

# **STANDARDS FOR LEAD EXTRACTION**

## **A consensus document from UK lead extractors**

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### **INTRODUCTION**

This document was produced following a meeting of UK extractors in September 2018. Representatives from all UK extraction centres were invited to the meeting. The contents of the document were discussed and agreed unanimously by those present at the meeting. This document has subsequently been circulated and agreed by the group.

### **BACKGROUND TO LEAD EXTRACTION**

The majority of lead extraction procedures in the Western world are performed transvenously by cardiologists and/or cardiac surgeons.

The European task force<sup>1</sup> has attempted to calculate the total transvenous extraction need based on 1.5 times the reported prevalence of infection in patients with implanted cardiac devices as a proportion of lead extraction will be for non-infectious indications. The reported prevalence of infection in registries and national databases ranges from 1-4%.

The National Cardiac Rhythm Audit reported that the UK implanted 785 devices per million population in 2015/16. Based on the conservative 4% prevalence of extraction, we are looking at 31 per million population per year in the UK.

The purpose of this document is to define the standards of care for lead extraction within the UK based on the existing evidence, literature and expert consensus.

### **INDICATIONS FOR LEAD EXTRACTION**

The indications for lead extraction are well documented in the HRS consensus document on lead extraction<sup>2</sup> supported by the EHRA position paper<sup>1</sup>. The common indications for lead removal are infection, venous occlusion, mechanical lead failure, advisory or recall because of potential lead malfunction. Recommendations for lead removal apply to those in whom the benefits outweigh the risks.

### **DEFINITIONS**

Lead extraction is defined as "removal of a lead that has been implanted for more than one year, or a lead regardless of duration of implant, requiring the assistance of specialised equipment that is not included as part of the typical implant package, and/or removal of a lead from a route other than via the implant vein."<sup>2</sup> This is to be distinguished from "lead explant" which is "a lead removal using simple traction techniques (no locking stylet, telescoping sheaths or femoral extraction tools)<sup>2</sup>."

## **THE LEAD EXTRACTION TEAM**

It is recommended that centres that undertake lead extraction should have a dedicated team that works together to perform all lead extraction. The team should consist of the following:

- **Primary Operator:** the lead cardiologist/cardiac surgeon performing the lead extraction who is properly trained (see below) and experienced in device implantation, lead extraction and the management of complications. In most instances this will be a consultant cardiologist or cardiac surgeon, however, in exceptional circumstances this could be an appropriately trained junior doctor.
- **Secondary Operator:** a consultant cardiologist/surgeon or suitably trained member of staff capable of supporting the procedure.
- A cardiothoracic surgeon well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available.
- Anaesthesia support from an experienced cardiothoracic anaesthetist with the facility for TOE monitoring (available immediately if the procedure is not being undertaken under GA).
- Radiographer capable of operating fluoroscopic equipment
- Scrubbed assistant, non-scrubbed assistant (theatre runner) and cardiac physiologist all appropriately trained in lead extraction and familiar with the procedure and the equipment necessary for lead extraction.

## **FACILITIES AND LOCATION**

Explant of most pacemaker leads, particularly active fixation leads, within the first 12 months of implant can usually be managed without problems by the implanting clinician / centre with the use of a stylet and screw retraction on active fix leads and simple traction.

Where there is doubt about the ease of removal/revision, referral to a centre with lead extraction experience and facilities should be considered.

All leads over 12 months in duration or that may require the use of adjunct tools for extraction should be referred to a lead extraction centre.

If the site appears infected, it is preferable that the referral is made without intervening upon the wound in the interim.

## **TRAINING REQUIREMENTS / PROCEDURE NUMBERS**

The EHRA document "Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper"<sup>1</sup> describes minimum recommended numbers for operators and minimum numbers of procedures per year.

Primary operators should have undertaken a minimum of 75 lead extraction and be continuing to undertake 15 procedures per year.

Data from the ELECTra registry suggested >30 cases (not leads) per centre per year as reasonable as there were demonstrable differences in outcome measures when this was used.

However, it is recognised that competence can only be defined effectively in terms of patient outcome. Published data from a variety of sources<sup>1, 3-6</sup> demonstrates that a high quality service should expect a successful lead

extraction rate of at least 94%, with a mortality rate of less than 0.8% and a major complication rate (death, cardiac/vascular tear, pulmonary embolism or stroke) of less than 1.7%. Therefore, all centres should have robust audit of these procedures and be able to demonstrate that they meet these outcome requirements. Provided this can be demonstrated, it is acceptable to perform fewer procedures, however, this must be kept under continuous review to pick up and change in these outcome parameters. It is, therefore, mandatory that all centres and operators submit their data in a timely fashion to the national CRM audit database.

## **FACILITIES**

Lead extraction procedures must only be performed at centres with on-site cardiac surgery. Procedures can be performed in either operating rooms, or procedural laboratories specifically allocated for device implantation procedures.

