The Musgrove Park Pacing Document

June 2012, Dr Mark J Dayer

Version 18.

Index

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The purpose of this document is to:

1. Provide standards, policies and protocols that we should adhere to in the department.
2. Act as a point of reference when questions arise

I would like to thank all of those who have provided suggestions and articles for this document.

Dr Mark Dayer, June 2012

Latest Changes

1. The documents have been removed and links installed. This has shrunk the size of the document to allow for easier distribution.

2. Please note that **all** patients are now screened for MSSA. Pacing procedures should not normally be undertaken without such screens being available, unless it is clinically urgent. In this situation decolonisation should start immediately and continue until the swab results are available.

3. I want to emphasise that antibiotics should be given **within half an hour** of the start of the procedure.

4. Liquiband flex is now the preferred tissue adhesive. Liquiband should not be used.

5. The recommendation that **all trainees should be directly supervised by a senior operator**.

6. The consent forms have been updated.

7. Please note the latest advisory on St Jude Riata leads.

8. Treatment indications. There is updated guidance on the management of patients with inherited cardiac conditions.

Implantation Standards

The HR-UK competency standards 2010 lay down some minimum stipulations, some of which I have reproduced here:

For Doctors

1. There should be at least 2 active implanting consultants per centre.
2. At least 1 implanter should have accreditation in device therapy (HRUK or IBHRE).
3. Each implanter should perform 35 primary pacemaker implants / year.
4. Each implanter performing ICD and/or CRT procedures should perform 10 primary ICD implants / year and/or 10 primary CRT implants / year.

For Physiologists

1. At least 1 physiologist should have accreditation in device therapy (HRUK or IBHRE).
2. All physiologists must undertake appropriate CPD in device therapy and associated patient advice including implications for driving according to DVLA guidelines.
3. Each physiologist should be actively involved in 35 primary pacemaker implants / year
4. Each physiologist undertaking ICD and or CRT procedures should perform 10 primary ICD implants / year and/or 10 primary CRT implants / year.

For Nurses

1. Arrangements should be made that at least 2 nurses are denoted as specialist arrhythmia nurses/centre.
2. All specialist nurses must undertake appropriate CPD in device therapy and associated patient advice including implications for driving according to DVLA guidelines (see DVLA guidelines).

The full HR-UK document can be found here.

A more comprehensive document from the Pan-London Arrhythmia project group is can be found here.

Booking

We have lists on:

1. Tuesday am
2. Wednesday am/pm - Complex
3. Thursday am
4. Friday am - Complex

Stuart Walker will do ad hoc lists when required.

There has to be some priority given to emergency cases, and therefore elective work may have to be cancelled. The highest priority needs to go to:

1. Those with a temporary wire in situ - they should be done on the next pacing list if appropriate.
2. Those with an infected system - similarly they should be done on the next pacing list if appropriate.
3. Those patients without a temporary wire yet who are unstable should be done on the next pacing list if appropriate or a temporary wire should be sited.

There are "stable" in patients who should wait to be swabbed for MRSA/MSSA and listed according to list availability and whether decolonisation is required.

We should set a target that no patient should wait as an in-patient for longer than one week, unless there are clinical reasons for delaying the procedure.

Outpatients who have been cancelled need to be rebooked within 1 month.

To facilitate the management of inpatients and patients who have had to be cancelled we have devised a points system to guide the booking of lists. Lists can be booked to 5 points but no more. There should be no more than 3 elective points per list, generally speaking, to leave time for in-patient cases.

ILR, 1 point
B/C (no TPW) or VVI, 1.5 points
DDD or B/C with TPW, 2 points
ICD, 2.5 points
Upgrade (excluding new LV lead), 3 points
CRT-P/D or upgrade including new LV lead, 5 points

It is important that we keep track of waiting times. As is always the case, allowing space to deal with emergency cases results in less efficient use of lab time.

Treatment Indications

From the HR-UK document (HR-UK competency standards 2010) "It is recognised that published guidance does not cover all patient groups and may not be appropriate in certain situations. Furthermore, clinical judgement based on published evidence must be used for indications not yet considered by NICE. However, it is important to demonstrate compliance with best practice and regular audit of device indications and outcomes is strongly recommended".

There are a number of important areas of practice that I wish to highlight:

1. Patients with a dilated cardiomyopathy and significant LV dysfunction with an EF of <35% who have a history of syncope or who have non-sustained VT on prolonged cardiac monitoring are a candidate for an ICD. NICE have not commented on this group. They have **not** recommended that these patients do not have an ICD. There is evidence that patients with DCM benefit, just as patients with ICM benefit[1].

2. I have included more detailed guidance for the indications of ICDs in patients with inherited cardiac conditions.

3. There has been a recent meta-analysis looking at the benefits of CRT pacing in patients with a QRS duration of <150ms[2]. This has strongly suggested that such patients do not benefit. This should be highlighted to patients and specifically discussed prior to a decision being reached about implantation. Similarly there are data that patients with RBBB may not benefit[3,4].

4. It is important to comply with NICE technology appraisal TA88 on pacing mode for symptomatic bradycardia due to sick sinus syndrome and/or AV block. That is that dual chamber pacing should be used, unless there is chronic atrial fibrillation or "when patient-specific factors, such as frailty or the presence of comorbidities, influence the balance of risks and benefits in favour of single-chamber ventricular pacing". This is a standard to which we are audited. "Centres implanting >10% of patients in sinus rhythm with VVI(R) devices should review their practice in accordance with NICE guidance."

The technology appraisals/guidelines that we should be adhering to are:

1. Heart failure - cardiac resynchronisation: NICE TA120

2. Implantable cardioverter defibrillators (ICDs) for the treatment of arrhythmias: NICE TA95

3. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

4. Heart Rhythm UK Position Statement on Clinical Indications for Implantable Cardioverter Defibrillators in Adult Patients with Familial Sudden Cardiac Death Syndromes

5. 2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy

Indications in Greater Detail

Implantable Cardioverter Defibrillators

The NICE guidance is detailed first, followed by recommendations from HR-UK and finally a review of the latest 2011 guidance for HCM.

ICDs are recommended for patients for both primary and secondary prevention.

Secondary Prevention

That is, for patients who present, in the absence of a treatable cause, with one of the following:

1. Having survived a cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF).

2. Spontaneous sustained VT causing syncope or significant haemodynamic compromise.

3. Sustained VT without syncope or cardiac arrest, and who have an associated reduction in ejection fraction (LVEF of less than 35%) (No worse than class III of the New York Heart Association functional classification of heart failure).

Primary Prevention

That is, for patients who have:

1. A history of previous (more than 4 weeks) myocardial infarction (MI) and either:

    a. Left ventricular dysfunction with an LVEF of less than 35% (no worse than class III of the New York Heart Association functional classification of heart failure)
    and
    b. non-sustained VT on Holter (24-hour electrocardiogram [ECG]) monitoring
    and
    c. inducible VT on electrophysiological (EP) testing.

    or

    a. left ventricular dysfunction with an LVEF of less than 30% (no worse than class III of the New York Heart Association functional classification of heart failure) *and*
    b. a QRS duration of equal to or more than 120 milliseconds.

2. A familial cardiac condition with a high risk of sudden death, including:

    a. Long QT syndrome
    b. Hypertrophic cardiomyopathy
    c. Brugada syndrome
    d. Arrhythmogenic right ventricular dysplasia

3. Patients who have undergone surgical repair of congenital heart disease

There are a number of comments about this list:

1. We have already commented on DCM.

2. Patients who have undergone surgical repair of congenital heart disease is considered too broad a brush, and we will be guided by the GUCH consultants.

3. List 2a to 2d is not exhaustive, and also there are further nuances for each of these conditions and risk stratification is important on a case-by-case basis. HR-UK have issued further guidance for patients with inherited cardiac conditions[5] and this is reviewed below and there is also detail in the ACC/AHA 2008 guidelines[6] and the latest HCM guidance[7].

Long QT Syndrome

A QTc of >450ms in men and 460ms in women is abnormal. The longest QT interval in individual leads should be used, unless it is >40ms longer than other leads. The precise methods for measuring the QT interval is described in the 2009 AHA/ACCF/HRS guidelines[8]. The overall risk of SCD in patients with LQTS on beta-blockers is estimated to be around 0.1% per annum. Indicators of high risk include:

1. Personal history of aborted SCD.

2. Syncope and QT prolongation >500ms.

3. There is little evidence to support that the sudden death of a sibling is a risk factor.

Note beta-blockers such as nadolol (40mg-320mg/day) or propranolol (80mg-640mg/day) which block β1 and β2 receptors are preferred to more cardioselective beta blockers such as bisoprolol.

Current ACC/AHA/ESC Guidance

Class I. Implantation of an ICD along with the use of betablockers is recommended for LQTS patients with previous cardiac arrest (level of evidence: A).

Class IIa. Implantation of an ICD with continued use of betablockers can be effective to reduce SCD in LQTS patients experiencing syncope and/or VT while receiving beta-blockers (level of evidence: B).

Class IIb. Implantation of an ICD with the use of beta-blockers may be considered for prophylaxis of SCD for patients in categories possibly associated with higher risk of cardiac arrest such as LQT2 and LQT3 (level of evidence: B).

HR-UK Recommendations

1. Long QT syndrome patients presenting with ventricular fibrillation/cardiac arrest without reversible precipitant should undergo ICD implantation in addition to oral beta-blockade (Estimated risk 3.37% per annum).

2. Long QT syndrome patients experiencing continuing syncope despite beta-blockade or left cardiac sympathetic denervation (LCSD) (when VT/VF has not been excluded as the cause of syncope) should undergo ICD implantation (Estimated risk 2.18% per annum).

3. The identification of an LQT2 or LQT3 genotype should not by itself constitute an indication for ICD implantation (Estimated risk 0.6% per annum (LQT2), 0.56% per annum (LQT3)).

