usable d/t electrical dysfunction, regardless of whether it is connected to the CIED or not.

• **Abandoned lead**
  - A functional or nonfunctional lead that is left in place and is not connected to the CIED.
Definitions of procedure

• **Lead removal**
  - Removal of a lead using any technique

• **Lead explant**
  - Removal without tools or with implantation stylets
  - All removed leads < 1 year

• **Lead extraction**
  - At least one lead removal with specialized equipment
  - At least one lead > 1 year
Indications for lead extraction

- CIED infection – pocket or systemic (I)
- Uncontrollable chronic pain (IIa)
- Thrombosis or vascular issues
  - Thromboembolic events (I)
  - SVC stenosis or occlusion preventing new lead implantation (I)
  - CIED-related SVC syndrome (I)
  - Ipsilateral venous occlusion (IIa)
- For MRI use (IIa)
- Recalled leads (IIa)
- Radiation therapy (IIa)
- Leads with potential future threat (IIb)
- Severe TR, Lead perforation

2017 HRS expert consensus on CIED lead management and extraction
Change of how to remove leads

**IN THE PAST**

- Direct manual traction
- Weights and pulleys systems
  - Ineffective and life threatening
- Cardiac surgery
  - High costs and morbidity

**AT PRESENT**

Transvenous removal
- Cost effective
- Relatively safe
Then, why don’t we just **extract**
the ‘wrong’ lead?
Lead extraction is NOT simple

1. **Subclavian**
   - Exsanguination, hemothorax, vein laceration

2. **Brachiocephalic**
   - Vein laceration requiring sternotomy

3. **SVC**
   - Exsanguination, hemothorax, laceration

4. **RA**
   - Cardiac tamponade from RA injury

5. **Tricuspid valve**
   - TR from valvular damage

6. **RV**
   - Cardiac tamponade, ventricular avulsion
Lead extraction is NOT simple

SVC adhesion

*Courtesy of Dr. N Strathmore*
## Extraction procedure-related complications

The rate of major complications is 1.4~1.9%.

<table>
<thead>
<tr>
<th>Major Event</th>
<th>Incidence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.19%–1.20%</td>
</tr>
<tr>
<td>Cardiac avulsion</td>
<td>0.19%–0.96%</td>
</tr>
<tr>
<td>Vascular laceration</td>
<td>0.16%–0.41%</td>
</tr>
<tr>
<td>Respiratory arrest</td>
<td>0.20%</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>0.07%–0.08%</td>
</tr>
<tr>
<td>Pericardial effusion requiring intervention</td>
<td>0.23%–0.59%</td>
</tr>
<tr>
<td>Hemothorax requiring intervention</td>
<td>0.07%–0.20%</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>0.07%</td>
</tr>
<tr>
<td>Thromboembolism requiring intervention</td>
<td>0.07%</td>
</tr>
<tr>
<td>Flail tricuspid valve leaflet requiring intervention</td>
<td>0.03%</td>
</tr>
<tr>
<td>Massive pulmonary embolism</td>
<td>0.08%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor Event</th>
<th>Incidence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pericardial effusion without intervention</td>
<td>0.60%–6.20%</td>
</tr>
<tr>
<td>Hematoma requiring evacuation</td>
<td>0.07%–0.16%</td>
</tr>
<tr>
<td>Venous thrombosis requiring medical intervention</td>
<td>0.90%–1.60%</td>
</tr>
<tr>
<td>Vascular repair at venous entry site</td>
<td>0.10%–0.21%</td>
</tr>
<tr>
<td>Migrated lead fragment without sequelae</td>
<td>0.07%–0.13%</td>
</tr>
<tr>
<td>Bleeding requiring blood transfusion</td>
<td>0.20%</td>
</tr>
<tr>
<td>AV fistula requiring intervention</td>
<td>0.08%–1.00%</td>
</tr>
<tr>
<td>Coronary sinus dissection</td>
<td>0.16%</td>
</tr>
<tr>
<td>Pneumothorax requiring chest tube</td>
<td>0.13%</td>
</tr>
<tr>
<td>Worsening tricuspid valve function</td>
<td>1.10%</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.32%–0.59%</td>
</tr>
</tbody>
</table>

2017 HRS expert consensus on CIED lead management and extraction
Then, what about abandonment?
Problems of abandoned leads
Maximal number of leads in a vein

Result of EHRA survey

![Graph showing the maximal number of leads in a vein for young and old age groups.](Image)

- **SVC**
  - Young age: [Graph Details]
  - Old age: [Graph Details]

- **Subclavian**
  - Young age: [Graph Details]
  - Old age: [Graph Details]

