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Effectiveness of Various Medications on Post Operative Pain of Vital Teeth after Root Canal Therapy

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Abstract

***Background*:** Postoperative pain following root canal therapy is of concern for endodontic patients and dentists. Despite the fact that the pain relief afforded by endodontic is effective, it is rarely immediate and complete. The purpose of this double blind study was to compare the efficacy of betamethasone, indomethacin, ibuprofen, used commonly to control post endodontic pain or a placebo.

***Materials and Methods*:** This randomized, double blind, placebo controlled study included 100 patients with symptomatic, vital and one canal tooth. Patients were randomly allocated into one of the four groups to receive treatment three times a day with ibuprofen (400 mg), betamethasone (2 mg), indomethacin (75 mg) or placebo following completion of root canal treatment. The patients recorded pain intensity on a special chart (visual analogue scale) at time intervals of 6, 12, 24, and 48 hours after treatment. ANOVA and *t*-test was used to determine statistical significance. *p*-value<0.05 was considered statistically significant.

Results: In the placebo group, the mean pain score was significantly higher than in all the groups in different time after treatment. In the ibuprofen group, patients experienced significantly more pain than in the indomethacin and betamethasone groups, in 6 and 12 hours after treatment but the difference was not significant in 24 and 48 hours. The mean pain score was not significant difference between indomethacin and betamethasone group.

***Conclusion*:** The results demonstrate that the betamethasone and indomethacin may be more effective than ibuprofen for the management of postoperative pain after nonsurgical endodontic treatment when patients present with moderate to severe pain.

Introduction

Undoubtedly, nowadays the root canal treatment is performed more easily and with less pain, but a significant percentage of patients suffer from post-treatment pain, while the purpose of root canal therapy is to relieve the pain or prevent it. Using the correct techniques of anesthesia, the pain during treatment is highly relieved. However, the root canal post-treatment pain still remains as a problem [1]. Even while endodontic treatment is performed with an acceptable standard, a mild post-treatment pain is not a rare phenomenon and occurs in 30-10% of cases [2, 3]. Patient tolerates such pain or relieves it using common analgesics. On the other hand, the previous studies show that the incidence of moderate to severe pains following treatment is an unusual event which 6-12% of the patients experience it [3, 4]. In general, mechanical, chemical or biological damages to periapical tissues during endodontic treatment are of factors causing moderate to severe pains. It has been suggested that certain factors such as age, gender, and race, type of tooth, the pulp condition, pre-treatment pain and history of allergy have a significant effect in emergence of such pains [5, 6]. Furthermore, it has been revealed that the psychological factors such as fear of dental treatment and anxiety influence on the pain perception as well as patient response threshold [7]. The result of previous studies shows that there is a relationship between the existence of endodontic pre-treatment anxiety and post-treatment pain. Physiopathologically, an acute inflammation is developed in the periapical tissues and this phenomenon is responsible for the pain after endodontic treatment [9]. Various drugs including narcotic analgesics, NSAIDS, acetaminophen and steroids have been used to relieve post- endodontic pains. However, a clear, definite and explicit horizon has not been proposed to solve the problems of patients and clinicians. The aim of the present study is to compare the effect of betamethasone, indomethacin, and ibuprofen to reduce post- endodontic pain. This is a double-blind study. These drugs were selected because betamethasone and indomethacin have the most inflammatory effect each in their own families. Ibuprofen is also the prototype and gold standard of NSAID drugs. On the other hand, there is no comprehensive study on the effect of first two drugs on post-endodontic pains.

Materials and Methods

This is a double-blind placebo-controlled randomized

interventional clinical trial. All of 100 patients were selected among the patients referred to endodontic department of Zahedan Dentistry School based on the following criteria to investigate the effect of ibuprofen, indomethacin and betamethasone on post-endodontic pains. The inclusion criteria: the tooth was single canal and vital pulp based on clinical evidences and vital tests. There was no apparent periapical lesion according to radiograph images. Patients had moderate to severe pain. Patients with the following conditions were excluded exclusion criteria: patients less than 18 years old, those who had used analgesics within 4 hours ago [10], those who mentioned following diseases in their medical history: gastrointestinal diseases (peptic ulcer, ulcerative colitis, gastro esophageal reflux), liver and kidney dysfunction, mellitus diabetes, asthma, infectious diseases (systemic fungal infection, tuberculosis, herpes simplex), mental illness (acute psychosis and depression, etc.), hypertension, hemorrhagic disorders, osteoporosis and any disorder and history which bans administration of NSAID and steroids [1, 10], pregnant women or nursing mothers, recent use of opioids, MAOI, tricyclic antidepressants, carbamazepine, diuretics, anti-coagulant, history of opioid addiction.

