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The utility of adding symptoms and signs to the management of injury-related pain

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ABSTRACT

Objective: Improved pain assessment and management in the emergency department (ED) is warranted. We aimed to determine the impact on pain management, of adding symptoms and signs to pain assessment.

Patients and methods: A single center before-and-after study was conducted, supplemented by an interrupted time series analysis. The intervention included the addition of clinical presentation (CP) of the injury and facial expression (FE) of the patient to pain assessment scales of patients with soft tissue injures. Pain intensity was categorized as: mild, moderate, and severe. We compared types of pain relief medications, use of strong opioids, and pain relief efficacy between pre and post intervention phases.

Results: Before-and-after analysis revealed a significant reduction in the use of strong opioids. The adjusted relative ratio for the use of strong opioids in the post intervention phase was 0.63 (95% CI: 0.48–0.82). This reduction was mostly driven by less use of strong opioids in patients reporting severe pain (from 17.3%–7.9%) ($P < 0.0001$). A larger proportion of patients in the post intervention phase than in the pre intervention phase received weak opioids and nonsteroidal anti-inflammatory drugs (NSAIDs) (27.4% vs 19.1%, $P = 0.002$), and a larger proportion did not receive any pain relief medication (19.8% vs 10.5%, $p < 0.0001$). The use of strong opioids increased with higher levels of FE and CP. Among patients with mild injury and reporting severe pain, the odds of receiving a strong opioid was nearly 9 times (OR = 8.9, 95% CI: 4.0–19.6) higher among those who were with an unrelaxed FE and showed pain behavior than those with relaxed FE. Interrupted time-series analysis showed that the mean ΔVAS (VAS score at entry minus VAS score at discharge) in the post intervention phase compared with the pre intervention phase was not statistically significant ($P = 0.073$). The use of strong opioids in the post intervention phase was significantly reduced ($P = 0.017$).

Conclusion: Adding symptoms and signs to pain assessment of patients admitted with soft tissue injuries decreased the use of strong opioids, without affecting pain relief efficacy.

Introduction

Pain is considered the most common reason for emergency department (ED) visits worldwide [1–3]. Policy statements by the British College of Emergency Medicine [4] and the American College of Emergency Physicians [5] have emphasized the importance of prompt, safe, and effective pain management in the ED. Yet, assessment and management of acute pain in the ED is in need of improvement [6]. Pain is often under-treated and delayed [2]. On the other hand, the possibility of over-prescribing strong opioids in the ED has recently drawn considerable attention [7,8]. A recent statement by the American Academy of Emergency Medicine endorsed a patient-specific, pain syndrome-targeted approach, which is based on non-pharmacological and pharmacological measures [9], and which urges ED physicians to carefully consider the harms, as well as benefits, of opioid analgesics [9]. Our medical center, like other medical centers in Israel, uses a three-step pain ladder protocol for treating injury-related pain in the ED. Based on a pain ladder initially suggested by the World Health Organization (WHO) for treating cancer pain, this protocol has been adopted, with some modifications, by the British College of Emergency Medicine [4] and by others, for management of acute pain in the ED [10]. Briefly, the protocol recommends non-opioid

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drugs for mild pain, non-steroidal anti-inflammatory drugs (NSAIDs) or weak opioids for moderate pain, and strong opioids for severe pain. Since pain perception is subjective, pain assessment and management is a challenging task; this raises questions regarding the reliability of existent pain rating scales. Overestimation of pain intensity by patients and medical staff can result in unnecessary use of high-intensity pain relief medications such as strong opioids. The consequences of such have been under scrutiny due to reports that even a single exposure to opioids in the ED may increase the risk of long-term opioid use [7,8,11]. Therefore, determining therapy based solely on patient-reported pain can be erroneous and even dangerous. Moreover, some patients reporting moderate to severe pain are effectively treated with medications suitable for mild pain [12,13]. Improved pain assessment will eventually lead to more adequate pain management and perhaps to a more rational use of strong opioids in the ED. The use of facial expression (FE) for estimating pain intensity has been extensively discussed and investigated in regard to pediatric patients [14–16] and mechanically ventilated patients [17]. It is widely agreed that facial expression could be useful in assessing pain intensity [18]. In contrast, the clinical presentation (CP) of soft tissue injuries has not been incorporated into pain scales. This study aimed to determine the appropriateness and efficacy of pain management of patients with soft tissue injuries in the ED, and to determine the utility of adding symptoms and signs to the management of injury-related pain. We hypothesized that adding FE of the patient and the CP of the injury to current pain assessment scales could lead to a more rational use of strong opioids without affecting pain management efficacy.

