Original Article

A Clinical Study Evaluating the Effectiveness of Commercially Available Dentifrices in Controlling Gingivitis

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Abstract

Introduction: Bacterial plaque is the forerunner to gingivitis and if untreated can lead to periodontitis. The incorporation of ingredient like antiplaque and antigingivitis into a dentifrice is an attractive option to augment mechanical cleaning procedures.

Objective: To compare the clinical efficacy of the dentifrices in controlling gingivitis.

Methodology: A 4 week randomized controlled, double blind; parallel design clinical study was conducted. A sample size of 30 subjects was obtained. Subjects were randomised into Group I and II of 15 each. Groups were compared by ANOVA and the significance of mean difference within and between the groups was done by Tukey's post hoc test.

Result: The mean GI score in both group decreases (improve) after the treatments and the decrease (improvement) was evident higher in group I as compared to group II. Comparison of gingival index score in group I and II revealed similar ($p>0.05$) gingival index score between the groups at 0 wk and 2 wk, while decreased significantly at 4 wk ($p<0.05$) in group I as compared to group II.

Conclusion: The result from this study confirms that a dentifrice containing 0.3% triclosan, 2.0% PVM/ MA copolymer is efficacious in reducing gingivitis and supragingival plaque.

Keyword: Dentifrices, substantivity, antiplaque,

Introduction

Bacterial plaque (biofilm) is the forerunner to gingivitis, and is widespread in general population. If left untreated, gingivitis can lead to periodontitis, which may further lead to chronic infection and loss of attachment.[1] Based upon survey data, it has been suggested that over 75% of adult population is affected by gingivitis.[2]

Even with effective tooth cleaning, bacteria colonizes on the tooth surface, most notably around the gingival margin and interdental spaces which if untreated can result in periodontal pocket, bone resorption, and tooth loss.[2]

Having a disease free oral cavity is now more important than ever.[3] Worldwide, many techniques and products are designed to achieve improved oral health like floss, dentifrices, toothbrush etc. Professional procedures such as prophylaxis and scaling/ root planning provide clinically proven and accepted benefit.[4]

The delivery of an active ingredient with antiplaque and antigingivitis benefits can be through a dentifrice or a mouthrinse. The incorporation of such ingredient into a dentifrice is an attractive option to augment mechanical cleaning procedures, as dentifrices are typically used along with a toothbrush for routine oral hygiene.[4]

To meet this need, the oral health professionals need evidence to support a recommendation to their patients for the daily use of a dentifrice that is supplemented by an antiplaque and antibacterial agent.[1, 2] This clinical research aims to evaluate the effect of commercially available dentifrice in controlling gingivitis.

Aim & Objectives

Aim: To evaluate the effect of commercially available dentifrice in controlling gingivitis.

Objectives: To compare the clinical efficacy of both the dentifrices in controlling gingivitis.To collect baseline data.

Materials & Method

A 4 week randomized controlled, double blind; parallel design clinical study was conducted. A sample size of 30 subjects was obtained based on the records available in previous studies.

Test product used in the clinical study was:

1. Colgate total pro gum health (ingredients are 0.3% Triclosan, 2.0% PVM/ MA copolymer).
2. Colgate dental cream (ingredients are Triclosan without copolymer).

Commercially available dentifrice containing 0.243% sodium fluoride in a silica base acted as a washout product. Both the product were painted by a white paint by the manufacturer and was coded from 1 to 30 to mask the identity of the dentifrices.

Ethical clearance was obtained from ethical committee of BBDCODS, Lucknow and informed consent was obtained from each subjects.

Inclusion Criteria

1. Subjects between the age 18 to 30 years and who are available for 5 week duration of the study.
2. With atleast 20 uncrowned permanent natural teeth (excluding third molars).
3. Subjects were required to present at baseline with a mean gingival index score of atleast 1 as determined by the use of the Loe- Silness Gingival Index.

Exclusion Criteria

1. Had prosthesis, orthodontic bands, or advanced periodontal disease, tumor(s) of the soft or hard oral tissues or ≥ 5 carious lesion requiring immediate restotrative treatment.
2. Had a history of allergies to personal care/ consumer products or their ingredients, or they could not refrain from eating or drinking due to medical conditions for a

period of upto 4 hours.
3. Pregnant or breast feeding women.
4. Used antibiotics at any time during the one month period prior to entering the study.

