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Original Research Article

Evaluation of clinical efficacy of a herbal gumcare dentifrice in the reduction of plaque and gingival inflamation – A single blind clinical study

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ARTICLE INFO	A B S T R A C T			
Article history: Received 08-06-2020 Accepted 07-08-2020 Available online xx xx xxxx	Background : Plant and plant product based dentifrices have received great attention in reducing gingival inflammation. In this study, the effectiveness of a herbal tooth paste formulation in the reduction of plaque and gingival inflammation was assessed. Aim: to evaluate the clinical efficacy of a herbal gumcare toothpaste in the reduction of plaque as well as gingival inflammation. In this study, blind aligned study conducted over a pariod of 20 days.			
<i>Keywords:</i> Herbal toothpaste Gingivitis Plaque	 gingival inflammation – a single blind clinical study conducted over a period of 30 days. Objective: A single-blind clinical case study with 30 participants assigned to a single group was designed to investigate the effectiveness of a herbal-based dentifrice in the control of plaque and gingivitis. Materials and Methods: 30 patients who had established gingivitis participated in the study. All participants had at least 20 natural teeth with probing depths not greater than 3 mm and a plaque index score of 2 or more at baseline. At baseline, the clinical parameters such as gingival index, plaque index and papilla bleeding index were evaluated. Results: At the end of the study, there was found to be statistically significant reduction in the gingival index, plaque index and papilla bleeding index scores in the subjects in comparison to baseline. Conclusion: It was concluded that the herbal-based toothpaste was effective as in the control of plaque and gingivitis 			
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1. Introduction

Dental plaque deposit on teeth is a concern for both cosmetic reasons and its pathogenic nature. Presence of plaque may be the culprit for various problems such as dental caries, gingivitis, periodontal problems, and halitosis. Many mechanical aids are used worldwide to remove or control plaque, including tooth brushes, dental floss, mouth rinses, and dentifrices.¹ Mechanical plaque removal is one of the most accepted methods of controlling plaque and gingivitis. But it is expected that less than one-third of the population can effectively perform mechanical plaque removal. Several preventive agents are known to have beneficial effects in the control of plaque and to reduce or prevent oral disease.²

Self-performed mechanical plaque removal is one of the most accepted methods of controlling plaque and gingivitis.³ It is estimated that less than one-third of the population of developed nations can be expected to practice mechanical plaque removal. Mechanical plaque control is time consuming and some individuals may lack motivation for these procedures. There has been a search for years for herbal agents that can support patient- dependent mechanical plaque control and thus reduce or prevent oral disease.^{4,5}

Lately, there has been a growing interest in natural and plant based products mainly due to the fact that principal ingredients of the herbs possess many medicinal properties which may effectively be utilized for plaque control and prevention of gingivitis.

The ingredients of the herbal toothpaste include meswak, vajradanti, babool, clove, camphor, walnut extract and

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almond. In the modern era, the beneficial role of meswak such as antiseptic, antimicrobial, anticariogenic and analgesic effects are scientifically proven.⁶ The astringent and anti-bacterial properties of Meswak help reduce tooth decay, fight plaque and prevent gum diseases.

Barleria prionitis or Vajradanti, is known to have antiinflammatory properties. The leaves of this flower are also believed to provide relief in tooth ache and treating bleeding gums.⁷ These properties of this shrub are utilized in the remedy of dental diseases.

Babool (Accacia nilotica) which has long been used for the treatment of tooth problems. It has been proved as effective medicine in treatment of toothache (bark).⁸ T Francis Xavier⁹ Barira Islam, Mohd Akram¹⁰ have stated that Babool has shown to posses antibacterial activity against Streptococcus mutans and Enterococcus faecalis

Clove known to possess antioxidant, antimicrobial, antifungal, as well as anaesthetic property (anodyne)

Camphor is clinically proven to have antiseptic and astringent property

Almonds have calcium and protein content which shields and reinforce teeth against destructive bacteria that can cause dental caries and gingival disease.

Walnuts contain plant protein called folacin, dietary fiber and minerals like magnesium, iron potassium and zinc. It also has Vitamins including thiamine, niacin, vitamin E, vitamin B6,, which are beneficial for teeth. The magnesium and phosphorus in walnuts plays a key role in maintenance of dental health.

2. Materials a nd Methods

This was a single-centre, single blinded study comprising 30 patients. The study duration was 30 days, in which Plaque Index, Gingival index and Papilla Bleeding Index scores were measured at baseline, day 15, day 30. The study protocol was initially submitted to the Ethical Committee of the P.D.M. Dental College and Research Institute (PDMDCRI), Bahadurgarh, Haryana, India.

