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Original Article

Evaluation of pretreatment with gelofen and novafen on pain relief after endodontic treatment; A double-blind randomized clinical trial study

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Abstract

Introduction: Feeling pain after root canal therapy has always been a major problem for patients and dentists. One of the suggested methods to manage the pain is using the prophylactic medication before treatment process. This study aimed at investigating the comparison of pretreatment with novafen versus gelofen on reducing the pain after root canal therapy.

Materials &Methods: This double-blind randomized clinical trial study was conducted on 60 patients aged 18-65 who were indicated for root canal therapy. Patients were randomly assigned to receive gelofen capsules (400mg), novafen capsules (200mg) and placebo two capsules by every patient of these groups one hour prior to sampling. Pre/post-treatment pain was measured using Visual Analog Scale (VAS) before treatment and 4, 8, 12, 24 and 48 hours after treatment.

Results: Both novafen and gelofen indicated significant analgesic effect during the study period ($p<0.001$). Pain severity within 8 hours after treatment was significantly lower in novafen group than two other groups ($p=0.03$). The difference between the severity of pain did not show any association to their place of life and gender in any groups.

Conclusion: Our findings revealed that the prophylactic novafen in comparison to gelofen had a better analgesic effect in short-term and could be a good candidate for the management of post-endodontic treatment pain.

Keywords: Pain, Root canal therapy, Tooth root, Dentists, Patients

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ارزیابی پیش درمانی با ژلوفن و نوافن بر تسکین درد پس از درمان اندودونتیک؛ یک مطالعه کارآزمایی بالینی دو سو کور

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چکیده

مقدمه: احساس درد پس از درمان ریشه دندان همواره از مشکلات عمده بیماران و دندانپزشکان محسوب می گردد. یکی از راهکارهای پیشنهاد شده جهت پیشگیری از درد ، پیش درمانی قبل از مداخله دنداپزشکی است. مطالعه حاضر با هدف مقایسه پیش درمانی با نوافن در مقایسه با ژلوفن در کنترل درد پس از درمان ریشه دندان است.

مواد و روش ها: مطالعه حاضر به روش کارآزمایی بالینی تصادفی شده دو سو کور بر روی ۶۰ بیمار با بازه سنی ۶۵-۱۶ سال که اندیکاسیون درمان ریشه دندان را داشتند صورت پذیرفت. بیماران بصورت تصادفی به سه گروه تقسیم شدند. گروه ژلوفن (کپسول ۴۰۰ میلی گرم)، گروه نوافن(کپسول ۲۰۰ میلی گرم) و گروه پلاسبو که هر بیمار یک ساعت قبل از مداخله درمانی دو عدد کپسول را دریافت می نمود. میزان در قبل و ۴،۸، ۱۲، ۲۴و ۴۸ ساعت پس از درمان با استفاده از مقیاس VAS توسط هر بیمار ثبت گردید.

یافته ها: ژلوفن و نووافن اثرات ضد دردی معنی داری در طول دوره مطالعه داشتند ($p<0.001$) همچنین در گروه نوافن شدت درد ۸ ساعت پس از درمان نسبت به سایر گروه ها اختلاف معنی دار داشته است($p=0.03$) از طرفی شدت درد درمیان دو جنس و محل سکونت بیماران اختلاف معنی دار نداشته است.

نتیجه گیری: بر اساس نتایج بدست آمده پیش درمانی با نووافن اثرات ضد دردی بیشتری در کوتاه مدت در مقایسه با ژلوفن دارد و می تواند به عنوان یک انتخاب در کاهش دردهای پس از اعمال اندودونتیک مطرح گردد.

واژگان کلیدی: درد، درمان ریشه،ریشه دندان، دندانپزشکان، بیماران

Introduction

Pain and anxiety that sometimes happen during dental treatment need to be considered properly. [1] Endodontic procedures are usually performed without any pain during the treatment, but there is a possibility of experiencing pain after treatment. In a clinical study, 7 %, 15 % and 21 % of patients had severe, moderate and weak pain, respectively after root canal therapy. [2]Complaining about pain or flare-up after treatment was reported in those with feeling pain before beginning the procedure. Therefore, people who usually suffer from pain after treatment are the same individuals that are complaining about pain before treatment. For the tooth pain and particularly the pain after endodontic root canal is the use of analgesics including: Non-Steroidal Anti Inflammatory Drugs (NSAIDs) and acetaminophen are the most frequent administered drugs.[2] According to the immunological and histological studies, cyclooxygenase-2 enzyme exists in human dental pulp and inflamed pulp contains cells that contain cyclooxygenase-2, while very few of these cells are found in normal pulp. NSAIDs are the kind of drugs that act as controller of inflammatory pain by binding to plasma proteins. [3,4] On the other hand, these drugs could have undesirable side effects such as one of the gastrointestinal discomforts due to their restraining property on cyclooxygenase enzyme. The expression of mucin proteins which protect the intestinal mucosal cell growth was suppressed by non-selective NSAIDs and this expression was restored by PGE2. [5] Gelofen is a derivation of propionic acid and a member of anti-inflammatory non-steroidal drugs (NSAIDs) classification. Gelofen is used in curing weak to moderate pain, inflammation after surgery, dental pain and migraine. Gelofen has less gastrointestinal impacts than other NSAIDs; however, it can causes abdominal pain, nausea, vomiting, gastrointestinal bleeding and ulcers of the small intestine, Novafen is a compound drug containing 325

