Extraction of pacemaker and implantable cardioverter defibrillator leads: a single-centre study of electrosurgical and laser extraction

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Received 15 June 2009; accepted after revision 20 August 2009; online publish-ahead-of-print 29 September 2009

Aims Both electrosurgical dissection (EDS) and laser tools are effective in the extraction of chronic implanted endovascular leads. It is unclear which is superior. We undertook a retrospective single-centre study to assess this.

Methods and results In our institution from 2000 to 2004, all extractions requiring an ablative sheath were performed using the EDS system. In 2004, an excimer laser system was acquired, which became the first choice. Consecutive patients undergoing extraction requiring an ablative sheath (EDS or laser) were studied. From 2000 to 2007, 140 leads were extracted from 74 patients (EDS 31 and laser 43). Procedural success was non-significantly higher in the laser vs. the EDS group (95 vs. 87%). In the EDS group, one patient suffered tamponade requiring surgery; in the laser group, one patient suffered a significant pericardial effusion treated conservatively. There were no deaths. Procedure and fluoroscopy times were similar between groups. More patients were referred for primary surgical extraction in the EDS vs. the laser era (7 vs. 0, \(P = 0.003\)).

Conclusion Lead extraction using an ablative sheath is safe and effective. In our small study, there were no significant differences between EDS and laser sheaths in terms of success, time, or safety.

Keywords Pacemaker • Implantable cardioverter defibrillator • Electrophysiology • Lead extraction • Laser • Diathermy

Introduction

The last decade has seen an exponential rise in implantable cardiac device use. The broadening of the indications for implantable cardioverter defibrillators (ICDs) and the proven efficacy of cardiac resynchronization therapy (CRT), coupled with the increasing use of devices in patients with congenital heart disease and inherited channelopathies, have seen implantation rates rise, especially in younger patients. Furthermore, lead failure, with the consequent need for lead replacement, has been a continued problem. With the growth and changing demographics of device use, the endovascular extraction of transvenous leads has become increasingly important.

Although many leads can be safely extracted manually, the use of additional extraction tools has been shown to improve success rates.³–⁵ The most recent advance in extraction has seen the development of sheaths powered by ablative energy sources that free the lead from attached fibrous tissue. The two most widely available such technologies are the excimer laser sheath (Spectranetics, Colorado Springs, CO, USA) and the electrosurgical dissection (EDS) sheath (Cook Vascular Incorporated, Vandergrift, PA, USA).³–⁵ Although these two powered sheaths have been shown to improve success rates when compared with mechanical extraction alone, there have been no published studies directly comparing the two technologies. We therefore performed a single-centre retrospective cohort study of consecutive patients undergoing lead extraction that required the use of a powered sheath.

Methods

The excimer laser sheath delivers pulses of ultraviolet light at 308 nm through optical fibres that run along the length of the sheath and terminate at the end.⁶ The laser vaporizes water molecules, disrupting...
fibrous tissue and separating the lead from tissue. Though well suited to fibrotic tissue, it does not cut well through dense calcification.6

The EDS system uses radiofrequency (RF) energy in a similar way to a surgical cautery tool. Radiofrequency energy is conducted between two bipolar tungsten electrodes at the tip of the sheath, disrupting the fibrous tissue immediately surrounding the lead.7 The RF energy is delivered through only a small arc of the sheath tip. This theoretically allows a degree of targeting of the tissue dissection, though also potentially reducing its efficiency.

Southampton University Hospital is a regional centre for lead extraction, covering a population of ~2.8 million people. From 2000 to 2004, all extractions requiring the use of an ablative sheath were performed using the EDS system. In 2004, the Unit acquired an excimer laser extraction system, which then became the first-line technology used when traction alone was not successful. We retrospectively analysed the success and complication rates for consecutive patients undergoing lead extraction in our institution, using an EDS system (2000–04) and a laser sheath (2005–07) as the first-line ablative extraction tools.

