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Original Article

Effectiveness of two different herbal toothpaste formulations in the reduction of plaque and gingival inflammation in patients with established gingivitis – A randomized controlled trial☆

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ABSTRACT

Background: Plant based toothpastes have received great attention in reducing gingival inflammation. Studies show contrasting results regarding the effectiveness of these toothpastes. In the present study, the effectiveness of two herbal tooth paste formulations in the reduction of plaque and gingival inflammation was assessed. Nicotine content in the toothpastes was assessed using GCMS.

Material and methods: 50 patients with established gingivitis were included in the study. The subjects were randomly assigned to either the test (Parodontax®) or the control (Colgate® herbal) group. There were 5 drop outs in the study in the control group after baseline examination. No prophylaxis was undertaken prior to commencement of the study, and no attempt was made to modify the participant's oral hygiene habits. A brief case history was recorded at baseline. The Turesky (1970) modification of the Quigley, Hein (1962) Plaque index (PI), the Loe and Silness (1963) Gingival Index (GI). Unstimulated salivary samples were collected at baseline and 30th day and the pH was measured using a salivary pH meter (CL-51B; Systronics New Delhi, India).Comparisons (intergroup and intragroup) were analysed by the *t*-test. Groups were also compared regarding age by means of *t* test, and association between group and sex was verified by means of the chi-square test. All statistical tests employed a level of significance of $\alpha = 0.05$. There were reports of presence of nicotine and its derivatives in herbal toothpaste after the study was nearing completion. Hence we assessed for the presence of nicotine in both the toothpaste using the methods described by Aggarwal *et al.*[24]

Results: When the two groups (test and control groups) were evaluated, after 30 days, the test group presented an average 21.08% reduction in plaque and the control group showed 31.85% reduction in plaque scores. The mean reduction in gingival index (GI) scores was 25.92% and 19.14% in the test and control groups respectively. There was no significant difference between the groups in GI, PI and salivary pH levels. There was no evidence of nicotine or related compounds in both the tooth paste.

Conclusion: Both herbal based dentifrices reduce plaque levels and gingival inflammation. But, it did not alter the pH of the saliva. However, there were no additional benefits of the Parodontax® toothpaste over Colgate® Herbal toothpaste. There was no evidence of nicotine or related compounds in both herbal toothpaste.

1. Background

Plaque induced gingivitis is the second most common oral disease after dental caries. It is thought to affect at least 75% of the population worldwide.[1] Gingivitis begins in the child hood and its prevalence increases with age.[2] It has been reported that plaque induced gingivitis is seen in dentate individuals of all age group.[3]

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Self-performed mechanical plaque removal is a proven method of controlling plaque and gingival disease.[4] However, tooth brushing and flossing are difficult tasks and depend on individual dexterity. Thus, many patients might not be able to completely remove plaque on all teeth surfaces. Mechanical plaque control is a time-consuming procedure, and some individuals may lack motivation for maintaining good oral hygiene. In an effort to enhance the efficacy of mechanical tooth-cleaning procedures, antimicrobial agents have been added to dentifrices.[5,6]

In recent times, considerable research is being done on mouth rinses and toothpastes based on plant extracts. Parodontax® (GlaxoSmithKline, Middlesex, United Kingdom) has received great attention in reducing gingival inflammation. It is composed of sodium bicarbonate, sodium fluoride (1,400 ppm) and herbal ingredients: Chamomile, (supposed to have anti-inflammatory properties and to decrease gingival inflammation); Echinacea, (is reputed to stimulate the immune response); Sage and Rhatany (anti-hemorrhagic properties); Myrrh, (claimed to be a natural anti-septic); and Peppermint oil (claimed to have analgesic, antiseptic and anti-inflammatory properties). Colgate® herbal toothpaste comprises of calcium carbonate, chamomile, sage, myrrh, eucalyptus and sodium monoflurophosphate.

Some studies reported that Parodontax® is able to reduce plaque and gingivitis,[7,8] while others showed no significant advantage when compared to a control.[9–11] In most of the trials conducted thus far, the study subjects received dental prophylaxis and oral hygiene instructions before the commencement of the trial. This may not be true in the majority of the population where plaque removal is unsupervised, hence, increased likelihood of greater plaque accumulation and gingival disease.

The results of clinical trials on established gingivitis patients will represent the vast majority of the dentifrice users. It has also been shown that the pH of total saliva changed significantly towards an alkaline range when herbal products were used.[12] Nicotine, a compound commonly seen in Tobacco is well known for its addiction and dependence potential. Nicotine increases blood pressure, heart rate and respiratory rate by facilitating the release of catecholamines. It increases the levels of free fatty acids, blood sugar and interferes with antioxidant activity.[24] It is known to cause several studies have reported the presence of nicotine and related compounds in herbal toothpastes.[24] The primary objective of our study was to assess the efficacy of Parodontax® toothpaste on the reduction of plaque and gingival inflammation on established gingivitis as compared to control (Colgate® herbal toothpaste) and to assess the pH of the saliva at baseline and 30th day. We also assessed the presence of nicotine in both the herbal toothpastes.