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mg acetaminophen, 200 mg ibuprofen and 40 mg of caffeine. [6] Acetaminophen affects the central and peripheral nerve system. Ibuprofen has also an anti-inflammatory effect. Caffeine is also a narcotic analgesic. [7] Several studies have been performed and evaluated on the impacts of analgesics on pain after endodontic therapy. In most of the studies, prescribing drugs were suggested after starting endodontic treatment [8]; but still the best pre-treatment choice for pain management is a matter of controversy. Thus, we aimed to compare the effect of pretreatment with gelofen versus novafen in the management of the post endodontic pain relief.

Methods

This double-blind randomized placebo clinical trial study was performed on 60 patients who referred to the endodontic department in Babol University of Medical Sciences in the first semester of 2013-2014. The protocol was approved by research review board, Babol University of Medical Sciences, Babol, Iran and registered in Iranian Clinical Trials Registry (IRCT id: IRCT 2014041316973N2). All the patients were indicated for root canal therapy. The inclusion criteria of the study were having age range of 18 to 65 years old, no use of any other analgesic during treatment process or 12 hours before starting medication, having the ability of reading, understanding and filling the questionnaire, having teeth with alive pulps and no periapical lesion. The exclusion criteria of the study were as follows: having systemic diseases (Lupus, Diabetes mellitus etc), renal, nervous, heart or liver diseases, cancer or severe abnormalities, allergy to NSAIDs, pregnancy or lactation, alcohol consumption, uncontrolled hypertension, current smokers.

After explaining the objectives of the study and obtaining the written informed consent, the process was started by endodontic students. Groups, each containing 20 subjects, were randomly assigned to receive gelofen capsule (400 mg; by Zakaria Tabriz Pharmaceutica), novafen capsule (200 mg; by Darou Pakhsh Tehran Holding Co.) and placebo (containing flour and starch), all of them were packaged in identical 500 mg capsules with the same color and size and then encoded by a third person unaware of the study protocol. Each participant received a package containing 2 capsules and consumed them 60 minutes before sampling. They were obligated not to take any pain relief or other medication, but in the case of acute pain, they were allowed to take acetaminophen codeine that should be reported in their next visit. Explanation about the pain after 24 and 48 hours were also recorded in their document that including: spontaneous pain, acute pain, or no pain. According to double-blind study design, both the patient and the dentist were not aware of the type of random a location. They underwent the root canal therapy including cavity preparation, cleaning and preparing all the canals until the canals were ready to be filled. All the teeth tried to be cleaned at once and canal obturation was performed at the same time. The canals were antisepticised by normal saline (physiological saline solution) and then the teeth were dressed by Cavite. Lidocaine (2%) and epinephrine 1/800000 were used for local anesthesia. AH26 was used as sealer. Cleaning the canals was performed by step-back method and canals were filled using lateral technique.

Visual Analog Scale (VAS) criteria were used to evaluate and determine the pain severity before beginning the treatment and also the pain relief after treatment. A pain assessment form was given to each patient. Then, they were informed about the method of explaining their pain intensity by using digits 0 to 10 (0 for no pain and 10 for the highest severity of pain) by considering the time. Reckoned times after performing treatment in the application were 4, 8, 12, 24, and 48 hour, respectively. At the end of process, the data were analyzed by SPSS 18 software and VAS pain scores were compared using one-way ANOVA and post hoc Tukey test. P less than 0.05 was considered as statistical significance.

Results

In a total of 60 patients, 24 (40%) were men and 36(60%) were women. Forty one (68.3%) and 19 (31.7%) participants were living in urban and rural areas, respectively. Mean and standard deviation of the age of the participants in the Novafen, Gelofen, and placebo groups were 36.5±12.72, 31.3±9.95 and 41.35±13.14 years old, respectively. No significant difference was found in distribution of genders between groups (p=0.15). As indicated in table 1, the mean severity of pain was reported based on VAS concerning the time of taking the drug in three groups.

