EMERGENCY DEPARTMENT PAIN MANAGEMENT IN ADULT PATIENTS WITH TRAUMATIC INJURIES BEFORE AND AFTER IMPLEMENTATION OF A NURSE-INITIATED PAIN TREATMENT PROTOCOL UTILIZING FENTANYL FOR SEVERE PAIN

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Abstract—Background: Pain management in the emergency department (ED) remains suboptimal. Nursing staff protocols could improve this, but studies show divergent results. Objective: Our aim was to evaluate a nurse-initiated pain-management protocol in adult patients with traumatic injuries in the short and in the long term, utilizing fentanyl for severe pain. Methods: In this pre–post implementation study, ED patients were included during three periods. The protocol allowed nurses to administer acetaminophen, non-steroidal anti-inflammatory drugs, or fentanyl autonomously, based on Numeric Rating Scale pain scores. Primary outcome was frequency of analgesic administration at 6 and 18 months after implementation. Secondary outcomes were pain awareness, occurrence of adverse events, and pain treatment after discharge. Results: Five hundred and twelve patients before implementation were compared with 507 and 468 patients at 6 and 18 months after implementation, respectively. Analgesic administration increased significantly at 18 months (from 29% to 36%; p = 0.016), not at 6 months (p = 0.19) after implementation. Pain awareness increased from 30% to 51% (p = 0.00) at 6 months and to 56% (p = 0.00) at 18 months, due to a significant increase in pain assessment: 3% to 30% (p = 0.00) and 32% (p = 0.00), respectively. Post-discharge pain treatment increased significantly at 18 months compared to baseline (from 25% to 33%; p = 0.016) and to 6 months (from 24% to 33%; p = 0.004). No adverse events were recorded. Conclusions: Implementation of a nurse-initiated pain-management protocol only increases analgesic administration in adult patients with traumatic injuries in the long term. Auditing might have promoted adherence. Pain awareness increases significantly in the short and the long term. © 2016 Elsevier Inc. All rights reserved.

Keywords—pain; pain management; trauma; orthopedics; musculoskeletal disorders

INTRODUCTION

Almost 20 years ago, pain was recognized as the “fifth vital sign” (1). This has been emphasized by the American Pain Society, the Joint Commission International, and several other scientific and professional organizations.

Patients in the emergency department (ED) frequently need treatment of acute pain, with a reported prevalence in adult patients between 61% and 79% (2–4). In patients
with traumatic injuries, the prevalence of pain is even higher, with a reported rate of 90% (5). Despite these figures, pain is frequently treated inadequately. Adult patients with traumatic injuries receive pharmacologic pain treatment in 11–74% (5–8). However, studies addressing the relationship between pain score documentation and analgesic administration show conflicting results (9,10). Incremental pain assessment did not lead to a significant increase in analgesic administration in trauma patients (9). Implementing a template chart, in which it was compulsory to note pain scores, improved pain assessment but not pain treatment (10). Introduction of a pain protocol for emergency physicians decreased unsatisfactory analgesia and increased use of intravenous (i.v.) opiates in patients with musculoskeletal injuries (11). Several studies examined the effect of introducing a nursing staff pain protocol using morphine or pethidine administered i.v. or intramuscularly (i.m.) (12–17). This seemed effective and safe in treating pain of varying causes; nonetheless, several opioid-related adverse events were described (12–14). Nursing staff pain protocols can be divided into two types. They can be nurse-driven, in which nursing staff is allowed to administer analgesic drugs after initial approval and signing off by the treating physician. They can also be nurse-initiated, in which nursing staff is mandated to administer analgesia autonomously, without any interference of a physician beforehand, as a standing order. The latter was reported in three studies investigating opioids in patients with pain from all (non-traumatic) causes (12,14,17). Because results were divergent and different study populations were studied using heterogeneous methods, evidence is lacking on whether a nurse-initiated pain protocol improves pain management in adult patients with acute traumatic injuries. The objective of this study was to evaluate the effect of introducing a pain-management protocol based on Numeric Rating Scale (NRS) pain scores using fentanyl in severe pain, in adults with acute traumatic injuries. Primarily, the effect on frequency of analgesic administration in the short term as well as long term is evaluated. We hypothesized that analgesic drugs, in general, would be administered more frequently after implementation of a formal nurse-initiated pain protocol, and that this effect would be maintained in the long term.

