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Original Research Article

A prospective experimental comparative study on the clinical and antimicrobial effects of chlorine dioxide based toothpaste and mouthrinse in periodontitis patients- A One Year Follow-up Study

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Abstract

Aim: The present study was aimed to assess and compare the clinical and antimicrobial effects of sodium chlorite based toothpaste and mouthrinse in periodontitis patients.

Materials and methods: A total 50 generalized chronic periodontitis patient between the ages of 18 and 55 years were enrolled in the study and divided under two categories (A and B). Clinical and microbiological parameters were recorded prior to phase 1 therapy; and subjects were put on conventional oral hygiene regime and sodium chlorite based toothpaste and mouthrinse.

Results: The results of this study showed that there was significant decrease in clinical and microbiological parameters from baseline to 12 months in both the groups ($p < 0.01$). The subjects under test group (sodium chlorite based toothpaste and mouthrinse) showed a highly significant reduction to all the parameters as compared to subjects under group B.

Conclusion: sodium chlorite based toothpaste and mouthrinse will be a true alternative for maintaining oral hygiene.

Keywords: Chlorine Dioxide, Mouthrinse**,** Periodontitis

1.Introduction

Mouth acts as a window to lot of systemic diseases and serves as a port of entry of the various infections that can alter and affect the immune status of the person. The oral cavity has the potential to harbor at least 600 different bacterial species, and in any given patient, more than 150 species may be present, surfaces of tooth can have as many as billion bacteria in its attached bacterial plaque.[1] Periodontitis is a destructive inflammatory disease of the supporting tissues of the teeth and is caused either by specific microorganisms or by a group of specific microorganisms, resulting in progressive destruction of periodontal ligament and alveolar bone with periodontal pocket formation, gingival recession, or both.[2] Dental plaque biofilm cannot be eliminated. However, the pathogenic nature of the dental plaque biofilm can be reduced by reducing the bio-burden (total microbial load and different pathogenic isolates within that dental plaque biofilm) and maintaining a normal flora with appropriate oral hygiene methods.[3]

Toothbrushing is the most common and most accessible means of preventive oral health care available. The primary purpose of brushing the teeth with a dentifrice is to clean the accessible tooth surfaces so as to minimize the accumulation of dental plaque, stains and food debris. Toothpaste manufacture over the last several decades has been driven by a combination of dental research findings and marketing forces. The recent past has witnessed

resurgence in the use of sodium chlorite based dentifrices; the main application of sodium chlorite is the generation of chlorine dioxide. An insufficient amount of clinical trials on sodium chlorite based mouth rinses and dentifrices has been reported, which is in stark contrast with a plethora of such for conventional oral care products. In, addition as only a limited number of studies on sodium chlorite based products (Dentifrice and Mouthrinse) have been published, it has not been determined whether they are superior, equivalent or substandard to conventional dentifrices and mouthrinse in improving oral health.

Hence an attempt has been made in the present study to assess and compare the clinical and antimicrobial effects of sodium chlorite based toothpaste and mouthwash in periodontitis patients with conventional alcohol based toothpaste and mouthwash without sodium chlorite.

2. Materials and Methods

The present study was conducted in the Department of Periodontology, Pravara Institute of Medical Sciences, Loni, Maharashtra, India. The research protocol was approved by the University Research and Ethical Committee. Verbal and written informed consent was obtained from all subjects prior to their voluntarily enrollment in the study.

2.1 Study population

The subjects enrolled in this study were selected from the Outpatient Department of Periodontology, Pravara Institute of Medical Sciences, Loni, Ahmednagar, Maharashtra, India. The study included a total of 50 subjects with chronic periodontitis and all 50 subjects were grouped into two categories (A and B) and each group was comprised of 25 subjects each as illustrated in Table 1. Exclusion criteria for the patient enrolled in the study were: (1) Presence of any systemic neurological disorder (e.g. epilepsy or schizophrenia), (2) presence of a disease with possible effects on the immune system (e.g. chronic infections or cancer), (3) patient who have received antibiotics or nonsteroidal anti-inflammatory drug (like ibuprofen) in past 9-11 weeks, (4) patients who have received periodontal treatment in past 6 months, (5) pregnant and lactating mother, (6) patient with artificial prosthesis, (7) patients who smokes or consumes tobacco in any form, (8) patients suffering with arthritis, (9) patient with any type of heart disease (myocardial infarction, coronary heart disease, etc.), (10) female patient using intrauterine birth control devices or birth control pills, (11) obese individuals (30 and above range as per WHO body mass index cut-off for weight categories for Asians), (12) presence of diabetes mellitus (13) participants not willing to participate in the study.

