

## Editorial

## Transvenous Lead Extraction of Cardiac Implantable Electronic Devices: Who, When, How and Where?



## Extracción de electrodos transvenosos de dispositivos electrónicos implantables cardiacos: ¿quién, cuándo, cómo y dónde?

Ayman A. Hussein and Bruce L. Wilkoff\*

Sydell and Arnold Miller Family Heart and Vascular Institute, Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Department of Cardiac Pacing and Electrophysiology, Cleveland Clinic, Cleveland, Ohio, United States

Article history:

Available online 16 November 2015

## INTRODUCTION

The use of cardiac implantable electronic devices (CIED) has greatly increased over the past 2 decades.<sup>1</sup> In parallel, there has been a growing need for device and lead extraction. The subsequent development of tools, techniques, and standards for transvenous lead extraction (TLE) has improved both the safety and efficacy of these procedures.<sup>1,2</sup> However, these remain complex interventions that require well trained personnel and a well-equipped facility with tools and strategies to deal with life-threatening complications, should they occur.

In this condensed review, we discuss the topic of TLEs with an emphasis on the key elements including: a) qualifications of the primary operator; b) procedural indications and factors to account for in decision making, as well as the c) tools, and d) techniques for TLE: “The who, when, how and where?”

## WHO: IMPORTANCE OF THE TEAM AND QUALIFICATIONS OF THE PRIMARY OPERATOR

A key element for safe and successful TLEs is a team whose members have well defined roles for which they are very well trained. All team members should be capable of delivering appropriate timely support to other members of the team, especially when complications occur. Team members must be familiar with the indications, process, and potential complications of TLEs, as well as protocols for their management.

The primary operator is usually a cardiac electrophysiologist and/or a cardiac surgeon, who is well trained not only in TLEs but in device and lead implants and all aspects of lead and device management. Expert consensus documents from the Heart Rhythm Society<sup>1</sup> and European Heart Rhythm Association<sup>3</sup> specify a minimum of 40 leads or 40 extraction procedures respectively to be performed under the direct supervision of an experienced operator and these procedures need to encompass various vascular

access approaches and extraction tools. Beyond training, a primary operator needs to perform at least 20 TLEs (leads or procedures) every year to maintain his own skill set and the skill set of the supporting team. Published data suggest that TLE procedural success improves dramatically with operator experience.<sup>4,5</sup>

A cardiac surgeon must be available for immediate intervention, should open heart surgery be required to manage a major complication. Similarly, the anesthesia cardiopulmonary bypass team must be well qualified to manage a patient undergoing open heart surgery. The primary operator is usually supported by a scrubbed assistant, given that TLE procedures require the manipulation of multiple tools and pieces of equipment. Non-scrub personnel usually consist of 2 registered nurses who can provide equipment, assist in emergencies, and most importantly activate emergency protocols when needed.

## WHEN: INDICATIONS AND CONSIDERATIONS IN DECISION MAKING

The Heart Rhythm Society expert consensus document provides a comprehensive summary of TLE indications.<sup>1</sup> These have expanded over the years due to improvement in technology and safety profiles of the extraction procedures.

The strongest indications for TLE are CIED infections as evidenced by valvular endocarditis, lead endocarditis, sepsis, device pocket abscess, device erosion, chronic draining sinus, or even with occult gram-positive bacteremia in the absence of an alternative source. These infection-related indications carry a class I recommendation in the guidelines.

The second group of class I indications in the Heart Rhythm Society consensus document relates to venous access or endovascular complications. These include thromboembolism from thrombus on a lead or a lead fragment, bilateral subclavian or superior vena cava occlusion precluding implantation of a needed transvenous lead, planned stent deployment in a vein that already contains a transvenous lead, symptomatic superior vena cava stenosis or occlusion; and ipsilateral venous occlusion preventing venous access for addition of a required lead when there is a contraindication to use the contralateral side.

\* Corresponding author: Cleveland Clinic Foundation, 9500 Euclid Ave, J2-2, Cleveland, Ohio, 44195, United States.

E-mail address: [wilkoffb@ccf.org](mailto:wilkoffb@ccf.org) (B.L. Wilkoff).

The third group of class I indications pertains to extracting functional leads in patients with life-threatening arrhythmias secondary to retained leads, as well as leads that pose an immediate threat to the patient if left in place (due to their design or failure) and in patients with leads that interfere with the proper function of their CIED or the treatment of a malignancy.