**Study Design**

This is a retrospective, comparative pre–post implementation observational study. The formal pain protocol was implemented in daily clinical practice in January 2012. Patients were included during three periods. All consecutive patients within these periods were screened if eligible for inclusion in the study. The periods were: 1) between June 1 and June 30, 2011 (baseline); 2) between July 1 and July 31, 2012 (6 months after implementation); and 3) between July 1 and July 31, 2013 (18 months after implementation).

**Study Setting and Population**

All patients were included at the ED of a Dutch Level I trauma center. The inclusion criteria were age 18 years or older and any traumatic injury within 48 h before presentation. Exclusion criteria were presence of an endotracheal tube (ETT); hemodynamic instability (systolic blood pressure < 90 mm Hg); Glasgow Coma Scale < 13 without presence of an ETT; intoxication (as clinically diagnosed by the treating physician); self-inflicted injury; cognitive impairment; pregnancy; transfer from another hospital; allergies for analgesics, and daily use of pain medication or suffering from chronic pain.

**Pain Management Protocol**

Before implementation, all ED nurses had to attend a 1-h educational session before they could use the pain-management protocol (Figure 1). This was based on a national Dutch pain treatment guideline (18). Pain is assessed using the 11-item, ED-validated NRS pain score; in which 0 is no pain and 10 is the worst pain imaginable (19). Patients are classified as mild pain (NRS 1–3), moderate pain (NRS 4–6), or severe pain (NRS 7–10). Nurses administer analgesia autonomously, depending on these pain scores. Legislation in The Netherlands allows this as long as there is an up-to-date approved protocol in place. The analgesic drugs administered are acetaminophen (APAP) orally or i.v., oral non-steroidal anti-inflammatory drugs, and in case of severe pain, fentanyl i.v.

**Study Protocol**

Patient’s charts were reviewed before implementation and compared with charts at 6 months and 18 months after implementation of the pain management protocol. To improve accuracy and minimize inconsistencies in data collection, the criteria for medical chart review proposed by Worster et al. were used (20). This means that two trained data abstractors (M.L.R. and F.J.S.) extracted..
the data, independently from each other, from the hospital medical record database, using standard case report forms and the inclusion and exclusion criteria already mentioned. One of the data abstractors (F.J.S.) was not aware of the purpose of the study during data collection. An independent clinical epidemiologist was appointed as a monitor in order to screen data abstraction and to perform random spot checks.

The following study variables were recorded from the patient charts: administered analgesics and administered and ordered by whom; NRS pain scores; advice or prescription for analgesics after discharge and occurrence of adverse events (defined a priori as occurring after administration of analgesic drugs; a respiratory rate < 12 breaths/min; oxygen saturation < 95%; systolic blood pressure < 90 mm Hg; nausea, vomiting, pruritus, or need for naloxone for reversal). Other parameters that were recorded were age, sex, localization of pain, mode of transportation to the ED, diagnosis, treatment in the ED, and disposition.

Outcomes

The primary outcome of the study was frequency of analgesic administration before and at 6 and 18 months after implementation of the pain protocol.

Secondary outcomes were pain awareness (defined as the proportion of documented NRS pain scores or administration of analgesics), occurrence of adverse events and pain treatment after discharge (combined end point of advice regarding analgesic use or prescription for analgesia).

Sample Size Calculation and Data Analysis

According to pilot data, we estimated the average proportion of analgesic administration to be 35%. In order to detect a difference in proportions between the three groups characterized by a variance of proportions of 0.2%, using a significance level of 0.05 and a power of 80%, the sample size of each group needed to be 366. We estimated that collecting patient data during a period of 1 month at each time point would yield at least this number of included patients.

