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Evaluating the Effectiveness of Herbal Toothpaste Containing 18 Herbal Ingredients on Dental Plaque and Gingival Health: A Pilot Study

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Abstract: The aim of the present study was to evaluate the efficacy of herbal toothpaste on dental plaque and gingival health. In the present study conducted among 60 volunteers from a dental institution were randomly allocated into two groups i.e., the herbal toothpaste/test group and conventional toothpaste/control group equally. The plaque score and gingival scores were assessed at baseline, 2nd week and 4th week using modified Quigley Hein plaque index and Loe H & Silness P gingival index respectively. 59 out of 60 participants completed the study. In both the groups, the plaque and gingival scores were reduced from baseline to final visit and it was found to be statistically significant (p = 0.000). The inter group comparison of plaque scores and gingival scores were found to be statistically non-significant with p > 0.05. Hence it can be concluded that the herbal based toothpaste is as effective as the conventionally formulated dentifrice in the control of plaque and gingivitis.

Keywords:- *Herbal Dentifrice, Oral Health, Oral Hygiene.*

I. INTRODUCTION

Dental plaque build-up on teeth is problematic because of both its aesthetic and pathogenic character [1]. Dental caries, gum conditions, and halitosis may all be brought on by dental plaque. It is well known that gingivitis and plaque are closely linked, and the best way to prevent periodontal disease is to use the best plaque management techniques. Across the world, a variety of mechanical aids are used to remove or reduce plaque, such as tooth brushes, dental floss, mouthwash, and dentifrices. Out of which toothbrushing using a toothpaste is one of the common practices used to mechanically remove and control the dental biofilm to help prevent caries and oral diseases [2]. Due to the advancement in the health-related researches, several types of toothpastes are available in the market. The most commonly used antiplaque/anti-gingivitis agents in conventional toothpastes are triclosan, stannous chloride/fluoride and zinc citrate/chloride [3]. But some of these contents have undesirable effects like staining of teeth and altered taste [1]. This led to the search of natural components which are considered to be of no side effects. According to the World Health Organization, 80 percent of the population receives their main medical care from medicinal plants. For more than 2000 years, individual and combinations of various medicinal plants have been used as herbal remedies to maintain oral hygiene and reduce inflammation [4]. The anti-microbial and excellent abrasive qualities of herbal toothpaste are said to be similar to those of conventional toothpaste, and it is widely accessible and usually considered safe [5]. Herbal plants like Embilica Officianalis , Terminalia Chebula, Zingiber Officinale, Salvadora Persica, Piper Nigrum [6-9] Syzygium Aromaticum, Azardirachta Indica, Glycyrrhiza glabra, Cinnamon Verum [10], Elettaria Cardamomum, Citrus Bergamia, Eucalyptus Globulus, Mentha Arvensis, Rosmarinus Officianalis and Curcuma Longa [11-13] showed significant effects in control of micro-organisms which causes dental caries and periodontal diseases.

This study was aimed to evaluate the effectiveness of herbal tooth paste *Edinora prime* which contains about 20 herbal and natural ingredients over dental plaque and gingivitis.

II. METHODS

A. Study design

The study was a Pilot, triple-blinded randomized control trial conducted in a dental institution from July to September 2022.

The study was registered prospectively in clinical trial registry – India (CTRI/2022/07/044225). Prior to the start of the study, dental students from CIDS were invited to participate in the study. Among those who voluntarily accepted the invitation, 60 participants were randomly selected and allocated into control and test group equally.

B. Eligibility criteria

Inclusion criteria: (i) Males and females in good general health aged 18 to 30 years available for the duration of the study. (ii) A minimum of 20 natural teeth with facial and lingual scorable surfaces. Exclusion criteria : (i)

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Individuals who are under antibiotics or anti-inflammatory drugs. (ii) History of dental prophylaxis or treatments in the past month. Individuals undergoing orthodontic treatment. (iii) History of significant adverse effects following use of oral hygiene products such as toothpastes and mouth rinses. (iv) History of diabetes or hepatic or renal disease, or medical or inflammatory conditions or transmittable disease. (v) Oral soft tissue pathology. (vi) History of active or severe periodontal disease with bleeding gums and loose teeth.

