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Lead Extraction in the Contemporary Setting: The LExICon Study. An Observational Retrospective Study of Consecutive Laser Lead Extractions

Oussama Wazni, MD
Cleveland Clinic

Laurence M. Epstein, MD
Brigham and Women's

Roger G. Carrillo, MD
Mt. Sinai Medical Center

Charles Love, MD
Ohio State University

Stuart W. Adler, MD
St. Paul Heart Clinic

See next page for additional authors

Authors
Oussama Wazni, MD; Laurence M. Epstein, MD; Roger G. Carrillo, MD; Charles Love, MD; Stuart W. Adler, MD; David W. Riggio, MD; Shahzad S. Karim, MD; Jamil Bashir, MD; Arnold J. Greenspon, MD; John P. DiMarco, MD, PhD; Joshua M. Cooper, MD; John R. Onufer, MD; Kenneth A. Ellenbogen, MD; Stephen P. Kutalek, MD; Sherri Dentry-Mabry, MSN; Carolyn M. Ervin, PhD; and Bruce L. Wilkoff, MD

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Oussama Wazni [1], MD, Laurence M. Epstein [2], MD
Roger G Carrillo [3], MD, Charles Love [4], MD, Stuart W. Adler [5], MD,
David W. Riggio [6], MD, Shahzad S. Karim [7] MD, Jamil Bashir [7], MD,
Arnold J. Greenspon [8], MD, John P. DiMarco [9], MD, PhD,
Joshua M. Cooper [10], MD, John R. Onufer [11], MD, Kenneth A. Ellenbogen [12], MD,
Stephen P, Kutalek [13], MD, Sherri Dentry-Mabry [14], MSN
Carolyn M. Ervin [14], PhD
Bruce L. Wilkoff [1], MD

From

1)Cleveland Clinic, 2) Brigham and Women's ,3) Mt. Sinai Medical Center, 4) Ohio State University, - 5)St. Paul Heart Clinic, 6)Arizona Heart Hospital, 7)University of British Columbia, 8)Thomas Jefferson University , 9) University of Virginia, 10) University of Pennsylvania ,11) Sentara Cardiovascular Research, 12)Virginia Commonwealth University , 13) Drexel College of Medicine , 14) Spectranetics Corp

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Correspondence to:

Oussama M. Wazni, MD
Director of EP Labs
Cardiac Pacing and Electrophysiology
Department of Cardiovascular Medicine/J2-2
9500 Euclid Avenue
Cleveland, Ohio 44195
Email:waznio@ccf.org
Phone: 216-444-2131
Fax: 216-636-6952

ABSTRACT

Background: The need for lead extraction has been increasing in direct relationship to the increased numbers of Cardiovascular Implantable Electronic Devices (CIED).

Objectives: We sought to examine the safety and efficacy of laser assisted lead extraction and the indications, outcomes and risk factors in a large series of consecutive patients.

METHODS: Consecutive patients undergoing transvenous laser assisted lead extraction at 13 centers were included.

RESULTS: Between January 2004 and December 2007, 1449 consecutive patients underwent laser assisted lead extraction of 2405 leads (20-270 procedures/site). Median implantation duration was 82.1 months (0.4–356.8 mo). Leads were completely removed 96.5% of the time, with a 97.7% clinical success rate where by clinical goals associated with the indication for lead removal were achieved. Failure to achieve clinical success was associated with body mass index (BMI) <25 and in low extraction volume centers. Procedural failure was higher in leads implanted for >10 years and when performed in low volume centers. Major adverse events (MAE) in 20 patients were directly related to the procedure (1.4%) including 4 deaths (0.28%). MAE were associated with patients with a BMI <25. Overall all-cause in-hospital mortality was 1.86%; 4.3% when associated with endocarditis, 7.9% (endocarditis & diabetes), 12.4% (endocarditis & creatinine ≥2.0). Indicators of all-cause in-hospital mortality were pocket infections, device related endocarditis, diabetes and creatinine ≥ 2.0.

CONCLUSIONS: Lead extraction employing laser sheaths is highly successful with a low procedural complication rate. Total mortality is substantially increased with pocket infections or

device related endocarditis, particularly in the setting of diabetes, renal insufficiency or BMI <25. Centers with smaller case volumes tended to have a lower rate of successful extraction.

