A Comparative Study of Fluoride Containing Chlorhexidine and Non Chlorhexidine Mouthrinses in a Teenage Group

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Abstract:

Background: Mouthwashes are important means used in chemical control of dental plaque. There is strong evidence suggestive of better effectiveness, when fluoride is added to chlorhexidine mouthwash.

Objectives: The study was planned to assess the effect of a mouthrinse containing Chlorhexidine (CHX) and amine/stannous fluoride (AmF) on plaque accumulation, gingivitis and salivary fluoride levels in comparison with two mouthrinses containing either essential oils (EO) or cetylpyridinium chloride (CPC) with sodium fluoride (NaF) in a teenage group.

Methodology: For this study 90 healthy teenage between 12 and 20 years were recruited for participation. The experimental gingivitis model consisted of a 2-weeks recruitment phase, followed by a 6-day rinsing period with one of the 4 mouthrinse formulations was used for the study. At the end of the pre-phase period and the rinsing period (Day-0/Day-6), gingival index (GI), plaque index (PI) and salivary fluoride levels were recorded. The statistical analyses were performed using Wilcoxon sign test and the dependent t test.

Results: A reduction in plaque re-growth was seen for the CHX+AmF formulation rinse, although there were no significant differences among all groups ($p>0,001$). During the experimental periods, the gingivitis indices increased significantly for all formulations ($p<0,001$), except for the CHX+AmF formulation. The CHX+AmF formulation scored higher levels of salivary fluoride at the end of the rinsing period ($p>0,001$).

Conclusion: We would like to conclude that the adjunctive use of AmF containing CHX mouthrinses to mechanical oral hygiene should be recommended for teenage at risk groups.

Keywords: CT KUB, Radiation safety, Minimise radiation

Introduction:

Plaque is the primary etiological factor in gingival inflammation. Lack of proper maintenance of oral hygiene measures result in formation of pathogenic plaque [1]. Therefore, plaque control

represents the cornerstone of good oral hygiene practice [2]. Majority of patients might not use these mouthrinses as a oral hygiene product effectively owing to the degree of awareness and

motivation required [2,3]. Hence, to improve the potential deficiencies of daily self performed oral hygiene regime an adjunctive chemical plaque control approach is desirable.

Mouthrinses are the most frequently used chemical plaque control at home and are in use for centuries as breath fresheners, medicaments, antiseptics and can be used as a vehicle to deliver anti-plaque ingredient in the oral cavity for plaque control [4]. Normally, a therapeutic mouthrinse contains an active ingredient

Over the years, studies have showed that chlorhexidine digluconate (CHX) is the most effective antimicrobial agent used for plaque control [5,6]. However, the side effects of CHX, primarily staining, taste alteration, and enhancing supragingival calculus formation, limit its potential for long-term use, while promoting interest in research to determine the efficacy of alternative antiplaque agents. The three antimicrobial systems classified as safe and efficacious for the treatment of plaque-induced gingivitis by the FDI plaque subcommittee were cetylpyridinium chloride (CPC), amine/stannous fluoride (AmF/ SnF₂), and essential oils (EO) [7].

Hence, the present study was planned to assess the effect of a mouthrinse containing CHX and AmF on plaque accumulation and salivary fluoride levels in comparison with two mouthrinses containing either EO or CPC with NaF in a group of school children aged 12-20 years.

Materials and Methods

This prospective study was conducted at Department of Dentistry, Parul Institute of Medical Sciences and Research, Parul University, Vadodara, Gujarat, India from July 2020-May 2021.

For this study, eighty-two systemically healthy children between 12-20 years of age were recruited. To qualify, the participants had to have at least 20 teeth, show no signs of periodontal destruction, have no caries or extensive restorations, and have not been exposed to systemic antibiotics during the past 6 months.

The experimental gingivitis model consisted of a 2-week recruitment phase, followed by a 6-day rinsing period during which each participant abstained from all mechanical plaque control measures, but rinsed twice daily with one of the 4 mouthrinse formulations (Table 1) [7,8]. The CHX formulation (Elgydium Fluoride mouthwash, Pierre Fabre Oral Care, France) was used as a positive control rinse, and the 0.9% sodium chloride (NaCl) formulation was used as the negative control rinse.

