

Brief report

Initial Experience With Excimer Laser-Assisted Pacemaker and Defibrillator Lead Extraction

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ABSTRACT

Explantation of chronically implanted pacemaker or defibrillator leads can be technically demanding. We present the results of the first 44 leads extracted with excimer laser sheaths in 25 patients with a median lead implantation time of 7 years (range: 2 to 20 years). Indications for extraction were lead fracture in 17 patients, pocket infection in 4, septicemia in 2, and lead endocarditis in 2 cases. Complete extraction was achieved in 43 leads (97.7%), while the lead tip (<4 cm) was abandoned in 1 case. There was no in-hospital mortality. The excimer laser-assisted system is a safe and efficient alternative for pacemaker and defibrillator lead extraction. This technology has resulted in excellent outcomes in our series, allowing us to treat remarkably difficult cases.

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Experiencia inicial con la extracción de electrodos de marcapasos y desfibrilador asistida con láser *excimer*

RESUMEN

La extracción de electrodos de marcapasos y/o desfibriladores de larga evolución puede ser una técnica exigente. Presentamos los resultados de la extracción asistida por láser *excimer* de los primeros 44 electrodos en 25 pacientes, con una mediana de tiempo de electrodo implantado de 7 (2-20) años. Las indicaciones para la extracción fueron fractura de electrodo en 17 casos, decúbito de bolsa en 4, bacteriemia en 2 y endocarditis sobre electrodo en 2 casos. Se logró la extracción completa de 43 electrodos (97,7%), mientras que en 1 caso se abandonó la porción distal de menos de 4 cm del electrodo. No se produjo mortalidad intrahospitalaria. El láser *excimer* se presenta como una alternativa segura y eficaz para la extracción de electrodos de marcapasos o desfibrilador, con resultados excelentes en nuestra serie.

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INTRODUCTION

At the present time, there are a number of tools and techniques for the extraction of pacemaker and/or defibrillator leads that have been shown to be effective, but all of them are associated with a certain degree of risk for the patient.¹

In this article, we report a retrospective, descriptive non-comparative study of the first 25 patients who underwent excimer laser-assisted endovascular lead extraction in our institution. The primary objectives of the study were the analysis of the rates of primary success, partial or failed extraction, conversion to surgical extraction with median sternotomy, vascular complications, and in-hospital mortality.

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METHODS

Patients

Between June 2008 and July 2010, 25 patients required the explantation of pacemaker or automatic implantable cardioverter defibrillator (AICD) leads by means of excimer laser. The demographic data, comorbidities, characteristics of the procedure, and outcomes were collected by reviewing the medical records.

The criteria for inclusion in the laser-assisted extraction group were: patients with leads that had been implanted more than 2 years earlier in whom an initial attempt at mechanical extraction using a stylet had failed, and patients with leads implanted more than two years earlier in whom an upper limb phlebography demonstrated the presence of thrombosis/occlusion of the subclavian/innominate venous system. The exclusion criteria were: patients with leads that had been implanted less than 2 years earlier, and patients with lead endocarditis with vegetations > 2 cm.

Excimer Laser System

The ClearRS[®] system for the extraction of pacemaker and/or AICD leads (The Spectranetics Corporation, Colorado Springs, Colorado, United States) is made up of several complementary devices. The first, the Lead Locking Device (LLD)[®], is a stylet that expands radially, lending body along the entire length of the cable. The second device, the Spectranetics Laser Sheath (SLS) II[®], is associated with a cold (50 °C) xenon chloride excimer laser capable of dissecting, by means of a combination of photolytic and photothermal mechanisms, the fibrous scar tissue surrounding the cable. The sheaths are available in 3 diameters: 12 French (Fr), 14 Fr and 16 Fr. In each case, approximately 35 cm of the sheath are introduced,² but the total length ranges between 65 cm and 85 cm.

Finally, the CVX-300 Excimer laser system² emits pulses of 135 ns (wavelength, 308 nm), with a repetition rate of 25 to 40 Hz. The energy fluence at the distal end of the sheath can be regulated between values ranging from 30 to 60 mJ/mm².

Procedure

All the laser-assisted extractions were carried out in a cardiac operating room, under general anesthesia and using the ClearRS[®] lead extraction system. The intraoperative protocol in our institution involves the preparation of the patient for emergency sternotomy, should it be necessary, invasive monitoring via radial artery, and placement of a central venous catheter. A cardiopulmonary bypass system and a perfusionist are present in the operating room. The entire procedure is performed under fluoroscopic guidance. The laser sheath is maintained straight in a coaxial direction with respect to the lead (Video 1). The activation of the laser ceases approximately 2 cm from the lead tip, after which the stylet is drawn gently to a position in which the lead becomes unanchored (Fig. 1).

