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Comparative Evaluation of Four different Dentifrices of Preventive or Complementary medicinal System on Dental Plaque and Gingivitis- A Randomized Double Blinded Clinical Trial

Research Article

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Abstract

Background and Aim: Dental caries is the most common non communicable disease, highly prevalent in peoples of all walks of life which possess a major public health concern. Dental Plaque is implicated in caries causation which is related with shifts in the microbial balance of the biofilm especially streptococci. Clinicians should prevent this interference to the natural microbial balance of the biofilm which can be accomplished through regular tooth brushing with dentifrices containing antibacterial agents. To compare the effectiveness of Probiotic, Green tea, Chlorhexidine and Fluoride containing dentifrices on dental plaque and gingivitis.
Materials and Methods: A double blinded, parallel group, randomized controlled clinical trial was conducted among healthy adults. Subjects were randomly allocated to four groups (n=13). Group I- Green tea dentifrice, Group II- Fluoridated dentifrice, Group III- Chlorhexidine dentifrice & Group IV- Probiotic dentifrice. Plaque & Gingival index scores were recorded at Baseline, 15th & 30th day of follow up. Paired t test & One way ANOVA were used to compare the mean differences of Plaque Index, Gingival Index scores at two and three time periods respectively.
Results: The mean plaque and gingival index was significantly reduced by all the treatment groups at 30th day follow up. However, Group III showed the highest reduction & was found to be statistically significant ($p<0.05$).
Conclusion: All the four groups exhibited antiplaque and antigingivitis activity by bringing about significant reduction in mean Plaque & Gingival Index at 30th day follow up. Among all the treatment modalities, Group III (chlorhexidine dentifrice) showed more excellent results compared to other groups.
Clinical Significance: To establish optimal oral health and to reduce dental disease burden in the community, public can be encouraged to use the dentifrices used in the present study for their regular oral hygiene practice, as the observed antiplaque and antigingivitis efficiency were almost similar to the established or gold standard Fluoride containing conventional dentifrice.

Keywords: Probiotic Dentifrice; Green Tea Dentifrice; Chlorhexidine Dentifrice; Plaque Index; Gingival Index.

Introduction

The World Health Organization (WHO) has ranked dental caries, as number three among all chronic noncommunicable diseases and has affected 60-90% of school children worldwide [1, 2]. Plaque-induced gingivitis is the most commonest form of periodontal disease [3] which is considered to be the second most common dental disease after dental caries, affecting more than 75% of the population worldwide [4, 5]. Dental plaque biofilm structures possess a high resistance to most chemical antibacterial compounds and therefore, the use of mechanical oral hygiene procedures such as tooth brushing, dental flossing and interdental brushing were considered to be the most effective method for plaque removal [6].

The European Workshop (1998) on Mechanical Plaque Control

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highlighted the significance of regular oral hygiene practices in effectual removal of dental plaque to strengthen dental and periodontal health throughout lifetime [7]. A relatively high degree of determination, manual dexterity and potent oral hygiene regime are needed to accomplish the level of oral hygiene necessary to control bacterial plaque formation. So using an anti-plaque or an anti- gingivitis agent can amplify mechanical plaque removal which in turn produce an antimicrobial effect. An anti-plaque agent is defined as the chemical that has an effect on plaque sufficient to benefit caries and gingivitis. An anti-gingivitis agent is defined as the chemical which reduces the gingival inflammation without necessarily influencing bacterial plaque [8].

Several oral hygiene measures have been adapted to eliminate plaque and to preserve oral health for life time. One among them is toothbrushing. As tooth brushing is considered to be 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 [9].

A recent systematic review explored the impact of dentifrice formulation on the ability of various materials to prevent biofilm attachment and regrowth. The results reported have indicated that dentifrices containing fluoride and no active antiplaque ingredients in their formulations displayed only weak inhibitory effects against the regrowth of oral biofilms when compared to water or saline solutions [10]. As a result of this, manufacturers have incorporated several active and natural ingredients to commercially available dentifrices to improve their surface-active properties against dental plaque biofilms.