Transvenous lead extractions are reasonable to perform (class II indications) for patients with persistent occult gram-negative bacteremia, those with lead or device-related severe chronic pain that is not medically manageable in the absence of an acceptable alternative, and in patients with ipsilateral venous occlusion preventing access for the addition of a required lead in the absence of a contraindication to use the contralateral side. In addition, abandoned functional leads which may interfere with the proper function of a CIED, leads which may pose a future threat to the patient, and abandoned functional leads are a class II indication. In patients requiring magnetic resonance imaging scans, TLE may be reasonable when imaging is an absolute necessity with no alternatives and in patients who are receiving a magnetic resonance imaging-compatible CIED system.

While the patient-specific risks of TLE vs lead abandonment need to be evaluated on a case-by-case basis, the decision making process can be challenging in patients with class II indications. In these scenarios, patient age, operator and facility experience, number and age of implanted leads and comorbid conditions, including prior sternotomy, have a strong impact on the decision. Due to the inherent potential for morbidity and mortality, TLE may not be warranted in patients with a poor prognosis and whenever the risks of intervention clearly outweigh the risks of lead abandonment.

Finally, TLEs are contraindicated (class III) for superficial or incisional infections without involvement of the device or the leads, and in patients requiring long-term suppressive antibiotics to treat chronic bacteremia from a source other than the CIED.

## HOW: PREPROCEDURAL CONSIDERATIONS, TOOLS AND TECHNIQUES

### Preprocedural Considerations

A detailed patient assessment and thorough procedural preparation is mandatory, including the complete CIED management history and patient comorbid conditions. This allows formulation of a long-term CIED management plan especially in pacemaker-dependent patients and those who were responders to cardiac resynchronization therapy. An understanding of the physical properties and condition of the implanted leads and their age is fundamental to developing the extraction and reimplantation strategy. In cases of device infection, a transesophageal echocardiogram provides baseline information. Very large vegetations or valvular endocarditis that qualifies for surgical therapy makes a surgical extraction strategically preferable. A previous sternotomy or thoracotomy changes the approach to rescue surgical interventions, which are much more challenging in an emergent setting. The location of an internal mammary vascular graft is important in these patients and might indicate a rescue lateral thoracotomy instead of a sternotomy.

In our current practice, all patients undergo the procedure under general anesthesia, with invasive hemodynamic monitoring and large bore central venous access. Patients who are pacemaker dependent receive a temporary pacer wire usually from a femoral venous access. Sterile preparation usually includes the device/extraction site, the contralateral site, the chest, and bilateral groins.

### Tools

Multiple tools might be required for a successful extraction procedure. The development of new tools for TLE has added to both the safety and efficacy of TLE procedures.

#### Locking Stylets

The ability of the operator to successfully extract a lead with traction is directly dependent on the lead structure and its tensile strength.<sup>6</sup> Locking stylets were developed with a primary goal to control the tensile properties of the lead body. They reinforce the tensile strength of the lead body, transmission of the traction force to the tip of the lead and therefore reduce the risk of elongation and fracture of the lead body, facilitating complete removal.<sup>7</sup>

The 2 most commonly used locking stylets are the Liberator<sup>®</sup> (Cook Medical, United States) and Lead Locking Device<sup>®</sup> (Spectranetics, United States). The former locks at the distal tip of the stylet while the latter grabs at multiple points along the body of the lead. The Bulldog<sup>™</sup> and One-Tie<sup>®</sup> tools (both Cook Medical, United States) are also useful adjuncts to provide control of the lead body.

In our practice, locking stylets facilitate complete lead removal in over 98% of lead extractions.

#### Mechanical Telescoping Sheaths

These sheaths are not powered and consist of an inner flexible sheath and an outer more rigid sheath constructed in Teflon, polypropylene, or steel. Telescoping sheaths are advanced along the body of the lead to allow disruption of fibrous tissue. Alternation of inner sheath advancement over the rail of the lead body with the outer sheath disrupts the fibrotic attachments of the lead to the other leads and vein. The sheaths are pushed along with alternating clockwise and counterclockwise movements and sufficient tension on the locking stylet. Sufficient traction on the locking stylet with appropriate positioning of the lead in the vascular space allows it to act as a rail for the advancing sheath and to avoid injury to the lead or the blood vessels.

In our practice, and in many published reports, telescoping sheaths have proved necessary to the success of TLEs.<sup>7-9</sup>

#### Powered Sheaths

These sheaths use various energy sources to facilitate disruption of encapsulating adhesions around the lead. The most commonly used is the Excimer Laser system (Spectranetics, United States), which employs a pulsed ultraviolet laser with a wave length of 308 nm. The sheath is advanced over the body of the lead and the pulsed laser is applied when fibrous adhesions interfere with sheath advancement. The laser pulses originate circumferentially from the sheath tip and allow destruction of fibrous adhesions by photochemical and photothermal reactions.<sup>10</sup> At the tip of the sheath, laser energy allows ablation of tissue at a depth of 50  $\mu$ m from the tip.