Patients and methods

This study was conducted at a teaching hospital with a level II trauma center, which serves a population of nearly 700,000 inhabitants and has approximately 135,000 adult patient visits per year to the ED.

Study design

A before-and-after study was conducted, supplemented by an interrupted time series analysis to evaluate the impact of adding two new objective variables (FE and CP) to pain assessment scales. During phase I which lasted from January to March 2016 we assessed the appropriateness and efficacy of existing pain management in the ED. Eligible patients were patients who were admitted to the ED due to traumatic soft tissue injury and suffered from pain due to their injury. Assessment of pain in this hospital is based on the visual analogue scale (VAS) [19]. This parameter is recorded for every patient upon admission to the ED. If the patient is pain-free, "no pain" is recorded. For the purposes of the study we decoded the pain rating scale into 3 groups; mild pain was designated for VAS score 1–3; moderate pain was designated for VAS score 4–6; and severe pain was designated for VAS score 7-10. The efficacy of pain management was determined by the decline in pain intensity from entry to discharge (see below). Data were obtained using the Chameleon Medical Record (Elad Health, Tel-Aviv, Israel), a web-based electronic medical record information system that includes inpatient administrative and clinical information. The variables accessed included age, gender, type of injury, and VAS scores upon entry and discharge, and pain control medication used during ED stay. The hospital's policy for pharmacological therapy for acute pain in the ED is as follows: for mild pain, acetaminophen and dipyrone; for moderate pain, NSAIDs and weak opioids (i.e. codeine and tramadol), and for severe pain, strong opioids (oxycodone, morphine and fentanyl) are recommended. Patients who reported pain but who refused to receive pain control medication were categorized as "refused pain control medication". The type of pain control medication used for every level of pain is at the discretion of the medical staff. For example, some patients reporting the highest level of pain may receive medications that are usually used for mild pain and vice versa. For the purposes of the study, we registered the most potent pain relief medication provided to any injured patient during ED stay.

Intervention

In phase II, which lasted for 22 months (May 2016 to February 2018), two variables were added to the pain intensity assessment tool, FE of the patient at admission and CP of the injury (Table 1). In order to minimize any inter-rater reliability of scoring by the nursing staff, a training phase for one month was carried out between phase I and II (April 2016). The FE scale was categorized according to three conditions: 1= relaxed FE, 2 = unrelaxed FE, and 3 = unrelaxed FE together with pain behavior. The later was defined as any behavior that indicates that an individual was experiencing pain, such as: crying, sighing, and shouting, and non-vocal behavior (resting, guarding, and positioning) (Fig. 1). CP included two categories: 1, indicating mild injury and 2, indicating moderate to severe injury. The assignment of CP was carried out upon arrival to the ED, we did not modify the assignment if the workup resulted in a higher value (for example, a fracture instead of a sprain).

Table 1
Criteria definition of the two variables added to pain assessment at entry to the emergency department.

Score	Clinical presentation	Facial expression
1	- Without any obvious injury, or with traumatic bruises and other injuries that occur to the surface of the body and do not involve open wounds (such as abrasions, blisters, bruises, lacerations, puncture wounds, small cuts, scrapes, hematoma, and splinters). - Strains and sprains - Mild first degree burns (superficial with erythema only)	Relaxed and without explicit facial expression of pain
2	- Closed fractures for which no open wound exists. - Avulsion fracture, hemarthrosis. - Open wounds–broken skin or outward opening, beyond the superficial skin surface (including embedded foreign body, stab wounds, and impaling wounds) - Burns (chemical burns, electrical burns, heat burns, scalds, and unspecified burns) - Limb injury with bone exposure / deformation. - Nonfatal amputations of fingers or toes	Unrelaxed facial expression
3	N/A	Unrelaxed facial expression with pain behavior [a]

[a] Pain behavior; vocal behavior (crying, sighing, and shouting) or non-vocal behavior (guarding, and positioning).

