Emergency Physicians Insurance eXchange

EPIX Patient Safety Briefs

Preventing Dilaudid (HYDROmorphone) Adverse Drug Events

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A hospitalized patient experiencing pain receives an overdose of intravenous Dilaudid (HYDROmorphone) after a physician prescribes the IV dose in the same amount as the oral dose the patient had been taking at home; neither the pharmacist nor nurse captures the error.

A nurse administers the wrong dose of HYDROmorphone confusing it with morphine.

These are not uncommon scenarios...

EPIX has seen a number of claims related to adverse drug events from Dilaudid (HYDROmorphone). Errors in the administration and dosage can be fatal. The Pennsylvania Patient Safety Authority (PA PSA) issued a memo after noting over 1694 reports of medication errors related to Dilaudid over a 20 month period.[1] A Canadian study reported 251 deaths from Dilaudid overdoses in the province of Ontario from 1985 to 2003.[2] Fatalities can occur at 51 ng/mL or more.[2] The FDA approved labeling was revised for Dilaudid® (1 mg/mL, 2 mg/mL, 4 mg/mL) and Dilaudid-HP (10 mg/mL) to help prevent associated medication errors.[3]

Dilaudid is a semisynthetic opioid agonist used to treat chronic pain, such as patients with cancer, as well as acute pain, such as an acute onset of abdominal pain. It has been listed in the top ten drugs causing patient harm by the MEDMARX database, the PA PSA, and the Office of Inspector General (OIG) Department of Health and Human Services report on "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries."[4, 16] Other organizations have issued safety alerts as well, the Institute for Safe Medication Practices (ISMP) and the Food and Drug Administration (FDA). It is unsettling that a drug used as frequently as Dilaudid (HYDROmorphone) can lead to so many adverse events, medication errors, and gaps in knowledge about its efficacy and potency.

Some hospitals either use just the brand name *Dilaudid* or the generic and brand name together such as *Dilaudid (HYDROmorphone)*. This is because of the many errors in which nursing staff confused

HYDROmorphone with morphine. For this reason, tall man lettering was used to try and distinguish it from morphine. This is also why ISMP created the *home run = touchdown* scenario. If you get a home run you score 1 point so a 1 mg dose of Dilaudid is equivalent to 7mg of morphine. In football, each touchdown gives you 7 points.

One study in an emergency department at an academic medical center looked at 198 patients presenting with severe pain. The ED physicians and nurses were reluctant to give 7 to 10 mg of morphine. However, it was observed that most of the same practitioners were not reluctant to give a dose of Dilaudid that was equivalent.[14]

Dilaudid also has a black box warning. Anyone involved in ordering or giving this medication should be familiar with the black box warning.

Black Box Warning

High Potency Formulation

Highly concentrated HYDROmorphone injection (10 mg/mL) indicated only in opioid-tolerant patients; do not confuse with standard parenteral opioid formulations; overdose and death could result.

Abuse Potential, Resp. Depression

Potent Schedule II opioid agonist w/ high abuse potential and respiratory depression risk; concomitant alcohol, other opioids, and CNS depressants may increase the risk of potentially fatal respiratory depression.[5]

Risk Reduction Strategies

Consider the following Dilaudid (HYDROmorphone) safe-use guidelines for dosing, monitoring, storage, pain management, and patient safety:

Storage

- **Store Dilaudid separately from morphine** in the automated dispensing cabinet (ADC) and take steps to ensure staff does not confuse the two drugs through distinct labeling.
- Do not store Dilaudid and morphine in the same strength. For example, store 2 mg (or less) vials of Dilaudid and 4 mg vials of morphine.
- Ensure that the pharmacy has a process in place to prevent them from mistakenly placing morphine in drug dispensing machines instead of Dilaudid.
- Request that the pharmacy always label as *Dilaudid* or *Dilaudid (HYDROmorphone)* to avoid confusion with morphine and use tall man lettering. Use both the brand name of Dilaudid and generic name on order sets, electronic orders, and medication administration records. Seventy percent of the wrong drug reports involved mix-ups with morphine.[1]
- **If narcotics are stored in an automated medication dispensing machine, or ADC, allow emergency access to morphine, but consider requiring pharmacy review of all orders for Dilaudid prior to administration.**[1] This recommendation may not be practical in some facilities if it results in a delay in timely medicating a patient in need.
- Consider putting Dilaudid (HYDROmorphone) on the high-alert medication list. Some emergency departments require an independent double check when removed from the automated dispensing cabinet. Some ADCs may require a witness. Some ADCs have the capability of asking *"This is DILAUDID. Is that correct?"* when nurses retrieve it from the

system.[10]

Dosing

- Overdosing of patients with Dilaudid appears to be complicated by physicians and nurses not recognizing a safe dose. The literature has inconsistent recommendations about the appropriate starting dose and frequency:[6]
    - The current recommended dose (Lexi-Comp) is 0.2 to 0.6 mg every 2 to 3 hours for opioid-naïve patients and 1-2 mg every 3 to 4 hours for acute pain. Some facilities may start out with 0.5 mg IV. Some facilities are stocking 4 mg doses of Dilaudid in the ED and routinely administering doses of 1 mg or more. **It is highly recommended to not stock 4 mg doses.** For patient safety the FDA reduced the labeling requirements to 0.2 mg to 1 mg (originally 1 mg to 2 mg).[3]
- **Be sure your facility does not allow titrating orders, such as "1- 4 mg IV push until pain is relieved."**
- Make sure your providers are aware of the current recommendation for dosing and use the lowest possible dose. Consider working with the pharmacy and therapeutics committee to draft a pain management protocol or guideline. Many guidelines start out with a dose of 0.5 mg IV.
- IV Dilaudid (HYDROmorphone) should be given over 2 to 3 minutes. The nurse should document this in the medical record such as *Dilaudid given over 3 minutes from 1600 to 1603*. The onset of action after IV Dilaudid is 5 minutes and it peaks at 20 minutes. It can remain working 4 to 5 hours. It can also be given by epidural, orally, and by IM and subcutaneous injections.
- Use dosing charts in the emergency department and in the computerized order entry system and pharmacy information system.

