

Anti-plaque efficacy of Hi-Ora mouthrinse and 0.12% chlorhexidine gluconate in patients with chronic gingivitis: A case–control study

Melwin Mathew¹, Joyshree C², Velagapalli Jessie Ratan³, Votturu Kartheek⁴, Thirumalai S⁵, Mohan Nayak Banothu³

¹Department of Periodontics and Oral Implantology, Faculty of Dentistry, Manipal University College, Melaka Campus, Bukit Baru, Melaka, Malaysia, ²Consultant Periodontist, Chennai, Tamil Nadu, ³Department of Orthodontics and Dentofacial Orthopedics, Lenora Institute of Dental Sciences, Rajahmundry, ⁴Department of Conservative Dentistry and Endodontics, CKS Teja Institute of Dental Sciences and Research, Tirupati, Andhra Pradesh, ⁵Department of Periodontology, Sri Venkateswara Dental College, Ariyur, Puducherry, India

Abstract

Background: Chlorhexidine (CHX) gluconate has remained the gold standard chemical plaque control agent till date, though, being associated with several disadvantages including its tendency to stain teeth and leading to irritation of soft tissues. To overcome these inherent disadvantages, there has been a surge of studies in the recent past to evaluate the efficacy of herbal mouthrinses as against CHX.

Objective: The present study was planned to compare the anti-plaque efficacy of Hi-Ora mouthrinse as against 0.12% CHX in patients with chronic gingivitis.

Materials and Methods: The present study was designed as a case–control study including 90 patients with chronic gingivitis who were divided into 3 groups including Group A in which 0.12% CHX was prescribed, Group B in which patients were prescribed Hi-Ora and Group C in which normal saline was prescribed after oral prophylaxis while the mean Gingival Index (GI) and Plaque Index (PI) scores were recorded on the 5th postprocedural day.

Results: The mean GI score in CHX group was found to be 0.70 ± 0.25 as against 0.66 ± 0.16 in Hi-Ora and 1.59 ± 0.55 in normal saline groups. Similarly, the mean PI score in CHX group was found to be 0.80 ± 0.31 as against 0.77 ± 0.30 in Hi-Ora and 1.86 ± 0.61 in normal saline groups.

Conclusions: The results of the present study suggested Hi-Ora to be more effective than 0.12% CHX in reducing the mean GI and PI scores among all the 3 groups.

Keywords: Case–control studies, chlorhexidine, gingivitis, normal saline

Address for correspondence: Dr.Melwin Mathew, Department of Periodontics and Oral Implantology, Faculty of Dentistry, Manipal University College, Melaka Campus, Bukit Baru, Melaka, Malaysia.

E-mail: drmelwinmathew@gmail.com

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INTRODUCTION

Plaque is considered to be the prime etiological factor in gingival inflammation while as a mainstay to maintaining good gingival and periodontal health, mechanical plaque control measures including toothbrush, floss and interdental brushes have been used since ages. However, the degree of motivation and skill required for an effective use of these measures might be beyond the ability of majority of the patients. Hence, a chemical plaque control approach remains highly desirable to deal with the potential deficiencies of daily self-performed oral hygiene methods. Several antimicrobial agents, including chlorhexidine (CHX) gluconate and metronidazole etc., have been used as established chemical plaque control measures in the contemporary times.^[1]

CHX gluconate has remained one of the most effective chemical plaque control agent reported till date and has been successfully used in the management of plaque-induced gingivitis. CHX is a positively charged cationic bis-biguanide with a broad spectrum antimicrobial role and that can be adsorbed to a variety of negatively charged sites in oral cavity including the mucous membranes, salivary pellicle on the teeth and several components of the biofilm on tooth surfaces including the pathogenic bacteria, extracellular polysaccharides and glycoproteins. The possible role of CHX for its anti-plaque activity was first reported by Loe and Schiott in 1970. Moreover, CHX has a distinct ability to be retained in oral cavity for several hours after application because of its high affinity for and subsequent retention by oral tissues making it a useful agent even in prevention of plaque re-growth and bacterial colonization.^[2]