Regardless of whether the extraction is performed in the EP lab or in theatres it is essential that a cardiac surgeon and surgical team are immediately available with access to equipment to perform emergency sternotomy or thoracotomy within 5 to 10 mins.

## **EQUIPMENT**

High quality fluoroscopy must be available and the operating table must allow vascular access to the patient from both sides and from the femoral and subclavian approaches.

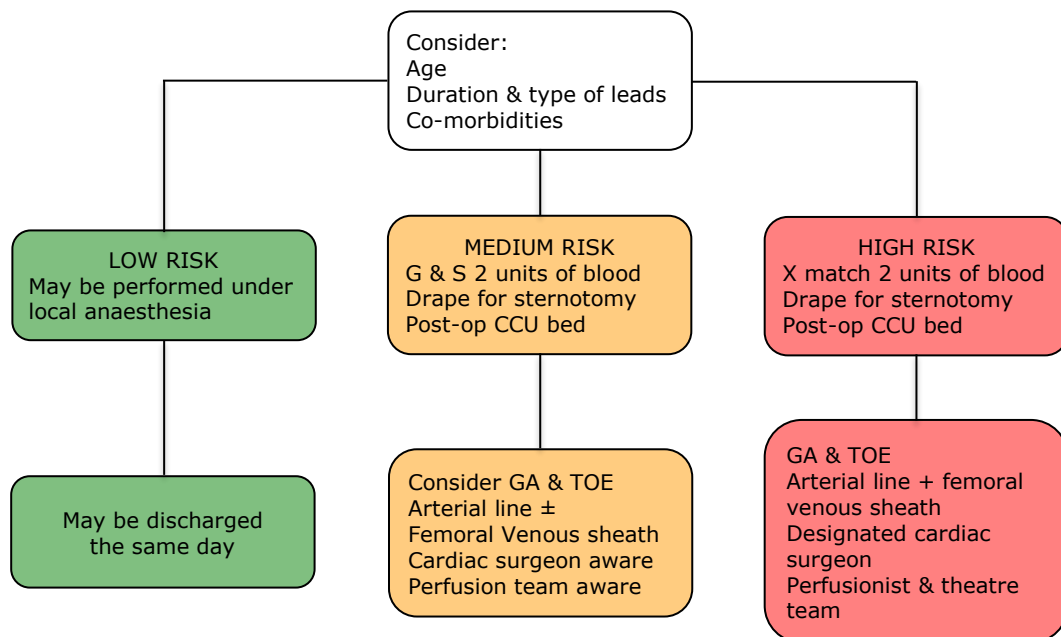
Equipment required for extraction should include a variety of the extraction tools. These may include, but are not restricted to, locking stylets; snares, grasping or other devices used to engage or entrap and remove the lead or lead fragments; mechanical and laser sheaths.

Other equipment includes general anaesthesia equipment, invasive and non-invasive arterial pressure monitoring, oxygen saturation and CO<sub>2</sub> monitoring, transthoracic and transoesophageal echo, pericardiocentesis tray, water seal/vacuum containers for chest tube drainage, temporary transvenous pacemaker and connectors, transcutaneous temporary pacing and defibrillation equipment, intravenous contrast agents, fluids, pressors and other emergency medications in the procedure room. Equipment for cardio-pulmonary bypass must be readily available.

Consider availability and access to deployment of the Bridge™ Occlusion Balloon in the event of an SVC injury.

## PATIENT RISK STRATIFICATION

Consider: age, BMI, Duration, number and type of leads; co-morbidities, LV ejection fraction



**Below are suggestions on how one might classify risk:**

### LOW RISK

Examples would include:

Active fixation pacemaker (not ICD) leads, duration 1-2 years, normal BMI, good LV function

### MEDIUM RISK

Examples would include:

Active fixation leads duration 2 – 10 years; passive leads and single coil ICD leads. Leads in otherwise high-risk patients may be treated as amber based on operator discretion

### HIGH RISK

Examples would include:

Leads older than 10 years

### LEADS >20 YEARS OLD AND PATIENTS WITH PREVIOUS STERNOTOMY

These patients have the highest risk of complications and therefore each case should be discussed in an MDT format with cardiologists and cardiac surgeons to discuss the risks and benefits of extraction plus the approach (transvenous versus surgical). Risks and benefits of transvenous versus surgical lead extraction should be considered and discussed with the patient.

It is recognised that it is good practice to consider a multi-disciplinary approach involving cardiologists and cardiac surgeons prior to lead extraction.

### LEAD EXTRACTION IN PATIENTS WITH CONGENITAL HEART DISEASE

These patients form a small but important group. They should all be reviewed / discussed in a congenital / ACHD multidisciplinary meeting and a surgeon specialising in congenital heart disease should be aware or available as appropriate.

## **CIED RE-IMPLANT**

Each patient should be carefully evaluated to determine if there is a continued need for a new CIED, plus the timing and siting of the CIED in line with HRS guidance.

## **REFERENCES**

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