The introduction of laser sheaths represents a landmark in the field and these sheaths have become a cornerstone in TLEs. While successful extraction is possible without laser tools, these are the most versatile tool after the locking stylet. Published reports have demonstrated that they allow a more efficient complete lead removal compared with mechanical telescoping sheaths without increasing procedural risks.<sup>11-13</sup>

Also very versatile and particularly so for the disruption of fibrous or calcified tissue is the Evolution<sup>®</sup> and the Evolution<sup>®</sup> RL

mechanical dilator sheaths (Cook Medical, USA). These are hand powered sheaths with either a stainless steel spiral cut dissection tip (non RL) or a decagon-shaped tip (RL). In our experience, this sheath has been very useful as either a primary tool or for rescue when other tools had failed to achieve successful extraction,<sup>14</sup> especially with heavy calcifications at venous access sites.

#### *Femoral (Snaring) Workstations*

A snare approach using the Byrd femoral or internal jugular Workstation<sup>TM</sup> (Cook Medical, United States) is useful when the lead material is not accessible from the implant vein such as in cut or fractured leads; often as a rescue when extraction attempts from the implant vein fail. It can be used as the primary approach for extraction.

This workstation has a 16-F outer sheath with a one-way hemostasis valve which allows the introduction of a 12-F inner sheath and/or various snares. Available snares include Needle's Eye Snare, tip-deflecting wire, Dotter basket, Tulip, and Amplatz gooseneck snares. These snares could be used to grab onto and retrieve lead fragments and have allowed us in many cases to achieve a complete extraction of lead material. In our experience, snaring workstations are required in about 2% of all TLE cases.

#### **Technical Considerations**

In most cases, one incision may be sufficient for extractions via the implant vein but occasionally 2 separate incisions may be required with one over the vascular entry site and the second at the level of the pocket. For pockets with erosions, 1 incision is made at the level of the vascular access site and in general an elliptical incision is made to excise the eroded area. In CIED infections, all fibrous tissue encapsulating the device is usually debrided. In all TLEs, all leads and anchor sleeves are dissected free from adhesions at the level of the pocket and close to the vascular access site before the extraction attempts. When reimplantation is planned in the same procedure, we usually obtain venous access for reimplantation before any extraction attempts.

During lead extractions, the major principles to follow are dissection of fibrotic adherences as needed, control of the entire lead body, and countertraction at the tip of the lead. Locking stylets are used to control the conductor coil down to the tip of the lead and a suture tied at the insulation usually binds the lead's outer insulation and conductor together. We usually follow a step-wise approach to extractions. Sometimes mild traction with a standard stylet or traction on a locking stylet with insulation-bound suture is effective. If not sufficient, powered sheaths are used, primarily laser sheaths in our practice. Femoral workstations and snares are usually the rescue strategy for TLE being performed via the implant veins.

During advancement of powered or nonpowered sheaths over the body of the lead, sufficient traction on the lead is applied to allow it to serve as a rail for the advancing sheath. This is important to avoid vascular injury by the advancing sheath, especially at the level of venous turns (innominate-superior vena cava junction, superior vena cava-right atrium junction). Counter-pressure is exerted with the advancing sheath and is the simultaneous forward force, which allows disruption of fibrous adhesions. Once the sheath has been advanced to the interface between the lead tip and myocardium, counter-traction is applied and refers to holding the sheath static and pulling the lead into the sheath, pushing off the last bit of fibrosis, leaving it behind on the myocardium. This technique limits direct pulling on the heart, distorting the wall motion, and reduces the risk of myocardial perforation.

#### **WHERE: LOCATION MATTERS**

Catastrophic complications requiring major surgical or endovascular interventions rarely occur in large-volume centers with experienced operators. In our practice, these have occurred in about 1% of TLE cases but were still associated with about 35% 1-month mortality when they occurred.<sup>15</sup> Nonetheless, about two-thirds of patients with catastrophic complications were rescued with immediate surgical or endovascular interventions.

This finding emphasizes the Heart Rhythm Society and Heart Rhythm Association consensus document recommendations that TLE must be only performed at centers with fully accredited cardiac surgery and cardiac catheterization programs. The cardiothoracic surgeon must be physically on site and the surgical team readily available to intervene with a thoracotomy or sternotomy within 5 to 10 minutes of a superior vena cava tear. Otherwise, a fatal outcome is very likely to occur.

