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Research Paper

Comparative Evaluation of Staining Effect of 0.2% Chlorhexidene Mouthwash with Antidiscoloration System and 0.2% Chlorhexidene Mouthwash – A Clinical Study.

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ABSTRACT
BACKGROUND : *Chlorhexidene is the most effective antiseptic mouthwash till date. However the side effects like tooth discoloration and bad tastes are its drawbacks. The aim of this study is to evaluate the degree of staining and clinical efficacy of a chlorhexidene mouthwash with an antidiscoloration system (ADS) versus 0.2% chlorhexidene mouthwash (traditional).*
METHODS *: This comparative study was carried out on 20 non-smoking patients with chronic periodontitis. All patients used either 0.2% chlorhexidene mouthwash with ADS (test group = bottle A) or 0.2% chlorhexidene mouthwash (control group = bottle B) for 15 days. Each patient was first made to rinse with a randomly assigned mouthwash for 15 days followed by a 15 day washout period. Subsequently, each patient used the other mouthwash. Before each cycle, a full oral prophylaxis was performed. The gingival, plaque and staining indexes were recorded.*
RESULTS : *Statistically no signficant differences were observed in plaque and gingival indices. The results showed less tooth staining with the test group ($p<0.01$).*
CONCLUSION : *The test group with ADS had less staining than the control group without ADS. However the two mouthwashes were found to be equally effective as antiplaque and antigingivitis agents.*
KEYWORDS: *antidiscoloration system, chlorhexidene, mouthwash, staining.*

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I. INTRODUCTION

Dental plaque is the main etiological factor of the most prevalent periodontal diseases.[1] Studies have clearly demonstrated that the ability to control the onset or progression of periodontal disease is improved by regular plaque-control practices.[2] As noted by De Paola et al., mechanical oral hygiene methods of plaque removal require time, motivation and manual dexterity.[3] Chemotherapeutic agents can play a pivotal role as adjuncts of mechanical plaque control procedures. The use of chemotherapeutic agents as adjuncts of mechanical at-home plaque control is recommended.[4] In most cases, during phase I therapy, the clinician recommends the use of an antimicrobial agent for reducing plaque and gingivitis, as an adjunctive therapy. Clinical studies have shown that many of these antimicrobial agents have inhibitory effects on plaque and gingivitis compared to negative controls or placebos, in the absence of toothbrushing.[5]

Chlorhexidene is considered the gold standard agent for its clinical efficacy in chemical plaque control.[6,7] Loe and Schiott (1970) firstly studied its application in dentistry. The study showed that rinsing for 60 seconds twice per day with 10 ml of a 0.2% chlorhexidine gluconate solution in the absence of normal tooth cleaning, inhibited plaque regrowth and the development of gingivitis.[8] Chlorhexidene has broad antibacterial activity with very low toxicity and strong affinity for epithelial tissue and mucous membranes.[7] Besides its antiplaque effect, chlorhexidene is substantive, thus reducing levels of microorganisms in saliva upto 90% for several hours.[6,7] Bacterial resistance has not been reported with long-term oral use and there is no evidence of super-infection by fungi, yeast or viruses. However, two pronounced side effects – superficial staining of the teeth and altered taste perception have been recognized almost immediately.[9] This may compromise patient compliance for esthetic reasons. The mechanisms of chlorhexidine staining have been proposed.They include

the degradation of the chlorhexidine molecule to release parachloraniline, catalysis of Maillard reactions, protein denaturation with metal sulfide formation and precipitation of anionic dietary chromogens.[10-12]

Studies have shown different methods to eradicate or minimise staining on enamel and cementum. These results show the effectiveness of a 0.2% chlorhexidene with antidiscoloration system (ADS) mouthwash compared to a 0.2% chlorhexidene mouthwash.[13-15] The ADS system is composed of ascorbic acid and sodium metabisulphate. But the controversy exists about the clinical efficacy of the chlorhexidine products with ADS. Consequently, a clinical validation of such products appears necessary.

The aim of this clinical study was to assess the degree of staining and clinical efficacyof a 0.2% chlorhexidene mouthwash with ADS compared to a 0.2% chlorhexidene mouthwash in patients with chronic periodontitis over a 15-day period. The secondary objectives of this clinical investigation were to determine patient compliance patterns assigned by the clinician, and the possible occurrence of other side effects, besides staining, after use of the mouthwash.

