Should They Stay or Should They Go? Current Controversies in Lead Extraction

Lead Extraction Is Preferred for Lead Revisions and System Upgrades

When Less Is More

Melanie Maytin, MD; Laurence M. Epstein, MD

Cardiovascular implantable electronic device (CIED) use has increased exponentially during the past decade, with >4.5 million active devices and >1 million new leads implanted annually. With expanded CIED use and indications for device therapy, observed complications have increased in parallel. The occurrence of more frequent device system revisions for complications, system upgrades, and/or lead malfunction and longer patient life expectancies have mandated a paradigm shift toward premeditated lead management strategies from implant to removal or replacement. Consequently, clinicians increasingly are faced with the challenging choice of extraction or abandonment of sterile, superfluous leads. The decision is difficult and highly controversial, with limited rigorous evidence and passionate arguments on either side.

Response by Henrikson on p 424

We contend that although decisions regarding extraction in these situations must be made on a case-by-case basis after considering multiple patient- and physician-related variables, lead extraction should be the preferred management strategy for lead revisions and system upgrades. Randomized, controlled trials of extraction versus abandonment are lacking, but the available evidence from observational, cohort, and registry studies supports the contention that the potential future benefit of lead extraction outweighs the risks of lead abandonment and that lead abandonment should be viewed as a "palliative procedure" that "just postpones the inevitable future lead extraction." In patients with venous occlusion undergoing the addition of a lead with plans to preserve the existing leads (eg, VVI to DDD implantable cardioverter defibrillator, or DDD implantable cardioverter defibrillator upgrade to BiV implantable cardioverter defibrillator), venoplasty, when possible, is the preferred approach. In many such patients, the venous obstruction is short in length and can often be easily passed with a wire and dilator. Our comments below relate to patients in whom lead abandonment is being considered.

Background

Lead extraction has undergone an explosive evolution since its inception as a rudimentary skill with limited technology and therapeutic options. Early techniques involved simple manual traction that frequently proved ineffective for chronically implanted leads and carried a high risk of myocardial avulsion, tamponade, and death. The significant morbidity and mortality associated with these early extraction techniques limited their application to life-threatening situations such as infection and sepsis. The past 30 years have witnessed significant advances in lead extraction technology, resulting in safer and more efficacious techniques and tools and thereby...
providing the skilled extractor with a well-equipped armamentarium. With the development of the discipline, we have witnessed a growth in the community of transvenous lead extraction (TLE) experts coincident with a marked decline in the incidence of procedure-related morbidity and mortality, with more recent registries at high-volume centers reporting high success rates with exceedingly low complication rates (Figure 1). Accordingly, this has resulted in expanded indications for TLE (Table 1), although noninfectious indications for TLE remain a controversial topic.

**Risks of TLE**

With the introduction of locking stylets and successful intravascular countertraction techniques, TLE has grown from a rare specialty reserved for life-threatening lead conditions to an increasingly practiced and often used tool with continually expanding indications. Simple traction was much less effective for chronically implanted electrodes and was associated with a significant risk of myocardial avulsion. The creation of the locking stylet and telescoping sheath represented significant advances in TLE, allowing for critical opposing forces of traction and countertraction and yielding a higher degree of success and safety. The introduction of the laser sheath improved extraction success rates dramatically. In PLEXES, 301 patients with 465 pacing electrodes were randomized to nonlaser versus laser-assisted extraction. Extraction efficacy improved from 64% with traditional extraction techniques to 94% with laser-assisted extraction, although significant crossover between groups occurred.

