



HERBAL MOUTHRINSE (HI-ORA) VERSUS 0.12% CHLORHEXIDINE (CHX): HOW FAR WE HAVE REACHED, AN EVIDENCE BASED STUDY

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Abstract:

The present study was planned to compare the efficacy of herbal mouthrinse (Hi-Ora) as against 0.12% chlorhexidine (CHX) in the treatment of patients with chronic gingivitis. The present study was designed as an observational, evidence based study including 120 patients with chronic gingivitis who were divided into 3 groups based on the mouthrinse prescribed, while the mean Gingival Index (GI) and Plaque Index (PI) scores were recorded after 3 weeks. The data was analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). On analyzing the results, the mean GI scores (post-intervention) were found to be 0.72 ± 0.29 in the CHX group, while 0.69 ± 0.18 in the Hi-Ora, and 1.61 ± 0.57 in the normal saline groups, with the results being statistically significant ($p < 0.0001$). Similarly, the mean PI scores in the present study were found to be 0.82 ± 0.36 in the CHX group, with the corresponding values being, 0.81 ± 0.29 in the Hi-Ora, and 1.87 ± 0.63 in the normal saline groups. The results in case of the mean PI scores were, also, found to be statistically significant ($p < 0.0001$). The results of the present study suggested herbal mouthrinse (Hi-Ora) to be equally efficacious as 0.12% CHX in reducing the mean GI and PI scores in patients with chronic gingivitis.

Keywords: chlorhexidine, Hi-Ora, gingivitis, normal saline

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INTRODUCTION:

Plaque is considered to be the prime etiologic factor in gingival inflammation, while several factors have been shown to modulate the clinical expression of gingival inflammation in response to plaque accumulation (Murakami et al., 2018). The most common clinical features of plaque-induced gingivitis include inflammatory changes confined to the free gingival margin along with attached gingiva, presence of high bacterial plaque (burden), reversibility of inflammatory changes on removal of plaque biofilm, and stable attachment levels on the periodontium which may or, may not have experienced alveolar bone loss (Trombelli et al., 2018; Trombelli et al., 2018). The diagnostic criteria for gingivitis are based largely on the clinical features, while radiographs are not considered essential since gingivitis is considered to be a disease process that affects and involves only the soft tissues (gingival soft tissues) without secondary bone involvement. The clinical signs of gingivitis include erythema in relation to the inflamed gingival soft tissues, swelling with loss of knife-edged gingival margins, and blunting of papillae, bleeding and discomfort on clinical probing and/or, a tendency for spontaneous bleeds based on the severity of inflammation, and pain, limiting function in the involved region (Murakami et al., 2018). Under the classification system of the American Academy of Periodontology (AAP), gingivitis is defined as an inflammatory condition which is confined to the tissues of marginal gingiva, which if left untreated, can involve other areas of the gingiva, and periodontal tissues, resulting in eventual alveolar bone and tooth loss in the area of involvement (Chapple et al., 2018). Although there are no objective, clinical criteria for defining the severity of gingivitis, Gingival Index (GI) by Löe H can be used to describe the extent of gingivitis (mild, moderate and severe) based on the clinical signs and symptoms (Löe, 1967).

Chlorhexidine (CHX) gluconate, developed in the 1950's, is still considered the gold standard and one of the most effective anti-plaque agents with clinically proven, broad spectrum, antimicrobial efficacy, although, long-term usage of CHX is limited by its disagreeable taste and tendency to lead to staining of the teeth (Gürkan et al., 2006; Helms et al., 1995). CHX is a cationic, bis-biguanide which gets adsorbed to a variety of negatively charged sites in the oral cavity including mucous membranes, salivary pellicle and plaque biofilms, which are considered to be the prime etiologic factors in gingival inflammation. Moreover, CHX has a distinct

