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12 Nov 2018

Non Cardiac Implantable Devices (NCID) and its perioperative management

Key Points

- Non-cardiac implanted devices are on the rise with new indications, so as an anaesthetists/intensivists probability of encountering such patients increases.
- Implanted electrical devices are prone not only to electromagnetic interference (EMI) but also to other factors during surgery causing device malfunction or patient harm.
- We need to adopt safe perioperative strategies to reduce the risk of adverse events.
- Knowledge of device and its effect on physiology of patient is of utmost importance.

MCQ

1. Indications for spinal cord stimulation include:
    a. CRPS
    b. Failed back surgery syndrome
    c. Post-operative pain
    d. Post-amputation pain

2. True statements about the implants are:
    a. Diathermy can cause thermal injury to brain or spine
    b. Electrical interference can cause reprogramming of major consequence
    c. Management of device should be discussed during WHO team brief
    d. ICU or HDU admission recommended post-operatively for neurological observation

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3. Regarding vagal nerve stimulator (VNS), true statements are:
    a. Recommended by NICE for depression
    b. Electrode are implanted on both vagus nerves
    c. Vagal nerve stimulation may worsen obstructive sleep apnoea
    d. Patient with VNS has increased risk of aspiration

4. The following procedures can be performed safely in patients with deep brain stimulator in situ:
    a. MRI scanning
    b. Angiography
    c. Defibrillation
    d. CT scanning

5. MRI scanning can be performed in patients with:
    a. Cochlear implant
    b. Prosthetic heart valve
    c. Total hip replacement
    d. Retinal implant

Answers: 1. TTFT 2. TTTF 3. TFTT 4. FTTT 5. TTTT

Introduction

In recent years there has been explosion in the use of noncardiac implantable electronic medical devices with various indications pouring in from new research. As an anaesthetist, we are very likely to encounter patients with these devices not only coming through our theatre doors but also in other areas like radiology, endoscopy suite, intensive care. In the absence of anaesthetic guidelines for non-cardiac electronic medical devices, anaesthetists

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should ensure risk reduction strategies to enhance patient safety. This article will describe the various non-cardiac devices available and its vulnerability to various environments.

As a general rule, implantable medical devices consist of three components:

- Pulse generator
- Electrodes
- Cable connecting electrodes with generator

Individual devices vary in location as per the requirement and its use for the specific purpose.

Deep Brain Stimulator

Deep brain stimulation is minimally invasive neurosurgical intervention initially successfully used in Parkinson's disease and then continue to expand to cover wider range of disorders[1]. Common brain targets for deep brain stimulator include subthalamic nucleus, nucleus accumbens, thalamus and globus pallidus internus. The exact mechanism of action of this neurostimulation remains unclear[2]. The leads for DBS are implanted in the targeted area with the use of stereotactic frame with CT/MRI guidance. The lead passes through a burr hole in the skull and electrodes are tunnelled subcutaneously from head and neck attaching to pulse generator in chest wall.

Implantation of lead usually well tolerated with regional nerve blockade and/or local anaesthetic infiltration except for uncooperative patients or those with severe movement disorder. Dexmedetomidine can be considered for conscious sedation. Benzodiazepines are not recommended because of interference with electrode placement. DBS interaction with various other devices and diagnostic tests has been discussed in later section.

Vagal nerve stimulator

Vagal nerve stimulator (VNS) finds its use in the management of medically refractory epilepsy and can be used for treatment resistant depression[3]. Vagal stimulating electrode in implanted on left vagus nerve within the carotid sheath and pulse generator placed just below left clavicle, under general anaesthesia. The left is preferred over the right vagus nerve for VNS placement because of the greater number of cardiac efferent fibres from the right vagus nerve, whose stimulation may result in more frequent adverse cardiac

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complications. The postulated mechanism of action includes increased vagal nerve afferent signalling that modulate cerebral neuronal excitability through either the limbic system, noradrenergic neurotransmitter or generalised brainstem arousal systems[4]. It's worth noting few side effects of chronic vagal nerve stimulation which includes worsening of OSA (obstructive sleep apnoea), laryngo-pharyngeal dysfunction and change in heart rate variability. The VNS can be modified using special magnet whose information can be obtained from manufacturer/ device implanting team.