The side effects encountered with the use of fluoridated toothpaste formulations has also led to the search of novel and safe alternatives. In recent years, substitutes for fluorides such as green tea, probiotic and chlorhexidine tooth pastes have been proposed to possess antiplaque and antigingivitis properties.

Clinical trials conducted in the recent years have evaluated the beneficial effects of green tea, probiotic and chlorhexidine by means of various delivery systems and vehicles such as mouthrinse, chewing gum, tablets, lozenges and powder. Therefore, there are only limited data and very few studies have explored the clinical effectiveness of green tea, probiotic and chlorhexidine dentifrices, since dentifrices are considered to be the most ideal vehicle for the daily delivery of antimicrobial and antiplaque agents.

Hence, the present study was conducted to compare the effectiveness of Probiotic, Green tea, Chlorhexidine and Fluoride containing dentifrices on dental plaque and gingivitis.

Materials and Methods

Study Design

The present study is a double blinded, parallel group, randomized controlled clinical trial.

Sample Size Estimation

The sample size was calculated using a priori by G*Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany) based on the study by Burton et al., [11]. The minimum sample size of each group was determined following these input conditions: power of 0.95 and $P \leq 0.05$ and the sample size arrived was 13 per group.

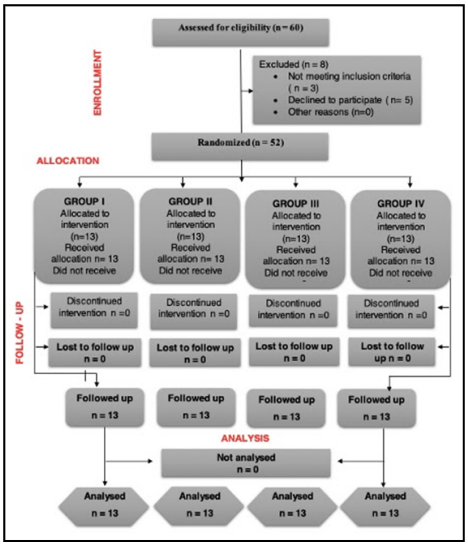
Ethical Clearance and Informed Consent

Prior to the start of the study, ethical clearance was obtained from the Institutional Ethics Committee, Saveetha university {SRB/SDMDS12ORT16}. Trial was submitted to Clinical Trial Registry- India and the acknowledgement number for this trial will be REF/2015/10/010000 and the Registration Number is CTRI/2016/10/007404. Written Informed consent was obtained from all the participants who were willing to participate in the study.

Eligibility Citeria

Apparently healthy individuals without any known positive history of systemic illness between 18-25 years of age group with a DMFT score of less than 3, mild-to-moderate Gingival Index

Figure 1. Image represents a flow chart of the randomization followed in the study.



score (Loe and Silness J.,1963) and with Good to Fair Plaque Index score (Silness and Loe.,1964) and with a habit of tooth brushing twice daily were included in the study. Participants with a history of routine use of mouth-rinses in the previous 3 months and with a history of allergic or idiosyncratic reactions to product ingredients, and those who were undergoing orthodontic treatment were excluded from the study.

Sequence generation

Sequence generation was done using Computer-generated block randomization with a block size of four to generate the assignment schedule well in advance by a third person who was not involved in the study. The investigator was blinded to the sequencing of the block and allocation of the groups. Fifty-two participants were randomly allocated to four groups (n = 13): Group I - green tea dentifrice, Group II - fluoridated dentifrice, Group III - Chlorhexidine dentifrice, and Group IV – probiotic dentifrice (refer Fig 2).

Allocation Concealment

SNOSE (Sequentially numbered, opaque, sealed envelopes) method was followed for allocation concealment, which concealed the sequence until interventions were assigned. Participants were assigned their study numbers as they sequentially entered into the study. Based on the group assigned, respective treatment was carried out.

