

Guidelines for the perioperative management of patients with implantable pacemakers or implantable cardioverter defibrillators, where the use of surgical diathermy/electrocautery is anticipated.

Introduction

The provision of implantable pacemakers and implantable cardioverter defibrillators (ICDs) to treat heart problems is increasing and as a consequence more patients with these devices are likely to present for elective or emergency surgery. The use of surgical diathermy/electrocautery can give rise to electrical interference and this can present additional risks when used in patients implanted with pacemakers and ICDs. Energy can also be induced into heart lead systems causing tissue heating at lead tips through high frequency current. Therefore, appropriate precautions need to be considered.

Manufacturers of implantable pacemakers and ICDs either contraindicate the use of surgical diathermy/electrocautery, or give strong warnings against its use – especially the monopolar mode of operation. There may however be situations where the risk/benefit analysis favours the use of surgical diathermy/electrocautery, particularly in emergency situations.

Wherever possible, surgical diathermy/electrocautery should be avoided with these devices. However, where surgical diathermy/electrocautery is deemed essential, the use of bipolar surgical diathermy/electrocautery should first be considered bearing in mind that even in this mode a possibility for interference remains.

This document is intended to provide guidance when patients with these devices need to undergo surgical intervention and has been prepared at the request of the MHRA's Committee on the Safety of Devices (CSD) and in consultation with Heart Rhythm UK (HRUK).

Planned surgical procedures

Patient screening

Since all surgical procedures (except emergency) are planned in advance, the identification of patients having these devices should be effected through routine pre-admission screening. Although pre-admission forms may request patients to declare if they have a pacemaker/ICD, this should be independently verified.

Recording pacemaker/ICD details

When a pacemaker/ICD is identified it should be clearly recorded in patient notes and marked for the attention of key clinical and surgical staff (surgeon, anaesthetist, cardiologist etc). Patients with these devices are usually provided with a registration card or 'passport' recording details of the device and its manufacturer. Where possible the following key information should be noted for future reference:

- device manufacturer, model number, serial number
- implanting hospital, follow-up hospital
- date of implant
- reason for implant (e.g. heart block etc)

Clarification of indication for device implant and device status

In advance of the surgical procedure, the patient's pacemaker/ICD follow-up clinic should be contacted to confirm their cardiac condition and to determine in particular:

- indication for device implant
- extent of any heart failure
- degree of pacemaker dependency
- implant complexity (bradycardia support, arrhythmia control, cardiac resynchronisation therapy)
- if the device is at or approaching replacement phase
- if the device is subject to a manufacturer or regulatory agency safety advisory notice
- if the device is part of a clinical investigation where restrictions may apply

Considering additional perioperative support

Prior to surgery the anaesthetist and surgeon involved should discuss the implications of the patient having an implanted pacemaker/ICD. Where surgical diathermy/electrocautery cannot be avoided, the surgical team should contact the patient's cardiac follow-up centre for advice.

Where the surgical procedure is remote from the pacemaker/ICD and the device has been checked and verified within the last three months (especially battery condition), risk of malfunction will be minimal. However, where the procedure will be close to the implant and where the use of surgical diathermy/electrocautery is likely, then risk of malfunction is increased. Consequently, the patient's follow-up clinic should be contacted to advise to what extent support may be required from a cardiac pacing/ICD physiologist before, during and/or after the surgical procedure to:

- confirm the correct functioning of the pacemaker/ICD and to check the condition of the battery and leads etc prior to surgery
- advise if adjustments to sensing/pacing parameters are required (the majority of devices will not require changes prior to or after surgery)
- programme an ICD prior to surgery to a 'monitor only' mode to prevent inappropriate therapy/shock delivery, in the event of accidental sensing of electrical interference
- programme a pacemaker to avoid or minimise inappropriate inhibition, or high rate pacing through the 'tracking' of electrical interference, where there is a degree of pacemaker dependency
- programme rate response function to 'off' in those devices that use the minute ventilation method of physiological pacing
- programme the implant's 'sleep mode' to OFF if late surgery is planned
- confirm device functionality on completion of surgery.

During surgery

At the time of surgery the following should be considered when surgical diathermy/electrocautery is to be used on patients having an implantable pacemaker/ICD:

- availability of cardio-pulmonary resuscitation, temporary external/transvenous pacing, and external defibrillation equipment
- availability of appropriate cardiac personnel
- monitoring the patient's ECG from the outset of surgery and before the induction of anaesthesia
- if using an ECG monitor which has a 'paced' mode, give careful consideration to whether the use of this mode would be advantageous or not. (In the unlikely event of pacing pulses failing to capture the heart, an ECG monitor set to 'paced' mode may misinterpret the pacing spikes as the patient's QRS complexes and incorrectly display a heart rate when the patient is actually in asystole)
- use of an alternative method of detecting a patient's pulse such as an arterial line or pulse oximeter (as a minimum)
- where detectable pacemaker inhibition occurs, the surgeon should be informed immediately and diathermy either used intermittently or discontinued
- where the use of monopolar diathermy/electrocautery is unavoidable –
 - > limit its use to short bursts
 - > ensure that the return electrode is anatomically positioned so that the current pathway between the diathermy electrode and return electrode is as far away from the pacemaker/defibrillator (and leads) as possible
- where either monopolar or bipolar diathermy/electrocautery is used –
 - > ensure that cables attached to diathermy/electrocautery equipment are kept well away from the site of implant
 - > consider alternative external/transvenous pacing where pacing from the implant is significantly affected during the use of diathermy/electrocautery
- for patients where the ICD is deactivated and where access to the anterior chest wall will interfere with surgery (or the sterile field), consider connecting the patient to an external defibrillator using remote pads.