Brugada Syndrome

The diagnosis of Brugada syndrome requires the presence of the type I Brugada ECG pattern (Coved ST elevation, J point elevation ≥ 2mm), the absence of cardiac structural disease and at least one of [9]:

1. Syncope
2. Prior cardiac arrest
3. Documented / inducible polymorphic VT
4. Ventricular fibrillation
5. Family history of SCD < 45 years
6. Nocturnal agonal respiration

Indicators of a high risk of SCD are:

1. A personal history of aborted SCD or syncope
2. A spontaneous type I ECG
3. Male gender
4. South East Asian Origin

A family history of SCD or a SCN5A mutation do not carry an increased risk of SCD.

Current ACC/AHA/ESC Guidance

Class I. An ICD is indicated for Brugada syndrome patients with previous cardiac arrest.

Class IIa. An ICD is reasonable for Brugada syndrome patients with spontaneous ST segment elevation in V1, V2, or V3 who have had syncope; an ICD is reasonable for Brugada syndrome patients with documented VT that has not resulted in cardiac arrest.

Class IIb. EP testing may be considered for risk stratification in asymptomatic Brugada syndrome patients with spontaneous ST elevation.

HR-UK Recommendations

Brugada syndrome patients presenting with ventricular fibrillation/cardiac arrest without reversible precipitant should undergo ICD implantation (Estimated risk 7.7%-13.8% per annum).

Brugada syndrome patients with syncope (when VT/VF has not been excluded as the cause of syncope) should undergo ICD implantation (Estimated risk 1.9%-8.8% per annum).

A firm recommendation regarding ICD implantation in patients with a spontaneous type 1 ECG without symptoms cannot be made at this time; either a conservative strategy or ICD implantation based on results of EP testing can be supported by different series. An EP study is not unreasonable. A negative EP study has a high negative predictive value in asymptomatic patients.

Asymptomatic individuals who require a drug to induce the type 1 ECG pattern are at low risk of sudden death and the risks of ICD therapy are likely to outweigh the benefits in this group.

Catecholaminergic Polymorphic VT

Patients are usually children, adolescents or young adults who present with syncope occurring during exercise or emotion and:

1. Bidirectional VT or
2. Polymorphic VT or
3. Idiopathic VF

There may be a family history. There is no evidence of structural heart disease. There is a tendency to sinus bradycardia. I suspect that older patients will begin to be diagnosed with this condition as awareness increases.

Current ACC/AHA/ESC Guidance

Class I. Implantation of an ICD along with the use of beta-blockers is recommended for patients with CPVT who are survivors of cardiac arrest (level of evidence C).

Class IIa. Implantation of an ICD along with the use of beta-blockers can be effective for affected patients with CPVT with syncope and/or documented sustained VT while receiving beta-blockers (level of evidence C).

HR-UK Recommendations

Catecholaminergic polymorphic ventricular tachycardia patients presenting with ventricular fibrillation/cardiac arrest without reversible precipitant should undergo ICD implantation in addition to oral beta-blockade or LCSD (Estimated risk 1.2% per annum).

Catecholaminergic polymorphic ventricular tachycardia patients experiencing sustained VT or syncope (when VT/VF has not been excluded as the cause) despite beta-blockade or LCSD should be considered for ICD implantation.

Recommendation: Catecholaminergic polymorphic ventricular tachycardia patients experiencing exercise-induced sustained VT despite beta-blockade or LCSD should be considered for ICD implantation.

Arrhythmogenic Right Ventricular Cardiomyopathy

Patients usually present in their late teens or twenties with palpitations, syncope or SCD. The ECG shows T wave inversion in V1-V3 ± RBBB. Epsilon waves are occasionally present. The ECG during VT is characteristically LBBB. There are particular echocardiographic / MRI features that are beyond the scope of this guideline[10].

Current ACC/AHA/ESC Guidance

Class I. Implantable cardioverter defibrillator implantation is recommended for the prevention of SCD in patients with ARVC with documented sustained VT or VF (level of evidence: B).

Class IIa. Implantable cardioverter defibrillator implantation can be effective for the prevention of SCD in patients with ARVC with extensive disease, including those with LV involvement, one or more affected family members with SCD, or undiagnosed syncope when VT or VF has not been excluded as the cause of syncope (level of evidence: C).

Class IIb. EP testing might be useful for the risk assessment of SCD in patients with ARVC (level of evidence: C).

HR-UK Recommendations

Arrhythmogenic right ventricular cardiomyopathic patients presenting with ventricular fibrillation/cardiac arrest (Estimated risk 21% per annum) or poorly tolerated VT (Estimated risk 9% per annum) should undergo ICD implantation.

Arrhythmogenic right ventricular cardiomyopathic patients presenting with syncope (when VT/VF has not been excluded as the cause of syncope) should undergo ICD implantation (Estimated risk 8% per annum).

Arrhythmogenic right ventricular cardiomyopathic patients presenting with ventricular arrhythmias and severe structural disease should be considered for ICD implantation.

Arrhythmogenic right ventricular cardiomyopathic patients who are asymptomatic with mild disease are at low risk of sudden death (Estimated risk 0.1% per annum), and the risks of ICD therapy may outweigh the benefits in this group.

Hypertrophic Cardiomyopathy

The latest guidelines for the diagnosis and treatment of HCM were released at the end of 2011[7]. There is a need to risk assess patients and the latest guidance is reproduced below. See figure 1.

Risk Stratification

Class I

1. All patients with HCM should undergo comprehensive SCD risk stratification at initial evaluation to determine the presence of the following (Level of Evidence: B):
    a. A personal history for ventricular fibrillation, sustained VT, or SCD events, including appropriate ICD therapy for ventricular tachyarrhythmias.
    b. A family history for SCD events, including appropriate ICD therapy for ventricular tachyarrhythmias.
    c. Unexplained syncope.
    d. Documented NSVT defined as 3 or more beats at greater than or equal to 120 bpm on ambulatory (Holter) ECG.
    e. Maximal LV wall thickness greater than or equal to 30 mm.

Class IIa

1. It is reasonable to assess blood pressure response during exercise as part of SCD risk stratification in patients with HCM (Level of Evidence: B).

2. SCD risk stratification is reasonable on a periodic basis (every 12 to 24 months) for patients with HCM who have not undergone ICD implantation but would otherwise be eligible in the event that risk factors are identified (12 to 24 months) (Level of Evidence: C).

Class IIb

1. The usefulness of the following potential SCD risk modifiers is unclear but might be considered in selected patients with HCM for whom risk remains borderline after documentation of conventional risk factors:
    a. CMR imaging with LGE (Level of Evidence: C).
    b. Double and compound mutations (i.e., >1) (Level of Evidence: C).
    c. Marked LVOT obstruction (Level of Evidence: B).

Class III: Harm

1. Invasive electrophysiologic testing as routine SCD risk stratification for patients with HCM should not be performed (Level of Evidence: C).

ICD Recommendations

The decision to place an ICD in patients with HCM should include application of individual clinical judgment, as well as a thorough discussion of the strength of evidence, benefits, and risks to allow the informed patient's active participation in decision making *(Level of Evidence: C).*

Class I

1. ICD placement is recommended for patients with HCM with prior documented cardiac arrest, ventricular fibrillation, or haemodynamically significant VT *(Level of Evidence: B).*

Class IIa

1. It is reasonable to recommend an ICD for patients with HCM with:
    a. Sudden death presumably caused by HCM in 1 or more first-degree relatives (Level of Evidence: C).
    b. A maximum LV wall thickness greater than or equal to 30 mm (Level of Evidence: C).
    c. One or more recent, unexplained syncopal episodes (Level of Evidence: C).

2. An ICD can be useful in select patients with NSVT (particularly those <30 years of age) in the presence of other SCD risk factors or modifiers (Level of Evidence: C).

3. An ICD can be useful in select patients with HCM with an abnormal blood pressure response with exercise in the presence of other SCD risk factors or modifiers (Level of Evidence: C).

4. It is reasonable to recommend an ICD for high-risk children with HCM, based on unexplained syncope, massive LV hypertrophy, or family history of SCD, after taking into account the relatively high complication rate of long-term ICD implantation (Level of Evidence: C).

Class IIb

1. The usefulness of an ICD is uncertain in patients with HCM with isolated bursts of NSVT when in the absence of any other SCD risk factors or modifiers (Level of Evidence: C).

2. The usefulness of an ICD is uncertain in patients with HCM with an abnormal blood pressure response with exercise when in the absence of any other SCD risk factors or modifiers, particularly in the presence of significant outflow obstruction (Level of Evidence: C).

