Extracting Versus Abandoning Sterile Pacemaker and Defibrillator Leads

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Nonfunctional or recalled cardiac implantable electronic device leads can be revised with either lead extraction (LE) or lead capping (LC). Factors that influence this decision and comparative outcomes of these strategies are unclear. We reviewed data from our institution to identify patients who received LE (n = 296) or LC (n = 192) from 2006 to 2012. Patients with infectious indications for lead removal were excluded. We compared unanticipated device-related procedures, defined as cardiac implantable electronic device procedures not for device upgrade or battery depletion, using a proportional hazards model adjusted for differences in baseline characteristics. Secondary outcomes were procedural complications, hospitalizations, and all-cause mortality. Patients who received LE were younger and more likely to have an operator with extraction experience (76% vs 26%, p <0.001). Leads removed by experienced extractors versus nonextractors had longer dwell times (4.2 ± 3.6 vs 0.9 ± 1.1 years, p <0.001). Over a median follow-up of 3.0 (interquartile range = 3.2) years, the adjusted risk of unanticipated device-related procedures was similar for LE versus LC (hazard ratio 1.04, 95% confidence interval 0.62 to 1.75). Complications, hospitalization rates, and mortality rates were also similar between the 2 groups. In conclusion, lead revision strategy is influenced by operator extraction experience and dwell time of leads. In our analysis, we found no difference in outcomes between the 2 strategies. **(Am J Cardiol 2015;115:1107−1110)**

Cardiac implantable electronic devices (CIEDs) use has substantially increased over the past decade, driven by expanding indications.[1−11] Because of the high rates of lead failures[12,13] and recalls,[14,15] and the aging of the population,[16] clinicians often encounter the need to replace a sterile, nonfunctional, or recalled lead or to upgrade a device with resulting superfluous but functional leads. In these situations, the clinician has to decide between extracting the nonfunctional or superfluous lead or abandoning it and adding a new lead. Anecdotally, the decision is often driven by whether the clinician caring for the patient is an "experienced extractor" or not. The decision between extracting or abandoning the CIED lead is not easy as it requires careful assessment of short- and long-term trade-offs. On the one hand, lead extraction carries an incremental procedural risk of death or other major complications,[17] but on the other hand, it is likely to decrease the long-term risks[18] of vascular complications and the need for future extractions of older leads in the event of infection, for example. This study was therefore designed to identify the factors that influence the decision of lead extraction (LE) versus lead capping (LC) and examine the comparative outcomes of these 2 strategies.

Methods

This study was approved by the Internal Review Board of the University of Pittsburgh. All patients who underwent lead revision procedures at the hospitals of the University of Pittsburgh Medical Center (UPMC) from January 1, 2006, to December 31, 2012, constituted the study cohort. Patients with CIED-related infections were excluded from this analysis.

Demographic and clinical data of the patients were obtained from review of the electronic medical records, including patient age, gender, New York Heart Association class of heart failure, and left ventricular ejection fraction. Co-morbid conditions including coronary artery disease, diabetes mellitus, and renal disease were also included in the data set. The use of antiplatelet and anticoagulation agents in the perioperative period was ascertained from medical orders and pharmacologic database. Preoperative laboratory values including hemoglobin levels, serum creatinine, and the international normalized ratio were recorded. Lead revision surgery was considered the index procedure. Previous device and lead data were obtained from the electronic medical record and included the type of device, the number, chamber, dwell time, manufacturer, and model number of each lead. Details of the index procedure and subsequent CIED-related procedures were abstracted from the operative notes.

Patients were followed to the primary end point of the first unanticipated CIED-related procedure, which was defined as any CIED-related procedure performed after the index procedure for any reason other than battery depletion or device upgrade, including procedures for device infection or malfunction or venous complications. Mortality data were obtained from the electronic medical records, including scanned death certificates and Social Security Death Index records. All-cause 30-day readmissions, all-cause hospitalizations, and cardiac-specific hospitalizations were also recorded through August 2014. Cardiac-specific hospitalization was defined as

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See page 1109 for disclosure information.

