Lead Extraction—Indications, Techniques, and Complications

Charles J Love, MD, FACC, FAHA, FHRS, CCDS

Professor of Medicine, and Director, Cardiac Rhythm Device Services, Division of Cardiovascular Medicine, The Ohio State University

Abstract

Management of pacemaker and implantable cardioverter–defibrillator (ICD) lead complications and the prevention of these occurrences continues to become more important as the number of implanted devices continues to rise. For many situations, especially device infections, removal of the leads is a critical part of managing the patient and obtaining a cure. What is becoming more apparent is that forward thinking in terms of removal of superfluous leads may allow easier and safer removal when performed earlier. The preparation of the patient, procedure, indications, and hospital requirements for the performance of lead extraction are discussed in this article.

Keywords

Lead extraction, pacemaker, implantable cardioverter–defibrillator (ICD), lead complications, lead management

Lead extraction is now being recognized as but one lead management strategy. Lead management is a higher level of thinking in terms of how to manage patients with cardiac implantable electronic devices (CIEDs) that utilize wires (leads) to sense, pace, and/or defibrillate the heart. Although new leadless systems are beginning to appear, they are still in the investigational stage. Nonetheless, millions of patients remain with devices that utilize standard lead systems. On occasion, a lead may need to be removed for any one of a number of reasons, as will be discussed below. When that time comes, the techniques that have been developed over the past 25 years come into play.1–8

One must first define the terms that will be used when discussing this topic.9 Lead removal is the process of taking out a lead by any technique. Lead explant is a term used for removal of a lead by simple traction utilizing only the tools typically used to implant the lead (e.g. standard stylet, helix extension/retraction tool, etc.). Lead extraction is used to describe the removal of a lead that has been implanted for more than a year, when specialized extraction tools are required (regardless of implant duration), or when an approach other than that used to implant the lead is required.

The second set of terms that must be defined relate to the outcome of the procedure.9 The most important result of lead removal is clinical success. This refers to the achievement of the goal of the procedure without causing a major complication. The goal may be to place a new lead through an occluded vessel, resolution of an infection, removal of superfluous leads, resolution of pocket-related symptoms (such as pain), or elimination of a lead or portion of a lead that poses a risk of arrhythmia, perforation, or other hazard. It is possible to achieve clinical success without removing 100% of the targeted lead or leads. However, a procedural success is the removal of all targeted leads and lead materials from the vascular space without a significant complication.

Prior to performing a lead-extraction procedure, the operator and the team that will be assisting the operator must have sufficient experience and training to allow the procedure to occur successfully and safely.9,10 The primary operator should be trained by having direct experience in the procedure. This involves hands-on experience of at least 40 lead extractions as a primary operator. Exposure to multiple lead types utilizing different extraction tools and approaches is necessary. While the recently introduced computer simulator training tool is very useful to the operator and team, it is a great starting point rather than a substitute (at least as yet) for significant extraction experience.11 The tissue model simulator is a good tool to see and learn how laser extraction works, but it is currently not a good real-life tool and lacks the feel of working in the vascular space.

Published reports indicate that experience is critical to reduce complication rates, with the steepest decline in complications occurring after the first 30 cases, and additional decline through 400 cases.7 Likewise, success rates are lowest when the operator has performed <20 cases, and the rates remain low when <60 cases are performed over a four-year period. This suggests that continued
implantable cardioverter-defibrillators

exposure to the procedure on a regular basis is required to maintain proficiency. For this reason, a minimum of 20 leads extracted per year is recommended to maintain the most basic level of competency not only of the operator but also of the extraction team. During training, and indeed during maintenance of proficiency, leads that are simply explained by traction should not be counted. Training and ongoing experience must be with leads that require sheaths, snares, or other implements in order for the operator to realize any benefit from the experience.9,10,14

In order to perform extraction safely and effectively, well-trained support staff must be involved in the procedure. The staff must be familiar with the procedure, instruments, and potential complications. They must be able to recognize and to respond quickly when a potential or actual mishap occurs. If possible, it is advisable to train the staff using the newly available computer-based simulator. This will help them to recognize the critical portions of the procedure and to know when and how to respond in these situations.

Lead extraction should only be performed in a hospital setting where the services required to perform all aspects of the operation are available, and where personnel who are able to perform emergency rescue procedures are present. Should a complication occur, there is simply no time to move the patient to another facility; the difference between life and death may be only a matter of minutes. The hospital must have an accredited cardiovascular surgery program in place. The cardiovascular surgeon must not only be immediately available, but must have an accredited cardiovascular surgery program in place. The cardiovascular surgeon must not only be immediately available, but this individual must have knowledge of the types of injury sustained during lead extraction and be capable of making repairs.9 Failure to understand the anatomy and mechanisms of extraction injury may significantly delay the performance of the optimal rescue operation. For example, if a lead is being extracted from an azygous vein, a median sternotomy would be an ineffective method of entry into the chest (a right lateral thoracotomy is necessary in this situation). Thus, communication between the extractor and the cardiovascular surgeon (if it is not the same individual) is critical.