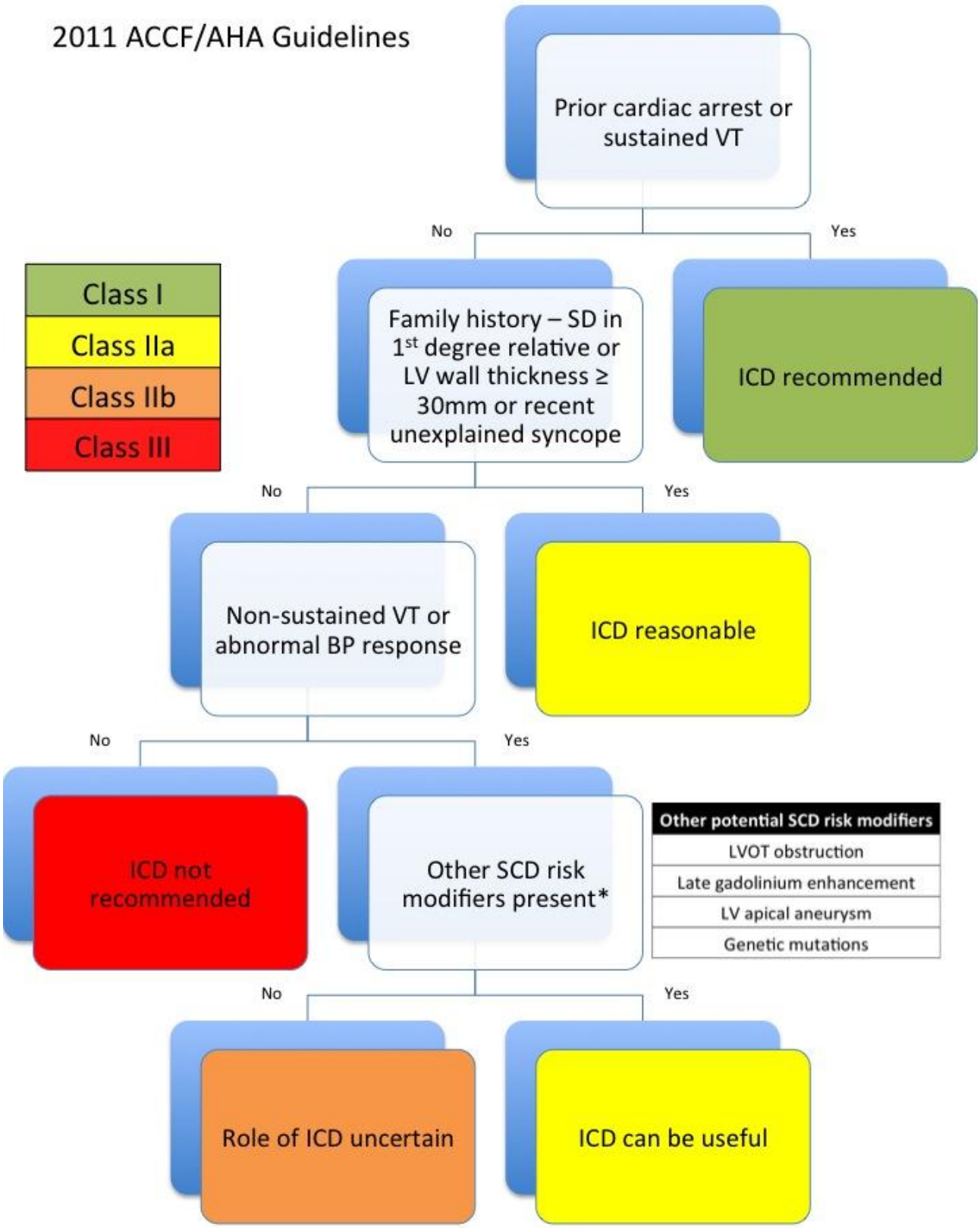
Class III: Harm

1. ICD placement as a routine strategy in patients with HCM without an indication of increased risk is potentially harmful (Level of Evidence: C).

2. ICD placement as a strategy to permit patients with HCM to participate in competitive athletics is potentially harmful (Level of Evidence: C).

3. ICD placement in patients who have an identified HCM genotype in the absence of clinical manifestations of HCM is potentially harmful (Level of Evidence: C).

Figure 1 – Recommendations for ICDs in HCM. Modified from the 2011 ACCF/AHA Guidelines[7]



Cardiac Resynchronisation Therapy

This section has been lifted from NICE technology appraisal guidance and should be read in conjunction with 'Implantable cardioverter defibrillators for arrhythmias' (NICE technology appraisal guidance 95).

Cardiac resynchronisation therapy with a pacing device (CRT-P) is recommended as a treatment option for people with heart failure who fulfil all the following criteria:

1. They are currently experiencing or have recently experienced New York Heart Association (NYHA) class III–IV symptoms.

2. They are in sinus rhythm:
    a. either with a QRS duration of 150 ms or longer estimated by standard electrocardiogram (ECG)
    b. or with a QRS duration of 120–149 ms estimated by ECG and mechanical dyssynchrony that is confirmed by echocardiography.

3. They have a left ventricular ejection fraction of 35% or less.

4. They are receiving optimal pharmacological therapy.

Cardiac resynchronisation therapy with a defibrillator device (CRT-D) may be considered for people who fulfil the criteria for implantation of a CRT-P device and who also separately fulfil the criteria for the use of an ICD device as recommended in NICE technology appraisal guidance 95.

At present there are no reliable indicators of dyssynchrony and therefore we do not assess this routinely[11]. Furthermore, a recent meta-analysis has suggested that patients with a QRS duration of < 150ms do not benefit from cardiac resynchronization therapy[2] and this should be highlighted to patients prior to implantation.

Similarly there appears to be no clinical benefit gained by CRT pacing in patients without left bundle branch block[3,4].

It is likely however that less symptomatic patients benefit from CRT pacing[12] and it seems appropriate to be more generous in the interpretation of symptoms until NICE guidance catches up.

It may be appropriate to implant patients with a CRT device who have been referred to a transplant centre who fulfil none of the indications, as it is still unknown who benefits from such devices and if such patients do benefit it may obviate the need for such a procedure. Such cases should be discussed with the transplant centre first.

We do implant patients with atrial fibrillation. It is imperative that heart rate control is adequate and strong consideration should be given to AV node ablation. There is now clear evidence that it can be of benefit[13] and it is in line with guidance from the AGWSCS and ESC[14].

Simple Pacing

This guidance has been derived from the ACC/AHA/HRS 2008 guidelines for device-based therapy[6].

Recommendations for Permanent Pacing in Sinus Node Dysfunction

Class I

1. Permanent pacemaker implantation is indicated for SND with documented symptomatic bradycardia, including frequent sinus pauses that produce symptoms. (Level of Evidence: C)

2. Permanent pacemaker implantation is indicated for symptomatic chronotropic incompetence. (Level of Evidence: C)

3. Permanent pacemaker implantation is indicated for symptomatic sinus bradycardia that results from required drug therapy for medical conditions. (Level of Evidence: C)

Class IIa

1. Permanent pacemaker implantation is reasonable for SND with heart rate less than 40 bpm when a clear association between significant symptoms consistent with bradycardia and the actual presence of bradycardia has not been documented. (Level of Evidence: C)

2. Permanent pacemaker implantation is reasonable for syncope of unexplained origin when clinically significant abnormalities of sinus node function are discovered or provoked in electrophysiological studies. (Level of Evidence: C)

Class IIb

1. Permanent pacemaker implantation may be considered in minimally symptomatic patients with chronic heart rate less than 40 bpm while awake. (Level of Evidence: C)

Class III

1. Permanent pacemaker implantation is not indicated for SND in asymptomatic patients. (Level of Evidence: C)

2. Permanent pacemaker implantation is not indicated for SND in patients for whom the symptoms suggestive of bradycardia have been clearly documented to occur in the absence of bradycardia. (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for SND with symptomatic bradycardia due to nonessential drug therapy. (Level of Evidence: C)

Recommendations for Acquired Atrioventricular Block in Adults

Class I

1. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with bradycardia with symptoms (including heart failure) or ventricular arrhythmias presumed to be due to AV block. (Level of Evidence: C)

2. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with arrhythmias and other medical conditions that require drug therapy that results in symptomatic bradycardia. (Level of Evidence: C)

3. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients in sinus rhythm, with documented periods of asystole greater than or equal to 3.0 seconds or any escape rate less than 40 bpm, or with an escape rhythm that is below the AV node. (Level of Evidence: C)

4. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level in awake, symptom-free patients with AF and bradycardia with 1 or more pauses of at least 5 seconds or longer. (Level of Evidence: C)

5. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level after catheter ablation of the AV junction. (Level of Evidence: C)

6. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with postoperative AV block that is not expected to resolve after cardiac surgery. (Level of Evidence: C)

7. Permanent pacemaker implantation is indicated for third-degree and advanced second-degree AV block at any anatomic level associated with neuromuscular diseases with AV block, such as myotonic muscular dystrophy, Kearns-Sayre syndrome, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy, with or without symptoms. (Level of Evidence: B)

8. Permanent pacemaker implantation is indicated for second-degree AV block with associated symptomatic bradycardia regardless of type or site of block. (Level of Evidence: B)

9. Permanent pacemaker implantation is indicated for asymptomatic persistent third-degree AV block at any anatomic site with average awake ventricular rates of 40 bpm or faster if cardiomegaly or LV dysfunction is present or if the site of block is below the AV node. (Level of Evidence: B)

10. Permanent pacemaker implantation is indicated for second- or third-degree AV block during exercise in the absence of myocardial ischemia. (Level of Evidence: C)

Class IIa

1. Permanent pacemaker implantation is reasonable for persistent third-degree AV block with an escape rate greater than 40 bpm in asymptomatic adult patients without cardiomegaly. (Level of Evidence: C)

2. Permanent pacemaker implantation is reasonable for asymptomatic second-degree AV block at intra- or infra-His levels found at electrophysiological study. (Level of Evidence: B)

3. Permanent pacemaker implantation is reasonable for first- or second-degree AV block with symptoms similar to those of pacemaker syndrome or hemodynamic compromise. (Level of Evidence: B)

4. Permanent pacemaker implantation is reasonable for asymptomatic type II second-degree AV block with a narrow QRS. When type II second-degree AV block occurs with a wide QRS, including isolated right bundle-branch block, pacing becomes a Class I recommendation. (See "Chronic Bifascicular Block.") (Level of Evidence: B)

Class IIb

1. Permanent pacemaker implantation may be considered for neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with any degree of AV block (including first-degree AV block), with or without symptoms, because there may be unpredictable progression of AV conduction disease. (Level of Evidence: B)

2. Permanent pacemaker implantation may be considered for AV block in the setting of drug use and/or drug toxicity when the block is expected to recur even after the drug is withdrawn. (Level of Evidence: B)

Class III

1. Permanent pacemaker implantation is not indicated for asymptomatic first-degree AV block. (Level of Evidence: B) (See "Chronic Bifascicular Block.")

2. Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block at the supra-His (AV node) level or that which is not known to be intra- or infra-Hisian. (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for AV block that is expected to resolve and is unlikely to recur (e.g., drug toxicity, Lyme disease, or transient increases in vagal tone or during hypoxia in sleep apnoea syndrome in the absence of symptoms). (Level of Evidence: B)

Recommendations for Permanent Pacing in Chronic Bifascicular Block

Class I

1. Permanent pacemaker implantation is indicated for advanced second-degree AV block or intermittent third-degree AV block. (Level of Evidence: B)

2. Permanent pacemaker implantation is indicated for type II second-degree AV block. (Level of Evidence: B)

3. Permanent pacemaker implantation is indicated for alternating bundle-branch block. (Level of Evidence: C)

Class IIa

1. Permanent pacemaker implantation is reasonable for syncope not demonstrated to be due to AV block when other likely causes have been excluded, specifically ventricular tachycardia (VT). (Level of Evidence: B)

2. Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of a markedly prolonged HV interval (greater than or equal to 100 milliseconds) in asymptomatic patients. (Level of Evidence: B)

3. Permanent pacemaker implantation is reasonable for an incidental finding at electrophysiological study of pacing-induced infra-His block that is not physiological. (Level of Evidence: B)

Class IIb

1. Permanent pacemaker implantation may be considered in the setting of neuromuscular diseases such as myotonic muscular dystrophy, Erb dystrophy (limb-girdle muscular dystrophy), and peroneal muscular atrophy with bifascicular block or any fascicular block, with or without symptoms. (Level of Evidence: C)

Class III

2. Permanent pacemaker implantation is not indicated for fascicular block without AV block or symptoms. (Level of Evidence: B)

3. Permanent pacemaker implantation is not indicated for fascicular block with first-degree AV block without symptoms. (Level of Evidence: B)

Recommendations for Permanent Pacing After the Acute Phase of Myocardial Infarction

Class I

1. Permanent ventricular pacing is indicated for persistent second-degree AV block in the His-Purkinje system with alternating bundle-branch block or third-degree AV block within or below the His-Purkinje system after ST-segment elevation MI. (Level of Evidence: B)

2. Permanent ventricular pacing is indicated for transient advanced second- or third-degree infranodal AV block and associated bundle-branch block. If the site of block is uncertain, an electrophysiological study may be necessary. (Level of Evidence: B)

3. Permanent ventricular pacing is indicated for persistent and symptomatic second- or third-degree AV block. (Level of Evidence: C)

Class IIb

1. Permanent ventricular pacing may be considered for persistent second- or third-degree AV block at the AV node level, even in the absence of symptoms. (Level of Evidence: B)

Class III

1. Permanent ventricular pacing is not indicated for transient AV block in the absence of intraventricular conduction defects. (Level of Evidence: B)

2. Permanent ventricular pacing is not indicated for transient AV block in the presence of isolated left anterior fascicular block. (Level of Evidence: B)

3. Permanent ventricular pacing is not indicated for new bundle-branch block or fascicular block in the absence of AV block. (Level of Evidence: B)

4. Permanent ventricular pacing is not indicated for persistent asymptomatic first-degree AV block in the presence of bundle-branch or fascicular block. (Level of Evidence: B)

Recommendations for Permanent Pacing in Hypersensitive Carotid Sinus Syndrome and Neurocardiogenic Syncope

Class I

1. Permanent pacing is indicated for recurrent syncope caused by spontaneously occurring carotid sinus stimulation and carotid sinus pressure that induces ventricular asystole of more than 3 seconds. (Level of Evidence: C)

Class IIa

1. Permanent pacing is reasonable for syncope without clear, provocative events and with a hypersensitive cardioinhibitory response of 3 seconds or longer. (Level of Evidence: C)

Class IIb

1. Permanent pacing may be considered for significantly symptomatic neurocardiogenic syncope associated with bradycardia documented spontaneously or at the time of tilt-table testing. (Level of Evidence: B)

Class III

1. Permanent pacing is not indicated for a hypersensitive cardioinhibitory response to carotid sinus stimulation without symptoms or with vague symptoms. (Level of Evidence: C)

2. Permanent pacing is not indicated for situational vasovagal syncope in which avoidance behaviour is effective and preferred. (Level of Evidence: C)

Recommendations for Pacing After Cardiac Transplantation

Class I

1. Permanent pacing is indicated for persistent inappropriate or symptomatic bradycardia not expected to resolve and for other Class I indications for permanent pacing. (Level of Evidence: C)

Class IIb

1. Permanent pacing may be considered when relative bradycardia is prolonged or recurrent, which limits rehabilitation or discharge after postoperative recovery from cardiac transplantation. (Level of Evidence: C)

2. Permanent pacing may be considered for syncope after cardiac transplantation even when bradyarrhythmia has not been documented. (Level of Evidence: C)

Recommendations for Permanent Pacemakers That Automatically Detect and Pace to Terminate Tachycardias

Class IIa

1. 1 Permanent pacing is reasonable for symptomatic recurrent SVT that is reproducibly terminated by pacing when catheter ablation and/or drugs fail to control the arrhythmia or produce intolerable side effects. (Level of Evidence: C)

Class III

1. Permanent pacing is not indicated in the presence of an accessory pathway that has the capacity for rapid anterograde conduction. (Level of Evidence: C)

Recommendations for Pacing to Prevent Tachycardia

Class I

1. Permanent pacing is indicated for sustained pause-dependent VT, with or without QT prolongation. (Level of Evidence: C)

Class IIa

1. Permanent pacing is reasonable for high-risk patients with congenital long-QT syndrome. (Level of Evidence: C)

Class IIb

1. Permanent pacing may be considered for prevention of symptomatic, drug-refractory, recurrent AF in patients with coexisting SND. (Level of Evidence: B)

Class III

1. Permanent pacing is not indicated for frequent or complex ventricular ectopic activity without sustained VT in the absence of the long-QT syndrome. (Level of Evidence: C)

2. Permanent pacing is not indicated for torsade de pointes VT due to reversible causes. (Level of Evidence: A)

Recommendation for Pacing to Prevent Atrial Fibrillation

Class III

1. Permanent pacing is not indicated for the prevention of AF in patients without any other indication for pacemaker implantation. (Level of Evidence: B)

Recommendations for Pacing in Patients With Hypertrophic Cardiomyopathy

Class I

1. Permanent pacing is indicated for SND or AV block in patients with HCM as described previously (see "Sinus Node Dysfunction," and "Acquired Atrioventricular Block in Adults"). (Level of Evidence: C) When risk factors for SCD are present, consider a DDD ICD.

Class IIb

1. Permanent pacing may be considered in medically refractory symptomatic patients with HCM and significant resting or provoked LV outflow tract obstruction. (Level of Evidence: A) When risk factors for SCD are present, consider a DDD ICD.

Class III

1. Permanent pacemaker implantation is not indicated for patients who are asymptomatic or whose symptoms are medically controlled. (Level of Evidence: C)

2. Permanent pacemaker implantation is not indicated for symptomatic patients without evidence of LV outflow tract obstruction. (Level of Evidence: C)

Recommendations for Permanent Pacing in Children, Adolescents, and Patients With Congenital Heart Disease

Class I

1. Permanent pacemaker implantation is indicated for advanced second- or third-degree AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output. (Level of Evidence: C)

2. Permanent pacemaker implantation is indicated for SND with correlation of symptoms during age-inappropriate bradycardia. The definition of bradycardia varies with the patient's age and expected heart rate. (Level of Evidence: B)

3. Permanent pacemaker implantation is indicated for postoperative advanced second- or third-degree AV block that is not expected to resolve or that persists at least 7 days after cardiac surgery. (Level of Evidence: B)

4. Permanent pacemaker implantation is indicated for congenital third-degree AV block with a wide QRS escape rhythm, complex ventricular ectopy, or ventricular dysfunction. (Level of Evidence: B)

5. Permanent pacemaker implantation is indicated for congenital third-degree AV block in the infant with a ventricular rate less than 55 bpm or with congenital heart disease and a ventricular rate less than 70 bpm. (Level of Evidence: C)

Class IIa

1. Permanent pacemaker implantation is reasonable for patients with congenital heart disease and sinus bradycardia for the prevention of recurrent episodes of intra-atrial re-entrant tachycardia; SND may be intrinsic or secondary to antiarrhythmic treatment. (Level of Evidence: C)

2. Permanent pacemaker implantation is reasonable for congenital third-degree AV block beyond the first year of life with an average heart rate less than 50 bpm, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptoms due to chronotropic incompetence. (Level of Evidence: B)

3. Permanent pacemaker implantation is reasonable for sinus bradycardia with complex congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds. (Level of Evidence: C)

4. Permanent pacemaker implantation is reasonable for patients with congenital heart disease and impaired haemodynamics due to sinus bradycardia or loss of AV synchrony. (Level of Evidence: C)

5. Permanent pacemaker implantation is reasonable for unexplained syncope in the patient with prior congenital heart surgery complicated by transient complete heart block with residual fascicular block after a careful evaluation to exclude other causes of syncope. (Level of Evidence: B)

Class IIb

1. Permanent pacemaker implantation may be considered for transient postoperative third-degree AV block that reverts to sinus rhythm with residual bifascicular block. (Level of Evidence: C)

2. Permanent pacemaker implantation may be considered for congenital third-degree AV block in asymptomatic children or adolescents with an acceptable rate, a narrow QRS complex, and normal ventricular function. (Level of Evidence: B)

3. Permanent pacemaker implantation may be considered for asymptomatic sinus bradycardia after biventricular repair of congenital heart disease with a resting heart rate less than 40 bpm or pauses in ventricular rate longer than 3 seconds. (Level of Evidence: C)

Class III

1. Permanent pacemaker implantation is not indicated for transient postoperative AV block with return of normal AV conduction in the otherwise asymptomatic patient. (Level of Evidence: B)

2. Permanent pacemaker implantation is not indicated for asymptomatic bifascicular block with or without first-degree AV block after surgery for congenital heart disease in the absence of prior transient complete AV block. (Level of Evidence: C)

3. Permanent pacemaker implantation is not indicated for asymptomatic type I second-degree AV block. (Level of Evidence: C)

4. Permanent pacemaker implantation is not indicated for asymptomatic sinus bradycardia with the longest relative risk interval less than 3 seconds and a minimum heart rate more than 40 bpm. (Level of Evidence: C)

Implantable Loop Recorders

Implantable loop recorders (ILRs) are being implanted increasingly frequently, particularly with the release of the new NICE guidelines (Transient loss of consciousness in adults and young people, CG109).

All loop recorders should be approved by the clinical lead for cardiology prior to implantation.

In terms of preparation for the procedure, the same guidelines that are used for permanent pacing are relevant.

All patients should be seen by the arrhythmia nurses prior to implantation.

All patients should be monitored remotely.

We have a separate ILR proforma. We have trained a specialist nurse to implant loop recorders and the documents relevant to this process can be found here.

