RESEARCH ARTICLE

EFFICACY OF THE CHLORHEXIDINE CONTAINING DENTIFRICE ON REDUCTION OF PLAQUE AND GINGIVAL INFLAMMATION

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ABSTRACT

Aim: The aim of the study was to determine the plaque and gingivitis reducing effect of a dentifrice containing chlorhexidine and compare with control toothpaste during the course of 3 months. **Materials and Methods:** This randomized, double-blind study looked prospectively at participants over a 3 month period. Plaque score and gingivitis score was assessed in 40 participants, who were divided into two parallel groups. The participants used either chlorhexidine containing toothpaste (test group) or commercially available fluoridated triclosan containing toothpaste (control group). Parameters were assessed at baseline and again after 1and 3 months. **Results:** After 3 months of product use, both groups had less gingivitis compared with the baseline evaluation (p=0.001). At this time point, the test group showed a statistically significant lower gingival index values compared with the baseline (p=0.001). No statistically significant difference between either of the groups at various time points was detected with regard to plaque index score. **Conclusion:** Although there was a statistically significant difference at 3 months between test and control groups in reduction of gingival index values, this difference was too small to be considered clinically meaningful.

INTRODUCTION

Dental plaque is a bacterial biofilm adhering to the tooth surfaces. It is mainly composed of complex bacterial populations organized in a carbohydrate matrix also containing a small number of epithelial cells, leukocytes, macrophages and inorganic components such as calcium and phosphorus. This biofilm structure confers these bacterial populations a high resistance to most chemical anti-bacterial compounds and makes the use of mechanical oral hygiene procedures such as tooth brushing, dental flossing and inter-dental brushing the most effective method for plaque removal (Herrera, 2005). Good plaque control preserves oral health for a lifetime. Many clinical studies clearly indicate that the major deposits of plaque form in stagnation areas, such as the proximal areas, gingival margins, and defects in the teeth (Perry, 1995). These areas are protected from the natural cleansing mechanisms of oral tissues. Thus, emphasis must be placed on the effectiveness and efficacy of plaque removing devices used to facilitate oral hygiene in these elusive areas (Perry, 1995). As tooth brushing is the most common oral hygiene method, dentifrices are the most ideal vehicle for the daily delivery of antibacterial agents. These chemotherapeutic agents should provide a preventive effect against caries and gingivitis

(Frandsen, 1985).Chlorhexidine (CHX) is a cationic antiseptic with action against a wide array of bacteria including Gram-positive and Gram negative bacteria, dermatophytes and some lipophilic viruses. CHX acts on the bacterial cell membrane by changing its structure. As a result, osmotic equilibrium is lost, the membrane extrudes, vesicles are formed and the cytoplasm precipitates (Davies, 1973).The superiority of this agent as opposed to other chemical agents derives from its increased persistence (substantivity), which in turn prolongs its anti-bacterial action. The use of CHX in dentifrices gained little attention because of its possible interaction with anionic ingredients contained in toothpaste (such as sodium lauryl sulphate, SLS) and competition for oral retention sites.5 Therefore, there are only limited data evaluating the clinical efficacy of CHX dentifrices and further studies need to be performed in this field. Hence the aim of this study was to determine the efficacy of chlorhexidine containing dentifrices on reduction of plaque and gingival inflammation and compare it with triclosan containing toothpaste (control toothpaste) during a 3-month randomized clinical trial.

MATERIALS AND METHODS

A randomized double-blinded clinical trial was conducted in the Department of Periodontics Govt Dental college Srinagar,

to assess and compare the efficacy of chlorhexidine containing and triclosan containing toothpaste in controlling plaque and gingivitis over a 3 month period. The study population consisted of 40 dental students of both sexes, with age ranging from 18 to 24 years. The subjects were randomized to one of the two brushing groups using the coin toss method by a second examiner who was not involved in the recording of clinical parameters. Group 1 (n=20) - Brushing twice daily using modified bass technique with chlorhexidine containing toothpaste (Test toothpaste). Group 2 (n=20) - Brushing twice daily using modified bass technique with commercially available fluoride toothpaste containing triclosan (control toothpaste). The subjects were informed about the study, and their consent to take part in the study was obtained in a prescribed form. The study was carried out in accordance with ethical standards of the institutional ethical committee.

