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Assessment of Analgesic Effects of Paracetamol Alone and Diclofenac + Paracetamol in Patients Undergoing Dental Extraction

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Case Study

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ABSTRACT

Aim: To assess and compare the analgesic efficacy of paracetamol alone and diclofenac + paracetamol combination in patients undergoing dental extraction.
Materials and Methods: An open-label, randomized trial was conducted on 180 patients (20–50 years) allocated into two groups, with postoperative pain assessed using the Numerical Rating Scale (NRS) at immediate, day 1, and day 3 intervals.
Results: Both regimens reduced pain, but diclofenac + paracetamol showed significantly lower NRS scores on day 1 and day 3 ($p < 0.001$), with no reported complications in either group.
Conclusion: While paracetamol is effective for mild pain, diclofenac + paracetamol provides superior relief for moderate to severe pain post-extraction, without additional adverse effects.

Keywords: Acetaminophen, Analgesics, Diclofenac, Non-Narcotic, Postoperative Pain/drug therapy, Tooth Extraction, therapeutic.

Introduction

Pain is an unpleasant sensation that results from an acute tissue injury and causes the release of painful substances like histamine and serotonin. Prior to, during, and following surgery, all patients undergoing Dental Extraction whether small or large scale, need to minimize or relieve pain.[1]

Pain management is one of the main challenges to any oral and maxillofacial surgeon after any minor or major surgical procedure. Since pain is a qualitative and subjective variable rather than a quantitative and objective one, measuring pain is typically challenging. Furthermore, pain varies depending on a number of factors, including personal ethics, cultural norms, age, sex, and the type of surgery done.[2]

Any tooth extraction that is surgically performed and results in poorly controlled pain is a verified pain model. From one to three hours following surgery, the pain is regular and predictable, lasting anywhere from mild to severe.[3] Oral and maxillofacial surgeons gives priority to patients' pain relief as soon as possible to enable them to

return to their regular daily activities and masticatory function.[4]

After the dental extraction, the perfect medication should be used to relieve pain, lessen trismus and inflammation, promote healing, and have less side effects. Narcotics were once used to treat severe acute or chronic pain, and they were also employed as potent analgesics.[5] However, using large amounts of opioids can have a number of adverse effects, such as apnea, respiratory depression, nausea, vomiting, itching, and physical and mental dependence.[6]

Paracetamol

The brain's specific inhibition of cyclooxygenase activity is the mechanism of action of paracetamol. Instead of directly inhibiting an active site, this activity seems to be decreasing COX, which has to be oxidized in order to function. The metabolite of paracetamol, AM404, may have the ability to alter the brain's endogenous cannabinoid system and increase the amount of endogenous cannabinoid/vanilloid and amide receptors that neurons may reabsorb, hence decreasing pain. TRPV1 is also directly activated by AM404, which inhibits the brain's pain signals.[7]

Diclofenac

The main mechanism of action is believed to be the inhibition of COX) to prevent prostaglandin production. Diclofenac has a number of other molecular targets that may be involved in its pain-relieving effects.

1. Blockage of voltage-dependent sodium channels.
2. Blockage of acid-sensing ion channels.
3. Positive allosteric modulation of KCNQ- and BK-potassium channels.

The purpose of the present study is to assess and compare the effectiveness of the analgesic effects of diclofenac sodium with paracetamol and paracetamol alone following tooth extraction.[7]

Materials and Methods

The present study was designed as an open label, parallel group, randomized trial, in which 180 patients were randomly allocated to two different groups. They are selected as per inclusion/exclusion criteria after obtaining written informed consent. Patients aged between 20 to 50 years undergoing tooth extraction under local anesthesia and who has the ability to complete a 10 cm Numerical Rating scale(NRS)8 were only included in the study.

Inclusion Criteria

1. Healthy patients with age group between 20 -50 years.
2. Patients undergoing dental extraction under local anesthesia.
3. No Known Allergy to NSAIDs.

Exclusion Criteria

1. Medically Compromised patients.
2. Patient having any deleterious habits, parafunctional habit (ex, bruxism).
3. Pregnant or lactating women.
4. Transalveolar, Surgical extraction associated with any pathology.

