Title: **Effect of Green Mouthwash on the Incidence of Alveolar Osteitis following Surgical Removal of Mandibular Third Molar: a Randomized Double Blind Study**

Running Title: **Green Tea Mouthwash and Alveolar Osteitis**

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**Abstract**

Aim: The aim of the present study was to evaluate the effectiveness of green tea mouthwash to reduce the incidence of alveolar osteitis (AO) following surgical removal of mandibular impacted third molars.

Methods: In a split-mouth and double blind study, patients underwent surgical extraction of bilateral impacted third molars and randomly received green tea or placebo mouthwash to rinse with twice per day during the first postoperative week. The predictor and outcome variables of the study were type of mouthwash and incidence of AO, respectively. Other study variables were age, gender, radiographic index of difficulty, experience of surgeon, number of anesthetic cartridges injected, and socket irrigation volume. To analyze data, t-test and chi-square were performed and the significance level was set at P-value < 0.05.

Results: Total of 57 patients (23 males and 34 females) with mean age 24.35 ± 4.92 years old underwent 114 surgeries. 19 cases of AO were detected during the first postoperative week with the overall frequency of 16.67%. The frequency of AO following rinsing with green tea and placebo mouthwashes were 12.28% and 21.05%, respectively. No significant difference was found between the frequency of AO in green tea group in comparison to placebo (P-value > 0.05). However, the risk of developing AO while rinsing with green tea mouthwash was 0.58 of that of the placebo mouthwash.

Conclusion: Rinsing with green tea mouthwash is beneficial after impacted third molar surgery regarding prohibiting AO development.

Keywords: Alveolar Osteitis, Dry Socket, Green Tea, Mouthwash, Third Molar.

**Introduction**

The most common complication following permanent tooth extraction is alveolar osteitis (AO) with the rate of 1% to 4% in non-operative extractions [1]. The rate of AO reaches 5% to 30% in surgical extractions of impacted mandibular third molars. This phenomenon is marked by severe and progressive pain, foul taste, halitosis, and regional lymphadenitis which develop 24 hours to 72 hours after extraction [2].

AO is self-limited and would resolve within 5 to 10 days after initiation. It should be noted that 45% of cases need up to 4 visits until the complete resolution of AO. While the aim of the healthcare providers is not only to provide treatment but also to bring relief of pain for patient, prevention of AO is one of the challenges oral and maxillofacial surgeons face [1-4].

As a result, various techniques have been proposed to attenuate the incidence of AO including local and systemic application of antibacterial, anti-inflammatory, antiseptic, antifibrinolytic, and clot supporting agents [2].

Green tea (Camellia Sinensis) is one of the well-known drinks in the Eastern countries. It is very rich in various polyphenol compounds including catechins and possesses antioxidant, antiviral, antibacterial, antidiabetic, antimutagenic, and anti-inflammatory properties [5]. It has been documented that green tea is effective against caries and periodontal diseases [6-8]. In the realm of oral and maxillofacial surgery, green tea has been used to control postoperative pain following mandibular third molar surgery and also to control pain and trismus in cases with acute pericoronitis [9, 10]. However, there exists no evidence on the effect of green tea mouthwash on the incidence of AO.

The aim of the present study was to investigate the efficacy of green tea mouthwash in reducing the risk of AO development following bilateral mandibular third molar surgery. The null hypothesis was that the incidence of AO following rinsing with green tea mouthwash after impacted mandibular third molar surgery equals to the incidence observed following rinsing with placebo mouthwash.

**Materials and Methods**

The study was performed at Oral and Maxillofacial Surgery Clinic of Mashhad dental school, Iran. All participants provided a signed detailed informed consent and the study protocol was approved by the Ethical Committee of Mashhad University of Medical Sciences.

**Study Design**

The study was designed as a double blind clinical trial and conformed to the Helsinki Declaration.

**Study Population**

The study sample consisted of 58 patients in need of managing bilateral impacted mandibular third molar between April 2012 and October 2012. To be included in the study patients had to be 18-30 years old; have American Society of Anesthesiologists physical status (ASA) of I or II; have bilateral impacted mandibular third molars; have moderate difficulty level in both sides based on the sum score of spatial direction, depth of impaction, and relationship with ramus on the panoramic radiograph [4, 11].

