Arrhythmia device lead extraction: Factors that necessitate laser assistance

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BACKGROUND: The removal of pacemaker and implantable cardioverter defibrillator (ICD) leads has become a common procedure. The need for laser use has considerable implications regarding cost and expertise. It is not an option at all centres and introduces an element of risk to the procedure. Anticipation of the need for laser assistance may be of benefit to procedure planning.

METHODS: Data on all patients undergoing lead extraction at London Health Sciences Centre (London, Ontario) between July 2001 and October 2006 were reviewed. Variables were assessed for independent association with the need for laser assistance. A prediction rule for laser use was created based on the multivariate model.

RESULTS: From July 2001 to October 2006, 154 patients underwent lead extraction, with laser assistance required in 106 patients (68.8%). One hundred seven patients (69.5%) had pacemakers and the remainder had ICDs. The mean ($\pm$ SD) device age was 7.6 ± 5.7 years, with 1.9 ± 0.9 leads requiring extraction. Clinical success was achieved in 152 patients (98.7%). Multivariate analysis revealed that laser use was less likely among men (OR 0.24, 95% CI 0.069 to 0.84; $P=0.026$) and among septal patients (OR 0.25, 95% CI 0.072 to 0.84; $P=0.025$), and more likely with ICDs than pacemakers (OR 4.40, 95% CI 1.50 to 12.91; $P=0.0069$) and with each additional year of device age (OR 1.46 per year, 95% CI 1.26 to 1.70; $P<0.0001$).

CONCLUSIONS: Laser assistance was required in 68.8% of cases, with clinical success in 98.7% of patients. Laser use was less likely among septal patients and men, and more likely with ICD leads and increasing time since lead implant. It was not possible to derive an accurate prediction rule for cases that would not need laser assistance. Therefore, it is prudent to ensure that a laser and appropriate infrastructure is available for lead extractions, and that the patient is aware of the possible need for laser assistance, along with the risks entailed.

Key Words: ICD; Lasers; Lead extraction; Pacemakers

Pacemaker and implantable cardioverter defibrillator (ICD) lead extraction has become a common procedure, largely in response to increasing rates of device implantation. Cutting tools such as radiofrequency cautery and laser assistance have made extraction of the majority of leads a realistic goal, facilitating safe dissection of leads from venous walls to which they often adhere (1-4). However, the need for laser use has considerable implications regarding cost and appropriate expertise, and is not an option at all centres. Furthermore, while laser use permits extraction of highly fibrosed and calcified leads, it also inherently increases the probability of cutting through venous and endocardial structures. Awareness of factors associated with the need for laser assistance before extraction is attempted may allow for improved procedure planning. Institutions without laser facilities may avoid unsuccessful attempts at lead removal before patient transfer, and those with laser facilities available may benefit

L'extraction des électrodes de dispositifs d'arythmie : Les facteurs qui exigent une assistance laser

HISTORIQUE : L'extraction des électrodes de stimulateur cardiaque et de défibrillateurs à synchronisation automatique (DSA) est devenue une intervention courante. La nécessité de recourir au laser a des répercussions considérables du point de vue du coût et des compétences. Cette intervention ne peut être effectuée dans tous les centres et comporte un élément de risque. Le fait de prévoir la nécessité d'une assistance laser peut être bénéfique à la planification de l'intervention.

MÉTHODOLOGIE : Les auteurs ont analysé les données sur tous les patients qui ont subi une extraction d'électrodes au *London Health Sciences Centre* (à London, en Ontario) entre juillet 2001 et octobre 2006. Les variables ont été évaluées pour établir leur association indépendante avec la nécessité d'assistance laser. Les auteurs ont créé une règle de prédiction d'utilisation laser d'après le modèle multivarié.

RÉSULTATS : De juillet 2001 à octobre 2006, 154 patients ont subi une extraction d'électrodes, et 106 (68,8 %) ont eu besoin d'une assistance laser. Cent sept patients (69,5 %) avaient un stimulateur cardiaque et les autres, un DSA. L'âge moyen du dispositif ($\pm$ ÉT) était de $7,6 \pm 5,7$ années, $1,9 \pm 0,9$ électrodes devant être extrait. Chez 152 patients (98,7 %), on a obtenu un succès clinique. L'analyse multivariée a révélé que le laser était moins probable chez les hommes (RRR 0,24, 95 % IC 0,069 à 0,84; $P=0,026$) et les patients septiques (RRR 0,25, 95 % IC 0,072 à 0,84; $P=0,025$) et plus probable chez les personnes ayant un DSA qu'un stimulateur cardiaque (RRR 4,40, 95 % IC 1,50 à 12,91; $P=0,0069$) et par année d'usure du dispositif (RRR 1,46 par année, 95 % IC 1,26 à 1,70; $P<0,0001$).