ability to be retained on to the soft and hard tissues of the oral cavity (after adsorption) with a tendency to release the drug slowly over a prolonged period of time, enabling its action for several hours (substantivity), aiding in the prevention of plaque re-growth and bacterial colonization (Mali et al., 2012). There is no dearth of studies that have proven the antimicrobial efficacy of CHX for its potent and broad spectrum, antimicrobial activity against a plethora of gram-positive and gram-negative bacteria, and even, fungi and certain viruses. As a matter of concern, though, commercially available mouthrinses containing CHX have been reported with certain disadvantages including altered/metallic taste, irritation of soft tissues and staining of the teeth over a period of time as the major complaints (Mali et al., 2012; Narayan and Mendon, 2012). Also, CHX has been shown to induce cytotoxic and also, genotoxic effects in the host cells over a period of time (Liu et al., 2018). Recently, there have been few studies which have validated herbal mouthrinses as an effective substitute to CHX. A recent systematic review and meta-analysis investigated the efficacy of a green tea-based herbal mouthrinse in terms of the mean Gingival Index (GI) and Plaque Index (PI) scores and demonstrated that the herbal mouthrinse was not significantly different compared to the gold standard CHX, in reducing plaque and gingival inflammation (Mathur et al., 2018). Similarly, Kaur et al, also, concluded from the results obtained in their study that the green tea-based mouthrinse served as an effective anti-plaque agent, while emphasizing the need for further studies in this regard to explore the long-term benefits of green tea mouthrinses as an effective substitute to CHX (Kaur et al., 2014). The three major groups of plant polyphenols, including stilbenes, flavonoids, and proanthocyanidins, have been found to exhibit significant anti-caries activity, and efficacy against periodontitis and candidiasis in various pre-clinical studies conducted in the past, however, a strong general consensus and evidence for the same is lacking. There have been a plethora of clinical studies that have researched on similar areas, though, conflicting reports have been obtained in the various randomized controlled trials (RCTs) conducted so far (Varoni et al., 2012). In similar context, herbal mouthrinse (Hi-Ora) used in the present study has been reported with proven, anti-plaque and antimicrobial properties (Narayan and Mendon, 2012). It has active herbal ingredients in the form of 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 Miswak (*Salvadora persica*), salvadorine, yields trimethylamine on hydrolytic cleavage exerting bactericidal effect, while simultaneously having a stimulatory action on the gingiva. Tannins present in Miswak inhibit the action of enzyme, glucosyl transferase, reducing plaque build-up, as, also, the sulfur compounds which have independent antibacterial effect. The silica present in Miswak, also, acts as a mild abrasive and removes stains on the teeth (Narayan and Mendon, 2012). The present study was planned to compare the clinical efficacy of herbal mouthrinse (Hi-Ora) as against 0.12% chlorhexidine (CHX) in the treatment of patients with chronic gingivitis.

MATERIALS AND METHODS:

The present study was designed as an observational, evidence based study in the Department of Periodontology over a period of 1 and ½ years to evaluate the clinical efficacy of herbal mouthrinse (Hi-Ora) as against 0.12% chlorhexidine (CHX) in the treatment of patients with chronic gingivitis. Prior to the commencement of the study, the study protocol was approved by the Institutional Ethics Committee via letter approval no. SDDC/IEC/09-377-2021. Furthermore, the patients who fulfilled the inclusion criteria were explained in detail about the study protocol in vernacular language, while a written informed consent was obtained before their inclusion in the study.

Sampling criteria used: The present study included 120 patients with chronic gingivitis in an age range of 20 to 45 years. The patients included in the study had reported with a tendency for bleeding during brushing and/or, spontaneous bleeds, metallic/altered taste, pain/soreness, halitosis, difficulty in eating, appearance of red, swollen gingiva and reduced oral health-related quality of life (QoL) as the major reporting complaints and were diagnosed with mild to moderate gingivitis on the basis of established clinical criteria of change in color, contour, consistency, texture, size, and position of gingiva (Murakami et al., 2018; Trombelli et al., 2018; Trombelli et al., 2018). The selected patients were allotted to the specified groups based on the simple randomization technique, while patients with a minimum of ten teeth in each arch, only, were included in the study. The patients who were diagnosed with any stage or, grade of periodontitis

[according to the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions, co-presented by the American Academy of Periodontology (AAP), and the European Federation of Periodontology (EFP)] (Chapple et al., 2018), patients who presented with a known hypersensitivity to mouthrinses, patients with systemic diseases and pregnant and lactating females were excluded from the study. The patients who were unwilling to participate in the study or, expressed their inability to complete the treatment protocol and follow-up required, were, also, excluded.

