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Acetaminophen Versus Liquefied Ibuprofen for Control of Pain During Separation in Orthodontic Patients: A Randomized Triple Blinded Clinical Trial

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Received: 28 Jan. 2014; Accepted: 07 Feb. 2015

Abstract- The aim of this randomized clinical study was to investigate the effectiveness of acetaminophen 650 mg or liquefied ibuprofen 400 mg in pain control of orthodontic patients during separation with an elastic separator. A total of 101 patients with specific inclusion criteria were divided randomly into three groups (acetaminophen, liquefied ibuprofen, and placebo). They were instructed to take their drugs one hour before separator placement and every six hours afterward (five doses in total). They recorded their discomfort on visual analog scales immediately after separator placement, 2 hours later, 6 hours later, at bedtime, and 24 hours after separator placement. Repeated measure analysis of variance (ANOVA) was used to compare the mean pain scores between the three groups. Data were collected from 89 patients. The pain increased with time in all groups. Pain scores were statistically lower in the analgesic groups compared with the placebo group (P .value<0.001), but no statistically significant difference was found in mean pain scores between the two drug groups (acetaminophen and liquefied ibuprofen) (P .value=1). Acetaminophen and liquefied ibuprofen have similar potential in pain reduction during separation.

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Acta Med Iran, 2016;54(7):418-421.

Keywords: Acetaminophen; Liquefied ibuprofen; Pain control; Separation; Orthodontics

Introduction

Orthodontic tooth movement (OTM) is a mechanotransduction event involving a release of various biochemical mediators causing the feeling pain (1). Pain and discomfort are major drawbacks of orthodontic procedures. Data suggests that roughly 90-95% of orthodontic patients report pain during different steps of treatment (2). For most patients, the peak of the pain occurs 24 hours after force application and lasts for one week (2). In some patients, pain is the most important reason for avoiding orthodontic treatment or discontinuing it (3).

Pain and methods of controlling it are widely studied in the orthodontic literature. Researchers have examined various types of drugs including aspirin, acetaminophen, ibuprofen, flurbiprofen, and naproxen (4). In particular, acetaminophen and ibuprofen have been assessed and compared with each other in recent studies (5-7).

In one study, when comparing acetaminophen 650 mg and ibuprofen 400 mg, both taken one hour before

separator placement, no difference was observed between these two drugs in terms of pain reduction (7), while in another study ibuprofen 400 mg turned out to be more effective than acetaminophen 1000 mg, both taken 1 hour before and again 6 hours after separator placement (8).

In both of these studies, the pain was reduced but not eliminated. There is no standard protocol for pain control in orthodontic patients. The aim of this randomized clinical study was to investigate the effectiveness of multiple doses of acetaminophen 650 mg or liquefied ibuprofen 400 mg in pain control of orthodontic patients during separation with elastic separator and to investigate whether or not increased doses of analgesics can eliminate the pain in orthodontic patients in the separation phase.

Materials and Methods

The study was a randomized triple blinded clinical trial. A total of 101 patients who required separator placement recruited in this study, after explaining the

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steps of the study and obtaining informed consent and ethical committee approval. Participants were orthodontic patients of Dental faculty of Tehran university of medical sciences in 2010.

Participants' inclusion and exclusion criteria

Inclusion criteria: All patients started orthodontic treatment that required separators, had no systemic or gastrointestinal diseases, had not taken analgesics or any other drugs currently, had no contraindication to the use of either acetaminophen or liquefied ibuprofen, their weight was above 40 kg, and their first molar were without decay or filling or periodontal problem. The last criterion was checked through clinical observation, probing, and panoramic radiographs.

Exclusion criteria: Each subject received over the counter doses of acetaminophen (650 mg), liquefied ibuprofen (400 mg), or placebo to take orally one hour before separator placement and every 6 hours until 24 hours (5 doses).

To determine the sample size, we did a pilot study and according to the results of a pilot study with one-way ANOVA (Minitab software), considering $\alpha=0.05$ and $\beta=0.2$, a minimum of 29 patients per group was required for valid statistical analysis. To divide the patients into three groups, block randomization method was used. Each block contained three coded pockets (acetaminophen, liquefied ibuprofen, and placebo) and consisted of one sex (male or female). The random allocation and coding of drugs was performed by an operator outside the study and was concealed in an envelope. So, the patients were divided into three equal groups. In each group, the male to female ratio was equal, and the patient and the operator were blind of the kind of drug.

To ensure that the patients were blind to the experimental group, the analgesics and placebo were placed in identical capsules. Orthodontic separators (3M Unitek) were placed in the mesial and distal contact of first molars in all quadrants.

Each patient's level of pain was assessed by five questionnaires, each consisting of one visual analog scale (VAS). The VAS is an established method for assessing pain responses by experimental subjects (7). This scale is a line of 100 mm length, where one end reads "no pain", and the other end reads "most severe pain"; the patient is asked to mark the line at a point proportionate to the severity of pain that he feels.

The patients were asked to mark the degree of pain with their teeth together during chewing or biting. Data were collected immediately after separator placement, 2 hours after placement, 6 hours after placement, at

bedtime and 24 hours after separator placement. The patients were asked to put each questionnaire in a pocket and seal it after marking the scale. If additional analgesics were taken by the patient before completing the questionnaires, this should be mentioned in the questionnaire and the patient would be disqualified from the study. In the next session, the patient returned the questionnaires to the operator.