A plethora of studies have proven the efficacy of CHX administration in various forms and it is still considered the gold standard chemical plaque control agent for its potent and broad-spectrum antimicrobial efficacy against both gram-positive and gram-negative bacteria as well as fungi and certain viruses. Numerous *in-vitro* studies have shown that even in low concentrations, CHX causes destruction of cell membranes of microorganisms and leads to an escape of low molecular weight molecules leading to cell death. A higher concentration of CHX, on the contrary, leads to precipitation and coagulation of proteins in the cytoplasm of exposed microbes exerting antimicrobial action. These properties, eventually, interfere with biofilm formation and prevent gingivitis.^[2]

As a matter of concern, however, it has, also, been seen that commercially available mouthrinses containing CHX have several disadvantages including their tendency to stain

teeth and leading to irritation of soft tissues as being the most common complaints. To overcome these, naturally occurring antimicrobial agents are being used individually or, in combination.^[3] In this list, even, normal saline has been shown to have mild anti-plaque activity when used with dexterity.^[2] A plethora of studies have suggested possible use of herbal mouthrinses as significant adjuncts to mechanical plaque control measures as against CHX. Hi-Ora is one such herbal mouthrinse which is proven to have significant anti-plaque and antimicrobial properties. It has active herbal ingredients that act against common oral bacteria and fungi.^[3] The present study was, thus, planned to compare the anti-plaque efficacy of Hi-Ora mouthrinse as against 0.12% CHX in patients with chronic gingivitis.

MATERIALS AND METHODS

The present study was designed as a case–control study including 90 patients with chronic gingivitis, diagnosed on the basis of established criteria of changes in the color, contour, consistency, texture, size and position of gingiva in addition to the tendency to go for bleeding on probing or, spontaneous bleeds, in an age range of 20 and 45 years, with a minimum of ten teeth present in each arch. The patients who presented with known hypersensitivity to mouthrinses, those who were diagnosed with advanced periodontal disease, patients with systemic diseases and pregnant and lactating females were excluded from the study. The patients who were unwilling to participate in the study and complete the treatment protocol were, also, excluded. The study protocol was approved by the Institutional Ethics Committee through letter approval no. SDDC/IEC/07-39-2018 while a written, informed consent was obtained from each participant before their inclusion into the study. The selected patients were divided into 3 groups with 30 patients in each group using simple randomization process including Group A in which 0.12% CHX was prescribed, Group B in which patients were prescribed Hi-Ora and Group C in which normal saline was prescribed (as a control) after oral prophylaxis. The mean Gingival Index (GI) (Loe and Silness, 1963) and Plaque Index (PI) (Silness and Loe, 1964) scores were recorded on the 5th postprocedural day by a single observer who was blinded for the groups to avoid recording bias.^[4,5] For the purpose of scoring, the gingival tissues surrounding each tooth were divided into four main areas including the disto-labial, labial, mesio-labial and lingual margins of gingiva while the teeth and associated soft tissues were lightly air dried and then wiped with cotton rolls before assessment. For scoring in case of GI, score 0 was allotted in case of absence of inflammatory component/normal gingiva while Score 1 was allotted for mild inflammatory

component including slight change in color with evidence of edema, though, with evidence of no bleeding on probing, Score 2 in case of moderate inflammatory component including features such as erythema, edema, hypertrophy and bleeding on probing while Score 3 for severe inflammatory changes including marked erythema, hypertrophy, ulceration and a tendency for spontaneous bleeds.^[4] For the purpose of scoring for the PI, an explorer was passed across the tooth surface in the cervical third and near the entrance to gingival sulcus while Score 0 was allotted in case there was no plaque, Score 1 in case plaque was detected near the free gingival margin and adjacent areas of the tooth while it was detected only by running a probe across the tooth surface, Score 2 in case of moderate accumulation of plaque deposits within the gingival pocket, on the gingival margin and adjacent tooth surface and Score 3 for abundance of deposits within the gingival pocket and near the free gingival margin and adjacent areas of the tooth.^[5] Furthermore, during the assessment of GI and PI scores, the examination for the PI scores was preceded by examination for the GI scores since manipulation of gingival tissues, in case of inflammation, led to bleeding on provocation [Figures 1-4]. Postprocedural instructions included brushing twice a day with a soft brush with the prescribed rinse to be used after brushing.

