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RESEARCH ARTICLE

A COMPARATIVE EVALUATION OF ANTIPLAQUE AND ANTIGINGIVITIS EFFECT OF MOUTH RINSE CONTAINING 0.05% SODIUM HYPOCHLORITE – A CLINICAL TRIAL

Dr.Nilkanth Mhaske, *Dr. Supriya S. Mhaske, Dr.Neelima Rajhans, Dr.Sharvari T. Tawale, Dr.Nikesh Moolya, Dr.Radhika Kumar and Dr.Dhanesh sabale

Department of Periodontics, Y.C.M.M. and R.D.F's Dental College Ahmednagar, Maharashtra, India

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ABSTRACT

Introduction: As we know it is difficult to remove plaque on all surfaces with the help of mechanical plaque control agents alone, hence there is need for chemical plaque control as an adjunct to mechanical plaque control methods. Unfortunately in low-income individuals who are unable to afford dental self-care products and thus research is required to provide efficacious and low cost plaque control agent.

Aim: The aim of this study was to evaluate the effect of 0.05% sodium hypochlorite mouthwash on supragingival biofilm and gingival inflammation and compare its effects with 0.2% chlorhexidine mouthwash.

Material and Methods: A total of 30 patients with gingivitis were be selected according to the inclusion and exclusion criteria and allocated randomly to three groups containing 10 patients each. At the baseline visit all the patients will received full mouth scaling and will be advised to rinse twice daily with distilled water in group 1, 0.2% chlorhexidine in group 2 and 0.05% sodium hypochlorite mouthwash in group 3 for 21 days. Clinical parameters such as plaque index, gingival index, bleeding on probing were assessed at various intervals.

Results: At the day 21the average plaque index in increased to 1.19 water rinse group and to 0.22 in the chlorhexidine group, and 0.61 in the sodium hypochlorite group.

Average loe and sillness gingival index had decreased to 0.894 in the water rinse group and to 0.066 in the chlorhexidine group, and to 0.24 in the sodium hypochlorite rinse group.

And the average percentage of bleeding on probing had decreased to 66.3% in the water rinse group, and to 41.07% in the chlorhexidine group and to 56.7% in the sodium hypochlorite rinse group. Differences were statistically significant compared to water group.

Conclusion: Dilute sodium hypochlorite resulted in significant reductions in gingival inflammation and supragingival biofilm accumulation. Dilute sodium hypochlorite may represent an efficacious, safe and affordable antimicrobial agent in the prevention and treatment of periodontal disease.

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INTRODUCTION

Gingival and periodontal diseases having worldwide distribution are considered an important health issue in developing and developed countries (Petersen and Ogawa, 2000). Gingivitis is defined as inflammation of marginal gingiva with clinical characteristics of redness and swelling along with reversible destruction of collagen (Mariotti, 1999). Dental plaque plays a paramount role in etiology of various gingival and periodontal diseases and existence of direct relationship between presence of dental plaque and development of gingivitis has been proved (Powell, 1965).

Corresponding author: Dr. Supriya S. Mhaske,
Department Of Periodontics, Y.C.M.M. and R.D.F's Dental College Ahmednagar, Maharashtra, India.

For successful treatment and prevention of periodontal diseases effective plaque control procedures is of utmost importance. Combination of mechanical and chemical plaque control methods have been used (Brecx, 2000). Scaling and root planing have long represented the reference standard in periodontal treatment. Plaque removal in accessible areas is difficult by mechanical plaque control methods alone, and hence need of adjunctive chemical plaque control methods are advisable (Van Der Weijden and Hioe, 2005). Although number of anti microbial agents have been used to control plaque and gingivitis. Chlorhexidine is considered as gold standard mouthwash among the (CHX) Chlorhexidine binds strongly to tissue, and showing broad bactericidal and bacteriostatic spectrum of action, but has several adverse effects that are altered taste sensation, mucosal irritation,

