

Original Article

An analogical study of two mouth rinses on plaque and gingivitis among school children aged 12-15 years in Jamshedpur, Jharkhand, India

Chakraborty Pareshnath^{*1}, Kumari Archana¹, Prasad Anushree², Pratheeth G³, Spoorthi Sri⁴ and Krishnamurthy K¹¹Department of Orthodontics and Dentofacial Orthopaedics, Awadh Dental College and Hospital, Jamshedpur, Jharkhand, India²Department of Conservative Dentistry and Endodontics, Awadh Dental College and Hospital, Jamshedpur, Jharkhand³Department of Oral Medicine and Radiology, C.K.S. Theja Institute of Dental Sciences, Tirupathi, Andhra Pradesh⁴Resident Doctor, Hyderabad, Andhra Pradesh, India***Corresponding Author**

Dr. Chakraborty Pareshnath
 Post-Graduate Student,
 Department of Orthodontics and
 Dentofacial Orthopaedics
 Awadh Dental College and Hospital
 Jamshedpur, Jharkhand, India
 E-mail: drpareshnathc@gmail.com

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Abstract

Context and Background: Mechanical methods are known for prevention and control of periodontal diseases since long. It is important to consider these procedures too yet they are labor-intensive and difficult for many patients. Based upon this consideration and aiming to make dental plaque control more accessible to a significant proportion of population, less labor-intensive methods are highly desirable. Consequently, efforts have been made to utilize chemical agents in conjunction with or even instead of mechanical plaque control procedures and have been tested by incorporating them into mouthwashes.

Aims and objectives: The aim of the present study was to assess the effect of a plain chlorhexidine (CHX) mouth rinse on plaque and gingivitis scores; and to compare a chlorhexidine-sodium fluoride (CHX+NaF) mouth rinse with a plain chlorhexidine (CHX) mouth rinse without fluoride among a group of children in Jamshedpur, Jharkhand, India.

Methods: Using a double blind randomized controlled clinical trial, 60 subjects aged 12-15 years were grouped into 3 groups: CHX; CHX+NaF; and Placebo. In each one of the 3 groups, the subjects discontinued all oral hygiene measures and continued with the experimental set-up randomly assigned. Levels of gingivitis and plaque scores were assessed at baseline and at the end of 1 and 3 months by using Silness and Loe Plaque Index and Loe and Silness Gingival Index.

Results: The effectiveness of CHX+NaF mouth rinse is superior with regard to inhibition of plaque and gingivitis scores as compared to CHX alone. For CHX+NaF, mean reduction was 1.37854 whereas for CHX, it was 1.18486 for plaque score between baseline and 3 months. For gingivitis score, the mean reduction was 1.0516 for CHX+NaF whereas 1.0659 for CHX between baseline and 3 months.

Conclusion: Chlorhexidine in combination with active ingredient Sodium Fluoride inhibit the plaque and gingivitis more effectively as compared to Chlorhexidine alone. This combination along with the well-established effect of fluoride in the prevention of caries is an important contribution to dental public health.

1. Introduction

Bacterial plaque plays an essential role in the development of periodontal disease since its accumulation inevitably leads to gingivitis.[1] The physio-pathological mechanisms by which gingivitis progresses to periodontitis are not well understood; this is the reason as to why preventing periodontal disease is based mostly on adequate plaque control methods.[2] Periodontal diseases frequently begin in childhood and often have lifelong sequel. Hence, the removal of bacterial biofilm is a decisive component in the prevention and treatment of these diseases.[3] Mechanical methods are known for prevention and control of periodontal diseases since ages. Some authors consider that they are time-consuming for both professionals as well as patients.[4] It is important to consider these procedures too yet they are labor-intensive and difficult for many patients.[4,5] Based upon this consideration and aiming to make dental plaque control more feasible as well as accessible to a significant proportion of population, less labor-intensive methods are highly desirable. Consequently, efforts have been made to utilize chemical agents in conjunction with or even instead of mechanical plaque control methods and have been tested by incorporating them into mouthwashes. Over the years, a number of enzyme preparations, antiseptics and surface active agents, have been used as supplements to routine mechanical plaque control methods including a daily tooth cleaning program.[6,7]