The treatment protocol requested 3 visits from each participant in the study center. At the first visit, the participants underwent a professional tooth cleaning and oral hygiene instructions were followed for a 2-week period in which the subjects were asked to practice a high standard of plaque control at home. All subjects were given the same toothpaste and toothbrush (Colgate-Palmolive Company, USA) [9]. Neither the subjects nor the examiners knew which formulation was assigned to a subject. All of the groups were delivered in identical opaque white bottles. All subjects entering the rinse phase had a mean age of 14.01 years (range 15-20 years). No significant differences were revealed in the demography of the groups.

At the end of the pre-phase period, gingival index (GI) and plaque index (PI) were assessed and recorded as baseline examinations, followed by a professional tooth cleaning in the Department of Periodontology at the same college (Day-0). 80 subjects who had a $GI \leq 0.5$ were then selected to enter the rinse phase of the study. Then, in the Department of Pedodontics, the saliva samples were collected from subjects under close supervision no earlier than two hours after a meal between 9:00 and 12:00 to evaluate the fluoride concentration of the saliva as baseline examination (Day-0). Prior to collection of each sample, the subjects were asked to sit and relax. The paraffin-stimulated saliva was collected for five minutes in a graduated sampling tube and transported to the laboratory in ice. The use of the study products was explained to the subjects by an individual not involved in the clinical data recording.

The first rinsing was performed under supervision in the study center. The subsequent rinsing was performed by the subjects at home each morning and evening during the 6-day study period. The use of additional mouthrinse preparations, dentifrices, and mechanical tooth cleaning measures was not allowed. The participants were randomly divided into four treatment groups of 20 subjects and rinsed with 10 ml. of the study product for 1 min twice a day. The subjects were instructed not to eat, drink, or rinse for 30 min. following the rinse. On day 6, subjects received a re-examination of their oral soft and hard tissues and were scored for PI and GI (Day-6). Immediately after recording the indexes, to determine the fluoride level, stimulated saliva samples were collected and fluoride ion activities were measured (Day-6).

Following clinical indices (at baseline and after the rinse phase of the study, Day-0 and Day-6), data were recorded for monitoring the plaque accumulation and gingival situation of the participants before and after the rinse phase of the study: Turesky Modification of Quigley-Hein Plaque Index (TMQHP) with the use of a 0.2 % erythrosine disclosing agent and gingival index (GI) [10]. All clinical parameters were measured with a William's probe calibrated in millimeters.

Salivary fluoride levels (at baseline and after the rinse phase of the study, Day-0 and Day-6) were

also assessed, and the fluoride ion activities were measured by means of a fluoride ion-specific electrode (Model 94-09, Orion Research, Inc., Cambridge, MA) and a reference electrode. The electrodes were immersed in buffered water between periods of use and were equilibrated in a suitable buffer standard NaF solution immediately before use.

Statistical Analysis

A data analysis was performed using prizm software.. The Kruskall-Wallis test was used to measure the fluoride, plaque index, and gingival index levels. In the event of significant results, the Mann-Whitney U test was used for comparisons between two groups. A p value < 0.05 was considered statistically significant.

Results

All subjects satisfactorily completed the rinsing regimens. The impact of all mouthrinse formulations on the plaque formation, together with the reduction rate in the plaque index is summarized in Table 2.

A reduction (Day-6/Day-0) in plaque index was seen for the CHX+AmF formulation rinse, although there were no significant differences among all groups ($p>0.05$).

Table 1: Factors examined in the study

GROUP NAME	PRODUCT NAME	MANUFACURE	INGREDIENT	FLOURIDE TYPE/LEVEL
GROUP 1	ORAL B Tooth & Gum care mouth rinse	Procter & gamble, USA	Cetylpyridinium Chloride Mint Flavour	Sodium fluoride (0.05%) (226ppm F)
GROUP 2	Elgydium Fluoride	Pierre Fabre oral Care, France	Fluorinol, Chlorhexidine, Siliglycol.	Amine fluoride (250ppm F)
GROUP 3	Listerine Fluoride	Johnson, Johnson	Water sorbitol solution, potassium sorbate, flavors, poloamer 407, sucralose, citric acid, Cetylpyridinium Chloride	Sodium fluoride (0.0221%) (0.01% w/v fluoride ion)

