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Perioperative Management of Pacemakers (PM) and Implantable Cardioverter Defibrillators (ICD) in South Africa

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Summary

PMs and ICDs are cardiac implantable electronic devices (CIEDs) that are becoming increasingly sophisticated and the perioperative management of these devices is changing along with this development. Traditionally, PM functions have been changed to asynchronous modes during surgery because of the fear of electromagnetic interference (EMI) from diathermy causing oversensing and subsequent loss of pacing. ICDs have been switched to off mode to prevent inadvertent shocks during EMI. This may lead to patient harm, due to R-on-T phenomenon in PM set in asynchronous mode and undiagnosed perioperative v-tach or v-fib in patients who have ICDs in off mode. PM-on and ICD-on strategies are becoming more acceptable, depending on the site of surgery. Intraoperative magnet use is currently underutilised and may have advantages to changing PM and ICD settings in patients who may otherwise have had the CIED functions switched off. Reversal of functions to preoperative settings may be achieved in the operating theatre without the need of a PM technologist.

Background

Approximately 7500 PMs and ICDs are implanted every year into patients in South Africa. Discovery Medical Aid submissions for PMs and ICDs number 7200 per year, but this figure includes new devices, temporary pacemaker insertion, generator replacement for end of service (EOS) or end of life (EOL) and lead changes or repositioning (see Figure 1).[1,2] With patient longevity rates increasing, it is becoming more likely that anaesthetists will encounter patients with PMs and ICDs, especially in the elderly. The medical technologists who specialise in CIEDs provide an important service in interrogating these devices and anaesthetists need to work closely with them in providing the optimum perioperative care when patients with devices present for surgery. All patients presenting for surgery need a recent interrogation of their device and the information presented to the surgical team. The anaesthetist should make decisions regarding pacemaker management in conjunction with the technologist, cardiologist and surgeon (see Figure 4).

Modern PMs and ICDs

PM technology was developed 60 years ago and recent advances, especially over the last 10 years have taken a relatively crude device that initially provided an asynchronous pacing beat to the right ventricle as a life saving procedure for patients with complete heart block to the sophisticated modern device that paces on demand, reacts to exercise by increasing the heart rate to a pre-set level and in the operating environment can distinguish between a sensed beat and EMI. Many of the guidelines for the management of PMs and ICDs were published at the beginning of the current decade and could do with a complete revision, taking into account the developments of these devices over the last 10 years.

Perioperative considerations

PMs The anaesthetist has to weigh up the pros and cons of either leaving a PM with its usual settings (PM-on) or asking the technologist to change the settings to asynchronous mode (either DOO or VOO). The problem that may be experienced with a PM left in DDD mode is oversensing due to electromagnetic interference (EMI) when the PM senses the EMI as electrical activity of the heart and inhibits the generation of a paced beat. This may result in periods of asystole while diathermy is being used. Modern PMs have algorithms that can distinguish between EMI and normal electrical activity in the heart and may ignore diathermy induced EMI completely or change the PM setting temporarily to DOO. The problem of a PM changed to asynchronous mode is that an R-on-T phenomenon may occur, which may result in ventricular fibrillation if an asynchronous beat is delivered during the refractory period of the cardiac cycle. The benefits of a PM-on protocol are that the chances of an undiagnosed R-on-T phenomenon occurring perioperatively are reduced and in addition, that the PM settings do not have to be reset by a technologist postoperatively. If the anaesthetist is planning to follow a PM-on protocol, the preoperative interrogation should include the PM response to magnet application as well as the ability to apply a magnet intraoperatively to manage oversensing if it occurs due to EMI (see Figure 7).

Many pacemakers are implanted today for disease of the sinu-atrial node (Sick sinus syndrome - SSS) where the patient experiences syncope due to bradycardia associated with SSS. These patients have normal atrioventricular conduction and the PM is set on AAI. Changing the PM to DOO or VOO may result in asynchronous ventricular contraction because the ventricular

