

Management of Acute Trauma Pain in the Emergency Department – A Comparison of Intramuscular Ketorolac, Diclofenac and Tramadol

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ABSTRACT

Introduction: Trauma is a chief cause of pain and suffering. A large number of studies have shown that pain relief provided to patients in the ED is grossly inadequate. Diclofenac, tramadol and ketorolac are the most commonly used intramuscular analgesics and hence selected for this comparative study. The aim of this study was to compare the analgesic duration, efficacy and side effect profile of diclofenac, tramadol and ketorolac administered intramuscularly in patients who presented to the ED with acute trauma pain.

Material and methods: In a prospective double-blinded study, 90 patients presenting to the ED with musculoskeletal trauma were randomly selected and divided into 3 groups - Group A received 1 ml (50mg) Diclofenac; Group B received 1ml (30mg) Ketorolac; Group C received 1ml (50mg) Tramadol. The efficacy of the drug was measured by observing: pain score, onset & duration of action, rescue drug use, and the patient's global impression of efficacy of drugs. Collected data was analysed using ANOVA.

Results: The time taken to administer the first dose of rescue analgesic was significantly ($P < 0.05$) delayed in the Group B (276mins). Overall, mean scores were significantly better with (Group B) and were not significantly different between other (Group T) and (Group A).

Conclusion: Ketorolac was a better analgesic compared to diclofenac and tramadol in managing acute trauma pain.

Keywords: Acute Pain, Diclofenac, Trauma, Ketorolac, Tramadol.

INTRODUCTION

Pain is a primary impetus for patient presentation to the Emergency Department (ED), and hence, its treatment should be a priority for acute care providers. Trauma is a chief cause of pain and suffering. A large number of studies have shown that pain relief provided to patients in the ED is grossly inadequate.¹⁻⁵ The average time from arrival to the ED, the choice and administration of an analgesic and the adequacy of pain relief provided to the patients is a subject of much debate. The variety of analgesic agents available to the ED practitioner is also continually broadening. There are dozens, even scores, of drugs that can be used depending on the clinical circumstances.

Analgesic development for acute pain has primarily been documented in postoperative pain models: orthopedic pain, abdominal pain, pain related to obstetrical/gynecologic procedures, and dental pain^{6,7}, hence we have undertaken this study to assess the pain score of patients presenting to the ED with trauma and to compare the most commonly used NSAID's, Ketorolac and Diclofenac with the synthetic

opioid, Tramadol, in alleviating acute trauma pain in the ED. The intramuscular route has theoretically the advantage of not requiring monitoring and thus can be administered quickly even in a crowded ED and hence we have selected this route of administration.

MATERIAL AND METHODS

The study was conducted on 90 adult patients presenting with musculoskeletal trauma, to the Emergency department of Fr Muller Hospital, Thumbe, which is a unit of Fr Muller Medical College, Mangalore. Patients with acute pain (pain score greater than 3), presenting with musculoskeletal trauma (limbs or back) who were conscious with GCS 15 in a haemodynamically stable condition (BP greater than 90/60).

Patients with abdominal or chest pain, history of bleeding diathesis, Pregnant and lactating women, patients with major head injury or impaired consciousness, acute intoxication with drugs or alcohol, any drug allergy or on any long-term medication and other conditions that might impair ability to score pain was excluded from the study.

Design of study

A Prospective Randomized Comparative Interventional Study was conducted after obtaining ethical clearance. 90 patients with trauma presenting to the Emergency Department of Fr Muller Hospital Thumbe, was included in the study.

These patients were randomly allocated into 3 groups of 30 each; Group A received 1 ml (50mg) Diclofenac; Group B received 1ml (30mg) Ketorolac; Group C received 1ml (50mg) Tramadol. The drug solutions were administered intramuscularly to all patients in a double blind manner whereby neither the nurse who gave the injections nor the observer who assessed the various parameters was aware of the drug used.

Parameters were observed at baseline and after 15, 30, 60,

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How to cite this article: Lulu Sherif, Kiran Shetty. Management of acute trauma pain in the emergency department – a comparison of intramuscular ketorolac, diclofenac and tramadol. International Journal of Contemporary Medical Research 2020;7(3):C4-C6.