Drugs were purchased from Parmis Teb Azma as powder. Starch was used as placebo. These medications were coded and packed into four groups A, B, C and D by pharmacologists as same opaque pink capsules. Each capsule contains either betamethasone (2 mg), ibuprofen (400 mg), indomethacin (75 mg) or a placebo (Starch-Merck), respectively. It was decided to drug groups' codes will be opened after the completion of the study by pharmacologist. Before starting the treatment, the required comments about the ongoing study were presented for patients. After giving the necessary information to patients, the written consent was obtained and recorded in their documents. The treatment was performed in one session by one person. After anesthesia (lidocaine 2% with epinephrine 1/80,000) and access cavity preparation, the tooth was isolated with rubber dam, the working length was determined and confirmed by radiography. Canals were cleaned and shaped using step-back method, the apical region was prepared to size 35 and canal was irrigated with normal saline. Canals were filled using gutta percha (GAPADENT-Germany) and AH26 sealer (Dentsply-Germany) using lateral condensation technique. Periapical radiograph was taken at the end and the accuracy of endodontic therapy was approved. After completion of treatment, each patient was provided with one package containing 6 coded capsules and instruction. The patients were requested to use one capsule immediately after the treatment and continue to use up to 48 hours based on instruction (along with each coded drug package, a rescue medication package was provided containing 8 tablets of acetaminophen codeine (300/10 mg) [10] and instruction. The patients were strongly recommended to use of rescue medicine provided the lack of pain control using coded drugs and instant contact with the project manager. The patients were recalled that they do not have any limitation whatsoever about the project manager contact). In order to measure the intensity of post-treatment pain, some forms were given to patients to report their eventual pain during 6, 12, 24, and 48 h after treatment as follows: no pain (0), mild pain (1-3): (the pain that is recognizable, but not uncomfortable and does not need analgesics), moderate pain (4-6): (the pain that is distressing, but tolerable and will relieve with analgesics) and severe pain (7-9): (the pain that is uncomfortable, and it was difficult to endure, and it does not alleviate with analgesics). The patients were requested to return the information forms after 48 h. The forms were statistically analyzed using ANOVA and t-test using SPSS-15. Eventually, drug codes were deciphered: A was (placebo), B (betamethasone), C (ibuprofen) and D was (indomethacin), respectively.

Results

All of 100 patients who were treated, 10 patients were excluded due to use of rescue medication. Eight patients did not return pain assessment questionnaire. Table 1 summarizes demographic data of 82 patients who participated in this study including pre-treatment pain and distribution of treated teeth. During the first 6 hours after treatment, only 10 patients used rescue medication; 5 patients in the placebo group, 3 patients in the ibuprofen group, one patient in indomethacin group and one patient in betamethasone group, respectively. Patients used rescue medication after coordination. They were advised to refer as soon as possible.

Dependent *t*-test was used to examine pre-treatment pain intensity variations in each group with time intervals of 6, 12, 24 and 48 hours after treatment. Analysis of variance (ANOVA) was used to compare pre-treatment and post-treatment pain intensity between different groups. $p<0.05$ was considered statistically significant. Statistical analyzes were performed using SPSS-15. Table 2 represents the average pain intensities for all groups. All groups showed a significant reduction in pain level within the first 6 hours after treatment compared to pre-treatment pain intensity ($p<0.05$). A significant difference was observed between placebo group and other groups in all intervals. The difference between ibuprofen and indomethacin and betamethasone was significant only for 12 hours. The highest and lowest pain reduction was observed in the betamethasone and placebo groups, respectively. During the first 6 hours, 90.4% of patients in betamethasone group and 86.3% of patients in indomethacin group had no pain/mild pain. While none of the patients in the placebo group and 63.1% of patients in ibuprofen group had no pain or mild pain (Table 3). Based on the ANOVA results, during the first 6 hours, the difference between the mean pain intensity in the placebo group and other groups was significant ($p=0.001$). Also, there is a significant difference between ibuprofen and betamethasone groups ($p=0.001$) and ibuprofen and indomethacin groups ($p=0.001$). However, the difference between betamethasone and indomethacin groups was not significant. Thus, patients in indomethacin and

