University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

ICD implant/CRTD: Departmental Procedure

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EVIDENCE FOR PRACTICE:

There are certain patient groups at risk of developing life-threatening ventricular arrhythmias such as ventricular tachycardia (VT) or ventricular fibrillation (VF). These patients include those with predisposing genetic conditions, those who have survived previous ventricular arrhythmias and heart failure patients particularly those having suffered a myocardial infarction (MI).

VT is potential life threating arrhythmia because it can reduce cardiac output and, depending on the patient and the rate of arrhythmia, lead to symptoms ranging from palpitations and dizziness to cardiac arrest. In the case of VF this will rapidly bring on cardiac arrest and ultimately death unless treated quickly. Implantable cardioverter defibrillator (ICD) devices are used to provide therapy to treat both these arrhythmias.

The device is designed to detect, interpret arrhythmias and deliver therapy in the form of either rapid anti tachycardia pacing (ATP) or deliver an electrical charge to terminate the arrhythmia.

Devices providing cardiac resynchronisation therapy with defibrillation (CRTD) are used to deliver this therapy to protect against such arrhythmias in patients with heart failure. In this setting CRTD devices also improve coordination of contraction between the left and right ventricles with the aim of improving pump function and circulation, while aiming to reduce patient symptoms of heart failure.

CONSENT:

Written consent is required and is obtained and recorded as per trust policy (REF).

Procedure for consent to examination and treatment
Controlled document No. 024 v 6 (issued 10/9/2013)

Procedure for consent to examination and treatment
Controlled document No. 412 v 5 (issued 16/08/2013)

Mental Capacity act 2005

INDICATIONS:

Indication for implantation of ICD or CRTD and choice of appropriate device is agreed at MDT meeting using consultant opinion and NICE guidelines [(2)] as identified below.

ICDs are recommended as options for:

Patients with previous serious ventricular arrhythmia, without a treatable cause:

- Have survived cardiac arrest due to VT or VF
- Have spontaneous sustained VT with haemodynamic compromise (e.g. syncope)
- Have sustained VT, without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less, but symptoms no worse than NYHA class III.

Patients at risk of VT or VF eg:

- Long QT syndrome
- Brugada
- HCM
- ARVD
- Surgical repair of congenital heart disease

Heart failure patients

ICD, CRT-P or CRT-D are recommended for people with heart failure who have LV dysfunction with LVEF ≤ 35% as described below[(2)]

	NYHA class			
QRS interval	**I**	**II**	**III**	**IV**
<120ms	**ICD if there is a high risk of sudden cardiac death**			**ICD and CRT not clinically indicated**
120–149 ms No LBBB	ICD	ICD	ICD	CRT-P
120–149 ms with LBBB	ICD	CRT-D	CRT-D or P	CRT-P
≥150 ms with or without LBBB	CRT-D	CRT-D	CRT-D or P	CRT-P
LBBB, left bundle branch block; NYHA, New York Heart Association				

CONTRAINDICATIONS:

Absolute contraindications:

- Refusal of the patient to give consent for the procedure.
- Lack of required equipment or staff to perform the procedure
- Allergy to steroid (dexamethasone sodium phosphate)
- Patients who do not wish to have a device implanted for either religious or restriction to their lifestyle for example driving implications.
- Active infection with raised biomarkers.
- Presence of a mechanical tricuspid valve.

Relative contraindications

- Pregnancy.
- Patients with abnormal clotting cascade.

LIMITATIONS TO PRACTICE:

- Lack of control of anticoagulation status and obtaining an acceptable INR leading to increased risk of bleeding. Warfarin therapy is not routinely stopped for the procedure.
- Active infection may limit the appropriateness of the procedure depending on the nature and site of the infection and the urgency of the implant.
- Inability of the patient to lie flat on the operating table.
- Kidney disease with patients on dialysis, implant scheduled on a non-dialysis day, and implant usually on opposite side to dialysis site.
- Prior mastectomy will normally lead to implant of device on the contra-lateral side
- Tricuspid valve disease with severe tricuspid regurgitation.
- Venous abnormalities such as persistent left superior vena cava (SVC) leading to difficulty with access for delivering the pacing, assessed at start of procedure through performing a venogram.
- Patients with dementia and difficulty lying still during the procedure.
- Patient allergy to drugs used during the procedure including sedation, analgesia and prophylactic antibiotics.

CRITERIA FOR COMPETENCE:

The cardiac physiologist must be at Band 6 level or above and have appropriate experience and knowledge in device implantation, follow-up and troubleshooting. Knowledge of the devices and equipment available for implant is essential and competent to deal with potential emergencies. Assessment on new staff should take place through the departmental training packs. Ongoing assessment of competence is assessed at the yearly appraisal.