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Table 1
Baseline characteristics

Variable	Extract Lead (N= 296)	Abandon Lead (N= 192)	P-Value
Age (years)	60±17	67±13	<0.001
Women	35%	31%	0.42
Coronary artery disease	40%	50%	0.07
Diabetes Mellitus	22%	28%	0.13
End-stage renal disease	3%	1%	0.17
New Heart Association Class	2.4±0.7	1.3±0.7	0.26
New Heart Association Class			0.47
I	5%	10%	
II	44%	46%	
III	50%	43%	
IV	1%	1%	
Ejection fraction (%)	37±15	38±15	0.58
Serum Creatinine (mg/dL)	1.21±0.98	1.13±0.47	0.31
Hemoglobin (g/dL)	13.1±1.9	13.0±1.6	0.78
International normalized ratio	1.23±0.27	1.30±0.37	0.011
Aspirin	58%	65%	0.12
Clopidogrel	12%	16%	0.27
Warfarin	36%	43%	0.12
New oral anticoagulation agents	1.3%	2.0%	0.35
Type of device implanted			0.74
Pacemaker	21%	20%	
Defibrillator	40%	37%	
Cardiac resynchronization pacemaker	2%	2%	
Cardiac resynchronization defibrillator	37%	41%	
Experienced extractor operator	76%	26%	<0.001
Use of Laser-powered sheaths	57%	–	–
Follow-up duration (years)	2.9±2.1	3.1±1.9	0.30

Table 2
Patient outcomes

	Extract Lead (N= 296)	Abandon Lead (N= 192)	P-Value
Major Complications	6%	3%	0.13
Minor Complications	3%	3%	0.63
30-day readmission rate	9%	5%	0.13
All-cause hospitalization rate	49%	50%	0.81
Cardiac-specific hospitalization rate	30%	30%	0.91
Unanticipated device-related procedure	18%	15%	0.34
Death	24%	27%	0.42
Length of stay (days)	1.8±2.4	1.6±1.9	0.17

any hospitalization in which the admitting physician was a member of the Heart and Vascular Institute of UPMC. Major and minor complications were also collected during the follow-up period with definitions adopted from the 2009 Heart Rhythm Society expert consensus statement on lead extraction in patients with CIEDs.[19] Operators were classified as experienced extractors or nonextractors. An experienced extractor was defined as one who has experience performing long-term lead extractions using powered laser sheaths and who is familiar with extraction tools including locking stylets.

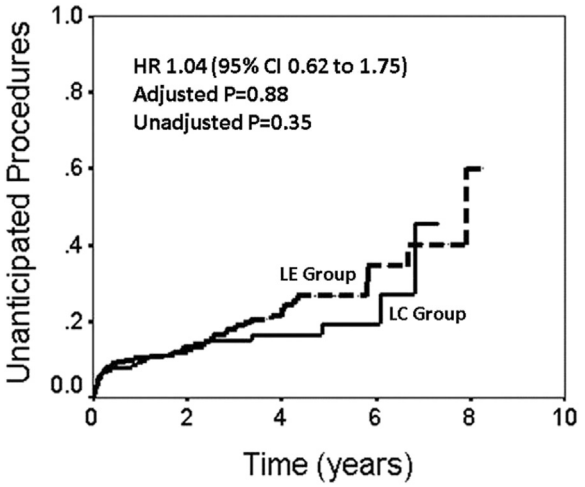

Figure 1. Nelson−Aalen cumulative hazard curves comparing the rates of unanticipated CIED-related procedures between the "lead extraction" versus "lead capping" groups.

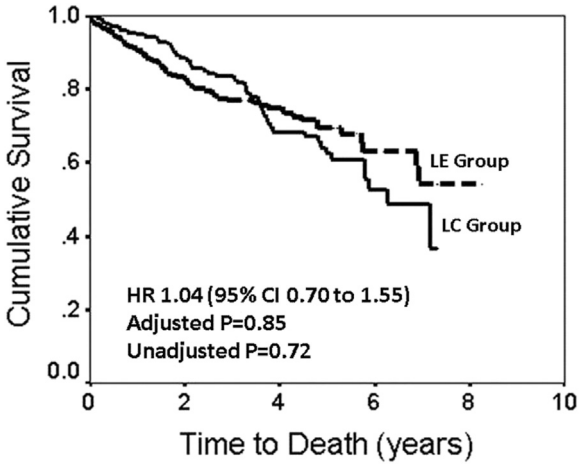

Figure 2. Kaplan−Meier curves comparing the overall survival of patients in the "lead extraction" versus "lead capping" groups.

A total of 16 operators at our institution performed 488 procedures of CIED lead revisions.

Baseline characteristics were presented for the LE and the LC groups as mean ± standard deviation for continuous variables and as rates for dichotomous variables and were compared using the Student's t and chi-square tests, respectively. A p value <0.05 was considered statistically significant. Kaplan−Meier curves were constructed for overall survival and Nelson−Aalen cumulative hazard curves were constructed for other clinical outcomes, comparing LE and LC groups using the log-rank test. Cox proportional-hazard models were constructed for each clinical outcome to adjust for any unbalanced covariates ($p < 0.10$ at baseline comparison). All statistical analyses were performed on SPSS version 10.1 (Armonk, NY).

Results

Of the original 644 lead revisions performed from January 2006 to December 2012 at UPMC hospitals, 488 met the