Lead Extraction Considerations for the Referring Cardiologist

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Abstract: The population of patients with cardiac implantable electronic devices (CIEDs) continues to grow due to increasing indications in an aging population and breakthroughs in both the medical and the surgical care of patients with heart disease. As a result, there has been a growing need for device and lead extractions due to the growing population of patients with CIEDs and the subsequent need for system upgrades or revisions because of complications, infections, and lead advisory alerts.

Key Words: cardiac devices, lead extraction

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The population of patients with cardiac implantable electronic devices (CIEDs) continues to grow due to increasing indications in an aging population and breakthroughs in both the medical and surgical care of patients with heart disease.[1] In parallel, an increasing number of patients and physicians are dealing with complications and challenges inherent to device and lead management. Transvenous lead extraction (TLE) is a particularly important aspect of lead management with challenges related to the complexity of these interventions, but also to clinical decision making and indications. In clinical practice, there has been a growing need for device and lead extraction due to the growing population of patients with CIEDs and the subsequent need for system upgrades or revisions because of complications, infections,[2,3] and lead advisory alerts.

In this condensed review, we will discuss aspects of TLE with a special focus on considerations that would be relevant to the referring cardiologist.

LEAD BINDING AND FIBROSIS

The challenges and risks of TLE procedures are primarily related to lead adherence and binding, which preclude lead removal by simple manual traction. Fibrosis and binding (Fig. 1) develop between the leads, the vessels, and the heart.[4] After implantation, leads are fully encapsulated with a fibrous sheath in 4–5 days.[4,5] This progresses over time to extensive fibrosis and involves ongoing inflammation and calcification.[6] The most common binding sites are at the point of venous entry, the superior vena cava (SVC), and the lead–endocardium interface. In many cases, tissue fibrosis and calcification of the binding sites make these anchor points stronger than the surrounding tissues. Manual traction alone for lead removal would, therefore, result in tissue avulsion or perforation. As such, lysis of adhesions with various tools is a cornerstone of TLE procedures. Beyond dwell time and hardware burden, determinants of extensive binding and scarring remain unknown, but it has been suggested that younger patients tend to develop more vigorous fibrotic responses and calcification.[7] Lead-to-lead binding is another factor, which adds complexity to TLE, and is perhaps more challenging to overcome than lead-to-vessel binding. In fact, both TLE failure and complication rates have been directly related to lead dwell time and lead burden.[1,8–13]

LEAD MANAGEMENT PLANNING

To avoid device and lead-related morbidity and complex extraction situations, a well-conceived lead management plan is essential. This includes a careful assessment of the CIED indication, measures to avoid infection at the time of device implant, a proper selection of device and leads, assessment of risks of extraction versus abandonment of leads at the time of system revision or upgrade, and timely recognition and management of device-related complications such as infection, venous occlusion, or device and lead malfunction.

The decision-making process in CIED implantation should follow a thorough evaluation of the indication and critical assessment for the risks and benefits accounting for patient characteristics and comorbid conditions. At the time of implant, the lower infection risk and lower risk of extraction complications and failures with simple CIED systems should be weighed against the higher infection risk and challenging extractions of complex CIED systems. Similarly, the need for device upgrade should be assessed with extreme caution because of an elevated risk of infection with such interventions.[14]

The extraction of defibrillator leads is more complex than that of pacemaker leads owing to their larger size, more complex design, and the number of components. In the absence of indications for pacing or the anticipated need for antitachycardia pacing or resynchronization therapy, a subcutaneous defibrillator should be considered whenever possible to avoid implantation of intravascular hardware. Defibrillator coils are particularly associated with more extensive fibrosis and binding, especially in the SVC where tears at the time of extraction carry a significant mortality risk.[15–17] In fact, the extraction of dual coil defibrillator leads is more complex and carries with it more risks than extraction of single coil leads.[17] It is, therefore, important to use single

