

Evaluation of Efficacy of Locally Delivered Red Ginseng Gel as an Adjunct to Scaling and Root Planing in the Treatment of Chronic gingivitis Patients with Type II Diabetes Mellitus: A Clinical Study

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Abstract

Periodontitis is an inflammatory disease destroying tooth supporting structures. Although the microbial insult is the predominant etiological factor, host inflammatory response plays a major role in tissue destruction. Increased prevalence and severity is evident in patients with chronic periodontitis and Diabetes mellitus. Red Ginsengs are reported to contain anti-allergic, anti-inflammatory, anti-oxidative, and immunomodulatory effects. It also seems to be beneficial in the control of blood sugar levels in both diabetic and nondiabetic patients. The present study aimed to evaluate the effect

of locally delivered red ginseng gel in the management of chronic gingivitis with type 2 diabetes mellitus patients. Thirty-five systemically healthy patients were randomly allocated to the test group [red ginseng gel] or the control group [Chlorhexidine gel]. Full mouth Gingival Index (GI) and Full mouth Plaque Index (PI) were evaluated at baseline and on the 7th day. 35 sites in 15 patients (age 20-55 years) were randomly selected for the study. The mean plaque index score at baseline for Test sites was 0.84 ± 0.13 and after 6 weeks it was further decreased to 0.61 ± 0.14 . The mean Gingival index score at baseline for Test sites was 0.85 ± 0.11 and

after 6 weeks it was further decreased to 0.69 ± 0.13 .

Within the limitation of the study, red ginseng gel can be recommended as an adjunct for mechanical periodontal therapy and can be used for long term maintenance in supportive periodontal therapy in patients of chronic gingivitis with type II diabetes mellitus patients.

Keywords: Ginseng, Gingivitis, Chlorhexidine, Plaque, Periodontitis, Diabetes.

Introduction

Periodontitis is an inflammatory disease causing the destruction of tooth supporting structures. Although the microbial insult is the predominant etiological factor, host inflammatory response plays the major role in tissue destruction. Periodontitis is considered as sixth complication of Diabetes mellitus. Increased prevalence and severity is evident in patients with chronic periodontitis and Diabetes mellitus.

The ultimate goal of periodontal therapy is to reduce the microbial load. However it does not eliminate all the pathogens which reside deep into the connective tissue. (Vennila 2016) ¹. Antimicrobial agents are therefore used systemically or locally as an adjunct to periodontal therapy in the management of chronic periodontitis. These agents aim to reinforce mechanical periodontal treatment and to support the host defense system in overcoming the infection by killing subgingival pathogens that remain after conventional mechanical periodontal therapy (Vennila 2016) ¹.

Antimicrobial agents have been used both systemically as well as locally as an adjunct to scaling and root planing. Chlorhexidine (CHX) is one of the most effective antimicrobial agents for plaque control and to reduce dental inflammation. Local side effects associated with the use of chlorhexidine are unpleasantness, alteration of taste sensation and costly to the patient ². Despite the great benefit of chlorhexidine gluconate as

an antiplaque agent, the search continues for active ingredients that could prevent dental inflammation without affecting the biological equilibrium within the oral cavity. ³

So to overcome these, there is a continuous search for an alternative agent with lesser adverse effects and profound antimicrobial and added anti-inflammatory effects. In that context the herbal products are considered because of their equally qualifiable effects and less adverse reactions.

Red ginsengs are one among the herbs, which are slow growing perennial plants with fleshy roots, belonging to Panax species (Panax ginseng) of Arilaceae family. The pharmacological effects of Red Ginseng are reported as anti-allergic, anti-inflammatory, anti-oxidative and immunomodulatory effects. ⁴ It inhibits inflammation by its potent effects on MAP kinase pathway, COX-2, and NF-kB. It inhibits pro inflammatory cytokines like TNF alpha. ⁵ It has also been reported to reduce the expression of MMP-3. ⁶ It also seems to be beneficial in the control of blood sugar levels in both diabetic and non-diabetic patients. Some studies have shown that Ginseng supplementation could decrease fasting blood sugar levels and insulin sensitivity in people with type 2 diabetes. In spite of its beneficial effects and minimal adverse effects there are no studies to evaluate the effects of red ginseng extracts as gel in the management of chronic gingivitis with type 2 diabetes mellitus.

Therefore the aim of the present study was to evaluate the effect of locally delivered red ginseng gel in the management of chronic gingivitis with type 2 diabetes mellitus patients.

