



Original Research Article

To evaluate the clinical efficacy of a herbal gumcare gumpaint in the reduction of probing depth and gingival inflammation – A single blind clinical study

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ABSTRACT

Background: Periodontal disease is characterized by inflammation and destruction of supporting tissues of the teeth. Bacterial plaque is the primary etiological agent in periodontal diseases. In addition to mechanical plaque removal measures, chemical plaque control measures have also been advocated which can be used as an adjunct to mechanical measures. These together can reduce plaque associated gingivitis.

Aim: to evaluate the clinical efficacy of a herbal gumpaint in the reduction of probing depth and gingival inflammation – a single blind clinical study over a period of 21 days.

Materials and Methods: Total 30 subjects who had been diagnosed as having established gingivitis between 18 to 65 years were included in the study who were part of a single group herbal gum astringent. The gingival index (described by Loe H. and Silness P) and plaque index (described by Tureskey et al. Modification of Quigley Hein Index) scores were measured and recorded at baseline, 15 days and 21 days interval. All the values at each time were recorded on appropriate forms during assessment.

Conclusion: It was concluded from the present study that the herbal gum astringent was found to be effective in improving gingival status and resulted in significant improvement in clinical parameters.

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1. Introduction

Periodontal disease is characterized by inflammation and destruction of supporting tissues of the teeth. Bacterial plaque is the primary etiological agent in periodontal diseases.

Experimental gingivitis studies have proved the role of plaque in the etiology of periodontal infections and demonstrated the direct relationship between plaque levels and development of gingivitis.¹

Mechanical periodontal therapy, like scaling is the first recommended step in the management of gingivitis and periodontitis. They are an indispensable phase of periodontal therapy, but there are factors such as accessibility or presence of plaque retentive areas that can limit instrumentation. Therefore, in addition to

mechanical plaque removal measures, chemical plaque control measures have also been advocated that can be used as an adjunct to mechanical measures, which together can reduce plaque associated gingivitis.^{2,3}

Several chemical plaque control agents have been evaluated for their effectiveness on supragingival plaque including bis-biguanides, essential oils, enzymes, and even herbal extracts. Some of these substances have been associated with various adverse effects incapacitating their long term use, so new formulations of equal efficacy and fewer side effects are required to be evaluated. Herbal formulations can provide an effective option for safe and long-term use.^{4,5}

The various herbal ingredients used for their therapeutic uses include Kali marich (pepper), Neem, Tulsi, Clove, Vitamin C extract from oranges, Almond extract.

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Kali marich or pepper has antifungal, antibacterial and antiviral qualities which make it an excellent anti-infective essential oil for all types of infection. Its use can stop infections from taking hold in the body.^{6,7}

Clove is known for its medicinal properties as Antioxidant, Antimicrobial, Antifungal, Antiviral,⁸

It is also known to possess anesthetic property (anodyne). Clove has essential oils, containing about 50% carvone, rosmarinic acid. It has analgesic, antifungal, antioxidant, aromatic and astringent properties.

Alum / phitkari - Aluminum has demonstrated activity against oral bacteria. Early studies have indicated that several aluminum salts, including potassium aluminum sulfate (alum), inhibit the growth of salivary bacteria.

Neem - known to possess medicinal properties such as Anti-inflammatory, Antiarthritic Antipyretic, Hypoglycaemic Antifungal, Antibacterial, Antitumour. Its use has long been advocated for dental therapeutics. Neem (*Azadirachta indica*) originates from northeast India. It is also known as Margosa or the Persian lilac. In Indonesia, this plant is called Mimba. In India this plant is referred to as the village pharmacy because of its ability to cure many disorders ranging from bad teeth and bed bugs to ulcers and malaria.⁹

Green tea - The active compounds in green tea are from a group of polyphenols called catechins. There are four catechins present in green tea: Epicatechin gallate (ECg), epicatechin, epigallocatechin and epigallocatechin gallate (EGCG)

Green tea also contains organic compounds like carotenoids, tocopherols, ascorbic acid and minerals like chromium, magnesium, selenium and zinc.¹⁰

Immunity - Polyphenols and flavonoids found in green tea help in boosting immune system,

Human $\gamma\delta$ T cells mediate innate immunity to microorganisms via T cell receptor-dependent recognition of unprocessed antigens with conserved molecular patterns. These non-peptide alkylamine antigens are shared by tumor cells, bacteria, parasites and fungi.¹¹

Vitamin C is taken from orange extracts for the herbal formulation of gum paint. It is known to support periodontal health through maintenance of gingiva, periodontal ligament, cementum and alveolar bone. This is partly due to the essential role of vitamin C for the synthesis of collagen. It is also known to promote healing, reduce oxidative stress and formation of Reactive oxygen species produced as a result of gingival inflammation. Through these actions it helps in enhancing health of the supportive periodontal tissues.

