



## Effect of Biotene mouth wash on prevention of alveolar Osteitis after extraction of permanent Mandibular first molar Teeth

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### ABSTRACT

**Objective:** Biotene mouthwash is an antimicrobial agent used in prevention of periodontal disease, xerostomia and halitosis. it seems that no study has been conducted to evaluate its effect on prevention of alveolar osteitis(AO) .So the purpose of the study is to evaluate effective of biotene mouthwash on prevention of alveolar osteitis after extraction of permanent mandibular teeth and to investigate association of risk factors of AO with incidence of AO.

**Methods and materials:** This randomized double blind clinical trial was conducted in oral and maxillofacial surgery department of Tabriz dental faculty. In case group (n=192), the patients received Biotene mouthwash and used it, three times a day for one week. Control group (n=197) received 0.09% sterile saline solution and used it similar to case group. The patients with the symptoms of AO were recalled for the diagnosis of alveolar osetitis on the third postoperative day.

**Results:** In the experimental group 6 ( 3.1%) of AO incidence was found. While in the control group, 17 (8.6%) of AO was observed. The reduction in the incidence of AO in case group was statistically significant in comparison with control group  $p=0.03$ ,  $p<0.05$  for fisher`s exact test (Chi-square test). smoking was a variables that has significant relation to increased rate of AO,  $p=0.235$ ,  $p<0.05$ .

**Conclusion:** It was concluded that the use of Biotene mouthwash can be effective in reducing the incidence of dry socket after extraction of mandibular teeth. Smoking was significantly associated with the increased incidence of alveolar osteitis.

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### Introduction

Dry socket or alveolar osteitis (AO) is delayed healing but is not associated with an infection.<sup>1</sup>

Another synonyms of AO are dry socket, alveolitis sicca dolorosa, alveolalgia, osteomyelitis fibrinolytic osteitis, post extraction osteomyelitis and delayed wound healing.<sup>2</sup>

AO is one of the most common complication following dental extractions. It`s frequency thorough all dental extractions is 1% to 4% and thorough impacted mandibular third molar is 5% to 30%.<sup>3</sup>

AO occurs in 2 to 3 days after tooth extraction as a moderate to severe pain. The clot in the tooth socket is totally or partially been removed.<sup>4</sup> However these signs and symptoms are characterized in the absence of erythema, fever and swelling.<sup>5</sup> The severity of pain can effect patient`s normal functions, so it is required to therapeutic interventions in order to relive pain.

Epidemiological studies identified different risk factors for AO such as : gender, age, surgical trauma, smoking, surgeon`s inexperience and use of oral contraceptives.<sup>6</sup>

Varies etiologies like Birn`s fibrinolytic theory<sup>7</sup> and bacterial theory<sup>8</sup> are cited for AO and varies pharmacological agents are introduced and studied for prevention of AO such as

CHX in forms of gel<sup>9</sup> and mouthwash<sup>10</sup>, use of topical<sup>11</sup> and systemic antibiotics.<sup>12</sup> Biotene mouthwash (Laclede, Inc-USA) is an antibacterial mouthwash. it is shown that use of this mouthwash can reduce the side effects of post extraction xerostomia and halitosis.<sup>13</sup> It contains an enzyme complex similar to enzymatic complex of oral cavity such as lysozym, lactoferrin and lactoperoxidase.<sup>13</sup> Use of this mouthwash may decrease bacterial load of oral cavity and decrease the incidence of AO. The aim of this study is to evaluate the effect of biotene mouthwash on the prevention of AO after extraction of permanent mandibular first molar teeth.

### Methods and materials

This clinical trial is a randomized double blind prospective study which carried out in Tabriz dental faculty at university of Tabriz medical sciences and in the oral and maxillofacial center. Inclusion criteria include following: age range beyond 18 years, not using other types of mouthwashes, antibiotic one month before extraction, NSAIDS and narcotics one week before extraction, not having systemic uncontrolled disease like uncontrolled diabetes, immunosuppression, using oral contraceptives.