Clinical protocol followed: The selected patients were divided into 3 groups with 40 patients in each group using simple randomization technique, including Group A in which 0.12% CHX (Hexidine® 60 ml, ICPA Health Products Ltd., Mumbai, India) was prescribed, Group B in which patients were prescribed herbal mouthrinse (Hi-Ora) (Himalaya Drug Company, Bangalore, India), and Group C in which normal saline was prescribed (as control) after oral prophylaxis. The herbal mouthrinse (Hi-Ora) (Himalaya Drug Company, Bangalore, India) used in the present study consisted of the extracts of Miswak/Pilu (*Salvadora persica*) 5mg, Bibhitaka (*Terminalia bellerica*) 10mg, Nagavalli (*Piper betle*) 10mg, essential oils, namely, Gandhapura taila (*Gaultheria fragrantissima*) 1.2mg, Ela (*Elettaria cardamomum*) 0.2mg, flavoring agents, Peppermint satva (*Mentha*)1.6mg and Yavani satva (*Trachyspermum ammi*) 0.4mg in 30ml w/v. The clinical parameters of gingivitis were assessed on the basis of improvement in the mean Gingival Index (GI) (Löe and Silness, 1963) and Plaque Index (PI) (Silness and Löe, 1964) scores after 3 weeks, checking for any significant variations in the clinical parameters recorded, while the post-procedural instructions included brushing twice a day with a soft brush with the prescribed rinse, after brushing, post-meals. The subjects were advised to swish the mouthrinse in the prescribed strength (10 ml twice a day for 1 week) around in the mouth for duration of 30 seconds and then, spit-out. There were no drop-outs reported in the study, while the patients complied with the instructions given as assessed on the re-call visits of the patients.

Observational parameters and bias in recording parameters: For the purpose of scoring in case of Gingival Index (GI), the gingival tissues surrounding each tooth were divided into four main areas including the disto-

labial, labial, mesio-labial and lingual margins, while the teeth and associated soft tissues were lightly air-dried and then, wiped with cotton rolls (Löe and Silness, 1963). For the purpose of scoring for the Plaque Index (PI), an explorer was passed across the tooth surface in the cervical-thirds and near the entrance to the gingival sulcus, while the findings were recorded (Silness and Löe, 1964). During assessment for the mean GI and PI scores, the examination for the PI scores was preceded by assessment for the GI scores to avoid chances for bleeding, in case of inflammation, on manipulation of the gingival tissues. Also, the clinical parameters were recorded by a single observer who was blinded for the groups to avoid recording bias.

Statistical analysis: The data was analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). Independent t-test was used to assess whether the means of two groups were statistically different from one other, while Tukey's post-hoc test, also, known as Tukey's Honest Significant Difference test was used to assess the significance of differences between different pairs of group means. $p < 0.05$ was considered statistically significant.

RESULTS:

The present study was designed as an observational, evidence based study including 120 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 herbal mouthrinse (Hi-Ora), and Group C in which normal saline was prescribed (as control) after oral prophylaxis, while the mean Gingival Index (GI) and Plaque Index (PI) scores were recorded after 3 weeks, checking for any significant variations in the clinical parameters recorded. Also, the study reported no drop-outs during the follow-up visits, while the patients complied with the instructions given as assessed on the re-call visits of the patients. Table 1 reveals the comparison of the mean GI scores in the groups using Independent t-test wherein the mean GI score (post-intervention) was found to be 0.72 ± 0.29 in the CHX, 0.69 ± 0.18 in the Hi-Ora, and 1.61 ± 0.57 in the normal saline groups, with the results being statistically significant ($p < 0.0001$). (Table 1) Likewise, Table 2 reveals the comparison of the mean PI scores in the groups with the mean PI score in the CHX group, being 0.82 ± 0.36 , with the corresponding values, being 0.81 ± 0.29 in the Hi-Ora, and 1.87 ± 0.63 in the normal saline groups, with statistically significant results ($p < 0.0001$). (Table 2) On inter-group comparisons using Tukey's post-hoc test, the results were found to be statistically significant when compared individually between CHX and normal saline, and Hi-Ora and normal saline groups ($p < 0.0001$), though, insignificant when compared between CHX and Hi-Ora, for both GI ($p = 0.890$) and PI ($p = 0.931$) scores. (Table 3)

