Complications of Lead Extraction: Prevention and treatment

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Potential complications of transvenous lead extraction

Major Complications

- Death
- Cardiac avulsion (percutaneous or surgical)
- Vascular Injury requiring intervention (percutaneous or surgical)
- Pulmonary embolism requiring surgical intervention
- Respiratory arrest/anesthesia related complication prolonging hospitalisation
- Stroke
- CIED infection at previously non-infected site

Minor Complications

- Pericardial effusion not requiring intervention
- Hemotorax not requiring intervention
- Pocket haematoma requiring reoperation
- Upper extremity thrombosis resulting in medical treatment
- Haemodynamically significant air embolism
- Migrated lead fragment without sequelae
- Blood transfusion as a result of intraoperative blood loss
- Pneumothorax requiring chest tube
- Pulmonary embolism not requiring surgical intervention


This document was endorsed by the American Heart Association (AHA).

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Lead extraction: success, morbidity, and mortality in large series

![Graph showing success, major complications, and mortality percentages over time with data from various studies.]

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Maytin M Circ Arrhythm Electrophysiol 2010
Factors Affecting risk assessment in lead extraction

- Patient-related
- Team-related
- Lead-related

Tools, Techniques and Approaches -related
Factors affecting risk assessment in lead extraction

- Patient-related

  - Gender, Age, BMI
  - Comorbidities
    - Infections
    - Diabetes
    - Renal Failure
    - Heart Failure
Factors related to the Outcome of Transvenous Lead-Extraction: Patients

1449 patients, 13 centers, during 3 year period, lead extraction for infection in 57%, blood stream ± vegetation (DRE) in 29% (LExICON)

<table>
<thead>
<tr>
<th></th>
<th>DRE</th>
<th>rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>66.3 y</td>
<td>62.2 y</td>
</tr>
<tr>
<td>Diabetes</td>
<td>38.8%</td>
<td>23.3%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>24.2%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Complications</td>
<td>1.7%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Mortality</td>
<td>4.3%</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Indicators of all-cause in-hospital mortality were pocket infections, device related endocarditis, diabetes and creatinine ≥2

Factors Affecting risk assessment in lead extraction

- **Lead-related**

  Type, Number and Position

  Dwell time

  **Damage:** Fracture  
  Protrusion  
  Insulation failure  
  Intravascular free-floating lead  
  (previous attempt of extraction)

  **Lead-tissue interaction:** adhesion and/or calcifications

  **Vegetations**
212 consecutive pts, 456 leads extracted from 2002 and 2008, single-center, single-operator experience
30 days FU

Higher complication rates (vs literature) probably because
1) Iller population: 80% CAD (mean FE 36%); 58% diabetes; 69% CHF
2) Operator learning curve is included

3.5 fold increase in the risk for every incremental RV lead extracted
ICD vs PM lead extraction showed a trend to higher complication rate

Previous open heart-surgery is associated with less risk

JCE 2009; 20; 171-175
Improved success rate of cardiac resynchronization therapy implant by employing an active fixation coronary sinus lead

Guido Luedorff¹, Wolfgang Kranig¹, Rainer Grove¹, Endrik Wolff¹, Gerd Heimlich², and Joachim Thale¹

Figure 3 (Top left) X-ray view showing a lateral target vein (RAO 0°). (Top right) A conventional pass of the peripheral end of the lateral target vein (arrow). However, in this position, phrenic nerve stimulation occurred. (Bottom left) When the same left ventricle lead was placed in the more proximal part of the target vein (arrow), it became unstable and dislodged into the coronary sinus (not shown). (Bottom right) An Attain Starfix™ active fixation lead was placed in the proximal part of the lateral target vein and the fixation lobes were deployed (arrow). In this position, left ventricle lead and stimulation threshold were stable without phrenic nerve stimulation.
408 patients implanted - 23 months FU

Complications:

- 22 events in 19 subjects  5%
- PNS requiring reintervention  2.5%
- Dislodgements (2/3 in first 5 imp): 0.7%

CONCLUSION  The Medtronic 4195 is safe and highly efficacious. It affords the physician more choices in lead placement location and has a remarkably low dislodgement rate.

