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Supplemental Technical Information
relating to
Bradycardia Pacemakers



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1. Introduction

Assessment/interrogation of pacemakers should only be performed with appropriate infrastructure and by appropriately trained staff. The main aim should be to ensure safe function of the pacemaker tailored to the individual and to meet national standards. Personnel performing follow-up should have a comprehensive knowledge of the advanced features of individual devices, and 'care pathways' should be in place to manage pacemaker related problems and device advisories/recalls.

This document provides a general overview of pacemaker follow-up and discuss the more advanced features of current pacemaker technology that need to be managed and optimised at the time of pacemaker follow-up.

2. Pacemaker Follow-up

The frequency of pacemaker follow-up varies from centre to centre. In most cases a first follow-up after discharge from the implant hospital should be within 12 weeks. Thereafter follow-up will be generally every six or 12 months. In the paediatric population this should be at least every six months. More intense follow-up will be necessary as the device approaches the elective replacement indicator (ERI) (for example, 75% of battery capacity consumed equates to intensified follow-up). Reviews should be every 3 months once indicated. A history should be taken from all patients to identify whether there are likely to be any pacemaker related problems or clinical problems that may be aided by alternate device programming. Specifically, change in symptoms such as pre-syncope, syncope, dyspnoea, lethargy, palpitations, and chest pain should be defined. A full medication review should be considered as part of the follow-up process.

The device should be interrogated using the appropriate programmer and software. The minimum essential data evaluated and recorded at each follow-up is; pacing lead impedance; Sensed P/R wave amplitude; Pacing threshold; and Battery voltage and impedance. Pace/sense statistics and heart rate histograms should also be included where such data is stored on the device.

Once the pacemaker is interrogated analysis of intracardiac electrograms should be performed at the baseline state and during intrinsic rhythm (if previously pacing) followed by pacing lead integrity. In the majority of cases this will be in the form of a measured impedance value (older devices may not have this feature). Providing this is satisfactory pacing and sensing threshold values should be recorded. It is imperative that comparison with previously recorded values and analysis of trends be sought so that potential problems can be predicted. Most modern devices record additional information that can be significant in patient care. This may be in the form of rate histograms, recorded electrograms, activity levels, high rate events, mode switches, etc.

3. Capture management

Many devices now have the ability to determine the pacing threshold and adjust the output of the device to just above this threshold. Before the introduction of this modality the output was set at a fixed level, usually a minimum of twice the threshold of the most recent pacing check. Algorithms to check threshold usually require the delivery of a pacing pulse at decrementing outputs and the evaluation of a sensed evoked response following this pulse. If no evoked response is recorded a pacing pulse at a fixed high output is delivered to ensure capture. Often this testing is programmed to occur at nighttimes so as to avoid symptoms. Key requirements to such a system are the determination of the evoked response and ability to distinguish from the polarisation signal (i.e. pacing "spike"). Evoked response may take a period of weeks/months to stabilise in terms of consistency of amplitude and may vary with changes in the patients' physiology and pharmacotherapy. A requirement of such a system is a bipolar lead, which is generally programmed to unipolar pacing polarity and bipolar sensing. Some devices examine the period following a test pulse looking not for an evoked response but for a sensed intrinsic atrial electrogram indicating failure to capture and thus intrinsic activity.

Capture management algorithms are currently well established in ventricular pacing and are beginning to evolve in atrial pacing. This automatic facility has potentially a number of benefits. By reducing the output there will be less drain on the battery and potentially increased device longevity. This has been demonstrated to increase device longevity by up to 65%¹. More importantly the device has the ability to adjust to alterations in threshold, which is an important safety mechanism. It is possible for the threshold of the lead to increase for a number of reasons, including device related problems such as micro displacement, or changes in physiology such as electrolyte abnormalities, or alteration in pharmacology such as antiarrhythmic drugs. These changes will be very apparent when the threshold trend data are reviewed.

While algorithms are designed to adjust lead amplitude to a sudden/dramatic increase in lead threshold, a safety margin, which amounts to less than the battery doubling voltage, may not prolong battery longevity. This is dependant on the specific manufacture's algorithm. Due care and knowledge of particular algorithms is vital prior to programming on any capture management algorithm.

4. Sensing Assurance

Medtronic pacemakers use a specific feature called 'sensing assurance', which is an auto-adjusting ventricular sensitivity algorithm for R wave sensitivity². After sensed ventricular events, Medtronic pacemakers reset the sensing threshold to a multiple of the programmed sensitivity, up to a maximum of 75% of the sensed R wave. The value of auto-adjusting sensitivity then decays exponentially from the end of the (sense) blanking period with a time constant of 450 ms until it reaches the programmed (maximum) sensitivity. Medtronic have recently

¹ Erdinler I, Akylo A, Okmen E, et al. Long Term follow-up of pacemakers with an autcapture pacing system. *Jpn Heart J* 2003;43:631-41

² http://www.medtronic.com/physician/brady/kappa/kappa700_sense_asur.html

introduced the same modality for the atria. This is programmable so it can be switched on and off.

