

## Double-blind randomized placebo-controlled clinical trial of efficacy of preoperative diclofenac sodium in the control of post-endodontic pain

Nimra Iqbal<sup>1</sup>, Ana Gupta<sup>2</sup>, Rohit Kochhar<sup>3\*</sup>, Manju Kumari<sup>4</sup>

<sup>1,2</sup>Postgraduate Student, <sup>3</sup>Professor and HOD, Dept. of Conservative Dentistry and Endodontics, I.T.S Dental College, Greater Noida, Uttar Pradesh, India

**\*Corresponding Author: Rohit Kochhar**

Email: [dr\\_rohitkochhar70@yahoo.com](mailto:dr_rohitkochhar70@yahoo.com)

### Abstract

**Aim:** The aim of the present study was to compare the efficacy of preoperative diclofenac sodium in the control of post-endodontic pain.

**Materials and Method:** Sixty patients were randomly selected and clinical examinations were conducted by three operators. The patients were randomly allocated using simple randomization technique into 2 experimental groups: Group 1, diclofenac sodium (VOVERON SR, 100 mg-oral) and Group 2, placebo (sucrose tablets). Both medications were administered 30 min before conventional root canal therapy. To maintain the double-blind design, a second investigator provided the two agents, and each tablet was disguised so that the patient as well as the operator was not aware of the medication. Patients were instructed to complete a pain diary; 6, 12, and 24 h after root canal instrumentation. The method used to measure clinical pain intensity was the visual analogue scale (VAS), which consisted of a 10 cm line anchored by two extremes, "no pain" and "pain as bad as it could be." Thus, the pain intensity was assigned into four categorical scores: a) None (0); b) Mild (1-3); c) Moderate (4-6); and d) Severe (7-10).

**Results:** Among the 60 volunteers who completed the study, 63.63% had mild pain and 36.37% had severe pain. Post endodontic pain showed a statistically significant difference between group 1 and group 2 at 6hr, 12hr and 24hr ( $p < 0.05$ ).

**Conclusion:** Post endodontic pain was substantially reduced by preoperative administration of a single oral dose of diclofenac sodium as compared to the placebo group.

**Keywords:** Diclofenac sodium, Post endodontic pain, Visual analogue scale.

### Introduction

The severity as well as the incidence of postoperative pain are associated with specific dental treatments, the highest being root canal therapy.<sup>1</sup> The postoperative pain incidence has been reported to range from 3% to 58% after root canal treatment.<sup>2</sup> Pak and White showed that post-obturation pain (POP) prevalence was 40% at 24 hours, and reduced to 11% at 1 week.<sup>3</sup> The severity of pain was substantially decreased within the first 2 days. In another study, 12% of patients experienced severe pain within 24 to 48 hours following treatment.<sup>4</sup>

There is a strong relationship between pulp status and postoperative pain.<sup>5</sup> It is suggested that patients with severe preoperative endodontic pain, vital pulp, symptomatic teeth without periradicular lesions and level of anxiety experience more postoperative pain.<sup>6</sup>

The postoperative pain is due to exacerbation of inflammatory response and release of inflammatory mediators which include prostaglandins that activate sensitive nociceptor in periapical tissues. A variety of drugs have been used to manage postoperative pain such as opioids, non-steroidal anti-inflammatory drugs and combinations of drugs.<sup>7</sup> Amongst these, the most recommended class of pain relievers in dentistry today are the NSAIDs.<sup>8,9</sup> NSAIDs function by inhibiting the cyclooxygenase enzymes and preventing the generation of new prostaglandin molecules; however, they have no effect against existing molecules in circulation.<sup>10</sup>

The incidence of postoperative pain has been reported to be greater in single visit root canal treatment than multiple visits. Therefore, the aim of the present study was to evaluate the efficacy of NSAIDs compared with sucrose

tablets in reducing postoperative endodontic discomfort in patients. Also, the timing of drug administration was assessed to set a protocol for single visit endodontics.

### Materials and Methods

The study was conducted in the department of Conservative Dentistry and Endodontics, and institutional ethical clearance was obtained. Sixty patients were randomly selected and three operators conducted the clinical examinations. The examination included palpation and percussion evaluation, thermal tests (cold), periapical radiograph and mobility assessment.

The inclusion criteria for the study were, patients with a vital tooth and irreversible pulpitis but without periapical abscess; and patients with moderate-severe pain. The exclusion criteria included patients who reported any sensitivity or other adverse reaction to NSAIDs, on anti-inflammatory drugs and analgesics, requirement for prophylactic antibiotics, with hypertension, mental disabilities, pregnancy or lactation, systemic diseases, and patients allergic to diclofenac sodium. Using simple randomization technique, the patients were randomly divided into 2 experimental groups: Group 1, diclofenac sodium (VOVERON SR, 100 mg-oral) and Groups 2, placebo (sucrose tablets).

The medications (for both the groups) were administered 30 min before root canal therapy. The double-blind design was maintained, a second investigator provided the two agents (diclofenac sodium and sucrose tablets), the operator as well as the patient were not aware of the medication as each tablet was disguised. Treatment was completed in single visit in all cases.