Crossley, et al, Heart Rhythm, Vol 7, No 4, April 2010
24 (6%) attempted revision

- 12 leads were completely removed (mean 195.4 days)
- 7 leads were repositioned (mean 135.4 days)
- Failure in 5 patients (21%) (mean 558 days)

Of the 7 leads requiring modification that were implanted for more than 1 year, 4 (57%) were unable to be extracted

Crossley, et al, Heart Rhythm, Vol 7, No 4, April 2010
Complication must be expected!!
A case of suspect perforation of right ventricular apex
Extraction Profile Performance of Expanded Polytetrafluoroethylene-covered Defibrillator Leads in Comparison to Traditional Leads

Di Cori A, Cori A. et al. Heart Rhythm 2010

A

Gore-Tex™
Endotak
Reliance G

B

Medtronic Sprint Quattro

C

St Jude Medical Durata

Patients %

Extraction Time (min)

Group A

Group B

Group C

* Group A vs Group B  p<0.05
** Group A vs Group C  p<0.05
Female 48y old, sepsys, 1 ICD lead in RVOT (17y dwelling time, unsuccessful attempt)
Factors Affecting risk assessment in lead extraction

- Tools, Techniques and Approaches

  Tools availability

  Techniques and Approaches expertise
Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction

FDA Manufacturers and User Defined Experience (MAUDE) database from 1995 to 2008: 57 deaths and 48 serious cardiovascular injuries associated with device-assisted lead extraction were reported.

<table>
<thead>
<tr>
<th>COMPLICATION</th>
<th>FATAL IN (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVC laceration</td>
<td>18/28 = 64%</td>
</tr>
<tr>
<td>Haemopericardium</td>
<td>2/6 = 33%</td>
</tr>
<tr>
<td>Innominate vein tear</td>
<td>1/4 = 25%</td>
</tr>
<tr>
<td>RA tear</td>
<td>1/4 = 25%</td>
</tr>
<tr>
<td>Hypotension 3, Haemorrhage 2,</td>
<td></td>
</tr>
<tr>
<td>RV perforation 1, Unspecified 2,</td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolus 1</td>
<td></td>
</tr>
</tbody>
</table>

OTHER CAUSES OF DEATH

Hypotension 3, Haemorrhage 2, RV perforation 1, Unspecified 2, Pulmonary embolus 1

Table 1 Lead extraction devices associated with reported deaths and serious injuries in the FDA MAUDE database 1995–2008

<table>
<thead>
<tr>
<th>Lead extraction device</th>
<th>n</th>
<th>Number of events</th>
<th>Death</th>
<th>Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excimer laser sheath</td>
<td>45</td>
<td>25</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Mechanical dilator sheath</td>
<td>8</td>
<td>6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Electrosurgical dissection sheath</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Polypropylene or Teflon dilator sheath</td>
<td>24</td>
<td>6</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Unspecified extraction devices</td>
<td>26</td>
<td>18</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>105</td>
<td>57</td>
<td>48</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

These findings suggest that device-assisted lead extraction is a high-risk procedure and that serious complications including death may not be mitigated by emergency surgery. However, skilled standby cardiothoracic surgery is essential when performing pacemaker and ICD lead extractions. Although the incidence of these complications is unknown, the results of our study imply that device-assisted lead extractions should be performed by highly qualified physicians and their teams in specialized centres.

RG Hauser et al  Europace 2010; 12: 395-401

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Personal Experience on Lead Extraction

1. Superior Approach: using the implant vein
2. Inferior Approach: Femoral Approach
3. Internal Jugular Approach: (personal technique from ‘97)
Importance of coaxial orientation of *any* sheath to avoid vascular injury
Right Superior Venous Entry

Internal Transjugular Approach

Maria Grazia Bongiorni
Editor

From Simple Traction to Internal Transjugular Approach
Foreword by Bruce L. Wilkoff

Springer
Factors affecting risk assessment in lead extraction

Team Related

- Experience and volume
- Staff Training
- Surgical back-up

LexlCon Study 2010

Table 5
Demographic Characteristics: Procedural MAE

<table>
<thead>
<tr>
<th>Center size (LALE experience over 4-yr study period), cases</th>
<th>MAE (n = 20)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤60</td>
<td>6 (2.88%)</td>
<td>0.0532</td>
</tr>
<tr>
<td>&gt;60–≤130</td>
<td>8 (1.70%)</td>
<td></td>
</tr>
<tr>
<td>&gt;130</td>
<td>6 (0.78%)</td>
<td></td>
</tr>
</tbody>
</table>
Multicenter experience, **5 high-volume centers**, 348 pts (349 leads) extracted from May 2005 to August 2009; 49.4% with simple traction, 50.6% with CTS assistance.

