Extraction of Old Pacemaker or Cardioverter Defibrillator Leads by Laser Sheath Versus Femoral Approach

Running title: Bordachar et al.; Laser versus snare for lead extractions

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Abstract

Background: Some operators routinely extract chronically implanted transvenous leads from a femoral, while others prefer a superior approach. This prospective study compared the safety and effectiveness of laser sheaths versus femoral snare extractions.

Methods and Results: 1) Single-center study: 101 patients referred for unequivocal indications to extract ≥1 transvenous lead(s) > 4 years of age were randomly assigned to extractions with a laser sheath (group I: n=50) versus a snare via femoral approach (group II: n=51). 2) Multicenter study: 358 patients underwent extraction of old transvenous leads using laser sheaths (n=218, group III) in 3 centers, and from a femoral approach (n=138, group IV) in 3 other centers. 1) Single-center study: the success and complications rates were similar in groups I and II. No patient died from a periprocedural complication. The procedural duration (51±22 vs. 86±51 min) and duration of total fluoroscopic exposure (7±7 vs. 21±17 min) were significantly shorter (each p<0.01) in group I than in group II. 2) Multicenter study: we observed 2 procedure-associated deaths in group III versus 1 in group IV. Major procedural complications were observed in 3% of patients in group III, versus 3% in group IV (p=ns). The rates of complete, partial and unsuccessful extractions were similar in groups III and IV.

Conclusions: Old transvenous leads were extracted with similar success and complication rates by the femoral and laser approaches. However, the femoral approach was associated with longer procedures and a longer duration of fluoroscopic exposure.

Key words: pacemaker lead; cardioverter defibrillator lead; femoral lead extraction; laser lead extraction; pacing lead complication
Introduction

As the rate of cardiac devices implanted increases rapidly worldwide, extractions of chronically implanted endocardial leads are being attempted by a growing number of physicians. Great progress has been made, providing implanting physicians with safer techniques and effective tools to extract pacing and cardioverter defibrillator (ICD) leads, including locking stylets, dilator sheaths, transfemoral snares, retrieval baskets and laser-assisted sheaths. However, the extraction of chronically implanted transvenous lead systems remains a complex procedure, associated with considerable morbidity and mortality. Some operators extract them routinely from a superior approach, while others prefer the femoral approach. Before powered sheaths became available, the femoral approach was often preferred, and remains the approach of choice for the removal of ruptured or cut leads. The superior approach, using a laser sheath, was studied in the randomized PLEXES trial and has since been adopted by a large number of medical centers.

In absence of a direct randomized comparison between femoral and superior approaches, we undertook 1) a prospective single-center randomized study, to compare the safety and effectiveness of laser sheath versus femoral snare extractions, and the radiation exposure associated with each, and 2) a non-randomized comparison of registries from several French centers specialized in lead extractions from the femoral or superior approach.

Methods

The criteria for inclusion in either study were 1) presence of $\geq 1$ transvenous lead implanted $>4$ years earlier, 2) unequivocal indication for lead extraction, 3) accessibility of the lead from the
subclavian or cephalic vein and 4) informed consent granted by the patient. Complete extraction was defined as the removal of the entire lead, and partial extraction as the removal of most of the lead components, except for the electrode tip or <2.0 cm of wire or insulation. Procedures were classified as unsuccessful when these endpoints were not reached. In case of failure of the femoral or superior approach, the investigator was free to choose an alternate technique to complete the extraction procedure. Procedural complications were classified as major or minor. Major complications were life-threatening or required a major treatment intervention, such as venous or myocardial perforation, pericardial tamponade, major tricuspid regurgitation, symptomatic pulmonary embolism and lead migration. Minor complications included pericardial or thoracic effusion requiring no intervention, pocket hematoma, silent pulmonary embolism and trivial tricuspid regurgitation.

**Patient groups**

*Single-center study* Between November 2007 and February 2009, 101 consecutive patients referred to the hospital of Pessac for lead extractions were randomly assigned to a laser sheath (group I; n=50) versus femoral (group II; n=51) approach. All extraction procedures were performed by a same team of 2 operators. This study was reviewed and approved by our institutional Ethics Review Committee.