Pre-operative Assessment

All patients should undergo some form of pre-operative assessment prior to pacemaker implantation. Patients should be assessed at the earliest opportunity. The purpose is to:

1. Prepare the patient psychologically for the procedure, including explaining what the procedure entails and possible complications. A consent form should be given to the patient, as should appropriate literature.
2. Ensure the procedure is appropriate.
3. Ensure the procedure is safe.
4. Identify any potential problems, including procedure related problems and problems with aftercare.

The pacing proforma should start to be completed:

All patients who are having an ICD or reveal device inserted should see the arrhythmia nurses pre-operatively in addition to attending POAC.

All patients should be given a copy of their consent form prior to the procedure and a copy of the pacemaker leaflet. For patients receiving a new implant/upgrade the appropriate Arrhythmia Alliance leaflet and/or Cameron Health documentation should be included. These can be found here.

Useful links:

British Heart Foundation

Pacemakers
ICDs

Arrhythmia Alliance

Booklets

Day case pacing

Day case pacing was reported as being safe and acceptable in 1989[15]. The study was extended and the conclusions did not change[16]. It is now routine practice in many trusts. The audit commission recently identified our trust as an outlier and suggested we could reduce the number of bed days occupied by pacemaker patients by 373 per annum (Report, see page 11). We have moved towards day case pacing and recent data suggest our average length of stay for routine pacing procedures has declined.

A number of criteria need to be met for a patient to be suitable, as not all patients will be.

1. Only CRT patients need to be kept overnight – this is because of a small, but recognised, risk of pro-arrhythmia shortly after implant [17].

2. The patient should be done on a morning list.

3. The patient should have someone at home who is able to look after them.

4. The chest X-ray should be done at least 4 hours after the procedure.

5. The pacing check should be done at least 4 hours after the procedure.

6. The procedure should have proceeded without complications and the operator should be happy for the patient to go home.

Consent Forms

The consent forms have been reviewed and revised to reflect the real-world complication rates that occur in this centre. There are different consent forms for different procedures. They can be found here.

The amount of information which can be included on the trust consent forms is limited and it is important to have a thorough discussion with the patient.

Generally speaking a person capable of performing that procedure should obtain consent. Preferably the person performing the procedure should obtain consent. Foundation year doctors should not obtain consent.

Antiplatelets and anticoagulants

There seems little doubt that heparin bridging in patients taking warfarin is not cost-effective, lengthens hospital stays and may be less safe. It should be remembered that aspirin and clopidogrel also raise the risk of bleeding and dual antiplatelet therapy appears to raise the risk of bleeding to an even greater extent. Pocket haematoma is a recognised risk factor for infection. Based on a review of the literature by Tompkins and Henrikson[18], I would recommend a more nuanced approach:

1. Withholding aspirin or clopidogrel for 5 days when it has been prescribed for primary prevention of cardiovascular events.

2. In patients on dual antiplatelet therapy, withhold clopidogrel alone for 5 days when it:
    a) **Is not** if required to prevent in-stent thrombosis following PCI,
    b) **Is not** within 3 months of NSTEMI/MI,
    c) **Has not** been prescribed following a prior TIA/CVA.

3. Warfarin should be withheld in patients with low risk of thromboembolic events (i.e. AF without prior stroke/TIA).

4. Warfarin should be continued in patients:
    a) With prosthetic valves,
    b) With AF with prior TIA/CVA,
    c) On current treatment for:
        i. DVT
        ii. PE
        iii. Left atrial or ventricular thrombus.
        iv. Certain thrombophilias – e.g. Protein C deficiency

If warfarin is continued, the procedure can proceed if the INR is less than or equal to 3.0. The haematologists have supported this policy. If severe bleeding occurs then octaplex or beriplex should be administered as per protocol. If this is required the event should be reported to the clinical lead and the haematologists.

Operations should not be performed on patients taking Dabigatran or Rivaroxaban. These agents are not clearly reversible. If it is not safe to stop anticoagulation they should be transferred onto warfarin.

If the agents can be stopped then the following guidance should be followed:

For Dabigatran (Pradaxa)

Renal function (CrCl in ml/min)	Estimated half life (hours)	Stop Dabigatran before elective surgery	
		High risk of bleeding or major surgery	Standard risk
≥80	≈13	2 days before	24hours before
≥50-<80	≈15	2-3 days before	1-2 days before
≥30-<50	≈18	4 days before	2-3 days before

For Rivaroxaban (Xarelto)
"If an invasive procedure or surgical intervention is required, Xarelto should be stopped at least 24 hours before the intervention, if possible and based on the clinical judgement of the physician. If the procedure cannot be delayed the increased risk of bleeding should be assessed against the urgency of the intervention.

Xarelto should be restarted after the invasive procedure or surgical intervention as soon as possible provided the clinical situation allows and adequate haemostasis has been established."

More information can be found for Dabigatran here and Rivaroxaban here.

On the morning of the procedure the patient should have an APTT taken, and possibly a thrombin time.

The platelet count should also be noted, and if there is a count less than 100 haematological advice should be sought. Similarly, if there are known bleeding tendencies these should be noted and discussed with the haematologists prior to the procedure.

There is no indication for taking a routine group and save sample.

Device Selection

We have a limited number of devices on the shelf. Selection should be as follows:

1. VVI PPM – Biotronik Talos

2. DDD PPM
    a. Ventricular pacing all the time – Biotronik Talos
    b. SSS or need to avoid ventricular pacing – Medtronic Sensia
    c. Vasovagal syncope – Biotronik Evia
    d. Need for MRI scan in the future – Medtronic Ensura/Advisa
    e. Sorin Reply devices may be available on request for patients < 50Kg.

For ICDs we currently use Biotronik and Medtronic. Single chamber ICDs should be used preferentially, unless there are documented ventricular or atrial arrhythmias where an atrial lead may be beneficial for diagnostic purposes. Devices with IS-4 headers may be considered for patients <50Kg.

For CRT-Ds and CRT-Ps we use Boston and Medtronic.

External subcutaneous ICDs (Cameron Health) may be considered for younger patients (<60) with no pacing indication (ARVC, CPVT, Brugada, Idiopathic VF, LQTS). The manual for programmer use is embedded here, as are the documents relating to its approval as a new procedure and a specific leaflet for patients.

We are trying to move towards a situation where all devices can be remotely monitored and are MRI safe. This will take many years due to financial constraints.

Admission Checklist

- The admission to hospital must be used not only to ensure the patient is prepared for the device implant from a physical but also a psychological viewpoint.

- Consent should be obtained prior to arrival in the lab by the operator or someone capable of performing the procedure.

- The indications for insertion of the implantable device should be reviewed.

- Any history of recent or current infection must be noted.

- Any significant co-morbidity must be recorded, in particular LV impairment, respiratory disease, renal dysfunction and diabetes. Any previous anaesthetic problems should be documented.

- The MRSA/MSSA status and decolonisation regime should be reviewed and documented.

- The drug history is vital especially in relation to warfarin, clopidogrel and aspirin use.

- Allergies, particularly to penicillin, must be noted.

- Whether the patient is right or left handed must also be documented.

- Examination: the physical examination should record any signs of infection as well as the ability to lay flat – particular attention should be paid to pain and breathing issues.

- The chest X-ray should be reviewed.

- Pacemaker implants will generally be performed under local anaesthesia. ICD implants may be performed under local anaesthesia with sedation. For elective procedures the patient should be starved of solids for 6 hours and clear fluid for 2 hours prior to receiving intravenous sedation.

- An intravenous cannula should be inserted on the contralateral side to the intended pacemaker site unless a venogram is envisaged. Venograms are likely where access is likely to be difficult (BMI>35kg/m^2) or where there has been a previous device implanted and new leads are required, when a venogram should always be performed prior to operation.

- All women of child-bearing age must have a pregnancy test and/or sign an LMP form.

- The chest should be clippered using an electric razor near the site of pacemaker insertion. The groin should also be clippered if a temporary pacing wire is required.

- The trust antimicrobial policy on prophylactic antibiotics should be followed.

- Patients should have EMLA cream applied at the earliest opportunity and paracetamol given approximately 1 hour prior to the procedure.

Device Related Infections – Prevention

Introduction

Device related infection is a common and difficult problem. Between 0.5-2% of patients experience this (higher rates with complex devices) and it is associated with higher healthcare costs and around a 5% mortality, rising if there is endocarditis[19]. Risk factors for infection, aside from operator experience include[19-23]:

1. Early reintervention (OR 15.04)
2. Corticosteroid use (OR 13.90)
3. Renal failure (OR 11.97)
4. CRT-D implantation (OR 7.57)
5. Fever < 24 hrs. prior to implant (5.83)
6. Renal insufficiency (OR 5.46)
7. Box change (OR 3.67)
8. Oral anticoagulant (OR 2.82)
9. Heart failure (OR 2.57)
10. Presence of TPW (OR 2.46)
11. Male gender (2.23)

Recommendations

There are a number of recommendations and guidelines as to how to reduce device related infection. There is some evidence from units that have had a spike in device-related infections, that a comprehensive IC program can reduce device-related infections[24]. Our recommendations are based upon the measures outlined in that document.

Pre-operative care

1. All patients should be screened for MRSA and MSSA and should not normally undergo pacemaker implantation if positive. If positive these patients should be decolonized before the procedure. For patients in whom emergency implantation is required and whose status is unknown, decolonisation should start immediately after the procedure. It can be stopped if the patient is found to be MRSA/MSSA negative.

2. Decolonisation for both MRSA and MSSA should take place 5 days before the procedure date. In emergency situations this will not be possible, but in semi-elective situations the procedure should be delayed. In emergency situations decolonisation should start straight away and then continue after the procedure until swab results are known. Note that there is clear evidence for the use of Mupirocin according to a recent Cochrane review. Patients are recommended to use Bactroban (Mupirocin) nasally 3 times per day and Skinsan or Octenisan wash daily for the five days prior to the procedure. There is also a standard letter to GPs. More detailed management of patients with MRSA can be found here.

3. Screening of operators/staff may be required if:

    a) Infections persist despite the measures in this document being undertaken

b) If the same organisms are isolated in many different patients

We will be guided by microbiology if this is necessary.

4. Patients with open wounds which are known to be colonized, or have active infection should not normally undergo pacemaker implantation until these issues have been resolved unless clinically imperative.

