Laser lead extraction allows for safe and effective removal of single- and dual-coil implantable cardioverter defibrillator leads: A single-centre experience over 12 years

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Abstract

OBJECTIVES: Lead extraction in patients with multiple or old leads of an implantable cardioverter defibrillator (ICD) is challenging. As adhesions are common at the side of the shock coils, we investigated success and procedural complication rates of laser lead extraction procedures in single- and dual-coil leads.

METHODS: Between January 2001 and June 2013, 41 single- and 145 dual-coil ICD leads were extracted from 171 patients using laser sheaths. Procedural data, success rates and complications were collected into a database and retrospectively analysed.

RESULTS: The mean patient age was 58.2 ± 16.1 years. The mean time from initial lead implantation to extraction was 50.3 ± 18.4 and 45.8 ± 14.5 months in the single- and dual-coil group, respectively (P = 0.1). In the single-coil group, complete procedural success was achieved in 36 of 37 (97.3%) cases, and clinical success in all cases (100.0%). In the dual-coil group, complete procedural success was seen in 131 out of 134 (97.8%) patients, and clinical success in 132 of 134 cases (98.5%). The transvenous extraction failed in 2 cases (1.5%). The overall complication rate was 2.7% in the single-coil group and 3.7% in the dual-coil group, respectively (P = 1.0). No deaths occurred during the 30-day follow-up. The mean laser treatment time was 1.8 ± 1.5 min for the single-coil group and 2.5 ± 1.2 min for dual-coil group (P = 0.002).

CONCLUSIONS: Laser lead extraction allows for safe and effective removal of ICD leads. Compared with single-coil leads, the extraction of dual-coil leads is associated with longer laser treatment times but without statistically significant differences in complications and procedural success rates.

Keywords: Laser lead extraction • Implantable cardioverter defibrillator • Lead extraction management

INTRODUCTION

Lead extraction in patients with multiple leads or old implantable cardioverter defibrillator (ICD) leads is challenging [1]. Following renewed guidelines, the number of implanted ICD and CRT devices has been rising in recent years [2–4]. Similarly, the number of ICD leads that need to be extracted is growing.

Different mechanisms contribute to fibrotic encapsulation of the leads after transvenous cardiac device implantation [5]. The lead adhesions usually increase over time, and young patients tend to develop fibrotic adhesions at an earlier stage after surgery compared with elderly patients [6].

Due to their high-voltage coils and their diameter and design, ICD leads especially enable fibrotic tissue in-growth. Furthermore, in dual-coil leads, the superior vena cava (SVC) coil is often positioned in a region that poses an increased extraction risk [7, 8]. We therefore compared success rates and complication rates of laser lead extraction procedures for single- and dual-coil leads.

MATERIALS AND METHODS

Between January 2001 and June 2013, 171 patients with ICDs were treated using laser lead extraction at our university hospital. The majority of the patients were referred from external hospitals; the remaining patients were from our Electrophysiology outpatient clinic.
Indications for lead extraction

Indications for lead extraction were as follows: local infection in 61 patients (35.7%), systemic infection (sepsis and endocarditis) in 31 patients (18.0%), lead dysfunction in 74 patients (43.3%), venous occlusion in 2 patients (1.2%), lead migration in 1 patient (0.6%) and chronic pain in 2 patients (1.2%). If extraction of a dysfunctional lead led to an upgrade, this was classified as an extraction of a dysfunctional lead, not an upgrade. Every case was discussed by an interdisciplinary heart rhythm team that included an electrophysiologist and a cardiac surgeon.

Extraction and reimplantation technique

Patients without contraindications received preoperative phlebography. All patients were treated under general anaesthesia in an operating room or hybrid OR using fluoroscopic guidance. An arterial line placed in the left radial artery was used for continuous blood pressure monitoring. Transoesophageal echocardiography, followed by 3D imaging, was performed. Cardiopulmonary bypass was on standby in all cases.

Initially, the device was removed. After preparation of the leads, the sleeves were removed. Lead locking devices were placed. Manual traction was applied, but was not sufficient in all of these cases. Therefore, laser lead extraction was conducted using the Laser Sheath II (40 Hz) or GlideLight (80 Hz) (Spectranetics Corporation, Colorado Springs, CO, USA). Laser lead extractions were performed with a single sheath technique without outer sheaths. Sheath sizes were 14 or 16 French.

