

Comparison of antiplaque effectiveness of herbal toothpaste: A randomized triple-blinded cross-over clinical trial

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Abstract

Background: Cleansing the teeth with a toothbrush and paste is an indubitable mechanical plaque control method practiced by almost everyone. Eliminating dental plaque is an essential, fundamental and mandatory step to prevent the occurrence of periodontal diseases that are rife globally. The aim of the present study is to compare the antiplaque effectiveness of a prepared herbal and commercially available dentifrice. **Materials and Methods:** Thirty healthy individuals within the age group of 18–25 years were recruited to participate in the study. After achieving induced gingivitis and measuring plaque levels using Turesky modification of the Quigley Hein Plaque index in all the subjects, they were randomly divided into test arms A and B. Commercial dentifrice was distributed to one group, whereas the other group received prepared herbal dentifrice. Supervised brushing was carried out for 5 min, and plaque amounts after brushing were noted. After a washout period of 1 week, the same steps were repeated as per the cross-over study protocol. Unpaired *t*-test and paired *t*-tests were employed with $P < 0.05$. **Results:** Both the toothpastes show the difference in plaque scores immediately after brushing when compared to baseline and was statistically significant ($P = 0.001$). The mean plaque scores of commercial dentifrice (1.93 ± 1.52) were less than that of the prepared herbal dentifrice (2.35 ± 1.39) after brushing. **Conclusion:** The prepared herbal dentifrice had good antiplaque action. However, the plaque inhibitory action of self-prepared herbal toothpaste was marginally less when compared to commercial dentifrice.

Keywords: Cross-over study, dental plaque, dentifrice, gingivitis, plaque index

Introduction

Cleansing the teeth with a toothbrush and paste is an indubitable mechanical plaque control method practiced by almost everyone.^[1] The primary objective of using a dentifrice is to completely remove the plaque biofilm on the tooth surface and to additionally protect the tooth from carious attacks.^[2] Apart from these two basic functions, certain dentifrices are specifically formulated to act as anticalculus agents, tooth-whitening agents, antimicrobial agents, or erosion-preventive agents.^[3] However, eliminating dental plaque is an essential, fundamental, and mandatory step to prevent the occurrence of periodontal diseases that are rife globally. Dental plaque is a biofilm-harboring innumerable microorganism and is an elemental factor for the initiation and progression of periodontal diseases.^[4] The strains of *Streptococcus mutans* present in the plaque are the pioneer cariogenic bacteria. They bring about alterations in the plaque metabolism causing demineralization to predominate.^[5] Hence, the antiplaque effectiveness is an imperative property preferred in any dentifrice.

Although toothpastes are popularly prescribed to be used on twice a day basis, the safety issues are often overlooked. Certain ingredients present in a commercially available dentifrice might prove to be hazardous. Even though only pea-sized dollops of the paste are used twice daily, the chemicals present can get easier access into the systemic circulation, owing to the high absorbent capacity of the oral cavity.^[6] Therefore, employing a homemade dentifrice with noncontroversial and safer ingredients can be an effective alternative.

Surfactants, abrasives and therapeutic agents are the three major components identified in any commercially available

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How to cite this article: Shanmugapriya R, Arunmozhi U, Kadhiresan R, Sabitha S, Anirudhya R, Sujatha G. Comparison of antiplaque effectiveness of herbal toothpaste: A randomized triple-blinded cross-over clinical trial. AYU 2019;40:109-13.