*Multicenter study* The purpose of the multicenter study was to compare the experience of 6 medical centers, which have expertise in the femoral or superior approach. From January 2007 to December 2008, 356 patients with unequivocal indications underwent extractions of ≥1 transvenous lead(s) implanted > 4 years before the procedure. In 218 consecutive patients (group III), the leads were extracted from a superior approach at 3 separate centers, and in 138
consecutive patients (group IV), the leads were extracted from a femoral approach at 3 other centers. In each center, individual patient data were consecutively collected and entered into a digital database.

**Extraction techniques**

**Femoral approach** The technique of femoral lead extraction implemented in this study has been previously described. The procedure was performed under general anesthesia in a surgical suite, with the chest and abdomen prepared for emergency sternotomy. The standard procedure started with removal of the generator and liberation of the proximal end of the lead. A locking stylet was introduced and advanced as far inside the lead as possible. Once in place, the stylet was locked in its position. For leads with retractable screws, withdrawal of the screw was attempted. In a second step, under fluoroscopic surveillance, the distal end of the lead was detached by continuous and gradual traction to allow its snaring. Great care was taken to avoid excessive traction that might uncoil the lead. Femoral extractions were performed by means of a 14F sheath or a large 16F sheath with a Byrd Workstation™ hemostatic retrieval set (Cook Vascular, Bloomington, IN), inserted via the femoral vein and advanced through the inferior vena cava into the right atrium. A Dotter™ helical basket (Cook Vascular) or a Needle’s Eye® Snare (Cook Vascular) was used to grasp the lead floating inside the atrium, which was drawn into the sheath and extracted. If the distal lead fixation was not successfully detached from its myocardial insertion, a Needle’s Eye® Snare was used, as previously described. If the femoral approach was unsuccessful, the investigator was free to choose any alternate technique to complete the extraction procedure.
Superior approach

Our technique of superior extraction has been described previously. The initial steps and surgical preparation were the same as those used for the femoral approach. A CVX-300® Excimer laser system (Spectranetics Co, Colorado Springs, CO) was used, with 16F, 14F or 12F sheaths, as appropriate for the diameter of the lead. The laser and outer sheaths were advanced over the lead body to the first site of fixation, before the delivery of 5 – 10 sec bursts of excimer laser energy, separated by 10 sec interruptions (while the laser sheath was advanced under gentle pressure and traction was applied on the locking stylet) to ablate the tissue and free and advance the sheath to the next binding site. The sheath was usually advanced over the lead until its end was a few mm away from the endocardium. The outer sheath was advanced and countertraction was applied to remove the lead. If the laser approach was unsuccessful, the investigator was free to choose any alternate technique to complete the extraction procedure.

Patient follow-up

A chest X-ray and an echocardiogram were systematically obtained before and within 48 h after the extraction procedure. The patients were seen in the ambulatory department within 2 months after their discharge from the hospital.

Statistical analysis

In the single-center study, the time required to remove all the targeted leads and the duration of fluoroscopic exposure were recorded. The procedural success rate, procedural complications, duration of fluoroscopic exposure and overall duration of the procedure were compared between the 2 study groups. In the multicenter study, the data from all medical centers were pooled and
the procedural success and complications rates were analyzed. The patients included in the single-center study were excluded from the multicenter analysis. Means of continuous variables were compared by Student’s t-test at 5% level of significance, after assumption of equality of variance with the Fisher’s test (FET). Differences in dichotomous categorical variables were considered significant when the Chi-square test (or FET in presence of limited sample sizes) yielded a p value <0.05.

Results

Single-center study

Patient and lead characteristics  Table 1 shows selected baseline characteristics of the 101 patients enrolled in the randomized study. Mean age, gender distribution, lead implantation duration, number of leads extracted and indications for extraction were similar in both groups.

Success rates and complications No patient died from a periprocedural complication. The procedural outcomes were similar in both groups (p=0.99, FET). Specifically, complete extractions were achieved in 44 patients (88%) in group I, versus 45 patients (88%) in group II. Partial extractions were achieved in 5 patients (10%) in group I versus 5 patients (10%) in group II, while the procedure was unsuccessful in 1 patient (2%) in each group. The unsuccessful extraction by laser was completed from the femoral approach with complete extraction of the lead. The unsuccessful extraction by femoral approach was not successfully completed by any other technique. The indication for extraction was a ruptured ICD lead in a young patient. The right ventricular coil was left inside the cavity without further clinical manifestations. Therefore, the ultimate complete extraction rates after rescue, using the other technique, were 90% when the
procedure began with the superior approach versus 88% when initiated from the femoral approach, the ultimate partial extraction rates were 10% versus 10%, and the ultimate failure rates were 0% versus 2%, respectively, (p=0.62, FET).