Method and Material

35 sites in 15 patients (age 20-55 years) were randomly selected for the study. Patients should have at least 14 natural teeth in the oral cavity. Proper informed consent

was signed by the patients and the procedure was also institutional ethical committee with explained to them. Ethical clearance was granted by the strg983797608039804796-07.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> The patients with moderately controlled type-II diabetes mellitus and glycated hemoglobin A1c (HbA1c%) in the range of 7%-8%. Chronic Gingivitis patients should have Gingival index (GI) ≥ 1, Plaque index (PI) ≥ 1 were selected for the study. 	<ul style="list-style-type: none"> Patients with a known history of systemic diseases as hypertension, Human Immunodeficiency Virus (HIV), bone disorders, renal disorders, radiation therapy, cancer patients, infectious diseases, and any other systemic disease that can alter the course of periodontal disease. History of prolonged use of steroids/immunosuppressive agents/anticoagulants, antimicrobial therapy within the previous 3 months Patients with aggressive periodontitis, history of periodontal therapy in the preceding 6 months, Type-1 Diabetes Mellitus, Pregnant/Lactating women History of tobacco in any form.

The following clinical parameters recorded were Plaque Index (PI) Gingival Index (GI) HbA1c%. All clinical parameters were recorded at baseline, 6 weeks, and whereas HbA1c% levels were recorded at baseline and 6 weeks post-therapy.

Preparation of Red Ginseng gel (Test site)

Freshly cultivated ginseng roots were collected from the local vendor. The ginseng roots were washed, cut into small pieces, and homogenized in sterile distilled water. Then it was grinded to form a uniform gel. The obtained gel was then stored in sterile container.

Control Site

For the control sites, commercially available Rexitine M forte gel TM 15gm (containing chlorhexidine 1%, Metronidazole 1%, lignocaine 2%) was used.

Result

35 sites in 15 patients (age 20-55 years) were randomly selected for the study. The mean plaque index score at baseline for Test sites was 0.84 ± 0.13 and after 6 weeks it was further decrease to 0.61 ± 0.14 . The decreased plaque index score was significantly higher ($P > 0.05$)

compared from baseline to 6 weeks. The mean plaque index score at baseline for Control sites was 0.87 ± 0.08 and after 6 weeks it was decreased to 0.73 ± 0.16 . ($P > 0.05$) When comparison was made between Test sites and Control sites, the Test sites showed significantly reduced mean plaque index score compared to Control sites. ($P > 0.05$) (Table 1)

The mean Gingival index score at baseline for Test sites was 0.85 ± 0.11 and after 6 weeks it was further decreased to 0.69 ± 0.13 . The decreased Gingival index score was significantly higher compared to baseline as well as after 6 weeks ($P > 0.05$). The mean gingival index score at baseline for Control sites was 0.95 ± 0.05 and after 6 weeks it was decreased to 0.78 ± 0.07 ($P > 0.05$). When comparison was made between Test sites and Control sites, the Test sites showed significantly reduced mean gingival index score compared to Control sites. ($P > 0.05$) (Table 2)

The mean HbA1c% levels at baseline was 7.69 ± 0.26 which reduced to 7.1 ± 0.21 after 6 weeks which showed statistically significant difference with $p < 0.05$ (Table 3).

Discussion

The aim of the present study was to evaluate the effect of locally delivered red ginseng gel with that of chlorhexidine gel in the management of chronic gingivitis with type 2 diabetes mellitus patients.

Red ginsengs are slow growing perennial plants with fleshy roots, belonging to *Panax* species (*Panax ginseng*) of Arilaceae family. The pharmacological effects of Red Ginseng are reported as anti-allergic, anti-inflammatory, anti-oxidative and immunomodulatory effects (Hanghuihong et al in 2011) ⁴. It 2016 meta-analysis of eight studies found the benefits of using ginseng as part of a treatment program for type 2 diabetes included improved fasting glucose levels, postprandial (after eating) insulin, and insulin resistance, with no significant effects on A1C.⁷ Red ginseng has been formulated as mouthrinse and was compared with chlorhexidine and a placebo in a study by Subramaniam et al 2019.⁸ In dentistry this is the first study where ginseng gel was used in chronic periodontitis patients having type II diabetes mellitus as compared to chlorhexidine.