Condensed Abstract:

Between January 2004 and December 2007, 1449 consecutive patients underwent laser assisted lead extraction of 2405 leads. 96.5% of leads were completely removed, with a 97.7% clinical success rate. Procedural failure was associated with longer implant duration and low volume centers. Major adverse events (MAE) related to the procedure occurred in 20 patients including 4 deaths (0.28%). All-cause in-hospital mortality was 1.86.

Laser assisted lead extraction is highly successful with a low procedural complication rate. Total mortality is increased with pocket infections or device related endocarditis, Centers with smaller case volumes have a lower rate of successful extraction.

INTRODUCTION

The need for percutaneous transvenous lead extraction has been increasingly required in direct relationship to the increased numbers of Cardiovascular Implantable Electronic Devices (CIED) and is expected to continue to grow.

Unfortunately the components of the CIED, the leads and pulse generators, do not function perpetually. As the population and the CIED ages, components of the system need to be extracted for a variety of reasons including infection, lead malfunction, venous stenosis and occlusion, as well as safety alerts. Perceptions of lead extraction safety and effectiveness and the outcomes of patients undergoing transvenous lead extraction have been based on early, relatively small trials, and a voluntary reporting of outcomes in a multicenter extraction registry (1-3). Historically the perceived risk of extraction has limited the referral and performance of this procedure to patients with life-threatening situations (Class 1 indications). Growing physician experience and the development of newer tools have impacted the outcomes of transvenous lead extraction and thereby indications.

The goal of this study was to determine the contemporary safety and efficacy of excimer laser assisted lead extraction, in a large series of consecutive patients presenting to 13 centers. In addition, the indications for extraction, outcomes and risk factors for complications and mortality were determined.

Methods

Consecutive patients who underwent laser assisted lead extraction (LALE) utilizing the CVX-300® (Spectranetics, Colorado Springs, CO) and the SLS II®

(Spectranetics) laser sheath between January 1, 2004 and December 31, 2007 were included. Patients were excluded if another non-laser, non-traction device was utilized in the same procedure.

Data was collected at 13 sites in the US and Canada. A pre-study, self-reported questionnaire, to determine lead extraction caseloads over the previous four year period, and practice type (academic vs. private practice) was utilized to ensure a wide range of settings and experience. Centers were divided into 3 groups (small ≤60 cases, mid >60 and ≤130 and large >130 cases). The protocol was reviewed and approved by the institutional review board of each center.

Definitions published in 2000 in the North American Society of Pacing and Electrophysiology (NASPE, now the Heart Rhythm Society, HRS) guidance document on transvenous lead extraction were used to calculate the safety and effectiveness of the extraction procedure and the rates of procedural (radiographic) and clinical success and complications(4).

Indications for lead extraction were classified as 1) pocket infection, 2) device related endocarditis (DRE), 3) pain, 4) venous stenosis or occlusion, 5) functional but abandoned or 6) non functional leads.

Pocket infection was defined as erythema with or without purulent discharge, device erosion, fat necrosis, and/or adherence of device to the skin, which may be accompanied by pain. All other infections in the presence of a CIED were considered device related endocarditis (DRE). This included all persistent bacteremia or sepsis in the absence of another identifiable source or vegetations on the leads or valves in the presence of a device. Pain was defined as a lead extraction done to relieve pain associated

with the device and leads without suspected infection. Extraction for non functional lead status was defined as being related to a mechanical lead failure established on the basis of clinically significant alterations in pacing, sensing, lead impedance, or inappropriate tachycardia therapies.

Leads may be extracted when upgrading one system to another such a pacemaker to an ICD or a pacemaker/ICD to a cardiac resynchronization device when ispilateral venous occlusion or stenosis is encountered. In addition, concern regarding possible interference with another device, treatment of malignancy or causing another medical condition were indications for extraction. Potential future venous occlusion and infection due to superfluous abandoned leads were also reasons for extraction of the functional lead. If venous stenosis or occlusion was present, then the extraction indication was so designated, but if the concern was for abandoning leads then the indication was designated a "functional abandoned lead."

