

ABSTRACT

Gender, smoking status, and oral contraceptive use may all increase the risk for development of alveolar osteitis (dry socket), following the extraction of impacted mandibular third molars. In a randomized, double blind, placebo controlled, parallel group study (n = 271) conducted to evaluate Peridex® (0.12% chlorhexidine gluconate) versus placebo oral rinse, prophylactic use of the chlorhexidine mouthrinse reduced the subject level incidence of alveolar osteitis by approximately 38% with a corresponding odds ratio (OR) of 1.87. Statistical analyses were performed to assess the relationship of potential risk factors in the development of alveolar osteitis. Specifically, logistic regression was used to model risk factors and their interactions with treatment response. In this model, smoking was related to a slight increase in the incidence of alveolar osteitis (OR = 1.20), although this difference was not statistically significant (p = 0.33). Similarly, the observed incidence of alveolar osteitis for females not using oral contraceptives was directionally higher, although not statistically significant, when compared to that of males (OR = 1.18, p = 0.64). Among females, oral contraceptive use was related to a significant increase in the incidence of alveolar osteitis (OR = 1.92, p = 0.035). Importantly, study results indicate that the effect of the chlorhexidine therapy relative to placebo therapy on alveolar osteitis incidence was consistent across gender, smoking status, and oral contraceptive use. **While this study showed oral contraceptive use in females to be a risk factor for the development of alveolar osteitis, prophylactic use of Peridex® mouthrinse resulted in a significant reduction in alveolar osteitis incidence irrespective of risk factor status.**

INTRODUCTION

Potential patient related risk factors for alveolar osteitis include smoking and oral contraceptive use. Smoking has been reported to increase the risk for alveolar osteitis following extraction of impacted mandibular third molars by more than 300%. In contrast, other studies have failed to demonstrate a difference in the incidence of alveolar osteitis between smokers and non-smokers.

Oral contraceptive use in females has also been reported to increase the risk of alveolar osteitis by two to three fold, when compared to males. However, other studies have reported the incidence of alveolar osteitis between females using oral contraceptives and those not using oral contraceptives to be similar. The data examining smoking and oral contraceptive use in subjects developing alveolar osteitis, while somewhat equivocal, suggest that they are risk factors.

OBJECTIVE

In this study, putative risk factors (smoking and oral contraceptive use) for the development of alveolar osteitis and their impact on the efficacy of a 0.12% chlorhexidine gluconate mouthrinse were assessed.

MATERIALS AND METHODS

This study was a randomized, double-blind, placebo controlled, parallel group, single center, clinical trial involving 271 evaluable healthy adult (≥ 18 years of age) subjects with impacted mandibular third molars in need of extraction. Subjects self-reported current smoking habits and oral contraceptive use at the beginning of the study.

The two treatment groups consisted of a 0.12% chlorhexidine gluconate (Peridex®) oral rinse or a placebo rinse without chlorhexidine gluconate. Treatment groups were balanced according to gender, current smoking habits, and the number of impacted mandibular third molars to be extracted. Subjects performed unsupervised oral rinsing twice a day for 1 week prior to and 1 week following the surgery with their assigned rinse. This regimen included a supervised pre-surgical rinse immediately prior to the surgery. All rinsings were 15 ml in volume and 30 seconds in duration.

Surgeries were performed by staff oral surgeons, staff general dentists, and general dentistry residents using a consistent surgical technique. Following surgery, subjects experiencing and reporting symptoms were seen for clinical evaluation. All subjects were contacted by telephone 3 to 4 days post-operatively to evaluate postoperative status and reinforce product compliance. Routine postoperative evaluation of all subjects regardless of symptomatology was performed on the seventh day following the extraction(s). At all postoperative clinical appointments, diagnosis for alveolar osteitis was assessed based on the presence of both subjective (persistent or increasing postoperative pain) and clinical findings (loss or necrosis of blood clot or exposed alveolar bone). Subjects who presented with one or two mandibular third molar sockets with alveolar osteitis were considered positive alveolar osteitis cases.

Logistic regression was used to assess the status of gender, oral contraceptive use and smoking status as risk factors for alveolar osteitis. The initial regression model included terms for gender, oral contraceptive use (yes/no), smoking status (yes/no), treatment and all two-way interactions with treatment. Interaction terms were included to assess the consistency of treatment effect across potential risk factors. Based on the findings of the first model, a second model was run including only main effects. Tests for effects of smoking and oral contraceptive use were one-sided with the alternative being an increased risk. All other tests were two-sided.

RESULTS

Subjects were well balanced between treatment groups with respect to baseline demographics and number and degree impaction(s) (Tables 1 & 2). None of the interactions with treatment were statistically significant (all p-values were greater than 0.30). This indicates that the statistically significant treatment effect seen in the overall study results (Odds Ratio=1.87, p<0.05) was relatively consistent across risk factors.

Of the 170 evaluable female subjects, 35% (59) were using oral contraceptives and 65% (111) were not. The subject based incidence of alveolar osteitis was 35.6% in females using oral contraceptives versus 21.6% in females not using oral contraceptives, representing a 65% increase in alveolar osteitis in females using oral contraceptives. The corresponding odds ratio was 1.92 ($p = 0.035$). The observed incidence of alveolar osteitis for females not using oral contraceptives was directionally higher, although not statistically significant, when compared to that of males (OR = 1.18, $p = 0.64$), (Table 3).

Smoking was not related to a significant increase in the incidence of alveolar osteitis (OR = 1.20, $p = 0.33$), (Table 3).

Table 1. Subject Demographics

Treatment	(n)	Male	Female	Age (Mean)	Age (Min-Max)
Chlorhexidine	136	51	85	22.2	18 - 50
Placebo	135	50	85	22.4	18 - 54
Overall	271	101	170	22.3	18 - 54

Table 2. Characterization of Third Molar Extractions by Treatment

	Chlorhexidine	Placebo
Number of Extractions		
1	33	30
2	103	105
Status of Impaction		
Soft Tissue	25	26
Partial Bony	190	185
Full Bony	24	29

Table 3. Risk Factors for Alveolar Osteitis (AO)

	N (Subjects)	AO (#)	AO (%)	Odds Ratio ^a	P-Value
Birth Control					
No, Male	101	20	19.8%		
No, Female	111	24	21.6%	1.18 ^b	0.640
Yes, Female	59	21	35.6%	1.92 ^c	0.035
Smoking					
No	230	55	23.9%		
Yes	41	10	24.4%	1.20	0.330

^aadjusted for all other factors
^brelative to males
^crelative to females not using oral contraceptives

CONCLUSION

- Smoking was not related to a significant increase in the incidence of alveolar osteitis.
- Oral contraceptive use in females was found to be a risk factor for the development of alveolar osteitis.
- Prophylactic use of Peridex[®] mouthrinse resulted in a significant reduction in alveolar osteitis incidence irrespective of risk factor status.