



A COMPARATIVE EVALUATION OF ANTI- PLAQUE EFFICACY AND CONSUMER SATISFACTION OF A HERBAL TOOTHPASTE AND A COMMERCIALY AVAILABLE NON- HERBAL TOOTHPASTE: A RANDOMISED CONTROLLED TRIAL

Dental Science

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KEYWORDS

INTRODUCTION:

Dental plaque is titled as a reservoir of pathogenic microorganisms and a crucial etiological factor associated with periodontal diseases.¹ Hence, it is one of the major culprits known to disturb the oral equilibrium, and if not removed regularly, it can pave way to a sequelae of events such as gingivitis, periodontal inflammation, dental caries and halitosis, due to the release of bacterial toxins, acid production and anaerobic respiration.^{2,3}

Maintenance of optimal oral health, thus, requires a regular and consistent use of mechanical and chemical oral hygiene measures to control plaque at an individual level.⁴ In the modern era, there are diverse agents known to control plaque, but among them, the role of dentifrices, is quite inconclusive. These are marketed as toothpastes, toothpowders and tooth gels.¹

Although modern toothpastes contain several beneficial agents (due to its herbal extracts, high fluoride content, enzymes, antibacterial agents, anti-calculus agents, whitening chemicals and specific pigments), which aims to improve the tooth esthetic quality, some of the substances also give rise to certain perturbed effects such as tooth staining, altered taste sensation and may also hamper the usual microflora in much excess and prolonged doses, leading to certain hypersensitive reactions.^{4,6} Some recent studies report that modern toothpastes have carcinogenic effects too.⁷

An allegory that herbal products are much better than the conventional non herbal products have been instilled in the minds of the Indian population. They have gained much popularity from ages due to its traditionalism, natural ingredients, formulations without alcohol, artificial preservatives, colors and flavors.⁸ Some of the active ingredients in herbal toothpastes are chamomile - anti- inflammatory, echinacea – immune stimulatory properties, sage and rhatomy- anti hemorrhagic properties, myrrh – a natural antiseptic, peppermint oil – analgesic, antiseptic and anti- inflammatory properties.⁶

According to the Swot Analysis Report 2017, the brand 'Patanjali Dant Kanti Dental Cream' had ascended into the Indian market system less than a decade, but the current scenario reports these are being tenanting a huge measure of the market within a limited time span.⁹

Hence, the objective of this study was to assess the anti- plaque efficacy and satisfaction of the consumers using a commercially available herbal toothpaste in comparison with the conventional, pharmacologically proven and worldwide popular non herbal toothpaste, and henceforth to identify as to why people resort to herbal products.

The null hypothesis is that there is no difference in the anti- plaque efficacy and consumer satisfaction on using the two toothpastes.

MATERIALS AND METHODOLOGY:

The present study was a triple blinded, concurrent parallel, interventional randomized controlled clinical trial conducted at K.L.E Society's Institute of Dental Sciences, Bangalore, Karnataka during the month of September 2018 over a period of 15 days. It was carried out on 30 subjects in the age groups of 18- 21 years old.

Informed consent was taken prior to their participation in the study. The ethical clearance for the study was obtained from the Institutional Ethical Review Board, K.L.E Society's Institute of Dental Sciences, Bangalore.

Selection Criteria:

The inclusion criteria were:

- Students enrolled to BDS, aged 18- 21 years old,
- Subjects in good general and periodontal health,
- Subjects with no adverse habits,
- Subjects who agree to comply with the study visits.

The exclusion criteria were:

- Subjects who were uncooperative,
- Subjects with any systemic illnesses/ under any medications,
- Subjects who are undergoing orthodontic treatments/ under extensive intra oral prosthesis/ with any developmental defects,
- Subjects who are allergic to any type or contents of toothpastes.

Based on previous studies, a sample size of 30 at 80% power and 95% confidence interval was estimated, after adjusting for a 10% drop out rate.¹⁰ Hence, 30 study subjects who fulfilled the selection criteria were recruited for the study.

The materials that were used for the study included 2 different toothpastes: 1. Herbal toothpaste: Patanjali Dant Kanti Dental Cream, and 2. Non herbal toothpaste: Colgate Dental Cream, and basic dental diagnostic instruments.

Study Procedure:

Those subjects who fulfilled the selection criteria were invited to participate in the study. Among them, 30 subjects were randomly selected using simple random sampling.

The study was scheduled in the following manner:

- At the baseline: Randomization and allocation
- 7th and 15th day Plaque Assessment
- Consumer Satisfaction Questionnaire - distribution

1. At the Baseline:

After obtaining Informed Consent from the students and the Principal of K.L.E Society's Institute of Dental Sciences, Bangalore, an open-ended, self- administered questionnaire was distributed to the study participants. It comprised of general information such as socio-

demographic details and socioeconomic status (Kuppuswamy' Scale), which was filled in by the subjects themselves.