Patients were excluded from the study if they were smoker, were lactating or pregnant, were taking contraceptive drugs, had received systemic antibiotics during the previous two weeks, had any periapical lesion on panoramic radiograph, or had received more than two anesthetic cartridges perioperatively.

**Study Variables**

The predictor variable of the study was the type of mouthrinse used after each surgery (green tea or placebo). After the surgical extraction of the first tooth patients were instructed to rinse with green tea or placebo mouthwash (allocated randomly) and after the second surgery (which was one month after the first one) rinsed with the other mouthwash.

The outcome variable was the incidence of AO development during the first postoperative week. The criteria to diagnose AO were severe and progressive pain starting 1-3 days after surgery along with clot loss, halitosis, foul taste, or regional lymphadenitis.

In addition to the predictor and outcome variables, the data regarding demographic (age, gender), preoperative (radiographic index of difficulty, experience of surgeon), and perioperative variables (number of anesthetic cartridges injected, socket irrigation volume) were also collected.

**Mouthwash Preparation**

The green tea and placebo mouthwashes were prepared in the pharmacology laboratory of the Mashhad University of Medical Sciences. The first step was to prepare the extract of green tea: drying Camellia Sinensis leaves in 40 ̊C for 45 minutes, powdering with electrical mortar, mixing 100 grams of powder with 500 ml of water, filtering the mixture 48 hours later and removing the sediment, storing the remnant solution in room temperature for 4 days. After the mentioned period the powder of green tea extract was obtained. The second step was to solve 5 g of the extract in 100 ml distilled water in order to produce 5% mouthwash. Then the prepared rinse poured into 250 ml dark bottles. The placebo mouthwash consisted 250 ml distilled water. In order to meet the blindness of patient to the mouthwash type, the mint flavor added to both green tea and placebo mouthrinses.

**Data Collection**

All surgeries were performed by a single experienced surgeon using an identical protocol: applying povidone iodine solution periorally, injecting 2% lidocaine + 1:80,000 epinephrine cartridges to block either inferior alveolar and long buccal nerves, creating a mucoperiosteal envelop flap, removing and recontouring bone and sectioning tooth with a low-speed handpiece under sufficient sterile solution irrigation, irrigating extraction socket with 60 ml of sterile normal saline, suturing the flap using 3–0 silk sutures. A regimen of anesthetic (Acetaminophen, 325 mg, every 6 h, in case of pain) was prescribed after each surgery.

Following each surgery, the patient received a 250 ml mouthwash bottle to rinse with 15 ml two times per day during the first postoperative week. It should be noted that patients were instructed to start rinsing 24 h after surgery. Allocating each side to the study (rinsing with green tea mouthwash) or control (rinsing with placebo) was performed by the flip of a coin. Neither patient nor surgeons were aware of the randomization.

In order to evaluate the healing process two follow-up appointments were held during the first postoperative week (2nd and 7th days after surgery) by another surgeon unaware of the randomization. Moreover, patients were instructed to come back if they faced any persistent or progressive pain. In case of AO, treatment protocol consisted socket irrigation with sterile normal saline, intra-alveolar dressing with alvogyl iodoform (Septodont, Cambridge, ON, Canada), and systemic analgesic (in some cases along with systemic antibiotics) prescription.

**Statistical Analysis**

Appropriate descriptive statistics including mean, frequency, and standard deviation were measured for each variable. In order to analyze the data, t-test and chi-square tests were performed using the Statistical Package for Social Sciences software, version 11.5 (SPSS, Chicago, IL) with the significance level set at P-value < 0.05.

**Results**

60 patients met the inclusion criteria and participated in the study. However, 57 patients completed the study as one patient did not participate the second surgery within the study period and two patients received more than two carpules to obtain anesthesia. Among the participants, 34 were female (59.6%). The mean age of patients was 24.35 ± 4.92 years old. While the study design was split-mouth, no significant differences were found between the demographic variables of both groups (Table 1). In addition, there were no significant differences in the difficulty level of impacted tooth and number of injected carpules in either group (Table 1).

Among 114 surgeries (in 57 patients), 19 cases (in 13 patients) of AO were observed for the frequency of 16.67%. Based on the chi-square analysis, no significant association was found between the incidence of AO and gender, difficulty score, or number of anesthetic carpules injected. In addition, there were no significant differences in the mean age of the patients who developed AO when compared with patients without AO development (Table 2).