betamethasone groups experienced significantly less pain. Within 12 hours after treatment, while only 5% of patients in the placebo group had no pain/mild pain, 100% of patients in ibuprofen, indomethacin and betamethasone groups showed this level of pain. Most analgesia related to betamethasone group 85.7%, indomethacin 76.5% and ibuprofen 36.8%, respectively. Within 12 hours after treatment, similar to the first 6 hours, the differences between the mean pain intensity in the placebo group and betamethasone, ibuprofen, indomethacin groups (p=0.001), ibuprofen and betamethasone groups (p=0.001) and ibuprofen and indomethacin groups (p=0.001) were significant. The mean pain intensity in the betamethasone group was less than indomethacin, but this difference was not significant. Thus, the second day after treatment, patients in the ibuprofen group showed a level of analgesia similar to betamethasone and indomethacin groups (94.7% versus 100%), while in the placebo group during the first 24 hours after treatment, 55% of patients still experienced a moderate pain. But, after 12 hours of treatment, there was no patient with moderate pain experience in the other groups (Table 5).

After 48 hours of treatment, over half of the patients in the placebo group still had mild pain and 19% experienced moderate pain (Table 4). Within 24 and 48 hours after treatment, the difference between the mean pain intensity in the placebo group and other groups was still significant (p=0.001). However, no significant difference was observed between other groups. According to t-test, the comparison of pre and post-treatment pain intensities in each group showed that within the first 6 hours after treatment, the pain intensity begins to decrease which continues its declining trend to 48 hours. The pain reduction was statistically significant in all groups (p<0.05). Of 82 patients, 23 subjects reported side effects. The side effects were mild and there was no need to modify the treatment plan. Patients in the placebo group reported the highest rate of CNS (35%) and GI (20%) side effects. Headache and nausea were the most commonly reported gastrointestinal and nervous side effects. The reported side effects in the treatment groups were significantly less than the placebo group (Table 5).

Table 1. Demographic and clinical characteristics of the study population

	Placebo (A)	Betamethasone (B)	Ibuprofen (C)	Indomethacin (D)
Number of Patients	20	21	19	22
Gender				
Female	14	17	13	15
Male	6	4	6	7
Average age (Yr)	29	24.47	31.33	27.93
Tooth				
Anterior	7	12	9	19
Premolar	13	9	10	12
Pre-treatment Pain (Mean±SD)	7.6±1.2	7±1.6	6.4±1.9	6.7±1.6

Table 2. Mean of pain intensity value (VAS)* for each groups at each time point

Group		Before	After 6 h	After 12 h	After 24 h	After 48 h
Placebo	Mean±SD(N)	7.6±1.23(20)	6.3±1.26(20)	5.2±1.32(20)	3.6±1.63(20)	1.9±1.66(20)
Betamethasone	Mean±SD(N)	7±1.64(21)	1.1±1.19(21)	0.09±0.3(21)	0.0±0.0(21)	0.0±0.0(21)
Ibuprofen	Mean±SD(N)	6.4±1.92(19)	3.3±1.94(19)	1.3±1.21(19)	0.1±0.45(19)	0.0±0.0(19)
Indomethacin	Mean±SD(N)	6.7±1.60(22)	1.31±1.39(22)	0.2±0.45(22)	0.0±0.0(2)	0.0±0.0(22)
Total	Mean±SD(N)	6.9±1.63(82)	2.9±2.55(82)	1.6±2.25(82)	0.9±1.74(82)	0.4±1.16(82)