Simple random sampling was done at the baseline using lottery method and all the 30 subjects were randomly allocated into 2 groups:

Group A (Cases) - Patanjali Dant Kanti toothpaste

Group B (Controls) - Colgate Dental Cream.

The study employed a triple blinding procedure wherein the principal investigator, the participant and the statistician were blinded. During toothpaste allocation, the PI was unaware of the distribution and a female co-worker randomly allocated the toothpastes to the study groups.

The subjects were also blinded with respect to the particular toothpaste that they used throughout the study period. All the toothpastes were covered with white plain papers so as to achieve blinding. The statistician was also blinded regarding the groups during the time of data analysis.

Proper instructions were given to the subjects in both the study groups, A and B, as to brush their teeth using Modified Bass Technique, for a period of 3 - 4 minutes, by viewing at the mirror, twice daily in the morning and night before going to bed. A quantity of 15mm of the toothpaste was told to be used each time for brushing. A new, medium bristled toothbrush was supplied to all the study participants. No other dental aids were to be used during the study period. A whole mouth oral prophylaxis was given at the baseline, so as to get a homogenous sample for the study.

2. 7th and 15th day Plaque Assessment:

A Type III Clinical examination was carried out on the 7th and the 15th day in the Department of Public Health Dentistry, by positioning the subject in sitting position on a dental chair and examined under artificial light. Pre-sterilized armamentarium was used to carry out the examinations.

The examination was done by a single examiner - the Principal Investigator - on both the study groups to assess the plaque using Silness and Loe Plaque Index (1964) with plain mouth mirrors and #23 explorers. The Kappa Coefficient value for intra-examiner reliability was 0.89, and was found to be good.

On the 15th day, the oral cavity was also examined for the adverse reactions on the soft and hard tissues by the Principal Investigator.

3. Questionnaire Distribution:

A pre-validated, closed-ended questionnaire was distributed to the study participants, which included questions on the satisfaction of the toothpastes that were given (color, taste, consistency, flavor, quality). They were also asked about any oral health improvements or adverse effects seen on using the toothpastes, and if they would continue using the product even after the study period is over.

Those who required any form of treatment during the study period were referred to the Department of Public Health Dentistry, K.L.E Society's Institute of Dental Sciences, Bangalore.

Statistical Analysis:

The data collected were entered into Excel spreadsheet. The univariate and bivariate statistical tests were generated using SPSS Statistical Software, version 16.0.

- Intergroup comparisons were analyzed using paired t test.
- Consumer satisfaction profile for the test group (group A) was analyzed using the Mann-Whitney U test.

All the statistical tests employed a level of significance of $\alpha = 0.05$.

RESULTS:

All the data were found to be normally distributed and were represented in the form of tables. There were 30 subjects in the study group, with 15 in each group, which included 16 males and 14 females.

Table 1: Mean Silness and Loe Plaque Index (1964) scores and paired samples t test on the 7th and 15th day for intergroup comparison of both the groups:

		Mean± SD	Mean	t value	P value
7th day scores	Test group (15)	0.620±0.35	0.324	4.201	0.001
	Control group (15)	0.567±0.40			
18th day scores	Test group (15)	0.296±0.30	0.285	2.745	0.016
	Control group (15)	0.282±0.27			

The plaque indices for both the test group and the control group was assessed. The plaque scores were reduced on the 15th day, when compared to the 7th day and was found to be statistically significant on the 15th day ($p = 0.04$). [Table II] This shows that both the toothpastes have a demonstrable effect on the dental plaque on the 7th and 15th days. Intergroup comparisons were made between the test group and the control group and there was a statistically significant difference among them.

Table 2: Assessment of consumer satisfaction of the test group.

Question	Group (N)	Mann-Whitney U test	Asympt. Sig. (2 tailed)
1. How was the product used?	15/30	67.50	0.025
2. Color of the product?	15/30	30.0	0.000
3. Consistency of the product?	15/30	67.50	0.015
4. Flavor of the product?	15/30	75.0	0.034
5. Quality of the product?	15/30	82.50	0.073
6. Taste of the product?	15/30	67.50	0.028
7. Side effects on using the product?	15/30	97.50	0.150
8. Health improvements on using the product?	15/30	97.50	0.446
9. Future use of the product?	15/30	75.0	0.073

The consumer satisfaction for the test group was assessed using the Mann-Whitney U test [Table II] and most of the variables (product, color, consistency, flavor and side effects) were found to be statistically significant ($p < 0.05$), except for the quality, improvement and future usage. This shows that most of the subjects were not satisfied on using the product due to its color, consistency, flavor and taste, when compared with the other toothpastes they had used.

