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Comparison of two analgesics used for pain relief after placement of orthodontic separators

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ABSTRACT

Objective: The purpose of this study was to assess the possible effect of two analgesics: paracetamol (500 mg) and ibuprofen (400 mg) on pain and routine life of the patients after placement of orthodontic separators.

Methodology: Ninety patients aged 11–41 years undergoing fixed comprehensive orthodontic treatment requiring placement of different orthodontic separators participated in the study. Following placement of separators, the participants were randomly assigned to 1 of 3 groups: paracetamol (500 mg) given every 6 h for 3 days, ibuprofen (400 mg) given every 8 h for 2 days and control group in which no analgesic was given. A questionnaire comprising of 7 questions was distributed to the participants and were asked to report their feeling of pain. The collected data were tabulated and the statistical analysis was performed using ANOVA, chi-square test, and *t*-test with a significance level of p < 0.05.

Results: In general, the level of pain was high for all groups in the first three days. Then it was gradually reduced until the 7th day of the study. Few patients reported feeling of pain during their sleep whereas a significant reduction of the pain was reported during eating and chewing after the 3rd day of separators. However, some participants felt continuous pain on the 1st and 2nd days and it was reduced gradually on the 3rd day until the 7th day following application of separators.

Conclusion: The patients prescribed ibuprofen did not report any problem with tooth movement along with significant reduction in pain as compared to paracetamol. Pain relief medication after placement of separators should be taken only if patient feels intolerable pain but not as routine practice.

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1. Introduction

A fixed orthodontic treatment requires separation of molars to create adequate space for the placement of bands that anchor the appliance and support the auxiliary labial and lingual attachments (Juneja et al., 2011). Separators are commonly used to create this space because insufficient space causes improper band placement. To avoid improper band seating, orthodontists use different types

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of separators such as brass wire, Latex elastics, elastomerics, Kesling separators, NEET separators or springs and Maxian elastic separator (Malagan et al., 2014). The pain mechanism is associated with the placement of orthodontic separators that create space mesially and distally to teeth by a process related to changes in the periodontal ligament (PDL) that increase the number of multinuclear osteoclasts, promote osteoclastic bone resorption and thereby allow tooth movement. Orthodontic force produces pressure to the PDL that leads to ischemia, inflammation, and edema. As a result of inflammation, high levels of prostaglandins, histamine, serotonin, bradykinin, substance P and cAMP are released to the PDL (Wise and King, 2008). The pain may also be induced by pulp irritation during orthodontic tooth movement (Angelopoulou et al., 2012; Asiry et al., 2014; Farias et al., 2016; Krishnan, 2007; Panda et al., 2015). It has been reported that most of the patients reported non-stop pain after 4 h following the placement of separators, which proceeded to the second day. After

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that, a decline in the curve of pain intensity was observed at 24 h (Asiry et al., 2014). Ngan et al. reported similar findings, wherein the level of pain was significantly higher on the 4th and 24th hour (Ngan et al., 1989).

Prostaglandins (PG) E such as PGE1 and PGE2 are important mediators of bone resorption contributing to orthodontic tooth movement and also involved inmediation of orthodontic pain (de Carlos et al., 2006). The most commonly prescribed medications for orthodontic pain relief consists of Non steroidal antiinflammatory drugs (NSAIDS) (Gameiro et al., 2007; Krishnan, 2007). The NSAID's blocks PG production thereby relieving the pain and at the same time delays or inhibits orthodontic tooth movement due to the inhibition of PG synthesis (Salmassian et al., 2009). Previous studies have reported the use of different analgesics such as aspirin, ibuprofen, acetaminophen, rofecoxib and paracetamol for relieving orthodontic pain, but all this study had difference of opinion for the same analgesics (Arias and Marquez-Orozco, 2006; Bernhardt et al., 2001; Bondemark et al., 2004; Gameiro et al., 2007; Kehoe et al., 1996; Ngan et al., 1994; Pozzi and Gallelli, 2011; Salmassian et al., 2009; Walker and Buring, 2001). Therefore, the present investigation was carried out to assess the possible effect of two analgesics: paracetamol (500 mg) and ibuprofen (400 mg) on pain after placement of orthodontic separators and the effect of pain on their routine life. The null hypothesis was that there was no difference of the possible effect of the used analgesics and control on pain after placement of orthodontic separators.