In addition to surgical back-up, both transthoracic and transesophageal high-quality echocardiography must be immediately available. It is not uncommon for a patient to become hypotensive during an extraction procedure. Differentiation between vagal responses, pericardial tamponade, and hemothorax must be made immediately so that the proper resuscitation response can be initiated. A pericardiocentesis kit must be in the room. It is also highly recommended that if the procedure is not being performed in a cardiac surgery operating room, a thoracotomy tray with a working chest saw should be in the room as well. The patient should be typed and crossmatched for red blood cells should this be required emergently. Many operators prefer to have the blood in the procedure room, especially in high-risk cases. If general anesthesia is not being used for the operation, anesthesia services should be immediately available as well.9

The operating room should have high-quality fluoroscopy. Many of the leads can be difficult to visualize under fluoroscopy, especially if they begin to stretch apart or pieces fall off them. Some extraction tools can be difficult to visualize as well. Knowing where the sheath and the lead are located is critical to both procedural success and prevention of complications. Finally, the operator should have available a wide array of instruments, sheaths, locking stylets, and snares. Having just one tool to perform an extraction is analogous to attempting to fix a car with a single wrench. It might work out for you sometimes, but you will be guaranteed to fail sooner or later due to lack of other tools.

The indications for lead extraction are absolute for some situations and relative for others.9 For the most part, one is not so much dealing with a risk versus benefit, but rather risk versus risk. There are certainly risks to removing leads, but often the risk of not removing a lead, or delaying lead removal to a later point in time, results in an even higher risk. This latter factor is one of increasing importance. It is known that extraction difficulty and complication risk increases the longer a lead is implanted. Therefore, if there is a reasonable expectation that at some point in the future a lead will need to be removed, it is easier and safer to do so sooner rather than later. It is also well-recognized that each time the device pocket is opened there is a risk of infection.10,12–16 This risk is considered to be in the range of 2–4%. By removing superfluous leads during the same operation as implant of the new lead(s), the additional infection risk of opening the pocket to extract at a later time may be avoided. This is the rationale for removing superfluous leads (especially those that are non-functional) when new leads are added. However, it is also crucial to recognize the risk relative to each individual lead. This risk will vary with duration of implant for that lead, the presence of calcification on the lead, the construction and type of lead (implantable cardioverter-defibrillator [ICD] leads may prove more difficult than a pacing lead of similar implant duration due to fibrotic ingrowth and attachment to the shock coils),21 and the experience and skill level of the operator. In many (if not most) cases, the latter may prove to be the most important risk factor.

There is now no debate about the need to extract leads when the device pocket is infected or when there is an intravascular or intracardiac infection (i.e. endocarditis). Similarly, most bacteremia associated with Staphylococcus results in colonization of the lead material, and therefore also represents a class I indication for extraction. Although antibiotic therapy is needed to suppress and ultimately cure these types of infection, recurrence is the rule unless the intravascular and pocket hardware is removed. It is also important to note that once the CIED or lead system has eroded, the system is now contaminated (even if true infection is not present), and the ability to successfully salvage the pocket is quite small. Indeed, the vast majority of salvage procedures result in subsequent pocket abscess and infection, eventually necessitating device removal and lead extraction.24,27

An increasingly common reason for extraction involves the need to create new venous access due to an occluded vein when there is a need to place new leads, such as for addition of a lead for cardiac resynchronization therapy or a lead for an implantable defibrillator.28–30 Some physicians favor abandonment of the initial implant site and use of the contralateral site. The problem with this approach is that there is a chance of causing a bilateral venous occlusion and thus creating a superior vena cava syndrome. It should

38
Lead Extraction—Indications, Techniques, and Complications

be noted that there are only two upper chest sites for implant, and if both sides become unavailable, the remaining options are less than optimal.

Other indications for lead extraction include chronic, unremitting, and severe pain that is felt to be due to the leads, a lead or lead fragment that is responsible for thromboembolic events or arrhythmias, a lead that may be compromised or entrapped due to planned stent deployment, leads that may interfere with the treatment of a malignancy (such as breast cancer), and leads that interfere with the operation of another CIED. Severe pain is a rather rare case, but does occur, often with radicular pain down the ipsilateral arm. There may be severe point tenderness at the place of lead insertion into the deep tissues. Severe pocket pain must be carefully evaluated, as it may also be a sign of occult pocket infection. It is unwise to stent a vessel that has a lead present, as this will incarcerate the lead and make it difficult or impossible to extract in the future should the need arise.

