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## Oral paracetamol vs diclofenac for the management of post-operative pain: Clinical study across the range of surgeries

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### Abstract

**Background:** Non-steroidal anti-inflammatory drugs (NSAID) help relieve the discomfort of fever and reduce inflammation and associated pain. Post-surgery pain is most of the time unavoidable and NSAIDs are best strategies to combat the same as compared to opioids.

**Objective:** In the present study we aimed to assess the analgesic efficacy and safety of paracetamol in comparison with diclofenac for postoperative pain relief when administered orally.

**Methods:** Randomly selected 90 patients who underwent different surgery under general anesthesia. Patients were divided into three groups to receive paracetamol (500 mg/kg), diclofenac (100 mg/kg) and placebo. Participants were assessed for the level of pain prior to treatment and upto 8 hrs post-treatment using visual analogue scale to score from 0-5. Statistical analysis of continuous data was done by unpaired t-test and one-way ANOVA.

**Results:** Both paracetamol and diclofenac were effective for postoperative pain relief. We did not notice significant differences between paracetamol and diclofenac group at any time points, however, both treatments were effective in reducing pain score significantly from 1 hr to 6 hrs post treatment.

**Conclusion:** Both paracetamol and diclofenac drugs are safe to provide analgesia through oral route in postoperative period and can be used irrespective of type and intensity of surgery without any major significant side effects.

**Keywords:** Diclofenac, paracetamol, post-operative pain management, assessment of pain

### Introduction

In patients undergoing surgery, acute pain is defined as pain present in a surgical patient after a procedure. The effective relief of pain is the utmost important due to its significant physiological benefits and elimination of discomfort with a minimum of side effects [1]. Various agents which are in practice for post-operative pain management are from the pharmacological class of opioid or nonopioid (Non-steroidal anti-inflammatory drugs (NSAID) administered via different routes (oral, intravenous, neuraxial, regional) depending on the patient's convenience [2]. For major surgeries, although healthcare professionals are mainly dependent on the opioid based agents for postoperative analgesia, associated side effect profile of opioids such as sedation, nausea, ileus, constipation, drug dependence, etc., prompted to reduce its use and find out the better options [3,4].

One of the commonly prescribed NSAID is diclofenac chemically known as Dichloronilino phenylacetic acid. It shows anti-inflammatory, analgesic, and antipyretic effects. It is effective in treating acute, chronic pain as well as inflammatory conditions of different etiologies such as surgery, infection or pain due to inflammation [5]. It acts via an inhibition of prostaglandin synthesis by inhibiting COX-1 and COX-2 enzymes [6].

Another commonly prescribed over-the-counter drug for pain management is Paracetamol, also known as acetaminophen or N-acetyl-p-aminophenol. It is most widely used agent for relieving pain and for treating fever attributed to its analgesic and antipyretic (fever reducer) action. It has only weak anti-inflammatory activity and best classified as a mild analgesic [7]. The mechanism of action involved is the inhibition of cyclooxygenase (COX) in the brain, which is highly selective for COX-2 [8]. It is emerging as a safe and quite effective drug, also having lesser side effects than diclofenac.

In the present study, we aimed to evaluate the efficacy of diclofenac compare to paracetamol as a preemptive analgesia after extraction of tooth.

## Material and Methods

To conduct the study, institutional approval by the ethical committee of our institute and written informed consent from the participants were obtained.

### Inclusion criteria

The study population consisted of 90 randomly selected individuals. They are as per the American Society of Anaesthesiologists (ASA) I and II class and age in the range of 18 to 60 years of either sex, weighing within 50-70 kg. All patients underwent elective surgical procedure under general anesthesia for one of the four categories of surgical operation: abdominal, gynaecological, limb and ENT.

### Exclusion criteria

Patients having preexisting severe liver and renal dysfunction and allergy to either drug were excluded in our study. Participants with known systemic illness, allergy to NSAIDs, recent antibiotic or analgesic treatment history, pregnant participants and individuals with peptic ulcers were also not considered to take part in this study as diclofenac or paracetamol drug treatment may worsen the conditions or which may induce drug related adverse events.