LASER EXTRACTION

Laser sheaths were employed in all cases when the leads could not be explanted by simple traction. The extraction procedure has been described in detail previously(3). In brief the lead was prepared by inserting a locking stylet into the inner coil lumen when possible. A suture is then tied onto the insulation and the locking stylet. The laser sheath was then advanced over the lead. Laser application was performed at binding sites and advanced gradually from one binding site to another until the tip of the lead was reached. Once abutting the myocardium a combination of traction and countertraction was performed and the lead was freed.

The procedural and clinical success definitions employed in this study were as defined in the NASPE 2000 Policy Statement(4). Procedural success was defined as complete or partial, and is identified for each lead extracted. Complete success was defined as the ability to remove "all lead material from the vascular space". Partial success was defined as "removal of all but a small portion of the lead; this may be the electrode, 4 cm or less of conductor coil, and/or insulation, or the latter two combined." Procedural failure is defined as "abandoning a significant length of lead (more than 4 cm) after attempted removal". Clinical success, defined as achievement of "all clinical goals associated with the indication for lead removal," was identified only once for each procedure. At a minimum, the clinical goals included: "resolution of the clinical indication for lead removal"; "absence of major complications and control of pacing status". Clinical failure was defined as the "inability to achieve all of the clinical goals" outlined above(4).

DATA COLLECTION PROCEDURES

In each institution, a patient identification log was generated which included all lead extractions. Each patient was given a unique identifier. Each medical record was reviewed from admission to discharge and an initial Data Collection Form (DCF) was completed by a trained data collector. To reduce potential bias, a blinded trained second data collector then independently reviewed the medical record and completed a second DCF on a random selection of ≥10% of the medical records and 100% of the medical records of patients who had sustained an adverse event during hospitalization.

Definitions for major and minor complications (adverse events) are described in the NASPE 2000 Policy Statement(4). A major adverse event (MAE) was defined as

"any complication related to the procedure that required procedural intervention or transfusion to prevent death, threat to life, or any complication related to the procedure that resulted in death or serious harm to bodily function or structure". A minor adverse event was "any complication related to the procedure that required medical or minor procedural intervention to remedy or prolonged hospital stay or limited the patient's function but did not threaten life, cause death or cause serious harm to bodily function or structure".

The clinical events committee (CEC) reviewed all adverse events. The CEC members were blinded to all patient and site identifiers. The events were reviewed and adjudicated as Major or Minor and categorical relationships were defined in relation to 1) LALE procedure, 2) another procedure, or 3) pre-existing conditions. Within the pre-existing conditions category, specific medical conditions or treatments were further evaluated for relationship to the event, including: sepsis, use of anticoagulants, renal insufficiency, and loss of biventricular pacing.

DATA ANALYSIS

Data analyses were conducted using the SAS system, version 9.1 (SAS Institute Inc., Cary, NC, USA). Descriptive statistics for continuous variables were expressed as mean, median, standard deviation and ranges. Discrete variables were expressed as frequencies and percentages. Proportions, such as implant duration category versus procedural/clinical success and procedural MAE versus center size, were compared using the chi-squared test. Fisher's exact test was used for small cell sizes (<5). Median implant duration of lead time for MAE versus those leads without MAE was assessed utilizing the Wilcoxon Rank Sum Test, due to lack of normality. All tests of significance

were two-sided, with statistical significance set at $p<0.05$. In addition, surrogate modeling was performed for the duration of lead implant in patients who had more than one lead extracted. The longest duration of any lead with LALE was then used to represent the individual patient.

Multivariate logistic regression analysis was performed to determine predictors within 6 categories: 1) Clinical failure, 2) Procedural failure, 3) Procedural MAE, 4) All-cause in-hospital mortality, 5) All-cause in-hospital mortality in the infected population (DRE+ pocket infection), and 6) All-cause in-hospital mortality in the DRE population. Predictors were selected from the previously conducted univariate analyses where the coefficients were significant. Additional covariate relationships were analyzed, interaction/confounding testing was also performed to produce a predictive model at $p<0.05$. Model-building strategy and goodness of fit test was derived from Hosmer and Lemeshow (5). The candidate variables included in the models included 1) Type of lead (pacer or ICD)., 2) Duration of the lead implantation, 3) Volume of procedures at the center, 4) Body mass index size <25 (underweight and normoweight), 5) Renal insufficiency defined as a pre-procedure serum creatinine ≥2.0 mg/dL 6) Diabetes, 7) Endocarditis, 8) Pocket infection, 9) Age > 65 years, and 10) Gender.

