"Δυσκολίες στην εκφύτευση ηλεκτροδίων"

Παναγιώτης Ιωαννίδης

Διευθυντής Τμήματος Καρδιακής
Ηλεκτροφυσιολογίας & Βηματοδότησης
Βιοκλινικής Αθηνών

39ο Πανελλήνιο Καρδιολογικό Συνέδριο
Αθήνα, 18-20 Οκτωβρίου 2018
16-Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States
1993 to 2008

Arnold J. Greenspon, MD,* Jasmine D. Patel, PhD,† Edmund Lau, MS,‡ Jorge A. Ochoa, PhD,§ Daniel R. Frisch, MD,* Reginald T. Ho, MD,* Behzad B. Pavi, MD,* Steven M. Kurtz, PhD§

PM Lead survival

ICD Lead survival

Arnsbo and Moller, Pacing Clin Electrophysiol. 2000;23:1401-6

Maisel and Kramer, Circulation 2008;117:2721-3
## Indications for Transvenous Lead Extraction (1)

<table>
<thead>
<tr>
<th>Infection</th>
<th>Class I</th>
<th>Class IIa</th>
<th>Class IIb</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Sepsis or lead/valvular endocarditis&lt;br&gt;• Pocket infection/erosion/adherence&lt;br&gt;• Valve endocarditis without involvement of the CIED&lt;br&gt;• Occult Gram+ bacteremia</td>
<td>• Persistent occult Gram- bacteremia</td>
<td>• Superficial infection with no device involvement&lt;br&gt;• Other source of chronic bacteremia</td>
<td></td>
</tr>
</tbody>
</table>

### 50-60% of the lead extraction procedures

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## Indications for Transvenous Lead Extraction (2)

<table>
<thead>
<tr>
<th>Venous thrombosis or stenosis</th>
<th>Class I</th>
<th>Class IIa</th>
<th>Class IIb</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinically significant TE event</td>
<td>Bilateral subclavian vein or SVC occlusion and need for new lead</td>
<td>Planned stent deployment in a vein where there is a lead</td>
<td>Ipsilateral venous occlusion when contralateral side can be used for new lead</td>
</tr>
<tr>
<td></td>
<td>Symptomatic SVC stenosis/occlusion</td>
<td>Ipsilateral venous occlusion when contralateral side cannot be used for new lead</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications for Transvenous Lead Extraction (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
</tr>
<tr>
<td>Chronic pain</td>
</tr>
<tr>
<td>Functional leads</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Non-functional leads</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
## Estimated needs for transvenous lead extraction

<table>
<thead>
<tr>
<th>New implants / million / year</th>
<th>Prevalence of infection (%)</th>
<th>Prevalence of lead extraction (%)</th>
<th>Lead extractions / million / year</th>
</tr>
</thead>
<tbody>
<tr>
<td>500</td>
<td>1 - 4</td>
<td>1.5 - 6</td>
<td>7.5 - 30</td>
</tr>
<tr>
<td>1000</td>
<td>1 - 4</td>
<td>1.5 - 6</td>
<td>15 - 60</td>
</tr>
<tr>
<td>1500</td>
<td>1 - 4</td>
<td>1.5 - 6</td>
<td>22.5 - 90</td>
</tr>
<tr>
<td>2000</td>
<td>1 - 4</td>
<td>1.5 - 6</td>
<td>30 - 120</td>
</tr>
</tbody>
</table>
Intracardiac findings near the leads and electrodes

M. Bongiorni, Transvenous lead extraction, Spinger-Verlag Italia 2011
Definitions

Success vs Failure

Complete success:

• Removal of all the targeted leads

Clinical success:

• Retention of a small portion of a lead that does not negatively impact the outcome goals of the procedure. This may be the tip or a small part (<4 cm) of the lead (conductor coil, insulation, or the two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome. Absence of any permanently disabling complication or procedure-related death.

Failure:

• Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedural-related death.
- Finline 4480 (atrial) 5F
- Finline 4457 (ventricular) 5F
2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS

Clinical procedural success
Retention of a small portion of a lead that does not negatively impact the outcome goals of the procedure. This may be the tip or a small part (<4 cm) of the lead (conductor coil, insulation, or the two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection, or cause any undesired outcome. Absence of any permanently disabling complication or procedure-related death.