Chlorhexidine (CHX) is considered as a safe and effective antiseptic for the reduction of plaque, gingivitis and mutans streptococci levels, both in plaque as well as saliva.[8] Undesirable effects such as taste disturbances, tooth discoloration and mucosal erosions,

however, limit the duration of use of chlorhexidine to just a few weeks.[9] Fluorides, on the other hand, have been well-known for their anti-cariogenic role. The fluoride based mouth rinses are probably one of the most commonly used agents for caries prevention. However, the anti-gingivitis potential of sodium fluoride in combination with chlorhexidine has rarely been evaluated.[10,11]

Chlorhexidine reduces plaque acid formation for several hours preventing the decrease in pH and additionally, has great effectiveness in the reduction of gingivitis too.[2] At present, no chlorhexidine-sodium fluoride products are commercially available and there is limited literature available on the synergistic effect of chlorhexidine-sodium fluoride products on gingivitis scores in the form of mouth rinse among teenagers who are particularly prone to gingivitis.[12] Hence, this study was planned to assess the effect of mouth rinse containing chlorhexidine and sodium fluoride on plaque accumulation and gingivitis scores in comparison with a mouth rinse containing chlorhexidine alone in a group of school children aged 12-15 years in Jamshedpur, Jharkhand, India. The aim of the present study was to assess the effect of plain chlorhexidine mouth rinse on plaque and gingivitis scores; and to compare a chlorhexidine-sodium fluoride based mouth rinse with a plain chlorhexidine mouth rinse without fluoride among a group of children in Jamshedpur, Jharkhand, India.

2. Material and Methods

This study involved a randomized controlled clinical trial with double blind design. The study design was approved by ethical committee of Awadh Dental College and Hospital, Jamshedpur,

Jharkhand, India. Since the study was a clinical trial spread over a period of 3 months, 60 school children of Kendriya Vidyalaya aged 12-15 years studying in eighth and ninth class and residing in boy's hostel were selected by simple random method. The permission from the Hostel Authority was obtained for continuous cooperation and support during the study period.

2.1 Inclusion criteria

Subjects who gave written informed consent along with their parents with good general health of children, a minimum 12 gradable teeth, agreement for continuous cooperation and support during the study period and agreement to comply with the study visits and procedures were included in the study.

2.2 Exclusion criteria

Subjects on antibiotic therapy since last three months, history of early onset periodontitis, acute necrotizing ulcerative gingivitis, gross oral pathology and with a history of treatment for cancer, seizure disorders and conditions that interfered with the examination procedures were excluded.

A written informed consent was taken from the participants as well as their parents prior to the start of study. Before examination was started, personal information regarding the subjects were recorded in specially prepared proformas. Level of gingivitis and plaque scores were assessed at baseline and at the end of 1 month and 3 months by using Silness and Loe Plaque Index and Loe and Silness Gingival Index under artificial light using plane mirror, probes and explorers. Whenever plaque was not visible, the explorer was passed across the tooth surfaces in the cervical third. The probe was then made to run along the soft tissue wall near the gingival sulcus to evaluate bleeding component of the Gingival Index. The students were randomly numbered 1-60 and mouth rinse samples were numbered randomly 1-60 by mouth rinse manufacturers. The coding was done by the manufacturer and the three different solutions were known only to the manufacturers. It was later known to the investigator at the end of the study.