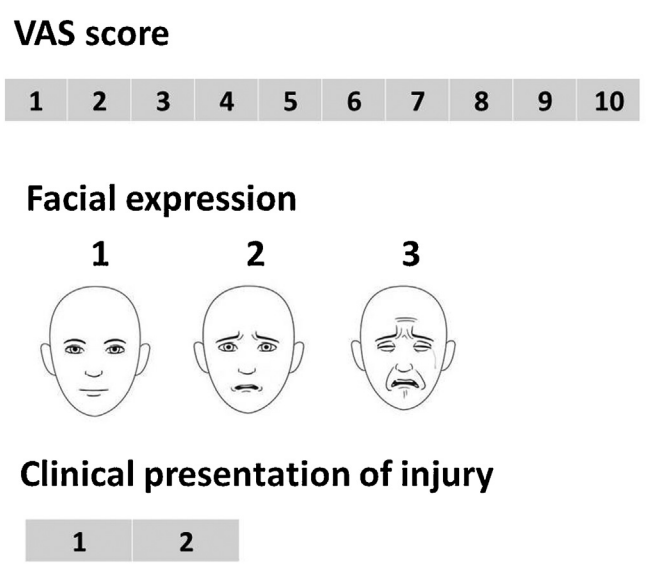

Fig. 1. Pain assessment chart used by medical staff at the emergency department. **Footnote**: **VAS;** visual analogue scale **Facial expression.** 1; relaxed facial expression, 2; unrelaxed facial expression, 3; unrelaxed facial expression with pain behavior. **Clinical presentation of injury.** 1; mild injury, 2; moderate to severe injury.

In addition, we did not change or intervene in existing guidelines for pain control in the ED.We included patients (aged > 15 years) who were admitted to the ED due to traumatic soft tissue injury. Patients were excluded from the analysis if they had any condition that impaired their ability to assess pain intensity, such as altered consciousness or significant cognitive impairment, or if they were under the influence of alcohol or substances. In addition, we excluded patients with major trauma and those for whom pain assessment at the end of treatment was not possible. Effective pain management was defined based on insights from previous studies [20,21], as a reduction in pain intensity by at least 30% between pain scores at admission and at discharge from the ED, or by a decline in pain to a lower intensity group [22].

Before-and-after analysis

Outcomes in the 3-months period before and 22-months after the intervention were compared. The primary outcomes were use of strong opioids and ΔVAS (VAS score at entry minus VAS score and discharge). Categorical variables are presented with frequencies and percentages and continuous variables are presented with means and ranges. Continuous variables were examined using the *t*-test (or Wilcoxon two sample test). A two- tailed p-value of 0.05 was used to determine significance. An interrupted time-series analysis was performed using segmented regression to adjust for any secular trend as previously described [23]. Interrupted time series analysis can control for auto-correlated errors, and can also adjust for potential serial correlation of the data [24]. Data were available for 3 months prior and 22 months after the intervention. An aggregate dataset containing daily averages of ΔVAS was created for the analysis. All statistical analysis were performed in the program SAS version 9.4 (SAS Institute Inc. Cary, NC).

The study was approved by the local ethics committee. IRB number: 0090-16-EMC.

Results

In the 3 months before the intervention (phase I), we retrieved data of 1900 patients who visited the trauma center due to traumatic injury and had pain intensity assessment at entry and discharge. In the 22 months after the intervention (phase II) we assembled data from 9222 patients for whom we had pain intensity assessment at entry and discharge, together with FE at entry and CP of the injury (Fig. 2). Demographic characteristics, distribution of pain scores at entry to the ED, and the causes of injury were similar between the patients from the two phases (Table 2).