Bongiorni et al. 2018 EHRA expert consensus statement on LE. Europace 2018;00,1-11
Tools and techniques for lead extraction

- Simple traction
- Locking stylets
- Mechanical non-powered telescoping sheaths
- Powered sheaths
- Snares
- Endovascular occlusion balloons
Tools and techniques for lead extraction

• Simple traction
• Locking stylets
• Mechanical non-powered telescoping sheaths
• Powered sheaths
• Snares
• Endovascular occlusion balloons
• Γυναίκα, 85 ετών
• Σύνδρομο νοσ. φλεβοκόμβου
• Εμφύτευση VVIR βηματοδότη προ 2ετίας
• Σύνδρομο βηματοδότη
• Αύξηση βηματοδοτικού ουδού
• Επαγγελματία, 85 ετών
• Σύνδρομο νοσ. φλεβοκόμβου
• Εμφύτευση VVIR βηματοδότη προς 2ετίας
• Σύνδρομο βηματοδότη
• Αύξηση βηματοδοτικού ουδού
• Γυναίκα, 85 ετών
• Σύνδρομο νοσ. φλεβοκόμβου
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• Αύξηση βηματοδοτικού ουδού
Tools and techniques for lead extraction

- Simple traction
- Locking stylets
- Mechanical non-powered telescoping sheaths
- Powered sheaths
- Snares
- Endovascular occlusion balloons
• 86-year-old man
• LVEF: 25%
• Need for permanent RV pacing
• Device replacement and upgrade to CRT-D
• Pocket infection
• 61-year-old man
• Ischemic CM
  LVEF:30%
• Initial ICD implantation 2010
• Device replacement and upgrade to CRT-D in 2016
• RV lead failure
• 61-year-old man
• Ischemic CM LVEF: 30%
• Initial ICD implantation 2010
• Device replacement and upgrade to CRT-D in 2016
• RV lead failure
• 61-year-old man
• Ischemic CM LVEF: 35%
• Initial ICD implantation 2010
• Device replacement and upgrade to CRT-D in 2016
• RV lead failure
• 61-year-old man
• Ischemic CM LVEF:30%
• Initial ICD implantation 2010
• Device replacement and upgrade to CRT-D in 2016
• RV lead failure
• 61-year-old man
• Ischemic CM
  LVEF: 30%
• Initial ICD implantation 2010
• Device replacement and upgrade to CRT-D in 2016
• RV lead failure
- 61-year-old man
- Ischemic CM LVEF: 30%
- Initial ICD implantation 2010
- Device replacement and upgrade to CRT-D in 2016
- RV lead failure
• 75-year-old man
• DCM
• RV and LV ventricular lead damaged
Tools and techniques for lead extraction

• Simple traction
• Locking stylets
• Mechanical non-powered telescoping sheaths
• Powered sheaths
• Snares
• Endovascular occlusion balloons
Telescopic sheaths
Tools and techniques for lead extraction

- Simple traction
- Locking stylets
- Mechanical non-powered telescoping sheaths
- Powered sheaths
- Snares
- Endovascular occlusion balloons
Telescoping sheath

Stainless steel

Polypropylene

Teflon

Evolution sheath

Excimer laser

Electrosurgical
Excimer Laser

Ultraviolet light

Vaporization of the tissue attachements

Wilkoff et al. J Am Coll Cardiol 1999;33:1671-6

Kennergren et al. 2007;9:651-656
### Pacemaker Lead Extraction With the Laser Sheath: Results of the Pacing Lead Extraction With the Excimer Sheath (PLEXES) Trial

Bruce L. Wilkoff, MD, FACC,* Charles L. Byrd, MD, FACC,† Charles J. Love, MD, FACC,** David L. Hayes, MD, FACC,§ T. Duncan Sellers, MD, FACC,** Raymond Schaefer, MD,†† Victor Parsonnet, MD, FACC,§ Laurence M. Epstein, MD, FACC,** Robert A. Sorentino, MD,†† Christopher Reiser, Pt;D‡‡

