

COMPARATIVE STUDY OF ANALGESIC EFFECTIVENESS OF TRAMADOL AND KETOROLAC IN THE PAIN MANAGEMENT OF SURGICAL REMOVAL OF THIRD MOLAR: A RANDOMIZED DOUBLE BLINDED STUDY

ABSTRACT

AIM: Assessing the efficacy of drug in controlling pain intensity after surgical removal of impacted mandibular third molar teeth and to compare the effects. **MATERIAL AND METHODS:** A double-blind, randomized, controlled clinical trial was conducted. 40 patients were randomly selected and divided into two equal groups. Group A received 50 mg of tramadol orally and Group B received 10 mg of ketorolac orally. In both groups dose was repeated for next 24 hrs. Visual analogue scale was used for the collection of pain intensity from the patients. **RESULTS:** The results revealed, in Group A, the analgesia started within 1 hour and reached the maximum analgesic effect in 4 hours, pain intensity was 1.8 out of 10, on visual analog scale. In Group B, analgesia started within 1 hour and showed its maximum analgesic effect. The pain intensity was 2.5 on visual analog scale. The analgesic effect of 50 mg tramadol lasted up to 6 hours and that of ketorolac lasted for 5 hour. **CONCLUSION:** The study shows that 50mg tramadol is a suitable and safe analgesic for the relief of post-extraction pain and is more effective than 10mg ketorolac with prolonged analgesia and minimal side effects, we recommend studies with randomized clinical trials with larger sample size are needed it in clinical practice.

CHETHAN, R*
RAMAMUTHY, TK*
PATIL, Shilpa*
REDDY, Satheesha*

KEYWORDS

Tramadol. Ketorolac. Third molar. Impacted. Extraction.

INTRODUCTION

Wisdom tooth is the last tooth to erupt into the oral cavity, frequently these teeth are either partially impacted or completely impacted in the jaw bone. They might not always come into the mouth normally. Impacted asymptomatic third molar are prophylactically removed in order to prevent the anticipated complications like cystic transformation, pericoronitis, periodontal lesions of the distal surface, leading to pain and swelling. To avoid these problems it is always better to remove the tooth¹.

Pain associated with surgical removal of mandibular third molar ranges between moderate and severe². During the surgery, tissue damage, inflammation and other noxious stimuli trigger a range of changes in the central nervous system and the subsequent pain after this procedure is frequently serve for which management of post extraction pain with analgesia leads to increased patient satisfaction³⁻⁵. According to literature, pain after surgical extraction of a third molar reaches its highest intensity 4-6 hours after surgery.⁶

The visual analogical scale (VAS) is considered the best and easiest method to measure post extraction pain⁶.

Hence the current study was carried out with the objective of evaluating comparatively the analgesic effects of two commonly used analgesics, 50mg tramadol and 10mg

ketorolac, keeping in view giving the quicker, prolonged and safer post extraction analgesic after mandibular third molar tooth extraction for quicker recovery of the patient from the post extraction pain. There were some reports published the comparing the preemptive analgesia, Parenteral tramadol and ketorolac in maxillofacial surgery^{2,15,9,10}.

MATERIAL AND METHODS

Study was a double-blind, randomized controlled clinical trial conducted in our institution AECS Maaruthi College of Dental Sciences and research center bangalore, the study was conducted in accordance with the provisions of the declaration of Helsinki, and the internal ethical committee gave its approval. All the individuals were well informed about the study, methodology and also about the visual analog scale prior to tooth extraction. Each patient gave his or her written, informed consent to participate and had the right to withdraw from the trial at any time. The sample size of 40 patients was calculated as 20 patients in each group, using as response variable the first analgesic rescue medication for postoperative pain.

Inclusion criteria were as follows: age 18 to 25 years, either gender, free of systemic disease, clinical and radiographic diagnosis of an impacted third molar, no pain associated with the subject third molar up to the day of

the surgery, and grade II or III difficulty of extraction.

Exclusion criteria included the use of analgesics 24 h before the procedure, history of seizure disorder, oral contraceptive use, End stage renal disease, known hypersensitivity to the study medications.