Study participants were divided into two groups – Group A and Group B as per a generated randomization sheet. The extraction procedure was be carried out using a routine and standardized procedure under local anesthesia using 2% lignocaine with 1:80,000 adrenaline. Treatment with the antibiotic and analgesic corresponding to each group will start when the patient's pain reaches moderate to severe intensity Numerical Rating Scale (NRS)8 5-8) after extraction with amoxicillin 500 mg every 8 h for 5 days. Group A will be given diclofenac 50 mg + paracetamol 325 mg every 12 h for 3 days, and Group B will be given paracetamol 650 mg every 8 h for 3 days. If the patient had no relief in pain then rescue analgesic (keterolac 10mg orally) will be given to a maximum of 4 doses per day, and such patients will be excluded from the study. The comparison of the effectiveness of both drugs was done in both groups for similar procedures (type

and duration). Postoperative assessment of analgesia was done by determining the parameters at intervals of 12 hr, 24 hr, and 3rd day.

Statistical Analysis

The data for the present study were entered in Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation, frequency, and percentage. The level of significance for the present study was fixed at 5%.

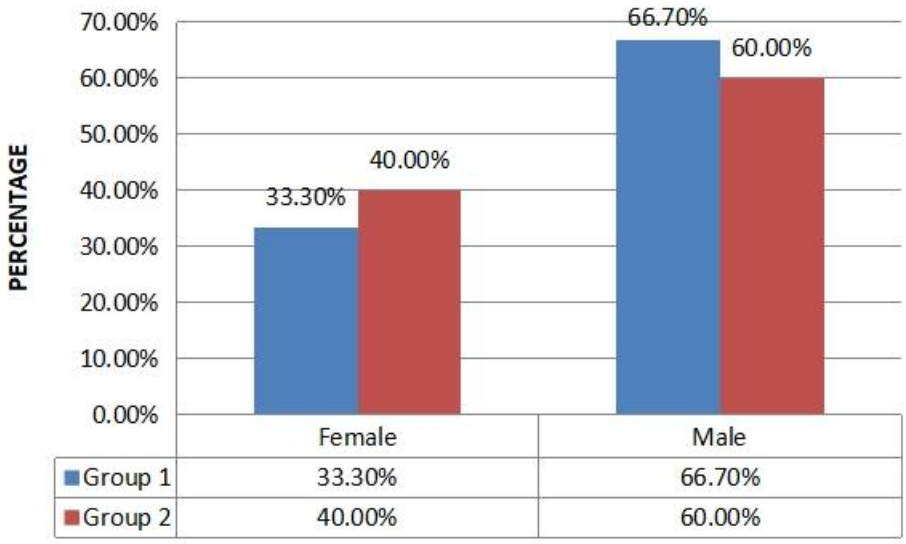
The intergroup comparison will be done using the independent t-test/ and the intragroup comparison between time intervals will be done using the Paired t-test. The Shapiro–Wilk test was used to investigate the distribution of the data, and Levene's test to explore the homogeneity of the variables.

Results

The gender distribution of the study subjects was analyzed across two groups. In Group 1, there were 90 participants, consisting of 30 females (33.3%) and 60 males (66.7%). In Group 2, there were also 90 participants, with a slightly higher proportion of females (36, or 40.0%) compared to Group 1, while males made up 54 participants (60.0%). Overall, the results indicate a predominance of male participants in both groups, with males representing more than 60% of the subjects in each group. The proportion of females was slightly higher in Group 2, but the gender distribution remained relatively consistent across the two groups.

	Female	Male	Total
Group 1	30	60	90
	33.3%	66.7%	100.0%
Group 2	36	54	90
	40.0%	60.0%	100.0%

Group -1 Paracetomol Alone, Group -2: Diclofenac + Paracetomol.



The results of pain assessment, measured using the Numerical Rating scale (NRS), were recorded at three different time points: immediately post-operation, on the 1st day, and on the 3rd day following the procedure for both **Group 1** and **Group 2**.

Immediately after the surgery (post-op), both groups experienced similar levels of pain, with **Group 1** reporting a mean VAS score of **7.91** and **Group 2** reporting a mean of **7.96**. The P-value for this comparison was **1.000**, indicating no significant difference in pain between the groups at this time point.

On the **1st day post-operation**, a significant difference in pain levels emerged, with **Group 1** reporting a mean score of **6.66**, while **Group 2** had a lower mean of **4.36**. The P-value for this comparison was **0.001**, which is statistically significant, indicating that **Group 2** experienced less pain than **Group 1** on the first day after surgery.