Inclusion Criteria

- The presence of gingivitis with full mouth gingival index scores (GI)$\geq$ 1 according to Loe and Silness gingival index
- The presence of a minimum of 20 teeth.
- The absence of a removable partial denture.

Exclusion Criteria

- Use of systemic or topical (oral) antimicrobial therapy in the previous 4weeks
- Presence of systemic disease that have influence on periodontium.
- Hypersensitivity to any of the components of the tested medications.
- Pregnancy, lactation

Primary End point of the Study: Assess the gingival index scores (Loe and Silness) and the plaque scores (Silness and Loe) to estimate the oral hygiene status and thereby, determine the efficacy of chlorhexidine containing dentifrices on reduction of plaque and gingival inflammation at the end of 3 months.

Study Protocol: A proforma was prepared for the study so as to have a systematic and methodical recording of all observations and information. Clinical examinations were done in a dental chair under standard conditions of light, using a mouth mirror and William's periodontal probe. Clinical findings were recorded at six sites on each tooth (distobuccal, mid-buccal, mesio-buccal, disto-lingual, mid-lingual, and mesiolingual), excluding third molars.

Clinical Assessments: Oral hygiene status was assessed using Gingival Index and Plaque Index at baseline. Gingival index scores were recorded using the Loe and Silness Gingival Index, after which a plaque disclosing agent was used. A two-tone disclosing solution that stains bacterial plaque on teeth, enabling us to visualize plaque, was utilized. It stains older plaque blue and newer plaque pink. Two minutes after application of the disclosing solution, the subjects were asked to rinse the mouth with water. The amount of plaque was recorded using the Silness and Loe Plaque Index. After 1 and 3 months of toothpaste use, oral hygiene status was reassessed using Gingival Index (Loe and Silness) and Plaque Index (Silness and Loe) using two tone dye disclosing agent. The use of the appropriate brushing technique, as previously instructed, was stressed upon at each visit.

Randomization, Blinding and Supply of the Products

- All products were supplied in identical tubes.
- The subjects were randomly assigned to either Group 1 (Test group) or Group 2 (Control Group) by flip of a coin and they were unaware as to their allocation to either the test or the control group.
- A Second examiner, who was not involved in the recording of clinical parameters distributed toothpastes.

Statistical Test Used: First, analysis of variance (ANOVA) was used to detect differences within the two groups at various different time points. Inter-group differences between baseline and various follow-up time points were determined using the student's T test for independent variables

RESULTS

All 40 subjects successfully completed the study period of 90 days. None dropped out, and all the subjects maintained their recall appointments. Means and standard deviations of all parameters assessed at the different time points are shown in Table 1

Gingival Index: The Gingival index scores in the test group decreased from baseline subsequently to the 3months follow-up. Statistically significant differences could be detected after 1, and 3 months of product use for the test product versus baseline (p=0.001) as shown in table 2 Post hoc tests using the Bonferroni correction revealed that there was a reduction in Gingival index with test toothpaste from baseline to 1 month (1.24 ±0.29 vs. 0.97 ± 0.21, respectively), which was statistically significant (p = 0.001). At 3 months Gingival index had been reduced to 0.94 ± 0.19, which was statistically significantly different from baseline (p =0.001) but was not significantly different from value at 1 month (P = 0.248).The control group showed a decrease in GI values from baseline to the reexamination points at 1, and 3 months, which were significantly better at all time points (p=0.001) compared with the baseline as shown in table 3. Post hoc tests revealed that there was a reduction in Gingival index with from baseline to 1 month (1.30 ±0.21 vs. 1.04 ± 0.21, respectively), which was statistically significant (p = 0.001). At 3 months Gingival index was 1.06 ± 0.19, which was statistically significantly different from baseline (p =0.001) but was not significantly different from GI at 1 month (P =0.89). No significant differences between the two groups could be seen at 1 and 3 months intervals as shown in table 4.