RESULTS

During the period of January 1, 2004 to December 31, 2007 a total of 1449 patients underwent LALE in the 13 centers (See Appendix for Centers and cases/ center). Physicians had a mean of 11.4 ± 6.32 (range 2.0, 19.0 years, median 13.0) years of experience with lead extraction and a mean of 7.87 ± 3.56 (range 2.0, 13.0 years, median 8.0) years of experience with LALE at the study completion. In these patients extraction

was attempted on 2405 leads including 1684 pacemaker (70%), 703 defibrillator (29.2%), and 18 (0.7%) unknown leads. Most leads were active fixation leads (1226 Active, 832 Passive, 347 Unknown). Patient characteristics can be seen in Table 1. The mean age of patients was 63.4±17.1 years; 71.8% of the patients were male and the mean left ventricular ejection fraction (EF) was 37.7%±16.6. Diabetes Mellitus was present in 403 (27.8%), and 728 (50.2%) had coronary artery disease. Among the 349 patients with a reported NYHA class, 41.6% had Class III heart failure symptoms at the time of the extraction. Most leads were extracted from the right ventricle (63.5%, n=1528) and right atrium (32%, n=769); 11 (0.5%) were located in the SVC, 70 (2.9%) were coronary sinus leads and 27 (1.1%) were unknown. The median implant duration was 82.1 months (range 0.4–356.8). The number of patients at each site ranged from 20 to 270 patients.

The indications for lead extraction in the study are presented in Table 2. The most common indication for extraction was infection (56.9%, n=825) with 29.2% (n=423) related to DRE and 27.7% (n=402) due to pocket infections. Venous stenosis or occlusion was noted in 4.5% (n=65), and pain at the device implant or lead insertion site accounted for 0.8% (n=12). Non-functional leads represented 26.6% (n=386) and functional but abandoned leads represented 11.1% (n=161). Of the functional and non functional leads extracted the Medtronic Sprint Fidelis® lead, with or without documented failure, contributed 2.5% (n=61) of the patients with 100% clinical and procedural success.

Overall, 2322 leads (96.5%) were completely and 56 leads (2.3%) were partially removed with a combined success rate of 98.8%. Clinical success was achieved in 1416 patients (97.7%). (Table 3)

The multivariate model indicated that failure to achieve clinical success was associated (model likelihood ratio of p=0.0128) with patient body mass index (BMI) < 25 and when the extraction center volume was ≤ 60 cases over a period of 4 years. In contrast the multivariate model indicated that failure to achieve procedural success was associated (model likelihood ratio of p=0.0005) with lead implantation durations of ≥ 10 years and when the extraction center volume of extraction was ≤ 60 cases over a period of 4 years.

PROCEDURAL ADVERSE EVENTS

All-cause adverse events collected during the hospitalization included 63 major adverse events in 58 patients (4.0%), and 27 minor adverse events in 26 patients (1.8%). Of these, 24 major events in 20 patients (1.4%) and eight minor events in eight patients (0.6%) were directly related to the lead extraction portion of the procedure. In addition, a total of 27 patients (1.86%) died during the index hospitalization of which four (0.28%) were deemed to be directly related to the extraction procedure. Table 4 lists all major and minor adverse events noted in the study. The multivariate model indicated that only patients with a BMI <25 (p=0.0132) were more likely to experience a procedural MAE related to the lead extraction procedure. Procedural MAE were not significantly associated with any other parameter as listed in Table 5.

IN HOSPITAL MORTALITY AND COMORBIDITIES

Patients requiring transvenous lead extraction have overlapping comorbidities which increase the risk for death during their hospitalization. The multivariate model indicates that patients with creatinine ≥ 2.0, diabetes mellitus, BMI <25 and with

infection (pocket infection or DRE) were all at increased risk of death (model likelihood ratio of $p<0.0001$).

