NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of laser sheath removal of pacing leads

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared by Bazian Ltd in December 2002.

Procedure names

- Laser sheath removal of pacing leads.
- Laser assisted removal of pacing electrodes.

Specialty society

- British Cardiovascular Interventional Society.

Description

Indications

Removal of pacemaker leads that have been in place for at least a few months.

A pacemaker is a device inserted to maintain the rhythm of the heart. During insertion, one or more leads are passed through the veins into the right side of the heart and the other ends are attached to the pacemaker unit. The unit is usually placed under the skin of the chest.

Pacemaker leads may need to be removed or changed if they malfunction, cause heart rhythm problems, or become infected. If the leads have been in place for more than a few months, they can become tightly attached by scar tissue to the heart and the veins they pass through, making removal difficult and risky.

About 20,000 cardiac pacemakers are inserted in England each year, although how many need to be removed each year is not known (Department of Health Hospital Episode Statistics, ungrossed for missing data, 2000-2001).

Summary of procedure

Pacing leads can be removed simply by pulling them out, but this may fail or cause damage to the heart or large veins. Damage may lead to bleeding into the sac around the heart, which then restricts its ability to pump (pericardial tamponade), or bleeding directly into the chest (haemothorax).

More recently developed techniques involve inserting sheaths around the lead to dislodge it from the surrounding scar tissue, but this may be time consuming. If removal fails, open chest surgery may be required. In some cases, the leads may be detached from the pacemaker unit and then simply left inside the patient.

Laser-assisted removal of pacing leads is claimed to be quicker and less risky than other methods. It involves passing a double-layered sheath over the pacing lead, starting with the end that lies outside the body. The inner layer of the sheath is fibreoptic and can transmit a laser beam. The outer layer is more rigid. The double sheath is passed slowly down over the lead and the laser destroys the scar tissue as the sheath advances. Near the heart wall, the more rigid outer sheath is advanced to provide countertraction for removal of the pacing lead.

The procedure is generally carried out under X-ray control. It may take several hours.

Literature reviews

Appraisal criteria

Studies with clinical outcomes on the removal of cardiac pacing electrodes or leads using a laser sheath were included. Some studies also included people requiring removal of implantable defibrillator leads.

List of studies found

One systematic review was found.[1] It included eight studies, all of which were case series. Only one of the studies appeared specifically to examine the use of a laser sheath system.[2] The systematic review did not examine benefits and harms of the laser system compared with other ways of extracting chronically implanted leads. It concluded that minimally invasive techniques to remove chronically implanted transvenous pacing leads were effective. The rate of successful lead removal was 78–97%; the procedure failed in 4–7% and fewer than 5% of people required open surgery.

One randomised controlled trial was found.[3]

One historical controlled study was found.[4]

FIfteen case series including two or more people were found. The table give details of three largest.[2,5,6]

References to smaller studies are given in the Appendix.