After ethical approval was granted, subjects were selected from the outpatient section of the Department of Periodontics, P.D.M. Dental College and Research Institute (PDMDCRI), Bahadurgarh after a written informed consent was taken from them.

30 patients who has clinically established gingivitis were assigned to a single group in the study (considering the dropouts / exclusions, additionally 10 patients were evaluated for the clinical parameters during the use of the herbal gumcare toothpaste)

The subjects were randomly assigned Herbal toothpaste for brushing their teeth

Volunteers received a tube containing 100 gm of herbal gumcare toothpaste.

For the purpose of standardization, the following was incorporated in the study:

- 1. No prophylaxis undertaken for any participant prior to study commencement.
- 2. All the subjects were given tooth brushes at the beginning of the study
- 3. They were instructed to apply 15mm of toothpaste on the brushing surface of the toothbrush and brush twice daily (morning and night) for a period of 2 min for 30 days using Bass method using the given toothpaste and toothbrush

A brief case history was recorded and all patients were to undergo a full mouth periodontal examination at baseline, day 15 and on day 30. The plaque and gingival inflammation was assessed on all the teeth at the buccal, lingual, mesial and distal aspect with the exception of 3rd molar.

2.1. Inclusion criteria

- 1. Patients agreeing to comply with study protocol and instructions
- 2. Patients in good health in age range of 18-70 yrs
- 3. Subject should have at least 20 natural permanent teeth in dentition
- 4. Periodontal pockets not greater than 3mm.
- 5. All subjects who are deemed medically fit.
- 6. Subjects having Gingival index score not more than 1.9.
- 7. Subjects who had a plaque index of greater than 2 at baseline.

2.2. Exclusion criteria

- 1. Teeth with deep periodontal pockets (depth more than 3mm)
- 2. Smokers and tobacco chewer
- 3. Patients with systemic diseases or compromising medical condition.
- 4. Patients on antibiotics one months prior to treatment.
- 5. Patients using orthodontic appliances either fixed or removable
- 6. Patients who have been using any mouth rinse containing chemical agents in previous 3 months.
- 7. Patients allergic or sensitive to any medication or toothpaste.
- 8. History of any surgical procedure in the selected area in the past six months.
- 9. Pregnant and lactating women, smokers, acute myocardial infarction within the past 6 months, use of pacemaker and uncontrolled metabolic diseases.
- Patients with clinically diagnosed periodontitis, nonplaque induced gingival leision, leukemia-associated gingivitis, drug induced gingival enlargement, or experimentally induced gingivitis are excluded.

2.3. Clinical parameters evaluated

- Plaque Index: The index teeth were stained for plaque using an erythrosine disclosing solution and cotton swab. The amount of plaque was scored using the Turesky-Gilmore-Glickman modification of the Quigley Hein plaque index (1970),
- 2. Gingival Index : was recorded using the Gingival Index(GI) by Loe and Silness (1963).
- 3. Papilla Bleeding Index Muhlemann 1977

3. Statistical Methods

Analysis was performed using SPSS software Version 21.0

(Parametric) Paired t-test was used to analyze the comparison of the mean differences of scores at the three time evaluations of clinical parameters - day 0,15,30.

4. Results

Table 1: Descriptive data of change in PI, GI and PBI at different interval of time after use ofgumcare toothpaste

		e		
Variable	Mean	SD	Minimum	Maximum
Baseline				
PI	2.62	0.355	2.03	3.04
GI	1.63	0.178	1.04	1.87
PBI	2.44	0.230	1.90	2.9
15 DAYS				
PI	2.15	0.244	1.60	1.53
GI	.28	0.157	0.91	1.7
PBI	1.77	0.187	1.40	2.3
30 DAYS				
PI	1.75	0.326	1.19	2.19
GI	0.94	0.253	0.50	1.30
PBI	1.25	0.174	0.70	1.50

5. Discussion

In recent times, there has been a renewed interest in the use of herbal based products. In the indigenous systems of medicine, different components of different plants have been used in medicinal preparations to clean teeth or in treatment of oral diseases including periodontal disease.^{11–13} Herbal-based toothpastes are as effective as the conventionally formulated dentifrices in the control of plaque and gingivitis.¹⁴

Dental plaque is the main culprit for gingival inflammation and dental caries. Chronic gingival inflammation may lead to tissue destruction, and if left untreated, may progress into the more destructive stages of periodontitis. Hence, plaque and gingivitis control is vital in maintenance of oral health. This can be achieved effectively by mechanical plaque control using tooth brush and medicated toothpastes. The primary purpose of this study was to evaluate the efficacy of herbal dentifrice in the

Table 2: Descriptive data of change in PI, GI and PBI at different interval of time after use ofgumcare toothpaste