Submitted: 20-Jul-2019

Revised: 13-Jan-2020

Accepted: 24-Jan-2020

Published: 20-Mar-2020

Access this article online

Quick Response Code:



Website:
www.ayujournal.org

DOI:
10.4103/ayu.AYU_185_19

dentifrice or toothpaste.^[2] Abrasives and surfactants are the classic formula excipients blended with the active ingredients to bring about the paste form. Aluminum oxide, hydrated silica, sodium bicarbonate (NaHCO₃), calcium compounds, etc., are some of the conventionally used abrasives. Triclosan, a therapeutic ingredient, is commonly used as an antiplaque agent in toothpastes and fluoride formulations as anticaries agents. Evidence in the literature sheds light on the endocrine-related disturbances associated with triclosan.^[7] Lee *et al.*^[8] in their study have concluded that triclosan may promote breast cancer via estrogen receptor-mediated signaling cascade. Injudicious use of fluoride-containing toothpastes specifically among young children can be a risk factor to dental fluorosis.^[9] Sodium lauryl sulfate (SLS) is employed to act as a surfactant or detergent that promotes foaming and uniform dispersion of toothpastes. SLS is known to alter oral mucosal barriers and is frequently associated with aphthous ulcers.^[10-13] The compound can diminish the viability of the oral mucosal cells such as the fibroblasts and keratinocytes.^[14,15] Therefore, it is prudent to research for an alternative for triclosan and the excipient SLS.

Incorporating essential oils that promote oral health in place of triclosan and SLS can be beneficial. Coconut oil and clove oil are easily available and can be readily used to prepare dentifrices. Clove essential oil possesses antibacterial and anti-inflammatory properties.^[16,17] In a study done by Moon *et al.*,^[18] its antibacterial effect against cariogenic and periodontopathic organisms has been proved. Coconut oil has antibacterial effect against *S. mutans* and *Lactobacilli*; two organisms convincingly associated with dental caries.^[19] Furthermore, these essential oils apparently have no side effects which make them more desirable substitutes. Numerous studies have compared the antiplaque effectiveness of different toothpastes.^[20-25] However, there is a dearth of evidence in assessing and comparing the plaque inhibitory property of prepared herbal dentifrices. Hence, the aim of the present study is to compare the antiplaque effectiveness of prepared herbal and commercially available dentifrice.

Materials and Methods

The study was designed as a triple-blinded randomized cross-over clinical trial to compare the antiplaque effectiveness of two toothpastes. After obtaining the ethical approval from the institutional review board, 30 healthy individuals were enrolled for the study. Written informed consent was obtained from all the individuals after explaining the purpose of the study. The study was registered with the Clinical Trial Registry of India (REF/2017/11/016079). Individuals within the age group of 18–25 years having good general and oral health were included in the study. Individuals who were allergic to toothpastes, those who used mouthwashes regularly, those who were under orthodontic treatment, those who on antibiotics in the last 2 weeks, and those who suffered from

systemic conditions were excluded from the study. The study was initiated as a pilot study, and hence, the sample size was limited to thirty.

All the study individuals were subjected to thorough oral prophylaxis to achieve similar and comparable baseline plaque levels. They were then instructed to abstain from brushing for the next 72 h to establish gingivitis and plaque accumulation. Constant monitoring was possible as all the individuals were recruited from the same hostel. After 72 h, the study participants were asked to gather in one place and were randomly divided into two groups, test arm A and B. Randomization was carried out using the lottery method by the trial coordinator. Participants were randomized in a ratio of 1:1 to receive either of the interventions. Subjects were uniform within the sequences, i.e., sequence AB and sequence BA. The trial coordinator then allocated test arm A with prepared herbal toothpaste and test arm B with commercially available toothpaste on a random basis. The herbal dentifrice was prepared by mixing 1 g of NaHCO₃, 2–3 drops of essential peppermint oil, 1 drop clove of oil, 1 ml of coconut oil, and 4–5 drops of water. The ingredients of the commercial dentifrice consisted of aluminum oxide, stannous fluoride, SLS, triclosan, spearmint, and peppermint. Both the toothpastes were of similar color and flavor. Furthermore, they were distributed from analogous tubes to facilitate blinding among the participants and investigators. Two calibrated investigators recorded plaque scores at baseline level using Turesky modification of the Quigley Hein Plaque Index for all the individuals.