Complication rates with TLE directly parallel operator experience. Major and minor complications are reduced by
<table>
<thead>
<tr>
<th>Indication</th>
<th>Class I</th>
<th>Class IIa</th>
<th>Class IIb</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infection</strong></td>
<td>Procedure should be performed</td>
<td>Reasonable to perform procedure</td>
<td>Procedure may be considered</td>
<td>Procedure should not be performed</td>
</tr>
<tr>
<td>1. Definite CIED infection, eg, valvular endocarditis, DRE, or sepsis (LOE: B)</td>
<td>1. Persistent occult Gram-negative bacteremia (LOE: B)</td>
<td>1. Superficial or incisional infection without involvement of device/leads (LOE: C)</td>
<td>1. Superficial or incisional infection without involvement of device/leads (LOE: C)</td>
<td></td>
</tr>
<tr>
<td>2. CIED pocket infection, eg, abscess, erosion, or chronic draining sinus (LOE: B)</td>
<td>1. Ipsilateral venous occlusion precluding ipsilateral implant of additional lead without contraindication to contralateral implant (LOE: C)</td>
<td>2. Chronic bacteremia due to a source other than CIED when long-term suppressive antibiotics are required (LOE: C)</td>
<td></td>
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</tr>
<tr>
<td>3. Valvular endocarditis without definite lead and/or device involvement (LOE: B)</td>
<td>1. Ipsilateral venous occlusion precluding ipsilateral implant of additional lead without contraindication to contralateral implant (LOE: C)</td>
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<td>4. Occult Gram-positive bacteremia (LOE: B)</td>
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<tr>
<td><strong>Thrombosis or venous stenosis</strong></td>
<td>1. Clinically significant TE events associated with thrombus on lead or fragment (LOE: C)</td>
<td>1. Leads with potential interference with CIED function (LOE: C)</td>
<td>1. Redundant leads with &lt;1 year of life expectancy (LOE: C)</td>
<td></td>
</tr>
<tr>
<td>2. Bilateral SCV or SVC occlusion precluding implant of needed TV lead (LOE: C)</td>
<td>2. Leads, due to design or failure, may pose immediate threat if left in place (LOE: C)</td>
<td>2. Known anomalous lead placement (SCA, Ao, pleura, etc) or through a systemic atrium or ventricle* (LOE: C)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Planned stent deployment in vein with TV lead already to avoid entrapment (LOE: C)</td>
<td>3. Abandoned leads (LOE: C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Symptomatic SVC stenosis/occlusion (LOE: C)</td>
<td>4. Need for MRI without alternative (LOE: C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Ipsilateral venous occlusion precluding implant of additional lead when contralateral implant contraindicated (AVF, shunt or vascular access port, mastectomy) (LOE: C)</td>
<td>5. Need for MRI conditional CIED system (LOE: C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Functional leads</strong></td>
<td>1. Life-threatening arrhythmias due to retained leads (LOE: B)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Leads, due to design or failure, may pose immediate threat if left in place (LOE: B)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Redundant leads with &lt;1 year of life expectancy (LOE: C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Can be considered w/surgical backup</td>
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50% with increased operator experience from 20 to 300 cases performed. Large-scale, multicenter, randomized trials have confirmed the effect of experience on outcomes. Likewise, observational registries of experienced, high-volume extractionists have consistently demonstrated even higher success rates (99%) with exceedingly low major complication (1.0%) and mortality (0.3%).

Similar outcomes have been reported with TLE for lead revision or device system upgrade. The safety and efficacy of telescoping sheaths for lead extraction in the setting of subclavian vein thrombosis were first reported by Le Franc et al. They described 2 patients with defibrillator systems and thrombosis of the implant vein who required the implantation of new pacing and defibrillator electrodes. Recanalization of the implant vein was achieved without complication through TLE with the use of locking stylets and telescoping sheaths. Bracke et al. evaluated 20 patients undergoing TLE for upgrade from an abdominal to a pectoral system or from a single- to a dual-chamber device. Thirty leads were extracted with 96.7% complete procedural success and 100% clinical success. No deaths or procedure-related complications occurred. The risk of extraction is similar to other well-accepted cardiovascular procedures. In a recent publication, catheter ablation for atrial fibrillation, a completely elective procedure, was associated with a major complication rate of 4.5% and a mortality rate of 0.15%.

Decisions regarding extraction must be made on a case-by-case basis after considering multiple patient- and physician-related variables. An invasive approach, with the potential for significant morbidity and mortality, may not be warranted in patients with a poor prognosis or for whom the risks of intervention clearly outweigh the benefits. In addition, lead extraction should be performed by those experienced in the procedure and with the necessary tools available to attain complete success and in a setting prepared and committed to the complete and safe performance of the procedure.

