MEDICATION ERRORS

Template for Disaster?
Fatal Injection into Wrong Port of Implanted Infusion Pump
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PROBLEM: Implantable infusion pumps are sometimes used to deliver outpatient parenteral drug therapy over long periods of time. Intrathecal drug therapy commonly includes opiates to treat intractable chronic pain and the muscle relaxant baclofen (e.g., Lioresal, Novartis) to treat spasticity associated with multiple sclerosis, cerebral palsy, and spinal cord injuries. Because these pumps can accurately deliver very small volumes over the long term, concentrated medications may be used to extend the time between each refill of medication.

One advantage of the intrathecal route for opiate delivery is that much lower doses are needed than with other routes of administration. For example, the parenteral-to-intrathecal ratio for morphine is approximately 100:1. With lower doses, the risk of adverse effects, ideally, should be less. However, massive intrathecal opiate overdoses have occasionally occurred during the course of filling or refilling the pumps, resulting in various adverse outcomes, including myoclonic seizures, pulmonary edema, respiratory depression, coma, and death.

The Food and Drug Administration (FDA) has received reports of fatal overdoses caused by the accidental intrathecal injection of concentrated morphine while Medtronic SynchroMed infusion pumps were being refilled. The SynchroMed pump, a titanium device, is surgically implanted under the skin in the abdomen or flank area with a catheter that resides in the intrathecal space. Centered on the front of the device is a small injection port leading to a drug reservoir. Reservoirs hold either a 10- or 18-mL volume and permit the drug supply to be replenished periodically via passage of a thin needle through the skin and into the reservoir port.

One model of the pump also has a second port on its periphery, which provides direct access to the intrathecal space via the catheter (Figure 1). This catheter access port is useful mainly for myelography, removal of cerebrospinal fluid (CSF), and troubleshooting problems such as catheter patency. According to an FDA MedWatch report that we reviewed at ISMP, attempts to refill the pump reservoir using the catheter access port resulted in the accidental injection of concentrated morphine into the intrathecal space. The patient died as a result. Similar errors have been reported in the literature.1,2

Fatal mishaps caused by selecting the wrong port during refilling of the pump still happen. In the pump’s refill kit, Medtronic supplies a template to locate the reservoir port; however, there is also a catheter access kit with a similar-looking template to find the side port for direct intrathecal access (Figure 2). If the wrong kit is used, the medication intended for the reservoir could be injected into the intrathecal space.

Medtronic has taken steps to reduce the risk of errors. The catheter access port accepts only a very thin needle, which is included in the kit. Even though the refill kit contains a larger needle that does not fit through the catheter access port, this safety feature does not prevent an error if a catheter access kit is accidentally used during a refill. In that situation, the template locates the port with direct access to the CSF, and the thin needle (provided with the kit) easily enters the port. In this way, medication intended for the drug reservoir could be injected into the catheter access port.

A pamphlet provided in the refill kit contains a vague picture on the cover to warn personnel not to use the side catheter access port for refilling. Written precautions appear inside the pamphlet, but these can be overlooked. A short written warning appears on the outside cover of the catheter access kit, but this might also be missed. The templates themselves offer no warnings that would help prevent such a devastating error.

SAFE PRACTICE RECOMMENDATION: Here are some suggestions to reduce errors when implantable pumps are used:

1. Prescriptions should be standardized.
   a. Standardized order sets should be created to address implanting, reprogramming, refilling, and other modalities (e.g., myelography) involving these pumps.
   b. Because the catheter access kit and refill kit have distinct product num-

Figure 1  Medtronic SynchroMed pump. The catheter access port is at the top, and the reservoir port is at the center. It is filled with medication through the skin with a needle that is inserted into a port at the center of the pump face.

Figure 2  SynchroMed templates. Clear plastic overlays are placed over the palpated pump to help locate the correct port. Left, The refill kit template allows only reservoir access. Right, The catheter access kit template allows only catheter access. Accidental use of this template during refilling of the pump has led to fatalities.
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Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP (www.ismp.org) or the USP (www.usp.org) Web site or communicated directly to ISMP by calling 1-800-FAILSAFE or via e-mail at ismp-info@ismp.org.


The reports described in this column were received through the USP-ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP (www.ismp.org) or the USP (www.usp.org) Web site or communicated directly to ISMP by calling 1-800-FAILSAFE or via e-mail at ismp-info@ismp.org.

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