Procedural outcomes and long-term survival associated with lead extraction in patients with abandoned leads

Faisal M. Merchant, MD, FHRS,*† Thor Tejada, MD,* Adarsh Patel, BS,* Jad El-Khalil,* Yaanik Desai, BA,† Brent Keeling, MD,†‡ Omar M. Lattouf, MD,†‡ Angel R. Leon, MD, FHRS,*† Mikhael F. El-Chami, MD, FHRS*†

*From the *Division of Cardiology, Section of Cardiac Electrophysiology, Emory University School of Medicine, Atlanta, Georgia, †Emory University School of Medicine, Atlanta, Georgia, and ‡Division of Cardiac Surgery, Emory University School of Medicine, Atlanta, Georgia.*

BACKGROUND The decision to abandon or extract superfluous sterile leads is controversial.

OBJECTIVE The purpose of this study was to compare procedural outcomes and long-term survival of patients with and those without abandoned leads undergoing lead extraction (LE).

METHODS Retrospective review of all patients who had undergone transvenous LE at our institution from January 2007 to May 2016 was performed. Patients were stratified into 2 groups based on the presence (group 1) or absence (group 2) of abandoned leads.

RESULTS Among 774 patients who had undergone LE procedures, 38 (4.9%) had abandoned leads (group 1). Dwell time of the oldest extracted lead was longer in group 1 vs group 2 (7.6 ± 4.9 years vs 5.6 ± 4.4 years; $P = .017$), as was infection as an indication for LE (76% vs 33%; $P < .001$). A bailout femoral approach was more commonly required in group 1 than in group 2 (18.4% vs 6%; $P = .007$). Complete procedural success rates were similar (92.1% in group 1 vs 95.0% in group 2; $P = .439$), but there was a trend toward lower clinical success in group 1 (92.1% vs 97.4%; $P = .088$), primarily due to failure to remove all hardware in the setting of infection. Major procedural complication rates were similar (2.6% in group 1 vs 1.2% in group 2; $P = .397$), as was long-term survival (mean follow-up 2.3 ± 2.2 years).

CONCLUSION Abandoned leads at the time of LE were associated with increased procedural complexity, including a higher rate of bailout femoral extraction, and may be associated with lower clinical success. Among appropriately selected patients, consideration should be given to LE instead of abandonment.

KEYWORDS Abandoned lead; Device infection; Femoral extraction; Laser extraction; Lead extraction

(Heart Rhythm 2018;■:1–5)

Introduction

Transvenous lead extraction (TLE) has become an increasingly important part of lead and device management programs. In the setting of cardiovascular implantable electronic device (CIED) infection, TLE is generally recommended in order to facilitate removal of all hardware and clearance of infection.[1] However, much less consensus exists on the management of sterile (i.e., noninfected) leads, which may be rendered superfluous at the time of lead revision or device upgrade. Several potential reasons have been suggested to favor extraction rather than abandonment of superfluous leads. Chiefly among them are the potential for increased risk of long-term venous occlusion in the setting of increasing numbers of leads such that TLE of superfluous leads may facilitate long-term vascular patency.[2] Additional considerations include the risk of either tricuspid valve regurgitation or functional stenosis due to increasing numbers of transvenous leads and the potential for lead–lead interaction between active and abandoned leads.[2,3]

Perhaps the most compelling reason to favor TLE of superfluous leads is that lead extraction (LE), if required at a later time, may be made significantly more difficult, and potentially more risky, by the presence of abandoned leads. However, making a clinical decision based on the potential increased risk of extraction complexity with abandoned leads is difficult because of the relative paucity of data on how much more difficult and risky TLE is with abandoned leads. A number of studies have compared retrospective outcomes among those patients who have undergone extraction vs abandonment of superfluous leads[4–10]; however, much less is known about the incremental risk and complexity of TLE in the setting of abandoned leads.[11] Additionally, the impact of abandoned leads at the time of TLE on long-term survival has not been evaluated.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. All authors have reported that they have no relationships relevant to the contents of this paper to disclose. **Address reprint requests and correspondence:** Dr. Faisal M. Merchant, Emory University Hospital Midtown, 550 Peachtree St, MOT 6th Floor, Atlanta, GA 30308. E-mail address: faisal.merchant@emoryhealthcare.org.