2.2 Clinical Protocol

Patients received a verbal description about the clinical protocol to be followed in this clinical study. In order to have the unbiased and accurate clinical data, we followed a double blind protocol in the study for enrollment of the patients in terms of treatment plan (Phase 1 Therapy). Also categorization of patients were done randomly, with oral products regime (With and without chlorine dioxide) to be followed after the phase 1 therapy. After enrollment of the subjects in the study, Phase 1 therapy (Complete scaling and root planing) was done by similar EMS ultrasonic scaler to all the subjects enrolled in the study. Subjects under both the groups were advised to brush twice daily 5 minutes with modified bass method technique (Technique demonstrated to each subject) and similar medium bristle tooth brushes were provided to each of the subject during the study course to maintain standardization. The subjects were further advised for a mouthrinse twice daily (10 ml in quantity for 1 minute).

2.3 Clinical parameters protocol

Clinical parameters of periodontal disease that were evaluated were gingival index (GI), plaque index (PI) and clinical attachment loss (CAL).

2.3.1 Gingival index

The teeth selected as index teeth were 16, 12, 24, 32, 36 and 44. The tissues surrounding each tooth were divided into four gingival scoring units: Disto-facial papilla, facial gingival margin, mesio-facial papilla and the entire lingual gingival margin. A blunt instrument such as a periodontal probe was used to assess the bleeding tendency of the tissues. The index for each index tooth was recorded and then calculated by dividing total number of index teeth examined. This provided the GI for the individual.

2.3.2 Plaque index

All teeth were examined on four surfaces (i.e. mesiobuccal, buccal, distobuccal and lingual/palatal) after using a disclosing agent. Plaque Index = Total plaque score/Number of surfaces examined

2.3.3 Clinical attachment loss

The clinical attachment level was examined with William's graduated probe. Clinical attachment level (CAL) represents distance from cementoenamel junction to the base of the gingival sulcus or periodontal pocket. Average CAL of the person is calculated by dividing the total clinical attachment

level by the number of teeth examined. Chronic periodontitis is sub classified as mild or slight, moderate and severe periodontitis based on CAL according to American Academy of Periodontology 1999 classification of periodontal diseases. If gingival recession is present then, loss of attachment is calculated by the distance between the cement enamel and gingival margin to be added to pocket depth.

2.4 Microbiological protocol

Subgingival plaque samples were collected for specific bacterial examination that is, *Aggregatibacter actinomycetemcomitans* (Aa), *Fusobacterium nucleatum* (Fn), *Porphyromonas gingivalis* (Pg) and *Prevotella intermedia* (Pi). Subgingival plaque samples were then collected from the sample sites using the standardized paper point (Dentsply)® which were inserted to the depth of the periodontal pocket until resistance was felt. The paper points were retained for 20 s in the collection sites. The samples site selected was maxillary first molar in all the cases to maintain the standard protocol. After 20 s the paper point was removed from the sample site and immediately transferred into Robertson's cooked meat transport (RCM) in a test tube for specific bacterial culturing. In the laboratory, the RCM was subjected to vortex homogenization for 60 s before incubated anaerobically (Gas pack system) for 2-3 days.

3. Results

Distribution of mean and standard deviation values of all the clinical and microbiological parameters of both the groups (A and B) were illustrated in Tables 2 and 3. By applying Student's Paired 't' test, there was a significant decreased from baseline to 12 months for mean values of clinical and microbiological parameters in both the groups i.e. $p<0.01$; while group A shows higher decrease than group B. Graph 1 shows comparison of mean values of clinical parameters in Group A and Group B at 12 months i.e. by applying Student's Unpaired 't' test there was a highly significant difference between mean values of clinical parameters of GI and PI in Group A as compared with Group B (i.e. $p<0.01$). Similarly, Comparison of mean values of microbiological parameters in Group A and Group B at 12 months i.e. By applying Student's Unpaired 't' test there was a highly significant difference between mean values of *Aggregatibacter Actinomycetemcomitans, Fusobacterium Nucleatum, Porphyromonas Gingivalis and Prevotella Intermedia* in Group A as compared with Group B (i.e. $p<0.01$) as seen in Figure 2.

Table.1: Distribution of chronic periodontitis patients in study groups (A and B)

Group	Patient Clinical Protocol	No. of Subjects
A	Chronic periodontitis patients with complete oral prophylaxis (Scaling and Root Planing) followed by use of chlorine dioxide based toothpaste and mouthrinse. (Oxyfresh® Toothpaste and Oxyfresh® Mouthrinse)	**25**
B	Chronic periodontitis patients with complete oral prophylaxis (Scaling and Root Planing) followed by use of conventional alcohol based toothpaste and mouthrinse. (Conventional Alcohol based toothpaste and Mouthrinse)	**25**

Table 2 Distribution of mean and standard deviation values of clinical parameter in Groups (A and B)