Blinding

Although the investigator knows about the study design and dentifrices that were used in the study, investigator is unaware about which dentifrice has been assigned to each study participant. Therefore, both the investigator and microbiologist were blinded in this study.

Study Procedure

Step 1: Obtaining preoperative details and informed consent from study participants-Prior to the treatment, a careful medical and dental history was taken. Preoperative data for each participant were recorded in a predesigned proforma which includes age, gender and address. The study design was explained to the qualified participants and informed consent was obtained.

Step 2: Application of plaque test disclosing solution (refer Fig 3)- Plaque test is generously applied to the surfaces of the teeth with the help of applicator brush. The study participants were instructed to rinse the mouth.

Step 3: Evaluation of plaque under polymerization blue light (refer Figure 3).

The surfaces of the teeth are illuminated with a polymerization blue light. Any areas affected by plaque appear brightly fluorescent. The teeth appear blue and the gingival tissues appear dark blue.

Step 4: Scores and Criteria for recording Plaque (Silness and Loe) and Gingival Index (Loe and Silness) - Plaque index was recorded for the entire dentition prior to oral prophylaxis with the help of plaque test disclosing solution. Gingival index was recorded for the entire dentition and in all the surfaces of the teeth. The surfaces include distobuccal, mid buccal, mesiobuccal, palatal surface. The mean score of plaque and gingival index is recorded in the pre structured proforma.

Step 5: Oral Prophylaxis - A complete oral prophylaxis was performed for all the subjects in order to standardize the study participants.

Step 6: Oral hygiene instructions and tooth brushing technique- A standardized toothbrush and the toothpastes were allocated ac-

Figure 2. Image represents the four groups to which the study participants were allocated to. Group I : Green tea dentifrice, Group II: Fluoridated dentifrice, Group III: Chlorhexidine dentifrice, Group IV: Probiotic dentifrice.

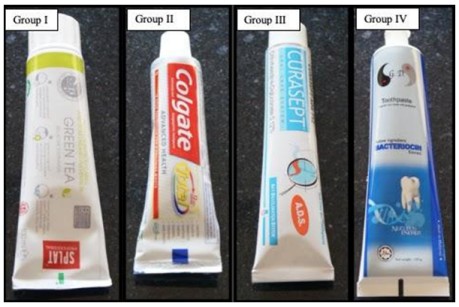
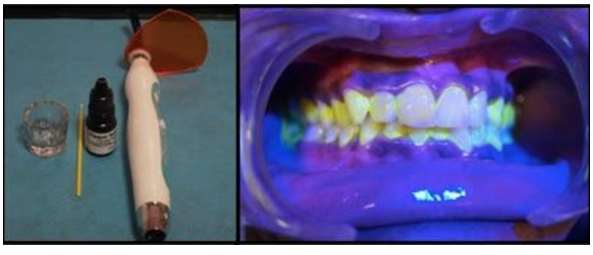


Figure 3. Image represents the application of plaque disclosing solution and evaluation of plaque under polymerization blue light.



cording to the group. Oral hygiene instructions with an emphasis on the appropriate brushing technique were given.

Outcome Measure

The investigator recorded the mean score of plaque and gingival index after the use of tested products at baseline, 15th day and 30th day and compared the effects of four dentifrices to determine the percentage reduction in mean plaque and gingival index score between these groups.

Statistical Analysis

Data was entered in Microsoft excel spreadsheet and analysed using IBM SPSS software version 20.O (Armonk, NY: IBM. Corp., USA). Numerical data were presented as mean and standard deviation values. For the test, a p value of <0.05 is to be considered statistically significant. Shapiro Wilks test used to test the normality of the data set. Paired t test was used to compare the mean differences of Plaque Index, Gingival Index scores at two time points. One way ANOVA And Post Hoc Tukey's test was used to compare the mean differences of Plaque Index, Gingival Index scores at three time points.

