

# Research Paper: Comparison of Prophylactic and Post Operation Effects of Zingiber Officinale and Ibuprofen on Periodontal Flap Surgery Pain



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## ABSTRACT

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**Introduction:** According to investigators' findings, pain after periodontal flap surgery is a common occurrence so that its control is very important in the treatment procedure. Although Ibuprofen is the most common drug for the pain control in dentistry, this drug has its own side effects. The purpose of this investigation is to compare the prophylactic and post operation effect of ginger; Zingiber Officinale (Zintoma) and Ibuprofen on the pain after surgical treatment of periodontal flap

**Materials and Methods:** The samples of this study were collected from 46 patients attending the dental clinic in Guilan University of Medical Sciences, Rasht, Iran. Patients were classified into three groups. The first group received placebo, the second group received Ibuprofen and the third group received Zintoma. The amount of pain were recorded by two main measurement criteria of VAS and VRS at different times and then the data were analyzed using SPSS21. P value was considered <0.05.

**Results:** 12 hours after surgery, most patients in Ibuprofen group (n=39) and Zintoma group (n=36), reported no pain while, most patients in placebo group (n=25), reported less pain. Statistical analysis shows that the Zintoma group had significantly more effect on pain.

**Conclusion:** It seems that Zintoma has almost the same impact of Ibuprofen in reducing the pain. While it has less side effects, it is better to use it as an analgesic drug in controlling the pain after periodontal flap surgery.

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## Introduction

The pain after periodontal flap surgery is a common occurrence which varies considerably between individuals (1). Pain severity is influenced by multiple factors including the nature, duration, and the extent of surgery and also such psychological factors as stress. It usually experienced within 3 days after surgery and should gradually decrease throughout the healing phase (1, 2). It has been recognized that preventing the pain before it starts or before nociceptive data are transmitted is more reliable and efficient than trying to reduce when it has already started (2).

Drugs for acute pain management are divided into two main groups including steroidal and non-steroidal anti-inflammatory agents (3). These are more effective than narcotics due to their critical role in blocking the source of pain which is inflammation (4). Pain and discomfort followed by periodontal surgery are commonly relieved by Ibuprofen that is an efficient non-steroidal anti-inflammatory agent which acts by inhibiting the production of cyclooxygenase enzyme and preventing the biosynthesis of prostaglandins (1). However, it has its own negative side effects which can be nominated as gastrointestinal upset, hemorrhage, skin eruptions, itching, confusion, headache and the like (5).

Ginger and its component is one of the most common agents in east traditional medicine which are used as an anti-inflammatory, antimicrobial, anti-oxidant drug to treat such disorders as arthritis since many years ago (6). Due to research studies, it can also lessen skin edema resulting from its antagonistic effect and also it reduces pain that may be because of substance P release (6).

To our knowledge, there isn't any research study focused on analgesic effect of ginger in periodontal flap surgery. Hence, the purpose of this study, with regard to the proved anti-inflammatory activity of this drug and also the considerable merit of the drug to relieve pain on different sites of the body except oral cavity (7), and also due to having fewer side effects than NSAID drugs, we decided to conduct a study to compare the prophylactic effect of

Zingiber Officinale and ibuprofen on pain after periodontal flap surgery in dental clinic, Guilan.

## Materials and Method

The population in this double-blind clinical trial, randomized and placebo-controlled study consisted of 46 adult patients admitted to a private clinic of dental faculty in Rasht from June 2014 to August 2014, with moderate to advanced chronic periodontitis who were candidate for periodontal flap surgery.

The sample size for comparing the efficiency of the 3 groups of the study on the pain after surgery, with reliability of 95% and test power of 90% and considering the clinical differences (n=46 per group, total= 138 samples).

After approving the study at oral and maxillofacial evolutionary medicine research center at Dentistry University in Rasht, and also after approving in medical ethics committee at Medical University in Guilan, a total of 46 adult patients referred to a private clinic with moderate to advanced chronic periodontitis which were candidate for periodontal flap surgery participated in this study. All patients have been selected for the same type of treatment and the same disease progression.