Groups	Clinical Parameters	Baseline	6th Month	12th Month
Group A	**GI**	2.76±0.27	1.25±0.29	0.66±0.27
	Pl	2.64±0.26	1.13±0.26	0.552±0.24
	PD	5.92±0.81	3.68±0.62	2.68±0.62
	CAL	5.92±0.81	3.68±0.55	2.68±0.55
Group B	**GI**	2.84±0.10	1.46±0.24	0.85±0.10
	PI	2.82±0.10	1.45±0.21	0.80±0.088
	PD	5.92±0.64	3.72±0.67	2.72±0.67
	CAL	5.92±0.81	3.72±0.61	2.72±0.61

GI: Gingival Index; PI: Plaque Index; PD: Probing Depth and CAL: Clinical Attachment Loss

Table 3 Distribution of mean and standard deviation CFU values of Microbiological parameter in Groups (A and B)

Groups	Microbiological Parameters	Baseline	6th Month	12th Month
Group A	***Aa***	31.52±6.64	23.04±6.71	17.52±6.64
	Fn	32.32±5.81	23.88±5.92	18.36±5.75
	Pg	30.4±6.09	21.88±6.21	16.36±6.10
	Pi	31.72±6.06	23.32±5.89	17.80±5.96
Group B	***Aa***	32.52±5.79	26.04±5.88	21.52±5.78
	Fn	31.56±5.41	25.12±5.47	20.6±5.35
	Pg	30.88±5.52	24.4±5.53	19.88±5.52
	Pi	31.64±6.10	25.20±5.98	20.72±6.08

CFU: Colony Forming Units;_Aa: Aggregatibacter Actinomycetemcomitans; Fn: Fusobacterium Nucleatum; Pg: Porphyromonas Gingivalis and Pi: Prevotella Intermedia

Table No.4: Comparison of mean values of clinical parameters in Group A and Group B at 12 months

Clinical parameters at 12 months	Group A Mean ± SD	Group B Mean ± SD	Unpaired 't' test value	'p' value	Result
Gingival Index (GI)	0.66±0.27	0.85±0.10	3.33	p<0.01	highly significant
Plaque Index (PI)	0.55±0.24	0.80±0.088	14.26	p<0.01	highly significant
Clinical Attachment Loss (CAL)	2.68±0.55	2.72±0.61	0.25	p>0.05	not significant
Probing Depth (PD)	2.68±0.62	2.72±0.67	0.22	p>0.05	not significant

Table No. 5: Comparison of mean values of microbiological parameters in Group A and Group B at 12 months

Microbiological parameters at 12 months	Group A Mean ± SD	Group B Mean ± SD	Unpaired 't' test value	'p' value	Result
Aggregatibacter Actinomycetemcomitans	17.52±6.64	21.52±5.78	3.78	p<0.01	highly significant
Fusobacterium Nucleatum	18.36±5.75	20.6±5.35	2.47	p<0.01	highly significant
Porphyromonas Gingivalis	16.36±6.10	19.88±5.52	3.59	p<0.01	highly significant
Prevotella Intermedia	17.80±6.09	20.72±6.21	3.25	p<0.01	highly significant

Figure 1: Graph showing Comparison of mean values of clinical parameters in Group A and Group B at 12months