2. Materials and methods

The present study was in accordance with the declaration of Helsinki regarding human experimentation adopted in 1964 and revised in 2013. The study was registered by the Ethical Committee, College of Dentistry Research Center, King Saud University (IR 01880).

2.1. Study population

The population of this research project comprised of all patients attending the orthodontic clinics in Riyadh, Kingdom of Saudi Arabia during January to June 2016.

Ninety patients aged 11–41 years undergoing fixed comprehensive orthodontic treatment and requiring placement of orthodontic separators were included in the study. Following placement of separators, participants were randomly assigned to 1 of 3 groups. First group was given paracetamol (500 mg) every 6 h for 3 days; second group was given ibuprofen (400 mg) every 8 h for 2 days and control group in which no analgesic was given. Two patients in control group were excluded from the study due to taking of analgesics.

A survey form was distributed for all participants. Participants who were in the control group were asked not to take any medicine unless the pain is intolerable.

The patients of the control group who reported taking any analgesic were excluded from the study. Participation in this study was purely on volunteer basis. The exclusion criteria includes any patient with a medical disorder, psychological disorder, under any pain or anxiety medication, smokers, pregnant women and patients who refused to give informed consent. All qualified participants in this study were asked to fill the questionnaire.

2.2. Development of the questionnaire

The questionnaire used in this study was based on the questions used by Bondemark et al. (2004) and Erdinc and Dincer (2004). The

questionnaire comprised of 10 questions. The first three questions included gender, age and occupation, whereas the remaining 7 questions were about the severity of pain for seven days.

The following are the list of questions: Did you feel pain after placement of the separators, was it painful during eating/biting/ chewing, was it painful that you had to change your regular food to a softer food such as banana or yogurt, was it painful that your routine life activities were influenced such as sports and time/ meeting with friends, did the pain awake you at night, have you consumed any pain relief medicine other than the one the dentist gave you, if any and what type of pain did you experience.

2.3. Statistical analyses

Statistical analyses using independent *t*-tests, chi square test and one way.

ANOVA to compare between different groups and variables tested were performed.

All statistical analyses were established with a significance level of p < 0.05. The statistical analysis was performed with SPSS Version 16.0. The Power of sample size was ninety percent.

3. Results

The mean age of the participants was 24.81 ± 7.12 years. The percentage of Saudi participants was 56% (50) and that of non-Saudi was 44% (40). Among participants, 33% (30) were males and 67% (60) were females. The distribution of patients among the three groups was as follows: control group 36% (32), paracetamol group 32% (29), and ibuprofen group 32% (29).

There were significant differences among different groups (p value). In general, the level of pain was high for all groups in first three days and then gradually reduced until seventh day (Tables 1 and 2).

Q1. Did you feel pain after the treatment? (Fig. 1)

The results depict patients' responses to the feeling of pain. One way ANOVA and the independent *t*-tests indicated significant differences among responses of the three groups.

Q2. Was it painful during eating/biting/chewing? (Fig. 2)

One way ANOVA showed highly significant differences among the three groups (p < 0.008).