Equal amounts of the allotted toothpaste were then dispensed to the respective individuals. The modified Bass brushing technique was taught to all the participants, and supervised brushing was carried out for 3–5 min using medium bristle toothbrush. Immediately after brushing, plaque scores were recorded again by the two calibrated investigators. A washout period of 1 week was given to prevent the carry-over effects from the intervention administered in the first phase. After 1 week, the individuals again underwent thorough scaling and were asked to abstain from brushing for 72 h. The same procedures were repeated and the toothpastes were switched over between test arms A and B. The plaque scores were recorded and the values obtained were tabulated in Microsoft Excel 2007. The results were subjected to statistical analysis using SPSS software version 20.0 (Statistical Package for the Social Sciences for Windows; SPSS Inc., Chicago, IL, USA). The statistician was not aware of what toothpaste was allotted to which group and in which order, thus ensuring triple blinding. To assess the normal distribution of the variables, one sample Kolmogorov–Smirnov test was employed. The variables were normally distributed. Hence, unpaired *t*-test was used for intergroup comparisons and paired *t*-test was employed for within-group comparisons. The confidence interval was determined to be 95% ($P < 0.05$).

Results

All the individuals completed the trial with good compliance and no untoward incidents were reported. Figure 1 gives details on exclusion criteria and depicts the randomized cross-over study design. Table 1 shows the gender distribution and the mean age of the thirty participants. There was no statistically significant difference among the distribution of the individuals.

Table 2 shows within-group comparisons between herbal and commercial dentifrice. Both the toothpastes showed the difference in plaque scores immediately after brushing when compared to baseline. This difference was found to be highly significant ($P = 0.001$). The mean plaque score difference was more with commercial dentifrice (1.65 ± 0.40) than herbal dentifrice (1.55 ± 0.83).

Table 3 shows the intergroup comparison between the two dentifrices. There were no statistically significant differences at baseline for both the dentifrice ($P = 0.064$). However, the mean plaque scores of commercial dentifrice (1.93 ± 1.52) were less than that of herbal dentifrice (2.35 ± 1.39) after brushing. Independent sample *t*-test showed the difference to be statistically significant ($P = 0.001$). Although commercial dentifrice showed a statistically significant reduction of plaque scores compared to herbal dentifrice, this difference was only marginal.

Table 1: Mean age and distribution of the study population based on their gender in the test arms A and B

Study group	Gender		Mean age \pm SD
	Male	Female	
Group A	8	7	20.9 \pm 1.41
Group B	7	8	20.2 \pm 1.02
Total	15	15	

SD: Standard deviation

Table 2: Within group comparisons of the plaque scores for herbal and commercial dentifrice

Plaque score difference	<i>n</i>	Mean \pm SD	<i>P</i>
Herbal dentifrice	30	1.55 \pm 0.83	0.001**
Commercial dentifrice	30	1.65 \pm 0.40	0.001**

**Significant at 1% interval. SD: Standard deviation

Table 3: Comparative assessment of the mean plaque scores at baseline and after brushing for both the tooth pastes

Time period	Group	<i>n</i>	Mean plaque scores \pm SD	<i>P</i>
Baseline	Herbal dentifrice	30	3.90 \pm 1.06	0.064
	Commercial dentifrice	30	3.58 \pm 1.61	
After brushing	Herbal dentifrice	30	2.35 \pm 1.39	0.001**
	Commercial dentifrice	30	1.93 \pm 1.52	

**Significant at 1% interval. SD: Standard deviation

Discussion

Dental plaque remains the principal etiological factor for majority of dental disorders. Oral hygiene methods preliminarily aim to eliminate the plaque accumulation.^[26] Among the various plaque control methods, the practice of brushing the teeth with a paste is widely embraced. A plethora of toothpaste brands is available in the market asserting the anticaries, antiplaque, or antimalodor potencies. These allegations are considered as “cosmetic claims” that can often be misleading. The downside is that any cosmetic product can be marketed devoid of approval from a regulatory body. Only the manufacturers are expected to ensure that the goods are safe to use and do not cause any impairment to health.^[27] Toothpastes also fall under the cosmetic products group with each brand chasing to be on the top. To survive the race, newer toothpastes are constantly being developed using myriad combinations of different chemical ingredients. Hidden in the shadow of benefits are certain unethical properties of these compounds which concern safety.

