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Comparative Evaluation of the Efficacy of Two Different Analgesics on Postoperative Pain after Root Canal Treatment: A Randomised Controlled Trial

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Conflicts of Interest: Nil

Abstract

Background: Postoperative pain remains a common challenge in endodontics, often indicating treatment failure. Preoperative analgesic strategies, particularly NSAID combinations, are employed to mitigate post-instrumentation discomfort. This study evaluates and compares the analgesic efficacy of Aceclofenac plus Paracetamol versus Ibuprofen plus Paracetamol in managing postoperative pain following root canal treatment.

Materials and Methods: This randomized controlled trial included 36 patients with symptomatic irreversible pulpitis, randomly assigned to two groups. Group 1 received Aceclofenac (100 mg) with Paracetamol (500 mg), while Group 2 received Ibuprofen (400 mg) with Paracetamol (500 mg). Standard endodontic procedures were performed under local anesthesia and rubber dam isolation. Postoperative pain was assessed using the Visual Analog Scale (VAS) on Day 1 and Day 4. Data were analyzed using independent-sample t-tests, with a significance level set at $p<0.05$.

Results: The preoperative VAS scores were comparable between groups ($p=0.262$). At 24 hours, the Ibuprofen + Paracetamol group showed a significantly greater reduction in pain ($p=0.0014$). By Day 4, pain scores continued to decline in both groups, with the Ibuprofen combination maintaining a statistically significant advantage ($p=0.0456$). The findings indicate that the Ibuprofen-Paracetamol combination provides superior and sustained analgesic effects compared to Aceclofenac-Paracetamol.

Conclusion: The combination of Ibuprofen with Paracetamol demonstrates enhanced early and prolonged postoperative analgesia in endodontic patients,

supporting its clinical utility in managing post-treatment pain. Further research is warranted to explore the underlying mechanisms and long-term outcomes.

Keywords: Aceclofenac, Ibuprofen, Post-operative pain, Root canal treatment.

Introduction

Posttreatment pain remains a prevalent challenge in endodontic practice, frequently serving as an indicator of treatment failure. The incidence of pain following root canal therapy varies significantly, with reported prevalence rates ranging from 10.6% to 82.9%[1,2]. To mitigate post-instrumentation discomfort, clinicians utilize various pharmacological strategies, including preoperative oral medications, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, centrally acting analgesics, inhaled NSAIDs, and local injections of steroids or anaesthetics[3]. Among these, preoperative oral NSAID administration is considered a straightforward and effective method, primarily targeting the reduction of inflammatory mediators such as prostaglandins involved in pain perception[4].

Aceclofenac is a potent NSAID belonging to the phenylacetic acid group. Its excellent safety profile makes it more acceptable to patients and promotes better treatment compliance[5]. Another commonly used NSAID, ibuprofen, acts peripherally and demonstrates significant anti-inflammatory potency through reversible and balanced inhibition of COX-1 and COX-2 enzymes. Its efficacy in managing post-endodontic pain is well-documented, with strong clinical evidence supporting its use[6]. The combination of NSAIDs with paracetamol has been shown to enhance analgesic efficacy while minimizing adverse effects7]. However, current endodontic literature lacks comprehensive evaluation of such drug combinations. Hence, the present clinical study was undertaken to assess and compare the analgesic efficacy of two pharmacological agents (Aceclofenac +paracetamol and Ibuprofen+ paracetamol) in alleviating postoperative pain following root canal treatment in patients with symptomatic irreversible pulpitis.

Materials and Methods

The manuscript of this Randomized Controlled Trial has been written according to the Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) 2020 guidelines (Figure 1)

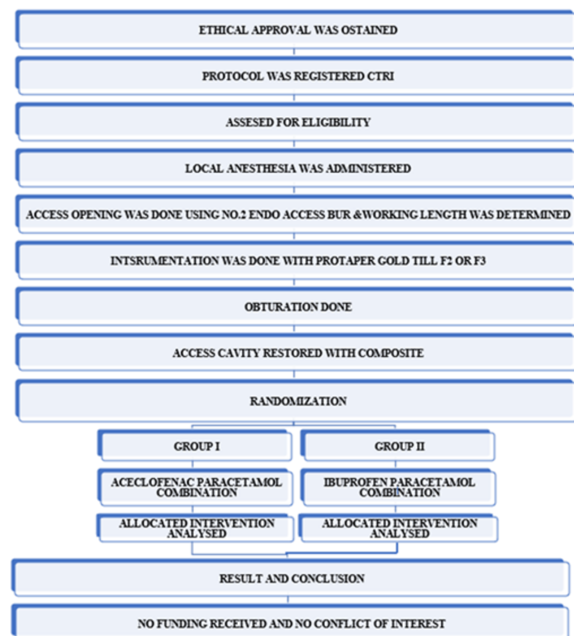

Figure 1: PRIRATE flowchart of the study

Ethical approval and sample size determination:

This randomized controlled trial was conducted in the Dental College and Hospital after gaining approval from Institutional Ethics Committee (IEC/GDCHN/40/2024). The study was registered in the clinical trial registry of India. Sample size was calculated using data from study by Parirokh et al [8] with a formula incorporating alpha error (1.96), beta error (0.84), resulting in approximately 18 samples per group.