Although uncommon, multiple leads can interact, causing false electrical signals. These false signals can cause oversensing by the CIED resulting in inhibition of pacing or delivery of a shock. Some patients requiring breast surgery or radiation therapy may need to have the device and leads removed and relocated in order to allow surgical and/or radiation therapies to be performed.30–33

The most controversial indication for removing leads is that related to the need for magnetic resonance imaging (MRI). Although some MRI-compatible systems are just coming to market in the US (one is currently available outside the US), most devices currently marketed are labeled such that use of MRI is contraindicated. This is due to the potential for heating of lead systems and interference with the device operation. Permanent damage to the device itself is rare but possible. Leads that have been abandoned and are not connected to a pacemaker or ICD are at highest risk for heating and possibly causing stimulation of the myocardium. Some experts feel that all leads should be removed (especially those not connected to a device) prior to an MRI scan, while others have shown that MRI may be safe under very specific conditions. In either case, leaving abandoned leads behind creates an even greater challenge should the need for an MRI be critical for a patient.34

Preparation of the patient for a lead-extraction procedure involves knowing the patient, knowing the devices, and being ready for the operation. A history and physical examination are needed prior to the operation so that there is a clear understanding of the patient’s health, comorbid conditions, anticoagulation and platelet inhibition status, and the indication for the device. Although implants may proceed safely with an international normalized ratio (INR) of up to 2.5, this is not advisable for lead extraction. Any congenital anomalies relating to the great vessels, the heart, or any known vascular anomalies should also be considered. Importantly, a significant number of patients may not require a new device implant. The original indication for implant may not be valid at the time of extraction, or may have been soft to begin with at the original implant. This is especially important when it comes to a decision in terms of if and when to re-implant a device when an infection is present. If the patient is pacemaker-dependent, effective and stable temporary pacing should be established. The device should be programmed to a non-rate-responsive mode, and arrhythmia detections and shock therapies should be disabled. Proper antibiotics as therapy or prophylaxis should be administered.

One must know the devices that are implanted, especially the leads. Knowledge of the lead construction, fixation type, and date of implant is important when planning the extraction procedure. A chest X-ray is also important, as additional undocumented leads or hardware may be present. If the indication for extraction is infection or suspected infection, an echocardiogram (preferably transesophageal) is important to see if there are any large vegetations present.17–19 The presence of vegetations >2cm may require an approach other than transvenous in order to remove the infected tissue and to prevent a large pulmonary embolic event. Blood cultures should be drawn as well when infection of any part of the system is suspected or confirmed. Good venous access should be obtained to allow for administration of medications, blood, and fluids should the need arise. It can also be used to facilitate placing the patient on extracorporeal mechanical oxygenation (ECMO) should this be emergently necessary. Finally, arterial access for blood pressure monitoring is preferred by many operators, allowing beat-to-beat monitoring and also facilitating the initiation ECMO if needed.

Informed consent of the patient remains a critical part of patient preparation. Patients must understand the procedure to be performed, the potential benefits of the operation, and the true balance of risks involved. Simply stating a published success and complication rate is not sufficient. These percentages will vary with the leads to be extracted, the individual factors specific to the patient, and not least the percentages as they apply to the operator as an individual.

Performance of the actual lead extraction itself has certain core principles; however, the actual tools used may vary from one operator to another.3 First, any targeted lead must be dissected free from the surrounding and underlying tissues at the implant site. Any associated prosthetic materials such as suture, suturing sleeves, caps, adapters, or other prosthetic materials should be removed. If the lead has not been implanted for a long time, and especially if it is an isodiametric active-fixation design, an attempt to retract the fixation screw with subsequent traction on the lead often leads to removal of the lead. This is also true for many coronary vein leads. The disadvantage of this technique is that it does not allow one to maintain access to the venous system, thus if the intention is to re-implant via an occluded vessel, one should avoid removing the lead in this fashion.