Emergency procedures

Wherever possible, the steps outlined above (see **During surgery**) should be followed when handling emergency cases.

Where it is not possible for the pacemaker/ICD to be checked before surgery then device function should be checked as soon as feasible post-operatively.

Ensure that cardio-pulmonary resuscitation, temporary external/transvenous pacing, and external defibrillation equipment are available.

For patients with ICDs, consideration may be given to positioning a clinical magnet over the implant site to inhibit inappropriate shock delivery through noise detection. However, it should be noted that:

- inhibition of shock delivery will only be effective during magnet placement and that this should be secured to the patient for the duration of surgery using Micropore tape (or equivalent)
- any subsequent VT/VF will need to be treated using external defibrillation equipment,

- shock delivery can not be inhibited for those ICDs where the clinician has programmed the device not to respond to an external magnet
- where a magnet has been applied the ICD must be checked post operatively to determine therapy delivery status.

For patients with pacemakers, securing a magnet over the pacemaker implant site will not necessarily guarantee asynchronous (non-sensing) pacing. Magnet response may vary between manufacturers' models and according to particular programmed settings.

Clinical magnets for this application may be made available from the local cardiac pacing centre.

If an ICD is deactivated, consider connecting the patient to an external defibrillator using remote pads if access to the anterior chest wall will interfere with surgery or the sterile field.

In the event of a prolonged, life-threatening arrhythmia, conventional advanced life support procedures should be followed.

Some pacemakers are programmed to allow a lower intrinsic or paced rate during the patient's sleeping period (night rate). This mode is initiated automatically at the time set by the patient's clinician and a reduction in paced rate may therefore be observed in patients undergoing night surgery. Appropriate heart rate can be restored via temporary external/transvenous 'overdrive' pacing.

About implantable pacemakers and cardioverter defibrillators

Pacemakers/ICDs are highly sophisticated electronic medical implants which monitor and respond to very small electrical signals sensed within the heart. Although some pacemakers treat bradycardia, some are also able to treat heart arrhythmias through particular methods of pacing. Pacemakers are now available to provide corrective resynchronisation of left and right sides of the heart. Early implantable cardioverter defibrillators were designed to mainly treat arrhythmias such as ventricular tachycardia or ventricular fibrillation through pacing and shock delivery but now incorporate complex pacing functions.

Both pacemakers and cardioverter defibrillators have been designed with a high degree of tolerance to electrical and magnetic interference fields and special filtering components have been incorporated to minimise the effects of these. A problem may arise, however, if the energy level of a nearby field is very high, or has a frequency component that is close to cardiac range.

Interference generated by monopolar surgical diathermy/electrocautery can be sufficient to temporarily inhibit pacemaker output, or may give rise to a temporary increase in pacing rate. The release of substantial energy may also cause devices to enter a safety mode of operation with subsequent restricted function. Also if the energy field is close, programmed parameters may be reset to the manufacturer's default settings, thereby losing patient settings programmed by the clinician. Where a device's internal power source has significantly depleted to a point where device replacement is needed, such interference can cause the device to stop functioning completely. In ICDs there is a possibility that the interference signal may be misinterpreted as ventricular tachycardia or ventricular fibrillation causing inappropriate initiation of therapy.

Where a pacemaker (or an ICD with a pacing function) uses an impedance-based rate-responsive pacing function (e.g. minute ventilation), then signals from physiological/cardiac monitoring equipment can be sensed by the implant resulting in inappropriate high rate pacing. Temporarily programming the device to a non-rate response mode will prevent this.

Alternatively, a monitoring device that does not employ thoracic impedance measurements could be used.

Pacemakers and ICDs have a magnetic switch which will respond to a magnet when positioned over the implant site. The nature of the response to magnet placement will depend upon how the device is currently programmed by the clinician.

For some pacemakers, placing a magnet over the device may result in asynchronous pacing, whilst in others a period of device diagnostics is initiated after which pacing is resumed.

For ICDs, placing a magnet over the device can inhibit delivery of shock therapy but only where the device is programmed to respond in this way.

Placing a magnet over an implantable pacemaker or cardioverter defibrillator will therefore not necessarily modify or suspend therapy. Further information about magnet status should be confirmed by the patient's follow-up/implanting centre.

This information together with the document below is intended to provide guidance when patients with implantable pacemaker and cardioverter defibrillators need to undergo surgical intervention and has been prepared at the request of MHRA's Committee on the Safety of Devices (CSD) and in consultation with Heart Rhythm UK (HRUK).