Tulsi is known as “ Holy Basil” in the Indian subcontinent. Belonging to the family Labiatae, it is grown in tropical and sub tropical belts including India This plant has been examined pharmacologically for antimicrobial, immunomodulatory, anti-inflammatory,

hypoglycemic, chemoprotective and analgesic activities.¹²

Almonds provide varied healthful effects. They are rich in nutrients such as monounsaturated fats, magnesium, protein and vitamin E as well as fibre content and phytochemicals. They help strengthening the tissues around the tooth.

2. Materials and Methods

This was a single - centre, single blinded study comprising 30 patients. The study duration was 21 days, in which clinical parameters - Plaque Index and Gingival Index and Papilla Bleeding Index scores were measured at baseline, day 15, day 21. 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 with established gingivitis assigned to a single group in the study (considering the dropouts / exclusions, additionally 10 patients are evaluated for the clinical parameters during the use of the herbal gumpaint)

1. All subjects enrolled into study received a herbal gumcare gumpaint.
2. No prophylaxis was undertaken prior to beginning of the study.
3. All the subjects were given tooth brushes at the beginning of the study and instructed to brush twice daily with the assigned toothbrush and their regular toothpaste using modified bass technique for 21 days.
4. The brushing technique was demonstrated by the conducting clinical staff and all participants made to brush at least once after demonstration to make them appreciate the benefits of using this technique.
5. Subjects were instructed to apply a single drop of the gumpaint gently by finger or soft tooth brush on the gingiva and massage twice daily and to leave it for five minutes before rinsing.
6. Subjects were also be asked to refrain from all other unassigned forms of oral hygiene aids, including dental floss, chewing gum or oral rinse during the study.

A brief case history was recorded and all patients underwent a full mouth periodontal examination for the assessment of clinical parameters at baseline, day 15, day 21 for the amount of plaque and gingival inflammation (measured 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 – 65 yrs.
3. Subject should have at least 20 natural permanent teeth
4. No periodontal pockets greater than 4mm.
5. All subjects who are deemed medically fit.
6. Subjects having Gingival index more than 1.
7. At baseline, all the subjects had to have a plaque index of greater than 2.

2.2. Exclusion criteria

1. Smokers and tobacco chewer.
2. Patients with systemic diseases or compromising medical condition.
3. Patients on antibiotics one months prior to treatment.
4. Patients using orthodontic appliances either fixed or removable
5. Patients who have used mouth rinse containing chemical agents in previous two months.
6. Patients allergic or sensitive to any medication or toothpaste.
7. History of any surgical procedure in the selected area in the past two months.

2.3. Clinical Parameters Evaluated

The following parameters are recorded:

1. **Plaque Index (PI):** The index teeth were stained for plaque using an erythrosine disclosing solution and cotton swab. The plaque score was determined using the Turesky-Gilmore-Glickman modification of the Quigley Hein plaque index (1970)¹³,
2. **Gingival Index (GI):** was recorded using the Gingival Index (GI) by Loe and Silness (1963)
3. **Papillary Bleeding Index (PBI):** Muhlemann 1977
4. **Periodontal probing depth (PPD)**

2.4. Statistical methods

Analysis was performed using SPSS software Version 21.0

(Parametric) Paired t-test was used to compare the mean differences of scores at the three time evaluations of clinical parameters – day 0,15,21.

3. Results

It was found that there was a highly significant difference in the reduction of clinical parameters assessed. In conclusion, herbal gumpaint has high clinical efficacy in the reduction of probing depth and gingival inflammation.

4. Discussion

Plaque is the main agent responsible for the breakdown of periodontal tissues leading to periodontal disease. The removal of plaque regularly is of paramount importance in the prevention of periodontal disease. The inability of the population to perform adequate mechanical tooth cleaning has stimulated the search for chemotherapeutic agents to improve plaque control and prevent gingivitis. Herbal products have been used extensively in reducing plaque. Phytotherapeutic products have been investigated with these purposes and have shown satisfactory results. The evaluation of efficacy of this herbal formulation on gingivitis and its use in the treatment of gingivitis was carried out. In the present study, a significant reduction in PI, PBI and GI scores at day 15 and day 21 time intervals was observed with the use of the gum astringent. The positive clinical effects can be attributed to their various ingredients.