C. Ethical approval and Informed consent

The study was approved by Institutional Ethics Board of Coorg Institute of Dental Sciences (CIDS), Virajpet. The present study was conducted in accordance to the Declaration of Helsinki as revised in 2013. Prior to the start of the study, a written informed consent was obtained from the participants.

D. Materials

This study consisted of two groups: Group A/control group and Group B/test group. In Group A, participants received Colgate toothpaste with amino shakti as control and in Group B, the participants received *Edinora Prime toothpaste* containing herbal ingredients such as *glycyrrhiza glabra, Embilica Officianalis, Terminalia Chebula, Terminalia Belerica, Zingiber Officinale, Salvadora Persica, Piper Nigrum, Syzygium Aromaticum, Elettaria Cardamomum, Citrus Bergamia, Cinnamon Verum, Eucalyptus Globulus, Mentha Arvensis, Rosmarinus Officianalis, Azardirachta Indica, Curcuma Longa, Cocos Nucifera* and *Aloe vera.* A two-toned plaque disclosing agent was used for staining the dental plaque for scoring.

E. Clinical assessment

The clinical examination was conducted by a single calibrated investigator using mouth mirror and WHO probe at baseline, 2nd week and 4th week. The dental plaque was assessed using modified Quigley Hein plaque index [14] and gingivitis was scored using Loe and Silness gingival Index (1963) [15].

F. Primary outcome

The plaque scores and gingival scores at baseline, 2nd week and 4th week was analysed in both Group A and Group B.

G. Blinding

All the participants in both the arms, investigator, study coordinator and biostatistician were blinded throughout the study.

H. Randomization and allocation concealment

The participants were randomly allocated into control and test group using a chit method. The control and test toothpaste were supplied as similarly labelled identical pre coded plain white tubes. An investigator blinded to patient's clinical data dispensed the pre weighed toothpaste tubes to the study participants. Along with the toothpaste, a medium sized tooth brush was given and a demonstration of modified bass method of tooth brushing using a study model was done.

I. Product description and usage protocol

The coded tubes contained either the control or test toothpaste. The study participants were asked to brush twice daily with the allotted toothpaste using modified bass method for 4 weeks. At the end of the study, participants were asked to return the toothpaste tubes for measuring the weight of remaining toothpaste.

J. Statistical analysis

The data was collected and transferred to excel. The data was analyzed using IBM SPSS software version 23. Descriptive statistics included mean, standard deviation, frequency and percentage. Inferential statistics included Friedman test, Wilcoxon signed rank test, Paired t test and independent t test. The level of significance was set at 0.05 at 95% confidence interval.

III. RESULTS

Flow chart for the study is shown in Fig. 1. Out of 60 participants, 59 participants completed the trial. one participant from the control group was excluded from the study due to loss of follow up. The mean age of the participants was 21.22 ± 2.44. Test of normality revealed that plaque and gingival scores are not normally distributed and therefore non-parametric tests were used to compare these scores. A normally distributed data was found for weights of toothpaste tubes and therefore parametric test were performed to compare those data.

A. Plaque scores

In control group, the median plaque score at baseline was 0.88, at second week it was 0.72 and at 4th week it was 0.70. In the test group, median plaque score at baseline was 0.91, at second week it was 0.70 and at 4th week it was 0.55. The comparison of plaque scores in both control and test group was found to be statistically significant with $p = 0.000$. But, the comparison of plaque scores at baseline, 2nd week and 4th week between the control and test group was found to be statistically non-significant with $p > 0.05$ (Table.1).

B. Gingival scores

In control group, the median gingival score at baseline was 0.344, at second week it was 0.30 and at 4th week it was 0.20. In the test group, median plaque score at baseline was 0.285, at second week it was 0.16 and at 4th week it was 0.10. The comparison of gingival scores in both control and test group was found to be statistically significant with $p = 0.000$. But, the comparison of plaque scores at baseline, 2nd week and 4th week between the control and test group was found to be statistically non-significant with $p > 0.05$ (Table.2).