Protocols on Pain Management and Reversal Agents

- Standardize pain management protocols and protocols on the use of reversal agents. Use a standardized format for documenting pain control and monitoring parameters.[7]
- *Ensure that oxygen and Narcan (naloxone) is available where opioids are administered.* The ED may want to establish a protocol for reversal agents as a standing order that the nurse can use if the emergency physician or provider is tied up. The provider can sign the order off later after the patient is stabilized.

Monitoring

- Adopt guidelines regarding the need for **repeat vital signs** (including pulse oximetry) and timeframes for discharge of patients following narcotic administration. Dilaudid has caused severe hypotension and confusion in some patients.
- **Make sure patients who receive Dilaudid are monitored and closely observed.** Consider use of capnography measure or ETCO2 in high-risk patients and patients on a Dilaudid patient controlled analgesia (PCA) pump. End tidal CO2 can detect early signs of inadequate ventilation and provide an earlier warning than the pulse oximetry.
- CMS, Hospital Conditions of Participation (CoPs), under tag number 405 and 409, require hospitals to have a policy on patients receiving opioids. The policy **must include how often vital signs are to be taken in addition to what must be done to assess patients** such as blood pressure, respiratory rate, pulse rate, pulse oximetry, and when ETCO2 must be used.
    - An article from the ISMP recommended that staff do not rely on pulse oximetry readings alone to detect opiate toxicity. Use capnography to detect respiratory changes caused by opiates, especially for high-risk patients.[9]

- Dilaudid can increase the potential for falling in patients especially who are at high risk so staff should inform patients to call for assistance.
- Dilaudid can increase delirium in patients at high risk.[4]
- Observe patients for any signs of hives and significant itching and ensure the emergency department physician or provider is immediately notified of any adverse drug event (ADE). The most common reactions reported to the PA Patient Safety Authority were central nervous system reactions and respiratory complications. Narcan (naloxone) can be given to patients with respiratory depression.
- Some practitioners will order an antiemetic along with the Dilaudid to prevent nausea and vomiting.
- Dilaudid (HYDROmorphone) can cause miosis, or pinpoint pupils, a common sign of opioid overdose.

High-risk Patients

- **Be aware of special risk patients who should not receive, or only cautiously receive, Dilaudid.** In such patients, *even moderate therapeutic doses of narcotic analgesics dangerously decrease pulmonary ventilation* while simultaneously increasing airway resistance to the point of apnea or even death.[11, 12] Patients with the following conditions have contraindications/cautions to Dilaudid use:
    - Asthma, acute or severe
    - Elderly (older than 65) or debilitated patients
    - Chronic obstructive pulmonary disease (COPD) or cor pulmonale; patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression
    - CHF, sleep apnea, renal, hepatic or pulmonary impairment.
    - Acute alcohol use or other opioids and central nervous system depressants (sedative hypnotics)
    - Severe renal or liver failure, hypothyroidism, Addison's disease, psychosis, gall bladder disease, or delirium tremens
    - Patients on drugs that can potentiate sedation such as benzodiazepines
    - History of substance abuse
    - Sensitivity to latex or sulfites[8,Smith as quoted by Howard]
- A complete list of cautions is available at https://online.epocrates.com/u/10b229/hydromorphone/Black+Box+Warnings.

Admission, Transfer, Testing, or Discharge

- If patients are to be admitted and you are writing a transition order for admission that includes Dilaudid, **include an order for frequent monitoring of the patients with complete vital signs on the floor as well as an order instructing nursing to notify the attending physician if pain is ongoing**. Some groups only write for one dose of pain medication so the attending provider will be notified if the patient complains of ongoing, unrelieved pain.
- Use a *ticket to ride* or other process to communicate to the transport team, radiology staff, ultrasound staff or others that are caring for the patient so they are aware that the patient has been given Dilaudid and continue use of the pulse ox.
- **Make sure radiology staff who return the patient back to the ED after an x-ray connect the patient back up to their pulse ox.**
- Consider use of a wheelchair to discharge any patient who has received a dose of Dilaudid.

Education

- Provide education to all staff at orientation and annually that includes risk reduction strategies for Dilaudid use in the ED. Include information on prescribing, monitoring, and safe use, including dosing norms especially for the management of opioid-naïve patients. The PA Patient Safety Authority has five self-assessment questions that can be used for education and assessment. It is located at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Pages/home.aspx.
- Consider annual competency assessments for all physicians and providers who prescribe Dilaudid (HYDROmorphone). The PA PSA also has a HYDROmorphone Risk Reduction toolkit on "Prescribing Considerations Associated with HYDROmorphone" at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/hydromorphone/Documents/insert.pdf.
- Some hospitals require emergency department physicians and providers to undergo a privileging process to verify proficiency with PCA pain management. Some emergency departments are using PCA especially those with a boarding and overcrowding issue as there may be a significant delay in getting patients to their room when admitted.[13]

*Written by Jeanie Taylor RN, BSN in March, 2012 and revised and updated by Sue Dill Calloway RN, MSN, JD June, 2016.

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