Hypoglossal nerve stimulator

Hypoglossal nerve stimulator has been recommended for moderate to severe OSA who cannot tolerate CPAP machines and has been endorsed by NICE[5]. Stimulation of hypoglossal nerve by the device during inspiration mitigate airflow obstruction by reducing pharyngeal collapsibility during sleep. Device containing neurostimulator is implanted subcutaneously in the chest with stimulator lead attached to hypoglossal nerve at the base of tongue and sensor lead for ventilation in chest wall that detects breathing.

Phrenic nerve stimulator

Phrenic nerve stimulation is used to reanimate the diaphragm of patients with absent central respiratory derive which include central hypoventilation syndrome and spinal cord injury above C4. Leads are placed around the phrenic nerve bilaterally and these leads are attached to radio receiver in subcutaneous pocket. The rate and amplitude of the current is controlled by external battery-operated radio transmitter. Phrenic nerve stimulator may interfere with the ventilator in anaesthetised patient.

Sacral nerve stimulator

Sacral nerve stimulator usually considered for urinary incontinence, urinary retention and bladder pain syndrome in which conventional treatment methods have failed but in recent years indications has been expanded to include pelvic floor dysfunction[6]. It consists of lead inserted into sacral foramen at S3 and generator implanted subcutaneously in the hip area.

Spinal cord stimulator and dorsal root ganglion stimulator

First described in 1967 for chronic pain syndromes and extensively used now for failed back surgery syndrome, CRPS, refractory angina, cancer pain, neuropathic pain and its use

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continue to grow with new advancements[7]. Mechanism of action is multifactorial which includes inhibition of wide dynamic range neurons (WDR), activation of GABAergic inhibitory interneurons in dorsal horns and activation of supraspinal mechanisms. It consists of percutaneous lead inserted into the epidural space and then connected to implantable pulse generators (IPG) which can be uploaded with various programs and patient can choose to switch between programs.

Dorsal root ganglion stimulator is a variance of SCS which targets the dorsal root ganglion which operates at the interface of the peripheral and central nervous systems and has an advantage of focused stimulation over an SCS. It is used to treat chronic pain particularly in areas that are difficult to treat with SCS such as hand, foot, knee or groin[8].

Peripheral nerve stimulator

Peripheral nerve stimulation is a technique in which peripheral nerve are stimulated to control pain. PNS has been used for CRPS, pain due to peripheral nerve injuries and migraine headaches. It involves surgery that places a small electrical device along the peripheral nerves connected to implantable generator once trail period is successful.

Cochlear implant

Cochlear implant is used for treatment in patients with severe sensorineural hearing loss. It consists of microphone behind the ear connected to device on the skin which communicates with device placed inside the skull that eventually stimulates the auditory nerve. Inside each cochlear implant is a magnet which could interfere with brain MRI. To ensure MRI compatibility for cochlear implant recipients, these contains removable magnet and some newer versions of cochlear implants have no-magnet options. Most CIs are approved for routine(1.5T) MRI but it is recommended to consult the exact manufacture for the device information.

Retinal nerve stimulator

Retinal implant (Argus II) approved in USA in 2013 and is mainly indicated for patients with severe retinitis pigmentosa. It has been implanted in patients from severe age-related macular degeneration recently. Argus II retinal implant patients can undergo MRI at 1.5 or 3T according to manufacturer instructions.

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Gastric pacemaker

Gastric electrical stimulator is indicated for gastroparesis refractory to medical therapy and approved by NICE. The leads are laparoscopically implanted under GA into the muscle wall of the stomach and then connected to pacemaker subcutaneously in the upper abdomen.

Implanted pumps

Implanted infusion pumps may be used to treat chronic pain, muscle spasticity and other diseases including diabetes. The system consists of a pump implanted subcutaneously in the lower abdominal wall connected to catheter in the desired space for medication. The pump can be programmed via telemetry to control infusion modes. It is recommended to consult the manufacturer regarding the MRI safety as few pumps are MRI conditional.

Peri-operative considerations of patient with non-cardiac implantable devices (NCID)

As the rate of technological advances improves rapidly in this field, in an ever-changing patient population, there are not any specific advice or guidelines which helps clinicians in managing patient with these devices.