Table 1: Comparison of mean Gingival Index (GI) scores in groups using Independent t-test

| Group | Mean±S.D | Mean Diff. | t-value | p-value |
|---------------|-----------------|------------|---------|----------|
| 0.12% CHX | 0.72 ± 0.29 | | | |
| Normal saline | 1.61 ± 0.57 | -0.88 | -5.0689 | 0.0001** |
| Hi-Ora | 0.69 ± 0.18 | | | |
| Normal saline | 1.61 ± 0.57 | -0.91 | -8.8939 | 0.0001** |
| 0.12% CHX | 0.72 ± 0.29 | | | |
| Hi-Ora | 0.69 ± 0.18 | -0.02 | -0.7383 | 0.4637 |

** $p < 0.0001$ - Highly significant

Table 2: Comparison of mean Plaque Index (PI) scores in groups using Independent t-test

| Group | Mean±S.D. | Mean Diff. | t-value | p-value |
|---------------|-----------------|------------|---------|----------|
| 0.12% CHX | 0.82 ± 0.36 | -1.05 | -8.4859 | 0.0001** |
| Normal saline | 1.87 ± 0.63 | | | |
| Hi-Ora | 0.81 ± 0.29 | -1.07 | -8.7825 | 0.0001** |
| Normal saline | 1.87 ± 0.63 | | | |
| 0.12% CHX | 0.82 ± 0.36 | -0.01 | -0.3811 | 0.7049 |
| Hi-Ora | 0.81 ± 0.29 | | | |

** $p < 0.0001$ - Highly significant

Table 3: Inter-group comparisons of mean Gingival Index (GI) and Plaque Index (PI) scores in groups using Tukey's post-hoc test

| Tukey's post-hoc test | p-value |
|-----------------------------|----------|
| Gingival Index (GI) | |
| 0.12% CHX vs. Normal saline | 0.0001** |
| Hi-Ora vs. Normal saline | 0.0001** |
| 0.12% CHX vs. Hi-Ora | 0.890 |
| Plaque Index (PI) | |
| 0.12% CHX vs. Normal saline | 0.0001** |
| Hi-Ora vs. Normal saline | 0.0001** |
| 0.12% CHX vs. Hi-Ora | 0.931 |

**p<0.0001- Highly significant

DISCUSSION:

The efficacy of natural products and plant extracts in the management of dental ailments has been evidenced by numerous studies (Chinsebu, 2016; Palombo, 2011; Škrovánková et al., 2012). In the present study, as well, the mean GI scores (post-intervention) were found to be 0.72 ± 0.29 in the CHX group, while 0.69 ± 0.18 in the Hi-Ora, and 1.61 ± 0.57 in the normal saline groups, with the results being statistically significant ($p < 0.0001$). Likewise, the mean PI scores in the present study were found to be 0.82 ± 0.36 in the CHX group, with the corresponding values being, 0.81 ± 0.29 in the Hi-Ora, and 1.87 ± 0.63 in the normal saline groups. The results in case of the mean PI scores were, also, found to be statistically significant ($p < 0.0001$) in the present study. Similar results were obtained in the study conducted by Jaidka et al who observed maximum anti-plaque, anti-gingivitis and antibacterial effects in case of herbal mouthrinse (Hi-Ora) group, while minimum effect in case of CHX group, in contradiction to the previous studies which indicated CHX to be the gold standard and the most effective chemical anti-plaque agent available (Jaidka et al., 2015).

