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Case Report

Intrathecal Pump Exposure to Electromagnetic Interference: A Report of Device Interrogation following Multiple ECT Sessions

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Background: Intrathecal drug delivery systems represent an increasingly common treatment modality for patients with a variety of conditions, including chronic pain and spasticity. Pumps rely on electronic programming to properly control and administer highly concentrated medications. Electromagnetic interference (EMI) is a known exposure that may cause a potential patient safety issue stemming from direct patient injury, pump damage, or changes to pump operation or flow rate.

Objectives: The objective of our case report was to describe an approach to evaluating a patient with a pump prior to and following exposure to EMI from electroconvulsive therapy (ECT), as well as to document findings from device interrogations associated with this event.

Study Design: Case report.

Setting: Academic university-based pain management center.

Results: We present the case of a patient with an intrathecal pump who underwent multiple exposures to EMI in the form of 42 ECT sessions. Interrogation of the intrathecal drug delivery system revealed no safety issues following ECT sessions. At no time were error messages, unintentional changes in event logs, unintentional changes in pump settings, or evidence of pump stall or over-infusion noted.

Conclusion: Communication with multiple entities (patient, family, consulting physicians, and device manufacturer) and maintaining vigilance through device interrogation both before and after EMI exposure are appropriate safeguards to mitigate the risk and detect potential adverse events of EMI with intrathecal drug delivery systems. Given the infrequent reports of device exposure to ECT, best practices may be derived from experience with EMI exposure from magnetic resonance imaging (MRI). Although routine EMI exposure to intrathecal drug delivery systems should be avoided, we describe one patient with repeated exposure to ECT without apparent complication.

Key words: Baclofen, intrathecal drug delivery system, electromagnetic interference, electroconvulsive therapy, safety, pump interrogation, intrathecal pump, pump stall

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Intrathecal drug delivery systems permit the targeted administration of medications to the intrathecal space, and may be used to treat a variety of conditions including chronic pain and spasticity (1). Since the first implantation in 1981, the number of implanted intrathecal drug delivery systems has grown such that available aggregate follow-up time for these devices tracked via post-implantation safety systems has increased to include almost 6,000 patients and more than 180,000 cumulative patient-months (2). A growth in implantation of pumps has also increased the likelihood that these devices will

encounter undesirable and potentially unsafe clinical environments.

Electromagnetic interference (EMI), an energy field generated by medical equipment, represents one such potential problem for intrathecal pumps (3). Case reports and larger studies of patients with intrathecal pumps exposed to EMI have usually focused on interference from magnetic resonance imaging (MRI) (4-8). However, patients may encounter other sources of EMI from a variety of treatments or equipment that include but are not limited to radiation therapy, diathermy, and electroconvulsive therapy (ECT).

This case report is unique in presenting the results of device interrogation of an intrathecal pump before and after multiple exposures to EMI from ECT. How a physician should address potential exposure of intrathecal pumps to EMI from non-MRI sources has not been fully addressed in the literature. We describe considerations for communication regarding the risk of exposure, the range of potential effects of EMI, and safeguards to consider when encountering patients in similar clinical environments.

Case Report

A 43-year-old man with a medical history significant for traumatic brain injury following a motor vehicle accident and prior episodes of catatonia, depression, and hypertension had undergone intrathecal baclofen pump implantation (8840 SynchroMed II B, Model 8637-40, 40-mL reservoir; Medtronic, Minneapolis, Minnesota) for spasticity 9 years earlier. He was brought in by family members to our hospital due to worsening catatonia in the setting of recent changes to his parenteral medication regimen. Following admission, catatonia was unresponsive to escalating medication management under the direction of the psychiatry service. As a result, the psychiatry service recommended electroconvulsive therapy (ECT) as the next, most appropriate treatment. The service obtained consent from the patient's family and consulted the chronic pain service prior to the first ECT treatment. The risks associated with ECT in a patient with an intrathecal pump were discussed with the patient, the patient's family, the psychiatry service, and the device manufacturer. The patient and patient's family elected to proceed with the proposed treatment plan.