C. Weight of toothpaste tubes

In control, the mean weight of toothpaste at baseline and 4th week was 70.303 ± 1.92 and 12.145 ± 1.5 respectively. In the test group, it was 70.173 ± 1.4 and 11.9 ± 1.12 respectively. The intra group comparison of weight of toothpaste in both control and test groups were found to be statistically significant with $p = 0.000$. The intergroup

comparison of weight of toothpaste between the groups were found to be statistically non- significant with p > 0.05.

IV. DISCUSSION

The current study was conducted to evaluate the effectiveness of herbal toothpaste against dental plaque and gingival health. In the current study, a significant reduction in plaque and gingival scores are noted in both the control and test groups. We found that the comparison of plaque scores from baseline to 4th week among the herbal toothpaste/test group and conventional tooth paste/control group was statistically significant with p < 0.05. This result is in accordance with similar studies conducted by ***Pradeep Kumar Singh, K. V. V. Prasad and Apoorva Kotian (2018)*** [16]**,** ***Kalyana-Chakravarthy Pentapati, Meena Anand Kukkamalla, Hanan Siddiq and Neeraja Sabnis (2020)*** [17], where the comparison of plaque scores from baseline to 30th day among both herbal and conventional tooth paste group were found to be statistically significant with p < 0.05. But these results are in contrast with the studies conducted by ***Jacob George, Shashikant Hegde, Rajesh KS and Arun Kumar (2009)*** [18], where they reported that the comparison of plaque scores from baseline to 30th day among the conventional tooth paste group was found to be statistically non-significant with p >0 .05. The inter group comparison of plaque and gingival scores between the herbal and conventional tooth paste in the current study was found to be statistically non-significant with p > 0.05. This result is in accordance with the studies conducted by ***Jacob George, Shashikant Hegde, Rajesh KS and Arun Kumar (2009)*** [18]**,** ***Pradeep Kumar Singh, K. V. V. Prasad and Apoorva Kotian (2018)*** [16]**, and** ***Kalyana-Chakravarthy Pentapati, Meena Anand Kukkamalla, Hanan Siddiq and Neeraja Sabnis (2020)*** [17], where they reported that the intergroup comparison of plaque scores and gingival scores between herbal toothpaste and conventional toothpaste were found to be statistically non-significant with p >0.05. From these results it is evident that herbal tooth paste has the potential to reduce the plaque and gingival scores. In the current study, the comparison of the mean weight of the toothpaste in both the groups were found to be statistically significant and this indicates that all the participants were using toothpaste as instructed by the investigator.

➢ *Limitation*

This study was conducted among the dental students and that might be a reason for low plaque and gingival scores at the baseline.

V. CONCLUSION

This pilot study revealed that the herbal toothpaste and conventional toothpaste have the potential to reduce the plaque and gingival scores in a 4-week time period. The intergroup comparison of the plaque and gingival scores were found to be statistically non-significant and thus we can conclude that, the herbal tooth paste Edinora prime toothpaste is as effective as conventional toothpaste in reducing the dental plaque and maintaining gingival health.

Conflict of interest and source of funding statement

No potential conflict of interest relevant to this article was reported.

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Table 1: Intra and inter group comparison of plaque index scores at baseline, 2nd and 4th week

Group		Baseline	2nd week	4th week	P-value*
Control	Mean (SD)	0.8455 (0.23006)	0.7179(0.24503)	0.6886(0.24566)	
	Median (IQR)	0.88 (0.31)	0.72 (0.4)	0.7 (0.4)	0.000
Test	Mean (SD)	0.8870(0.22237)	0.6543(0.21261)	0.6060 (0.19842)	
	Median (IQR)	0.91 (0.31)	0.7 (0.33)	0.55 (33)	0.000
P-value**		0.638	0.170	0.116	

Values are represented in mean (SD) and median (IQR)
P-value**: Mann Whitney U test
P-value*: Friedman test

Table 2: Intra and inter group comparison of gingival index scores at baseline, 2nd and 4th week

Group		Baseline	2nd week	4th week	P-value*
Control	Mean (SD)	0.3683(0.26657)	0.2831(0.22711)	0.2621(0.21114)	
	Median (IQR)	0.344(0.48)	0.3(0.4)	0.2(0.4)	0.000
Test	Mean (SD)	0.3840(0.30029)	0.1993(0.18590)	0.1947(0.1789)	
	Median (IQR)	0.285(0.48)	0.16(0.3)	0.1(0.23)	0.000
P-value**		0.939	0.159	0.216	