Results

Fig 4 and 5 shows the changing trends of Mean Plaque index and Mean Gingival Index scores of Group I, II, III, IV at baseline, 15th and 30th day. All the four groups showed a reduction in mean plaque index and gingival index scores from baseline to 15th day of follow up. During 30th day follow up, there was no reduction in Group I & IV, but Group II & III showed a reduction. However Group III showed a highest reduction in mean Plaque index scores of 0.92 and mean Gingival index scores of 0.91 at Baseline to 30th day of follow up period.

Fig 6,7 depicts percentage reduction of Plaque index and Gingival index scores of Group I, II, III, IV at two time points. All the four groups showed a percentage reduction of plaque index and gingival index scores from Baseline to 15th day & from Baseline to 30th day while during 15th to 30th day follow up, there was no reduction in Group I and IV which in turn showed a negative plaque index value of -0.34, -0.48 and gingival index negative value of -24.49, -0.16 respectively, but Group II & Group III showed a reduction of 17.5, 19.01 and 0.23 & 18.83 with respect to plaque and gingival index scores. However Percentage reduc-

Figure 4. Image represents the changing trends of Mean Plaque Index scores of Group I, II, III, IV at baseline, 15th and 30th day.

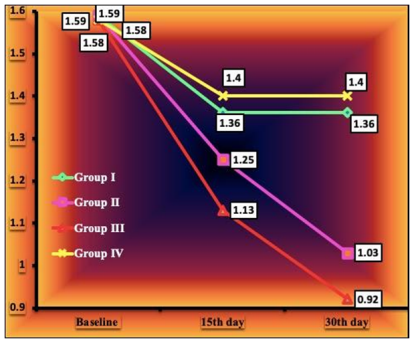


Figure 5. Image represents the changing trends of Mean Gingival Index scores of Group I, II, III, IV at baseline, 15th and 30th day.

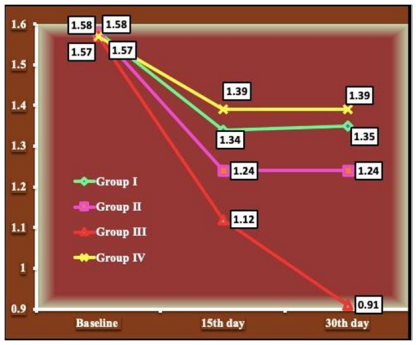
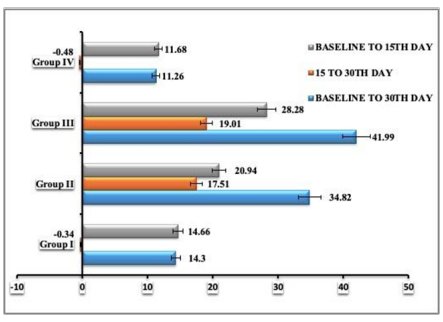


Figure 6. Image represents percentage of reduction of plaque index scores of Group I, II, III and IV from baseline to 15th day to 30th day.



tion of Plaque index and Gingival Index scores of Group III was found to be highest among all the four groups at two point comparison from Baseline to 30th day which is 41.99 and 41.72 respectively.

Table 1 and 2 shows the comparison of Mean Plaque index and Gingival Index scores (Silness and Loe) of Group I, II, III, IV at two time points using Paired 't' test. Both Group II & Group III showed a statistically significant difference in mean plaque index and gingival Index scores at two point comparison. However the mean difference for Plaque index and Gingival index scores for Group III from Baseline to 30th day are 0.66 ± 0.05 and 0.65 ± 0.06 which clearly signifies that Group III to be superior among all the dentifrices tested.

Figure 7. Image represents percentage of reduction of gingival index scores of Group I, II, III and IV from baseline to 15th day to 30th day.

