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Case Report

SynchroMed II Intrathecal Pump Memory Errors Due to Repeated Magnetic Resonance Imaging

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Cancer patients with severe refractory pain are often managed with implantable drug delivery systems (IDDS). The only drugs with US Food and Drug Administration approval for intrathecal use are morphine, ziconotide, and baclofen. Other drugs used and mixed include, hydromorphone, bupivacaine, sufentanil, and fentanyl. These patients often undergo magnetic resonance imaging (MRI) for disease-related monitoring and diagnoses. Although uncommon, IDDS can fail to resume normal functioning after MRI, potentially causing complications. The magnetic field of an MRI will temporarily stop the rotor of the pump motor and suspend drug delivery for the duration of the MRI exposure. The pump should resume normal operation when removed from the MRI magnetic field, but there is a potential for a delay in the return of proper drug infusion and a delay in the logging of motor stall events after an MRI in the SynchroMed II pumps. A 57-year-old man who underwent multiple MRIs with an implanted IDDS experienced 2 separate memory failures leading to multiple complications. After the first pump malfunction, the patient developed withdrawal symptoms and was treated in the emergency department. The first time, a memory reset resolved the problem. The second time, 29 months later, the patient was admitted to the hospital to manage withdrawal symptoms and the pump had to be exchanged with a new device. Post-MRI pump interrogation should be performed on all patients with IDDS to ensure proper functioning of the pump. Special attention should be paid to patients receiving baclofen, as acute withdrawal can be very serious, even deadly.

Key words: Cancer pain, MRI, IDDS, SynchroMed II, baclofen, withdrawal, stall.

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Implantable drug delivery systems (IDDS) are used to treat severe, chronic, and refractory cancer pain, in patients whose pain is not well managed by systemic analgesics and in those that have serious side effects from therapy (1,2). The SynchroMed EL and SynchroMed II drug administration systems (Medtronic Inc., Minneapolis, MN) are implantable, programmable, site-specific drug delivery systems.

The SynchroMed II pump is able to detect motor stall and motor stall recovery. The patient is alerted of a motor stall event by an audible alarm. Motor stall events are also recorded and can be reviewed by clinicians in the pump event log (3).

Current drugs approved by the US Food and Drug Administration for intrathecal use include ziconotide, baclofen, and morphine. Yet many other drugs are used via the intrathecal route for the treatment of pain, including hydromorphone, bupivacaine, clonidine, sufentanil, fentanyl, and some other less frequently used drugs (4).

IDDS are particularly useful for treating refractory cancer pain (5,6). In a 200 patient randomized clini-

cal trial, Smith et al (6) showed pain and drug toxicity scores significantly reduced by an average of 27% in 30 patients with refractory cancer pain, who failed comprehensive medical management. Cancer patients with IDDS often require magnetic resonance imaging (MRI) to monitor their disease state and rule out any progression. In 2008, Medtronic released an urgent medical device correction, reporting 9 events of a delay in proper pump infusion after MRI (occurrence rate of 0.014% of all pumps sold worldwide) and 70 reports of a delay in the logging of motor stall events (occurrence rate of 0.11% of all pumps sold worldwide) in a 3-year period (3).

MRI produces electromagnetic interference (EMI) causing the motor gears of the IDDS to temporarily bind due to the alignment of the pump rotor magnet with the MRI magnetic field (3). Presumably, the motor should resume normal function post-MRI, but there is a potential for MRI-related complications. Complications include injury or operational changes to the pump (7). Injury can result if the implanted pump increases in temperature and thereby damages surrounding tissue. Operational changes to the pump are caused by a prolonged IDDS motor stall, which results in a loss of therapy and a return of symptoms. There is a potential for permanent motor stall if the pump is oriented 90 degrees to the z-axis of a 1.5 or 3.0-T MRI scanner (7). This can demagnetize internal pump motor magnets causing an irreversible stoppage of the motor. A delay in proper infusion of medications such as baclofen is particularly dangerous because baclofen withdrawal can lead to a potentially fatal condition (8). Acute withdrawal of intraspinal clonidine can cause malignant rebound hypertension (9). EMI from MRI can also cause a delay in the logging of motor stall events. In this case the pump resumes normal drug delivery after the MRI, but the pump log erroneously indicates that an extended interruption occurred (7).

Although De Andres et al (10) reported no adverse events associated with IDDS function after MRI in a 2011 3-year prospective study (n = 43), the safety of MRIs in patients with implanted devices remains unclear. Protocols should be in place to avoid any delay or unnecessary cancellations of MRIs in patients with IDDS and also provide a post-MRI pump interrogation to assure proper functioning of the device.