CONCLUSIONS : Il a fallu recourir à l'assistance laser dans 68,8 % des cas, avec un succès clinique chez 98,7 % des patients. Le recours au laser était moins probable chez les patients septiques et les hommes, et plus probable chez ceux qui avaient des électrodes de DSA et avec le passage du temps depuis l'implantation des électrodes. Il n'a pas été possible de dériver une règle de prédiction précise pour les cas qui ne nécessitaient pas d'assistance laser. Par conséquent, il est prudent de s'assurer qu'un laser et une infrastructure pertinente sont en place pour extraire des électrodes et que le patient est au courant de la possibilité d'assistance laser et des risques que cette utilisation comporte.

from advance planning for determining the appropriate location of the extraction, resources that will be required, and patient counselling regarding anticipated risk and complexity.

METHODS

Data on all patients undergoing lead extraction at London Health Sciences Centre (London, Ontario) between July 2001 and October 2006 were maintained in a lead extraction database. Lead extraction was defined as the surgical removal of pacemaker or ICD leads beyond one year from initial implant. As a measure of procedure complexity, laser use and fluoroscopy time were considered to be more reliable than procedure duration, which integrates anesthesia time, the variable role of the trainee as primary operator and the need for device reimplantation. Lead extraction was defined as successful if the lead was completely removed, partially successful if the lead tip and a short

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TABLE 1
Patient characteristics

Variable	Mean $\pm$ SD	n
Age, years	64.5 $\pm$ 16.0	154
Weight, kg	81.7 $\pm$ 16.1	151
Height, m	1.70 $\pm$ 0.10	144
Body mass index, kg/m ²	28.3 $\pm$ 5.3	144

segment of the lead remained (less than 4 cm), and failed if more than 4 cm of the lead was retained (1). Clinical success was defined as removal of the device without complications and with resolution of the underlying clinical issue, whether infection, erosion or venous obstruction.

The protocol for extraction was reviewed and passed by the University of Western Ontario (London, Ontario) Research Ethics Board for Health Sciences Research involving human subjects. Both written and verbal consents were obtained before the procedure. Extraction was performed in the operating room by a cardiac electrophysiologist under sterile conditions. In case complications arose during the procedure, preparation and draping was suitable for cardiac surgery. A cardiac surgeon was on location and available in case of such an emergency. The extraction procedure has previously been described (1,5). Briefly, the device pocket was opened and the generator was removed. After dissection of the leads from adherent connective tissue and removal of the suture sleeves, the active fixation mechanism of the lead tip was retracted, if applicable. The lead was cut proximally and a locking stylet (LLD; Spectranetics, USA) was advanced to the tip of the lead and locked in place. A silk suture was then tied to the lead, and traction on both the lead locking device and insulation suture was applied to extract minimally adherent leads. The locking stylet and suture were then threaded through a 12 Fr, 14 Fr or 16 Fr laser sheath (Spectranetics), based on lead diameter and operator estimate of the optimal sheath to avoid 'snow-plowing', which is accumulation of tissue at the distal end of the sheath, preventing the sheath from progressing along the lead. Under fluoroscopic guidance, the laser, along with an outer sheath, was then advanced over the lead, which was held under firm traction. Laser energy was applied to free the lead from the vessel wall if and when binding sites were encountered. Once the laser sheath reached the distal electrode, the lead tip was removed using countertraction. Patients were admitted overnight for observation, and underwent transthoracic echocardiography and chest x-ray the following morning. Device reimplantation was performed at the discretion of the supervising physician. This was typically 48 h to 72 h after extraction for infection or erosion, with temporary pacing and continuous telemetry in the interim period (6).