Exclusion criteria are: non fulfillment of one or all of the inclusion criteria, trauma to alveolous in the form of alveolar fracture or soft tissue laceration during extraction.

All of the patients who participated in this study gave their informed consent. The study was approved by the ethics Committee of Tabriz medical sciences. This was a single examiner blinded trial. Blinding was achieved by using a blinded dental examiner (oral and maxillofacial surgeon) qualified to take clinical diagnosis of dry socket and *separate* from the treating dental student. The blinded examiner collected all the clinical diagnosis of dry socket at baseline (screening visit) and second visit in third postoperative day and was unaware of subject allocation and blinded to randomization until the second visit in third postoperative day. Upon entering the study the subjects were assigned to binders with an individual identification number. Each binder had a sealed envelope which randomized the treatment allocation. 400 subjects were randomized according to a computer generated pseudo-random code using the method of random permuted blocks to either test or control group. The clinicians were not aware of the randomization sequence.

Patients randomly divided into case and control groups. Each group contains 200 patients. The patients underwent procedure under local anesthesia, lidocaine 2% with epinephrine 1/80000 (persocaine-E Darou Pakhsh). Mandibular first molar teeth underwent anesthesia by inferior alveolar nerve block technique. Teeth extracted atraumatically by undergraduate fifth year dental students and after extraction of teeth, they gave patients postoperative instructions. In mouthwash group they asked them to pick up 15 cc of Biotene mouthwash by suction swab and use it two times a day for one week. In the control group the patients follow the same instructions and use normal saline placebo instead of Biotene mouthwash in the same manner.

Data analyzed by the surgeon In the third postoperative day all the patients recalled to unit to evaluate the extraction site. Diagnosis of AO was confirmed following these signs and symptoms. Disintegration of clot in the extraction socket, moderate to severe pain in the alveolus, halitosis, absence of swelling and erythema in the area.

Data were analyzed using spss for windows xp (version 16, spss Inc, Chicago, il, usa) statistical software. Descriptive statistics and bivariate data Multiple binary logistic regression was used to test for the significance of associations between selected variables analysis, chi-square for comparison of frequencies.

## Results

A total of 389 patients participated in this study. 192 was in the case group and 197 patients was in the control group. The average age was 52.5 years old. 237 patients were female and 152 were male. 128 patients were smokers and 261 were non smoker. There was no statistically significant association between the development of dry socket and patients age, sex.

8 patients from mouthwash group and 3 patients from normal saline group were excluded from the study because they didn't attend in recall period. In the case group 6(3.1%) of AO was found while in the control group 17(8.6%) of AO was found. The reduction in the incidence of AO in case group was statistically significant in comparison with control group,  $p=0.03$ ,  $p<0.05$  for fisher's exact test (Chi-square test). 128 patients were smokers (58 patients in the case and 70 in the control group. Incidence of AO in smokers group was higher

than nonsmokers group. smoking was a risk factor that has significant relation to increase rate of AO,  $p=0.235$ ,  $p<0.05$ .

**Table 1-Data on age, gender, smoking, and AO incidence in two groups**

\*  $p=0.03$ ,  $p<0.05$  for fisher's exact test (Chi-square test).

	Mouth wash	sterile saline
	group n=192	group n=197
Age, mean (yr)	52	51
Gender		
Female, n (%)	115 (59.9)	122 (61.9)
Male, n (%)	77 (40.1)	75 (38.1)
Smoker		
Yes, n (%)	58 (30.2)	70 (35.5)
No, n (%)	134 (69.5)	127 (64.5)
Alveolar osteitis *		
Yes, n (%)	6 (3.1)	17 (8.6)
No, n (%)	186 (96.9)	180 (91.4)

