ORIGINAL ARTICLE

Comparison of Efficacy of Naproxen Versus Ibuprofen in the Management of Post-Operative Endodontic Pain in Teeth with Irreversible Pulpitis

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OBJECTIVE: Efficacious pain control after endodontic treatment is a major concern in clinical dentistry. One of the most debilitating challenges in the endodontic treatment of teeth with irreversibly inflamed pulps are achieving profound anesthesia and successfully alleviating postoperative endodontic pain. This study aimed to compare the effect of Naproxen and Ibuprofen on post-operative endodontic pain in teeth with irreversible pulpitis.

METHODOLOGY: A single-blind randomized control trial was conducted by recruiting 116 patients who presented with irreversible pulpitis and were divided into two groups of 58 each through a simple randomization technique using the lottery method. Post-operative pain for both groups was measured with a Visual analogue scale (VAS). This was a 10 cm scale, with markings at every 1 cm anchored by the end points of "no pain" on the right and "worst pain" on the left. After initial root canal treatment, Group A was given Naproxen 550 mg (Synflex), while Group B was given ibuprofen 400mg (Novafen). Each patient was given instructions to record pain, if they experienced any pain post-treatment, and then take the painkiller given to them and again record the pain after 24 hours. Data was analyzed using SPSS version 25. For descriptive analysis, mean and standard deviation were reported for age, BMI, and VAS score, whereas frequency and percentages were calculated for categorical variables like gender and pain relief.

RESULTS: Naproxen reduced more pain on VAS pain score than ibuprofen in terms of efficacy in teeth with irreversible pulpitis but the results were insignificant (p-value 0.164). There was no significant effect of age, gender, BMI, and educational status on post-operative pain. The baseline characteristics of the patients in the study are given in Table 2.

CONCLUSION: Both drugs (Naproxen & Ibuprofen) can be used to reduce post-operative pain in teeth with irreversible pulpitis

KEYWORDS: Endodontic. Irreversible pulpitis. Efficacy.

HOW TO CITE: Usman Z, Tanvir H, Sultan ZA, Ehsan S, Rehman A, Ismail Z. Comparison of efficacy of naproxen versus ibuprofen in the management of post-operative endodontic pain in teeth with irreversible pulpitis. J Pak Dent Assoc 2024;33(3):73-77.

https://doi.org/10.25301/JPDA.333.73

Received: *12 September 2022*, ***Accepted:*** *07 October 2024*

INTRODUCTION

Patients, who have to go through conventional root canal treatment, mostly have pulpal and periapical infections with or without pain-associated central sensitization (excitability of neurons is increased within the central nervous system) and peripheral sensitization (threshold is decreased with an increase in excitability of the peripheral ends of nociceptors).[1] This increased pain reaction creates difficulty in pain reduction, especially when neurogenic mediators released in case of inflammation have produced morphogenetic modification in neurons, in response to that the nerve ?bers become resistant to the anesthetic.[2] This situation creates difficulty for the clinician in attaining the most favorable analgesia during the procedure.[3] Non-steroidal anti-inflammatory drugs

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(NSAIDs), are commonly used for post-endodontic pain management.[4] They are leading contributors in reducing pain and inflammation. by reducing inflammatory mediators being recognized as causing pain[5] Naproxen is a non-steroidal anti-inflammatory drug (NSAID) of the propionic acid class[6] used for pain fever, swelling, and stiffness preparations.

Ibuprofen blocks COX-1 and COX-2 receptors and has pain-relieving and anti-inflammatory action.[7] Sheikh A et al reported reduction of pain score from 5.84 to 0.92 in the ibuprofen group after 24 hours with a standard deviation of 1.95.[8] Shami et al reported a reduction of pain score from 6.82 to 0.97 in Naproxen after 24 hours with a standard deviation of 1.06.[9],[10] Mehrvarzfar et al.[13] found that when patients take naproxen right after treatment results in a reduction in post-operative pain following pulp removal and root canal treatment of teeth with symptomatic pulpitis. Therefore, this study was planned to compare the efficacy of Naproxen and Ibuprofen in post-operative pain reduction. The results of this study will help in determining better post-operative medication.

