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RESEARCH ARTICLE

EFFECTIVENESS OF COMMERCIALLY AVAILABLE HERBAL TOOTHPASTE (DANTKANTI) ON PERIODONTAL HEALTH PARAMETERS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

The aim of this randomized, double blind controlled trial was to verify the effectiveness of a commercially available herbal dentifrice (Dantkanti) on the reduction of plaque and gingivitis. Fifty volunteers with were randomly assigned to either a test group (herbal dentifrice) or positive control group after meeting the eligibility criteria. The present study had a controlled double blind crossover experimental design, consisted of 2 x 4 weeks experimental periods, separated by a ten day washout period. The dentifrices were distributed according to the protocol of the study to the respective group. Plaque and gingivitis assessments were carried out at baseline and after 28 days of product use. All examinations were conducted by the same calibrated investigator. Subjects were instructed to brush their teeth twice times daily using their assigned dentifrice for 28 days. There was a significant reduction in plaque levels in both the test and control groups. However, there was no significant difference between the groups. A significant reduction in gingivitis was observed in both groups, although there was no significant difference between them. The authors concluded that both dentifrices were effective in reducing plaque and gingivitis in subjects with established gingivitis.

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INTRODUCTION

Epidemiological studies confirm the close relationship between dental plaque and gingivitis. Throughout the world, dental plaque growth and inflammation of gingival tissue are ubiquitous and strongly linked, irrespective of age, gender or racial/ethnic identification. (Theilade and Theilade, 1976) The periodontal diseases caused dental plaque can prevented by simply opting oral hygiene measures. (Abdellatif and Burt, 1987) Tooth brushing with dentifrices is an easy method of plaque control, which is widely practiced form of oral hygiene in most of the countries. (Lang *et al*., 1973) Tooth brush is the principal instrument in plaque control, however, the best results can be achieved when it is used in adjunct with the dentifrices as well as other chemical plaque control agents like mouthwashes. (Caton *et al*., 1993; Addy *et al*., 1994)

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Toothpaste used as an adjunct chemical agent with tooth brushing and efficacy of toothpaste merely depends on its chemical composition, which is constantly changing due to manufacturer's competition. The cleaning abilities of toothpaste based on abrasives the antibacterial agents, which, in turn, are provided by a variety of substances with different abilities to inhibit the growth of germs in the oral cavity. (Kornman, 1986) One of the most effective agents for supragingival plaque control is chlorhexidine. However, a significant reduction of its ant plaque potential may be observed when it is used in a toothpaste preparation. (Brecx *et al*., 1990) Triclosan has also been incorporated into dentifrices, and some studies have demonstrated a significant reduction of plaque and gingivitis. (Davies *et al*., 2004) The use of different chemicals in toothpaste to produce a direct inhibitory action on plaque formation is now a well-established approach in preventing periodontal disease as well as most accepted methods too. (Addy and Renton-Harper, 1996; Van der Ouderaa, 1991) But on the other hand, it has been reported

that these chemical agents may not achieve permanent complete plaque removal, therefore additional application of herbal microbial agents is the subject of interest which produce least side effect and maximize the efficacy of dentifrices. (Fabiana Ozaki *et al*., 2006) Interest in alternative toothpastes based on herbal extracts has increased recently because of its fewer side effects and also its popularity to being natural. Herbal compounds mentioned and used in ancient medicine are of growing interest in the field of dental disease prevention as the result of its various herbal containing products are available in the market. There has been an increased availability of oral health care products in India, each claiming to be more effective than others with their unique composition in improving oral health. One of them is Dantkanti herbal toothpaste, a product of Patanjli, which is widely endorsed by the company through the print media as well as electronic media. Though the product is endorsed in the market by the company, but it still lacks the literature, which support its effectiveness in plaque control. Hence, with the increased popularity of herbal dentifrices and severe paucity of data, provokes us to undertake a randomized control trial for the checking effectiveness of Dantkanti toothpaste in plaque control.

