The effectiveness and side effects of 0.1% and 0.2% chlorhexidine mouthrinses: A clinical study

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Objective: The study compared two commercial chlorhexidine mouthrinses (Chlorhexamed 0.1% and Corsodyl 0.2%) for their effects on dental plaque and gingival inflammation, their side effects (e.g., tooth staining and mucosal irritation), and patient acceptance.

Method and materials: One hundred thirty healthy volunteers were randomly distributed into two groups of 65 each. Each volunteer had gingivitis or chronic marginal periodontitis and used the rinse two times a day for 4 weeks. The sulcular bleeding index, approximal plaque index, gingival index, and a discoloration index were taken at baseline and once a week thereafter. The patients were questioned about taste disturbances, mucosal irritation, and their perception of the taste of the mouthrinse.

Results: In both groups, after 4 weeks, the mean sulcular bleeding index, approximal plaque index, and gingival index scores had decreased significantly. The discoloration index had increased significantly in both groups. There were no statistically significant differences between the two mouthrinses in any of these measurements. There were no significant differences in side effects reported by the two groups.

Conclusion: The increase in concentration of chlorhexidine provided no clinical advantages or disadvantages.

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Key words: chlorhexidine mouthrinse, gingival inflammation, gingivitis, periodontitis, plaque, side effect, tooth staining

Clinical relevance

Because 0.1% and 0.2% chlorhexidine mouthrinses showed no significant differences in their effectiveness or their side effects, the lower concentration solution can be recommended for supplemental therapy in patients with periodontal disease.

Antibacterial ingredients in mouthrinses are able to stop or to slow down bacterial growth significantly by discouraging the attachment of early plaque, which is then unable to metabolize. Of the different irrigants available, chlorhexidine is the most commonly used, and it is also available in different concentrations. The efficacy of chlorhexidine has been proven over several years in in vitro and in vivo studies. The mechanism is based on adhesion of the positively charged chlorhexidine digluconate molecule to the negatively charged cellular wall. The chlorhexidine molecule binds mainly to phosphate groups in lipopolysaccharides and carboxyl groups localized in proteins. This results in an interruption of the transmembrane transport and therefore a loss of low molecular substances in the cell. On the other hand, chlorhexidine is not able to penetrate the oral mucosa, or established plaque, because of its charge.

Furthermore, chlorhexidine digluconate appears to inhibit adhesion of bacteria to surfaces by displacing calcium from its binding site and deactivating the enzyme, glycosyltransferase. After an individual rinses with chlorhexidine, depending on the pH, up to 30% of the antiseptic will remain in the oral cavity because of adhesion to glycoproteins on oral surfaces. Therefore an effect similar to a depot effect can be assumed.

Chlorhexidine-containing irrigants are used in addition to periodontal treatments or surgery. Different concentrations are commercially available. The aim of this study was to compare the effects and side effects of 0.1% and 0.2% chlorhexidine solutions during a treatment period of 4 weeks.
Method and materials

One hundred thirty male volunteers (mean age: 28.3 ± 7.6 years) from among recruits to the German army, asking for dental surgery and having at least clinically manifested gingivitis or chronic marginal periodontitis, were asked to participate in this study. All volunteers gave their informed consent in accordance with accepted ethical standards.

The total of 130 patients was randomly distributed into two groups of 65 each. The first group used 0.1% Chlorhexamed (Blendax), and the second group used 0.2% Corsodyl (Lingner and Fischer). All volunteers received the same new toothbrush (Blendax Medic Compact) and an amine fluoride–containing toothpaste (Elmex) to prevent the interaction of sodium monofluorophosphate toothpastes or sodium lauryl sulphate. The volunteers were instructed in adequate oral hygiene.

During the following 4 weeks, they brushed their teeth twice a day, in the morning and evening after meals. Afterward, they were to rinse with 15 mL (one dose-cap) of the mouthrinse, according to manufacturer’s recommendations, for 1 minute. No professional prophylaxis was done.

