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Acacia Arabica Gel: Herbal Approach In The Management Of Chronic Generalized Gingivitis - A Clinical Trial

Roopa Adinarayana

Professor and Head, Department of Periodontics, Rama Dental College Hospital & Research Centre, Kanpur

Jawahir Ahmad

Senior lecturer, Department of Periodontics, Rama Dental College Hospital & Research Centre, Kanpur

Saranik Sarkar

Saswati Sarmah

Ruhi Sharma

Aastha Singh

Post Graduate Student, Department of Periodontics, Rama Dental College Hospital & Research Centre, Kanpur

Abstract:

Background: Various herbal formulations are now available that claim to act as effective plaque control agents and also help in counteracting inflammatory changes in gingiva. Gum Tone gel is one such polyherbal product containing Acacia Arabica as its main constituent.

Aim: The aim of the study was to evaluate the efficacy of Acacia Arabica gel as an antiplaque and antiinflammatory agent in subjects with chronic generalized gingivitis.

Material and methods: A randomized clinical trial carried out for a period of 1 month, 40 subjects were selected for the study. 20 patients were selected for local application of Gum tone gel after scaling, whereas 20 subjects were alloted for local application of placebo drug after scaling. Clinical evaluation was carried out using GI, PI & PBI values at baseline, 10 days and 1 month.

Results: Statistically significant reduction of PI, GI & PBI values were observed in the test group on compared to the placebo group on 10 th day and at 1 month.

Conclusion: This study conclude that Acacia arabica containing gel could be useful in the treatment of chronic generalized gingivitis.

Keywords: Acacia arabica, Herbal gel, Antiplaue, Antiinflammatory, Gingivitis

I. INTRODUCTION

Periodontal disease is recognized as a major public health problem throughout the world and is the most common cause of tooth loss in adults. Periodontal disease is a general term used to describe several pathological conditions that affect the supporting structures /tissues of teeth.

The success of periodontal therapy depends upon dealing with the negative environmental and behavioral factors and the reduction or elimination of periodontal pathogens.

Mechanical plaque removal using a toothbrush and other oral hygiene aids has been found to be an effective way to control gingival inflammation. The human limitations associated with adequate mechanical plaque removal have resulted in widespread occurrence of gingivitis. Many chemical agents have been tested as adjuncts to mechanical methods which can reduce plaque and its associated gingivitis.

There has been a rise in the awareness and interest in pursuing alternative natural preparations among population; especially to avoid the rising dilemma of side effects caused by synthetic allopathic medications. The screening of plant extract and plant products for antimicrobial activity, has shown that plants represent a potential source of new anti - infective agents. Various studies have proven to show excellent medicinal properties of different herbal products in various medical and dental diseases.

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Certain plants used in folk medicine serve as a source of therapeutic agent by having multi potential effects in addition to their antimicrobial activity. Herbal formulations can provide an option for safe and long-term use. Gumtone gel (Charak Pharma Pvt. Ltd, India) is one such polyherbal formulation with *Acacia arabica* as its main ingredient.

Acacia arabica gum is a traditional oral hygiene substance which has been used for centuries by many communities in the Middle East and North Africa. It consists mainly of arabica, a complex mixture of the calcium, magnesium and potassium salts of arabic acid. There are also other constituents such as tannins, cyanogenic glycosides, oxidases, peroxidases and pectinases; all of which have been shown individually to exhibit antimicrobial properties.

Thus the present study was carried out as a randomised placebo clinical trial designed to evaluate the short term clinical effects of a commercially available, prescription gel containing *Acacia Arabica* to the reduction of plaque and gingival inflammation in subject with gingivitis.

II. MATERIALS & METHODS

After obtaining ethical clearence from the Institute, 40 patients(23females and 17 males) were selected from the outpatient department of periodontology of Rama Dental College Hospital & Resaerch centre. Patients diagnosed with chronic generalized gingivitis, aged 20–40 years(mean age-32.5years), having at least 20 natural teeth, and continue to have the complaint of bledding and spongy gums one week after scaling were included in the study. All patients fulfilled the clinical criteria of the gingival index(Loe and Silness)>1, pocket probing depth≤ 3mm, clinical attachment loss=0, with no evidence of radiographic bone loss.