If the lead cannot be removed by simple traction, or if the intention is to open an occluded vessel for a new implant, the lead(s) should be prepared. The end of the lead is cut, removing the connector, and (when present) the inner conductor coil is exposed. If an infection is present or suspected, pocket tissue swabs and actual pocket tissue specimens should be obtained. Culture of the tissue itself has been shown to yield a higher percentage of positive results in order to identify a causative bacterial species.
Implantable Cardioverter–Defibrillators

At this point, a decision needs to be made in terms of the approach to actual lead removal. Most operators prefer to use the implant site approach, as this saves time and requires only one venous access site, and most of the extraction tools have been designed to work from this site. In some cases, the lead may be heavily fibroosed to the venous anatomy, and extraction may be deemed difficult or dangerous. In this situation, some advocate using a jugular approach. In performing the latter, the lead is prepared as noted, but venous access is obtained via the right internal jugular vein. The lead is then grasped using a snare and the free end is pulled out of the vein. The lead is then prepared as noted below, using the same tools as for the standard superior approach. The difference is that this creates a straight approach along the lead down to the atrium, preventing the need for a sheath to make a bend around the inominate into the superior vena cava (SVC). The theory is that removing the lead in this manner may reduce the risk for SVC tear. A third approach is available using the femoral vessels. Venous access is obtained from the right femoral vein using a 16 Fr sheath. A variety of snares and catheters may be used to grasp or entangle the lead and pull it into the sheath. This approach is especially useful when the lead has been transected or only a lead fragment is present.

A locking stylet or lead-locking device is then placed into the lead and advanced to the most distal point possible. This provides stability and strength to the lead and a means to provide traction on the lead without pulling the lead apart. A suture is then tied around the insulation near the cut end of the lead, and the other end is tied to the stylet. This provides compression on the lead components to prevent the lead from pulling apart, and also provides additional stretch on the insulation to prevent the latter from bunching up in front of the extraction sheath. Note that some leads are lumenless. These leads cannot be prepared with a locking stylet, and one must use of a strong suture or snaring/extension device such as the Cook Medical Bulldog™ device; otherwise, the lead preparation is the same.

For either of the superior approaches (pocket site or jugular), once the lead has been prepared a countertraction sheath should be applied. All sheaths work utilizing the same concept. A semi-rigid sheath is applied over the lead and advanced to a binding site. The sheath uses mechanical (standard polypropylene or newer rotational Evolution™ sheaths), electrical (Electrosurgical Dissection Sheath, Perfecta®), or laser photoablative energy (Spectranetics, Inc.) to pass through the binding site. The goal is to safely advance the sheath through the binding sites and vasculature to the electrode–myocardial interface. Most operators have their preferred sheath technology, however, no single technology works in all situations. It is important to possess working knowledge of several different sheath types to have the best chance of successfully and safely removing the greatest number of leads. At this point the sheath is not advanced further, but the lead is drawn up to the sheath using traction on the lead. The sheath provides countertraction against the myocardium, thus bracing it around the lead tip. In nearly all cases, the lead safely releases from the myocardium and is withdrawn from the sheath. If the intent is to re-use the same insertion site (such as in a non-infected case), a guidewire may be placed through the sheath to allow for continued access to the vessel.

If there had been a complete occlusion, one may need to perform a venoplasty to allow enough room to implant multiple leads.

Extraction from the femoral route may be required if the lead has been completely severed, although some operators prefer the femoral approach as their primary method of extraction. Using one of a variety of snares and guidewires, the lead may be grasped and pulled down into the atrium or inferior vena cava. At this point, the free end of the lead can be grasped in a snare and pulled into the femoral sheath. The sheath is advanced to provide countertraction as necessary and the lead is removed. This approach is often best for attempting to grasp fragments of a lead that has fallen apart during an extraction attempt from above.

Complications from lead extraction are primarily related to the possibility of damage to the venous system and myocardium. Although lead extraction does have the potential for significant complications, the death rate should be in the range of 0.3%, with other major complications <1.5%. Major complications include death, cardiac avulsion or tear, vascular tear, and pulmonary embolism. Death is almost always due to rapid and massive blood loss. Percardial tamponade is one of the more common major complications, although if treated rapidly by pericardiocentesis and, if necessary, thoracotomy, it can be resolved with excellent results. Tears in the venous system that are above the pericardial reflection may result in massive hemothorax. This is much more difficult to contain and to repair. Rapid volume replacement and repair of the tear is necessary, but often the associated hypotension may prove too difficult to overcome, and cerebral anoxia occurs. It is for these reasons that preparation for such complications must be made, and that all members of the team must be ready to observe for signs of hypotension and patient compromise.

Other complications may occur, and have been classified as minor. These include venous thrombosis, pocket hematoma, vascular damage at the extraction site requiring repair, air embolism, migration of lead fragment, and minor hemothorax or pneumothorax. Although these events are significant and must be treated quickly, they are not life-threatening in most instances.