The results of the present study were, also, found to be in accordance with the findings of the study conducted by Asiri et al who observed a significant reduction in the mean GI and PI scores in both the groups using herbal mouthrinse (Hi-Ora) and CHX, concluding of the possibility of herbal mouthrinses to be used as an efficient replacement for CHX, in the pretext of the inherent adverse effects seen with its long-term usage (Asiri et al., 2016). Aspalli et al, also, concluded from the results obtained in their study that herbal mouthrinse (Hi-Ora) can effectively be used in the treatment of plaque-induced gingivitis, as against the gold standard CHX (Aspalli et al., 2014). Likewise, Bhat et al, Shetty et al and Gupta et al observed no significant difference in the antimicrobial properties of herbal mouthrinses (Hi-Ora in case of the studies conducted by Bhat

et al and Shetty et al, while a combination of 50% conc. each of Terminalia chebula and cinnamon extracts in case of the study conducted by Gupta et al), and CHX, concluding both to be equally effective in inhibiting microbial growth, with exceptionally, fewer adverse effects noted in case of the herbal mouthrinse groups (Bhat et al., 2013; Gupta et al., 2015; Shetty et al., 2013). In similar context, Pathan et al, also, found no statistically significant difference between herbal mouthrinse (Hi-Ora) and CHX groups in their study, when the clinical efficacy of the two was compared on select organisms in the in-vitro and ex-vivo models used in their study (Pathan et al., 2017). In yet another study conducted by Subramaniam and Gupta, the authors concluded that herbal mouthrinse (Hi-Ora) was highly efficacious in decreasing the oral microbial load in chronic gingivitis patients (Subramaniam and Gupta, 2013). Similarly, Siddeshappa et al, also, concluded from their study that herbal mouthrinse (Hi-Ora) was statistically, equally efficacious in reduction of plaque and gingivitis, with potent antimicrobial activity as against chlorine dioxide mouthrinse (Siddeshappa et al., 2018).

Another notable finding in the present study was that the results were found to be statistically significant when compared between CHX and normal saline, and Hi-Ora and normal saline groups ($p < 0.0001$), though, insignificant when compared between the groups using CHX and Hi-Ora, for both GI ($p = 0.890$) and PI ($p = 0.931$) scores, in accordance with the findings of most of the previous studies including the studies conducted by Bhat et al, Shetty et al and Gupta et al who observed no significant difference in the clinical efficacy of herbal mouthrinse (Hi-Ora) and CHX in their studies (Bhat et al., 2013; Gupta et al., 2015; Shetty et al., 2013). In a similar study conducted by Malhotra et al, the authors supported the fact that, though, herbal mouthrinse (Herboral, in their study) was less effective than CHX, it was more acceptable to patients as an alternative to CHX (Malhotra et al., 2011). Similarly, Biswas et

al and Vaish et al, also, observed that, though, CHX was found to be more efficacious in terms of improvement of the mean GI and PI scores than herbal mouthrinse (Herboral), both CHX and herbal mouthrinse (Herboral) were found to be equally effective in reducing bleeding on probing, a significant clinical indicator in assessing the severity of gingivitis, in the affected patients (Biswas et al., 2014; Vaish et al., 2012). Also, unlike CHX, herbal mouthrinse (Herboral) was not associated with discoloration of teeth and/or, unpleasant taste and was found to be better accepted by patients, as against CHX (Malhotra et al., 2011; Vaish et al., 2012). Likewise, Parwani et al, also, observed the least GI and PI scores in the 0.2% CHX group, followed by herbal mouthrinse group, while the highest in the normal saline group (Parwani et al., 2013). Herbal mouthrinse used in the study conducted by Parwani et al was composed of babool chaal/*Acacia arabica* (20% w/v) as astringent, darim leaves/*Punica granatum* (10% w/v) as astringent, chameli leaves/*Jasminum grandiflorum* (10% w/v) as an anti-microbial, mulethi/*Glycyrrhiza glabra* (5% w/v) as astringent and neem/*Azadirachta indica* (2% w/v) as an astringent and anti-microbial agent, while other contents (in small quantities) included alum (1.5% w/v), suhaga (1% w/v), Kapoor (0.5% w/v), laung (1% w/v), and menthol (0.5% w/v) (Parwani et al., 2013).