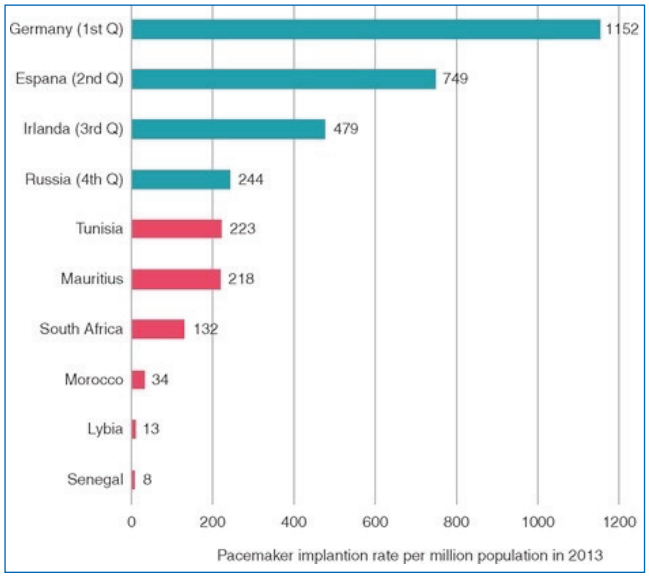

Figure 1: Implantation rate estimated to be 138.25/million in 2016 (total population 54146735, total number 7485) US rates are double Germany

lead is usually placed in the right ventricle. The left ventricular conduction and contraction is delayed and this may result in reduced left ventricular efficiency. These patients would benefit from a PM-on protocol.

ICDs are potentially problematic in that an ICD-on protocol may result in unwanted and repeated shocks due to EMI being misinterpreted by the device as ventricular fibrillation. This can lead to myocardial damage and depletion of battery life. It has been shown that ICDs do not respond to EMI if the operation site is below the iliac crest and that the diathermy dispersive pad is placed at a site to lead current away from the ICD.[3] If an ICD-on protocol is to be used, the anaesthetist should be aware of the response to application of a magnet to the specific device (see Figure 8).

An ICD-off protocol may result in undiagnosed v-tach or v-fib in the perioperative period and case reports have been published where patients have died at home after the device was not checked and turned on postoperatively. International literature is clear that the responsibility for resetting the ICD belongs to the anaesthetist and not to the technologist.[4] An ICD-off protocol may result in unnecessary external cardioversion for v-tach because anti-tachy pacing (ATP) is disabled. ATP reduces the need for shocks in patients who develop v-tach as many tachyarrhythmias can be terminated by the rapid pacing before the device has to deliver a shock (see Figure 3).

The standardised pacemaker codes are depicted in Figure 2.[5] Multisite ventricular pacing refers to cardiac resynchronisation therapy (CRT) for the left and right ventricles. It is utilised in patients with left bundle branch block to resynchronise left and right ventricular contraction to occur simultaneously. This may improve cardiac output by up to 15% in patients with heart failure due to reduced ejection fraction. Multisite atrial pacing is used experimentally to treat atrial fibrillation.[6]

Revised NASPE/BPEG Generic (NBG) Pacemaker Code

I	II	III	IV	V
Chamber(s) Paced	Chamber(s) Sensed	Response to Sensing	Rate Modulation	Multisite Pacing
O = None	O = None	O = None	O = None	O = None
A = Atruim	A = Atrium	T = Triggered	R = Rate Modulation	A = Atrium
V = Ventricle	V = Ventricle	I = Inhibited		V = Ventricle
D = Dual (A + V)	D = Dual (A + V)	D = Dual (T + I)		D = Dual (A + V)

Pacing Clin Electrophysiol. 2002 Feb;25(2):260-4

Figure 2: Pacemaker Codes

Implantable Cardioverter Defibrillator (ICD) and Anti-Tachycardia Pacing (ATP)

Patients with recurrent ventricular tachycardia and/or ventricular fibrillation or those at risk for developing these arrhythmias may have an implantable cardioverter defibrillator (ICD) placed in the left subclavian region. The ICD senses the R-R interval and if the interval reduces to a predetermined level, the device algorithm reads this as ventricular tachycardia and can deliver a repetitive sequence of eight rapid paced beats to try to break the re-entry condition of v-tach. If this fails to cardiovert the v-tach, a high voltage shock is delivered (see Figure 3). The shock is delivered from the coils to the generator in a triangulated vector to incorporate the left ventricle. (The high voltage coils around the pacemaker leads act as the cathode and the pulse generator acts as the anode). ICDs recognise supraventricular tachycardias (SVTs, AF and sinus tachycardia) via atrial sensing, but cannot cardiovert them. This is designed to prevent unnecessary shocks. ICDs may deliver anti-bradycardia therapy if required to do so.[7] A magnet applied to an ICD will generally disable the anti-tachycardia therapy while it is in situ, but will have no effect on anti-bradycardia therapy or rate responsiveness.