Baseline examination included a first consultation examination as well as documentation of Community Periodontal Index of Treatment Needs (CPITN); decayed, missing, and filled teeth; approximate plaque index (API); sulcular bleeding index (SBI); gingival index (GI); and a discoloration index (DI). As a color indicator for plaque, plaque indicator tablets (Blendax) were used. The volunteers chewed the tablets for 1 minute and rinsed with water two times for 15 seconds. Afterward the plaque was assessed visually. Possibilities for plaque scoring were present or absent. The plaque index is calculated as the percentage of disto-approximal sites having a positive plaque score.

The volunteers were examined weekly over a period of 4 weeks. During the appointments, the gingival index and the discoloration index were documented. Oral hygiene instructions were repeated and reinforced on demand. The discoloration index was scored as shown in Table 1. The volunteers were questioned about taste disturbances (no disturbance, minor disturbance, or major disturbance), mucosal sensitivities (no sensitivities, minor sensitivities, or major sensitivities), and their individual assessments of treatment success. The taste of the mouthrinse (good, bad, or neutral). During the weekly consultations, the mucosa were investigated for erosions. At the final examination, the approximal plaque index and the sulcular bleeding index were assessed again, and all discolorations were removed by professional prophylaxis. All results were coded to ensure anonymity.

Except for the questionnaire, statistical analysis was carried out using the t test for paired and unpaired samples. The 5% significance level was designated as statistically significant and the 0.1% level as highly significant. For statistics, a t value was calculated from the quotient of the mean difference of the comparable values and the mean error. If the calculated t value for the chosen probability of error is equal to or larger than a critical t value, taken from statistical tables, the resulting difference is of significant interest.

Results

In this study, the mean number of decayed, missing, and filled teeth for the recruits examined was 14.0 ± 7.8. For assessment of the periodontal condition of the recruits, the CPITN index was used. Four volunteers were scored CPITN 1/I, 85 were scored CPITN 2/II, 25 were scored CPITN 3/III, and 16 were scored CPITN 4/III. At baseline, the mean approximal plaque index was 70.1% (±23.9%), the mean sulcular bleeding index was 82.1% (±18.7%), and the mean gingival index was 2.2 (±0.4).

During the treatment period, the API decreased significantly (P < .001) in both groups (Fig 1). No statistically significant difference in the API values was found between the two groups.

The SBI also decreased significantly (P < .001) in the Chlorhexamed group and in the Corsodyl group (Fig 2). There was no statistically significant difference in the SBI reduction achieved by the 0.1% and the 0.2% chlorhexidine groups.

The GI decreased significantly (P < .001), from 2.2 (±0.4) to 1.1 (±0.5) in the Chlorhexamed group and from 2.2 (±0.4) to 1.0 (±0.5) in the Corsodyl group (Fig 3). Again, no statistically significant difference was found between Chlorhexamed and Corsodyl.

All volunteers involved in this study showed yellow-brownish discolorations of their teeth and tongues. In both groups, the tooth discolorations were mainly located in pits and fissures as well as at the cervical margin. After 4 weeks of treatment, the degree of discol-
Fig 1 Decrease in the approximai plaque index (API) scores during the treatment period of 4 weeks.

Fig 2 Decrease in the sulcus bleeding index (SBI) scores during the treatment period of 4 weeks.

Fig 3 Decrease in the gingival index (GI) scores during the treatment period of 4 weeks.

Fig 4 Increase in the discoloration index (DI) scores during the treatment period of 4 weeks.

oration increased from 34.2% (± 16.4%) at baseline to 48.4% (± 15.3%) in the Chlorhexamed group and from 30.4% (± 15.8%) to 45.2% (± 15.9%) in the Corsodyl group (Fig 4). The increases were statistically significant (P < .001) for each group, but no statistically significant difference was found between groups.

Erosions of the mucosa were not found in any volunteer. One recruit in the Corsodyl group showed a slight desquamation of the gingiva. One recruit had a painful inflammation of the gingiva in the second quadrant, and another recruit had an ulcer at the front palatal arc in the fourth week of treatment. None of the irritations proved to be correlated to the mouthrinse therapy.