The management of these patients should include:

- Assessment of the patient, hence the disease process for which the patient has the implant in-situ.
- The management of the device itself.
- Environmental influence on the device in the peri-operative setting.

Assessment of the patient

- Patient should be seen in a high risk pre-operative clinic if having elective surgery.
- Thorough history and examination of the patient would reveal the site of device, reasons for insertion of the device, the actual disease process for which the device is inserted.
- Current medications

Management of the device

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Pre-operative

The preoperative visit/clinic review should obtain the following information:

- Device type and location
- Device manufacturer
- last checked and functionality
- Effectiveness of the device in controlling symptoms
- Quality of symptom control post insertion and problems when turned off
- Instructions for disabling and restarting the device
- Discussion with the team who implanted the device -safety concerns, programability should be discussed.

Intra-operative

Key aspects are:

1. **Safety of the patient/discussion on WHO checklist**- Anaesthetic, surgical and theatre team should be made aware about the device in situ and its implications should be discussed at team brief.
2. **Safety of the device** -

- Maintenance of adequate theatre temperature (20-24°C) and humidity (50%-60%) to reduce static electricity charge[9].
- Electromagnetic interference (EMI) is the effect of Electromotive Force (EMF) on NCID which could be:

Conducted EMI

Resultant of direct EMF contact to the body such as monopolar electrocautery, lithotripsy, diathermy, ECT, nerve stimulation

Radiated EMI

Placement of a patient with a device into EMF such as CT or MRI scan. That can either affect functioning of the device or the device can cause interference on scanned image.

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EMI can affect the device in following ways

- Turn the device on/off
- Changing/resetting the frequencies of the device
- Tissue damage at the site of insertion
- Damage to the device itself

Environmental influence on the device

Surgical diathermy

- Diathermy can cause EMI which can interfere/ damage device and can cause injury to patient[10].
- Bipolar diathermy potentially safer than monopolar.
- If monopolar cannot be avoided then consider turning device off, place pad as far as possible from the device, AVOID the use of full-length grounding pad/plate and use a non-conductive bed.

GI Electrocautery and endoscopy

- GI endoscopy without biopsy is completely safe and does not require modification in technique
- GI Biopsy, tissue coagulation and sphincterotomy usually require monopolar electrocautery, but Bipolar and Multipolar Cautery can be used in “bicap” probes used to control bleeding from ulcers or vascular lesions.
- Other specific devices such as Olympus heat probe (Olympus Japan) have nonconductive teflon coated tip heated by internal electric resistor with minimises the travel of current through the tissue hence safer with devices[11].

Emergency Cardioversion/ Pacing /Defibrillation

- Evidence for effects of NCID is sparse but its well-known from implantable cardiac devices and external defibrillators/cardioverters[12].
- Steps that may minimise the risk of damage include

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- Position paddles far away and perpendicular to the NCID
- Attempt to use the lowest setting of output as possible
- Confirmation of NCIDs functionality post procedure

Electroconvulsive therapy (ECT)

- Performed under GA, placement of bitemporal electrodes with passage of a predetermined current for 20 seconds.
- Manufactures generally do not recommend use of ECT in patients with existing head or neck NCIDs, the theoretical concerns are that it may induce heating of the deep brain stimulator electrodes causing brain tissue damage and/or induced seizures can alter the position of the leads of the implantable device[13].
- If a non-head and neck device is in-site then ECT may be safer as the current used is significantly less than defibrillation.

Neuraxial anaesthesia

- Spinal anaesthesia is not contraindicated in SCS or sacral nerve stimulator as electrode placement around L1 or above for SCS.
- Before attempting the spinal some pre- neuraxial anaesthesia checks is recommended- Xray to check the placement of the electrode to avoid the damage during needle insertion. The aim should be to place spinal needle lower than the insertion point of the electrode.
- Epidural anaesthesia is generally contraindicated unless epidural is placed in completely a different region to the stimulator such as performing a lumbar epidural in a patient with thoracic stimulator[14].

