

## Effect of Pretreatment Paracetamol & Aceclofenac on Postendodontic Pain: An In Vivo Study

\*Dr. Pratik Upadhyay, Dr. Vaishali Parekh, Dr. Chintan Joshi,  
Dr. Niraj Kinariwala, Dr. Vishal Changlani

(Department of Conservative Dentistry and Endodontics, Karnavati School of Dentistry, Gandhinagar, India)

\*Corresponding author:- Dr. Pratik Upadhyay

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**Abstract:***Aim:* The aim of this in vivo study is to compare the effect of pretreatment paracetamol & aceclofenac on postendodontic pain. **Materials & Methodology:** 90 patients were divided into three groups of 30 patients and were given medication 30 minutes before the beginning of the procedure. Preoperative medication includes Paracetamol, Aceclofenac, and Placebo tablets. When instrumentation was completed, the canals were dried using paper points & intracanal medicament placed. The access cavity was closed with provisional restorative material. Patients were instructed to maintain a pain diary at 6, 12, and 24 hours. The data was statistically analyzed by one way ANOVA followed by Tukey's post-hoc test. **Results:** The result showed that postoperative pain reduction by aceclofenac is better at 6 hours and 12 hours followed by paracetamol and placebo. **Conclusion:** It can be concluded that aceclofenac was better in postoperative pain reduction when administered preoperatively 30 minutes before the beginning of the procedure. Aceclofenac was associated with the lowest level of postendodontic pain followed by paracetamol.

**Key Words:** Non-Steroidal Anti-Inflammatory Agents, Root Canal Therapy, Pain control, Inflammation Mediators, Post-endodontic Pain

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### I. Introduction

Patients visit dentists and seek dental treatment for various reasons. These include routine dental checkups, appointed visits for definitive dental treatment, for information about a problem, and because the patient is experiencing pain or other warning signs that affect them. The occurrence of pain is perhaps the most frequent reason for an unplanned visit to the dentist and most general dentists would probably see at least one or two patients with pain almost every working day.<sup>1</sup>

Dental pain (35.3%) is the most common reason for visiting a dental clinic followed by decay of teeth (27%). Dental pain undesirably affects quality of life and normal functioning and daily living of people, and most dental visits are intended at immediate relief of pain. Patients often turn up for dental care at the later stages of the dental disease when blatant symptoms such as pain and extreme uneasiness appear, rather than earlier. In other words, patients opt for a problem-oriented visit rather than a prevention-oriented one.<sup>2</sup> Pain following root canal treatment (RCT) is unpleasant scenario for both the patient and the dental practitioner as the number of patients experiencing pain following RCT range from 2.53% to 58%.<sup>3</sup>

Although the use of local anesthetic will reduce and lower the threshold of pain, the post-operative pain is common in some procedures, especially in patients who have experienced pain prior to treatment.<sup>4</sup> The pain relief afforded by endodontic treatment is effective but rarely immediate and complete. Post-endodontic pain is usually mild in nature and rarely lasts longer than 72 hours and is usually well managed with non-steroidal anti-inflammatory agents (NSAID) or acetaminophen. Some patients will continue to have pain at moderate to severe levels that stays for several days even after suitable endodontic treatment.<sup>5</sup>

In Endodontics, an important facet of pain control and pain prevention includes anxiety reduction and control of pre/trans-operative pain through local anesthetic techniques and use of pharmacological drugs like steroidal and non-steroidal anti-inflammatory drugs.<sup>6</sup> A preoperative single oral dose of anti-inflammatory drugs can regulate the release of inflammatory mediators and reduce the amount of side effects compared with repeated doses during the postoperative period.<sup>7</sup> The number of studies performed for evaluation of the use of nonsteroidal anti-inflammatory drugs (NSAIDs) for the purpose of postendodontic pain management after root canal instrumentation are few. Hence, the aim of this study is to evaluate, clinically, the effectiveness of single oral dose of aceclofenac and paracetamol administered 30 minutes prior to initiation of root canal treatment in comparison with placebo and to check the effectiveness of same on postendodontic pain reduction.