## Discussion

In this study permanent mandibular first molar teeth were selected. With the respect that the incidence of AO in mandible is higher than maxilla and in mandibular molars is 10 times higher than in maxilla<sup>4</sup>, we select mandibular first molar teeth for extraction. Generally two main theories are identified in relation to etiology of AO. Birn's fibrinolytic theory<sup>7</sup> and bacterial theory. In spite of the fact that conclusive etiology of AO is not expressed, it seems that both of these theories included in the incidence of AO. In regard to antibacterial agents of Biotene mouthwash such as lactoferrin, lactoperoxidase and glucose oxidase, It seems that the reduction in the incidence of AO can be due to reduction in the bacterial load of oral cavity and also reduction in fibrinolytic producing bacteria like *treponema denticola*<sup>4</sup>. the only study regarding Biotene mouthwash carried out by warde P et al<sup>14</sup>, assessed effect of Biotene mouthwash and toothpaste on signs and symptoms of postradiation xerostomia. In this clinical randomized trial they found significant difference in reduction of pain, improvement of signs of xerostomia in mouthwash group comparing to normal saline group. It seems that no study carried out regarding the effect of biotene mouthwash on the incidence of AO. So the result of this study can not be compared to studies that uses other mouthwashes. For example Arta and Eskandarnejadin in 2007 compare topical application of Metronidazole gel 0.25% in the incidence of alveolar osteitis after mandibular third molar surgery and concluded that topical application of metronidazole gel 0.25% with good oral hygiene can significantly reduce the incidence of dry socket and also reduce pain in second postoperative day<sup>15</sup>.

Mesgharzade and Helli in 2005 evaluated the effect of Irsha anti plaque mouthwash (shafa Co, Iran) on prevention of AO and found significant reduction in the incidence of AO in

mouthwash group in comparison with control group (normal saline)<sup>16</sup>.

Varies studies have confirmed that CHX mouthwash can be effective in reduction of prevalence of AO.<sup>9,10,12</sup> The preparation contains 12% alcohol, which may be of concern to clinicians and patients because regular use of alcohol increases the risk of oropharyngeal cancer.<sup>17</sup> So using other types of mouthwashes particularly alcohol free mouthwashes like Biotene mouthwash can be good alternative .however we have not assessed the side effects of mouthwash in our study. Smoking has been shown to reduce neutrophil chemotaxis and phagocytosis, and impede production of immunoglobulin.<sup>4</sup> Removal of the clot through suction and negative pressure during smoke inhalation has also been suggested.<sup>3</sup> In this study smoking was a risk factors that has a significant relation to increased rate of AO. This relation between smoking and AO is confirmed by other studies.<sup>18</sup> However Hedstrom et al in 2004 didn't find significant relationship between smoking and AO.<sup>19</sup>

In this study trauma to extraction site was excluded from the study. Birn stated that the increased fibrinolytic activity in dry socket is elicited by enhanced liberation of tissue activators from the alveolar bone consequent to trauma or infection.<sup>19</sup> . Birn relates damage to cells and alveolar bone to release of tissue activators of fibrinolytic activity (factor XII or Hage-man factor, urokinase from blood, tissue, and endothelial plasminogen activators). Nitzan proposed that the plasmin described by Birn was not activated by tissue activators but was an independent agent produced by bacteria. *Treponema denticola* as the producer of plasmin-like products was known to multiply and lyses blood clots without producing the clinical symptoms and characteristic of infection, such as redness, swelling, or pus formation, and had been previously isolated from dry sockets.<sup>19</sup> In regard to antibacterial agents of Biotene mouthwash such as lactoferrin, lactoperoxidase and glucose oxidase, It seems that the reduction in the incidence of AO can be due to reduction in the bacterial load of oral cavity and also reduction in fibrinolytic producing bacteria like *treponema denticola*<sup>4</sup> and has not any effect in trauma pathway- inducing dry socket. So inclusion of trauma as a risk factor in this study can increase the incidence of dry socket and make a bias in our study. So trauma excluded from study. For the same reasons some other factors such as high number of cartilages excluded from study.

It was concluded that the use of biotene mouthwash can be effective in reducing the incidence of dry socket after extraction of mandibular first molar teeth.

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