Improved Safety Needed in Handling Elastomeric Reservoir Balls Used for Pain Relief

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PROBLEM: The ON-Q PainBuster Post-Op Pain Relief System (I-Flow LLC/Kimberly Clark) provides continuous infusion of a local anesthetic directly into the patient's surgical site for effective, non-narcotic postoperative pain relief for up to 5 days. However, many hospitals and outpatient surgical centers have reported potentially harmful practices associated with the device. One hospital reported a serious event that might have been linked to premature emptying of the reservoir ball that holds the medication. A patient had been sent home with an ON-Q pump filled with a local anesthetic. The surgeon asked the patient to come back in 5 days so that the pump could be refilled for another 5 days. Two days after the refill, the patient was brought to the emergency department (ED) in cardiac arrest.

The ED staff noticed that the medication reservoir ball of the ON-Q pump was empty. Initially, they did not know which drug the patient had received or how quickly it had been delivered because the device was unlabeled. Because of its simplicity of design, the ON-Q pump does not record the infusion history, so there was no record of how fast the drug was delivered.

When the ED staff learned that the pump contained a local anesthetic, a drug level was obtained. However, this laboratory test had to be performed by an external facility. The results were not readily available to help guide treatment or to determine the cause of the patient's cardiac arrest. Later, the local anesthetic level was found to be somewhat elevated. Rescue efforts were unsuccessful; the patient died, although his death did not appear to be related to the incident. The hospital staff could only speculate on the cause of the premature emptying of the medication reservoir ball (patient tampering was suggested) and whether drug toxicity played a role.

This article describes other potential problems associated with ON-Q pumps.

Lack of staff education. The Institute for Safe Medication Practices (ISMP) has received reports of patients with an ON-Q pump in postoperative units, where the staff had never seen the pumps and had not been instructed in how to use them.

Pumps used without the pharmacy's involvement. In many reported instances, the pumps were first used in a pilot test in the operating room (OR), or they were used regularly without the knowledge of the pharmacy. The first encounter with the device often occurred when nurses called the pharmacy because the reservoir ball was empty and they didn't know what to do, or the pharmacy staff was informed that a "pain ball" trial would begin the next day. One hospital reported that the only way the pharmacy knew about the use of the ON-Q pump was through unit-based pharmacists who happened to learn about them from nurses.

Lack of profiling of orders by the pharmacy. Even when a pharmacy knows how to use these devices, orders for the medications are rarely profiled or screened. In many cases, the pumps are started in the OR, and the "order" is part of the intraoperative documentation. As a result, an order is not sent to the pharmacy for drugs being delivered by the pump. Some pharmacists told the ISMP that they later began to use a standard order form for ON-Q pumps. One pharmacist revealed that she had to build special-order templates for the pumps. Pharmacists may also have to remember to screen for drug interactions and allergies if this screening does not occur automatically.

Medications prepared outside of the pharmacy. Many ON-Q pumps are not filled in the pharmacy; they are filled in the OR, where there is seldom a system of independent double-checks and where labeling and hand-off communication might not be sufficient.

The ISMP learned about an error in which the pumps for two patients were filled with a local anesthetic that contained **EPINEPH**rine rather than the local anesthetic alone. (Vasoconstrictors such as **EPINEPH**rine are not recommended for continuous infusion via ON-Q pumps.) In one case, the nurse noticed the error and corrected it after the patient received only 1 mL of the wrong drug. In the other case, severe tissue damage developed and the patient required follow-up care.

Pharmacy preparation of medications has sometimes been met with resistance because surgeons claim they don't know until the end of the procedure whether they want to use the pump. The product may also be marketed in a way that promotes physician autonomy and touts filling of the pumps by the surgeon or anesthesiologist in the OR as an advantage; however, the ISMP discourages this marketing strategy. One hospital pharmacist reported that she thought the pharmacy was preparing all medications for the ON-Q pumps, only to learn that surgeons were also preparing pumps in the OR.