### Patient randomization and treatments

To maintain double-blind conditions, the drugs formulations (tablet) were unpacked and the medication for each patient was presented in identical individual packs. Patients were divided into three groups as follows to receive either paracetamol, diclofenac or placebo.

**Group A:** 1 tablet of paracetamol (500 mg/kg) (n=30)

**Group 2:** 1 tablet of diclofenac (100 mg/kg) (n=30)

**Group 3:** Placebo tablet to match paracetamol/diclofenac (n=30)

### Assessment of Pain

On admission to the study, the degree of pain intensity was assessed as mild, moderate or severe by observation and by the patients' comments.<sup>9</sup> The treatment was given and 2 h later the degree of analgesia was assessed, with reference to the previous pain, by the same investigator. Analgesia was classified no relief, partial relief, considerable relief (if the patient was pain-free while lying still) and complete relief (if the patient was pain-free on moving). All observations were made by the authors. Postoperative data collection was in the form of modified visual analogue scale (VAS) score where score '0' indicates no pain and score '5' indicates severe pain<sup>[10]</sup>.

### Statistical analysis

Data were collected and tabulation was formed, and statistical analysis of continuous data was done by unpaired t-test and Chi-square test was applied for discrete data. The results were considered statistically significant with P value <0.001.

## Results

### Demographic characterization

Considering level of pain from different surgery that patient undergone we have distributed them equally to receive different treatments. Details is presented in Table 1A and 1B. There was no difference between the groups in respect of age or sex, and the distribution of patients within

treatment groups was reasonably uniform based on the surgery undergone. The patients were distributed equally within the four treatment groups according to their initial degree of pain. This helps to nullify the confounding effect of age, sex and surgery on the pain behaviour and thus outcome of the results.

**Table 1:** Demographic distribution of subjects participated in the study

**A:** Distribution of subjects based on surgery undergone

Types of surgery undergone		Abdominal (n=25)	Gynaecological (n=20)	Limb (n=23)	ENT (n=22)
No of patients	Paracetamol (N=30)	8	8	7	7
	Diclofenac (N=30)	9	7	7	7
	Placebo (N=30)	8	6	8	8

**B:** Gender and age-based distribution of subjects in different groups

Participants		Male	Female	Mean Age
No of patients	Paracetamol (N=30)	15	15	43.3±8.78
	Diclofenac (N=30)	15	15	45.56±9.67
	Placebo (N=30)	15	15	44.89±5.93

### Effect of treatment on postoperative VAS score

VAS score in the range of 0 to 5 was noted prior to any treatment and upto 8 hrs post-treatment. Mean of VAS score in the group which consist of patient with any surgery undergone is considered for statistical analysis (Table 2). Though, in placebo control group, VAS did not differ significantly from baseline, we have noticed significant change in the patients from paracetamol and diclofenac group ( $P<0.01$  at 1-8 hrs time point). In paracetamol group, VAS reduced significantly at 1 hr ( $P<0.01$ ), 2 hrs ( $P<0.01$ ), 3 hrs ( $P<0.01$ ), 4 hrs ( $p<0.01$ ) and 6 hrs ( $p<0.05$ ). However, at 8 hrs time point difference was not significant. In Diclofenac group, similar results were observed to that of paracetamol. VAS reduced significantly at 1 hr, 2 hrs, 3 hrs, 4 hrs (all  $p<0.01$ ) and 6 hrs ( $p<0.05$ ). However, at 8 hrs time point difference was not significant. VAS values at the end of 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup> and 8<sup>th</sup> hours postoperatively were comparable and statistically insignificant (Table 2).

