Review article:

Non-Cardiac implanted electronic device (IED) : Its implications and interactions

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ABSTRACT

Advanced technology and varied indications have increased the number of patients with non-cardiac implanted electronic device in situ. There is limited knowledge about the effect of these devices when these patients use another electronic device .These electronic devices often interact with other electronic devices, machinery causing alarm and discomfort to the patient . Patients with implanted electrical devices (IEDs) are vulnerable to electromagnetic interference (EMI) from electrical equipment used in the patients. As growing popularity for non-cardiac IEDs increase, so too does the likelihood of encountering these interactions. This article aims to seek existing literature on the subject mainly the implication and interactions of an IED in situ.

KEY WORDS : Non-cardiac IED

INTRODUCTION

IEDs are widely used for number of div-erse medical indications.There is general ignorance, and paucity of literature about the implications and interactions of non-cardiac implanted electronic devices with other lectronic equipment. Implantable electronic devices (IEDs) are susceptible to a wide range of external interference

METHODOLOGY

A comprehensive search of the literature was performed for articles in English targeted toward major subtopics associated with Non cardiac implanted electronic devices. The literature search for this review was conducted in Jan 2013 using MEDLINE (1990 to Dec 2012) and PUBMED (1990 to Dec 2012). The bibliography of each article was then reviewed to seek additional information. The review does not address perioperative care of patients undergoing implantation of such electrical devices

BRIEF OVERIEW OF THE NON-CARDIAC IEDs

There are a number of non-cardiac implanted electronic device available for varied indications,[1] these include1) Spinal cord stimulators (SCS) which have been around for more than a decade these are indicated for conditions like FBSS (failed back surgery syndrome), refractory angina pectoris, CRPS (complex regional pain syndrome),[2,3] neuropathic pain due to damage to a peripheral nerve and for the relief of vascular ischaemic pain. 2) Deep brain stimulators which are used to treat tremors and Parkinson's disease [4,5].3) Sacral nerve stimulator for conditions like neurogenic bladder [6,7,8].4)

Others like vagal nerve stimulators, phrenic nerve stimulators, diaphragmatic stimulator

[9,10] 5)Bone stimulator for bone healing[11,12] 6)Laryngeal stimulator to prevent aspiration [13].7)Gastric pacemaker [14,15] In general, IEDs are comprised of three components. The first component is the pulse generator, which is battery powered and can be externally programed. Second component is the electrodes designed for implantation in the target tissue. The electrodes are of different sizes, lengths, and design, as required for insertion. The third component is the cable connecting the pulse generator to the electrodes. Individual devices vary with respect to location of the pulse generators and their programability.[1]

The different components of an IED in particular the spinal cord stimulator are implanted electrodes in the epidural space, connecting leads joining up to an implanted pulse generator (IPG) which is battery-powered similar to a cardiac pacemaker. The electrodes can be bipolar or multipolar and multiple electrodes can be used. The technique of electrode insertion can be either percutaneously or surgically by a laminectomy procedure. The electrodes are sited depending on the particular area that needs to be stimulated. The sacral nerve stimulators are sited close to the sacral nerve as they emerge from the sacral foramina. The patient has the flexibility to switch the device on and off with a hand held programmer and may vary voltage and frequency within physician determined limits.[1]

DAILY LIFE EQUIPMENTS

A chronic pain patient with an IED in situ may have an interaction between the special bed mechanics and the SCS in situ due to the ignorance surrounding IED and electro-magnetic interference (EMI) in day-to-day life applications. Most sources of electromagnetic interference are non biologic and few are capable of causing clinically significant interference, however in the rapidly evolving technology driven environment several devices could cause interference with implanted device both within and outside the hospital environment. The biologic source of interference could be extremes of temperature and irradiation that can cause the pulse generator to malfunction. Contemporary pulse generators are protected from most sources of interference because the circuitry is shielded inside a stainless steel or titanium case and the body tissues provide some protection by reflection and absorption of external radiation. [16]

The patients should be counselled that when their SCS is switched on, they should not drive, climb, or operate dangerous machinery or equipment, and they must take care with their choice of activity, in case an unexpected surge from the IED causes distraction or a motor activity.[17] Patients have reported that even a walk past the Tesco security gates have given them a sudden zap . There have been reports of individuals with implanted electronic devices being shocked while passing through retail antitheft systems and airport security systems. However the MHRA advice is that they are not aware of any evidence of interference problems between airport security body scanners and implanted electronic medical devices. The patients should always carry relevant information about their IED to present to officials.[17]