The examinations were conducted at baseline, after 1 month and 3 months by a single trained examiner to rule-out the possibility of inter-observer bias. The students who were assigned with particular numbers were provided with the mouth rinse with the same number. The subjects were divided into three groups according to the type of

mouth rinse so that the effect of different mouth rinses could be assessed: Group 1 (chlorhexidine; (CHX)); Group 2 (chlorhexidine + sodium fluoride; (CHX+NaF)); and Group 3 (placebo). The subjects discontinued all oral hygiene measures and were treated with the experimental mouth rinse samples randomly assigned. The subjects started their first mouth rinse with the specific solution from each group under the supervision of the investigator, following a daily routine of mouth rinsing, twice a day. 10 ml of mouth rinse samples from their respective bottles were measured and administered to the students and they were instructed not to ingest anything for the following 30 minutes after using the mouth rinse.

The subjects were also instructed to report any spells of sickness, change in taste perception or visible staining of teeth during the course of the study. Once the study was completed, the manufacturer in the factory did the decoding of the mouth rinse groups. For each subject, Plaque Index and Gingival Index means were calculated and subjected to statistical analysis by a paired t-test. A p-value less than 0.05 was considered to be statistically significant.

3. Results

Table.1 reveals that a general improvement in plaque scores were noticed amongst all the participants at the time of examination after 1 month as compared from the baseline. During the examination performed at 3 months, the mean plaque scores showed to be declining in groups 1 and 2 due to use of mouth rinses as prescribed. There was a statistically significant difference seen between groups 1 and 2 at 1 month and 3 months' intervals. Statistically significant differences were also seen between groups 1 and 3; and 2 and 3. Similarly, when the groups were compared individually, the results showed that group 2 was having the least mean plaque score followed by group 1 at the end of three months (p=0.010). Table 2 reveals that the gingival scores showed to have declined at the time of examination done after 1 month when compared with the baseline. However at the end of 3 months, a decrease in the mean gingival score was observed in group 2 with a statistically significant difference seen between group 2 and 3. Statistically significant difference was also seen between groups 1 and 3. Similarly, when the groups were compared individually, the results showed that group 2 was having the least mean plaque score followed by group 1 at the end of 3 months (p=0.000).

Table 1: Comparison of the mean plaque score of Plaque Index amongst the study groups

Groups	PI at 0 th month (baseline)			PI at 1 month			PI at 3 months		
	Mean	t	p-value	Mean	t	p-value	Mean	t	p-value
1(CHX)	1.4647	-0.063	0.950	0.42934	3.256	*0.002	0.27984	2.784	*0.010
2(CHX+NaF)	1.4751		(>0.05)	0.15210		(<0.05)	0.09656		(<0.05)
3(Placebo)	1.3462	0.665	0.510	1.34010	-7.341	*0.000	1.34350	-8.008	*0.000
2(CHX+NaF)	1.4751		(>0.05)	0.15210		(<0.05)	0.09656		(<0.05)
3(Placebo)	1.3462	0.589	0.560	1.34010	-5.048	*0.000	1.34350	-6.419	*0.000
1(CHX)	1.4647		(>0.05)	0.42934		(<0.05)	0.27984		(<0.05)

*p<0.05 (statistically significant); PI = Plaque Index

Table 2: Comparison of scores of Gingival Index amongst the study groups

Groups	GI at 0 th month (baseline)			GI at 1 month			GI at 3 months		
	Mean	t	p-value	Mean	t	p-value	Mean	t	p-value
1(CHX)	1.2741	1.007	0.320	0.52316	2.876	*0.007	0.2082	6.377	*0.000
2(CHX+NaF)	1.1483		(>0.05)	0.25366		(<0.05)	0.09670		(<0.05)
3(Placebo)	1.1335	0.665	0.510	1.15950	-7.879	*0.000	1.1760	-9.292	*0.000
2(CHX+NaF)	1.1483		(>0.05)	0.25366		(<0.05)	0.09670		(<0.05)
3(Placebo)	1.1335	0.980	0.333	1.15950	-4.615	*0.000	1.1760	-8.326	*0.000
1(CHX)	1.2741		(>0.05)	0.52316		(<0.05)	0.2082		(<0.05)

