Recommendations for the Management of Implanted Neurostimulation & Intrathecal Drug Delivery Devices During the COVID-19 Pandemic

Neuromodulation therapies defined as "the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body" are utilised in the treatment of a diverse range of medical conditions. These therapies require the placement of a long-term implant in most patients with a requirement for long term management[1].

COVID-19 is an infectious disease caused by a newly discovered coronavirus. Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness[2].

The data from China suggest that 15–20% of COVID-19 cases require hospitalization, with around 15% of cases presenting with severe symptoms and 5% requiring intensive care[3]. Elective surgery is not carried out in many regions, enabling to create more critical care facilities. This practice recommendation/guidance is aimed at managing the neuromodulation devices during the pandemic. Neuromodulation chapters have published their local COVID-19 Resource, which are specific to each country[4,5].

Guidance on Intrathecal Drug Delivery Devices (ITDD)

Background: ITDD is utilised in the management of pain and spasticity, therefore drugs or drug combinations infused by ITDD vary considerably between individual patients. While some may cause sudden severe and life-threatening withdrawal reactions other are known to cause no withdrawal effects[6]. Abrupt interruption of intrathecal baclofen has in cases, resulted catastrophic multi-organ failure[7] while abrupt withdrawal of intrathecal clonidine has resulted in hypertensive crisis and cardiomyopathy[8].

Clinicians should judge each case on its own merit, the below are general recommendations and should not be seen as guidelines:

1. Avoid insertion of any new ITDD except for highly selected cancer pain cases where the benefit is considered to outweigh the risk of acquiring a COVID-19 pneumonia.
2. ITDD replacements are urgent procedures that need to be carried out in a timely manner to prevent drug withdrawal.
3. ITDD replacements require in person meeting with patients although the consenting discussion can be done remotely and documented in the patient's notes in line.
4. Physicians may elect to replace ITDD early in the pandemic or delay the replacement until the end of covid-19 pandemic if the device end of life allows it.

5. The timing of ITDD device replacement should be discussed and agreed with patients in light of the changing situation. The option and consequences of non-replacement of the ITDD and therapy discontinuation should be discussed.

6. In few highly selected cases the physician may consider oral substitution to be an appropriate replacement for the ITDD infusion for the duration of the pandemic. This should be considered in discussion with the patient and only in cases where abrupt drug withdrawal is not known to cause life threatening reactions.

7. For other ITDD troubleshooting use telemedicine where possible to resolve issues except in cases were the presenting symptoms suggest malfunction of a component of the ITDD system with threatening or actual symptoms of drug withdrawal, where face to face contact is necessary.

8. The ITDD caring team should make every effort to track their patients through the pandemic. In the event of a patient being admitted to intensive care contact should be made with the responsible clinician and discussion around the need for and timing of ITDD refill initiated.

9. ITDD refills necessitate an in-person meeting with the patient to enable device programming. These can be carried out in hospital or in cases at the patient's residence.

10. ITDD refills are intimate procedures that require the operator to come within a distance of less than 1 meter from the patient in order to refill and program the device. Local guidance on personal protective equipment use should be followed.

11. Where feasible the patient should be laid flat for an ITDD refill, in order to maximise the distance between them and the operator. A preliminary temperature check as well as a check on symptoms of COVID-19 is advisable before embarking on the procedure.

12. ITDD refills need to be carried out in a timely manner to prevent abrupt drug withdrawal, a number of strategies can be utilised to mitigate the risk of exposure to COVID infection associated with repeated hospital attendances, these include:

    a. Where feasible and in discussion with patients, clinicians may elect to use a higher drug concentration for the duration of the pandemic. This should reduce the frequency of ITDD refills. There is no evidence of worsening of symptoms of pain or spasticity from use of higher concentration[9,10]. The risk of development of an intrathecal granuloma needs to be balanced against the risk of COVID infection particularly in the elderly and vulnerable populations.

    b. Ziconotide therapy cessation is not associated with withdrawal symptoms[11]. In cases of ziconotide only infusions, clinicians may consider not refilling the ITDD for the duration of the pandemic, patients should be warned that the ITDD device will alarm regularly for the foreseeable future.

    c. Opioid only ITDD infusions may, after discussion with patients, be substituted with oral equivalent. This should only be considered in vulnerable individuals since opioid equivalence is not an exact science and withdrawal symptoms are more likely to occur than not.

d. Where abrupt intrathecal opioid discontinuation has been agreed there will be a need for careful remote daily follow up of the patient to allow for timely management of withdrawal symptoms and adjustment of oral opioid dosage. Patients should be advised that their ITDD will alarm intermittently.

e. Routine oral substitution of baclofen or clonidine is not advised due to potential for life threatening withdrawal effects.

f. Where hospital ITDD refills are considered to be too risky and therapy discontinuation not an option, home refills should be considered in order to reduce the exposure of vulnerable or immunosuppressed individuals to the hospital environment.

g. In suspected or symptomatic patients, consider the possibility of delaying the refill if low reservoir alarm date allows until the patient has served a self-isolation period recommended.

h. Where an ITDD refill delay is not possible in a symptomatic or confirmed COVID-19 positive patients, proceed to refill the ITDD in a nominated part of the hospital for COVID-19 positive procedures and using necessary PPE as per local guidance.

Guidance on Neurostimulation Devices

Recommendations

1. Avoid insertion of any new neurostimulation devices during the mitigation and delay phase of the pandemic.

2. All in person contact is minimised. For most neurostimulation devices troubleshooting use telemedicine where possible to resolve issues. For example, postoperative wound reviews, stimulation and re-charging technique, drug queries can be resolved by videoconference, or email or text messages.

3. Implant infections can cause sepsis and neuraxial infections. These are medical emergencies and should be treated promptly at appropriate centre as per the centre's standard operating procedure.

4. Loss of neurostimulator function (e.g. pain relief) due to lead migration, lead fracture, and implantable pulse generator (IPG) battery depletion is not a reason to surgically revise the neurostimulator until planned elective surgery is re-introduced.

5. Personalised alternative methods of symptom control should be discussed with each patient until till such time that elective surgery is considered safe. Psychological support should be offered where needed.

6. Patients requiring an IPG change for movement disorders, represents an exceptional category given that sudden expiration of the battery not only risks clinical deterioration of the patient but also strains the hospital resources by prolonging the hospital stay or

even necessitating ITU admissions. Surgery to replace batteries should go ahead based on clinical judgement.

7. Decisions regarding whether to replace IPGs in Vagal Nerve Stimulation systems during the Covid-19 pandemic should be made in consultation with the patient's epileptologist who will be in the best position to judge the likely risks and consequences of increased seizures in any given patient in the event that their IPG failed

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