**Table 2:** Postoperative VAS score

Group	Paracetamol (N=30)	Diclofenac (N=30)	Placebo (N=30)
VAS (- 1 hr)	4.67±0.56	4.71±0.78	4.6±0.6
VAS (0 hr)	4.65±0.54	4.72±0.45	4.63±0.48
VAS (+1 hr)	2.05±0.24**	2.11±0.14**	4.13±0.54
VAS (+2 hr)	1.45±0.18**	1.35±0.14**	4.25±0.38
VAS (+3 hr)	1.89±0.25**	1.75±0.19**	4.54±0.5
VAS (+4 hr)	2.25±0.29**	2.33±0.34**	4.31±0.41
VAS (+6 hr)	3.45±0.33*	3.68±0.34**	4.67±0.62
VAS (+8 hr)	3.87±0.39	3.95±0.44	4.68±0.65

### Effect of treatment on VAS across different surgery groups

We have further analysed the VAS score in different surgery groups who received different treatment. For statistical simplification, we have considered VAS score only at 2 hrs time point in this setting (Table 3). Irrespective of surgery

undergone, paracetamol as well as diclofenac reduced the VAS score at 2 hrs time point significantly ( $p < 0.01$ ). On the

other hand, in the placebo receiving group we do not find such reduction in VAS in nay of the surgery group.

**Table 3:** Effect of treatment on VAS in different surgery groups

Types of surgery undergone			Abdominal (n=25)	Gynaecological (n=20)	Limb (n=23)	ENT (n=22)
Pain score (VAS) at 2 hr post	Paracetamol (N=30)	(- 1 hr)	4.75±0.66 (n=8)	4.72±0.76 (n=8)	4.82±0.86 (n=7)	4.52±0.46 (n=7)
		(+2 hrs)	2.33±0.29* (n=8)	2.42±0.31* (n=8)	2.33±0.22* (n=7)	2.36±0.23* (n=7)
	Diclofenac (N=30)	(- 1 hr)	4.74±0.69 (n=9)	4.67±0.32 (n=7)	4.62±0.43 (n=7)	4.68±0.63 (n=7)
		(+2 hrs)	2.18±0.19* (n=9)	2.21±0.12* (n=7)	2.28±0.18* (n=7)	2.18±0.23* (n=7)
	Placebo (N=30)	(- 1 hr)	4.64±0.59 (n=8)	4.59±0.41 (n=6)	4.65±0.76 (n=8)	4.61±0.58 (n=8)
		(+2 hrs)	4.53±0.59 (n=8)	4.36±0.32 (n=6)	4.78±0.47 (n=8)	4.46±0.47 (n=8)

### Need of rescue analgesia

In group of patients receiving paracetamol, 18 patients asked for rescue analgesia; among them, 5 required in 2 h postoperatively and 13 asked in 4–6 h postoperatively. In group of patients receiving diclofenac, 17 patients asked for rescue analgesia; among them, 8 required in 2 h postoperatively and 9 required in 4–6 h postoperatively. Use of rescue analgesia in both the groups was statistically nonsignificant for different surgery groups. In the placebo group, rescue analgesia required in many patients.

### Discussion

This study was performed to investigate the effects of single dose of paracetamol and diclofenac for postoperative analgesia. We have Groups A and B were comparable and there was no statistically significant difference seen with regard to weight, ASA grade, mean age, gender distribution, duration of surgery, and type of surgeries. The patients were distributed equally within the four treatment groups according to their initial degree of pain. This helps to nullify the confounding effect of age, sex and surgery on the pain behaviour and thus outcome of the results. We have selected doses, time, and route of administration as per previous studies [11, 12]. Pain assessment was done by using VAS scoring system which is described as the simple, effective, and easiest way to measure the intensity of pain [9, 10]. In our study, we observed VAS score to decide the time to give the dose of the analgesic postoperatively and also to compare the quality and duration of analgesia between both the study groups. Patients were evaluated on VAS prior to any treatment and in the immediate postoperative period at 1, 2, 4, 6 and 8 hrs after administration of analgesic drug. This time points are selected based on the pharmacokinetic properties of the diclofenac and paracetamol [13].

The mean VAS score in paracetamol and diclofenac was nonsignificant at all the time intervals suggesting that paracetamol and diclofenac provide equal analgesia. Similarly, on comparing the mean VAS in paracetamol and diclofenac groups for different surgery undergone P value was not significant. We have analysed VAS score at 2 hrs in different surgery groups and found it nonsignificant between the paracetamol and diclofenac treatment groups. Our results are comparable to previous studies [14].

### Conclusion

Both paracetamol and diclofenac drugs are safe to provide analgesia through oral route in postoperative period without any major significant side effects. The duration and quality of analgesia in both groups were similar in postoperative period.

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