Sample selection

Sampling was conducted using the convenience method. The study included healthy individuals aged 18–60 years

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with single-rooted vital teeth, complete root formation, and a diagnosis of symptomatic irreversible pulpitis. Exclusion criteria comprised multirooted or non-vital teeth, systemic illness, recent antibiotic or NSAID use, medication allergies, contraindications to lignocaine or apex locator use, latex allergy, pregnancy, lactation, immature roots, root resorption, calcified canals, facial swelling, tenderness on percussion, periapical lesions, TMJ disorders, systemic infections, and immunocompromised status. Eligible patients were informed about the study and enrolled after providing written consent.

Study Intervention

A comprehensive case history was obtained for all selected patients. Clinical assessment focused on mandibular incisors, canines, and first or second premolars diagnosed with symptomatic irreversible pulpitis. Pulp vitality was tested preoperatively using an electric pulp tester (C Pulse, Foshan Coxo, China), and radiographic evaluation (Carestream Dental India Pvt Ltd) was performed to assess periapical status. Local anesthesia with Lignocaine containing 1:80,000 adrenaline (Xicaine, ICPA Health) was administered. Rubber dam isolation (Hygienic, Coltene, India) was applied, and access cavities were prepared using Endo Access Bur size 2 (Dentsply Sirona) under continuous water irrigation.

Pulp tissue was removed using a broach (Mani Inc., Japan), and working length was established with stainless steel K-files (Mani Inc., Japan) and verified with an apex locator (J. Morita Co., Tustin, CA), as well as confirmed radiographically. The working length was re-verified throughout the procedure. Initial hand instrumentation was performed up to size 20 K-file, followed by canal preparation with Protaper Gold rotary files (F2 or F3 – 20/0.06 or 25/0.06) as per manufacturer's guidelines, using an electric endomotor (Orikam).

Throughout instrumentation, canals were irrigated with 10 mL of 3% sodium hypochlorite (NaOCl) (Prime Dental Products Pvt. Ltd., India), delivered using RC Twents (Prime Dental). Following irrigation, canals were dried with paper points (Diadent, Korea) and obturated using gutta-percha (Diadent, Korea) and AH Plus sealer (Dentsply Maillefer, Germany). Access cavities were then restored with direct composite resin (Ivoclar Vivadent).

Postoperatively, all patients were provided with a Visual Analog Scale (VAS) form. Group 1 received an Aceclofenac-paracetamol combination, while Group 2 received an Ibuprofen-paracetamol combination. Follow-up assessments were conducted on Day 1 and Day 4 after treatment. Pain intensity (both verbal and numerical via VAS) and the number of analgesic tablets consumed were recorded in the patient's chart. The collected data was entered into a Microsoft Excel spreadsheet and subjected to statistical analysis

Statistical analysis

The VAS data was analyzed-using independent- sample T-test to compare the incidence of pre and post- operative pain at all the time intervals amongst the two groups. Differences were considered significant when probabilities were <0.05.

Results

Demographic data of participants was analyzed. Mean of age for participants in group I was 45.38±10.79 and group II was 42.33±8.01., group I consisted of 6 female and 12 male whereas group II consisted of 5 male and 13 female.

The pre-operative mean VAS score was 5.77 ± 1.27 in the Aceclofenac+Paracetamol group and 5.27 ± 1.36 in the Ibuprofen+Paracetamol group. The difference was

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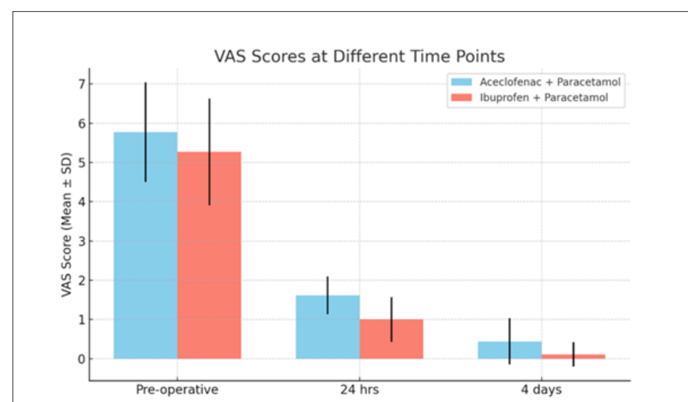
not statistically significant (*p = 0.262*), indicating that both cohorts experienced comparable levels of baseline pain, thereby allowing for an unbiased assessment of the analgesic efficacy during the postoperative period. The results from the 24-hour follow-up demonstrate that both treatment groups experienced a significant reduction in postoperative pain, with the Ibuprofen plus Paracetamol group showing a notably greater decrease compared to the Aceclofenac group. The statistical significance (p = 0.0014) underscores the superior early analgesic effect of the combination therapy, likely attributable to the synergistic action of both drugs in mitigating pain pathways.