5. Patients who have had antibiotics should not undergo implantation of a pacemaker within 30 days unless there is a pressing clinical indication[24].

6. Patients should shower or bath (or have a bed bath) on the day of surgery where possible (NICE CG74), possibly with an antibacterial agent such as triclosan[24] although a Cochrane review, has emphasised that there is no clear evidence for the use of antiseptics. We have produced specific guidance about this.

7. Electrical clippers with a single use head on the day of surgery should be used. Razors should not be used (NICE CG74). If razors are used the patient should be cancelled unless there it is an emergency.

8. In patients with poor blood glucose control it may be reasonable to use a sliding scale perioperatively, although further research is required[25]. There is a good summary in Anethesia and Analgesia[26].

9. Antibiotic prophylaxis should be used as per protocol (Flucloxacillin 1g iv or Teicoplanin 400mg iv and Gentamycin 3mg/kg iv) **and within 30 minutes of the procedure**. There is surprisingly little evidence for this, although what is there is clear that antibiotics are better than no antibiotics[27,28] and the use is supported by a now withdrawn Cochrane review. Whether antibiotics are required after the procedure remains unclear. There is some logic to giving antibiotics for 48 hours to allow the skin to heal, but longer courses do not appear beneficial[29]. We have recently changed the policy following discussion with the microbiologists to give 7 doses of flucloxacillin 500mg 6 hourly post procedure (or clindamycin 300mg 6 hourly for 7 doses). If a patients' MRSA status is unknown then it is advised that the patient should have 3 doses of teicoplanin – at induction, and at 12 and 24 hours post procedure.

10. There is also no clear evidence on whether antibiotics should be given into the pocket. Povidone-iodine irrigation of the pocket does not appear to help[30]. An antibacterial envelope may do[31].

Intra-operative care

1. There is little evidence to suggest that putting devices in in operating theatres is safer than putting devices in in catheter laboratories[32]. There are standards for ventilation for health care facilities[33]. These specify minimum recommended standards for air changes, humidity and temperature. We have had recommendations from the health protection agency that there should be a minimum of 10 air changes per hour in each lab, preferably 18-20. We appear to have a greater number of air changes in our labs (see link). There is also general

information for the specification of labs for diagnostic imaging (HBN 6) and more general guidance on ventilation (HTM 03-01).

2. There should be minimal movement of staff into and out of the theatre (NICE CG74).

3. Scrubbing with chlorhexidine, rather than povidone-iodine is recommended for 5 minutes prior to the procedure. There is some evidence that new alcohol-based scrubs may be more effective. The no-touch technique should be used when gowning and gloving. The guidance can be found in a Cochrane review. If the operator is allergic to chlorhexidine, then until the alcohol-based scrubs are available, then povidone-iodine should be used.

4. Staff should wear hats and masks. It is accepted that there is little evidence for this practice. Hats and masks should not be re-used.

5. The surgical safety checklist should be performed. See below.

6. Oxygen saturations should be maintained above 95% (NICE CG74).

7. Maintaining patient normothermia is important; hypothermia appears to be an important risk factor for surgical site infection (NICE CG74).

8. A venogram should only be used where access problems are felt likely to be an issue. A venogram should be performed where new leads are to be inserted and there is a pre-existing device. Of note the cephalic vein should be used where possible to minimise the risk of pneumothorax. An ultrasound probe should be available to facilitate axillary vein access. Generally speaking the venflon should be placed on the contralateral side.

9. The instruments should be inspected prior to use. Any which appear to have rust on them should be discarded as per advice from infection control. They should be sent back to CSSD for de-rusting and re-sterilisation.

10. The skin should be prepared using chlorhexidine rather than povidone-iodine, unless there is a documented allergy[34] (Also NICE CG74). We use Chloroprep. The applicator should be applied over the area to be incised in a gentle back and forth manner for 30 seconds, before wider painting of the surgical field is undertaken. The skin should be allowed to dry naturally and completely before applying the drape.

11. There are also some limited data that Integuseal reduces contamination of wounds[35] and we should consider using this.

12. Drapes, which adhere to the wound itself, should not be used[36].

13. Box changes should not be performed by operators who have performed less than 50 procedures.

14. Diathermy use should be minimised (NICE CG74).

15. There are some data to suggest that monofilaments are superior to braided sutures[37] and if braided sutures are to be used then antimicrobial coated sutures are beneficial[38]. After a

trial of ethibond (a braided synthetic suture) we have reverted to silk, as both Richard Kilbey and myself found that securing the leads was difficult. We now use vicryl plus (2-0, 31mm 1/2c round bodied needle, 70cm), an antiseptic coated version of vicryl.

16. Anecdotally both Mike James and myself have noticed that using Surgicel has been associated with infection. This may simply be an association rather than a causal link, but for the time being use of this should be avoided if at all possible, although it may still have a role if there is excess bleeding.

17. It is unclear whether gentamicin given into the pocket reduces infection.

18. There is no evidence that tissue adhesives are superior to sutures for closing the skin layer[39], but they may be used for convenience. Liquiband should not be used as it does not have the tensile strength, rather liquiband flex is most appropriate.

Post-operative care

1. Lead coats should be washed between procedures.

2. It is unclear whether post-operative antibiotics need to be given. It is common practice in many units and we have made it standard practice. Many studies which have examined the role of antibiotic use in preventing pacemaker-related infection have used post-operative antibiotics[40,41]. We have changed the policy following discussion with the microbiologists to give 7 doses of flucloxacillin 500mg 6 hourly post procedure (or clindamycin 300mg 6 hourly for 7 doses).

3. There is very little evidence-based advice for washing after pacemaker insertion. Dermabond can be wetted on the evening after surgery, but should not be soaked or scrubbed. For skin wounds closed with nylon the wound can be washed the following day[42], and this is in line with other studies[43]. We have advised, after consultation with infection control, that wounds not covered with tissue adhesive should be covered for two days and can be washed on the third day.

The WHO Surgical Safety Checklist

A modified surgical safety checklist has been devised. This should be performed for every procedure and the document placed in the patients' notes. This is a must do. There are good reasons why we should do this which are beyond the scope of this guideline. Further information on the rationale behind this and videos of how to perform (and not perform) the surgical safety checklist can be found here and here.

Monitoring of the Patient During the Procedure

The patient should be monitored during the procedure:

1. The welfare of the patient should be checked on a regular basis

2. Oxygen saturations and respiratory rate should be monitored continuously

3. Blood pressure should be measured every 10 minutes, unless directed to repeat more often

4. If sedation is given, then oxygen is likely to be necessary and a mask should be applied prior to draping the patient.

Temporary Pacing

Temporary pacing is to be avoided.

In this centre, due to the absence of an ultrasound probe in the pacing room, a femoral approach must be recommended (NICE - TA49). A 5F lead is to be preferred and the sheath should be withdrawn at the end of the procedure unless there is concern over bleeding or unless an oversized sheath has been inserted to permit central access.

Please note that following a death due to MRSA septicaemia, antibiotics should be commenced at the time of implantation (Teicoplanin + Gentamycin) as per microbiological protocols until the time of pacing wire removal or implantation of a new system; the presence of a temporary pacing wire is a recognised risk factor for infection of the new system.

Because of the risk of infection the general aim should be to insert a permanent system on the next available list, unless it is thought that the wire will only be required briefly.

A temporary pacing wire is not recommended where a box change is to be performed and there is no evidence of an underlying rhythm. Sedation should be given and external pacing pads applied. There is evidence that the insertion of a temporary wire increases the risk of device-related infection and the procedure itself is not without complication.

Contrast Media Use

The trust-wide policy should be adhered to. Careful use of fluids is required in many patients however, and therefore a case-by-case assessment will be required.

Analgesia and Sedation

1g of paracetamol po should be given prior to the procedure and EMLA cream applied to the site of the likely incision.

Sedation should be offered to patients if required. Currently we tend to use morphine and midazolam, however, outside of cardiology there is an increasing tendency to use of fentanyl (25mcg of fentanyl is equivalent to 2.5mg morphine). Fentanyl tends to induce less nausea and itching compared with morphine but may not be as good at controlling pain, and therefore it may not be sensible to change practice[44].

The safe sedation policy should be adhered to.

There are a number of important points:

- In accordance with the guidelines for general anaesthesia, for elective procedures, patients should be starved of solids for six hours and clear fluid (this includes coffee or tea with skimmed milk) for two hours prior to receiving intravenous sedation.

- No more than 10mg of midazolam should be given – if more is required the assistance of an anaesthetist should be sought.

- If as a consequence of sedation it proves difficult to rouse the patient the assistance of an anaesthetist should be sought.

Surgical Technique

Be aware of the correct scrubbing technique and use a closed glove technique.

It is recommended that the previous operation note is read prior to any revision.

In the NICE clinical guideline on the prevention of surgical site infection, incise drapes are not routinely recommended. Non-iodophor drapes have been associated with increased rates of infection. Iodophor impregnated drapes should not be used with chlorhexidine – and chlorhexidine has been shown to reduce the rates of infection.

With regards to local anaesthetic, bupivacaine lasts for considerably longer than lignocaine, but less can be given:

Bupivicaine:	2mg/kg	1%, 10mg/ml, 14mls for 70Kg man typically
Lignocaine:	3mg/kg	1%, 10mg/ml, 21mls for 70Kg man typically
Lignocaine with adrenaline:	7mg/kg	1%, 10mg/ml 49mls for 70Kg man typically

We have an intralipid policy in the case of overdose.

If possible the old scar should be excised, but this may not be possible if there has been considerable migration of the device, and may be more challenging if diathermy is not available. A marker pen can help to ensure a good cosmetic result.

Toothed forceps are less damaging to the skin than non-toothed forceps.

We are continuing to use silk to secure the leads, having trialled ethibond.

The device should not be under the suture line and the pocket should be enlarged if this is the case.

Currently I use a combination of subcutaneous antibiotic coated Vicryl and Liquiband flex to close the wound. The topical cyanoacrylate material does not conclusively reduce wound infection, but is convenient for patients. There are a number of different closure techniques, and there is a good argument for using monofilament sutures. Interrupted sutures requiring removal are not recommended except in the case of wound infection.