Use of the pump with drugs other than local anesthetics. The ON-Q pump is designed to deliver local anesthetics to surgical sites for non-narcotic pain relief. The prescribing information suggests using ropivacaine (Naropin, Fresenius Kabi USA/APP), bupivacaine (Sensorcaine, AstraZeneca), or lidocaine (Xylocaine, AstraZeneca). However, I-Flow also provides information about stability when various local anesthetics

are mixed with dexamethasone (e.g., Decadron, Merck); ketorolac (Toradol, Roche) plus morphine sulfate (e.g., MS Contin, Purdue Pharma); ketorolac plus morphine; ceftriaxone (Rocephin, Roche); or ce**FAZ**olin (Ancef, GlaxoSmithKline). The implication is that mixing the local anesthetics with other drugs is safe and perhaps even effective. However, the company does not supply data to support this and does not make any specific recommendations about using these products with ON-Q pumps.

The ISMP also received reports that surgeons were adding vancomycin (Vancocin, Roche) and even fentanyl (Sublimaze, Janssen-Cilag), to the local anesthetic. With a simplistic pump that promises a delivery accuracy of ±15% of the labeled infusion rate (±20% for models with adjustable flow rates), using this pump with antibiotics and drugs such as ketorolac, morphine, and fentanyl might not be advisable.

Varying infusion rates. The accuracy of the pump's delivery rate depends on filling the reservoir ball with an exact amount of medication. The proper fill volume can vary, based on the type of pump and duration of therapy. Infusion rates are affected in the following situations:

- Overfilling or underfilling the reservoir ball results in variable infusion rates.
- The flow restrictor part of the pump must be in contact with the patient's skin and should be kept away from any cold therapy (e.g., ice packs), or the medication will be infused more slowly than expected (Table 1).
- Taping over the filter may affect the flow rate, as specified in Table 1.
- If the dial is not clicked into place at the proper numerical setting, flow rates can be unpredictable.
- Confusion may ensue if dual catheters are used to determine the correct infusion rate, with each port infusing half of the total volume of medication. If patients receive too much bupivacaine, ropivacaine, or lidocaine—the drugs most often used with ON-Q pumps—cardiotoxicity may result.

Varying concentrations. The ISMP heard from a pharmacist who viewed a

Table 1 Strategies for the Safe Use of ON-Q Pumps

Before Using the Pumps
• Grant privileges to surgeons through the credentialing process before they can insert the catheters and prescribe ON-Q pumps. • Establish protocols that include indications; models and tubing to be used for each indication; steps for prescribing, preparing, and dispensing the device and associated medications; testing of knowledge and skills; "hand-off" communication between practitioners; patient and family education; and patient monitoring. • Have the P&T committee approve the drugs that can be given by ON-Q pumps, taking into consideration the accuracy of the infusion rate (±15% to ±20% of the desired rate) and conditions that could influence the rate (e.g., heat and cold). • Ensure that clinical staff members are instructed before they use ON-Q pumps (even before a "trial" use). The manufacturer may provide orientation materials and some staff education upon request. • Include the signs of cardiotoxicity associated with bupivacaine, ropivacaine, and lidocaine and the risks associated with pump use.
Prescribing the Pumps
• Establish standard order sets for prescribing the pumps and specific medications. • Specify any concomitant analgesics that are acceptable or that should be avoided. • Require activation of the appropriate order set before the patient is transferred from the operating room. • Use the device for a maximum of 5 days without refills, as recommended by the manufacturer.
Placing the Catheters and Setting Up the Pumps
• Ensure that the catheter is properly inserted in the tissue or in the adjacent nerves surrounding a wound. Do not insert the catheter directly into a joint. • Label the pump with the name of the drug, the concentration, the infusion rate (in milliliters/hour and dose/hour), and the starting date. • Make sure that the adjustable rate controller (available on some models) is clicked into place under the specified rate of infusion. • Apply an occlusive dressing over the catheter insertion site. • Tape the flow restrictor to the patient's skin. Do not tape over the filter.
Dispensing the Pumps and Medication
• Establish standard concentrations for local anesthetics (and other drugs, if appropriate) used in the pumps. • Develop pharmacy-compounding procedures for preparing all mixtures of drugs. • Establish order sets in the pharmacy computer that will facilitate automated screening of the drug being used for the appropriate dose, drug interactions, allergies, and duplicated therapy. • Have the pharmacy prepare the medication reservoir balls following a protocol that specifies the exact amount of solution to instill based on the duration of therapy and the expected rate of infusion. Outsourced compounding may also be used. • In the pharmacy, require an independent double-check of the drug, its strength, and the total volume that was added to the reservoir ball by comparing the prescriber's order with the protocol.
Providing Nursing Care
• All medications administered via the pump must be listed as an entry on the nursing medication administration record (MAR). • Verify that the occlusive dressing over the catheter site is intact. • To ensure accurate flow rates, regularly check that the flow restrictor is taped to the patient's skin. • Keep the pump at room temperature. • Instruct patients to keep the pump in the carrying case on the outside of their clothing.