* The pain intensity is considered a number between 0 and 9 based on VAS

Table 3. Frequency distribution of pain before and during first 6 and 12 h after treatment

Group	Pre-treatment Pain Intensity				Pain Intensity after 6 h				Pain Intensity after 12 h			
	No pain N(%)	Mild N(%)	Moderate N (%)	Severe N (%)	No pain N (%)	Mild N (%)	Moderate N (%)	Severe N (%)	No pain N (%)	Mild N (%)	Moderate N (%)	Severe N (%)
Placebo	0 (0)	0 (0)	7 (35)	13 (65)	0 (0)	0 (0)	12 (6)	8 (40)	0 (0)	1 (5)	15 (75)	4 (20)
Betamethasone	0 (0)	0 (0)	13 (61.9)	8 (38.1)	77 (33.3)	12 (57.1)	2 (9.5)	0 (0)	18 (85.7)	3 (14.3)	0 (0)	0 (0)
Ibuprofen	0 (0)	0 (0)	10 (52.6)	9 (47.9)	2 (10.5)	10 (52.6)	7 (36.8)	0 (0)	7 (36.8)	12 (63.2)	0 (0)	0 (0)
Indomethacin	0 (0)	0 (0)	9 (40.9)	13 (59)	7 (31.8)	12 (54.5)	3 (13.6)	0 (0)	16 (76.5)	6 (23.5)	0 (0)	0 (0)

Table 4. Frequency distribution of pain 24 and 48 hours after treatment

Group	Pain Intensity after 24 h				Pain Intensity after 48 h			
	No pain N(%)	Mild N(%)	Moderate N(%)	Severe N(%)	No pain N(%)	Mild N(%)	Moderate N(%)	Severe N(%)
Placebo	0 (0)	9 (45)	11 (55)	0 (0)	4 (19)	12 (62)	4 (19)	0 (0)
Betamethasone	21 (100)	0 (0)	0 (0)	0 (0)	21 (100)	0 (0)	0 (0)	0 (0)
Ibuprofen	18 (94.7)	1 (5.3)	0 (0)	0 (0)	19 (100)	0 (0)	0 (0)	0 (0)
Indomethacin	22 (100)	0 (0)	0 (0)	0 (0)	22 (100)	0 (0)	0 (0)	0 (0)

Table 5. The percentage of subjects in each groups who reported side effects

Group	Number	GI (nausea)*	CNS**	Other***
Placebo	20	20 (4)	35 (7)	0(0)
Betamethasone	21	9 (2)	4 (1)	0(0)
Ibuprofen	19	5 (1)	10 (2)	5 (1)
Indomethacin	22	13 (3)	9 (2)	0(0)

Numbers in parentheses indicate number of patients. GI*= nausea, CNS**= headache, Other***= sweating

Discussion

It is quite obvious that some patients may experience different levels of pain and discomfort following endodontic treatment and thereby have become challenging. Such pains are often attributed to inflammation of the periodontal ligament which themselves attributable to some factors including cleaning and shaping of canals, bleeding, materials and debris being pushed into the periapical area and secondary occlusal trauma. Depending on the severity of damage to the periapical tissues, and depending on the nature and cause of damage, the post-endodontic pains may take a few hours to several days [9]. Thus, the proper, scientific and principal management is considered to be an important issue. Hyllested et al. review a considerable number of dental and medical literatures in order to provide a solution to overcome serious pain in different areas. They studied the effects of NSAID drugs and their combination and other drugs in controlling post-treatment pains [11].

Accordingly, they found that in large operations, gynecology and orthopedics, the use of NSAID medications and acetaminophen to control post-treatment pains cause no significant difference. According to the Hyllested et al., no endodontic studies were included, but they concluded that it seems that NSAID medicines are effective in dental treatments. Endodontic literature is full of studies which compared the performance of one, two or more different drugs with different mechanisms with placebo in reducing the pain [8]. The aim of the present study is to compare the performance of three drugs with placebo in reduction of post- endodontic pains. The results show that the oral administration of betamethasone (6 mg/d) is far more effective than other drugs in reducing post- endodontic pains. This indicates that the sufficient quantities of drug enter into the periapical area tissues systematically by oral administration of betamethasone. However, it doesn’t seem that the performance of betamethasone in this area is a special effect, but it is similar to other effects on other body areas and systems. In terms of mechanism, in addition to suppressing vascular dilation that occurs in inflammation, steroids prevent the phospholipid membrane release and consequently inhibit the cyclooxygenase enzyme, which is essential for synthesis of prostaglandins [1].