Although mortality was higher in patients with DRE compared to pocket infection, this difference was not statistically significant 4.35% vs. 1.7% ($p=0.06$). The overall demographic comparisons of patients with infection versus those without infection are listed in Table 6.

There were 825 (56.9%) patients with device related infections, 423 with DRE and 402 with pocket infections. The infected patients were more likely to be male, older and had slightly better ejection fractions. In addition, they were more likely to be diabetic (35.0% vs. 18.3%, $p<0.0001$) and have renal insufficiency with a creatinine ≥ 2.0 mg/dl (16.0% vs. 6.4%, $p<0.0001$). The all-cause in-hospital mortality in infected patients was also increased (3% vs. 0.3%, $p<0.0001$, OR=9.7), but there was no association with clinical success rate or procedure related MAE rates. Table 6 Separately, the DRE patient cohort in-hospital mortality was much higher (4.3%, 18/423) compared to the pocket infection patient cohort (1.7%, 7/402). When diabetes or renal insufficiency was additionally present, the DRE patients fared more poorly. Among those DRE patients with concomitant diabetes, 7.9% (13/164) died versus 2% (5/253) without a history of diabetes ($p=0.0075$, OR 4.3). The odds of an in-hospital mortality were 7.0 times higher in DRE patients with renal insufficiency (creatinine ≥ 2.0) than among those with DRE and creatinine <2.0 (12.4% vs. 2.0%, $p<0.0001$).

DISCUSSION

We evaluated the safety and efficacy of laser assisted lead extractions using current indications based on the NASPE 2000 Policy Statement. Since the initially reported experiences which employed earlier editions of the extraction tools and largely represented the learning curve with laser extraction techniques, this consecutive patient experience represents the mature contemporary practice in multiple centers with varying degrees of experience. Each of the earlier studies addressed the efficacy and safety of the initial models of laser sheath. In this study, the modified SLS II sheath was employed, which has improved mechanical properties enhancing advancement over the lead. Compared to previous studies, LALE was associated with higher procedural and clinical success and a similar procedural related major complication rate, but a lower procedural mortality rate. BMI<25 predicted procedural MAE and clinical failure, while renal insufficiency, diabetes, BMI <25 and presence of pocket infection or DRE were all independent predictors of all cause in-hospital mortality. The somewhat higher all-cause in-hospital mortality of 1.86% reflects the complex co-morbid conditions of this patient population, especially DRE.

The original PLEXES trial, a randomized prospective clinical trial, compared the first iteration of the 12-French SLS laser sheath to a non-laser cohort in 301 subjects with 465 chronic pacemaker leads(3). The procedural success in the laser group was 94% with an associated major complication rate of 1.96% compared to 64% success rate with the use of only locking stylets and nonpowered telescoping sheaths . The use of laser tools resulted in quicker lead extraction; 10.1 ± 11.5 min vs. with 12.9 ±19.2 min without laser

(p , 0.04) (3). Subsequently, when the total initial experience of laser lead extraction in the United States was reported by Byrd et al on 2,561 pacing and defibrillator leads from 1,684 patients at 89 sites, the procedural success rate was 90% with a major complication rate of 1.9% with an in-hospital death rate of 0.8% (6). Only implant duration independently predicted procedure failure and female gender was the only multivariate predictor of complications(5). In agreement with the study by Byrd et al, we found that longer implantation duration was associated with procedural failure. In contrast with Byrd et al, we found no association between gender and adverse events directly related to lead extraction; instead BMI <25 (underweight and normal weight) also predicted procedure related MAE. Additionally, in our study clinical or procedural failure was associated with low procedure volumes.

Device related infections continue to be the most common indication for extraction (2,3,6,7). Local infection at the pocket site has a variety of presentations including erosion, erythema, frank purulent discharge or wound dehiscence, which may be accompanied by pain. It is important to recognize and treat these local manifestations of infection promptly and effectively so as to prevent festering indolent infections which may lead to bacteremia and possible resultant endocarditis as these latter more serious sequela are associated with a higher mortality rate(6). In our study, although the in hospital mortality consequence of DRE was numerically larger, the less impressive manifestations of pocket infection were statistically not distinguishable from the DRE patients. While there is clear indication that the entire device system should be removed in the presence of systemic infection, there has continued to be some controversy regarding localized pocket infection. The NASPE 2000 guidelines stated that it was

acceptable to remove the device and cut the exposed parts of the leads. Such a strategy is proving to be unsuccessful and puts the patient at risk of smoldering infection which could spread and increase the patient's risk of death (8).