Major complications were observed in 2 patients in group I, including 1 superior vena cava perforation requiring open-chest repair and 1 hemothorax requiring thoracocentesis. Right atrial perforation requiring sternotomy was the single major complication observed in group II. A single patient in group I suffered a minor complication (pocket hematoma) versus 2 patients in group II (1 pericardial effusion and 1 trivial tricuspid regurgitation). These differences in rates of major and minor complications were not statistically significant.

**Duration of procedure and fluoroscopic exposure** The procedural duration (51±22 vs. 86±51 min) and duration of total fluoroscopic exposure (7±7 vs. 21±17 min) were significantly shorter (each p<0.01, Student’s t-test) in group I than in group II.

**Multicenter study**

**Patient and lead characteristics** Table 2 shows selected baseline characteristics of the 356 patients enrolled in the non-randomized study. Mean age, gender distribution, lead implantation duration, number of leads, leads characteristics and indications for extractions were similar in groups III and IV.

**Success rate and complications** We observed 2 procedure-related deaths in group III (0.9%) versus 1 in group IV (0.7%). The 2 deaths in group III were due to perforations of the right atrium and the superior vena cava, respectively. The single death in group IV was due to a perforation of the superior vena cava. Emergency surgical repair was unsuccessfully attempted in these 3 patients.
The leads were completely extracted in 186 patients (85%) in group III, versus 118 patients (86%) in group IV. Partial extractions were achieved in 26 (12%) and 16 (11%) patients, in group III and group IV, respectively, while the extraction procedure was unsuccessful in 6 and 4 patients, respectively (3% in each group; \( p=1.00 \), FET). The 6 unsuccessful laser extractions were completed by femoral approach in 2 patients, partially completed in 2, and remained unsuccessful in 2 patients who suffered no further complication. Long fragments of lead remained inside the hearts of the 4 patients who underwent unsuccessful extractions in group IV. A sternotomy was performed to complete the extraction in 1 patient who had developed endocarditis. The 3 other patients remained asymptomatic. Therefore, the ultimate complete extraction rates after rescue, using the other technique, were 86% when the procedure began with the superior approach, versus 86% when initiated from the femoral approach, the ultimate partial extraction rate were 13% versus 11%, and the ultimate failure rates were 1% versus 3%, respectively (\( p=0.36 \), FET).

Major procedural complications were observed in 6 patients (2.8%) in group III, versus 4 patients (2.9%) in group IV (\( p=1.00 \), FET). In group III, a hemothorax occurred in 1 patient, pericardial tamponade requiring drainage in 2, superior vena cava perforation in 1, subclavian vein injury requiring emergency surgical repair in 1, and severe tricuspid regurgitation in 1 patient. In group IV, pericardial tamponade occurred in 1 patient, hemothorax requiring thoracocentesis in 1, and severe tricuspid regurgitation in 2 patients. Before discharge from the hospital, 2 patients in group III and 2 patients in group IV died of causes unrelated to the extraction procedures. The mortality and the adverse events were contributed evenly across the six centres.
Discussion

Important information was gathered in this study of extractions of pacemaker and ICD leads implanted for several years. Regardless of the technique implemented, complete or partial extractions were achieved in >95% of procedures. The rates of mortality and of major complications, although low, were not negligible and indicate that these procedures must be performed by a trained team working in an environment equipped with immediate surgical backup. We found no significant difference between the proximal approach, using laser, and the femoral approach, using snares, with respect to procedural success and complication rates. However, procedures performed from the femoral approach were longer and were associated with a longer exposure of the operators and patients to fluoroscopy.

