Effectiveness of novel herbal dentifrice in control of plaque, gingivitis, and halitosis — Randomized controlled trial

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ABSTRACT

Background and aim: Plaque is a common etiological factor for common oral conditions like gingivitis, periodontitis, dental caries and halitosis. We aimed to evaluate the efficacy of a novel herbal dentifrice in control of plaque, gingivitis, and halitosis in comparison to control dentifrice.

Experimental procedure: We conducted a randomized controlled, single center, double-blinded parallel arm clinical trial. Participants were randomly distributed with commercially available herbal dentifrice or control dentifrice. Assessments of plaque, gingivitis, halitosis, unstimulated saliva pH were done at baseline and at one month by a trained and calibrated periodontist. All the participants were given new toothbrushes one week before the start of the study. They were asked to brush with the designated dentifrices for 2–4 min, twice daily for one month.

Results and conclusion: A total of 79 participants were recruited for this study, out of which 75 participants completed the follow-up. Inter-group comparisons of all the variables at baseline showed no significant differences in the mean plaque index, gingival index, halitosis and pH between test and control groups respectively. Intra-group comparisons showed a significant decrease in mean plaque, gingival and halitosis at follow-up than at baseline in both test and control groups. No significant differences between test and control groups were seen in the mean plaque index (P = 0.792), gingival index (P = 0.292), halitosis (P = 0.266), pH (P = 0.742) at follow-up after adjusting the respective baseline scores. The novel herbal dentifrice could be a suitable alternative for the control of plaque, gingivitis, and halitosis.

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1. Introduction

Dental plaque is a microbial biofilm, which is a complex accumulation of 3-dimensional arrangement of bacteria. In the oral cavity, bacterial biofilms are found on both hard and soft tissues.1 Plaque is a common etiological factor for common oral diseases like gingivitis, periodontitis, and dental caries.2,3 Microbial degradation of organic substrates in the oral cavity can also cause halitosis. Over 80–90% of the cases, halitosis is caused by oral conditions such as dental plaque, impacted food or debris, tongue coating, periodontal disease, peri-implant disease, and many others.4

Optimal plaque control plays a pivotal role in the prevention and control of gingivitis and periodontal diseases. Many mechanical plaque control aids are currently available to remove or control plaque.5 Brushing of teeth twice a day and daily flossing is shown to be highly effective in plaque reduction. However, over 50% of adults still shown to have gingivitis on an average of 3–4 teeth.6 Hence, various chemical formulations were tried in dentifrices to prevent plaque and gingivitis.

As some of these chemical substances may have undesirable side effects, such as staining of teeth, alteration of taste, abrasion of
teeth, ulceration of oral mucosa, etc., interest in natural-based dentifrices has increased lately. Moreover, herbal dentifrices can help in the control of common oral diseases without the need for chemical agents. Thus, amidst growing evidence of connecting oral health and whole body health, ‘naturally occurring’ active ingredients of herbal medicines, in the least harmful way, offers milder and long-lasting methods for restoration of health. Many clinical trials have been published on the reduction of supragingival plaque and gingivitis and the positive effect of toothbrushing with herbal dentifrices.

Numerous herbal dental dentifrices are now commercially available out of which Sudanta dentifrice (Sri Sri Tattva Sudanta) has received attention as it has an all-natural, fluoride-free composition. It is a polyherbal composition of Cloves (Syzygium aromaticum), Cinnamon (Cinnamomum zeylanica), Black pepper (Piper nigrum), Bakul (Mimusops elengi), Mayaphal (Quercus infectoria) and Camphor (Cinnamomum camphora). Hence, we aimed to evaluate the efficacy of novel herbal dentifrice in control of plaque, gingivitis, and halitosis in comparison to control dentifrice. This study would help to understand the benefits of Ayurveda based herbal dentifrice over a control dentifrice in controlling plaque, gingivitis, and halitosis.

