



A COMPARATIVE STUDY ON THE STAINING EFFECT OF CHLORHEXIDINE MOUTHWASHES WITH AND WITHOUT ANTI DISCOLOURATION SYSTEM: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

AIM: The use of chlorhexidine (CHX) has been recommended for a number of clinical applications including plaque control in the post-operative period. The use of chlorhexidine is burdened by some side effects that could affect patient compliance. The most notable among that is the staining it produces. New mouthwash containing CHX with anti-discolouration (ADS) promises not only to prevent plaque formation but also to avoid staining. The aim of this clinical trial was to evaluate the staining effect of CHX mouthwash with and without anti discoloration system compared with that of control group (saline).

MATERIALS AND METHODS: A randomized, controlled clinical trial was conducted in 45 students. After phase I, patients were randomly assigned to either group I (saline), group II (0.2% CHX without an ADS), or group III (0.2% CHX with an ADS). During the 12-week experimental period, rinsing with 10 mL mouthwash or placebo was performed twice daily. In order to assess the staining effect Lobene stain index was recorded at baseline, 4 weeks, 8 weeks and 12 weeks.

RESULT: Staining index data in the 3 groups showed that all the groups showed staining at the end of 12 weeks but group II presented an increase in the average value of the staining index at all time intervals compared to group I and group III.

CONCLUSION: The study concluded that CHX with ADS prove to be an effective solution to the problem of staining caused by CHX in long-term.

KEYWORDS : mouthwash, chlorhexidine, stains, bacteria

INTRODUCTION

Plaque control is the most important aim that the clinician together with the patient must achieve to obtain an effective prevention of periodontal disease. Many studies conducted in animal models have established that the presence of pathogenic bacteria is an indispensable condition that makes possible the onset and development of gingival and periodontal diseases. Studies have also demonstrated that daily tooth brushing, and flossing are not practiced consistently and are not done for adequate amount of time to thoroughly remove the plaque. Because of these drawbacks of home oral care practices, other methods of oral care are required¹.

Among the therapies commonly used to maintain control of plaque, the antiseptic Chlorhexidine (CHX), from bisbiguanide family is certainly the most studied and the most effective for the inhibition of plaque and for the prevention of gingivitis: it is recognized by more than twenty years as the gold standard for its anti-plaque and anti-bacterial activity in oral hygiene. It is an effective anti-bacterial agent for chemical plaque control and it is extensively used in the reduction of plaque and gingivitis by 60%. CHX is absorbed rapidly on dental surfaces, mucous membranes, and salivary proteins and is released gradually over 8 to 12 hours. It is used in dentistry as a solution (water + chlorhexidine) in various concentrations (0.2 and 0.12%) or as a gel (1 and 0.5%) or more recently in tablet or spray form².

However, the use of CHX is burdened by some side effects, mainly related to stains, alterations in taste and erythematous – desquamative lesions of oral mucosa. Among them, the most frequent is represented by brown pigmentations that appear on the dental surfaces, prosthetic and composite restorations and tongue after its prolonged use. Different systems have been introduced in order to reduce the brown pigmentations and other side effects caused by the use of this mouthwash, one of them being CHX ant discoloration system (ADS). Therefore, the aim of the study was to clinically evaluate the staining effect of 0.2% chlorhexidine mouthwash with and without ADS for 4, 8 and 12 weeks³.

MATERIALS AND METHODS

1. Study population and clinical examination

This Randomized controlled clinical trial included a total of 45 participants from department of Periodontology, Rajarajeswari Dental College and Hospital, Bangalore belonging to the age group of 18- 40 years. Ethical clearance was obtained by the institutional ethical committee of Rajarajeswari dental college and hospital, Bangalore. Written informed consent was obtained from each participant after the purpose and procedure of the study were explained.

Individuals belonging to the age group of 18 to 40 years, systemically healthy patients and patients who have not received any periodontal treatment for the last 6 months prior to the clinical examination were included in the study. Exclusion criteria included smokers, alcoholics, pregnant and lactating women, individuals with the history of systemic diseases or immune deficiency and patients with a history of periodontal surgical treatment in the past 12 months on the involved sites.

Before commencement of the study, the participants were screened according to the inclusion criteria. Participants were randomly allocated into three groups. Patients were asked to rinse twice daily with 10 ml of saline solution in group I, 10 ml of 0.2% CHX in group II and 0.2% CHX with an ADS solution in group III.

At the baseline, Lobene stain index⁴ were recorded before scaling and root planing. Staining (only area) Index were assessed according to the following clinical criteria:

Value 0: Absence of pigmentations

Value 1: Pigmentation covering up to 1/3 of the region

Value 2: Pigmentation covering 1/3 to 2/3 of the region

Value 3: Pigmentation covering 2/3 of the region.

Staining (only intensity) Index were assessed according to the following clinical criteria:

Value 0: No stain

Value 1: Light pigmentations

Value 2: Moderate pigmentation

Value 3: Marked pigmentation.

After the phase of oral prophylaxis at the baseline visit, the participants were recalled at 4 weeks, 8 weeks and 12 weeks to record Lobene stain index. The participants were asked to abolish all other chemical plaque control measures during the study period. During the experimental period, the participants were asked to rinse with 10ml of samples twice a day in each group for 3 months.

