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ORIGINAL RESEARCH

Intranasal Fentanyl for On-the-Hill Analgesia by Ski Patrol

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Introduction—Intranasal fentanyl offers a means for safe and effective pain management in austere environments. Prehospital analgesia traditionally involves intravenous or intramuscular medication. However, for wilderness rescuers, these methods are often impractical.

Methods—We conducted a retrospective review of health records to evaluate the safety and efficacy of intranasal fentanyl administered by EMT-Basic certified ski patrollers. Our primary aim was to measure the reduction in initial pain scores to subsequent measurements at 5, 10, and 15 min using the pain numeric rating scale (0–10). Clinically significant reduction in severe pain has been established as ≥1.8 points. We used paired t-tests and multilevel modeling to measure statistical significance and potential interactions and reviewed patient charts for adverse events, including respiratory depression or the use of naloxone.

Results—We compiled the results from the winter seasons for 2007 through 2012 and 2016 through 2020. A total of 247 patients were included. The initial pain score was 8.6±1.5 (mean±SD). The decrease in pain scores from 0 to 5, 10, and 15 min, respectively, was −1.8, −2.4, and −2.9 (P<0.0001), which demonstrated a clinically and statistically significant decrease in pain scores. There were no adverse events.

Conclusions—Traditional standard of care analgesics are invasive, elongate scene times, and increase the risk of environmental exposure and provider needlestick. Intranasal fentanyl offers a safe, noninvasive, and rapid analgesia that is well-suited for austere winter environments, such as those encountered at ski resorts. This study demonstrates the safety and efficacy of the administration of intranasal fentanyl by EMT-Basic certified providers.

Keywords: alpine ski accidents, winter rescue, prehospital, EMS, pain management

Introduction

The undertreatment of acute pain continues to be a pervasive problem in the prehospital setting.[1–4] Adequate pain control can decrease the risk of subsequently developing posttraumatic stress disorder.[5] Barriers to timely and effective prehospital analgesia include lack of certified personnel and restrictive protocols.[6–10] For rescuers like ski patrollers, these barriers are further compounded by the unique difficulties of a winter environment. The transport of an injured patient by ski patrol often involves a long and uncomfortable sled ride, with transport times ranging from 10 min to more than an hour for more prolonged evacuations. On-the-hill analgesia can rapidly reduce the patient's pain and mitigate worsening pain with movement and positioning during wilderness transport. Traditionally, the standard of care for analgesia in the prehospital setting has been the use of intravenous (IV) or intramuscular (IM) medications.[8] Intranasal administration of medications has become increasingly used because of its noninvasive nature, decreased time to administration, and reduced risk of needlestick injury.[4,11,12] In the winter wilderness setting, the invasive nature of IM/IV access necessitates exposing the patient—increasing risk for hypothermia

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and risk of unpredictable drug efficacy due to potentially decreased extremity perfusion.[4]

Fentanyl is a lipophilic, potent opioid analgesic and is thus ideally suited for intranasal (IN) administration. Intranasal fentanyl has an onset of 2-7 min and a duration of just under an hour, making it highly comparable to IV opioids.[13,14] Numerous studies have demonstrated the safety and equivalent efficacy of IN fentanyl as compared with IM/IV morphine,[4,13,15–18] IV fentanyl,[14,19] and subcutaneous (SQ) fentanyl.[20] Intranasal fentanyl has been successfully implemented for pain management for a variety of patients in whom IV access is difficult or not otherwise indicated, such as pediatric patients in the emergency department,[13,21] breakthrough cancer pain,[22] postoperative and minor burn patients.[23]

Intranasal fentanyl presents a noninvasive alternative for prehospital analgesia. The United States National Scope of Practice Model limits the administration of pain medications by EMS providers, depending on their level of certification, but states may expand the scope of practice associated with certification levels at their discretion.[8] International EMS organizations in New Zealand[24] and Germany[25] introduced a protocol that enabled their paramedic-level providers (previously unable to give narcotic medications) to provide IN fentanyl guided by online medical direction. Both studies showed a mean reduction in pain of 3 and 4.6, respectively, and found no serious adverse events. The equivalent safety and efficacy of SQ and IN fentanyl administration by EMT-B providers has been demonstrated in a study of a Quebec EMS system in which only a small subset of patients experienced minor adverse events, such as hypotension, nausea, and mild sedation. No serious adverse events occurred, and no naloxone reversal was used.[20]