2. Materials and methods

We conducted a randomized controlled, single center, double-blinded parallel arm clinical trial to evaluate the efficacy of herbal novel dentifrice on control of plaque and gingivitis. Permission to conduct was sought from the institutional ethics committee, IEC: 222/2018 and the trial was registered with the Clinical Trial Registry of India (CTRI/2018/05/014049). The scope of the study with possible benefits and harms were explained to all the participants, and informed consent was sought. The study was conducted among the adolescent students of government polytechnic college, Udupi. We included participants willing to participate, aged 18 and above with plaque and gingivitis score of more than 2. Subjects with a history of use of antibiotics or anti-inflammatory drugs in the last one week, allergy to any herbal products or rampant caries or subjects with more than 30% of the teeth missing or crowns or large restorations were excluded. Participants were screened for inclusion and exclusion criteria, and eligible consented participants were randomized by block randomization (block size = 4) into either the test or control group. Serial opaque cardboard boxes with pre-assigned numbers corresponding to block randomization code were used to allocate the participants into their respective groups ensuring the blinding of the outcome assessor or the examiner (Fig. 1). Sample size calculation was done using PS program version 3.1.6 (power and sample size calculations) based on the findings of the previous study. It was estimated that 36 subjects were needed in each group with a mean difference of 0.2 and standard deviation of 0.3 to reject the null hypothesis that the population means of the test and control groups are equal with a power of 80% and confidence interval of 95%.

2.1. Interventions

Participants in the test group were given commercially available herbal non-fluoridated dentifrice (Sudanta toothpaste, Sriveda Sattva Pvt ltd, Bangalore, India) containing extracts of Cloves (Syzygium aromaticum - stem and buds oil-2mg), Cinnamon (Cinnamomum zeylanica – bark oil 0.5 mg), Black pepper (Piper nigrum - fruit-liquid extract-2mg), Bakul (Mimusops elengi – bark liquid extract-5mg), Mayaphal (Quercus infectoria – Galls liquid extract-1mg) and Camphor (Cinnamomum camphora), Sodium benzoate (Preservative – 5 mg), Base-Q. S, Aqua-Q.S. Participants in the control group were given commercially available 1000 ppm fluoridated dentifrice (Colgate Total, Colgate-Palmolive India Pvt ltd, Solan, Himachal Pradesh, India). All the dentifrices were dispensed after masking with thick black adhesive tape to ensure proper blinding of the product.

2.2. Outcome assessment

Plaque was evaluated by Turesky, Gilmore, Glickman modification\(^1\) of Quigley-Hein Plaque Index\(^2\) using a disclosing agent (range: 0 to 5). Gingivitis was assessed by Talbott, Mandel, Chilton modification\(^3\) of Loe and Silness Gingival index (range: 0 to 3).\(^4\) Two secondary measures were calculated from the above plaque and gingival indices as described previously.\(^5\) The plaque severity score was calculated by assessing the number of teeth with a score of 3 or more divided by the number of teeth evaluated. The gingivitis severity score was calculated by determining the number of teeth with bleeding divided by the total number of teeth examined. Halitosis was evaluated using a handheld breath analyzer (Tanita Corporation of America Inc. IL, USA) as per the manufacturer instructions. Unstimulated Saliva pH assessment was done using pH ion strips as per the manufacturer instructions. All the assessments were done at baseline and at the end of one month. Clinical evaluation was done by a trained calibrated periodontist (MA). Allocation concealment, participant allocation, halitosis score measurement, and salivary pH assessment was done by a trained calibrated examiner (HS). Intra-examiner reliability for plaque and gingivitis were 0.93 and 0.92 respectively.

2.3. Instructions to the participants

All the participants were given new toothbrushes one week before the start of the study. They were asked to brush with the designated dentifrices for 2–4 min/day, twice daily for one month. A record of the tooth brushing was given to participants to evaluate tooth brushing behavior. All the participants have reported to perform tongue cleaning. Participants were asked to refrain from using any other oral health care products during the course of the study.

2.4. Statistical analysis

All the analysis was done using SPSS version 18. A p-value of <0.05 was considered statistically significant. Independent sample t-test was done to evaluate the inter-group group comparisons. ANCOVA was done to assess the inter-group differences at one month after adjusting for baseline values.