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The pain severity after 8 hours was significantly lower in novafen group compared to other groups (gelofen and placebo) (p=0.03). Mean intensity of the pain in groups taking gelofen and novafen compared to placebo over 12 hours and 48 h was lower after treatment but there was no significant difference among three groups which indicated that there was no long term analgesic effect than the placebo. According to repeated measures analysis, pain decreased in all three groups after treatment (p<0.001). The trend of reducing the pain intensity within 48 hours among studied groups was displayed in figure1.

In addition, the difference between the severity of pain did not show any association to their place of life and gender in any groups.

Table1. Mean severity of pain in studied groups based on VAS

Group	Before treatment	4 hours after treatment	8 hours after treatment	12 hours after treatment	24 hours after treatment	48 hours after treatment
Novafen	5.55±1.14	2.7±1.3	1.75±1.25	2.55±1.35	1.75±1.74	1±1.02
Gelofen	5.95±1.31	3.25±1.51	2.45±0.88	2.8±1.43	1.65±1.08	0.7±0.73
placebo	5.15±1.03	2.35±1.755	2.5±0.68	3.4±1.6	1.8±1.67	1±1.33
p-value	0.1	0.16	0.03	0.18	0.95	0.59

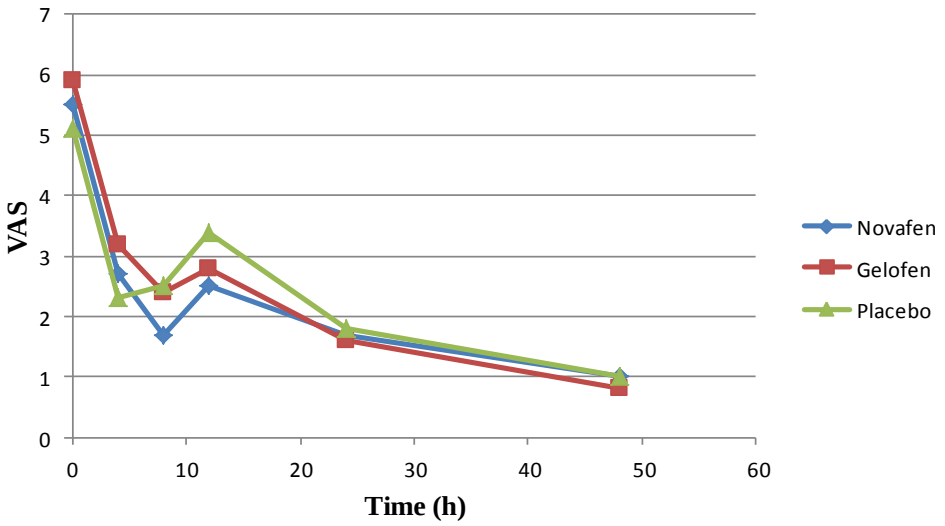


Figure1. Mean of VAS changes by time in three study groups

Discussion

The present study indicated that comparing the placebo, gelofen and novafen showed a significant effect on reducing the pain after root canal therapy. Previous studies investigated the pain killer consumption before the root canal therapy and documented significant results which were consistent with our findings. [9-11] According to our findings, 8 hours after root canal therapy, the analgesic effect in novafen group was significantly higher than two other groups, but novafen effect was almost the same after 12, 24 and 48 hours long-term follow up. Arsalan et al. revealed that 6-hour period, both 20 mg of tenoxicam and 200 mg of ibuprofen provided significantly better pain relief than the placebo. [12] In a similar study prophylactic ibuprofen administration significantly reduced postendodontic pain at 4 and 8 h after initiation of root canal therapy in compare with etodolac and a placebo. [13] Also, Wells et al. compared the use of ibuprofen versus ibuprofen/acetaminophen for postoperative endodontic pain in a randomized double-blind study and found that there were decreases in pain levels and analgesic use over time for both groups.[14] Most studies suggested that the pain intensity reached to the highest level after 24 to 48

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hours. [12, 15] Therefore, we mostly focused on the determination of pain intensity after 48 hours. In the current study, the pain intensity decreased in all groups, which was statistically significant and showed that root canal therapy was independently efficient for decreasing the pain. Novafen is a compound drug that its prophylactic property can decrease the pain after root canal therapy and in comparing with gelofen has a significant effect on reducing the short-time postoperative pain.

Although among the studied populations there was no significant side effect mentioned by the subjects, long term use of these drugs may arise some levels of common side effects such as: nausea and dizziness, headache, gastrointestinal discomfort and etc. However, previous studies did not report any significant difference between groups in their short term period. [16,17] We encountered several limitations in this study in regard to the small sample size and duration of the study period. Future RCT studies with larger sample size are suggested to reach more valid results.