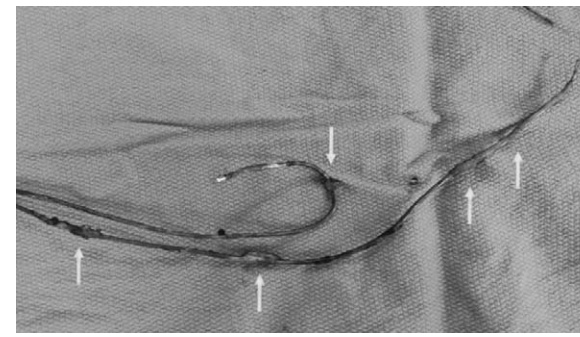

FIGURE 1. Fibrosis on extracted leads (arrows).

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coil leads whenever possible, especially in young adults who would ultimately require multiple generator changes or system revisions in their lifetime. Special consideration should be given to battery longevity, typically shorter for more complex systems, which implies the need for pocket interventions for generator changes and their associated risks of infection. Similarly, programming to minimize device and battery use is important to prolong the battery's life.

A careful preoperative assessment at the time of CIED implant should identify and treat any potential source for device infection. Particular attention should be given to treat any ongoing infection and work-up any fever occurring within the preceding 24 hours.[18] It is also important to treat chronic skin conditions and avoid any indwelling catheters or tubes at the time of implant. Antimicrobial therapy for nasal colonization with staphylococcal species is considered at some centers with data to support its use to prevent surgical site infection in the general population of patients admitted for surgical interventions.[19] However, data are still lacking in CIED implants.

Perioperatively, standard measures for reducing surgical site infection should be followed, including the use of antiseptic solutions for skin preparation[20] and the preoperative use of antibiotics,[18,21–24] typically a single dose of intravenous antibiotic with staphylococcal coverage within 60–90 minutes before skin incision. The choice of antibiotic agent varies depending on the local rates of methicillin resistance. Recently, an antibiotic-coated mesh envelope was introduced and found to prevent biofilm formation on implanted devices in animal studies and to reduce the risk of CIED infections in observational studies in high-risk patients.[25–28] A bioabsorbable form of this envelope is currently being evaluated in a large randomized trial (WRAP-IT: Worldwide Randomized Antibiotic Envelope Infection Prevention trial, NCT02277990).

During the implant procedures, in addition to following standard implantation techniques and skin closure, it is important to ensure hemostasis because of an increased risk of infection with hematoma formation,[14,24,29] especially with subsequent pocket intervention for hematoma evacuation. From an anticoagulation standpoint and as indicated, uninterrupted Coumadin carries a lower risk of significant hematoma compared with heparin bridging.[30] The clinical experience with novel anticoagulants (direct thrombin inhibitors, anti-XA) is still limited, but these are typically stopped 48 hours before device implant procedures whenever feasible. Otherwise, many operators have been performing these procedures with uninterrupted anticoagulation with novel agents when their continuation is absolutely necessary.

At the time of system revisions or an upgrade, many operators abandon functional or dysfunctional leads, but the practice of lead abandonment remains controversial.[1,31–34] Although it avoids the acute risk of lead extraction, such strategy ultimately leads to a higher burden of leads that may result in vascular complications, a lead–lead interaction, complex intravascular and intracardiac adhesions, valvular regurgitation, and possibly a higher risk of infection.[35] It is important to note that magnetic resonance imaging (MRI) scans can be routinely done in patients with MR conditional systems and with relatively low risk in normally functioning non-MR conditional systems, but are precluded in patients with abandoned leads. In our practice, as it is the case in many centers with experience in lead extractions, we prefer lead extraction over abandonment whenever possible, accounting for a patient's age and comorbidities. Referrals to centers with expertise in lead management, especially extractions, should be considered whenever physicians are facing the clinical dilemma of lead extraction versus abandonment.

