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Comparative effect of fluoride, essential oil and chlorhexidine mouth rinses on dental plaque and gingivitis in patients with and without dental caries: a randomized controlled trial

Abstract: *Objectives:* The objective of this study was to compare the effectiveness of fluoride, essential oil (EO) and chlorhexidine (CHX)-containing mouth rinses on dental plaque and gingivitis and to compare their relative efficacy in patients with and without dental caries. *Material and methods:* A randomized, controlled, double-blind, crossover clinical trial was conducted for a period of 8 weeks. Thiry-six qualifying subjects, aged 12–44 years, were included in the study. Subjects were divided into caries and caries-free groups and were randomly assigned to one of the following mouth rinse groups: fluoride; EO; CHX and saline as negative control. Subjects used their respective mouth rinse for a period of 7-days each with 1-week wash-out periods. Primary efficacy variables were Quigley–Hein plaque index (PI) and Loe and Silness gingival index. *Results:* Fluoride and CHX mouth rinses showed significant reduction in plaque after use of mouth rinses ($P < 0.05$). However, no significant differences were observed with respect to each other in reducing gingivitis ($P > 0.05$). Further significant differences were found in reducing plaque and gingivitis in caries-free subjects in comparison to those with caries ($P < 0.05$). *Conclusion:* All the three mouth rinses significantly reduced plaque accumulation and gingivitis especially in caries-free subjects in comparison to those with caries, and amongst the three, fluoride and CHX proved to be more effective than EO mouth rinse.

Key words: dental caries; gingivitis; mouth rinses; plaque

Introduction

The most prevalent infectious oral diseases in humans, caries, and periodontal diseases, are associated with dental plaque. The removal of bacterial biofilm is a decisive component in the prevention and treatment of these diseases. Because of the difficulty to ensure adequate removal of plaque by mechanical means, there is a great interest in the use of antimicrobial agents to replace or to be adjuncts to the mechanical approaches (1,2). Mouthwashes, a safe and effective delivery system for antimicrobials, have been evaluated for antiplaque properties and have been the subject of considerable research.

Amongst various chemical agents used in mouth rinses, the two most popular and accepted by the American Dental Association's Council for Dental Therapeutics are chlorhexidine (CHX) and essential oil (EO) mouth rinses (3). Numerous long-term studies have demonstrated the effectiveness of mouth rinses containing antimicrobial active ingredients such as CHX and EO in preventing and controlling both *supra* gingival plaque and gingivitis when used adjunctively to mechanical oral hygiene (4). Fluorides have also been used abundantly in oral health products including the mouth rinses. They are proved to be effective in reducing caries and inhibit carbohydrate utilization of oral microorganisms by blocking enzymes involved in the bacterial glycolytic pathway (5). Only two studies in the past demonstrated the comparative efficacy of mouth rinses containing CHX and EO and fluorides in the adult population (4, 6).

Further, the daily removal of dental plaque is considered to be an important factor in prevention of dental caries. The prevalence of this disease is continuously increasing with change in dietary habit of people and increased consumption of sugar. The prevalence of dental caries is approximately 60–65% in India (7). Even though there is a clinically relevant evidence to suggest that mouth rinses containing active agents are effective against dental caries as such, there is a deficiency in studies determining the comparative effect of these mouth rinses in patients with and without dental caries. Hence, this study was designed with the following objectives:

1 To compare the effectiveness of fluoride, EO and CHX-containing mouth rinses on dental plaque and gingivitis and

2 To compare their relative efficacy in patients with and without dental caries.

Materials and methods

Ethical clearance was obtained from the Institutional Review Board of Sri Sai College of Dental Surgery (SSCODS), Vikarabad. All the subjects willing to participate signed an informed consent form after the nature of the study was fully explained to them.

Study population

The study participants comprised of 36 subjects (22-Females, 14-Males), selected from the patients attending the Outpatient Department (OPD) of Public Health Dentistry of SSCODS, Vikarabad. Their age ranged between 12 and 44 years. Subjects who met inclusion criteria underwent an oral examination for caries evaluation. All examinations were conducted by a single, experienced dental examiner and WHO criteria were used for diagnosing dental caries World Health organization (8). Further, subjects were equally enrolled into caries and caries-free groups. The purpose of dividing the subjects into groups as having caries and caries-free is to test the comparative effect of different mouth rinses in relation to their caries status. The inclusion criteria applied were subjects with good general health and no symptoms of destructive periodontal disease, and with a minimum of 24 permanent teeth with six teeth in each quadrant. The exclusion criteria were subjects under antibiotic treatment, smokers and presence of fixed or removable prostheses, and orthodontic appliances.

