ORIGINAL RESEARCH

Comparative Evaluation of Topical Application of Boswellia Serrata Gel with Chlorhexidine Gel in Management of Gingivitis: A Clinical Study

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Abstract

Aim: To evaluate and compare the efficacy of the topical application of Boswellia serrata gel and chlorhexidine gluconate gel in depletion of gingival inflammation and plaque in study participants diagnosed with plaque-induced gingivitis.

Materials and methods: A total of 60 study participants diagnosed with chronic gingivitis in the age-group 18–40 years signed up for the research and were categorized into three equal groups. Group I: scaling + Boswellia serrata gel, group II: Scaling + Chlorhexidine gluconate gel, group III: scaling + placebo gel. A detailed case history including Gingival Index (Loe and Silness, 1963), Plaque Index (Silness and Loe, 1964), and Sulcus Bleeding Index (Muhlemann & Son, 1971) was recorded in their first visit which were reassessed after 14 days (second visit) and 21 days (third visit) and comparison was made with the baseline data.

Results: The mean scores for Plaque Index, Gingival Index, and Sulcus Bleeding Index were significantly decreased during 2nd and 3rd visit after 14 and 21 days, respectively when compared with baseline scores. No significant difference was recorded between group I and group II (test groups) whereas there was significant difference between the test groups and group III (control group).

Conclusion: Both Boswellia serrata gel and chlorhexidine gluconate gel were similar in action when used for topical application along with scaling and polishing in the management of chronic gingivitis study participants.

Clinical significance: Boswellia serrata gel can be used as an adjunct to scaling and root planing as a long-term intervention due to its low cost availability and better tolerance when compared to the widespread side effects of chlorhexidine.

Keywords: Frankincense, Gingivitis, Periodontal disease, Plaque, Sallaki.

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Introduction

Periodontal disease is characterized by inflammation and disintegration of investing tissues of the teeth. Plaque biofilm is the major etiological agent in periodontal diseases. It has been proven in many experimental studies that plaque plays the main role in the etiology of gingivitis and a direct relationship between amount of plaque and the progression of gingivitis has been demonstrated.[1] Scaling and root planing is the primarily endorsed step for providing remedy for plaque induced periodontal diseases and are an imperative phase of periodontal treatment. However, there are certain setbacks such as accessibility or presence of plaque in retentive areas that can restrict instrumentation. Therefore, in addition to mechanical periodontal therapy, the utilization of chemical agents as an adjunct has been demonstrated to obtain optimum plaque control, which collectively reduces plaque-induced gingivitis.[2,3] Numerous chemical plaque control agents comprising bisbiguinaides, essential oils, enzymes, and herbal extracts have been assessed for their effectiveness on plaque biofilm.[4] Chlorhexidine digluconate is regarded as gold standard in dental medicine for the inhibition of plaque biofilm. Chlorhexidine gel has proven to be efficacious but it has a few after effects, for instance, brown staining of the teeth, erosions on oral mucosa, and unpleasant bitter taste. Therefore, there is a necessity of a substitutive medicine that is safe and inexpensive. Traditional Indian herbal formulations can easily serve this purpose and can be used for prolonged period.[5]

Boswellia serrata, commonly known as Frankincense, *Salai guggul*, *olibanum* and Sallaki in Sanskrit, is native to Iran and is commonly found in dry mountanious regions of India, Northern Africa, and Middle East.[6]

Boswellia serrata has been utilized as a potent remedy for arthritis, diarrhea, boils, fever, cardiovascular diseases, oral ulcerations, sore throat, and bronchitis. Allied medicine firmly illustrates its use as an antiarthritic, anti-inflammatory, antihyperlipidemic, antiatherosclerotic, analgesic, and hepatoprotective.[7]

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The resin of Boswellia species has been employed as incense in numerous religious ceremonies since an eternity. It is also utilized for the treatment of inflammatory conditions, as remedy for microbial infection and cancer.[8] Despite being a miraculous product having historical, cultural, and therapeutic significance, Boswellia has been under researched.

Frankincense has also been used in the form of mouthwash[9] and chewing gum for preventing gingival bleeding, halitosis, and healing gingival wounds.[10]

However, insufficient reports about Boswellia serrata extract as potential therapy for periodontal diseases have been submitted. Till date, no studies evaluated Boswellia serrata as a topical gel in the management of gingivitis.