Case Description

A 55-year-old man with a history of renal carcinoma postnephrectomy, developed back pain and progressive numbness. After a T9 vertebrectomy, he developed mid thoracic intermittent pain that did not respond to oral analgesics and adjuvants. The pain was characterized as intense, sharp, stabbing with activity, but absent at rest. On the numerical pain rating scale where 0 is no pain and 10 is the worst pain imaginable, he rated his worst pain at 8/10, least 1/10, and average 3/10.

Before IDDS implantation, a 4-day intrathecal catheter trial was conducted, infusing a mixture containing 96 µg/d fentanyl and 96 µg/ per day intrathecal clonidine with good response.

A SynchroMed II system was implanted and the patient had good initial analgesia. Over the next 2.5 years the patient underwent 11 MRIs. After each MRI except for one, the pump was interrogated and it was verified that it had resumed normal function. The patient's pump contained a mixture of fentanyl 4,000 µg/mL, clonidine 1,000 µg/mL, and bupivacaine 20 mg/mL infusing at a rate of 450 µg/d based on fentanyl when he received a subsequent MRI. Directly after the MRI, he noticed his pump was beeping and experienced increased pain, agitation, nausea, and uncontrollable shaking. He was seen in the emergency department and received a fentanyl 50 µg/h patch, clonidine 0.1mg patch, fentanyl citrate 1,600 µg, and 4 mg intravenous hydromorphone to prevent withdrawals. Interrogation of the pump revealed a memory failure. The pump was reprogrammed and set to infuse at the same rate as before plus a single bolus of the solution based on fentanyl 300 µg. The patient's withdrawal symptoms promptly resolved.

Over the next 2.5 years the patient underwent 7 more MRIs. It was verified by interrogation that the IDDS resumed normal function. At this point the analgesic solution had been changed to fentanyl 1,000 µg/mL, clonidine 300 µg/mL, bupivacaine 10 mg/mL, and baclofen 150 µg/mL. The pump was delivering a dose of 275 µg/d fentanyl, 2.75 mg/d clonidine, 2 mg/d bupivacaine, and 41.25 µg/d baclofen. The patient had some trouble with ejaculation after the addition of baclofen to the mixture and had an MRI of the spine to rule out any intrathecal granuloma (11). The day after he underwent an MRI, he was seen for increased pain and withdrawal symptoms. Interrogation of the pump was attempted using 3 different hand held devices, and all indicated a malfunction alert. The patient was given 400 µg fentanyl citrate lozenge, fentanyl 25 µg transdermal patch, 20 mg oral baclofen, and clonidine 0.1 mg patch. All medication was removed from the pump, replaced with saline, and the patient was ad-

mitted for 23 hour observation through the emergency department. The malfunctioning pump was explanted and replaced with a new pump, which was refilled with the aforementioned medications. The explanted pump was sent to Medtronic for analysis and they reported no visual anomaly and that the pump was functioning per specification. Flow testing confirmed the pump was dispensing accurately. The pump memory error was likely a programmer-indicated issue and cleared after initializing.

Over the next week, the patient experienced irritation and had serosanguineous fluid in the subcutaneous pocket surrounding the intrathecal pump that failed to resolve with antibiotics. The pump pocket was revised; however, due to poor wound healing, the pump was finally explanted.

Conclusion

Despite the low rate of occurrence of IDDS malfunctions after MRI, complications due to pump stall or memory malfunction can be serious. We recommend that pumps be interrogated after each MRI. Medtronic has 2 types of programmable pumps on the market, SynchroMed EL and SynchroMed II pumps.

Both should always be interrogated after MRI exposure in order to confirm proper pump functionality. The SynchroMed EL model does not detect or alarm for motor stalls. If the clinician suspects a stall, a pump roller study should be performed. If interrogation shows that the MRI scan caused a "Pump Memory Error" the clinician must reprogram the pump in order for proper infusion to resume. The SynchroMed II model will detect a motor stall and record it in the pump event log and the audible motor stall alarm will usually occur within 20 minutes of MRI exposure (for pumps programmed to deliver at least 0.048mL/d) (3).

Detection of motor stall recovery and recording of the recovery in the pump event log will usually occur within 20 minutes after the removal of the pump from the magnetic field. If the pump is set to deliver at minimum rate, this motor stall recovery may take up to 90 minutes. Sometimes the SynchroMed II pump event log may not register motor stall recovery until the pump has been interrogated a second time (3).

Electromagnetic interference from the MRI scan can change the pump to "safe state" (infusion will be at a minimum rate of 0.006mL/d). In such a case, the clinician must reprogram the pump in order for the prescribed drug infusion to restart (3).

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