

The Effect of Herbal Serum on the Management of Gingivitis Adjunctive To Non-Surgical Therapy. A Randomised Controlled Clinical Trial.

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ABSTRACT

Aim: To evaluate the clinical efficacy of a herbal serum in the management of gingivitis.

Background: Chronic gingivitis is one of the most prevalent diseases in India. Regular chemical methods of controlling gingivitis, like use of Chlorhexidine, triclosan, povidone iodine and various phenolic compounds shows several side effects such as discolouration of teeth, unpleasant taste, allergies, etc when used for extended periods3. Thus an advanced herbal serum which overcomes the unwanted effects of the aforementioned agents is utilized to assess its adjunctive role with SRP for gingivitis treatment.

Materials and Methods: The study design is single blinded, randomized, controlled clinical trial with a duration of 21 days. 30 patients fulfilling inclusion criteria were randomly assigned into two treatment groups Test (15 subjects) and Control (15 subjects). In test group, scaling and root planning done followed by application of herbal serum. In control group scaling and root planning alone was done. The clinical parameters such as, gingival index, gingival bleeding index, plaque index and sulcular probing depth were analyzed at baseline and after 21 days.

Results: In the test group, the mean values of plaque index, gingival index, bleeding index and pocket depth reduced from 2.2 to 1.1, 1.3 to 0.5, 0.8 to 0.3, 2.1 to 1.7 respectively, which is statistically significant. In the control group, mean values of plaque index, gingival index, bleeding index and pocket depth reduced from 2.3 to 0.6, 1.4 to 0.08, 0.8 to 0.07, 2.3 to 1.3 respectively. There is a marked difference in the reduction of bleeding index in the test group in comparison with control group with a p value of 0.006.

Case Report (ISSN: 3065-4505)

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Conclusion: From the outcomes obtained in the present study it can be concluded that this herbal formulation is a veritable adjunct to SRP for treatment of

gingivitis.

Keywords: Herbal serum; Gingivitis; Scaling and root planning

INTRODUCTION

Scaling and root planing (SRP) is the foundation of periodontal therapy. The primary objective of SRP is complete elimination of the plaque biofilm. This essential

step controls gingivitis which left unchecked progresses to periodontitis. To ensure optimal outcomes, several adjuncts have been used with SRP.

Some of the agents employed as adjuncts are chlorhexidine, triclosan, povidone iodine and various phenolic compounds. But these chemical agents have several

side effects like teeth discolouration, unpleasant taste, allergies, etc. on prolonged usage.

It is an organic era now and the focus has shifted to green. Since ancient times, herbs have been used as agents for periodontal treatments. The various herbs are

pepper, clove, alum, etc. These herbal formulations can be a safe alternative for long term usage. One of the newer formulations in the category is the Purexa gum

serum.

This formulation comprises of neem, green tea, vitamin C and Tulsi. Neem possesses anti-inflammatory, antifungal, and antibacterial properties. The catechin

contained in the green tea provides bactericidal effects on black pigmented, gram negative, anaerobic rods. It is a well-established fact that Vitamin C enhances

healing. Additionally, Tulsi with a major component of eugenol in it provides moderate analgesia via inhibition of COX-2 pathway. Thus, this herbal concoction

with key ingredients is used adjunctive to scaling and root planning to improve the therapeutic outcomes.

MATERIALS AND METHODS

This study was designed as a single blinded, randomized, controlled clinical trial. The duration of the study was 21 days. The clinical parameters such as, gingival

index, gingival bleeding index, plaque index and sulcular probing depth were analyzed at baseline and after 21 days. The study protocol was initially submitted to

the Ethical Committee of Krishnadevaraya college of dental sciences and hospital, Bengaluru, India. After ethical approval was granted, subjects were selected

from the outpatient section of the Department of Periodontics, Krishnadevaraya college of dental sciences and hospital, after a written informed consent was taken

from them.

Inclusion criteria

1. Systemically healthy subjects

2. Good patient compliance

3. Age range 18-65 years

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Case Report (ISSN: 3065-4505)

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- 4. Patients with at least 20 teeth
- 5. Probing depth ≤ 4 mm
- 6. Gingival index ≥ 1
- 7. Plaque index ≥ 2

Exclusion criteria

- 1. Patients who have used mouth rinse containing chemical agents in previous two months.
- 2. Patients on antibiotics one month prior to treatment.
- 3. Patients using orthodontic appliances either fixed or removable
- 4. Subjects with deleterious habits like smoking, tobacco chewing
- 5. Patients allergic or sensitive to any medication or toothpaste.
- 6. History of any surgical procedure in the selected area in the past two months.