MEDICAL HEALTHCARE EQUIPMENTS

Electronic devices implanted in a patient may be affected by other IEDs or medical

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equipment that a patient may come in contact with within a health care facility. They have the potential to adversely affect an IED. These devices may include cardiac pacemakers, which are a relative contraindication to IED implantation and vice versa. The cardiac pacemakers usually operate in the demand mode. They monitor intrinsic cardiac activity and may be inhibited by spontaneous extra cardiac electrical activity.

The extraneous electrical activity from IED may be sensed and interpreted as appropriate cardiac activity. The pacemaker may then either respond by inhibition of pacing or by reverting to asynchronous pacing mode. Inhibition of pacing can be potentially dangerous for the patient whilst the asynchronous pacing is less dangerous but still compromises the pacemaker function. [17]

CT SCAN

There are not many reports of interaction of x-rays produced by CT scanners and IED. However Pennsylvania Patient Safety Authority received a report of a patient experiencing unanticipated electrical stimulation and shock from an implanted electronic neurostimulator during a computed tomography (CT) scan with a 64-slice CT scanner. The device manufacturer confirmed that this has happened before with 64-slice scanner and recommended that IED should be turned off . Some IED may measure the change in voltage induced by ionizing radiation. That change in voltage level may be significant enough to interfere with the normal operation of implanted devices. A malfunction of the IED during a CT scan leading to a shock to the patient could result in the patient experiencing pain or cause the patient to move, thereby compromising the quality of the image. The amount of interference depends on a number of factors, including the amount of tissue between the implanted electronic device and the CT scanner and the x-ray dose rate. [18] Effect of CT is more during dynamic scanning as a portion of the patient remains stationary within the plane of the x-ray beam.[18]The cause of CT scanner interference on electronic devices is due to newer scanners designed for faster scans. Faster scan time is achieved by increase in the x-ray dose rate. The higher dose rate increases the likelihood of interference. The effect of CT scans on implantable electronic devices is transient because the interference occurs only during the time of x-ray exposure. The implantable device would resume normal operation, but sometimes, the device might need to be reprogrammed. Irre-versible damage will occur if the x-ray dose is very high. High dosage is usually only used during radiotherapy, not diagnostic procedures.[18] The effect of a CT scan on patients with IEDs would also depend on the type of implantable device. A scout view will identify any IED before the actual scan. The CT scout view uses a much lower x-ray dose rate and which would not interfere with the implanted device.[19] Non-life-supporting implanted devices should be turned off during the scan . CT technician should be informed so that patient's safety is not compromised.

MRI SCAN

The interaction of MRI and IED is complex. Magnetic field interaction with IED induces electric current which may cause functional disruption of the device. The magnetic field may produce lead movement with loss of effect or neural damage, heating of the components resulting in discomfort and tissue damage, or software malfunction.[20] In

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addition, the location of the leads in relation to the site of interest may cause image corruption. Though there have been a small series of cases of MRI with IED without any problems,[21] There have been case reports of successful MRI with a VNS, sacral nerve stimulator and bladder pace maker though some precautions were taken.[22,23]

On the other hand there are two case reports of serious injury after MRI with DBS but the scanning was done outside device manufacturers guidelines. [24,25] Other imaging modalities should be used if possible. The advice of a radiologist should be sought, the majority would not advise a MRI with an IED in situ. Sometimes if a MRI is needed it may be necessary to remove the IED prior to the investigation.

DIATHERMY& ELECTROCAUTERY

Treatment modalities like short wave diathermy, microwave diathermy, and therapeutic ultrasound diathermy are hazardous to a patient with an IED and can cause nerve or tissue damage, which is permanent even if the device is switched off.[1] Manufacturers technical manual contradict the use of diathermy in patients with IED but it does not include surgical electro cautery. Safety recommendations for electro cautery use are same as in cardiac IED.