Conclusion

Considering the findings of the present study, pretreatment with novafen in comparison to gelofen reduced the severity of pain, and novafen could be suggested for short-term pretreatment for post endodontic procedures.

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Conflict of interest: Authors declared no conflict of interest.

References

1.Dionne RA. Suppression of dental pain by the preoperative administration of flurbiprofen. Am J Med 1986; 80:41-9.

2.Ehsani M, Moghadamnia AA, Zahedpasha S, Maliji G, Haghanifar S, Mir SM, et al. The role of prophylactic ibuprofen and N-acetylcysteine on the level of cytokines in periapical exudates and the post-treatment pain. Daru 2012;20:30.

3.Peres MF, Ribeiro FV, Ruiz KG, Nociti-Jr FH, Sallum EA, Casati MZ. Steroidal and non-steroidal cyclooxygenase-2 inhibitor anti-inflammatory drugs as pre-emptive medication in patients undergoing periodontal surgery. Braz Dent J 2012;23:621-8.

4.Nakanishi T, Shimizu H, Hosokawa Y, Matsuo T. An immunohistological study on cyclooxygenase-2 in human dental pulp. J Endod 2001;27:385-8.

5.Tanaka K, Suemasu S, Ishihara T, Tasaka Y, Arai Y, Mizushima T. Inhibition of both COX-1 and COX-2 and resulting decrease in the level of prostaglandins E2 is responsible for non-steroidal anti-inflammatory drug (NSAID)-dependent exacerbation of colitis. Eur J Pharmacol 2009;603:120-32.

6.Sweetman SC. Martindale: The Complete Drug Reference. 37th ed. Londan: Pharmaceutical Press; 2011.p.299.

7.Mehrvarzfar P, Abbott PV, Saghiri MA, Delvarani A, Asgar K, Lotfi M, et al. Effects of three oral analgesics on postoperative pain following root canal preparation: a controlled clinical trial. Int Endod J 2012;45:76-82.

8.Jackson DL, Moore PA, Hargreaves KM. Preoperative nonsteroidal anti-inflammatory medication for the prevention of postoperative dental pain. J Am Dent Assoc 1989;119:641-7.

9.Madani ZS, Moghadamnia AA, Panahi A, Poorsattar Bejeh Mir A. Analgesic effect of etoricoxib compared to ibuprofen on post endodontic pain. Oral Health Dent Manag 2013;12:186-90.

10.Malmstrom K, Kotey P, Coughlin H, Desjardins PJ. A randomized, double-blind, parallel-group study comparing the analgesic effect of etoricoxib to placebo, naproxen sodium, and acetaminophen with codeine using the dental impaction pain model. Clin J Pain 2004;20:147-55.

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[DOR: 20.1001.1.22519890.2015.4.1.5.2]

[DOI: 10.22088/cjdr.4.1.37]

11.Bailey E, Worthington HV, van Wijk A, Yates JM, Coulthard P, Afzal Z. Ibuprofen and/or paracetamol (acetaminophen) for pain relief after surgical removal of lower wisdom teeth. Cochrane Database Syst Rev 2013;12:CD004624.

12.Arslan H, Topcuoglu HS, Aladag H. Effectiveness of tenoxicam and ibuprofen for pain prevention following endodontic therapy in comparison to placebo: a randomized double-blind clinical trial. J Oral Sci 2011;53:157-61.

13.Menke ER, Jackson CR, Bagby MD, Tracy TS. The effectiveness of prophylactic etodolac on postendodontic pain. J Endod 2000;26:712-5.

14.Wells LK, Drum M, Nusstein J, Reader A, Beck M. Efficacy of Ibuprofen and ibuprofen/ acetaminophen on postoperative pain in symptomatic patients with a pulpal diagnosis of necrosis. J Endod 2011;37:1608-12.

15.Jalalzadeh SM, Mamavi A, Shahriari S, Santos FA, Pochapski MT. Effect of pretreatment prednisolone on postendodontic pain: a double-blind parallel-randomized clinical trial. J Endod 2010 ;36:978-81.

16.Gilron I, Tu D, Dumerton-Shore D, Duggan S, Rooney R, McGrath M, et al. The effect of triple vs. double nonopioid therapy on postoperative pain and functional outcome after abdominal hysterectomy: A randomised double-blind control trial. Eur J Anaesthesiol 2014; [Epub ahead of print]

17.Mesgarani A, Mirzaeerad S, Moghadamnia AA, Mahyar M, Poorsattar Bejeh Mir A, Ehsani M. Nalgesic effects of gabapentin and ibuprofen on the pain in post therapy of root canal; a randomized double-blind clinical trial. Caspian J Dent Res 2014;3:8-13.

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