In this study, non-pocket infections, which presented as bacteremia, lead or valvular vegetations, and/or sepsis were defined as device related endocarditis. We elected to classify this group of patients as having DRE because when there is persistent bacteremia it is assumed that any intravascular device is seeded and therefore infected. About half of all infections were classified as DRE, and these patients were older and had a higher rate of diabetes and renal insufficiency (defined as a creatinine ≥2.0). Despite the fact that the clinical success and MAE rates were similar to patients with no DRE, the risk ratio for all-cause in-hospital mortality in this group of patients was 4.8 times higher (4.3%). Patients with DRE and concomitant diabetes had a four times higher mortality risk (7.9%) and DRE plus renal insufficiency yielded a 6.3 times higher mortality risk (12.4%). This is all compared to the mortality rate in patients without DRE (patients with either pocket infections or not infected) of 0.9%.

The literature reports DRE represents 10-23% of all device infections (8-10). DRE represented 51% of device infections in this analysis and is likely due to the broader definition employed in our study and the referral patterns of some study centers. This broader definition was chosen as the clinical implications of endocarditis, bacteremia and sepsis in the setting of a CIED are the same: each requires complete extraction of the CIED and prolonged antibiotic therapy.

Mortality rates of DRE treated medically with antibiotics alone are very high, as much as 66% in some series; this is compared to a strategy that employs device

extraction where mortality in the literature is reported to be 13-21% (11-14). In our study the all-cause in-hospital mortality rate for the DRE population was 4.3%, 1.7% for pocket infection and 0.3% for all non infected patients. This emphasizes the seriousness of bacteremia and/or vegetations in patients with a CIED system, but also the seriousness of pocket infections. In such patients it is imperative to extract and remove the pulse generator, the active and abandoned leads and debridement of the infected pocket tissue.

In agreement with previous studies the presence of nonfunctional and abandoned leads was the second most common indication for extraction(2,3,15). Extraction of leads in non-infected patients is considered controversial by some physicians, since there are alternative approaches. Non functional leads may be abandoned rather than extracted. As the duration of implant for devices and leads increases along with an aging population, a large number of leads become nonfunctional. These can either be extracted at the time of another planned procedure such as an upgrade, or be left to be extracted when there is no other choice, such as in the presence of infection.This may result in a large number of leads in any one patient which over time may pose an increased risk of complications. Abandoned leads may also serve as a nidus for lead related endocarditis. In patients with device implants of more than 6 months, endocarditis usually resulted from bacteremia from a remote source(16).. Suga et al. reported that up to half of all abandoned pacemaker leads (611/1207) in their cohort became nonfunctional. They found that more abandoned leads were associated with a greater number of complications(17). Silvetti et al. reported on abandoned leads in young patients. Five and 10 years after lead abandonment, 2 patients developed lead endocarditis of a total of 18 patients with abandoned leads. The authors concluded that abandonment just postpones inevitable lead

extraction(18). In this study we found that the success rate was high and the complication rate exceeding low for the removal of non-functioning leads. Extraction after some years of abandonment may be more difficult and be associated with increased risk. In this study there was a progressive increase in procedural failure with prolonged implantation duration. The cumulative rate was 0.75% at 5 years, 0.93% at 10 years, 1.2% at 15 years, 2.4% at 20 years and 10.9% at 25 years. Procedural failure was statistically increased when leads were implanted for >10 years. Extraction of leads may also be needed to establish and retain venous access if the target vein is occluded in a situation when there is a need for upgrade from a pacemaker(19). In this study, extraction for this indication was also associated with a high success rate and low complication rate. When considering extraction for a non infection related indication it is very important to weigh the risks for a particular patient, including operator experience, against the risk of abandoning these leads. The decision to extract should be individualized and discussed in detail with the patient and family.

