Device Infections
Management and Indications for Lead Extraction

Siva K. Mulpuru, MD; Victor G. Pretorius, MBChB; Ulrika M. Birgersdotter-Green, MD

An 83-year-old woman is referred for lead extraction as a result of pacemaker pocket infection. She has a history of atrial fibrillation and complete heart block after an AV node ablation. A left-sided pacemaker was placed in 2007. One month before admission, she developed urosepsis, followed by an infection of the pacemaker pocket. Blood cultures revealed methicillin-sensitive Staphylococcus aureus. She was admitted to an outside institution where the device was removed, but the leads were left in place after a failed attempt to remove the leads with traction alone. A new single-chamber pacemaker was placed on the right side. On presentation to our institution, the patient appeared quite ill. Physical examination documented congestive heart failure and evidence of pocket infection at sites on both the right and left sides of the chest. Serum chemistry was significant for worsening renal function. A chest x-ray demonstrated a large right pleural effusion. The patient was taken to the hybrid operating room for further management. A transesophageal echocardiogram performed under general anesthesia showed a large pericardial effusion compromising ventricular filling, and a pericardial drain was placed. A temporary pacing wire was placed in the right ventricular apex via a femoral approach. The recently implanted right-sided pacemaker system could then be removed with traction under fluoroscopic guidance. The 2 left-sided leads were extracted with locking stylets and a laser sheath. Both wounds were extensively debrided, and bilateral wound vacuums were placed. An active fixation pacemaker lead was then placed via a right internal jugular approach and connected to a previously used, resterilized pacemaker to provide temporary/permanent right ventricular pacing. Finally, a right-sided chest tube was placed.

The patient remained hospitalized for 2 weeks for management of her infected pacemaker sites and sepsis, with her initial care in the intensive care unit and with collaboration with medical teams from cardiology, cardiothoracic surgery, and infectious disease. A new left-sided pacemaker system was subsequently placed, and the patient is doing well after discharge from the hospital.

This recent case at our institution highlights many of the challenges encountered in managing patients with cardiac implantable electronic device (CIED) infections. An early diagnosis and knowledge of indications for lead extraction are paramount to patient survival. Equally important is the overall management of the patient, including the procedural approach, pacing requirements, and wound care. Finally, successfully managing these often very complex patients can be done only through a team approach using a hospital’s many resources. These aspects of CIED infection management are discussed in this review.

Scope of the Problem
As indications for CIEDs increase with time,1-3 associated complications are being seen more frequently. Because people live longer with associated comorbidities,4 there is a general trend for an increase in CIED infections.5 The number of hospitalizations related to CIED infections increased 3.1-fold between 1996 and 2003 (2.8-fold for permanent pacemakers and 6.0-fold for implantable cardioverter-defibrillators),6 and more important, CIED infection increases the risk of in-hospital death by >2-fold. Financial consequences and healthcare use during CIED infection add substantial strain to the healthcare delivery system.6

Various observational studies suggest that device infection rates range from 1% to 7%.7-11 In general, implantable cardioverter-defibrillators have a higher rate of infection compared with pacemakers.12 Factors that increase the risk of device infection include diabetes mellitus, previous glucocorticoid therapy, underlying malignancy, operator inexperience, multiple lead placement, advanced patient age, oral anticoagulant use,13 frequent generator replacement, heart failure, fever before device implantation,14 use of temporary pacing catheters,14 nonpectoral (abdominal or thoracoscopic) implantations,15,16 and renal dysfunction.13,17,18 On the other hand, antibiotic prophylaxis seems to reduce the risk of infection.19,20

Making the Diagnosis
Pathogenesis
CIED infections can be broadly categorized as follows:

1. Superficial infection: pocket or subcutaneous tissue infection. Erosion can occur as a result of pressure from the underlying CIED system on the superficial tissues, leading to infection. Perioperative pocket contamination...
Clinical Signs and Symptoms