5. Rate response

Rate response (adaptive) pacing allows an increase in heart rate with level of physical activity. A number of activity sensors have been developed using different algorithms such as QT interval, minute ventilation, stroke volume, and accelerometers. Some devices have combined or so called blended sensors. The rate response is programmable with an upper limit and sensitivity. These parameters have the potential to significantly impact on an individual's performance and thus effort should be spent in tailoring the settings of rate response to an individual. Careful analysis of the counters should enable an assessment of the appropriateness of the current rate sensor settings. The decision to program rate response, although advantageous, should be taken with due consideration to the age of the patient, the relative activity of the individual, additional health issues, and pharmacological treatment. The increased use of β -blockers in the management of heart disease can also account for an inadequate increase in heart rate with activity and thus should be taken into account when adjusting the device settings. An inadequate sensitivity or upper limit may produce symptoms of lethargy, dyspnoea, palpitations, or pre-syncope on exertion. Certain manufacturers have sensor assessment tests that give an opportunity for the Cardiac Physiologist to adjust parameters at the clinic with immediate evaluation of the effects on the patient.

6. Mode switching and atrial arrhythmia algorithms

The ventricular rate of DDD pacemakers is dependant on the atrial rate. Therefore, there is the potential for fast ventricular rates to be tracked by the pacemaker should the patient develop an atrial tachycardia. This is not an unusual occurrence in paced patients. A significant number of patients with sinus node disease have tachycardia-bradycardia syndrome and there is an increasing incidence of atrial fibrillation with increasing age. It has been demonstrated that the incidence of atrial fibrillation in paced patients is as high as 13% with an overall risk of 2–3% per year developing atrial fibrillation³. The most common reason (38%) for reprogramming a pacemaker at the time of follow-up is for an arrhythmia and the most frequent programming change is the stimulation mode (81%)⁴. Fast tracking of atrial tachyarrhythmia is usually prevented by algorithms known as automatic mode switching (AMS). The detection of the atrial arrhythmia will depend on the algorithm but usually involves the detection of sudden onset of a fast atrial rate. This will then produce a change in the programmed mode switching from DDD to DDI(R), VDI or VVI mode. The device will revert back to dual chamber mode when sinus rhythm is restored. The number of mode switching events is recorded providing an accurate assessment of the number of episodes of atrial arrhythmias. This can also be cross-referenced from electrograms and rate histograms to detect AF

³ Lamus GA, Pashos CL, Normand SL, et al. Permanent pacemaker selection and subsequent survival in early Medicare pacemaker recipients. *Circulation* 1995;91:1063-9

⁴ Martinelli M, de Arrula Melo S, Nishioka SAD, et al. Atrioventricular pacemaker. Incidence and cause of reprogramming in long-term follow-up. *Arg Bras Cardiol* 2001;76:11-14

with fast ventricular response where available. This provides invaluable information that may allow the clinician to alter the patient's medical management or consider more interventional approaches such as catheter ablation. It also provides a mechanism for assessing the response to such an intervention.

If the patient has retrograde conduction through the atrio-ventricular node then there exists the potential mechanism for a pacemaker-mediated tachycardia (PMT) to develop with ventricular tracking of the retrograde atrial conduction. Most devices contain algorithms to prevent this and these should be considered if retrograde ventricular-atrial conduction has been demonstrated. PMT can occur with anything that causes dissociation of the atria from the ventricles, e.g. loss of atrial sensing or capture, ventricular premature contractions (VPCs), oversensing or undersensing.

A number of triggers of atrial arrhythmias and specifically atrial fibrillation have been demonstrated⁵. These include atrial premature contractions (APC), pauses post APC, and increased vagal tone. Many currently available devices have algorithms that may be activated in order to reduce the number of episodes of atrial arrhythmias by suppressing APC activity or reducing the short-long sequence seen with an APC. Algorithms aim to dynamically overdrive pace the atrium by pacing at a rate just above the intrinsic rate or "smooth" the atrial rate by pacing after APCs, thus preventing short-long cycle lengths. In those patients who have vagally mediated atrial fibrillation the prevention of a sudden reduction in atrial rate can be eliminated by atrial pacing. Typically this may occur after vigorous physical exercise. The early recurrence of atrial fibrillation (ERAF) has also been addressed by some algorithms by high rate atrial pacing immediately after the termination of atrial arrhythmia (generally associated with Vitatron devices). Some devices have the ability to treat atrial arrhythmias using anti-tachycardia pacing in a manner similar to Implantable Cardioverter Defibrillator (ICD) therapy for ventricular tachycardia.

