Sangeeetha Subramaniam et al /J. Pharm. Sci. & Res. Vol. 11(7), 2019, 2570-2573

ISSN:0975-1459
Journal of Pharmaceutical Sciences and Research
www.jpsr.pharmainfo.in

Comparison of Clinical Effectiveness of Red Ginseng Mouthwash with Chlorhexidine in Generalized Chronic Periodontitis Patients – A Randomised Controlled Clinical Trial

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Abstract

Introduction : Chlorhexidine is the gold standard mouthwash till date. But it has adverse effects like tooth staining ,etc. . In order to overcome these , herbal products with equally-qualifiable effects and least adverse reactions are used. The present herbal mouthwash in the study is composed of Red-Ginseng with anti inflammatory, anti-oxidative and immunomodulatory effects. So the aim of the present study w to evaluate the clinical effectiveness of a herbal mouthwash containing Red Ginseng on clinical parameters like Plaque Index , Gingival Index , Bleeding Index and also to compare its clinical effectiveness with that of Chlorhexidine in patients with Generalised Chronic Periodontitis

Materials And Methods : Generalized chronic periodontitis patients with PPD of ≥4mm and CAL of >2mm or both in atleast 30% of the sites are recruited for the study. A total of 30 patients are taken as sample and randomized into Group-A(Red Ginseng) , Group-B(Chlorhexidine) & Group-C(Placebo) ten each. Supragingival scaling done. Patients are instructed to use their respective mouthwash , 10ml twice daily for 21 days. Plaque Scores (O'leary in 1975) , Bleeding Scores(Ainamo & Bay in 1972) , Gingival index(Loe&Sillness in 1963) , PPD & CAL are taken at baseline and 4 weeks

Results : Our results indicates that Red Ginseng mouthwash has similar effects as of that of chlorhexidine in reducing the FMBS & Gingival Index. It shows a highly significant reduction of FMBS & Gingival Index when compared with placebo.

Conclusion : Red Ginseng has comparable effects as Chlorhexidine and can be recommended for long term use in maintenance because of less reported side effects.

Key words : mouthwash , herbal , chlorhexidine , panax ginseng , plaque index

INTRODUCTION

Periodontitis is an immunoinflammatory disorder leading to the destruction of tooth supporting hard and soft tissues causing pocket formation , recession or both . The etiological triad of the periodontitis is comprised of the pathogenic microbiota , the exaggerated inflammatory response and other modifying environmental factors . Although the microbial insult is the predominant etiological factor, host inflammvtory response plays the major role in tissue destruction.

Upon the management of periodontal disease and conditions , there are various non surgical and surgical protocols. But without plaque control measures , the success of the therapeutic protocols are questionable. Though mechanical plaque control measures are primarily necessary , chemical plaque control always stay as a strong adjuvant in the context of producing synergistic effects for preventive strategy and periodontal maintenance .

Chemical plaque control aids in prevention of periodontal disease by reducing the microbial load , improving the treatment effects and post therapeutic maintenance. Chemical plaque control comprises of various aids like mouthrinses , gels , gums , lozenges etc., among which mouth rinses are most widely recommended by the healthcare professionals. But , majority of these agents focuses on microbial load reduction than altering the host response to the microbial insult.

Till date , Chlorhexidine is a gold standard mouthwash due to its outstanding bacteriocidal and bacteriostatic effects.[1] They are profoundly used for their privileged properties like substantivity and pin cushion effects. Despite its clinical effectiveness it has multiple adverse effects like tooth discolouration, unusual/unpleasant taste or odour, mucosal irritation , parotitis[2] , etc. Though its antimicrobial effects are proven by various studies , its action on the inflammatory component of the host remains questionable.

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.[3] It inhibits inflammation by its potent effects on MAP kinase pathway,COX-2, and NF-kB . It inhibits pro inflammatory cytokines like TNF-alpha.[4] It has also been reported to reduce the expression of MMP-3.[5] In spite of its beneficial effects and minimal adverse effects there are no studies to evaluate the effects of red ginseng extracts as mouthwash.

The present study is aimed to evaluate the clinical effectiveness of a herbal mouthwash containing Red

Ginseng on various clinical inflammatory parameters like plaque index , gingival index , bleeding index and also to compare its clinical effectiveness with that of chlorhexidine in patients with Generalised Chronic Periodontitis

MATERIALS AND METHODS

The present study is a randomized controlled clinical trial , approved by the Institutional Review Board.

Sample size calculation:

Based on the study done by Anirban et al in2011,the sample size was calculated with 80% power and 5% alpha error. Accordingly a total of 30 generalized chronic periodontitis patients were recruited for the study

GROUP A : RED GINSENG GROUP

GROUP B : CHLORHEXIDINE GROUP

GROUP C : PLACEBO GROUP

A total of 30 Generalized chronic periodontitis patients with ten patients in each group were considered. Patients are selected when presented with a Probing pocket depth ≥4mm and clinical attachment level of ≥2mm . On the other hand patients with any systemic diseases which modify the periodontal disease , past periodontal therapy within 6 months were excluded. In addition , patients taking any other antibiotic or anti-inflammatory medication or usage of anyother mouthwash were also not considered for the study.

