



Research Article

EFFICACY OF 0.25% SODIUM HYPOCHLORITE ORAL RINSE IN PATIENTS WITH CHRONIC PERIODONTITIS: A RANDOMIZED CONTROLLED TRIAL

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ARTICLE INFO

Article History:

Received 14th November, 2016

Received in revised form 13th December, 2016

Accepted 24th January, 2017

Published online 28th February, 2017

Key words:

Chronic Periodontitis, Sodium hypochlorite, Subgingival irrigation, Mouth rinse.

ABSTRACT

Background & Objectives: Periodontal therapy is aimed at the removal of pathogenic biofilms by mechanical therapy and its conversion to healthy microbiota by antimicrobial and antiseptic agents. The aim of present randomized controlled clinical trial was to determine the efficacy of 0.25% sodium hypochlorite twice weekly oral rinse in chronic periodontitis.

Materials and Methods: 40 patients suffering from chronic periodontitis were randomized into test and control group. Professional subgingival irrigation with 0.25% sodium hypochlorite (test group) and mineral water (control group) into periodontal pocket was done followed by oral rinsing twice a week for 3 months. At day 14, subgingival irrigation was repeated and oral hygiene instructions were reinforced. Clinical parameters including Gingival index, Plaque index, Papillary Bleeding Index, Probing depth and Clinical attachment level were recorded at baseline and 3 months. Data analysis was carried out using SPSS package (Ver 10.5).

Results: Test group showed significant improvements in PBI, PD reduction and CAL gain compared to baseline over a period of 3 months ($p < 0.001$). No significant differences were seen in values of any clinical parameter in the control group. Intergroup comparison showed highly statistically significant differences for PD and CAL at 3 months ($p < 0.001$).

Conclusion: Periodontal therapy can be profited from the adjunctive use of sodium hypochlorite subgingival irrigation and oral rinse. Further studies are needed with larger sample size to evaluate the long term benefits of sodium hypochlorite in the prevention and treatment of chronic periodontitis.

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INTRODUCTION

Periodontal disease is a global health concern and contributes to almost half of the global chronic diseases. It is well recognized that pathogenic microorganisms are the culprit behind gingivitis and periodontitis as reported by Harold Loe 1969 in his classic experimental study in 1965 but the diversity of the organisms makes characterization difficult. Recently, newer periodontal pathogens have been ascribed to the disease. Thus, to identify and eradicate specific disease causing organisms remains a challenge.

At present, periodontal treatment is based on mechanical debridement, systemic and locally delivered antimicrobials followed by maintenance therapy. Though removal of pathogenic biofilms with scaling and root planing forms the basis of periodontal therapy, the use of antimicrobials and antiseptics have gained wide importance due to their broad range of action against periodontopathic organisms. An array of antiseptics has been tried for subgingival irrigation and controlled release into the periodontal pocket. Slots J 2012 authored an article titled "Low Cost Periodontal Therapy" in 2012 and opinions an affordable professional therapy for low income population with proven efficacy and safety. The

global increase of antibiotic resistant bacteria makes it imperative to use highly antibacterial and virucidal antiseptics for the treatment of periodontal disease.

Sodium hypochlorite is the most commonly used irrigant in endodontic practice due to its antibacterial activity. Experimentally, it was found to oxidize polysaccharide matrix in oral biofilms and thus rendering biofilms non pathogenic Costerton J 1995. It is highly bactericidal, nontoxic, does not stain and is low in cost. The active species is undissociated hypochlorous acid which is lethal to most bacteria, fungi and viruses. Interference of cytoplasmic membrane integrity by an irreversible enzymatic inhibition, biosynthetic alterations in cellular metabolism and phospholipid degradation Slots J 2002 explains the antimicrobial effectiveness of sodium hypochlorite. At low concentrations, it was shown to interfere with the ability of nuclear factor- κ B signalling pathways to activate pro-inflammatory gene programmes. Sodium hypochlorite presents with high surface tension and minimum inhibitory concentration lower than 1% for resistant microorganisms. The concentration rise is in proportionate to the antimicrobial effect and tissue dissolution capacity. Thus, due to the high surface tension, antimicrobial action can be achieved with the

diluted solution Barbin E L 2001. Preparation of a solution for subgingival irrigation of sodium hypochlorite is usually from household bleach containing 5.25–6.0% of available chlorine. Inactivation of the periodontal bacteria was seen with a minimum concentration of 0.01% chlorine in vitro Rutala WA 1998. Perova MD 1990 found improved periodontal histological healing with the application of 0.1% hypochlorite for 10min during periodontal surgery. 0.1% sodium hypochlorite solution has been designated as a mild antiseptic mouth rinse by the American Dental Association Council Sebastian Ciccio 1984.