DISCUSSION:

The world is shifting more towards natural products, wanting for a healthier lifestyle. Whilst the market is flooded with herbal products, the field of dentistry too is at no exception to it.¹¹

Toothbrushes in adjunction to toothpastes remains the mainstay of oral health since ages and is considered as a primary tool in overall plaque control. Dentifrices, available in various forms and with extra beneficiary effects, has been primarily viewed in as a vehicle for delivering fluorides, for the control of tartar and halitosis.⁵

According to the WHO estimates, more than 80% of the people in the developing countries depend upon the traditional folk of medicine for their health needs.¹² It is generally estimated that over 6000 traditional plants in India are being used in folk and herbal medicine.¹³ Over ancient times, natural herbs such as neem, tulsi, clove oil, ajwani and others when used alone or in combination has been significantly proven to be safe and effective medicines against oral problems like bleeding gums, halitosis, mouth ulcers and dental decay. The major strength of these natural herbs is that their use has been reported with little or no side effects, with no added alcohol formulations and preservatives.¹²

Although there are numerous varieties of herbal toothpastes available throughout the country, one of the most recently marketed herbal dentifrice is Patanjali Dant Kanti (manufactured by Patanjali Ayurved Limited, Delhi, India).

Various studies have been conducted through ages to compare the anti-plaque and anti-calculus effects of herbal dentifrices with the conventional non herbal ones. It is imperative that clinical trials verify the efficacy of any new product available in the market and the current study was carried out in this context. Very few or none of the studies have assessed the consumer satisfaction of the herbal dentifrices which is a pinnacle in the success of a particular product. Thus, the current study attempted to assess the antiplaque efficacy and consumer

satisfaction of Patanjali toothpaste in comparison with the worldwide used Colgate Dental Cream.

The age group selected for the study population is 18-21 years as the prevalence of plaque and gingivitis is high in this population¹⁴ and this age group comprises of adolescents with independent thinking and people who would be more prone to accept changes in their lifestyles.

The results of the present study is in accordance with the earlier studies conducted by various herbal dentifrices.^{15, 1, 19, 20, 4} The present study evaluated the efficacy of dentifrices using the clinical plaque index (PI) to assess the plaque and the results were in comparison to a study conducted by R. Hosadurga et al¹⁵, which had used Colgate Herbal as the control and Pardontax as the test group. Similar studies were conducted by Jacob George et al¹⁸, wherein the herbal dentifrices were found to be as efficacious as the non-herbal dentifrices.

The mean plaque scores in this study for the control and test group are 0.284 and 0.324 respectively. In the t test analysis done, the test group has a significantly higher plaque score than the control group which shows that the herbal dentifrice is not as efficient in maintaining oral hygiene compared to the control group. This finding was in contrast to a study conducted by Kuldeep Singh¹⁸, which showed that the test group had significantly less dental caries and gingival index.

A study done by S. Hosadurga et al¹⁵ and Ketaki Upadhye et al²¹ concluded that the non-herbal toothpastes have superior anti-calculus and anti-plaque efficacies compared to the control groups.

This may be due to the control selection in those studies which had 0.3% triclosan and 2.0% PVM/MA copolymers (anti-microbial action) respectively that extrapolated the results.

A study done by Shreya Shetty et al¹⁶ showed that herbal toothpastes are marginally better than the conventional non-herbal toothpastes, taking the microbial aspects too into consideration. However, the present study did not consider the microbiological aspects and was one of the limitations of the study.

The study period for the present study was fixed as 15 days as it takes the same time period for obvious plaque formation to be visible around the tooth surfaces.

None of the studies have assessed the consumer satisfaction of the herbal dentifrices and this study adds to its credit. But, as the results depict, these toothpastes did show any added benefits from the conventional non-herbal toothpastes. The findings of the satisfaction profile on using the herbal toothpaste were in comparison to the study findings by S. Anupriya et al¹⁷.

The present study is not without its limitations. A cross over study design with a wash period could have given more reliable results as it eliminates the chance of variable host response. Also, a longer time duration for the study could have thrown light on the long term effects, advantages and disadvantages of the toothpastes. A study population recruited from the city, which included a wider and larger age group and of various socio economic status could have given more improved results. Another limitation is that the credibility to the mode of tooth brushing technique and the type of toothbrush used is questionable, although proper instructions priori. These limitations could be dealt with to conduct future studies extensively.

The findings in this paper reveal that there are certain pertained factors that play a vital role to make up the mind of a consumer to select and continue using the product. Consumers' perception and preferences stand at the vertex of a success scale to inflate a product in the market.

CONCLUSION:

It can be concluded that herbal toothpaste have much similar anti-plaque efficacy when compared to the conventional toothpastes and consumer satisfaction was poor with certain aspects such as colour, consistency, flavor and taste. None of the subjects had any side effects on using the product throughout the study period.