Study Procedure

Subjects who met inclusion/ exclusion criteria received a baseline gingivitis examination. Oral prophylaxis was performed for the qualifying subjects. Subjects were given washout products and a Colgate soft bristle manual toothbrush. Subjects were instructed to use these products only and to brush twice daily for the washout period of one week. Subjects returned to the clinic after commencement of 1 week. Subjects were randomised into 2 groups (I and II) of 15 each.

In Group I- 1 to 15 numbered dentifrice were given and in Group II- 16 to 30 numbered dentifrices were given along with the toothbrush. Subjects were instructed to brush teeth with their assigned dentifrice and toothbrush only, twice daily for 1 minute. There were no restrictions regarding diet or smoking during the course of the study, but were instructed to refrain from any oral hygiene procedures for 12 hours, drinking and smoking for 4 hours prior to their examination at the end of 2 week and 4 weeks.

Subjects returned after 2 weeks and 4 weeks of product use. Gingival Index was recorded during the examination using Loe and Silness Gingival Index and the data was sent for analysis.

Statistical Analysis

Data was summarized as Mean ±SD. Groups were compared by repeated measure analysis of variance/ANOVA and the significance of mean difference within and between the groups was done by Tukey's post hoc test. A two sided (α= 2) p value less than 0.05 ($p< 0.05$) was considered statistically significant. Analysis was performed on SPSS software.

Result:

Basic characteristics: The basic characteristics (age and gender) is summarised in Table 1. . Further, in both the groups, the frequency (%) of male was higher than female with slightly higher being in group II. Comparing the sex proportion (M/F) between the two groups, χ^2 test revealed similar sex proportion between the two groups.

Characteristics	Control (n=15) (%)	Study (n=15) (%)	t/χ_2 value	P value
Age (years)	21.64± 4.27	22.17± 4.16	0.34	0.733
Sex: Females Males	6(40.0%) 9 (60.0%)	7 (46.7%) 8 (53.3%)	0.14	0.713

Table 1: Basic characteristics of two groups

Primary outcome measure: the pre(0 wk) and post(2 and 4 wk) gingival index score of two groups are summarised in Table 2 and 3 and also shown graphically in Fig 1 and 2. Table 2 and figure 1 both showed that the mean GI score in both group decreases (improve) after the treatments and the decrease (improvement) was evident higher in group I as compared to group II.

Further comparing the GI score within the groups, Tukey's test revealed insignificant ($p> 0.05$) changes in GI score over the period in group II, though it decresed 8.9% and 19.7% respectively at 2 wk and 4 wk as compared to 0 wk and 11.8% at 4 wk as compared to 2 wk.

However, in group I, it decreased significantly ($p<0.001$) both at 2 wk (40.1%) and 4 wk (84.7%) as compared to 0 wk in Fig 2.

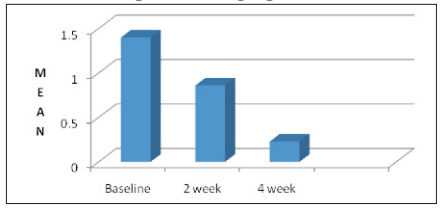
Further in group I, the mean GI score also decreased significantly ($p<0.001$) at 4 wk

Time period	Gingival Index Scores Mean± SD	Mean change from baseline	P value[1]
Baseline	1.40± o.86	-	
2 weeks	0.86± 0.57	0.54± 0.35	0.0001*
4 weeks	0.23± 0.22	1.17± 0.69	0.0001*

(74.4%) as compared to 2 wk.

*significant, [1]Paired t test

Table 2: Comparison of gingival index score in



Group 1

Fig1: Comparison of Gingival Index score in group

Comparison of gingival index score in group I and II: Tukey's test revealed similar ($p>0.05$) gingival index score between the groups at 0 wk and 2 wk, while decreased significantly at 4 wk ($p<0.05$) in group I as compared to group II.