All surgical procedures were carried out in the Department of Oral and Maxillofacial Surgery by the same surgeon, and evaluations were carried out by an independent investigator. Anaesthesia was by nerve block of the lingual, buccal, and inferior alveolar nerves using 2% lignocaine, once anaesthesia was obtained, surgery was started. Difficulty of extraction was based on a modified scale of Parant et al.⁷ as follows: Grade I, extraction with forceps and elevators; Grade II, extraction by osteotomy; Grade III, extraction by osteotomy and coronal section; Grade IV, extraction by osteotomy, root and coronal section; Grade V, complex extraction; Grade VI, extraction with special techniques. In each patient, impacted mesio angular mandibular third molar with grade II or III difficulty was extracted.

The individuals were unaware of the analgesic which they had taken during the study. The drugs ketorolac 10mg and tramadol 50mg were procured from the pharmacy and they have been assigned a code. Patients were randomly assigned in either treatment groups with an assigned code.

The patients were divided into two groups containing 20 patients in each group. All the codes of administered drugs were disclosed only after the pain assessment. The group A received tramadol 50mg oral dose after the extraction and dose repeated after 6 hours. The group B received ketorolac 10mg oral dose after the extraction and dose was repeated after 6hrs. Pain assessment was done by verbal rating using visual Analogue Scale⁶ [0 – no pain, 2 – mild pain, 4 – tolerable, 6 – distressful pain, 8 – severe pain and 10 – totally disabling pain].

After the tooth extraction, drugs were given after 1hour, the pain assessment at time points of 1hr after medication, 2hr, 3hr, 4hr, 5hr, 6hrs. The patient's vital signs including heart rate, respiratory rate and blood pressure were recorded at every time point after the assessment of pain intensity.

Qualitative variable data are expressed as percentages or proportions. T test was used for statistical analysis. A difference was considered statistically not significant in 1st, 2nd, 3rd hr it was more than 5% ($p > 0.05$), 4th, 5th, 6th hr was statistical significant it was less than 5% ($p < 0.05$).

RESULTS

In our study, the analgesic effect for group A who were taken tramadol started within 1st hour and reached the maximum analgesic effect in 4 hours. The average rating

of pain intensity is 1.8 on visual analogue scale for the maximum analgesic effect felt at 4th hour and with the first dose the analgesic effect sustained for 6 hours.

The analgesic effect for group 'B' who were taken ketorolac started with in 1st hour and showed its maximum analgesic effect. The pain intensity scored on visual analog is 2.5 at 1st hour. But the effect was not sustained till the next dose. The patients felt the pain in the 5th hour itself. The patients pain intensity scored '3.5' in 5th hour and '4.3' in 6th hour on visual analog scale. Figure 1 (Mean VAS score of pain in two groups) show the mean values of pain perceived by the patients in two groups. The p values were more than 0.05 and were considered statistically not significant in 1st, 2nd and 3rd hour. The p values were less than 0.05 in 4th, 5th and 6th hour and were considered statistically significant.

According the observations, the analgesic effect is reached quickly in group 'B' who received ketorolac. However, the duration of analgesia is more in group 'A' patients who received tramadol. Many patients in group who received ketorolac complained of pain before the dosing schedule time i.e. 6 hours.

DISCUSSION

Post extraction analgesia can increase the patients comfort, decrease the pain and stress after tooth extraction. The present study was designed to assess and compare the

efficacy and the patient satisfaction of two most commonly used analgesics like tramadol and ketorolac.

In all evating postoperative pain, Tramadol is an alternative drug to morphine. It is centrally acting analgesic because of its combined effects as an opioid agonist, with selectivity for μ -opioid agonist and a serotonin and noradrenalin reuptake inhibitor, with better analgesic action without the risk of development of tolerance and physical dependence. From the literature it has been considered as safest postoperative analgesic⁸⁻¹¹.