Acquired data were defined as absolute numbers, percentages, calculated \( p \) values and odds ratios (OR) with 95% confidence intervals (CIs). Normality of continuous data was tested by inspecting the frequency distributions (histograms). The homogeneity of variances was tested using Levene’s test for equality of variances. Chi-square analysis or Fisher’s exact test were used for statistical testing of categorical data. Student’s \( t \) test was used for statistical testing of continuous data. In all tests, a \( p \) value < 0.05 was considered to indicate statistical significance. For the primary dichotomous outcome, the inter-observer reliability of the two independent data abstractors was calculated using cross-tabulation and reported as Cohen’s \( \kappa \). All data were recorded and analysed in a digital database, using IBM SPSS Statistics, version 22.0 (2013, IBM Corp, Armonk, NY).

RESULTS

A total of 1,487 patients were included in the study (Figure 2). Five hundred and twelve patients were
included in the historical reference (baseline) group and 507 and 468 patients in the intervention groups at 6 and 18 months, respectively. For demographics, see Table 1. The patient groups were comparable regarding baseline characteristics.

Table 2 shows that frequency of analgesic administration increased from 29.1% at baseline to 32.9% at 6 months ($p = 0.19$). At 18 months, analgesic administration was significantly improved compared to baseline (36.3%; $p = 0.016$). Pain awareness increased significantly from 29.9% to 50.7% at 6 months ($p = 0.00$) and to 56.2% at 18 months ($p = 0.00$).

The use of NRS pain scores increased from a very low number of 2.9 before implementation to 30.0% at 6 months ($p = 0.00$) and 31.8% at 18 months ($p = 0.00$). Patients in all groups rated their pain fairly equal. Most patients reported their pain as being moderate or severe. Comparing analgesic administration according to pain severity was only possible for 6 and 18 months, because at baseline, NRS pain scores were documented in only a few patients. There were no significant differences between analgesic administration at 6 and 18 months for patients with mild pain (12% to 3.1%; $p = 0.193$); moderate pain (39.7% to 50%; $p = 0.256$) and for patients with severe pain (68.9% to 61.4%; $p = 0.456$).

Before implementation, analgesics (non-opioid) were administered fully autonomously by nurses in 92 patients (61.7%). This figure increased to 130 patients (77.8%) at 6 months ($p = 0.002$) and to 90% at 18 months ($p = 0.00$). A comparison between 6 and 18 months also yielded a significant difference ($p = 0.002$).

Table 3 shows the results of the analysis of type and route of analgesic administration and the comparison between the baseline patient group before implementation and both treatment groups at 6 and at 18 months after implementation. Use of fentanyl increased at 6 months (from 10.7% to 21%; $p = 0.014$) and at 18 months (21.2%; $p = 0.012$) and morphine use declined significantly, from 12.8% to 1.8% at 6 months ($p = 0.00$) and to 4.1% at 18 months ($p = 0.005$).

Dosages of all administered analgesics were according to the protocol, dosages of morphine ranged from 2.5 to 5 mg each. Intravenous analgesic administration increased significantly from 20.1% to 29.9% at 6 months ($p = 0.045$) and to 32.4% at 18 months ($p = 0.014$), contrary to i.m. administration, which decreased significantly from 6% to 1.2% at 6 months ($p = 0.019$) and to 0.6% at 18 months ($p = 0.007$). Pain treatment after discharge did not differ between baseline and 6 months (25.4% and 24.1%; $p = 0.644$), but increased significantly at 18 months compared to baseline (from 25.4% to 32.8%; $p = 0.016$). When comparing all data obtained at 6 months with data obtained at 18 months, all outcomes were not significantly different, except for pain treatment after discharge, which increased from 24.1% to 32.8% ($p = 0.004$). No adverse events related to administered analgesics were reported.

Regarding the primary study outcome, frequency of analgesic administration, the interobserver reliability of the two independent data abstractors yielded a $k$ of 0.87.