7. Event counters

Counter information provides data regarding the total number or percentage of paced and sensed events in both the atrium and the ventricle since the counters were reset. Counters are usually reset at the completion of the last pacemaker check. It will also indicate the number of atrial and ventricular extrasystoles, atrial/ventricular tachycardia, and will also indicate the number of times certain algorithms are activated—for example, mode switch, rate drop response, etc. With the knowledge of the patient's underlying cardiac status and rhythm this information can be used to program the device optimally. It is important that the amount of pacing that a patient receives from their device is carefully evaluated each time. The general principal should be to encourage as much intrinsic activity as is possible and physiologically appropriate. This has been extensively researched by the DAVID trial⁶. Promotion of intrinsic activity ensures more physiological cardiac performance, has less drain on the battery life, and may make the individual less pace dependant. Ventricular pacing has been proven to

⁵ Mitchell ARJ, Sulke N. How do atrial pacing algorithms prevent atrial arrhythmia? *Europace* 2004;6:351-62

⁶ Wilkoff BL, Cook JR, Epstein AE, et al. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) trial. *JAMA*. 2002;288:3115-3123.

be dys-synchronous; leads to regional myocardial wall abnormalities, and may actually be pro-arrhythmic. This has to be balanced with the patient's degree of electrical conduction abnormality and potential chronotropic insufficiency. Encouraging intrinsic activity is usually possible by altering parameters such as the atrioventricular (AV) delay (when encouraging intrinsic R wave) or lower rate limit (when encouraging intrinsic P wave). A number of algorithms have modifiable AV delays that aim to maximise intrinsic conduction. Modern devices have special pacing features that allow AAI pacing with ventricular safety back up e.g. MVP (MED) and AAI safeR (ELA).

The recorded electrograms allow analysis of potentially non-symptomatic events, although the time of recording is made and subsequently can be correlated with symptom history. Myopotential interference is now less of a problem as many pacemaker systems have bipolar leads (often thought to be more of a hazard with Unipolar leads). However, some patients have unipolar leads that have been in place for many years and are functioning appropriately. Occasionally insulation complications can warrant programming of leads from bipolar to unipolar. This should be deemed a temporary fix only as, if successful, it suggests an outer insulation defect surrounding the cathodal electrode of the bipolar lead. Inappropriate sensing of myopotential activity in these circumstances may lead to inhibition of pacing and potentially syncope if the patient is pacemaker dependant. Having the ability to correlate counters with the electrograms makes the diagnosis of this issue relatively straightforward. Patient triggered diagnostics may be recorded by activating a device held by the patient or in the case of some devices activation using a magnet⁷. Stored electrograms (if available) at the time of symptoms will establish whether the cause is an arrhythmia or device related problem. This allows the device to be used and the clinical data applied in a similar manner to an implanted loop recorder (though not routinely used). Additional asymptomatic stored electrograms may include prognostically significant ventricular arrhythmias or asymptomatic atrial arrhythmias that may indicate the need for formal anticoagulation. A limitation of stored electrograms is the compression of the data in order to record adequate electrogram sequences. This can produce less clear recordings in some cases. If the diagnostics do not contain the relevant information for patients who are symptomatic then alternative tests should be organised, e.g. ambulatory monitoring, head-up tilt table testing, or blood pressure monitoring.

8. Troubleshooting

At routine follow-up it should be possible to identify any problems with the pacemaker system performance. System problems may relate to the hardware in terms of the pulse generator and leads or there may be a software issue in terms of device programming.

An important aspect of pacemaker follow-up is the management and systems employed to react to device alerts or recalls. Pulse generator failures are extremely unusual but do occur. This may present in a number of ways, ranging from complete system failure and inability to communicate with the device to premature battery depletion or malfunction of one or more components of the

⁷ Machado C, Johnson D, Thacker JR, et al. Pacemaker patient-triggered event recording accuracy, utility and cost for the pacemaker follow-up clinic. *Pacing Clin Electrophysiol* 1996;19:1813-8

device. Lead related problems are more commonplace and should be identified at a pacemaker follow-up visit. Lead failure may occur for many reasons such as lead fracture, displacement, exit block, drug treatment, etc. Lead failure may be seen at pacemaker follow-up by a change in sensed electrogram (size or interference), pacing threshold, or impedance. Most of these data are presented at follow-up in trend graphs. If a lead related problem is suspected then radiological imaging will be required. In the first instance this is likely to be a plain chest radiograph, but more careful assessment may be required with high intensity fluoroscopic screening. Chest X-rays for assessment of pacemaker systems should be taken using AP and Lateral projections with over-penetration. If a lead failure is suspected then facilities to admit the patient for further imaging or device revision should be available, although may not be necessary depending on patients pacemaker dependency.