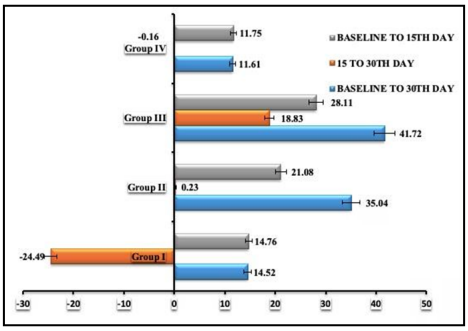


Table 1. Comparison of Mean Plaque index scores (Silness and Loe) of Group I, II, III, IV at two time points. Paired 't' test(p<0.05)*.

Groups	N	Plaque Index scores			
		Time points	Mean difference	t value	p value
I	13	Baseline to 15th day	0.23 ± 0.06	13.72	P< 0.05
		15th to 30th day	-0.004 ± 0.08	-1.89	P>0.05
		Baseline to 30th day	0.22 ± 0.06	13.66	P< 0.05
II	13	Baseline to 15th day	0.33 ± 0.06	19.09	P< 0.05
		15th to 30th day	0.22 ± 0.04	16.78	P< 0.05
		Baseline to 30th day	0.55 ± 0.07	28.29	P< 0.05
III	13	Baseline to 15th day	0.45 ± 0.06	23.81	P< 0.05
		15th to 30th day	0.21 ± 0.03	20.98	P< 0.05
		Baseline to 30th day	0.66 ± 0.05	45.61	P< 0.05
IV	13	Baseline to 15th day	0.18 ± 0.03	17.29	P< 0.05
		15th to 30th day	-0.06 ± 0.02	-0.79	P> 0.05
		Baseline to 30th day	0.17 ± 0.44	14.6	P< 0.05

Table 2. Comparison of Mean Gingival index scores (Loe and Silness) of Group I, II, III, IV at two time points. Paired 't' test(P< 0.05)*.

Groups	N	Gingival Index scores			
		Time points	Mean difference	t value	p value
I	13	Baseline to 15th day	0.23 ± 0.06	13.72	P< 0.05
		15th to 30th day	-0.003 ± 0.08	-1.59	P>0.05
		Baseline to 30th day	0.23 ± 0.06	13.57	P< 0.05
II	13	Baseline to 15th day	0.33 ± 0.06	19.09	P< 0.05
		15th to 30th day	0.03 ± 0.06	1.76	P>0.05
		Baseline to 30th day	0.33 ± 0.06	19.43	P<0.05
III	13	Baseline to 15th day	0.44 ± 0.06	23.58	P< 0.05
		15th to 30th day	0.21 ± 0.04	16.41	P< 0.05
		Baseline to 30th day	0.65 ± 0.06	38.08	P< 0.05
IV	13	Baseline to 15th day	0.18 ± 0.03	17.29	P< 0.05
		15th to 30th day	-0.02 ± 0.04	-1.897	P> 0.05
		Baseline to 30th day	0.18 ± 0.04	16.46	P< 0.05

Table 3 and 4 shows the comparison of Mean Plaque index and Gingival index scores (Silness and Loe) of Group I, II, III, IV at three time points using One way ANOVA. There was a statistically significant difference in mean Plaque index and Gingival index scores among all the groups at 15th and 30th day follow up. However Group III showed the highest reduction in mean Plaque index and Gingival index scores at 15th and 30th day of follow up period which was found to be 1.32 ± 0.05, 0.92 ± 0.04 and 1.12 ± 0.05, 0.91 ± 0.04 respectively.

Table 5 and 6 shows the Tukey HSD Post hoc analysis in Group III for Plaque index and Gingival index scores at Baseline, 15th and 30th day. Post hoc analysis showed a significant difference in mean Plaque Index scores from baseline to 15th day (0.450) and baseline to 30th day (0.667)and 15th to 30th day (0.216) which was found to be statistically significant (P < 0.05) and the Post hoc analysis for mean Gingival Index scores showed a significant difference from baseline to 15th day (0.443)and baseline to 30th day (0.656)and 15th to 30th day (0.213) which was also found to be statistically significant (P< 0.05).

