



## Comparison of Analgesic Efficacy of Piroxicam and Ketorolac in Impacted Mandibular Third Molar Surgery: A Prospective Randomized, Double Blind Clinical Study

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Received: 02 July 2024

Revised: 18 August 2024

Accepted: 03 September 2024

Published: 31 October 2024

### Abstract

**Background:** Postoperative pain following third molar extraction is said to be one of the most acute postsurgical painful conditions with patients require some form of analgesic to deal with it. This study examined the clinical efficacy of piroxicam and ketorolac in managing pain and swelling after lower third molar extraction. **Material & Methods:** This randomized controlled study was conducted among 24 patients requiring trans-alveolar mandibular molars extraction. GROUP A (12 patients) who were given a single dose of 20 mg piroxicam orally. GROUP B (12 patients) who were given 10 mg ketorolac QID orally. Pain and swelling was evaluated on 1st, 3rd, 7th, and 14th post-operative day. **Results:** The two study groups were comparable by age and gender. The mean (SD) pain score was lower in Group A (Piroxicam) as compared to Group B (Ketorolac) on Day 1 and 3 and it was found to be statistically significant ( $p < 0.001$ ). There was no significant difference in the mean (SD) pain score between the two groups by Day 7 and 14 of follow up. There was statistically significant reduction in swelling in Group A patients on Day 1, 3 and 7 as compared to Group B patients ( $p < 0.001$ ) but by Day 14 no statistically significant difference in swelling reduction was detected across the two groups. **Conclusions:** Both piroxicam and ketorolac were effective in reducing postoperative pain and swelling following removal of mandibular third molars with piroxicam showing better control in early postoperative days.

**Keywords:-** Impacted third molar, Ketorolac, Piroxicam, Pain, Swelling.

### INTRODUCTION

An impacted tooth is the one that is unable to fully erupt in its normal functional occlusion /

location by its expected age of eruption, as it is blocked by overlying soft tissue or bone or another tooth.<sup>[1]</sup> In addition to being necessary to prevent clinical symptoms, surgical



extraction of impacted third molars can lead to a number of postoperative problems, including trismus, discomfort, edema, and impairment of the inferior alveolar/lingual nerve. Various factors can influence patient discomfort, such as complexity and duration of the surgery, the technique used for extraction, iatrogenic consequences, etc. Reducing these variables enhances the patient's quality of life, boosts treatment satisfaction, and lessens anxiety about surgical procedures.<sup>[1,2]</sup>

Dental pain following third molar extraction is said to be one of the most acute postsurgical painful conditions. The postoperative pain experienced following the third molar surgery under local anaesthesia is typically moderate to severe lasting for 24 hours reaching its maximum intensity in the early postoperative period and in the most cases, patients require some form of analgesic to deal with it.<sup>[2,3]</sup> In addition to the pain, discomfort and swelling, due to restricted movement of the temporomandibular joint caused by inflammation, individuals undergoing oral surgery may experience other unfavourable outcomes like reduced ability to function or restricted food intake.<sup>[2,3,4]</sup>

In general, treatment for pain, trismus, and swelling after lower third molar surgery may include nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>[5,6]</sup> Most NSAIDs function by inhibiting cyclooxygenase (COX) and therefore, among other actions, ultimately result in an inhibition of prostaglandin production. In accordance to their relative inhibition of COX isoenzymes, NSAIDs can be classified as nonselective, COX-2 preferential, or COX-2 selective. Both ketorolac and piroxicam are nonselective COX inhibitors and both NSAIDs

competitively block COX, thereby inhibiting prostaglandin synthesis. Various studies have investigated the efficacy of the more traditional NSAIDs.<sup>[5,6,7,8]</sup> The present study investigated the clinical efficacy of piroxicam and ketorolac in managing pain and swelling after lower third molar extraction. It was hypothesized that both ketorolac and piroxicam would have similar clinical efficacy when administered orally in volunteers after lower third molar surgery.

## MATERIAL AND METHODS

This randomized controlled study was conducted from October 2022 to January 2023 in the Department of Oral and Maxillofacial Surgery of a Dental college and Research Institute in North India. The study population consists of Patients requiring trans-alveolar mandibular molars extraction aged between 18 to 40 years with normal hematologic profile, ASA 1 & 2, with good oral hygiene and surgical site free of active infection and consenting for the study. Those patients who were medically compromised, or having acute peri-apical pathology, who were smokers and tobacco abusers, and either pregnant or lactating were excluded from the study.

