ORIGINAL RESEARCH

Effect of Neem containing Toothpaste on Plaque and Gingivitis—A Randomized Double Blind Clinical Trial

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ABSTRACT

Aim: The present study was designed to assess the effect of toothpaste containing neem on plaque and gingivitis.

Materials and methods: Randomized, double blind clinical trial was designed. Thirty first year dental students volunteered to participate in the study. Neem containing tooth paste was used as an intervention. Clinical examination was carried out using Silness and Loe plaque index (PI) and Loe and Silness gingival index (GI). Independent t-test and paired t-test was used for the intergroup and the intragroup comparison.

Results: Out of 30 participants, 22 (73.3%) were females and eight (26.7%) were males. A statistically significant difference was found between the test and control group after intervention with respect to the PI and GI.

Conclusion: Neem containing toothpaste can be used as an adjunct for maintenance of oral hygiene.

Clinical significance: Regular brushing with neem toothpaste might act as an adjunct to maintenance of good oral hygiene, and thus improve oral health.

Keywords: Gum bleeding, Herbal dentifrice, Parallel study design, Tooth deposits.

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INTRODUCTION

Dental plaque is a microbial biofilm which is invariably present on the hard and soft tissues of the oral cavity. It contains a complex blend of various microorganisms. Plaque is considered as the precursor of dental caries, gingivitis and periodontitis. Optimal plaque control forms the basis for prevention and control of dental caries and as well the periodontal disease.[1]

Elimination of microbial dental plaque biofilm prevents gingivitis, periodontitis and dental cavities.[2] A wide range of chemicals, mainly antimicrobial agents, have been added to dentifrices in order to produce a direct inhibitory effect on formation of plaque. The efficiency of agents, such as chlorhexidine and triclosan, has been well documented.[3]

The growing field of alternative medicine has shown that dentifrices based on plant extracts are available in the market. Consumers who prefer using herbal products often view these products as being safer than products that contain chemicals. The term herbal toothpaste on the label implies that most of dentifrices active ingredients are plant based.[4] Dentifrices labeled as natural typically do not include ingredients, such as synthetic sweeteners, artificial colors, preservatives, additives, synthetic flavors, and fragrances. One such herbs which is easily available and commonly used is neem. Neem tree, the 'tree of a thousand uses' has been in use for its medicinal, cosmetic, agricultural and other purposes due to its antifungal, antibacterial, antiviral, pest-control, sedative and health beneficial effects. This tree, (in Sanskrit, Nimba

and Arishta) is a native of India, and is cultivated in all parts of the subcontinent on account of its medicinal properties.[5] Neem leaves have been used in the treatment of gingivitis and periodontitis. The possible mechanism of anti-inflammatory action of neem is by inhibiting prostaglandin E and 5 HT, and thus reducing the inflammation. The antibacterial action can be explained by 'Azadirachtin' that is known to destroy bacterial cell wall, and thus inevitably inhibit the growth of bacteria, also the breakdown of cell wall disturb osmotic pressure and leads to cell death. But still, its use to treat gingivitis and periodontitis is not very clear.[6] Hence, the present study was designed to assess the effect of a toothpaste containing neem on plaque and gingivitis.

MATERIALS AND METHODS

The study was designed as a randomized double blind, parallel, controlled clinical trial. The study population included first year dental students of Coorg Institute of Dental Sciences, Virajpet, Karnataka.

The study protocol was approved by the Institutional Review Board of Coorg Institute of Dental Sciences, Virajpet. All volunteers were asked to sign informed consent.

Out of 40 first year students, 30 students met the inclusion criteria and consented to take part in the study. Students who were regular users of toothbrush and toothpaste for maintaining oral hygiene and willing to participate formed the study participants. Students with known systemic illness, recent antibiotic and anti-inflammatory therapy, history of allergy to toothpaste, who were undergoing orthodontic treatment and who wore prosthodontic appliances were not included in the study.