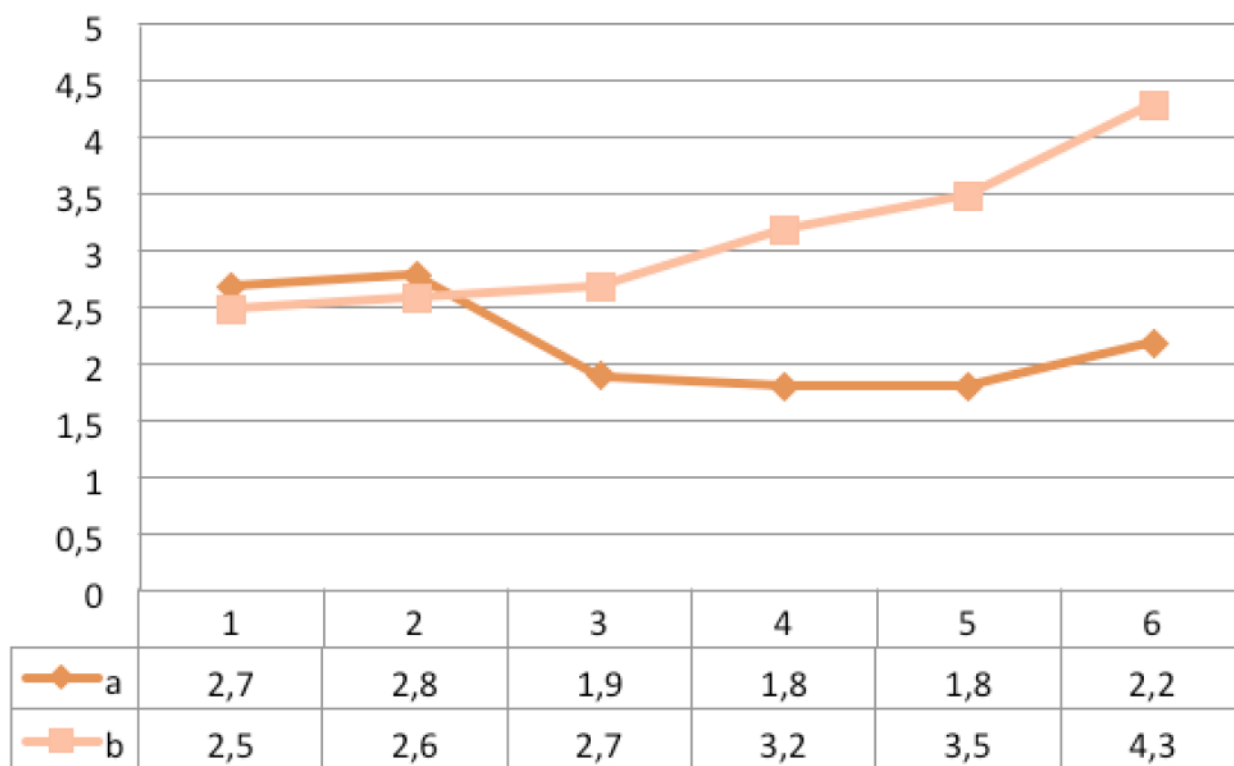
Ketorolac tromethamine is a member of the pyrrolo-pyrrole group of nonsteroidal anti inflammatory drugs (NSAIDs). Ketorolac produces its effect through the inhibition of prostaglandin synthesis, the fatty acid that promotes pain, additional mechanisms of action including a modulator effect on opioid receptors and stimulation of nitric oxide release^{8,12}.

Main focus was on the study of pain intensity of the commonly used analgesics, tramadol and ketorolac. Tramadol started within 1st hour and reached the maximum analgesic effect in 3 hours. the average rating of pain intensity is 1.8, similar results were found by, Shaik M M et al.¹⁴, ketorolac started with in 1st hour and showed its maximum analgesic effect. The pain intensity score is 2.5, similar results were found by Mario et al.⁷,

Shaik et al¹⁴. From the current study it has been proved that both the drugs are giving better analgesic effect. Ketorolac is showing its analgesic effect very rapidly but the action sustained only up to 4 hours. Whereas

tramadol analgesic effect started after 1 hour and sustained for the longer time i.e. more than 6 hours (Figure 1).

Figure 1. Comparison of pain intensities of Tramadol and Ketorolac.



CONCLUSION

The overall study profile proved that tramadol is a suitable and safe analgesic with longer duration of action and less adverse effects for relief of post extraction pain after third molar extraction and is more effective than ketorolac with a long sustained analgesic action.

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