### Risks of Abandoned Leads

As aforementioned, clinicians are frequently confronted with the challenging decision of superfluous lead management. Rigorous evidence from large-scale, randomized trials is lacking, and the available registries and cohort studies have been published in the form of observational registries. Given these limitations, the approach to lead management should be individualized, and the decision to abandon leads should be made on a case-by-case basis after careful consideration of the patient's medical history, current symptoms, and the potential impact of lead management on their quality of life. The use of specialized equipment, such as locking stylets and telescoping sheaths, can facilitate the safe and effective extraction of leads, minimizing the risk of complications associated with incomplete removal.

### Table 1. Continued

<table>
<thead>
<tr>
<th>Indication</th>
<th>Class I</th>
<th>Class Ia</th>
<th>Class IIb</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonfunctional leads</td>
<td>3. Leads that interfere with CIED function (LOE: B)</td>
<td>1. Leads, due to design or failure, with potential threat if left in place (LOE: C)</td>
<td>1. At time of indicated CIED procedure without contraindication to TLE (LOE: C)</td>
<td>1. Redundant leads with &lt;1 year life expectancy (LOE: C)</td>
</tr>
<tr>
<td></td>
<td>4. Leads that interfere with treatment of malignancy (radiation, surgery) (LOE: C)</td>
<td>2. CIED implant would yield &gt;4 leads on 1 side or &gt;5 leads through SVC (LOE: C)</td>
<td>2. Need for MRI conditional CIED system (LOE: C)</td>
<td>2. Known anomalous lead placement (SCA, Ao, pleura, etc) or through a systemic atrium or ventricle* (LOE: C)</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>1. Severe chronic pain at device or lead insertion site with significant discomfort not manageable by medical or surgical techniques and without acceptable alternative (LOE: C)</td>
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<td></td>
</tr>
</tbody>
</table>

Adapted from 2009 Heart Rhythm Society Expert Consensus on Transvenous Lead Extraction. DRE indicates device-related endocarditis; TE, thromboembolic; SCV, subclavian vein; SCA, subclavian artery; Ao, aorta; TV, transvenous; LOE, level of evidence; and MRI, magnetic resonance imaging. Other abbreviations are as defined in text.

*Can be considered with surgical backup.

<ref>Le Franc et al. They described 2 patients with defibrillator systems and thrombosis of the implant vein who required the implantation of new pacing and defibrillator electrodes. Recanalization of the implant vein was achieved without complication through TLE with the use of locking stylets and telescoping sheaths. Bracke et al. evaluated 20 patients undergoing TLE for upgrade from an abdominal to a pectoral system or from a single- to a dual-chamber device. Thirty leads were extracted with 96.7% complete procedural success and 100% clinical success. No deaths or procedure-related complications occurred. The risk of extraction is similar to other well-accepted cardiovascular procedures. In a recent publication, catheter ablation for atrial fibrillation, a completely elective procedure, was associated with a major complication rate of 4.5% and a mortality rate of 0.15%.</ref>
studies are often underpowered, generating more confusion than answers (Table 2). Recently, the preliminary results of the REPLACE registry have been reported. The prospective, observational study of 713 patients at 62 centers undergoing device generator change with planned lead addition or revision documented a 15.3% major complication rate with a 1.1% mortality rate at 6 months. In comparison, a 4.2% major complication rate and a 0.6% mortality rate were observed in the same registry in patients undergoing generator change without lead addition or revision. These results demonstrate an increased complication rate with device system upgrade with lead abandonment. The risks of system upgrade versus lead abandonment cannot be interpreted in isolation, and it is plausible that both factors contribute independent risks.

Preserving Venous Access

The controversy surrounding the abandonment or extraction of superfluous leads frequently centers incorrectly on the argument of maintaining venous patency. In fact, the primary benefit of removing rather than replacing a lead is preserving venous access, that is, the continued use of the implant vein to preserve contralateral or alternative venous access for future use. Although this distinction may appear to be a matter of semantics, the difference is paramount to the rationale in favor of extraction. As the number of younger individuals receiving CIED and life expectancies increase, the device-years per person will also increase along with the attendant potential risks of infection, lead malfunction, and the need for system upgrade—augmenting the likelihood of the eventual need for implantation via the contralateral venous system. Consequently, physicians performing implants are required to evaluate and implement the best lead management strategy for each individual, not only for the immediate indication in favor of extraction. As the number of younger individuals receiving CIED and life expectancies increase, the device-years per person will also increase along with the attendant potential risks of infection, lead malfunction, and the need for system upgrade—augmenting the likelihood of the eventual need for implantation via the contralateral venous system. Consequently, physicians performing implants are required to evaluate and implement the best lead management strategy for each individual, not only for the immediate procedure but also for future procedures, hence, the imperative to preserve venous access and not venous patency.

