Safety of an ED High-Dose Opioid Protocol for Sickle Cell Disease Pain

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Introduction: A nurse-initiated high dose, opioid protocol for vaso-occlusive crisis (VOC) was implemented. Total intravenous morphine sulfate equivalents (IVMSE) in mgs] and safety was evaluated.

Methods: A medical record review was conducted for all ED visits in adult patients with VOC post protocol implementation. Opioids doses and routes administered during the ED stay, and six hours into the hospital admission were abstracted and total IVMSE administered calculated. Oxygen saturation (SPO2), respiratory rate (RR), administration of naloxone or vasoactive medications, evidence of respiratory arrest, or any other types of resuscitation effort were abstracted. A RR of <10 or SPO2 <92% were coded as abnormal. Descriptive statistics report the total dose. Logistic regression was used to predict abnormal events. Predictors were age, gender, ED dose (10 mg increments) administered, and time from 1st dose to discharge from ED.

Results: 72 patients, 603 visits, 276 admitted. The total (ED & hospital dose) mean (95% CI) mg IVMSE administered for all visits was 93 mg (CI 86, 100), ED visit 63 mg (CI 59, 67) and hospital 66 mg (CI 59, 72). The mean (SD) time from administration of 1st analgesic dose to discharge from the ED was 203 (143) minutes, (range = 30-1396 minutes). During two visits, patients experienced a RR <10; while 61 visits were associated with a SPO2 <92%. No medications were administered, or resuscitative measures required. Controlling for demographics and evaluated at the average total ED dose, the longer patients were in the ED, patients were 1.359 times more likely to experience an abnormal vital sign. Controlling for demographics and evaluated at the average total time in the ED, for every 10 mg increase in IVMSE, patients were 1.057 times more likely to experience an abnormal vital sign. The effect of ED dose on the odds of experiencing an abnormal vital sign decreased by a multiplicative factor of 0.0970 for every 1 hour increase in time until discharge. The larger the dose administered in less time, the more likely patients experienced an abnormal vital sign.

Discussion: High opioid doses were safely administered to patients with sickle cell disease.

Key words: Pain; Sickle cell; Emergency department

Between 1999 and 2007 nearly 1.5 million visits were made to emergency departments in the United States for the treatment of sickle cell disease (SCD). Of these visits, 67% were for management of vaso-occlusive crisis (VOC) pain, and 11% were for chest pain.[1] VOC pain is severe, onset is sudden, and it typically requires treatment with intravenous opioids. Guidelines from the American Pain Society and National Heart, Lung and Blood Institute are outdated, thus lending little guidance regarding VOC treatment.[2,3] In an effort to provide evidence-based recommendations for the ED management of VOC, the National Heart, Lung and Blood Institute will release an Expert Panel Report, *Evidence-Based Management of Sickle Cell Disease*, in 2014.[4] Approximately 50% of adults with SCD experience chronic pain requiring daily at-home opioid use.[5] The resultant opioid tolerance that develops often necessitates very high analgesic doses when the patient experiences a VOC.

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Nevertheless, some emergency care providers resist administering opioids in large quantities or in short dosing intervals.

Previous investigations have supported the safety and efficacy of opioid titration protocols for patients with severe pain in an ED setting.[6–11] However, total doses administered in these studies ranged between 3.3[9] and 12.6 mg[6] of intravenous morphine sulfate equivalents (IVMSEs), an amount significantly less than is often required by opioid-tolerant patients. Furthermore, none of these studies included patients with SCD, nor did they report total opioid doses administered over the entire ED stay. Although no existing data describe a typical analgesia dose for opioid-tolerant individuals, anecdotal experience indicates that some patients with SCD have required (and have tolerated) up to 12 mg of IV hydromorphone in a single dose.

Thus, the safety of a high-dose opioid protocol involving frequent opioid readministration for unrelieved pain in a population of adults with VOC treated in the emergency department remained to be investigated. In the present study, such a protocol was implemented. We report the opioid dosing of a cohort of patients with VOC received in one emergency department and the safety of the protocol. To more fully assess the effects of analgesics administered in the emergency department, the study also included any doses administered (and their safety outcomes) during the first 6 inpatient hours for all subjects who were admitted to the hospital.

The aims of this project were to (1) report the total IV morphine sulfate equivalents (in milligrams) administered throughout the entire ED visit and during the first 6 inpatient hours, if the patient was admitted (the data collection time frame); (2) investigate the frequency of abnormal vital sign findings (low respiratory rate or oxygen saturation) and the need for interventions (opioid reversal or resuscitation measures) that occurred during the data collection time frame; and (3) identify key predictors of abnormal vital signs and the need for rescue interventions, if required.

Methods

DESIGN

A retrospective, structured medical record review was conducted at the hospital in which the protocol was implemented. Institutional Review Board approval was obtained at the study site, and a waiver of verbal and written consent was obtained.

SETTING

The project was conducted in a large, urban emergency department with approximately 80,000 annual visits. The study facility is a not-for-profit teaching hospital located in the Midwestern United States, with a 4-year emergency medicine residency program. The ED care team is composed of approximately 100 staff nurses, 30 ED faculty physicians, and 40 ED resident physicians. This particular hospital was selected as the study site because it averages 2 adult visits per day for SCD. Quality improvement evaluation at the facility noted significant analgesia administration delays, and both patients and providers expressed frustration with the care delivered. There was also considerable physician and nurse variability in how analgesics were ordered and delivered to individual patients.

SAMPLE

All adults (≥ 18 years old) with SCD treated at the research site emergency department for a VOC (as defined by the International Classification for Diseases, 9th revision) during the 13-month study period (August 2008 through September 2009) were eligible for inclusion. Exclusion criteria for both the study and the analgesia protocol included (1) allergy to morphine sulfate or hydromorphone; (2) abnormal vital signs upon arrival defined as temperature > 38.3 °C (101 °F), heart rate > 110 beats/min, respiratory rate < 10 or > 24 breaths/min, or a pulse oximeter saturation level < 93% on room air; and (3) the presence of specific symptoms: atypical chest pain, shortness of breath, severe headache, dizziness or other neurologic or mental status symptoms, priapism, or abdominal pain.

VOC ANALGESIC PROTOCOL

A multidisciplinary SCD quality improvement team consisting of a hematologist, ED physicians and nurses, and a patient with SCD developed an analgesic protocol (Figure) and monitored outcomes, as reported elsewhere.[12,13] Briefly, the protocol guided the nurse to administer an initial opioid dose prior to physician evaluation of the patient and then to provide a second and third dose after notifying the attending ED physician or a third- or fourth-year emergency medicine resident. A minimum of 20 minutes was required between doses, and only 3 doses were included in the protocol. A respiratory rate of less than 10 breaths per minute or a sedation score of 2/4 or 3/4 on the hospital-approved sedation scoring tool precluded administration of additional analgesia. The hospital-approved sedation scoring tool was as follows:

0 = None (awake and alert): Administer opioid if still in pain
1 = Mild (responds to normal voice): Administer opioid if still in pain
2 = Moderate (responds to loud voice/shaking): Hold opioid, assess SpO_2 and respiratory rate