

A Study of Analgesic Efficacy of Ibuprofen and Diclofenac Sodium in Acute Pulpitis Patients

Komali G^{1*}¹Professor and Head, Department of Oral Medicine and Radiology, Panineeya Mahavidyalaya institute of Dental Sciences, Hyderabad, India.

ABSTRACT

Aim: Ibuprofen 400mg and Diclofenac Sodium 50mg marketed today inhibit Cox-1 and Cox-2 and have selectivity for Cox-1. Ibuprofen 400mg is an established analgesic in the management of acute dental pain. Diclofenac Sodium 50mg is also used in the management of acute pain, but there are very few studies comparing its analgesic efficacy with Ibuprofen.

Materials and Method: A double blind randomized study was carried out to compare the analgesic efficacy, safety and potency of Ibuprofen and Diclofenac Sodium in acute pulpitis patients with moderate to severe pain. 60 patients with acute pulpitis were enrolled in the study and Ibuprofen 400mg and Diclofenac Sodium 50mg were randomly given to them. Self-administered questionnaire was given to the patients and they were asked to note the intensity of initial pain on Visual analogue scale.

Results: Time of onset of action of drugs, Time to peak effect, Total analgesic effect and tolerability of the drugs were assessed. From the present study it was found that there were statistically significant differences in the onset of action of drug and Time to peak effect. Onset of action was early in Ibuprofen and Time to peak effect was early in Diclofenac sodium. Patients rated both drugs to be equally good on Global evaluation scales.

Conclusion: It was found that Diclofenac Sodium is more potent compared to Ibuprofen.

Keywords: Analgesic, Diclofenac Sodium, Ibuprofen.

INTRODUCTION

Pain is defined by the "International Association for the study of pain" as 'Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage'¹. Pain is classified clinically into two types as acute and chronic depending on its duration².



Acute dental pain model has been well established for the assessment of efficacy of

analgesics in short-term studies³. Rating scales are the most commonly used method of assessing acute pain and its relief. Research on efficacy of different types of measurements of pain has proved that visual analog scale provided useful measure of pain experience for use in clinical settings⁴.

Massler and Pawlack in 1977 and Torneck in 1981 established that pulps of teeth with irreversible pulpitis and without a clinical pulp exposure contained no demonstrable bacteria. Early stages of irreversible pulpitis represent an immunologic response of pulpal tissue to antigenic substances produced as a result of the carious lesion^{5,6}.

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*Correspondence Dr. Komali G.

Department of Oral Medicine and Radiology, Panineeya Mahavidyalaya institute of Dental Sciences, Hyderabad, India.

Email: komali_garlapati@yahoo.co.in

The invention of NSAIDs has significantly improved the management of pain in dentistry⁷. Because of their demonstrated efficacy and safety in relieving moderately severe pain in outpatient setting, dental practitioners now rely completely on NSAID analgesics⁸. This study was carried out to evaluate the analgesic efficacy, potency and side effects of Ibuprofen and Diclofenac sodium in acute pulpitis patients.

Ohnhaus in 1975 found that VAS reflects more precise changes in the intensity of the pain experiences⁹. Vane in 1971 showed that all NSAIDs tested were potent inhibitors of prostaglandin synthesis¹⁰. In 1975, both the Dental pain model and Ibuprofen (Motrin, Upjohn) were established in the analgesic field. Since that time, the dental pain model has become the most useful method for evaluating peripherally acting analgesics, and Ibuprofen has become one of the most popular agents in this class^{3,11}. Diclofenac has analgesic, antipyretic and anti-inflammatory activities. It is an inhibitor of cyclooxygenase and is equipotent for both Cox enzymes. Single doses of 50-100 mg or up to 150mg per day is also useful in short term treatment of acute musculoskeletal injury, acute painful shoulder, post-operative pain and dysmenorrhea^{7,12}.

The measures that were considered for the evaluation of analgesic efficacy were pain intensity, onset of analgesia, estimation of total analgesia, overall evaluation of the drug and percentage of patients who took the rescue medication. All these measures were derived from subjective recordings by the patients^{13,14}.

