Comparative Assessment of a Standard Oral Hygiene Regimen with and without Mouthwash and Related Clinical Findings over a 14-day Period

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Abstract

Background and aims. The goal of this study was to evaluate the clinical efficacy of a standard oral hygiene routine (daily tooth brushing and flossing) along with cetylpyridinium chloride (CPC) mouthwash in comparison to the same protocol without mouthwash in chronic periodontitis patients during a 14-day period.

Materials and methods. This comparative study was carried out on 50 non-smoking patients with chronic periodontitis; 25 patients followed an oral hygiene regimen using a toothbrush and dental floss (control group) and the remaining 25 used the mentioned protocol along with CPC mouthwash (test group) for 14 days. The plaque index (PI), modified gingival index (MGI) and probing pocket depth (PPD) were assessed. Wilcoxon and Mann-Whitney U tests were used to evaluate and compare the prevalence of indices between the two groups. Statistical significance was set at P<0.05.

Results. The results showed greater improvement of MGI in the test group (P=0.001). No statistically significant differences were observed in PI (P=0.47) and PPD (P=0.43) between the two groups.

Conclusion. Adding mouthwash to a standard oral hygiene regimen may improve some clinical gingival parameters when compared with an oral hygiene routine without a mouthwash.

Key words: Dental plaque, hygiene, mouthwash, periodontitis.
**Introduction**

Daily supragingival dental plaque removal has a marked effect on prevention of caries, gingivitis and periodontitis. Mechanical biofilm removal by proper tooth brushing and regular use of dental floss can greatly help in bacterial plaque control. Dental plaque is considered the primary etiologic factor for the two most prevalent oral diseases, namely dental caries and periodontal disease. Studies have clearly indicated that regular plaque control practices may be able to prevent the development or progression of periodontal disease.

Considering the continuous formation of dental plaque, gingival and periodontal health can be maintained by mechanical plaque removal. Dental plaque should be removed before the development of gingival inflammation. Previous studies have demonstrated that effective plaque control can improve oral health, although mechanical means of cleaning usually fail to provide the optimal level of oral health because their application is usually not thorough or consistent.

Chemotherapeutic agents have been suggested as adjuncts to mechanical plaque control for oral home care. In most cases, during phase I therapy, the clinician recommends the use of antimicrobial agents as an adjunctive treatment to reduce dental plaque and prevent gingivitis.

In order to improve the efficacy of mechanical oral hygiene practices, several antimicrobial agents were added to mouthwashes and some even aimed to replace the mechanical plaque removal. Metal salts (tin fluoride, zinc, or copper), essential oils, phenols (triclosan), fluoride (sodium fluoride or stannous fluoride), bisbiguanides (chlorhexidine), quaternary ammonium compounds (cetylpyridinium chloride: CPC), sanguinarine, and oxygenating compounds are some of the antimicrobial agents.

Clinical studies have demonstrated that many of these antimicrobial agents have inhibitory effects on plaque formation and development of gingivitis when compared with negative controls or placebos in the absence of tooth brushing. However, when used in combination with tooth brushing, these antimicrobial agents do not always show a significant effect on decreasing plaque formation or gingivitis when compared with negative controls. Chlorhexidine is considered as the gold standard in this respect due to its clinical efficacy in chemical plaque control.

Interdental cleansing is an essential part of an optimal oral hygiene routine. Different mouth rinses, dental floss and interdental brushes have been introduced for oral care. Chemotherapeutic agents, especially in the form of mouthwash, can play an important role as an adjunct to non-surgical periodontal treatments and preventive strategies.

This clinical study aimed to assess the effectiveness of an oral hygiene routine (daily tooth brushing and flossing) with CPC-rinse and compare it with an oral hygiene routine without mouthwash in chronic periodontitis patients during a 14-day period.

**Materials and Methods**

**Study Population**

A total of 60 patients (30 males and 30 females, aged 32 to 53 years) was initially recruited in this study. Ten patients were excluded because they did not follow the study protocol. The Ethics Committee of Dental Research Center of Shahid Beheshti University of Medical Sciences approved the study protocol with the following number: 1391-1-97-10114. This article presents the results of the study mentioned above. All patients signed written informed consent.

**Study Design**

This comparative, randomized, double-masked study compared an oral hygiene routine (daily tooth brushing and flossing) with Vi-One mouthwash (ROJIN Co., Tehran, Iran) with an oral hygiene routine without the mouthwash in patients with chronic periodontitis over a 14-day period.