### *Inclusion criteria:*

Patients were selected in the age range between 18 and 65 years (age range was similar for both males and females), they had no allergy to non-steroidal anti-inflammatory drug or ginger, and they were not in pregnancy or lactation period and they were able to read, understand and complete the patient information form and VAS, respectively, and they had no medical history of diseases such as: mitral valve prolapse - cardiac, joint or artificial valve rheumatic - cardiac infarction - cerebral apoplexy- high blood pressure that is not treated- hyperparathyroidism- hepatitis- epilepsy- bleeding disorders - ulcers - liver or kidney problems.

### *Exclusion criteria:*

Patients who are not cooperative, those

who takes analgesics, and who took any other medications were excluded from the study.

In this study, patients were categorized into three main groups. One group was given placebo (a capsule containing starch), another group was given Ibuprofen (400mg) and the last group was given Zintoma capsules (250mg) containing ginger extracts. Three under-testing drugs put into prepared hard gelatin capsules of 250 mg and in the same packets, each of which was marked with a special code. Those patients who did not response to the prescribed medications, were asked to take a packed drug with rescue dose (acetaminophen 325 mg) in order to lessen the post-operative pain. Subjects were randomized into one of the 6-fold permutations of ABC (ABC, ACB, BCA, BAC, CAB, and CBA) so the sequence of treatment was observed for them. However, the time interval between surgeries was a good time to wash out but to avoid creating inspiration effects (positive inspiration due to using high effect drug and negative inspiration due to using low effect drug), samples were assigned to receive medication randomly. Therapist and the patient were unaware of used drug. Medications and Dosage encoded by in charge person was delivered with the following description:

#### ***Placebo:***

Two placebo capsules were given one hour before surgery and subsequent doses were given 2 capsules every six hours for three days (capsules containing starch was used as a placebo).

#### ***Ibuprofen:***

Two capsules containing tablet of Ibuprofen 200 mg was given one hour before surgery and subsequent doses were given every 6 hours for 3 days.

#### ***Ginger:***

Two capsules of Zintoma 250 mg, which is contained an extract of the ginger (Figure 1), was given one hour before surgery and subsequent doses were given two capsules every 6 hours for 3 days.

Since stress and anxiety varies from patient to patient, and it may affect the perception of pain, therefore, to eliminate the effect of this variable, all the samples were included in each group. For each quadrant a periodontal flap was provided under local anesthetic of two percent Lidocaine with epinephrine of one hundred thousand. With the application of Gracey curette and use of ultrasonic tools, debridement was performed completely. At least a 4-week interval between surgery sessions (which were done at different sites in the same patients) was adjusted for sufficient healing. Pain severity was measured immediately after fourth hours, eighth hours, twelfth hours, twenty-fourth hours and forty-eight hours after surgery. Two methods of measuring pain intensity, VAS and VRS were used in this study. Visual analogue scale includes a ten-centimeter line that one end represents no pain and the other end represents very severe pain. In verbal rating scale, the patients were asked to choose one of the five cases of no pain / low pain / moderate pain / severe pain / unbearable pain. The rationale behind using two methods of measurement in this study is that since pain is a subjective variable, and it depends on the patient's sayings and may be the patient is unable to properly express her/his pain through visual analogue scale, therefore, we could raise the reliability of the study by applying verbal rating scale.

Due to ethical considerations of study, all participants were given acetaminophen adjunct of 325 mg and they were instructed to take the medication as needed. They were asked to take note the usage of the drug including hours of use and number of drugs in their program.

#### ***Data Analysis:***

After data collection, data were entered into the SPSS 21 software. The test of Repeated Measure ANOVA was used in order to compare the amount of pain score based on VAS criteria. Bonferroni test was used at measurement times based on VAS, to compare pain scores between the two groups of the study. FREEDMAN test was used at measurement times based on VRS,

to compare pain scores. ANOVA was used with post-hoc test of Tokay HSD to compare the amount of adjunctive medications. The significant level of the tests was considered at  $P < 0.05$  and tests were considered bilateral.

