PROBLEM: A 63-year-old opioid-naive patient, weighing 109 kg, was admitted to a hospital with fractures sustained in a fall. She was given two doses of morphine 4 mg and one dose of HYDROMORPHINE 1 mg in the emergency department.

Upon arrival at the inpatient unit, she was started on HYDROMORPHINE patient-controlled analgesia (PCA), which included a basal infusion of 0.5 mg/hour, a demand dose of 0.2 mg with a lockout interval of 10 minutes, and a 4-hour limit of 6 mg. Continuous pulse oximetry was not in use. Five hours later, the patient was found to be unresponsive. Her respirations were six per minute, and her nail beds were beginning to turn blue. Oxygen saturation was checked with pulse oximetry and found to be 44%.

The rapid response team was called, oxygen was started, and two doses of naloxone were administered. In 15 minutes, the patient was alert and talking. It was then that the patient told a nurse that she has had sleep apnea and had previously used a continuous positive airway pressure (CPAP) machine at home.

The patient hadn’t been using the CPAP machine recently. When the admitting nurse asked her whether she had used any medical equipment at home, she said “No.” The patient’s body mass index (BMI) was 38.6 (a BMI of 40 or more represents morbid obesity), placing her at risk for sleep apnea and hypoxemia during PCA therapy.

Although no permanent harm ensued, the hospital’s medication safety team used this case as a learning opportunity. Three root causes of the event were identified as follows.

Dosing guidance. The PCA standard order form did not help guide prescribers to select appropriate doses; instead, it provided a broad range of doses. For example, the range for a HYDROMORPHINE basal infusion dose was 0.1 to 0.5 mg/hour, and there was no guidance for selecting appropriate candidates for basal infusions. Many prescribers routinely selected a 0.5-mg/hour basal infusion, regardless of patient characteristics. A basal opioid infusion was not appropriate for this opioid-naive patient.

Studies have shown that patients with basal opioid infusions are at least five times more likely to experience respiratory depression.1–4 The American Pain Society cautions against using continuous basal infusions because studies have failed to demonstrate significant differences in the quality of analgesia with or without basal infusions.4 There might also be an increased risk of programming errors when basal infusions are prescribed.3

Patient screening. The patient was not sufficiently screened for obstructive sleep apnea and other risk factors for PCA-induced respiratory depression. The facility had a sleep apnea screening process in place for preoperative patients, but because this patient was not a surgical candidate, screening did not take place.

The incidence of respiratory depression in PCA patients ranges from 0.19% to 5.2%, depending on how it is measured.1,4 Table 1 includes risk factors for respiratory depression in PCA patients.

Patient monitoring. No process was in place to trigger an evaluation of the need for continuous pulse oximetry monitoring (or capnography for appropriate patients) during PCA.

SAFE PRACTICE RECOMMENDATIONS: The hospital’s medication safety team addressed these root causes by standardizing the PCA dosing process and revising the standard PCA order form as follows:

• The form guides prescribers to select an appropriate dose on the basis of the patient’s age and opioid tolerance by including default doses for three types of patients: most patients, patients older than 64 years of age or with sleep apnea, and opioid-tolerant patients.
• Basal infusions have been eliminated except in opioid-tolerant patients.
• Basal infusions are prohibited in patients with sleep apnea.
• Opioid orders are rearranged to match the sequence in which the medications appear on the facility’s smart intravenous pumps.
• A registered nurse is required to screen the patient for obstructive sleep apnea before initiating PCA. A respiratory therapist performs further assessment if the screening shows two or more risk factors (Table 2).
• Continuous pulse oximetry (or capnography, if appropriate) is required during PCA if the patient has a continuous opioid infusion or

Table 1 Risk Factors for Respiratory Depression During Patient-Controlled Analgesia (PCA)

- Use of basal infusion
- Advanced age
- Obesity
- Upper abdominal surgery
- Obstructive sleep apnea
- Concurrent use of central nervous system depressants
- Impaired renal, pulmonary, hepatic, or cardiac function
- Pump programming errors
- Families and visitors pushing the PCA buttons (PCA by proxy)
- Lack of opioid tolerance

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sleep apnea, if the patient is morbidly obese, or if the patient is older than 64 years of age.

• Education now includes instructions to the patient’s family not to push the PCA button for the patient (PCA by proxy).

• The hospital also uses smart pumps for PCA therapy, with one standardized concentration for each drug, and dose limits are set in the pump library. Before the conversion to smart pumps, two PCA programming errors had occurred in recent years, leading to serious respiratory depression. Vast improvements in programming accuracy have been reported since the switch to the smart pumps.

The Institute for Safe Medication Practices also recommends avoiding basal infusions unless the patient is “opioid-tolerant.” Unfortunately, this term is not well understood. It is defined as “those patients who have received opioids regularly for approximately 7 days or more.” Opioid-naive patients who present with high opioid requirements may be an exception and may require a basal infusion, but additional safety steps should be implemented under these conditions.

Our two-part series in P&T in December 2007 and January 2008 included many recommendations to improve PCA safety, including the following:6,7

• evaluating the patient’s level of pain, alertness, and vital signs, including rate and quality of respirations, every 2 to 4 hours.

• evaluating patients with minimal verbal and tactile stimulation to obtain an accurate assessment of their level of sedation.

• monitoring patients more frequently during the first 24 hours and at night, when hypoventilation and nocturnal hypoxia may occur.

• using early warning devices, such as apnea alarms at night, and pulse oximetry or capnography, which can alert practitioners to respiratory insufficiency.

References


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