Values are represented in mean (SD) and median (IQR)
P**: Mann Whitney U test
P*: Friedman test

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Table 3: Intra and inter group Comparison of weight of toothpaste at baseline and 4th week

Group	Baseline	4th week	P-value*
Control	70.303 ± 1.92	12.145 ± 1.5	0.000
Test	70.173 ± 1.4	11.9 ± 1.12	0.000
P-value**	0.769	0.483	

Values are represented in mean ± SD
P**: Independent t test
P*: Paired t test

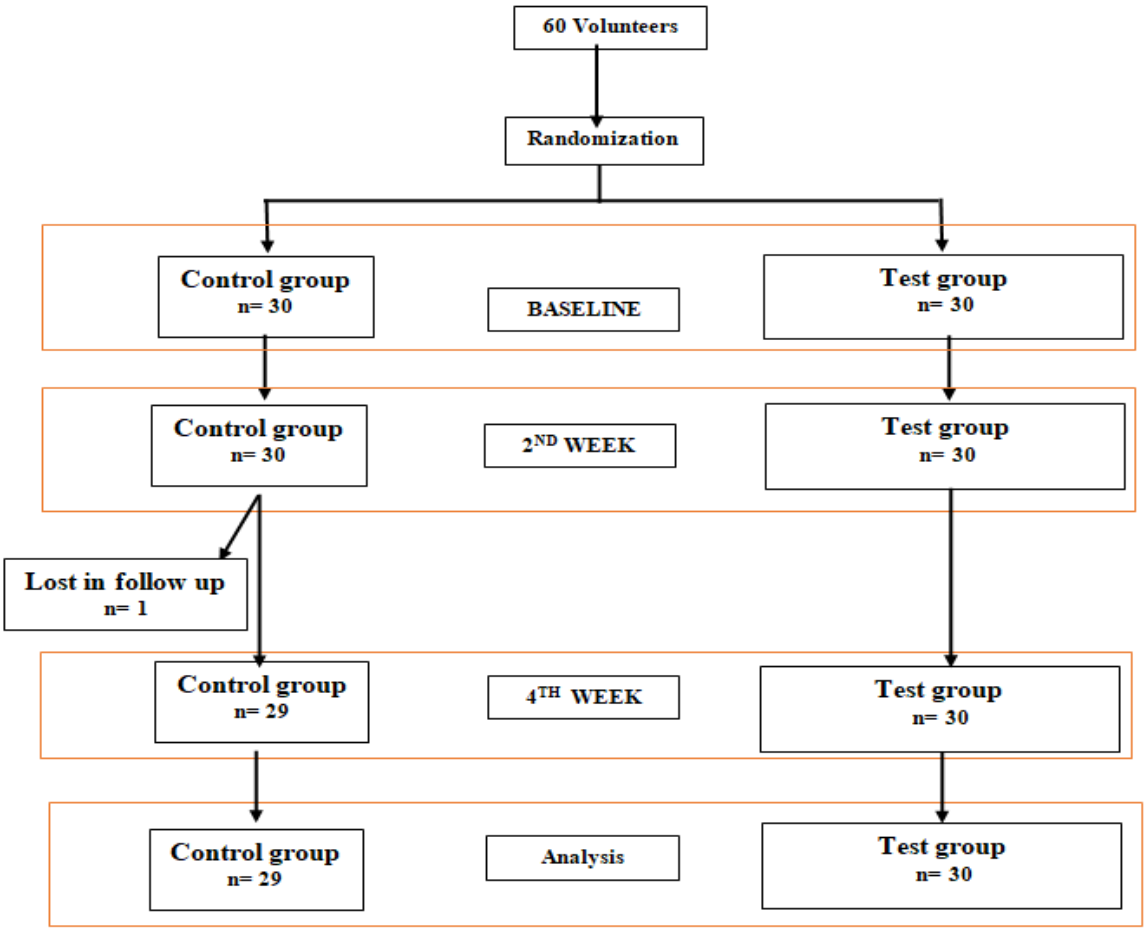

Fig 1: Study design

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