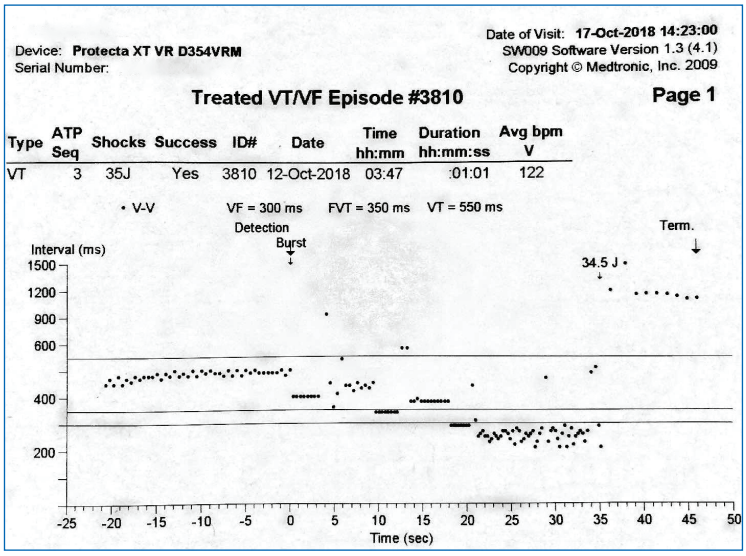

Figure 3: De-Identified printout from a patient's ICD showing an episode of V-Tach with attempted anti-tachy pacing (ATP) followed by successful 34.5 J defibrillation. Image supplied by Medtronic SA.

Preoperative Pacemaker Interrogation is Considered Standard of Care: Individual Prescription ℞

Is Tech available:
1. Type PM/ICD/CRT-P or D
2. Manufacturer and Model
3. Indication and date of insertion
4. Pacemaker Dependency
5. Battery Life (BOL/EOL/RRT) – replace prior to surgery
6. Pacemaker Settings and thresholds checked if new leads
7. Recent Activity
8. Effects of magnet application (and removal)
9. Reset rate if scope of operation requires
10. Device or Lead Alert/Recall status

Is Tech unavailable in an emergency:
1. CXR
2. ECG for dependency
3. Patient Card
4. Cardiologist
5. Manufacturer 24 hour helpline
6. Last Interrogation PM <12 months, ICD < 6 months, CRT-D or P <3 months
7. Magnet application preoperatively to assess PM rate changes or ICD Tones
8. Blind magnet application not recommended unless emergency

Figure 4. Preoperative Pacemaker and ICD Interrogation

Preoperative pacemaker interrogation is considered to be the standard of care and should be scheduled during the week prior to surgery. The PM technologist should provide the information as shown in Figure 4 and in consultation with the technologist and cardiologist and taking into account the planned surgery, the anaesthetist should decide on the perioperative PM management (see Figure 7).

If a PM-on strategy is to be followed, it is vitally important that the effects of magnet application and removal to the specific PM are known. It may be advantageous to reset the base rate of the pacemaker, even though a PM-on protocol is followed. For example, a base rate of 60 may be increased to 70 or 80 if haemodynamic challenges are expected, such as blood loss or neuraxial anaesthesia.

If the PM settings are to be changed, this should be done on the day of surgery and preferably reversed to the preoperative settings as soon as possible after the ESU is no longer required.

If an ICD-on strategy is to be followed, it is important to note that placing a magnet over the ICD will not change the underlying PM function and this has to be changed independently of the anti-tachyarrhythmia function. This should be considered in PM dependent patients if the surgery is close to the ICD and/or leads.

	CIED	Response to Magnet Application
PM	Pacemaker	85 beats per minute (65 BPM if RRT) DOO, VOO or AOO and disables rate responsiveness
ICD	Implantable Cardioverter-Defibrillator	Suspends Anti- Tachyarrythmia Therapy and Anti-Tachycardia Pacing (ATP) and has no effect on PM functions. 10s even tone in Med
CRT	Cardiac Resynchronisation Therapy	85 beats per minute (65 BPM if RRT) DOO
CRT-D	Cardiac Resynchronisation Therapy with Cardioverter-Defibrillator	Suspends Anti- Tachyarrythmia Therapy and Anti-Tachycardia Pacing (ATP) and has no effect on PM functions
Leadless PM	VVI implanted directly into RV	Depends on Manufacturer: Medtronic – no effect St Jude - VOO

Figure 5: Response to magnet application in Medtronic PM and ICDs

CRT devices need to be checked within 3 months because the coronary sinus leads have poorer contact compared to the right ventricular leads and higher thresholds are accepted. This may result in faster battery drain and thus reduce longevity.