The electro cautery used in routine surgical practise continues to be one of the most common potential of EMI for patients with implanted device. It is usually in a unipolar configuration between the cauterising instrument (cathode) and the indifferent plate (the anode). Bipolar cautery uses a bipolar instrument for coagulation. The frequency is usually between 300 and 500 kHz (at frequencies of less than 200 kHz muscle and nerve stimulation may occur. It is a very similar situation with radiofrequency denervation procedure where radiofrequency lesioning involves the passage of very high frequency current (about 300 kHz) down a 27G thermocouple probe. Electrocautery can damage the leads and cause temporary suppression of neurostimulator output and may even cause reprogramming of the device , hence bipolar electrocautery should be used. If a unipolar electrocautery is required, the ground plate should be kept at a distance from the IED and the leads. [1, 26 ,27]

IED & PERIPHERAL NERVE STIMULATORS

Peripheral nerve stimulators which are used for nerve localisation during peripheral nerve taken.[28] The electrical current should be applied in such a fashion that it would not cross the pulse generator and lead system. High pulse duration and high frequency setting should be avoided. The use of ultrasound guidance for localising peripheral nerve is highly recommended. [1]

SURGERICAL PROCEDURES

A thorough preassessment is essential before planning any procedure. Details and documentation of any IED in situ should be noted and the details of product information card confirmed. The original pain team who implanted the IED should be informed that their patient is scheduled for surgery and their advice sought regarding switching off and resuming IED post procedure. The concerned surgeon and the anaesthetist need to be informed regarding the IED in situ.[1]

Guidelines for surgery in a patient with IED in situ should be informed to all perioperative team members before the patient is taken up for any procedure. The theatre temperature

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should be maintained between 20^0C and 24^0C and the humidity maintained at 50% to 60%. This is important as it reduces the possibility of build-up of static electricity in the environment .[29]

DEFIBRILLATION

The anterior posterior type paddles are recommended for defibrillation in patients with IED in chest area. The position of paddles should be perpendicular to the IED and the anterior paddle should be placed as far away from the pulse generator as possible. The lowest defibrillator current setting possible should be used and finally we need to confirm that the IED is functioning properly after defibrillation.[30]

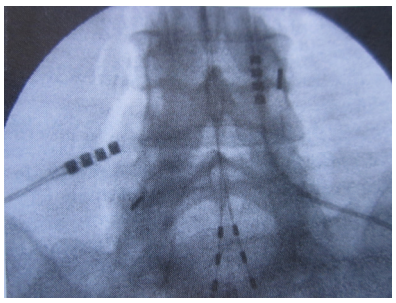
SPINAL ANAESTHESIA

Spinal anaesthesia to patients with an IED or sacral nerve stimulator may be given. But before attempting spinal anaesthesia, the clinician should obtain an Xray, as the stimulator entry site and the course of the connecting cable may be in the spinal needle insertion region. An epidural catheter, can potentially reach a higher level above the needle insertion site.[1] Therefore great care should be taken if a neuraxial block is considered, as there is a risk of damaging the leads or causing infection, necessitating removal of the device. [31]

CONCLUSION

Patients with complex chronic pain and other clinical conditions need IED. Number of patients with IEDs is increasing with increased indication, technical expertise and established patient treatment protocol .The implanted electronic devices are invaluable to patients. The possibility of such patients presenting for other surgical or pain procedure or using any electronic device will become common place. A well-defined management plan with guidelines needs to be defined as many of these patients will require use of other electronic device, surgery or MRI. Both doctors and patients need to be educated about basic principles pertaining to IEDs to ensure patient safety and reduce any mishaps. We all need to understand the associated interactions and methods to tackle them appropriately.

Fig 1: X-Ray showing implanted electrodes



References

1. L. Venkatraghavan et al. Non –cardiac implantable electrical devices: brief review and implications for anaesthesiologists. Can J Anesth 2009; 56:320-326

2. Peng PW, Fedoroff I, Jacques L, Kumar K. Survey of practice of spinal cord stimulator and intathecal analgesic delivery the management of pain in Canada. Pain Res Manag 2007; 12:281–5.

3. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. J Neurosurg2004; 100: 254–67.

4. Pereira EA, Green AL, Nandi D, Aziz TZ. Deep brain stimulation :indications andevidence. Expert Rev Med Devices 2007; 4: 591–603.

5. Gross RE. Deep brain stimulation in the treatment of neurologicaland psychiatric disease. Expert Rev Neurother 2004; 4: 465–78.

6. Jezernik S, Craggs M, Grill WM, Creasey G, Rijkhoff NJ. Electrical stimulation for the treatment of bladder dysfunction: current status and future possibilities .Neurol Res 2002 ;24:413–30.