MATERIALS AND METHODS

The present study was designed as a randomized, double blind, crossover controlled trial carried out in between the month of March 2014 and July 2014. Initially 50 patients (mean age of, 21.8±3.28 years and range 18-25 years) were enrolled randomly in this study. The selection was based on following eligibility criteria:

Age ≥18 years, a minimum of 15 teeth, good general health, a baseline Plaque Index (PI) mean>1.5 (Addy and Renton-Harper, 1996) and the presence of established gingivitis. Established gingivitis was defined as a baseline using Gingival Index (GI). (Löe and Silness, 1963) GI mean was based as inclusion criteria used by Binny *et al*. (1996) Subjects were recruited from engineering college, who was living in different hostel but sharing common hostel mess in order to standardize their diet. Exclusion criteria were: presence of systemic disease, using drugs affecting periodontal disease, antibiotic therapy for periodontitis or gingivitis during the last three months, the use of orthodontic appliances, continuous use of mouth rinses containing chemical agents in the previous 3 months and any history of allergies to toothpaste or herbal medicine. All subjects provided with verbal and written information, concerning the study and after entering the study, a written consent form regarding all information received from them. The study protocol was approved by the Ethics Committee of Swami Devi Dyal Hospital and Dental college, Golepura Barwala Distt. Panchkula. All procedures in this experiment were performed according to the ethical principles established by the Declaration of Helsinki. The present study had a controlled double blind crossover experimental design, consisted of 2 x 4 weeks experimental periods, separated by a ten day washout period. This time period was deemed sufficient to balance the carry-over effect from the preceding treatment. (Tangade *et al*., 2012) The baseline plaque, gingival and bleeding indices were measured for phase one scoring, on all teeth at the buccal, mesial, distal and lingual aspects, with the exception of third molars. The participants were stained for plaque using an erythrosine disclosing solution and cotton swabs. The amount of plaque was scored using the Turesky (Turesky *et al*., 1970) modification of the Quigley, Hein (1962) Plaque Index (PI), Gingival inflammation was recorded using the Gingival Index (GI) (Löe and Silness, 1963) and bleeding in response to gentle probing in the gingival sulcus (Amoian *et al*., 2010) was assessed at the midbuccal, mesiobuccal, mid palatal/lingual and distopalatal/lingual surfaces of each index tooth and the % of sites which bled (BoP%) calculated for each subject. The main investigator who was previously calibrated conducted all measurements. For calibration, two measurements were performed by one-hour interval. Intra-examiner calibration was performed in 5 patients until an 80% agreement was obtained.

All patients were instructed in the use of the oral hygiene items. They were asked to brush their teeth thrice daily using the Bass technique for approximately 2 min. The subjects were randomly assigned to either the test or positive control group. The random allocation sequence was generated by one of the authors, who used a random-number table. The random allocation sequence was concealed from the main investigator until the dentifrices were assigned to the participants. The investigator and study subjects were unaware of the contents of each tube. The blending was kept intact throughout the study period. Volunteers in the test group received a toothpaste tube containing 30 g of Herbal dentifrice containing "Vajradanti (Barleria prionitis), Pilu(Salvadora), Bakul (Mimusops), Babool (Acacia arabica), Akarkara Extract(Anacydus Pyrethrum), Majuphal(Quercus), Karpur(Dryobalanops camphora), Vidang Extract(Embelia ribes), Nimb or Neem Extract(Azadirecta indica) Lavang Extract(Caryophyllus aromaticus), Haldi (turmeric) and the Base Material calcium carbonate, sorbitol, silica, sodium lauryl sulphate, titanium dioxide, sodium silicate, carrageenan, sodium monofluorophosphate, sodium bicarbonate, sodium saccharin, triclosan, flavor, in aqueous base.

Subjects in the control group received a toothpaste tube containing 30 g of Regular toothpaste containing calcium carbonate, sorbitol, silica, sodium lauryl sulphate, titanium dioxide, sodium silicate, carrageenan, sodium monofluorophosphate, sodium bicarbonate, sodium saccharin, triclosan, flavor, in aqueous base. No prophylaxis were undertaken prior to commencement of the study, and no attempt was made to modify the volunteer's oral hygiene habits. After 28 days, the subjects returned for another appointment, in which the amounts of plaque and gingival inflammation and bleeding on probing % were scored again by the same investigator and the scores were titled as the final score for phase one. To check for compliance, the participants were asked to return their assigned tubes, so that the investigator could verify the amount of dentifrice that was used.

This was followed by a washout period of 10 days during which the subjects returned to their regular oral hygiene practice. The test and control toothpastes were interchanged alternatively at the beginning of second study phase and the

scorings were done at the same time intervals. The scores were titled as baseline and final scores of the second phase as described in Figure 1.

Statistical Analysis: Statistical analysis was performed using a statistics package (SPSS 11.0 for Windows). The protocol-defined primary outcome variable shows the reduction of PI, GI and BoP% from baseline.