A clinical practice guideline of wilderness analgesics gave IN fentanyl a strong recommendation as a potentially safe and effective analgesic in the austere setting but lacked studies specifically targeting the wilderness setting.[4] In these more austere settings, pain management is limited by local protocols and access to qualified personnel. In the United States, only a small subset of professional ski patrols are EMS-affiliated and have protocols that allow for the advanced practice administration of any opioid analgesia.[26] For EMS-affiliated ski patrols, administration of opioid analgesics is further limited to personnel with paramedic-level certifications or higher, comprising an even smaller subset of patrollers.[7]

We present data on the use of IN fentanyl in ski patrol or wilderness settings. Intranasal fentanyl eliminates many barriers to achieving on-the-hill analgesia presented by environmental and austere factors. It is also available in needleless, prefilled syringes,[27] increasing administration efficiency, decreasing dosing errors, and eliminating needlestick risk.

To address the gap in pain management protocols, in 2007, the Taos Ski Patrol applied for a New Mexico EMS special skills protocol that enabled patrollers with the minimum certification of EMT-B to undergo specific training to provide eligible patients with on-the-hill IN fentanyl analgesia under the direction of a physician. In this study, we evaluated the reduction in pain scores and adverse events in patients who received IN fentanyl at Taos Ski Valley in the 13 y since the protocol's adoption. We evaluated the safety and efficacy of the Taos special skills protocol.

Methods

This retrospective health records review evaluated acute pain management at Taos Ski Valley, NM. We reviewed patient charts from the 2007−2012 and 2016−2020 seasons. Data from the 2013−2015 season were not included because they were misplaced when the clinic moved to a new location. Eligible subjects included those seen and evaluated by ski patrol personnel for acute, painful orthopedic injuries and who received IN fentanyl as outlined by Taos Ski Patrol's special skills protocol (Figure 1). Results were excluded if no pain scores were recorded. The study was approved and deemed exempt by the University of Vermont institutional review board (11/8/19, STUDY00000583).

The special skills protocol was approved by the New Mexico EMS special-use advisory board in 2007 and updated in 2010. In the protocol, ski patrollers with a minimum certification of EMT-B were required to participate in an initial 3-h training on narcotic pharmacology, pharmacokinetics, dosing, administration, and FDEA regulations. When evaluating a patient, the ski patroller verbally elicited the patient's subjective pain score using the 0 to 10 numerical rating scale (NRS-11), which has been validated by multiple studies.[28-30] If the patient had severe pain, defined as >7, the patroller requested physician online medical control and verified the rationale, the patient's sex, age, weight, medical allergies, and narcotic history, and then requested permission to administer a standardized dose. Literature recommendations for IN fentanyl dosages range from 1 to 2 $\mu g \cdot kg^{-1}$.[31] Standardized dose ranges were established to increase efficiency at the scene and to minimize dosing errors and variability caused by user technique and atomizer dead space (Table 1).

If approved by medical control, the patroller called for fentanyl, which was kept in a locked box in patrol

Indication: Relief of severe pain (>7/10) caused by traumatic injury in an alert and oriented patient.
Contraindications: Opiate allergy, significant blunt chest trauma, the possibility of closed head injury or diminished level of consciousness.

1. Determine indication for intranasal medication and lack of contraindications.
2. Request online medical control.
   a. Verify chief complaint, the patient's sex, age, weight, medical allergies, narcotic history.
   b. Request permission to administer a standardized dose, using closed loop communication.
3. Ensure naloxone is available.
4. Using a 3 mL syringe, with plastic anti-stick safety needle, draw up the prescribed dosage of fentanyl (50 mcg·mL^{-1}).
5. Remove the needle and attach the atomizer onto the syringe for administration.
6. Inspect the patient's nostrils for blood or mucous discharge which may limit mucosal absorption.
7. Verify patient and dosage information with a secondary patroller at the scene.
8. Lean patient's head back slightly, or lay supine.
   a. Administer 0.5 mL of fentanyl into alternating nares.
   b. Utilize short firm pushes to create a fine spray.
9. Monitor the patient for allergic and adverse reactions.

