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EDITORIAL

Neuromodulation and obstetric anaesthesia

Neuromodulation is a rapidly evolving area of medical practice and obstetric anaesthetists are likely to encounter patients with neuromodulatory devices in situ more frequently.

Defined by the International Neuromodulation Society as "the alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body",[1] neuromodulation is now used to treat a seemingly ever expanding range of conditions.[2] Neuromodulation systems have traditionally been reserved as second or third line treatments – generally considered only after other medical and surgical options have failed. In the past, systems have been considered prohibitively expensive and implantation has required major invasive surgery. However, in recent years, new generation systems have become progressively smaller and easier or less destructive to insert.

Despite the continuing lack of Class 1 evidence of effectiveness in pain management, the evidence of cost-effectiveness of neuromodulation compared with medical treatment alone is likely to support the expansion of use, both in terms of absolute numbers of patients and in the range of indications.[3–5]

Most neurostimulation systems consist of distal electrode(s) placed adjacent to a target site, with connecting leads tunneled over a variable distance to a subcutaneous Implanted Pulse Generator (IPG). The IPG has an integrated battery, which is either replaced surgically every few years, or more commonly now (especially in younger patients) is charged remotely using an external induction charging system. This device is generally worn intermittently by the patient, typically a few hours per week, in close proximity to the IPG.

Common neuromodulation targets include various intracranial and neuraxial sites, as well as peripheral nerves. However, many additional potential targets and modes of neuromodulation are emerging.

Deep brain stimulation (DBS) has been used extensively for Parkinson's disease, and less commonly for a range of other conditions including myotonic syndromes, tremor associated with multiple sclerosis, and psychiatric conditions such as intractable depression, Tourette's syndrome and obsessive compulsive disorder.[6,7] Spinal cord stimulation is most commonly used for failed back (surgery) syndrome (FBSS)[8–10] and complex regional pain syndrome (CRPS).[11–15] Peripheral nerve stimulators can be used for mononeuropathies such as occipital or trigeminal neuralgia. Recently, dorsal root ganglion (DRG) stimulators have been used for more localized pain conditions such as post-thoracotomy pain, post-herpetic neuralgia and post-herniorrhaphy pain. Sacral nerve stimulators can be used both for pain conditions and bladder or bowel sphincter dysfunction. In this issue of the journal, Ansó et al. present a case report of a young patient with a sacral nerve stimulator used very effectively to treat bladder sphincter dysfunction associated with Fowler's Syndrome.[16]

The field of neuromodulation also encompasses intrathecal drug delivery therapies, which supply infusions of medications directly into the cerebrospinal fluid (CSF). The infusion is run from a pump, typically implanted over the iliac fossa in the lower abdominal wall. A catheter runs subcutaneously from the pump into the intrathecal space, commonly introduced at either the L2–3 or L3–4 intervertebral space. Intrathecal medications include baclofen to relieve the spasticity of cerebral palsy or spinal cord injury, and analgesics for chronic (especially malignant) pain.

Whilst many intracranial systems are used in older patients, there are already case reports of women with DBS systems requiring obstetric care.[17,18] There are also multiple case reports (and short case series) of pregnant women with cervical and thoracic spinal[8,10–15,19–22] and sacral nerve stimulators[23,24] in situ. Several case reports have been published of successful epidural analgesia in the presence of intrathecal infusion pumps.[25,26]

Management of neuromodulation systems during pregnancy

There is currently a lack of meaningful human research to assess the impact of neuromodulation systems on pregnancy (or vice versa) – most particularly, there is a paucity of data on the theoretical implications of the resulting electromagnetic fields on the developing fetus. Some animal data exist, such as studies examining the reproductive health of laboratory rats and dairy cattle exposed to high voltage powerlines.[27–29] However, in the absence of good quality human data, current recommendations from all neuromodulation device companies are that devices be switched off for the duration of pregnancy. Accordingly, the Food and Drug Administration (FDA) and similar bodies have not licensed

neuromodulation systems for use during pregnancy. Neither the companies – nor the authors of this editorial – can be seen to condone the 'off label' use of neuromodulation during pregnancy. However, this should not preclude a rational discussion of the risks and benefits that this may involve, and consideration of research that could potentially be undertaken in the future in order to further delineate these risks. This may represent an example in clinical practice where the theoretical risk of an unknown harm needs to be weighed against the genuine risk of known morbidity.