Table 1

The independent *t*-test for the first two days showing the 'p' value comparison between ibuprofen vs paracetamol, ibuprofen vs control, and paracetamol vs control groups.

	lbuprofen vs paracetamol	Ibuprofen vs control	Paracetamol vs control
Q1-D1	0.925	0.0001	0.001
Q2-D1	0.421	0.015	0.001
Q3-D1	0.098	0.290	0.006
Q4-D1	0.023	0.692	0.006
Q5-D1	0.711	0.022	0.053
Q7-D1	0.519	0.021	0.002
Q1-D2	0.758	0.020*	0.008
Q2-D2	0.743	0.081	0.042
Q3-D2	0.109	0.759	0.050
Q4-D2	0.0001	0.855	0.0001
Q5-D2	0.510	0.245	0.615
Q7-D2	0.049	0.284	0.382

Q = Question, D = Day.

* Significant < 0.05.

Table 2

The Chi-square test for first two days comparing ibuprofen vs paracetamol, ibuprofen vs control and paracetamol vs control groups.

	lbuprofen vs paracetamol	Ibuprofen vs control	Paracetamol vs control
Q1-D1 Q2-D1	0.612 0.293	0.001 0.013	0.001 0.001
Q3-D1	0.89	0.212	0.007
Q4-D1	0.023	0.442	0.007
Q5-D1	0.457	0.020	0.045
Q6-D1 07-D1	0.246	0.0001	0.0001
01-D2	0.500	0.024	0.009
Q2-D2	0.500	0.083	0.042
Q3-D2	0.100	0.488	0.052
Q4-D2	0.0001	0.529	0.0001
Q5-D2	0.353	0.185	0.420
Q6-D2	0.694	0.0001	0.0001
Q7-D2	0.049	0.223	0.273

Q = Question, D = Day.

^{*} Significant < 0.05.

Q3. Was it painful that you had to change your regular food to a softer food such as banana or yogurt? (Fig. 3)

One way ANOVA showed highly significant differences between the treatment groups and the control on the first day (p < 0.028, p < 0.008) and on the second day (p < 0.0001). Q4. Was it painful that your leisure activities were influenced, for example, music, sport, time with friends? (Fig. 4)

The data when subjected to the analysis of variance depicted significant differences among the treatment groups at p < 0.023 level of confidence.

Q5. Did the pain awake you at night? (Fig. 5)

One way ANOVA showed highly significant differences between the control group and the treatment groups (ibuprofen and paracetamol) on the first day (P < 0.023, P < 0.001). However, on the second day, the significance was only with the paracetamol group only (p < 0.049).

Q6. Have you consumed any pain relief medicine? (Fig. 6)

Fig. 7 show that participants of both treatment groups reported taking the recommended analgesic drugs from day 1 to 7.

Q7. What type of pain you experienced? (Fig. 7)

One way ANOVA revealed significant differences between the treatment groups (ibuprofen and paracetamol) (p = 0.024, 0.003) on the first day, with no significant different on the second day.



pain after treatment

Fig. 1. Patient response about feeling of pain after placement of the separators in different groups.



pain during eating or chewing

Fig. 2. Patient response about feeling of pain while eating/biting/chewing.





Fig. 3. Patient response to change of food style.



pain during sport

Fig. 4. Patient response about feeling of pain during the practice of sports activities or go out with friends.

4. Discussion

The present study evaluated the possible effect of two analgesics: paracetamol (500 mg) and ibuprofen (400 mg) on pain and routine life of the patients after placement of orthodontic separators. Previous studies have reported that the patient start feeling pain and discomfort within 4 h after insertion of separators and the level of discomfort tends to increase during the next 24h period but decreases almost to zero on the 7th day (Ngan et al., 1989). Similar conclusions were drawn by Asiry et al. and Ngan et al. who reported the incidence of pain and discomfort among their patients during chewing and biting of back teeth after placement of the separators (Asiry et al., 2014; Ngan et al., 1989). Rakhshan and Rakhshan (2015) also reported that all patients in their investigation felt some degree of pain and discomfort while chewing fibrous, sticky, or firm foods. However, consuming of soft foods significantly reduced their pain (Rakhshan and Rakhshan, 2015).