Table 1. Plaque Index median scores before and after crossover phases among herbal and control groups

PI Score	Before Crossover				After Crossover			
Group	Baseline	Final	Change	P	Baseline	Final	Change	P
Herbal	2.17	1.3	0.87	*	1.7	1.2	0.5	*
Control	2.1	1.9	0.28		1.6	1.5	0.1	

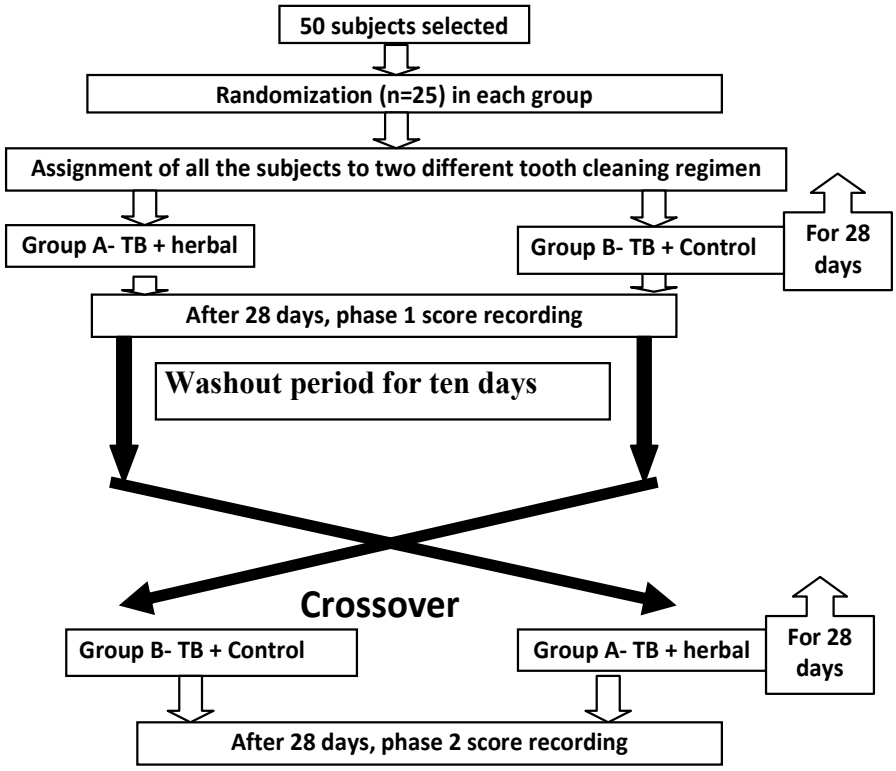
Table 2. Gingival index, median scores before and after crossover phases among herbal and control groups

GI Score	Before Crossover				After Crossover			
Group	Baseline	Final	Change	P	Baseline	Final	Change	P
Herbal	2.01	1.08	0.93	*	1.9	1.4	0.5	*
Control	1.91	1.82	0.1		1.45	1.41	0.04	

Table 3. Bleeding on probing (BOP) % median scores before and after crossover phases among herbal and control groups

BOP% Score	Before Crossover				After Crossover			
Group	Baseline	Final	Change	P	Baseline	Final	Change	P
Herbal	11.3	8.5	2.4	*	11.7	8.5	3.1	*
Control	11.7	10.9	1.5		10.9	10.5	0.8	

DESIGN OF THE STUDY



showing flowchart for the design of the study.

At the 4 week visit, a median change from the baseline for PI, GI and BoP% for both herbal and control groups was calculated, before and after crossover. The distribution of the variables was not normal, so group medians were compared using the Mann-Whitney U test. A median value was calculated for each of the study phases and an overall median of the differences from baseline was calculated, before and after crossover. Mann-Whitney U-test was applied to compare data between the herb and control groups. Any differences with $p<0.05$ was considered significant.

RESULTS

Table 1 represents the highest median plaque index score change among herbal dentifrice groups with 0.69, before crossover whereas the least differential change score between baseline and 28 days was reported with 0.1 for the control group, after crossover. The difference between the test (herbal) and control toothpaste was statistically significant for pre and post crossover design. Table 2 shows the reduction of the median gingival index score of 0.94, in the herbal group between baseline and 28 days, before crossover whereas least differential median gingival index score reduction of 0 was reported after crossover in the control group. Thus, there was a significant reduction between the gingival index scores of herbal and control group before and after crossover. Table 3 shows marked differences in BOP% after crossover, which was reported to be 3.1 and 0.8 respectively, among the herbal and control dentifrice groups.