Patients were non-smokers suffering from chronic periodontitis with more than 20 teeth in their mouth, and without any systemic diseases such as uncontrolled diabetes, cardiovascular disease or infectious diseases. Patients who were pregnant, nursing or using antibiotics or anti-inflammatory drugs were excluded from the study. Chronic periodontitis was defined as a plaque-induced periodontal infection associated with gingival inflammation, bleeding on probing from the gingival pocket, reduced resistance of the periodontal tissues to probing (periodontal pocketing >4 mm), clinical attachment loss >1 mm, and alveolar bone loss. The patients were randomly divided into 2 groups. Twenty-five patients followed a 14-day protocol of rinsing with an undiluted 10-mL dose of a mouthwash for 1 minute, twice daily (morning and evening) after an oral hygiene routine (daily tooth brushing and flossing) and 25 controls practiced an oral hygiene routine without the mouthwash.
The mouthwash samples for the study were previously labeled and masked. Before starting the mouthwash cycle, the patients were asked not to drink coffee, wine, tea, etc. for 1 hour before or after using the mouthwash; complete supra- and subgingival scaling and root planing were also performed 14 days prior to the baseline (day 0). The probing pocket depth (PPD) was measured and recorded at four sites per tooth (mesiobuccal, distobuccal, midbuccal and midlingual/palatal) using a standard Williams probe (Hu-Friedy, Chicago, IL, USA) at baseline (day 0) and on day 14. Plaque index (PI) was also calculated at the time intervals mentioned above, using the O’Leary Plaque Index. Modified gingival index (MGI) was calculated as well. The brushing technique used during the study was the modified Bass technique (G.U.M, John O. Butler Co, Chicago, USA). At the beginning of the study, each patient was provided with sodium lauryl sulfate-free toothpaste containing 0.05% fluoride, a regular toothbrush, an interdental toothbrush and dental floss. Clinical assessments and collection of data were performed by a clinician blinded to group assignment (with 93% reproducibility).

Data Analysis
The results were evaluated using factorial analysis of variance. All the variables were compared between the two groups on day 14. Data were analyzed using SPSS 15 software. Wilcoxon and Mann-Whitney U tests were used to evaluate and compare the prevalence of indices between the two groups. Statistical significance was set at P<0.05.

Results
A total of 60 patients (30 males and 30 females, aged 32–53 years) were initially enrolled. The mean number of teeth in the patients’ mouth was 21.2 (excluding third molars). Ten patients were excluded because they did not follow the study protocol. Final analysis was conducted on 14 females and 11 males with a mean age of 35.6 years in the test group and 12 females and 13 males with a mean age of 38.3 years in the control group. No patient reported any complication or unexpected complaint.

The mean baseline values for PPD and PI were 4.47 mm and 67.76% in the test group, respectively. The differences in baseline PPD and PI between the two groups were 0.15 mm and 4.66%, respectively, with no statistically significant differences (P=0.28 and P=0.45, respectively). The mean reductions in PI and PPD were 44.68% and 1.75 mm, respectively, after 14 days of routine oral hygiene practice in the control group. During the same time period, PI decreased from 67.76% to 29.88%, and PPD decreased from 4.47 to 3.34 mm in the test group due to the use of the mouthwash. All the differences in both groups were statistically significant as shown in Table 1.

Both methods were effective in reducing plaque index, probing pocket depth and modified gingival index. However, the only significant difference between the two groups was in MGI reduction; which showed a greater improvement in the test group (1.76 vs. 1.16, P=0.001).

Discussion
Several researchers have suggested the application of chemotherapeutic agents as adjuncts to mechanical plaque control at home. According to some in vitro microbiological studies, antimicrobial agents are capable of penetrating into the bacterial biofilm and exerting their bactericidal properties. Furthermore, chemical agents have the ability to reach the interproximal areas that are difficult to clean and inhibit bacterial growth and subsequent biofilm formation on the soft tissue. Application of these chemical agents is safe and seems to have no effect on increasing resistant species. In addition, to date, no study has found a correlation between mouth rinses containing alcohol and oral cancer. In brief, chemical plaque control should be recommended to patients who have difficulty in maintaining a good oral hygiene with the use of mechanical oral hygiene measures alone. At present, chlorhexidine digluconate is the most extensively studied and the most effective anti-plaque and anti-gingivitis agent. However, it has several side effects that necessitate the search for alternative agents.