Sample size calculation

This study was designed to detect a potential mean difference between control and test groups of 0.4 with 80% power and 95% CI for detecting a statistically significant difference in plaque and gingivitis scores at the 0.05 probability level. Assuming a SD of 0.31 the estimated required sample size was 26 for each regime. In view of this, a sample size of 36 subjects were recruited to allow for subject loss during the trial.

Study design

The study was designed as a single centre, randomized, cross-over double-blind study. The study was conducted in Department of Public Health Dentistry of SSCODS, from February to April 2011. Blinding was done by an independent observer who is not the part of the main study. The participants were randomized into groups based on computer analysis by a statistician. Each of them was allocated with all the four mouth rinse formulations. The mouth rinses were supplied in separate 250 ml plastic bottles sealed and coded as A, B, C and D. Along with the mouth rinse, individual measures of 20 ml each were provided. The allocated formulations were used as per the instructions of the manufacturers. The participants had to appear daily at the same time (between 1 and 3 h after the rinsing in the morning) for evaluation of the plaque index (PI) and gingival index (GI). Each subject was assigned a code number according to the order of subject's enrolment and recalled at regular intervals to test the efficacy of mouth rinses. A total of nine visits were scheduled. Subjects were treated for 7 days in each session, with a 7-day wash-out period to avoid carry-over effects. The total length of the experimental period was 57 days. So, each subject was evaluated for eight times (Fig. 1). At their initial visit (Visit 1), each subject received oral prophylaxis and was provided with a kit for oral hygiene containing a dentifrice and soft tooth brush and was instructed to use the kit throughout the study period. A demonstration on tooth brushing was given to all the subjects and was asked to brush in a similar way. Subjects were then instructed on the use of mouth rinses and oral hygiene instructions were given. Patients were then asked to follow their normal diet and daily routine activity. At their 2nd visit, which was planned over 7 days after Visit 1, subjects were assessed for PI and GI after which each subject received allocated mouth rinse and were asked to rinse their mouth twice daily for 7 days. At their next visit (3rd visit) after 1 week, subjects were assessed for their PI and GI after use of mouth rinse. In a similar way, Visits 4 and 5, 6 and 7 and 8 and 9 followed, but with a 7-day wash-out period in between the use of each mouth rinse as per allocated schedule.