INFRASTRUCTURE FOR LEAD EXTRACTIONS AND PREPROCEDURAL PLANNING

Standards from the Heart Rhythm Society (HRS)[1] and European Heart Rhythm Association (EHRA)[36] have been established for TLE programs and operators to optimize outcomes and avoid serious complications. The primary operator is usually a cardiac electrophysiologist and/or a cardiac surgeon, who is well trained in TLEs and all aspects of lead and device management. Published data suggest that TLE procedural success improves dramatically with an operator's experience.[10,37] A cardiac surgeon must be available for immediate intervention such as should open heart surgery be required to manage a major complication. Catastrophic complications, which require major surgical or endovascular interventions, are not common in large volume centers with experienced operators. In our practice, these have occurred in about 1% of TLE cases, but still carried about a 35% mortality risk at 1 month.[38] Nonetheless, about two-thirds of patients with catastrophic complications were rescued with immediate surgical or endovascular interventions. This emphasizes the HRS and EHRA recommendations that TLE must be only performed at centers with fully accredited cardiac surgery and cardiac catheterization programs.

Before the extraction procedure, both the referring cardiologist and the operating physician should conduct a detailed assessment and thorough procedural preparation. This would include an understanding of comorbid conditions and CIED management history to formulate a long-term CIED management plan, especially in pacemaker-dependent patients and in those who were responders to cardiac resynchronization therapy. Preprocedural planning also involves assessment to understand the physical properties and condition of the existing leads and their age, which would facilitate formulating both the extraction and reimplantation strategies.

INDICATIONS FOR LEAD EXTRACTION

Infection

CIED infections remain the strongest and most common indication for TLE. CIED infections are typically evidenced by concomitant valvular endocarditis, lead endocarditis, sepsis, a device pocket abscess, device erosion, a chronic draining sinus, or even the presence of occult gram-positive bacteremia in the absence of an alternative source. These infection-related indications carry a class I recommendation in the clinical practice guidelines.[1]

In parallel to increasing rates of CIED implants, there has been an increase in CIED infections at a rate that seems to have followed a faster disproportionate trend in the rate of increase of newly implanted devices.[2,39] This may reflect the growing population and changing demographics of patients with CIEDs.[40] In fact, CIED implant recipients are increasingly older with multiple coexisting comorbid conditions.[41–43] Also, the rates of implants of devices, which are at higher risk of infection due to hardware burden or the inherent characteristics of their recipients, such as dual chamber pacemakers and defibrillators or cardiac resynchronization therapy devices, have increased over time.[3,42] Despite an increasing awareness, the institution of infection control practices, and the improvement in CIED and lead design, CIED infections continue to occur and are life-threatening.[40,44] Half of all CIED infections occur within a year after device implant or pocket intervention.

Microbiology

As far as culprit pathogens are concerned, we recently reported our experience, as a TLE referral center spanning the course of the past decade,[45] and showed that staphylococcal species account for most CIED infections, which is consistent with previous reports.[41,46–51] Compared with data published in the preceding decade,[50] we observed an alarming increase in the rates of methicillin resistance, with 1 in 3 CIED infections caused by a methicillin-resistant staphylococcal organism and half of all staphylococcal infections were found to be methicillin resistant. This may reflect the common inappropriate use of broad spectrum antibiotics and suggests acquisition of culprit

organisms in health-care environments in a significant proportion of patients.

Clinical Presentation

The clinical presentation is variable with local signs and symptoms at the pocket site present in about 60% of cases,[52] such as erythema, swelling, or drainage. However, these may lack specificity especially with recent pocket interventions. Erosion at the device pocket is, by definition, infection of the device even in the absence of inflammation or purulence. Systemic signs and symptoms such as fever and chills may or may not be present and lack both sensitivity and specificity in CIED infections. The diagnosis could, therefore, be challenging.

Workup

When a CIED infection is suspected, at least 2 sets of blood cultures should be sent before the initiation of antibiotics. This is important given that some patients with a bloodstream infection may not manifest systemic toxicity or peripheral leukocytosis. When positive, especially with staphylococcal species, cultures provide a strong clue that the clinical syndrome is due to a CIED infection. Of note, percutaneous aspiration of the device pocket should not be performed because of low diagnostic yield and the theoretical risk of introducing microorganisms.