The patients who satisfied the above mentioned criterias were informed about the nature of the study and written consent was obtained from the subjects who were willing to participate. After recruitment the Probing pocket depth , Clinical attachment level , Full Mouth Plaque scores (O'Leary T 1975)[6] ,Full Mouth Bleeding scores(Ainamo and Bay 1972)[7] and Gingival index(Sillness and Loe 1963)[7], were recorded by a single caliberated examiner . Following this a supragingival scaling was done to all the 30 patients.

The patients were randomly allocated to either of the three groups of the study. The groups are the following :

GROUP A : RED GINSENG GROUP : The patients of this group were prescribed with the Red Ginseng mouthwavsh(dr. dental care commercial mouthwash) . The patients are instructed to use 10ml of the mouthwash with the given measuring cup twicw daily , for 21 days.

GROUP B : CHLORHEXIDINE GROUP : The patients of this group were prescribed with Chlorhexidine mouthwash. The patients are instructed to use 10ml of the mouthwash with the given measuring cup twice daily , for 21 days.

GROUP C: PLACEBO GROUP : the patients of this group were prescribed with a placebo mouthwash without any active ingredients. The patients are instructed to use 10ml of the mouthwash with the given measuring cup twice daily , for 21 days.

The clinical readings were repeated at the end of 4 weeks.

Statistical Analysis :

The statistical analysis was done by SPSS version 7. For quantitative variables like Probing pocket depth and Clinical attachment level the intra group comparison was done with paired-t test. Inter group comparison was done with ANOVA test and F ratio was calculated. For qualitative variables like Plaque score , Bleeding score and Gingival index the intragroup comparison was done with Mann-whitney U test and Intergroup comparison was done with Kruskal wallis test.

RESULTS

Table 1 revealed the baseline comparison of the clinical parameters. There were no statistical siginificant differences were seen among the parameters at the baseline between the groups revealing the homogeneity of the samples.

Table 2 revealed that there were statistically significant differences found in the values of FMBS & Gingival index indicating a good reduction in those scores at 4 weeks in the Red Ginseng group.

Table 3 revealed the intragroup comparison of the chlorhexidine group where there was a statistically significant differences found in relevance with FMPS , FMBS & Gingival Index with a good reduction in all the three values at 4 weeks

Table 4 revevled that there were no statistical differences in the clinical parameters between baseline and 4 weeks in the placebo group.

Table 5 revealed the intergroup comparison of all the clinical parameters at 4 weeks. There was a significant difference seen in FMBS & Gingival Index

When comparing the Red Ginseng group (Group A) with CHX group (Group B) there was no significant differences seen , whereas when comparing it with control group(Group C) there was a singnificant difference in FMBS & Gingival index.(table 6)

TABLE 1: COMPARISON OF CLINICAL PARAMETERS AT BASELINE

CLINICAL PARAMETERS	RED GINSENG Mean ± S.D.	CHX Mean ± S.D.	PLACEBO Mean ± S.D.	P-VALUE ($p<0.05$)
AGE	59.1±17.4	62.1±8.3	51.2±2.03	0.179
PROBING POCKET DEPTH	5.3±0.81	5.0±1.33	5.4±1.35	0.714
CLINICAL ATTACHMENT LEVEL	6.7±0.94	6.2±0.91	6.2±0.71	0.361
FMPS	87.8±12.96	94±6.18	90.5±10.76	0.418
FMBS	87±5.75	93±5.35	88.4±8.78	0.138
GINGIVAL INDEX	3.0±0.0	2.6±0.51	2.9±0.31	0.06

FMPS - Full Mouth Plaque scores

FMBS – Full Mouth Bleeding Scores

TABLE 2 : INTRAGROUP COMPARISON OF THE CLINICAL PARAMETERS IN RED GINSENG GROUP(GROUPA)

CLINICAL PARAMETERS	BASELINE Mean ± S.D	4 WEEKS Mean ± S.D	P-VALUE (p<0.05)
PROBING POCKET DEPTH	5.3±0.81	5.1±0.50	0.167
CLINICAL ATTACHMENT LEVEL	6.7±0.94	6.5±0.84	0.168
FMPS	87.8±12.96	87.5±10.59	0.21
FMBS	87±5.75	65.8±13.71	0.002
GINGIVAL INDEX	3.0±0.0	2.1±0.57	0.000

FMPS - Full Mouth Plaque scores
FMBS – Full Mouth Bleeding Scores

TABLE 3 : INTRAGROUP COMPARISON OF THE CLINICAL PARAMETERS IN CHLORHEXIDINE GROUP (GROUP-B)