**DISCUSSION**

The hypothesis of the current study was that analgesic drugs would be administered more frequently after implementation of a formal nurse-initiated pain protocol in the short term and that this effect would be maintained 1 year later. The results show that, in the short term, 6 months after implementation, there is no increase, however, 1 year later, at 18 months after implementation, there is a significant increase in frequency of analgesic administration. This increase might be due to frequent audits of patient charts and continuous personal feedback to nursing staff. In our department, quality and safety experts, appointed among nursing and physician staff, evaluate all aspects of quality care, including pain management. They provide immediate feedback in case of pain scores are not recorded during daily clinical practice. Once a month, they perform spot checks on patient charts. Information about pain documentation and management is extracted and recorded in a report; results are compared to other departments throughout the hospital.
regular audits are necessary as well.

Although the difference in analgesic administration between 6 and 18 months was significant, the absolute difference was only 3 individuals, mainly due to the group sizes. It must be noted that although this was the case, all groups contained ample patients according to the sample size calculation and the study was sufficiently powered.

Frequency of analgesic administration might be considered a surrogate endpoint and decrease in pain scores could have been superior as an endpoint. However, due to lack of documentation of these scores this was not possible. Besides, although it could be reasoned that frequency of analgesic administration does not reflect adequacy of pain management, all analgesics were administered according to standard dosages, as mentioned in the protocol. As the current primary outcome does not take into account patients who deny offered analgesics, and the fact that refusal of analgesics is seldom documented

Table 2. Analgesic Administration, Pain Awareness, and Numeric Rating Scale Pain Scores at 6 and 18 Months Compared to Baseline Before Implementation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before Implementation, n (%)</th>
<th>6 Months, n (%)</th>
<th>p Value; OR (95% CI)</th>
<th>18 Months, n (%)</th>
<th>p Value; OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesic administration</td>
<td>149 (29.1)</td>
<td>167 (32.9)</td>
<td>0.19; 1.20 (0.92–1.56)</td>
<td>170 (36.3)</td>
<td>0.016; 1.39 (1.06–1.82)</td>
</tr>
<tr>
<td>Pain awareness</td>
<td>153 (29.9)</td>
<td>257 (50.7)</td>
<td>0.00; 2.41 (1.87–3.12)</td>
<td>263 (56.2)</td>
<td>0.00; 3.01 (2.31–3.92)</td>
</tr>
<tr>
<td>NRS documented</td>
<td>15 (2.9)</td>
<td>152 (30.0)</td>
<td>0.00; 14.29 (8.20–24.4)</td>
<td>149 (31.8)</td>
<td>0.00; 15.38 (8.93–27.03)</td>
</tr>
</tbody>
</table>

CI = confidence interval; NA = not available; NRS = Numeric Rating Scale; OR = odds ratio.
Table 3. Analgesic Drugs, Route of Administration and Treatment After Discharge at 6 and 18 Months Compared to Baseline Before Implementation