During the study period, reimplantation was performed as a one-step approach from the contralateral side in patients without systemic infection and with negative blood cultures. In all patients, antibiotic prophylaxis was given for reimplantation. In patients with elevated infection indicators or positive blood cultures, a two-step approach was chosen. In pacemaker-dependent patients, for temporary pacing, a new active fixation pacemaker RV lead was inserted at the ipsilateral side, subcutaneously tunnelled and connected to an external pacemaker device, as previously described by Pecha et al. [9].

Definitions

Laser lead extraction was defined as the removal of leads using an excimer laser sheath with a lead locking device. Laser treatment time was defined as the time from the start until the end of laser use.

Outcomes were determined according to the recommendations for lead removal from the Heart Rhythm Society [10].

Statistical analysis

Continuous values are displayed as mean ± standard deviation and were compared by the Mann-Whitney test or Student’s t-test, as appropriate. Categorical variables are expressed as numbers and percentages and were compared by Fisher’s exact test or the χ² test, as appropriate. P < 0.05 was considered statistically significant; all reported P-values were two-tailed. SPSS 21.0 (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis.

RESULTS

Patients

The mean patient age was 58.2 ± 16.1 years (range 18-79), and 121 patients were male (70.8%). A total of 51 patients (29.8%) had a prior sternotomy. Patient characteristics are presented in Table 1. Baseline data analysis displayed no statistically significant differences between the patients in the single- or dual-coil groups.

Leads

Single-coil leads accounted for 41 (22.0%) of 186 leads extracted; the remaining 145 (78.0%) were dual-coil leads (Fig. 1). Lead tip fixation was active in 149 leads (80.1%) and passive in 37 leads (19.9%). A total of 84.4% (157) of the leads were implanted from the left side, while 15.6% (29) were implanted from the right side. The mean time from initial lead implantation to extraction for single-coil leads was 50.3 ± 18.4 and 45.8 ± 14.5 months for the dual-coil leads (P = 0.1). The mean number of ICD leads treated per patient was 1.08. The maximum number of ICD leads treated in a single patient was 2. Seven patients had both single- and dual-coil leads. Complete lead extraction was achieved in all of those patients. No complications occurred during extraction procedures. Patients with both lead types were excluded from the study.

Different lead models from various manufacturers (Medtronic, St Jude, Biotronic, Guidant, Boston Scientific), including medical adhesive back-filled (MABF) leads and ePTFE-coated (Gore-Tex) leads, were extracted. However, regarding extraction success or complications rates, we did not observe any differences between the different types of leads. In Table 2, demographics of the treated leads are shown.

Table 1: Patients’ characteristics

<table>
<thead>
<tr>
<th>Patients</th>
<th>Single coil (n = 37)</th>
<th>Dual coil (n = 134)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>56.3 ± 16.6</td>
<td>59.9 ± 15.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>28 (75.7)</td>
<td>93 (69.4)</td>
<td>0.5</td>
</tr>
<tr>
<td>Prior cardiac surgery, n (%)</td>
<td>13 (35.1)</td>
<td>38 (28.3)</td>
<td>0.4</td>
</tr>
<tr>
<td>Indication for lead removal, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local infection</td>
<td>17 (45.9)</td>
<td>44 (32.8)</td>
<td>0.1</td>
</tr>
<tr>
<td>Systemic infection</td>
<td>5 (13.5)</td>
<td>26 (19.4)</td>
<td>0.4</td>
</tr>
<tr>
<td>Lead dysfunction</td>
<td>14 (37.8)</td>
<td>60 (44.8)</td>
<td>0.5</td>
</tr>
<tr>
<td>Venous occlusion</td>
<td>0</td>
<td>2 (1.5)</td>
<td>1.0</td>
</tr>
<tr>
<td>Lead migration</td>
<td>0</td>
<td>1 (0.7)</td>
<td>1.0</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>1 (2.7)</td>
<td>1 (0.7)</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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Success rates

In the single-coil group, complete procedural success was achieved in 36 of 37 (97.3%) cases, whereas clinical success was achieved in all cases (100.0%). No extraction failure occurred in this group. In the dual-coil group, complete procedural success was observed in 131 of 134 (97.8%) patients, while clinical success was seen in 132 of 134 cases (98.5%). The extraction attempt failed in 2 cases (1.5%). Statistical analysis showed no significant differences between the extraction success rates for the single- and dual-coil groups, as displayed in Table 3.