Before and after analysis

The pain relief medications provided to the patients during phase I and phase II are shown in Table 3. The only significant differences in types of pain relief medications were noted among patients reporting severe pain at entry. We found that a smaller proportion in phase II than phase I received strong opioids, 7.9% vs. 17.3% ($P < 0.001$). A larger proportion of patients in phase II than phase I received weak opioids and NSAIDs (27.4% vs 19.1%, $P = 0.002$), and a larger proportion did not receive any pain relief medication (19.8% vs 10.5%, $p < 0.0001$). Altogether, 2.7% of patients in phase II received strong opioids, compared to 4.7% in phase I ($P < 0.0001$), and 10.8% vs 8.9% received weak opioids and NSAIDs ($p = 0.025$). Nearly 60% of patients in both phases did not receive pain control medications, ranging from 10.5% in patients with severe pain and up to 77.7% in patients with mild pain (Table 3). The main reason for not administering analgesia for patients with mild pain was patients' refusal to receive medications based on their perception that their pain was not severe enough to necessitate pain control medication. However, in patients with higher pain intensity (moderate and severe pain), other reasons were noted such as recent intake of analgesia prior to hospital admission and concerns about side effects from drug therapy including long-term risk of dependency. The vast majority (88.4%, n = 8154) of patients in phase II presented with mild injury (CP = 1); only 11.6% (n = 1068) had moderate to severe injury (CP = 2). The allocation of the various FE scores was concordant with the type of injury and the patients' own perception of their pain intensity (Fig. 3). Of the patients who did not receive any pain relief medication (n = 5583), 74.1% (n = 4138) had minor injuries (CP = 1) with relaxed FE (FE = 1). Of those who presented with mild injury (CP = 1), only 1.9% received strong opioids, compared with 9.3% of those presenting with moderate to severe injury (CP = 2) (OR = 5.3, 95% CI: 4–6.8, $p < 0.0001$). The vast majority of patients reporting severe pain exhibited unrelaxed facial expression (FE = 2) (n = 1096, 56.8%) and mostly with low CP score (Table S1). Of the patients reporting severe pain with relaxed FE and minor injury (FE = 1, CP = 1) (n = 518), only 17 (3.3%) received strong opioids (Table S1). However, with higher scores of FE and CP, higher proportions of patients received weak and strong opioids ($p < 0.0001$), and smaller proportions received type I drugs or no treatment ($p < 0.0001$). Among patients reporting severe pain with minor injury (CP = 1), unrelaxed FE with pain behavior (FE = 3) was associated with an increased odds of using strong opioids by nearly 9 times compared to relaxed FE (FE = 1) (OR = 8.9, 95% CI: 4.0–19.6, $P < 0.001$). Among patients with mild pain and mild injury (n = 5555), only 0.8% received strong opioids and 78.5% did not receive any treatment (Table S2). Higher values of FE (an increase from FE = 1 to FE = 3) among patients with mild injury and mild pain (CP = 1) increased the odds for the use of strong opioids by nearly 3 times (OR = 2.9, 95% CI; 1.6–5.5). Similar trends were noted for patients reporting moderate pain (Table S3). Lastly, the proportion of patients that received pain relief medication by first aid responders prior to ED admission was comparable between the two phases of the study (6.8% and 7.3%, respectively) (data not shown). The proportion of patients who reported a decrease of at least one level in pain group intensity ($\Delta \geq 1$), where Δ is the difference between pain group level at entry and pain group level at discharge, was lower in the post intervention phase (2.9) compared with the pre intervention phase (3.6) (adjusted relative ratio of mean ΔVAS before and after intervention was 0.89; 95% CI:

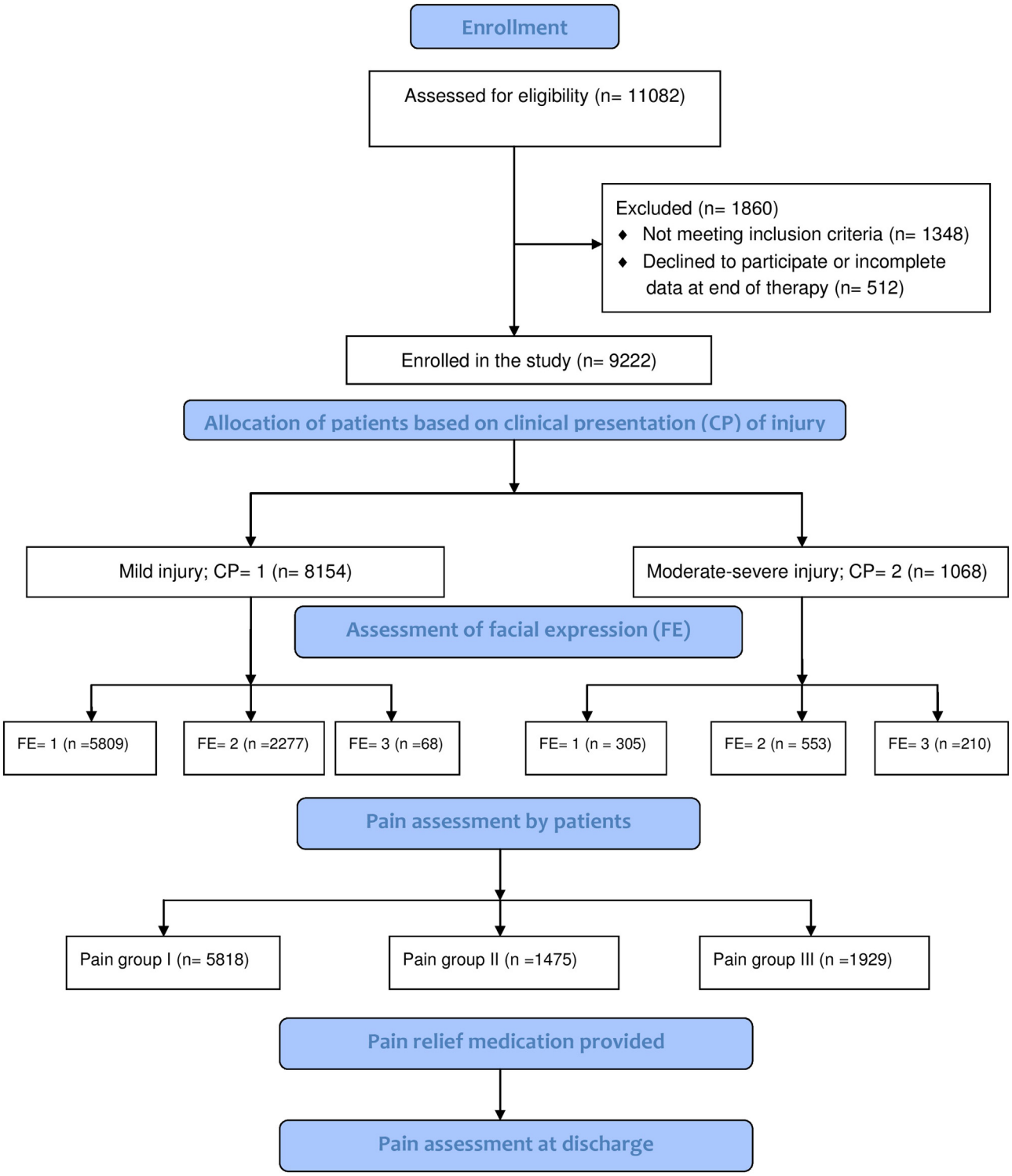

Fig. 2. Patient flowchart and flow diagram of patient eligibility and study conduct.

0.83-0.99), suggesting that pain efficacy was reduced in the post intervention phase. Adjusted relative ratio for the use of strong opioids in the post intervention phase was 0.63 (95% CI: 0.48-0.82).

Interrupted time-series analysis

Interrupted time-series analysis controls for secular trends in the data and therefore reduces bias that might be present in a simple 2-time-period model (simple pre–post measurement and analysis). The analysis showed that the mean ΔVAS in the post intervention phase compared with the pre intervention phase was not statistically significant (P = 0.073) (Fig. 4), clearly indicating that pain efficacy did not change in the post intervention phase. This analysis also confirmed the above mentioned results that the use of strong opioids in the post intervention phase was significantly reduced (P = 0.017).

Table 2
Characteristics of patients with injury- related pain during pre (I) and post (II) intervention phase.

	Phase I	Phase II	P value
No. of patients	1900	9222	
Mean age (range)	40.8 (15-94)	38.9 (15-100)	0.07
Sex-male (%)	64.7	63.2	0.08
No. of patients of each pain group at entry (%)			
Mild pain (VAS score 1-3)	1220 (64.2)	5818 (63.1)	0.3
Moderate pain (VAS score 4-6)	293 (15.4)	1475 (16)	0.5
Severe pain (VAS score-7-10)	387 (20.4)	1929 (20.9)	0.6
Cause of Injury-no. (%)			
Falls and domestic injurues	1112 (58.5)	5554 (60.2)	0.1
Motor vehicle traffic accident	619 (32.6)	2770 (30)	0.03
Work related injury	88 (4.6)	512 (5.5)	0.1
Physical assault (including domestic violence)	53 (2.8)	281 (3.1)	0.4
Sports and recreational activities	28 (1.4)	105 (1.1)	0.2

VAS: visual analog scale.

Table 3
Pain relief therapy according to pain group during the two phases of the study.