SAMPLING TECHNIQUE

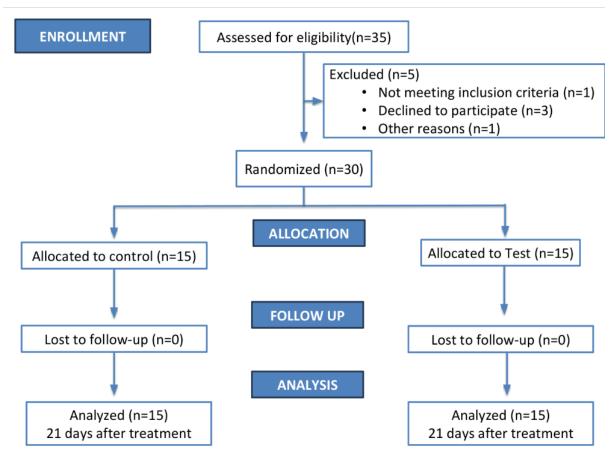
Purposive Sampling technique will be done. All the patients who meet the eligibility criteria will be screened and will be enrolled in the study. Randomization of procedure will be performed by a single examiner. 30 patients fulfilling inclusion criteria will be randomly assigned into two treatment groups (Test and Control). The treatment allocation sites to the test and control group will be assigned by means of a sealed envelope containing a code derived from a computer-generated randomized list to receive either.

Test group (n=15) - Scaling and root planing along with herbal formulation.

Control group (n=15) – Scaling and root planing alone.



Consort Flow Diagram



PROCEDURE

On baseline visit

- A detailed case history is recorded.
- Patient's clinical parameters are recorded using UNC 15 probe with the help of occlusal stents.

Clinical parameters include: Plaque Index, gingival index, gingival bleeding index, sulcular probing depth.



TEST GROUP

Scaling and root planning done followed by application of herbal serum.

Application of serum: two drops of the serum is taken on a clean fingertip and is applied gently all over gingiva for at least 30 seconds.

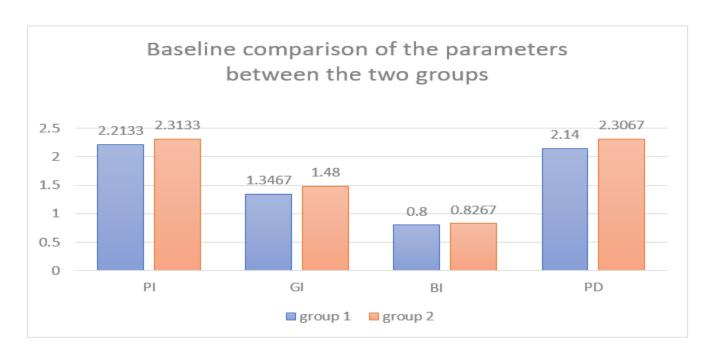
CONTROL GROUP

Scaling and root planing alone is done.

Patients are recalled after 21 days for re-evaluation. All the clinical parameters are reassessed.

Table 1: Baseline comparison of the parameters between the two groups.

	group 1				group 2					
	N	Mean	Std. Deviation	Median	N	Mean	Std. Deviation	Median	Mann whitney u Test statistic	P value
PI	15	2.213	0.29488	2.1	15	2.313	0.35429	2.2	97	0.505
GI	15	1.347	0.39437	1.2	15	1.48	0.30752	1.5	1.03	0.31
BI	15	0.8	0.25912	0.8	15	0.827	0.22824	1	106	0.788
PD	15	2.14	0.52071	2.2	15	2.307	0.55352	2.4	0.849	0.4



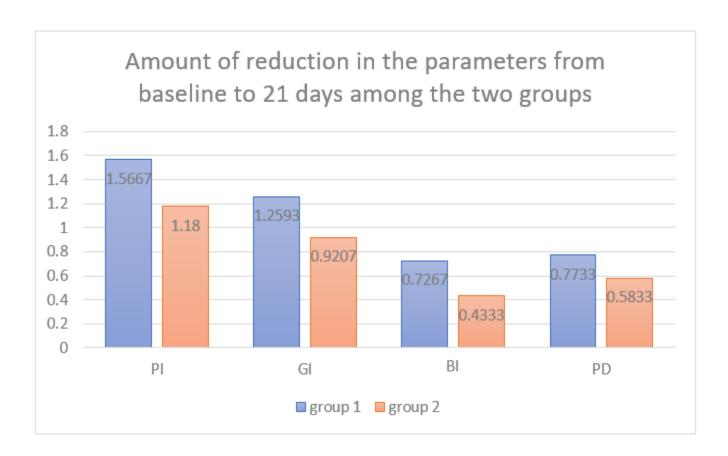


At baseline the two groups were comparable.