Echocardiography is key in the diagnostic workup with transesophageal echocardiography (TEE) being more sensitive than transthoracic echocardiography (TTE), especially for detecting small vegetations and for examining the SVC-right atrium portions of the leads. As such, TTE is frequently not helpful in ruling out the diagnosis of lead-related endocarditis. In addition, patients can develop both right-sided lead-related endocarditis and left-sided endocarditis with possible perivalvular extension, situations where TEE is superior to TTE. Nonetheless, TTE provides information regarding other prognostic baseline factors such as pericardial effusion, ventricular dysfunction and dyssynchrony, pulmonary vascular pressure estimations, in addition to providing baseline data which would serve as reference for additional studies.

Management and Prognosis

Once the diagnosis of CIED infection is confirmed, lead extraction should be performed to remove all CIED hardware including the device and leads, regardless of their location (endovascular, subcutaneous, epicardial).[1,40] It is important to emphasize that an infection of any component of the CIED system implies infection of the entire system and relapse rates are elevated with retained hardware.[1,40] At the time of extraction, additional cultures should be obtained, including the entire device capsule and tip of leads.

From a prognosis standpoint, CIED infections carry a risk of death up to 66% if left untreated and this risk is decreased to about 18% with antibiotics and complete extraction.[1,49,53,54] The prognosis is even worse with endovascular infections.[52]

NONINFECTIOUS INDICATIONS FOR EXTRACTION

Noninfectious indications for TLE include primarily device recalls and vascular occlusion. Device recalls are the second most common indication for extraction after CIED infection, but decision making on whether to extract or not in these patients is often challenging and much less straightforward compared with the management of CIED infections.

The Fidelis [Medtronic (Dublin, Ireland)] and Riata [St Jude (Saint Paul, MN)] leads have been subject to FDA advisory recalls and extensive extraction efforts. The Fidelis lead suffered from early fracture of the "pace-sense" and high-voltage conductor portions of the lead, which led to noise, oversensing, and inappropriate or ineffective shocks. The Riata lead suffered from insulation failure resulting in an externalization of high-voltage cables and potential electrical failure. Externalized cables can also lead to thrombus formation and can be a potential nidus for infection. Although the patient-specific risks of TLE versus lead abandonment need to be evaluated on a case-by-case basis, the decision-making process can be challenging in patients with recalled leads, especially when undergoing generator changes with recalled leads that are still functional. In the setting of recalled leads, 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 whether to extract or not. Because of 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. Referrals to centers of excellence in lead extraction and management are important to formulate and execute an optimal lead management plan.

Venous access or endovascular complications, which may indicate lead extraction, include thromboembolism from a thrombus on a lead or a lead fragment, bilateral subclavian or SVC occlusion precluding implantation of a needed transvenous lead, planned stent deployment in a vein, which already contains a transvenous lead, symptomatic SVC stenosis or occlusion, and ipsilateral venous occlusion that prevents venous access for the addition of a required lead when there is a contraindication to use the contralateral side.

The extraction of functional noninfected leads is also indicated in patients with life-threatening arrhythmias secondary to retained leads, and for 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. For patients who require MRI scans, lead extraction may be reasonable when imaging is an absolute necessity with no alternatives. To be noted, as clinical practice transitions to implantation of MRI-compatible lead systems, the presence of abandoned or superfluous leads precludes performing MRIs, and this issue needs to be accounted for in the decision-making process of lead extraction versus abandonment.

LEAD EXTRACTION TOOLS

Locking Stylets

The successful extraction of a lead is directly dependent on the lead structure and its tensile strength.[7] Locking stylets reinforce the tensile strength of the lead body, allowing transmission of the traction force to the tip of the lead during extraction, reducing the risk of elongation and fracture of the lead body, and thereby facilitating complete removal of the lead.[55] In our practice, locking stylets have been proven necessary for complete lead removal in over 98% of lead extractions. The two most commonly used locking stylets are the Liberator (Cook Medical; Bloomington, IN) and Lead Locking Device (Spectranetics; Colorado Springs, Colorado). The bulldog and one-tie tools (both Cook Medical) are also useful adjuncts to provide control of the lead body.