**Sample size:** Sample size calculation was based on the mean (SD) swelling of  $6.0 \pm 2.2$  mm at day 2 in one group and of  $3.2 \pm 2.2$  mm in another group. Taking a 95% confidence level and a power of 90 the calculated sample size was found to be 12 in each group.<sup>[9]</sup>

**Recruitment and randomisation:** After checking for eligibility following the predetermined inclusion & exclusion criteria a total of 24 patients were selected consecutively for this study. Patients were randomly divided

into two groups of 12 patients each using restricted block randomisation technique using a block size of 4 by sealed envelopes. The two groups are: GROUP A (12 patients) who were given a single dose of 20 mg piroxicam orally. GROUP B (12 patients) who were given 10 mg ketorolac QID orally. Both the participants and researcher were masked to which group the patient belongs to. All participants underwent routine blood investigations.

**Surgical Procedure:** Skin preparation and isolation of surgical field was accomplished with the help of povidine-iodine. Local anaesthetic solution was given using classical inferior alveolar nerve block technique. Wards incision was placed using No. 15 blade and Mucoperiosteal flap was raised. Bone guttering and tooth sectioning was done with 702 bur. Tooth was elevated from the socket. Extraction socket was irrigated with saline and primary closure of the surgical wound was done with 3-0 silk sutures. Patients were prescribed medicine either piroxicam or ketorolac orally according. Both the subject and researcher were blinded to about the group allocation.

#### Parameters:

1. Pain: Pain intensity was assessed using a 10-level visual analog scale (VAS) with the patient placing a mark on the scale to indicate the pain intensity ranging from no pain [0] to severe/ unbearable pain [10].
2. Swelling: Three facial measurements were taken respectively from the lateral canthus to the angle of mandible, tragus of the ear to the corner of mouth and the tragus of ear to the soft tissue pogonion. The arithmetic sum of these measurements (preoperative facial swelling or FS) worked as the baseline

data for calculation of post-operative swelling.

Follow up: Pain and swelling was evaluated on 1st, 3rd, 7th, and 14th post-operative day. Pain was evaluated using 10-point visual analog scale (VAS), with a score of "0" equals "no pain" and "10" equals "very severe pain." All the evaluations were carried out by investigator blinded to the patients' group assignment. Facial swelling percentage was calculated as the difference of pre-operative and post-operative facial measurements divided by the pre-operative facial measurement and multiplying it to 100.

**Statistical analysis:** Data entry was done in MS Excel spreadsheet and checked for completeness and consistency. Data analysis was performed using IBM SPSS version 22. Descriptive statistics like percentages, proportions, mean and standard deviation were generated. Fischer's exact test/chi-square test, t-test were performed for statistical analysis. A p-value <0.05 was taken as the level of significance.

**Ethical issues:** Approval for the study was obtained from the Institutional Ethics Committee. Informed consent was taken from all participants and strict confidentiality was maintained for all collected data.

## RESULTS

A total of 24 patients were recruited with age ranging from 25 to 40 years with mean (SD) age of 33.8(4.46) year and a median age of 34 year. Females constituted (13, 54.2%). The patient were divided into two groups: Group A of 12 (twelve) patients who were given a single dose of 20 mg piroxicam orally and Group B of



12(twelve) patients who were given 10 mg ketorolac QID orally. There was no statistically significant difference between the two groups by age or gender at the baseline [Table 1].

The mean postoperative pain score (VAS) was highest at post-operative day 1 and gradually reduced over the 3rd, 7th and 14th day of follow

up in both the groups. The mean (SD) pain score was lower in Group A as compared to Group B on Day 1 and 3 and it was found to be statistically significant ( $p < 0.001$ ). There was no significant difference in the mean (SD) pain score between the two groups by Day 7 and 14 of follow up [Table 2].

**Table 1:** Showing comparison by gender and age groups in the two groups (N=24)

Variable		Group A N(%)	Group B N(%)	p-value
Gender	Female	07(53.8)	06(46.2)	0.682
	Male	05(45.5)	06(54.5)	
Age group	<34 yr	06(54.5)	05(45.5)	0.669
	≥34 yr	06(46.2)	07(53.8)	

**Table 2:** Showing comparison of Post-operative pain (VAS) score of the two groups using T-test (N=24)

Post-operative day	VAS score (Mean±SD)		Mean difference (95% CI)	t-value	p-value
	Group A (N=12)	Group B(N=12)			
Day 1	4.83±0.718	6.50±0.522	-1.66(-2.19 to -1.13)	-6.504	0.001*
Day 3	2.92±0.669	4.25±0.754	-1.32(-1.93 to -0.730)	-4.584	0.001*
Day 7	1.42±0.515	1.92±0.900	-0.50(-1.12 to -0.121)	-1.670	0.109
Day 14	0.42±0.515	0.67±0.651	-0.25(-0.747 to 0.247)	-1.043	0.308