CLINICAL PARAMETERS	BASELINE Mean ± S.D	4 WEEKS Mean ± S.D	P-VALUE (p<0.05)
PROBING POCKET DEPTH	5.0±1.33	4.3±0.91	0.25
CLINICAL ATTACHMENT LEVEL	6.2±0.91	6.3±0.94	0.34
FMPS	94±6.18	81.4±7.56	0.01
FMBS	93±5.35	60±6.98	0.00
GINGIVAL INDEX	2.6±0.51	1.9±0.31	0.001

FMPS - Full Mouth Plaque scores
FMBS – Full Mouth Bleeding Scores

TABLE 4 INTRAGROUP COMPARISON OF CLINICAL PARAMETERS IN PLACEBO GROUP (GROUP-C)

CLINICAL PARAMETERS	BASELINE Mean ± S.D	4 WEEKS Mean ± S.D	P-VALUE (p<0.05)
PROBING POCKET DEPTH	5.4±1.35	4.5±0.50	0.06
CLINICAL ATTACHMENT LEVEL	6.2±0.71	6.0±0.99	0.21
FMPS	90.5±10.76	81.5±6.19	0.50
FMBS	88.4±8.78	85.7±6.29	0.13
GINGIVAL INDEX	2.9±0.31	2.5±0.52	0.03

FMPS - Full Mouth Plaque scores
FMBS – Full Mouth Bleeding Scores

TABLE 5 : INTERGROUP COMPARISON OF CLINICAL PARAMETERS AT 4 WEEKS

CLINICAL PARAMETERS	RED GINSENG Mean ± S.D	CHX Mean ± S.D	PLACEBO Mean ± S.D	P-VALUE (p<0.05)
PROBING POCKET DEPTH	5.1±0.50	4.3±0.91	4.5±0.50	0.06
CLINICAL ATTACHMENT LEVEL	6.5±0.84	6.3±0.94	6.0±0.99	0.35
FMPS	87.5±10.59	81.4±7.56	81.5±6.19	0.131
FMBS	65.8±13.71	60±6.98	85.7±6.29	0.000
GINGIVAL INDEX	2.1±0.57	1.9±0.31	2.5±0.52	0.030

FMPS - Full Mouth Plaque scores
FMBS – Full Mouth Bleeding Score

TABLE 6 : COMPARISON OF RED GINSENG GROUP TO CHLORHEXIDINE AND PLACEBO GROUP

CLINICAL PARAMETERS	GROUP A VS B (p-values)	GROUP A VS C (p-values)
PROBING POCKET DEPTH	0.07	0.06
CLINICAL ATTACHMENT LEVEL	0.31	0.08
FMPS	0.49	0.50
FMBS	0.124	0.000
GINGIVAL INDEX	0.171	0.05

FMPS- Full Mouth Plaque Scores
FMBS – Full Mouth Bleeding Scores
p- values - p<0.05

DISCUSSION

Chlorhexidine is considered one of the gold standard mouthwashes since the day it is found. But its long term usage is restricted because of its unpleasant taste alterations and its ability to stain the teeth.[2] This lead to a continuous search in the alternate with comparable efficacy & reduced adverse effects.

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 (Hang hui hong et al in 2011). In dentistry this is the first study where red ginseng is formulated as mouthrinse and compared with chlorhexidine and a placebo.

The results of the present study revealed that in the Red Ginseng group there is a significant reduction of FMPS , FPBS and Gingival index between baseline & 4 weeks. This emphasises the antibacterial & anti-inflammatory effects of chlorhexidine which is already proven. The red ginseng group also demonstrated a significant reduction of of FMBS & Gingival index between baseline & 4 weeks. This indicates that red ginseng has potent anti-inflammatory & anti-oxidant properties. 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 (lorne . j hofseth and Michael. J . wargovich in 2016). It has also been reported to reduce the expression of MMP-3 (Ki rim kim et al in 2010). These properties of red ginseng would have attributed to the reduction of fmbs & gingival index.

Red Ginseng exhibited almost a comparable results as that of chlorhexidine after 4 weeks of use. This indicates that the anti-inflammatory properties of red ginseng are similar to chlorhexidine. There was a difference in FMPS , because Red Ginseng does not possess anti-bacterial property. But based on the recent models of pathogenesis not only bacteria , also the host immunoinflammatory response plays a vital role in modifying the periodontal disease. Thus it is necessity to get agents with profound immunomodulatory properties to act as an adjuvant to mechanical plaque therapy. It is also revealed that Red Ginseng has improved FMBS & Gingival Index than placebo group. This once again favors the anti-inflammatory role of Red Ginseng.

When coming to the adverse effects there were no reported side effects with Red Ginseng even on a daily basis consumption in tea form . 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. [8, 9, 10]

CONCLUSION

Thus within the limitations of present study , it is proven that red ginseng has a comparable anti-inflammatory effects as chlorhexidine with no reported side effects. Thus this red ginseng mouthwash can be recommended as an adjunct for mechanical periodontal therapy and long term maintenance in supportive periodontal therapy as a mouthrinse.

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