GROUP 4	Control/Placebo	Eczacıbaşı, Baxter, Turkey	0.9% Naocl	
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Table 2: Effect of mouthrinses on 6-Day plaque re-growth

Mouth rinse	Day 0	Day 6	p ^a	Changes in Plaque regrowth	p ^b
Oral B	0,57(0,33-1,07)	1,84(1,50-2,09)	<0.001	1,19(0,82-1,37)	0.784
Elgydium	0,68(0,34-1,14)	1,64(1,39-2,09)	<0.001	1,20(0,33-1,50)	
Listerine	0,57(0,28-1,22)	1,75(1,38-2,24)	<0.001	1,0(0,66-1,30)	
Control	0,35(0,22-0,65)	1,61(0,33-2,23)	<0.001	1,05(0,78-1,70)	

a: Comparison intra group(Wilcon isaret test)

b:Comparison between group(Kruskal wallis test)

Table 3: Changes in gingival index scores over time (Day-0/Day-6)

Mouth rinse	Day 0	Day 6	p ^a	Changes in gingival index scores	p ^b
Oral B	0,02(0-0,16)	0,24(0,15-0,33)	<0.001	0,13(0,08-0,24) ^c	0.002
Elgydium	0,13(0,10-0,42)	0,16(0,10-0,26)	0.842	0,01(-0,08-0,08) ^{c,d,e}	
Listerine	0,09(0,06-0,13)	0,21(0,11-0,32)	<0.001	0,13(0,07-0,21) ^d	
Control	0,12(0,07-0,14)	0,20(0,16-0,25)	<0.001	0,11(0,06-0,14) ^c	

a: Comparison intra group(Wilcon isaret test)

b: Comparison between group(Kruskal wallis test)

c: stastitically significant difference between Oral B and Elgydium(p<0.001)

d: stastitically significant difference between Listerine and Elgydium(p<0.001)

e: stastitically significant difference between Control and Elgydium(p=0.000)

Table 4: Difference in salivary fluoride level(Day 0/day 6)

Mouth rinse	Day 0	Day 6	p ^a	Changes in salivary fluoride levels/ppm	p ^b
Oral B	0,13(0,11-0,17)	0,11(0,10-0,12)	0.012	-0,02(-0,05-0) ^{c,d,e}	0.002
Elgydium	0,19(0,11-0,55)	0,29(0,13-0,65)	0.002	0(-0,10-0,10) ^{c,g}	
Listerine	0,40(0,16-0,71)	0,12(0,11-0,31)	<0.001	-0,24(0,40-0,04) ^{d,f}	
Control	0,09(0,08-0,12)	0,01(0,01-0,01)	<0.001	0,07(0,11-0,05) ^{e,g}	

a: Comparison intra group(Wilcon isaret test)

• Comparisons between groups (Kruskal Wallis testi).

• Statistically significant difference between groups Oral B and Elgydium (p<0,001).

• Statistically significant difference between groups Oral B and Listerine (p<0,001).

• Statistically significant difference between groups Oral B and Control (p=0,029).

• Statistically significant difference between groups Elgydium and Listerine (p<0,001).

• Statistically significant difference between groups Elgydium and Control (p<0,001).

The GI of each group at the beginning and end of the rinsing period is shown in Table 3. During the experimental periods, without oral hygiene but with the use of different mouthrinses, the gingivitis indices increased significantly for all formulations ($p < 0.05$), except for the CHX+AmF formulation, which showed a statistically insignificant increase at the endpoint (Day-6) ($p > 0.05$).

The impact of the different mouth rinse formulations on the salivary fluoride levels is shown in Table 4. When the change in salivary fluoride levels over time (Day-6/Day-0) was considered in each group, the CHX+AmF formulation scored higher levels of salivary fluoride at the end of the rinsing period ($p > 0.05$), when compared to the other formulations. Conversely, salivary fluoride level changes among all groups were significant over time (Day-6/Day-0) ($p < 0.05$).

