Clinical predictors of adverse patient outcomes in an experience of more than 5000 chronic endovascular pacemaker and defibrillator lead extractions

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BACKGROUND It is difficult to predict adverse patient outcomes associated with transvenous lead extraction (TLE) procedures.

OBJECTIVE The purpose of this study was to examine the safety and efficacy of chronic endovascular pacemaker and implantable cardioverter-defibrillator (ICD) lead extraction and risk factors associated with adverse patient outcomes.

METHODS Consecutive patients undergoing TLE at the Cleveland Clinic between August 1996 and August 2011 were included in the analysis. Univariate and multivariable logistic regression analyses were performed to evaluate for associations with outcomes. Continuous data are given as median (25th, 75th percentile). Categorical data are given as number (percentage).

RESULTS In total, 5521 leads (4137 [74.9%] pacemaker, 1384 [25.1%] ICD) were extracted during 2999 TLE procedures (patient age 67.2 [55.2, 76.2] years, 30.2% female). Lead implant duration was 4.7 (2.4, 8.3) years, and 2.0 (1.0, 2.0) leads were extracted per procedure. Powered sheaths were used in 74.9% of procedures. Overall, there was 95.1% complete procedural success, 98.9% clinical success, and 1.1% failure, with 3.6% minor complications and 1.8% major complications. All-cause mortality within 30 days of TLE was 2.2%. Multivariable predictors of major complications included cerebrovascular disease, ejection fraction $\leq$15%, lower platelet count, international normalized ratio $\geq$1.2, mechanical sheaths, and powered sheaths. Multivariable predictors of all-cause mortality within 30 days of TLE included body mass index <25 kg/m^2, end-stage renal disease, higher New York Heart Association functional class, lower hemoglobin, higher international normalized ratio, lead extraction for infection, and extraction of a dual-coil ICD lead.

CONCLUSION TLE in this single-center experience was highly successful. Risk factors associated with adverse patient outcomes were identified.

KEYWORDS Implantable cardioverter defibrillator; Pacemaker; Lead; Extraction; Complications

ABBREVIATIONS **BMI** = body mass index; **CIED** = cardiac implantable electronic device; **HRS** = Heart Rhythm Society; **ICD** = implantable cardioverter-defibrillator; **INR** = international normalized ratio; **MCVI** = major cardiovascular injury; **NYHA** = New York Heart Association; **TLE** = transvenous lead extraction

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Introduction

Cardiovascular implantable electronic device (CIED) utilization has grown substantially in response to broadening evidence-based indications.[1–3] In tandem there has been a growing need for system revisions and lead extraction.[4–8] It is estimated that the demand for transvenous lead extraction (TLE) has reached an annual extraction rate of 10,000 to 15,000 leads worldwide.[9] Major complications, including vascular laceration, cardiac avulsion, and even death, may occur during TLE. In a large contemporary multicenter observational series of laser-assisted pacemaker and implantable cardioverter-defibrillator (ICD) lead extractions, the

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incidence of major complications was 1.4%, with 0.3% procedural mortality.[10]

Despite the overall safety of TLE, it remains difficult to predict when adverse patient outcomes will occur. The ability to predict complications is critically important because for each individual patient, the risks and benefits of extracting existing leads vs allowing the leads to remain must be weighed. Adequate risk assessment also allows for consideration of referring the procedure to a more experienced operator and may aid in making decisions about the location of the procedure (electrophysiology laboratory vs operating room) and cardiothoracic surgery backup (at bedside vs immediately available).

We have a unique opportunity to explore TLE risk prediction given our large procedural volume. Our objectives were to examine the safety and efficacy of chronic endovascular pacemaker and ICD lead extraction and the risk factors associated with adverse patient outcomes.

Methods

We retrospectively analyzed consecutive patients who underwent TLE of pacemaker and ICD leads at the Cleveland Clinic between August 1996 and August 2011. Lead extraction was defined in accordance with the 2009 Heart Rhythm Society (HRS) TLE consensus statement.[9] Patients who did not meet the criteria of lead extraction were excluded. Demographic, historical, and procedural data were obtained from the electronic medical records and prospectively collected institutional databases. The Social Security Death Index was used to determine the dates of death that occurred after procedures. The study was approved by the Institutional Review Board of the Cleveland Clinic.

The TLE procedures were performed in the electrophysiology laboratories at the Cleveland Clinic with a cardiothoracic surgeon immediately available on site. Invasive hemodynamic monitoring and large-bore venous access were uniform, and a temporary pacemaker wire was placed as indicated. Most cases were performed with the patient under general anesthesia. Minimal traction was applied to all leads at the beginning of each case. If this did not result in successful lead extraction, a powered sheath was used.

Powered sheaths included the initial generation and SLS II Excimer Laser Sheath (Spectranetics, Colorado Springs, CO), Evolution Mechanical Dilator Sheath (Cook Medical, Bloomington, IN), and Perfecta Electrosurgical Dissection Sheath (Cook Medical). In some instances, mechanical sheaths, snares, and/or a femoral approach were needed for successful extraction. The names and manufacturers of these specialized extraction tools are provided in Online Supplementary Table 1.

Procedural outcomes were defined in accordance with the 2009 HRS consensus guidelines.[9] Intraprocedural and postprocedural (i.e., those evident within 30 days) complications were not differentiated in the analysis. Major complications, as defined by the HRS guidelines, include heterogeneous outcomes that may be associated with different risk factors. For instance, vascular laceration and infection of a previously noninfected site both are considered major complications, but the occurrence of each likely is not associated with the same patient or procedural risk factors. In an effort to find better predictors of catastrophic complications, we combined procedure-related deaths, laceration of a major thoracic blood vessel, myocardial avulsion, pericardial effusion requiring pericardiocentesis, and hemothorax requiring chest tube placement into a composite outcome called major cardiovascular injury (MCVI).

Statistical analysis

Continuous data are given as median (25th, 75th percentile). Categorical data are given as number (percentage). For univariate analysis, continuous variables were compared with the Mann-Whitney U test. Categorical variables were compared with the χ^2 test or Fisher exact test, as appropriate. Variables with $P \leq .10$ in the univariate analysis were included in the multivariable logistic regression analysis.

To avoid potential selection bias that would occur if only complete cases were included, missing values in the predictors were multiply imputed using multivariate imputation by chained equations (MICE) methodology before conducting multivariable logistic regression analysis. Ten copies of the imputed complete datasets were generated. Models were first built on each copy of the imputed datasets separately and then were aggregated into 1 final regression model for making statistical inference.

Backwards variable selection based on bayesian information criterion (BIC) was used to select variables in the final model. The odds ratio and the P value for the overall association with outcomes were reported for each variable in the final models. Restricted cubic splines were applied to continuous variables when significant nonlinear relationships presented. Data were collated and analyzed using the open source software R (R Foundation for Statistical Computing, Vienna, Austria) with additional package mice. $P \leq .05$ was considered significant.

Selected continuous variables were evaluated using clinically meaningful dichotomous end points. In instances where each had $P \leq .10$, the variable with the lowest P value was used for multivariable logistic regression analysis. If the P values were equivalent, the continuous variable was preferentially selected.

Variables were not included in the multivariable analysis if they were highly correlated with others (e.g., creatinine and end-stage renal disease) or redundant (i.e., no tools required for extraction). Length of procedure and fluoroscopy time were excluded from the multivariable logistic regression analysis because longer procedure and fluoroscopy times were thought to represent that complications had occurred rather than predicting that complications had occurred. The length of procedure and fluoroscopy time encompassed the entire case, including the additional procedural time and use of fluoroscopy needed to diagnose and manage complications.