Initially, all the subjects in both the groups underwent a washout period of 2½ days to rule out any possible carry over effects of the previously used oral hygiene products. The washout was done by brushing with water alone and then followed by a treatment period of 30 days. Baseline clinical examination was carried out to assess plaque using Silness and Loe plaque index (PI) and gingivitis by Loe and Silness gingival index (GI) by a single trained, calibrated examiner. Intra-examiner agreement for PI and GI was evaluated by repeat measurements on 10 patients at an interval of 1 hour. The Kappa coefficient for PI was found to be 0.76 and GI was 0.8. After recording the indices participants were subjected to prophylaxis to render them plaque, stain and calculus-free. Following the prophylaxis, the study participants were randomly allocated into test group and the control group. Randomization was done by the random number table. The random allocation sequence was generated

and was concealed from the main investigator. The test group was given neem containing toothpaste and control group was given the conventional toothpaste, with color and taste similar to the experimental toothpaste. The tubes containing the dentifrices were previously packed similarly and coded to warrant that neither the examiner nor the volunteers knew their content. The participants were given similar type of toothbrush and taught tooth brushing technique for the purpose of standardization. Furthermore, participants were instructed to brush twice daily (morning immediately after waking up and night before going to bed) for 2 minutes using the toothbrush and toothpaste given to them. Tick charts were given to check compliance of the study participants towards frequency of tooth brushing. In addition, the participants were asked to bring the dentifrice tubes at the end of the trial, to confirm whether the participants had used the products or not. Participants were also instructed to refrain from any other oral hygiene aids (like dental floss, tooth pick, etc.) during the study duration. Randomization, allocation concealment and distribution of the toothpaste was done by the co-researcher who was not involved in the clinical examination. The subjects were recalled for clinical examination after 30 days. The co-researcher revealed the content of each tube only after completion of the study.

STATISTICAL METHODS

Statistical package for the social sciences for windows version 17.0 was used for data analysis. Descriptive statistics was used to summarize the results. The data were analyzed using independent t-test and paired t-test. The level of significance was set at 5%.

RESULTS

Out of 30 volunteers, 22 (73.3%) were females and 8 (26.7%) were males. The mean age of the study participants was 18.97 ± 0.71. Allocation of study subject into test and control groups is as depicted in Flow Chart 1.

At baseline, the mean plaque scores of the test and the control group was 0.97 ± 0.18 and 0.78 ± 0.20 respectively. There was no significant difference in the mean plaque scores between the groups. The mean plaque scores in the test group reduced to 0.66 ± 0.19 and the control group was 0.76 ± 0.29 post-intervention. This reduction in the mean plaque score within the test group at baseline and between the groups post-intervention was statistically significant ($p < 0.001$). This is as shown in Table 1.

At baseline, the mean gingival scores of the test and the control group was 0.46 ± 0.21 and 0.43 ± 0.17 respectively. There was no significant difference in the scores between the groups. A statistically significant

Table 1: Intra- and Intergroup comparisons of plaque index at baseline and after intervention

		Test group (mean ± standard deviation)	Control group (mean ± standard deviation)	t-value	p-value
Baseline (n = 15)		0.97 ± 0.18	0.78 ± 0.20	2.14	0.124
Post-intervention (n = 15)		0.66 ± 0.19	0.76 ± 0.29	5.83	0.001*
	t-value	6.41	– 3.38		
	p-value	0.001*	0.112		

*Statistically significant

Table 2: Intra- and Intergroup comparisons of gingival index at baseline and after intervention

		Test group (mean ± standard deviation)	Control group (mean ± standard deviation)	t-value	p-value
Baseline (n = 15)		0.46 ± 0.21	0.43 ± 0.17	3.34	0.640
Post-intervention (n = 15)		0.33 ± 0.17	0.42 ± 0.17	4.12	0.001*
	t-value	2.80	– 2.30		
	p-value	0.014*	0.411		