Pocket and subcutaneous tissue infections may present with pain, swelling, redness, discharge, and wound dehiscence (Movie I in the online-only Data Supplement). Once the expulsion of pus occurs, pain improves and chronic fistula formation can take place. Systemic signs of infection, including fever, chills, malaise, fatigue, and anorexia with weight loss, are present with lead infection or bacteremia and are usually absent in localized pocket infection. Increased markers of inflammation like erythrocyte sedimentation rate, C-reactive protein, leukocytosis, microscopic hematia, and anemia are the most common laboratory abnormalities. Erosion at the pocket site can happen as a result of chronic infection or localized tissue trauma, leading to tissue disruption and infection (Figure 2). Pneumonia, bronchitis, pulmonary embolism with lung infarction, and metastatic seeding of other organ systems can occur from lead endocarditis. Valve endocarditis caused by CIED infection can present with heart failure secondary to stenosis or regurgitation from the vegetations. CIED infection should also be suspected in patients with fever of unknown origin with no signs of pocket inflammation.

Diagnostic Evaluation of CIED Infection

When clinical signs and symptoms suggest CIED infection, 2 sets of blood cultures should be obtained before initiation of any antimicrobial therapy. Staphylococcus aureus bacteremia may point to CIED infection. Transesophageal echocardiography is superior to transthoracic echocardiography for the detection of lead or valvular endocarditis and associated complications. Transesophageal echocardiogram also provides prognostic information like the presence of cardiac dysfunction, effusion, pulmonary hypertension, and degree of dys synchrony and serves as a baseline study for follow-up examinations. A mass adherent to leads in patients with positive blood cultures most likely represents a vegetation (Figure 3 and Movie II in the online-only Data Supplement). Radioactive-tagged white blood cell scans can reveal infection around pacemaker generators or leads, but the limited sensitivity of these tests reduces their practicality. The role of positron emission tomography/computed tomography studies to differentiate infection from inflammation needs to be defined further. Aspiration of a CIED pocket is discouraged because the diagnostic yield is low and because it can potentially lead to the introduction of microorganisms. Tissue culture and Gram stain of the pocket and lead tip will help identify the offending organism.

Microbiology

Skin flora (Gram-positive, coagulase-positive Staphylococcus aureus and coagulase-negative Staphylococcus epidermidis) account for most of the pocket and intravascular infections (Figure 1). CIED infection within 2 weeks of pocket manipulation is most commonly attributable to Staphylococcus aureus infection. Streptococci, Propionibacterium species, Corynebacterium species, Gram-negative bacilli, non tuberculous mycobacteria, Aspergillus, Coccidioides species, and Candida can occasionally cause CIED infections. Methicillin resistance is common among staphylococci, and occasionally polymicrobial infections are seen. Staphylococcus aureus bacteremia associated with CIED infection frequently results from seeding of a secondary source of infection. During early Staphylococcus aureus bacteremia (<3 months from pocket manipulation), clinical signs of CIED infection are frequently seen, whereas in late bacteremia (>1 year from pocket manipulation), an infected CIED system is infrequently the source. Staphylococcus aureus is often associated with more prolonged bacteremia and higher mortality. Coagulase-negative staphylococci infections are generally associated with multiple pocket revisions and higher numbers of leads at the time of infection. Gram-negative bacteremia in the absence of pocket or soft-tissue infection rarely seeds the CIED system and can be treated without CIED system removal.

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Management of Patients With Device Infection

Overall Assessment

Hemodynamic and respiratory parameters and other comorbidities determine the optimal location for management, from in-hospital intensive care unit care for patients with multorgan failure to home care with parenteral or enteral antibiotics. Superficial or incisional pocket infections can usually be treated with 10 days of oral antistaphylococcal antibiotics. However, complete removal of CIED hardware is required in patients with established infection presenting with systemic manifestations or associated complications. Indications for complete CIED removal, including lead extraction as a result of infection, are summarized in the Table. Percutaneous lead extraction is feasible in the majority of cases. Open surgical extraction is reserved for patients who have large vegetations and in whom percutaneous extraction is unsuccessful or concomitant cardiac surgery is required.