Statistical methods

Statistical analysis was performed using SAS software version 9.1 (SAS Institute Inc, USA). $P < 0.05$ were considered to be significant. Results were expressed as mean $\pm$ SD if normally distributed, and also as median with interquartile range (IQR) if the distribution was not normally distributed. Continuous variables were assessed for normal distribution using the Shapiro-Wilk statistic. Univariate testing was performed using the χ^2 test for categorical variables, and the Student's t test or the Mann-Whitney U test for normally and non-normally distributed data, respectively. Multivariate analysis was performed using standard logistic regression methods. A prediction model for laser use was created based on the coefficients of significant variables in the multivariate model. Values of predictive accuracy within the inception cohort were presented. Discrimination was assessed according to the area under the receiver operating characteristic (ROC) curve (c statistic), and calibration was assessed using the method of Hosmer-Lemeshow, with lack of fit indicated by $P < 0.05$. With the absence of a separate testing cohort, overestimation of the c statistic (ie, optimism)

TABLE 2
Device and procedure details (n=154)

Device/procedure variable	
Implantable cardioverter defibrillator	47 (30.5)
Pacemaker	107 (69.5)
Laser used	106 (68.8)
Device age, years	7.6 $\pm$ 5.7
Leads attempted, n	1.9 $\pm$ 0.9
Leads removed, n	1.9 $\pm$ 0.9
Laser time, s	95.5 $\pm$ 126.8
Laser applications, n	9.8 $\pm$ 8.4
Fluoroscopy time, min	11.2 $\pm$ 13.3

Data are presented as n (%) or mean $\pm$ SD

was calculated and corrected by a bootstrapping method using 1000 samples.

RESULTS

From July 2001 to October 2006, 154 patients underwent lead extraction, with attempted removal of a total of 278 leads. Among these 278 leads, fixation details were available for 154, among which 96 (62%) had active fixation mechanisms. Baseline patient characteristics are shown in Table 1. One hundred seven patients (69.5%) had pacemakers and the remainder had ICDs. The mean $\pm$ SD device age was 7.6 $\pm$ 5.7 years, with 1.9 $\pm$ 0.9 leads requiring extraction. The indication for extraction was pocket erosion in 22 patients (14.3%), pocket infection in 60 patients (39%), sepsis in 32 patients (20.8%) and debulking of the venous system in 40 patients (26%). This was the first extraction procedure for all patients. Laser assistance was required for extraction in 106 procedures (68.8%). Device and procedure variables, along with indications for extraction, are summarized in Table 2. Among those requiring laser assistance, the mean number of applications was 9.8 $\pm$ 8.4 (median 7.0, IQR 7.5), with a total laser time of 95.5 $\pm$ 126.8 s (median 60 s, IQR 60 s). The mean total fluoroscopy time (including device reimplant) among all patients was 11.2 $\pm$ 13.3 min (median 7.2 min, IQR 9.8 min), and among those requiring laser assistance, it was 11.7 $\pm$ 11.7 min (median 8.0 min, IQR 9.6 min).

Clinical success was achieved in 152 patients (98.7%), with resolution of local or systemic infection, eroded pocket healing or system debulking with new lead placement. One patient died of ongoing sepsis despite uneventful successful device extraction. A second patient developed pericardial tamponade from right ventricular perforation, which was successfully drained by needle, with recurrence and surgical repair. The patient subsequently died of multiorgan failure during the ensuing intensive care unit admission.

Complete extraction was possible for 270 of 278 leads (97.1%) attempted. Successful extraction of at least one intact lead was possible in 146 (94.8%) patients, partial success occurred in six patients (3.9%) (four for debulking and two for pocket infection, all of which resolved clinically) and failure occurred in two patients (1.3%) (septic, subsequently requiring long-term antibiotics). Among the latter eight patients, five were men, four had positive blood cultures, seven had pacemakers and four had lead rupture with manual traction. Four of the eight patients had laser-assisted procedures. The mean age of those with partially successful or failed extraction was 67.4 $\pm$ 25.3 years, the mean device age was 10.3 $\pm$ 9.3 years (range one to 26 years) and the mean body mass index was 24.9 $\pm$ 3.7 kg/m². Multivariate analysis (Table 3) revealed that successful extraction of at least one lead was less likely with more advanced device age (OR 0.83 per year, 95% CI 0.70 to 0.98; $P = 0.036$).