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before Implementation</th>
<th>6 Months, n (%)</th>
<th>p Value; OR (95% CI)</th>
<th>18 Months, n (%)</th>
<th>p Value; OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesic drug</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>APAP</td>
<td>110 (73.8)</td>
<td>141 (84.4)</td>
<td>0.02; 1.92 (1.10–3.36)</td>
<td>139 (81.8)</td>
<td>0.087; 1.59 (0.93–2.71)</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>46 (30.9)</td>
<td>40 (24.0)</td>
<td>0.17; 0.71 (0.43–1.16)</td>
<td>41 (24.1)</td>
<td>0.18; 0.71 (0.43–1.17)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>16 (10.7)</td>
<td>35 (21.0)</td>
<td>0.014; 2.20 (1.16–4.17)</td>
<td>36 (21.2)</td>
<td>0.012; 2.23 (1.18–4.22)</td>
</tr>
<tr>
<td>Tramadol</td>
<td>3 (2.0)</td>
<td>2 (1.2)</td>
<td>0.67; 0.59 (0.097–3.58)</td>
<td>5 (2.9)</td>
<td>0.73; 1.47 (0.35–6.29)</td>
</tr>
<tr>
<td>Morphine</td>
<td>19 (12.8)</td>
<td>3 (1.8)</td>
<td>0.0; 0.13 (0.036–0.43)</td>
<td>7 (4.1)</td>
<td>0.005; 0.29 (0.12–0.72)</td>
</tr>
<tr>
<td>Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intravenous</td>
<td>30 (20.1)</td>
<td>50 (29.9)</td>
<td>0.045; 1.69 (1.01–2.85)</td>
<td>55 (32.4)</td>
<td>0.014; 1.90 (1.14–3.17)</td>
</tr>
<tr>
<td>Intramuscular</td>
<td>9 (6.0)</td>
<td>2 (1.2)</td>
<td>0.019; 0.19 (0.04–0.89)</td>
<td>1 (0.6)</td>
<td>0.007; 0.092 (0.012–0.74)</td>
</tr>
<tr>
<td>Oral</td>
<td>116 (77.9)</td>
<td>126 (75.4)</td>
<td>0.62; 0.87 (0.52–1.47)</td>
<td>125 (73.5)</td>
<td>0.37; 0.79 (0.47–1.32)</td>
</tr>
<tr>
<td>Rectal</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td>0.47; 1.01 (0.99–1.02)</td>
<td>0 (0)</td>
<td>0.47; 1.01 (0.99–1.02)</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>5 (3.4)</td>
<td>0 (0)</td>
<td>0.022; 1.04 (1.0–1.07)</td>
<td>2 (1.2)</td>
<td>0.26; 0.34 (0.066–1.80)</td>
</tr>
<tr>
<td>Pain treatment after discharge</td>
<td>117 (75.4)</td>
<td>109 (24.1)</td>
<td>0.64; 0.93 (0.69–1.26)</td>
<td>140 (32.8)</td>
<td>0.016; 1.43 (1.07–1.91)</td>
</tr>
</tbody>
</table>

APAP = acetaminophen; CI = confidence interval; OR = odds ratio.

in detail, the composite endpoint of pain awareness was chosen as a secondary outcome. Using this endpoint, patients who receive analgesics can be accounted for, although no NRS pain score was documented, as well as patients whose NRS pain score was documented but no analgesics prescribed. In daily practice, these situations occur frequently. Reasons could be accidental, patients might not have been able to score their pain for whatever reason, or work pressure might have been high at that specific moment. Another reason includes injuries that are initially painful, but would not require analgesics, such as sprained ankles, that are usually satisfactorily managed with ice, elevation, and splinting.

Pain awareness increased to more than half of all patients and is mainly due to an increase in assessment using NRS pain scores. This means that nursing staff is significantly more aware of the occurrence of pain in adult patients with traumatic injuries after implementation of the protocol, although analgesics are not administered more frequently until 18 months after implementation. To our knowledge, this is the first ED study that uses pain awareness as a clinical endpoint, and this might add more information to future pain studies. In order to detect changes in analgesic prescription habits among physicians, we also evaluated pain treatment after discharge. Along with an increase in nursing administration of analgesics, pain treatment after discharge also increased at 18 months compared to baseline. It seems that behavioral changes arose not only among nursing staff, but also among physician staff.

There was a significant shift from i.m. to i.v. administration of analgesia, as described in earlier studies (15,16). The advantages of i.v. administration are faster onset and ease of titration. This is the first study investigating i.v. fentanyl as a standing order to be administered autonomously by nursing staff. Fentanyl was chosen because of its faster onset and hemodynamic stability compared to, for example, morphine. This practice seems safe, as no adverse events were recorded. However, since the incidence of serious opioid-related adverse events is rather low, we cannot exclude, based on our sample size, that severe adverse events might occur with a low incidence. Obviously, fentanyl was prescribed significantly more frequently, at the expense of morphine, as fentanyl was mentioned explicitly in the protocol. In some instances, morphine was still utilized after implementation; this was ordered explicitly by the treating physician due to physician’s preference or need for long-term analgesics in case pain was expected not to decrease soon by concomitant treatment (e.g., surgical treatment or immobilization). Of the patients with severe pain, 60–70% received analgesics at 6 and 18 months. This number is comparable with a study evaluating mandatory pain scoring as an intervention (9). As it is reasonable to expect that a patient with severe pain would not refuse analgesic treatment when offered, underestimation of pain severity by health care staff might play a role. This is a well-known phenomenon and might lead to suboptimal pain treatment (21). In a study, the authors found that only 22% of patients who would have liked to receive APAP, actually received this, despite having a protocol in place (22).