Statistical analysis used

The results obtained were tabulated and subjected to statistical analysis wherein inter-group comparisons

between different groups were drawn by using analysis of variance (ANOVA) and Tukey's *post hoc* test while $P < 0.05$ was considered statistically significant.

RESULTS

Table 1 reveals gender-wise distribution of the patients while Tables 2 and 3 reveal intergroup comparisons of the mean GI and PI scores in the groups using ANOVA and Tukey's *post hoc* test, respectively. The mean GI score in CHX group was found to be 0.70 ± 0.25 as against 0.66 ± 0.16 in Hi-Ora and 1.59 ± 0.55 in normal saline groups indicating least GI scores in Hi-Ora group while the results were found to be statistically highly significant ($P < 0.0001$). Similarly, the mean PI score in CHX group was found to be 0.80 ± 0.31 as against 0.77 ± 0.30 in Hi-Ora and 1.86 ± 0.61 in normal saline groups indicating the least PI scores in Hi-Ora group, once again, with statistically significant results ($P < 0.0001$) [Table 2]. The results of the present study, thus, suggested Hi-Ora to be the most effective rinse in reducing the mean GI and PI scores among all 3 groups. Furthermore, on inter-group comparisons, the results were found to be statistically significant when compared between CHX and normal saline and Hi-Ora and normal saline groups, though, insignificant between groups using CHX and Hi-Ora in case of both GI and PI scores [Table 3].

Table 1: Gender-wise distribution of the patients

Group	Gender	
	Male (%)	Female (%)
Group A - 0.12% CHX group	20 (67)	10 (33)
Group B - Hi-Ora group	21 (70)	9 (30)
Group C - Normal saline group	19 (63)	11 (37)

CHX: Chlorhexidine



Figure 1: Armamentarium used in study



Figure 2: (a) Immediate post-procedural, (b) Post-procedural photograph on 5th day

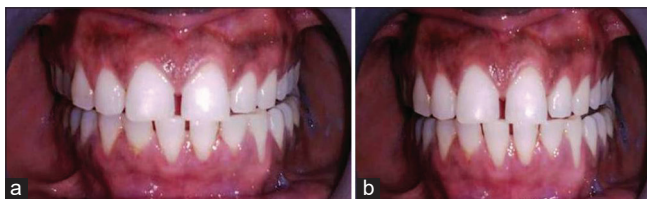


Figure 3: (a) Immediate post-procedural, (b) Post-procedural photograph on 5th day

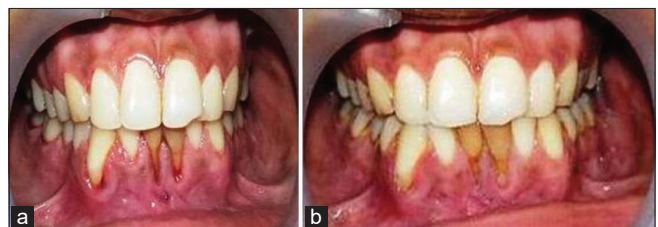


Figure 4: (a) Immediate post-procedural, (b) Post-procedural photograph on 5th day

Table 2: Intergroup comparisons between different groups using analysis of variance

Clinical parameter	Group (mean±SD)			P	Post hoc test
	Group A-0.12% CHX group	Group B-Hi-Ora group	Group C-normal saline group		
GI	0.70±0.25	0.66±0.16	1.59±0.55	<0.0001**	NS > CHX > HO
PI	0.80±0.31	0.77±0.30	1.86±0.61	<0.0001**	NS > CHX > HO