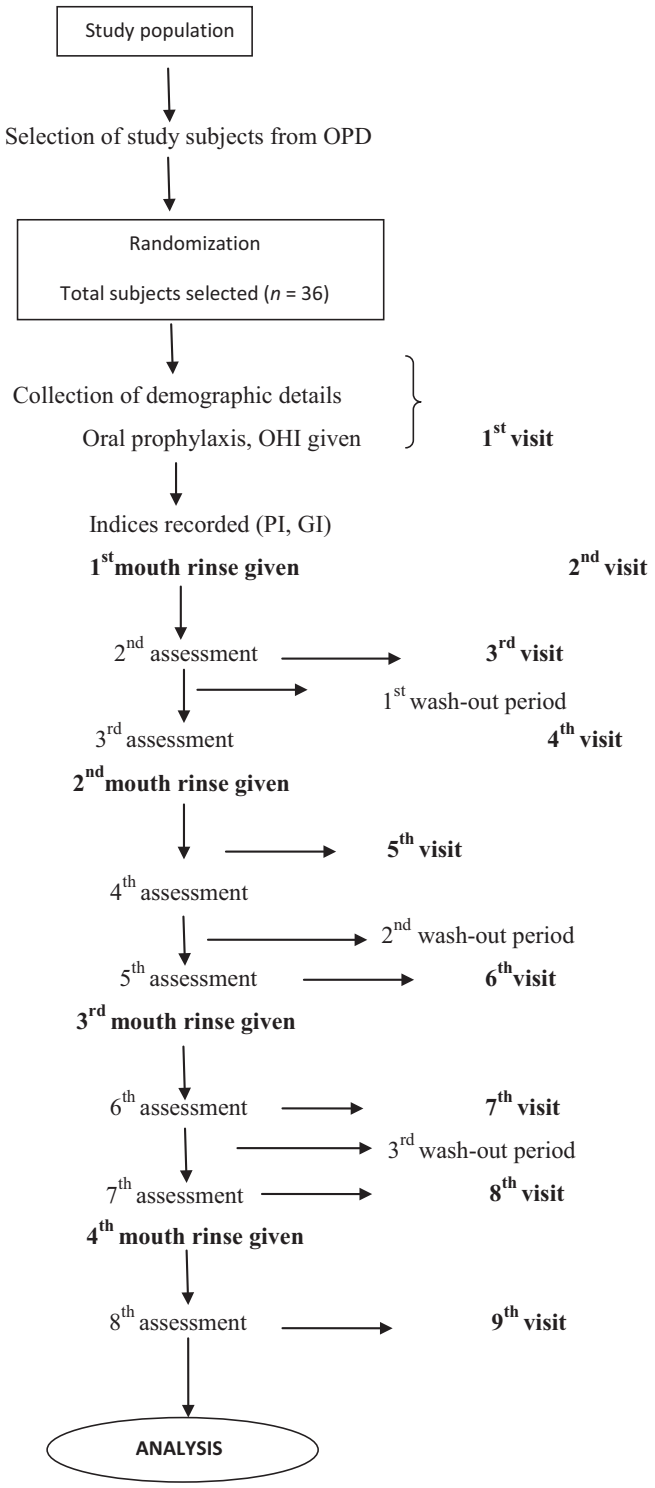

Fig. 1. Flow chart depicting the study design.

Treatment products included in the study are as follows:

1 S-Flo (Sodium Fluoride-0.2% w/v).
2 Listerine (Thymol-0.06%, Eucalyptol-0.09%, Menthol-0.04%).
3 Rexidine (CHX gluconate-0.2% w/v).
4 Placebo rinse (Sodium chloride-9% w/v).

Each subject was assigned a total of four bottles of mouth rinse, one for each of the four formulations under investigation.

Outcome variables

Supragingival plaque was assessed by means of the Turesky modification of the Quigley–Hein PI Turesky *et al.* (9). Scoring of the plaque was performed after staining with erythrosine solution. Gingivitis was evaluated by means of Loe & Silness GI [Loe & Silness (10)]. PI and GI scores were recorded at Visits 2–9 on all scorable teeth.

Statistical analysis

Statistical evaluations were conducted by the computer program Statistical Package for Social Science (SPSS Inc., Chicago, IL, USA) version 19.0. Paired *t* test, Independent sample *t* test and Analysis of variance test were used for the total number of comparisons done. Student–Newman–Keuls test was used as a *post hoc* test to evaluate for significant differences between treatments. Also the GI and PI data of treatment phase were tested for difference using a parametric crossover analysis (ANCOVA) with calculation of carry-over effects (fixed factor analysis) with before values as a covariate and adjustment of baseline values. The *P*-values below 0.05 were accepted as statistically significant for the total number of comparisons performed.

Results

A total of 36 subjects completed the baseline survey. The study sample was categorized based on various criteria such as age, sex, education and caries status for the purpose of statistical analysis. The mean age of the study subjects in caries group was 30.50 ± 5.6 and caries-free group was 27.61 ± 5.5. Amongst 18 subjects in caries group, 33.3% (6) were males and 66.7% (12) were females. Whilst amongst 18 subjects in caries-free group, males constituted around 44.4% (8) and females around 55.6% (10). A total of six participants – three from the caries and three from caries-free groups had dropped out during the study period. Four of them have dropped out due to changes in employments to other places and other two of them were excluded from the study as they were under antibiotic use for a certain time during the study period and hence were not analysed. Hence a total of 83.3% (30) of study subjects has completed the study with 15 in each group [Table 1].