## II. Material And Methods

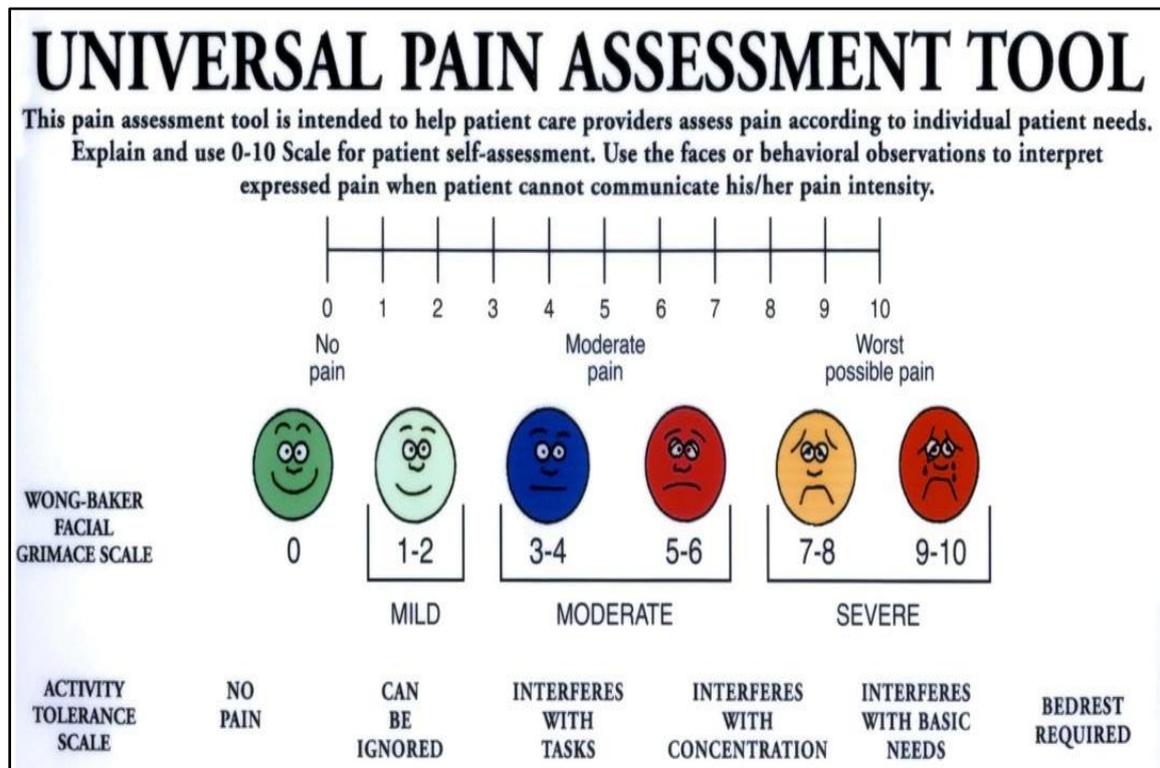
A total of 90 subjects who reported to the Department of Conservative Dentistry & Endodontics were selected for the study. Ethical clearance was obtained from Karnavati School of Dentistry Ethics Committee (KSDEC). All patients received a detailed description of the proposed treatment and gave informed written consent.

All patients with age range 18-55 years, both male and female, requiring nonsurgical endodontic therapy in single or multirrooted teeth having pain and irreversible pulpitis with or without periapical abscess, were included in the study. Patients who had taken analgesic and anti-inflammatory drugs before 24 hours, those requiring prophylactic antibiotics, those with any known allergy to NSAIDs used in the study as well as pregnant or lactating patients were excluded from the study.