DISCUSSION

Nature is the best physician for all kinds of disease and so, for oral disease too. In the present times herbal products are of growing interest for treating various ailments because of its fewer side effects and low cost. Herbal toothpaste is one of those products which are frequently found in the market, which promising the best oral health with their unique composition. There are several dentifrices, which has already set their standards in maintaining the oral hygiene, so, it is important to keep check on the newer dentifrices for their effectiveness in oral hygiene by undertaking the clinical trial. In this trial, we examined a dentifrice containing "Vajradanti (Barleria prionitis), Pilu(Salvadora), Bakul (Mimusops), Babool (Acacia arabica), Akarkara Extract(Anacydus Pyrethrum), Majuphal(Quercus), Karpur(Dryobalanops camphora), Vidang Extract(Embelia ribes), Nimb or Neem Extract(Azadirecta indica) Lavang Extract(Caryophyllus aromaticus), Haldi (turmeric) and the Base Material calcium carbonate, sorbitol, silica, sodium lauryl sulphate, titanium dioxide, sodium silicate, carrageenan, sodium monofluorophosphate, sodium bicarbonate, sodium saccharin, triclosan, flavor, in aqueous. The plaque-reducing effects of other herbal-based active agents has been previously described by various studies. (Tangade *et al*., 2012; Turesky *et al*., 1970; Quigley and Hein, 1962; Amoian *et al*., 2010; Willershausen *et al*., 1991; Pannuti *et al*., 2003) Present study reveals that, the application of herbal-based dentifrice has shown considerable reduction in the plaque accumulation and gingival inflammation, when tested in both the phases of the crossover randomized control trial. Plaque Index median change reduction was reported to be 0.93 and 0.1 for herbal group and 0.53 and 0.04 for the control group, before and after crossover, which shows a higher reduction of plaque when compared between the herbal and control groups. This kind of reduction in PI for herbal products is in accordance with studies (Fabiana Ozaki *et al*., 2006; Binney *et al*., 1996; Tangade *et al*., 2012). The reduction in PI scores may be due to the combined effect of various herbal ingredients as antimicrobial property like which is supported by Vajradanti (Barleria prionitis), Pilu (Salvadora), Bakul (Mimusops), Babool (Acacia arabica), Akarkara Extract (Anacydus Pyrethrum), Karpur (Dryobalanops camphora), Vidang Extract (Embelia Ribes), Nimb or Neem Extract (Azadirecta indicia) Lavang Extract (Caryophyllus aromaticus). (Almas, 2001; Mohamed I Gazi, 1991; Gupta *et al*., 2012; Shetty *et al*., 2013; Choudhary *et al*., 2015), Haldi (turmeric). (Digra *et al*., 2014)

Median GI scores reported in this two arm cross over design were also higher in the herbal group, in both the phases of the study. These results are in accordance with a study conducted with other herbal product. (Pannuti *et al*., 2003; Almas, 2001; Mohamed I Gazi, 1991) Again the anti-inflammatory property of various herbal ingredients in the test dentifrices may be responsible for the same. (Almas, 2001; Mohamed I Gazi, 1991; Gupta *et al*., 2012; Shetty *et al*., 2013; Choudhary *et al*., 2015; Digra *et al*., 2014) A study by Willerhausen *et al*. (1991) have reported that the pH of the total saliva was significantly displaced into the alkaline range by the use of herbal products. In the present study, significant reduction in bleeding on probing was observed by herbal product, when tested before and after crossover study design, in comparison to the control dentifrice group. This reduction is in line with the findings of Amonian *et al*. (2010) This reduction in bleeding may be due to astringent and anti-inflammatory effect of "*Acacia Arabica,* Barleria prints, Azadirecta indicia Mimusops. (Choudhary *et al*., 2015; Digra *et al*., 2014; Willershausen *et al*., 1991)

Conclusion

The results of this study have given useful information about the positive effects of herbal toothpaste dantkanti on decreasing plaque, gingivitis and BoP % scores. It is suggested that, the use of the toothpaste containing Vajradanti (Barleria prionitis), Pilu(Salvadora), Bakul (Mimusops), Babool (Acacia arabica), Akarkara Extract(Anacydus Pyrethrum), Majuphal(Quercus), Karpur(Dryobalanops camphora), Vidang Extract(Embelia ribes), Nimb or Neem Extract(Azadirecta indica) Lavang Extract(Caryophyllus aromaticus), Haldi (turmeric) babul extract could be an useful aid in obtaining a significant reduction in parameters for PI, GI and BoP% compared to the control paste. It may be recommended for daily oral hygiene procedures.

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