After 1 week of the study period, a statistically significant difference was observed in the PI scores amongst test groups

Table 1. **Distribution of study subjects based on age and gender**

Variable	Caries (*N* = 18)	Caries-free (*N* = 18)
Age (Mean ± SD)	30.50 ± 5.628	27.61 ± 5.543
Gender		
Male	6 (33.3%)	8 (44.4%)
Female	12 (66.7%)	10 (55.6%)

Table 2. **Comparative efficacy of various mouth rinses in relation to PI scores per group and per visit**

Group	*N*	Before	After	*P*-value	*Post hoc* test values
CHX	30	1.93 ± 0.515	1.42 ± 0.383	0.000	0.44019[d]
EO	30	2.21 ± .0368	1.73 ± 0.268	0.000	1.7290[b]
Fluoride	30	1.96 ± 0.488	1.47 ± 0.430	0.000	0.42964[cd]
Placebo	30	2.44 ± 0.338	2.34 ± 0.383	0.095	2.2230[a]

Different superscripts are statistically significant using Student–Newman–Keuls test yet $P < 0.05$.

Table 3. **Comparative efficacy of various mouth rinses in relation to GI scores per group and per visit**

Group	*N*	Before	After	*P*-value	*Post hoc* test values
CHX	30	1.30 ± 0.271	0.97 ± .210	0.000	0.9710[d]
EO	30	1.34 ± 0.282	1.10 ± .219	0.000	1.1030[bcd]
Fluoride	30	1.34 ± 0.285	1.03 ± .210	0.000	1.0273[cd]
Placebo	30	1.44 ± 0.387	1.37 ± .347	0.077	1.3250[a]

Different superscripts are statistically significant using Student–Newman–Keuls test yet $P < 0.05$.

as compared to the control group ($P < 0.05$). Fluoride, EO and CHX mouth rinses significantly reduced PI scores in comparison to placebo rinse ($P < 0.05$). When a comparison was done between test mouth rinses, fluoride and CHX mouth rinse groups showed greater PI score reductions in comparison to EO group based on *post hoc* tests ($P < 0.05$) [Table 2].

Statistically significant difference was also observed in the GI scores amongst test groups as compared to the control group ($P < 0.05$) at the end of the study period. All the test groups proved to be equally effective in reducing GI scores based on *post hoc* tests ($P < 0.05$) [Table 3].

When PI scores were compared in subjects with and without dental caries, a statistically significant difference was observed in the placebo mouth rinse group, after the use of mouth rinse amongst subjects with and without dental caries ($P < 0.05$). In CHX, EO and fluoride mouth rinse groups, a statistically significant difference in PI scores was observed in caries-free subjects in comparison to those with caries ($P < 0.05$) [Table 4].

Test mouth rinses significantly reduced GI scores in caries-free subjects when compared to those with caries ($P < 0.05$). In the placebo mouth rinse group, a statistically significant difference was observed in GI scores after the use of mouth rinse for 7 days amongst subjects with and without dental caries ($P < 0.05$) [Table 5]. Pair-wise comparisons of four mouth rinses in relation to PI and GI scores before and after treatment showed insignificant carryover effect ($P > 0.05$).

Discussion

The present study was designed to investigate the efficacy of CHX, EO and fluoride mouth rinses as an adjunct to daily mechanical oral hygiene measures in reducing plaque accumulation and gingivitis. The study was carried out in a double-blind crossover design. The study population comprised of subjects attending OPD of SSCODS, Vikarabad who were

Table 4. **Comparison of PI in subjects with and without dental caries**

Group	*N*	Caries Before	caries-free Before	Caries After	Caries-free After
Placebo	30	2.69 ± 0.218	2.19 ± 0.236	2.57 ± .250	2.12 ± 0.362
P-value		0.000		0.000	
EO	30	2.40 ± 0.282	2.02 ± 0.348	1.87 ± 0.212	1.59 ± 0.252
P-value		0.002		0.003	
Fluoride	30	2.30 ± 0.254	1.62 ± 0.421	1.77 ± 0.251	1.17 ± 0.349
P-value		0.000		0.000	
CHX	30	2.29 ± 0.269	1.56 ± 0.440	1.73 ± 0.253	1.10 ± 0.356
P-value		0.000		0.000	