		Phase I (without FE and CP) n = 1900						Phase II (FE and CP included) n = 9222				
		No. of patients receiving pain relief therapy [a] (%)						No. of patients receiving pain relief therapy [a] (%)				
		None	Type I	Type II	Type III			None	Type I	Type II	Type III	P value
Pain group [b]	**No.**					**Pain group**	**No.**					
1	**1220**	947 (77.7)	191 (15.7)	70 (5.7)	12 (0.9)	**1**	**5818**	4509 (77.5)	919 (15.8)	334 (5.7)	56 (0.9)	0.9
2	**293**	135 (46)	123 (41.8)	25 (8.5)	10 (3.4)	**2**	**1475**	692 (45.6)	606 (41.1)	132 (8.9)	45 (3)	0.9
3	**387**	41 (10.5)	205 (52.9)	74 (19.1)	67 (17.3)	**3**	**1929**	382 (19.8)	865 (44.8)	529 (27.4)	153 (7.9)	<0.0001
Total	**1900**	1123 (59.1)	519 (27.3)	169 (8.9)	89 (4.7)	**Total**	**9222**	5583 (60.5)	2390 (25.9)	995 (10.8)	254 (2.7)	<0.0001

[a] Type I: Acetaminophen and dipyrone; Type II: NSAIDs and weak opioids (codeine and tramadol); Type III: Strong opioids (oxycodone, fentanyl, and morphine).
[b] Pain group I –mild pain (VAS score 1–3); Pain group II – moderate pain (VAS score 4–6); Pain group III- severe pain (VAS score-7-10).

Discussion

When considered together, the before-and-after study and interrupted time series analysis show that adding clinical presentation of the injury and facial expression of the patient led to significant reduction in the use of strong opioids without affecting pain management efficacy. In addition, we found that the allocation of FE and CP scores by medical staffs was concordant with the patients' own perception of their pain intensity. As the largest reductions in pain intensity were achieved using strong opioids, we sought to determine how and when medical staff members determine to administer strong opioids. Given the subjectivity of pain report, we hoped that adding symptoms and signs would be instrumental in providing insights into management strategies. As expected, with higher scores of CP, stronger opioids were administered. Among patients with severe pain and moderate to severe injury (CP = 2), 28% with an FE score of 3 (unrelaxed facial expression and pain behavior) received strong opioids, compared to 4% with an FE score of 1 (relaxed facial expression). Similarly, among patients with mild injury (CP = 1), the odds of receiving a strong opioid was higher among those with FE = 3 than FE = 1; by almost 9 times among those with severe pain, and by almost 3 times among those with mild pain. The significantly lower use of strong opioids in patients presenting with severe pain, yet with relaxed FE, mainly resulted from a significant increase in the use of NSAIDs and weak opioids. In addition, more of these patients did not receive any pain relief medication. Detailed analysis of pain relief medication provided to patients reporting severe pain showed that distinguishing between mild injury (CP = 1) and moderate-severe injury (CP = 2) yielded a statistically significant and substantial reduction in the use of strong opioids. The difference was especially profound in patients who presented with unrelaxed FE but without pain behavior; for this group, slightly more than half of those presenting with moderate to severe injury (CP = 2) were treated with weak opioids or NSAIDs. Interestingly, the distinction between the two degrees of injury did not seem relevant to the determination of pain medication among patients presenting with the highest FE score, i.e. unrelaxed facial expression with pain behavior. This observation highlights the impact of FE on treatment preferences made by medical staffs. Pain management efficacy was less prominent with lower scores of pain intensity. This presumably resulted from use of less potent drugs for people reporting mild pain, and consequently insufficient pain relief. Notably, a considerable number of patients reporting pain at all three levels were not treated with any pain relief medication. About 18% and 10% of patients, in both phases, reporting moderate and severe pain, respectively, were discharged without any decrease in pain intensity. Though it is hard to make firm conclusions about the efficacy of pain control in the ED based on the patients' own perception of pain [25], these figures are reasonably better than previous reports [2]. As expected, with higher scores of pain intensity, the proportion of patients not treated with pain relief medication was lower, ranging from 10 to 20% in patients with severe pain, compared to about 78% in patients with mild pain. The main reason for not administering analgesia in this cohort was patients' refusal to receive medications based on their perception that their pain was not severe enough to necessitate medical treatment. Other reasons included recent intake of analgesia prior to hospital admission and concerns about side effects from drug