Device interrogation at that time revealed infusion of baclofen (2,000.0 mcg/mL) in flex mode with basal rate of 4 mcg/hour with bolus administration of 75.1 mcg doses every 6 hours, for a cumulative daily dose of 394.0 mcg/day. The patient then underwent his first ECT session. While recovering in the post-anesthesia care unit, the patient underwent device interrogation within the first hour after the procedure. The device demonstrated no evidence of pump stalling, no error messages were displayed, the event logs noted no changes, and the pump settings remained unchanged. No evidence of pump over-infusion was noted on physical examination or with questioning of the patient and his family. The anesthesiologist, psychiatrist, and nurse involved in the patient's care were educated about symptoms and signs of baclofen withdrawal and overdose.

The patient underwent subsequent ECT sessions at periodic intervals ranging from one day to 10 days, with gradual improvement in catatonia. Device interrogation following ECT sessions revealed identical results. An intentional change in device settings to increase the dose of baclofen occurred between ECT sessions 18 and 19, but otherwise no unplanned changes in pump performance or inappropriate effects were noted. In total, the patient underwent 42 ECT sessions. Device interrogation immediately followed 38 of these sessions. Following 4 sessions, the device was not interrogated at the time of hospital admission, transfer, or discharge. In the case of all 4 sessions, the device was interrogated after an additional ECT session, with no documentation of error messages or changes in settings. At no time did the device demonstrate evidence of pump stalling, an error message, change in settings, or evidence of over-infusion.

The patient and the patient's next of kin provided consent for this case report.

Conclusions

The safety profile of intrathecal drug delivery systems to EMI exposure is largely unknown for psychotherapeutic procedures such as ECT in patients with implanted infusion systems (3). Concern exists that induction of electrical current may result in heating of the pump, which then leads to over-infusion of medication. This increase in highly concentrated medication may then result in a potentially life-threatening drug overdose. Despite repeated exposures to ECT, no adverse sequelae for the patient or intrathecal pump was found in this clinical scenario.

Recognition of the unknown risks in communication with patients, families, and other providers and heightened vigilance through device interrogation pre- and post-EMI exposure represent common safeguards to reduce the chances of patient harm. Although

exposure of intrathecal drug delivery systems to EMI is not recommended as routine practice, this report demonstrates that multiple exposures of a pump to ECT took place without any detected changes in device performance for one patient.

References

1. Prager J, Deer T, Levy R, Bruel B, Buchser E, Caraway D, Cousins M, Jacobs M, McGlothlen G, Rauck R, Staats P, Stearns L. Best practices for intrathecal drug delivery for pain. *Neuromodulation* 2014; 17:354-372.
2. Weaver T, Wells M, Roediger M, Stromberg K. Medtronic Product Performance Report. Minneapolis, MN: Medtronic. Available at: http://professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/2013-ppr-report.pdf. Accessed July 16, 2015.
3. Medtronic Syncromed Isomed implantable infusion systems. Information for prescribers. Minneapolis, MN: Medtronic. Available at: http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_213801.pdf. Accessed July 16, 2015.
4. Aram G. Medical Device Correction: Important Information on Potential MRI Effects. Minneapolis, MN: Medtronic. Available at: http://professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/synchromed_mri_hcp_ltr.pdf. Accessed July 16, 2015.
5. Diehn FE, Wood CP, Watson RE Jr, Mauck WD, Burke MM, Hunt CH. Clinical safety of magnetic resonance imaging in patients with implanted SynchroMed EL infusion pumps. *Neuroradiology* 2011; 53:117-122.
6. De Andres J, Villanueva V, Palmisani S, Cerda-Olmedo G, Lopez-Alarcon MD, Monsalve V, Minguez A, Martinez-Sanjuan V.The safety of magnetic resonance imaging in patients with programmable implanted intrathecal drug delivery systems: A 3-year prospective study. *Anesth Analg* 2011; 112:1124-1129.
7. Post MRI Pump Interrogation Guidelines. Minneapolis, MN: Medtronic. Available at: http://professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/synchromed_mri_inter_gdl.pdf. Accessed July 16, 2015.
8. Fink M, Taylor MA. The many faces of catatonia: Delirious mania, excited catatonia, and oneiroid state. In: Fink M, Taylor MA (eds). *Catatonia: A Clinician's Guide to Management*. Cambridge University Press, New York, NY, 2006, pp 51-56.