DOI: <http://dx.doi.org/10.21276/ijcmr.2020.7.3.32>



180 and 300 minutes (5 hrs) of drug treatment. The efficacy of the drug was measured by observing: pain score, onset & duration of action, rescue drug use, and the patient's global impression of efficacy of drugs.

Pain was assessed by the Numeric Rating Score, VAS.⁸ The patients were instructed to rate their pain intensity on a scale of 0 ('no pain') to 10 ('the worst pain imaginable'). Some patients found this difficult with only verbal instructions but was able to point to the number on the scale that described the intensity of their pain.

Just before starting treatment heart rate and blood pressure was recorded in each patient and any fluctuations in the clinical parameters after giving the drug was analyzed. Patients who had no relief of pain with the study drug even after 30 minutes or an increase in NRS was given intravenous butorphanol 1mg. Number of patients requiring rescue drug and time when required was noted in each group.

Onset of action of drug was recorded as within 0-15 minutes and 15-30 minutes. The duration of action was taken as the time interval between the onset of action and first recurrence of pain or demand for analgesic.

At the end of study period all patients were asked to rate the overall efficacy of drug used as good, very good or excellent. The tolerability of the drug was assessed on the basis of acceptance of the drug. The parameters assessed were nausea & vomiting, epigastric pain, headache, dizziness/faintness, vertigo, allergic manifestations and injection site pain.

RESULTS

Demographic data

The mean Age group was 40.8 years. The mean weight was 57.63 kg. (Table 1) The gender distribution had 56 males and 34 females. All 90 patients included did not meet the exclusion criteria, so none had to be excluded from the study sample.

Clinical data

Table 2. shows that the time taken to administer the first dose of rescue analgesic was significantly ($p < 0.05$) delayed in the Group Ketorolac as compared to Group Diclofenac and Group Tramadol (276 mins, 202 mins and 195 mins respectively). The Group Ketorolac had the longest duration of action when compared to the other two drugs. (Table 3). There were no significant changes in the hemodynamic status of all three groups after study drug administration. Two patients in the Tramadol group complained of nausea but not significant. No other clinically significant side effects were recorded. All the three drugs had similar tolerability and the patients rated all three drugs as good.

DISCUSSION

The prevalence of pain in the ED is high; recent studies indicate that 78% of visits to the ED are prompted by pain of various sorts. Dr. Knox H. Todd, from the Pain and Emergency Medicine Institute at Beth Israel Medical Center in New York, reviewed the results of the Pain and Emergency Medicine Institute (PEMI) study. This prospective, multicenter study assessed the current state

of ED pain management practice. The study included 842 patients at 20 hospitals in the United States and Canada. On arrival, pain intensity was severe. Only 60% of patients received analgesics and only after lengthy delays (median, 90 minutes). For, 41% of patients, pain intensity either did not change during the ED visit (34%) or it increased (7%). Almost three quarters of patients had moderate or severe pain when they were discharged.¹

Historically, analgesic development for acute pain has primarily been done in postoperative pain models: orthopedic pain, abdominal pain, pain related to obstetrical/gynecologic procedures, and dental pain. Although this is valuable work, it has all been done on postoperative pain. There are a number of other sites of acute pain being treated in the ED, and as Dr. Todd discussed, the timeliness and effectiveness of pain treatment in the ED could improve.

An Acute Pain Clinical Trial was conducted in 47 urgent care centers, including 39 EDs.⁹ The objective of this trial was to compare the analgesic efficacy and safety of tramadol/acetaminophen vs hydrocodone/acetaminophen vs placebo using an ankle sprain with partial ligament tear as a model of acute musculoskeletal pain. The primary efficacy outcome was total pain relief during the first 4 hours. The results of the trial showed that there was statistical separation in pain relief with both active groups, but no separation in pain intensity. The results of our study demonstrate that ketorolac provides effective analgesia in acute trauma pain. Patients who received a single IM dose of ketorolac experienced pain relief that was superior to diclofenac and tramadol based on VAS score and time required for rescue analgesia. The time taken to administer the first dose of rescue analgesic was significantly ($P < 0.05$) delayed in the Group Ketorolac (276mins).