Occasionally patients will report deterioration in their symptoms or onset of new symptoms. It should be possible by appropriate use of the diagnostic information presented by the device to determine whether this is a pacemaker related issue or not. The psychological impact of pacemaker therapy should not be underestimated. The dependence on device therapy can have devastating consequences in some patients. It is important to be able to offer the appropriate support and counselling to patients in these circumstances.

9. Battery status

Interrogation of the pacemaker will give an assessment of the current status of the battery. This information, combined with the patient's history - that is, percent pacing - enables a prediction of the life expectancy of the device to be displayed. Battery measurements are usually assessed several times each day. Battery status allows for planning of the next pacemaker follow-up and ultimately pulse generator replacement. In most situations placing a magnet over the device will default to a fixed pacing mode at a rate determined by the battery status. For example, a fixed pacing rate of 100/min may indicate satisfactory battery measurements with a reduction to 85/min for elective replacement time and < 85/min for end-of-life. These figures will vary from device to device but should be readily available at the time of pacemaker follow-up. A more accurate and ultimately a better predictor of impending / future battery failure is to keep a record of the steady increase in battery impedance or reduction in battery voltage. Impedance is typically 100 ohms at implant with values above 3Kohm at intensified follow-up. There is variation in the actual values for elective replacement depending on the device manufacturer and for this reason caution must be taken to ensure appropriate values are used for each device. Battery voltage is typically 2.8V for Lithium -Iodide batteries at implantation with a gradual reduction to 2.45V – 2.55V at elective replacement (depending on manufacturer).

10. Environmental interaction.

The pacemaker industry has concentrated significant resources into the prevention of environmental interaction with pacemaker systems. However, increasing environmental sources of electromagnetic radiation makes this challenging. Electromagnetic interference has the potential to cause a pacemaker to respond in a number of ways: inappropriate inhibition or triggering of pacemaker output, asynchronous pacing, reprogramming to backup mode, or even irreversible damage to pacemaker components. Patients should be advised as to the potential complications of environmental interactions with their device, and if necessary an assessment of device interaction with their working environment and/or anomalous sources of interference should be sought.

11. Device advisories and recalls

There is a certain inevitability that as pacemaker technology progresses there will be some device failures. When these are identified national regulatory authorities such as the Food and Drug Administration (FDA) in the USA and the Medicines and Healthcare Regulatory Agency (MHRA) in the UK issue advisories. In the last decade advisories in the USA affected 500,000 pacemakers and ICDs. Every centre performing pacemaker follow-up should have in place an established policy on dealing with device related advisories and a mechanism of disseminating information to the appropriate personnel.

Usually the pacemaker manufacturer makes recommendations. This may involve software/programming changes, increased follow-up or in some cases device extraction/replacement. In most situations these decisions will be made on clinical grounds with a shared decision with the patient. The mechanism and pathway to making these decisions need to be defined. It is clear that different centres and physicians manage advisories in different ways. All centres should have in place local procedures to facilitate the timely reporting of adverse incidents involving pacemakers to the appropriate authority. In the UK this is done by means of an online reporting system to the MHRA that results in a rapid turn around and investigation of potential problems.

12. Remote device follow

The facility for transtelephonic monitoring (TTM) of pacemakers has been in place for many years. Its uptake has varied between healthcare systems. As the sophistication of pacemaker devices increases the mode of follow-up will inevitably change. The vast amount of data that can now be retrieved from a pacemaker is likely to continue to increase and so the manner of follow-up has to adapt. Most pacemaker manufacturers now have in place systems that allow remote pacemaker follow-up. The real advantage of this system is the ability for more regular but less intrusive follow-up and the potential to troubleshoot in a more expeditious manner. Programming of devices in a remote fashion carries a number of regulatory issues and concerns with safety and so it is likely that remote pacemaker follow-up will be limited to interrogation only.

13. Future

There have been dramatic changes in pacemaker technology over a relatively small timescale. Pacemaker follow-up has mirrored this in terms of its complexity and level of expertise required to keep up with these technological advances. It is likely that the next phase in the development of technology will be advances in various physiological data obtained from devices. Increasingly ICD technology provides us with biomedical data such as heart rate variability, transthoracic impedance, etc. As sensors are developed to assess cardiac output, contractility and blood pressure it is likely that pacemaker follow-up will involve more clinical interpretation of these types of data rather than the mostly technical data that are presented at the moment. In response to this there is a trend towards increasing the automatic management of such technical aspects of device function. With remote data management strategies we are likely to see a more holistic and comprehensive approach to patient follow-up.