Figure 1. Taos Ski Patrol intranasal fentanyl administration protocol.

headquarters on the mountain, in accordance with FDEA narcotic protocol. The patroller then drew up fentanyl (50 μg·mL^{-1}) from a vial and delivered the dose using a mucosal atomizer device (Wolfe Tory Medical, Salt Lake City, UT) in fractions of 0.5 mL in alternating nares because of volume limitations of intranasal administration.[32] Before administration, the patroller confirmed the dosage in a second closed-loop communication with another trained patroller at the scene. Repeat doses were possible under online control. A protocol remained in place for paramedic-level patrollers to give additional IM morphine if needed.

The responding ski patroller elicited the initial pain score (at 0 min) and subsequent pain scores (at 5, 10, and 15 min), with minimal interruption to transportation. The ski patroller also recorded patient characteristics, dosage information, and the occurrence of any adverse events (such as respiratory depression, nausea, vomiting, or the use of the naloxone reversal agent). The data were recorded on a standardized paper records maintained by the ski patrol organization.

The study team collected and reviewed the patients' pain scores, basic characteristics, and adverse events. Due to missing timepoint data, the analyses were performed using multilevel modeling to estimate the least square means, with the patient as a random effect, and time nested within patient. The data are presented as least square mean±SD. Based on prior validated studies, we determined that the clinically meaningful reduction in severe pain was >1.8 points.[33-35] Complete case analyses were also conducted using paired t-tests for each follow-up timepoint compared with time at 0 min. Multilevel modeling was used to evaluate for the differences in pain scores associated with several variables, such as sex, age, weight-based dose, and initial pain score. Statistical significance of the interactions was evaluated using F-tests. Statistical significance was determined by $P \leq 0.05$.

Table 1. Standardized dosage regimen for Taos Ski Patrol

Patient weight (kg)	*Fentanyl dose (μg)*
≥68	100
45-67	75
23-44	50
≤22	<50

Results

We compiled the results from the winter seasons of 2007 through 2012 and 2016 through 2020. A total of 247 patients were included; 4 patients were excluded due to lack of documented pain scores. We were unable to locate data from 2012 to 2016, and data were incomplete for 28 patients, for whom medication dosage or pain scores at one or more timepoints were missing, so we used multilevel modeling to estimate least square mean±SD. Before the special skills protocol was instituted at Taos, IM morphine was used infrequently (between, 5−7 times per year). Since the protocol was adopted in 2007, an average of 30 injured skiers received on-the-hill analgesia each year. Patient age was 33±18 y, ranging from 6 to 74 y, with 59% of patients identifying as male. The most common injuries involved the lower leg, shoulders, and obvious deformities and/or dislocations. Detailed patient demographics are summarized in Table 2. The initial pain score was 8.6±1.5. Using multilevel modeling, the decreases in pain scores from 0 min were −1.8, −2.4, and −2.9, respectively, for

Table 2. Patient characteristics and demographics, n (%)

Characteristic	*Pooled*[a]	*Female*	*Male*
Total	247	99 (41)	141 (59)
Demographics			
Age (y) mean±SD	33±1	34±2	33±1
(range)	(6–74)	(7–74)	(6–74)
<18	52 (21)	23 (26)	23 (19)
18–29	70 (29)	21 (24)	37(30)
30–39	39 (16)	11 (12)	23 (19)
>40	83 (34)	34 (38)	39 (32)
Mechanism of injury			
Fall (unspecified)	73 (59)	25 (56)	45 (62)
Twisting fall	14 (11)	6 (13)	8 (11)
Fall on rocks	4 (3)	1 (2)	2 (3)
Fall from jumping	6 (5)	0 (0)	6 (8)
Object strike	10 (8)	6 (13)	4 (5)
Collision	4 (3)	2 (4)	1 (1)
High speed	9 (7)	2 (4)	7 (10)
Fall from lift	2 (2)	2 (4)	0 (0)
Fall walking	1 (1)	1 (2)	0 (0)
Injury			
Shoulder	67 (31)	20 (22)	46 (39)
Clavicle	13 (6)	3 (3)	10 (8)
Trunk	6 (3)	4 (4)	2 (2)
Hip/Pelvis	12 (6)	5 (5)	7 (6)
Elbow	5 (2)	4 (4)	1 (1)
Wrist	14 (6)	6 (7)	6 (5)
Forearm	7 (3)	2 (2)	4 (3)
Humerus	14 (6)	6 (7)	8 (7)
Thumb	1 (<1)	0 (0)	1 (1)
Arm unspecified	4 (2)	1 (1)	2 (2)
Knee	15 (7)	14 (15)	1 (1)
Femur	11 (5)	4 (4)	7 (6)
Lower leg	38 (17)	20 (22)	17 (14)
Ankle	5 (2)	2 (2)	3 (3)
Foot	1 (<1)	0 (0)	1 (1)
Leg unspecified	5 (2)	1 (1)	3 (3)
Obvious deformity	34 (16)	5 (5)	27 (23)
Initial pain score			
<8	51 (21)	20 (23)	27 (23)
8	55 (23)	17 (20)	33 (29)
9	37 (15)	13 (15)	15 (13)
10	97 (40)	36 (42)	40 (35)
Weight-based dose			
Under ideal	15 (7)	4 (5)	7 (7)
Ideal	193 (89)	68 (86)	96 (92)
Over ideal	10 (5)	7 (9)	1 (1)
Rescue dose			
1 dose	213 (89)	79 (80)	104 (76)
2+ doses	25 (11)	10 (10)	16 (12)
IN fentanyl	17 (7)	8 (8)	11 (8)
IM morphine	8 (3)	2 (2)	5 (4)

[a]Pooled data include all patients, including 7 for whom sex was not recorded.

each additional time point at 5, 10, and 15 min (a linear trend across time, $P<0.0001$). The time at 0 min represented the time of initial pain score at time of first IN fentanyl administration (Figure 2). Using a paired t-test, we found both a clinically significant decrease in pain scores from 0 min of >1.8 and statistical significance of $P<0.0001$, at all time intervals from 0 min. There were no adverse events such as respiratory depression or use of naloxone.

Table 3 contains the variables of sex, age, initial pain score, and weight-based dose, which were evaluated for significance of interactions. Only the baseline pain score showed a statistically significant interaction. Patients with a higher initial pain score had a statistically greater decrease in pain ($P<0.0001$). There was no difference in pain reduction between age groups ($P<0.93$) or sex ($P<0.25$). When evaluating the standardized dose of fentanyl administered, some patients received less or more than the ideal weight-based dose. Few patients received higher (>2 $\mu g \cdot kg^{-1}$) or lower (<1 $\mu g \cdot kg^{-1}$) doses per weight (n=10 and n=15, respectively). No statistical difference in pain scores was found with respect to weight-based dose ($P<0.32$). No adverse events occurred for any patients, including those receiving the higher than ideal dose. We found that female patients and younger patients were more likely to receive non-ideal weight-based doses. Seventy percent of the patients who received non-ideal doses were less than 21 y old. All but one of the 15 patients receiving a higher than ideal dose was female.

Seventeen patients (7%) received additional fentanyl doses and 8 patients (3%) received additional IM morphine. No non-opioid medications were given on the hill. When examining the response of patients who received a single dose, the decrease in pain from 0 min was statistically significant at all time intervals ($P<0.001$). For those who received a repeat rescue dose of either IN fentanyl or IM morphine, there was no significant decrease in pain from 0 to 5 min ($P=0.20$), as measured from administration of the initial dose. However, the decrease in pain from 0 to 10 min and from 0 to 15 min was significant ($P=0.02$ and $P=0.003$). When comparing pain scores for single vs repeat doses using the multilevel model, the initial 0-min pain scores were similar in both samples. At both 5 and 10 min, the sample of patients receiving a repeat dose were more likely to have a smaller decrease in pain scores than those receiving a single dose. However, at 15 min, the decrease in pain scores was statistically similar in both samples. There were no significant differences in patient demographics between samples.

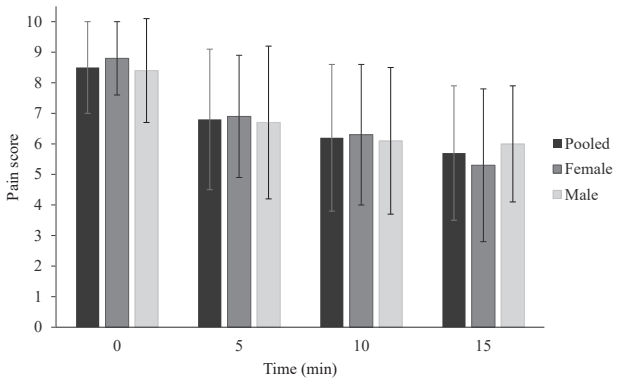

Figure 2. Pain score by time as estimated by least square mean. The error bars represent the standard deviation.

Discussion

Our study found that patients who received on-the-hill IN fentanyl had a statistically significant and clinically meaningful decrease in pain scores with no adverse events. Before the special skills protocol was adopted at Taos Ski Valley, IM morphine had been used as on-the-hill analgesia, albeit rarely. Intranasal fentanyl was found to be a safe and efficacious alternative that markedly increased the usage of on-the-hill analgesia. We found that IN fentanyl offers a safe, effective, noninvasive approach to rapid analgesia when administered by EMT-B certified providers in the ski patrol setting.

The analysis of potentially interacting variables found no statistically significant decrease in pain scores for age, sex, or weight-based ideal dose. Additionally, patients who presented with higher initial pain scores were more likely to have larger decreases in their reported pain. This finding has been similarly noted in the literature.[34,36] A study of postoperative pain in patients in a Colombian hospital found that patients who endorsed severe pain required a larger decrease in NRS-11 pain scores to note a meaningful decrease in pain relief when compared with patients who reported moderate pain.[34]

Repeat IN fentanyl doses and additional IM morphine were seldom administered. Patients who received rescue doses had smaller decreases in pain at 5 min than patients receiving a single dose despite the fact that they presented with similar initial pain scores. However, after the rescue doses were administered, they experienced pain relief equivalent to the pain relief reported by the patients who received a single dose. No adverse effects were found for any patient, including those who received higher than the ideal weight-based or repeat doses. We observed that 14 of 15 patients who received the higher than ideal dose were female, which may relate to standardized dosing in patients who had lower body weight.

Challenges remain in achieving adequate analgesia using IN fentanyl. It is volume-limited with an ideal volume of 0.15 mL per naris to prevent nasal runoff.[32,37,38] However, our study and several other studies[20,39] successfully used larger volumes of 0.5 mL per naris in several aliquots. In one study, doses greater than 50 μg were further divided, which may have helped decrease nasal runoff.[20] In addition, vasoconstriction caused by exposure to a cold environment leads to decreased mucosal absorption and slower onset of action.[40] These barriers highlight the possibility of under-dosing even those patients who receive an ideal weight-based dose.

To improve nasal delivery and absorption, several studies have shown the efficacy and safety of higher concentrations of fentanyl (available in concentrations of 300 to 1000 $\mu g \cdot mL^{-1}$)[37,41] and other more potent opioids such as sufentanil.[42–44] These formulations offer an alternative means of overcoming the volume limitations of IN administration. As the concentration increases, smaller dosing errors may increase the risk for serious adverse effects due to their potency. Using a lower concentration of fentanyl (50 $\mu g \cdot mL^{-1}$) with an emphasis on repeat dosing, as outlined in the Taos protocol, allows for titrating as well as standardizing IN and IV medications.