Plaque Index: The test group showed decrease of PI values from baseline, to 1and 3 months follow-up. There was no statistically significant difference between baseline and re-evaluation at different time points as shown in table 5. The control group showed a decrease of PI scores from the baseline to the 1 and 3 month follow-up visits. However, no statistical significance was observed at any time point as shown in table 6. Plaque indexscores compared between the control group and the test group at different time intervals revealed no significant difference asshown in table 7. From the results obtained, it was inferred that there was a statistically significant reduction in the gingival index scores in both the groups, while the reduction in plaque index score was not statistically significant as compared to the baseline scores. However the difference between the two groups was not statistically significant at both recall intervals.

Table 1. Means and standard deviations of clinical parameters at various follow up time point

Parameter	Time point	Test tooth paste (Mean ± SD)	Control toothpaste (Mean ± SD)
Gingival Index	Baseline	1.24± 0.29	1.30 ± 0.21
	1 month	0.97 ± 0.21	1.04 ± 0.21
	3 month	0.94 ± 0.19	1.06 ± 0.19
Plaque Index	Baseline	1.41± 0.31	1.50 ± 0.27
	1 month	1.34 ± 0.28	1.42 ± 0.26
	3 month	1.37 ± .27	1.45 ± 0.28

Table 2. Pair wise comparison of gingival index scores of test group at two time points

Time	Mean difference	Standard error	P value
Baseline and 1 Month	0.275	0.056	0.001 (S)
Baseline and 3 months	0.305	0.062	0.001(s)
1 month and 3 months	0.030	0.016	0.248(NS)

Table 3. Pair wise comparison of gingival index scores of control group at two time points

Time	Mean difference	Standard error	P value
Baseline and 1 Month	0.260	0.028	0.001 (S)
Baseline and 3 months	0.240	0.031	0.001(s)
1 month and 3 months	0.020	0.19	0.890(NS)

Table 4. Between group comparison of Gingival Index scores (Test & Control group)

Gingival index	Test (mean±SD)	Control (mean±SD)	Mean difference	t- value	P value
Baseline and 1 Month	1.24± 0.29	1.30 ± 0.21	-0.06	-0.685	0.497(NS)
Baseline and 3 months	0.97± 0.21	1.04 ± 0.21	-0.07	-1.056	0.298(NS)
1 month and 3 months	0.94 ± 0.19	1.06 ± 0.19	-0.12	-2.009	0.052(NS)

Table 5. Pair wise comparison of plaque index scores of test group at two time points

Time	Mean difference	Standard error	P value
Baseline and 1 Month	0.075	0.038	0.182 (S)
Baseline and 3 months	0.054	0.044	0.952(s)
1 month and 3 months	-0.030	0.018	0.331NS)

Table 6. Pair wise comparison of plaque index scores of control group at two time points

Time	Mean difference	Standard error	P value
Baseline and 1 Month	0.080	0.030	0.010(S)
Baseline and 3 months	0.070	0.027	0.056(s)
1 month and 3 months	0.030	0.025	0.748NS)

Table 7. Between group comparison of Plaque index scores (Test & Control group)

Plaque index	Test (mean ±SD)	Control (mean ±SD)	Mean difference	t- value	P value
Baseline and 1 Month	1.41± 0.31	1.50 ± 0.27	-0.11	-1.14	0.264(NS)
Baseline and 3 months	1.34 ± 0.28	1.42 ± 0.26	-0.08	-0.08	0.352(NS)
1 month and 3 months	1.37 ± 0.27	1.45 ±0.280	-0.08	-0.93	0.358(NS)