Table 2 Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Wilkoff BL[3] Randomised controlled trial Multicentre study in nine institutions, USA 1995 to 1996 301 people with 465 leads (size 12 French or less) • n = 153 people (244 leads) laser removal, average age 65 • n = 148 people (221 leads) standard lead removal using sheath with counterpressure and countertraction (non-laser), average age 66 Follow up length: not stated, assumed until hospital discharge	Complete lead removal: • laser 95% people • non-laser 96% people p = 0.83 **Analysis by number of leads** Complete extraction of leads: • laser 94% leads • non-laser 64% leads p < 0.001 Failure to extract leads: • laser 3% leads • non-laser 34% leads p < 0.001 Mean operation time per lead: • laser 11 minutes • non-laser 15 minutes p < 0.04	Deaths (number of people): • laser 1 (from tamponade) • non-laser 0 Tamponade (number of people): • laser 1 • non-laser 0 Haemothorax (number of people): • laser 1 • non-laser 0 Heart valve damage (number of people): • laser 1 • non-laser 0 Thrombosis within chest veins (number of people): • laser 1 • non-laser 2	Randomisation method not stated: people were randomised, not leads. Baseline characteristics of groups similar. Power adequate to detect significant differences in efficacy outcomes, but not complications. Blinding not described. Outcomes appropriate. Follow up appropriate. No losses to follow up. Some outcomes analysed by number of leads. No funding from manufacturers.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Nagele H[4] Historical controlled study Hamburg, Germany 1995 to 1999 82 people with pacing and defibrillator leads (average age not stated in abstract) • n = 24 laser removal (1999 onwards) • n = 58 conventional lead extraction (non-laser) (1995 to 1999) - manual traction (n = 23) - other traction devices (n = 24) - snare catheters (n = 6) - open chest surgery (n = 5) Follow up length: not stated	Complete extraction of leads: • laser: 98% 44/45 leads (96% in paper*) • non-laser: 76% Lead fragments remained: • laser: 1/24 • non-laser: 15/62 Mean operation time: • laser: 93 minutes • non-laser: 82 minutes p = "not significant" * this percentage was miscalculated in the paper.	**Complications** (number of people) Laser: • death 1 Non-laser: • death 2 • pericardial tamponade 1 • pulmonary abscess 1 • pulmonary embolism 1 • sepsis 1	Paper in German, information taken from English abstract. Controls were historical. Outcomes appropriate. Longer operation time may reflect differences in the way that operation time measured.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Byrd CL[5] Case series Multicentre study from 89 sites in USA 1995 to 1999 n = 1684 people with 2651 pacemaker leads size 12 to 16 French, average age 64 years Inclusion criteria: aged 18 years or older, duration of lead implantation ≥ 1 year, lead accessible Exclusion criteria: lead too large for laser sheath, recent pulmonary embolus, unsuitable for open-chest surgery Mean follow up: 69 days	Note: figures refer to number of leads, not people complete lead extraction: 90% partial extraction of leads: 3% failure to extract leads: 7% mean operation time: 16 minutes	Major complications (number of people): • in-hospital death 13 • tamponade 23 • haemothorax 6 • pulmonary embolism 2 • migrating lead fragments 1 At follow up (1212 people): • asymptomatic 1105 • complications related to lead removal including arm swelling, pleural effusions, pain, bruising, small pulmonary embolus and infection: 30	Uncontrolled case series. Large so results likely to be precise.. Losses to follow up: 462. Outcomes appropriate. Note: this study includes people enrolled in the study by Wilkoff BL.[3]

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Epstein LM[6] Case series Multicentre study from 52 sites in USA 1996 to 1998 n = 863 people with 1285 pacemaker leads size 12 to 16 French, age range 4 to 103 Inclusion criteria: duration lead implantation ≥ 1 year, lead accessible Exclusion criteria: recent pulmonary embolus, unsuitable for open-chest surgery, lead too large for laser sheath Mean follow up: 1 month	Note: figures refer to number of leads, not people complete lead extraction (12F lead): 89% partial extraction of leads: 3% failure to extract leads: 9% mean operation time: 13–15 minutes depending on sheath size	Complications (number of people): • perioperative death 7 • tamponade 13 • perforation of superior vena cava 5 At follow up (859 people): total late complications 14 • vein thrombosis and arm swelling 7 • pocket haematoma 2 • pericardial effusion without sequelae 2	Uncontrolled case series. Large so results likely to be precise. Losses to follow up: 18%. Outcomes appropriate. Included people likely to overlap with those in Byrd CL.[5]
Kennergren C[2] Case series Multicentre study in 11 European hospitals 1996 to 1998 n = 149 people with 179 pacemaker and defibrillator leads, size 12 to 16 French, average age 68 years, range 14–94 Inclusion criteria: unable to remove leads by simple traction Follow up: to hospital discharge	Note: figures refer to number of leads, not people complete lead extraction: 89% partial extraction of leads: 6% failure to extract leads: 5% median extraction time: 10 minutes (range 1–189 minutes) mean hospital stay: 3 days	No deaths occurred ventricular perforation: 1 tamponade: 1	Uncontrolled case series. No longer term follow up: late complications would not be observed. Outcomes appropriate.

Validity and generalisability of the studies

The studies were all carried out in settings applicable to the UK.

The one randomised controlled trial was of reasonable quality.[3] The unit of randomisation was the person, not the lead, but the researchers compared the main efficacy findings by lead. This may have led to under- or overestimation of differences in outcome between the people whose leads were removed by laser and those whose leads were removed by standard methods. The study was underpowered to detect differences in safety outcomes. It only included people with narrow pacemaker leads of size 12 French or less.