NSAID's belong to the level 1 analgesic ladder of pain management according to the WHO classification. It can be used alone for weak or moderate pain and in association with level 2 analgesics for intense or severe pain. The main points are that NSAIDs are associated with some serious side effects, namely gastro-intestinal bleeding and renal insufficiency. Ketorolac, a pyrrolo pyrrole derivative and Diclofenac, an aryl acetic acid derivative are the two most extensively used NSAIDs.

The indication of weak opioids - level 2 according to the WHO classification - could be for moderate to intense pain, or when pain is partially or unrelieved with level 1 analgesics. Tramadol is both a serotonin and noradrenaline reuptake inhibitor and an opioid agonist. This drug can be associated with some side effects like sedation, confusion, dizziness and hallucination. Nausea and vomiting are the most common adverse effects.

Bhanu Prakash Kolasani and Jayaraju Juturu conducted a prospective, randomized, double blind clinical study wherein 70 patients with renal pain admitted in the ED was treated with intramuscular ketorolac and diclofenac for pain relief. The parameters were observed at baseline and after 15, 30, 60, 180 and 300 minutes after injection. The efficacy of the drug was measured by observing: pain score, onset

& duration of action, rescue drug use and patient's global impression on efficacy of drugs. The mean pain scores at 15, 30, 60, 180 and 300 minutes were 56.53 ± 15.27 , 30.14 ± 8.05 , 15.36 ± 6.68 , 7.03 ± 6.20 , 2.13 ± 1.05 respectively in the ketorolac group, whereas in the diclofenac group the same values were 65.91 ± 16.22 , 32.33 ± 7.59 , 16.13 ± 7.41 , 8.72 ± 6.55 and 2.36 ± 1.97 . Both drugs were effective in relieving pain of renal colic and maintaining it over time as well. When decrease in value of pain score was compared between the two groups at various intervals of time, there was a statistically significant ($p < 0.05$) decrease in pain score at 15 minutes for ketorolac group indicating that it was slightly more effective in early phase compared to diclofenac. In either group there was no statistically significant difference regarding duration of action and side effect profile.¹⁰ This study showed similar results to our study.

Sadasivam Balakrishnan, Ratinder Jhaj and Vishnu Raj conducted a study in the ED of a tertiary care hospital to assess the adequacy of pain relief, in patients with RTA. They included patients with peripheral limb injuries with a glasgow coma scale (GCS) of 15. Subjects with head injury, unconsciousness, and a pain score of less than 7 on a 10 point visual analog scale (VAS) were excluded. The patients were asked to rate their pain severity on the VAS. They were then allowed to follow the normal ED protocol of the institute. The time to analgesic administration, the drug given, dose, and route of administration were noted. Half an hour after the analgesic administration the patients were again asked to rate their pain severity on the VAS. The total duration of time spent in the ED was also noted. During the five year period, 560 patients were eligible to be included; out of which 76% were males. The median VAS on first assessment at ED department was 8 (7-10). The initial assessment of the patient by an intern was immediate, and analgesic administered within 10 minutes. The analgesics prescribed were intramuscular ketorolac 60 mg in 6.8%, intramuscular tramadol 100 mg in 22.72%, and intramuscular diclofenac 75 mg in 70.45% of the patients. The median VAS half an hour after the administration of ketorolac -6 (5.5-8.3), tramadol -6 (5.5-8.6), and diclofenac -7 (6.2-8.8). There was no significant pain relief noted with any analgesic (Wilcoxon-Signed Rank Test) including tramadol. They noted that most analgesics were administered intramuscularly.² This study was contrary to our study where they found no significant difference with all three drugs.

CONCLUSION

The results of our study demonstrate that ketorolac provides effective analgesia in acute trauma pain. Patients who received a single IM dose of ketorolac experienced pain relief that was superior to diclofenac and tramadol based on VAS score and time required for rescue analgesia.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 10-02-2020; **Accepted:** 28-02-2020; **Published:** 20-03-2020