Ninety patients were randomly assigned to 3 groups using Quickcalcs (GraphPad Software, Inc. 2016)

- Group A - Paracetamol (500 mg)
- Group B - Aceclofenac (100 mg)
- Group C - Placebo (Sucrose tablet)

The medications were administered 30 minutes before the beginning of endodontic treatment. Each patient was anesthetized with a solution of 2% lidocaine HCl with 1:100,000 epinephrine, followed by access opening and occlusal reduction. Working length was determined by both radiograph and apex locator Root ZX mini (J. Morita Corp, Tokyo, Japan) using number 15 size K-file (Mani Inc., Tochigi, Japan), and subsequently, the canals were cleaned and shaped using a step-back technique. Copious irrigation with 0.9% normal saline solution and 2.5% sodium hypochlorite was used between each file throughout the entire procedure. When instrumentation was completed, the canals were dried using paper points & intracanal medicament was placed (RC Cal, Prime Dental Products Pvt. Ltd., India.). The access cavity was closed with the eugenol-free provisional restorative material (Orafil G, Prevest Denpro Limited, India). Patients were instructed to maintain a pain diary at 6, 12, and 24 hours after root canal instrumentation. Post-operative pain was assessed through Universal Pain Assessment Tool explained to the patient. Combination of Diclofenac & Paracetamol was prescribed to the patients as rescue medicine if needed.



### Statistical analysis

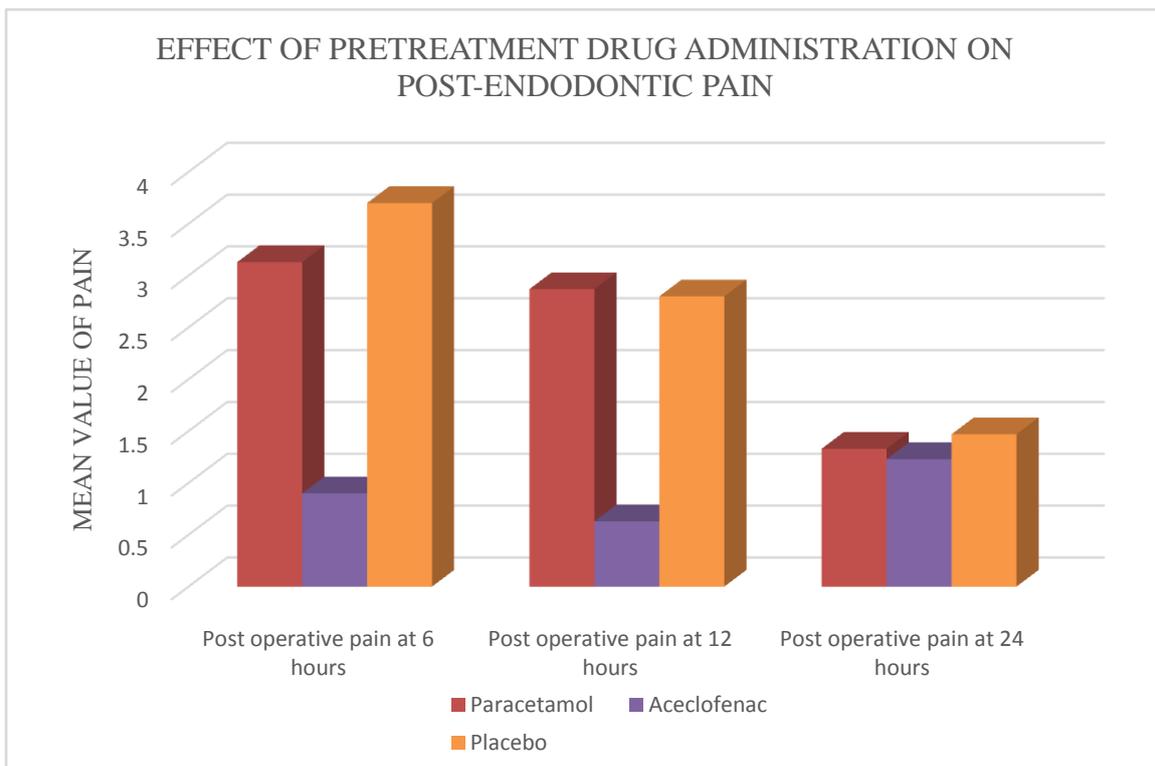
Data were collected and then analyzed. Pain experienced by subjects belonging to different drug groups was analyzed using one-way analysis of variance (ANOVA) followed by the Tukey post hoc test. All calculations were performed using Statistical Package for Social Sciences (Version 19.0. SPSS Inc. Chicago, Illinois, US. The level  $P < 0.05$  was considered as the cutoff value or level of significance.

