

Effects of sea salt based oral rinse on *Streptococcus mutans* level and oral ecology in gingivitis subjects with high caries susceptibility: A randomized clinical study

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*Article History:

Received: 02/04/2018

Revised: 21/04/2018

Accepted: 21/04/2018

DOI: <https://doi.org/10.7439/ijbar.v9i4.4730>

Abstract

Background: The etiologic role of a pathogenic dental plaque biofilm in the development of gingivitis and dental caries is well documented. This study evaluates the rationale for incorporating sea salt based mouth rinse into a daily oral hygiene regimen along with mechanical plaque control methods on gingival inflammation and caries susceptibility level in mild to moderate gingivitis patients.

Methods: A prospective, double-blinded, randomized parallel-group controlled study involving 40 subjects was conducted to assess efficacy and safety. Subjects were randomized to receive either the study rinse (H2Ocean) or a water-only preparation. The oral hygiene index (OHI) and *S. Mutans* Level were measured at baseline and at the end of the study period.

Results: Sea salt mouth rinse was significantly better than the control, with respect to both the change in OHI score by 28.89% and *S. mutans* level by 35%. No adverse effects were noted in any of the study groups.

Conclusion: Sea Salt mouth rinse is a safe and effective treatment for preventing the development of gingival inflammation and *S. mutans* level in mild to moderate gingivitis population. Further research is needed to evaluate its long-term effects.

Keywords: Sea Salt, Plaque, *S. mutans*, Dental Caries.

1. Introduction

Dental caries and periodontal disease have historically been considered the most important global oral health burdens. Dental caries is still a major health problem in most industrialized countries as it affects 60–90% of school-aged children and the vast majority of adults. Worldwide, the prevalence of dental caries among adults is high as the disease affects nearly 100% of the population in most of countries. [1-3]

Although overall improvements in oral health have occurred in many developed countries over the last 30 years, oral health inequalities have emerged as a major public health challenge because lower income and socially disadvantaged groups experience disproportionately high levels of oral disease. Oral diseases are however largely preventable. The challenge is to create the opportunity and

conditions to enable individuals and communities to enjoy good oral health.[1]

During the last 50 years advances in the oral health sciences and in technology, have not only increased our understanding of the nature of these diseases and their causes, but also introduced and tested new approaches to their prevention. [4]

The prevention of dental caries and periodontal diseases is targeted at the control of dental plaque. In this context, chemical agents could represent a valuable complement to mechanical plaque control. The active agents should prevent biofilm formation without affecting the biological equilibrium within the oral cavity. [5] Several chemical plaque control agents have been evaluated for their effectiveness on supragingival plaque including bisbiguinides, essential oils, enzymes, and even herbal

extract. Some of these substances have been associated with various side effects incapacitating their long-term use, so new formulation of equal efficacy and fewer side effects are required to be evaluated.

Hence, aim of the present study was to evaluate the efficacy of sea salt based oral rinse (H2Ocean) with conventional oral hygiene measure in gingivitis patients in terms of clinical parameter i.e. Oral Hygiene Index and microbiological parameters i.e. *S. mutans* Level.

2. Material and Methods

The study was done at Department of Periodontology, Pravara Institute of Medical Sciences, Loni, Maharashtra, India. It was a randomized, double blinded placebo controlled clinical study. After an informed consent, a total 40 gingivitis patients with poor oral hygiene between the ages of 18 to 55 years were enrolled in the study under fixed inclusion and exclusion criteria as listed below.

2.1 Inclusion Criteria

- 1) Adult population (18 Years & Above).
- 2) Presence of all lower arch (Mandible) anterior teeth.
- 3) Willing to participate voluntarily in the study.
- 4) The patient should have a minimum of 20 sound permanent teeth with minimum of 5 teeth to be present in each arch quadrant
- 5) Systematically healthy subjects.
- 6) Gingivitis subjects with poor oral hygiene.
- 7) Salivary *S. mutans* colonization with moderate to severe Colony Forming Units (CFUs).