The exclusion criteria were 1) patients with known allergies to the constituents of the formulation, 2) history of any local or systemic antibiotic therapy within past 6 months, 3)history of any immunocompromised condition, haematological disorders or systemic disease like diabetes, 4)pregnant and lactating womens, 5)smokers and patients using any form of smokeless tobacco, 6) patients undergoing orthodontic treatment. All the patients were well educated and informed about the study and patient's consent form was obtained.

Selected patients were assigned to one of the two groups. 20 patients were selected for the test group, received local application of Gumtone gel; whereas 20 patients for the control group received placebo gel.

The main ingredient of 40 gm polyherbal gel were 0.8 w⁄w % *Acacia arabica*, 0.4 w⁄w % *Barleria prionitis*, 0.24 w⁄w % *Emblica officinalis*, 0.24 w⁄w % *Terminalia chebula*,0.24 w⁄w % *Terminalia belerica*, 0.2 w⁄w % *Vitexnegundo*, 0.08w⁄w% *Quercus infectoria*, 0.04 w⁄w% *Melia azadirachta*, 0.24 w⁄w % *Acacia catechu*, 0.02w⁄w % *Messua ferrea* and 0.02 w⁄w *% Embelia ribes*.

The placebo gel was obtained from Charak Pharma Pvt. Ltd. and it was without any active ingredient.

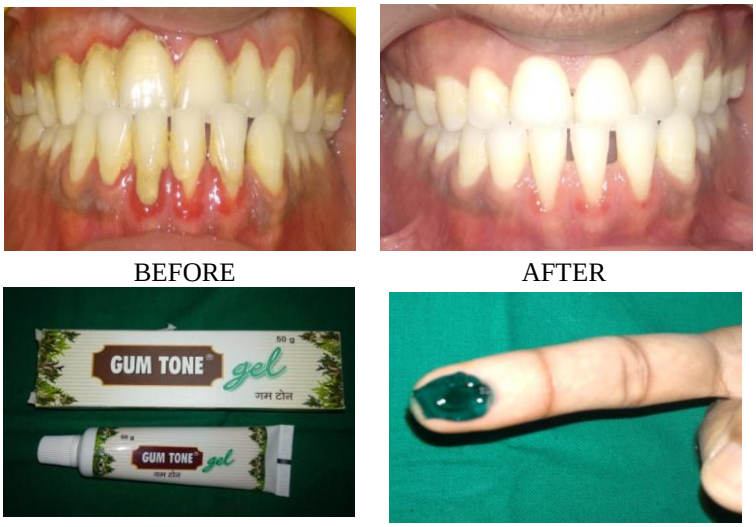
III. STUDY PROCEDURE

After selecting the patients, fulfilling the inclusion and exclusion criteria, at the first session a medical history was taken; clinical parameters were determined by taking plaque index by Silness and Loe(1964), gingival index by Loe and Silness(1963) and papillary bleeding index by Muhlemann(1977).

After the baseline readings were recorded, the test group advised to apply Gumtone gel after supragingival scaling whereas control group advised to apply placebo gel after scaling(Fig.2). The subjects comprising test group were given the Gumtone gel and were instructed to apply a pea sized amount of gel either with their finger or with the help of a soft toothbrush in a circular motion(Fig.1). The application procedure was demonstrated to the patients and they were asked to massage the gel on the gums in a circular motion for 2-3minutes and were told to rinse thoroughly after 5 minutes. They were asked not to consume food or water for at least 15 minutes after applying the gel. The instruction was to use the gel two times daily, in the morning and before bedtime. The patients were asked to continue with their regular oral hygiene measures. No other oral hygiene aids such as dental floss, mouthwash or chewing gums were advised as they may influence the results of the study. All the patients were asked to bring their gel tubes at the second visit to ensure the compliance of the patients. The gel was discontinued after seven days, and the clinical parameters were again assessed at 10th day and 1month.

Oral hygiene maintenance was reinforced in every visit and patients were questioned regarding any adverse reaction to the gel application.