Lead Selection

Lead selection is at the discretion of the operator. Active fix atrial leads should generally be used in patients who have undergone cardiac surgery. There is evidence that straight screw-in atrial leads offer better stability[45,46].

Active fix ventricular leads of 7F or less should generally not be implanted at the right ventricular apex. They should not be advanced with the stylet fully in.

At present there is no conclusive evidence that septal pacing is superior to right ventricular apical pacing, and therefore this should be left to the discretion of the operator. Harry Mond has produced a cogent argument as to why we should pace separately and guides on how to do it correctly[47]. St Jude produce the 'Mond' stylet for pacing in the RVOT Trials are on-going.

I have taken the view that IS-4 technology is not yet mature, although this is likely to change over the next year or two, however St Jude do produce an ICD with an IS-4 lead which has a small header and small can. This device could be considered for patients with a BMI of < 20 or a body weight of < 50Kg.

Screening

HCAs and Screening

We have successfully trained a number of HCAs to undertake screening for any procedures performed in the pacing lab. The documentation can be found here.

Screening at the End of the Procedure

It is unacceptable to leave any equipment in a patient and such an event can result in significant penalties for the trust. It is imperative to account for all equipment at the end of the procedure and screening should be performed to ensure that no equipment has been left in the patient including wires, needles or swabs. Only radio-opaque swabs should be used.

Skin dose

During occasional procedures there will be concern over the total radiation dose to the patient. The policy can be found here.

Post Implant Care

Patient problem/need	*Aims of Care*	*Actions*
Potential risk of bleeding from wound site Risk of vasovagal event	To prevent bleeding Early identification of problems	1. May sit up immediately with assistance. 2. May mobilise when effects of sedation have worn off and patient able. 3. Observe and record BP, heart rate, O_2 saturations, PAR score, sedation score every 15mins for 1hr then every 30min for 1hr then hourly for 4hrs then every 4 hrs. 4. Observe wound site for bleeding/discharge swelling as above. 5. If bleeding or severe swelling occurs inform a doctor and apply direct manual pressure for at least 10 minutes or until bleeding ceases. It is then appropriate to apply a pressure dressing for 4 hours.
Risk of pneumothorax	Observe for signs - Shortness of breath - Difficulty in breathing - Reduced oxygen saturations - Chest pain	1. Monitor O_2 saturations as above. 2. CXR 4 hrs. post implant for all new systems or sooner if operator directs.
For box change with TPW	To prevent bleeding from leg Early identification of problems	1. Haemostasis should be achieved in the pacing room by manual pressure. 2. Patient should lie flat for 1hr, then sit for 1hr then mobilise. 3. Observe puncture site for bleeding/swelling when recording observations. 4. If bleeding or swelling occurs apply direct pressure for 10 minutes, or until bleeding ceases.
Hydration and nutritional needs	To maintain needs	1. May eat or drink on return to ward depending on sedation levels. 2. Encourage oral fluids.
Potential risk of lead displacement.	To reduce the risk of lead displacement To identify lead displacement	1. Patient must not elevate the arm on implant side above shoulder level for 1 month (N/A for box change). 2. Observe for signs of displacement - change in BP, heart rate. Obtain 12 lead ECG. 3. Contact pacing technicians on ext. 2360 for device check. 4. Arrange chest X-ray. 5. Contact implanting Dr if lead displacement has occurred.
Pain from wound site	To alleviate/reduce to an acceptable level for the patient	1.Assess pain level frequently. Use verbal/non-verbal /vital signs. Commence pain chart where appropriate. 2. Offer regular analgesia, monitor and record effect. 3. Assist to comfortable position. 4. Encourage diversional activities where applicable.
Healing of wound	To promote healing without complications	1. Manage the wound aseptically. 2. Remove dressing after 2 days unless directed otherwise. 3. Explain to the patient that they can wash it after 3 days. 3. Arrange appointment in Day Case for suture removal if required.
Educational, Psychological, Social and Spiritual needs	To reduce anxiety, promote return to normal activities.	1. Allow patient time discuss anxieties and fears. 2. Ensure patient has appropriate literature and post care advice 3. Contact BHF Arrhythmia nurses if patient requires further support.

Pacing Check and Chest X-ray Post Procedure

These should be done 4 hours after the procedure and should be documented in the notes. The operator should generally review the chest X-ray. The patient should also be reviewed by the operator at this stage and may then be discharged if appropriate.

The chest X-ray should be checked for:

1. The presence of a pneumothorax or haemothorax or other complication.

2. The position of the leads.

3. That the leads have been fully inserted into the box.

4. That there are no retained items.

Post-operative Wound Care

We have reviewed the advice we give to patients about their wounds and it is now in the pacing leaflet. It bears repeating here:

Advise the patient that if they develop a temperature, or the wound becomes red or inflamed, they should contact the pacemaker clinic promptly or the cardiac day unit or coronary care.

If glue has been used to close the wound please ensure that it is left uncovered. Advise the patient that the glue will start to flake off after 7 days. They can shower on the same evening of the procedure but should not soak the area; the area should be patted dry with a clean towel.

If there is a dressing covering the wound site it should be removed after 2 days and the wound left uncovered. The wound should be kept clean and dry for 3 days after the procedure. The patient can then shower normally and pat the area dry with a clean towel.

If there are dissolvable sutures closing the wound the sutures will dissolve and no further action is needed.

If there are non-dissolvable sutures then the patient should be given an appointment to come back to the Cardiac Day Unit to have them removed, usually 7 days after the procedure.

ICD Testing and VT Stimulation

ICD Testing

The current recommendations are that patients with an ICD in situ should undergo a defibrillation threshold (DFT) test. In practice we do not actually test the DFT and simply ensure that the device successfully detects and treats ventricular fibrillation. Due to the changes in the sedation policy we can no longer test at implantation unless there is an anaesthetist present. Our current practice is to test electively after the procedure, and we have a list on the second Wednesday afternoon of the month.

More recent data have called into question its value[48] and there are increasing calls to stop this practice. Therefore this policy requires regular review. The risk of complications appears low[49,50]. Of note if repeated testing is required, at least 5 minutes should elapse between inductions.

We have a separate proforma for DFT testing.

If patients have atrial fibrillation they should have an INR of > 2.0 for 3 weeks prior to DFT testing. They may be DFT tested on Dabigatran, but they should be on the dose of 150mg bd in keeping with our current policy. This may change in the future. DFT testing should not take place if the patient is on Rivaroxaban, at present.

If patients have left ventricular thrombus they should have an echo to demonstrate that it has resolved prior to DFT testing. Other reasons for not testing include known untreated severe coronary artery disease and patient preference.

We have a document that is sent out to patients prior to their admission.

VT Stimulation

There are very few indication for a VT stimulation study. The protocol is as follows:

1. Drive train 600ms, 1 extrastimulus from 400ms down in 20ms intervals to refractory, then a second extrastimulus down to refractory.
2. Drive train 500ms, as above.
3. One site only – RV apex or RVOT.

Complications and Audit

Complications are an important issue relating to permanent pacemaker implantation. We are a centre that offers experience to first and second year registrars, and it can be expected that we will have a higher rate of complications and procedures will take longer[51]. Out long-term complication rate has been published[52]. More recently our complication rate has been falling. This is probably because we now have fewer operators and we are supervising each registrar led implant. This practice should continue.

There are a number of standards laid down by HR-UK:

1. Each centre must maintain a database of implants and complications within 12 months for pneumothorax and requiring re-intervention. This is currently maintained on CVIS. Monthly uploads to CCAD should be undertaken no more than 3 months in arrears.

2. Standards for complications have been defined:

    a. Ventricular lead displacement 1.0%
    b. Atrial lead displacement 2.0%
    c. Pneumothorax 1.3%
    d. Perforation 0.4%
    e. Infection 0.6%

    Whether these represent real-world complication rates remains to be seen. Our current rates are much higher than this, hence the production of this document.

3. Immediate anaesthetic support should be available for ICD implantation. We can say that we have this in that we can fast-bleep the on-call anaesthetic team.

It is explicitly stated that if an implanters complications exceed these limits then practice should be reviewed and advice sought from within the centre or elsewhere.

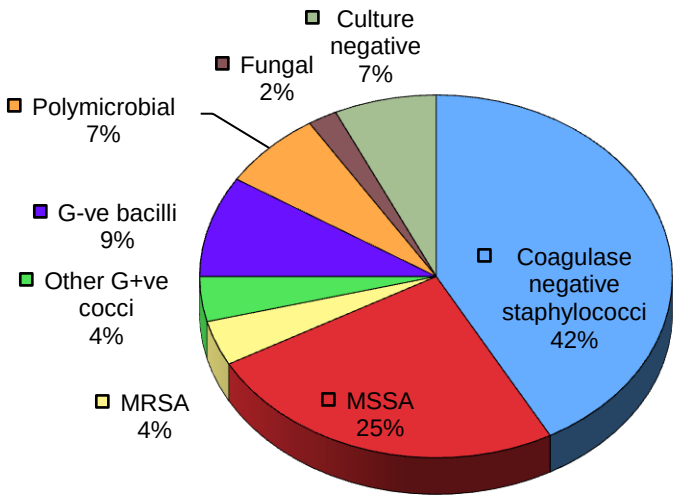
All complications must be reported to the device lead.

The national audits can be found here.

Device Related Infections – Management

Any patient with a suspected device related infection should be admitted immediately. The infection should be reported to the clinical lead. Blood cultures should be taken and echocardiography arranged. Antibiotics should be commenced after discussion with the microbiologists, but should include both gram positive and negative cover. Vancomycin and Gentamycin are appropriate until organisms and sensitivities are known. Please see the pie chart below for details on the typical microbiology with device related infections[20]. In the vast majority of cases device extraction should be considered. This should be performed as soon as is practicable – typically on the next list.

Microbiology of Device Infections
Sohail et al. 2007[20]



The AHA have released guidelines for the management of device related infection[53]. I have included specific references on outcomes[54] and Staphylococcus aureus[55]. These guidelines say:

- CIED removal is not required for superficial or incisional infection at the pocket site if there is no involvement of the device. Seven to 10 days of antibiotic therapy with an oral agent with activity against staphylococci is reasonable.

