# Predictors and outcomes of lead extraction requiring a bailout femoral approach: Data from 2 high-volume centers

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**BACKGROUND** Lead extraction (LE) infrequently requires the use of the "bailout" femoral approach. Predictors and outcomes of femoral extraction are not well characterized.

**OBJECTIVE** The aim of this study was to determine the predictors of need for femoral LE and its outcomes.

**METHODS** Consecutive patients who underwent LE at our centers were identified. Baseline demographic characteristics, procedural outcomes, and clinical outcomes were ascertained by medical record review. Patients were stratified into 2 groups on the basis of the need for femoral extraction.

**RESULTS** A total of 1080 patients underwent LE, of whom 50 (4.63%) required femoral extraction. Patients requiring femoral extraction were more likely to have leads with longer dwell time (9.5 ± 6.0 years vs 5.7 ± 4.3 years; $P < .001$), to have more leads extracted per procedure (2.0 ± 1.0 vs 1.7 ± 0.9; $P = .003$), and to have infection as an indication for extraction (72% vs 37.2%; $P < .001$). Procedural and clinical success was lower in the femoral extraction group than in the nonfemoral group (58% and 76% vs 94.7% and 97.9 %, respectively; $P < .001$). Major periprocedural complications (0% vs 1.3%; $P = 1.0$) and periprocedural mortality (0% vs 0.8%; $P = 1.0$) were similar between the 2 groups.

**CONCLUSION** In this study, femoral extraction was needed in ~5% of LEs. Longer lead dwell time, higher number of leads extracted per procedure, and the presence of infection predicted the need for femoral extraction. Procedural success of femoral extraction was low, highlighting the fact that this approach is mostly used as a bailout strategy and thus selects for more challenging cases.

**KEYWORDS** Lead extraction; Femoral extraction; Outcomes; Device infection; Lead failure

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## Introduction

Pacemaker and implantable cardioverter-defibrillator (ICD) lead extraction (LE) is essential for the treatment of device-related infections and is often needed for the management of lead malfunction or recall or in the context of chronic venous occlusion at the time of lead revision or device upgrade.[1,2] Despite the availability of different tools that make LE safer and more successful, this procedure continues to carry significant risks and occasional failures.[3–5] Extraction via the implant vein (typically the subclavian vein), often coined the "superior approach," is the predominant method of LE. LE via the femoral vein (ie, "inferior approach") is an alternative approach occasionally used as a primary method for extraction,[6–8] but more commonly used in cases where the superior approach has failed to completely remove all targeted pacing or ICD leads. A few studies have compared outcomes of extractions performed using the superior vs inferior approaches as the primary strategy.[7,8] However, data on femoral LE as a "bailout" after failure of the superior approach to achieve complete procedural success are limited, particularly in the contemporary era of laser-powered sheaths to facilitate extraction.

We sought to determine predictors of need for femoral LE as a bailout strategy and to define outcomes of femoral extraction in a large cohort of patients undergoing LE at 2 high-volume centers.

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## Methods

Consecutive patients undergoing transvenous LE at Emory Healthcare (January 1, 2007, to May 31, 2016) and the University of Pittsburgh Medical Center (January 1, 2011, to August 31, 2016) were retrospectively identified. The institutional review boards of the Emory University and University of Pittsburgh approved the study protocol.

*LE* was defined according to the Heart Rhythm Society (HRS) consensus statement[1] as

1. extraction of any lead implanted for >1 year;
2. leads, irrespective of implant duration, requiring specialized extraction tools (locking stylets and mechanical or laser-powered sheaths) for removal; and
3. the use of an alternate venous route (vein different from the implant vein) for LE.

Procedures that did not meet the above criteria were considered lead explant, but not extractions, and were thus excluded from this analysis.

The decision to perform LE along with all the technical aspects of the procedure was at the discretion of the electrophysiologist performing the procedure. According to the standard of practice at both centers, extraction was initially attempted via the superior approach, with femoral extraction reserved for cases where the superior approach was not completely successful. Demographic and clinical data along with procedural details and outcomes were ascertained by medical record review. Patients were divided into 2 groups: group 1 included those who required attempts at extraction via the femoral approach and group 2 included those who underwent attempts at extraction via only the superior approach.