In total, 182 ICD leads were completely extracted: 39 of 41 (95.1%) single-coil leads and 143 of 145 (98.6%) dual-coil leads ($P = 0.9$).

Either 14 or 16 French laser sheaths were used for the extraction procedures. However, the sheath sizes did not correlate with the type of lead that had to be extracted.

Subclavian vein occlusion was seen in 6 (3.5%) patients. Laser lead extraction allowed for recanalization of all occluded veins and enabled vascular access for reimplantation of a new lead.

The mean laser treatment time was 1.8 ± 1.5 for the single-coil group and 2.5 ± 1.2 min for the dual-coil group, corresponding to a significantly longer laser treatment time in the dual-coil group ($P = 0.002$).

Complications

No intra- or perioperative death occurred in any patient and the 30-day survival rate was 100%.

The overall complication rate for patients in the single-coil group was 2.7%. A 26-year-old female experienced a major complication, a tear at the SVC right atrial junction during the extraction procedure for pocket infection. She was implanted with two active fixation, single-coil ICD leads, which had been implanted for 81.5 and 46.5 months, respectively, and one active fixation right atrial lead. After immediate sternotomy and installation of cardiopulmonary bypass, the venous tear was successfully patched without further complications. This patient left the hospital well and without further incident. No minor complications occurred in this group.

The overall complication rate in the dual-coil group was 3.7%. A 72-year-old male experienced a major complication, right atrial perforation during the laser extraction of an ICD lead for systemic infection, which necessitated a sternotomy. The patient had two active fixation right atrial and right ventricular pacemaker leads and one active fixation dual-coil ICD lead, which had been implanted for 86.0 and 50.0 months, respectively. He recovered from the surgical procedure and was discharged from the hospital. Minor complications occurred in 4 patients (3.0%). Two patients (1.5%) developed a pocket hematoma that had to be revised surgically. One patient (0.7%) had a discrete pericardial effusion without haemodynamic relevance, which was managed conservatively. One patient (0.7%) experienced a pneumothorax requiring chest tube drainage.

We did not observe a significant deterioration of tricuspid insufficiency after lead extraction in any of the patients. Furthermore, no embolization of debris or clinically relevant pulmonary embolism was seen. However, especially in patients with lead vegetations, the occurrence of a microembolism into the lungs cannot be excluded.
DISCUSSION

In this study that compared single- versus dual-coil lead extraction, we demonstrated a procedural success rate of 97.3%, and a clinical success rate of 100% in the single-coil group. In the dual-coil group, complete procedural success was observed in 131 of 134 (97.8%) patients, while clinical success was seen in 132 of 134 cases (98.5%). Furthermore, no statistically significant differences in overall complication rates were observed between the two groups (single coil 2.7%, dual coil 3.7%; \( P = 1.0 \)). However, extraction of dual-coil leads was associated with longer laser treatment times.

A previous study by Malecka et al. [8], comparing the extraction of pacemaker (PM) and ICD leads, showed similar major complication rates in both groups (PM 1.2%, ICD 2.5%; \( P = 0.67 \)). However, the extraction of PM leads was associated with fewer minor complications (2.3 vs 7.6%; \( P = 0.043 \)).

Data comparing the safety and efficacy of laser lead extraction of single- and dual-coil ICD leads are still limited [7, 11]. Previous publications observed that the construction of the ICD leads with high-voltage therapy coils triggers the growth of vascular and myocardial adhesions, adding to the challenge of lead extraction. Furthermore, lead diameter and design might play an important role. Specifically, the SVC coil is often positioned in a region that poses an increased risk for transvenous lead extraction [5, 8, 12].