Discussion

Plaque accumulation and subsequent gingivitis are common in orthodontic patients because of the challenge of controlling oral hygiene with the combination of brackets, bands, wires and elastomeric ligatures. Poor oral hygiene can eventually lead to the formation of white spot lesions, decay and hyperplastic gingival tissue that may require intervention by a general dentist upon the completion of orthodontic treatment.^[8]

Human dental plaque is one of the ecosystems in which maximum numbers of microorganisms are observed. Though a wide array of anti-plaque agents are available in the market^[9], we have chosen pure composition, one brand with chlorhexidine (Mouthwash Hexidine® i.e., 0.2% chlorhexidine gluconate) and another with sodium fluoride (Clohex Plus® i.e., 0.2% chlorhexidine gluconate and 0.05% sodium fluoride) to see if there is any conjugated and synergistic effect in inhibiting plaque.

The daily supplement use of antibacterial mouthrinse in maintaining oral hygiene measures is important in inhibiting plaque formation. The cationic antiseptic chlorhexidine has often been used as a positive control during the assessment of

other agents potential on plaque accumulation. However, the side effects limit its duration of use. Recently, chlorhexidine +fluoride mouthrinse formulations have become a current issue promising better tolerance and similar efficacy^[10].

Researchers have suggested that fluoride enters into the plaque directly or indirectly. The retention of fluoride in the mouth after application of dental products such as dentifrices and mouthrinses may be associated with an oral fluoride reservoir. As the reservoir may serve as storage for fluoride, which releases its contents into saliva gradually and fluoride that is present in the mouth in a labile form is likely to be the most beneficial. Therefore, both fluoride and chlorhexidine containing mouthrinses have come into the market as they inhibit dental caries and plaque

Researchers have suggested that fluoride enters into the plaque directly or indirectly. The retention of fluoride in the mouth after application of dental products such as dentifrices and mouthrinses may be associated with an oral fluoride reservoir. Such a reservoir may serve as storage for fluoride, which releases its contents into saliva gradually, and fluoride that is present in the mouth in a labile form is likely to be the most beneficial. As a result of this common knowledge, both fluoride and CHX containing mouthrinses have come into the market suggesting that they inhibit the development of dental caries and plaque. Jayaprakash *et al*^[11] demonstrated that the use of mouthrinse with the CHX-NaF combination in addition to mechanical cleaning had better results than both mechanical cleaning alone or in combination CHX containing mouthrinse in the means of reducing plaque and gingival index scores, at the end of the 6 month.

Joyston-Bechal and Hernaman^[12] revealed that the combination of fluoride and CHX has been very effective on both plaque and gingival bleeding. Recently, non-CHX fluoride containing products are available with a long-term usage advantage and have been used as supplements to regular tooth cleaning.

The present study was designed to determine the short-term plaque inhibiting effect of AmF

containing CHX mouthrinse compared to two of non-CHX NaF containing mouthrinses. Two non-CHX containing mouthrinses, one containing a fixed combination of 4 essential oils and NaF and the other containing CPC and NaF, were included in the comparative plaque and gingivitis re-growth study reported herein.

A number of studies have examined salivary fluoride levels after application of fluoride-containing mouthwashes. In all these, cases salivary fluoride levels were examined after a single use of such treatments [13]. Unlike previous studies, in this study, the fluoride release into saliva by NaF and AmF containing mouthrinses was compared over a 6-day washout period.

On the other hand, the statistical analysis revealed a clear-cut difference between the CHX group and all three non-CHX containing mouthrinse preparations with respect to GI and salivary fluoride levels. Moreover, the CHX group showed similar GI at the start (day 0) and endpoint (day 6) of the clinical trial. The significant difference may be due to the effect of AmF. A significant amount of evidence is available that supports that fluoride exposure from mouthrinses with AmF or NaF was sufficient to build up reservoirs of fluoride. Qgaard *et al.* [14], revealed that fewer lesions and decreased gingival inflammation developed on the upper anterior jaw in the AmF-containing mouthrinse group compared with that of NaF containing.

Conclusion

We would like to conclude that the adjunctive use of AmF containing CHX mouthrinses to mechanical oral hygiene should be recommended for teenage at risk groups.

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