Triclosan and SLS are two constantly used compounds in any commercial dentifrice. Triclosan is well known for its antiplaque and antibacterial effects.^[23] However, the compound has shown to bring about alterations in thyroid hormone levels by upregulating hepatic catabolism.^[7] Triclosan has recently been suspected to be a carcinogen. Further, Yazdankhah *et al.*^[28] have suggested that the prolonged use of triclosan can eventually lead to the development of microbial resistance. SLSs are excipients that bring about foaming in toothpastes. SLS breaks the phospholipid bonds in tongue, thereby altering the function of gustatory cells. This compound is also linked with skin irritation and canker sores.^[29] Viable alternatives to the commercial pastes could be herbal dentifrices with unadulterated ingredients. With the emergence of “Do It Yourself” (DIY) trend in healthcare segment, herbal toothpastes could gain popular grounds.^[30] Hence, in the present study, a DIY herbal dentifrice was prepared and its antiplaque effectiveness was assessed.

Essential oils such as clove oil and coconut oil were used along with NaHCO_3 which acted as the principal abrasive. To combat the unpleasant taste of NaHCO_3 , peppermint oil was added to act as a flavoring agent. Clove oil is a very strong free radical scavenger and an antifungal agent. It also has bactericidal effects on multi-resistant *Staphylococcus* spp.^[17,18] Coconut oil is an edible oil and an Indian household commodity. It has antimicrobial properties and reduces the levels of cariogenic bacteria in the oral cavity.^[19] NaHCO_3 is an alkaline compound and a mild abrasive. They are available in the form of baking soda in households. The alkalinity of the ingredient can help neutralize acidic environments in dental plaque.^[31] All these ingredients are readily and easily available in the market and hence a DIY preparation is possible.

The current study was designed to be a cross-over trial to bring down internal variability among cases and controls. Since the

