

Risk of Collateral Lead Damage in Percutaneous Cardiac Implantable Electronic Device Extraction

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ABSTRACT

OBJECTIVES The study sought to assess the risk of collateral lead damage during cardiac implantable electronic device extraction.

BACKGROUND With the increasing numbers of cardiovascular implantable electronic devices, there has been an increase in the number of percutaneous device and lead extractions. It is unknown how often collateral damage (defined as the need for unintended lead extraction, or loss of lead's integrity or dislodgement) occurs in the planned retained leads.

METHODS In this retrospective study, 108 patients who underwent incomplete cardiovascular implantable electronic device removal at the University of California, San Diego from September 2010 to September 2015 were included. The authors established the integrity of previously functioning leads at the end of each procedure as well as on follow-up visits using parameters including lead impedance change, threshold change, drop in P- or R-wave signal amplitude, or presence of lead noise.

RESULTS Only 4 of 143 leads (2.7%) were found to have collateral damage. One right atrial (RA) lead had a clear insulation break, the second RA lead was found dislodged, and the third RA had a constant noise. The right ventricular lead was found to have a new high pacing threshold. Collateral lead age, extracted lead implantation site, collateral lead implantation site, and mode of lead extraction (laser, traction, or rotational dilator) did not have a significant correlation with the outcome of collateral lead damage.

CONCLUSIONS Lead extraction can be performed safely; however, there is a small risk of damaging adjacent leads. Close follow-up is needed, especially for the first few months, to assess for the reconnected leads' integrity. (J Am Coll Cardiol EP 2017;■:■-■) © 2017 by the American College of Cardiology Foundation.

The use of cardiac implantable electronic devices (CIEDs) has been steadily increasing over the last few years. In the United States alone, there are more than 3 million patients with CIEDs and roughly 400,000 implantations each year (1). With the increasing numbers of CIEDs, there has been an increase in the number of percutaneous device and lead extractions. In many cases, the indication for CIED removal is infection, which totals two-thirds of all extractions and necessitates removal of the entire system. With other indications such as

lead malfunction or abandoned leads, 1 or several leads may be left in place. The majority of extractions are performed by electrophysiologists and cardiac surgeons (2). There are several techniques and tools available for lead extraction including simple traction, traction with devices, mechanical sheaths, laser sheaths, electrosurgical sheaths, rotating threaded-tip sheaths, extraction snares, and telescoping sheaths (3). Binding sites are commonly encountered during extraction, with the most common binding sites being the venous entry, the subclavian vein,

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ABBREVIATIONS AND ACRONYMS

CIED = cardiovascular
implantable electronic device

ICD = implantable
cardioverter-defibrillator

RA = right atrium

RV = right ventricle

UCSD = University of
California, San Diego

the superior vena cava, the right atrium (RA), and the tricuspid valve (2). In addition, lead-to-lead binding also occurs; however, there is a paucity of data regarding collateral damage (defined as the need for unintended lead extraction, or loss of lead integrity or dislodgement) that occurs in the retained leads. We conducted this study to assess for collateral lead damage.

METHODS

STUDY DESIGN. A retrospective study of all patients who underwent incomplete CIED removal at the University of California, San Diego (UCSD) Health System from September 2010 to September 2015 was performed for a total of 108 patients. Electronic medical records were analyzed for baseline demographics, clinical characteristics including ischemic or nonischemic cardiomyopathy, left ventricular ejection fraction when available, comorbid conditions, oral anticoagulants, types of devices, extracted leads' position, method of extraction, and procedural complications, if any. The integrity of previously functioning leads was established before the extraction and after the extraction prior to skin closure. The CIED system was then interrogated in standard follow-up and data collected up to 12 months of follow-up. Clinically relevant changes in lead parameters including impedance, threshold, and P- and R-wave amplitudes were assessed and documented (Table 1). Presence of lead noise was also assessed before and after the lead extraction as well as on follow-up visits up to 12 months. The study was approved by the UCSD institutional review board. The data were extracted by 2 coauthors and checked for interobserver variation by random assignment of 5% of cases for cross checking of extracted data and accuracy. The patients were excluded if follow-up data were not available (either in UCSD health records or with patients' referring physicians) or if the complete CIED system was extracted. Leads from all main manufactures were represented among the patients included in the study.

PROCEDURE TECHNIQUE. All elective lead extraction patients underwent gated computed tomography scanning of the chest and a CXR within 2 weeks of their procedure date. Patients who were referred from other facilities underwent the studies on admission. Their CIEDs were interrogated before the procedure to determine pacemaker dependence and information was obtained regarding lead type, lead duration, and fixation mechanism (active vs. passive). This

information was also obtained for any abandoned leads when possible. The procedure was conducted in a hybrid operating room, and the extraction team consisted of an electrophysiologist, cardiothoracic surgeon, anesthesiologist, cardiac electrophysiology fellow, device company representative, and operation room nursing team.

All patients underwent 5-F arterial sheath insertion in the femoral artery and 6-F venous sheath in the femoral vein, in addition to an internal jugular vein central line placement. If the patient was pacer dependent, temporary venous pacing was established via the femoral venous sheath. Tachytherapies were disabled for implantable cardioverter-defibrillators (ICDs) and rate response was turned off with the device programmed to VVI 40. A transesophageal echocardiogram probe was placed for continuous monitoring and high quality fluoroscopy was used throughout the procedure. PEAK PlasmaBlade (Medtronic, Minneapolis, Minnesota) was used for tissue dissection to reduce the risk of thermal injury to the surrounding structures including CIED leads (4). Regular stylets, locking stylets, clearing stylets, laser sheaths (Spectranetics, Colorado Springs, Colorado), and controlled mechanical rotational sheaths (Cook Medical, Bloomington, Indiana) were used where applicable. After opening the CIED pocket, the pulse generator was removed and regular stylets were placed in the leads to disengage the active fixation mechanism (when applicable) while applying traction (a stiff stylet was also placed in the collateral leads to reduce lead buckling during the extraction). The next step was to exchange the nonlocking stylet with a locking stylet and advance a laser sheath (along with an outer sheath) over the lead. The size of the sheath was determined by the size and type of lead (pacer lead, single- or dual-coil ICD lead) and was upsized if excessive resistance was encountered per the primary extractor's discretion. If there was significant binding or evidence of significant calcifications, a mechanical rotational sheath was used as needed. After the lead was removed, transesophageal echocardiogram was used to assess for any effusion and all leads were sent to pathology for analysis.

STATISTICAL ANALYSIS. We expressed continuous variables as mean \pm SD and categorical variables as percentages. A Student *t* test with unequal variances and Fisher exact test were used to assess the association between baseline variables shown in Table 2. To assess the impact of various covariates on lead malfunction, we used logistic regression analysis and Fisher's exact test as shown in Table 3. The following models were assessed using generalized estimating equations.

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