Table 5. **Comparison of GI in subjects with and without dental caries**

Group	*N*	Caries Before	Caries-free Before	Caries After	Caries-free After
Placebo	30	1.65 ± 0.357	1.22 ± 0.293	1.55 ± 0.288	1.18 ± 0.306
P-value		0.000		0.000	
EO	30	1.65 ± 0.357	1.22 ± 0.293	1.55 ± 0.288	1.18 ± 0.306
P-value		0.004		0.004	
Fluoride	30	1.47 ± 0.231	1.20 ± 0.275	1.12 ± 0.165	0.94 ± 0.217
P-value		0.007		0.018	
CHX	30	1.44 ± 0.223	1.16 ± 0.249	1.08 ± 0.160	0.86 ± 0.201
P-value		0.004		0.003	

allocated on a random basis into the study based on inclusion and exclusion criteria. The two main outcome parameters used in the study were GI and PI. These clinical indices offer simple screening methods which have stood the test in many studies (11). A 7-day wash-out period was considered between the uses of respective mouth rinses. The data analysis in this study showed that there were no carry-over effects. In the present study, a total of six participants were lost to follow up during the study period due to various reasons. However, analysis of the data taking into consideration the drop-outs did not change the demographic distributions and hence did not affect results.

Our observations confirm results reported in previously published studies. The finding that there was a statistically significant reduction in PI scores in all the test groups in comparison to the placebo rinse group is consistent with results of previously reported studies (3, 6, 12, 13). This reflects the antimicrobial activity of these mouth rinses which tended to reduce plaque formation in these individuals.

In the present study, fluoride and CHX mouth rinse formulations were found to have comparable antiplaque efficacy followed by EO mouth rinses. The present findings are similar to those obtained by Brecx *et al.* (3) where tooth cleaning was performed as an adjunctive to mouth rinsing similar to that in the present study. The findings of which were in contrast to a study conducted by Reip *et al.* (12). where EO mouth rinse was found to be most effective. These differences could be attributed to differences often encountered in clinical studies due to the difference in baseline Pl scores between these studies involving different population groups.

Consistent with other studies (14, 15), in the present study, the Gl scores also fell significantly in all test groups from baseline. In addition, the scores revealed that all test rinses were equally effective in reducing GI scores. The present findings were similar to those obtained by Brecx *et al.* (3), Zimmermann (16) and Netuschil *et al.* (17) Whilst these findings were found to be in contrast to studies conducted by Brecx *et al.* (6) where CHX was found to be more effective than EO and fluoride mouth rinses in improving gingival health. The above finding might have been obtained due to differences in CHX formulations tested in these studies and can also be attributed to different study periods considered in these studies.

The improvements observed in all the study groups are certainly in due part to the ' Hawthorne effect'. However, these improvements must be attributed not only to the 'study effect' but also to the efficacy of the active substances. Earlier *in-vivo* studies present similar results of the use of mouth rinses to those of the present study. The second objective of this study was to compare efficacy of mouth rinses in subjects with and without dental caries. The study is unique because as of now, no comparison has been done on testing the efficacy of the mouth rinses in relation to the subject caries status. At baseline, PI and GI scores were found to be significantly higher amongst subjects with caries. This finding is in contrast to previous studies where a significant correlation was lacking between subject's caries status and plaque indices, even though, a few studies have found a connection between effective oral hygiene and reduced caries index (18, 19). This finding might have been obtained due to difference in the indices used and different study populations involved in these studies.

In line with the results, all the test mouth rinses were found to be effective in reducing plaque and gingivitis scores in caries-free subjects in comparison to those with caries. The findings also show that fluoride and CHX mouth rinses are slightly superior to EO rinse in reducing the PI and GI scores in these subjects. Hence, it is suggested that each of these products may have a distinct and useful place in the management of patients with dental caries. These results cannot be correlated directly with other studies due to the relative lack of literature on comparison of mouth rinses in relation to subject's caries status. However, this finding shall be considered with caution taking into consideration initial baseline PI and GI scores in both the subjects and also the smaller sample size used in the study. The results indicate that further studies are warranted, with a larger sample size, where each group to be followed longitudinally, and by using various combinations of mouth rinses such that more reliable data can be obtained for suggesting their use in subjects with and without dental caries.

Conclusion

All the three mouth rinses significantly reduced plaque accumulation and gingivitis especially in caries-free subjects in comparison with those with caries. Amongst the three, fluoride and CHX proved to be more effective than EO mouth rinse.

Disclosure

The authors confirm that no financial assistance was received from the manufacturers of any of the products used in the study. The authors have never been employed or served as consultants to the manufacturers of any of the products mentioned in this study.

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