Competence should be re-assessed if a physiologist performs less that 35 pacemaker implants a year, this number including more complex devices such as ICD and CRTD (BHRS 2013). It is desirable for the physiologist to hold or be working towards BHRS certification in pacing and devices. Ideally, two physiologists will be available to facilitate completion of pacing admin and completion of the SOLUS database.

PROTOCOL AND SKILLS AUDIT:

- Completion and documentation of the WHO check list. (REF) This covers
  - Patient ID
  - Intended intervention
  - Antibiotics
  - Allergies
  - Equipment required
  - Staff
  - Application of defibrillation pads.
  - Surgical site

- Documentation of procedure and patient information on haemodynamic monitoring equipment.

- Establish monitoring of heart rate, rhythm, blood pressure, oxygen saturation, application of defib pads and diathermy ground patch if required.

- Provide the operator with accessories required to perform procedure whilst maintaining sterility for example threshold testing cables, peel-away sheaths and diathermy. For a CRTD implant, additional equipment will include left ventricle (LV) delivery catheter, coronary diagnostic catheters and venogram balloon.

- Once access to the venous system is acquired provide operator with lead(s). During placement of leads, monitor ECG for potential arrhythmias.

- In the event of asystole or the patient becoming pacing dependent this will require a further set of threshold testing cables attached to an external temporary pacemaker or the pacing system analyzer (PSA) to provide back up pacing.

-In the event of ventricular tachyarrhythmia this can be treated by defibrillation if required, first ensuring the patient is sufficiently sedated or has lost consciousness.

- Conduct lead tests, measure and document electrical parameters using PSA and convey results to operator. Confirm satisfactory parameters before proceeding further. Unsatisfactory parameters would require reposition of the lead(s).

- Implanting the LV lead will usually require a venogram utilising the venogram balloon to identify target vessels for lead placement. LV delivery catheter will be used to wire and place lead in the coronary venous branch. This may require use of diagnostic angiography catheters and wires to assist this positioning.

-Once the leads have been positioned and tested the device is handed to the operator, is attached to the leads and inserted into the device pocket.

- If the device has wireless telemetry, testing through the device can be started once it is secured in the pocket.

- Program the device based on measurements obtained and according to the patients specific indication for bradycardia and tachycardia. For example different programming for primary or secondary prevention indications ([3])

-A defibrillation test (DFT) may be performed at this stage at the operator's discretion. During the test, the patient heart rhythm is intentionally put into a life threatening arrhythmia. The implanted device should then recognise the arrhythmia and delivered treatment to restore a normal heart rhythm.

If this is the case, a band 7 physiologist with BHRS accreditation and experience of defibrillation testing of the procedure should be present.

-If DFT is unsuccessful this may require reprogramming, and possibly further intervention to revise lead choice.

Complete pacing admin

- Ensure post implant check is documented in procedure care pathway or inpatient file
- Pacing file
- Local data base (SOLUS)

- Discharge info
    - Follow-up appointment
    - Discharge info sheet
    - Wound care advice sheet
    - Pacemaker ID card

CLINICAL INCIDENT REPORTING AND MANAGEMENT:

All adverse outcomes are discussed and documented in the monthly mortality and morbidity meeting held at the cardiology grand round. Refer to service pathway (LINK or REF).

Weekly multidisciplinary team (MDT) meeting for electrophysiology (EP), CRM devices, hypertrophic cardiomyopathy (HCM) and adult congenital heart disease (ACHD) for discussion of patient outcomes and treatment pathways.

All past and present information is ultimately fed into the national NICOR CRM database via SOLUS.

All incidents will be reported in line with trust policy with on line incident forms:

Link:

http://uhbhome/online-incident-reporting.htm

REFERENCES:

1. British Heart Rhythm Society (2013) Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults.
2. NICE (2014) Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. Technology appraisal guidance TA314
3. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. (2015)

4. Brignole M. et al. (2013) 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *European Heart Journal*, 34, 2281-2329

5. British Heart Rhythm Society (2013) Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults.

6. Epstein A. E. et al. (2012) ACCF/AHA/HRS Focused Update of the 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. A Report for the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*, 60, 1297 – 1313.

7. Epstein A. E. et al. (2008) ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices). *Circulation*; 117: e350-e408.

8. NICE (2014) Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. Technology appraisal guidance TA314

9. NICE (2014) Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88) TA 324.