

# Comparative Evaluation Of Premedication With Flurbiprofen And Prednisolone On Post Endodontic Pain In Teeth With Symptomatic Irreversible Pulpitis: A Randomized Clinical Trial

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## Abstract

**Background:** Root canal treatment is an endodontic procedure that encompasses cleaning & shaping i.e. preparation of root canals followed by obturation of the prepared canals. Pain is a very common sensation that occurs a few hours after root canal treatment (RCT).

**Objective:** To evaluate and compare the efficacy of premedication with flurbiprofen and prednisolone on post-endodontic pain in teeth with symptomatic irreversible pulpitis.

**Results:** As per efficacy in both groups, in Group A, 44 (55%) showed effective results whereas in Group B, only 20 (25%) patients showed effective results.

**Conclusion:** A single pretreatment dose of flurbiprofen has a prolonged effect in reducing post-endodontic pain as compared to prednisolone.

**Keywords:** Flurbiprofen; Prednisolone; Non-Steroidal Anti-Inflammatory Agents; Pretreatment Analgesic, Visual Analog Pain Scale

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## 1. Introduction

Root canal treatment is an endodontic procedure that encompasses cleaning & shaping, i.e. preparation of root canals followed by obturation of the prepared canals. Pain is a very common sensation that occurs a few hours after root canal treatment (RCT).<sup>1</sup> According to the literature, approximately 80% of patients presenting with preoperative pain continued to have moderate to significant postoperative endodontic pain.<sup>2</sup> The following are the leading causes of pain during and following endodontic treatment: over-instrumentation, periapical extrusion of root canal irrigants, medicaments or filling materials, periapical contamination and occlusal abnormalities.<sup>3,4</sup> The peri-radicular tissue damage causes a local inflammatory process regulated by chemical mediators like prostaglandins, bradykinin, serotonin and cytokines released from damaged tissues, resulting in pain and/or swelling.<sup>3-5</sup> Therefore, one of the important parts of endodontic therapy is to reduce postoperative endodontic pain. Patient confidence and attitude towards endodontic therapy can be

improved by preparing the patient regarding expected postoperative pain and prescribing medications.<sup>2,6</sup>

Use of preoperative steroidal as well as non-steroidal anti-inflammatory drugs, intracanal medicaments and occlusal reduction are various recommended methods to manage inter-appointment and post-obturation pain.<sup>2-4</sup> Preoperative analgesics can reduce the postoperative pain and postendodontic analgesic intake, due to a reduction in central as well as peripheral sensitization.<sup>5</sup>

Flurbiprofen, a non-steroidal anti-inflammatory drug is a phenylalkanoic acid derivative. It acts by inhibiting cyclooxygenase I and cyclooxygenase II enzymes which causes a decrease in the concentrations of prostaglandins.<sup>7</sup> Prednisolone, on the other hand, is a synthetic glucocorticoid, a derivative of cortisol. It inhibits the action of phospholipase A2 by stimulating the production of a glycoprotein known as lipocortin and thus prevents the formation of arachidonic acid and subsequently the inflammatory mediators.<sup>5,8</sup>

Most of the studies support the use of anti-inflammatory drugs for endodontic pain but some trials are not in favor of these drugs.<sup>5</sup>

In a study, during therapy and for 8 hours after treatment, ibuprofen and indomethacin significantly reduced postoperative pain compared to placebo; however, at 12- and 24 hours post-treatment, there were no significant differences between them.<sup>9</sup> In another study, in cases of irreversible pulpitis, the ketorolac group demonstrated a significant reduction in pain levels at the end of six hours compared to the other medications. In comparison to the other medicines, the prednisolone group had significantly lower pain scores after 12 hours.<sup>(5)</sup> Yet in another study, Incidence of pain was reduced relative to risk by 20.31% at 6 hours, 23.39% at 12 hours, and 28.85% at 24 hours. At 6, 12, and 24 hours, prednisolone significantly reduced post-obturation pain severity compared to placebo (P 0.001). The relative risk decrease for using placebo capsules was 54%, while the reduction for taking analgesics was 55%. There were no negative consequences noted.<sup>(10)</sup>

The purpose of this study is to compare the efficacy of premedication with flurbiprofen and prednisolone on post-endodontic pain in teeth with symptomatic irreversible pulpitis. As no such study has been conducted on this topic before in our local population of Khyber Pakhtunkhwa, this study will help us in drafting and subsequently recommending certain guidelines and standard operating procedures which will not only update local health researchers in better management of such patients in future but will also help in reducing morbidities associated with symptomatic irreversible pulpitis in our local population of Khyber Pakhtunkhwa. To evaluate and compare the efficacy of premedication with flurbiprofen and prednisolone on post-endodontic pain in teeth with symptomatic irreversible pulpitis.

