

DOES GREEN TEA (CAMELLIA SINENSIS) MOUTHWASH REDUCE PAIN AFTER PLACEMENT OF ORTHODONTIC SEPARATORS? A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Aim: The aim of this randomized controlled trial (RCT) was to determine whether gargling with green tea was effective in reducing pain after orthodontic elastomeric separators placement.

Materials and methods: A total of 50 patients with an age range between 13 and 17 years were recruited and randomly allocated in a ratio of 1:1 to the green tea mouthwash group (GTG) and the control group (CG). Patients in GTG were instructed to gargle with green tea mouthwash after two hours from separators placement and every eight hours afterwards for a week, while participants of CG were asked not to rinse their mouths. The patients in the two groups were instructed not to use any kind of local or systemic analgesics throughout the duration of the study. A 10-cm horizontal visual analog scale (VAS) was used to assess the pain at two hours, six hours, bedtime, 24 hours, and then daily after separators placement for seven days.

Results: One patient in each group was lost to follow up and one patient in the CG was excluded because of using analgesics; therefore, 23 patients in the CG and 24 patients in the GTG were analyzed. Although the pain scores were lower at all time points in GTG group, the difference between the two groups was statistically non-significant.

Conclusion: Gargling with green tea mouthwash three times daily does not seem to significantly reduce the pain after orthodontic elastomeric separators placement as compared to controls.

Keywords: green tea mouthwash, visual analog scale, pain control, orthodontic separators, randomized

controlled trial.

INTRODUCTION

Pain and fear of it are two of the main reasons that affect the patients' acceptance and compliance with the orthodontic treatment ¹. One of the most painful orthodontic procedures is the placement of the orthodontic elastomeric separators before molar banding and initial archwire placement which is accompanied by unpleasant consequence on patient daily activities, chewing, and sleep ²⁻⁴. Perception of pain during orthodontic treatment occurs due to pressure, ischemia, inflammation, and edema in the compressed periodontal ligaments during orthodontic tooth movement (OTM) ⁵. The orthodontic patient starts to discern the pain during the first two hours after orthodontic force application which gradually increases to reach its peak at night or morning of the second day, then it decreases over the subsequent 3-7 days ⁶⁻⁹. The main goal of orthodontist should not only to provide appropriate treatment to restore function and improve the appearance but also should control the pain or at least reduce it ¹⁰.

The most commonly used method to control the pain is the administration of 'over the counter' analgesics (OTC) before or after orthodontic appliance activation ^{2,11-13}. Paracetamol which exerts its action through the inhibition of prostaglandin (PG) synthesis in the brain and the spinal cord, and non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and aspirin, which work peripherally

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by the inhibition of the cyclooxygenase (COX) enzyme, thereby decreasing synthesis of PGs, are among the most frequently ingested OTCs^{14,15}. The use of OTCs may result in some adverse effects and complications; in addition, NSAIDs may interfere with the rate of OTM¹⁶⁻¹⁸. Therefore, it is preferable to use a nonpharmacologic available alternative that has no side effects nor interfere with the rate of OTM.

Green tea, *Camellia sinensis*, is one of the most popular drinks the world over. Its green color and natural micronutrients are preserved by steaming the freshly harvested leaves to destroy the enzymes responsible for breaking down the color pigments in the leaves that allows the tea to maintain its green color. Green tea contains polyphenols and catechins which have antioxidant, anti-diabetic, anti-mutagenic, anti-viral, anti-bacterial, and anti-inflammatory effects. The major polyphenolic compounds in green tea are epicatechin, epicatechin 3-gallate (ECG), and epigallocatechin 3-gallate (EGCG). The anti-inflammatory effect of green tea is attributed to the high concentration of EGCG which can inhibit the effects of COX-2¹⁹.

Three studies²⁰⁻²² addressed the effect of green tea mouthwashes in reducing pain in the oral cavity. One study²⁰ showed that green tea rinse was effective in reducing pain after impacted third molar surgery. The second study²¹ demonstrated that green tea mouthwash was more effective than chlorhexidine (CHX) mouthwash in controlling pain and limited mouth opening related to acute pericoronitis. The third one²² investigated the effect of green tea gargling on the outcome of pain reduction after orthodontic appliance placement. The results of this study showed that green tea mouthwash was not effective in reducing orthodontic pain.

The aim of this randomized controlled trial (RCT) was to determine whether gargling with green tea was effective in reducing pain after orthodontic elastomeric separators placement.

MATERIALS AND METHODS

Subjects

This was a 2-arm parallel group RCT that had an allocation ratio of 1:1. The ethics committee of the Faculty of Medicine, Assiut University, Assiut, Egypt approved this RCT (No. 17300593). Patients were included in this study if they fulfilled the following inclusion criteria: scheduled for separators placement for molar banding, medically free with no systemic health problems, tight interproximal contacts between the teeth where the separators were going to be placed, and with age range between 13 and 17 years. Conversely, patients with cleft lip and palate, syndromes, mental or cognitive impairment, pregnancy, history of previous orthodontic treatment, chronic pain conditions necessitating taking analgesics, teeth problems that cause pain (caries or pulpitis), and gingival inflammation or periodontitis were excluded. Before the start of this trial, a detailed description of the study was given to the included patients and an informed consent was obtained from each patient.