**III. Result**

In the present study, 90 subjects were included. At 6-hour interval, the mean value for group A, B, and C are 3.13, 0.9 and 3.7 respectively. This indicates that aceclofenac group is more effective at 6 hours than other two groups. The values for paracetamol group is less but very near to placebo group, which is least effective of all. At 12-hour interval mean value for group A, B and C are 2.87, 0.63 and 2.8 respectively. This indicates that the values for aceclofenac group are lowest & thereby it is more effective at 12 hours. At 12 hours, the values for paracetamol group and placebo group are in same range. At the 24-hour interval, the mean value for group A, B, and C are 1.33, 1.23 and 1.47 respectively that indicates that the values for all three groups are in same range. Intergroup comparison by Tuckey Post Hoc test showed that postoperative pain reduction by aceclofenac was statistically significant at 6-hour and 12-hour interval in comparison with paracetamol and placebo. At the 24-hour interval, postoperative pain reduction was statistically insignificant by aceclofenac, paracetamol, and placebo.

**Table No. 1:** Shows postoperative pain ratings of patients of the three groups at 6 hours, 12 hours and 24 hours.

GROUPS	Post-operative pain at 6 hours			
	N	Mean	Std. Deviation	Significance
Paracetamol	30	3.13	2.46	
Aceclofenac	30	0.9	0.845	0.001*
Placebo	30	3.7	2.654	
GROUPS	Post-operative pain at 12 hours			
	N	Mean	Std. Deviation	Significance
Paracetamol	30	2.87	2.776	
Aceclofenac	30	0.63	0.85	0.001*
Placebo	30	2.8	2.398	
GROUPS	Post-operative pain at 24 hours			
	N	Mean	Std. Deviation	Significance
Paracetamol	30	1.33	2.46	
Aceclofenac	30	1.23	0.845	0.857
Placebo	30	1.47	2.654	



#### **IV. Discussion**

Pain management is a major concern in dentistry. Studies have shown that the major reason why over 50% of adult do not seek routine dental care is the fear of pain. The objective of root canal therapy is to relieve and/or prevent associated pain and suffering.<sup>8</sup> Although the pain may not indicate endodontic failure, relief of this pain is often more important to the patient than the success or the failure of the treatment.<sup>9</sup>

Postoperative discomfort reduction by various preoperative means is a tried and tested method. Here, we predict symptoms that arise after treatment and try to deal with them before they begin. For those patients presenting with preoperative pain, it has been reported that up to 80% of this population will continue to report pain of different degrees even after endodontic treatment.<sup>10,11</sup>

A number of factors concerning the etiology of postoperative pain have been evaluated. The causative factors of pain comprise mechanical, chemical, and microbial injuries to the pulp or periradicular tissues which are induced or exacerbated during root canal treatment.<sup>12</sup> For example, a clear indication of the relationship between microbial interactions and periapical tissues is that flare-ups are more likely to occur in necrotic cases (infected) than in vital cases (non-infected).<sup>13,14</sup> Mechanical irritation to the periradicular tissues include over-instrumentation and over-extension of filling materials, chemical irritation include apical extrusion of irrigants, intra-canal medicaments and filling materials.<sup>15,16,17</sup>

Many endogenous chemical mediators, particularly prostaglandins, have been associated with inflammation and its related pain. For dental pain, nonsteroidal anti-inflammatory drugs (NSAIDs) are one of the most frequently taken analgesic medications. NSAIDs inhibit inflammation and induce analgesia by inhibiting the activity of cyclooxygenase enzyme COX. Two forms of COX enzymes have been identified, COX-1 and COX-2. COX-1 enzymes are present in tissue at all times and responsible for synthesizing prostanoids that have a cytoprotective function. COX-1 enzymes regulate normal cell activities in the stomach, kidneys and platelets. COX-2 enzymes normally are not present in tissue (other than in kidneys) and come into play when tissue injury and inflammation occur. Thus, NSAIDs exert their analgesic, antipyretic and anti-inflammatory action by central as well as peripheral mechanism. The main disadvantage of long-term therapy with NSAIDs is the risk of gastrointestinal disturbances. Unfortunately, GI side effects have often limited their clinical utilization.<sup>18</sup>