Discussion

Oral diseases including dental caries, periodontal diseases, and tooth loss may significantly impact a person's overall health [12] and these diseases qualify as major health problems owing to their high prevalence and incidence in all regions of the world [13].

The Centers for Disease Control and Prevention (CDC) suggests that everyday use of a toothbrush is essential for maintaining optimum oral health [14]. It is noteworthy that toothbrushing as an isolated effect, i.e., without the therapeutic effect of fluoride, has only a limited effect on caries control [15, 16]. Thus, regular tooth brushing with a fluoridated toothpaste is essential to control caries [15-17]. Even-though fluoridated toothpastes were considered to be gold standard for prevention of dental caries, concern has been expressed that dental fluorosis, enamel defects

Table 3. Comparison of Mean Plaque index scores (Silness and Loe) of Group I, II, III, IV at three time points. One way ANOVA(p<0.05)*.

Time points	N	Plaque Index scores			
		Groups	Mean ± SD	F value	p value
Baseline	13	I	1.59 ± 0.08	0.007	P>0.05
		II	1.59 ± 0.08		
		III	1.58 ± 0.09		
		IV	1.58 ± 0.09		
15th day	13	I	1.35 ± 0.07	31.189	P< 0.05
		II	1.25 ± 0.07		
		III	1.13 ± 0.05		
		IV	1.40 ± 0.08		
30th day	13	I	1.36 ± 0.07	66.359	P< 0.05
		II	1.03 ± 0.05		
		III	0.92 ± 0.04		
		IV	1.40 ± 0.07		

Table 4. Comparison of Mean Gingival index scores (Loe and Silness) of Group I, II, III, IV at three time points. One way ANOVA(p<0.05)*.

Time points	N	Gingival Index scores			
		Groups	Mean ± SD	F value	p value
Baseline	13	I	1.58 ± 0.08	0.041	P>0.05
		II	1.58 ± 0.08		
		III	1.57 ± 0.09		
		IV	1.57 ± 0.08		
15th day	13	I	1.34 ± 0.07	31.235	P< 0.05
		II	1.24 ± 0.07		
		III	1.12 ± 0.05		
		IV	1.39 ± 0.08		
30th day	13	I	1.35 ± 0.08	108.049	P< 0.05
		II	1.24 ± 0.07		
		III	0.91 ± 0.04		
		IV	1.39 ± 0.08		

Table 5. Tukey HSD Post hoc analysis in Group III for Plaque Index scores at Baseline, 15th and 30th day.

GROUP	Time Points		Mean Difference	p value
GROUP III	Baseline	15th day	0.450*	P< 0.05
		30th day	0.667*	
	15th day	Baseline	-0.450*	P< 0.05
		30th day	0.216*	
	30th day	Baseline	-0.667*	P< 0.05
		15th day	-0.216*	

Table 6. Tukey HSD Post hoc analysis in Group III for Gingival Index scores at Baseline, 15th and 30th day.

GROUP	Time Points		Mean Difference	p value
GROUP III	Baseline	15th day	0.443*	P< 0.05
		30th day	0.656*	
	15th day	Baseline	-0.443*	P< 0.05
		30th day	0.213*	
	30th day	Baseline	-0.656*	P< 0.05

caused by young children chronically ingesting excessive amounts of fluoride during the period of tooth formation (up to the age of 6 years), is increasing in both fluoridated and non-fluoridated communities, and the early use of fluoride toothpastes by young children may be an important risk factor [18, 19]. The side effects encountered with the use of fluoridated toothpaste formulations has led to the search for novel and safe alternatives. This necessitates the need for the study.

In the present study, Fluorescein based disclosing solution was used to disclose plaque due to its several advantages over other plaque disclosing agents. Fluorescein, stains only the plaque, the gums, tongue and restorations keep their own colour. In addition, Fluorescein is not visible in daylight and as a result, the use of this agent does not entail any esthetic impairment [20]. Disclosing agent was applied all over the surfaces of the teeth and Plaque Index by Silness & Loe (1964) was recorded. To detect the changes in gingival inflammation, Gingival Index by Loe & Silness (1967) was used in the present study.