To the best of our knowledge, a very few studies till date have evaluated the effect of 0.25% sodium hypochlorite subgingival irrigation and twice-weekly oral rinsing on gingivitis and periodontal pockets Galvan 2013. In view of the aforementioned scenario, the aim of the study is to evaluate the effect of 0.25% sodium hypochlorite subgingival irrigation and twice-weekly oral rinsing in chronic periodontitis.

MATERIALS AND METHODS

A total of 40 patients reporting to the out-patient who were diagnosed with chronic periodontitis were enrolled into the study. The study is a feasibility study where it was decided to take 20 sample size in each group with 90% power and 5% level of significance. The ethical clearance for the study was obtained from the ethical board of the institution. Patients aged between 25 to 70 years, with a minimum of 10 natural teeth present, presence of at least two teeth with periodontal pockets 5 mm in depth and those who had not undertaken any periodontal treatment in the prior 6 months were selected for the study. Patients unable to comply with the research protocol, those with systemic antibiotic therapy 6 months prior to study entry, those on medications known to potentially affect periodontal status, pregnant or lactating females, Type I or non-stable type II diabetics and smokers were excluded.

Selected patients were randomized using „allocation concealment“ method in a single-blinded manner into test and control group. Test group received professional subgingival irrigation with 0.25% sodium hypochlorite into periodontal pocket and oral rinsing twice a week and control group received professional subgingival irrigation with mineral water into periodontal pocket and oral rinsing twice a week. The patients were educated about the disease and subject of the study and an informed consent was obtained. All the patients received a comprehensive clinical examination and oral hygiene instructions at baseline and baseline clinical parameters were recorded. All the measurements were standardized using customized acrylic stents with grooves.

The recordings were made using a UNC 15 probe (Hu-Friedy’s). Professional subgingival irrigation with either 0.25% sodium hypochlorite (Test) or mineral water (Control) was done at randomly assigned sites with periodontal pockets 5 mm in depth. At day 14, the same type of procedure was repeated and oral hygiene instructions were reinforced. Patients were instructed for oral rinsing at home twice a week for 3 months and the procedure for dilution and the rinsing was provided in writing. Patients were asked to rinse their mouth twice weekly for 30 seconds with either 15 ml of 0.25% sodium hypochlorite solution or mineral water. Post

treatment evaluation & follow up was done at 3 months. Bleeding on Probing, Plaque Index, Gingival index, Probing pocket depth and Clinical Attachment level were recorded using UNC-15 probe.

Statistical Analysis

The results were averaged for continuous data and number and percentage for dichotomous data were presented as Table and Figure. Normality Assumption was checked by using Shapiro

Wilk’s test. The Shapiro Wilk’s test showed that data was not normal, so non parametric analysis was carried out. Paired t-test and unpaired t-test was used to determine statistical difference in the groups and between the groups respectively in the parameters measured. In all the above tests, the “p” value of less than 0.05 was accepted as indicating statistical significance.

Statistical Package for Social Science (SPSS) package (Ver 10.5) was used for data analysis.

RESULTS

No statistical significant differences were observed in the mean age and gender distribution in test group 20 patients and control group 20 patients at baseline and 3 months. The test group showed improvements in PI and GI scores at 3 months follow up visit when compared to baseline levels but the improvements were not statistical significant (p > 0.001). Statistical significant differences were seen in the values of papillary bleeding index in the test group at 3 months (p=0.021). At baseline, there were no statistical significant differences between the probing depths at probing sites. The test group showed highly significant changes in PD and CAL from baseline to 3 months (p < 0.001) (Table 1). Mean probing depth reductions from baseline to 3 months were 1.4±0.493 mm for the test group while for the control group, the values increased by 0.15±0.168 mm. No statistical significant differences were seen in the values of any clinical parameter in the control group from baseline to 3 months (Table 2).

Table 1 Comparison of changes in clinical parameters in Group A from baseline to 3 months

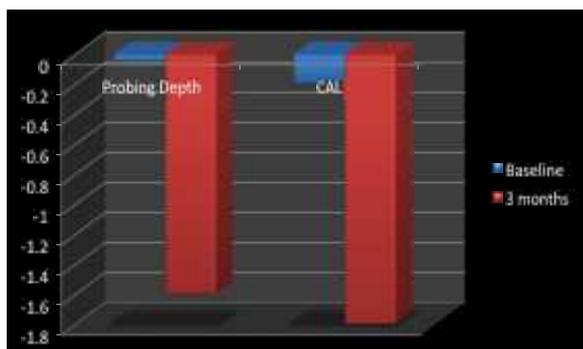
Parameter	Visit	N	Mean	SD	t test*	p value
Plaque Index	Baseline	20	1.05	.224	1.000	.330
	3 Month	20	1.00	.324		
Gingival Index	Baseline	20	1.25	.444	1.831	.083
	3 Month	20	1.10	.308		
Papillary bleeding index	Baseline	20	1.35	.489	2.517	.021
	3 Month	20	1.10	.308		
Probing depth	Baseline	20	5.10	.308	8.304	.000
	3 Month	20	3.70	.801		
CAL	Baseline	20	4.70	.105	8.304	.000
	3 Month	20	3.52	.191		