The reduction in plaque and gingivitis scores in test group can be attributed to the effect from the herbal ingredients like Vitamin C extract, Neem, tulsi, clove, Green tea extract, almond.

The use of herbs in dental treatment has been advocated from many centuries.

As per different studies, five phenolic amides were isolated from black pepper, which revealed high antioxidant activity, which was more effective than some naturally occurring antioxidants.¹⁵ These investigations revealed the efficacy of black pepper in bioactive phytochemical components of promising medicinal importance.

Clove is also famous for its ability to kill parasites. It is powerful addition to an antiparasite

program. When used topically, it helps to numb the skin and relieve many aches and pains. One of its main components, eugenol, is still used by dentists to numb the gums for dental procedures. Use of clove oil when used on the back of the tongue can help stave off tobacco cravings. Clove oil helps to dissolve warts and other abnormal growths.

Aluminum is known to possess antimicrobial activity, against cariogenic streptococci as well as normal oral flora and periodontal pathogens, by significantly reducing the ability of streptococci to colonize on enamel surfaces and decreasing the colloidal stability of oral bacteria. More recently, use of alum mouth rinse has also shown significant reductions in salivary levels of *Streptococcus mutans* in children. Skjorland et al (1978),⁵ Putt et al (1996)⁶ and Bihani and Damle (1997) evaluated the effect of 0.02 M alum mouth rinse on plaque inhibition and observed significant reductions in the amount of plaque after 2 to 4 weeks of supervised use

Neem has been of particular interest to the field of dentistry for it has a long history treating teeth and gum problems.⁹

Table 1: Descriptive data of change in PI, GI, PPD and PBI at different interval of time after use of herbal gumpaint

Variable	Mean	SD	Minimum	Maximum
Baseline				
PI	3.54	0.773	2.23	4.89
GI	2.19	0.390	1.62	2.96
PPD	3.40	0.563	2.00	4.00
PBI	2.10	0.290	1.59	2.83
15 DAYS				
PI	2.38	0.615	1.56	3.90
GI	1.25	0.275	0.83	1.86
PPD	2.66	0.479	2.00	3.00
PBI	1.50	0.267	0.92	1.94
21 DAYS				
PI	1.70	0.531	1.15	3.20
GI	1.03	0.166	0.84	1.52
PPD	2.40	0.498	2.00	3.00
PBI	1.12	0.216	0.79	1.72

Table 2: Mean difference in PI, GI and PBI at between different interval of time after use of herbal gumpaint

Variable	Mean Difference	SD	t-value	p-value
PI				
Baseline-15 Days	1.15	0.491	12.870	0.000*
Baseline-21 Days	1.83	0.555	18.081	0.000*
15 Days-21 Days	0.67	0.378	9.814	0.000*
GI				
Baseline-15 Days	0.94	0.364	14.114	0.000*
Baseline-21 Days	1.16	0.362	17.521	0.000*
15 Days-21 Days	0.22	0.190	6.321	0.000*
PPD				
Baseline-15 Days	0.73	0.520	7.712	0.000*
Baseline-21 Days	1.00	0.643	8.515	0.000*
15 Days-21 Days	0.26	0.449	3.247	0.003*
PBI				
Baseline-15 Days	0.60	0.240	13.735	0.000*
Baseline-21 Days	0.98	0.255	21.181	0.000*
15 Days-21 Days	0.38	0.229	9.127	0.000*

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

Various studies have demonstrated that Neem can inhibit the growth of *Streptococcus mutans* and can be used in mouth rinses to reduce periodontal diseases (Marco Antonio Botelho, Rinaldo Araujo dos Santos).^{9,14,15}

Green tea has the following mechanism of action

The endoplasmic reticulum and mitochondria release oxygen. This oxygen gets converted into hydrogen peroxide, which in turn releases reactive oxygen species molecules. These reactive oxygen species molecules can lead to damage of DNA and RNA. They also oxidize proteins (enzymes, histones), lipids and can also activate cell suicide or autolysis.