Statistical Analysis

The data are expressed as the mean \pm standard deviation, median [interquartile range], frequency distribution or simple percentage, as appropriate. The SPSS software package (version 17.0, SPSS Inc., Chicago, Illinois, United States) was employed for the statistical analysis.



Figure 1. Two leads extracted after 5 years of implantation, explanted using the excimer laser, that had developed severe adhesions to the vascular endothelium.

RESULTS

Between June 2008 and July 2010, 25 patients (22 men and 3 women) with a mean age of 57.4 ± 18.6 years underwent laser-assisted lead extraction. The baseline characteristics of the patients and the procedure are summarized in Table 1.

Eight patients had a dual-chamber pacemaker, 10 had a single-chamber AICD, and 7 had a dual-chamber AICD. In all, 44 leads were explanted (16 atrial leads and 28 ventricular leads), since 2 patients also had older encapsulated leads that were extracted during the same procedure. Eleven atrial leads (68.7%) and 18 ventricular leads (64.2%) were active fixation leads. The median time of lead implantation was 7 years [2 to 20 years], and 6 patients (24%) had leads that had been implanted more than 10 years earlier.

The indications for lead extraction were lead dysfunction/fracture in 17 cases, pocket erosion/local infection in 4, septicemia in 2 and pacemaker lead endocarditis in 2. In both cases of pacemaker lead endocarditis, the treatment involved between 2 and 4 weeks of intravenous antibiotic therapy, depending on the antibiogram, prior to the extraction of the leads. None of the patients had vegetations measuring over 2 cm on the tricuspid valve and/or the leads.

Five patients had moderate left ventricular dysfunction (left ventricular ejection fraction [LVEF], 35% to 50%) and another 6 patients had severe dysfunction (LVEF <35%). Three patients had previously undergone cardiac surgery.

The complete extraction of 43 leads (97.7%) was achieved; in 1 case, the tip of a lead (<4 cm) was abandoned with no complications. In every case, the extraction was achieved using ClearRS[®] laser technology alone. A 14 Fr sheath was used in 14 patients (56%) and a 16 Fr sheath was employed in the remaining 11 (44%).

There were no in-hospital deaths. In patient 4 of the series, an intraoperative tear was produced on the underside of the right ventricle, which was repaired surgically without consequences. None of the patients in the series developed significant tricuspid insufficiency following lead explantation.

During the study period, this technique was ruled out in 1 patient with a dual-chamber pacemaker implanted 6 years earlier and ventricular lead endocarditis because he had vegetations measuring over 2 cm. In this case, the extraction was performed by means of surgery with cardiopulmonary bypass.

DISCUSSION

At present, a number of multicenter studies present the excimer laser technique as a safe and effective alternative for the extraction of retained pacemaker leads.

The use of excimer laser-assisted lead extraction techniques was first reported in 1996, with success rates ranging between 81% and 100%.^{3,4}

The prospective, randomized, multicenter trial entitled Pacemaker Lead Extraction with the Excimer Sheath (PLEXES)³ included 301 patients, with a total of 465 leads to be explanted, and compared the excimer laser technology with different techniques that did not involve laser (mechanical extraction). The rate of complete lead extraction was 94% in the laser group versus 64% in the other group ($P < .001$). The mean time to achieve the extraction and that of radiation exposure was significantly shorter in the group of patients treated with the excimer laser technique (10.1 ± 11.5 min) than in the mechanical extraction group (12.9 ± 19.2 min) ($P = .04$). There were no significant differences between the groups in terms of complication rates.