Boswellia serrata has antibacterial and anti-inflammatory effects. It is easily available and economical. Therefore, the effect of the topical application of Boswellia serrata gel as an adjunct for therapeutic intervention for plaque-induced gingivitis was evaluated in this research.

This study was hypothesized to obtain improvement in clinical parameters with the topical application of Boswellia serrata gel when compared with 2% chlorhexidine gluconate gel when used as an adjunct to nonsurgical plaque removal.

Materials and Methods

A randomized, double-blind, controlled clinical study was done on 60 study participants who were randomly selected from the outpatient section of Department of Periodontics, P.M.N.M Dental College and Hospital, Bagalkot. Sample size was calculated by randomized convenience sampling method and was expanded by 35% for compensating for dropouts. Ethical clearance for the research was obtained from the Institutional Review Board (PMNMDCH/2126/2019–20) and written duly signed consent forms were obtained from the study participants (Flowchart 1).

The study participants were randomly divided into three groups with 20 participants in each group (n= 20):

- Group I: Scaling + Boswellia serrata gel
- Group II: Scaling + chlorhexidine gluconate gel (Hexigel, ICPA Health Products, Mumbai, India)
- Group III: Scaling only.

Inclusion Criteria

- Systemically healthy study participants diagnosed with gingivitis, aged 18–40 years, having at least 20 natural teeth excluding third molars.
- Participants efficient in maintaining satisfactory oral hygiene were included in the study.

Exclusion Criteria

- Study participants with a known history of allergy to any chemical or herbal products used in the study.
- Participants who have undergone scaling and root planing in the past 6 months.
- Study participants on any systemic antibiotics, anti-inflammatory, and corticosteroids therapy in past 3 months.
- Study participants on chewing and smoking tobacco, pregnant, and lactating mothers.
- Study participants on hormonal therapy, having other infections or pathology in oral cavity other than gingivitis were excluded from the study.

The observation was carried out by a single calibrated examiner. A detailed case history including Gingival Index (Loe and Silness, 1963), Plaque Index (Silness and Loe, 1964), and Sulcus Bleeding Index (Muhlemann & Son, 1971) was recorded from all the participants in their first visit. A demonstration of modified bass toothbrushing method was given after full mouth supragingival scaling. Instructions were given to study participants to apply a pea-sized amount of gel by a clean finger on the gingiva (three times per day for Boswellia serrata group and two times per day for CHX group) and leave it for 5 minutes before rinsing. Study participants were refrained from other oral hygiene aids, for example, interdental aids, chewing gums, or mouthwashes during the study. All the study participants were followed up on 14th and 21st day and clinical parameters were recorded.

Preparation of Gel

Pure Boswellia serrata extract was obtained and an aqueous gel was prepared which consisted of the following constituents: Boswellia serrata (0.40 gm), gelatin (12 gm), glycerin (wetting agent)— 0.2 mL and purified water (100 mL). A homogenizer was used to homogenize the ingredients in order to obtain the gel.[12] The same method was used for preparation of placebo gel in which the test extract was not added.

Appraisal of Physical Properties

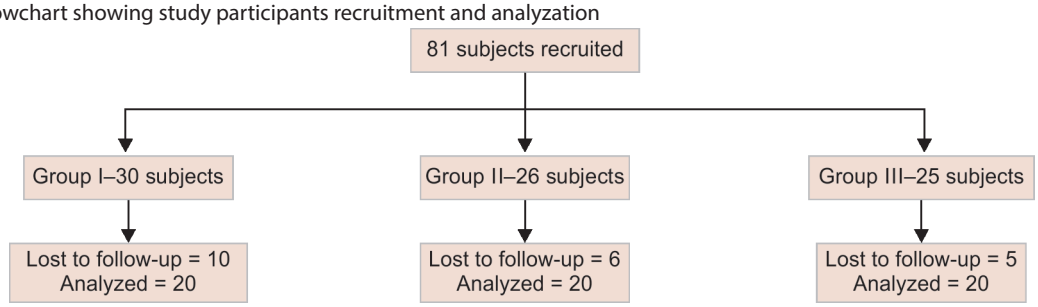
Homogeneity

The gel shows satisfactory homogeneity by visual observation.

pH

pH was measured 2 hours after mixing 2.5 gm of obtained gel with 25 mL. The values were triplicated and average was recorded.