Study groups, sample size calculation, randomization, and blinding

For a study with a power of 80% and an alpha value of 0.05 using a standard deviation (SD) of 2.5 cm on the visual analog scale (VAS)²³ and a clinically significant difference of 2.5 cm, 20 patients per group were required. Considering an attrition rate of 25%; therefore, a minimum of 50 patients were needed. For randomization, a computer random list was generated using spreadsheet (Microsoft Excel, Microsoft Office 2016, Microsoft, Redmond, Wash) and concealed using consecutively numbered opaque sealed envelopes, which were opened only after the patient had agreed

to participate and had consented. Blinding of the operator and patients was not possible because they were either asked to rinse their mouths or not. On the other hand, data analysis was done by a blinded analyst. Fifty participants were randomly allocated with a ratio of 1:1 to two groups: green tea mouthwash group (GTG) and control group (CG) with a mean age of 16.06 ± 0.95 and 15.48 ± 1.20 , respectively.

Methods

A separator applicator (American Orthodontics, Sheboygan, WI, USA) was used to place the elastomeric separators (Ortho Organizers, Carlsbad, CA, USA) for all included patients. The separators were placed mesial and distal to 1st molars on both sides for upper and lower dental arches. Patients in GTG were instructed to gargle with green tea mouthwash made by mixing 10 g sachet of green tea (Lipton, Unilever Mashreq, Borg El-Arab City, Alexandria) with 200 ml of hot water for 10 minutes after two hours from separators placement and every eight hours afterwards for a week. On the contrary, participants of CG were asked not to rinse with any kind of mouthwash. The patients in the two groups were instructed not to use any kind of local or systemic analgesics. After a period of one week, the separators were removed to fit bands and to place the orthodontic brackets.

Data collection

A 10-cm horizontal VAS numbered from zero to 10 was used to assess the pain with zero indicating no pain, five indicating moderate, and 10 indicating intolerable pain. The patients were asked to mark the number corresponding to the level of pain felt at two hours, six hours, bedtime, 24 hours, and then daily at 9:00 PM after separators placement for seven days. After that, the VASs were collected and analyzed.

Statistical analysis

We used Statistical Package for the Social Sciences software (SPSS, Windows version 26, SPSS Inc., Chicago, Illinois, USA) to perform all statistical analyses with a *P* value less than 0.05 considered as the significance level. Shapiro-Wilk test was used to check for normality of pain score values. We used the independent t-test for normally distributed data and Mann-Whitney test for non-normally distributed data to check whether there was a difference between the mean pain scores in GTG and CG at different time points.

Results

There were non-statistically significant differences between the two groups regarding the age and sex of the included patients (Table 1).

Table 1. Demographic characteristics of the included patients.

| | GT (n = 24) | CG (n = 23) | P value |
|--------------------|------------------|------------------|---------|
| Age (years) | | | |
| Range | 13 – 17 | 13.6 – 17 | |
| Mean ± SD | 16.06 ± 0.95 | 15.48 ± 1.20 | 0.068 |
| Gender | | | |
| Male | 14 (58.3%) | 11 (47.8%) | 0.471 |
| Female | 10 (41.7%) | 12 (52.2%) | |

SD= standard deviation.

Two patients (one patient in each group) were lost to follow up; in addition, one patient in the CG took analgesics as she could not withstand

the pain. Therefore, 23 patients in the CG and 24 patients in the GTG completed the trial. Although the pain scores were lower at all time

points in GTG, the differences between GTG and CG were non-statistically significant (Table 2). The mean pain scores in the two groups showed that the pain increased gradually from two hours after placement of

the orthodontic separators and reached the highest values after 24 hours. Then, the pain scores decreased from day two and reached its lowest values on day seven (Table 2).

Table 2. Mean pain scores at different time points in green tea mouthwash group and control group.

| Time | Green tea group (GTG) (n= 24) Mean ± SD | Control group (CG) (n= 23) Mean ± SD | P value* |
|----------|---|--|----------|
| 2 hours | 2.00 ± 0.933 | 2.61 ± 1.234 | 0.091 |
| 6 hours | 3.25 ± 1.113 | 3.57 ± 1.161 | 0.316 |
| Bedtime | 4.54 ± 1.215 | 4.83 ± 1.193 | 0.423 |
| 24 hours | 5.79 ± 1.179 | 5.96 ± .928 | 0.411 |
| Day-2 | 5.38 ± 1.013 | 5.70 ± .974 | 0.285 |
| Day-3 | 4.58 ± 1.213 | 5.00 ± 1.206 | 0.244 |
| Day-4 | 3.29 ± 0.955 | 3.35 ± 0.714 | 0.803 |
| Day-5 | 1.96 ± 0.690 | 2.22 ± 0.850 | 0.332 |
| Day-6 | 1.29 ± 0.751 | 1.43 ± 0.788 | 0.687 |
| Day-7 | 0.63 ± 0.647 | 0.78 ± 0.600 | 0.345 |

*Significance at $P \leq .05$.