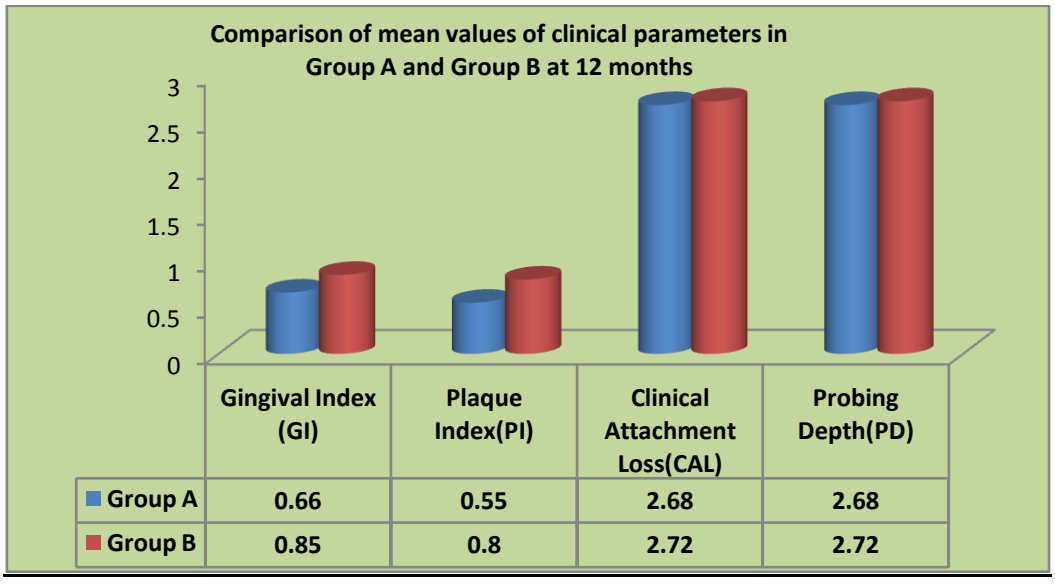
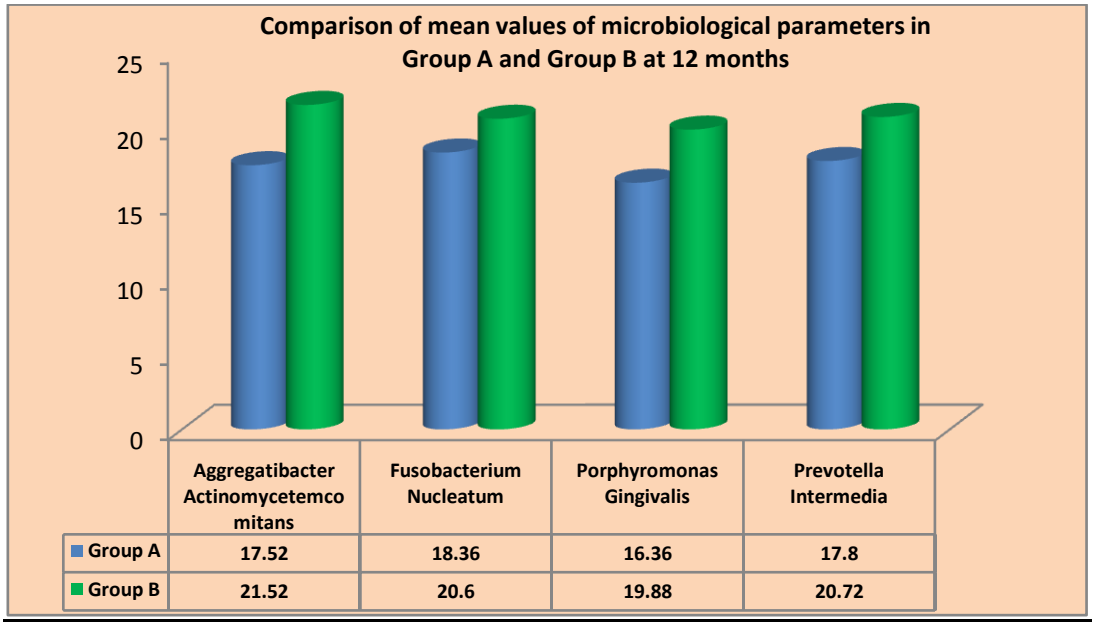


Figure 2: Graph showing Comparison of mean values of microbiological parameters in Group A and Group B at 12 months



4. Discussion

The significant clinical and microbiological improvement in Group A subjects (chlorine dioxide based toothpaste and mouth rinse) support that the hypothesis that Sodium Chlorite (Stabilized chlorine dioxide) may acts as a strong ingredient to restrict the proliferation of sub gingival anaerobic microbiota via oxygenation and neutralization of toxins (Bacterial proteolytic enzymes) produces by the bacteria in the oral cavity. The stabilized chlorine dioxide based products used in this study (Oxyfresh® Power Paste, and Oxyfresh® Power Rinse) also destroy the volatile sulfide compounds, which further reduce the triggering of gingival inflammation. The key benefits for these products also include non staining, alcohol free, non-irritating, no taste alterations, and sodium lauryl sulfate free (Foaming agent in toothpaste that initiate canker sore).

This study also revealed that the bactericidal activity of stabilized chlorine dioxide oral rinse (Oxyfresh® Power Rinse) has marked bactericidal effects against with pathogens of periodontitis, i.e. *Aa*, *Fn*, *Pg* and *Pi*. These results are consistent with previous studies evaluating a stabilized chlorine dioxide oral rinse against polymicrobial suspensions and biofilm environments.[5][6] The zinc acetate with xylitol further prevents the colonization of initial plaque formation and removes halitosis causing volatile organic compounds.

The comparative assessment revealed that sodium chlorite (Stabled Chlorine Dioxide) based dentifrice (Oxyfresh® Power Paste) and mouth wash (Oxyfresh® Power Rinse) has an edge over the conventional based dentifrice and mouth wash due to the above mentioned hypothesis and mechanism of the system that focus on the oxygenation of anaerobic environment and lead to disruption of the biofilm.

Well-designed multi centric longitudinal clinical trials with more number of subjects in different demographic locations for longer duration period should be done to evaluate the completely the effect of chlorine dioxide based oral hygiene products.

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