Antimicrobial therapy should be tailored on the basis of the results of Gram stain and cultures with antibiotic sensitivity assays. Initial choice of antibiotic should be vancomycin because the bulk of CIED infections are attributable to *S. aureus*. Later, treatment should be switched to an appropriate antibiotic on the basis of sensitivity analysis in patients without β-lactam allergy. The duration of antibiotic treatment should be at least 2 weeks for pocket infections and 4 to 6 weeks for systemic infection with bacteremia and associated complications like valvular endocarditis, osteomyelitis, diskitis, septic arthritis, mycotic aneurysm, and septic thrombophlebitis. Concomitant intravascular hardware such as dialysis catheters, prosthetic valves, and vascular grafts must be presumed to be infected and removed or replaced when feasible before replacement with a new CIED.

CIED Removal

Lead management refers to overall lead monitoring, management of associated complications (infection, malfunction, thrombosis, and vascular complications), issues related to device upgrades (abandonment versus extraction), and management of device-related imaging issues (magnetic resonance imaging and delivery of radiation therapy). Decisions are made after assessing risk versus risk rather than risk versus benefit for individual patients. Removal of the leads without any specialized equipment is called lead explantation, whereas lead removal with the use of specialized equipment (locking stylets, specialized sheaths, femoral, or jugular extraction tools) is called lead extraction.

Most pacemaker leads implanted within a year can be explanted without the use of any specialized equipment. As leads stay longer in the vascular system, fibrotic reaction occurs around the leads, causing them to adhere to the vessel wall. The amount of fibrosis is dependent on the insulation materials, surface area of the implantable cardioverter-defibrillator coils, time from implantation duration, flow state in the venous system, number of the leads, and various patient-specific factors such as renal insufficiency predisposing to dystrophic calcification or hypertrophic scar. Once fibrotic reaction occurs, attempts to remove leads with simple traction can cause major vascular or myocardial complications.

Table. Indications for Transvenous Extraction as a Result of CIED Infection

<table>
<thead>
<tr>
<th>Indication</th>
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<td>Definite CIED infection with</td>
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<tr>
<td>Lead endocarditis</td>
</tr>
<tr>
<td>Valvular endocarditis</td>
</tr>
<tr>
<td>Pocket infection with abscess formation</td>
</tr>
<tr>
<td>Superficial erosion</td>
</tr>
<tr>
<td>Chronic draining sinus</td>
</tr>
<tr>
<td>Occult Gram-positive bacteremia</td>
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<tr>
<td>Persistent occult Gram-negative bacteremia</td>
</tr>
<tr>
<td>Valvular endocarditis without evidence of device infection</td>
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CIED indicates cardiac implantable electronic device.
Lead Extraction Techniques

Lead extraction has evolved over the past 3 decades from an open surgical procedure to predominantly a percutaneous-transvenous procedure. Current transvenous techniques were developed by Byrd and colleagues.\(^4\) The lead is dissected free from the pocket; all prosthetic material (anchoring sleeve and sutures) is removed; and the connector is cut off. A locking stylet is inserted through the inner lead coil all the way to the tip of the lead for fixation. Insulation and conductor materials are secured to the locking stylet with a nonstretchable suture to provide support and to form a rail to hold countertraction on the lead. A variety of specialized sheaths can then be advanced over the prepared lead to dissect the fibrous tissue and free the lead within the vasculature. Teflon, polypropylene, and stainless steel sheaths were initially used but have largely been replaced by next-generation laser sheaths and rotating mechanical sheaths, which are easier and safer to use. The techniques for lead preparation, countertraction, and dissection remain the same regardless of the instruments used or indications for extraction.

Occasionally, when the superior approach fails, alternative routes of extraction should be considered. A variety of femoral extraction tools and snares have been developed for lead extraction. Growing experience with right internal jugular extraction also makes it a safe alternative. These alternative approaches or open extraction can be used when lead fragments break off and are retained after conventional extraction.

Open surgical extraction is indicated in patients with leads that are extravascular as a result of misplacement through arterial structures or of erosion through the venous or myocardial wall. Large vegetations (>2 cm) on the lead or the tricuspid valve also warrant evaluation by a cardiac surgeon. Special attention should be paid to vegetation characteristics. Vegetations large enough to block the main pulmonary artery or major branches should not be extracted percutaneously. A solid cauliflower-like vegetation should be removed with an open surgical procedure, as opposed to a thin windsock-like vegetation that might be extracted percutaneously (Figure 4). Upgrading the extraction sheath to a larger size than recommended can allow the extraction of small vegetations along with the lead. Cardiac surgical consultation should be obtained when a cardiac abscess is suspected or identified on echocardiographic, computed tomographic consultation should be obtained when a cardiac abscess is suspected or identified on echocardiographic, computed tomographic or magnet resonance imaging.