calculus formation, high cost (Wu, 2000). Therefore research has begun to find out effective antimicrobial agent, with less adverse effect and which is economical one. Sodium hypochlorite is well known chlorine based antimicrobial agent. Sodium hypochlorite occurs naturally in activated human neutrophils and macrophages, and plays an important antimicrobial role in the innate immunity system (Gray *et al.,* 2013). It does not evoke allergic reactions, is not a mutagen, carcinogen or teratogen, and has a century-long safety record. Undissociated hypochlorous acid is active component in sodium hypochlorite solution. The mechanism of action of sodium hypochlorite involves the inhibition of key enzymatic reactions within the microbial cell, protein denaturation, and inactivation of nucleic acid. Sodium hypochlorite interacts with infectious agents and host cell through main reaction: saponification, neutralization, chloramination (Boddie *et al.,* 2000). Sodium hypochlorite has been used in endodontics as root canal disinfectant at concentration 1to 6 % for a century and less no of periodontal studies have been discussed on clinical effectiveness of sodium hypochlorite. The American dental association council on dental therapeutics has designated 0.1%Sodium hypochlorite a "mild antiseptic mouth rinse" and suggested its use for direct application to mucous membranes (American Dental Association, 1984). Sodium hypochlorite have ability to inactivate pathogenic bacteria at lowest concentration 0.01% (Rutala *et al.,* 1998). To know the effectiveness of dilute sodium hypochlorite as a mouth rinse in the treatment of periodontal disease required further study. The aim of the present study was to evaluate and compare the effects of 0.05% sodium hypochlorite on supragingival and biofilm and gingival inflammation.

MATERIALS AND METHODS

A total 30 subjects were selected from Department of Periodontology Of Yashwantrao Chavan Memorial Medical Medical And Rural Developement Foundations Dental College Ahmednagar. Subjects included with inclusion criteria– healthy subjects with moderate to severe gingivitis, were required to have at least 20 natural teeth, age 18 to 35 years. Exclusion criteria were the use of systemic or topical antibiotic therapy within 6 months prior to the initiation of the study, the presence of systemic diseases such as diabetes, clotting disorder or human immunodeficiency virus (HIV) infection, acute necrotizing gingival disease, immunosuppressive drug therapy or use of medications producing gingival enlargement, smoking of > 10cigarettes ⁄ day, reduced salivary flow, current orthodontic treatment, or failure to consent to participate in the study. The study was conducted according to the protocol outlined by ethical committee of YCMM AND RDF'S dental college Ahmednagar.

Sodium hypochlorite Formulation = 0.05%

0.05 working solution =5 ml 10%naocl solution +995 ml distilled water. A 10% (101g ⁄ l) sodium hypochlorite stock solution was purchased from a chemical drugstore. A fresh sodium hypochlorite working solution was made every 24 hours and stored in dark disposable bottles.

Study design

This study was conducted as a randomized, controlled, single-blinded study, clinical trial in parallel groups according to the consort criteria (Altman *et al.,* 2011).

The study included 30 subjects with gingivitis, were selected according to the inclusion and exclusion criteria and allocated randomly to three groups containing 10 subjects, each (Group 1, Group 2 and Group 3). At the baseline visit all the subjects received full mouth supra and subgingival scaling as well as professional polishing with a rubber cup and dentifrice and were advised to rinse twice daily with 15 ml of distilled water in Group 1, 15 ml of 0.2% chlorhexidine in Group 2 and 15 ml of fresh solution 0.05% sodium hypochlorite mouthwash in Group 3 for 21 days . Clinical outcomes were assessed by using a Loe and Silness gingival index (L&SGI) (Loe, 1963), Quigley–Hein plaque index (QHPI) as modified by Turesky *et al.,* 1970 to record plaque index plaksee disclosing agent used to disclose plaque which contains erythrosine. To determine oral hygiene status, the presence or absence of bleeding on probing and visual signs of inflammation, and adverse events were evaluated by questionnaire, visual examination and clinical photographs. Clinical measurements and photographs were obtained at baseline (after scaling), every 7 days, and at the termination of the study on day 21. Measurements were obtained by one Examiner, who was masked to the mouth rinse used by the subjects.

Patient instruction

The study subjects were instructed to do oral hygiene measures for 21 days. Each group was randomly assigned ten subjects. Group 1 rinsing with distilled water, in Group 2 with chlorhexidine 0.2% and Group 3 rinsing with 0.05% sodium hypochlorite. Subjects were instructed to rinse with 15 ml of the assigned study solution, twice daily for 60 s. They were instructed not to rinse their mouth with water or drink anything or eat food for half an hour. Plaque index (QHPI) and L&SGI and the percentage of sites that bleeding on probing (BOP) were recorded at baseline (after scaling), and after 21 days of the study. Clinical photographs were taken at baseline, after 7 days and after 21days. To monitor adverse events on hard and soft tissue were evaluated by questionnaire, visual examination and clinical photographs.