Flowchart 1: Flowchart showing study participants recruitment and analyzation



Rheology and Viscosity

Brookefield viscometer was employed for rheological properties. The measurements were recorded at an interval of 30 seconds (between speed settings of 10–100 rpm) in both increasing and decreasing order.

Spreadability

A glass slide was marked and 0.5 gm gel was spread within a cm of diameter. It was covered with a glass slide which was stabilized with 100 gm weight. The increased diameter was recorded.

Syringeability

The syringeability of the gel was evaluated by passing the gel through a 21-gauge needle for its potential use as a local drug delivery agent for the intervention of deep periodontal pockets.

Patch Test

The gel was applied on the forearms of study participants for 48 hours. They were asked several questions based on the experience like ease of application, immediate and long-term sensation after application, scent, itching, etc.

Statistical Analysis

All data was put through statistical analysis using SPSS software. Descriptive statistics like frequencies and percentage for categorical data, Mean & Standard deviation for numerical data has been presented.

Intergroup comparison (>2 groups) was done using one-way ANOVA followed by pairwise comparison using *post hoc* test. Intragroup comparison using repeated measures ANOVA (for >2 observations) followed by *post hoc* test was done. Comparison of frequencies of categories of variables with groups was carried out using chi-square test.

For all the statistical tests, $p < 0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

Results

The demographic data including age and gender depicted in Tables 1 and 2 was found to be statistically nonsignificant among the three groups.

Table 1: Intergroup comparison of mean age of the subjects

Group	*N*	*Mean*	*Std. deviation*	*Std. error*	*p-value*
I	20	24.65	5.669	1.268	
II	20	23.75	4.290	0.959	0.821[#]
III	20	23.70	6.001	1.342	

[#]statistically nonsignificant difference

In the intergroup comparison between the three groups, there was statistically nonsignificant difference between Gingival Index (GI) at Baseline and Sulcus Bleeding Index (SBI) at baseline whereas there was statistically significant difference in Plaque Index between the groups for Plaque Index at Baseline with higher values in group III (Figs 1 to 3). A statistically highly significant reduction was seen between the groups for GI, PI, and SBI at both 14 days (14D) and 21 days (21D) intervals with higher values in group III. In the intergroup comparison of differences, there was a statistically significant difference seen for the values between the groups ($p < 0.01$) with higher values in group II. In the intergroup pairwise comparison of difference, there was a statistically nonsignificant difference seen between group I and II whereas statistically significant difference was seen between groups I and III and group II and III.

In the intragroup comparison, there was a statistically highly significant difference seen for the values between the time intervals ($p < 0.01$) for all the variables with higher values at baseline (Tables 3 to 5). There was highly significant difference seen in intragroup pairwise comparison for the indices between all the group except in group III wherein statistically nonsignificant difference was seen in 14th and 21st day interval for GI and SBI.

Discussion

Plaque-induced gingivitis results from interlinkage between host immune system and plaque biofilm. Aggregated microorganisms in the biofilm triggers the host immune response culminating the chain of events ultimately leading to chronic gingival inflammation. Nonsteroidal anti-inflammatory drugs as an adjunct to mechanical periodontal therapy has been advocated for reduction of inflammation. Nonetheless, it has been linked to complications like gastrointestinal bleeding, high blood pressure, congestive heart, and renal failure.[10] Botanical therapeutic products have been scrutinized with these rationale and have shown pleasing outcomes.[11] The oleo- gum resin of Boswellia serrata entails 30–60% resins, 5–10% essential oils, and rest is inclusive of polysaccharides like galactose, arabinose, etc.[12]

Leukotrienes cause inflammation by stimulating free radical damage, calcium dislocation, vasoconstriction, increased vascular permeability, cell adhesion, and chemotaxis.[10] Boswellia serrata contains four major pentacyclic triterpenic acids which play a major role in inhibition of proinflammatory enzymes namely, 5-lipoxygenase, 5-hydroxyeicosatetraenoic acid (5-HETE), and leukotriene B4. Boswellic acids are specific (either interacts directly with 5-lipoxygenase or blocks its translocation) and does not affect 12-lipoxygenase or cyclooxygenase activity.[13] The predominant boswellic acids, AKBA, and 11-keto-β-boswellic acids regulate proinflammatory cytokine cascade comprising tumor necrosis factor-α (TNF-α) and interleukin-1β (IL-1β) by inhibit nuclear factor kappa B (NF-κB).[7]

Table 2: Intergroup comparison as per sex distribution

		I	*II*	*III*	*Total*	*Chi-square value*	*p-value of Chi-square test*
Sex	Female	10	5	5	20		
	Male	10	15	15	40	3.750	0.153[#]
	Total	20	20	20	60		

[#]statistically nonsignificant difference

In the present study, the anti-inflammatory and antiplaque properties of Boswellia serrata extract in the form of topical gel was investigated for the management of plaque-induced gingivitis.