Within 4 to 5 days of implant, near-complete encapsulation of intravascular pacing leads with a fibrin sheath has been observed in addition to extensive thrombosis. Younger patients develop more vigorous fibrotic responses and more frequently develop progressive calcification. Several clinical studies have similarly demonstrated the common occurrence of venous stenoses and occlusion after endovascular pacing and defibrillator lead placement; however, the venous pathology is frequently asymptomatic. Similarly, asymptomatic venous thrombosis is commonly observed in patients with abandoned leads, again with little clinical significance. In contrast, little is known about the effects of lead extraction on venous patency, and attempts to study this have been confounded by ipsilateral reimplantation, making it impossible to isolate the effects of extraction.

CIED upgrade or lead revision can be and certainly has been accomplished despite venous occlusion. The solution frequently involves venoplasty, unconventional ipsilateral venous entry, or contralateral venous access with tunneling or complete abandonment of the original system. Each approach is fraught with flaws. Tunneled leads can be painful both at implant and chronically and can be apt to erode. Moreover, contralateral implantation should not be considered a reasonable alternative to lead extraction. It is our opinion that preservation of venous access is essential to responsible lead management (Figure 2A–C). Although venoplasty and unconventional ipsilateral venous access avoid the unnecessary use of the contralateral venous system, both result in increased lead burden, have uncertain effects on lead survival, and carry potential present and future risks. Furthermore, in some cases, venoplasty of the occluded vein may not be possible. In this situation, extraction is the only option to avoid contralateral lead placement.

Infection

Coincident with the upsurge in CIED use, there has been a disproportionate rise in CIED infection (0.8 to 19.9% of CIED patients). Between 2003 and 2006, the number of CIED implants increased by 12% while the number of CIED infections rose by 57%. Several risk factors for CIED infection have been identified, including the presence of >2 pacing leads and cardiac resynchronization therapy. Data regarding the risk of CIED infection in patients with abandoned leads have failed to demonstrate an increased risk of device-related infection but are limited by small sample size and abbreviated follow-up periods. In young patients with abandoned leads, Suga et al noted a significant increase in infection and asymptomatic venous occlusion in patients with multiple leads, although the end point was driven largely by venous pathology. Similar to the experience reported by Silvetti and Drago, all patients with CIED infection underwent complete device system removal. In addition, 44% of patients with asymptomatic venous occlusion required TLE for ipsilateral venous access, whereas the remaining 56% underwent contralateral implantation for lead revision.

Untreated device-related infection is associated with mortality rates as high as 66%. Mortality is reduced to 18% in patients treated with extraction and antibiotics, and eradication of CIED infection requires complete removal of the entire system. The occurrence of device-related infection in the setting of previously abandoned leads increases both the difficulty and risk of the extraction procedure owing to the longer implant duration and lead-lead binding. Although rigorous data regarding CIED infection risk and lead abandonment are lacking, the risk of device-related infection with increasing lead burden and the associated mortality with incomplete treatment mandating TLE require careful
Table 2. Risks of Lead Abandonment

