

# Analgesic Efficacy of Diclofenac and Ibuprofen/Paracetamol Combination in Post Extraction Cases

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## ABSTRACT

### Introduction

Postoperative pain management is essential post-extraction for early mobilization and rehabilitation to enhance recovery and to reduce morbidity. Diclofenac and Ibuprofen and Paracetamol combination are two most common NSAIDs used in the postoperative pain control. The objective of this research is to find the analgesic efficacy of diclofenac and ibuprofen/paracetamol combination in post extraction cases.

### Methods

Two hundred fifteen patients (n=215) of age group 20-60 years who underwent extraction of upper or lower third molar impacted teeth were divided randomly into two groups (T1 and T2). T1 group (n=105) received Tab. Diclofenac 100mg and T2 group (n=110) received Tab Ibuprofen and Paracetamol combination. Analgesic efficacy of Diclofenac was compared with that of Ibuprofen and Paracetamol combination at post-op day 1, day 3 and day 5. Analgesic efficacy was measured using Visual Analogue Scale (VAS) and Verbal Rating Scale (VRS).

### Results

Pain intensity decreased significantly at all the time points in both the groups. The analgesic efficacy of Diclofenac was significantly higher than Ibuprofen and paracetamol combination as estimated by VAS mean score at day 1 and day 3 post-operative period ( $p < 0.001$ ). But based upon the VRS mean score at post-operative day 1, day 3 and day 5, there was no statistically significant difference between two treatment groups.

### Conclusions

This study showed that Diclofenac potassium was more effective than Ibuprofen and Paracetamol combination for reducing postoperative pain associated with extraction of third molar impaction. Few number of patients in both treatment groups developed gastrointestinal upset.

**Keywords:** Diclofenac; Ibuprofen and paracetamol; Postoperative pain; Visual analogue scale.

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## INTRODUCTION

International Association for the Study of Pain has defined pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.”<sup>1</sup> Postoperative pain is considered a form of acute pain due to surgical trauma with an inflammatory reaction.<sup>2</sup> All of the patients undergoing extraction of immobile tooth will experience post operative pain beginning 1-3 hr after the procedure and can range in intensity from moderate to severe.<sup>3</sup> The postoperative period of such condition is characterized by pain, trismus and inflammation as the most frequent complications.<sup>4</sup> A number of drugs are available for post-operative pain management. In addition to opioids, effectiveness of non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ketorolac, diclofenac, ibuprofen, indomethacin, tenoxicam in managing of post-operative pain has been confirmed.<sup>5</sup> One of the commonly prescribed NSAID is diclofenac that possesses analgesic, anti-inflammatory, and antipyretic properties. Diclofenac is effective in treating acute, chronic pain and inflammatory conditions it shows good pain control and has good analgesic efficacy after extraction.<sup>6</sup> Another commonly prescribed over-the-counter drug is Paracetamol and Ibuprofen combination. Paracetamol is usually used for pain reliever and for treating fever as it has both analgesic and antipyretic action whereas ibuprofen also have anti-inflammatory action providing synergistic effect.<sup>1</sup> At present, most clinical trials are comparing the analgesic efficacy of different drugs with reference medication paracetamol, due to its analgesic capacity, good tolerability, and near total lack of complications or side effects when administered. The aim of this study was to investigate the efficacy of diclofenac potassium as compared to Ibuprofen and Paracetamol combination in post-extraction pain control in third molar impaction cases.

## METHODS

A hospital based cross sectional study was conducted at College of Medical Sciences Teaching Hospital (CMS-TH), Bharatpur-10, Chitwan during the period from March 2022 to August 2022. The ethical clearance was taken from Institutional Review Committee (IRC) of COMSTH-IRC/2022-001. All patients between age group of 20-60 years undergoing open extraction of upper and lower third molar impaction were included in the study. Pregnant woman, patient with history of sensitivity to NSAIDs, Uncontrolled hypertension, and patients on anticoagulant therapy were excluded from the study. The total of 215 patients who attended oral surgery department for extraction of either upper or lower impacted third molar and required postoperative pain management were included for the study.

All the participants were provided with verbal information regarding study protocol and written consent was taken to participate in the study. All the patients who underwent extraction of impacted third molar were randomly divided into two treatment groups: Treatment Group One (T1) and Treatment Group Two (T2) with lottery method. Sample size was measured as 105 patients in T1 group and total of 110 patients in T2 group. Only patients who reported on follow up at post-operative Day 1, Day 3, and Day 5 were included in the sample. T1 group included the patient receiving Diclofenac 100 mg twice a day and T2 group included the patient receiving Ibuprofen+ Paracetamol combination thrice daily in postoperative period. Patients were informed about the possible side effects of drug.

Analgesic efficacy of both drugs in the treatment groups was measured by Visual Analogue Scale (VAS) and Verbal Rating Scale (VRS). VAS and VRS score were recorded at day 1, day 3, and

day 5 post-operatively. According to 5 point VRS, the marks were given as: 1 = no pain, 2 = mild pain, 3 = moderate pain, 4 = severe pain, 5 = very severe pain/overwhelming pain (the worst pain you can imagine).