Table 2: Comparison of the amount of reduction in the parameters from baseline to 21 days among the two groups.

	group 1			group 2				
	Mean	N	Std. Deviation	Mean	N	Std. Deviation	Man whitney u Test statistic	p value
PI	1.5667	15	0.46624	1.18	15	0.44433	58.5	0.025*
GI	1.2593	15	0.38351	0.9207	15	0.3558	58	0.022*
BI	0.7267	15	0.26583	0.4333	15	0.2743	47	0.006**
PD	0.7733	15	0.50915	0.5833	15	0.48465	86	0.269

PI, plaque index; GI, gingival index; BI, bleeding index; PD, pocket depth.



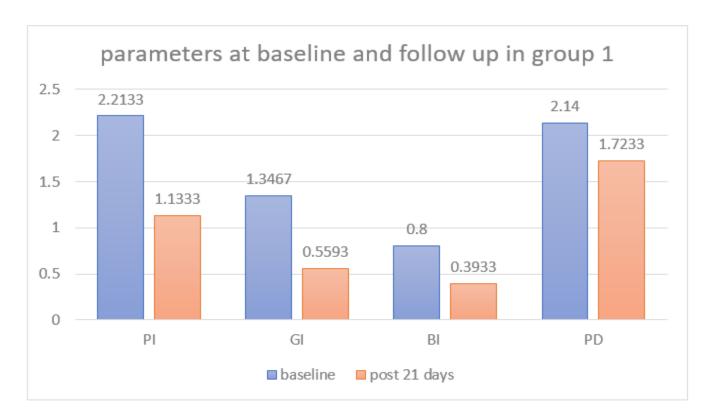


The amount of reduction seen in the parameters was greater in group1 than group 2. The difference was statistically significant for PI, GI and BI.

Table 3: Comparison of the parameters at baseline and follow up in group 1.

	baseline				Follow up					
	N	Mean	Std. Deviation	Median	N	Mean	Std. Deviation	Median	Wilcoxson sign rank Test statistic	P value
PI	15	2.213	0.29488	2.1	15	1.133	0.52053	1	-3.415c	0.001**
GI	15	1.347	0.39437	1.2	15	0.559	0.4456	0.6	-3.413c	0.001**
BI	15	0.8	0.25912	0.8	15	0.393	0.27894	0.5	-3.417c	0.001**
PD	15	2.14	0.52071	2.2	15	1.723	0.62987	1.9	-3.185c	0.001**

PI, plaque index; GI, gingival index; BI, bleeding index; PD, pocket depth.



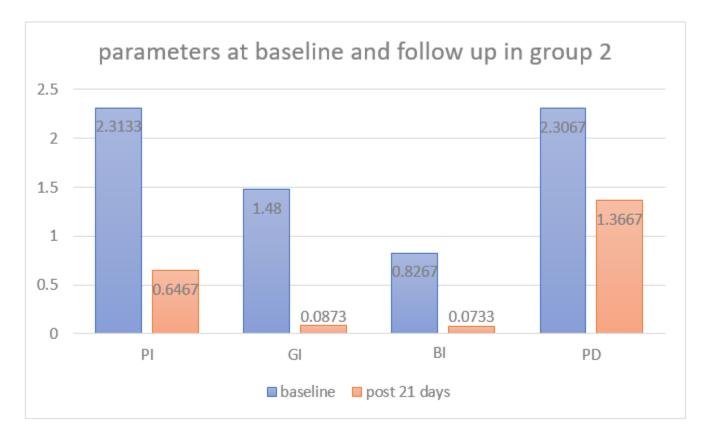
There was a statistically significant reduction in the parameters from baseline to follow up in group 1



Table 4: Comparison of the parameters at baseline and follow up in group 2.

	baseline				Follow up					
	N	Mean	Std. Deviation	Median	N	Mean	Std. Deviation	Median	Wilcoxson sign rank Test statistic	P value
PI	15	2.313	0.35429	2.2	15	0.647	0.63625	0.4	-3.414c	0.001**
GI	15	1.48	0.30752	1.5	15	0.087	0.15341	0.01	-3.433c	0.001**
BI	15	0.827	0.22824	1	15	0.073	0.12799	0	-3.250c	0.001**
PD	15	2.307	0.55352	2.4	15	1.367	0.41173	1.2	-3.307c	0.001**

PI, plaque index; GI, gingival index; BI, bleeding index; PD, pocket depth.