Mechanical Telescoping Sheaths

These nonpowered sheaths consist of an inner flexible sheath and an outer more rigid sheath made from Teflon, polypropylene, or steel. In our practice and in many published reports, telescoping sheaths have been proven necessary to the success of TLEs.[55–57] These sheaths are advanced along the body of the lead, with alternating clockwise and counterclockwise movements and sufficient tension on the locking stylet, to allow disruption of fibrous tissue.

Powered Sheaths

Powered sheaths employ various energy sources to disrupt encapsulating adhesions around the lead. The most commonly-used

powered sheath is the Excimer laser system (Spectranetics), which uses pulsed ultraviolet laser to allow destruction of fibrous adhesions by photochemical and photothermal reactions.[58] Published reports have demonstrated that laser sheaths allow more efficient complete lead removal compared with mechanical telescoping sheaths without increasing procedural risks,[13,59,60] and laser sheaths have become a cornerstone of lead extraction procedures.

The Evolution and Evolution RL mechanical dilator sheaths (Cook Medical) are hand-powered sheaths with either a stainless steel spiral cut dissection tip (non RL) or a decagon shaped tip (RL). These sheaths have been found to be very useful in TLE as either a primary tool or for rescue when other tools had failed to achieve successful extraction,[61] especially with heavy calcifications at venous access sites. Also available and similarly designed, the TightRail Rotating Dilator Sheath (Spectranetics) is more flexible, but only rotates the tip of the sheath.

Femoral Workstations

A snaring approach using the Byrd femoral or internal jugular Workstation (Cook Medical) is useful when the lead material is not accessible from the implant vein such as in cut or fractured leads, and often as a rescue when extraction attempts from the implant vein fail. In our experience, snaring workstations are required in about 2% of all TLE cases. Available snares include the Needle's Eye snare, a tip-deflecting wire, a Dotter basket, the Tulip, and Amplatz gooseneck snares.

TECHNICAL CONSIDERATIONS IN LEAD EXTRACTION

During TLE, the major technical principles to follow to allow safe and efficacious extractions are dissection of fibrotic adherences as needed, control of the entire body of the lead, and counter-traction 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. A step-wise approach is usually followed. Mild traction with a standard stylet or traction on a locking stylet with an insulation-bound suture is sometimes effective, and no powered tools would be required. When attempts to extract with manual traction are not successful, powered sheaths are employed, primarily laser sheaths in our practice. Femoral workstations and snares are usually used as a rescue strategy for TLE being performed via the implant veins.

During sheath advancement over the body of the lead, sufficient traction on the lead is applied so it serves as a rail for the advancing sheath. This is critical to minimize the risk of vascular injury by the advancing sheath, especially at the level of venous turns (innominate–SVC junction, SVC–right atrium junction). Counterpressure is applied with the advancing sheath and it is the simultaneous forward force that allows disruption of fibrous adhesions. At the level of the interface between the lead tip and myocardium, counter-traction is applied to limit direct pulling on the heart and to reduce the risk of myocardial perforation. This technique refers to holding the sheath static and pulling the lead into the sheath, pushing off the last bit of fibrosis and leaving it behind on the myocardium.

CONCLUSIONS

There is a growing need for lead and device extractions in clinical practice which parallels the growth in device implants. CIED infections remain the strongest and most common indication for lead and device extractions. The decision-making process is often complex on whether or not to extract noninfected leads, and the risks of extraction need to be weighed against the risks of lead abandonment on a case-by-case basis. Perhaps the best strategy to avoid device- and lead-related morbidity and complex extraction situations is to conceive a lead management plan and to refer to centers of excellence in lead management, as appropriate.

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