*Europace 2014;16:1674-8, modified.*
Problems of abandoned leads

• Symptoms or risk of death: less common

• Life-threatening arrhythmia

• Interfering with the treatment of a malignancy

• Limiting new lead implantation
  • More than 4 leads on one side or > 5 leads in SVC

• Interfering with the operation of a CIED system
  • Lead-to-lead interaction

• Potential future threat
  • Esp. recalled leads

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Previously abandoned leads may increase complexity of future extraction

- Cleveland Clinic 1996-2012, n=1,386 extractions for infected CIED

323 with abandoned leads vs. 1063 without abandoned leads

- Patients with abandoned leads had,
  - Failure to remove all hardware 13.0% vs. 3.7%
  - High rates of 1-month mortality 7.4% vs. 3.5%
  - Major / minor complications 11.5% vs. 5.6%
  - Longer procedure & fluoroscopic time
  - Requiring more specialized extraction tools or adjunctive vascular access

Clinical outcomes

Abandonment vs. Extraction
Abandonment vs. Extraction

- Medicare, de novo CIED between 2000 and 2013
- Lead addition or extraction ≥12 mon, infection excluded
- Abandonment (5746, 83.8%) vs Extraction (1113, 16.2%)
- Median f/u 2.4 yrs

- No difference in mortality at 5 yrs
- Extraction
  : lower infection risk at 5 yrs (HR 0.78)

Abandonment vs. Extraction

Outcomes One Year after ICD Lead Abandonment versus Explantation for Unused or Malfunctioning Leads: A Report from the NCDR®

- n=24908 → 1:1 propensity score matching, infection excluded

Extraction
  - More in-hospital death (0.21% vs 0.64%)
  - More in-hospital complication (2.19% vs. 3.77%)

- No differences in
  - Long-term mortality
  - Bleeding, infection, embolism, surgery

Comparison of outcomes in patients with abandoned versus extracted implantable cardioverter defibrillator leads

- Single center study
- Extraction (n=47) vs. Abandonment (n=37)
- Mean f/u 3.2 years
- No differences in
  - Surgical procedure
  - Thromboembolic events
  - Major complications or shock rates

No differences in long-term outcomes

Europace 2012;14:1764-70.
Data are limited by the observational nature and limited follow-up.

<table>
<thead>
<tr>
<th>I</th>
<th>C-EO</th>
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<tbody>
<tr>
<td></td>
<td><strong>Careful consideration with the patient on the decision on whether to abandon or remove a lead is recommended before starting the procedure. The risks and benefits of each course of action should be discussed, and any decision should take the patient’s preference, comorbidities, future vascular access, and available programming options into account.</strong></td>
</tr>
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<table>
<thead>
<tr>
<th>IIa</th>
<th>B-NR</th>
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<td></td>
<td><strong>Lead abandonment or removal can be a useful treatment strategy if a lead becomes clinically unnecessary or nonfunctional.</strong></td>
</tr>
</tbody>
</table>

→ Decisions must be on an individual case-by-case basis.

*2017 HRS expert consensus on CIED lead management and extraction*
Then...

Who can get a benefit from EXTRACTION safely?

4 Considerations

1. Indication for extraction

2. Patients

3. Leads

4. Experience of operator and center

2017 HRS expert consensus on CIED lead management and extraction.
1. Factors regarding ‘indication’ for extraction

- CIED infection – pocket or systemic
- Bilateral subclavian vein thrombosis
- SVC occlusion
- Ipsilateral venous occlusion with C/Ix to contralateral implant
- >4 in one vein or >5 through the SVC
- Potential for CIED interference
- Access to MRI

...“A lead will never be easier to extract than it is today.”
## 2. Factors regarding ‘patient’

<table>
<thead>
<tr>
<th>Factor</th>
<th>Associated risk (mortality or major complications)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.05</td>
</tr>
<tr>
<td>Female</td>
<td>4.5</td>
</tr>
<tr>
<td>Low BMI</td>
<td>1.8</td>
</tr>
<tr>
<td>CVA</td>
<td>2</td>
</tr>
<tr>
<td>Severe LV dysfunction</td>
<td>2</td>
</tr>
<tr>
<td>Advanced HF</td>
<td>1.3-8.5</td>
</tr>
<tr>
<td>Renal dysfunction</td>
<td>ESRD 4.8, Cr (&gt;2) 2</td>
</tr>
<tr>
<td>DM</td>
<td>Increase</td>
</tr>
<tr>
<td>PLT count</td>
<td>1.71</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>1/3-2.7</td>
</tr>
<tr>
<td>Anemia</td>
<td>3.3</td>
</tr>
</tbody>
</table>