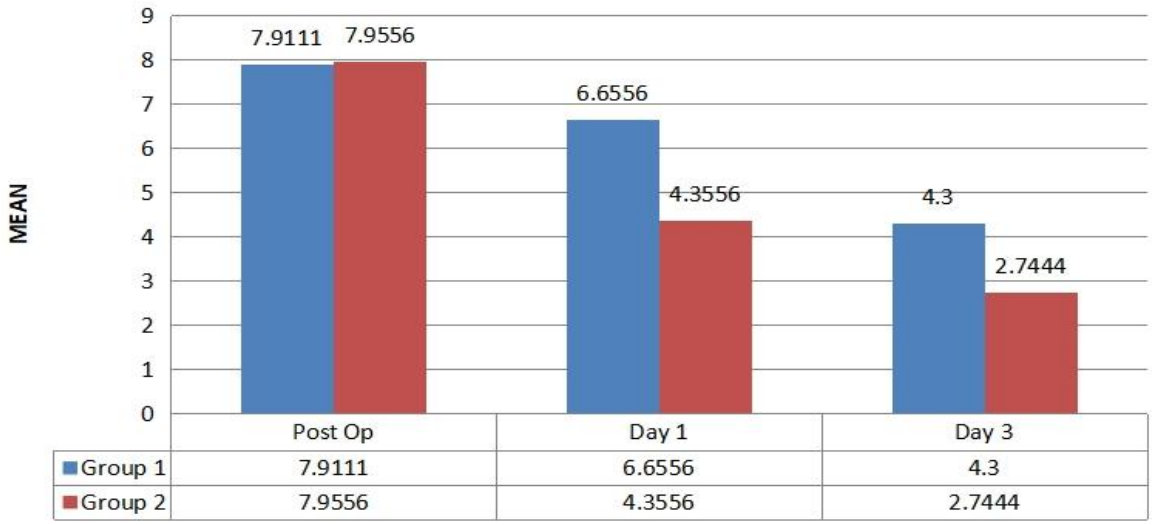
By the **3rd day post-operation**, the pain levels had decreased in both groups, with **Group 1** reporting a mean score of **4.30** and **Group 2** a lower mean of **2.74**. The difference in pain between the two groups remained statistically significant, with a P-value of **0.001**, further highlighting that **Group 2** experienced less pain than **Group 1** on the third day.

Pain based on vas scores ATPOST OP, IST Day, 3RD Day

	GP	N	Mean	Std. Deviation	Std. Error Mean	P value
Post Op	Group 1	90	7.9111	.86951	.09165	1.000(Non-Sig)
	Group 2	90	7.9556	1.06961	.11275	
Day 1	Group 1	90	6.6556	1.01849	.10736	0.001(Sig)
	Group 2	90	4.3556	1.05267	.11096	
Day 3	Group 1	90	4.3000	1.16552	.12286	0.001(Sig)
	Group 2	90	2.7444	.80114	.08445	

Group -1 Paracetomol Alone, Group -2: Diclofenac + Paracetomol

In conclusion, although the pain levels were similar immediately after the surgery, **Group 2** consistently reported significantly less pain than **Group 1** on both the 1st and 3rd days following the procedure.