2.2 Exclusion Criteria

- 1) Presence of any systemic neurological disorder (e.g., epilepsy or schizophrenia)
- 2) Presence of a disease with possible effects on the immune system.
- 3) Patient who have received antibiotics or NSAIDS (like Ibuprofen) in past 9-11 weeks and other medicines which could alter the oral microbial flora were excluded.
- 4) Patient on active treatment lined up any nearby medical procedure or surgery
- 5) Patients currently on periodontal treatment/oral surgical treatment.
- 6) Pregnant and lactating mother.
- 7) No active chemotherapy/radiation
- 8) Inability to use mouthwash
- 9) Subjects not willing to participate in the study.
- 10) Patients who smokes or consumes tobacco in any form.
- 11) Patients suffering with Diabetes, Arthritis any type of heart disease (MI, CHD, etc)
- 12) Female patient using intrauterine birth control devices or birth control pills.
- 13) Obese Individuals (30 & above range as per WHO BMI cut off for weight categories for Asians).

Subjects that meet the salivary *S. mutans* colonization with moderate to severe Colony Forming Units (CFUs) were only recruited to the study i.e. subjects with moderate to high caries susceptibility. The measurements recorded in the study were: Simplified Oral Hygiene Index (Greene and Vermillion) and *Streptococcus mutans* (*S. mutans*) level as illustrated in Table 1 and 2.

Table 1: Oral Hygiene Index (OHI) Inference

OHI-Score	Evaluation
0.0 to 1.2	Good
1.3 to 3.0	Fair
3.1 to 6.0	Poor

Table 2: Categorization of Colony Forming Units (CFU): Caries Risk Susceptibility

Score	CFU/ML	Caries Susceptibility
Class 0	< 10 ³	Negligible
Class 1	10 ³ -10 ⁴	Low
Class 2	10 ⁴ -10 ⁵	Moderate
Class 3	>10 ⁵	High

Patients received a verbal description about the clinical protocol to be followed in this clinical study. The subjects selected for the study were educated regarding the study being carried out and informed consent was obtained. Patients were initially screened for their gingival index (Loe and Silness) and 52 subjects having a Gingival Index score between 2 and 3 were selected. Salivary samples were taken from the selected 52 subjects for measuring the *Streptococcus Mutans Level* and 48 subjects who fall under the Class 2 (CFU Level 10⁴-10⁵) or Class 3 (CFU >10⁵) were only recruited for further continuation to the study. During the recruitment process 04 subjects further declined to quit the study and finally 44 subjects were selected for randomization. Also, categorizations of patients were done randomly, with oral products/regime be followed complete oral health assessment. Subjects were assigned to either Group A or Group B based on computer generated random allocation system as illustrated in Table 3.

Table 3: Subjects Grouped Under Study

Groups	Clinical protocol
Group A	Comprised of 20 gingivitis patients with poor oral hygiene. Complete prophylaxis followed by conventional oral hygiene measures and assigned with sea salt oral rinse i.e. H2Ocean Mouth rinse.
Group B	Comprised of 20 gingivitis patients with poor oral hygiene. Complete prophylaxis followed by conventional oral hygiene measures and assigned with placebo oral rinse i.e. distilled water with no active component.

During study 02 subjects voluntarily quit the study after 2.5 months and 02 subjects failed to follow the study protocol instruction and so been excluded from the evaluation criteria. Finally, the analysis of 40 subjects with

20 subjects under each category was assessed. Base line clinical parameter i.e. Oral Hygiene Index (OHI) and microbiology measurements (*S. mutans*) were recorded for both the groups at baseline. Recall visits was scheduled for all the subjects at 3rd month and all measurements were recorded again. The results of the study were subjected to statistical analysis.

3. Results

The age and sex wise distribution of subjects in the study were illustrated in Figure 1. The mean value of oral hygiene index at baseline in Group A was 3.54 ± 0.27 and in Group B was 3.60 ± 0.27 . By applying student unpaired “t” test the value of t was 0.70 with p value is 0.4865 i.e. $p > 0.05$ i.e. no significant difference was there at base line when we compare the oral hygiene index in group A and B. These results proved that at the time of recruitment of subjects i.e. at the base line the level of dental calculus and debris deposition was same among all the subjects under both the groups i.e. all the subjects had same clinical picture. At the base line all the subjects (100%) under both the group A and B fall under Class 2 and Class 3 of Salivary *S. mutans* Level as this was one of the inclusion criteria for the recruitment of subjects. These figures proved that all the subjects were equally susceptible to moderate to high caries risk at time of initiation of study.