## 3. Factors regarding ‘lead’

<table>
<thead>
<tr>
<th>Factor</th>
<th>Associated risk (mortality or major complications)</th>
</tr>
</thead>
</table>
| Number of leads extracted     | 3.5 for any complications  
                                 | 1.6 for long-term mortality                                                           |
| Presence of dual-coil ICD     | 2.7                                                                                    |
| Extraction for infection      | 2.7-30                                                                                 |
| Dwell time                    | 1.9                                                                                    |

*Am J Cardiol 2015;115:1107-110.*  
*PACE 2015;38:1297-303.*  
*PACE 2010;33:209-16.*
4. Factors regarding ‘operator and center’

<table>
<thead>
<tr>
<th>Factor</th>
<th>Associated risk (mortality or major complications)</th>
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<tbody>
<tr>
<td>Operator experience (&lt;50)</td>
<td>2.6 increase for procedure-related Cx.</td>
</tr>
</tbody>
</table>

**Table V. Reported Complications**

<table>
<thead>
<tr>
<th>Complication by Intervention (most serious event counted per patient)</th>
<th>Three Physicians With &gt; 300 Total Procedures (824 Patients)</th>
<th>14 Physicians With 20–120 Total Procedures (492 Patients)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Median sternotomy or thoracotomy repair</td>
<td>3 (0.4%)</td>
<td>4 (0.8%)</td>
<td></td>
</tr>
<tr>
<td>Transfusions</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Drainage – pericardiocentesis or chest tube</td>
<td>5 (0.6%)</td>
<td>1 (0.2%)</td>
<td></td>
</tr>
<tr>
<td>Other “major” complications</td>
<td>0</td>
<td>1 (0.2%)</td>
<td></td>
</tr>
<tr>
<td>Total “Major” Complications</td>
<td>8 (0.97%)</td>
<td>9 (1.8%)</td>
<td>0.0532</td>
</tr>
</tbody>
</table>

- MAE (n = 20)

<table>
<thead>
<tr>
<th>Center size (LATE experience over 4-yr study period), cases</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤60</td>
<td>6 (2.88%)</td>
</tr>
<tr>
<td>&gt;60–≤130</td>
<td>8 (1.70%)</td>
</tr>
<tr>
<td>&gt;130</td>
<td>6 (0.78%)</td>
</tr>
</tbody>
</table>

Recommendations on minimum training and volume
- a minimum of 40 leads as the primary operator

*Heart rhythm 2014;11:404-11.
**Facility**

- **Primary Operator:**
  A physician 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**
- **“Scrubbed” assistant (nurse/technician/physician)**

**Equipment**

- High-quality fluoroscopy
- Surgical instruments
- Extraction tools
- Extraction snares
- CIED implantation tools
- Transthoracic and transesophageal echocardiography

*Sufficient personnel and equipment are mandatory for high-risk lead extraction.*
Schemes to predict the risk following lead extraction
**Nomogram to predict 30-day all-cause mortality after lead extraction**

- The Cleveland Clinic, 1996-2011

- 2999 procedures for 5521 leads
  - PM (74.9%) + ICD (25.1%)

- 67 patients (2.2%) died by 30 days.

*Heart rhythm 2015;12:2381-6.*

[Link to Existing Formulas](http://www.r-calc.com/ExistingFormulas.aspx?filter+CCQHS)
Risk stratification scheme to categorize risk and decide how to approach

- The Mayo Clinic, 2013-2016
- 349 leads from 187 patients
  - PM (41.2%) + ICD (38.5%)
    + CRT (20.3%)
- 1st cause of Ix – CIED infection (48.7%)
- Major complication - 2.7%
Risk stratification scheme to categorize risk and decide how to approach

• This study used a novel risk stratification tool to prospectively categorize risk and allocate rescue strategies and surgical services for anticipated complications.

• Multidisciplinary team approach for higher risk vs. device laboratory for intermediate risk
Extraction is safe in the right situation

1. Indication for extraction

2. Patients

3. Leads

4. Experience of operator and center

• High success rate at removing all of leads > 95%
• Achieving clinical success ≈ 99%

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Summary

Abandonment vs. Extraction

• So far, no differences in long-term clinical outcome

• Decision should be individualized

• Only extract if safe
  • Right people: experienced operator, team and surgeon standby
  • Right tool: proper extraction specific tools
  • Right place: operating room, sufficient equipment
  • Right patient: low risk & inevitable indication
Thank you for your attention!