



Commonwealth of Massachusetts
Board of Registration in Medicine
Quality and Patient Safety Division

**REVIEW OF SAFETY AND QUALITY REVIEWS INVOLVING HYDROMORPHONE
September 2012**

Over the last several years, the Quality and Patient Safety Division (QPSD) has received Safety and Quality Review (SQR) reports of serious complications associated with hydromorphone (Dilaudid®) administration. This advisory is issued to draw providers' attention to this concern, to share some of the lessons learned by the reporting hospitals, and to support hospitals in the development of protocols, competency standards and other processes to ensure the safety of hydromorphone administration and monitoring. While some references are provided, this advisory does not include a comprehensive review of the literature; nor is it intended to provide specific recommendations for evidence-based practice.

Background

In May 2007, the QPSD issued an Advisory after receiving a number of SQRs associated with the administration of hydromorphone and morphine.¹ The Advisory noted at that time a lack of available information on appropriate dosing and pharmacokinetics of the drugs and unrecognized respiratory depression following their administration. The Advisory recommended protocols for the use (including monitoring) of morphine and hydromorphone, attention to the storage of the two drugs to reduce confusion, dispensing and administration guidelines, and careful Root Cause Analysis of events and near-misses involving these drugs.

Overview

QPSD received 26 SQR reports describing complications associated with the use of hydromorphone since the last Advisory in 2007; significant mortality and morbidity were noted. Nearly half of the involved patients were younger than 60 years old, most were female and most events occurred on the night shift.

In most cases the patients had co-morbidities that may have made them vulnerable to respiratory depression: 23% were obese, 19% had obstructive sleep apnea (OSA), 15% had asthma and 15% had other chronic conditions that compromised their respiratory status.

Most of the patients were "found unresponsive" after earlier being described as somnolent, lethargic, restless, sleeping or snoring, without intervention at that time. Most of the patients had no cardiac, respiratory or oxygen saturation monitoring in place at the time of the occurrence. The route of administration of hydromorphone was IV push (70%); PCA pump (15%); and epidural, oral or subcutaneous (15%). QPSD found that 23% of the cases involved hydromorphone alone; 77% involved hydromorphone and morphine, lorazepam or other medications potentially having an "additive" effect (such as sedatives and anti-anxiety medications).

Case Studies

Case One

- A physician ordered hydromorphone 2-4 mg IV every 3 hours prn for a patient's abdominal pain. The nurse obtained the medication from Pyxis, using an override after checking the dosing guideline, which indicated this was an allowable dose. The nurse gave 4 mg IV hydromorphone for the patient's description of 8/10 pain. The patient, who was monitored, became bradycardic and suffered respiratory arrest.

Learning

Based on the findings from review of the case, the hospital now prohibits override of Pyxis for hydromorphone without prior review by the Pharmacist. The recommended dosing range for hydromorphone was decreased and physicians are prohibited from ordering hydromorphone with a dosage range. All patients who are prescribed hydromorphone must be on oxygen saturation monitoring and patients with significant co-morbidities (such as OSA) must also be on cardiac monitors.

Case Two

- A patient was discharged after an uncomplicated out-patient procedure with a prescription for hydromorphone 4 mg 1-2 tablets every 4 hours as needed for pain. He took 10 tablets over 24 hours, along with his usual diazepam and psychiatric medications, became unresponsive at home and was brought to the ED.

Learning

Appropriate hydromorphone dosing for in-patients and out-patients was discussed with physicians, including consideration of the patients' regular medications and whether they are opiate naive. Nurses will review all post-op discharge orders and question any unusual choices of medication and/or dosing. Comprehensive patient/family education regarding the use of medications, possible side effects, signs and symptoms of possible overdose is provided.

Case Three

- A resident physician was asked to write an order for analgesia for reduction of a fracture; he wrote the order for 1-2 mg hydromorphone IV x1 prn pain. The nurse administered 2 mg hydromorphone. Following the procedure the patient was brought for x-rays. While waiting in the Radiology area he had a respiratory arrest.

Learning

In this case, the hospital found that the order for narcotics was written by an inexperienced resident without discussion with the supervising physician. The nurse gave the larger dose of hydromorphone based on her observation of the patient's pain. The procedure was done and the patient was moved to a hallway following the procedure, without oxygen saturation or cardiovascular monitoring. Two mg of hydromorphone given intravenously to an elderly patient with multiple co-morbidities will result in sedation that must be monitored.