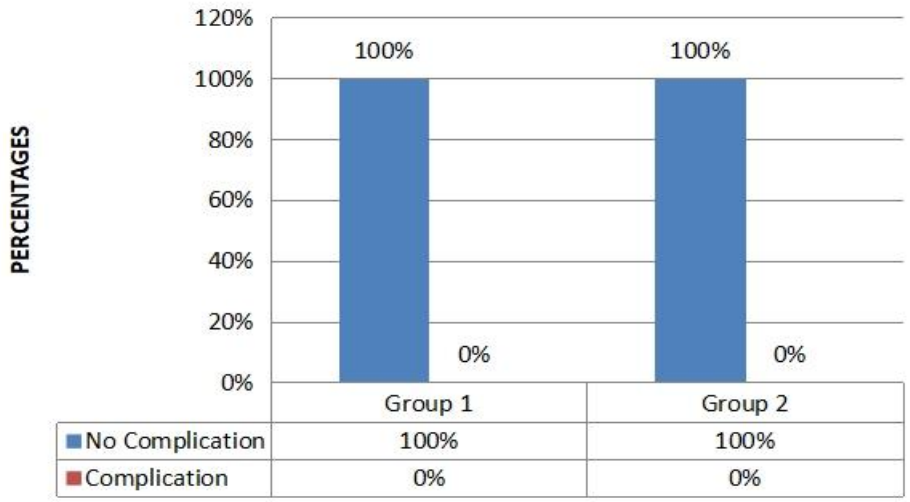


Intergroup Comparison of Complications between the Groups

	N	No Complication	Complication	P value
Group 1	90	90(100%)	0(00%)	1.000(Non-Sig)
Group 2	90	90(100%)	0(00%)	

Group -1 Paracetomol Alone, Group -2: Diclofenac + Paracetomol

The comparison of complications between **Group 1** and **Group 2** revealed no differences in the occurrence of complications. In both groups, all 90 participants (100%) reported no complications, and there were no cases of complications (0%). The P-value for this comparison was **1.000**, indicating no significant difference in complication rates between the two groups.



Intragroup Comparison of Pain Score between Post OP, Day 1 and Day 3 in Group 1

	N	Mean	Std. Deviation	Std. Error Mean	P value
Post Op	90	7.9111	.86951	.09165	0.001(Sig)
Day 1	90	6.6556	1.01849	.10736	
Day 3	90	4.3000	1.16552	.12286	

Group -1 Paracetomol Alone, Group -2: Diclofenac + Paracetomol

The pain scores in **Group 1** were compared at three time points: immediately post-operation, Day 1, and Day 3.

- **Post-Operative (Immediately after surgery)**: The mean pain score was **7.9111**, with a standard deviation of **0.86951** and a standard error of the mean of **0.09165**.
- **Day 1 (First day post-operation)**: The mean pain score decreased to **6.6556**, with a standard deviation of **1.01849** and a standard error of the mean of **0.10736**.
- **Day 3 (Third day post-operation)**: The mean pain score further decreased to **4.3000**, with a standard deviation of **1.16552** and a standard error of the mean of **0.12286**.

The P-value for the comparison of pain scores from post-operative to Day 1 was **0.001**, indicating a statistically significant reduction in pain levels between these two time points. Similarly, the pain score from Day 1 to Day 3 also showed a significant decrease, suggesting that the pain continued to improve over time. The results indicate that pain in **Group 1** decreased significantly from post-operative to Day 1, and further decreased by Day 3, reflecting a positive trend in recovery.

Intragroup Comparison of Pain Score between Post OP, Day 1, and Day 3 In Group 2

	N	Mean	Std. Deviation	Std. Error Mean	P value
Post Op	90	7.9556	1.06961	.11275	0.001(Sig)
Day 1	90	4.3556	1.05267	.11096	
Day 3	90	2.7444	.80114	.08445	

Group -1 **Paracetomol Alone, Group -2: Diclofenac + Paracetomol**

The pain scores in **Group 2** were compared at three time points: immediately post-operation, Day 1, and Day 3.

- **Post-Operative (Immediately after surgery)**: The mean pain score was **7.9556**, with a standard deviation of **1.06961** and a standard error of the mean of **0.11275**.
- **Day 1 (First day post-operation)**: The mean pain score decreased to **4.3556**, with a standard deviation of **1.05267** and a standard error of the mean of **0.11096**.
- **Day 3 (Third day post-operation)**: The mean pain score further decreased to **2.7444**, with a standard deviation of **0.80114** and a standard error of the mean of **0.08445**.

The P-value for the comparison of pain scores from post-operative to Day 1 was **0.001**, indicating a statistically significant reduction in pain levels between these two time points. Similarly, there was a significant decrease in pain scores from Day 1 to Day 3. These results suggest that **Group 2** experienced a significant reduction in pain from post-operative to Day 1, and this trend continued with further pain relief by Day 3, indicating a positive recovery trajectory.

