

**County Alameda
Public Health Department
Emergency Medical Services Division**

**Trial Study
The Prehospital Use of Fentanyl**

18 Month Report

March 24, 2009

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AN ANALYSIS OF THE PARAMEDIC ADMINISTRATION OF FENTANYL

INTRODUCTION

Pain is a common complaint in emergency medical services (EMS) patients. It is estimated that 14.8 million patients are transported by ambulance to emergency departments annually, and that 20 percent of them, approximately 2.9 million, have moderate to severe pain (McClean, Maio & Domeier, 2002, pp. 402- 405). In most EMS jurisdictions nationwide, paramedics manage pain with intravenous or intramuscular morphine sulfate (McManus & Sallee, 2005). Morphine sulfate has numerous side effects that include respiratory depression, hypotension, xerostomia, nausea and vomiting. Fentanyl and morphine are both counteracted by naloxone; however, fentanyl has a shorter onset of action, shorter duration, and far fewer side effects making it an appealing candidate for pre-hospital pain management. Little research exists regarding the use of fentanyl in the pre-hospital environment. Published studies show fentanyl to be a safe and effective alternative to morphine for out-of-hospital analgesia, citing a low clinical incidence of adverse reactions (Kanowitz, Dunn, Kanowitz, Dunn & VanBuskirk, 2006, pp. 1 - 7).

This study's intent is to prospectively assess the characteristics of the paramedic administration of fentanyl. Three transporting fire departments sought to determine if paramedics were able to adequately assess patient pain and safely utilize fentanyl to treat that pain in pediatric and adult patients. In addition the present study sought to retrospectively compare several clinical characteristics in patients treated with morphine sulfate to those within the fentanyl study group.

METHODS

Design

This was a prospective non-randomized study that compared select data to historical controls. Data for the patients who received fentanyl was compared to the patients who received morphine sulfate from an identical time period exactly one year prior. The design was approved by the Alameda County Medical Center/Alameda County Department of Public Health Institutional Review Board.

Setting

Three municipal fire departments in Alameda County participated in this study: Berkeley Fire Department, Albany Fire Department, and Piedmont Fire Department. All three agencies provide advanced life support (ALS) transport services with ambulances staffed by two paramedics. The cities served by the three agencies range in population from 10,952, in Piedmont, to 102,743, in Berkeley, and Albany at 16,444. Combined, the three fire departments respond to approximately 9000 medical aid requests per year and they treat an estimated four percent of these patients with opioid analgesics. Pain management is provided by an ALS paramedic according to Alameda County EMS protocol during transport to the receiving hospital. The three city fire departments are components of the Alameda County EMS System.

In the State of California, morphine sulfate is the only option for EMS practitioners for pain management. Fentanyl is not a component of the state paramedic scope of practice. The California EMS Authority approved this investigation as a "pilot study" pursuant to Health and Safety Code, Division 25, Section 1797.221.

Population

Between September 2007 and March 2009, patients received fentanyl if they presented with moderate to severe pain, requested pain control, and were six months old or greater. Moderate to severe pain was represented as a pain score of 4/10 or higher on any of the four pain scales used by the Alameda County EMS system. All findings and treatments were documented on a supplemental form specific to the fentanyl trial. Exclusion criteria included a history of renal or hepatic insufficiency, known opioid allergies, acute hemodynamic, respiratory, or neurological compromise, and head trauma. Patients who had already received opioid analgesics prior to paramedic arrival and patients whose care deviated from County or study protocols were also excluded. The researchers reviewed the charts of all patients who were treated with morphine by EMS personnel from the three fire departments between September 2006 and February 2007.

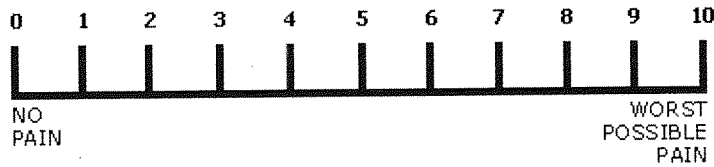
Intervention

The study intervention consisted of the participating agencies paramedics attending a two hour training session which first reviewed patient pain assessment and separately fentanyl administration. The instructions covered documentation, Alameda County EMS pain management protocols, narcotic diversion, research data collection, and patient pain assessment scoring.