DISCUSSION

In this trial, our goal was to assess the difference between GTG and CG with regards to pain scores after orthodontic separators placement along a duration of one week rather than change with time within each group.

This RCT showed that the pain scores in GTG were lower than pain scores in CG at all time points, but the differences between the two groups were not statistically significant. These results were concordant with a previous study²² which investigated the effect of green tea mouthwash in reducing pain after orthodontic appliance placement.

One possible reason for these similar results is the minimal pain associated with the

orthodontic procedures to the degree that no intervention is required. One study²⁴ demonstrated a low proportion of patients seek analgesics to relieve pain after fixed orthodontic appliance placement with decreased use of medications after the third day. Moreover, another study²⁵ found that only 27% of patients used analgesics for pain control after separator placement and 87% reported pain during the study period indicating the low pain intensity accompanying orthodontic treatment. The highest average VAS score recorded in our study did not surpass 5.96 indicating the moderate pain levels associated with orthodontic treatment. The absence of statistical difference might be

explained by the variability in individual pain experience which was confirmed in one study²⁶.

On the other hand, our results were not consistent with other studies^{20,21}. One study²⁰ showed that green tea rinse was effective in reducing pain after impacted third molar surgery. Another study²¹ demonstrated that green tea mouthwash was more effective than chlorhexidine (CHX) mouthwash in controlling pain and limited mouth opening related to acute pericoronitis.

One possible explanation of the non-congruent results was the difference in mechanism by which pain was produced. During orthodontic procedures, the pain is produced by the mechanical load resulting in compression of the periodontal ligaments which in turn results in inflammation and release of prostaglandins. In the two above mentioned studies^{20,21}, the pain was the result of inflammation, trauma, and surgical insult not the result of mechanical load.

The pain in our study reached its maximum intensity after 24 hours from separators placement which was consistent with the results of some studies^{12,27-29}. Conversely, these results were not consistent with two studies^{30,31}: one study³¹ showed that the pain reached its peak in 2 days, while the other³⁰ showed that the pain intensity pattern exhibited significant variations among patients.

This variability in results regarding the maximum intensity of pain among studies could be attributed to different sample sizes, different ethnicity of the patients, and different environmental factors influencing the sensation of pain³².

It was reported that the duration of one week was enough for the pain to subside^{9,33}, so we assessed the pain resulting from placement of the orthodontic separators along a period of one week. The duration of our study was

different with regards to other studies^{30,34}. One study addressed the pain for a duration of eight hours only³⁴ and another showed that some patients continued to feel pain throughout the 10 days period of the study³⁰.

There are conflicting results in the literature regarding the influence of age on pain perception during orthodontic treatment. Some studies reported that adults feel less pain than adolescents, while others reported opposite results^{7,24,35,36}. The age range in this trial was short (13-17 years); in addition, we did not include very young children and adults to avoid the effect of age as a cofounder.

It was shown that the orthodontic pain might be affected by analgesics^{15,37,38}, so efforts were done to avoid the use of analgesics. We asked the patients not to use analgesics during the study duration and to report if they took analgesics. One female patient in the control group could not withstand pain and was excluded because she took ibuprofen.

Limitations

One limitation of this study was that we investigated the pain after two hours from separators placement although instant placement of separators can be painful for some patients^{34,39}.

Another limitation was the inability to blind the operator and the patients to the groups because of the nature of the study, but the data analyst was blinded. The operator had to know the group to give the instructions and the patients knew in which group they were included after they took the instructions.

The existing evidence regarding the effect of sex on pain perception is contradicting. Some studies^{1,40} found non-significant influence of gender on pain related to orthodontic treatment. On the other hand, other studies^{41,42} showed that females might be more sensitive to pain than males, although sex was not a significant predictor of VAS values⁴¹. The randomization

resulted in a higher ratio of males in the GTG and a higher ratio of females in the CG with a non-significant difference between the two groups, but this could affect the results. Therefore, it is preferable to include only one gender to rule out the effect of sex as a cofounder.

To assess compliance of the patients with the given instructions, we asked the patients whether they took analgesics or not and whether they rinsed their mouths or not with no method available to confirm their responses; therefore, the results could be affected.

Among the limitations in this trial was the use of VAS only to assess pain, which is highly subjective and difficult to precisely assess, without the use of objective methods such as investigating the mediators of the orthodontic pain present in the gingival crevicular fluid.

CONCLUSION

Gargling with green tea mouthwash three times daily does not seem to significantly reduce the pain after orthodontic elastomeric separators placement as compared to controls. Further studies with larger sample size and combining subjective assessment of orthodontic pain with objective assessment such as pain mediators in the gingival crevicular fluid are needed to investigate whether using green tea as a mouthwash can be useful for reducing pain not only after separators placement but also after various orthodontic procedures.

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