Variable	Mean Difference	SD	t- value	p-value
PI				
Baseline-15 Days	0.46	0.302	8.354	0.000*
Baseline-30 Days	0.86	0.535	8.817	0.000*
15 Days-30 Days	0.40	0.269	8.170	0.000*
GI				
Baseline-15 Days	0.35	0.153	12.623	0.000*
Baseline-30 Days	0.69	0.303	12.541	0.000*
15 Days-30 Days	0.34	0.199	9.393	0.000*
PBI				
Baseline-15 Days	0.66	0.137	26.630	0.000*
Baseline-30 Days	1.18	0.163	39.779	0.000*
15 Days-30 Days	0.521	0.136	20.950	0.000*

*($p \le 0.05$ – Significant, CI = 95 %)

control of plaque and gingivitis.

Today, herbal products symbolize safety in contrast to synthetic products that are regarded as unsafe to humans and the environment. These evidences contribute to support and quantify the importance of screening natural plants.

Herbs like Meswak, Vajradanti, Neem, Turmeric, Cinnamon, Aloe Vera, Barleria prionitis L and Clove are nowadays frequently used in dentistry due to their numerous dental benefits.

Numerous studies have identified that silica in meswak possesses plaque inhibiting properties, plays vital role in caries prevention and helps in maintaining normal pH after chemical acidogenic attacks.^{15–17} The presence of calcium and chlorides in meswak inhibit the bacterial attachment on to the enamel surface hence providing a protective medium.¹⁸ In addition, meswak has an ability to remove plaque from the interproximal sites as well.

Barleria prionitis L. or Vajradanti is supposed to have an adjunctive role in the prevention of gingival diseases. The results proved that Barleria prionitis along with scaling and root planing leads to reduction in plaque formation, gingival bleeding and pocket depth.

The possible mechanism of action of Vajradanti as an anti-bacterial agent could be due to the organic components such as tannins, saponins, phenolic compounds, essential oils and flavonoids present in them. The antimicrobial potency of Barleria prionitis is attributed to the presence of five iridoidglucoside esters, acetyl barlerin 6,8, di-oacetyl shanzhisisde methyl ester, shanzhiside methyl ester verbascoide. It has been seen that crude extracts of Barleria prionitis are effective against dental caries-causing oral pathogens where modern therapy has failed.

The reasons for antimicrobial activity of Babool may include hydrophilic compounds such as polyphenols, gums (polysaccharides) and tannins. There is increasing evidence to support that the plants of genus Acacia are relatively high in bioactive secondary compound and are thus likely to hold promise for therapeutical use.

Clove (Sygium aromaticum) - Eugenol, a compound found in clove is known to have strong antifungal and antiinflammatory activities, and has been used in dentistry as an obtundant. Rosina khan, ¹⁹ N. Rusenova, P. Parvanov²⁰ 20 reported that clove has shown antibacterial activity against Streptococcus mutans and Enterococcus faecalis.

Camphor - Its antiseptic properties help relieve toothache and freshen breath. In ayurveda it is described in treatment of diseases like Danta Puya i.e. Pyorrhoea, and Danta Sula i.e Toothache.

The use of almonds in herbal toothpaste confer multiple uses :

- 1. Rich source of calcium, which is a mineral needed to maintain teeth integrity and strength.
- 2. High protein content
- They do not promote tooth decay like carb- and sugarheavy foods
- 4. Have astringent action on gums

Walnuts - The omega-3 fatty acids present in walnuts and flax seeds helps in lowering the risk of gingival disease which can damage teeth.

Walnuts are known to have a higher antioxidant activity than any other common nut.

The polyphenols in walnuts help fight this oxidative stress and inflammation. A subgroup of polyphenols called ellagitannins may be particularly involved in this role. ALA omega-3 fatty acid, magnesium and the amino acid arginine in walnuts also play a role in decreasing inflammation.

With regard to the three clinical parameters assessed in the study subjects – Plaque index, Gingival index, Papilla bleeding index, there was statistically significant difference in the mean values found in the reduction of these parameters.

Thereby indicating an improvement in the gingival health of the subjects using the herbal toothpaste over a period of 30 days.

6. Conclusion

The present study supports the fact that herbal dentifrices do not cause any adverse effects on the oral environment. After 30 days of the study, the subject group showed effective reduction of plaque and gingivitis, which was statistically significant. Several studies have proven the medicinal values of herbal products Hence, medicated herbal toothpastes can be safely used to control plaque and gingivitis.

No adverse reactions to dentifrices products were observed during the study. It can be concluded that clinically, herbal dentifrice is both safe and effective for plaque control and against gingivitis for oral health maintenance.

7. Source of Funding

Purexa Global Pvt Ltd.

8. Conflict of Interest

None.

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