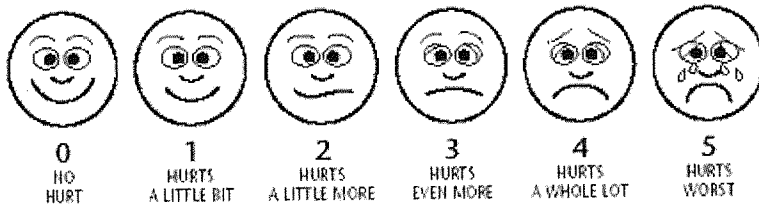
Paramedics utilized the Numeric Pain Scale (NPS) for all adult patients, the Wong Baker “Faces” scale for pediatrics, and the Face Legs Activity Cry Consolability scale (FLACC) for infants and children. Paramedics utilized the Pain Assessment in Advanced Dementia scale (PAINAD) for patients with dementia or cognitive impairment. All four scales provide pain scores ranging from 0 to 10.(See Figure 1.)

Figure 1.

NPS



Wong Baker Scale



FLACC

Category	Scoring		
	1	2	3
Face	No Particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly normal position, moves easily	Squirming, shifting back and forth, tense	Arched, ridged or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs; frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

PAINAD

Items	0	1	2
Breathing independent of vocalization	Normal	Occasional labored breathing. Short period of hyperventilation.	Noisy labored breathing. Long period of hyperventilation. Cheyne – Stokes respirations.
Negative vocalization	None	Occasional moan or groan. Lowlevel speech with a negative or disapproving quality.	Repeated troubled calling out. Loud moaning or groaning. Crying.
Facial Expressions	Smiling or inexpressive	Sad. Frightened. Frown.	Facial grimacing.
Body Language	Relaxed	Tense. Distressed pacing. Fidgeting.	Rigid. Fists clenched. Knees pulled up. Pulling or pushing away. Striking out.
Consolability	No need to console	Distracted or reassured by voice or touch.	Unable to console, distract or reassure.

The fentanyl was packaged in a concentration of 100 µcg/ 2 mL of normal saline, and paramedics administered fentanyl either IV or IM at 1 microgram per kilogram (1 µcg/kg) as a first dose for all included patients. Second and subsequent doses were repeated every 5 minutes at ½ the initial dose to a maximum of 3 µcg/kg, or until the patient was pain free or resting comfortably. Paramedics were directed to use half the dosage in patients over the age of 65 years. All patients were continuously monitored for changes in vital signs.

Paramedics completed a data collection form for every patient who received fentanyl (Table X).

Outcome Measures

The primary outcome measure was the reduction of pain from the time of initial patient assessment to the transfer of the patient care to emergency department staff.

DATA COLLECTION AND ANALYSIS

Population

From September 2007 to November 2008 a total of 318 patients were administered fentanyl. The categorical analyses of those administrations were as follows:

- Trauma = 206 (65%)
- Medical = 98 (31%)
- Cardiac/CHF = 11 (3%)
- Burns = 3 (1%)

The age ranges of these patients were as follows:

- 0 – 15 = 14 (4%)
- 16 – 25 = 40 (13%)
- 26 – 45 = 94 (29%)
- 46 – 65 = 91 (29%)
- 66+ = 79 (25%)

Of the 318 patients who received fentanyl only three adverse reactions were reported; two reported dizziness (0.006%) and one reported nausea (0.003%). No vital sign abnormalities were noted and none required naloxone for reversal. Only one of the 318 patients reviewed was excluded from the study due to a paramedic protocol violation (Noted in discussion). No incidents of diversion were reported by any of the three participating fire departments.

Fentanyl vs. Morphine Comparison

Of the 159 patients that received fentanyl during the documented time frame of September 1, 2007 to February 28, 2008, one (1) exclusion due to treatment error. 158 patients were compared to 83 patients one year prior who received morphine.

The retrospective chart review, found that 83 patients received morphine, but, due to poor patient assessments and documentation, by the treating paramedic, only 66 of the reported patient care reports contained usable data.

In this study, the onset of action for the reduction of patient pain was notably more rapid with fentanyl citrate than morphine sulfate. As displayed in figure 2, 16.6% of the patients that received fentanyl as compared to 2% morphine subjectively noted pain relief in under one (1) minute, 47% of fentanyl verses 14% of morphine at one (1) to two (2) minutes, 19.9% of fentanyl verses 36.0 % at two (2) to three (3) minutes, and 16.6% of fentanyl verses 48.0% of morphine at greater than three (3) minutes.

The reduction of pain, as noted on a one (1) to 10 pain scale in figure 3, was found to be almost double with fentanyl, 3.82 point pain reduction, as compared to morphine, two (2) point pain reduction, upon transfer of care (TOC) to the emergency department (ED).