MATERIALS AND METHOD

Patients attending Department of Oral Medicine Diagnosis and Radiology, Government Dental College, Bangalore with an acute pain of 24 hours or less than 24 hours duration were included in the study.

Criteria for selecting patients

Inclusion criteria: Patients in the age group between 18 and 50 years, apparently healthy individuals with no systemic disease like diabetes, hypertension or cardiac diseases, patients who

were not allergic to NSAIDs and patients with acute pulpitis having moderate to severe pain.

Exclusion criteria: Pregnant women, patients who were on NSAIDs for other painful conditions such as rheumatoid arthritis, TMJ arthritis and patients who had taken analgesic before entering the study in the past 24 hours.

Ibuprofen (400mg) and Diclofenac Sodium (50mg) were supplied by Sarabhai Piramal Pharmaceuticals. The dosage of these drugs were based on recommended doses in acute pain which was based on clinically proven studies. The identity of these drugs was concealed and was revealed only after results were obtained. Rescue medications Aceclofenac (100mg) and Paracetamol were provided as they have been proved to be effective in alleviating pain in dental extraction pain models.

A case history proforma was used to record the case history of the patients in detail. A self-administered questionnaire was given to assess the analgesic efficacy, potency, side effects and duration of action of drug^{15,16}. Visual analogue scale was used to assess the intensity of pain. Patients were informed about the nature of the study and their consent was obtained.

A double blind, randomized, parallel group study was carried out in 60 patients with acute pulpitis. The drugs were sealed in identical packets and were labelled randomly as A or B by the staff nurse.

At initial visit, a self-administered questionnaire was given and patients were asked to mark on the VAS indicating severity of pain. Patients with moderate or severe pain were randomly assigned to different group of drugs and were instructed to use drugs accordingly. Time of administration was noted and patients were instructed to inform immediately after slight reduction in pain which indicated the onset of action of the drug. Rescue medication was planned to be given to the patients who had same intensity of pain even after 90 minutes and they were not included in the study for further evaluations.

Patients were instructed to note the time of complete disappearance of pain or if there was no complete disappearance of pain even after 4 hours.

They were also told to notice the time of maximum relief from pain which indicated peak effect of the drug. Patients were provided with extra doses of medication and were told to note any side effects that they experienced which were mentioned in the

questionnaire during the study period of the drug. Patients were instructed to rate the drug on global evaluation scale after 8 hours and 24 hours duration and were recalled and reviewed after 24 hours.

Table 1: Age and gender distribution in both the drug groups.

	Ibuprofen	Diclofenac sodium	P value
Subjects analyzed	23	24	
Age (Mean + SD)	29.9 ± 6.8	27.0 ± 6.3	0.548
Gender	Females – 9/23 (39.1%) Males – 14/23 (60.9%)	Female – 8/24 (33.3%) Males – 16/24 (66.7%)	0.641

Table 2: Time of onset of action of drugs (in minutes) and Time to peak effect (in minutes) in both drug groups.

	Ibuprofen	Diclofenac Sodium	P value
Time of onset of action (mean ± standard deviation)	19.8 ± 8.5	27.6 ± 12.7	0.001
Time to peak effect (mean ± standard deviation)	71.2 ± 19.7	64.4 ± 24	0.0001

Table 3: Total analgesic effect after 6 hours and sleep variable in both the drug groups.

	Ibuprofen	Diclofenac Sodium	P value
Total analgesic effect over 6 hours	71.2 ± 19.7	64.4 ± 24	0.309
Sleep Variable	9	1	0.015
Sound	13	12	
Restless	1	2	

Patients were instructed to take medication 3 times daily after every 8 hours and were in contact over the phone to ensure that they have taken the medication on time and to make them follow study protocol.

RESULTS

60 patients were included in this study for the efficacy analysis of the two analgesics. 23

patients took Drug A (Ibuprofen 400 mg) and 24 Drug B (Diclofenac 50 mg) as 13 patients did not return for the post study visit and hence were eliminated from the study. The mean age of the patients was found to be 29.2 years (Table 1).

Accordingly, parametric test for testing equality of means in different groups was carried out namely one-way analysis of variance (ANOVA) using F-statistic. P value of the test was tabulated.

To test for homogeneity in the distribution of patients with respect to a characteristic over different classes for different drugs, Chi-square test was carried out.

There was no statistically significant difference between the distribution of patients by sex in Ibuprofen and Diclofenac Sodium.

There was statistically significant difference in the time of onset of action of drug with Ibuprofen group having early onset (Table 2). It was also found that Diclofenac had early peak effect when compared to Ibuprofen (Table 2).

To compare the means of the total analgesic effect over 6 hours with respect to 2 factors namely drug and level of employment (i.e. employed or unemployed) a two way analysis of variance (ANOVA) was carried out (Table 3). Patients who took Diclofenac Sodium had significantly less sleep (Table 3). There was significant difference between drug groups with respect to Global evaluation after 8 and 24 hours. The overall performance of the drug groups Diclofenac and Ibuprofen was rated by the patients to be equally good. 4.2% patients reported with gastritis in Diclofenac group. 8.6% patients reported with gastritis in Ibuprofen group. None of the patients in both the groups took rescue medication proving the analgesic efficacy of the drugs in acute dental pain. Comparison of relative potency between 2 drugs was done. In the present study Diclofenac 50mg was found to have greater potency compared to Ibuprofen 400mg.

DISCUSSION

Pain is a common complaint that often occurs in association with inflammation. Prostaglandins are mediators of pain and inflammation. 25 years ago, Sir Vane hypothesized that NSAIDs act by inhibiting cyclooxygenase (Cox) mediated conversion of arachidonic acid to prostaglandins which decreases the peripheral prostaglandin production there by reducing the pain¹⁷.

In this present study, acute irreversible pulpitis with continuous pain was chosen as pain model. In this pain model, the pain is usually moderate to severe, even excruciating and

throbbing and the pain can be continuous or interrupted. In contrast to post-operative pain model in which the duration of acute pain is only 3 to 8 hours, followed by spontaneous decrease for the next 12 hours. But, in acute pulpitis pain model, the pain intensity is same for longer time or rather increases with time due to increase in intra pulpal pressure¹⁸. Hence, this pain model has characteristics that helps in evaluation of all measures of analgesic efficacy of drugs.

In the present study, a total of 60 patients were enrolled with the mean age of 29.2 years which suggested that acute pulpitis occurred more commonly in young adults. In this study, the distribution of occurrence of severity of pain in relation to sex was not statistically significant, i.e., there was no significant difference in occurrence of severity of pain in males and females.

In this study, there was significant difference in the time of onset of action of Ibuprofen and Diclofenac Sodium. These results were consistent with the previous studies¹⁹. There was statistically significant difference in the time of peak effect between Diclofenac Sodium and Ibuprofen. The time to peak effect of these drugs correlated well with their peak plasma concentrations^{11,12,20}. The difference in the peak effect between the drugs can be attributed to their pharmacodynamics and pharmacokinetic profiles.

There was significant difference in the potency between Diclofenac Sodium and Ibuprofen. These results are consistent with the previous studies²¹. NSAIDs have been reported to produce dyspepsia, diarrhea, abdominal pain or nausea in greater than 50% of those consuming these drugs in the short term^{8,17}. In the present study, none of the patients in the drug groups reported with nausea, vomiting, diarrhoea, dyspepsia, dizziness or urticaria. One patient in Diclofenac Sodium and two patients in Ibuprofen group reported with gastritis. Though there were no adverse effects reported in the study group except for gastritis, a large sample size and long term studies are required to evaluate the adverse effects of these drugs.

The overall analgesic efficacy of a study drugs were assessed based on the measures of analgesic efficacy i.e. onset of action, time to peak effect, duration of action and total analgesic

effect^{22,23}. In this study, it was concluded that Diclofenac Sodium had greater potency than Ibuprofen.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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