In this context, what makes the corticosteroids in general and betamethasone in particular superior in suppressing inflammation and thereby reducing post-treatment pains is that these products prevent formation of such pain-causing factors such as lipoprotein peroxides which are far stronger compared with prostaglandins in the production of hyperalgesia; the task that NSAID anti-inflammatory drugs are not able to do. Thus, the effect of steroids to reduce inflammation and post-treatment pains is a complex, deep and thorough effect [1, 12]. This is also shown in this study so that the resulting relief of betamethasone was higher in all time periods compared with other drugs.

The statistical analysis of the data suggests that during the first 6 hours after treatment, the pain level of patients was significantly reduced in all groups. The mean reduction in pain intensity between the placebo and other treatment groups, similarly between ibuprofen and betamethasone groups and between ibuprofen and indomethacin was significant. However, there is no significant difference between betamethasone and indomethacin groups. This declining trend continues until the end of follow-up period. The results showed that betamethasone and indomethacin are more effective in pain control. It's at least consistent with theoretical principles that these two drugs have very prominent anti-inflammatory effects. The differences between the drugs are likely due to differences in the pharmacological activity of drugs [13]. The statistical analysis shows that indomethacin (75 mg) is more effective in reducing post-endodontic pains compared with ibuprofen (400 mg). On the other hand, betamethasone (2 mg) is superior to both. The results of Marshal and Walton also show that intramuscular injection of dexamethasone (4 mg) is effective in reducing post-treatment pains of re-treatment cases [1]. In this regard, the results of the present study are consistent with Marshal and Walton in terms of the effect of steroids in reducing post- endodontic pains.

Another controversial issue is the method of drug administration. Undoubtedly the most ideal method of prescription is intravenous injection. This is why the drug effect emerges instantaneously and provides a more predictable response. On the other hand, despite the fact that the oral administration of the medications is easier and economical, it should be noted that there is the possibility of unusual responses in this administration method due to variation of drug pharmacokinetics by numerous factors. Furthermore, in this method, the drug effects emerge with a delay. It should not be expected that the response of different patients to oral administration of the drug be the same and predictable. Hence, it is recommended that when the patient's clinical condition requires that a steroid product is administrated, the clinician use an injectable product. First, for exact drug matching and secondly to maintain the blindness nature of the study. In our study, betamethasone was administrated orally and placebo, ibuprofen and indomethacin were administered with same intervals. Administration of a single dose of an anti-inflammatory drug is unable to work more than 24 hours and then re-formation trend and the inflammation process continues to evolve. Therefore, for consistent and continuous efficiency and anti-inflammatory effects of a drug as well as predictable subside of inflammation and pain, any medication prescribed for this disease should be continued at least 3 days and up to 5 days for maximum benefit and minimum side effects [13].

Steroids are not the exception. Steroids should be administrated in sufficient quantities to be effective in the treatment of edema and pain. In critical situations, about 300 mg of cortisol is secreted by the adrenal cortex and thereby the body partly deals with inflammation.

In cases where external steroids suppress inflammation, depending on the severity and duration of inflammation, the dose of administrated steroid should be equal or higher that amount released by the body [13]. In this study, the daily dose of betamethasone was 6 mg which is equivalent to 250 mg of cortisol.

Side effects attributable to corticosteroids are related to supra-physiological doses and long-term treatment (high dose & long term). In the short-term treatments, the high administrated doses of steroids virtually have no harmful side effects and therefore are considered safe. This is an important and accepted principle in steroid therapy. Previous studies have shown that the administration of a single dose of 2 mg/kg dexamethasone will not lead to any side effects [14].