2. Methodology

This was a randomised, double blinded, parallel arm controlled trial. Subjects for the study were recruited from all the patients reporting to the outpatient, Department of Periodontics, Yenepoya Dental College, Yenepoya University. Institutional Ethical Clearance was obtained prior to the study (YUE C 139/25/7 113). The clinical trial was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. This study was registered in Clinical Trial Registry of India {CTRI/2013/10/004120 [Registered on: 31/10/2013]}.The first enrolment for the study was done on 27/07/2013 and the study was completed on 20/03/2015. Informed consent was taken prior to participation in the study. The outline of the study protocol is given in Fig. 1. The entire study protocol can be accessed at http://ctri.nic.in.

Based on previous studies, a sample size of 40, at 80% power and 95% confidence interval was estimated. 10% drop out rate was estimated and adjusted in the sample size. Hence 50 subjects (25 for each group) who fulfilled the inclusion criteria were recruited for the study. The inclusion criteria for the study were: Age $\geq$18 years, minimum of 14 teeth, good general health, baseline plaque score mean >1.5 (Turesky modification of Quigley Hein Index, 1970), established gingivitis (Loe and Silness index mean score >1). Exclusion criteria were presence of advanced periodontal disease (CPITN code 4 teeth), smokers, use of orthodontic appliances, use of antibiotics in previous 3 months, use of mouth rinses in previous 3 months, allergy to toothpaste or Parodontax® dentifrice and Colgate® herbal dentifrice.

The subjects were randomly assigned to either the test (Parodontax® toothpaste) or the control (Colgate® Herbal toothpaste) group. The random allocation sequence was done by one of the authors (V.A.B) using coin toss method. The random allocation sequence was not revealed to the main investigator (R.H.) until the dentifrices were assigned to the participants. The main investigator enrolled the subjects and assessed the study variables. Blinding and allocation concealment was controlled by the investigator (S.N.R.). He (S.N.R.) distributed the toothpastes in plain white tubes, as “group A” and “group B” tubes. The two investigators (R.H. & V.A.B.) and study subjects were unaware of the contents of each tube. The contents of each tube were revealed only after the completion of the study period. Subjects in the test group received a toothpaste tube containing 90 g of Parodontax® toothpaste (GlaxoSmithKline, Middlesex, United Kingdom). Subjects in the control group received a toothpaste tube containing 90 g of Colgate® Herbal toothpaste (Colgate – Palmolive India Limited, Mumbai, India) containing calcium carbonate, chamomile, sage, myrrh eucalyptus and sodium monoflurophosphate. The control dentifrice was modified by the investigator (S.N.R.).

No prophylaxis was undertaken prior to commencement of the study, and no attempt was made to modify the participant's oral hygiene habits. All subjects were instructed to apply 15 mm length (in order to standardise the quantity used) of the toothpaste on the brushing surface of the toothbrush and brush twice daily (Morning and night) for a period of 5–10 min for 30 days. A brief case history was recorded at baseline. Unstimulated salivary samples were collected at baseline and 30th day, with the patient sitting with the head down and the mouth open to allow the saliva to drip from the lower lip into a beaker for 2 min to collect about 2 ml of saliva over a given time and the pH was measured using a salivary pH meter (CL-51B; Systronics, New Delhi, India).[13]

At baseline and on the 30th day, the amount of plaque and gingival inflammation was measured on all teeth, at the buccal, mesial, distal and lingual aspects, with the exception of the third molars. The subjects were stained for plaque using an erythrosine disclosing solution and cotton swabs. The amount of plaque was scored using the Turesky[14] (1970) modification of the Quigley, Hein[15] (1962) index, following which the gingival inflammation was recorded using the Loe and Silness (1963) Gingival Index (GI).[16] All measurements were recorded by the main investigator (R.H.), who was previously calibrated. For calibration, two measurements were performed with 1-h interval. Intra-examiner calibration was performed in 5 patients until an 80% agreement was obtained. There were 5 drop outs in the study, 3 of them had moved abroad and 2 of them refused to come after baseline examination.

2.1. Extraction of nicotine from Parodontax® dentifrice and Colgate® herbal dentifrice

Nicotine was extracted from the control and Test tooth paste was done as described by Agarwal and Rajagopal cited by Agarwal and Ray.[24] Nicotine was extracted and isolated from the control and test tooth paste by taking 25 g of toothpaste in a conical flask. 15 mL of NH_3 (strong) was added to the flask, followed by 250 mL

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