The resolution of inflammation is measured by three important quitessential clinical parameters, namely, decrease in Gingival Index, Plaque Index, and Sulcus Bleeding Index. The results of the present study showed considerable decrease in the values of all the clinical parameters in both the test groups when compared with the control group ($p < 0.01$). Chlorhexidine gel showed better results when compared with Boswellia serrata gel. However, there was statistically nonsignificant difference between the two ($p < 0.01$). This may be due to the anti-inflammatory action demonstrated by boswellic acids leading to suppression of proinflammatory enzymes. This is in accordance with the study by Samani et al.[10] wherein Boswellia serrata was administered in the form of chewing gums. Another study conducted by Khoshbakht et al.[9] showed reduced PI, GI, and Bleeding Index on 21 days follow up intervention during which hydro-alcoholic extract of Boswellia serrata was administered as a mouthwash. A contrasting opinion has been evidenced by a Cochrane review about the anti-inflammatory properties of Boswellic Acids.[14] In our study, there was considerable decrease in Plaque Index which may be attributed to the antibacterial and antibiofilm effect of Boswellic acids. This is in agreement with an *in vitro* study conducted by Raja et al.[15] where Boswellia serrata showed inhibitory effect against all periopathogens.[15,16]

The participants in the present study did not report any complications upon administration of Boswellia serrata gel. They reported a cooling effect and a pleasant smell upon application which may be attributed to presence of essential oils in the extract.

To our knowledge, this is the first report of Boswellia serrata being used as a topical application for the treatment