II. MATERIALS AND METHODS

This is a comparative, single-centred, crossover, double-masked study between a mouthwash that contains 0.2% chlorhexidene and a mouthwash containing 0.2% chlorhexidene with ADS (Curasept Curaden). The study was conducted at the Department of Periodontics, Government Dental College, Srinagar. Informed written consent from the patients and ethical committee clearance were taken prior to the commencement of the study. A total of 20 patients (10 males, 10 females) aged 35-55 years were included in the study. The inclusion criteria for selecting the patients were non-smokers with chronic periodontitis, having at least 24 teeth in the functional dentition (third molars were excluded) and without systemic disease such as uncontrolled diabetes, cardiovascular disease and infectious disease. Patients who were pregnant, nursing or using antibiotics or anti-inflammatory drugs were also excluded.

The mouthwash samples for study were labeled as A (0.2% chlorhexidene mouthwash with ADS) and B (0.2% chlorhexidene mouthwash). The patients were provided mouthwash samples randomly by a dental hygienist masked to the researcher. Before each mouthwash cycle, a full mouth supragingival prophylaxis was performed and intraoral photographs were taken. The patients were instructed not to drink coffee, wine or tea one hour before or after using the mouthwash. Each patient had a 15-day cycle using an undiluted 10 ml dose of a first mouthwash for one minute, twice daily (morning and evening). At 7 and 15 days, the plaque index (PI),[16,17] gingival index (GI),[15,17] and Brecx staining index (BI)[18] were recorded. The three indexes were recorded on all the teeth in the patient's mouth, excluding third molars. The GI and PI were evaluated in the four gingival units of the same teeth (mesial, distal, mid-labial/buccal and palatal/lingual). BI was assessed only in two gingival units (buccal/labial and palatal/lingual). All patients remained 15 days without using any rinse in the washout period. Then they performed the second 15-day cycle with the second mouthwash. The same clinical parameters were recorded at the end of this second cycle. The brushing technique used during the study was modified Bass technique[19] alongwith interdental brushing.

The questionnaire filled by the clinician at 7 and 15 days when using mouthwashes A and B took into account PI, GI, BI and general information about the patient (age, sex, race etc.). The survey also included the questions related to the side-effects like taste modification or injury to the oral mucosa experienced by the patients during the study. After each cycle patients brought a filled questionnaire showing their compliance. A single masked researcher performed clinical assessments and data collection.

The results were analyzed using factorial analysis of variance. The primary outcome variable was patient pigmentation. Other variables evaluated were plaque reduction, gingival inflammation and other side effects like taste modification, mucosal irritation etc. All the variables were tested between the two different mouthwashes within the same patient and over time, between 7 and 15 days.

III. RESULTS

All the 20 patients (10 males and 10 females) completed the study. All patients were treated with a full supragingival prophylaxis before each mouthwash cycle and were reevaluated at days 7 and 15 when using each mouthwash. None of the patients reported any complication or any unexpected complaints. **Figure 1** shows PI at 7 or 15 days. The means and standard deviations of the PI for mouthwash A (0.2% chlorhexidene plus ADS) at 7 and 15 days were 0.069±0.082 and 0.079±0.127, respectively. For mouthwash B (0.2% chlorhexidene) the means and standard deviations of the PI at 7 and 15 days were 0.140±0.279 and 0.180±0.265, respectively. No statistically significant differences were observed in plaque reduction ($p \geq 0.05$) between the two mouthwashes. This means that the two mouthwashes were equally effective in reducing plaque in the patient.