The indications for LE were classified as follows:

1. infection (pocket infection or systemic infection);
2. lead malfunction;
3. at the time of device upgrade when venous occlusion precluded the addition of new leads and LE was required to gain access into the systemic venous circulation; and
4. other (patient/physician preference, ie, functioning recalled leads).

According to the 2009 HRS consensus statement, *complete procedural success* was defined as complete removal of all targeted lead(s) and lead material without any serious adverse events (SAEs) or death. *Clinical success* was defined as complete removal of all targeted leads and lead material or retention of a small portion of the lead(s) that does not negatively impact the outcome of the procedure. *Procedural failure* was defined as failure to achieve complete procedural or clinical success or the development of any SAEs or death. *SAEs* were also defined according to the HRS consensus statement[1] as death, need for urgent cardiac surgery, pericardial effusion requiring drainage, or a hemothorax requiring a chest tube. Of note, procedural success and failure were based on outcomes "per procedure" rather than "per lead" as per the HRS consensus statement.

*Primary outcomes* were defined as the incidence of death or SAEs as defined by the HRS consensus statement.

*Secondary outcomes* were defined as procedural and clinical success.

### Statistical methods

Continuous variables are presented as means ± SDs, while categorical data are presented as frequencies and percentages. Comparisons between groups were performed using the $t$ test, $\chi^2$ test, or Fisher exact test, as appropriate. A 2-tailed $P$ value $<.05$ was considered statistically significant. All statistical analyses were performed using STATISTICA (StatSoft, Tulsa, OK).

## Results

A total of 1080 patients underwent transvenous LE during the periods of interest, of whom 50 patients (4.6%) (group 1) required a femoral approach. The remaining 1030 (95.4%) patients (group 2) underwent extraction using only a superior approach.

Table 1 summarizes the demographic and clinical characteristics of the 2 groups. Patients in both groups had similar age, sex distribution, and body mass index. Patients in group 1 tended to have a higher prevalence of chronic kidney disease (defined as stage III or greater) (34% vs 22.8%; $P = .085$), but the difference was not significant. Patients in group 1 had more leads extracted per procedure (2.0 ± 1.0 vs 1.7 ± 0.9; $P = .003$) and had leads with longer dwell time that needed extraction (9.5 ± 6.0 years vs 5.7 ± 4.3 years; $P < .001$). The indication for LE was more likely to be infection in group 1 (72.0% vs 37.2%; $P < .001$) and less likely due to lead malfunction (24.0% vs 45.3%; $P = .003$).

One hundred percent of patients in group 1 required the use of a powered sheath (laser, 86%; mechanical sheath, 44%; some patients required both), while 70% of patients in group 2 required the use of a powered sheath ($P < .001$) (Table 2).

Complete procedural success rates were significantly lower in group 1 (58% vs 94.7%; $P < .001$) as were the rates of clinical success (76.0% vs 97.9%; $P < .001$).

For group 1, the partial extractions are 12 (24%) among those with infection and the partial successes for noninfectious indications are 9 (18%).

For group 2 (nonfemoral), the partial extractions in the setting of infection are 7 (0.68%) and the partial extractions for noninfectious indication are 33 (3.2%).

SAEs occurred in 14 patients and led to 8 periprocedural deaths. All SAEs occurred in group 2, without any SAEs occurring in those undergoing attempted femoral extraction. However, likely due to low event rates, the difference in SAE rates between groups was not significant (0% vs 1.36%; $P = 1.000$). Periprocedural mortality rates were also similar (0% vs 0.76%; $P = 1.000$) (Table 2).

Eight patients had a superior vena cava (SVC) tear: 6 resulted in hemothorax and 2 in pericardial effusion. Five of those resulted in death despite urgent surgery. Three patients survived and underwent urgent surgical repair. One patient