The patients were asked to describe the degree of their discomfort by choosing one of the vertical lines that corresponds to the intensity of pain that they were feeling. <sup>7</sup>In VAS technique, a 10 cm long scale ranged from 0-10 marks was shown to the patients where 0 marks represents no pain and 10 mark represents worst possible pain. Patient was explained to represent at '0' for "no pain at all" and at the '10' for "pain as bad as could possibly imagine" and was asked to mark the point of the scale where his/her pain lies which corresponds to the numerical index of the severity of the pain.<sup>8</sup>

Data were collected through a data collection

number and percentage (%). Difference between two independent groups was compared by unpaired student's t-test using SPSS for windows versions 20.0(Statistical Package for Social Science for Windows Version). Comparison was done at 95% confidence interval of the distribution of the data and p value < 0.05 was considered statistically significant.

## RESULTS

There were total 215 participants in the study ranging from 20-60 years. Among them 116 (54%) were males and 99(46%) were females. Of the total 215 patients the Mean ( $\pm$  SD) age of both Diclofenac (43.15 $\pm$  11.80) and Ibuprofen and Paracetamol combination (42.44 $\pm$ 11.69) treated group did not differ. Data are presented in Table 1.

VAS score has been depicted in Table 2. The difference in mean score between these two

**Table 1.** Age wise distribution of two treatment groups.

Variables	T1 (Diclofenac group) (n=105)		T2 (Ibuprofen + Paracetamol) (n=110)	
	Male	Female	Male	Female
20-30	8(15.09)	7(13.46)	12(19.05)	5(10.64)
30-40	8(15.09)	6(11.54)	10(15.87)	7(14.89)
40-50	15(41.51)	16(30.77)	19(30.16)	15(31.91)
50-60	22(41.51)	23(44.23)	22(34.92)	20(42.55)

sheet, by observation using VAS and VRS scale and by clinical examination. Statistical analysis was done as mean  $\pm$  standard deviation (SD) for quantitative variables and was presented in

treatment groups was statistically significant (p<0.05) at post-operative day 1 and day 3. However, VAS mean score at post-operative day 5 was not statistically significant (p>0.05). Based

**Table 2.** Comparison of VAS score between two treatment groups.

Post-operative day	T1 (Diclofenac group) (n=105)	T2 (Ibuprofen + Paracetamol) (n=110)	P-value
VAS Day 1	45.04 $\pm$ 6.37	49.54 $\pm$ 7.46	<0.001*
VAS Day 3	34.24 $\pm$ 4.36	41 $\pm$ 7.96	<0.001*
VAS Day 5	11.73 $\pm$ 2.93	12.01 $\pm$ 2.56	0.45

\*P<0.05 clinically significant, independent t-test

Post-operative day	T1 (Diclofenac group) (n=105)	T2 (Ibuprofen +Paracetamol) (n=110)	P-value
VRS Day 1	3.7± 0.6	3.8± 0.8	0.175
VRS Day 3	2.4 ± 0.6	2.6 ± 0.7	0.141
VRS Day 5	1.2 ± 0.4	1.3 ± 0.4	0.246

\*P<0.05 clinically significant, independent t-test

upon the VAS scale at day 1 and day 3 post-operatives, Diclofenac showed more pronounced analgesic effects compared to Ibuprofen and Paracetamol combination.

Based upon the VRS mean score at post-operative day 1, day 3 and day 5, there was no statistically significant difference between two treatment groups.

## DISCUSSION

Postoperative pain control is one of the most crucial components of managing surgical patients. Non-steroidal anti-inflammatory drugs and Opioids make up the two primary categories to treat post-operative pain. NSAIDs are frequently used in dental outpatients to treat post-extraction discomfort. The primary objective of the current study was to compare the analgesic effectiveness of Diclofenac with Ibuprofen + Paracetamol combination following surgical extraction of third molar impaction. Overall, there was a decrease in pain in both treatment groups. In terms of reducing the severity and intensity of pain, this study found that diclofenac potassium was statistically more effective than the combination of Paracetamol and Ibuprofen. A total of 215 patients ranging from age group 20-60 years of which 105 in Diclofenac group and 110 in Ibuprofen and paracetamol combination group were included in the current study, and their mean age was 42.79 years (42.79 ± 11.72), which suggested that third molar impaction requiring extraction occurred more commonly in adults. In our study