According to the chi-square analysis, no significant association was found between type of mouthwash and the frequency of AO. However, the risk of developing AO in sockets rinsed with green tea mouthwash was 0.58 of the sockets rinsed with placebo mouthrinse (Table 3).

The patients who returned with AO received the treatment protocol as described in the previous section (Materials and Methods) and were followed up until the complete resolution of the AO.

**Discussion**

The aim of the present study was to evaluate the efficacy of green tea mouthwash in reducing the frequency of AO following surgical removal of the impacted third molar. The null hypothesis was that the frequency of AO while rinsing with green tea mouthwash after mandibular impacted third molar surgery equal to the frequency observed following rinsing with placebo mouthwash. Our null hypothesis was rejected as the risk of developing AO after rinsing with green tea was nearly half of the risk when rinsing with placebo. However, the difference in the frequency of AO was statistically insignificant between two groups.

Considering other study variables, we did not observe any significant differences in the frequency of AO among various surgical difficulties, number of anesthetic cartridges injected, and two genders. In addition, there was no significant difference in the mean age of patients developing AO and other patients.

AO is one of the most common complications after the surgical removal of mandibular impacted third molars. As the reported rate of developing AO varies from 5% to 30%, the frequency observed in the present study (16.67%) was in accordance with previous studies [1, 2].

The frequency of AO decreased while rinsing with green tea during the first postoperative week. No other report exists in literature regarding the influence of green tea mouthwash on the development of AO. However, other chemicals including chlorhexidine have been found to be effective either as a mouthrinse or a bio-adhesive gel in reducing the risk of AO following mandibular third molar surgery [12-15].

The effectiveness of green tea rinse could be dedicated to its antibacterial activity. One of the proposed etiologies in development of AO is the bacterial activity that increases the fibrinolysis through the extraction socket. The bacterial byproducts are responsible for this phenomenon [2, 16]. Green tea contains catechins including epigallocatechin (EGC), epicatechin gallate (ECg), and epigallocatechin gallate (EGCg). These components are in charge of antibacterial activity of green tea which has previously used against periodontal diseases and caries [6-8]. In addition, Shahakbari et al [10] found that green tea mouthwash was also beneficial in the management of acute pericoronitis. Hence, the attenuation in the risk of developing AO would be the result of effective control over bacterial activity through rinsing with green tea.

In addition to the antibacterial properties, green tea has anti-inflammatory effects [5]. In this regard, it has been demonstrated that green tea mouthwash is effective in reducing postoperative pain following surgical extraction of mandibular third molars [9]. Moreover, it is beneficial in reducing the inflammation during the acute phase of pericoronitis and also in improving functional limitations (trismus) [10].

Although the effectiveness of chlorhexidine (either mouthwash or gel form) in reducing the frequency of AO has been reported in various studies, green tea mouthrinse has some advantages [12-15]; firstly it does not does not possess some side effects reported in rinsing with chlorhexidine including tooth discoloration and taste alteration [17]. Moreover, green tea attenuates the pain and lowers the number of taken analgesics during the first postoperative week [9]. While green tea is a common drink in eastern countries, the access could be another privilege of green tea in these regions [5, 9].

The present study was double blind and neither patients nor surgeons were aware of the type of mouthwash received after each surgery. In addition, to obscure the identification of rinse type according to taste and smell, mint flavor added to either mouthwash.

The role of gender in the frequency of AO is controversial as some reports suggest the higher risk in females while others state no difference between two genders [18-22]. In the present study, the possible effect of gender on developing AO was eliminated by the study design according to which same patient was involved in both groups. Moreover, taking oral contraceptive is one of the risk factors of AO in women that was set to be an exclusion criterion [4].

Smoking has been identified as a risk factor of AO development. Local and systemic effects of smoking lead to decrease in the level into which blood clot has filled the extraction socket [23, 24]. As a result, the smokers were excluded from the study population to prevent possible bias.

The other variable affecting the risk of AO development is the patient age; the peak age has been reported to be between 20 to 40 years old [1, 25]. In addition, to the fact that the split-mouth design eliminated the effect of age as a background variable, there were no significant difference in the mean age of patients with AO and other patients.