It is at this point where the consideration of center laser lead extraction experience is most important. Operator experience with laser lead extraction is important in determining clinical outcome. In this study, the small centers had a higher cumulative procedural MAE. A less experienced center (≤ 60 cases) was also associated with procedural and clinical failure. These findings are in agreement with prior studies demonstrating a significant learning curve for this procedure (20). Therefore, centers should consider their extraction volume when deciding to perform this procedure and whether extractions should be referred to higher volume centers.

LIMITATIONS

The major limitation of this study is its retrospective nature. Although this study is a consecutive series, patients who did not undergo laser assisted extraction were not included. Therefore there could have been selection bias, but the bias was most likely to the most challenging clinical scenarios as laser assisted extraction is reserved for leads with ingrown tissue and inability to be removed with traction only. It is possible that the high success rate and low complication rates in this study are due to the very experienced centers and operators in this study. However, in the community these more challenging cases are usually referred to centers experienced in LALE

Despite this limitation, the study is still valuable because it represents the current "real world" experience with LALE. Follow-up was limited in this study to hospital discharge or death. The study found a significant mortality in patients with DRE. A longer follow-up period would have been valuable in determining the ultimate outcomes in this patient population.

We only studied patients undergoing laser lead extraction. Other techniques are currently used. When compared to only countertraction sheaths, powered tools are much more effective as the results of the PLEXES trial revealed when this was compared to Laser powered sheaths. Electrosurgical dissection sheaths that use radiofrequency are also currently in use and achieve a much higher complete extraction rate than non powered countertarction sheaths 93% vs 73%. The electrosurgical powered sheaths also resulted in less time needed for complete extraction 9.6±6.2min vs. 21±9 min (20).

A new Evolution Mechanical Dilator Sheath (Cook Medical) with a stainless steel bladed rotating tip has been recently introduced and described (21). However the efficacy and safety has not been studied in a large patient population and has not been compared

to standard tools. There have been no studies comparing the different powered tools to each other.

CONCLUSION

Transvenous laser assisted lead extraction, is highly successful with a low procedural complication rate for a wide range of indications. Device related infection was the most common indication for lead extraction and both device related endocarditis and pocket infections carry a substantial in-hospital mortality risk despite successful removal of the infected device and leads. Therefore an increased emphasis must be placed on techniques that reduce the potential for device related endocarditis. Indicators of a decreased clinical and procedural success include average to small body mass index, lead implantation duration of over 10 years and extraction centers with small extraction volumes. The single indicator of lead extraction associated complications is an average or small body mass index, while in hospital mortality is increased by a clinical history of pocket infection or device related endocarditis as well as diabetes and renal insufficiency.

Table 1: Demographics & Risk Factors

1449 Patients; 2405 Leads	Results
AGE Gender	63.4±17.06 yrs 71.8% Males (n=1041)
EF	37.7±16.57 %
DM [a]	403 (28.1%)
CAD [b]	728 (50.1%)
ICD	703 (29.2%)
NYHA Class III [c]	145 (41.6%)

a: 1433 patients had data regarding history of DM available
b: 1435 patients had data regarding history of CAD available
c: 349 patients had data regarding NYHA Class available

Table 2: Indications for Lead Extraction

1449 Patients	Results
Infection	825 (56.9%)
DRE: Sepsis/Endocarditis/Bacteremia	423 (29.2%)
Pocket Infection/Erosion – No Bacteremia	402 (27.7%)
Functional, Abandoned Leads	386 (26.6%)
Nonfunctional Leads	161 (11.1%)
Venous Stenosis/Occlusion	65 (4.5%)
Chronic Pain at Device or Insertion Site	12 (0.8%)

Table 3: Procedural & Clinical Success

Procedural Success (per Lead)	**n (%)**
Complete	2322 (96.5%)
Partial	56 (2.3%)
Combined Complete and Partial	2378 (98.8%)
Failure	27 (1.1%)
Total	2405
Clinical Success (per Patient)	**n (%)**
Success	1416 (97.7%)
Failure	33 (2.3%)
Total	1449