REFERENCES:

1. Singh K, Singh P, Oberoi G. Comparative studies between herbal toothpaste (dantkanti) and nonherbal tooth paste. *Int J Dent Res*. 2016;4(2):53-6.
2. Kirch W, editor. *Encyclopedia of Public Health: Volume 1: A-H Volume 2: I-Z*. Springer Science & Business Media; 2008 Jun 13.

3. Mandal A, Singh DK, Siddiqui H, Das D, Dey AK. New dimensions in mechanical plaque control: An overview. *Indian Journal of Dental Sciences*. 2017 Apr 1;9(2):133.
4. Khairnar M, Dodamani A, Karibasappa GN, Deshmukh M, Naik R. Comparative Evaluation of Efficacy of Three Different Herbal Toothpastes on Salivary Alkaline Phosphatase and Salivary Acid Phosphatase-A Randomized Controlled Trial. *Journal of clinical and diagnostic research: JCDR*. 2016 Sep;10(9):ZC69.
5. Jayakumar A, Padmini H, Haritha A, Reddy KP. Role of dentifrice in plaque removal: a clinical trial. *Indian Journal of Dental Research*. 2010 Apr 1;21(2):213.
6. Joiner A. Whitening toothpastes: a review of the literature. *Journal of dentistry*. 2010 Jan 1;38:e17-24.
7. Kraivaphan P, Amornchat C. Comparative clinical efficacy of three toothpastes in the control of supragingival calculus formation. *European journal of dentistry*. 2017 Jan;11(1):94.
8. Al Habashneh R, Farasin R, Khader Y. The effect of a triclosan/copolymer/fluoride toothpaste on plaque formation, gingivitis, and dentin hypersensitivity: A single-blinded randomized clinical study. *Quintessence International*. 2017 Feb 1;48(2).
9. Analytical study of patanjali ayurveda limited in India; Prof. Abhinav Kataria; *International Journal of Latest Technology in Engineering, Management & Applied Science (IJLTEMAS) Volume VII, Issue I, January 2018*.
10. Tatikonda A, Debnath S, Chauhan VS, Chaurasia VR, Taranath M, Sharma AM. Effects of herbal and non-herbal toothpastes on plaque and gingivitis: A clinical comparative study. *Journal of International Society of Preventive & Community Dentistry*. 2014 Dec;4(Suppl2):S126.
11. Vyas S, Kulkarni S. Patanjali Dant Kanti: Is it worth all the hype!? Comparative evaluation with other herbal dentifrices for efficacy against *S. mutans*. *IJAR*. 2018;4(2):212-5.
12. Saraswathi MN, Karthikeyan M, Rajasekar S, Gopal V, Terminalia B. Roxb-A phytopharmacological Review. *International Journal of Research in Pharmaceutical and Biomedical Sciences*. 2012;3(1):96-9.
13. Vaish S, Ahuja S, Dodwad V, Parkash H. Comparative evaluation of 0.2% chlorhexidine versus herbal oral rinse on plaque induced gingivitis. *Journal of Indian Association of Public Health Dentistry*. 2012 Jul 1;10(19):55.
14. Vahabi S, Najafi E, Alizadeh S. In vitro antimicrobial effects of some herbal essences against oral pathogens. *Journal of Medicinal Plants Research*. 2011 Sep 23;5(19):4870-8.
15. Hosadurga R, Bloor VA, Rao SN, MeghRani N. Effectiveness of two different herbal toothpaste formulations in the reduction of plaque and gingival inflammation in patients with established gingivitis-A randomized controlled trial. *Journal of traditional and complementary medicine*. 2018 Jan 1;8(1):113-9.
16. Shetty S, Thoudam B, Bose A. Comparative Evaluation of the Effect of a Herbal Dentifrice and a Regular Dentifrice on Beneficial Oral Microflora-A Clinico-Microbiologic Study. *Int J Dent Oral Health*. 2015;1(4).
17. A study on consumer preferred perception towards patanjali products.
18. George J, Hegde S, Rajesh KS, Kumar A. The efficacy of a herbal-based toothpaste in the control of plaque and gingivitis: A clinico-biochemical study. *Indian Journal of Dental Research*. 2009 Oct 1;20(4):480.
19. Urvi H, Deepak D, Kevin S. Clinical effect of commercially available two herbal dentifrices on the control of plaque and gingivitis. *Int Journal of Scientific Res*. 2018 Feb.
20. Pradeep Kumar Singh, K. V. V. Prasad, Apoorva Kotian. "Efficacy Of Herbal And Non-Herbal Toothpaste In The Reduction Of Plaque, Gingivitis And Salivary Neutrophil Count"-A Randomized Clinical Study.
21. Upadhye K, Sanadi RM, Chitnis P. Comparative Evaluation of Dentifrice Containing Herbal Extract With Triclosan/Polymer Containing PVM/MA in Its Ability To Control Plaque and Gingival Inflammation.