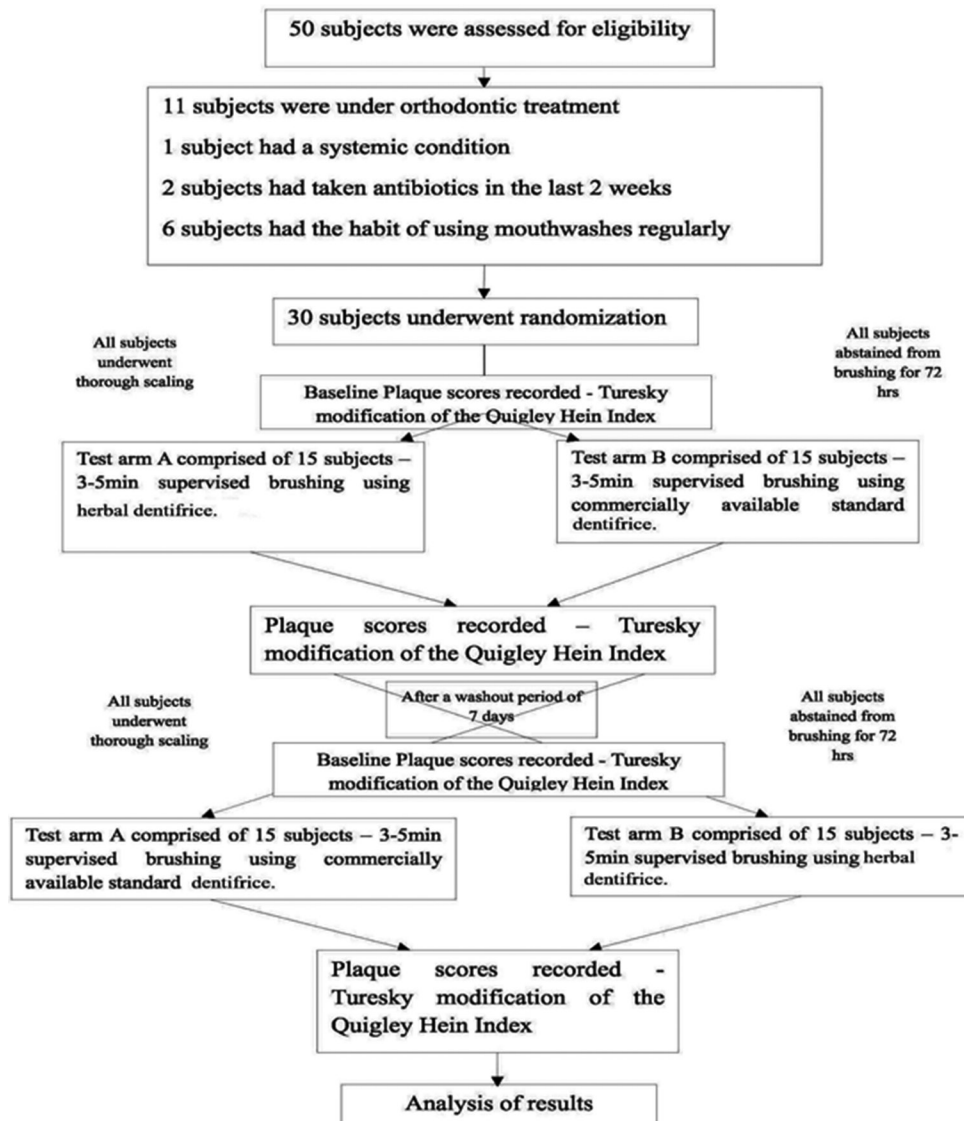


Figure 1: Flow diagram showing information on excluded subjects

cases and controls were the same individuals, the influence of confounding covariates is reduced. The trial was triple blinded to eliminate possible bias. Turesky modification of the Quigley Hein plaque index is a full mouth index and provides comprehensive method for evaluating plaque inhibitory action of various antiplaque agents.^[32] Hence, this index was used to assess plaque scores in the present study. Dental plaque re-growth amid two brushings is directly proportional to the amount of residual plaque on the teeth immediately after brushing.^[33] Therefore, the plaque levels forthwith after brushing were recorded in the present study. The results of the current study revealed that both the dentifrices brought down the plaque levels significantly. The results are similar to that of studies done by Moran *et al.*,^[23] Bhat *et al.*,^[20] Ganavadiya *et al.*,^[22] and Ozaki *et al.*^[21] where different dentifrices were compared. In each of the studies, all the different dentifrices used as interventions brought about significant reduction in plaque levels.

The results of the current study explicitly show that DIY toothpaste has satisfactory plaque reducing ability. Although not equal to that of the commercial toothpaste, the effects produced by the herbal dentifrice are appreciable taking safety into account. In the present study, triclosan containing commercial toothpaste reduced plaque levels better than that of the herbal dentifrice. This is in congruence with the study done by Moran *et al.*^[23] where triclosan-based toothpaste showed good plaque inhibitory action. In the current study, herbal dentifrice with three basic ingredients was formulated. Addition of more therapeutic compounds could have increased the plaque inhibitory potential as compared to the control dentifrice. There are variety of potential ingredients available in the market. The usage of different combinations of these ingredients could result in favorable results. Assessing plaque levels at different time intervals of 24 h, 48 h and 96 h will provide more reliable and valid results. Hence, future research should compare the plaque inhibitory action of dentifrices with

different formulations at varying time intervals to identify the better antiplaque agent.

Conclusion

Within the constraints of the present study, it can be concluded that the herbal dentifrice had good antiplaque action. However, the plaque inhibitory action of herbal dentifrice was marginally less when compared to commercial dentifrice. Using a dentifrice with safe ingredients is essential to combat plaque-induced dental disorders. A constant search for a better antiplaque agent should always be the goal.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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