Response to magnet application

The response to magnet application in Medtronic PM and ICDs is shown in Figure 5. It is important to note that there is no uniformity across the industry, and each manufacturer has a different set of responses to magnet application. This makes it imperative that the anaesthetist is aware of the specific response of the patient's device before applying a magnet. An indication of the enormity of this issue, is that in the USA, there are 1440 different types of device models across the different manufacturers.[7,8] Modern PM and ICDs respond in a determined manner to magnet application, and many of the problems associated with application have been dealt with. Examples include resetting device programming under the influence of a magnet and concurrent EMI, and switching off anti-tachy functions in ICDs which do not return once the magnet is removed. These problems do not occur in modern devices.

During surgery, magnet application needs to be carefully monitored. This is easily done in the patient with a PM, because magnet application will result in a fixed rate change, which is specific to the manufacturer. For example, Medtronic pacemakers change from the patient's usual settings to a rate of 85 beats per minute while the magnet is applied. This rate is 65 if the battery life is shortened (EOL) and the generator needs to be replaced (RRT). Therefore, as long as the heart rate is 85 bpm, the anaesthetist can be reassured that the magnet is correctly applied.

It is less clear in the case of ICDs. The Medtronic ICDs emit a tone for 10 seconds when the magnet is applied, but after this initial signal, there is no indicator to the anaesthetist whether or not the magnet is still in place and exerting its effect on the ICD. The magnet has no effect on the PM function of the ICD, so heart rate changes cannot be used as an indicator. It would make sense for the manufacturers to provide the anaesthetist with an ongoing signal to determine correct placement of a magnet over an ICD. Modern devices have Bluetooth functionality and an elegant

Operating Theatre Requirements

Monitoring and Emergency Measures:
1. ECG with filters on pacemaker detection
2. Pulse Oximeter trace
3. Arterial Line trace
4. Capnography
5. Acid Base status and electrolytes
6. CVC Guide Wire Insertion (Coronary sinus lead in CRT PM)
7. Temporary Pacemaker
8. Defibrillator Pads (paddles)
9. Magnet available

Defibrillator/ Pacing Pads should be placed front to back for maximum efficiency. In open heart surgery, pads will have to be placed side to side.

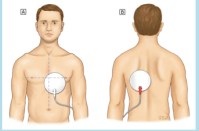

Figure 6: Operating Theatre Requirements

way of dealing with this problem would be to have a smartphone application that can read the wireless signals from the device.

PM-on or CRT-P-on protocol suggests that the PM settings are not changed during the standard preoperative technologist interrogation of the device. PM-on protocol will avoid inadvertent development of R-on-T phenomenon and implies that magnet application is possible if the situation of oversensing caused by EMI develops. In addition to this, the anaesthetist is able to remove the magnet when EMI is no longer being used. It takes away the need for postoperative high dependency unit care and a repeat call out by the technologist to reset the PM. The successful PM-on protocol requires the anaesthetist to follow the algorithm in Figure 7. A magnet can disable the rate responsiveness function in a PM and this is useful to prevent unwanted increases in heart rate, for example when the sternal saw is used in open-heart procedures, as the vibration of the saw may be misinterpreted as patient movement (see Figure 7).

ICD or CRT-D-on protocol suggests that the anti-tachycardia therapy of the ICD is not switched off perioperatively and that the device is allowed to sense tachyarrhythmias and deliver anti-tachycardia pacing (ATP) and shock if necessary. This provides protection to the patient in the event of V-Tach and/or V-fib, which may occur at anytime perioperatively. In order to prevent unnecessary ATP or shocks due to EMI being incorrectly read by the generator, a magnet should be available to place over the ICD to change the setting to ATP and Shock off. It is important to note that the anaesthetist should know exactly what happens to the specific ICD under the influence of magnet application and removal, that the patient position is such that the magnet can be properly secured during surgery and that the tone emitted by the generator is recognised. There are certain operating sites where it is safe to leave the ICD on and generally these are more that 15 cm (6 inches) from the generator and leads and below the umbilicus or ileac crest, as long as the ESU dispersal pad is sited away from the surgical site so that EMI is not directed towards the ICD.[3] For example, hip surgery is safe to proceed without switching off the anti-tachy therapy, as long as the dispersal pad is placed on the ipsilateral thigh.

The anaesthetist should consider switching off the anti-tachy therapy of the ICD if:

1. The operation site is within 15 cm of the generator or leads, especially if long bursts of unipolar diathermy are to be used. The argon beam ESU cannot be used in short bursts and may cause long periods of EMI.
2. A magnet cannot be reliably secured over the generator, such as in the prone position.
3. Certain operations such as hand surgery and ophthalmic operations where inadvertent shocks may lead to patient or operator harm. This would include operations at these sites performed under local anaesthesia. Thoracic operations would require the ICD-off because left chest procedures would render the anti-tachy functions ineffective because of poor tissue shock transfer due to high impedance when the chest is open. Also, in right chest procedures, it would be difficult to ensure proper application and security of the magnet if it was required.[9]

If the patient is pacemaker dependent, the anaesthetist may consider asking the PM tech to change the PM settings to DOO as in the PM-on protocol. It is also advisable to turn off rate responsiveness, as this function is not changed by magnet application in ICDs.