All extractions were performed by two operators with extensive experience with lead extraction (P.R.R. and J.M.M.). A standard approach to extraction was used. The pocket was opened and the leads dissected clear. If present, the active fixation mechanism was withdrawn and manual traction attempted. If unsuccessful, an appropriately sized locking stylet (Liberator Universal locking stylet, Cook Vascular Inc., Leechburg, PA, USA) was employed, and again manual traction was performed. If still unsuccessful, a powered sheath was used. From 2000 to 2004 this was the EDS system, and from 2005 to 2007 the laser system. From 2005 to 2007, although the laser sheath was the first-line technology, the EDS sheath was still available if the laser was not successful. Both sheaths were sized and operated according to the manufacturer’s recommendations. A femoral snare (Cook Vascular Inc.) was available and used at the operator’s discretion. All cases were performed under general anaesthesia with on-site cardiac surgical support available.

The records of all patients undergoing lead extraction were reviewed and only patients requiring the use of a powered sheath were included. The indication for lead extraction was classified into infection, lead malfunction, or system upgrade. A diagnosis of infection was based on clinical judgement as well as laboratory results. Lead malfunction was diagnosed based on a change in the lead pacing parameters. System upgrade included the upgrade of a pacemaker to an ICD, or upgrade to a biventricular device. Procedure time refers to the time between the patient entering and leaving the procedure room. Fluoroscopy time refers to the total time of fluoroscopic screening per patient. Procedural success was defined as complete fluoroscopic removal of all leads. Cases where the distal tip of one of the leads could not be completely extracted, and a small amount of lead (<1 cm) was left in situ, were also classified as procedural success, although the number of such cases was indicated in the results.

To assess for evidence of referral bias, where patients were preferentially referred for primary surgical rather than endovascular extraction in the EDS compared with the laser era, we assessed the number of patients referred directly for surgical extraction during the study period. Patients requiring associated valve surgery were excluded from this analysis, as they would not have been potential candidates for transvenous lead extraction.

Statistical analyses were performed using the SPSS 17.0 software package (SPSS, Inc., Chicago, IL, USA). Continuous variables are expressed as mean ± 1 SD and were compared using Student’s t-test. Comparison of dichotomous categorical variables was made by the χ² test. A P-value of <0.05 was considered significant.

Results

From 2000 to 2007, a total of 140 endovascular leads were extracted from 74 patients (age 65 ± 18 years, 70% male) with the use of an ablative sheath (Table 1). In 65% of the cases, the extracted device was a pacemaker, in 20% an ICD, and in 15% a CRT-D device. The EDS system was used as the first-line extraction sheath in 31 patients and the laser system in 43 patients. The patient characteristics in each group were broadly similar. However, the laser group were significantly more likely to have a device re-implanted during the same procedure (P = 0.03).

During the EDS era (2000–04), seven patients (six males) had surgical endovascular lead extraction as a first-line extraction procedure compared with none in the laser era (2005–07) (P = 0.003). The average age of these patients was 72 years and the average length of time the leads had been implanted was 7.6 years. Only one patient had a defibrillator. In total, 17 leads were extracted (8 atrial and 9 right ventricular) with no procedure-related deaths.

Complete procedural success (complete extraction of all leads) without the use of further extraction tools was achieved in 84% of the EDS group and 93% of the laser group (P = 0.21) (Table 2).

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Baseline characteristics and indications for lead extraction of 74 patients included in the study</th>
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<tbody>
<tr>
<td></td>
<td>EDS sheath (n = 51)</td>
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<tr>
<td>Average age</td>
<td>63 ± 17</td>
</tr>
<tr>
<td>Male (%)</td>
<td>74 (23)</td>
</tr>
<tr>
<td>Device type (%)</td>
<td></td>
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<tr>
<td>Pacemaker</td>
<td>71 (22)</td>
</tr>
<tr>
<td>ICD</td>
<td>23 (7)</td>
</tr>
<tr>
<td>CRT-D</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Number of leads</td>
<td>60</td>
</tr>
<tr>
<td>No. of leads per patient</td>
<td>1.9 ± 0.6</td>
</tr>
<tr>
<td>Lead type</td>
<td></td>
</tr>
<tr>
<td>Atrial</td>
<td>25</td>
</tr>
<tr>
<td>Right ventricular</td>
<td>33</td>
</tr>
<tr>
<td>Left ventricular</td>
<td>2</td>
</tr>
<tr>
<td>Indication for lead extraction (%)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>81 (25)</td>
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<tr>
<td>Lead failure</td>
<td>19 (6)</td>
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<tr>
<td>Device upgrade</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Lead implant duration (years)</td>
<td>6.7 ± 5.8</td>
</tr>
<tr>
<td>Device re-implanted during same procedure (%)</td>
<td>6 (2)</td>
</tr>
</tbody>
</table>