TEST GROUP (Figure 1)



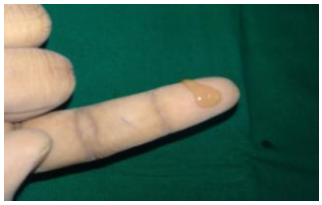
BEFORE AFTER

Acacia arabica gel

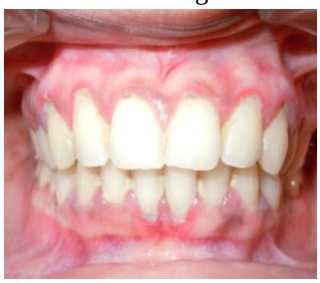
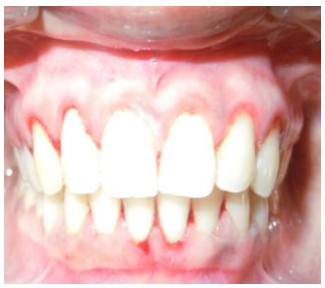
Figure 1

ISSN: 2394-4404

CONTROL GROUP (Figure 2)




Placebo gel

BEFORE AFTER

Figure 1

IV. STATISTICAL ANALYSIS

Comparison of mean values between test and control was done using independent sample t test. All the analysis was assessed using SPSS version 17. A p-value of <0.05 was considered statistically significant.

V. RESULTS

Randomized clinical trial carried out for a period of 1 month. A total no. 40 patients who participated and completed the study successfully. During the course of the study none of the patients complained of any adverse effect of the gel. There was no and clinical report of stains on the teeth and alteration in the taste. Patients very well accepted the gel.

The results of the study are as follows:

PLAQUE INDEX(PI)

In the test and control group the mean plaque indices were 2.75+0.44 and 2.74+0.44 respectively at baseline i.e. there was no difference between the test and control group at baseline. At 10th day mean plaque index in test group was significantly reduced to 0.45+0.51, whereas in control group mean was slightly reduced to 2.05+2.16. At 1 month the mean plaque in test group was 0.45+0.51, whereas in control group mean was reduced to 1.20+0.52. There was statistically significant (p value<0.001) reduction in plaque score in the test group when compared to the control group.

PAPILLARY BLEEDING INDEX(PBI)

In the test and control group the mean BOP index was 3.70+0.47 and 3.60+0.47 respectively at baseline and there was no difference between the groups. At 10th day mean BOP index was significantly reduced to 0.45+0.51 in test group whereas in control group mean BOP was 1.80+0.77. At 1 month the mean BOP score in test group was 0.35+0.49, whereas in control group the mean score was 1.40+0.60 and difference was found to be statistically significant(p value<0.001).

GINGIVAL INDEX(GI)

The mean GI index was 2.75+0.44 at baseline for the test group and 2.60+0.44 for the control group. At 10th day mean GI index was significantly reduced to 1.00+0.00 in test group and in control group it was 1.50+0.51, which was found to be statistically significant(p<0.001). At 1 month the mean GI was 1.15+0.37 in test group , whereas in control group the mean reduction was 1.70+0.47, and the inter-group and intra-group differences were found to be statistically significant(p value<0.001).

Mean values of clinical parameters for test and control groups during the course of study:

VARIABLE		GROUP				P VALUE
		TEST		CONTROL		
		MEAN	SD	MEAN	SD	
PI	baseline	2.75	0.44	2.74	0.44	>0.99; NS
	10 days	0.45	0.51	2.05	2.16	0.003; Sig
	1 month	0.45	0.51	1.20	0.52	<0.001; Sig
PBI	baseline	3.70	0.47	3.60	0.47	>0.99; NS
	10 days	0.45	0.51	1.80	0.77	<0.001; Sig
	1 month	0.35	0.49	1.40	0.60	<0.001; Sig
GI	baseline	2.75	0.44	2.60	0.44	>0.99; NS
	10 days	1.00	0.00	1.50	0.51	<0.001; Sig
	1 month	1.15	0.37	1.70	0.47	<0.001; Sig

Table 1

VI. DISCUSSION

Thorough subgingival debridement is the cornerstone of non-surgical periodontal therapy in controlling subgingival microflora. Effective supragingival plaque control is important in controlling the quantity, composition and rate of subgingival plaque formation and maturation (Dahlen et al., 1992; Hellstrom et al., 1996). Various adjunctive therapies such as chemotherapeutic agents, have been employed along with mechanical plaque control regimen (Mandel, 1988). These therapies have shown variable results. Recently, there has been a growing interest in natural products. While in vitro and animal studies may reveal the antimicrobial properties of these products, the only way to find out their real clinical effects is to conduct randomised clinical trials. It is important that clinical trials verify the efficacy of any medicinal product, instead of simply assuming that the product is effective based on the results of laboratory studies. Hence a study was conducted to evaluate the efficacy of herbal gel containing *Acacia arabica* along with other ingredients.

