Standards for insertion, follow up and explant of implantable loop recorders [ILRs] by non-medical staff

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First edition

1. Introduction

This document has been produced by a group of arrhythmia specialists from tertiary and district general hospitals and approved by the British Heart Rhythm Society [BHRS]. This document will be reviewed on a bi-annual basis.

The purpose of the document is to provide evidence-based guidance to facilitate the safe implantation and management of ILR's by nurses or physiologists.

Historically, ILR implants were undertaken by Cardiology Consultants or StRs but in recent years, this has shifted to non-medical colleagues performing implants with an increasing number of participating centres across the country. It was therefore felt important to produce this minimum standards document to support non-medical staff undertaking ILR implantation.

These standards include identification of patients with indications for insertion, the implantation procedure, follow up, data collection, and explant. This has been compiled from the best available evidence and Standard Operational Procedures in existence across the country (referred to at the end of this document).

This document is not intended to replace Trust policies and other legislation e.g. data protection and codes of conduct for nurses and physiologists, but as a supportive document.

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. 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.

2. Definitions

For the purpose of this document, ILR refers to implantable loop recorders. The ILR is a device that is positioned in the subcutaneous layer which automatically (and via patient activation) records an ECG. The device is implanted to aid in the diagnosis of unexplained syncope or symptomatic palpitations where abnormalities of cardiac rhythm are suspected.

The implanter is the person undertaking the procedure, not observing or entering data.

3. Indications

ILR implantation is indicated when patients have experienced symptoms of syncope, pre-syncope or intrusive palpitations which have not been documented with an ECG or other external cardiac monitoring but are suggestive of being of cardiac in origin.

NICE guidance states that patients who have loss of consciousness with a probable cardiac cause but have symptoms infrequently (less than once every two weeks), may be offered an implantable loop recorder as the first line of investigations (1).

The ESC guidelines give a class I recommendation for ILR implant where there is recurrent syncope of uncertain origin, absence of high-risk criteria and a high likelihood of recurrence within the battery life; Also in those with high-risk criteria in whom a comprehensive evaluation has not demonstrated a cause of syncope and who do not have conventional indications for primary prevention ICD or pacemaker. A IIa recommendation is given for ILR implantation for patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes (2).

There is contemporary evidence suggesting the use of ILRs in determining the cause of cryptogenic stroke when the cause may be related to atrial fibrillation and the ILR may have a role in excluding atrial fibrillation as a cause of patient's events (3).

The implanter should be aware of the rare occurrences of hypersensitivity to local anaesthetic agents or to materials present on the surface of ILRs and may therefore contraindicate insertion of the ILR.

4. Requirements for performing ILR insertion

Safe ILR insertion requires the appropriate environment, equipment and trained staff.

4.1 Room specification

- Implantation should be performed in the appropriate environment for sterile procedures (infection control approval).
- The treatment room should be situated within close proximity to medical assistance if required.
- The room should be suitable to accommodate a patient trolley, dressing trolley, all necessary equipment, and have a sink for aseptic hand washing.

4.2 Equipment

- All equipment for implantation and management of recognised complications must be immediately available.
- Clean dressing trolley, insertion pack, aseptic gowns and gloves, patient trolley.
- Device programmer with ECG monitoring facility.
- Local anaesthetic, prescription and patient records.
- Resuscitation trolley within close proximity (and telephone).

4.3 Emergency equipment

- A telephone must be available in the event of an emergency and full resuscitation equipment including defibrillator and cardiac arrest trolley must also be available. Resuscitation equipment should be checked regularly in accordance with Trust protocols.

4.4 Staffing requirements

- Practitioner competent in ILR implantation and cardiac physiologist proficient in the setup of ILR devices via programme.
- A further assistant may be required to assist with preparation with the patient and / or equipment.
- This should be considered a two-person procedure or if performed by a single operator, it should be possible for them to call for assistance easily from within the same building in the event of a problem e.g. cardiac rhythm complication.