**100% success rate**

<table>
<thead>
<tr>
<th>Indications for Extraction</th>
<th>Fracture</th>
<th>Prophylactic</th>
<th>Infection</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>49.4%</td>
<td>26.5%</td>
<td>22.8%</td>
<td>0.9%</td>
</tr>
<tr>
<td></td>
<td>0.6%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedural Complications</th>
<th>Traction</th>
<th>CTS Assistance</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths (n)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Major complications (n)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor complications: lead dislodgment (n)</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

In well trained laboratories lead extraction of Sprint Fidelis is a quite safe procedure.

JACC 2010; 56; 646-50

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These findings have significant implications for the management of patients who have Fidelis leads, and they demonstrate the importance of weighing clinical variables in assessments of ICD lead performance.
The overall risk of complications (19.8%) was greater in those who underwent lead removal than in those whose leads were abandoned (8.6%).
Lead extraction is a “battle” that requires a wonderful general, a great army and a careful strategy (...and a little bit of good luck!)
Our Experience in details............

Patients and Leads Characteristics
(January 1997 - March 2011)

<table>
<thead>
<tr>
<th>Patients</th>
<th>1681</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean range</td>
<td>65.7 63-95</td>
</tr>
<tr>
<td>Sex M / F</td>
<td>1278/403</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leads</th>
<th>3023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pacing period (months) range</td>
<td>70.8 1-420</td>
</tr>
<tr>
<td>Pacing / Defibrillating leads</td>
<td>2553/470</td>
</tr>
<tr>
<td>Exposed / Intravascular</td>
<td>2936/87</td>
</tr>
</tbody>
</table>
No Patient/Lead selection
(January 1997 - March 2011)
1681 Patients - 3023 Leads

Our population included:

Free floating leads → 87/3023 (3%)
Leads with a long dwell time → 612/3023 more than 10 y (20%)
Prev unsucc extraction attempts → 313/3023 (10%)
Vegetations → 514/3023 (17%)
### Major complications

**January 1997 – March 2011**

10/1681 pts (0.6%)

<table>
<thead>
<tr>
<th>Sex</th>
<th>6F/4M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>73.4 y</td>
</tr>
<tr>
<td>range</td>
<td>65-85 y</td>
</tr>
<tr>
<td>Infective indications</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CARDIAC TAMPONADE</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2 (RV)</td>
</tr>
<tr>
<td>Surgical Repair</td>
<td>2 (1 RV - 1 RA)</td>
</tr>
<tr>
<td>Pericardiocentesis</td>
<td>5 (2 RV – 1 RA – 1 CS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HEMOTHORAX</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (damaged lead)</td>
</tr>
</tbody>
</table>

**Deaths**

3/1681 pts (0.18%)

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**NO SVC Tears**

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Transvenous Lead Extraction - Results and Complications

Jugular approach
Personal Data 1997-2010: 1516 pts – 2703 leads

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**Patient preparation**

- History and Physical exam.
  (device, lead and adapter informations, pathologies, e.g. diabetes, heart failure, etc)
- Infective workout

- Chest X-ray
  (device and lead characterization: number, location, fixation mechanism, structural characteristics, etc)
- Baseline blood test
  (coagulation, renal function, haemocrome...)

- Blood units available

- Temporary pacing

- Invasive arterial pressure monitor

**Equipment**

- High quality fluoroscopy
- Extraction tools
- CIED implantation tools
- TTE/TEE/(ICE)
- Pericardiocentesis set
- Cardiothoracic Surgery stand-by
Factors related to the Outcome of Transvenous Lead-Extraction: Lead position

LL PROJECTION
The extraction of chronic implanted leads is a major procedure, challenging and sometime life-threatening.

Today, experienced team and proper environment warrant high success rate and very low complications incidence.

The procedure and approaches must be well planned and tailored to the lead and patient.
...because in lead extraction ... to be safe

...one size doesn’t fit all...

...a tailored procedure is necessary

THANKS FOR YOUR ATTENTION