## 2. Materials & Methods

It was a randomized control trial study conducted at the Department of Operative Dentistry & Endodontics, Sardar Begum Dental College & Hospital Peshawar from 26 Sept 2019 to 26 March 2020. The sample size was 160 (i.e. n=80) using 28.85% efficacy (reduction in pain at 24 h through Prednisolone) and 55% efficacy (reduction in pain at 24 h through flurbiprofen), 5% level of significance, 80% power of study with the help of WHO formula for sample size determination.

Permanent molars with symptomatic irreversible pulpitis (hot and cold sensitivity with throbbing pain > 3 VAS Score) for three weeks, patients from both genders above 18 to 60 Years and restorable teeth (remaining tooth height  $\geq$  2 mm at four locations) were included in the study. Patients with known allergy or hypersensitivity to the administered drugs, teeth with acute peri-apical conditions (acute apical periodontitis/ acute periapical abscess), patients who have taken analgesics or anti-inflammatory drugs in the last 6-12 hours, patients who used medication for pain postoperatively, pregnant or nursing women, patients with a history of significant medical conditions and patients not providing informed consent were excluded from the study.

This study was conducted after approval from the Ethical Research Committee of Sardar Begum Dental College, Peshawar. Eligible candidates were selected from patients visiting the Department of Operative Dentistry & Endodontics, Sardar Begum Dental College & Hospital, after their screening through the inclusion and exclusion criteria. Informed consent was obtained from the patients before the study (Annexure 1). Patients were randomly allocated into two groups i.e. A and B using the coin flip technique. Thirty minutes before starting the endodontic therapy, a single pretreatment dose of Flurbiprofen (100mg) was given to patients in Group A and Prednisolone (30mg) to patients in Group B. RCT was completed in a single visit by the principal operator. Teeth were anaesthetized by a nerve block using 2% lidocaine with 1:100,000 epinephrine. Isolation with a rubber dam was achieved followed by access cavity preparation. After determining proper working lengths, cleaning and shaping of root canals was performed with a hybrid technique, using hand K-files and the ProTaper manual file system. Sodium Hypochlorite (3%) was used for canal irrigation. Canals were then dried with paper points, and coated with Calcium Hydroxide Sealer (Sealapex) using lentulospirals. Single cone Gutta Percha technique was used for the obturation of root canals. Teeth were then restored with composite resin (3M ESPE) and reduced from occlusion. Patients were kept under observation for 3 hours after the administration of the drug. A pain medication was prescribed and patients were instructed to take it only if they experienced severe pain.

Patients' pain intensity experience was measured using the visual analogue scale (VAS), which consists of a 10-cm line anchored by 2 extremes, "no pain" and

“pain as bad as it could be.” Patients were asked to make a mark on the line that represents their level of perceived pain. They were instructed to complete a pain diary at specific intervals (i.e. at 6, 12 and 24 hours after the commencement of treatment) to determine efficacy in both groups. All subjects were called after 48 hours to return the pain diary and for a clinical evaluation. Patients using pain medication within 48 hours were excluded from the study.

The collected data was analyzed using statistical software SPSS version 23.0. Mean and SDs were calculated for quantitative variables like age pre-op pain and post-op pain at 6, 12 and 24 hours. Frequencies and percentages were calculated for categorical variables like gender and efficacy. Efficacy in both groups was compared through the chi-square test. Efficacy in both groups was stratified with age and gender. Post-stratification chi-square test was applied to see effect modifiers keeping *p* value < 0.05 was considered as statistically significant.

**3. Results**

As per descriptive statistics, in Group A, the mean and SDs for age were 39±13.40. Mean and SDs for pretreatment VAS Pain Score on 6±0.93. The mean and SDs for post-treatment VAS Pain Score was 2±1.00. In Group B, the mean and SDs for age were 43±12.90. The mean and SDs for pretreatment VAS Pain Score was 43±12.90. The mean and SDs for post-treatment VAS Pain Score was 5±0.87. (Table No. 1). In age-wise distribution, in Group A, 40 (50%) patients were in the 18-45 years age group. 40 (50%) patients were in the 46-60 years age group. In Group B, 40 (50%) patients were in the 18-45 years age group. 40 (50%) patients were in the 46-60 years age group. In gender-wise distribution, 60 (75%) were male patients, and 20 (25%) patients were female patients. In Group B, 60 (75%) were male patients, and 20 (25%) patients were female patients. As per efficacy in both groups, in Group A, 44 (55%) showed effective results whereas in Group B, only 20 (25%) patients showed effective results. (Table No. 2). Efficacy in both groups was stratified with age and gender and therefore can be seen in Table No. 3 and 4 respectively.