4.5 Competency

- Trainees should be observed a minimum of 20 times by a competent practitioner in ILR insertion. Competence to be assessed against a standard competency assessment tool for ILR insertion (see BHRS website for guidance). The assessor must sign to demonstrate competence has been achieved.
- Nurses or physiologists trained to implant ILR's, should perform a minimum of 20 new implants per year. This may differ according to the centre but is suggested as a guide.
- If the implanter does not perform this number per year (for example, if absent for a period of six months or more) then competence should be reassessed by

another competent practitioner and a further 'sign off' competency completed. It is suggested this would be for a further 5 implants.

- There should be a Standard Operating Procedure for each implanting centre and all relevant staff should read this and be familiar with equipment and environment being used.
- An aseptic technique should be used for the procedure.
- The implanter should also be competent to consent the patient and comply with their Trust consenting Policy.
- Implanters should have an agreed job description which details their responsibilities, and this adhered to within this expanded role.
- It is recommended that the implanter holds a British Heart Rhythm Society certificate (recognition of knowledge and practical experience in the field of cardiac rhythm management).
- Intermediate Life Support qualification with annual updates is recommended.

4.6 Procedure for implant

- The procedure for implant should follow the manufacturer implantation guidelines as per device being implanted.
- There should be a Standard Operating Procedure for each centre performing cardiac physiologist / nurse implants and this adhered to.
- Patients should be fully informed and consented with clear advice regarding implant, monitoring, follow up and wound care.
- There is little evidence for or against the use of prophylactic antibiotics. However, this may be reasonable in high-risk patients in line with local microbiology policy e.g. those with diabetes, renal failure etc (4).
- Interruption of direct oral anticoagulants or warfarin is not usually necessary, INR should be less than 3 (4). Any concerns to be referred to the Consultant in charge.
- The implanter should prepare for implant as per aseptic Trust technique.
- Administration of Lidocaine subcutaneously, from a legal prescription by a qualified independent prescriber. The cardiac physiologist or nurse administering the local anaesthetic, should act in accordance with their level of competence, comply with safe administration of medicines and abide by the Trusts medicines management policy (5, 6, 7).
- Clear documentation of the device implant should be entered in to the patient notes / electronic registry.
- ILR set up should be performed by the cardiac physiologist ensuring adequate sensing.

4.7 Complications

- Vagal episode, allergic reaction to local anaesthetic, erosion of device, bleeding and wound infection.

- Staff present at the time of implant should be competent to manage such events and have the back up of medical assistance if required.

5 Requirements for follow up

- Follow up should be arranged at or around four to six weeks post implant with a cardiac physiologist.
- At this time, the wound should be checked by the operator and a third party for the first 10 implants to ensure the service is working well.
- Onward follow up where remote, should involve a three-monthly review unless alerts are noted before this time.
- Where follow up is not remote, patients should be seen at intervals determined by the Consultant and implanting team, often for a download at three-monthly intervals.
- Patients will send symptomatic events through and there should be regular specified analysis opportunities for the cardiac physiologist to review these.

6 ILR explant

- When the ILR has reached battery expiry, it may be removed by a qualified practitioner. This should be by somebody competent in this surgical procedure and may therefore not be the original implanter.
- When a diagnosis has been made through the ILR (for example a bradyarrhythmia), the ILR may be removed at the time of pacemaker implantation.
- There is limited evidence relating to leaving the ILR in place or removing once monitoring is complete but review of current practice follows patient preference, removal at completion of battery life or removal once diagnosis is reached.
- Medtronic suggest in their manual 'Remove the device when it is no longer needed, when the battery is depleted, or before burial or cremation' (8).
- Abbott suggest 'interrogate the device and turn monitoring off before explanting, cleaning or shipping…. return all explanted devices to St. Jude Medical… and 'never incinerate the device because of the potential for explosion. Explant the device before cremation' (9).
- ILR removal must be discussed with the patient with appropriate consent taken.

7 Audit

- All implanters are expected to continually audit their practice.
- A well-managed database should be maintained of device implants to allow immediate tracing of patients and audit.

- A database of complications should also be held, in keeping with clinical governance. Complications at time of implant and at twelve months should be recorded.
- Advice and safety notices from manufacturers and the MHRA should be recognised and actioned accordingly.
- It is mandatory to submit the implant details to the national audit database www.ucl.ac.uk/nicor/audits/cardiacrhythm

8 Planned review date

July 2020

9 References

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Further information obtained from:

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