The amount of trauma during surgical extraction is one of the factors influencing the frequency of AO. Higher amounts of trauma would be present with lower experience of surgeon. Moreover, higher level of impaction enhances the need to remove further amounts of bone during surgery [16, 26]. As a result, to eliminate the interference of these factors as confounding variables, all surgeries were performed by a single experienced surgeon. Moreover, each tooth matched with a contralateral one with the same difficulty level.

It has been reported that epinephrine has the potential to decrease blood circulation and oxygen tension while increasing the fibrinolytic activity [2, 27]. Hence receiving more than two anesthetic cartridges was set to be an exclusion criterion. Furthermore no association was observed between number of injected cartridges and the frequency of AO.

Postoperative irrigation removes the debris and bacteria within the extraction socket and reduces the risk of AO occurrence [18]. The appropriate volume of irrigation would be 60 ml which has identical benefits in comparison to higher volumes [4, 27, 28]. Hence all the sockets were irrigated with identical amount of sterile saline (60 ml) to eliminate the confounding effect of lavage volume.

One of the main limitations of the present study was the sample size; possibility exists that with the higher number of patients the difference between the study and placebo group would reach the significance level. Moreover, further studies are recommended to compare the effectiveness of green tea with other measures of preventing AO development and also to evaluate its efficacy in combination with these modalities including chlorhexidine gel/mouthwash or platelet-rich fibrin [12-15, 27].

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Table 1: Demographic and surgical variables in two groups

|  |  |  |  |
| --- | --- | --- | --- |
| Variable | Green Tea | Placebo\* | P-value |
| **Sample Size** | 57 (50) | 57 (50) | - |
| **Gender (M/F)** | 23 (40.3)/34 (59.7) | 23 (40.3)/34 (59.7) | 1.000‡ |
| **Difficulty Level**  |  |  |  |
| Moderate | 57 (50) | 57 (50) | - |
| **Difficulty Score†** |  |  |  |
| 5 | 26 (45.6) | 23 (40.3) | 0.851§ |
| 6 | 22 (38.6) | 24 (42.1) |
| 7 | 9 (15.8) | 10 (17.6) |
| **N of Anesthetic Cartridges (1/2)** | 20 (35.1)/37 (64.9) | 16 (28.0)/41 (72.0) | 0.420§ |
| **Age** | 24.35 ± 4.92 | 24.35 ± 4.92 | 1.000‡ |

Data are reported in numbers with percentages in parentheses or mean ± standard deviation.

\*Reference group.

†According to the sum score of the tooth spatial direction, depth of impaction, and relationship with the ramus on the preoperative panoramic radiograph.

‡ Based on t-test

§Based on Chi-square

Table 2: Distribution of demographic and surgical variables according to the AO development

|  |  |  |
| --- | --- | --- |
| Variable | AO | P-value |
| Yes | No\* |
| **Gender (N of patients)** |  |  |  |
| Male | 4 (30.7) | 19 (43.2) | 0.423‡ |
| Female | 9 (69.3) | 25 (56.8) |
| **Difficulty Score (N of tooth)†** |  |  |  |
| 5 | 6 (31.6) | 43 (45.3) | 0.540‡ |
| 6 | 9 (47.4) | 37 (38.9) |
| 7 | 4 (21.0) | 15 (15.8) |
| **N of Anesthetic Cartridges (N of tooth)**  |  |  |  |
| 1 | 4 (21.1) | 32 (33.7) | 0.281‡ |
| 2 | 15 (78.9) | 63 (66.3) |
| **Age** | 25.67 ± 5.33 | 23.67 ± 4.78 | 0.367§ |

Data are reported in numbers with percentages in parentheses or mean ± standard deviation.

\*Reference group.

†According to the sum score of the tooth spatial direction, depth of impaction, and relationship with the ramus on the preoperative panoramic radiograph.

‡Based on Chi-square

§ Based on t-test

Table 3: Frequency of AO based on the type of mouthwash

|  |  |  |
| --- | --- | --- |
| Type of Mouthwash | AO | Total |
| Yes | No |
| Green Tea\* | 7 | 50 | 57 |
| Placebo\*† | 12 | 45 | 57 |
| Total | 19 | 95 | 114 |

\*patients who rinsed with green tea mouthwash had lower risk of developing AO in comparison to placebo; however, the difference was statistically insignificant (relative risk = 0.58; P-value = 0.209)

†Reference group.