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Lead Extraction in the Contemporary Setting: The LExICon Study

An Observational Retrospective Study of Consecutive Laser Lead Extractions

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Objectives This study sought to examine the safety and efficacy of laser-assisted lead extraction and the indications, outcomes, and risk factors in a large series of consecutive patients.

Background The need for lead extraction has been increasing in direct relationship to the increased numbers of cardiovascular implantable electronic devices.

Methods Consecutive patients undergoing transvenous laser-assisted lead extraction at 13 centers were included.

Results Between January 2004 and December 2007, 1,449 consecutive patients underwent laser-assisted lead extraction of 2,405 leads (20 to 270 procedures/site). Median implantation duration was 82.1 months (0.4 to 356.8 months). Leads were completely removed 96.5% of the time, with a 97.7% clinical success rate whereby clinical goals associated with the indication for lead removal were achieved. Failure to achieve clinical success was associated with body mass index <25 kg/m^2 and low extraction volume centers. Procedural failure was higher in leads implanted for >10 years and when performed in low volume centers. Major adverse events in 20 patients were directly related to the procedure (1.4%) including 4 deaths (0.28%). Major adverse effects were associated with patients with a body mass index <25 kg/m^2. Overall all-cause in-hospital mortality was 1.86%; 4.3% when associated with endocarditis, 7.9% when associated with endocarditis and diabetes, and 12.4% when associated with endocarditis and creatinine ≥ 2.0. Indicators of all-cause in-hospital mortality were pocket infections, device-related endocarditis, diabetes, and creatinine ≥ 2.0.

Conclusions Lead extraction employing laser sheaths is highly successful with a low procedural complication rate. Total mortality is substantially increased with pocket infections or device-related endocarditis, particularly in the setting of diabetes, renal insufficiency, or body mass index <25 kg/m^2. Centers with smaller case volumes tended to have a lower rate of successful extraction. (J Am Coll Cardiol 2010;55:579–86) © 2010 by the American College of Cardiology Foundation

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Abbreviations and Acronyms

BMI = body mass index

CIED = cardiovascular implantable electronic device

DRE = device-related endocarditis

LALE = laser-assisted lead extraction

MAE = major adverse event

NASPE = North American Society of Pacing and Electrophysiology

The need for percutaneous transvenous lead extraction has been increasingly required in direct relationship to the increased numbers of cardiovascular implantable electronic devices (CIEDs) and is expected to continue to grow.

Unfortunately, the components of the CIED, the leads and pulse generators, do not function perpetually. As the population and the CIED ages, components of the system need to be extracted for a variety of reasons including infection, lead malfunction, venous stenosis, and occlusion, as well as safety alerts. Perceptions of lead extraction safety and effectiveness and the outcomes of patients undergoing transvenous lead extraction have been based on early, relatively small trials, and a voluntary reporting of outcomes in a multicenter extraction registry (1–3). Historically, the perceived risk of extraction has limited the referral and performance of this procedure to patients with life-threatening situations (Class 1 indications). Growing physician experience and the development of newer tools have influenced the outcomes of transvenous lead extraction and thereby indications.

The goal of this study was to determine the contemporary safety and efficacy of excimer laser-assisted lead extraction, in a large series of consecutive patients who presented to 13 centers. In addition, the indications for extraction, outcomes, and risk factors for complications and mortality were determined.

Methods

Consecutive patients who underwent laser-assisted lead extraction (LALE) using the CVX-300 (Spectranetics, Colorado Springs, Colorado) laser system and the SLS II (Spectranetics) laser sheath between January 1, 2004, and December 31, 2007, were included. Patients were excluded if another nonlaser, nontraction device was used in the same procedure.

Data was collected at 13 sites in the U.S. and Canada. A pre-study, self-reported questionnaire to determine lead extraction caseloads over the previous 4-year period and practice type (academic vs. private practice) was used to ensure a wide range of settings and experience. Centers were divided into 3 groups (small ≤60 cases, mid >60 and ≤130 cases, and large >130 cases). The protocol was reviewed and approved by the institutional review board of each center.

Definitions published in 2000 in the North American Society of Pacing and Electrophysiology (NASPE) (now the Heart Rhythm Society) guidance document on transvenous lead extraction were used to calculate the safety and effectiveness of the extraction procedure and the rates of procedural (radiographic) and clinical success and complications (4).

Indications for lead extraction were classified as: 1) pocket infection; 2) device-related endocarditis (DRE); 3) pain; 4) venous stenosis or occlusion; 5) functional but abandoned; or 6) nonfunctional leads.

Pocket infection was defined as erythema with or without purulent discharge, device erosion, fat necrosis, and/or adherence of device to the skin, which may be accompanied by pain. All other infections in the presence of a CIED were considered device-related endocarditis. This included all persistent bacteremia or sepsis in the absence of another identifiable source or vegetations on the leads or valves in the presence of a device. Pain was defined as a lead extraction done to relieve pain associated with the device and leads without suspected infection. Extraction for nonfunctional lead status was defined as being related to a mechanical lead failure established on the basis of clinically significant alterations in pacing, sensing, lead impedance, or inappropriate tachycardia therapies.

Leads may be extracted when upgrading 1 system to another such as pacemaker to an implantable cardioverter-defibrillator or a pacemaker/implantable cardioverter-defibrillator to a cardiac resynchronization device when ipsilateral venous occlusion or stenosis is encountered. In addition, concern regarding possible interference with another device, treatment of malignancy, or causing another medical condition were indications for extraction. Potential future venous occlusion and infection due to superfluous abandoned leads were also reasons for extraction of the functional lead. If venous stenosis or occlusion was present, then the extraction indication was so designated, but if the concern was for abandoning leads, then the indication was designated a "functional abandoned lead."

Laser extraction. Laser sheaths were employed in all cases when the leads could not be explanted by simple traction. The extraction procedure has been described in detail previously (3). In brief, the lead was prepared by inserting a locking stylet into the inner coil lumen when possible. A suture is then tied onto the insulation and the locking stylet. The laser sheath was then advanced over the lead. Laser application was performed at binding sites and advanced gradually from 1 binding site to another until the tip of the lead was reached. Once abutting the myocardium, a combination of traction and countertraction was performed and the lead was freed.

The procedural and clinical success definitions employed in this study were as defined in the NASPE 2000 Policy Statement (4). Procedural success was defined as complete or partial and is identified for each lead extracted. Complete success was defined as the ability to remove "all lead material from the vascular space." Partial success was defined as "removal of all but a small portion of the lead; this may be the electrode, 4 cm or less of conductor coil, and/or insulation, or the latter two combined." Procedural failure is defined as "abandoning a significant length of lead (more