Role of Transesophageal Echocardiography

Intraoperative transesophageal echocardiogram not only is helpful for hemodynamic monitoring and diagnosing of pericardial or pleural effusions during extraction but also can divert the planned procedure to a safer approach on the basis of new intraoperative findings. Evidence of residual vegetations after extraction can also guide the duration of antibiotic therapy or delay the time for implantation of a new device. A high index of suspicion can lead to the discovery of infection or vegetation on other native or prosthetic valves, requiring an alternative or additional appropriate procedure such as valve replacement or aortic root replacement.

Lead Extraction Complications

Transvenous extraction is associated with several potential life-threatening complications, including death, stroke, myocardial and vascular avulsion injuries requiring thoracotomy, pulmonary embolism requiring surgical intervention, anesthesia and pulmonary complications associated with prolongation of hospitalization, and infection of previously noninfected sites. Major complication rates are \(<2\%\) and in-hospital mortality is \(<1\%\) in experienced centers.\(^42,43\) Older leads, extraction of implantable cardioverter-defibrillator leads, female sex, and the use of laser sheaths are independent predictors of major complications. Extraction of infected leads, especially when lead vegetations are present, poses the potential risk of septic emboli to the lung, which can result in acute pulmonary hypertension and hypoxemia from large pulmonary emboli, acute septic shock, respiratory failure, or lung abscess formation.

Personnel Training and Institutional Requirements for Lead Extraction

The Heart Rhythm Society lead extraction consensus statement clearly defines the physician training and facility requirements to perform lead extraction procedures safely. A team-based approach and a continual ongoing quality improvement program are stressed in the consensus statement. A minimum extraction of 40 leads as a primary operator and an annual volume of 20 lead extractions are recommended to maintain competence. Involvement of a cardiothoracic surgeon well versed in managing complications arising from lead extraction is critical for safe outcomes. Anesthesia support, access to fluoroscopy, echocardiography, and the roles of all nonphysician personnel are clearly defined in the statement. A hybrid operating room is an ideal setting for lead extraction, allowing seamless transition from percutaneous to open procedures when necessary.
Postextraction Management

Pacemaker-dependent patients may need temporary pacing support for several weeks after CIED removal before a new permanent implantation can be performed. An externally located temporary permanent pacing system can be implanted from the internal jugular or subclavian vein. An active fixation lead will ensure lead stability, enhance patient mobility, and afford a better chance to clear the systemic infection before CIED replacement (Figures 5 and 6).44,45 Patients who require defibrillation support can be treated with a temporary external wearable defibrillator before CIED reimplantation.46

Postextraction wound management is crucial to eradication of infection and timely healing. Complete debridement of the infected and avascular tissue or foreign materials can be accomplished by surgical dissection and electrocautery, leaving behind only viable tissue to heal. Vacuum-assisted closure therapy (KCI, San Antonio, TX) greatly enhances healing and patient comfort (Movie III in the online-only Data Supplement). The vacuum-assisted closure system consists of GranuFoam sponge material placed in the wound with a clear adhesive covering applied over the entire wound. A hole 0.5×0.5 cm is made in the occlusive dressing; a vacuum tube is inserted; and 125-mm Hg suction applied. Because the vacuum-assisted closure system is portable, the patient can ambulate. The GranuFoam sponge is changed every 72 hours and promotes healing by draining the pathogens away while converting an open draining wound to a closed system. The suction effect on the wound enhances angiogenesis, promotes cell division, and causes local elaboration of growth factors.44,47 With this technique, delayed primary closure can be achieved within 3 to 6 days after extraction. Vacuum-assisted closure may allow CIED reimplantation on the ipsilateral side at a shorter interval if ongoing medical or vascular access issues dictate earlier replacement.