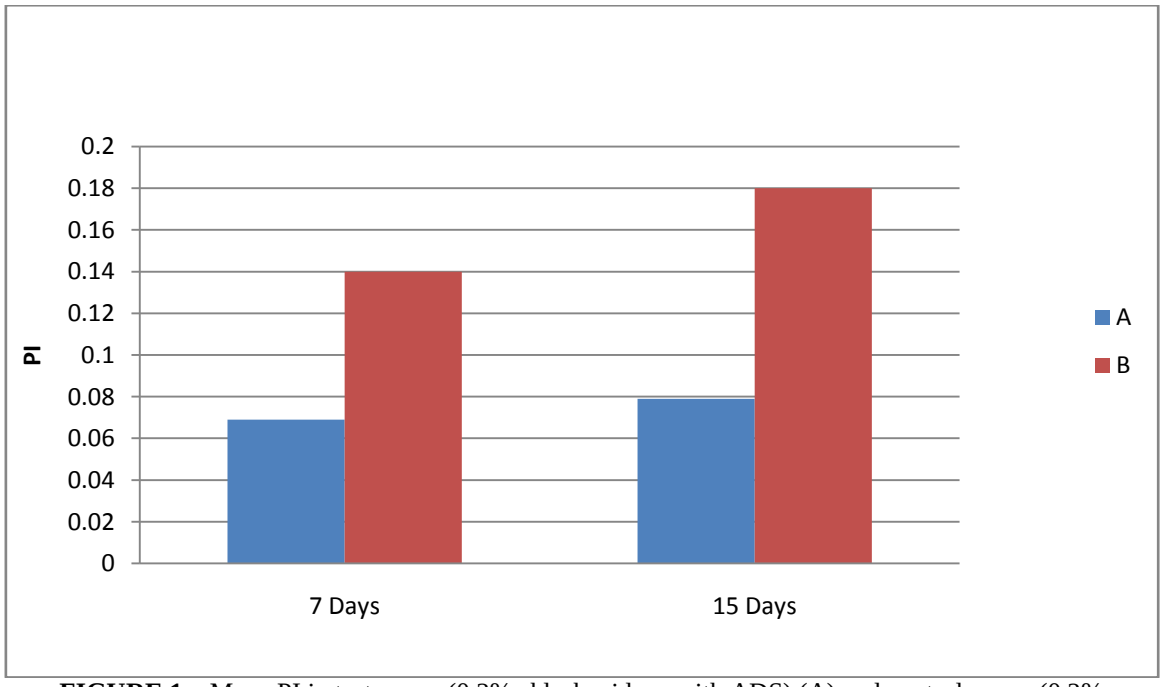

FIGURE 1 – Mean PI in test group (0.2% chlorhexidene with ADS) (A) and control group (0.2% chlorhexidene) (B) at 7 and 15 days.

The means and standard deviations of the GI for mouthwash A at 7 and 15 days were 0.059±0.071 and 0.080±0.082, respectively. The means and standard deviations for mouthwash B at 7 and 15 days were 0.215±0.360 and 0.077±0.072, respectively (**Figure 2**). The two mouthwashes presented a similar effectiveness on gingival inflammation with no statistically significant difference ($p \geq 0.05$).