A pilot survey was conducted to assess the frequency of efficacy of Naproxen and Ibuprofen in terms of reduction of postoperative pain in our department and the sample size of our study was calculated by the results of this pilot study. This study reported that 57% of patients, who were administered Naproxen, showed a reduction in post-operative pain from moderate-severe to absent-mild. In the case of Ibuprofen, 38% of patients showed a reduction in post-operative pain, with a statistically significant difference from that of naproxen. The results of the pilot study are as follows.

Table 1: Results of pilot study

	Drug		
Pain Reduction	**Naproxen**	**Ibuprofen**	**Total**
Yes	**8**	**5**	**13**
No	**6**	**9**	**15**
Total	**14**	**14**	**28**

METHODOLOGY

The present study was conducted to compare the effect of Naproxen and Ibuprofen on post-endodontic pain in irreversible pulpitis cases. This single-blind Randomized Controlled Trial (Simple Random sampling technique) was carried out in the Outpatient Department of Operative Dentistry at the Fatima Memorial Hospital in Lahore, Pakistan. This trial was registered on ClinicalTrial.gov (ClinicalTrial.gov identifier: NCT04947566). This study protocol was approved by the Institutional Ethical Review Board. The study was completed in six months from September 2nd, 2020 to February 25th, 2021. Informed, consent was taken from the participants before recruiting them to the study. Patients both male and female with symptomatic irreversible pulpitis, One tooth per arch with no opposing tooth involved were included in this study with an age range of 20-40 years. Exclusion criteria were: Patients who had any systemic disease while taking history e.g. diabetes, hypertension, pregnancy, Patients with history of taking analgesics 12 hours prior to treatment, Periapical pathologies (Periapical abscess, Periapical granuloma and Periapical cyst) seen as periapical radiolucency in periapical radiograph, Necrosed pulp that was identified by the absence of bleeding during access cavity preparation. The total sample size of 116 cases (58 in each group) of Irreversible Pulpitis was calculated at a 5% significance level through the 80% power of test - Prevalence (P1) for Naproxen was 61.53% and for Ibuprofen (P2) was found to be 38.46%. The prevalence of 90% is based on a pilot study which was carried out in our Department. The patients were randomly allocated into two groups by using the lottery method ensuring that that distribution is unbiased. The concealed chits, comprising 58 designated for Group A and 58 for Group B, were placed in containers A and B by random number table. Post-operative pain for both groups was measured with a Visual analogue scale (VAS). This was a 10 cm scale, with markings at every 1 cm anchored by the end points of "no pain" on the right and "worst pain" on the left. Pain score was measured for both groups before the initial endodontic procedure. Patients who had moderate to severe pain before the initiation of the root canal were included in this study.

To control Bias procedure was performed by the same person in both groups. In both groups, teeth were anesthetized using 1.8ml of 2% lignocaine containing 1:100,000 epinephrine and isolated with a rubber dam. An access cavity was prepared with a round bur and pulp was removed using hand files. Working length was determined using an electronic apex locator and confirmed with a periapical radiograph. Canals were prepared with crown down technique. Sodium hypo-chlorite was used as an irrigating solution. Canals were then dried with paper points with no intra-canal medicament and the access cavities were restored temporarily with cavit (Cavit 3M ESPE). Group A was given naproxen (Synflex 550 mg), while group B was given Ibuprofen (Novafen 400mg). Along with Performa and painkiller, they were sent back with the instructions to record pain immediately after initial treatment and take the painkiller given to them and then again record the pain after 24 hours post-operatively with a standard Visual Analogue Score (VAS) scored on a 10 cm scale, with markings at every 1 cm anchored by the end points of "no pain" on the right and "worst pain" on the

left. Pain was divided as mild (1-3), moderate (4-6), and severe (7-10). Patients were asked to record the number most precisely describing the amount of pain he or she experienced. Performas were taken from the patient when they reported back for their next appointment. All this data was recorded in a specially designed Performa (attached). Efficacy was labeled as per operational definitions. Data was analyzed using SPSS version 25. For descriptive analysis, mean and standard deviation were reported for age, BMI, and VAS score, whereas frequency and percentages were calculated for categorical variables like gender and educational status. A chi-square was used to determine the significance of the difference between the efficacy of naproxen and ibuprofen. Data was stratified for age, gender, BMI, and educational status. A p-value of 0.05 or less was taken as significant. Post-stratification chi-square was applied with p-value $\leq$0.05 considered as significant.