* paired t Test

Table 2 Comparison of changes in clinical parameters in Group B from baseline to 3 months

Parameter	Visit	N	Mean	SD	t test*	p value
Plaque Index	Baseline	20	1.05	.224	-1.000	.330
	3 Month	20	1.10	.308		
Gingival Index	Baseline	20	1.10	.308	-1.453	.163
	3 Month	20	1.20	.410		
Papillary bleeding index	Baseline	20	1.35	.489	-2.179	.062
	3 Month	20	1.25	.510		
Probing depth	Baseline	20	5.15	.489	-1.000	.330
	3 Month	20	5.30	.667		
CAL	Baseline	20	4.50	.688	-1.285	.214
	3 Month	20	4.70	.923		

* paired t Test



Graph 1 Comparison of mean changes in pocket depth and CAL measurements between Group A and Group B from baseline to 3 months

When the comparison was made between the groups, highly statistical significant differences were seen in the values of PD and CAL at 3 months in between the groups ($p < 0.001$). Also, highly statistical significant differences were appreciated in the mean change of the values of PD and CAL from baseline to 3 months (Graph 1). No adverse effects were observed in any of the patients.

DISCUSSION

Though mechanotherapy is still considered the gold standard for the removal of plaque and calculus, however, it has been observed that tooth brushing reduces only 60% of the plaque on interdental surfaces Gonzalez S 2014. Only 5-10% of the population uses dental floss and most of the mouthwashes provide only cosmetic benefit. Hence, the need for an effective and cost effective home care technique for the treatment of periodontal diseases is paramount. Sodium hypochlorite has been reviewed as an antimicrobial adjunct. It is safe, efficacious and possesses an antimicrobial and antiviral effect along with the tissue dissolution capacity.

In the present study, the effect of 0.25% sodium hypochlorite subgingival irrigation and twice-weekly oral rinsing in patients with chronic periodontitis has shown a significant improvement in clinical parameters at the end of 3 months. Each subject demonstrated good oral hygiene and healthy gingival status throughout the study. The test group (sodium hypochlorite) showed improvements in plaque and gingival index scores at 3 months follow up visit when compared to baseline levels. However, the results were not statistically significant. Similar improvements in plaque and gingival status have been reported in a number of previous studies Lobene RR 1972. Lobene¹¹ *et al* 1972 in a pilot study using 0.5% sodium hypochlorite found a 47% reduction in plaque. De Nardo 2012 *et al* observed a 48.1% reduction in plaque index scores and 52.4% reduction in gingival index scores. However, these changes in plaque and gingival scores could be the result of rigorous oral hygiene maintenance regime and regular follow-up by the patients throughout the study period. Also, a decrease in the number of gram-negative anaerobic bacteria was observed with sodium hypochlorite solution in patients with juvenile periodontitis which explains that bacteria may be destroyed by the direct antibacterial action of sodium hypochlorite solution Adcock 1983.

The test group revealed statistical significant improvement in PBI scores at 3 months follow up visit when compared to baseline levels, which represents a significant reduction in

bacterial load and gingival inflammation. This is in accordance to another study by Gonzales *et al* where in the mean percentage of bleeding on probing decreased to 53% in pockets of 4–7 mm depth indicating the resolution of deep probing depths exposed to sodium hypochlorite oral rinsing. Kalkwraf 1989 and De nardo *et al* observed a 35–60% reduction in bleeding in pockets 5 mm deep.

The test group showed highly statistically significant changes in PD and CAL from baseline to 3 months ($p < 0.001$). There was a reduction of 1.4 ± 0.493 mm in mean probing depth at the end of 3 months which could be attributed to the observation that sodium hypochlorite can interfere with the ability of dental plaque to produce an acidic environment¹¹. These results are in contrast to the study by Galvan *et al* who observed no significant decrease in pocket depth following the use of 0.25% sodium hypochlorite oral rinse which could be due to limited sample size. Hence, within the limitations of the study, there was a significant improvement in all the clinical parameters in sodium hypochlorite group after a period of 3 months. These findings suggest that sodium hypochlorite oral rinse along with adequate oral hygiene measures can prove to be a cost effective preventive and therapeutic measure for periodontal disease.

CONCLUSION

Periodontal therapy can definitely be promoted by the adjunctive use of sodium hypochlorite subgingival irrigation and oral rinse. However, periodontal mechanical therapy is still of extreme importance for the reduction of periodontal pathogenic species. Further studies are needed with larger sample size and microbiologic examination to evaluate the long term clinical effects of sodium hypochlorite in the prevention and treatment of chronic periodontitis.

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