Extraction of old leads

In the multicenter as well as in the single-center analysis, the rates of a) procedural success, b) mortality and c) major complications seemed concordant with previously published reports, regardless of the technique implemented.\textsuperscript{10,12} It appears, therefore, that recipients of old or very old leads should preferably undergo percutaneous laser or femoral procedures, instead of surgical extractions, which are associated with a higher mortality and major complications rates.\textsuperscript{9} On the other hand, the rates of fatal and major non-fatal complications measured in this study were not negligible and were unpredictable before the procedure. Despite the development of new and attractive techniques, the extraction of implanted material remains challenging and associated with some morbidity and mortality. This implies the observance of the international professional guidelines, which recommend that these procedures be performed a) by teams familiar with, and trained in different extraction techniques, and b) in a dedicated environment with immediate
access to surgical assistance and sternotomy. Without access to rapid and life-saving surgical repairs of perforated vessels or cardiac chambers, mortality would have been considerably higher in this study.

**Laser versus femoral approach**

The main objective of this study was to compare the femoral with the laser extraction technique. The development of the laser technique is recent, promoted by the publication of the PLEXES trial, which clearly showed its greater efficacy compared to standard techniques. Laser was associated with a considerably higher rate of successful lead extractions and shorter procedures, at the cost of a slightly higher risk of major complications. The femoral approach, which was developed nearly 20 years ago, is now exclusively used in a large number of medical centers for patients presenting with ruptured or floating leads, or after unsuccessful laser extractions.

This study was limited to patients presenting with leads that were non-ruptured and accessible from the proximal site, therefore, amenable to both techniques. We observed no significant between-groups differences in mortality, major complications and procedural success rates. It appears, therefore, that, for this kind of patients, operators can choose between these 2 techniques as a function of their own experience. Furthermore, an operator with experience with one or the other technique should be able to completely extract the majority of leads, including old ones. It is noteworthy that, when a laser extraction is incomplete, the femoral procedure sometimes allows a complete extraction by removing lead fragments left in the cardiac chamber. It seems, therefore, necessary to be proficient with both techniques in order to optimize the results of this type of procedure. The ability to use the femoral approach after an unsuccessful laser-based procedure, and not the converse, is a clear advantage of the laser extraction technique.
as a first choice.

Procedural duration and fluoroscopic exposure may seem less important endpoints than mortality, procedural success or complication rates. We found a significant difference in these 2 measurements in favor of laser extraction. The fluoroscopic time observed during the laser procedure is concordant with previously published exposures.\textsuperscript{12} During a procedure from the femoral approach, ensnaring of the lead by the lasso in a 3-dimensional space can be highly challenging and time-consuming. Furthermore, this part of the procedure is performed entirely under fluoroscopic surveillance, which increases considerably the amount of radiation exposure. Since their mean duration is shorter and less variable than the femoral approach, laser procedures are easier to fit inside the schedule of the operating department.

Protection of the medical staff against radiation exposure is an issue that has sometimes been neglected in the past. Recent studies have shown the serious risk represented by the emission of ionizing rays.\textsuperscript{14-16} Therefore, the lesser radiation exposure associated with laser procedures is a non-negligible advantage. Operators who extract leads (who are often the implanters of pacemakers and ICD, as well as responsible for various endocavitary ablations of arrhythmias) are exposed to considerable irradiation and excess risk of radiation-induced disorders. This represents an advantage in favor of laser procedures, in view of the identical success/complications ratio of the 2 approaches. The use of a radioprotective space, which has been found effective in the performance of endocavitary ablations of arrhythmias might also lower the irradiation associated with lead extraction procedures from the femoral approach.\textsuperscript{17}
Limitations of our study

While the single-center study was randomized, its size did not allow the drawing of conclusions regarding the comparisons of success and complication rates. On the other hand, it showed significant differences in the duration of both overall procedure and radiation exposure. The multicenter study was not randomized and was not designed to assess the mortality associated with these 2 techniques. Given the many non significant results, the power of the present study is questionable and despite the concordance of these 2 studies of different designs and sizes, a randomized multicenter will probably be needed to draw definitive conclusions. The number of patients included in this study was also insufficient to allow meaningful statistical comparisons of subgroups, such as pacemaker versus ICD leads, or active versus passive fixation. The radiation exposure was not directly measured with diode dosimeters. The distance between the operator and the origin of the radiations would probably influence the exposure to ionizing rays.