<table>
<thead>
<tr>
<th>Complication</th>
<th>Randomization</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamponade</td>
<td>Laser</td>
<td>Thoracotomy, death</td>
</tr>
<tr>
<td>Tamponade</td>
<td>Laser</td>
<td>Thoracotomy</td>
</tr>
<tr>
<td>Hemothorax</td>
<td>Laser</td>
<td>Chest tube</td>
</tr>
<tr>
<td>Valve damage</td>
<td>Laser</td>
<td>Medical treatment</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Nonlaser</td>
<td>Anticoagulation</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Laser</td>
<td>Anticoagulation</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>Nonlaser</td>
<td>Observation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Nonlaser</th>
<th>Laser</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leads (n)</td>
<td>221</td>
<td>244</td>
<td></td>
</tr>
<tr>
<td>Complete extraction*</td>
<td>142 (64%)</td>
<td>230 (94%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Partial extraction</td>
<td>4 (1.8%)</td>
<td>6 (2.5%)</td>
<td>0.87</td>
</tr>
<tr>
<td>Failure*</td>
<td>75 (34%)</td>
<td>8 (3.3%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Failed venous entry</td>
<td>14 (6%)</td>
<td>0</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Binding site impasse</td>
<td>42 (19%)</td>
<td>3 (1.2%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Lead disruption</td>
<td>14 (6%)</td>
<td>2 (0.8%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Lead diameter</td>
<td>3 (1.4%)</td>
<td>0</td>
<td>0.21</td>
</tr>
<tr>
<td>Acute complication†</td>
<td>0</td>
<td>3 (1.2%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Crossover to 12-F laser</td>
<td>72 (33%)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Crossover to 16-F laser</td>
<td>1 (0.5%)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Crossover to femoral</td>
<td>2 (0.9%)</td>
<td>5 (2.0%)</td>
<td>0.53</td>
</tr>
<tr>
<td>Clinical success of procedure (patients)</td>
<td>142 of 148 (95.9%)</td>
<td>145 of 153 (94.8%)</td>
<td>0.83</td>
</tr>
</tbody>
</table>

Lead Extraction in the Contemporary Setting: The LExlCon Study

An Observational Retrospective Study of Consecutive Laser Lead Extractions

Oussama Wazni, MD,* Laurence M. Epstein, MD,† Roger G. Carrillo, MD,§ Charles Love, MD,† Stuart W. Adler, MD,¶ David W. Riggio, MD,¶ Shahsaad S. Karmi, MD,§ Jamil Bashir, MD,§ Arnold J. Greenspon, MD,⊥ John P. DiMarco, MD, Pt(D),‡§ Joshua M. Cooper, MD,‡ John R. Orufer, MD,⊥⊥ Kenneth A. Ellenbogen, MD,⊥⊥ Stephen P. Kussle, MD,⊥⊥ Sherri Dentsy-Mabry, MSN,⊥⊥ Carolyn M. Ervin, Pt(D),⊥⊥ Bruce L. Wilkoff, MD⊥

13 sites in the US and Canada
2405 leads

<table>
<thead>
<tr>
<th>Procedural and Clinical Success</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete (Per Lead)</td>
<td>2,322 (96.5%)</td>
</tr>
<tr>
<td>Partial</td>
<td>56 (2.3%)</td>
</tr>
<tr>
<td>Combined complete and partial</td>
<td>2,378 (98.8%)</td>
</tr>
<tr>
<td>Failure</td>
<td>27 (1.1%)</td>
</tr>
<tr>
<td>Total</td>
<td>2,405</td>
</tr>
<tr>
<td>Clinical success (per patient)</td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>1,416 (97.7%)</td>
</tr>
<tr>
<td>Failure</td>
<td>33 (2.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>1,449</td>
</tr>
</tbody>
</table>

Procedure related
1.4% Major complications
0.28% Death

EVOLUTION® Mechanical Dilator Sheath Set.

COOK® MEDICAL
COOK MEDICAL

EVOLUTION® Mechanical Dilator Sheath Set.
Safety and efficacy of the new bidirectional rotational Evolution® mechanical lead extraction sheath: results from a multicentre Italian registry

Patrizio Mazzone†, Federico Migliore2‡, Emanuele Bertaglia3, Domenico Facchin3, Elisabetta Daleffe3, Vittorio Calzolari4, Martino Crosato4, Francesco Melillo1, Francesco Peruzza2, Alessandra Marzi1, Nicoleta Sora1, and Paolo Della Bella1

- Minor Complications: Pericardial effusion not requiring pericardiocentesis or surgical intervention (n=1), pneumothorax (n=1) and haematoma at the pocket requiring drainage (n=3)