Univariate analysis (Tables 4 and 5) revealed that device age was greater among those requiring laser assistance compared with those

TABLE 3
Multivariable regression on at least one lead extracted

Variable	OR (95% CI)	P
Age	0.98 (0.93–1.04)	0.49
Male sex	1.65 (0.15–18.55)	0.69
Weight (per kg)	1.06 (0.99–1.13)	0.12
ICD (versus PPM)	0.88 (0.075–10.40)	0.92
Device age (per year)	0.83 (0.70–0.98)	0.036*
Total leads	1.62 (0.47–5.53)	0.44
Sepsis	1.23 (0.16–9.53)	0.84
Staff	0.16 (0.013–1.96)	0.92
Positive culture	0.91 (0.13–5.88)	0.15
Laser used	8.18 (0.80–83.86)	0.077

* $P<0.05$ considered to be significant. ICD Implantable cardioverter defibrillator; PPM Permanent pacemaker

TABLE 4
Univariate analysis – categorical variables

Variable	Laser used, %	P
Sex		0.060
Male	66.1	
Female	82.1	
Blood culture		0.36
Positive	73.9	
Negative	67.1	
Physician		0.31
1	67.0	
2	74.6	
Device		0.12
Implantable cardioverter defibrillator	78.7	
Permanent pacemaker	66.4	
Sepsis		0.10
Yes	58.1	
No	73.2	

who did not (mean of 9.32 ± 5.7 years [median 9.0 years, IQR 9.0 years] versus 3.49 ± 3.0 years [median 2.15 years, IQR 4.0 years]; Mann-Whitney $P<0.0001$). Patients requiring laser assistance had more leads in place (mean 2.04 ± 0.9 versus 1.67 ± 0.8 ; $P=0.02$). There was a trend toward more laser use among women, with 82.1% of women requiring laser use compared with 66.1% of men ($P=0.060$).

Multivariate analysis (Table 6) revealed that laser use was less likely among men (OR 0.24, 95% CI 0.069 to 0.84; $P=0.026$) and among septic patients (OR 0.25, 95% CI 0.072 to 0.84; $P=0.025$). Laser assistance was required more often with ICDs than with pacemakers (OR 4.40, 95% CI 1.50 to 12.91; $P=0.0069$) and with each additional year of device age (OR 1.46, 95% CI 1.26 to 1.70; $P<0.0001$).

A prediction model for laser use was created based on the coefficients of the multivariate analysis. The ROC curve is illustrated in Figure 1. The model demonstrated a ROC curve score (c statistic) of 0.87 for discrimination, and adequate calibration ($\chi^2=3.47$; $P>0.90$). Bootstrapping with 1000 samples demonstrated a mean c-statistic of 0.876 ± 0.028 , and an overestimation of the model's ROC score by 0.026. The resulting adjusted ROC score was 0.83.

A prediction rule with high predictive accuracy for laser use could be created, but not for accurate prediction of avoiding laser use. Points were assigned as follows: one point per year of device age, three points for ICD, minus two points for being male and minus one point for having sepsis. A score greater than 10 predicted the need for laser assistance in 39 of 40 patients (97.5% predictive value), and among

TABLE 5
Univariate analysis – continuous variables

Variable	Laser used	Laser not used	P
Device age, years	9.32 (8.22–10.41)	3.49 (2.60–4.38)	$<0.0001^*$
Patient age, years	63.9 (60.9–67.0)	66.2 (61.3–71.1)	0.42
Patient weight, kg	81.8 (78.8–84.9)	81.4 (76.3–86.4)	0.9
Leads attempted, n	2.04 (1.86–2.21)	1.67 (1.44–1.91)	0.02*

Data are presented as mean (interquartile range). * $P<0.05$ considered to be significant

TABLE 6
Multivariable regression on laser used

Variable	OR (95% CI)	P
Age	1.00 (0.97–1.03)	0.92
Male sex	0.24 (0.069–0.84)	0.026*
Weight (per kg)	1.01 (0.98–1.04)	0.53
ICD (versus PPM)	4.40 (1.50–12.91)	0.0069*
Device age (per year)	1.46 (1.26–1.70)	$<0.0001^*$
Total leads (per lead)	1.54 (0.79–3.00)	0.2
Sepsis	0.25 (0.072–0.84)	0.025*
Staff	0.51 (0.19–1.34)	0.17
Positive culture	2.14 (0.78–5.77)	0.13

* $P<0.05$ considered to be significant. ICD Implantable cardioverter defibrillator; PPM Permanent pacemaker

Figure 1 Receiver operating characteristic curve for the prediction of the need for laser assistance. AUC Area under the curve

46 patients who did not need laser assistance, 45 were identified (97.8% specificity). A score of 10 or less was of no predictive value, predicting no laser needed in 45 of 114 patients (39.5% predictive value), and among 108 patients who required laser assistance, 39 were identified (36.1% sensitivity).