\*P <0.05

**Table 3:** Showing comparison of Post-operative swelling of the two groups using T-test (N=24)

Post-operative day	Swelling (Mean±SD)		Mean difference (95% CI)	t-value	p-value
	Group A (N=12)	Group B(N=12)			
Day 1	13.31 ±1.88	16.02 ±1.21	-2.70(-4.05 to -1.36)	-4.180	0.001*
Day 3	9.87 ±1.35	11.61 ±1.07	-1.74(-2.77 to .070)	-3.487	0.002*
Day 7	04.83 ±1.70	07.1±1.42	-2.35(-3.68 to -1.01)	-3.658	0.001*
Day 14	01.35 ±0.85	01.85±0.87	-0.50(-1.24 to -0.22)	-1.439	0.164

The mean (SD) facial swelling was highest at Day 1 post-operative and gradually reduced over the following days for the both groups. There was statistically significant reduction in swelling in Group A patients on Day 1, 3 and 7 as compared to Group B patients ( $p < 0.001$ ) but by Day 14 no statistically significant difference

in swelling reduction was detected across the two groups. [Table 3]

## DISCUSSION

Impacted mandibular third molars is one of the most common complaints that require surgical intervention. Extraction of an impacted tooth

may be associated with certain of intra- and postsurgical complications like pain, swelling, trismus etc. despite major advances in the practice of dentistry.<sup>[2,3]</sup> This study examined the clinical efficacy of managing postoperative pain and swelling using two NSAIDs, ketorolac and piroxicam administered orally after the lower third molar was extracted under local anesthesia.

The complication rate of 4.6-30.9% following the extraction of third molars is reported in the literature, which may occur intraoperatively or develop during the postoperative period. Studies have been undertaken exploring clinical efficacy of analgesics and anti-inflammatory drugs in controlling post-surgical pain and inflammation.<sup>[10,11,12,13,14,15]</sup> Lower third molar surgery is a well-accepted and commonly used procedure to evaluate clinical efficacy of anesthetics and anti-inflammatory drugs. The acute dental pain model is considered highly standardized and sensitive for assessing the therapeutic efficacy of analgesics, and the efficacy measures used are considered valid, reliable, sensitive, and specific methods to assess postsurgical pain.<sup>[16,17,18,19]</sup>

In this study the pain intensity gradually decreases over time from day 1 to Day 14 in both the groups. The piroxicam group had significantly lower pain intensity than that in the ketorolac group on day 1 and 3 but by Day 7 and 14 the pain intensity was similar between the two groups. Trnidade PAK et al,<sup>[2]</sup> in a study to compare the clinical efficacy of sublingual ketorolac and sublingual piroxicam in managing pain, trismus and swelling after lower third molar extraction in adult volunteers showed no significant differences observed between the NSAIDs evaluated. A study by

Srinivasulu Y et al,<sup>[11]</sup> showed higher efficacy of piroxicam in controlling pain intensity on day 1, 3 and 7 as compared to other NSAIDs.

The method used in this study to measure swelling is widely accepted as described by Schultze-Mosgau S et al,<sup>[20]</sup> It is a simple noninvasive, costeffective, and timesaving techniques which provides numeric data for determination of soft tissue contour changes. The results of this study showed gradual decrease in facial soft tissue swelling by 14<sup>th</sup> Day of follow up in both the groups, corroborating the results of other studies. The magnitude of swelling was significantly lower in the Piroxicam group upto the 7<sup>th</sup> Post-operative day but by the 14<sup>th</sup> Day of follow up no significant difference was detected between the groups in the degree of swelling. These data are in agreement with other studies that used other NSAIDs, which showed the effectiveness of NSAIDs in controlling pain and swelling after lower third molar extraction.<sup>[21,22,23,24,25,26]</sup>

This study showed that single dose of 20 mg piroxicam orally showed significantly better results in controlling pain up till the third post-operative day after surgical extraction of impacted third molar as compared to patients given 10 mg of ketorolac QID orally but by the 7<sup>th</sup> and 14<sup>th</sup> Post-operative days both regimens were equally effective. Similarly for controlling swelling single dose of Piroxicam 20 mg orally revealed significantly better results upto 7<sup>th</sup> post-operative day as compared to 10 mg of Ketorolac given QID but by the 14<sup>th</sup> day of follow up no significant difference in the amount of swelling was detected between the two groups.

The study is limited by the small sample size and subjective assessment method of pain assessment. The findings of the study demonstrated the efficacy of two most clinically used analgesics ketorolac and piroxicam in controlling pain and swelling on patients undergoing third molar surgeries.

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## CONCLUSIONS

The results obtained suggested that both piroxicam and ketorolac were effective in reducing postoperative pain and swelling following removal of mandibular third molars with piroxicam showing better control in early postoperative days.



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- Source of Support: Nil, Conflict of Interest: None declared