*p<0.05 (statistically significant); GI= Gingival Index

4. Discussion

The present study was intended to determine that active ingredient sodium fluoride in combination to chlorhexidine is more effective than chlorhexidine alone on plaque accumulation and gingivitis and showed to reduce the adverse effect of chlorhexidine. The combination of fluoride and chlorhexidine has been known to be very effective against both dental caries and gingivitis.[9,10] The teenage

population was chosen because these subjects are known to practice inadequate oral hygiene methods, experience more plaque scores and are more prone to develop subsequent gingivitis, but rarely demonstrate symptoms of periodontal diseases. Undoubtedly, the result of the research has shown that chlorhexidine in combination with sodium fluoride is superior to the chlorhexidine mouth rinse alone with regards to the inhibition of plaque accumulation.

The results of the present study are in coherence with the results obtained by in the studies conducted by Joyston and Hernaman[10,11] and Jenkins *et al*[13]. This can be explained according to Emilson CG [14] that small fluoride ion can reach mutans streptococci which survive in the retention sites and in incipient enamel lesions, interfering with their metabolic activities and subsequently, contributing to their death by deranged metabolic activities while delaying their re-appearance as well. Another possibility, according to Spets-Happonen *et al*[15], is the decrease of the ecological advantage of these bacteria in retention sites with low pH, since acid production is inhibited to a greater extent by the combination of chlorhexidine and sodium fluoride.[16]

Twetman and Peterson [16], employing varnish, also demonstrated a better effect on mutans streptococci when the substance was combined, emphasizing that, despite the utilized method, a probable synergic action can occur. Therefore, inhibition of cariogenic micro-organisms will, thereby, inhibit plaque accumulation which will further prevent the incidence as well as severity of caries and gingivitis. Consequently, a randomized double blind, experimental gingivitis model was designed to compare the effectiveness of chlorhexidine and chlorhexidine-sodium fluoride based mouth rinse to assess their effectiveness in reducing the plaque scores and gingivitis and the occurrence of associated adverse events. There was no significant difference found between the treatment procedure for plaque development with a lower capacity to retard the formation of new dental plaque and gingivitis development. Similarly, the chlorhexidine-sodium fluoride based mouth rinse resulted in a significant lesser development of gingivitis than the chlorhexidine mouth rinse alone and was found to be more effective. The possible reason for the effect of placebo in gingivitis reduction is, however, debatable. It appears that in clinical trials, a suggestion is made to the patient that a prescribed product is an effective treatment that leads to considerable improvement, irrespective of the therapeutic potential of the formulation.¹⁷ In terms of plaque accumulation, the use of CHX, in our study had shown the mean plaque score of 0.42934 and 0.27984 at 1 month and 3 months respectively while a study conducted by Carlos Carlos Alfredo *et al*[3] had shown the mean plaque score of 0.12 at baseline and 0.11 after 14 days. The difference in terms of mean plaque scores from our study and Carlos Alfredo *et al*[3] study may be due to the different duration of the experimental study. On the other hand, Jayaprakash *et al*[18], with an experimental design similar to our study, demonstrated statistically significant difference in mean plaque scores between CHX and CHX+NaF based mouth rinses wherein mean plaque reduction was 0.27984 for CHX+NAF based mouth rinse. In our study, it was 1.37854 at the end of 3 months. As far as adverse drug events were concerned, it was noticed that amongst the CHX users, oral tingling and burning sensation were most frequently reported while CHX+NaF group was more associated with soreness and oral ulceration.

5. Conclusion

This study showed that a combination of mechanical cleaning and supervised mouth rinse program is more beneficial for plaque control than the use of mechanical method alone. Based on the results obtained from the present study, it is reasonable to conclude that combination of CHX+ NAF was found to be significantly more effective in the reduction of gingivitis and plaque scores.

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