### Ethical Considerations:

The nature of the study was explained to each patient and a form of consent was obtained from patients. It was also noted that the study is not mandatory and there is no limitation to exit the program. All information about patients was also written and their names remained confidential and individual results were being presented anonymously.

### Results

In this study, 46 patients were examined from the effects of Zintoma, Ibuprofen and even placebo drugs on pain. Admitted samples (47.8 %) of were male ( $n=22$ ) and 52.2% of admitted samples were female ( $n=24$ ). The mean age of the patients was  $40.5 \pm 6.7$  years that the minimum age is 28 years and maximum age was 58 years. As figure 1 shows, the amount of pain in Zintoma ( $P=0.001$ ) and Ibuprofen ( $P=0.048$ ) groups was statistically significantly lower than the placebo group at all times. Moreover, the reported pain in both groups of Zintoma and Ibuprofen has been decreasing over time after surgery. Placebo group reported the maximum amount of pain 4 hours after surgery.

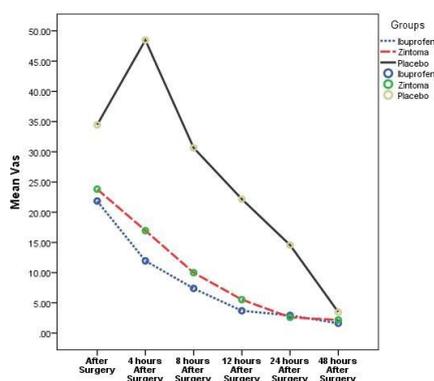


Figure 1: Comparison of mean VAS score at 3 separate times of measurement in three groups of the study.

The results indicates that at the time of measurement immediately after surgery, most patients in the ibuprofen group ( $n=25$ ) and Zintoma group ( $n=29$ ), reported less pain. While the majority of patients in the placebo group ( $n=33$ ) reported moderate pain. At the time of measurement, 4 hours after surgery, most patients in the ibuprofen group ( $n=26$ ) reported no pain. While most patients in Zintoma group ( $n=24$ ) reported less pain and the majority of patients in the placebo group ( $n=34$ ) reported moderate pain. At the time of measurement, 8 hours after surgery, most patients in Ibuprofen group ( $n=35$ ) and Zintoma group ( $n=29$ ), reported no pain while, most patients in placebo group ( $n=21$ ), reported moderate pain. At the time of measurement, 12 hours after surgery, most patients in Ibuprofen group ( $n=39$ ) and Zintoma group ( $n=36$ ), reported no pain while, most patients in placebo group ( $n=25$ ), reported less pain. At the time of measurement, 24 hours after surgery, most patients in Ibuprofen group ( $n=24$ ) and Zintoma group ( $n=42$ ), reported no pain and while, most patients in placebo group ( $n=22$ ), reported less pain. At the time of measurement, 48 hours after surgery, most patients in Ibuprofen group ( $n=43$ ) and Zintoma group ( $n=40$ ), reported no pain.

The G.E.E method of generalized linear model was used in order to control the effects of pills in different times of measurement with VAS score. The effect of ibuprofen on the pain control was statistically significant in comparison to placebo samples under the control of age, sex, and also the amount of adjuvant drugs at the time of study ( $p < 0.0001$ ) so that these groups had less VAS score of  $10.3 \pm 1.7$  than placebo group. Also, the Zintoma group had significantly more effect on pain than placebo group with the control of age, sex and adjuvant drugs so that this group had less VAS score of  $9.3 \pm 0.15$  than placebo group.