By the fourth postoperative day, pain scores continued to decline in both groups, yet the Ibuprofen + Paracetamol group maintained a statistically significant advantage (p = 0.0456). This sustained reduction suggests that the combination not only provides effective immediate relief but also offers prolonged analgesic benefits during the recovery phase. The findings support the clinical utility of Ibuprofen combined with Paracetamol for managing postoperative pain, potentially leading to improved patient comfort and satisfaction during recovery. Further research could explore the underlying mechanisms contributing to this sustained efficacy and evaluate long-term outcomes. (Table 1 and Graph 1)

Table 1: VAS of Pre-Operative, 24 Hrs Follow-Up and 4 Days Follow Up Of Study Groups. *means statistically significant $p<0.05$.

Time Point	Group	Mean Pain score	Std Dev	t-Statistic	Degrees of Freedom	p-Value
Pre-operative	Aceclofenac+Paracetamol	5.77	±1.27	1.14	33.84	0.262
	Ibuprofen+Paracetamol	5.27	±1.36			
24 hrs	Aceclofenac+Paracetamol	1.611	±0.48	3.48	33.04	0.0014*
	Ibuprofen+Paracetamol*	1.00	±0.57			
4 days	Aceclofenac+Paracetamol	0.44	±0.59	2.10	25.72	0.0456*
	Ibuprofen+Paracetamol*	0.11	±0.31			



Graph 1: VAS of Pre-Operative, 24 Hrs Follow-Up and 4 Days Follow Up of Study Groups

Discussion

Endodontic therapy encompasses the management of pre, intra-, and post-operative symptoms, with post-obturation pain recognized as a potential complication that may become chronic. This pain is associated with factors such as preoperative pain, periapical infection, retreatment procedures, intracanal medicaments, and iatrogenic damage to periapical tissues[9,10].A likely explanation for the post obturation pain is the amplification of preexisting inflammatory responses and peripheral sensitization[3]. Therefore, implementing supplementary approaches to manage post-obturation pain in these patient groups may prove advantageous, which

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subsequently influenced the inclusion criteria for this study.

Ibuprofen is a derivative of propionic acid and functions as a non-selective inhibitor of cyclooxygenase (COX) enzymes. In contrast, aceclofenac is a derivative of phenylacetic acid that selectively inhibits COX-2 and the synthesis of prostaglandin E2 (PGE2) in blood mononuclear and polymorphonuclear cells[11]. According to the existing literature, the combination of ibuprofen and paracetamol, accounting for 34.3% of prescriptions, constitutes the most prevalent analgesic regimen in India[12]. This preference is primarily attributable to ibuprofen's favorable safety profile, cost-effectiveness, and its demonstrated efficacy in providing potent analgesic and anti-inflammatory effects in the management of postoperative pain consequent to endodontic therapy[13]. Conversely, aceclofenac is recognized for its superior tolerability among NSAIDs, characterized by a markedly reduced incidence of gastrointestinal adverse effects[14]. Although combination drug therapies have gained considerable popularity, there is a limited body of published research concerning their efficacy in postoperative management. Therefore, this study has been undertaken to systematically investigate and address this gap in the literature.

The study conducted by Syed et al. identified several factors that significantly influenced the post-obturation pain experience, including age, gender, arch, and the presence of pre-operative pain. To establish a baseline for the current investigation, these factors were considered, ensuring that there were no statistically significant differences among them. This approach was employed to facilitate an accurate assessment of the analgesic efficacy without confounding influences.

The study utilized the Visual Analog Scale (VAS) to assess postoperative pain, given that the reliability of VAS as a tool for pain measurement is well-documented and extensively validated in scientific research[15]. The results from the 24-hour follow-up demonstrate that both treatment groups experienced a significant reduction in postoperative pain, with the Ibuprofen plus Paracetamol group showing a notably greater decrease compared to the Aceclofenac group. The statistical significance ($p = 0.0014$) underscores the superior early analgesic effect of the combination therapy, likely attributable to the synergistic action of both drugs in mitigating pain pathways. By the fourth postoperative day, pain scores continued to decline in both groups, yet the Ibuprofen + Paracetamol group maintained a statistically significant advantage ($p = 0.0456$). This sustained reduction suggests that the combination not only provides effective immediate relief but also offers prolonged analgesic benefits during the recovery phase. These results endorse the clinical effectiveness of combining Ibuprofen with Paracetamol for postoperative pain management, which may enhance patient comfort and satisfaction during recovery, consistent with findings reported in previous research[16–18].

Conclusion

Within the limitations of study, the combination of Ibuprofen and Paracetamol provides superior and sustained postoperative pain relief after endodontic treatment compared to Aceclofenac and Paracetamol, improving patient comfort.

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