Discussion

Numerous pain models have been developed for use in clinical trials, particularly in surgical and medical fields. In this study, tooth extraction was selected as the model due to its ability to reliably produce acute tissue trauma, which leads to inflammation and increased nociceptor sensitivity. This makes it a well-established and clinically relevant model for evaluating analgesic effectiveness.[9]

In dental practice, a wide range of NSAIDs and pain-relieving medications are commonly prescribed, yet patient responses can vary significantly. Effective studies of this nature require consistent pain levels, low placebo response, homogeneous populations, and good patient cooperation—all of which are characteristics of post-extraction pain. As newer pain management options emerge, dental practitioners can offer more tailored and effective pain relief.[7]

NSAIDs remain the most commonly used agents for managing symptoms like pain and inflammation. Their mechanism involves the inhibition of prostaglandin synthesis via the cyclooxygenase (COX) pathways. Most NSAIDs are organic acids with low pKa values, allowing them to concentrate in inflamed tissues. Their chemical structure, plasma half-life, and COX-1/COX-2 selectivity influence both efficacy and side effect profiles.[10]

Tissue trauma from extractions releases arachidonic acid, which is converted into prostaglandins. Diclofenac sodium, a widely used NSAID, inhibits both COX-1 and COX-2 enzymes and has demonstrated dose-dependent analgesic effects in previous studies. Paracetamol is frequently used in clinical trials as a reference drug due to its reliable pain relief and minimal side effects.[7]

Although diclofenac is effective, it is associated with gastrointestinal side effects due to prostaglandin inhibition. These effects range from mucosal damage shortly after ingestion to potential ulcers. However, studies have shown no increased risk of serious GI complications when NSAIDs are used short-term. In contrast, paracetamol has minimal effects on renal function and is generally safer, though it can be hepatotoxic in overdose or in chronic alcohol users.[6]

Understanding prostaglandin biology and NSAID pharmacology is essential for clinicians to use these drugs safely. Factors such as co-existing conditions and concurrent medications must be considered to minimize the risks of NSAID therapy. Using the lowest effective dose for the shortest period is recommended, especially in at-risk patients.[8]

Diclofenac, with greater COX-2 selectivity, spares platelet function and is less likely to cause bleeding. This was confirmed in the study, where no bleeding issues were observed. The study also emphasized the importance of evaluating pain over time and monitoring for adverse reactions. Over a four-day period, the frequency of medication use and patient-reported outcomes helped determine drug efficacy and safety.[7]

Pain typically peaks 6–8 hours after extraction as the local anesthetic effect fades. This was consistent with the study's findings, where pain intensity decreased over time, particularly in the diclofenac + paracetamol group. The Numerical Rating Scale (NRS), used to assess pain, provided a reliable and user-friendly tool for pain evaluation.

Significant reductions in average pain intensity were observed in both groups, though greater relief was seen in the combination therapy group at several time points. None of the patients in the diclofenac + paracetamol group required rescue medication, while 37.5% in the paracetamol-only group did.

Using a fixed-dose combination of diclofenac 50 mg and paracetamol 325mg twice daily not only improved pain relief but also enhanced patient compliance compared to the three-times-daily paracetamol monotherapy. Combining drugs with different modes of action and onset times results in better pain control and fewer side effects at lower doses.

The findings of our study align closely with those of the previous study conducted by Shah and Limdiwala (2015)[7], both evaluating the efficacy of a fixed-dose combination of diclofenac and paracetamol versus paracetamol alone in managing post-operative dental pain. In both trials, the **combination therapy demonstrated significantly greater pain relief** compared to paracetamol monotherapy, particularly during the first 24–72 hours post-extraction. Notably, **both studies reported minimal or no adverse drug reactions**, highlighting the safety and tolerability of the combination regimen for short-term use.

The results of our study closely align with those reported by Kubitzek et al. (2003)[11], both demonstrating the superior analgesic efficacy of diclofenac combined with paracetamol compared to paracetamol alone in managing postoperative dental pain. Kubitzek et al. found that a flexible dosing regimen of diclofenac 25 mg and paracetamol 1,000 mg effectively reduced pain, with comparable efficacy between the two active treatments, and significantly better outcomes than placebo.

As an open-label randomized study, this research adds valuable data, but further long-term and blinded studies are necessary to fully understand the safety and efficacy profile of such drug combinations.

Conclusion

Both treatment regimens demonstrated effectiveness.

For patients experiencing mild to moderate pain, paracetamol is recommended as the first-line therapy due to its favorable safety profile and affordability. However, in cases of moderate to severe pain or where significant inflammation is present, a combination of diclofenac and paracetamol is advised for faster and more effective pain relief—though clinicians should remain mindful of the potential for adverse drug reactions.

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