Proposed
BHRS STANDARDS FOR LEAD EXTRACTION

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BACKGROUND TO LEAD EXTRACTION

This document is not intended to disrupt or disenfranchise existing, successful device services. It should be regarded as a template for developing best practice when starting de novo and a recommendation to enable successful but inadequately resourced services to develop. It is recognised that competence can only be defined effectively in terms of patient outcome. Numbers given in this document are indicative and should not be taken in isolation as evidence of competence or the ability to provide a safe, high quality service.

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

The European task force[1] has attempted to calculate the total trans-venous 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%. ELECTRA reported that 50% of lead extractions may be performed in non-infected leads so this figure may be higher[2].

The National Cardiac Rhythm Audit reported that the UK implanted 785 devices per million population in 2015/16. Based on a 4% prevalence of extraction, an estimated need of 31 per million population per year in the UK is derived.

The purpose of this document is to define the standards of care for lead extraction within 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[3] supported by the EHRA consensus statement[4]. The common indications for lead removal are infection, venous occlusion, mechanical lead failure, advisory or recall because of potential lead malfunction. Recommendations to lead removal apply to those in whom benefits outweigh the risks.

For centres that implant cardiac implantable electronic devices (CIED) that do not perform lead extraction, if a procedure is planned on a patient with an existing CIED, it is recommended that a discussion with the patient and the local lead extraction centre is documented regarding a decision about lead extraction when:

i) The existing leads are >1 year old and there is concern about the potential for CIED or wound infection.

ii) It is clear that one or more of the existing leads will be redundant and the patient has a longevity of >10 years.

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.[3]" 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)[3]."

THE LEAD EXTRACTION TEAM

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

- Primary Operator: is the lead cardiologist responsible for the lead extraction and is scrubbed for the procedure. They should be properly trained (see below) and experienced in device implantation, lead extraction and the management of complications.
- Secondary Operator: is an assistant who may be a physician in training, a nurse or in particularly complex cases another consultant also trained and experienced in lead extraction techniques,
- A cardio-thoracic surgeon capable of assisting in the event of potential complications of lead extraction, on site.
- Anaesthesia support from a cardiothoracic anaesthetist with the facility for TOE monitoring (available, if the procedure is not being undertaken under GA).
- Radiographer capable of operating fluoroscopic equipment
- Scrubbed assistant (if no second operator), non-scrubbed assistant (theatre runner) and cardiac physiologist who meets the required recommendations and experience for complex device implant and follow up as stated in the: STANDARDS FOR IMPLANTATION AND FOLLOW-UP OF CARDIAC RHYTHM MANAGEMENT lDEVICES IN ADULTS January 2018

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 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"[1] 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 and < 30 cases (not leads) per centre as reasonable as there were demonstrable differences in outcomes measure 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[1,4-7] demonstrates that a high quality service should expect a successful lead extraction rate of at least 94%, with a procedural 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 database.

FACILITY

Lead extraction procedures should generally only be performed at centres with on-site surgery and cardiac catheterisation programs. Procedures can be performed in either operating rooms, or procedural laboratories specifically allocated for device implantation procedures. However, the room must be of adequate size to allow for emergency interventions such as thoracotomy and sternotomy. Non-surgical centres have demonstrated good outcomes with low complications rates, for lower risk lead extraction.

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/specialised sheaths. Balloons suitable for occluding the superior vena cava may be considered. Other equipment includes a transthoracic echo machine, general anaesthesia equipment, invasive and non-invasive arterial pressure monitoring, oxygen saturation and CO_2 monitoring, 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 and equipment for cardio-pulmonary bypass must be readily available.

PATIENT RISK STRATIFICATION

For the purposes of assessing the risk of the patient it is helpful to stratify patients into low, medium and high risk. No risk scoring system has been validated in large scale randomized trials but factors to consider when risk stratifying are: age, BMI, Duration, number and type of leads; co-morbidities, LV ejection fraction

Low risk

May be performed as a day case under local anaesthetic

Medium risk

May be performed under local or general anaesthetic. Consider group and save of blood, arterial line, femoral venous access and making the surgical team aware of the case.

High risk

Consider cross matching blood, general anaesthetic and having a designated surgical team on standby

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 with cardiologists and cardiac surgeons to consider the risks and benefits of extraction plus the approach (trans-venous vs surgical).

For all leads other than the "low risk" group, risks and benefits of trans-venous vs surgical lead extraction to be considered most importantly with the patient and where appropriately with cardiology and surgical colleagues.

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 the HRS guidance.

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