Pretreatment analgesia is providing analgesia to patients before endodontic treatment is started. This technique can decrease the establishment of central and peripheral sensitization, which has the potential to reduce postoperative pain and postoperative analgesic intake.<sup>19,20</sup> Oral surgery models have shown preoperative administration of the nonsteroidal anti-inflammatory drugs suppress postoperative pain more effectively than a placebo.<sup>21</sup> Administration of a nonsteroidal anti-inflammatory drug before root canal therapy will interfere with the inflammatory process before it begins; therefore, presumably decreasing postoperative pain.

Aceclofenac is a predominantly potent inhibitor of COX-2 which is used for pain management. It shares structural similarities with another NSAID, diclofenac. Indeed, the therapeutic index for aceclofenac was reported to be four times greater than that of diclofenac, a well-established NSAID in clinical use. It has shown better gastric tolerance when compared to other NSAIDs. In this study, it has shown to reduce pain effectively at 6 hours and 12 hours. This may be due to its pharmacokinetic properties. Its plasma half-life of approximately 4-6 hours & is more than 99% bound to plasma proteins.<sup>22, 23</sup>

Paracetamol was used in this study as it has lower adverse drug effects like gastrointestinal disturbances. It is a worldwide used analgesic and antipyretic. However, there is still debate about its exact mechanism of action. It primarily inhibits COX-2 and then COX-1. It may also affect additional inflammatory pathways by inhibiting other peroxidase enzymes such as myeloperoxidase. It has weaker analgesic activity and weak anti-inflammatory activity. This explains its inability to significantly reduce postoperative pain at 6 hours and 12 hours due to the inflammatory response of the body due to extrusion of debris following cleaning and shaping.<sup>24</sup>

Placebo used in this study follows ethical outlines. As the placebo group did not possess any of the anti-inflammatory/analgesic characteristics as those of aceclofenac & paracetamol, it is not expected to influence the inflammatory cascade. Therefore, placebo group resulted in a significantly lower reduction in postoperative pain at 6 hours and 12 hours. This suggests that endodontic treatment combined with placebo medication may reduce pain 24 hours after the initiation of treatment, which is in accordance with other studies.<sup>25</sup> At 24 hours all three drugs showed similar pain rating suggesting the effect of root canal treatment in pain reduction as well as metabolism of drugs in the body.

The oral route does bestow a convenient, economic and non-invasive route of administration to most patients. Oral administration was preferred because the technique is clinically effective and convenient; the use of intramuscular or intravenous injection may lead to discomfort and fear and is not well accepted by some patients.<sup>26,27</sup>

Universal pain assessment tool (UPAT) is newly designed and a comprehensive combination of various scoring systems like visual analog scale and faces scales for pain intensity and severity assessment. In the

present study, the Universal pain assessment tool was used to evaluate pain intensity as it is valid, reliable and easy to use by the healthcare professionals and well understood by patients.<sup>28,29,30</sup>

These findings were in concurrence with other studies who found that prophylactic administration of NSAID to patients reduced postoperative pain.<sup>31,32</sup> Further, future clinical trials are required to show the additional efficiency of pretreatment analgesics to prevent postendodontic pain.

There were a few limitations in the study. Pain perception varies greatly among individuals. For some patients with low pain threshold, even mild pain can be considered as severe, on the other hand for patients with high pain threshold severe pain might just be felt as mild pain. There are other factors also which will influence the pain felt by the patient such as the emotional status, psychological factors etc. Therefore, studies involving evaluation of pain will be affected by the varied response of patients. The reduction in pain can also be related to the removal of the source of pain itself. Similarly, their pain recording at the specified time may also not be totally accurate.

## V. Conclusion

Within the limitations of this study, it can be concluded that aceclofenac was better in postoperative pain reduction when administered preoperatively 30 minutes before the beginning of the procedure. Aceclofenac was associated with the lowest level of postendodontic pain followed by paracetamol.

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