Systems Improvements

A focus on systems improvement actions such as constraints, standardization, policy changes and education with monitoring, are stronger actions that are more likely to improve the safety of hydromorphone use.²

Some of the patient safety measures implemented by hospitals following these events are described.

Ordering Constraints and Standardization:

- Dosing and timing ranges for hydromorphone (and other opiates) were eliminated. Standard order sets were created for hydromorphone, and verbal orders were limited to dose changes. For example, one hospital limits dosing orders to 0.5 mg IV every 4 hours unless the patient is continuously monitored and under supervision of the Anesthesia service or a Pain Management physician. A Comprehensive Pain Service is now available to both inpatient and outpatient services.
- Hospital stock of hydromorphone was limited to 1 mg/ml vials and floor access was eliminated or tightly controlled and monitored.
- The override function for removal of hydromorphone from automated dispensing cabinets was eliminated.
- Some hospitals discourage the use of hydromorphone as a first line narcotic analgesic and require consultation/approval of Anesthesia or Pharmacy.

Education:

- The morphine/hydromorphone dosing equivalency (1:8) is frequently reinforced with both nurses and physicians.
- Physicians are discouraged from prescribing hydromorphone following outpatient procedures, particularly for those patients with respiratory or airway issues, or with medications that may have an additive effect to respiratory or CNS depression. Patients discharged with hydromorphone prescriptions are provided clear and detailed instructions for use, with precautions and warnings for concomitant use of other meds or alcohol.
- All patients for whom hydromorphone is considered are evaluated for OSA.

Policy:

- The clinicians who prescribe and administer hydromorphone are required to undergo a privileging process and annual competencies to verify proficiency with pain management and reversal.
- Medical records must include documentation that the prescriber considered important patient information that could affect the prescribing of hydromorphone (such as concomitant meds that can have an additive CNS or respiratory depressant side effect, age, impaired renal function).
- Patients prescribed hydromorphone are monitored (oxygen saturation, cardiac monitoring and increased vital sign checks) with particular attention to the following circumstances:
 - Patients with a past medical history of diabetes, obesity, respiratory diseases or those diseases potentially affecting their breathing (such as a history of pulmonary embolus, polio or amyotrophic lateral sclerosis) and patients who are post-op procedures involving their neck;
 - Patients who receive other medications having a respiratory or CNS depressant effect, including morphine, lorazepam, diphenhydramine, zolpidem, diazepam, and operative analgesia; and

- When patients are transported to an area with potentially limited observation, such as Radiology.
- Clear guidelines are established for physician or Rapid Response Team notification following staff (or family) findings of decreased mental or respiratory status.
- A High Alert Team investigates all adverse events involving hydromorphone.
- Nursing hand-off reports were standardized to include medications given and time of last (or next) dose.
- Documentation of pain assessment/reassessment after medication administration is audited, with immediate provider feedback and education

Conclusion

Use of hydromorphone in the hospital setting can lead to significant adverse reactions including respiratory arrest. The higher potency of hydromorphone relative to morphine, presence of co-morbidities such as obstructive sleep apnea, and concomitant use of medications that may have an additive depressive effect on respiratory and/or central nervous systems are important factors to consider when evaluating facility safety procedures. When developing guidelines and protocols for hydromorphone use, facilities should consider annual pain management competencies during the privileging process, staff education, restrictions on floor access to drug stock, limits on provider orders without pharmacy or pain service consultation and routine cardiac/respiratory monitoring of all at-risk patients and those receiving intravenous dosing.

End Notes:

¹Commonwealth of Massachusetts Board of Registration in Medicine. Patient Care Assessment Division. Hydromorphone: patient safety concerns with hydromorphone versus morphine. Advisory. May 2007. <http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/hydromorphone.pdf>.

²Commonwealth of Massachusetts Board of Registration in Medicine – Quality and Patient Safety Division. Assessing the strength of health care facility improvement actions. February 2012. <http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/assessing-strength.pdf>

Additional Resources:

Adverse drug events with HYDROmorphine: how preventable are they? Pennsylvania Patient Safety Advisory 2010 Sep; 7(3):69-75.
[http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7\(3\)/Pages/69.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7(3)/Pages/69.aspx)

Commonwealth of Massachusetts Board of Registration in Medicine - Quality and Patient Safety Division. Assessing the strength of health care facility improvement actions. February 2012.
<http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/assessing-strength.pdf>

Safe use of opioids in hospitals. Sentinel Event Alert. 2012 Aug 8; (49): 1-5.
http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf