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Pediatric Emergency Department Triage-Based Pain Guideline Utilizing Intranasal Fentanyl: Effect of Implementation

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ABSTRACT:

Background: Pain management guidelines in the emergency department (ED) may reduce time to analgesia administration (TTA). Intranasal fentanyl (INF) is a safe and effective alternative to intravenous opiates. The effect of an ED pain management guideline providing standing orders for nurse-initiated administration of intranasal fentanyl (INF) is not known. The objective of this study was to determine the impact of a pediatric ED triage-based pain protocol utilizing intranasal fentanyl (INF) on time to analgesia administration (TTA) and patient and parent satisfaction.

Methods: This was a prospective study of patients 3-17 years with an isolated orthopedic injury presenting to a pediatric ED before and after instituting a triage-based pain guideline allowing for administration of INF by triage nurses. Our primary outcome was median TTA and secondary outcomes included the proportion of patients who received INF for pain, had unnecessary IV placement, and patient and parent satisfaction.

Results: We enrolled 132 patients; 72 pre-guideline, 60 post-guideline. Demographics were similar between groups. Median TTA was not different between groups (34.5 minutes vs 33 minutes, p = 0.7). Utilization of INF increased from 41% pre-guideline to 60% post-guideline (p=0.01) and unnecessary IV placement decreased from 24% to 0% (p=0.002). Patients and parents preferred the IN route for analgesia administration.

Conclusion: A triage-based pain protocol utilizing INF did not reduce TTA, but did result in increased INF use, decreased unnecessary IV placement, and was preferred by patients and parents to IV medication. INF is a viable analgesia alternative for children with isolated extremity injuries.
INTRODUCTION

Acute pain is a common complaint among patients who present to the pediatric emergency department (PED) with concerns of extremity injury and numerous organizations have issued policy statements to promote improvements in analgesia administration. [1-4] Failure to treat pediatric pain may result in subsequent heightened physiologic and psychologic responses to pain and posttraumatic stress disorder.[2, 5, 6] In addition, disparities exist in analgesia provision for children regardless of provider training.[5, 7-10] Reported barriers to adequate treatment of pediatric pain include underestimation of pain, lack of knowledge of pain assessment tools and, fear of oversedation or other analgesia complications.[5, 8, 11]

To overcome these barriers, many institutions have initiated analgesia administration guidelines that include pain assessment scales, weight-based medication dosing, and options for medications and routes of delivery.[12, 13] Traditional routes of analgesia administration have disadvantages including diminished bioavailability due to first pass metabolism of oral medications and iatrogenic risk and pain with intravenous (IV) catheter placement. Intranasal (IN) administration offers analgesia delivery for a broad spectrum of clinical indications including pediatric pain associated with fractures.[14][15-26]

Prior studies show that the use of pain management guidelines may reduce time to analgesia administration (TTA) and increase the percent of patients receiving analgesia medications.[18, 27-30] The goal of this study was to compare median time to analgesia administration (TTA) before and after the implementation of a triage-based, nurse-initiated pain guideline for patients presenting with suspected orthopedic extremity injury. We also sought to examine
patient and parental satisfaction with the route of delivery and timeliness of analgesia as well as the potential decrease in IV catheter placement.

METHODS

Study Design and Setting

This was a prospective observational clinical study conducted at a tertiary care children’s hospital ED with an annual census of approximately 42,000 patients. Prior to initiation of the guideline, a physician order was required for opiate analgesia administration and providers routinely ordered opiates to be given either via IV or IN routes. In July 2011, we implemented a triage-based, nurse-initiated pain treatment guideline with standing orders for opiate analgesia delivery. We prospectively collected data on a convenience sample of patients before (February – June 2011) and after (August – December 2011) implementation, allowing a 2-month washout period for post-guideline subject enrollment.

Guideline Development and Implementation:

The pain guideline was developed by a multidisciplinary group of ED physicians, nurses, a nurse educator, and an ED pharmacist. The group reviewed the available literature to determine proper medication dosing, and pain scale choice. Ultimately the guideline provided standing orders for triage nurses to administer INF (2 mcg/kg, max 100 mcg, concentration 50 mcg/mL) to patients with a suspected isolated orthopedic injury, a qualifying level of pain as assessed on a pain score and normal mental status as defined as a Glasgow Coma Scale of 15. INF was administered via a mucosal atomizer device (LMA Nasal™, LMA Inc. La Jolla, CA) and the patient was placed on a continuous pulse-oximetry monitor for at least one hour. Current practice mandated that the treating physician order all IV catheter placements. However, per the
guideline, if IV access was anticipated, it was at the nurse’s discretion to request an IV order from the provider.

The guideline recommended use of the Wong Baker Faces (WBS) pain assessment scale for ages 3 to 8 years and the numeric rating scale (NRS) for ages 9 to 17 years. Patients with a self-reported pain score of ≥ 3 faces on the WBS or a pain score of ≥ 4 on the NRS were eligible to receive INF per the guideline. Repeat pain score and vital signs (BP, HR, O2 sat) were to be assessed 20 minutes after INF administration. After the guideline was developed and prior to study initiation, both nursing staff and ED physicians were trained on the guideline specific recommended interventions.

**Participant Selection Criteria**

Patients were eligible for the study if they were between 3 and 17 years of age with a clinically suspected isolated extremity injury and had a caregiver who spoke either English or Spanish and met criteria for treatment by the guideline as described above.

Patients were excluded if they had a pre-existing IV catheter, were unable to provide a self-reported pain score, had suspected or clinically-apparent multisystem trauma, were hemodynamically unstable, had a history of loss of consciousness associated with the current trauma, obvious airway compromise, oxygen saturation < 94% on room air, severe nasal congestion, active epistaxis, a history of allergy to any opiate medication, or a history of complex medical problems (including muscular dystrophies and congenital heart disease).

**Study procedures**

The local institutional review board approved this study. Eligible patients were screened for enrollment by a research assistant or physician during the hours a research assistant was
present in the emergency department (15 hours/day) and invited to participate in the study. Consent was obtained from parents and assent from patients > 7 years. Research assistants obtained consent following completion of the triage process. A data collection form was completed for each study subject during the ED visit. Pain management satisfaction questionnaires were distributed to patients and parents and completed prior to patient discharge from the ED. Patients and families were asked whether the child received any form of pain medication while in the ED. Those that received any analgesia were then asked: 1) if analgesia administration was timely (yes, no), 2) the amount of discomfort with medication delivery, if applicable [using a 100 mm visual analog scale (VAS)], and 3) their preferred route of analgesia administration for the future (IN vs. IV).

Outcomes

Our primary outcome was to compare median time to analgesia administration (TTA) before and after guideline implementation. We defined TTA as the time from ED arrival to time that any analgesic medication was administered. We also compared the difference in the proportion of subjects that received any form of analgesia (including oral acetaminophen or nonsteroidal anti-inflammatory), any form of opiate (IV morphine, IV fentanyl, IN fentanyl, or acetaminophen/hydrocodone) and any unnecessary IV catheter placement. We defined unnecessary IV catheter placement as any catheters placed only for administration of analgesia administration and not used for procedural sedation or other medications. Lastly, we compared the frequency of post-analgesia pain score documentation, change in pain score, and difference in patient and parent satisfaction with analgesia provision. Given that INF was in use with some frequency before guideline implementation and to better examine the association of
route of medication administration with certain outcomes, we also analyzed TTA and satisfaction data by route of medication delivery with a separate category for patients that received both IV and IN medications.

**Statistical Methods and Data Analysis**

Sample size was calculated a priori to detect a 15-minute difference in TTA (between the pre- and post-guideline groups), with a standard deviation of 25 minutes. For a power of 90% with a 5% significance level, the study required 60 patients per group. Statistical analyses were performed using the JMP program (Cary, NC; Version 10.0) and SPSS (Chicago IL, Version 24.0). The Mann-Whitney-Wilcoxon rank sum test (Mann-Whitney U test) was used to compare TTA between groups and by route of analgesia administration. The Fisher’s exact test was performed to analyze dichotomous data and proportions among cohorts. The t-test was used to compare normally distributed continuous outcomes between groups.

**RESULTS**

During the study period, we enrolled a total of 132 patients, 72 patients before and 60 patients after guideline implementation. One patient in the pre-guideline group was excluded due to lack of available information on TTA. Overall, groups were similar with regard to sex, age, median pain score, diagnosis, and proportion of patients undergoing operative repair (Table 1). We found no difference in overall TTA between the pre-guideline group compared to the post-guideline group (35 minutes vs. 33.0 minutes; \( p = 0.7 \)) as shown in Table 2. In addition, there were no observed differences between groups in proportion of patients receiving any form of analgesia including opiate and oral analgesia (Table 2). Utilization of INF increased from 41% to 60% in the post-guideline group. The frequency of post-analgesia pain score documentation
(84.5%, 91.7%; \( p = 0.3 \)), and the median change in pain score were similar for both groups (4, 5; \( p = 0.7 \)).

Comparing IN and IV routes of opiate analgesia administration over both the pre- and post-guideline period, we found that the median TTA was shorter for INF compared to IV opiate administration (-8.5 min; \( p = 0.015 \)) (Figure 1). In addition, patients who received INF had significantly higher median initial pain scores compared to IV opiate recipients (8, 6; \( p = 0.046 \)).

Before the guideline was introduced, 24% of patients had an unnecessary IV catheter placed. After the guideline was introduced, no unnecessary IV catheters were inserted, with an absolute decrease in 24% (\( p = 0.002 \)).

Patient and parent satisfaction survey results stratified by route of analgesia administration (including those who received both IV and IN) are shown in Table 3. The majority of parents and patients felt that the medication was delivered quickly regardless of route of medication administration. In addition, both parents and patients felt that the administration of medication resulted in a significant improvement in pain. Parents and patients rated the degree of pain associated with IV pain medication delivery to be higher than IN and these results were consistent in the group that had both routes (IV+IN) used for analgesia administration. Finally, the majority parents and patients in the IN and IV+IN group stated that they would prefer IN administration to IV administration in the future.

**DISCUSSION**
Numerous studies demonstrate the benefits of pain treatment guidelines in reducing of time to analgesia and the clear reduction of pain among those patients receiving opiate analgesia.[14-21, 23-27, 29, 31]

In our study examining the implementation of a triage-based INF pain treatment guideline for patients with suspected isolated upper extremity injury, we found no difference in the overall time to analgesia, frequency of analgesia provision, or efficacy of analgesia. We found a decrease in overall utilization of unnecessary IV catheters, an increase in use of INF for analgesia, and a positive change in patient and parent satisfaction with pain management.

Prior studies evaluating the implementation of pain guidelines in the ED setting demonstrate a reduction in time to analgesia.[18, 27, 28] Boyd et al.[29] found that introduction of nurse initiated analgesia increased the rate of analgesia provision by 14% and significantly decreased the mean time to analgesia by 50% (from 93 to 46 minutes). Holdgate et al.[18] noted that introducing an INF protocol increased the rate of analgesia administration by 13.5% and reduced the time to opioid administration in children from 63 to 32 minutes. Our median time to analgesia was approximately 30 minutes for all routes of delivery combined both before and after guideline implementation. Our failure to identify a difference in TTA may reflect a relative ceiling effect beyond which improvements may be challenging due to the logistic of medication administration in the emergency department. However, when we compared TTA by route, we found an 8.5 minute reduction for INF compared to IV administration suggesting that route of delivery may impact time to analgesia administration. Of note, patients who received INF also had a higher median pain score perhaps prompting faster treatment by the triage nurse leading to their tendency to administer INF.
Prior studies also demonstrate that Intranasal administration of fentanyl is beneficial and effective for pain relief in many different clinical settings including the emergency department, post-operative recovery, burn and oncology units, and in the out-of-hospital environment.[15-26] Similar to our findings, Borland et al. demonstrated equal analgesia effect of INF compared to IV morphine for pediatric patients for orthopedic injury along with a reduction in the percentage of patients requiring IV placement for acute pain management, similar to our findings.[16, 17, 19] Holdgate et al.[18] found that introduction of a nurse-initiated INF protocol in a general ED was associated with an overall increase in the number of children receiving opiate analgesia along with a shift toward INF. In our pediatric ED convenience sample, we did not find a difference in proportion of patients receiving opiate analgesia before and after guideline implementation however we also found a shift from IV opiate to INF during our study period.

Effective pain management is one of the critical determinants of both parental and patient satisfaction with emergency department visits.[32, 33] In our study, both patients and parents perceived analgesia administration as efficient. Though parents and patients reported equal effectiveness of INF and IV opiate, they found the pain associated with IN analgesia administration to be significantly less compared with the IV route. Those who received INF (either alone or with IV opiate) far preferred it to IV analgesia administration. Even among those who received IV analgesia alone, almost a quarter preferred an intranasal route. Overall preference for INF increased significantly post-guideline implementation, mirroring the increased utilization of INF in this group. Saunders et al.[13] also examined satisfaction of pain
management with INF and found it highly rated by not only patients and parents but also by providers.[15]

The IN route is most useful for patients who need single dose analgesia and it can be used as an efficient, effective and may obviate the need for IV placement.[15] Only one patient in the pre-group who initially received INF subsequently required IV placement for pain control; all other INF recipients undergoing subsequent IV placement required the IV for reasons other than pain control (i.e. reduction procedure, surgery, IV fluid administration).

LIMITATIONS

This study has certain limitations. Our sample size calculation did not account for a percentage of patients who might have received oral medication or no analgesia during their ED visit which may have reduced our power to detect a difference in our main outcome, time to analgesia. Patients were not enrolled in comparable time periods before and after guideline implementation and the seasonality of their visit may have also affected our results, although we note that the demographics of our two groups were very similar. Given our enrollment was limited by the availability of research assistants in the emergency departments, our findings may be subject to bias introduced by using a convenience sample and we cannot comment on overall use of analgesia in our emergency department. However, since this guideline was implemented throughout the ED with training of all emergency department nurses regarding the availability of standing orders, the convenience sample likely represents the global care received in our emergency department. There was no indication on the data abstraction form of the type of pain assessment tool used for each patient, though staff underwent training on proper tool to use for age. This may have underestimated the median pain score for our
younger patients in whom the WBS was used, which has a scale of 1-6 faces, however the median initial pain score and change in pain score were similar between groups. Staff education and training regarding INF triage guideline occurred prior to study implementation, which may have biased toward a higher INF provision frequency in the pre-guideline group thus possibly biasing our study toward the null. At the time of the study, interventions to allow for less painful IV placement, such as needle free injection systems, were not available; these measures may be standard in some emergency departments. Given our small sample size, our study was not designed to examine the safety of INF. Lastly, we acknowledge that a guideline utilizing standing orders allowing for nurse administration of analgesia may not be possible in other institutions.

CONCLUSION

We found that the introduction of a triage-based, nurse-initiated INF pain management guideline did not demonstrate a significant reduction in overall time to analgesia. However, we did find a slight reduction in time to analgesia for those receiving intranasal fentanyl compared to IV opiate, a significant reduction in unnecessary IV placement, and increased patient and parental satisfaction without compromising effectiveness of pain management.
REFERENCES

[19] Borland ML, Jacobs I, Geelhoed G: Intranasal fentanyl reduces acute pain in


**Figure 1.** Time to analgesia by route. The horizontal line represents the median value; the box ends denote the IQR. Whiskers demarcate the highest and lowest cases within 1.5 times the IQR. IQR = interquartile range.
Table 1. Demographics in pre-guideline and post-guideline groups

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Pre-guideline n = 71</th>
<th>Post-guideline n = 60</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>64.8</td>
<td>63.3</td>
<td>1.0^*</td>
</tr>
<tr>
<td>Median age, yrs (IQR)</td>
<td>9.8 (4.7, 13.9)</td>
<td>7.9 (3.9, 11.9)</td>
<td>0.8^†</td>
</tr>
<tr>
<td>Median pain score (QR)</td>
<td>7 (5, 9)</td>
<td>6 (5, 8)</td>
<td>0.7^§</td>
</tr>
<tr>
<td>Forearm fracture (%)</td>
<td>45.7</td>
<td>50.9</td>
<td>0.6^*</td>
</tr>
<tr>
<td>Deformed forearm fracture (%)</td>
<td>28.6</td>
<td>37.3</td>
<td>0.3^§</td>
</tr>
<tr>
<td>Supracondylar fracture (%)</td>
<td>14.3</td>
<td>14.0</td>
<td>1^*</td>
</tr>
<tr>
<td>Operative repair (%)</td>
<td>19.7</td>
<td>21.4</td>
<td>0.7^§</td>
</tr>
</tbody>
</table>

^ Fisher’s exact, § Wilcoxon rank sum, † T-test
Table 2. Pain Management Outcomes by Group

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Pre-guideline n = 71 (%)</th>
<th>Post-guideline n = 60 (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any analgesia</td>
<td>62 (87.3)</td>
<td>64 (90.0)</td>
<td>0.8^</td>
</tr>
<tr>
<td>Opiate</td>
<td>59 (83.1)</td>
<td>47 (78.3)</td>
<td>0.5^</td>
</tr>
<tr>
<td>Route</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IN</td>
<td>29 (40.9)</td>
<td>36 (60.0)</td>
<td>0.03^</td>
</tr>
<tr>
<td>IV</td>
<td>25 (35.2)</td>
<td>11 (18.3)</td>
<td>0.049^</td>
</tr>
<tr>
<td>PO</td>
<td>8 (11.3)</td>
<td>7 (11.7)</td>
<td>1^</td>
</tr>
<tr>
<td>Time to Analgesia, minutes, median (IQR)</td>
<td>35 (20, 50)</td>
<td>33 (19, 50)</td>
<td>0.7</td>
</tr>
<tr>
<td>Other Interventions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV placement</td>
<td>42 (59.9)</td>
<td>33 (55)</td>
<td>0.4^</td>
</tr>
<tr>
<td>Unnecessary IV</td>
<td>17 (23.8)</td>
<td>0 (0.0)</td>
<td>&lt;0.01^</td>
</tr>
<tr>
<td>Post-analgesia pain score documented</td>
<td>60 (84.5)</td>
<td>55 (91.7)</td>
<td>0.3^</td>
</tr>
<tr>
<td>Change in pain score (median; IQR)</td>
<td>4 (3, 6)</td>
<td>5 (3, 6)</td>
<td>0.9^</td>
</tr>
</tbody>
</table>

^Fisher’s exact; ^ Wilcoxon rank sum

IQR=Interquartile Range, IN=Intranasal, IV=Intravenous, PO=Oral
Table 3: Parent and Patient Satisfaction Survey Results

<table>
<thead>
<tr>
<th>Survey Question</th>
<th>Respondent</th>
<th>Route of Analgesia Administration</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>IV</td>
<td>IN</td>
<td>IV+IN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Parent n=37</td>
<td>Parent N=38,</td>
<td>Parent n=26</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient n=24</td>
<td>Patient n=26</td>
<td>Patient n=13</td>
<td></td>
</tr>
<tr>
<td>Degree of improvement of pain(^\d), VAS mean (95% CI)</td>
<td>Parent</td>
<td>7.0 (6.3, 7.7)</td>
<td>7.4 (6.9, 8.2)</td>
<td>7.4 (6.9, 7.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>8 (3.8, 8.6)</td>
<td>6.9 (4.4, 8.8)</td>
<td>7.7 (5.9, 7.7)</td>
<td></td>
</tr>
<tr>
<td>Perceived medication was given quickly, % (n)</td>
<td>Parent</td>
<td>86.1 (31)</td>
<td>86.8 (33)</td>
<td>92.3 (24)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>86.9 (23)</td>
<td>76.2 (20)</td>
<td>92.0 (12)</td>
<td></td>
</tr>
<tr>
<td>Pain level from medication administration, VAS mean (95% CI)(^\d)</td>
<td>Parent</td>
<td>3.4 (2.5, 4.5)</td>
<td>1.8 (0.8, 2.7)</td>
<td>IV=3.42 (2.2, 4.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IN=0.6 (0.3, 0.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>2 (0.4, 5.8)</td>
<td>0.25 (0, 1.4)</td>
<td>IV=0.35 (1.9, 5.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IN=0.2 (0, 1.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prefer IN to IV, % (n)</td>
<td>Parent</td>
<td>27 (10)</td>
<td>94.7 (36)</td>
<td>85.1 (22)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>25.0 (6)</td>
<td>100 (26)</td>
<td>91.6 (12)</td>
<td></td>
</tr>
</tbody>
</table>

\(^\d\) patients under 7 years of age not administered survey
\(^\d\) VAS=Visual Analog Scale measurement
IN=intranasal, IV=intravenous, CI=Confidence Interval
Figure 1

Time to Analgesic Administration (minutes)

Route of Analgesia Administration

IV

IN