Table 2 Characteristics of leads extracted with the new Evolution RL sheath

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of leads extracted with Evolution RL sheath, n</td>
<td>238</td>
</tr>
<tr>
<td>Mean number of leads extracted per patient ± SD, range</td>
<td>1.92 ± 0.44 (1–3)</td>
</tr>
<tr>
<td>Mean implant duration ± SD, range (months)</td>
<td>92.2 ± 52.9 (12–336)</td>
</tr>
<tr>
<td>Distribution of lead implant duration (months), n (%)</td>
<td></td>
</tr>
<tr>
<td>12–24</td>
<td>11/238 (4.6%)</td>
</tr>
<tr>
<td>24–48</td>
<td>26/238 (11%)</td>
</tr>
<tr>
<td>48–72</td>
<td>60/238 (25.2%)</td>
</tr>
<tr>
<td>72–96</td>
<td>49/238 (20.5%)</td>
</tr>
<tr>
<td>96–120</td>
<td>29/238 (12.2%)</td>
</tr>
<tr>
<td>&gt;120</td>
<td>63/238 (26.5%)</td>
</tr>
<tr>
<td>Passive fixation, n (%)</td>
<td>135 (56.3%)</td>
</tr>
<tr>
<td>Lead type, n (%)</td>
<td></td>
</tr>
<tr>
<td>Right atrium</td>
<td>86 (36.1%)</td>
</tr>
<tr>
<td>Right ventricle</td>
<td>38 (16%)</td>
</tr>
<tr>
<td>Coronary sinus</td>
<td>23 (9.7%)</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>91 (38.2%; 81 dual coil vs. 10 single coil)</td>
</tr>
<tr>
<td>Clinical success, n (%)</td>
<td>100%</td>
</tr>
<tr>
<td>Complete procedural success per lead/per patient, n (%)</td>
<td>235/238 leads (98.7%)/121/124 (97.6%)</td>
</tr>
<tr>
<td>Minor complications, n (%)</td>
<td>5 (4%)</td>
</tr>
<tr>
<td>Major complications, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Dilator sheath diameter, n (%)</td>
<td></td>
</tr>
<tr>
<td>9 F</td>
<td>36 (15%)</td>
</tr>
<tr>
<td>11 F</td>
<td>191 (80%)</td>
</tr>
<tr>
<td>13 F</td>
<td>16 (7%)</td>
</tr>
</tbody>
</table>
Tools and techniques for lead extraction

- Simple traction
- Locking stylets
- Mechanical non-powered telescoping sheaths
- Powered sheaths
- Snares
- Endovascular occlusion balloons
Snares

Free Lead Tip (open)
- Gooseneck Snare
- EnSnare

Lead Tip is Secure (closed)
- Needle’s Eye Snare
Snares for the poor
Snares for the poor
Snares for the poor
Snares for the poor
Tools and techniques for lead extraction

- Simple traction
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- Snares
- Endovascular occlusion balloons
Endovascular occlusion balloon

Azarrafiy et al. Heart Rhythm. 2017;14:1400-1404
Clinical outcomes of different extraction methods

- Clinical success:
  - Simple traction: 32%
  - Locking stylet: 44%
  - Mechanical dilator: 71%
  - Femoral snare: 97%
  - Laser sheath: 95%
  - EDS: 87%
  - Evolution®: ***

- Mortality
  - Simple traction: 6%
  - Locking stylet: 4%
  - Mechanical dilator: 2%
  - Femoral snare: 1%
  - Laser sheath: 0%
  - EDS: 0%
  - Evolution®: 0%

- Major complications
  - Simple traction: 5%
  - Locking stylet: 3%
  - Mechanical dilator: 2%
  - Femoral snare: 1%
  - Laser sheath: 0%
  - EDS: 0%
  - Evolution®: 0%

- Minor complications
  - Simple traction: 2%
  - Locking stylet: 1%
  - Mechanical dilator: 0%
  - Femoral snare: 0%
  - Laser sheath: 0%
  - EDS: 0%
  - Evolution®: 0%

**EDS: Electrosurgical dissection sheath**

Buiten et al. Europace 2015;17:689-700
Εκφύτευση ηλεκτροδίων
Τα μυστικά της επιτυχίας...

• Λύση των συμφύσεων και απελευθέρωση της καθήλωσης στην περιοχή της θήκης χωρίς τραυματισμό των ηλεκτροδίων
• Λύση των συμφύσεων μέχρι το όριο της υποκλειδίου
• Επιβεβαίωση της βατότητας του αυλού του ηλεκτροδίου
• Εισαγωγή του στυλεού αγκύρωσης μέχρι το απώτερο άκρο του ηλεκτροδίου
• Ελεγχόμενη έλξη για ομαλή αποδέσμευση του ηλεκτροδίου από τις αγγειακές και καρδιακές συμφύσεις
• Επιλεκτική χρησιμοποίηση θηκαρίων με ενέργεια
• Εξασφάλιση ετοιμότητας των υποστηρικτικών δομών σε περίπτωση επιπλοκής
Ευχαριστώ για την ωραία χαρά σας!
• Back-up Slides
Europe = 893,000,000 inhabitants

- Total 2012 = 493,573 PMs implanted
- Total 2012 = 84,716 ICDs implanted

Estimates for Europe 2012:
- 1,561,309 Low voltage leads
- 132,736 Tachy leads