Statistical analysis

A digital caliper was used to measure the VAS responses. All the measurements were done by a single operator. Intra-examiner reliability of the VAS measures was checked by re-measuring the data of 20 patients on separate days.

The data were analyzed in two parts: descriptive statistics for mean and standard deviation for the groups; and repeated measures analysis of variance (ANOVA) to compare the mean pain scores between the three groups.

Results

Twelve of the 101 patients (seven male and five female), recruited for the study did not complete the steps correctly; eight of them did not take the drugs correctly; and three of them did not fill the questionnaires. Thus, data were collected from 89 patients. In total, 32 patients in acetaminophen group, 29 in liquefied ibuprofen group, and 28 in the placebo group were included in the study.

56 percent of the patients were female in all three groups with the mean age 15.8 years for acetaminophen groups, 15.6 years for the liquefied ibuprofen group, and 15.3 years for the placebo group.

Intraexaminer reliability was considered to be high because all repeated scores were within 0.1 mm of the first measurements.

Patient's pain had significantly increased during 24 hours in all three groups ($P=0.042$) (Table 2).

The results of repeated measure ANOVA showed a statistically significant difference in mean pain scores between drug groups and placebo group ($P<0.001$). The mean pain scores in acetaminophen group and liquefied ibuprofen group were significantly lower than the placebo group. The within-subject contrast results revealed that this difference was statistically significant in all the experimental times (two hours later, six hours later, bedtime, 24 hours later).

No statistical difference was found in mean pain scores between two drug groups (acetaminophen and liquefied ibuprofen) ($P=1$) (Table 2).

Sex or age had no statistically important effect on pain perception in our study ($P>0.05$) (Table 1).

Table 1. Descriptive data of the groups

	Control group	Acetaminophen group	Liquefied ibuprofen group	P.value
Number	28	32	29	
Age	15.3 ± 3.15	16.8 ± 3.49	15.6 ± 4.17	0.73
Female/male	56%	57%	55%	0.86

Table 2. Mean pain scores at different times following separator placement

	0	2 hours later	6 hours later	At bed time	24 hours later
Control group	8.2±10.12	20.6±16/25	28.83±20.79	42.36±26.54	58.26±26.95
Acetaminophen group	7.13±9.97	8.76±14.72	11.76±13.14	17.36±16.63	22.83±18.73
Liquefied ibuprofen group	2.86±5.02	6.34±8.83	10.48±10.14	19±17.96	25.27±17.10
Significance (P-value)	--	B,C<A (<.000)	B,C<A (<.000)	B,C<A (<.000)	B,C<A (<.000)

Discussion

For most patients, the first step in fixed orthodontic therapy is the placement of bands on first molars, and according to many studies separation before bending is necessary. So, placement of separators is the first step of the treatment process, and the pain experienced during this procedure is not trivial, and the correct analgesic prescription is an optimization in orthodontic care. Pain control, in the first session of treatment, can also improve the patient’s motivation and cooperation. Moreover, pain produced by separator is comparable with that of orthodontic force. In both cases, the periodontal ligament is compressed during the first hours that impede vascular circulation and cell differentiation (7).

We used an elastic separator for separation in the current study because it is the most common method of separation among practitioners, and because clinical studies (9,10) have shown that 24 hours is enough for creating space between teeth for banding after separator placement, analgesics were prescribed for a period of one day.

In this study, standard over-the-counter doses of acetaminophen and liquefied ibuprofen were used. These analgesics act with different mechanisms of alleviating pain. Ibuprofen has analgesic, anti-inflammatory, and antipyretic properties, whereas acetaminophen has analgesic and antipyretic properties (7). We wanted to reveal if the anti-inflammatory mechanism has the benefit of reducing pain more efficiently or not.

In all three groups (acetaminophen, liquefied ibuprofen, and placebo), the mean pain has increased up

to 24 hours and the peak of pain was 24 hours after separator placement. This trend is similar to that seen in previous studies (11-13). The positive effect of analgesic prescription can be verified by noting that the mean pain scores of acetaminophen and liquefied ibuprofen groups were less than half of placebo group. Comparing with other studies that use one or two doses (6,14) one can see that the additional doses used in our experiments contribute to further reducing the pain in the long term. In Law’s study (6) that used a single dose of ibuprofen, the mean pain score at 24 hours was twice that of our analgesic groups and equal to that of our placebo group. The mean score of the control group in Law’s study was very close to our control group.

Although the scores of analgesic groups were dramatically less than the placebo group, but they were still more than ten, which cannot be clinically ignored and is an indicator of incomplete control of pain and discomfort with the protocol used in current study. Increased doses (1000 mg of acetaminophen and 800 mg of liquefied ibuprofen) with reduced intervals (every 4 hours) might further reduce or even prevent the pain.

The absence of difference between two drugs in our study is similar to the results of Bird (7) but is in contrast with Bradley’s results (8), and suggests that the analgesic effect of these analgesics dominates that of anti-inflammatory effect during the first 24 hours after separator placement as Bird has mentioned (7).

Acetaminophen and liquefied ibuprofen prescribed as the protocol in this study during separation phase can reduce pain significantly compared with placebo, but there is no significant difference between these two analgesics.

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