With a 2% lidocaine solution having 1:100,000 epinephrine, each patient was anesthetized and the access opening was done. The working length was determined by both 15 size K-file and radiograph, and cleaning and shaping of canals was done using a step-back technique. The canals were enlarged to a 2% (number 25) and 6% (number 25) rotary system. Between each file, irrigation was done with 2.5% sodium hypochlorite and normal saline solution (0.9% of NaCl). The canals were dried using paper points post instrumentation followed by obturation.

After root canal instrumentation, the patients were instructed to maintain a pain diary at 6, 12, and 24 h. The visual Numeric scale was used to measure the pain intensity, having 10 cm line with two extremes, "no pain" and "bad pain". The patients were asked to mark on the line that represented their level of pain. As rescue medicine, another dose of Diclofenac Sodium was prescribed to the patients, if needed. The intensity of pain was divided into four categorical scores: a. None (0); b. Mild (1-3); c. Moderate (4-6); and d. Severe (7-10).

The statistical analysis was performed using Fisher's exact test to study the comparisons. A Chi-square test was applied to analyze the status of pain at each level between groups. The program SPSS Version 16 was used for all calculations. The significance levels were set at 5% ( $p < 0.05$ ).

## Results

Out of the 60 volunteers who completed the study, 63.63% had mild pain and severe pain was reported by 36.37%. Diclofenac sodium treatment was associated with very low levels of endodontic pain. At 24hrs of endodontic treatment, in both the groups, few patients reported with pain. Post-endodontic pain showed a statistically significant difference between group 1 and group 2 at 6hr, 12hr and 24hr ( $p < 0.05$ ).

## Discussion

Postoperative pain is an unpleasant experience after root

canal therapy. Such pain arises as a consequence of periradicular damage and due to inflammatory mediators.<sup>11,12</sup> Based on data suggesting the potential involvement of anti-inflammatory process in the pathophysiology of endodontic pain, non-narcotic analgesics including NSAIDs and/or paracetamol have been used for treatment of post-endodontic pain.<sup>13</sup>

In the present study, the intensity of post-endodontic pain was evaluated by 100-mm visual Numeric scale in correspondence to the studies done by various authors.<sup>14-16</sup> The rescue medication (Diclofenac sodium) which was prescribed to both the groups was not taken by any patient. It was observed that sucrose tablets did not result in significant reduction of pain in comparison with diclofenac sodium at the 6-h, 12-h and 24-h time point (Table 1).

Oral administration of drugs was preferred because of its convenience and effectiveness, since the use of intravenous or intramuscular injection may lead to fear and discomfort in some patients.<sup>17-19</sup> 30 min before the root canal therapy, diclofenac sodium was administered. The primary mechanism responsible for its analgesic, anti-inflammatory, and antipyretic actions is inhibition of cyclooxygenase, which leads to inhibition of prostaglandin synthesis. Moreover, the high potency of diclofenac may be ascribed to the inhibition of lipoxygenase pathways, thereby reducing the formation of leukotrienes. It may also inhibit phospholipase A2. Pre-operative, single, oral dose of NSAIDs can modulate the release of inflammatory mediators and reduce the side effects compared with repeated doses during the postoperative period.<sup>20</sup> Pretreatment analgesia before root canal treatment may decrease the establishment of central sensitization whereby spinal neurons increase their responsiveness to peripheral nociceptive input<sup>16</sup> which could amplify postoperative pain.<sup>21</sup> Pre-operative administration, as well, would be of particular significance with glucocorticoids which may require time for their effects to be mediated.<sup>22</sup>

**Table 1:** Pain intensity in different groups at 6 hrs, 12 hrs and 24 hrs

Time Intervals	Clinical pain intensity	Group 1 (Diclofenac Sodium)		Group 2 (Placebo)		Total	
		No of patients	%Age Within Group	No of patients	%Age Within Group	No of patients	%Age Within Group
At 6hrs	No pain	30	100	8	26.66	38	63.33
	Mild	0	0	14	46.66	14	23.33
	Moderate	0	0	7	23.33	7	11.66
	Severe	0	0	1	3.33	1	1.66
At 12hrs	No pain	19	63.33	3	10.00	22	36.66
	Mild	9	30.00	15	50.00	24	40
	Moderate	2	6.66	11	36.6	13	21.6
	Severe	0	0	1	3.3	1	1.66
At 24hrs	No pain	23	76.66	13	43.33	36	60
	Mild	7	23.33	17	56.66	24	40
	Moderate	0	0	0	0	0	0
	Severe	0	0	0	0	0	0

Metri et al<sup>23</sup> in 2017 by using a visual numeric scale assessed postoperative pain at 6, 12, and 24h after preoperative administration of diclofenac sodium. They suggested that the effectiveness of preoperative administration of diclofenac sodium in the reduction of post-endodontic pain may help patients with a low pain threshold in pain prevention.<sup>23</sup> However, in a few endodontic and oral surgery procedures, the optimal moment for oral administration of NSAIDS was evaluated.<sup>18,24,25</sup> This double-blind randomized trial allowed sufficient comparison between both NSAID and Sucrose tablet groups.

### Conclusion

Postendodontic pain was significantly less in patients with preoperative administration of diclofenac sodium (single oral dose) as compared to the sucrose group. It is possible that in patients with a low pain threshold, these results might help to prevent postendodontic pain. Further studies with multiple variables are required to substantiate the results of the present study to achieve pain free dentistry.

**Conflict of Interest:** None.

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