Table 4: Adverse Events

All Cause Adverse Events	**n (%)**
Death	27 (1.86%)
Bleeding Requiring Transfusion	17 (1.17%)
Hematoma requiring drainage	13 (0.90%)
Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair	9 (0.62%)
Vascular tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair axillary artery tear requiring surgical repair	6 (0.41%)
Thrombosis of implant vein resulting in medical intervention	4 (0.28%)
Arrhythmia requiring cardioversion	3 (0.21%)
Hemothorax from any source requiring transfusion	2 (0.14%)
Pulmonary embolism not requiring surgical intervention	2 (0.14%)
Respiratory failure without arrest	2 (0.14%)
Pulmonary embolism requiring surgical intervention	1 (0.07%)
Stroke	1 (0.07%)
Vascular repair near the implant site or venous entry site	1 (0.07%)
Pericardial effusion not requiring pericardiocentesis or surgical intervention	1 (0.07%)
DVT lower extremity, post op	1 (0.07%)
Total Events	90
Minor Adverse Events Directly Related to Lead Extraction	**n (%)**
Thrombosis of implant vein resulting in medical intervention	3 (0.21%)
Arrhythmia requiring cardioversion	2 (0.14%)
Pulmonary embolism not requiring surgical intervention	1 (0.07%)
Respiratory failure without arrest	1 (0.07%)
Vascular repair near the implant site or venous entry site	1 (0.07%)
Total Events (Among 8 Patients)	8
Major Adverse Events Directly Related to Lead Extraction	**n (%)**
Cardiac avulsion or tear requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair	9 (0.62%)
Vascular tear (including axillary artery tear) requiring thoracotomy, pericardiocentesis, chest tube, or surgical repair	6 (0.41%)
Bleeding Requiring Transfusion	4 (0.28%)
Death secondary to another major complication {3 Vascular tears (2 SVC, 1 SVC/RA), 1 Cardiac Tear (RV)}	4 (0.28%)
Hemothorax from any source requiring transfusion	1 (0.07%)
Total Events (Among 20 Patients)	24

Table 5: Demographic Characteristics: Procedural MAE

MAE n=20	**n (%)**	**p-value**
Center Size (LALE experience over 4 yr study period)		
≤60 cases	6 (2.88%)	0.0532
>60 -≤130 cases	8 (1.70%)	
>130 cases	6 (0.78%)	
Location		
EP Lab	12 (1.43%)	1.00
OR	8 (1.36%)	
Anesthesia		
General	9 (1.16%)	0.68
IV Sedation	9 (1.58%)	
Unknown	2 (1.89%)	
Pre Op Arterial Line		
Present	17 (1.48%)	---
Absent	0 (%)	
Unknown	3 (1.07%)	
Gender		
Male	13 (1.25%)	0.66
Female	7 (1.72%)	
BMI		
< 25	11 (2.6%)	0.0164
≥25	5 (0.7%)	
Diabetes		
Yes	4 (1.00%)	0.62
No	16 (1.55%)	
Renal Insufficiency		
Cr ≥2.0	5 (3.11%)	0.05
Cr <2.0	13 (1.10%)	
Duration of Lead (Surrogate: longest lead represents each patient)		
0-5 years	4 (0.80%)	0.34
>5 to ≤10 years	7 (1.67%)	
> 10 years	6 (1.8%)	
Age	Mean (± SD)	
	64.5 ±21.4	0.78

TABLE 6: Device Related Endocarditis and Pocket Infection

	DRE + Pocket Infection [a] N (%)	Others n (%)	p-value
N	825 (56.9%)	624 (43.1%)	<0.0001
Male (n=1449)	618 (74.9%)	423 (67.8%)	0.003
Age (n=1449)	67.8 (±14.6)	57.6 (±18.3)	<0.0001
Ejection fraction ≤ 30% (n=1449)	449 (54.4%)	397 (63.6%)	0.0005
History of Diabetes (n=1449)	289 (35.0%)	114 (18.3%)	<0.0001
History of Renal Failure (CR ≥ 2.0) (n=1347)	125 (16.0%)	36 (6.4%)	<0.0001
History of Renal Failure (CR ≥ 2.5) (n=1347)	93 (11.9%)	19 (3.4%)	<0.0001
Clinical Success (n=1449)	810 (98.2%)	606 (97.1%)	0.24
Procedure related MAE (n=1449)	12 (1.5%)	8 (1.3%)	0.96
All Cause Mortality [b] (n=1449)	25 (3.0%)	2 (0.3%)	<0.0001 OR=9.7

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