The results of a European nonrandomized multicenter study, the Pacing Lead Surveillance Study in Europe (PLESSE), were

Table 1
Demographic and Clinical Characteristics of the Patients Who Underwent Laser-Assisted Endovascular Extraction of Pacemaker and/or Automatic Implantable Cardioverter Defibrillator Leads

Case	Age (yr)	Sex	Type of arrhythmia	Type of stylet	Laser sheath diameter (Fr)	Implantation time (months)	Indication for explantation	Complete extraction	Complication
1	40	Male	CAVB	LLD 2	14	197	Local infection	Yes	No
2	52	Male	CAVB	LLD 2	16	245	Lead fracture	Yes	No
3	45	Male	SMVT	LLD 2	16	101	Lead fracture	Yes	No
4	70	Male	CAVB	LLD 2	14	149	Local infection	Yes	Cardiac tamponade
5	73	Male	Ischemic LV dysfunction	LLD 1	14	90	Lead fracture	Yes	No
6	73	Male	CAVB	LLD 2	14	100	Lead fracture	Yes	No
7	73	Male	SMVT	LLD 2	14	91	Endocarditis	Yes	No
8	38	Female	VF	LLD 2	14	56	Lead fracture	Yes	No
9	76	Male	CAVB	LLD 2	14	24	Lead fracture	Yes	No
10	54	Male	HOCM	LLD 2	16	153	Lead fracture	Yes	No
11	55	Male	Brugada syndrome	LLD 2	14	40	Lead fracture	Yes	No
12	64	Male	SMVT	LLD 2	14	112	Lead fracture	Yes	No
13	59	Male	Brugada syndrome	LLD 2	16	57	Lead fracture	Yes	No
14	78	Male	Ischemic LV dysfunction	LLD 1	14	62	Local infection	Yes	No
15	15	Male	SMVT	LLD 1	14	51	Lead fracture	Yes	No
16	28	Female	HOCM	LLD 2	16	69	Lead fracture	Yes	No
17	74	Male	SMVT	LLD 2	16	93	Endocarditis	Yes	No
18	68	Female	VF	LLD 2	14	33	Lead fracture	Yes	No
19	47	Male	Ischemic LV dysfunction	LLD 2	14	46	Lead fracture	Yes	No
20	75	Male	CAVB	LLD 1	16	136	Septicemia	Yes	No
21	80	Male	CAVB	LLD 1	14	40	Septicemia	Yes	No
22	27	Male	HOCM	LLD 2	16	21	Lead fracture	Yes	No
23	33	Male	Brugada syndrome	LLD 2	16	42	Lead fracture	Yes	No
24	69	Male	Ischemic LV dysfunction	LLD 2	16	84	Local infection	Yes	No
25	70	Male	SMVT	LLD 2	16	60	Lead fracture	Yes	No

CAVB, complete atrioventricular block; HOCM, hypertrophic obstructive cardiomyopathy; LLD, lead locking device; LV, left ventricular; SMVT, sustained multifocal ventricular tachycardia; VF, ventricular fibrillation.

published in June 2007. It involved the use of the excimer laser for lead extraction⁴ and included 292 patients, with a total of 383 extracted leads. The mean implantation time of the leads was 74 months (range: 3 to 35 months). Complete extraction was achieved in 90.9% of the leads.

The major complications associated with the excimer laser extraction system are cardiac tamponade, tricuspid valve tear, pneumothorax, subclavian vein laceration with massive hemothorax, and tearing of the diaphragmatic wall of the right ventricle and/or of the cavoatrial junction.^{3,5} In the PLEXES trial, the rate of major complications was 2.6%, whereas in the PLESSE study, it was 2.7%.^{3,4} In our series, 1 patient developed a major complication, a tear in the right ventricle, for an incidence of 4%. This complication was probably due to the use of laser at a distance of less than 2 cm from the lead tip.

In a publication by Gaynor et al.,⁶ who analyzed the management of the leads of infected pacemakers, the use of the excimer laser is recommended in the treatment of cases of potential infection in order to ensure the extraction of all the exogenous material from the patient. In our series, 8 patients showed evidence of infection related to the device, with data indicative of systemic involvement in 4. As we have pointed out, we consider the presence of vegetations measuring over 2 cm on the lead or on the tricuspid valve to be a contraindication for endovascular extraction; in these cases, we advocate extraction by means of open surgery with cardiopulmonary bypass.

The excimer laser is presented as a safe and effective potential alternative for the extraction of chronically implanted leads, with

excellent results in our series, and one that enables the management of certain patients who would be difficult to treat with the other existing techniques.

Limitations

The study has the limitations inherent to descriptive non-comparative studies. The sample corresponds to the initial experience of our center and, thus, is subject to the influence of the learning curve associated with this technique. The small size of the sample could impede the detection of potential complications of this technique, given that in larger studies like the PLEXES or PLESSE trials the low incidence of complications ranged between 2.6% and 2.7%.

CONFLICTS OF INTEREST

None declared.

SUPPLEMENTARY MATERIAL



Supplementary material associated with this article can be found in the online version available at doi:10.1016/j.rec.2010.12.022.

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