In the recommendations issued by professional guidelines, a partial extraction was defined as the persistence of a <4 cm lead fragment. We, instead, defined partial extraction as a <2 cm residual fragment, which most often corresponds to the persistence of the very tip of the lead at the end of the procedure, usually associated with a high likelihood of long-term clinical success.

While the extraction of recently implanted leads might be challenging, and while the extraction of leads of any age must be viewed as risky, a large proportion of young leads can be extracted without using laser or the femoral technique. The duration of implantation influences significantly the success rate of lead extraction procedures. We deliberately limited our study to recipients of at least 1 lead older than 4 years. Consequently, the mean age of the leads that were explanted was considerably older than described in other studies, which might explain the higher
complications rate than previously published. However, our objective was to compare the 2 types of techniques, and the mean age of the leads used with both techniques was similar. This variable, therefore, had probably no impact on the results of our study. The older mean age of the leads that were explanted in our study also explains the relatively lower proportion of explanted ICD leads. The extraction of ICD leads is notoriously challenging and may be particularly difficult to grasp inside the femoral extraction sheaths.

Conclusions
Old transvenous leads were extracted with similar success and complication rates by the femoral and superior approaches. However, the femoral approach was associated with longer procedures and a longer exposure of patients and operators to radiation.

Conflict of Interest Disclosures: None

References:


<table>
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<tr>
<th></th>
<th>Group I (n=50)</th>
<th>Group II (n=51)</th>
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<tbody>
<tr>
<td>Age, y</td>
<td>69±15</td>
<td>72±15</td>
</tr>
<tr>
<td>Men/women</td>
<td>38/12</td>
<td>40/11</td>
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<tr>
<td>Left ventricular ejection fraction, %</td>
<td>57±14</td>
<td>53±14</td>
</tr>
<tr>
<td>Time from implantation, y</td>
<td>12±6</td>
<td>13±6</td>
</tr>
<tr>
<td>Number of leads per patient</td>
<td>2.3±0.7</td>
<td>2.1±0.6</td>
</tr>
<tr>
<td>Device</td>
<td></td>
<td></td>
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<tr>
<td>Pacemaker</td>
<td>44 (88)</td>
<td>43 (84)</td>
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<tr>
<td>Implantable cardioverter defibrillator</td>
<td>6 (12)</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Main procedural indication</td>
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<td></td>
</tr>
<tr>
<td>Endocarditis</td>
<td>21 (42)</td>
<td>19 (37)</td>
</tr>
<tr>
<td>Pocket infection</td>
<td>25 (50)</td>
<td>25 (49)</td>
</tr>
<tr>
<td>Dysfunction or upgrade</td>
<td>4 (8)</td>
<td>7 (14)</td>
</tr>
</tbody>
</table>

Values are means ± SD, or numbers (%) of observations in corresponding group.
All between-groups differences are statistically non-significant.
Table 2: Characteristics of the patients included in the multicenter study

<table>
<thead>
<tr>
<th></th>
<th>Group III (n=218)</th>
<th>Group IV (n=138)</th>
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<tbody>
<tr>
<td>Age, y</td>
<td>71±15</td>
<td>69±15</td>
</tr>
<tr>
<td>Men/women</td>
<td>168/50</td>
<td>106/32</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, %</td>
<td>53±18</td>
<td>50±13</td>
</tr>
<tr>
<td>Time from implantation, y</td>
<td>9±5</td>
<td>10±5*</td>
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<tr>
<td>Number of leads per patient</td>
<td>2.1±0.7</td>
<td>2.1±0.8</td>
</tr>
<tr>
<td>Device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacemaker</td>
<td>180 (83)</td>
<td>114 (83)</td>
</tr>
<tr>
<td>Implantable cardioverter defibrillator</td>
<td>38 (17)</td>
<td>24 (17)</td>
</tr>
<tr>
<td>Main procedural indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endocarditis</td>
<td>88 (40)</td>
<td>50 (36)</td>
</tr>
<tr>
<td>Pocket infection</td>
<td>94 (43)</td>
<td>61 (44)</td>
</tr>
<tr>
<td>Dysfunction or upgrade</td>
<td>36 (17)</td>
<td>27 (20)</td>
</tr>
</tbody>
</table>

Values are means ± SD or numbers (%) of observations in corresponding group
*p=0.07; all other between-groups differences are statistically non-significant
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