The need for and success of progressive protocols that enable providers with less advanced certification to provide pain management has been demonstrated in a diverse range of rural and prehospital settings.[6,8,20,24–26,31,45] Local protocols for non-EMS affiliated organizations often tightly restrict the ability of paramedics to provide an advanced level of care and pain management. Though standardized and evidence-based protocols that enable paramedics to provide an advanced level of care would help decrease barriers to prehospital analgesia, paramedics comprise only a small minority of ski patrollers, wilderness rescuers, and rural EMS providers.[6,8,31] The study of pain management by providers with less advanced training than the paramedic level thus far has been limited.[20] Our results have demonstrated the safety and efficacy of IN fentanyl with a clinically and statistically significant decrease in pain scores at all time intervals measured. This study is part of a growing body of evidence for innovative prehospital analgesia protocols.

LIMITATIONS

As we previously mentioned, we were unable to locate the data for 2013 through 2015. In the years that were included, missing data for patients such as pain scores, fentanyl dosage, etc, necessitated the use of multilevel modeling and led to the exclusion of several patients. As a

Table 3. Multilevel model for longitudinal pain score data with calculated least square mean±SD. Significance of variable interaction by time evaluated using F-test

Variable	*0 min*	*5 min*	*10 min*	*15 min*	*Interaction* P *value*
Pooled	8.6±1.5	6.8±2.3	6.2±2.4	5.7±2.2	<0.0001
Sex					0.25
Female	8.8±1.2	6.9±2.0	6.3±2.3	5.3±2.5	
Male	8.4±1.7	6.7±2.5	6.1±2.4	6.0±1.9	
Age					0.93
<18 y	9.1±1.2	7.1±2.1	6.6±2.2	6.4±1.9	
18-29 y	8.5±1.5	7.1±2.1	6.2±2.5	5.6±2.5	
30-39 y	8.4±1.5	6.5±2.6	6.0±2.2	5.7±2.4	
40+ y	8.4±1.8	6.5±2.3	6.0±2.4	5.7±1.9	
Initial pain score					<0.0001
<8	6.2±1.2	5.1±1.8	4.8±1.5	4.5±1.6	
8	8.0±0.1	6.6±1.9	5.6±2.3	6.0±2.0	
9	8.9±0.2	7.0±1.8	6.4±2.2	4.4±2.3	
10	10.0±0.1	7.7±2.4	7.2±2.3	7.0±2.0	
Weight-based dose					0.32
Under ideal	9.3±1.1	7.6±2.1	7.4±2.0	5.1±2.2	
Ideal	8.4±1.6	6.6±2.2	6.0±2.3	5.7±2.2	
Over ideal	9.6±0.7	8.4±2.0	7.4±2.9	6.0±3.2	
Number of doses					0.005
1 dose	8.5±1.5	6.6±2.3	6.0±2.4	5.7±2.4	
2+ doses	8.8±1.8	8.2±1.6	7.4±1.5	6.4±1.8	
Paired t-test	0.54	0.002	<0.001	0.69	

health records review, this study lacks the rigor of a randomized, blinded, placebo-controlled study. Several factors may have impacted the study's generalizability. For example, the time before intitial administration (0 min) can be affected by the time it takes for the rescuers to arrive, the role of splinting or other non-medication treatments for pain mitigation, and the possible effect of cold temperatures on reported pain scores. Also, because similar pain scores were not available for patients who did not receive IN fentanyl, there is a lack of an innate control group.

Conclusions

This study of the Taos protocol demonstrates that IN fentanyl administration by EMT-B certified providers could help further bridge the gap in pain management and provide safe and effective analgesia for other ski patrols, and potentially be applied to broader rural and austere settings. Intranasal administration of fentanyl is non-invasive, needleless, and available in prefilled syringes, making it well-suited for the winter wilderness setting. It offers a compelling alternative for safe and effective pain management in the austere setting. A national survey of ski patrols and other rescue groups is warranted to identify other opportunities for this mode of pain management and to also identify barriers toward broader implementation of IN fentanyl protocols.

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