DISCUSSION

Extraction of transvenous pacing and ICD leads has become an essential adjunct to arrhythmia device therapy. Access to lead extraction is, therefore, obligatory to physicians who implant and manage devices, and this can entail patient transfer to a tertiary or quaternary care

device centre, considerable cost and use of resources, and delays in device removal. These issues are unavoidable in patients who require laser-assisted removal of leads that otherwise could not be extracted. Indeed, leads that have been in place for longer than one year may be resistant to removal by simple traction, requiring the use of specialized equipment in centres with appropriate training and surgical backup (7). Undue cost, time and risk could, however, be avoided by the recognition of patients with readily removable leads. Among 154 patients referred to our centre for lead extraction, nearly one-third did not require laser assistance. If these patients had been identified in advance, alternative means may have been used for removal of the device. This could have included a wide range of possibilities, from device removal at the referring hospital to avoiding the time and cost implications of operating room time with cardiac surgical backup, and availability of specially trained staff at our referral centre.

We were able to completely extract leads in 94.8% of patients. Among the eight patients with partial success or failure, the only differentiating variable from the other 146 patients was the time since lead implantation. Each additional year since lead implantation reduced the odds of successful extraction by nearly one-fifth. Among patients with incomplete extraction, four had a lead fracture with traction alone, before attempted use of the laser. Such a situation can necessitate even further technical capability and equipment because it may become necessary to extract the distal portion of the lead via the femoral vein, using a femoral workstation.

Four variables were independently associated with the need for laser application at binding sites. Laser application was more likely with increasing time since lead implantation, and in the presence of ICD leads. It was less likely among patients with sepsis, and male patients. The two factors associated with the leads seem intuitive – greater time after implantation results in progressive fibrosis at sites of contact between the lead and the vessel wall. ICD leads have a larger diameter than pacing leads, providing a larger surface area for fibrosis; the shocking coils are commonly involved with fibrosis, causing them to adhere to the wall of the vein (8).

With regard to sepsis, anecdotal experience suggested that sepsis enabled a less intensive extraction process, borne out by the results of multivariate analysis. This may relate to the predominance of *Staphylococcus* species in sepsis, which are slime-producing, as is often observed in colonization of indwelling venous catheters. Our analysis confirmed that sepsis is independently associated with fewer requirements for laser assistance, significantly reducing the odds of laser use by three-quarters.

The observation that women had more than four times the odds of requiring laser assistance than men is perhaps more difficult to

explain. The explanation may be as simple as the correlation of body size with vessel calibre, with smaller veins and similar-sized leads in women, leading to increased fibrosis. It may also be due to a confounding factor, which may be a physiological variable related to fibrosis, more often present among one sex than the other. Alternatively, it may indicate a perception (such as the safety threshold for manual pressure on binding sites, or the risk attributed to laser application) held by the physician that is applied differently to men than to women.

From a clinical point of view, it is unfortunate that a prediction rule could not be derived that would allow anticipation of simple extraction without the need for laser backup. On the contrary, a scoring system was devised, which provided 97.5% accuracy in predicting the need for laser assistance, while only providing 39.5% accuracy in predicting cases for which a laser was not necessary. There would be far more clinical utility to the latter prediction in terms of avoiding undue cost, resources, personnel time and equipment involved with patient transfer to a laser-extraction centre, and with procedure planning. Therefore, it appears prudent to ensure the availability of a laser, an appropriate setting and properly trained personnel for any planned lead extraction. It is also necessary to ensure that the patient understands that laser use may be required, introducing an element of risk to the procedure. There is, unfortunately, no reliable combination of predictors that provides reassurance that an extraction will be simple and uncomplicated.

The limitations of the present analysis include those characteristic of a retrospective approach. Laser use could not be randomized and is therefore subject to potential bias. The variables assessed in the model may be confounded by other measures that were unrecognized or unavailable for assessment. Although we believe that our extraction experience is typical of medium-size extraction programs, our results may not apply to small- or large-volume centres with different approaches and patient populations.

CONCLUSIONS

Laser assistance was required for lead extraction in 68.8% of cases, with clinical success in 98.7% of patients. Laser use was less likely among septic patients and men, and more likely with ICD leads and increasing time since lead implantation. It was not possible to derive an accurate prediction rule for cases that would not need laser assistance. Therefore, it is prudent to ensure that a laser and appropriate infrastructure is available for lead extractions when leads have been in place for more than one year, and that the patient is aware of the possible need for laser assistance, along with the risks entailed. This will often necessitate referral to a properly equipped and trained tertiary care centre, rather than attempted removal by traction alone.

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