#### **CONCLUSIONS**

The field of TLEs has witnessed impressive developments in the past 2 decades. There is a growing need for lead and device extractions that parallel the growth in device implants. Infections remain the strongest indication for lead and device extractions. The extraction of noninfected leads remains controversial, but the risks of extraction need to be weighed against the risks of lead abandonment on a case-by-case basis. Major technological advances in the field have added safety and efficacy to the extraction procedures but these remain high-risk interventions that need to be performed by experienced operators in centers with appropriate surgical and endovascular back up. In such settings, the risk of catastrophic complications is low but immediate interventions are essential to avoid fatal outcomes.

#### **CONFLICTS OF INTEREST**

B.L. Wilkoff is a consultant to Medtronic Inc., St. Jude Medical Inc, Boston Scientific Inc., and Spectranetics.

#### **REFERENCES**

1. Wilkoff BL, Love CJ, Byrd CL, Bongiorno MG, Carrillo RG, Crossley 3rd GH, et al. Heart Rhythm Society expert consensus on facilities, training, indications, and patient management. *Heart Rhythm*. 2009;6:1085–104.
2. Wazni O, Epstein LM, Carrillo RG, Love C, Adler SW, Riggio DW, et al. Lead extraction in the contemporary setting: the LExIcon study: an observational retrospective study of consecutive laser lead extractions. *J Am Coll Cardiol*. 2010;55:579–86.
3. Deharo JC, Bongiorno MG, Rozkovec A, Bracke F, Defaye P, Fernandez-Lozano I, et al. Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. *Europace*. 2012;14:124–34.
4. Smith HJ, Fearnott NE, Byrd CL, Wilkoff BL, Love CJ, Sellers TD. Five-years experience with intravascular lead extraction. *U.S. Lead Extraction Database*. *Pacing Clin Electrophysiol*. 1994;17:2016–20.
5. Bracke FA, Meijer A, van Gelder B. Learning curve characteristics of pacing lead extraction with a laser sheath. *Pacing Clin Electrophysiol*. 1998;21:2309–13.
6. Smith MC, Love CJ. Extraction of transvenous pacing and ICD leads. *Pacing Clin Electrophysiol*. 2008;31:736–52.
7. Fearnott NE, Smith HJ, Goode LB, Byrd CL, Wilkoff BL, Sellers TD. Intravascular lead extraction using locking stylets, sheaths, and other techniques. *Pacing Clin Electrophysiol*. 1990;13:1864–70.
8. Byrd CL, Schwartz SJ, Hedin N. Intravascular techniques for extraction of permanent pacemaker leads. *J Thorac Cardiovasc Surg*. 1991;101:989–97.
9. Brodell GK, Castle LW, Maloney JD, Wilkoff BL. Chronic transvenous pacemaker lead removal using a unique, sequential transvenous system. *Am J Cardiol*. 1990;66:964–6.
10. Gijssels GH, van den Broecke DG, Sprangers RL, van Gemert MJ. Effect of force on ablation depth for a XeCl excimer laser beam delivered by an optical fiber in contact with arterial tissue under saline. *Lasers Surg Med*. 1992;12:576–84.

11. Wilkoff BL, Byrd CL, Love CJ, Hayes DL, Sellers TD, Schaerf R, et al. Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. *J Am Coll Cardiol*. 1999;33:1671–6.
12. Byrd CL, Wilkoff BL, Love CJ, Sellers TD, Reiser C. Clinical study of the laser sheath for lead extraction: the total experience in the United States. *Pacing Clin Electrophysiol*. 2002;25:804–8.
13. Epstein LM, Byrd CL, Wilkoff BL, Love CJ, Sellers TD, Hayes DL, et al. Initial experience with larger laser sheaths for the removal of transvenous pacemaker and implantable defibrillator leads. *Circulation*. 1999;100:516–25.
14. Hussein AA, Wilkoff BL, Martin DO, Karim S, Kanj M, Callahan T, et al. Initial experience with the Evolution mechanical dilator sheath for lead extraction: safety and efficacy. *Heart Rhythm*. 2010;7:870–3.
15. Brunner MP, Cronin EM, Wazni O, Baranowski B, Saliba WJ, Sabik JF, et al. Outcomes of patients requiring emergent surgical or endovascular intervention for catastrophic complications during transvenous lead extraction. *Heart Rhythm*. 2014;11:419–25.