STATISTICAL ANALYSIS:

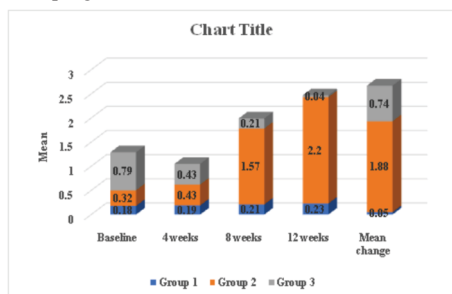
Descriptive and inferential statistical analysis has been carried out in the present study. The results were analysed by using SPSS version 18 (IBM Corporation, SPSS Inc., Chicago, IL, USA). Results on continuous measurements were presented on Mean SD (Min-Max). Normality of the data was assessed using Shapiro-Wilk test. Inferential statistics like Kruskal Wallis test is used to check difference between the groups. Friedman's test was done to check overall difference within a group over different time period. Intra group comparison over different time periods was assessed using Wilcoxon sign test. P value less than 0.05 was considered to be significant.

RESULT

Table No. 1: Comparison between and within the groups

	Group 1* (Mean±SD)	Group 2* (Mean±SD)	Group 3* (Mean±SD)
Baseline	0.18±0.04	0.32±0.04	0.79± 0.25
4 weeks	0.19±0.04	0.43±0.09	0.43± 0.23
8 weeks	0.21±0.04	1.57±0.24	0.21± 0.12
12 weeks	0.23±0.03	2.20±0.14	0.04± 0.01
Mean change	-0.05±0.03	-1.88±0.16	0.74± 0.25

*Statistically significant



Graph 1: Comparison of staining index between the groups at three different time intervals

All subjects completed the study. No subjects reported complications or unexpected complaints. Staining index data in the 3 groups showed that all the groups showed staining at the end of 12 weeks but group II presented an increase in the average value of the staining index at all time intervals compared to group I and group III. The differences between the groups were statistically significant. (Table 1 and Graph 1). There was lesser staining in group III subjects than the other two groups at 4, 8- and 12-week time intervals.

DISCUSSION

Chlorhexidine is considered as the gold standard in chemical plaque control regimen but has noted side effect of discolouration on prolonged use. This study was conducted to verify that CHX with the ADS system could eliminate or reduce pigmentation. After analysing the results obtained during our clinical study comparing 0.2% CHX mouthwash with ADS to the 0.2% CHX alone and saline solution, we observed that the mouthwash with ADS has noticeable decrease in staining. This was in accordance with the study conducted by Bernardi et al⁵, who found that a statistically significant difference was observed in the adverse effect of staining, demonstrating that the mouthwash with ADS prevented staining compared to CHX alone in healthy patients. Solis

et al⁶ also reported CHX with ADS had less staining than CHX alone during a usage period of 15 days. Grazianiet al⁷ in a randomized clinical trial compared CHX with and without ADS, and suggested that there was lighter staining found in the CHX with ADS group. This side-effect of CHX is attributed to its cationic nature. CHX binds strongly to bacterial cell membranes. At a low concentration, this causes increased permeability of bacterial cell walls with leakage of intracellular components. At a high concentration, CHX causes precipitation of the bacterial cytoplasm. In the mouth, CHX readily adsorbs to surfaces, including pellicle coated teeth. It is likely that the molecule attaches to the pellicle by one cation, leaving the other free to interact with bacteria attempting to colonize the tooth surface. CHX is highly active, so it can be easily deactivated by any anionic compound, including the anionic surfactants commonly used as detergents in toothpastes and mouthwashes and anionic thickeners. Accordingly, the antidiscoloration effect of ADS might originate from the deactivation of CHX, which could explain the compromised antiplaque effectiveness in the test group in the present study.⁸

CONCLUSION

The current study also proved that CHX with ADS caused less staining than CHX alone, thus proving to be an effective solution to the problem of staining caused by CHX in the long run.

REFERENCES

1. Marrelli M, Amantea M, Tatullo M. A comparative, randomized, controlled study on clinical efficacy and dental staining reduction of a mouthwash containing Chlorhexidine 0.20% and Anti Discoloration System (ADS). *Annali di Stomatologia* 2015; VI (2): 35-42.
2. Pereira R, PhadSG. Comparative Evaluation of 0.2% Chlorhexidine Mouth Rinse with and without an Antidiscoloration System: A Clinical Study. *Journal of Contemporary Dentistry* 2017; 7(1):53-56.
3. Zanatta FB, Antoniazzi R, Posing CK. Staining and calculus formation after 0.12% chlorhexidine rinses in plaque-free and plaque covered surfaces: a randomized trial. *J Appl Oral Sci.* 2010; 18(5):515-21.
4. Lobene RR. Effect of dentifrices on tooth stains with controlled brushing. *JADA.* 1968; 77:849-855.
5. Bernardi F, Pincelli MR, Carloni S, Gatto MR, Montebugnoli L. Chlorhexidine with an anti-discoloration system. A comparative study. *Int J Dent Hyg* 2004 Aug; 2(3):122-126.
6. Solis C, Santos A, Nart J, Violant D. 0.2% chlorhexidine mouthwash with an antidiscoloration system versus 0.2% chlorhexidine mouthwash: a prospective clinical comparative study. *J Periodontol* 2011 Jan; 82(1):80-85.
7. Graziani F, Gabriele M, D' Aiuto F, Suvan J, Tonelli M, Cei S. Dental plaque, gingival inflammation and tooth discolouration with different commercial formulations of 0.2% chlorhexidine rinse: a double-blind randomized controlled clinical Trial. *Oral Health Prev Dent* 2015; 13(2):101-111.
8. Li W, Wang RE, Finger M, Lang NE. Evaluation of the antigingivitis effect of a chlorhexidine mouthwash with or without an antidiscoloration system compared to placebo during experimental gingivitis. *Journal of Investigative and Clinical Dentistry* (2014); 5: 15-22.