Statistical analysis

The student's paired't' test was used to comparison of mean and SD values of all plaque index, gingival index, and bleeding on probing (%) in water, chlorhexidine and sodium hypochlorite group at baseline, after 7 days and after 21st days. ($p<0.01$) The tukey-kramer multiple comparison test was used to compare variation among mean values of plaque index, gingival index, and BOP. P values of ($p<0.01$) were considered to indicate statistical significance.

RESULTS

30 subjects completed the study with average age of subjects was 26.5±8.5 Clinical parameters compare the index values of all plaque index, gingival index, and bleeding on probing (%) in water, chlorhexidine and sodium hypochlorite group at baseline (after scaling), after 7 days and after 21st days. Table 1 shows the findings of study at baseline (after scaling) data indicated no difference between three groups for plaque index, gingival index, & bleeding on probing. At baseline all subjects received oral prophylaxis hence staining and plaque were absent.

Table 1. Clinical index values at days 0 and 21 in subjects using a Distilled water, Chlorhexidine, and Sodium hypochlorite oral rinse

	Distilled water			Chlorhexidine			Sodium hypochlorite		
	Plaque Index	Gingival Index	BOP (%)	Plaque Index	Gingival Index	BOP (%)	Plaque Index	Gingival Index	BOP (%)
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
Baseline	0±0	1.48±0.24	87.43±2.1	0±0	1.49±0.19	89.00±3.1	0±0	1.51±0.24	90.9±2.14
After 21 days	1.19±0.12	0.894±0.17	66.3±4.5	0.22±0.10	0.066±0.12	41.07±2.03	0.61±0.22	0.24±0.14	56.70±2.10
'p' value	p<0.01,	p>0.01,	p<0.01,	p<0.01,	p<0.01,	p<0.01,	p<0.01,	p<0.01,	p<0.01,

Figure 1. Dental plaque and staining subjects rinsing with distilled water, 0.02% chlorhexidine, And 0.05% sodium hypochlorite. The plaque-disclosing dye used on day 21 was a plaksee

At the day 21the average plaque index in increased to 1.19 water rinse group and to 0.22 in the chlorhexidine group, and 0.61 in the sodium hypochlorite group. Average loe and sillness gingival index had decreased to 0.894 in the water rinse group and to 0.066 in the chlorhexidine group, and to 0.24 in the sodium hypochlorite rinse group. And the average percentage of bleeding on probing had decreased to 66.3% in the water rinse group, and to 41.07% in the chlorhexidine group and to 56.7% in the sodium hypochlorite rinse group. All differences were statistically significant. Intraoral hard and soft tissue examination done to revealed adverse effect of sodium hypochlorite.

DISCUSSION

The present study was randomized clinical trial and closely followed the study design of De nardo *et al.,* 2012 but involved with other comparative group. The study investigated the effect of 0.05% sodium hypochlorite mouthwash as an antiplaque and anti-gingivitis agent and compares its effects with 0.2% chlorhexidine mouthwash. Chlorhexidine gluconate constitutes an efficacious mouth rinse in periodontal health care, which often is designated "gold standard" of oral chemotherapeutics agents. It is relatively expensive one, and along with some adverse effects such as extrinsic brown-black staining of teeth, altered taste sensation, increased calculus formation, and it is generally considered unsuitable for long tern usage. There exist a need to develop easily available affordable, effective plaque control techniques for prevention and treatment of periodontal diseases. Sodium hypochlorite commonly known as "bleach" is widely accepted as being safe and effective antiseptic against bacteria, fungi and viruses (Slots, 2000). Hypochlorous acid oxidizes and disrupt the cell membrane, the cell wall and various macromolecules of microorganisms (Sandra, 2015). The remarkable findings of the study was 0.05% sodium hypochlorite considered as a effective antiplaque agent as compared with the water rinse Group. When inter-group comparison was done results indicated a statistically no significant difference between chlorhexidine and sodium hypochlorite but it was significant when control group was compared with chlorhexidine and sodium hypochlorite.