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Groups Studied</th>
<th>No. of Patients</th>
<th>No. of Leads</th>
<th>Follow-Up</th>
<th>Primary End Point</th>
<th>Comparative Results: Abandon vs Remove</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wollman et al&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Retrospective cohort</td>
<td>Add HV vs replace HV</td>
<td>33 add vs 53 replace*</td>
<td>2.6 ±0.8 vs 1.4±0.7†</td>
<td>9.3±2.7 vs 6.7±3.8 y†</td>
<td>Event-free survival</td>
<td>⇣ (Add HV decision due to failed TLE attempt in 70%)</td>
</tr>
<tr>
<td>Wollman et al&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Prospective observational</td>
<td>Add P/S</td>
<td>151</td>
<td>2.3</td>
<td>3.6±2.3 y</td>
<td>Event-free survival</td>
<td>N/A (Conclude removal best given 28.5% failure rate of new P/S requiring repeat procedure)</td>
</tr>
<tr>
<td>Suga et al&lt;sup&gt;47&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Patients with ≥1 abandoned lead</td>
<td>433</td>
<td>2.8</td>
<td>3.1±2.7 y</td>
<td>Event-free survival</td>
<td>N/A (No. abandoned leads higher in those with complications)†</td>
</tr>
<tr>
<td>Furman et al&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Patients with ≥1 abandoned lead</td>
<td>152</td>
<td>NA</td>
<td>4 y</td>
<td>Event-free survival</td>
<td>N/A (Fatal embolization of cut lead)</td>
</tr>
<tr>
<td>Rettig et al&lt;sup&gt;49&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Patients with ≥1 abandoned lead</td>
<td>25</td>
<td>NA</td>
<td>1.8 y</td>
<td>Event-free survival</td>
<td>N/A (11% DRE and 28% new contralateral implant but study underpowered)</td>
</tr>
<tr>
<td>Siketti and Drago&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Young patients with abandoned leads</td>
<td>18</td>
<td>1.1±0.3 (abandoned)</td>
<td>4 y</td>
<td>Event-free survival</td>
<td>N/A (No sensing malfunction, venous thrombosis, or change in DFT)</td>
</tr>
<tr>
<td>Glikson et al&lt;sup&gt;34&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Abandoned HV or P/S</td>
<td>78</td>
<td>1.5 (abandoned)</td>
<td>3.1±2.0 y</td>
<td>Event-free survival</td>
<td>N/A</td>
</tr>
<tr>
<td>deCock et al&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Prospective observational</td>
<td>Patients with ≥3 leads vs age-matched dual-chamber controls</td>
<td>48</td>
<td>3.2 vs 2.0</td>
<td>7.4±2.0 y</td>
<td>Clinical venous occlusion, RHF, AF, hospitalizations, and mortality</td>
<td>N/A</td>
</tr>
<tr>
<td>Bohm et al&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Patients with ≥1 abandoned lead (epi/endocardial)</td>
<td>60</td>
<td>1.0 (abandoned)</td>
<td>NA</td>
<td>Event-free survival</td>
<td>N/A (20% event rate driven by migration of cut leads)</td>
</tr>
<tr>
<td>Sweeney et al&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Prospective observational</td>
<td>Device upgrades: add vs replace</td>
<td>58</td>
<td>NA</td>
<td>1.1±1.1 y</td>
<td>Event-free survival</td>
<td>⇣</td>
</tr>
<tr>
<td>Parry et al&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Retrospective observational</td>
<td>Patients with ≥1 abandoned lead (infectious vs non)</td>
<td>119</td>
<td>NA</td>
<td>NA</td>
<td>Event-free survival</td>
<td>N/A (42% vs 3% rate of major complications infectious vs non)</td>
</tr>
</tbody>
</table>

<sup>HV indicates high-voltage defibrillation lead; ⇣, no significant difference between extraction and abandonment; P/S, pace-sense lead; RHF, right heart failure; AF, atrial fibrillation; DFT, defibrillation threshold; DRE, device-related endocarditis; NA, not available; N/A, not applicable, refers to studies in which comparative analysis is not possible.

*Mean lead implant duration 7.4±2.9 y in the add-HV group vs 4.1±3.4 y in the replace group (P<0.05).

†P<0.05.
consideration of an individual’s future risk in the management decision regarding superfluous leads.

**Lead-Lead Interaction**

Lead-lead interaction between superfluous and active leads can result in the oversensing of specious signals and inappropriate inhibition of pacing with potential serious sequelae (Figure 3, A–C).\(^\text{72–74}\) Opponents of nonfunctional lead removal argue that the risk of electrical interference is avoided by eliminating contact between the active and abandoned leads and that this potential risk is not supported by available data.\(^\text{34,45,46}\) In fact, physical lead-lead interaction is only 1 mechanism of spurious signal generation. False signals can be created by the production of a galvanic current between 2 electrodes of different composition without physical contact between the active and abandoned electrodes.\(^\text{72,74}\) The lack of supportive data is a reflection of underpowered studies unable to detect a significant difference. Wollman et al\(^\text{45}\) observed a 2-fold increase in oversensing with inappropriate shocks in patients with an added as opposed to a replaced high-voltage lead. In a prior observational study of added pace-sense leads, Wollman et al\(^\text{46}\) found a 28.5% failure rate of the new pace-sense lead, with half of the failures attributed to oversensing. Because neither study clearly delineated the mechanism of oversensing (ie, lead fracture, T/P-wave oversensing, or lead-lead interaction), the exact incidence of lead-lead interaction is unknown. Of the patients with abandoned lead complications, 62% required reoperation for the addition of another pacemaker or high-voltage lead.