** $P < 0.0001$ - highly significant. SD: Standard deviation, CHX: Chlorhexidine, NS: Nonsignificant, GI: Gingival index, PI: Plaque index

Table 3: Intergroup analysis using Tukey's post hoc test

Clinical parameter	Post hoc test	P
GI	0.12% CHX versus Hi-Ora	0.918
	0.12% CHX versus normal saline	0.0001**
	Hi-Ora versus normal saline	0.0001**
PI	0.12% CHX versus Hi-Ora	0.94
	0.12% CHX versus normal saline	0.0001**
	Hi-Ora versus normal saline	0.0001**

** $P < 0.0001$ - highly significant. GI: Gingival index, PI: Plaque index, CHX: Chlorhexidine

DISCUSSION

Several factors have been shown to modulate clinical expression of gingival inflammation in response to plaque accumulation. Conceptually, one may regard periodontal disease as a host-microbial interaction in which both host and bacterial factors determine the outcome.^[1] Under the classification system of the American Academy of Periodontology, gingivitis is defined as an inflammatory lesion which is confined to tissues of the marginal gingiva. Gingivitis, if untreated, can lead to destruction of the periodontal tissues resulting in eventual tooth loss suggesting the significance of potential plaque control measures.^[1]

CHX, developed in the 1950s, is still considered the gold standard and one of the most effective anti-plaque agents available, although, long-term usage of the same is limited by its disagreeable taste and propensity to lead to staining of the teeth. The need for a new formulation with similar or, superior efficacy and with lesser side effects and safety, thus, has always been felt. Hi-Ora mouthrinse used in the present study is one such chemical plaque control adjunct with proven anti-plaque and antimicrobial properties.^[3] The present study, thus, aimed at evaluating the anti-plaque efficacy of Hi-Ora mouthrinse as against 0.12% CHX in patients with chronic gingivitis.

Hi-Ora is a herbal mouthrinse preparation containing miswak (*Salvadora persica*), bibhitaka (*Terminalia bellerica*), *Gandha purataila* and nagavalli (*Piper betle*) which are proven to have significant anti-plaque, antimicrobial, antiseptic and analgesic properties. Furthermore, the alkaloid present in *S. persica*, salvadorine, yields trimethylamine on hydrolytical cleavage exerting a bactericidal effect and stimulatory action on gingiva while mild bitter taste of the mouthrinse

stimulates salivary flow which is antiseptic. Furthermore, tannins present in miswak inhibit action of enzyme glucosyl transferase reducing plaque build-up while sulfur compounds have an independent antibacterial effect. In addition to all these potential advantages, the silica present in miswak, also, acts as an abrasive to remove stains.^[3]

Furthermore, the GI (Loe and Silness, 1963) used in the present study was indeed created to record qualitative changes in the gingival soft tissues while the PI (Silness and Loe, 1964), originally devised by Silness and Loe in 1964 and substantiated by Loe and Silness, later, in 1967, is unique among the indices used for assessment of plaque because it takes into account only the plaque thickness which is present near the gingival margin of the tooth and is one of the most widely used indices that has revealed good validity, reliability and ease of use over the years since the time of inception.^[4,5]

In the present study, a significant difference in the mean GI and PI scores ($P < 0.0001$) was observed at follow-up visit of patients on the 5th postprocedural day between the CHX versus normal saline and Hi-Ora versus normal saline groups similar to the findings of the study conducted by Parwani *et al.* who observed the least GI and PI scores in 0.2% CHX group followed by herbal mouthrinse group while highest in the normal saline group.^[6] Biswas *et al.*, also, observed CHX to be more efficacious in terms of improvement of GI and PI scores than herbal mouthrinse, though, both CHX and herbal mouthrinse were equally effective in reducing bleeding on probing.^[7] Similarly, Vaish *et al.* observed significant reduction in GI and PI scores in both the groups using CHX and herbal mouthrinse and improvement in GI and PI scores to be better in CHX group than herbal mouthrinse group, though, both the CHX and herbal mouthrinse were found to be equally effective in reducing bleeding on probing. Furthermore, unlike CHX, herbal mouthrinse was not associated with discoloration of teeth or, unpleasant taste and was found to be better accepted by patients as against CHX.^[8] Asiri *et al.*, also, observed significant reduction in GI and PI scores in both the groups using herbal mouthrinse and CHX concluding with the possibility of herbal mouthrinses to be used as an efficient replacement for CHX in the pretext of the inherent adverse effects seen with long-term usage of CHX.^[9]