Implementation of our nurse-initiated pain protocol means that opioid analgesics can be administered before physician’s assessment has been initiated. Traditionally, this is a precarious issue due to fear of masking symptoms and concerns of misdiagnosis once opioids are administered, especially in abdominal pain. However, the authors of a Cochrane Review concluded that opioid use before physician’s assessment does not increase risks of misdiagnosis in patients with acute abdominal pain (23). This is probably also true for patients with traumatic injuries.
Although our results show some improvement in pain assessment and treatment, it is very clear that there is still much to gain.

It could be that patient factors play a role, such as patient’s beliefs and opinions regarding pain medication. As described by Stalnikowicz et al., the most common misconceptions among patients are fear of adverse events; fear of addiction to pain medication; disbelief that analgesics actually work; and belief that pain medication should be given only when pain is unbearable (21). In addition, in health care staff, old routines might be harder to change than expected. A clinical nurse specialist described difficulties, challenges, and hurdles faced when trying to implement a nurse-initiated pain protocol in triage in the ED (24). This resulted in a rarely used protocol, due to practical issues and work pressure. Implementation of a protocol alone does not always lead to improvement and continuous feedback is necessary. It has been described that the greatest barriers to implementation of research-based nursing care dwell at an organizational level, such as lack of resources, limited staff, and lack of authority to change pre-existing protocols (25). Barriers at an individual level will also play a role, for example, lack of confidence, knowledge, and skills; no perceived reason to change practice; little expectations that practice will change for the better; and lack of motivation to change. As pain management increased after 18 months compared to 6 months, it could have been that nurses became more confident administering analgesics autonomously, however, levels of confidence were not measured in our study. Therefore, it is useful to investigate what persuasions and beliefs regarding analgesia exist among staff and also among patients in the ED. Knowledge of, communication, and education about these barriers might increase adherence to a nurse-initiated pain protocol.

LIMITATIONS

The before-and-after study design has inherent limitations and other factors might have influenced the results found after implementation of the pain protocol. Although we are not aware of important changes in personnel, staffing, or other changes in the department, the time frame of 1 year (between 6 and 18 months after implementation) is rather long and other confounding factors might have played a role. It could be that unidentified confounders have influenced the results and have led to significant changes in pain management, specifically the significant improvement at 18 months. The study was subject to the biases inherent in a retrospective study. In order to minimize bias, several study design criteria were used to increase the methodologic quality of this chart review (20). The study design lacked a missing-data management plan, however, main outcomes were dichotomous and always available from the hospital patient database.

When we would have chosen a prospective design, data had to be collected while being present with the nurse at the moment of treating a patient, which might have influenced actions and could have caused bias because of a Hawthorne effect (26). Finally, analgesia that was administered prehospital was not accounted for and could have influenced the results.

CONCLUSIONS

Implementation of a nurse-initiated pain protocol based on NRS pain scores improves pain awareness immediately and improves analgesic administration in the long term in adult patients with traumatic injuries. The use of i.v. fentanyl as a standing order in these patients appears to be safe. Barriers to implementation of the protocol and persuasions and beliefs among staff and patients regarding analgesia should be investigated in order to improve pain management and adherence to a nurse-initiated pain protocol.

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REFERENCES

ARTICLE SUMMARY

1. Why is this topic important?
   The topic is important, as pain management is a part of clinical daily practice of all emergency physicians. We know that pain management is not optimal and we need ways to improve this.

2. What does this study attempt to show?
   This study attempts to show the effect of implementation of a pain protocol in which emergency nurses can autonomously administer analgesics, including opioids, to adult patients with pain from traumatic injuries.

3. What are the key findings?
   Implementation of a nurse-initiated pain protocol improves pain awareness in the short term and pain management in the long term. Frequent audits might help achieve this result.

4. How is patient care impacted?
   Besides implementation, frequent auditing, personal feedback, and identification of barriers of implementation are necessary to successfully implement a nurse-initiated pain protocol in adult patients with traumatic injuries.