

Guidelines for Referring Physicians Regarding Patients who are Candidates for Lead Extraction

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Preamble

This document is intended to provide guidelines for physicians who have patients with implanted devices where consideration is given to extraction of the leads and/or system. Lead extraction is an invasive, highly specialized procedure that is performed in tertiary and quaternary referral centers by operators with significant expertise in this focused subspecialty. It is common for patients presenting with lead related problems to undergo initial evaluation and consideration of referral in centers without expertise in this particular field. The purpose of this document is to:

1. provide a brief review of the indications for extraction
2. summarize the nature of lead extraction, including the risks and benefits that can be explained to the patient
3. provide an overview of triaging candidates for lead extraction, including decisions regarding urgency and medical therapy while awaiting extraction
4. provide general guidelines for pre and post-op care in the patient undergoing lead extraction
5. provide a one page summary referral form that can be faxed

Brief Review of the Indications for Extraction

Lead extraction is a procedure that is performed in either the Electrophysiology Lab or Operating Room with intravenous sedation or general anesthesia. Leads that are less than a year old can often but not always be removed with simple traction. Older leads are best managed with formal extraction tools. This includes some form of locking stylet to provide consistent traction along the body of the lead, and dissecting sheaths for dissection of fibrotic tissue from the lead body to free up the lead for removal. The latter may represent mechanical sheaths, radiofrequency electrosurgical dissection sheaths or excimer laser sheaths. Data collected through an international registry from hundreds of extraction physicians demonstrated complete extraction of individual leads is successful in 95-98% of cases, with extraction of all but a residual component (less than 4 cm.) of the lead in a further 1-5%. Complete failure to remove the lead occurs in 1-3% of leads. Complication rates are in the order of 1 to 5% for all complications, 1 to 2% for major complications and death in .2 to .4 %.

The indications for lead extraction can be divided into three major categories:

- 1) Endovascular sepsis with leads as a primary source of sepsis, or secondarily infected. These patients often present with symptoms that include fever, and have positive blood cultures. They should undergo transthoracic and in most cases transesophageal echo to identify vegetations that adhere to the leads. This constitutes a medical emergency and should be treated aggressively with intravenous antibiotics and urgent consideration of lead extraction. Ideally, lead extraction is performed within 24-72 hours after the leads are identified as infected, particularly when fever persists despite antibiotic therapy. The

- second emergent indication for extraction is recurrent emboli attributed to the endovascular portion of the leads. The latter is clinically uncommon.
- 2) The second general indication for extraction is pocket related infection or erosion. Mechanical erosion, infection leading to erosion and frank infection is an urgent indication for lead extraction. In most situations, oral antibiotics are administered after blood and wound cultures are obtained. If the patient remains afebrile, the patient can be managed as an out-patient with careful observation. Ideally, lead extraction is performed within seven to fourteen days. Longer delays for referral and transport may be acceptable if the patient remains stable and antibiotics resolve evidence of acute infection.
 - 3) The third general indication for extraction is related to obtaining or maintaining vascular access for additional leads or relieving symptom related to venous obstruction. This occurs when there is no alternative venous access and lead replacement is desired, non functioning leads interfere with venous return or contribute to recurrent venous thrombosis, or there is agreement that leads should be removed to debulk the venous circulation or make room for new leads. This is becoming more common in relationship to changing therapy from pacing to defibrillation or to biventricular stimulation devices. This is typically an elective situation, where patients are referred, evaluated and undergo extraction as an out-patient based on the referral pattern and the waiting list of the specialty center.

Referral Logistics in Lead Extraction Patients

- 1) After initial discussion of the case between the patient's physician and the referral center, it is crucial to obtain detailed information regarding the implanted system. Ideally, this includes an implant report, all information regarding lead performance, age and characteristics, generator battery status, need for pacing (dependency) and frequency of therapies in the event of an ICD.
- 2) Urgency of referral and therapy should be agreed upon by the patient's physician and the referral center, based on the above general classification.
- 3) In the event of infection, it is common to consult Infectious Diseases to obtain input into optimal antibiotic management.
- 4) A discussion should be held with the patient regarding the nature of the procedure. This includes a general discussion of the technique, and the benefits and risks.
- 5) In patients with infection where postoperative care is expected to extend beyond 48 hours, the home hospital should be prepared to receive the patient back for ongoing wound and antibiotic care. This may need to include holding the bed to prevent the inability of the extraction center to accept new patients.

Procedure Risks

The risks of the procedure include but are not limited to minor or major vascular tear, hemothorax or pneumothorax, hemopericardium with acute pericardial tamponade, cardiac perforation and hemomediastinum, and the general background surgical risk of myocardial infarction, stroke, respiratory failure, etc. Death occurs in 0.2 to 0.4 % of patients and is typically related to vascular or cardiac tear with inability to repair rapid bleeding prior to exsanguination and death. Urgent cardiac surgical back-up is necessary in all referral centers. Despite this, death still occurs in rare instances. Patients with previous cardiac surgery are theoretically at a slightly lower risk of cardiac perforation because of previous

fibrous tissue, but are essentially impossible to resuscitate in the event of a vascular catastrophe because of the difficulties of redo surgery in an emergency situation.

Procedural Considerations

Prior to extraction, a chest x-ray and echocardiogram is typically performed. If reimplantation is considered, bilateral subclavian venous Doppler or a contrast venogram is performed to assess vein patency. Results of this should be made available to the specialty center. Patients with sepsis should be considered for transesophageal echocardiography. Post-operatively, patients undergo recovery based on the extent of the extraction and the anesthetic administered. The duration of hospitalization is influenced by the indication, the presence of infection and the timing of device reimplantation if necessary. In most patients where local or systemic infection is present, extraction centers will defer device reimplantation for 48-72 hours using temporary pacing if necessary to provide a bridge of antibiotic coverage in the absence of a permanent device. The practice in this regard is highly variable between centers. Sometimes, due to the presence or size of intracardiac vegetations it is better to consider open surgical techniques for either the extraction procedure or for epicardial placement of the replacement device and leads. Sometimes it is best to defer replacement of the pacemaker or defibrillator device for several weeks or months.

In patients with a successful extraction without ongoing concern regarding infection or reimplantation, the patient is typically discharged the following morning after overnight monitoring. An echocardiogram is performed along with a chest x-ray. Follow-up medical therapy is dictated by the underlying indication and concerns regarding ongoing infection in select patients. This outpatient therapy can include home IV antibiotic administration for some patients.

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Patient information booklets have been developed to provide information to patients and their families regarding the nature of the procedure. These can be obtained on line at www.londoncardiac.ca, or mailed or faxed by contacting the above individuals. Referring Physicians and Device Clinics can download additional copies of this document at www.londoncardiac.ca.