Bhat *et al.*, though, observed no significant difference in the antimicrobial properties of herbal mouthrinse and CHX concluding both to be equally effective in inhibiting the microbial growth while yet another study conducted by Shetty *et al.*, also, concluded herbal mouthrinse to be as effective as CHX as chemical anti-plaque agent with fewer adverse effects.^[10,11] Similar conclusions were drawn in the study conducted by Gupta *et al.* who observed herbal mouthrinse to be equally effective as CHX in reducing plaque and gingivitis in the patients studied. Furthermore, CHX was reported to lead to potential side effects, as reported by the patients, which limited its acceptability as against the herbal mouthrinse.^[12] In a similar study, Bagchi *et al.*, also, observed herbal mouthrinse and CHX to be equally effective as adjuncts to mechanical plaque control regimes in prevention of dental plaque and gingivitis.^[13]

In yet another study, Marrelli *et al.*, on analysis of clinical data from a trial carried-out with 3 different mouthrinses including 0.2% CHX concluded that, though, efficacy of CHX was found to be unmatched, all 3 mouthrinses tested were effective in reducing plaque formation in the absence of brushing as well as aided in protection of gingival tissues.^[14] Pathan *et al.*, though, in their study, found no statistically significant difference between herbal mouthrinse and CHX on select organisms in the *in-vitro* and *ex-vivo* models used in their study. Furthermore, based on the *ex-vivo* results obtained in their study, they concluded that none of the selected mouthrinses were statistically different from each other.^[15]

In a study alike, Subramaniam and Gupta found herbal mouthrinse to be effective in decreasing oral microbial load in chronic gingivitis patients in their study while Malhotra *et al.* concluded, from the findings of their study, that though herbal mouthrinse was found to be less effective than CHX as a potential plaque inhibitor, it was more acceptable to the patients including diabetics and xerostomics as an alternative to CHX.^[16,17] Contrary to the findings of these studies, though, Jaidka *et al.* observed maximum anti-plaque, anti-gingivitis and antibacterial effects in case of herbal mouthrinse and minimum effect in case of CHX in contradiction to the previous studies.^[18] Nevertheless, CHX still remains the gold standard as one of the most effective chemical anti-plaque agent, though, the results obtained in the present study emphasize need for further studies in this regard to substantiate clinical efficacy of herbal mouthrinses with similar or, higher antimicrobial efficacy than CHX to overcome the well-known disadvantages associated with long-term use of CHX.

Strengths and limitations of present study: The major strength of the present study was that it attempted to compare the anti-plaque efficacy of Hi-Ora mouthrinse as against 0.12% CHX which is the best available chemical anti-plaque agent till date in a strict case-control model while a potential limitation of the present study was that follow-up in the present study was done only for a shorter duration of time which mandates the need for further studies with potential follow-up periods to validate the results obtained in the present study as well as to check for the consistency of the effects seen with herbal mouthrinses over a prolonged period of time.

CONCLUSIONS

From the results obtained, it could be inferred that there was a significant difference in mean GI and PI scores ($P < 0.0001$) between the CHX versus normal saline and Hi-Ora versus normal saline groups, however, further multi-centric, randomized controlled clinical trials with larger sample sizes are mandated to come to valid conclusions.

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Conflicts of interest

There are no conflicts of interest.

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