Clearly the consequences of turning off neuromodulation during pregnancy vary depending on the indication for which the device was inserted. Patients with chronic pain will need to take alternative analgesia to replace the pain relief provided by the stimulator, and these analgesics themselves may have adverse effects during pregnancy (e.g. opioid dependence in the newborn). Alternatively, many chronic pain patients choose to endure poor pain control for the duration of the pregnancy, which may have its own psychosocial and physiological consequences. There is little research examining the holistic consequences of chronic pain on outcomes in pregnancy and reproductive health more broadly.[30,31] The patient described in Ansó's case report clearly suffered significant morbidity associated with turning off her device. It is quite conceivable that her repeated episodes of urinary sepsis could have independently threatened the viability of her pregnancy.

Many IPG systems are not designed to be turned off for prolonged periods of time and batteries become nonviable if allowed to completely discharge.

Implications of neuromodulation systems for obstetric anaesthetists

The most important question for the obstetric anaesthetist is whether neuraxial anaesthesia can be safely conducted and whether it is likely to be effective. There is no absolute contraindication to epidural or spinal anaesthesia. However, there is the theoretical risk of damaging spinal stimulation systems via direct trauma or infection. Pre-anaesthetic assessment should include a detailed record of the exact anatomical location of the entire system, including the electrodes, connecting leads and IPG. This information can be remarkably difficult to obtain, especially after-hours. Ideally, contact with the clinician who implanted the device should be made, with review of the original operation report.

Percutaneous spinal systems are commonly inserted via either the L2–3 or L3–4 interspace and then the electrodes are advanced under X-ray guidance to lie at the target location in the low thoracic epidural space. Plate electrodes are generally placed in the low thoracic epidural space via a laminectomy. Leads may be anchored adjacent to the interspinous ligament at the point of insertion. These electrodes are then tunneled to the IPG, which is typically implanted in the lower flank or upper buttock. One case report describes the use of ultrasound to delineate the exact location of an intrathecal catheter prior to epidural analgesia.[26]

It is also important to establish what other form of spinal surgery the patient has undergone, particularly in cases of FBSS. The integrity of the epidural space is important for the prospects of successful epidural analgesia. Any open back surgery from a posterior approach, including the insertion of plate electrodes via laminectomy, has the potential to compromise the epidural space at that level, leading to an increased risk of dural puncture and partial or total failure of epidural anaesthesia.

Spinal anaesthesia should be safe and effective and the risk to the system is minimised if the approach is made at a level anatomically separate from the location of the leads and electrodes. Whilst not globally recommended, prophylactic antibiotics would seem prudent, given the catastrophic consequences of iatrogenic infection which generally necessitates removal of the entire system.

If the patient has chosen to use the device during pregnancy, it would seem advisable to turn the stimulation or drug delivery device off for the duration of labour and birth, including during placement of an epidural catheter or during caesarean section. Neuromodulation systems can be turned off either with the patient's own control unit or by application of a magnet over the IPG, in a similar way to application of a magnet over a cardiac pacemaker.

Guidelines for the obstetric team

In addition to the considerations for anaesthetists, there are also important considerations for the obstetric team. Early involvement of a specialist pain physician may assist the obstetric team, and the woman herself, to weigh the relative risks and benefits of alternative analgesic options including continuing to use neuromodulation throughout the pregnancy.

The physiological changes of pregnancy can theoretically result in stretching, dislodgement or damage to electrodes and connecting leads. Previously, IPGs were commonly placed in a suprapubic or iliac fossa location where they could be damaged during caesarean delivery. Intrathecal pumps are also often located in this area. Implanted Pulse Generators are now typically located in the upper anterior chest wall or in the upper buttock or flank, and are at far less surgical risk.

Surgeons are advised to avoid monopolar diathermy in the vicinity of neurostimulatory systems as it may cause damage to the IPG. There is also potential for diathermy to heat the electrodes and this thermal energy maybe be transferred along the length of the electrode, resulting in burns to distant neural structures.