*Statistically significant

Flow Chart 1: Allocation of study subject into test and control groups
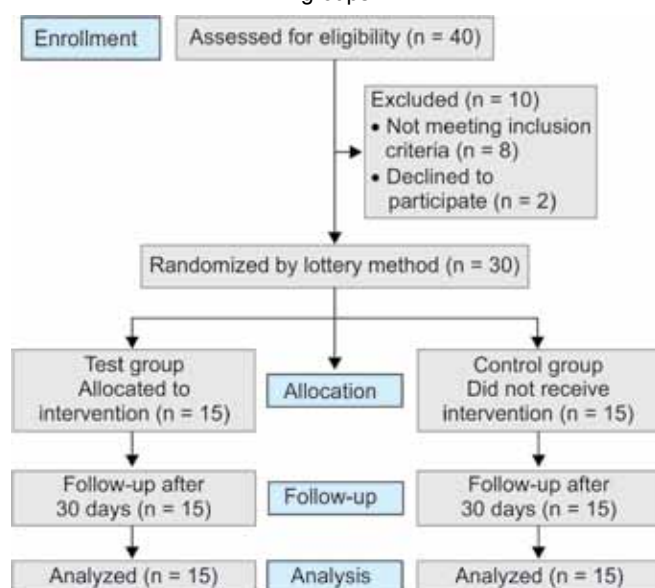
reduction in the mean gingival score was observed within test group at baseline and post-intervention. The mean gingival score in the test group was 0.46 ± 0.21 at baseline as compared to 0.33 ± 0.17 post-intervention. The mean gingival score in the control group was 0.43 ± 0.17 at baseline as compared to 0.42 ± 0.17 at month. A significant difference was observed between the test and control group following intervention (p < 0.001). This is as shown in Table 2.

DISCUSSION

The most common dental diseases are preventable and one of the prime requisites for prevention is use of anti-plaque agent. Most of the commercially available oral care products contains chemicals and synthetics. Owing to doubts regarding the safety of these products, there is a change towards the use of naturally occuring herbal products. One such herb which has shown multiple benefits for health and used since time immemorial is neem. Neem has been extensively used in all branches of healthcare and has become a cynosure of modern medicine. Because of its high medicinal properties it has been included in various formulations including tooth paste. This study was a sincere attempt to evaluate the effectiveness of neem containing toothpaste against plaque and gingivitis.

The test dentifrice had a good acceptance and did not show any untoward effects. The present study showed, within the test group there was a significant reduction in plaque and gingival scores after 30 days as compared to their baseline observation which is in accordance with the other studies.[1,7-9] However, no significant difference was found between groups at baseline. Post-intervention analysis between groups revealed a significant reduction in the plaque and gingival scores. The reduction in plaque scores in the control group may be attributed to the fact that since being enrolled in a study the students might have improved their brushing skills which in turn lead to reduced plaque accumulation. The significant reduction within the test group post-intervention might be attributed to penetration of active ingredients of the herbal extracts into the biofilm which in turn influenced plaque formation. Studies done by Saxer et al[8] and Mullally et al[9] have shown a significant reduction in plaque and gingival scores within the group but not between the group post-intervention. Another study[7] showed similar results.

The strength of the study was its randomized controlled design. The limitation of the study is its small sample size. In future, such a study has to be designed with larger sample size to further validate the present study results. Besides, experimental period of 30 days may not be sufficient to show conclusive evidence

of superiority of the test toothpaste over the control dentifrice.[10] In addition, the observed effect in clinical trials may be attributed to behavior change—Hawthorne effect rather than to the therapeutic effect of the test product. This is because subjects enrolled in oral hygiene studies usually improve their toothbrushing, irrespective of the product they receive. In addition, such clinical trials pose the novelty effect that may have an influence on the study results. Hence, although the present study results are promising toward use of herbal based toothpaste as being effective in reducing plaque and gingivitis, these results should be dealt with caution and further long-term studies with increased sample size has to be carried out.

CONCLUSION

Within the limits of this clinical study, regular use of neem containing toothpaste provided a significant reduction of dental plaque accumulation and improved the gingival health of the study participants.

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