Natural herbal products have been tested for their antiplaque and antibacterial activity in periodontal diseases. *Acacia arabica* (AA), commonly used in India as chewing stick ('Babul' or 'Kikar' datun) is one of such plant. The gum of AA has been used by many communities in daily oral hygiene regimen (Tyler et al., 1977). The composition consists of arabica which is a complex mixture of calcium, magnesium and potassium salts of arabic acid. Other constituents are tannins, cyanogenic glycosides, oxidases, peroxidases and pectinases with documented individual antimicrobial properties (Kirtikar and Basu, 1984). In vitro study provides evidence for the antibacterial and antiprotease activities of AA (Clark et al., 1993).

The present study reported statistically significant reduction in GI, PI and PBI scores when compared to the placebo group. The positive clinical effects of Gumtone gel can be attributed to its main ingredients, such as *Acacia arabica*, *Barleria prionitis*, *Mimusops elengi*, *Terminalia chebula* and *Melia azadirachta* [14]. Our study in accordance with the studies by Gazi et al.[15] and Brecx et al. in which oral prophylaxis was carried out prior to the experimental phase[16], and Aditi Somani, Singhal R., AR Pradeep, Pradeep S.Tangade, G Garg .The present study reported very slight reduction of GI, PI and PBI values in the control group which can be attributed to the Hawthorne effect (i.e., patients frequently appear to improve merely from the effects of being placed in a clinical trial)(JEFFCOT 1992).

An invitro study conducted by Clark DT, Gazi MI 1993 reported inhibitory action of acacia gum against Porphyromonas gingivalis and Prevotella intermedia and their enzymes is of possible clinical significance. This inhibitory effect on periodontal pathogens along with the inhibition of protease production by them can be attributed to active constituents like arabica, cyanoglycosides, oxidases, peroxidase and pectinases present in *Acacia*. Tannins are also found to be present in *Acacia* leading to its astringent and haemostatic effects. All these properties may be responsible for the antimicrobial, antigingivitis and antiplaque effects of *Acacia arabica*. Gazi concluded that *Acacia* gum has the potential to inhibit early plaque formation although the long-term effect may not be there. The anti-inflammatory activity of *Barleria prionitis*,another ingredient of gumtone gel, is proved by Singh et al. 'TAF', an active fraction from the plant *Barleria prionitis*, exhibited significant anti-inflammatory activity against different inflammagens like carrageenan, histamine and dextran along with the inhibition of vascular permeability[20]. Another constituent of formulation is *Terminalia chebula*, the extract of which strongly inhibits growth, sucrose induced adherence and glucan induced aggregation of *Streptococcus mutans*. It has been found that 10% mouthrinse of *Terminalia chebula* inhibits total salivary bacterial count, especially *S. mutans* and salivary glycolysis for up to three hours after rinsing. In a six-week clinical trial, 5% extract of *Melia azadirachta* resulted in a significant reduction of plaque and gingivitis scores compared to the placebo. Other constituents which can add to its activity include azadirachtins, nimbolides, flavoglycosides, coumarine derivatives etc.

All these herbal ingredients have been used for many centuries without any reported side-effects. Apart from this, gumtone gel can be used for an extended period of time unlike Chlorhexidine which causes tooth discolouration and has an unpleasant taste.

VII. CONCLUSION

The present study show that Acacia Arabica containing gel can decrease plaque, gingivitis and PBI score compared to placebo. Thus, this study suggest that gum tone gel may be useful herbal formulations for chemical plaque control in recurrent chronic gingivitis patients. Further long-term prospective studies are needed to confirm the results achieved in this short-term study.

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