De Nardo *et al.* (2012) did randomized investigator blinded, clinical trial to evaluate the effect of 0.05% sodium hypochloride mouth rinse as a antiplaque and antigingivitis agent, in prison inmates. The study was designed as an experimental gingivitis study. At the end of 21 days study period of sodium hypochloride grouped showed 38% less gingivitis and 47% less plaque than the water control group. Differences between the groups were statistically significant for all variables (P=0.001). The authors reported that subject

showed less bad breath and cleaner mouth, in absence of concomitant tooth-brushing for 21 days. The light brown extrinsic tooth staining was observed in sodium hypochlorite group, stain was easily removed by professional scaling .no other adverse effects were noticed .in the present study patients also reported complains about weird taste like bleach and light brown stains on teeth.

Lobene *et al.* 1997 did the study was based on experimental gingivitis study model without concomitant tooth-brushing. Results were found 47% greater plaque reduction with sodium hypochlorite irrigation than with water rinsing. Study concluded that sodium hypochlorite exerts a unique anti-biofilm effect by loosening the attachment of microorganisms to solid surfaces; he suggested that tooth-brushing following a sodium hypochlorite rinse may further enhance plaque removal.

Galvan *et al.* 2014 did the randomized, single blinded, controlled clinical trial to evaluate the periodontal effects of 0.025% sodium hypochloride twice weekly mouth rinse .30 subjects with periodontitis having pocket depth of ≥6 mm. included in the study, who completed the baseline and 2 week protocol with a subset of 12 who completed the 3month part of study. At the end of study sodium hypochlorite exhibited increases in plaque free buccal surfaces of 94%(test) versus 29%(control), and in plaque free lingual surface 195%(test) versus 30%(control). No adverse effects were detected. The bleach group showed statistically significant decreases in subgingival proportion of fusobacteria and gram negative enteric rods. Study concluded that 0.25%. Sodium hypochlorite produced marked reduction in dental plaque level and bleeding on probing and it May constituents a promising new approach to treat periodontal disease.

Gonzalez *et al.* 2014 this study examined the ability of 0.25% sodium hypochlorite oral rinse, used twice-weekly for 3 mo, to convert gingival bleeding sites to non bleeding sites in periodontitis patients. Data utilized from cohort study by Galvan et al. Study concluded that 0.25% sodium hypochlorite oral rinsing twice weekly produced a significant reduction in bleeding on probing, even in deep unscaled pockets. Sodium hypochlorite constitutes a valuable antiseptic in periodontal self-care.

According to current commercial mouth rinses have important limitations, including efficacy of plaque removal and high acquisition cost. So there is need to develop effective and affordable self care aid to prevent and treat periodontal disease. Sodium hypochloride seems to constitute an effective antiseptic agent in terms of efficacy safety, availability and convenience. In this present study sodium hypochlorite was tested at a concentration of 0.05% and applied mouth rinse twice a day. At this concentration it can be well tolerated. According to American dental association council on dental therapeutics designated 0.1% sodium hypochlorite a mild antiseptic mouth rinse and suggested its use for direct application to mucous membrane (Rutala *et al.,* 1998). At diluted concentration sodium hypochlorite does not shows contraindications. A 0.05% sodium hypochlorite concentration is 5 times more than the minimal antibacterial concentration of 0.01% but 10 times lower than 0.5% concentration used for supra gingival irrigation by loben et al. Further studies are required to determine the efficacy of sodium hypochlorite mouthrinse at different concentrations with larger sample size and longer duration along with microbiological analysis to further address its efficacy and effectiveness for large scale use commercially.

Conclusion

Present study evaluated & compared the efficacy of sodium hypochlorite mouth rinse with chlorhexidine mouthrinse & thus it can be concluded from the present study that:

- Sodium hypochlorite mouthrinse had significant inhibitory effect on plaque accumulation in patients having gingivitis.
- Sodium hypochlorite mouthrinse demonstrated significant reduction in gingival inflammation.

Dilute sodium hypochlorite at 0.05% conc. It effective as compare to water. And it may constituent a new approach which is effective and affordable to control and treats periodontal disease.

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