Time period	Gingival Index Score Mean± SD	Mean change from baseline	P value
Baseline	1.39± 0.84		
2 week	1.27± 0.78	0.12± 0.08	0.0001*
4 week	1.12± 0.71	0.27± 0.16	0.0001*

*significant, [1]Paired t test

Table 3: comparison of gingival index score in Group II

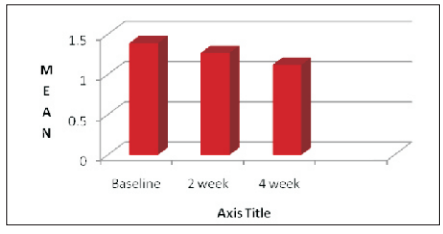


Fig 2 : Comparison of Gingival Index score in group II

Time period	Average percent change in Gingival index score mean± SD		P value[1]
	Group I	Group II	
Baseline to 2 wk	40.1	8.9	0.0001*
Baseline to 4 wk	83.3	19.7	0.0001*

*significant, [1]Unpaired t test

Table5: Average percent change in Gingival Index Score

Discussion

Result of the present study has shown that toothbrushing using toothpaste containing triclosan with PVM/ MA copolymer significantly reduces gingivitis than the toothpaste containing triclosan without copolymer, within 4 week period. This can be explained by the fact that triclosan being a bisphenolic antibacterial agent has low toxicity and a broad spectrum of activity against both gram positive and gram negative bacteria, but on combining with copolymer PVM/ MA its effectiveness and substantivity increases as the copolymer formation ensures delivery and retention of the triclosan on the hard and soft tissue. effective levels of triclosan are retained in the oral cavity [12] hours after brushing the teeth, allowing prolonged control of oral bacteria that causes plaque, gingivitis, tartar etc. Without the copolymer, triclosan would be rapidly lost from the mouth, reducing its clinical effect.[4,5]

Results are in agreement with clinical study done by Mankodi S et al [15], that a dentifrice containing 0.3% triclosan, 2.0% PVM/ MA copolymer, provides a significant reduction in plaque and gingivitis. Mc Clanahan SF [16] in his study on the effects of triclosan/ copolymer dentifrice on dental plaque and gingivitis in a clinical trial showed 4.2% reduction in Gingival Index Score.

In addition, research by Singh S[5] et al and Ayad F et al[6] demonstrate that a dentifrice containing 0.3% triclosan, 2.0% PVM/ MA copolymer, provides a superior anti- plaque and anti- gingivitis benefits. Effectiveness of using simple triclosan formulation has also been shown beneficial in this study.

This is in agreement with the study done by Renvent S et al [17], on comparison between 3 triclosan dentifrices showed a significant reduction in gingival bleeding during the study period. 18.2% and 13.7% toothpaste containing colgate and pepsodent, gingival bleeding index reduced from 0.3 to 0.2 ($p<0.001$).[9]

Study done by Niederman R[19] on an effects of triclosan containing toothpastes reduces plaque and gingivitis, the triclosan dentifrice significantly reduced gingivitis with weighted mean difference of 0.12 at the end of 6 months unsupervised use of dentifrices.

In a study done by Umashankar G et al[20] determining the effectiveness of

toothbrushing with dentifrices containing 0.3% triclosan on gingivitis and was noticed that there was marked improvement between gingival health and short term use of triclosan dentifrice with mean gingival score of 1.45+ 0.26 at the baseline and 1.30+ 0.28 at 4 week period.

Taking limitation into consideration control group was not used in this study as the efficacy of two dentifrices was evaluated and the results were compared with each other.

Conclusion

The result from this study confirms that a dentifrice containing 0.3% triclosan, 2.0% PVM/ MA copolymer is efficacious in reducing gingivitis and supragingival plaque. The results from this research, utilizing a head to head comparison of 2 commercially available dentifrices, also show that the dentifrice containing 0.3% triclosan, 2.0% PVM/ MA copolymer provide a greater level of antigingivitis efficacy than does a dentifrice containing triclosan without copolymer.

Recommendations

1. To educate the masses about the maintenance of oral health.
2. Prescribing the best available dentifrice to patient based on their need.
3. Dentist should have a proper knowledge about the types of dentifrices and other oral hygiene regime available.

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