When You Have Nowhere to Look, You Look Where You Can

Melanie Maytin, MD, MSc; Laurence M. Epstein, MD

Although many physicians implant cardiac implantable electronic devices, only a small fraction performs transvenous lead extraction (TLE). This has led to inconsistent and, at times, inappropriate patient management. Despite clear Class I recommendations for lead extraction for infected devices, patients all too often receive multiple debridements and rounds of antibiotics for device-related infection. In addition, in cases of device system upgrade and lead malfunction, lead after lead is often added, sometimes involving tunneling and frequently resulting in the elimination of vascular access. Why are more of these patients not offered or referred for lead extraction? In many cases, we believe the reason is unfounded fear of the procedure and a knowledge gap. In a survey performed by Spectranetics (Colorado Springs, CO), cardiologists perceived the major complication rate associated with the extraction procedure itself to be >5% and the mortality rate to be nearly 1.5%. Henrikson and colleagues performed a similar survey among 252 electrophysiologists (63% of whom identified themselves as performing TLE) with similar observations. More than 75% of respondents perceived the morbidity risk associated with TLE to be ≥2%, and close to 30% of respondents estimated the risk to be ≥5%. Among the group surveyed, the mortality risk with TLE was similarly perceived to be excessive despite the surprising preponderance of “extractionists” among the group. It is not surprising that more patients are not referred if this is the impression. In a global survey of 820 clinicians addressing the understanding of cardiac implantable electronic device infection and lead management, ≤50% of all respondents failed to correctly identify and implement Class I recommendations for device-related infection despite >60% of respondents identifying themselves as performing TLE. Clearly, data and education are needed, both of which are lacking. In this issue of Circulation, Deshmukh and colleagues present data from the National Inpatient Sample to give us a glimpse of the state of transvenous lead removal from 2006 to 2012 in the United States. The National Inpatient Sample is a large administrative database that is part of a family of databases developed for the Healthcare Cost and Utilization Project. It is the largest publicly available all-payer inpatient database and represents ~20% of the hospitals in the United States. In this analysis, from 2006 to 2012, the authors report that close to 92,000 patients underwent extraction, with a relatively small increase in the rate of transvenous lead removal from close to 11,000 in 2006 to just over 12,000 in 2012, an observation that does not coincide with available industry and published data. Industry estimates of TLE procedures range from 9,000 extractions in 2006 to 19,000 extractions in 2012 (Spectranetics, personal communication, B. Safyan). The exponential increase in TLE has similarly been described by a number of experts and high-volume centers. The patients were mostly male and white, mirroring the overall device population. More than 61% of extractions were performed for noninfectious indications. Infection was the indication for extraction in <30% of extractions in 2006 and was never >50% in any year. This is another discordant observation in direct contradiction to the published literature. Current estimates are that two thirds of all TLEs are performed for device-related infection, with infection rates increasing out of proportion to device implantation rates. In addition, Greenspon et al described a >200% increase in cardiac implantable electronic device infections from 2004 to 2008 using the National Inpatient Sample data set. The study describes complications and deaths that occurred during the index hospitalization in which patients underwent transvenous lead removal procedures. The reported overall complication rate was 8.3% with an in-hospital mortality of 2.2%. The most common complications included bleeding requiring transfusion (2.6%), respiratory compromise requiring mechanical ventilation (2.3%), vascular injury (2.0%), pneumothorax/ hemothorax (1.5%), and pericardial complications (1.4%). Importantly, the need for open heart surgery was only 0.2%. The rates of complications increased throughout the study period, from a low of 4.9% to a high of 10.6%. Despite the differences in defined complications in this study and defined major complications in the 2009 Heart Rhythm Society/American Heart Association Expert Consensus on TLE, the observed complication rate is far in excess of published single-center, multicenter, and registry data. Not surprisingly, the complication rate, in-hospital mortality, and costs were all higher for infectious indications for transvenous lead removal. Higher complication rates were associated with infection,
female sex, and the procedure being performed at a teaching hospital.

Although the authors should be commended for their work in collecting, analyzing, and interpreting such an exhaustive data set, we believe that this study exemplifies the limitations of large database analyses and restricts its interpretation, specifically with relation to the population sampled, complication rate reported, and trends in transvenous lead removal indication. First, the authors should be recognized for appropriately using transvenous lead removal, not extraction, in the title. Clearly, with absent data on lead/device implantation duration, it is possible that leads with implantation durations of <1 year were removed, which would not meet the definition of TLE.1 However, more important, the study population was identified using International Classification of Diseases, Ninth Revision, Clinical Modification procedure codes 37.77, 37.79, 37.89, or 37.99. Only 1 of these procedure codes is specific to lead removal. The other codes are for device pocket revision or relocation, revision or removal of the device, or “other operations on the heart and pericardium.” Additionally, the procedure codes for revision of a lead (37.75) or replacement of a transvenous atrial or ventricular lead(s)/removal or abandonment of existing transvenous or epicardial lead(s) with transvenous lead replacement (37.76) are notably absent.14 Consequently, the sample patient population is far from representative of the inpatient TLE population. In the evaluation of infectious indications for transvenous lead removal, it is surprising that the authors omitted the ubiquitously used International Classification of Diseases, Ninth Revision diagnosis code “infection and inflammatory reaction to a cardiac device, implant and graft” (996.61). Moreover, the National Inpatient Sample is an inpatient database that underwent a major redesign in 2012. Data from 2011 and earlier were a sample of hospitals that included all discharges from those hospitals, and data beginning in 2012 are a sample of discharges from all hospitals participating in the Healthcare Cost and Utilization Project. Not only does the sampling redesign significantly affect the population sample and validity of trends/yearly comparisons, but the very fact that the patient population is limited to inpatients eliminates a major portion of the TLE population and introduces significant selection bias. TLE is increasingly becoming an outpatient procedure with only the sickest patients or those with complications being admitted as inpatients. Therefore, comparing the study population with the population of published TLE data is inappropriate and likely explains the significant differences between the authors’ observations and available multicenter and registry data, specifically with respect to procedure volume and indications.