DISCUSSION

This 3-month-long clinical trial was designed to study the efficacy of the Chlorhexidine-based dentifrice. Although the statistical analysis showed a significant improvement of the GI using the test formulation, one can dispute if this effect can be considered clinically significant The use of the control toothpaste also resulted in improvement in the evaluated parameters. This may be because of the phenomenon known as the Hawthorne effect, which could be seen very often in studies which compared dentifrices in combination with tooth-brushing due to a higher awareness of oral health care (Wickstrom, 2000). The reduction of the GI by 24.5% and PI by 5% after 3 months as compared with the baseline data of the test group, as well as the reduction of GI by 18% and of PI by 5% after 3 months compared with the baseline data of the control group, indicates that the test toothpaste with its main

ingredient is more effective in reducing gingivitis. Various studies using different dentifrices have failed to show significant differences between the efficacy of the test and control toothpastes, although GI and PI were reduced compared with baseline values (Mankodi et al., 2002; Winston et al., 2002). The observed reductions in the present study regarding GI are in agreement with those found in other studies as reported by Mankodi et al. (2002) and Winston et al. (2002) According to a recently published review, there are some reasons to believe that CHX and dentifrices are incompatible, but the evidence for this does not allow the drawing of any definitive conclusion (Kolahi, 2006). Moreover, (1) incompatibility is known to occur in aqueous solutions and (2) all studies deal with (SLS)- dentifrices alongside CHX rinsing, but not with both ingredients present together in a single toothpaste. The study of Yates et al.

Which was based on home use and lasted 6 months, demonstrated that both CHX alone and CHX/fluoride formulations were more effective than the placebo in reducing plaque, gingival inflammation and bleeding (Yates et al., 1993). In a subsequent study, it was shown that CHX, as an ingredient of dentifrices, is able to reduce anaerobic counts in supragingival plaque (Maynard, 1993). Comparable clinical results concerning the effectiveness of CHX in toothpaste formulations were reported by others (Sanz et al., 1994; Jenkins et al., 1993). Surprisingly, no side effects such as tooth staining as described by Flotra et al. (Flötra, 1971) could be seen in the present study. In contrast, some investigations using 1% CHX toothpaste reported significantly more tooth staining in the test groups compared with the control groups (Yates, 1993; Jenkins, 1993). Sanz et al. tested a 0.4% CHX containing toothpaste in conjunction with a placebo mouthrinse (experimental group), a placebo rinse and a gum care dentifrice (control), and a 0.12% CHX rinse and a gum care dentifrice as a positive control (participants rinsed after tooth brushing). The authors reported significantly less staining and calculus when the experimental group was compared with the positive control group. It was suggested that these observations occurred because of the abrasive feature of the dentifrice. Thus, it seems that the abrasive character of dentifrices may partly overcome the negative effect of tooth staining while leading to a strong effect similar to that of a 0.12% rinse (Addy, 1989). Although it is well documented that there is a strong correlation between the efficacy of CHX and its staining potential, it may also be anticipated that some other ingredients of such complex toothpaste could have partly inactivated CHX (Addy, 1989). In the present study, the test toothpaste contained only 0.05% Chlorhexidine. Therefore, the non-occurrence of tooth staining may be explained by the abrasive effect of the toothpaste and a reduction in the concentration of CHX. Grundemann et al. studied the effects of the adjunctive use of an oxidizing agent peroxyborate to chlorhexidine to reduce the tooth staining in rinses. They concluded that the proportion of stained surfaces was significantly less when adding the oxidizing mouth rinse to chlorhexidine. Thus, the use of this agent should be tested with dentifrices containing chlorhexidine (Gründemann, 2000).

Limitation And Recommendation

Studies targeting the general population or patients with specific periodontal problems should be considered. Further longitudinal studies involving a larger study sample are needed to assess the long- term effectiveness of chlorhexidine containing dentifrice against plaque and gingivitis.