ICD, implantable cardioverter defibrillator; CRT-D, biventricular cardioverter defibrillator.
This rose to 87 and 95%, respectively (P=0.20), with the additional use of a femoral snare. This included three cases in the laser group where the distal tip of the ventricular lead (RV lead two cases and LV lead one case) could not be removed and was left in situ, with no clinical sequelae during follow-up. Both the procedure time (2.1 ± 0.8 h in the EDS group vs. 2.2 ± 0.8 h in the laser group, P=0.55) and fluoroscopy time (11.2 ± 10.0 vs. 11.9 ± 8.7 min, respectively, P=0.74) were similar in the two groups. There were no procedure-related deaths in either group.

In the EDS group, a femoral snare was used in two cases of which one resulted in procedural success. In three cases, it was not possible to extract the leads. In one case, the procedure was abandoned due to cardiac tamponade which required emergency cardiothoracic surgery.

In the laser group, procedural success was achieved with additional tools in two cases—a femoral snare in one and the EDS sheath in another. In one case, complete extraction was not possible. There was one case of a moderately sized post-procedural pericardial effusion (~1.6 cm) which was treated conservatively with no clinical sequelae.

### Discussion

In this retrospective single-centre study, we have shown that in the extraction of chronic endovascular leads, as a first-line tool, the EDS and excimer laser sheaths are comparable. The overall success rates—84% for the EDS and 93% for the laser when used alone, rising to 87 and 95%, respectively, when used in addition to the femoral snare—were high and similar between the two groups. In addition, the complication rates in both groups were low and not significantly different. During the study period, the number of patients referred directly for primary surgical lead extraction decreased significantly, from seven patients in the EDS era to no patients in the laser era (P=0.003). Furthermore, there was a non-significant trend for the laser group to have had their leads implanted for longer (8.8 vs. 6.7 years) and be more likely to have a defibrillator lead (40 vs. 29%). These factors suggest that during the study period, the complexity of cases taken on for percutaneous lead extraction increased. It may be that with increased confidence and experience with the laser extraction system, more complex cases were considered for percutaneous rather than surgical extraction, although with no reduction in success rates or safety.

Both EDS and laser extraction tools have been shown to improve success rates compared with mechanical extraction alone, although there are no data to suggest that the use of powered sheaths improves safety. The PLEXES trial randomized 301 patients with 465 chronically implanted leads to extraction with the laser or an inner telescoping sheath. Complete lead removal rate was 94% in the laser group and 64% in the non-laser group (P<0.001); there were no significant differences in complication rate between the groups. Neuzil et al. randomized 120 consecutive patients to extraction with the EDS tool or standard mechanical lead removal. Complete extraction was significantly higher in the RF group (93%) compared with the standard system (73%) (P<0.01), and again there were no differences in complication rate. Our study excluded patients in whom manual extraction alone was successful. If these patients had been included, overall success rates would be higher. Despite this, success rates in our study are similar to these previous trials.