3. Results

A total of 295 participants were screened for inclusion, and 79 participants were recruited for this study, out of which 75 (test = 37 and control = 38) participants completed the follow-up. Of this, majority were males (n = 60). The mean age of the participants in the test and control group was 20.32 ± 5.86 and 18.97 ± 3.47 respectively. Four participants could not attend the follow-up examinations due to their academic schedules (three participants were selected for industrial tour and one participant had failed in the examinations due to which they could not attend the follow-up visits). Taste of the toothpastes was acceptable to all the participants and no discomfort was reported with the use of either of the toothpastes.

Inter-group comparisons of all the variables at baseline showed no significant differences in the mean plaque index (P = 0.969),
Plaque severity index ($P = 0.733$), gingival index ($P = 0.553$), gingival severity index ($P = 0.626$), halitosis ($P = 0.821$), pH ($P = 0.539$) between test and control groups respectively (Table 1).

Intra-group comparisons were done for all the variables in test and control groups. It was seen that there was a significant decrease in mean plaque, plaque severity, gingival, gingival severity and halitosis at follow-up than at baseline in both test and control groups. However, there was a significant increase in salivary pH at follow-up than baseline in both test and control groups (Table 1).

Inter-group comparisons of all the variables at follow-up after adjusting the respective baseline scores was done using ANCOVA. No significant differences were seen in the mean plaque index ($P = 0.792$), plaque severity index ($P = 0.607$), gingival index ($P = 0.292$), gingival severity index ($P = 0.649$), halitosis ($P = 0.266$), pH ($P = 0.742$) between test and control groups respectively (Table 2).

4. Discussion

Plaque is the major etiologic factor for gingivitis, periodontitis, caries, and halitosis. Mechanical plaque control is the best approach for the elimination of plaque. Several chemotherapeutic plaque control agents have been studied. However most of them have side effects when used for an extended duration. Hence, numerous herbal products have emerged in the markets with more emphasis on herbal dentifrices. With increased awareness about the healthy lifestyle and natural products among the consumers, this has led to a growing demand for herbal oral health care products globally.

Herbal products used in indigenous medicine are of growing interest in the field of dental disease prevention. They can be safe and long term alternatives for the maintenance of optimal oral health. Our study has evaluated the effectiveness of one such novel herbal dentifrice over the control dentifrice. The test dentifrice in our study had polyherbal ingredients like cloves, cinnamon, black pepper, bakul, mayaphal and camphor.

**Table 1**

| Group             | Baseline | Follow-up | P-value | P-value | P-value |
|-------------------|----------|-----------|---------|---------|---------|
|                   | Mean     | SD        | Mean    | SD      |         |
| Plaque index      | 2.47 .70 | 1.27 .44  | <0.001  | 0.069   |
| Control           | 10.42 9.57 | 1.58 3.77  | <0.001  | 0.573   |
| Test              | 11.19 9.85 | 2.22 5.42  | <0.001  | 0.553   |
| Plaque severity index | 1.20 .23  | .90 .18   | <0.001  | 0.026   |
| Control           | 5.55 6.53 | .87 1.76  | <0.001  |         |
| Test              | 4.89 5.06 | .68 1.73  | <0.001  |         |
| Gingivitis index  | 1.26 .72  | .58 .64   | <0.001  | 0.821   |
| Control           | 6.46 .34  | 6.72 .36  | <0.001  |         |
| Test              | 6.41 .43  | 6.67 .40  | 0.001   | 0.539   |