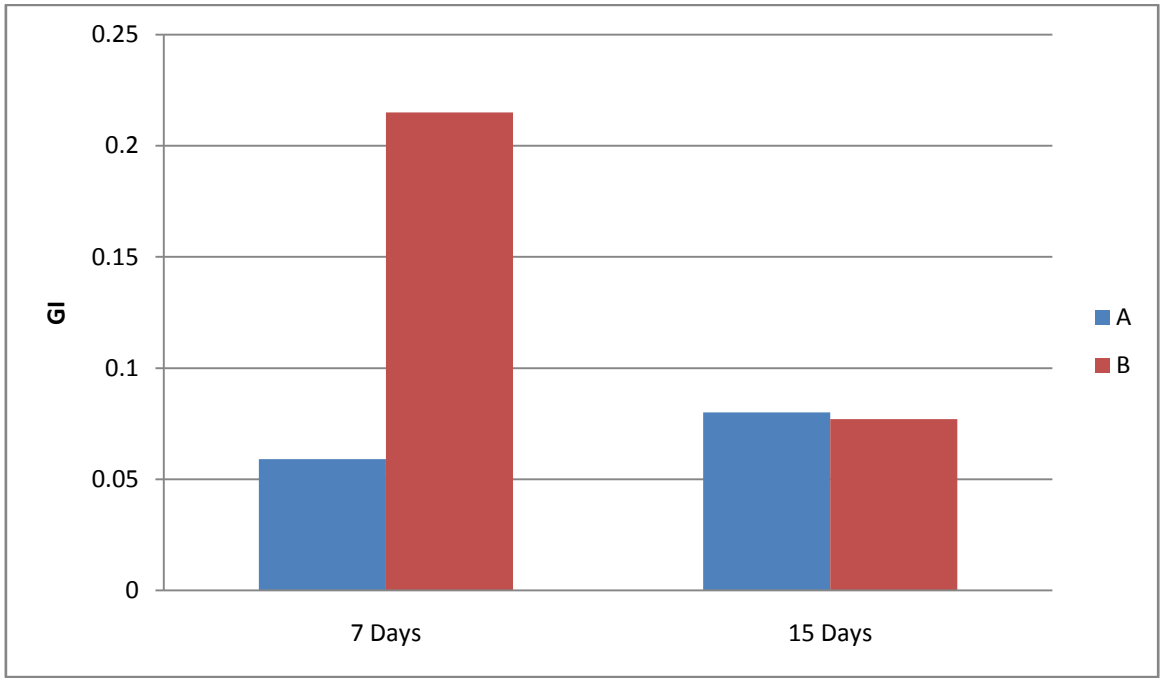

FIGURE 2 – Mean GI in test group (0.2% chlorhexidene with ADS) (A) and control group (0.2% chlorhexidene) (B) at 7 and 15 days.

The means and standard deviations of BI for mouthwash A at 7 and 15 days were 0.210±0.190 and 0.526±0.334, respectively. The means and standard deviations of the BI for mouthwash B at 7 and 15 days were 0.435±0.344 and 0.947±0.480, respectively (**Figure 3**). With mouthwash B, BI is much higher than with mouthwash A. The values obtained are statistically significant ($p \leq 0.05$). For any other side effects reported after the use of the mouthwashes, the results suggest no significant difference between the two groups ($p \geq 0.05$).

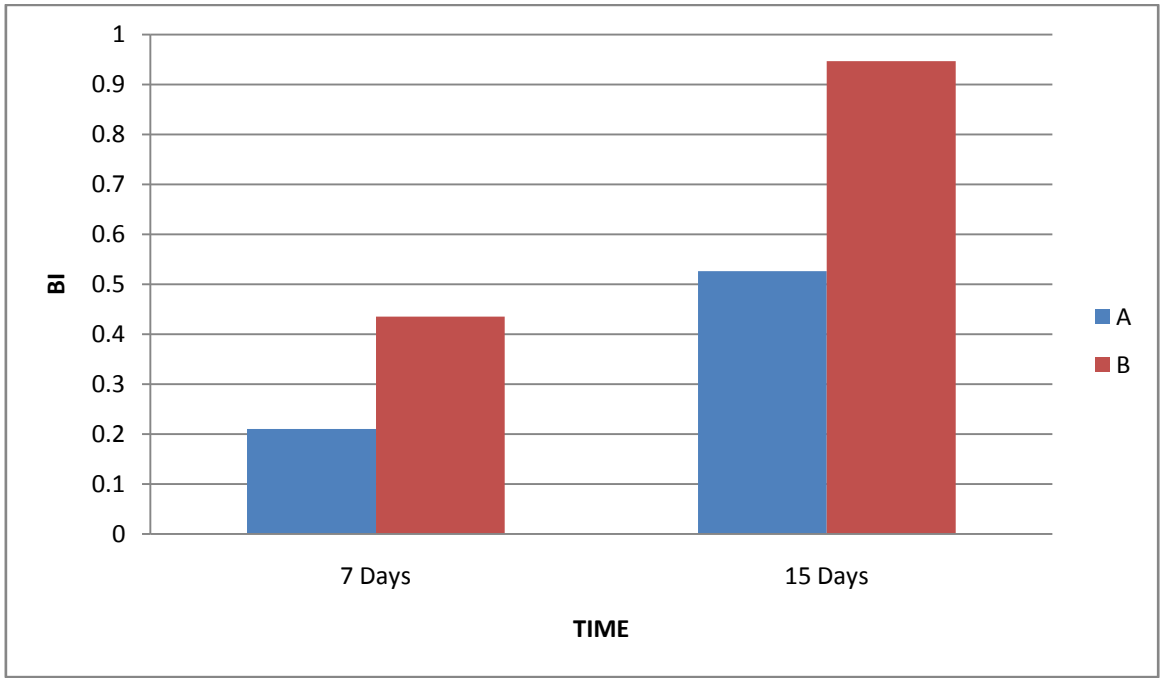

FIGURE 3 – Mean BI in test group (0.2% chlorhexidene with ADS) (A) and control group (0.% chlorhexxidene) (B) at 7 and 15 days.