The mean value of oral hygiene index at 3 Months in Group A was 1.17 ± 0.23 i.e. 66.94% improvement in oral hygiene and in Group B was 2.23 ± 0.46 i.e. 38.05% improvement in oral hygiene. By applying student unpaired “t” test the value of t was 9.03 with p value < 0.05 i.e. significant difference was there at 3 Months when we compare the oral hygiene index in group A and B. These statistics showed the potential benefits of sea salt based Oral Rinse (H2 Ocean) for the control of deposition of calculus and debris and thus maintained overall oral hygiene at good level by 28.89% as compared to control group who had fair oral hygiene only. For Salivary *S. mutans* level, In Group A only 03 subjects fall under Class 2 and 02 subjects under Class 3 i.e. 25% only where as in Group B 08 subjects fall under Class 2 and 04 subjects under Class 3 i.e. 60%. There is a 35% more subject falling under moderate to high caries risk susceptible zone in Group B as compared to Group A. This signifies the importance of sea salt based Oral Rinse (H2Ocean) as subjects under Group A were more preventive to dental caries.

4. Discussion

Dental biofilm forms via an ordered sequence of events, resulting in structured and functionally organized species rich microbial community and modern molecular biological techniques have identified about 1000 different bacterial species in the dental biofilm, twice as many as

be cultured. [6] Association of periodontal infection with organ systems like cardiovascular system, endocrine system, reproductive system and respiratory system makes periodontal infection a complex multiphase disease. [7]

Mechanical plaque control is the mainstay for prevention of oral diseases, but it requires patient cooperation and motivation; therefore, chemical plaque control agents act as useful adjuvants for achieving the desired results. The combination of mechanical and chemical plaque control measures by self-care and professionals is the most efficient method for prevention and control of periodontal diseases as well as dental caries. Hence, it is imperative for the clinicians to update their knowledge in recent advances in newer effective antiplaque agents for management of plaque biofilm-associated diseases.

The present study involved the use of a mouth rinse (H2Ocean), consisting of sea salt, the antimicrobial enzyme lysozyme, and xylitol, a polyalcohol commonly used as a non-sugar sweetener, to understand its effect on oral hygiene index and *S. mutans* level in mild to moderate gingivitis patients with moderate to high caries risk susceptibility.

The effects of rinsing the mouth with sea salt twice a day for a period of 90 days on plaque biofilm and *S. mutans* level is shown in Figure 2-3. There was statistically significant difference in the overall reduction from baseline in relation to the mean oral hygiene index scores and the *S. mutans* level when compared with the control group. This study advocated that nature derived sea salt based oral rinse are effective way to maintain gingival health and prevent tooth decay.

Results of this study are consistent with previous studies carried out investigating the effect of rinsing with sea salt-based mouth rinse. [8, 9] Michel *et al* [8] evaluated the effectiveness of sea salt rinse in street children of Manila, the Philippines, affected by mild-to-severe forms of periodontal disease. Most of these children were victims of abuse and neglect and were poor. The authors noted a decrease in gingival and periodontal indices at the end of the trial period during which each child rinsed with a solution containing 2.5 grams of sea salt in 20 ml of water. Mani *et al* [9] investigated thirty adults with gingivitis attending a dental college in the state of Maharashtra, India and reported a significant reduction in all clinical parameters in subjects rinsing with sea salt for a period of three months compared to those who did not use the rinse. However, one study conducted by Hoover J *et al* [10] reported that rinsing with sea salt for thirty days did not affect the gingival and plaque scores in a group of young adults. This may be contributed to the facts that study had comparatively small sample size, the relatively short trial period, and possibly compliance issues within the test subjects.