Imaging

- CT scans, Ultrasound, mammography and Plain X-rays are generally considered safe in implantable non- cardiac devices.
- MRI - Use of MRI in patients with NCID is a contentious issue with concerns regarding heating and burns at tissue level, disruption of the operation of the device leading to side effects, induced electrical current and magnetic field

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interaction. Manufacturer advice should be sought regarding the interaction of MRI with device as some of the newer devices are compatible with MRI of various strengths[15]. Website 'mrisafety.com' offers valuable information regarding implantable devices MRI safety.

- It is worth mentioning that in case of MRI on patients with DBS, temperature rises between 5-7.0°C can cause reversible tissue damage but temperature rises beyond 8.0°C will result in irreversible damage.

Postoperative Period

The NCID and the patient should be checked for the functioning of the device. The device should be interrogated regarding the settings, programmes, battery and its functionality.

If there is any doubt about the functioning of the device, it is advised to contact the parent specialty to review the patient and device before discharge.

Summary

With ever-increasing indications of NCIDs, it is of utmost importance for the anaesthetist to be well informed with the peri-operative management of NCIDs for the safety of the patient.

Future and further reading

Implantable medical devices have emerged from its infancy and progressing leaps and bounds with latest research evidence pouring in. Areas still to improve on include electrode technologies, sensors for closed loop neurostimulator control, wireless communication and battery free devices.

In the present world of cyber-crimes, implantable devices carry a risk as well[16].

For physics lovers, worth reading article on 'Power approaches for implantable medical devices' published in Sensors 2015 by Amar et al.

References:

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1. Bari AA, Thum J, Babayan D, Lozano AM. Current and expected advances in deep brain stimulation for Movement disorders. Prog Neurol Surg. 2018; 33:222-229.
2. Johnson MD, Miocinovic S, McIntyre CC, Vitek JL. Mechanisms and targets of deep brain stimulation in movement disorders. Neurotherapeutics 2008; 5: 294 – 308
3. Vagus nerve stimulation for treatment-resistant depression. NICE guidance IPG 330, 2009.
4. Krahl SE, Clark KB. Vagus nerve stimulation for epilepsy: A review of central mechanisms. Surg Neurol Int. 2012; 3(Suppl 4): S255-259.
5. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. NICE guidance IPG 598, 2017.
6. Otto SD, Burmeister S, Buhr HJ, Kroesen A. Sacral nerve stimulation induces changes in the pelvic floor and rectum that improve continence and quality of life. J Gastrointest Surg. 2010;14:636–644.
7. Xu J, Liu A, Cheng J. New advancements in spinal cord stimulation for chronic pain management. Curr Opin Anaesthesiol. 2017 Dec;30(6): 710-717.
8. International Neuromodulation Society 12th World Congress Neuromodulation: Medicine Evolving Through Technology June 6–11, 2015 Montreal, Canada. Neuromodulation: Technology at the Neural Interface, 18: e107–e399. doi: 10.1111/ner.12333.
9. Association of perioperative Registered Nurses. AORN guidance statement: care of the perioperative patient with an implantable electronic device. AORN J 2005; 82: 74-82.
10. Larson PS, Martin AJ. Safety concerns and limitations. Essential Neuromodulation. Elsevier; 2011.
11. Peterson BT, Hussain N, Marine JE, et al; Technology Assessment Committee. Endoscopy in patients with implanted electronic devices. Gastrointest Endosc. 2007;65:561-8.
12. Beinart R, Nazarian S. Effects of external electrical and magnetic fields on pacemakers and defibrillators. Circulation 2013;128:2799-2809.
13. Gahr M, Connemann BJ et al. Safety of electroconvulsive therapy in the presence of cranial metallic objects. J ECT. 2014 Mar;30(1):62-8.
14. Patel S, Das S, Stedman RB. Urgent caesarean section in a patient with spinal scord stimulator: implications for surgery and anaesthesia. The Ochsner Journal 2014;14:131-134.

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15. Dormont D, Seidenwurm D, Galanaud D et al. Neuroimaging and deep brain stimulation. Am J Neuroradiol 2010;31:15-23

16. Camara C, Peris-Lopez P, Tapiador JE. Security and privacy issues in implantable medical devices: A comprehensive survey. Journal of Biomedical informatics. 2015; 55: 272-289.