IV. DISCUSSION

Chlorhexidene digluconate is a broad-spectrum antiseptic, with a pronounced effect on both Gram-negative and Gram-positive bacteria. It has been shown to have both bacteriostatic and bactericidal activity, at a low and a high concentration, respectively. Its antiseptic activity is derived from its capacity to link to anionic groups (phosphate, sulphate and carboxylic group) present on the bacterial surface, causing an increase in cellular permeability and so an alteration in osmotic equilibrium. The chlorhexidene molecule is also able to link to the oral mucosa, enamel surface, salivary pellicle and salivary proteins. It is then slowly released into the oral cavity, maintaining effective concentrations on microrganisms in the following 24 h, showing therefore a high substantivity.[20] However, the use of chlorhexidene 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.[21] Since the effectiveness of the chlorhexidene is strongly correlated to the compliance of the patient, different systems have been introduced in order
to reduce the brown pigmentations and other side effects caused by the use of this type of mouthwash, adding to chlorhexidene different products such as peroxiborate, polyvinyl pyrrolidone or sodium metabisulphite and ascorbic acid.[20]

On comparing 0.2% chlorhexidene mouthwash containing ADS to the standard 0.2% chlorhexidene, it was observed that the 0.2% chlorhexidene mouthwash with ADS has the same antiplaque and antigingivitis effects as the traditional mouthwash with 0.2% chlorhexidene. Moreover a marked decrease in staining was observed with the test mouthwash. In terms of other adverse effects, it was found that two patients reported bad taste that may have resulted from the use of these mouthwashes, confirming previous studies by Moran J et al. in 1994,[22] Santos A in 2003,[13] Ciancio SG in 2000[23] and Armitage GC in 1999.[14]

Few studies have analyzed the staining produced after application of a mouthwash with ADS. Bernardi et al. in 2004,[24] conducted a study in which 15 patients with oral health without gingivitis were given 0.2% chlorhexidene mouthwash with ADS and 0.2% chlorhexidene mouthwash for 15 consecutive days with a 15 day intervening washout period between them. In this study it was concluded that there was no significant difference in relation to PI and GI between the two mouthwashes in healthy patients, but a statistically significant difference was observed in the adverse effect of staining, demonstrating that the mouthwash with ADS prevented pigmentation.[24] Solis et al. in 2011,[25] conducted a similar comparative study on 15 patients with chronic periodontitis and concluded that 0.2% chlorhexidene mouthwash with ADS has less staining than the 0.2% chlorhexidene mouthwash without ADS while the two mouthwashes seemed to be equally effective as antiplaque and antigingivitis agents.[25]

Our study performed in patients with chronic periodontitis corroborates the findings of Bernardi et al.[24] and Solis et al.[25] Cortellini et al. in 2008,[20] conducted a study using 0.2% chlorhexidene mouthwash for one week after periodontal surgery in 48 consecutive patients in treatment. The authors did not allow dental or interdental brushing over the area that underwent surgery. One week later at suture removal, a full professional prophylaxis was performed and the second mouthwash was given with the same indications of use as the first mouthwash. The results were consistent with those obtained in our study. Less staining was observed when using the 0.2% chlorhexidene mouthwash with ADS and similar effectiveness between the two mouthwashes in reducing gingival inflammation after surgery.[20]

There are some limitations of this study that have to be taken into account. The sample is small and the evaluation of staining used is subjective. Other more objective methods like spectrophotometry to measure staining are available, and by using those methods the results might have been different.

V. CONCLUSION

0.2% Chlorhexidene mouthwash with ADS produces less staining than 0.2% chlorhexidene mouthwash without ADS in patients with chronic periodontitis and it is equally effective as an antiplaque and antigingivitis agent during a 15 day period of use. The clinical manifestations and other possible adverse effects were minimal when using either mouthwash for a 15 day period.

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