RESULTS

116 patients were taken in this single-blinded randomized control trial with irreversible pulpitis and they were between ages of 20 years and 40 years, and were divided into two groups of 58 each. Group A included 38 female patients and 20 males. While Group B included 35 females and 23 male patients

21.6% of participants were in the age range of 20-26, and 42.2% were in the age range of 27-32. 36.2% were in the age range of 33-40 years. The mean age of the patients was 31 years with S.D 5.017. The baseline characteristics of patients in this study are mentioned in Table 2. Table 3 shows the efficacy of both drugs. Efficacy was calculated by a reduction in pain score after analgesic intake after the endodontic procedure from severe - moderate pain to mild pain- absent i-e VAS < 3 after 24 hours of the procedure. According to our study, 70.7% efficacy for group

Table 2: Demographic details of the participants included in the study

Characteristic	n (%)
Age	Mean: 31.10 +5.02
20-26	25 (21.6)
27-32	49 (42.2)
33-40	42 (36.2)
Gender	
Males	43 (37.1)
Females	73 (62.9)
Educational Status	
Illiterate	13 (11.2)
Primary	1 (0.9)
Middle	21 (18.1)
Matric and above	81 (69.8)
BMI	
18-25 (normal range)	87 (75)
25-30 (over weight)	29 (25)

Table 3: Comparison of efficacy of two drugs

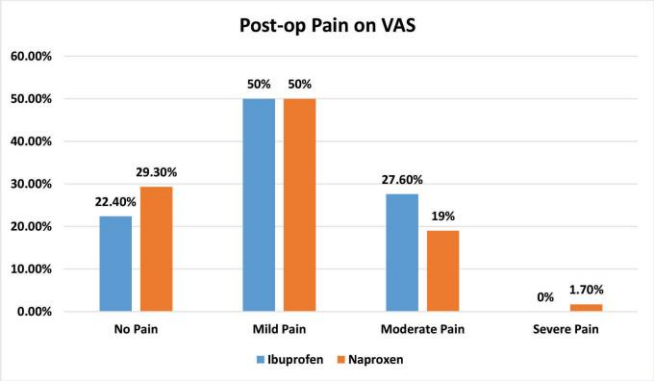
			Drug		Total	P-Value
			Naproxen	Ibuprofen		
Efficacy	Efficacious= <3	Count	41	35	76	0.329
		% within Drug	70.7%	60.3%	65.5%	
	Not effective > 3	Count	17	23	40	
		% within Drug	29.3%	39.7%	34.5%	
Total		Count	58	58	116	
		% within Drug	100.0%	100.0%	100.0%	

A (Naproxen) was noted and 60.3% efficacy was noted for group B (Ibuprofen). In group A (naproxen), the drug was not effective in 29.3% of patients and in group B (Ibuprofen) the drug was not effective in 39.7% of patients. The p-value for the efficacy of Naproxen and Ibuprofen was 0.329 which

Table 4: Effect of age on efficacy of both drugs

Age	Drug			Efficacy		Total	P-Value
				Efficacious= <3	Not effective > 3		
20-26	Drug	Naproxen	Count	10	4	14	0.434
			% within Drug	71.4%	28.6%	100.0%	
		Ibuprofen	Count	6	5	11	
			% within Drug	54.5%	45.5%	100.0%	
	Total		Count	16	9	25	
			% within Drug	64.0%	36.0%	100.0%	0.244
27-32	Drug	Naproxen	Count	17	7	24	
			% within Drug	70.8%	29.2%	100.0%	
		Ibuprofen	Count	13	12	25	
			% within Drug	52.0%	48.0%	100.0%	
	Total		Count	30	19	49	
			% within Drug	61.2%	38.8%	100.0%	
33-40	Drug	Naproxen	Count	14	6	20	1
			% within Drug	70.0%	30.0%	100.0%	
		Ibuprofen	Count	16	6	22	
			% within Drug	72.7%	27.3%	100.0%	
	Total		Count	30	12	42	
			% within Drug	71.4%	28.6%	100.0%	

Figure: Comparison of post-op pain in both the groups after 24 hours



was insignificant. Figure 1 shows the graphic presentation of the efficacy of both groups after 24 hours. Table 4 shows the effect of age on the efficacy of both drugs. There is no significant effect of age on the efficacy of both drugs (P value >0.05).