7. Peeren F, Hoebeke P, Everaert K. Sacral nerve stimulation: interstim therapy. Expert Rev Med Devices 2005; 2: 253–8.

8. Levin G, Ortiz AO, Katz DS. Non cardiac implantable pacemakers and stimulators: current role Roentgenol 2007; 188: 984–91.and radiographic appearance. Am J

9. McLachlan RS. Vagus nerve stimulation for intractable epilepsy: a review. Clin Neurophysiol 1997; 14: 358–68.

10. Henry TR. Therapeutic mechanisms of vagus nerve stimulation .Neurology 2002; 59: S3-14.

11. Anglen J. The clinical use of bone stimulators. J South Orthop Assoc 2003; 12: 46–54.

12. Paterson DC, Lew Relat Res 1980; 148: 117–28.is GN, Cass CA. Treatment of delayed union and non-union with an implanted direct current stimulator. ClinOrthop

13. Broniatowski M, Grundfest-Broniatowski S, Tyler DJ, et al. Dynamic laryngo tracheal closure for aspiration: a preliminary report. Laryngoscope 2001; 111: 2032–40.

14. Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of gastroparesis with electrical stimulation. Dig Dis Sci 2003; 48: 837–48.

15. Li FY, Jiang LS, Cheng JQ, Mao H, Li N, Cheng NS. Clinical9
application prospects of gastric pacing f epatol 2007; 22: 2055–.or treating postoperative
gastric motility disorders. J GastroenterolH

16. Electromagnetic inteference with implantable electronic devices. David L.Hayes.Mayo clinic Mayo Medical school, Rochester

17. Spinal cord stimulation for the management of pain: recommendations for the best clinical practise. British Pain Society; 2008

18. McCollough CH, Zhang J, Primak AN, et al. Effects of CT irradiation on implantable cardiac rhythm management devices. *Radiology* 2007 Jun; 243(3):766-74.

19. ECRI Institute. CT scans can affect the operation of implanted electronic devices. *Health Devices* 2007 Apr; 36(4):136-8

20. Is magnetic resonance imaging safe for patients with neuro stimulation systems used for deep brain stimulation? Neurosurgery 2005; 57:1056-627.

21. Andres JD, Valia JC, Cerda-Olmedo et al.Magnetic Resonance Imaging in patients with Spinal Neuro stimulation systems. Anaesthesiology 2007; 106:779-86

22. Benbadis SR, Nyhenhuis J, Tatum WO IV, Murtagh FR, Gieron M, Vale FL. MRI of the brain is safe in patients implanted with the vagus nerve stimulator. Seizure 2001; 10: 512–5.

23. Elkelini MS, Hassouna MM. Safety of MRI at 1.5 Tesla in patients with implanted sacral nerve neurostimulator. Eur Urol 2006; 50: 311–6.

24. Henderson JM, Tkach J, Phillips M, Baker K, Shellock FG, Rezai AR. Permanent neurological deficit related to magnetic resonance imaging in a patient with implanted deep brain stimulation electrodes for Parkinson's disease: case report. Neurosurgery
2005; 57: E1063.

25. Spiegel J, Fuss G, Backens M, et al. Transient dystonia following magnetic resonance imaging in a patient with deep brain stimulation electrodes for the treatment of Parkinson disease. Case report. J Neurosurg 2003; 99: 772–4.

26. Nutt JG, Anderson VC, Peacock JH, Hammerstad JP, Burchiel KJ. DBS and diathermy interaction induces severe CNS damage.Neurology 2001; 56: 1384–6.

27. Dommerholt J, Issa T. DBS and diathermy interaction induces severe CNS damage. Neurology 2001; 57: 2324–5.

28. McKay RE, Rozner MA. Preventing pacemaker problems with nerve stimulators. Anaesthesia 2008; 63: 554–6.

29. Association of peri Operative Registered Nurses. AORN guidance statement: care of the perioperative patient with an implantable electronic device. AORN J 2005; 82: 74–82.

30. Allen M. Pacemakers and implantable cardioverter defibrillators.Anaesthesia 2006; 61: 883–90

31. J H Raphael et al. Spinal cord stimulation and its anaesthetic implications. Continuing education in Anaesthesia, Critical care & Pain.Volume9, Number 3; 2009:78-81

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