### Discussion

The main findings of this study indicate that the Zintoma has a proper functioning in controlling pain after periodontal surgery and is almost the same as the performance of ibuprofen. The ways to reduce pain and its controlling mechanisms

are one of the interesting discussions of dental researchers especially in the field of periodontics. One way to cause the pain after surgery, is the production of enzyme Cox-1 and Cox-2 (8-10). These enzymes induced the production of prostaglandins, caused allergies. Therefore, the prostaglandin synthesis inhibitor drugs used to reduce the amount of prostaglandins, and decrease pain. In relation to this issue, various drugs have been used to reduce the pain associated with the treatment of periodontal surgery. Researchers are looking for medication with fewer side effects and better efficacy in pain reduction mechanism. In this regard, the use of ibuprofen causes gastrointestinal toxicity and long-term use leads to drug addiction in contrast, ginger due to various compounds and antioxidant effect it has fewer side effects. In this regard, in the present study, the effect of ginger, ibuprofen and placebo were compared after surgical treatment of periodontal flap. The major findings of this study indicate that ginger and ibuprofen are much more successful in reducing the pain compared to placebo, but the pain reduction effects of ginger and Ibuprofen are nearly identical. The findings of present study based on VAS criterion showed that, the amount of pain in Zintoma group was statistically lower than the placebo group at all times of pain measurement especially for 48 hours after surgery. In agreement with the results of this study, Rayati et al 2017 (11) who evaluated the anti-inflammatory effect of ginger powder and ibuprofen in post-surgical pain of the third molar found the same effect. The findings of this study were in accordance with the results of the studies by Rahnama in 2012 (8), Terry in 2011 (12), Haghghi 2005 (13) Wigler in 2003 [14] and Bidall in 2000 (6). Also, the amount of pain in Ibuprofen group, based on VAS criteria, was statistically lower than the placebo group at all times of pain measurement especially for 48 hours after surgery. This effect of Ibuprofen as a NSAID drug shows the efficiency of this drug for controlling low to moderate pain. Also, the results of this study are in accordance with the reports of other researchers like Ramezani in 2013 (8), Yaghooti in 2011 (15),

Haghghi in 2005 (13) and Bliddal in 2000 (6).

In comparing two groups of Ibuprofen and Zintoma, based on reported pain according to VAS criteria, both Ibuprofen and Zintoma groups had significant differences at the time of measurement immediately after surgery and at the time of 4 hours after surgery and 8 hours after surgery. At these times of measurement, the effect of Ibuprofen was better than Zintoma, but at other times of measurement (12, 24 and 48 hours after surgery) these differences were not significant. These results were not in accordance with other studies and this difference may depend on the type of study, site of operation, dose of drug usage and the time of using drugs. The study conducted by Ramezani et al in 2013 (9) investigated the prophylactic effect of ibuprofen and Zintoma on post-endodontic pain of 72 patients with irreversible pulpitis which showed that Ibuprofen has significant effect on pain control than Zintoma. The reason of difference between the results of these two studies may be related to dose and the time of used drugs, or may be due to the nature and mechanism of pain among patients of these two studies (Endodontic and Periodontic) and even it may be related to the type of research including the way of response by patient. The results of studies by Ozgoli, 2007 (16) and Haghghi, 2005 (13) demonstrated that there was no difference between the effects of Ibuprofen and Zintoma, which this difference may be due to the different mechanism and pain severity in these studies. Based on the use of adjuvant drug (acetaminophen) for pain reduction, there was not any difference between two groups of received Zintoma and Ibuprofen, but both groups used fewer drugs than placebo group. These findings demonstrated that the groups that received Zintoma and Ibuprofen had less pain compare to placebo group. Also, based on these findings we can conclude that both groups suffered the same pain level. The findings of present study, based on VRS criteria, showed that the highest number of reported pain in the ibuprofen group (70.3%) was no pain. The highest number of reported pain in the Zintoma group (62.7%) was no pain

and the highest number of reported pain in the placebo group (36.2%) was moderate pain. It indicates that Ibuprofen and Zintoma have the same effects in pain control and both of them have better efficiency than placebo. What can be mentioned as the limitation of the present study is the lack of patient's cooperation, and it is recommended to assess zintoma's analgesic effect on different types of periodontal surgery (mucoperiosteal, regenerative, resective) in order to reach the optimum results of the medication.

## Conclusion

The results of the present study showed that the effect of Zintoma and Ibuprofen was better than placebo. Also, the effect of Ibuprofen was better than Zintoma at the times of immediately after surgery, 4 hours and 8 hours after surgery and these two drugs had the same effects at other times of study (12, 24 and 48 hours).

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