- Complete removal of all hardware, regardless of location (subcutaneous, transvenous, or epicardial), is the recommended treatment for patients with established CIED infection.

The guidelines include a number of pathways to guide management which should be followed.

Lead Extraction

Leads and systems should only be extracted if they are less than 1 year old. All other patients should be referred to Bristol or Harefield for device extraction. I have included references to articles for patients[56] and the formal guidelines[57].

Pneumothorax and Haemothorax

The pneumothorax rate in our centre is too high. The cephalic route should be used preferentially. The axillary vein is an alternative.

All pneumothoraces should be reported to the clinical lead.

The management of pneumothoraces are detailed in the trust guidelines for the management of pneumothorax and chest drain insertion; these should be referred to.

Essentially if a small pneumothorax (<2cm) is noted and the patient is asymptomatic then the patient should have a chest X-ray the following day. Assuming the pneumothorax is no larger the patient should be brought back to the day unit in 1 week for a repeat film. If the pneumothorax is >2cm then it may be aspirated once in patients without underlying chest disease. If the pneumothorax remains then a chest drain should be inserted. Of note, it is clinically more appropriate to follow the non-trauma pathway despite the aetiology. The respiratory team are very helpful.

Follow-up Standards

The Heart Rhythm Society and European heart rhythm association have suggested follow-up standards[58], as have Heart Rhythm UK.

Arrangements for 24-hour cover should be in place for all device patients. This is particularly important for ICD patients where device-related and arrhythmic complications occur frequently and can be life-threatening.

Follow-up should be performed at nationally accepted intervals:

1. Within 2 months of implantation.

2. 6-12 monthly for bradycardia pacing.

3. 3-6 monthly for CRT and ICD therapy.

4. Patients should have urgent follow up if they report symptoms that may be associated with their device.

Remote monitoring of devices should be encouraged and should now be the standard of care. Currently HR-UK feels that yearly face-to-face follow-up is required even if remote monitoring is in place, although this could be reduced to yearly. This is currently being reviewed by HR-UK.

Clinic follow-up should include:

1. Wound review.

2. Device checks – battery, lead impedance, pacing thresholds, sensitivity. Any important changes or findings should be discussed with a consultant. The rate response behaviour should be assessed by examining the heart rate histograms, and if necessary by simple exercise testing, and adjusted appropriately

3. Recorded patient rhythm data
    a. Episodes of possible atrial fibrillation should be recorded and the GP notified (see below).
    b. Episodes of ventricular arrhythmias should be recorded and the appropriate consultant should be notified.

4. For CRT patients record should be made of % ventricular pacing. If the value falls below 95% the appropriate consultant should be notified.

Vitatron and Biatrial Generator Replacement Advice

Vitatron Pacemakers

We have a specific document detailing when to replace Vitatron pacemakers.

Biatrial Pacemakers

We have a small number of patients with biatrial devices in situ. Biatrial devices are no longer manufactured and therefore a like-for-like box change cannot take place. Some patients may not need a pacemaker.

The first question is whether the patient remains in sinus rhythm or not.

If they are in sinus rhythm the next question is whether atrial pacing alone can continue to suppress atrial fibrillation. Therefore it is reasonable to try for one month with no atrial pacing (DDI 40), left atrial pacing and right atrial pacing in turn. If there is clear benefit for one of the pacing modes then it is reasonable to change the device. We are currently recommending the Vitatron T70. We have had to swap out other models due to inefficiency. Although it is thought that atrial pacing is ineffective in preventing atrial fibrillation, this is clearly not the case for some individuals. If the patient is in chronic atrial fibrillation then the device should be turned down to VVI 40 if not already done so to determine the need for backup ventricular pacing. If there is a need then it is reasonable to change the device for a Talos SR.

Atrial Fibrillation

Atrial high rates are frequently detected at follow-up. Episodes may be brief or prolonged, and may or may not be associated with symptoms. Atrial fibrillation is recognised as increasing the risk of stroke and it important to ensure that patients take antiplatelets or anticoagulants depending on underlying risk factors. There is no consensus, however, as to how much atrial fibrillation, as detected by device diagnostics, is significant.

The literature[59,60] suggests that atrial fibrillation becomes a significant risk factor for stroke if there has been:

1. >10.8 hours in a 30 day period (1.5%) or

2. Any episode > 5 minutes

We have constructed a sample letter to send to GPs.

Electromagnetic Interference and Other Environmental Issues

Pacemakers are affected by electromagnetic fields, although they are increasingly shielded from their effects. A number of companies have produced specific documentation, which I have collected, but for copyright reasons cannot include in this document. The companies are usually happy to provide specific advice and guidance, and some companies, such as Medtronic, will perform site visits. St Jude provide specific information on pressure testing and their devices may be more appropriate for those who wish to continue diving.

We have had some specific guidance from Medtronic on the use of cochlear implants and CRT-D devices. A distance of 6" (15cm) should be maintained between the cochlear implant and CRT-D. The implant will not damage the device; if the device detects the magnet in the implant it will alarm. In this situation the person with the implant should move away from the person with the device.

Device Deactivation

Device deactivation is often performed too late. The final decision should always rest with the patient as long as they remain competent to make the decision. The subject should be raised prior to implantation, as this issue is likely to arise at some stage. A surprising number of patients do not believe that they can die with an ICD in situ. There has been a useful discussion article in BMJ palliative care[61]. The Heart Rhythm Society and European Heart Rhythm Association have released a consensus statement[62]. The Arrhythmia Alliance have produced a useful booklet. I have included a link to Bristol's guidance.

Radiotherapy and pacemakers

There is a theoretical risk that radiotherapy can damage permanent pacemakers if the pacemaker is in the line of the beam. Occasionally the presence of a pacemaker will shield the area that is targeted. In such situations it may be reasonable to move the pacemaker and close collaboration with the radiotherapists is required. A number of companies have produced guidelines around how much radiation their pacemakers can receive before they are likely to malfunction and these should be referred to. I have copies of these documents.

There is also the risk that radiotherapy may interfere with ICD detection of ventricular arrhythmias and there is the possibility of inappropriate shocks. Currently the recommendation is that the device should be:

1. Deactivated prior to radiotherapy, with a monitor zone left on.

2. It is then the responsibility of the radiotherapy department to monitor their patient for ventricular arrhythmias.

3. The patient should return to the department after the radiotherapy to have their device reactivated. Any events should be recorded and the pacing lead informed. Of note this should not be later than 5pm and the timing of radiotherapy should reflect this.

4. If emergency radiotherapy is required out of hours the device can be deactivated by placing a magnet over it, but the patient should be seen in the pacing department to have their device interrogated on the next working day and the patient should not be allowed home until this has occurred.

Pacemakers and Diathermy

The protocol for managing pacemakers and ICDs in the context of diathermy has been agreed and the document can be found here. A slide set is available on request.

Optivol alerts

In the future we should cascade these alerts to a fully functioning heart failure nurse specialist service. Currently as we receive the data we cannot ignore it. Optivol rises can signify impending heart failure decompensation or an increased likelihood of shocks and therefore someone needs to check on the patient. At present the cardiac physiologist should phone the patient. If they are feeling more unwell they should be advised to visit their GP. We have prepared a standard letter. Further details can be found here.

Driving

The DVLA at a glance guide should be used to determine eligibility for driving.

This document as it is subject to frequent review and the online site should always be checked.

Of note, this guide should be referred to after ATP or an ICD shock, irrespective of whether it is symptomatic or not, or appropriate or inappropriate.

Of note, after pacemaker implant the legal advice is not to drive for 1 week, unless there is an underlying condition which requires control for longer – for example sick sinus syndrome with syncope requires “control” for 4 weeks before driving can resume. Please note that the guidelines relating to HGVs are different.

MDA/MHRA Alerts

The MHRA website should be checked on a monthly basis for relevant alerts.

Particular alerts of current relevance include:

1. Cameron Health subcutaneous ICD. There is a current medical device alert for the Cameron Health subcutaneous ICD These models are no longer in circulation and the advisory does not apply to the current model. We have three patients Cameron health devices in; none are affected by this alert.

2. Sprint Fidelis Leads. Please note that the recommendation from Medtronic is that leads with problems should be replaced with an ICD lead rather than a new pace-sense lead if possible. It is imperative that certain programming changes are applied. It is recommended that lead replacement is undertaken when a box change is performed.

3. St Jude ICD leads Lead insulation issues in certain. This is turning into a bigger issue than initially anticipated. All patients attending for box change or who have noise on their leads identified at follow-up should have their leads screened. If externalised conductors are seen the lead should no longer be used. I would recommend discussing each case with the St Jude representatives.

4. Inappropriate ERI in certain Medtronic pacemakers.

5. Magnet instability and inappropriate battery readings in certain Sorin pacemakers.

6. Header issues on certain Boston ICDs implanted subpectorally.

7. PhD feature when applied in certain Sorin ICDs may inhibit pacing.

St Jude Riata Leads – Further Details

A total of 16 of the Silicone Riata models have been implanted in Musgrove Park between 2004 & 2008; the Riata / Durata Optim models (50% silicone & 50% Polyurethane) were mainly used 2008 onwards and are not affected.

1. The St. Jude Medical (SJM) quality system has identified a highly statistically significant difference in the performance of silicone insulated ICD leads in comparison to ICD leads with Optim insulation.

2. The MHRA recommend 3 monthly follow-up for 8F leads and 6 monthly follow-up for 7F leads.

3. When insulation failure is expected, additional testing such as patient shoulder and arm movements, deep respiration or x-ray are suggested.

4. The leads should be screened in 2 planes at box change. A device with remote/advanced monitoring capability is recommended if the lead is not changed.

5. If evidence of a protruding conductor is found, the risks and benefits of lead replacement should be evaluated on a case by case basis in discussion with the patient.

6. Prophylactic lead replacement is not recommended.

Accufix leads

The Telectronics Accufix and Encor leads have a retained stylet – in some situations that has eroded through the lead and perforated the atrium.

We should maintain a list of such patients and it is important that they attend for regular screening of their leads. Generally 6 monthly screening is recommended. Further details can be found at here.

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