There was a statistically significant reduction in the parameters from baseline to follow up in group 2

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RESULTS

All the 30 patients completed clinical trial. The herbal serum used in the study had good acceptance and showed no adverse effects such as allergy, or ulceration. At baseline, two groups were comparable in terms of plaque index, gingival index, bleeding index and probing pocket depth (Table 1). Both the groups had higher plaque and bleeding scores. After 21 days of scaling and root planning, the patients who used herbal serum as an adjunct, showed significant improvement in their gingival status

In the test group, the mean values of plaque index, gingival index, bleeding index and pocket depth has reduced from 2.2 to 1.1, 1.3 to 0.5, 0.8 to 0.3, 2.1 to 1.7 respectively, which is statistically significant (Table 3).

In control group the mean values of plaque index, gingival index, bleeding index and pocket depth has reduced from 2.3 to 0.6, 1.4 to 0.08, 0.8 to 0.07, 2.3 to 1.3 respectively (Table 4).

In comparison of the amount of reduction in the parameters from baseline to 21 days among the two groups, the mean values of plaque index, gingival index, bleeding index and pocket depth in test group is 1.5, 1.2, 0.7 and 0.7 respectively, whereas in control group it is 1.1, 0.9, 0.4 and 0.5 respectively (Table 2). Which indicates a higher reduction in test group. There is a marked difference in the reduction of bleeding index in the test group in comparison with control group with a p value of 0.006.

DISCUSSION

Dental plaque, which comprises of a well-established biofilm of bacteria is the main causative factor of periodontitis. Removal of this biofilm in its early stage is the key in preventing periodontal diseases.

Several methods of plaque removal include, mechanical methods, chemical methods, photodynamic therapy etc. Scaling and root planning being the gold standard in removing plaque and calculus, various toothpastes, mouthwashes, and astringents also help in reducing plaque effectively. Various herbal formulations have been used extensively in the plaque control. They improve the status of gingiva, by reducing inflammation.

In the present study, the efficacy of herbal serum as an adjunct to scaling and root planning was evaluated. A statistically significant reduction in bleeding index was observed in test group in comparison to control group with a p value of 0.006. This can be attributed to the anti-inflammatory action of the contents of this formulation.

Neem has free radical scavenging properties due to its rich source of antioxidants. It also plays role as anti-inflammatory via regulation of proinflammatory enzyme activities including cyclooxygenase (COX), and lipoxygenase (LOX) enzyme [14]. (Alzohairy MA, 2016)

Green tea catechin inhibit the growth of P. gingivalis, Prevotella intermedia and Prevotella nigrescens and adherence of P. gingivalis on to human buccal epithelial cells. It also showed bactericidal effect against black-pigmented, Gram-negative anaerobic rods, Porphyromonas gingivalis and Prevotella species, and the

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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 19 (Hirasawa M, et al in 2002)

Vitamin C obtained from diet reduces the inflammatory reaction in periodontal disease. The administration of vitamin C alone or with non-surgical treatment has shown effects for improving gingival indices, SBI, and GI. Vitamin C has a powerful anti-oxidative effect in living organisms, particularly at the intracellular level [17], and this is thought to decrease the oxidative stress generated in gingivitis. Additionally, vitamin C reduced the cytotoxic and apoptotic activity of Porphyromonas gingivalis in human periodontal ligament cells and human gingival fibroblasts, which may have contributed to these effects [16]. (Tada A, et.al 2019)

Preparations of tulsi leaves, O. sanctum are claimed to be effective in a wide spectrum of inflammatory and infectious diseases. The anti-gingivitis effect of O. sanctum extract can be attributed to compounds isolated from O. sanctum extract. Civilineol, Civilineol, Civilineol, Civilineol, Rosavinic acid, and Eugenol compounds in tulsi were considered to have anti-inflammatory activity or cyclooxygenase inhibitory activity [20]. (Kelm MA, et al, 2000)

Piperine present in black pepper possess antioxidant and antimicrobial properties. The free-radical scavenging activity of piperine might be helpful in chemoprevention and controlling progression of tumor growth. Additionally, it assist in cognitive brain functioning, boost nutrient's absorption and improve gastrointestinal functionality [13].

CONCLUSION

The use of various herbal formulations has been advocated from many centuries. The herbal serum used in this study has shown good improvement in the gingival status and reduced plaque and bleeding scores significantly. Hence it can be be used as an adjunct to scaling and root planing in the treatment of gingivitis.

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Case Report (ISSN: 3065-4505)



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Case Report (ISSN: 3065-4505)



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