† P-value for inter-group comparisons (independent sample t test); ‡ P-value for intra-group comparisons (paired t test).
antifungal properties. Pradeep et al. showed that piperine has an inhibitory action on nitric oxide production and tumor necrosis factor-alpha production, both of which have a known role in the pathophysiology of inflammation in periodontal disease. Another study reported that Piper nigrum (Piperine) could be used as potential therapeutic tools to regulate inflammatory responses and prevent/attenuate carcinogenesis. More recently, Bae et al. showed that administration of Piperine inhibited lipopolysaccharide (LPS)-induced inflammatory responses, leukocyte accumulation, and the production of tumor necrosis factor-alpha. Dwivedi and Singh have shown that Piperine has significant anti-biofilm effect of Streptococcus mutans. Quercus infectoria has also been pharmacologically documented to possess astringent, antibacterial, anti-inflammatory, anti-herbicidal, and anti-inflammatory properties. Mimusops elengi has various medicinal properties, like anti-viral, anti-inflammatory, antimicrobial antioxidant, analgesic, and astringent actions. Cinnamomum camphora has anti-inflammatory property and reduces the swelling and pain associated with inflammation.

All the ingredients used in the novel polyherbal dentifrice have anti-inflammatory, antibacterial, antioxidant properties. The effect of these ingredients in the present study was evident, and no significant differences concerning the mean plaque, plaque severity, gingivitis, gingival severity, halitosis, and mean pH levels were seen between the novel and control dentifrice after one-month follow-up after adjusting for respective baseline scores. These findings of the test dentifrice have an antimicrobial activity which could have had a decreased the scores of breathalyzer. Similarly, control dentifrice also had antimicrobials which had a significant effect. Moreover, the role of such antimicrobials to prevent caries cannot be underestimated with the constituents of the test dentifrice. The extracts of Syzygium aromaticum essential oil, Mimusops elengi, Quercus infectoria galls, have been shown to have antibacterial action on biofilms of Streptococcus mutans that has a potential role in caries initiation and development.

The possibility of hypersensitivity to herbal ingredients cannot be ruled out with the contents of the test dentifrice. One such ingredient that may have the potential for allergic reactions is Cinnamon which can cause Cinnamon contact stomatitis in some individuals. A recent review reported 12 case series and case reports involving 35 cases (24 females) secondary to the use of Cinnamon flavoured chewing gums. Most of them recovered after discontinuation of the same. Such allergies are rare in the mouth and is mainly due to the protective role of saliva and high vascularization in oral epithelium. Individuals and health care professionals should be well aware of this possible potential of allergic reactions to Cinnamon and the fact that the discontinuation of the same may be enough to diagnose and manage same.

Few limitations are noted in our study. Although an attempt was made to blind the participants for the dentifrices, there was still a possibility that participants could know the control interventions as it was routinely used dentifrice. Conversely, the participants in the test dentifrice might have also known due to the herbal flavour of the dentifrice. Hence, the possibility of bias could have occurred in both the groups. Also, evaluation of halitosis and pH in our study was evaluated using handheld portable breath analyzer and pH strips which are not a standard method. However, in this field study, it was not feasible to use any of the conventional techniques. Within the limitations of the study, the herbal dentifrice could be an alternative for the maintenance of oral health. Further, studies are needed to evaluate the long term benefits of the same with respect to the incidence of caries.

**Conflicts of interest**

Dr. Pentapati reports that product samples of both test and control groups, disclosing agent and hand held breath analyzer were provided by Sriveda Sattva Pvt Ltd, Bangalore, India.

**Appendix A. Supplementary data**

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtcme.2019.06.006.

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**Table 2**

Inter-group comparisons at follow-up after adjusting for baseline values.

|                  | Adjusted baseline | Test Mean±SE | Control Mean±SE | P-value |
|------------------|-------------------|--------------|-----------------|---------|
| Plaque index     | 2.47              | 1.3±0.07     | 1.27±0.07       | 0.792   |
| Plaque severity index | 10.8           | 2.16±0.75    | 1.63±0.74       | 0.607   |
| Gingival index   | 1.18              | 0.94±0.03    | 0.9±0.03        | 0.292   |
| Gingivitis severity index | 5.23       | 0.68±0.29    | 0.87±0.29       | 0.649   |
| Halitosis        | 1.28              | 0.43±0.1     | 0.59±0.1        | 0.266   |
| pH               | 6.43              | 6.68±0.06    | 6.7±0.06        | 0.742   |

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