In the largest retrospective multi-centre analysis to date by Epstein et al., which compared the extraction of 385 single-coil and 1791 dual-coil ICD leads, the procedural success rate did not differ between the two groups. However, extraction of dual-coil leads was associated with a higher rate of major complications (0% single coil, 1% dual coil; \( P = 0.031 \)) and longer procedure times (45.5 min, 7 min; \( P = 0.002 \)). Furthermore, they found dual-coil leads to be 2.6-fold more difficult to remove, after adjusting for risk factors such as sex, age, implant duration, extraction indication, fixation mechanism and the number of ICD leads removed (\( P < 0.0001 \)).

In line with this finding, we also observed similar procedural success rates for the removal of single- and dual-coil ICD leads. Furthermore, we found longer laser treatment times in the dual-coil group. In contrast to the published data by Epstein et al., we did not observe statistically significant differences for the complication rates between the two groups. However, there were fewer patients enrolled in this study than in that of Epstein et al. In the study by Epstein et al., there is only a difference of 1% in major complication rates between the two groups. Due to the large number of patients treated, this difference was statistically significant. We also observed a higher overall complication rate in the dual-coil group compared with the single-coil ICD group (3.7 vs 2.7%); however, the difference was not statistically significant in our study. Inclusion of more patients might have led to a statistically significant difference in the results.

Furthermore, in contrast to the published data by Epstein et al. [7], in our study all patients were treated with laser sheaths, which means that traction alone or the use of lead locking devices or dilator sheaths was not sufficient to extract the leads. Therefore, it has to be taken into consideration that we treated a patient cohort with higher risk for overall complications and extraction failures. This also might explain the higher rate of major complications in our study, compared with the results by Epstein et al. Similar to the results of Epstein et al., we did not observe any procedural mortality and the 30-day survival rate was 100%.

Although there was no statistically significant difference in the overall complication rate in our analysis, the longer laser treatment times in the dual-coil group might result from the higher complexity of dual-coil extraction procedures. The tissue that grows around the superior vena cava coil takes time to debulk with the laser, especially because the SVC coil is often located at a critical site, namely the innominate/SVC junction. This probably contributed to the prolonged laser treatment times in the dual-coil group. Especially in such high-risk extraction procedures, the extraction centre volume and experience of the operating team influence the results of the extraction procedure, as previously shown by Wazni et al. [13].

In our centre, laser lead extraction is the method of choice in cases that require powered sheaths. In our hospital, the most frequent indication for lead extraction was infected leads, which is often associated with lead vegetations. Here, we see a clear advantage for laser lead extraction. The laser vaporizes the lead vegetations into small microparticles, which do not cause clinically significant lung embolism, even in patients with large lead vegetations. The laser ablates a ring of tissue in contact with the tip to a depth of 50 microns. This rather shallow penetration depth allows surgeons to debulk the binding sites very precisely, without surrounding vessel injury. Furthermore, the flexibility of laser sheaths, without the need for an outer sheath, helps to avoid vascular complications.

A weak point of laser sheaths is debulking of heavily calcified adhesions. In some cases, the energy that can be delivered through the laser sheaths is not sufficient to dissolve those calcified lesions. Here, mechanical sheaths have more power and might help to extract leads that cannot be removed with a laser sheath alone. In some cases, the combination of both tools might be helpful to successfully extract the lead(s) without complication.

Our data have shown that, in a high-volume centre, removal of both single- and dual-coil ICD leads can be performed with excellent results. In most cases, the use of laser sheaths alone enables ICD leads to be extracted, but in some cases, specific mechanical extraction tools are required. This may be a result of adhesions and calcified fibrotic tissue in-growth at the side of the shock coils.

Limitations

This study is a retrospective analysis with the potential risk of bias by unknown confounders and our series is limited by its relatively small size, especially when it comes to the different lead models. The study probably does not have the statistical power to evaluate differences in extraction procedures of special leads (e.g. MABF or ePTFE leads). Furthermore, it is a single-centre study and experienced operators performed the extraction procedures, which may have influenced the results of the study.

Conclusion

ICD lead extraction in this single-centre experience using the excimer laser sheath was safe and effective. The extraction of dual-coil leads was associated with increased laser treatment times but had similar complication and procedural success rates, when compared with the extraction of single-coil leads.

Conflict of interest: Samir Hakmi and Hendrik Treede are proctors of Spectranetics Corporation.
REFERENCES