Intake of green tea can stop all these degenerative changes by inhibiting the action of the reactive oxygen species molecule.^{16,17}

4.1. Periodontal implications of Green tea

Various authors have studied the inhibitory effects of catechin contained in green tea on periodontal pathogens, which may provide the basis for beneficial effect of daily intake of green tea on periodontal health.

Green tea catechins inhibit the growth of *P. gingivalis*, *Prevotella intermedia* and *Prevotella nigrescens* and adherence of *P. gingivalis* on to human buccal epithelial cells.¹⁸

Green tea catechins with steric structures of 3-galloyl radical, EGCG, ECg and gallic acid, which are major tea polyphenols, inhibit production of toxic end metabolites of *P. gingivalis*. A study showed that green tea catechin, EGCG and ECg inhibit the activity of *P. gingivalis*-derived collagenase.¹⁹

Green tea catechin has a bactericidal effect on black-pigmented, Gram-negative anaerobic rods, *Porphyromonas*

gingivalis and *Prevotella* species. The combined use of mechanical treatment and the application of green tea catechin using a slow-release local delivery system was effective in improving the periodontal status. The peptidase activities in the gingival fluid were maintained at lower levels during the experimental period in the test sites, while it reached 70% of that at baseline in the placebo sites.²⁰

Alveolar bone resorption is a characteristic feature of periodontal disease and involves removal of both the mineral and the organic constituents of the bone matrix, a process mainly carried out by multinucleated osteoclast cells or matrix metalloproteinases (MMPs). EGCG inhibited osteoclast formation in a coculture of primary osteoclastic cells and bone marrow cells, and it induced apoptotic cell death of osteoclast-like multinucleated cells in a dose-dependent manner thus suggesting the role of green tea in the prevention of bone resorption.¹³

The Gram-negative bacterium, *Porphyromonas gingivalis*, has been reported to stimulate the activity and expression of several groups of MMPs, whereas EGCG has inhibitory effects on the activity and expression of MMPs.

Oxidative stress plays an important role in the pathogenesis of periodontal disease as well as many other disorders, and it is believed that antioxidants can defend against inflammatory diseases.²¹

Vitamin C lowers the risk of periodontal disease, and even facilitate healing of the periodontium due to its strong antioxidant capacity that allows it to inactivate reactive oxygen species that damage structure and function of tissues. Enhancing faster healing and epithelial repair.

4.2. Benefits of tulsi

4.2.1. Toothache

Tulsi contains significant amount of eugenol (1-hydroxy-2-methoxy-4 allyl-benzene) hence it acts as cox-2 inhibitors similar to modern analgesics. *Ocimum sanctum* leaves contain 0.7% volatile oil consisting about 71% eugenol and 20% methyl eugenol.²²

4.2.2. Oral infections

Tulsi leaves are quite effective in treating common oral infections. When chewed, tulsi leaves help in maintaining oral hygiene. Antibacterial agents namely carvacrol and terpene are present in this plant. Sesquiterpene *b-caryophyllene* also serves the same purpose. This constituent in FDA approved food additive which is naturally present in Tulsi.²³

4.2.3. Role of Tulsi in periodontal diseases

Tulsi leaves have been dried in sun and powdered for use in brushing teeth due to its therapeutic effect.²⁴ Tulsi has also proven to be very effective in preventing halitosis. Its

anti-inflammatory property makes it a suitable remedy for gingivitis and periodontitis, and it can be used for massaging the gingiva in these conditions.²⁵

Several pharmacological studies have established a scientific basis for therapeutic uses of this plant. It can prove beneficial in treating oral diseases also because of its antibacterial, anti-inflammatory, ulcer healing, antioxidant, immunomodulatory properties.

Almonds provide varied healthful effects. They are rich in nutrients such as monounsaturated fats, magnesium, protein and vitamin E as well as fibre content and phytochemicals.²⁶

They have calcium and protein content which shields and reinforce teeth against destructive bacteria that can cause dental caries and gingival disease. Known to also have astringent action on gingival tissues due to its high protein content.

5. Conclusion

The widespread occurrence of gingivitis provides the rationale for supplementing toothpastes with anti-gingivitis agents such as gum astringents. The current herbal formulation used in the clinical study showed significant clinical improvement in gingival bleeding and plaque index scores

Thus, study suggests that this herbal gum astringent formulation may be useful for plaque control in subjects with gingivitis.

6. Source of Funding

Purexa Global Pvt Ltd.

7. Conflict of Interest

None.

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