Alternatively, an open drainage system can be constructed with a Penrose or Jackson-Pratt drain in the base of the wound, or the wound can be allowed to close with secondary intention with daily wet to dry dressings, but wound healing using these approaches can be very slow.

Figure 5. Externally located temporary/permanent pacemaker.

Figure 6. X-ray image of temporary/permanent pacemaker with active fixation transvenous lead.

Routine bilateral venograms at the time of extraction aid in identifying venous access issues for subsequent reimplantation procedures. Venous access with an indwelling catheter should be obtained for long-term antibiotic administration after clearance of bacteremia.

Reimplantation

Up to one third of patients requiring extraction will require CIED reimplantation.37 An algorithmic approach for reimplantation is outlined in Figure 7. Generally, contralateral reimplantation is preferred in patients with CIED infections. Blood cultures are repeated after CIED removal, and many reports recommend clearing the bacteremia (blood cultures negative for 72 hours) before reimplantation.16,37 Contralateral vascular access issues may result in delay of reimplantation for an additional period of healing, reimplantation at deeper plane and at a distance from the ipsilateral healed pocket, or consideration of alternative reimplantation approaches such as epicardial or iliac implantation. One-stage contralateral implantation after infected CIED system removal is not recommended. Close collaboration with an infectious disease specialist can improve cure rates and long-term freedom from reinfection.

Alternative Conservative Measures of Treatment of CIED Infections

Patients with infected CIED systems who are high risk for extraction because of advanced age or short expected survival from comorbidities or patients who refuse removal can be treated with long-term suppressive antibiotics if they respond well with clearance of bacteremia.48 Debridement of infected pocket tissue, removal of all nonessential hardware with sterilization using scrubbing, pulsed lavage, and use of a closed antimicrobial irrigation system are an alternative to extraction in some high-risk patients.49,50 Small series of patients have been reported who were free of local and systemic infection at
a 1-year follow-up using these more conservative approaches to treatment.

**Pediatric Population**

Children with CIED infections have special issues in terms of treatment and device removal. Congenital vascular anomalies, small body habitus, the requirement for biventricular pacing, the presence of shunts, and a higher prevalence of epicardial systems add another layer of complexity to the management of CIED infections. Such patients should be evaluated by a team experienced in both percutaneous and open surgical extraction. Infection rates are generally higher in children compared with adults with CIED devices, but the general principles of management of CIED infection remain the same.51,52 Alternative routes of lead implantation (transatrial, epicardial high voltage leads in the pericardial sinuses) may be considered during reimplantation.

**Outcomes With CIED Infections**

CIED infections are associated with substantial morbidity and mortality with a sizable financial burden to the healthcare system.53,54 In 1 study, the standardized adjusted incremental and total admission costs for infection were $14,360 to $16,498 and $28,676 to $53,349 for pacemakers and implantable cardioverter-defibrillators respectively.55 Initial conservative management of confirmed CIED infection is associated with higher relapses and mortality. Contemporary studies suggest 3.7% in-hospital mortality in patients without endocarditis and up to 14% with associated endocarditis.27 The degree of tricuspid regurgitation after CIED removal, right ventricular dysfunction, and renal dysfunction are independent predictors of mortality at 6 months. Early and complete removal of CIED infected systems is associated with better outcomes.56

**Primary Prevention**

Paying meticulous attention to aseptic technique and achieving good hemostasis during initial implantation are critical to prevent CIED infections. Multiple studies have shown that the use of preprocedural antistaphylococcal antibiotics 1 to 2 hours before the procedure reduces CIED infection rates after implantation.57,58 Patient education to recognize signs and symptoms of infection and to understand the need for follow-up with healthcare providers should be emphasized. Mucosal injury causing transient bacteremia rarely results in CIED infection. Antibiotic prophylaxis at the time of mucosal manipulation such as dental procedures or endoscopic procedures is currently not recommended.58

**Conclusions**

The aging population and expansion of indications for CIEDs have led to a dramatic increase in associated infections. System-wide measures to prevent infection and multispecialty
team-based management of patients with CIED infections are essential for optimal outcomes.

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**Disclosures**

None.

**References**


**Key Words:** cardiac pacing, artificial defibrillators, implantable infection

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