The authors state in their Conclusion that “The number of adverse events in the literature likely underestimates the actual number of complications associated with transvenous lead extraction.” Although we agree with this statement, we also believe that this article overestimates the actual number for several reasons. The individual complications included in the overall postprocedural complication rate in this study represent a combination of both major and minor complications,1 with an unknown time period from transvenous lead removal to complication occurrence limiting the ability to compare these findings with available published data. Furthermore, the International Classification of Diseases, Ninth Revision codes used are far-reaching; for example, the complication “hemorrhage requiring transfusion” encompasses not only “hemorrhage accompanying a procedure” (998.11) but also “hematoma accompanying a procedure” plus “transfusion of blood” (998.12+99.0), a minor complication that is a result of the pocket procedure, not lead extraction. Additionally, given the limited data available in an administrative database, it is impossible to ascertain whether the complication was a direct result of the extraction procedure. Many of the complications could have been attributable to pre-existing conditions or to the reimplantation of the new lead. For example, pneumothorax is a very rare complication of TLE but a well-known complication of lead implantation, occurring in ≈1% to 2% of implantations. In addition, by the time many patients with endocarditis are referred for extraction, they have pre-existing septic pulmonary emboli and respiratory failure. Without adjudication of adverse events, it is impossible to establish a causal relationship with the transvenous lead removal procedure. In the Lead Extraction in the Contemporary Setting (LExICon) Study15 that included small-, medium-, and large-volume centers, all cases were adjudicated, and the TLE-related major complication rate was just under 2% compared with the major/minor complication rate of 8.3% (4.9%–10.6%) reported in the present study. Surprisingly, despite the differences in procedure populations, all-cause hospital mortality rates were very similar (1.86% in LExICon and 2.2% in the present study). The authors suggest that the mortality related to lead extraction is higher than previously reported. In fact, the vast majority of direct TLE-related mortality results in the need for emergent surgical intervention. In LExICon, the all-cause mortality was 1.96%, but lead extraction–related mortality was only 0.28%. In the present study, all-cause mortality was 2.2%, but there was a surgical intervention rate of only 0.2%, suggesting that the lead extraction–related mortality was, in fact, similar. The European Lead Extraction Controlled (ELECTRa) Registry, a “real-world” experience of TLE, prospectively enrolled 3524 patients from 76 centers in 19 countries between 2012 and 2014. Centers of all levels of TLE volume were included. The major complication rate was 2.7% and all-cause mortality was 1.4% with a 0.7% cardiovascular mortality rate, similar to the outcomes observed in LExICon.16

My (Dr. Epstein’s) father was an accountant and would sit for hours adding columns of numbers with his adding machine. He always told me that even if the numbers were off by only 2 cents, it was important, because it may indicate a much larger problem. When we read this manuscript, several things just did not “add up”: the percentage of extractions performed for infection and the overall number of transvenous lead removal procedures, to highlight a couple. We agree with the authors that the vast majority of the published data related to lead extraction emanate from high-volume referral centers. However, these centers are more comfortable with extraction, are more likely to extract for what has been called Class II indications such as failed leads and prophylactic extraction of advisory leads, and are more likely to be referred sicker patients with more comorbidities in need of more complex procedures. Even in these centers, the majority of extractions...
are performed for infection. We have traveled throughout the country to many community hospitals to spread the gospel of lead management, and at many of these centers, the only indication for TLE is infection. These “reluctant extractors” often only rarely perform Class II–indicated extractions. In the LExiCon study, the largest prospective observational trial of small-, medium-, and large-volume centers, infectious indications accounted for 57% of extractions from 2004 to 2007. In addition, the lead management community experienced the effects of the Fidelis advisory in 2007 and the Riata advisory in 2010. Most extraction centers saw an increase in the percentage of extractions for noninfectious indications for extraction over the course of the study period as opposed to a decrease. We cannot imagine a time when <30% of the extractions performed in the United States were for infection. In addition, in the real-world experience reported by the ELECTRa Registry, there was a 53% incidence of device-related infection indications for lead extraction. This emphasizes the limitations of large database research and how results must be critically interpreted before extrapolation to real-world results.

This study highlights the need for a prospective, national registry to truly show what is happening in the real world. Although the American College of Cardiology’s National Cardiovascular Data Registry for implantable cardioverter-defibrillators now includes lead revision data, it will not allow for centers to track their own outcomes and to provide pooled data to answer important questions. There are 15 centers on board, and we welcome others to join.

Although accurate national data are critical to the lead management community, the outcomes of the individual physician and center performing each individual patient’s extraction are what really matters to the patient. A patient’s decision to undergo an extraction or not involves an individual risk versus risk analysis. For a patient to perform such an analysis, we must provide accurate data about our own individual practices.

Disclosures
Dr Maytin is a consultant for Biotronik, Medtronic, Spectranetics, and St. Jude Medical. Dr Epstein has received research grants from and is a consultant for Boston Scientific, Medtronic, Spectranetics, and St. Jude Medical and has equity in and served as a board member for Carrot Medical.

References


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