The results revealed that, the separator placement influenced daily activities of the patients such as food habits, support and leisure activities on the first day, and then there was a notable decline in the number of participants on the following days except for the control group who reported an increased impact on the second day. The findings are consistent with those of Bondemarke et al. who found that among daily activities, eating is mostly affected after placing the separator, which is managed by choice of soft diet. However, the impact on leisure and support activities is either little or negligible (Bondemark et al., 2004). The level of pain was the highest for the first night and dropped by approximately half for the second night in all the three groups.

However, it was significantly reduced on the 2nd day and became zero on the 6th day in case of the treatment groups. But the control group again felt pain on the 5th day which reduced to zero on the 7th day. Our findings are similar to those of Asiry et al. (2014) who enunciated that 28% of participants felt pain in the first night and that gradually decreased within 5 days (Asiry et al., 2014).

As pain interferes with the normal life activities, fear of pain is therefore considered as one of the most important factors that sometimes discourage patients from seeking the orthodontic treatment (Ngan et al., 1989). It is therefore, imperative that the orthodontists must consider some effective pain control strategy for successful treatment of their patients. To counter this unpleasant situation, clinician prescribes some analgesic drugs that interfere with the inflammatory process and allow tooth movement leading to the lesser degree of the pain and discomfort. In the present investigations, 100% of the patients took medicine in case of ibuprofen group on the first day followed by 93.1% of patients in case of paracetamol group. In the case of both groups, the percentage of patients dropped to approximately 50% on the 3rd day.



pain during sleep

Fig. 5. Patient response about feeling of pain during sleep.



taking analgesic

Fig. 6. Patient response about taking the analgesic drug.

Although the control group was not prescribed any medication, yet, 3.1% of the patients in this group took medicine on the 5th day followed by 6.3% patients on the 6th day, which proved that the analgesic drugs are routinely used by the dental patients even without prescription (Steen Law et al., 2000). According to Asiry et al. (2014), 73.6% of patients in a study consumed analgesic drug on the first day of the placement of elastic separators followed by 60.5% on the second day and 21.0% on the third day. However, the authors did not report the type of medicine, patients used to manage their pain. On the other hand, ibuprofen is preferred analgesic drug which is used to treat the discomfort related to post orthodontic treatment, unless the patient is allergic to other NSAIDs, it is safe and effective to reduce the pain with few adverse

effects, and less gastric irritation (Ngan et al., 1994). Walker and Buring (2001) have reported that NSAIDs may inhibit the activity of osteoclast which is necessary for tooth movement and may impair orthodontic tooth movement (Walker and Buring, 2001). That is the reason Ngan et al. (1989) recommended the use of ibuprofen as a analgesic drug in the treatment of discomfort due to post orthodontic adjustments (Ngan et al., 1989). Steen Law et al. (2000) also reported the effectiveness of the preoperative dose of ibuprofen in alleviating post adjustment orthodontic discomfort 2 h after the appointment (Steen Law et al., 2000). These studies support our results wherein patients taking ibuprofen did not report any problem with tooth movement along with significant reduction in pain. None of the patients took medicine on the





Fig. 7. Patient response about nature of pain.

6th day after the treatment. So, based on the outcome of the present study, the null hypothesis was rejected as there was a difference in the possible effect of the used analgesics and control of pain, after placement of orthodontic separators.

This study has some limitations such as the control group was not given a placebo medicine to counter the placebo effect, different orthodontists gave instruction to the patient without standardizing the mode of instruction, type of separator was not standardized, the dose of the drug was not prescribed according to the age and weight of the patients and the intensity of pain was not measured.

5. Conclusions

Within the limitations of the study, the following conclusions are drawn.

The patients prescribed ibuprofen did not report any problem with tooth movement along with significant reduction in pain and did not affect much on routine life of patients as compared to paracetamol. Pain relief medication after placement of separators should be taken only if patient feels intolerable pain but not as routine practice.

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