Conclusion

Within their limits, the present results indicate that

- The twice daily application of the tested toothpaste formulation containing chlorhexidine as main ingredient showed statistically significant effectiveness in reducing gingival inflammation over a 3-month period and no statistically significant difference was seen compared to control toothpaste.
- No side effects such as tooth staining or mucosal alterations were observed during the entire study period of 3 months.

REFERENCES

Addy M., Wade WG., Jenkins S., Goodfield S. 1989. Comparison of two commercially available chlorhexidine mouth rinses: i. Staining and antimicrobial effects in vitro. *Clin Prev Dent.,* 11:10-4.

Davies A. 1973. The mode of action of chlorhexidine. *J Periodontal Res.*, 8:68–75.

Dolles OK, Gjermo P. 1980. Caries increment and gingival status during 2 year's use of chlorhexidine and fluoride containing dentifrices. *Scand J Dent Res.*, 88:22-7.

Flötra L., Gjermo P., Rölla G., Waerhaug J. 1971. Side effects of chlorhexidine mouth washes. *Scand J Dent Res.*, 79:119-25.

Frandsen A. 1985. Changing patterns of attitudes and oral health behavior. *Int Dent J.*, 35:284-90

Gründemann LJ., Timmerman MF., Ijzerman Y., van der Weijden GA., van der Weijden GA. 2000. Stain, plaque and gingivitis reduction by combining chlorhexidine and peroxyborate. *J Clin Periodontol.*, 27:9-15

Herrera D, Santos S, Ferrús J, Barbieri G, Trombelli L, Sanz M 2005. Efficacy of a 0.15% benzydamine hydrochloride and 0.05% cetylpyridinium chloride mouth rinse on 4-day de novo plaque formation. *J Clin Periodontol.*, 32:595-603.

Jenkins S., Addy M., Newcombe R. 1993. The effects of chlorhexidine toothpaste on the development of plaque, gingivitis and tooth staining. *J Clin Periodontol.*, 20:59-62.

Kolahi J. & Soolari A. 2006. Rinsing with chlorhexidinegluconate solution after brushing and flossing teeth: a systematic review of effectiveness. *Quintessence Int.*, 37:605-12.

Mankodi S., Lopez M., Smith I., Petrone DM., Petrone ME., Chaknis P., Proskin HM. 2002. Comparison of two dentifrices with respect to efficacy for the control of plaque and gingivitis, and with respect to extrinsic tooth staining: a six– month clinical study on adults. *J ClinDent.*, 13:228-33.

Maynard JH., Jenkins SM., Moran J., Addy M., Newc ombe RG., Wade WG. 1993. A-6 months home usage trial of a 1% chlorhexidine toothpaste. (II). Effects on the oral micro flora. *J Clin Periodontol.*20:207-11.

Perry DA., Schmid MO. 1995. Plaque control. In: Carranza FA, Newman MG, editors. Clinical Periodontology, 8th ed. WB Saunders Co :493–508.

Sanz M., Vallcorba N., Fabregues S., Müller I., Herkströter F. 1994. The effect of a dentifrice containing chlorhexidine and zinc on plaque, gingivitis, calculus and tooth staining. *J Clin Periodontol.*, 21:431-7.

Wickstrom G., Bendix T. 2000. The ''Hawthorne effect'' – what did the original Hawthorne studies actually show? Scand *J Work Environ Health.*26:363-7.

Winston JL., Bartizek RD., McClanahan SF., Mau MS., Beiswanger BB. 2002. A clinical methods study of the effects of triclosan dentifrices on gingivitis over six months. J Clin Dent.13:240-8

Yates R., Jenkins S., Newcombe R., Wade W., Moran J., Addy M. 1993. A 6-month home usage trial of a 1% chlorhexidine toothpaste. Effects on plaque, gingivitis, calculus and tooth staining. *J Clin Periodontol.*20:130-8.

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