In the present study the use of natural gel containing red ginseng showed nonsignificant reduction in the plaque score, gingival index score at 6th week when compared to Chlorhexidine gel. For instance it is already proven that red ginseng inhibits inflammation by its potent effects on MAP kinase pathway, COX-2, and NF-kB. It inhibits pro inflammatory cytokines like TNF alpha.⁵ It has also been reported to reduce the expression of MMP-3.⁶ These properties of red ginseng would have attributed to the reduction of plaque index & gingival index. Subramaniam et al 2019 ⁸ stated that red Ginseng mouthwash has similar effects as of that of chlorhexidine in reducing the full mouth bleeding score, & Gingival Index favoring the role of red ginseng as an anti-inflammatory agent.

The mean HbA1c% levels at baseline was 7.69 ± 0.26 which reduced to 7.1 ± 0.21 after 6 weeks. The change seen may be due to the reduction of micro-organisms and inflammation after the therapy. The decrease in local periodontal inflammation reduces the levels of pro-inflammatory cytokines which are implicated to impair insulin signaling and resistance.¹⁰

According to the study conducted by Chang-Eui Hong 2011[] an anti-inflammatory and anti-oxidative effects of Korean red ginseng extract have been proved. Anti-oxidant activity was investigated by measuring 1,1-diphenyl-2-picrylhydrazyl (DPPH) radical scavenging. Shasha Fan et al 2020[] did a review which could assist the basic researchers and clinical doctors to understand current status and clinical research, and perhaps could benefit for the reasonable and accurate design of future clinical studies. Ginseng was used in the form of drugs, extracts, formulating many other forms so that it can be delivered to the patients. Esra' Shishtar et al 2014[] did meta-analysis in which 30days assessment was done. Ginseng was used in both diabetic and non diabetic patients and it was found that fasting blood glucose was reduced, and proved the anti-diabetic property of the Ginseng.

Nam-Hun Lee 2011[] conducted a systematic review in which it was proven that use of ginseng is safe for humans. 411 studies were evaluated regarding ginseng. The factors which were evaluated were glucose metabolism, physical performance, psychomotor function, sexual function, cardiac function, pulmonary disease, and cerebrovascular disease. We found strong evidence of a positive effect of ginseng on glucose metabolism, psychomotor function, and pulmonary disease, whereas evidence suggests that ginseng is not effective at enhancing physical performance. Xiuge Tang et al 2019 [] conducted meta analysis in which

beneficial effects of ginseng were seen on kidney function. It also showed improved metabolism of serum lipids by ginseng and conventional medicines.

In cancer patients for maintaining the oral health ginseng based mouthwash was used which showed more beneficiary results compared to chlorhexidine in the systematic review conducted by the Nadeem Jeddy 2022[1]. Authors concluded that red ginseng with anti-bacterial, anti-inflammatory and anti-cancerous properties may be an alternative mouth rinse in cancer patients.

Evelyn Saba et al 2018[2] evaluated anti-inflammatory effect of the red ginseng extract. Ginseng has therapeutic effects on various bodily disorders ranging from minor inflammation to major cardiovascular diseases.

Tables

Table 1: Comparison of the mean plaque index scores between test and control group at baseline, and after 6 weeks.

Group	Baseline	After 6 weeks
Test	0.84± 0.13	0.61 ± 0.14
Control	0.87 ± 0.08	0.73 ± 0.16

Table 2: Comparison of the mean Gingival index scores between test and control group at baseline and after 6 weeks.

Group	Baseline	After 6 weeks
Test	0.85 ± 0.11	0.69 ± 0.13
Control	0.95 ± 0.05	0.78 ± 0.07

Conclusion

The main aim of the study was to know more about red ginseng in the gel form in cases of chronic gingivitis suffering from type II diabetes mellitus. It was observed that red ginseng showed a significant reduction in the gingival index, plaque index and HBA1C %. Within the limitation of the study, red ginseng gel can be recommended as an adjunct for mechanical periodontal therapy and long term maintenance in supportive periodontal therapy.

Immonoblast analysis was used to assess anti-inflammatory effect. Soo Im Chung 2016 [3] conducted a study in which, diet supplementation of ginseng powders, particularly aged ginseng, markedly reduced lipid peroxidation and enhanced the antioxidant enzymes activities. Authors concluded aged ginseng has greater in vitro and in vivo antioxidant capacity than the white and red ginseng.

When coming to the adverse effects there were no reported side effects with Red Ginseng. Apart from the daily usage it is also used in long term systemic therapy for diabetes, erectile dysfunction, rheumatoid arthritis & other inflammatory disorders without any adverse effects.^{11,12,13}.

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