1547-5271/$-see front matter https://doi.org/10.1016/j.hrthm.2018.01.018

We sought to describe procedural outcomes and long-term survival after TLE with and without abandoned leads.

Methods

The study protocol was approved by The Emory University Institutional Review Board. Retrospective review of all patients undergoing TLE at our institution from January 1, 2007, to May 31, 2016, was performed. Lead extraction was defined according to the Heart Rhythm Society (HRS) consensus statement[1]: extraction of any lead implanted for ≥1 year, a lead irrespective of implant duration that requires specialized tools for extraction, or any lead requiring extraction via access other than the implant vein. Leads that did not meet this definition were categorized as lead explants, but not extractions, and excluded from this study. The decision to perform LE and the technical aspects of the procedure were at the discretion of the treating physician. Our general institutional approach has been to reserve the femoral approach to LE as a "bailout" strategy in circumstances in which all targeted lead material cannot be removed via the implant vein.

Procedure indications were classified as follows:

1. CIED-related infection (pocket infection or systemic infection)
2. Lead malfunction or recall
3. Upgrade of an existing CIED to a device requiring additional leads when venous occlusion required extracting an existing lead for access
4. Other: physician or patient preference (i.e., chronic pain)

Procedural outcomes were defined according to the HRS consensus statement.[1] Complete procedural success was defined as complete removal of all targeted leads and lead material without any major complication or death. Clinical success was defined as removal of the targeted leads despite retention of a small portion/fragment that did not negatively impact the clinical goals of the procedure. Procedural failure was defined as failure to achieve procedural or clinical success or the occurrence of procedural death or major complication.

The primary endpoint was the incidence of periprocedural death or major complications as defined by the HRS consensus statement (procedural death, need for urgent surgery, hemopericardium requiring drainage, or hemothorax requiring a chest tube). Secondary endpoints included the incidence of procedural and clinical success associated with LE, need for bailout femoral extraction, and long-term survival after the extraction procedure. Patients were stratified into 2 groups based on the presence (group 1) or absence (group 2) of abandoned leads at the time of extraction. Abandoned leads were defined as functioning or nonfunctioning leads that remain *in situ* but had been abandoned at the time of previous CIED system replacement, revision, or upgrade. Baseline clinical characteristics, procedural details, and long-term outcomes including survival were obtained from review of the medical records and institutional databases.

Statistical analysis

Continuous variables are reported as mean ± SD, and categorical data are given as frequency and percentage. Comparison of survival between groups after LE was estimated using Kaplan–Meier analysis and tested with the log-rank test. For survival analysis, individuals were censored at the last date they were known to be alive based on review of the medical records and institutional arrhythmia clinic databases. A 2-tailed $P < .05$ was considered significant. Statistical analysis was performed using Statistica (StatSoft, Tulsa, OK).

Results

During the study period, 774 patients underwent TLE, of whom 38 (4.9%) had abandoned leads (group 1). Baseline characteristics, stratified by the presence or absence of abandoned leads at the time of extraction, are given in Table 1. Patients in group 1 were more likely than those in group 2 to have chronic kidney disease (stage III or greater) (34.2% vs

Table 1 Baseline characteristics

	Group 1 (n = 38)	Group 2 (n = 736)	*P* value
Age (years)	63.5 ± 14.4	61.6 ± 16.3	.640
Male	26 (68.4)	483 (65.6)	.861
Left ventricle ejection fraction (%)	41.6 ± 17.9	36.4 ± 16.7	.163
Coronary artery disease	18 (47.4)	297 (40.4)	.402
Hypertension	22 (57.9)	466 (63.3)	.496
Diabetes mellitus	11 (28.9)	213 (28.9)	1
Chronic kidney disease*	13 (34.2)	143 (19.4)	.037
Device type			
Implantable cardioverter–defibrillator	32 (84.2)	511 (69.4)	.068
Cardiac resynchronization therapy	11 (28.9)	117 (15.9)	.043
Dwell time of oldest extracted lead (years)	7.6 ± 4.9	5.6 ± 4.4	.017
Indication for extraction			
Infection	29 (76.3)	243 (33.0)	<.001
Lead malfunction	6 (15.8)	372 (50.5)	<.001

Values are given as mean ± SD or n (%).
*Stage III or greater.