Figure 1: Study Demographics

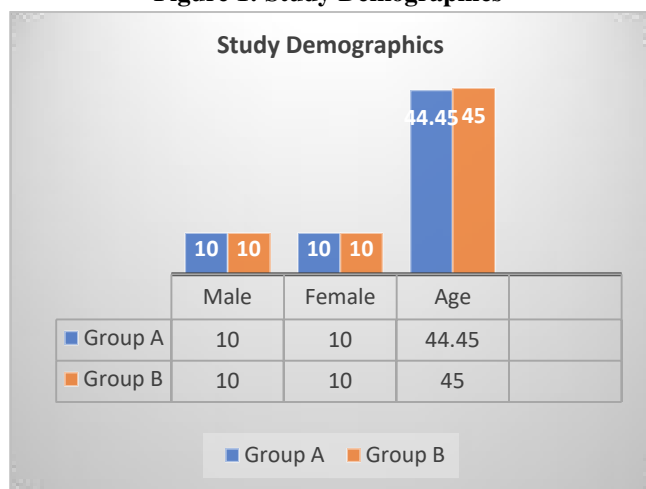


Figure 2: Group A Vs B: Oral Hygiene Index

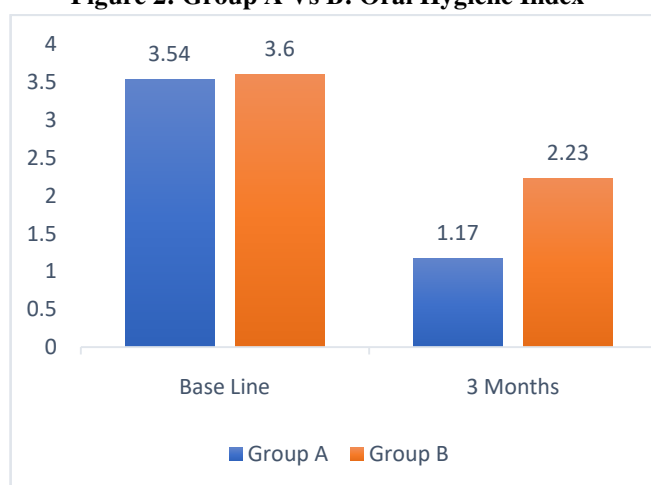
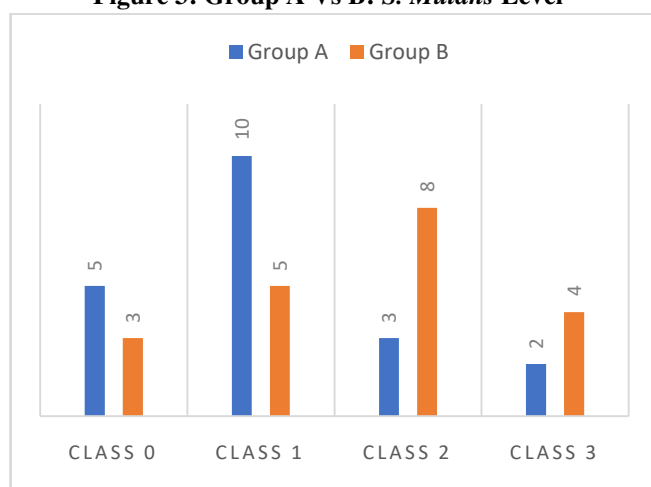


Figure 3: Group A Vs B: S. Mutans Level



5. Conclusion

Oral health is adversely affected when condition of poor oral hygiene with higher level of *S. Mutans* is present in the oral cavity. Professional monitoring and standard oral hygiene plays an important role in reducing the oral bio burden by removing debris, plaque and calculus in cases of gingivitis associated poor oral hygiene. Standard preventive and regular oral hygiene when supplemented with sea salt based Oral Rinse (H2Ocean) in gingivitis subjects significantly improves the oral hygiene and reduces the caries susceptibility risk even after 3 months of time. However, long term multi-centric clinical trial are needed further to establish the effects and potential outcome for sea salt based Oral Rinse (H2Ocean) under different periodontal conditions.

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