University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

Pacemaker/CRTP Implant: Departmental Procedure

CATEGORY:	Clinical Guidelines
CLASSIFICATION:	Clinical
Controlled Document Number:	CG268
Version Number:	1
Controlled Document Sponsor:	Dr Sern Lim (Consultant Cardiology)
Controlled Document Lead (Author):	Gaetabo Ferrante (Cardiology – Cardiac Physiologist) Simon Keatley (Cardiology – Cardiac Physiologist)
Approved By:	Clinical Guidelines Group
On:	May 2017
Review Date:	May 2020

EVIDENCE FOR PRACTICE:

Cardiac rhythm management (CRM) devices are used in patients with bradyarrhythmias and/or heart failure symptoms and are acknowledged to be effective at improvement in quality of life and potentially reducing mortality depending on the specific indication (BHRS 2013).

Symptoms that may be experienced by patients as a result of bradycardia include but not limited to dizziness, shortness of breath, fatigue and loss of consciousness. For heart failure symptoms it may include the above and also swollen ankles caused by fluid retention.

Although bradycardia is normally defined as a heart rate less than 60 bpm, in the context of pathologically slow heart rate and CRM, a heart rate of 40 bpm or less is of more likely to be of clinical relevance ([5]). Also, of principle importance is the presence or absence of symptoms in association with the bradycardia ([9]). Evidence of the bradyarrhythmia is obtained from investigations such as electrocardiogram ECG, Ambulatory ECG (AECG), implantable loop recorders (ILR) and potentially electrophysiological study (EP).

Heart failure can be generalised as being the result of any cardiac disorder that impairs the pumping function of the heart to deliver the required blood circulation leading to shortness of breath, fatigue and retention of fluid in the body (NICE 2014). In some patients with heart failure, changes to heart function can lead to reduced coordination, dyssynchrony, between the contraction and pumping function of the left and right sides of the heart. When there is evidence of this on the electrocardiogram (ECG), seen as widening of the QRS complex, is one of the factors which can help identify patients who may benefit from cardiac resynchronisation therapy (CRT). This therapy involves controlling the timing of the contraction of the right and left ventricles with the aim of improving the pumping function of the heart, reducing symptoms and prolonging life ([8]).

A pacemaker to treat bradycardia generally involves implanting a pulse generator with a lead in the right atrium, right ventricle or both and is programmed to pace the heart only when required. In contrast a CRT pacemaker will involve an additional lead to pace the left ventricle and programming in this patient population aims to pace as much as possible because only when pacing can the device deliver its resynchronising therapy ([7])

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:

Indications for implant of pacemakers and cardiac resynchronisation are described in detail in current guidelines [1,3,4,5,6].

Some examples of indications for standard pacing implant include:

1. Symptomatic sinus pauses
2. Symptomatic sinus bradycardia
3. Sinus node disease with heart rate below 40bpm even without clear symptom / rhythm correlation
4. 3rd degree or advanced 2nd degree AV block
5. Alternating left and right bundle branch block
6. Symptomatic bradycardia due to necessary drug therapy
7. Syncope due to spontaneous carotid sinus stimulation inducing pause > 3secs.

Indications for CRT pacing (including all of the following):

1. Heart failure symptoms while on optimal medical therapy
2. LVEF of 35% or less
3. NYHA class II, III or IV symptoms
4. QRS duration > 120ms

Published guidance does not cover all patient groups and in some situations may not be appropriate. Decisions regarding the need for implant and type of device required will also require clinical judgment of consultants and multi disciplinary team discussions. (BHRS 2013).

CONTRAINDICATIONS:

Absolute contraindications:

1. Patient declined to give consent for the procedure.
2. Lack of required equipment or staff to perform the procedure
3. Allergy to steroid (dexamethasone sodium phosphate)
4. Active infection with raised biomarkers.
5. Presence of a mechanical tricuspid valve for RV lead.

Relative contraindications

1. Pregnancy.
2. Patients with abnormal clotting profile.

LIMITATIONS TO PRACTICE:

Procedures may be made more challenging under the following circumstances:

1. Uncontrolled anticoagulation status.
2. Active infection may increase the risk of device infection.
3. Inability of the patient to lie flat on the operating table.
4. Kidney disease with patients on dialysis, implant scheduled on a non-dialysis day, and implant usually on opposite side to dialysis site.
5. Prior Mastectomy will normally lead to implant of device on the contra-lateral side
6. Tricuspid valve disease with severe tricuspid regurgitation.
7. 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.
8. Patients with dementia and difficulty lying still during the procedure
9. 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 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 than 35 pacemaker implants a year, this number including more complex devices such as ICD and CRTD. 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 adapted WHO check list. (REF) This covers

1. Patient ID
2. Intended intervention
3. Antibiotics
4. Allergies
5. Equipment
6. Staff
7. Need for external defibrillation.

1.1. Documentation of procedure and patient information on haemodyanmics monitoring equipment.
1.2. Establish monitoring of heart rate, rhythm, blood pressure, oxygen saturation, diathermy earth plate.
1.3. Provide the operator with accessories required to perform procedure whilst maintaining sterility. Threshold cables, Peel-away sheaths and diathermy. For a CRT implant in addition a LV delivery catheter, coronary diagnostic catheters, venogram balloon will be needed.
1.4. Once access to the venous system is acquired provide operator with pacemaker lead(s). During placement of leads, monitor ECG for potential arrhythmias.
1.5. In the event asystole and the patient becoming patient dependent this will require a further set of threshold cables attached to an external temporary pacemaker or the pacing system analyzer (PSA) to provide back up pacing
1.6. Conduct, measure and document electrical parameters using the pacing system analyzer and convey results to operator. Confirm satisfactory parameters before proceeding further. Unsatisfactory parameters would require reposition of the lead(s).
1.7. 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.

1.8. -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.

1.9. 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 and according to the patients specific indication with discussion with supervising consultant.

Complete pacing admin

1. Ensure post implant check is documented in procedure care pathway or inpatient file
2. Pacing file
3. Local data base (SOLUS)
4. Discharge info
   1.1. Follow-up appointment
   1.2. Discharge info sheet
   1.3. Wound care advice sheet
   1.4. 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.