In order to recommend a product for use in the clinical setting, its anti-plaque and/or anti-inflammatory properties should be approved in clinical trials. The aim of the present randomized clinical trial was to compare the efficacy of oral hygiene routines with and without a mouthwash during a 14-day period.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean ± SD</th>
<th>Mean diff</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MGI¶</td>
<td>2.95 ± 0.84</td>
<td>0.78</td>
<td>0.001</td>
</tr>
<tr>
<td>PI (%)</td>
<td>28.81 ± 10.39</td>
<td>2.14</td>
<td>0.47</td>
</tr>
<tr>
<td>PPD¥ (mm)</td>
<td>1.76 ± 0.62</td>
<td>0.16</td>
<td>0.43</td>
</tr>
</tbody>
</table>

¶: Modified Gingival Index
|: Plaque Index
¥: Probing Pocket Depth
*: P-value less than 0.05 was considered statistically significant.
The results of the present study revealed that both regimens had equal anti-plaque properties. However, greater anti-gingivitis effects (determined by MGI) were achieved by incorporating a mouthwash. It has been documented that addition of CPC-containing mouth rinses to the supervised or unsupervised mechanical oral hygiene practices has a small but significant effect on decreasing plaque accumulation and prevention of gingival inflammation.\(^3\) In terms of adverse effects, none of our patients reported bad taste or any other complaints due to the use of the mouthwash (mucosal injury, burning mouth or a bad taste when eating).

The significant reduction in gingival inflammation observed during our short study period may be attributed to several factors: (1) professional tooth debridement and direct contact with all patients; (2) participation in the study may have been a motivating factor for patients to improve their habitual oral hygiene practices; and (3) similarly, participants may have thought that the investigators expected to see a reduction in scores and hence strived to achieve that reduction through their oral hygiene efforts. The type of toothbrush used might also be responsible for changes. We recommended manual toothbrushes; although, Rosema et al designed an examiner-masked, randomized, three-group parallel design study comparing brushing twice daily with a manual toothbrush, a manual toothbrush and dental floss, and a powered toothbrush. In their study, dental plaque was significantly less with the powered toothbrush in comparison with the other two groups. Also, the powered toothbrush group experienced significantly less bleeding compared to manual brushing alone after 10 weeks and 6 months. Furthermore, a lower plaque level was maintained by subjects in the powered toothbrush group for 9 months following the 3-week treatment period; which was better than the manual toothbrush group with or without dental floss. The powered toothbrush was significantly superior to the manual toothbrush for prevention of gingival bleeding.\(^3\)

Haq et al\(^3\) reported that cetylpyridinium chloride mouthwash in combination with sodium fluoride-containing toothpastes were the only antiplaque agents with a significant difference with the control group.

Several studies have compared the effectiveness of different mouth rinses. Charles et al\(^3\) used a 2-week experimental gingivitis model and demonstrated that mouthwashes containing essential oil had superior anti-plaque/anti-gingivitis properties in comparison with those containing CPC.

One major concern in relation to such studies is the accuracy of clinical findings. Thus, we decided to hold several training sessions to instruct the examiner on the clinical parameters before initiation of the clinical trial. After training the examiner, the intra-examiner reproducibility was evaluated. The examiner was blinded to the randomization sequence and to the test or control quadrant.

Indications of mouthwashes are not limited to dental plaque removal from the tooth surfaces. They can be used for surface cleaning of partial dentures and reducing the incidence of preterm birth in high-risk populations.\(^3\) Therefore, future studies with a larger sample size are required in this respect.

More sophisticated analyses need to be performed for understanding the mechanism of antimicrobial effects of mouth rinses on planktonic and biofilm organisms.\(^4\) The plaque inhibitory effects of CPC mouthwash\(^7\) have to be further investigated as well.

**Conclusion**

An oral hygiene routine with a mouthwash may improve some gingival clinical parameters when compared with an oral hygiene routine without a mouthwash. In conclusion, this study showed that a supervised oral hygiene routine associated with cetylpyridinium chloride mouth rinse was more beneficial for control of gingival inflammation than mechanical oral hygiene practices alone. The incorporation of a mouthwash to standard oral hygiene practice had no significant benefit for gingival health determined by a reduction in pocket depth or plaque scores.

**Acknowledgement**

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