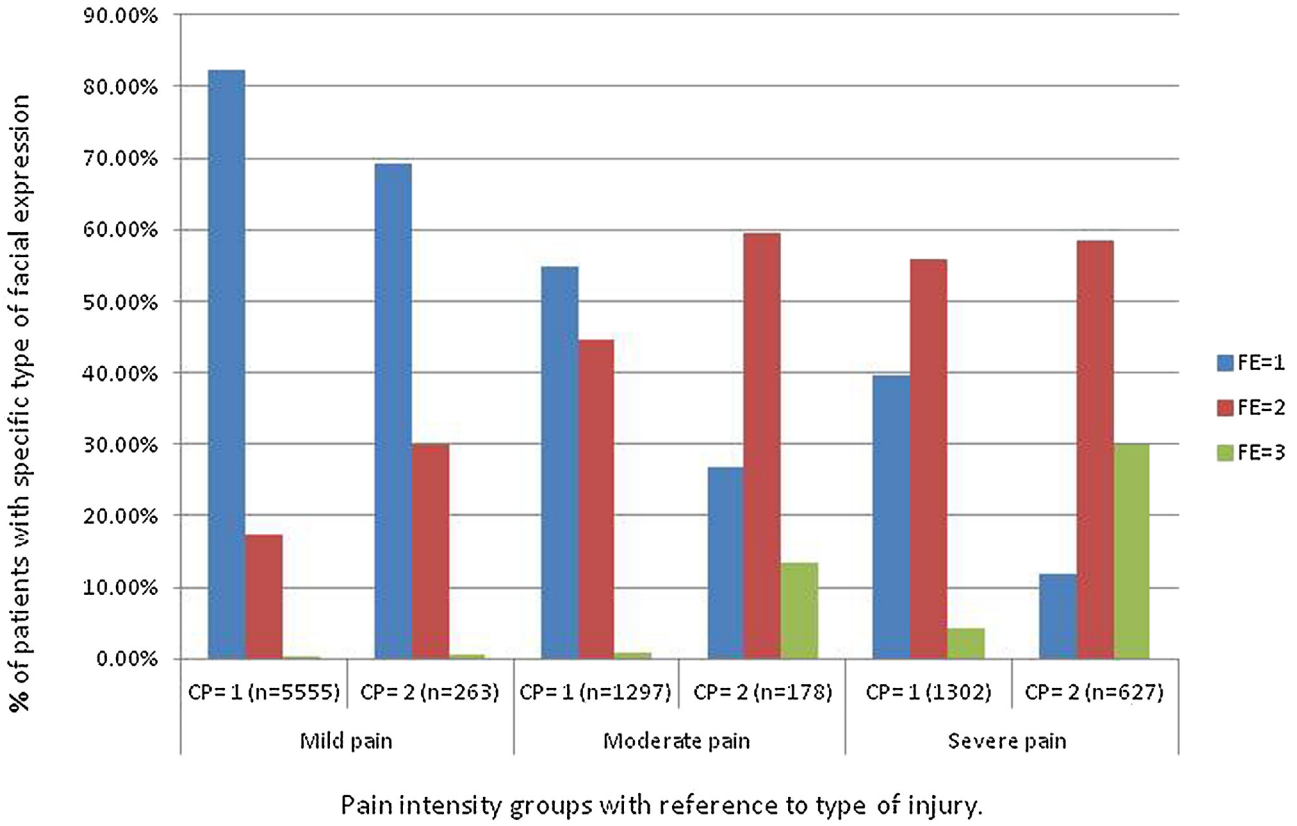

Fig. 3. Allocation of CP and FE scores for the various pain intensity groups.
Footnote: CP = 1; mild injury, CP = 2; moderate-severe injury. FE = 1; relaxed facial expression, FE = 2; unrelaxed facial expression, FE = 3; unrelaxed facial expression with pain behavior.