Diclofenac had superior analgesic efficacy (as determined by VAS score) than the combination of Ibuprofen and Paracetamol on day 1 and 3 postoperatively (i.e., significantly lower mean VAS score and  $p < 0.05$ ). The VAS score, however, did not substantially differ between the two treatment groups on postoperative day 5. The findings of this study are consistent with the results of study conducted by El Batawi et al., where Paracetamol and Diclofenac sodium was administered one hour preoperatively for children with traumatic dental treatments under general anesthesia where diclofenac sodium was more effective than Paracetamol for relieving postoperative pain.<sup>9</sup> Similarly, diclofenac was found to be more effective than paracetamol or ibuprofen for reducing postoperative pain associated with tooth extraction in a randomized control trial done by Gazal G et al., which postulated that the effectiveness of diclofenac potassium over ibuprofen & paracetamol could be as a result of the differences in the chemical properties rather than the mode of action.<sup>10</sup> The possible mechanism of the superiority of diclofenac over ibuprofen and paracetamol may be due to its faster absorption rate and rapid onset of action. The second possible reason could be as a result of the slight differences in their mechanism of action as diclofenac is a preferential COX-2 inhibitor.<sup>11</sup> Comparing the effectiveness, safety, and potency of Ibuprofen and Diclofenac sodium in acute pulpitis with moderate to severe pain, a study similar to this one conducted by Komali G et al. concluded

that Diclofenac Sodium is more potent than Ibuprofen.<sup>12</sup> Eslampour et al. also examined the efficacy of three analgesic medications given preoperatively to lessen postoperative discomfort related to photorefractive keratectomy in another trial. According to their research, patients who took diclofenac experienced less pain than those who took paracetamol and ibuprofen.<sup>13</sup> The great ability of diclofenac bound to plasma proteins (99%) may justify its potency over the ibuprofen & paracetamol. In addition, neutrophil chemotaxis and superoxide production at the inflammatory site are greatly reduced by diclofenac.<sup>14</sup>

## CONCLUSION

In the present study, the analgesic efficacy

(as measured by VAS score at post-operative day 1 and day 3) of diclofenac was superior to Ibuprofen and Paracetamol combination. Likewise, the findings of the present study are comparable with other studies and can be used as supportive evidence for further studies.

Nevertheless, a simple prospective study such as this is likely to suffer from biases regarding randomness, less sample size and subjective assessment of pain by the patients. Therefore, prospective longitudinal randomized double-blind studies should be designed for better assessment of analgesic efficacy and adverse effects between these two drugs.

## REFERENCES

- Raffaelli G, Orenti A, Gambino M, Peves Rios W, Bosis S, Bianchini S. Fever and pain management in childhood: Healthcare providers' and parents' adherence to current recommendations. *Int J Environ Res Public Health*. 2016;13(5):499. [DOI]
- Raj PP. Taxonomy and classification of pain. *The handbook of chronic pain*. 2007:41-56. [Full text]
- Kubitzeck F, Ziegler G, Gold MS, Liu JM, Ionescu E. Analgesic efficacy of low-dose diclofenac versus paracetamol and placebo in postoperative dental pain. *J Orofac Pain* 2003;17(3):237-44. [PubMed] [Full Text]
- Esteller-Martínez V, Paredes-García J, Valmaseda-Castellón E, Berini-Aytés L, Gay-Escoda C. Analgesic efficacy of diclofenac sodium versus ibuprofen following surgical extraction of impacted lower third molars. *Med Oral Patol Oral Cir Bucal*. 2004;9(5):448-53. [PubMed] [Full Text]
- James D, Justins D. Acute postoperative pain. In: Healy Tej, Knight PR, editors. *Wylie and Churchill Davidson's A Practice of Anesthesia*. 7th edition. London: Arnold; 2003. p.1213-34.
- Takayama K, Hirose A, Suda I, Miyazaki A, Oguchi M, Onotogi M, et al. Comparison of the anti-inflammatory and analgesic effects in rats of diclofenac-sodium, felbinac and indomethacin patches. *Int J Biomed Sci*. 2011;7(3):222-9. [PubMed] [Full Text]
- Flaherty SA. Pain measurement tools for clinical practice and research. *AANA J*. 1996;64(2):133-40. [PubMed]
- Keele KD. The pain chart. *Lancet*. 1948;252(6514):6-8. [DOI] [PubMed]
- El Batawi H. Effect of intraoperative analgesia on children's pain perception during recovery after painful dental procedures performed under general

- anaesthesia. *Eur Arch of Paediatr Dent.* 2015;16(1):35-41. [DOI] [PubMed]
10. Gazal G, Al-Samadani KH. Comparison of paracetamol, ibuprofen, and diclofenac potassium for pain relief following dental extractions and deep cavity preparations. *Saudi Med J.* 2017 Mar;38(3):284-29.
  11. Van Hecken A, Schwartz JI, Depré M, et al. Comparative inhibitory activity of rofecoxib, meloxicam, diclofenac, ibuprofen, and naproxen on COX-2 versus COX-1 in healthy volunteers. *J ClinPharmacol.* 2000;40(10):1109-1120.
  12. Komali G. A study of analgesic efficacy of Ibuprofen and Diclofenac Sodium in Acute Pulpitis Patient. *Adv Hum Biol.* 2014;4(3):48-53. [Full Text]
  13. Eslampour A, Malaekheh-Nikouei B, Abrishami M, Bayani R. Efficacy of extended-release oral diclofenac in postoperative pain management after photorefractive keratectomy. *J Ocul Pharmacol Ther.* 2013;29(7):670-3. [DOI]
  14. Hasçelik G, Sener B, Hasçelik Z. Effect of some anti-inflammatory drugs on human neutrophil chemotaxis. *J Int Med Res.* 1994 Mar-Apr;22(2):100-6.

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