In the present study, the dose of betamethasone is far less than the above amount. Therefore, in cases where the pain does not subside by conventional NSAID drugs, in order to alleviate and overcome the critical situation of the patient, the patient should not be deprived of the benefits of these drugs due to fearing the side effects of steroids. While such studies are done, attaching a placebo group is essential and represents an important clinical relationship. The cause of reduction of pain intensity in the placebo group is likely due to the nature of treatment. Oguntebi et al. and Hasselgren and Reit found that the decisive dental cure without medication relieves pain to some degree [15, 16].

The results of the present study also indicate that at all time intervals after treatment, the pain decreased in the placebo group compared with pre-treatment period and the pain reduction has been gradually declining. Therefore, in addition to drug therapy, it is emphasized on decisive treatment to reduce and control post- endodontic pains. However, it is possible that dramatically pain reduction in the placebo group may be due to the placebo effect. To control the variables that may influence the placebo effect, all prescribed medications were used as same pink opaque capsules. Previous studies show that different patients have different interpretations and commentaries of the medicine appearance. Buckalew and coffield conducted a study on this issue and concluded that the patients consider that the effect of larger capsules is stronger. Patients consider yellow capsule as antidepressants and white capsules as narcotics or analgesics [17]. Of 82 patients, 23 patients reported side effects attributable to the drug. The side effects were so mild that did not need to change the treatment plan neither required treatment to stop. Also, it is difficult to attribute them to the administrated drugs. Unlocking the drug codes at the end of the study showed that the most side effects were reported in the placebo group and the lowest side effects belong to treatment groups. It is shown that the effects attributable to NSAID drugs and corticosteroids are related to long-term treatments rather than short-period periods. The side effects reported by patients in our study are slightly lower than Menhinick's study. According to Menhinick, the group receiving placebo (starch) had the highest rates of side effects. The incidence of side effects in the groups receiving the active drug was significantly lowers [10]. Another important point in this study was the number of patients in terms of gender. Of 82 patients, 59 people were female and 23 patients were male. The number of females was higher compared with males in all treatment groups including the placebo group. Averbuch and Katzper evaluated the effect on ibuprofen on dental pains. The number of women participating in their study was higher than men. However, no gender effect was observed in response to the ibuprofen analgesic. This means that there is no difference in response to placebo and treatment drug in terms of gender or at least has not been approved. Unrah, Dao and Leresche [20] also conducted a study in this regard. Their findings showed that women report more severe levels of pain compared with men. Consequently, women refer to medical centers for treatment more rapidly [19, 20]. The literature review shows the higher number of women than men. This issue can be seen from patients routinely refer to the endodontic wards. Since the gender has a modifier effect in the sense of pain, conducting studies with consideration of this issue is recommended. In terms of health outcomes and applications, according to the nature of dental pains, especially endodontic pains, NSAID medications undoubtedly are useful in controlling post-operative pains. This issue has been proved by Penniston and Hargreaves, Rogers et al. [21, 22]. However, betamethasone as the most powerful product of corticosteroids group and indomethacin as the most prominent anti-inflammatory drug of NSAID drug family has not been studied or at least have been studied a little.

Betamethasone is a steroid product with powerful anti-inflammatory effects. Ibuprofen and indomethacin belong to propionic acid and indole families, respectively. Ibuprofen and indomethacin belong to the large family of NSAIDs. According to obtained results, it is recommended that ibuprofen would be used in post endodontic pains where the pain intensity is mild to moderate. But, in cases where the pain is so intense that ibuprofen does not alleviate the pain, provided that there is no restriction or prohibition, it is proposed to use either indomethacin or betamethasone. Adverse effects attributable to NSAID drugs and corticosteroids occur with high doses in long-term treatments. Therefore, in suppression of acute and short-term post endodontic pains, the patients should not be deprived of the benefits of these drugs due to fear of harmful side effects. It should be noted that no drug is absolutely safe. A drug that is useful for a patient may cause a problem in another patient. The clinician makes decision to prescribe or not to prescribe drug considering the patient's clinical condition and the amount of benefit or loss received by patients. Since there is still no bright horizon in the cases with the severe, persistent and intractable pain, further research is needed in this regard.

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Authors' Contributions

All authors had equal role in design, work, statistical analysis and manuscript writing.

Conflict of Interest

The authors declare no conflict of interest.

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