**5. Discussion**

Many patients fear endodontic pain, which can make it challenging for the treating clinician to manage. Before, during, or even after the tooth is treated, endodontic pain might happen. It is handled appropriately. <sup>(11)</sup>

**Table 1** Descriptive statistics (n=160)

Group a = flurbiprofen

Group B prednisolone efficacy in both groups

Numerical Variables	Group A (n=80)	Group B (n=80)	Overall (n=160)
Age	39±13.40	43±12.90	40±12.25
Pre-Treatment VAS Pain Score	6±0.93	7±0.62	6.5±0.85
Post-Treatment VAS Pain Score	2±1.00	5±0.87	3.5±0.90

**Table-2**

Group A = Flurbiprofen

Group B = Prednisolone

Efficacy	Treatment groups		Total	P Value
	Group A (n=80)	Group B (n=80)		
Yes	44 (55%)	20 (25%)	64 (40%)	0.0001
No	36 (45%)	60 (75%)	96 (60%)	
Total	80 (100%)	80 (100%)	160 (100%)	

**Table 3** Stratification of efficacy about age group (n=160)

Group A = Flurbiprofen

Group B = Prednisolone

Age Group	Efficacy	Group A (n=80)	Group B (n=80)	P Value
18-45 Years	Yes	19	10	0.036
	No	21	30	
46-60 Years	Yes	25	10	0.0007
	No	15	30	

**Table 4** Stratification of efficacy about gender (n=160)

Group A = Flurbiprofen

Group B = Prednisolone

Gender Group	Efficacy	Group A (n=80)	Group B (n=80)	P Value
Male	Yes	32	16	0.002
	No	28	44	
Female	Yes	12	04	0.009
	No	08	16	

There have been reports of pain occurring between 3 and 58% of the time during endodontic therapy. <sup>(12, 13)</sup> Large variations in pain prevalence may be caused by a variety of variables. Age and gender of the patient, mechanical or chemical injuries to the pulpal or periradicular tissues, microbiological factors, instrumentation techniques, percussion sensitivity before root canal therapy, and the type of intracanal materials are some of these. <sup>(14, 15)</sup>

Patient confidence and attitude towards endodontic therapy can be improved by preparing the patient regarding expected postoperative pain and prescribing medications. <sup>(2, 6)</sup> To manage discomfort during root canal therapy, several approaches are used. Use of preoperative steroidal as well as non-steroidal anti-

inflammatory drugs, intracanal medicaments and occlusal reduction are various recommended methods to manage inter-appointment and post-obturation pain. <sup>(2-4)</sup>

Preoperative analgesics can reduce postoperative pain and postendodontic analgesic intake, due to a reduction in central as well as peripheral sensitization. <sup>(5)</sup> Several medications have been successfully used to treat the pain of irreversible pulpitis for very long. NSAIDs, corticosteroids, opiates and acetaminophen are all used for this purpose. <sup>2-(6)</sup> Most of the studies support the use of anti-inflammatory drugs for endodontic pain but some trials are not in favour of these drugs. <sup>(5)</sup>

There is a flexible medication plan which would require premedicating a patient, 30 minutes before starting pulpectomy in response to irreversible pulpitis. Evidence proves that medications prescribed in this regime have a significant relieving role on post-endodontic pain in teeth presenting with irreversible pulpitis. <sup>(16, 17)</sup>

Flurbiprofen, a non-steroidal anti-inflammatory drug is a phenylalkanoic acid derivative. It acts by inhibiting cyclooxygenase I and cyclooxygenase II enzymes, this has a positive impact on lowering prostaglandin concentrations. <sup>7</sup> In a study conducted by Manuela S. et al. in 2021, flurbiprofen was proven to have better post-endodontic pain control than other drugs. <sup>(18)</sup> In another study conducted by Holstein et al in 2003, flurbiprofen among other NSAIDs performed well in post-endodontic pain. <sup>(7)</sup>

Prednisolone, on the other hand, is a synthetic glucocorticoid, a derivative of cortisol. It inhibits the action of phospholipase A2 by stimulating the production of a glycoprotein known as lipocortin and thus prevents the formation of arachidonic acid and subsequently the inflammatory mediators. <sup>(5, 8)</sup> In a study conducted by Jalalzadeh SM et al in 2010, prednisolone when given as a pretreatment drug to overcome post-endodontic pain, gave successful results as compared to other drugs. <sup>(19)</sup> In another study conducted by Maliha Muneer et al. in 2018, Pretreatment prednisolone was more effective for the prevention of Postendodontic pain in comparison to placebo. <sup>(11)</sup>

## 5. Conclusion

Compared to prednisolone, a single pretreatment dose of flurbiprofen had a greater long-lasting effect on reducing post-endodontic discomfort. However, larger descriptive & comparative studies are still needed to assess the efficacy of different drugs on postendodontic pain.

**CONFLICTS OF INTEREST-** None

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**Contributions:**

U.U.H, H.M - Conception of study

H.M - Experimentation/Study Conduction

Z.R, K.S - Analysis/Interpretation/Discussion

Z.R, K.S - Manuscript Writing

H.M - Critical Review

U.U.H, H.M, K.N - Facilitation and Material analysis

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