Conclusion

Lead extraction, once practiced by a few pioneers and experts, is now a widely practiced technique. It is difficult to obtain high-volume hands-on training, but this is mandatory to achieve good results with low complication rates. Proper preparation of the extraction team and the patient will yield the best outcomes in terms of safety and efficacy. Extraction should only be performed at institutions that are prepared to immediately and expertly manage complications that occur during the operation. Access to a wide array of extraction tools is helpful to ensure complete removal of all targeted leads. Management of infection by methods other than complete extraction are often doomed to fail, yielding a high recurrence rate of the infection or septic death of the patient. Other indications often must be weighed in terms of the risk to the patient relative to the procedure, the experience of the operator, and the potentially higher risk of needing to extract the lead at a later date.
2. Belott PH, Lead extraction using the femoral vein, Heart Rhythm, 2007;4:1102–7.
3. Smith MC, Love CJ, Extraction of transvenous pacing and ICD leads, Pacing Clin Electrophysiol, 2008;31:736–52.
4. Bongiorni MG, Soldati E, Zucchelli G, et al., Transvenous removal of pacing and implantable cardiac defibrillator leads using single sheath mechanical dilatation and multiple venous approaches: high success rate and safety in more than 2000 leads, Eur Heart J, 2008;29:2886–93.
5. Wilkoff BL, Byrd CL, Love CJ, 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(6):1071–76.
6. Koenigsmann G, Bucknall CA, Butler C, et al., PLESS investigators group, Eur Space, 2007;9(8):651–6.
7. Love CJ, Byrd CL, Wilkoff BL, et al., Lead extraction using a bipolar electrothermal dissection sheath: An interim report, Europace, Copenhagen, Denmark, 24–27 June 2001;223–8.
8. Byrd CL, Managing device-related complications and transvenous lead extractions. In: Ellenbogen KA, Kay GN, Wilkoff BL, Lau CP (eds), Transvenous Lead Extraction: Analysis of Data from 5339 Procedures in 10 Years. XIth World Symposium on Cardiac Pacing and Electrophysiology/Berlin, Pacing Clin Electrophysiol, 1999;22:6 (Pt II):A207.
9. Bracke FA, Meijer A, Van Gelder B, Learning curve characteristics of pacing lead extraction with a laser sheath, Pacing Clin Electrophysiol, 1999;22:2309–13.
10. Smith HI, Feamot ME, Byrd CL, et al., Intravascular extraction of chronic pacing leads: the effect of physician experience (abstract), Pacing Clin Electrophysiol, 1992;15:513.
11. Ghosh N, Yee R, Klein G, Kluhn A, Laser Lead Extraction. Is there a learning curve, Pacing Clin Electrophysiol, 2006;28:180–84.
12. Fowler VG Jr, Li J, Corey GR, et al., Role of echocardiography in evaluation of patients with Staphylococcus aureus bacteremia: experience in 163 patients, J Am Coll Cardiol, 1997;30:1072–8.
13. Lo R, D’Armas C, Cohen T, Kennin T, Incidence and prognosis of pacemaker lead associated masses: a study of 1,569 transesophageal echocardiograms, J Nucl Cardiol, 2006:18:599–601.
14. Love CJ, Current concepts in extraction of transvenous pacing and ICD leads, Cardiology Clinics, 2000;18(1):193–217.
15. Voigt A, Shalaby A, Sabo S, Rising rates of cardiac rhythm management device infections in the United States: 1996 through 2003, J Am Coll Cardiol, 2006;48:3:590–91.
16. Mela T, Chung M, Venkateshwar G, et al., Abstract 2434: Replacement of Cardiac Rhythm Devices: Is the Risk Different When Performed by Trained Electrophysiologists, in Academic or Private Practice? Results From the REPLACE Registry, Circulation, 2009;120:S637.
17. Sohail MR, Usman DZ, Khan AH, et al., Risk factor analysis of permanent pacemaker infection, Clin Infection Dis, 2007;45:166–73.
18. Bailey SM, Wilkoff BL, Complications of pacemakers and cardioverter-defibrillators: results of a large prospective study, Circulation, 2007;116:1349–55.
19. Kapa S, Fong L, Blockwell CR, et al., Effects of scatter radiation on ICD and CRT function, Pacing Clin Electrophysiol, 2008;31:727–32.
20. Munshi A, Wadasatwala T, Sharma PK, et al., Radiation therapy planning of a breast cancer patient with in situ pacemaker—challenges and lessons, Acta Oncol, 2008;47:255–60.
21. Patel OP, Shein M, Food and Drug Administration perspective. Magnetic resonance imaging of pacemaker and implantable cardioverter-defibrillator patients, Circulation, 2006;114:1322–3.
22. Wazni O, Epstein LM, Carrillo RG, 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(6):579–86.