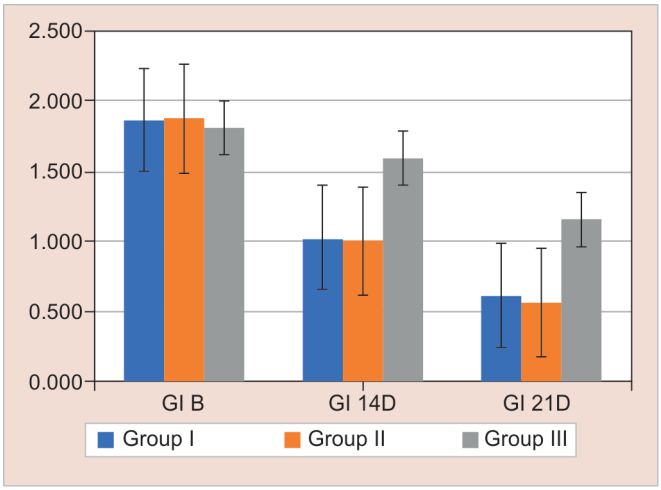


Fig. 1: Intergroup comparison of GI

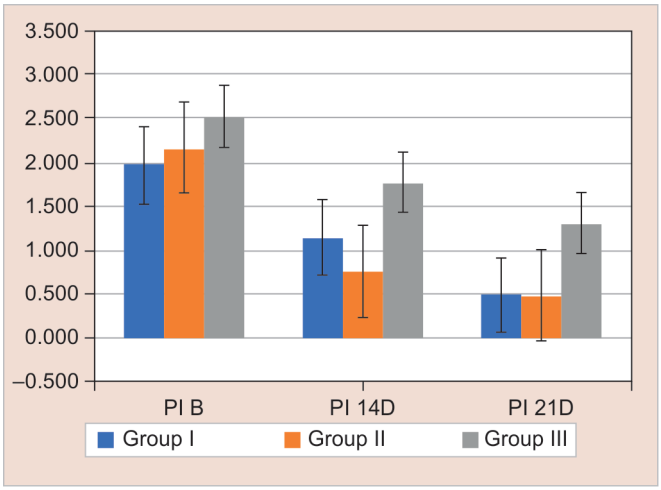


Fig. 2: Intergroup comparison of PI

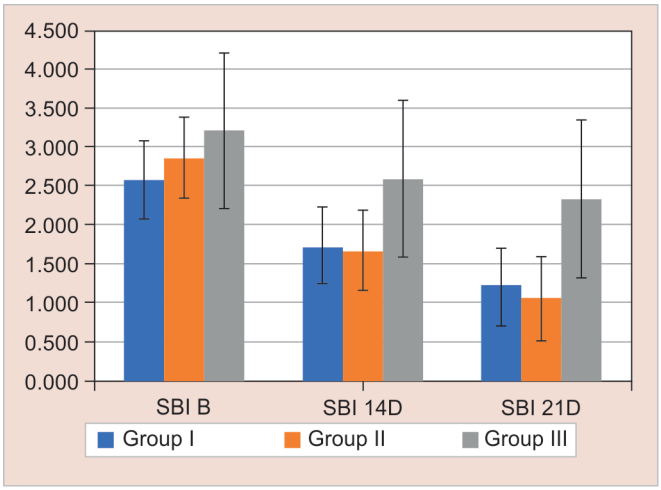


Fig. 3: Intergroup comparison of SBI

Table 3: Intragroup comparison of group I

Group	*Time*	*N*	*Mean*	*Std. deviation*	*Std. error*	*F-value*	*p-value*
GI Grp I	B	20	1.865,000	0.472,3769	0.124,3233		
	14D	20	1.026,500	0.396,7492	0.084,8120	36.734	0.000**
	21D	20	0.615,900	0.473,6524	0.129,3509		
PI Grp I	B	20	1.974,200	0.467,5632	0.106,7287		
	14D	20	1.134,600	0.565,3237	0.127,6463	52.562	0.000**
	21D	20	0.486,500	0.336,5463	0.073,7423		
SBI Grp I	B	20	2.576,000	0.735,6415	0.237,4567		
	14D	20	1.743,000	0.534,5872	0.087,3854	28.153	0.000**
	21D	20	1.217,830	0.428,3587	0.132,7367		

** statistically highly significant

Table 4: Intragroup comparison of group II

Group	*Time*	*N*	*Mean*	*Std. deviation*	*Std. error*	*F-value*	*p-value*
GI Grp II	B	20	1.876318	0.5854327	0.1329766		
	14D	20	1.027858	0.2679863	0.0619863	49.421	0.000**
	21D	20	0.567760	0.3136254	0.07243761		
PI Grp II	B	20	2.164000	0.5697388	0.1275788		
	14D	20	0.754850	0.3183466	0.0734364	96.119	0.000**
	21D	20	0.476200	0.2720856	0.0578363		
SBI Grp II	B	20	2.856000	0.7441567	0.1537649		
	14D	20	1.675000	0.4778482	0.1043869	53.440	0.000**
	21D	20	1.06500	0.3711081	0.0839692		

** statistically highly significant

Table 5: Intragroup comparison of group III

Group	*Time*	*N*	*Mean*	*Std. deviation*	*Std. error*	*F-value*	*p-value*
GI Grp III	B	20	1. 812,000	0.476,5235	0.093,2541		
	14D	20	1.591,000	0.386,4351	0.073,2437	10.427	0.000**
	21D	20	1.156,000	0.387,4573	0.086,4236		
PI Grp III	B	20	2.518,000	0.268,2179	0.063,6548		
	14D	20	1.768,000	0.367,8387	0.085,7687	47.958	0.000**
	21D	20	1.305,400	0.483,5871	0.105,7688		
SBI Grp III	B	20	3.212,000	0.657,5864	0.148,5858		
	14D	20	2.587,200	0.439,5629	0.094,3271	15.690	0.000**
	21D	20	2.326,000	0.339,8867	0.074,7326		

** statistically highly significant

of periodontal disease. The limitations of the present study are short follow up period and lack of microbiological analysis of periopathogens. Given that, longer time period is required to uncover the side effects of a new therapeutic agent, further longitudinal studies can be carried out with microbial evaluation to justify the results obtained. Another shortcoming on the present study is the low absorption of gel. To overcome this, nanoemmigel formulation of Boswellia serrata has been proposed for topical application.[6]

Conclusion

Within the limits of our study, Boswellia serrata has proved to be a promising intervention as an adjunct to mechanical periodontal therapy. However, Chlorhexidine still remains the gold standard. Due to the low toxicity and better patient acceptance, Boswellia serrata can be proposed to be used as an adjunct for long-term use.

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