There has only been one previous study comparing the EDS and laser extraction tools. This examined 450 consecutive lead extractions at a single centre between 1998 and 2001, but was published in an abstract form only. Laser was used to extract 354 leads and the EDS system 96 leads. Procedure time (130 ± 49 vs. 158 ± 65 min, P<0.002) and fluoroscopy time (13.3 ± 10.6 vs. 17.1 ± 15.1 min, P<0.05) were significantly lower in the EDS group. Furthermore, there were two deaths in the laser group and none in the EDS group. However, there was evidence of selection bias, with the laser groups having leads implanted for a significantly longer time than the EDS group (8.2 ± 5.0 vs. 6.6 ± 4.4 years, P<0.005), which may have confounded the results.

In comparison to one another, the EDS and laser tools have potential advantages and disadvantages. The laser system delivers circumferential energy from the end of the sheath. Although highly efficient at cutting through fibrous tissue, this lack of directionality on the laser can potentially place the lateral wall of the superior vena cava at increased risk of laceration as the laser is advanced, leading to vessel perforation. It is possible that this vessel damage may also predispose to vascular complications during lead re-implantation, although this is not our experience. An additional limitation of the laser sheath is that it does not cut through calcified adherences well, a drawback that has not been documented with the EDS system. As noted earlier, the EDS tool delivers RF energy through less than a quarter of the circumference of the sheath. Although potentially allowing the more precise targeting of energy delivery, this also may reduce the effectiveness of the system. In addition, the laser system is significantly more expensive than the EDS system.
As the variety of adjunctive tools increases, lead extraction techniques continue to evolve. The optimal method of combining these new tools and techniques is, however, unclear. As has been suggested by some authors, it may be that the EDS and laser systems should be seen as complementary rather than alternative technologies.7,8 In our study, the use of the EDS sheath is associated with a learning curve.11 During the 7-year study period, operator experience and the use of powered sheaths is associated with a learning curve.7,8 Furthermore, as with other new medical technologies, the use of powered sheaths is associated with a learning curve.11 During the 7-year study period, operator experience would have increased, and it is likely that the laser group benefited from the experience gained by the operators during the EDS era, which may have influenced the results. In addition, in our study, all procedures were performed by operators with extensive experience in endovascular lead extraction. It is not clear whether the high success and low complication rates achieved in this, and in other published studies, can be replicated by centres with either less operator experience or without the referral base to maintain a high procedural volume.

Our study has limitations. The data are non-randomized. Instead, we performed a historical comparison between patients extracted with the EDS system as a first-line tool and those extracted with the laser system as a first line. Although this design makes selection bias unlikely, it does mean that the two groups may differ as they reflect the changing demographics of device extraction patients. The laser group tended to have their leads implanted for longer (8.8 vs. 6.7 years) and was more likely to have a defibrillator lead (40 vs. 29%), likely reflecting the increasing length of time that devices have been in widespread use and the growing utilization of ICDs over the last decade, though neither was statistically significant. In addition, the laser group was significantly more likely to have a device re-implanted during the same procedure (P = 0.03). These factors are associated with more complex or prolonged extraction procedures.8 Furthermore, seven patients were referred directly for surgery during the EDS era compared with none during the laser era. As detailed above, taken together, these factors suggest a degree of referral bias, where more complex patients were taken on for device extraction using the laser system, where previously they may have been sent directly for surgical extraction. We do not have detailed information concerning the type of lead fixation used (active vs. passive), which could potentially influence our results. Lastly, the number of patients in our study is small, significantly reducing the power to detect a difference between the extraction tools. However, despite these limitations, our results do suggest that any difference between the two sheaths, in terms of success or complication rates, is likely to be relatively small.

In conclusion, the transvenous extraction of chronic endovascular leads using ablative sheaths is safe and effective. In our small observational study, there were no significant differences between the EDS and laser extraction systems in terms of success, procedural or fluoroscopy time, or safety. However, our results suggest that during the study period, the complexity of cases taken on for percutaneous lead extraction increased. It may be that the use of the laser system enabled more complex cases to be considered for percutaneous rather than surgical extraction.

Conflict of interest: J.M.M. and P.R.R. have received Honoraria and research grants from Medtronic, St Jude, Sorin, and Boston Scientific.

Funding
P.A.S. is supported by an educational grant from Medtronic.

References