table continues

Table 1 Strategies for the Safe Use of ON-Q Pumps *continued*

- Keep the flow restrictor away from cold therapies such as ice packs.
- Monitor patients' level of pain and responses to medication while they are using this device.
- If the patient is discharged home with an ON-Q pump, remove the rate-changing key from the dial, and keep the key with the health care practitioner in case the patient's pump needs to be adjusted.
- Secure the plastic cover over the dial with a standard tie wrap.

Educating Patients

- Show patients and caregivers how the pump works.
- Mention the items that patients should check periodically (e.g., the flow restrictor is taped to the skin, the medication ball will appear to be getting smaller each day, and pain is under control).
- Instruct patients about the signs of cardiotoxicity, when to call the physician, and how to clamp the tubing to prevent further drug administration if necessary.
- Provide patients with the manufacturer's guidelines, available at www.iflo.com/prod_onq_classic.php.

hospital protocol for ON-Q pumps. More than 17 concentrations were available for bupivacaine, ropivacaine, and lidocaine, because the staff had changed the concentration when they needed to change the dose (similar to the Rule of 6). The use of nonstandard concentrations has contributed to errors in preparation and dosages.

Unlabeled medications. Sometimes the drug reservoir ball (or the pump's tubing) is not labeled, particularly when the ball has been filled in the OR. If there is no order for the drug or pump, the medication being administered may be unknown by those providing care to the patient.

Undocumented drug administration. If the pharmacy profiles orders for ON-Q pumps, the drug therapy may appear on the nurses' computer-generated medication administration record (MAR). However, several hospital staff members informed the ISMP that the ON-Q pump did not appear on their MARs and that they do not monitor or document the type and amount of drug administered via this delivery method.

Extended duration of use. Some physicians refill the ON-Q pump after 5 days of use even though the manufacturer states that the pump should not be refilled. This pump is intended for only a single use (up to 5 days). After this point, the pump should be removed and discarded. Longer use may lead to concerns about infection control.

Concomitant analgesics. As with other forms of analgesia delivery, there are concerns about indeterminate maximum doses of the local anesthetics delivered by the ON-Q pump and the possible concomitant use of analgesics by other routes of administration.

For example, many longstanding order sets already include intermittent or continuous pain medications that might still be given despite the use of ON-Q pumps. Because the pharmacy might not be aware of the pump's use or might not be profiling related orders, unnecessary and potentially dangerous duplicated therapy might not be identified correctly.

In one instance, an ISMP consultant visited a hospital, where he reviewed a patient's chart. He noted concurrent orders for an ON-Q pump, patient-controlled analgesia, and ketorolac every 8 hours.

SAFE PRACTICE RECOMMENDATION. Suggested strategies for improving safety when using ON-Q pumps are presented in Table 1. Problems relating to the management of ON-Q pumps, as discussed here, may also pertain to elastomeric pumps made by other companies. All staff members should take steps to reduce the risk of errors and adverse events associated with these pumps in order to maximize the potential benefits of this form of pain control.

A failure mode and effects analysis (FMEA) should be considered in hospitals that are currently using these devices or are considering their use. ■