**Lead Burden and the Central Venous System**

Endovascular lead-induced venous stenosis and thrombosis are not limited to the implant veins. Although infrequent, multiple reports of superior vena cava (SVC) syndrome exist in the literature.\(^\text{75–82}\) Risk factors for the development of SVC syndrome include device infection, polyurethane leads, thrombophilia, and multiple leads.\(^\text{80–82}\) As a result, the 2009 Heart Rhythm Society Expert Consensus on Lead Extraction\(^\text{23}\) has assigned a class IIa indication to lead extraction for a CIED procedure that would result in \(>4\) leads on 1 side or 5 leads through the SVC. Symptomatic SVC syndrome requires an invasive approach with surgical or percutaneous venoplasty, frequently in association with lead extraction.\(^\text{77}\)

**Lead Burden and the Tricuspid Valve**

After endovascular lead implantation, fibrous adhesion of electrodes to the tricuspid valve in pathological specimens\(^\text{54,55}\) and regurgitant valve disease of varying clinical significance are observed commonly.\(^\text{83,84}\) The incremental risk of lead burden on tricuspid regurgitation has not been defined, although small, observational series of patients with abandoned leads have not demonstrated an increased risk of clinically significant regurgitant disease.\(^\text{57,40}\) More recently, isolated cases of severe tricuspid stenosis from excessive lead burden have been reported in patients with 4 and 5 endovascular pacing leads.\(^\text{85,86}\)

**Risk of Future Lead Extraction**

Perhaps the most important and certainly the most commonly overlooked risk of lead abandonment is the potential need for future lead extraction. As emphasized previously, the increasing incidence of CIED complications and longer patient life expectancies make the incremental likelihood of TLE in an individual lifetime significant. Moreover, TLE failure and complications are directly related to both lead implant duration and lead burden.\(^\text{5,23,37,39,87–89}\) In a prospective registry of \(>3500\) leads extracted at 266 centers, Byrd and colleagues\(^\text{37}\) noted a 2-fold increase in the risk of extraction failure with every 3 years of implant duration. Roux et al\(^\text{49}\) found a similar association between unsuccessful TLE and lead implant.

**Figure 2.** A–C, Bilateral subclavian vein and SVC occlusion. Twenty-year-old patient with complete heart block and numerous prior endovascular and epicardial pacing systems with complete loss of central venous access. A, Left upper-extremity venograph demonstrating severe stenosis of the left subclavian vein with extensive collateralization. B, Right upper-extremity venograph showing severe right subclavian stenosis and collateralization. C, Contrast injection in the right atrium, revealing complete occlusion of the SVC.
duration in addition to a higher incidence of complications in patients requiring bilateral extraction. More recently, 212 consecutive patients undergoing TLE were observed to have a 3.5-fold increase in TLE complications per additional right ventricular lead extracted and a 50% increase in the need for powered sheath assistance per year increase in implant duration of the oldest lead. These data are consistent with our own observations that lead-to-lead binding, particularly in the setting of multiple endovascular leads, is frequently more technically challenging than vessel-to-lead fibrosis. Although quantification of this potential risk is difficult, it cannot be ignored.
Risk Versus Risk