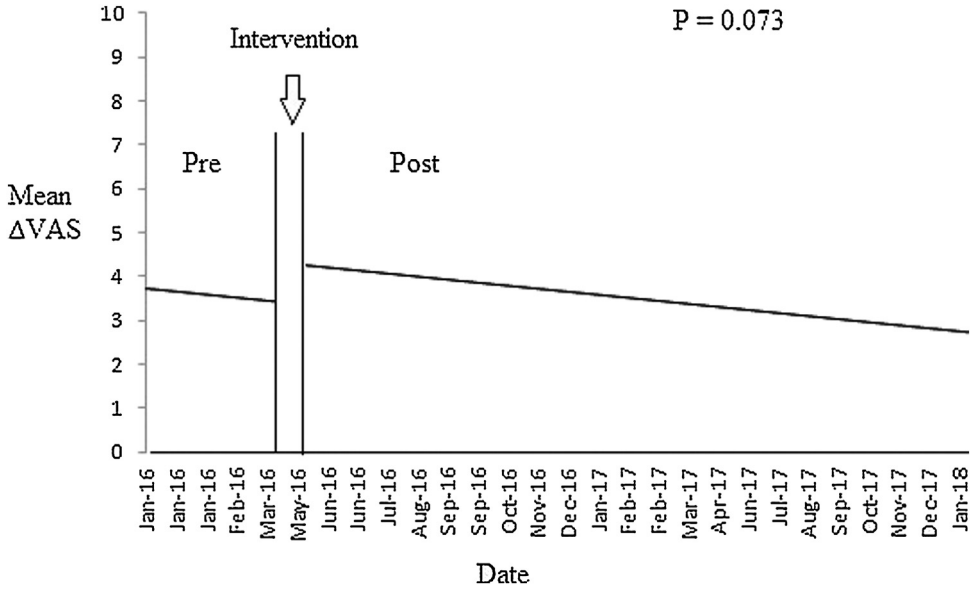

Fig. 4. Interrupted time series analysis 2016-2018.
Footnote: The lines represent linear predictions.

therapy including a long-term risk of dependency. These findings were compatible with observations from the US [26] and Australia [27]. Although the current study analyzed use of strong opioids in the ED and not discharge medication prescriptions, it has been suggested that even a single exposure to strong opioids in the ED may increase the risk of long-term opioid use [7,8,11]. The use of opioids in EDs in the US has become a public health concern due to its impact on what has been considered the greatest iatrogenic epidemic in the history of American medicine [28]. Furthermore, greater initial exposure (such as higher total dose and longer

duration prescription) has been linked with greater risks of long-term use [29], misuse, and overdose [30]. A recent study from the US showed that the most common diagnosis for which a patient received an opioid was an "injury-related complaint excluding fracture"; this comprised 20.5% of all ED opioid prescriptions [31]. In that study, 84% of the opioids prescribed were strong opioids (such as hydrocodone, hydromorphone, morphine, oxycodone, fentanyl, meperidine, and methadone) and the rest were weak opioids (codeine and propoxyphene). While deaths from abuse of opioids in the US are rampant, at 21.7 per 100,000 [32], the death rate in Israel is 1.3 per 100,000 and declining to 0.3/100,000 based on a recent study [33]. Among the reasons that could explain these huge differences in opioid-related deaths, is the nature of the Israeli public health system, which is characterized by strong regulation and an effective central computer system, with close monitoring of opioid prescriptions. In addition, while pharmaceutical companies in Israel are not allowed to advertise prescription drugs directly to the consumer, in the US, direct marketing and advertising of prescription drugs, including opioids, are freely permitted. Though some health authorities attribute an equal risk of long term abuse and dependency from weak and strong opioids [34], data from Israel suggest that the risk of dependency and overdose-related deaths due to weak opioids is substantially lower than for strong opioids [33]. These observations are consistent with a recent study from Germany that showed that tramadol carries a low potential for misuse, abuse, and dependency [35]. This study has some limitations that should be acknowledged when interpreting the findings. First, since the CP and FE scores were assigned by several members of the nursing staff, we cannot rule out misclassifications or errors regarding CP and FE. Second, an observer effect (Hawthorne effect) cannot be ignored in such a study; this may have affected decisions regarding treatment. Needless to mention that we did not intervene in any manner regarding the type of pain relief therapy provided. Third, some patients (7%) received pain control medications by first aid responders, this may have impacted the patients' response to pain control medications. Yet, the proportions of those who received such treatment were comparable between the two phases. Finally, this study was carried out at a single hospital and the results may not be generalizable to other institutions. Notably, this academic medical center serves a large multi-ethnic population consisting of Arabs (54%), Jews of Sephardic and Ashkenazi origin (43%), and other ethnicities (3%). This population is somewhat different from the general population in Israel (74.5% Jews, 21% Arabs, and 4.5% other ethnicities). Several observations have suggested that ethnicity could affect pain assessment and management, such that minorities usually report higher levels of pain, and this could affect treatment decisions [36]. However, we believe that the effect of ethnicity was perhaps minimal if at all.

Conclusions

This study showed that following the addition of two easily evaluated parameters to pain assessment of patients with traumatic injury, the proportion that received strong opioids significantly decreased, to the benefit of greater use of weak opioids and NSAIDs; while pain relief efficacy did not change. Another, unintended effect of this modification in pain assessment is that the proportion of patients that did not require any pain relief medication nearly doubled. This may have occurred based on the perception of patients, as well as medical staff members, that mild injuries do not always necessitate pain relief medication.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.injury.2019.08.022.

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