There are numerous ayurvedic plants which have great significance in dentistry. Literature is replete with the studies proving the clinical efficacy of various herbal/natural products in the management of dental conditions. Some of these herbal products have been used in mouthrinses as well, for their known therapeutic advantages, and proven clinical efficacy as significant anti-plaque and anti-gingivitis agents, including green tea, turmeric, neem, cranberry, Aloe vera, pot marigold, and triphala. The herbal extracts used in these mouthrinses such as triphala (*Phyllanthus emblica*, *Terminalia chebula*, and *Terminalia bellirica*), wintergreenoil (*Gaultheria procumbens*), garlic (*Allium sativum*), Miswak aqueous extract (*Salvadora persica*), ginger (*Zingiber officinale*), lemon extract (*Citrus limon*), and peppermint (*Mentha piperita*) are known to have antimicrobial activity on some of the common oral pathogens. In similar context, Waghmare et al conducted a study to compare the efficacy of turmeric mouthrinse and CHX in the prevention of plaque formation and gingivitis and concluded that CHX as well as turmeric mouthrinse can effectively be used as adjuncts to mechanical plaque control methods in prevention of plaque

and gingivitis, though, CHX was found to be more effective than turmeric mouthrinse, when only the anti-plaque property was considered (Waghmare et al., 2011). Likewise, Chatterjee et al conducted a study to assess the efficacy of neem-based mouthrinse and concluded that *Azadirachta indica*-based mouthrinse was equally efficacious when compared to CHX, with fewer side effects and that it may be used as an adjunct therapy in treating plaque-induced gingivitis (Chatterjee et al., 2011).

Elizabeth KM conducted a study to evaluate the antimicrobial efficacy of crude and methanolic extracts of *Terminalia bellerica* by disc diffusion method against 9 human microbial pathogens and concluded that *T. bellerica* possesses potential antimicrobial activity against the tested human pathogens (Elizabeth, 2005). Similarly, Pradeep et al, also, observed a significant reduction in the inflammatory parameters from baseline to follow-up intervals on using triphala mouthrinse in patients with chronic gingivitis concluding that triphala mouthrinse can be considered as a potential therapeutic agent in the treatment of gingivitis (Pradeep et al., 2016). In a recent study, Agarwal and Chaudhary conducted a double-blind, randomized, placebo-controlled, clinical trial to evaluate and compare the clinical and microbiological effects of *Matricaria chamomilla* mouthrinse as against the gold standard CHX in chronic periodontitis patients and concluded that chamomilla-based mouthrinse can effectively be used as an adjunct during the non-surgical periodontal therapy in chronic periodontitis patients, observing no major differences in the advantages obtained in the test group as compared to the group using CHX (Agarwal et al., 2020). In another similar study conducted by Abullais et al, the authors observed Manuka mouthrinse to be as effective as CHX in chronic gingivitis patients, with no significant differences observed in any clinical parameter at any point (Abullais et al., 2022). Nevertheless, the results obtained in the present study emphasize need for further studies in this regard to substantiate the clinical efficacy of herbal mouthrinses with similar antimicrobial efficacy than CHX to overcome the well-known disadvantages associated with the long-term use of CHX.

CONCLUSION:

Within its own limitations, the results of the present study suggested herbal mouthrinse (Hi-Ora) to be equally efficacious as 0.12% CHX in reducing the mean GI and PI scores in patients

with chronic gingivitis, however, further multi-centric, randomized controlled, clinical and microbial trials using different microorganisms, with larger sample sizes are mandated to come to valid conclusions.

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DATA AVAILABILITY: All data generated and analyzed are included within this research article.

ETHICAL APPROVAL: Prior to the commencement of the study, the study protocol was approved by the Institutional Ethics Committee via letter approval no. IHEC/014/09-2022.

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