The assertion that lead extraction should be the preferred management strategy for lead revisions and system upgrades mandates a comparison of the risks of extraction with the risks of lead abandonment (Figure 4). The risks of TLE are concrete, with large-scale, randomized trials and registries defining the success and complication rates, although this risk must be individualized on a case-by-case basis. The consideration of patient and lead characteristics and, perhaps most important, operator experience, must be factored into the risk assessment of extraction. Specific attention to the number of leads, implant duration, defibrillator versus pacing electrodes, and patient age must enter into the risk assessment process. In contrast, the risks of lead abandonment and, by extension, the potential risk of future TLE, are difficult to quantify. The majority of studies of abandoned leads are small registries or observational reports with a finite period of follow-up. In fact, most of these studies have follow-up times of <5 years. In contrast, in many of the extraction studies, the average implant duration was 6 to 7 years with leads as old as 32 years. Observed complications often do not reach statistical significance, not surprisingly owing to the short duration of follow-up and the small number of events that are frequently ascribed away or deemed unimportant. Moreover, most extraction experts would agree that the irrefutable risks of pacemaker and/or defibrillator lead abandonment are related to the potential need for future extraction—a risk that is essentially ignored despite the frequent need for transvenous or surgical extraction in the patients with complications of abandoned leads (29% to 100% of abandoned leads with complications).27,46,47,50,51 There is not only a potential need for future extraction but also an increased risk of TLE, given the increase in lead burden, lead-lead binding, and implant duration in the time after the initial lead replacement. Thus, lead decisions at the time of system revision or upgrade must weigh the present risks of extraction with the future risks of both lead abandonment and potential lead extraction.

Risk-risk analysis must also incorporate the indication for extraction. Device system revision or upgrade in the setting of bilateral subclavian vein thrombosis, SVC occlusion, or ipsilateral venous occlusion preventing ipsilateral implantation with contraindications to contralateral implant (eg, arteriovenous fistula, vascular access port, mastectomy, etc) are defined as class I indications for TLE.33 Class IIa indications include the need for lead implantation with ipsilateral venous occlusion preventing ipsilateral implantation without contraindications to contralateral implant or lead implantation that would result in >4 leads in the implant vein or >5 leads through the SVC. Despite the compelling nature of these TLE indications, careful consideration of patient and lead characteristics as well as operator experience is integral to risk evaluation and the decision process. Superfluous leads with the potential for CIED interference and abandoned or redundant leads represent a class IIb indication for extraction and are more controversial, requiring even more scrutiny of the potential complications.

Decisions regarding lead extraction must be made on an individual case-by-case basis, integrating various patient and lead characteristics and operator-related variables. TLE with the potential for significant morbidity and mortality may not be warranted in patients with a poor prognosis or for whom the risks of intervention clearly outweigh the risks of lead abandonment. In addition, those inexperienced in the procedure should not perform lead extractions, nor should those without the necessary tools available to attain complete success or in a setting not prepared and committed to the complete and safe performance of the procedure.23

Disclosures

Dr Maytin has no conflicts of interest to disclose. Dr Epstein has received research grants from and is a consultant for Boston Scientific, Medtronic, Spectranetics, and St. Jude Medical and has equity in and served as a board member for Carrot Medical.

References


**Key Words:** lead extraction ■ lead management ■ internal cardioverter-defibrillator ■ pacemaker

**Response to Melanie Maytin, MD, and Laurence M. Epstein, MD**

*Charles A. Henrikson, MD*

I agree with my opponents that the decision to remove extraneous leads at the time of pocket manipulation is a matter of balancing the risks of lead extraction versus the risks of lead abandonment. As detailed in my review and that of my opponents, the risks of lead extraction are well known and are likely decreasing as technology and techniques mature. However, the risks of lead abandonment are largely theoretical in nature. The few data available are mostly short to medium term in follow-up and often report complications that are of unclear significance, such as asymptomatic venous occlusion. Thus, the balance of the risks turns out to be a balance of known risks versus theoretical risks. I certainly concede that there will probably be patients of mine who will need extractions in the future from whom I could have extracted years ago at the time of system revision but chose not to. These patients will have older leads and require more difficult extractions. However, for each of these patients, there will likely be dozens, if not hundreds, of my patients with abandoned leads who will never require extraction. In addition, the risks of extraction may continue to decline in the future, making future extractions more attractive and potentially safer than current extractions. All said, given the paucity of data, I believe that a conservative approach to complex lead management will result in better outcomes for patients, shielding them from known risks today while exposing them only to theoretical risks in the future.
Lead Extraction Is Preferred for Lead Revisions and System Upgrades: When Less Is More
Melanie Maytin, Charles A. Henrikson and Laurence M. Epstein

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