It is important to note that if the anti-tachy function has been turned off (ICD-off), the settings must be restored as soon as possible after the procedure and the patient has to be observed in a high dependency unit until this has been achieved.

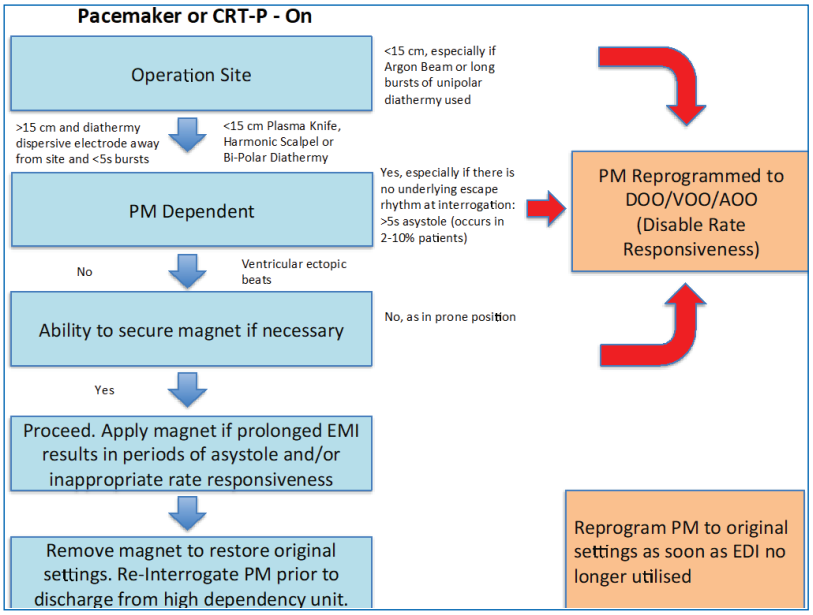

Figure 7: PM-on algorithm

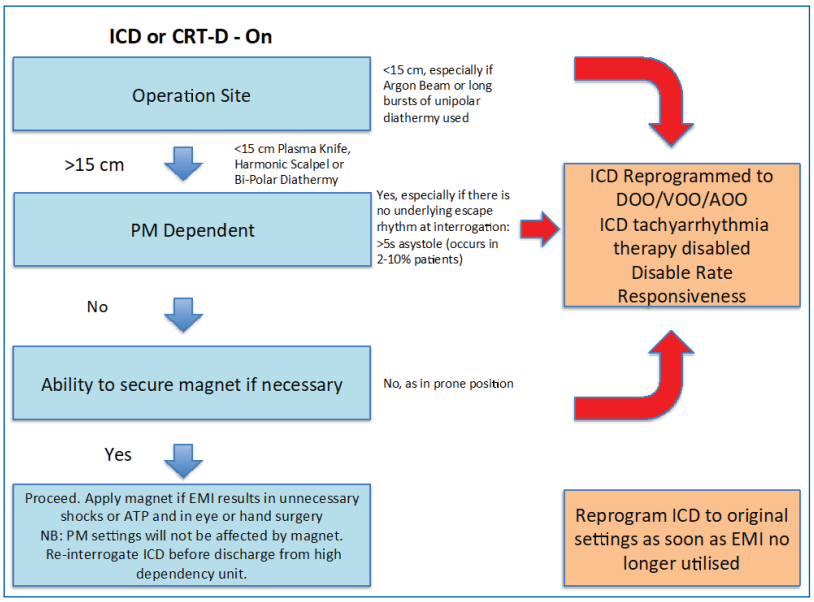

Figure 8: ICD-on algorithm

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Glossary of terms, abbreviations and acronyms

ATP – Anti Tachycardia Pacing

BOL –Beginning of Life

CIED – Cardiac Implantable Electronic Device

CRMD – Cardiac Rhythm Management Device

CRT – Cardiac Resynchronisation Therapy

EOL – End of Life

EOS – End of Service (same as RRT)

ESU – Electrosurgical Unit

ICD – Implantable Cardioverter Defibrillator

IPD – Implantable Pulse Generator

PM – Pacemaker

RRT – Recommended Replacement Time