Commercially available dentifrices were used in the present study which include Splat Green tea toothpaste (Group I) containing camellia sinensis leaf extract, Colgate total advance health (Group II) containing 1000ppm of sodium fluoride, Curasept (Group III) containing 0.12% Chlorhexidine and GD Probiotic Toothpaste(Group IV) containing bacteriocin.

The results of this research indicated that before any intervention, there were no significant differences in the baseline values between the groups. So, it was possible to make a comparison between the effectiveness of these groups on the plaque, gingival status, No side effects were observed during the study procedure.

There was a statistically significant difference in mean Plaque index & Gingival scores among all the groups at 15th and 30th day follow up. . However Group III showed the highest reduction in mean Plaque index scores at 15th and 30th day which was found to be 1.32 ± 0.05, 0.92 ± 0.04 respectively from baseline score of 1.58 ± 0.09. With respect to mean gingival index score, Group III showed highest reduction from Baseline score of 1.57 ± 0.09 to 1.12 ± 0.05, 0.91 ± 0.04 respectively. Similar results were obtained by a study done by Bhopale. D [21] which showed a statistically significant reduction in gingival index scores, while there was a reduction in Plaque index score but was not statistically significant. The observed reduction in the present study was in agreement with other studies [22, 23].

On the contrary, a study conducted by Hambire. C.U [24] concluded that reduction in Plaque and Gingival Index scores was observed in all the groups, highest reduction being observed in Green tea mouthwash followed by sodium fluoride and Chlorhexidine mouth rinses.

Comparable results were obtained in a study done by Nadkerny.P.V [25] reported a significant reduction in Plaque and Gingival Index scores by all treatment groups namely chlorhexidine and Probiotic. The author suggested probiotic mouth rinses can be used as an adjunct to mechanical Plaque control in the prevention of plaque & Gingivitis. Another study conducted by Kaur.H [26] showed both green tea catechin and chlorhexidine have comparable results in plaque reduction.

The findings must, for a number of reasons, be interpreted with caution. The sample size is less, hence further studies are recommended with larger sample size. Studies targeting the patients with specific oral health problems need to be considered.

Conclusion

In conclusion, within the limitations of this study, all the four groups exhibited antiplaque and antigingivitis activity by bringing about significant reduction in mean Plaque & Gingival Index scores at 30th day follow up. Among all the preventive modalities, Group III (chlorhexidine dentifrice) showed better results compared to other groups.

Clinical Significance

To establish optimal oral health and to reduce dental disease bur-

den in the community, public can be encouraged to use the dentifrices used in the present study for their regular oral hygiene practice, as the observed antiplaque and antigingivitis efficiency were almost similar to the established or gold standard Fluoride containing conventional dentifrice.

Acknowledgement

I express my heartfelt gratitude to my parents Dr. R. Prabakar and Mrs. Rukmani, my brother Dr. R. P. Srikanth for having provided me with every possible opportunity and I thank the Almighty for all the blessings throughout the successful completion of this project. I thank my professor Dr.Joseph John, my postgraduate seniors - Dr. Parvathy Premnath and Dr. Zoha Abdullah, my juniors - Dr. Vyshiali.S and Dr. Shiva Shankar. K, and my friends - Dr. Saraniya A.P and Dr. Shermila Ann Sherry for supporting and encouraging me during this project. I would like to thank Dr. Laliytha for helping us to acquire green tea toothpaste from the UK and my friend Mr. Cheran Deep Thota for acquiring chlorhexidine toothpaste from Australia and Dr. Nivashini for acquiring Probiotic toothpaste from Malaysia. Finally, I extend my appreciation and thanks to all the study participants for reporting for the follow-up and cooperating at every stage of the study.

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