Table 5 shows the effect of gender on the efficacy of both drugs. Naproxen was effective in 76.3% of females and ibuprofen was effective in 60% of females. Naproxen was effective in 60% of males and Ibuprofen was effective in 60.9% of males. No significant difference was found in the efficacy of drugs when compared in the genders (P value >0.05).

Table 5: Effect of gender on efficacy of both drugs

Gender				Efficacy		Total	P-Value
				Efficacious =<3	Not effective > 3		
Female	Drug	Naproxen	Count	29	9	38	
			% within Drug	76.3%	23.7%	100.0%	0.207
		Ibuprofen	Count	21	14	35	
			% within Drug	60.0%	40.0%	100.0%	
	Total		Count	50	23	73	
			% within Drug	68.5%	31.5%	100.0%	
Male	Drug	Naproxen	Count	12	8	20	1
			% within Drug	60.0%	40.0%	100.0%	
		Ibuprofen	Count	14	9	23	
			% within Drug	60.9%	39.1%	100.0%	
	Total		Count	26	17	43	
			% within Drug	60.5%	39.5%	100.0%	

DISCUSSION

This study aimed to determine a better analgesic drug, in terms of efficacy after root canal treatment. The results of the present study showed that Naproxen and ibuprofen had no significant difference in terms of efficacy in teeth with irreversible pulpitis (p-value 0.329). Polat et al. (2005) evaluated the post-operative pain response using ibuprofen and naproxen sodium.[11] The results revealed that one hour before archwire placement of patients taking 550 mg naproxen sodium resulted in significantly lower levels of pain at two hours, six hours, and nighttime as compared to those patients taking a placebo or ibuprofen. The results of this study were contrary due to various factors first, it was carried out to check the effects of Naproxen and Ibuprofen preoperatively. Secondly, it checks the effects on orthodontic pain. Thirdly, this study included patients in the age range of 10-25 years while the present study tried to keep the age factor constant by keeping patients between 20-40 years. M Raoof et al.[12] studied the effect of naproxen on post-operative pain in teeth with irreversible pulpitis. In accordance with this study administration of naproxen after treatment reduced postoperative pain following root canal therapy. This study was different than the present as it was comparing Naproxen with a placebo and was carried out on 68 patients while ours was carried out on 116 patients and was comparing Naproxen with Ibuprofen. In this study, RCT was done in a single visit while in ours it was done in two visits. This study used normal saline as an irrigant and our study used sodium hypochlorite as an irrigant. Mehrvarzfar et al.[13] found that taking naproxen right after treatment can result in a reduction in pain following pulpectomy and root canal preparation of teeth with irreversible pulpitis. This study compared the effects of single doses of three oral medications (Naproxen, Novafen, and Tramadol) on postoperative pain following the instrumentation of root canals in teeth with irreversible pulpitis. This study concluded that There was no significant difference between Naproxen and Novafen (P > 0.05), but Tramadol was less effective than the other two drugs (P < 0.05). The results of our study are in agreement with the study conducted by Mehrvarzfar et al.[13] but in our study, we compared two drugs instead of three.

Age, gender of patients, instrumentation techniques, mechanical or chemical injury to pulpal or peri-radicular tissues, microbiological factors, and the type of intra-canal medicaments are other important factors that can result in post-operative pain.[7] To control the effect of these variables in the present study the age group of the sample was limited from 20 to 40 years of age. Following this study, there was no significant effect of age on efficacy. To control the effect of gender on this study, males and females in both groups

were approximately equal and the results showed that the effect of gender on efficacy is not significant. In the present study, Sodium hypochlorite was used as an irrigant. In previous studies, intra-canal medicament was placed in all the canals whereas, to control other variables i.e. microbiological factors, after instrumentation, root canals were left empty. In previous studies, root canal was done in a single visit while in our present study, it was done in two visits. Conducting similar studies would be beneficial on teeth with irreversible pulpitis. Insignificant differences in efficacy of Naproxen and Ibuprofen in post-operative endodontic pain, according to our logistic regression analysis, would provide dentists and patients with alternative analgesic choices if future studies confirm such findings

CONCLUSION

This study concluded that Naproxen reduced more pain on VAS pain score than ibuprofen in terms of efficacy in teeth with irreversible pulpitis but the results were insignificant (p-value 0.329).

CONFLICT OF INTEREST

Authors hereby declare no conflict of interest in this study

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