A historical controlled study of people who had laser assisted lead removal was also found.[4] This study suggested better efficacy outcomes in the laser group than in the group receiving conventional types of lead removal, although this kind of study design is susceptible to confounding by period and other variables.

The large USA case series[5,6] and the European series[2] included people with pacemaker or defibrillator leads of up to size 16 French. The large USA case series are very large, so the findings can be used to estimate complication rates with precision.

Specialist Advisor's opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- Specialised procedure that should only be done in a few centres.
- Expensive.
- Laser removal has not been compared with diathermy.

References

Medicare Service Advisory Committee Application 1010. *Intravascular extraction of chronically implanted permanent transvenous pacing leads*. Final assessment report. Available from www.health.gov.au/jaf/msac

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Nagele H, Ismail M, Rodiger W. Excimer laser extraction of pacemaker and defibrillator leads. [German]. *Zeitschrift fur Kardiologie* 2001; 90: 550–6

Byrd CL, Wilkoff BL, Love CJ, Sellers TD, et al. Clinical study of the laser sheath for lead extraction: The total experience in the United States. *PACE - Pacing and Clinical Electrophysiology* 2002; 25: 804–8

Epstein LM, Byrd CL, Wilkoff BL, Love CJ, et al. Initial experience with larger laser sheaths for the removal of transvenous pacemaker and implantable defibrillator leads. *Circulation* 1999; 100: 516–25

Appendix: References to studies not described in the table

Reference	Number of study participants
Moon MR, Camillo CJ, Gleva MJ. Laser-assist during extraction of chronically implanted pacemaker and defibrillator leads. *Annals of Thoracic Surgery* 2002; 73: 1893–6	128
Bracke F, Meijer A, van Gelder B. Extraction of pacemaker and implantable cardioverter defibrillator leads: Patient and lead characteristics in relation to the requirement of extraction tools. *Pacing & Clinical Electrophysiology* 2002; 25: 1037–40	90
Rinaldi CA, Bostock J, Patel N, Buckell, CA. Determinants of procedural outcome of chronically implanted pacemaker and defibrillator leads using the Excimer laser sheath. *Heart* 2002, 87, 160–1.	80
Kennergren C. First European experience using excimer laser for the extraction of permanent pacemaker leads. *Pacing & Clinical Electrophysiology* 1998; 21: 268–70	45
Parsonnet V, Roelke M, Trivedi A, Rizvi SA, et al. Laser extraction of entrapped leads. *Pacing & Clinical Electrophysiology* 2001; 24: 329–32	62 leads
Costa R, Martinelli Filho M, Crevelari ES, Stolf NA et al. Laser assisted extraction of pacemaker and implantable defibrillator leads. *Arquivos Brasileiros de Cardiologia* 2001; 77: 235–42	36
Gilligan DM, Dan D. Excimer laser for pacemaker and defibrillator lead extraction: techniques and clinical results. *Lasers in Medical Science* 2001; 16: 113–21	34
Korley VJ, Hallet N, Daoust M, Epstein LM. A novel indication for transvenous lead extraction: upgrading implantable cardioverter defibrillator systems. *Journal of Interventional Cardiac Electrophysiology* 2000; 4: 523–8	20
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Cooper JM, Stephenson EA, Berul CI, Walsh E., et al. Implantable cardioverter defibrillator lead complications and laser extraction in children and young adults with congential health disease: implications for implantation and management. *Journal of Cardiovascular Electrophysiology*, 2003 14, 4: 344–9	14
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Levy T, Walker S, Paul V. Initial experience in the extraction of chronically implanted pacemaker leads using the Excimer laser sheath. *Heart* 1999; 82: 101–4	8
Nguyen KT, Neese P, Kessler DJ. Successful laser-assisted percutaneous extraction of four pacemaker leads associated with large vegetations. *Pacing & Clinical Electrophysiology* 2000; 23: 1260–2	4
Bracke FA, van Gelder LM, Sreeram N, Meijer A. Exchange of pacing or defibrillator leads following laser sheath extraction of non-functional leads in patients with ipsilateral obstructed venous access. *Heart* (British Cardiac Society) 2000; 83: E12O	3