In the questionnaire, 81.5% of the volunteers using Chlorhexamed reported no continuous taste disturbances (more than 15 minutes) after rinsing with the irrigant. In the Corsodyl group, 72.3% claimed no taste disturbances. Major disturbances were complained about by 1.5% of participants in the Chlorhexamed group and a higher percentage, 13.8%, of the patients in the Corsodyl group (Fig 5). In total, 27.6% of the volunteers in the Corsodyl group and 18.4% in the Chlorhexamed group had continuous (minor or major) taste disturbances during the treatment period.

While using the mouthrinse twice a day, only 1.5% of the volunteers in the Corsodyl group and none in the Chlorhexamed group noted major mucosal sensitivities. At the end of 4 weeks, 95.4% of the volunteers in the Chlorhexamed group and 92.3% in the Corsodyl group reported no increased sensitivities of the mucosa at all (Fig 6).

The recruits were asked about the taste of the mouthrinses. In the Chlorhexamed group 8.9% described the irrigant as good tasting, 37.5% as bad tasting, and 53.6% as neither good nor bad tasting. In the Corsodyl group, a larger percentage of the volunteers

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(18.2%) reported the irrigant to be good tasting, 29.1% found it to be bad tasting, and 52.7% believed it to be neither (Fig 7).

The volunteers were asked at the final consultation to give a personal estimation of the treatment success, when only the irrigant was used (Fig 8). No statistically significant difference could be found between the Chlorhexamed and the Corsodyl groups in their estimates of treatment success.

Discussion

The effectiveness of a medicine or a mouthrinse is often correlated to the therapeutic dose used. The aim of this study was to compare two commercially available chlorhexidine irrigants in different concentrations (0.1% and 0.2%) according to their effectiveness and side effects. Both mouthrinses, the 0.1% Chlorhexamed and the 0.2% Corsodyl, were highly effective in preventing and healing gingivitis. The decreases in the sulcular bleeding index, the gingival index, and the approximal plaque index scores were in accordance with results reported by other authors.1-6,12-17

“Chemical warfare” is not the only method for reducing gingivitis and bacterial adhesion to oral surfaces; most important is adequate oral hygiene by patients,8 using common devices such as toothbrushes and dental floss. Antibacterial irrigants also may be used by patients who are unable to practice sufficient daily oral hygiene because of their age18,19 or in cases where tooth surfaces are difficult to reach, for example, in patients with fixed orthodontic appliances.20 In addition, surgeons prescribe an antibacterial mouthrinse for patients undergoing maxillofacial surgery,22 implant surgery,23 and periodontal therapy24 to prevent postoperative infections25 and to disinfect the oral cavity before operative therapy.26

The therapeutic dose of the chlorhexidine irrigants ranges from 10 mg to 20 mg, twice daily, and has been
subject to research by other authors.²⁷ Mohd Asari et al²⁸ found no difference in the effectiveness of the 0.1% Eludril chlorhexidine irrigant and the 0.2% Corsodyl irrigant, when the irrigants were applied subgingivally with a nonelectric, air-pumped subgingival delivery system, in patients with chronic periodontitis, over a treatment period of 4 weeks. Their results agree with the results of the present study. Other researchers have found no clinical differences in the effectiveness of 0.1% and 0.12% chlorhexidine solutions.²⁹

The taste disturbances, the mucosal sensitivities, and the discolorations observed during the treatment period are similar to side effects reported in the literature.²³,³⁰ Many stains could not be removed by the volunteers themselves, so a professional prophylaxis was necessary during the last consultation of the study. Certain recommendations for elimination of these stains during the use of chlorhexidine as an irrigant have been presented in the literature.³¹

About 33% of the volunteers claimed the irrigant to be bad tasting, while more than 50% stated that the irrigants were neither good nor bad tasting. Evidently, chlorhexidine glucconate itself does not have an excellent taste, and manufacturers do not seem to able to modify the taste of their mouthrinses.

Conclusions

1. No statistically significant differences were observed in the effectiveness or side effects of two chlorhexidine mouthrinses (Chlorhexamed, 0.1%, and Corsodyl, 0.2%). Both irrigants were equally effective in reducing gingivitis, and their side effects, such as tooth staining and taste disturbances, were similar.

2. Because of these results, there appears to be no reason to increase the concentration of chlorhexidine from 0.1% to 0.2%.

3. The effect of chlorhexidine mouthrinses generally depends on dosage and not on concentration. Therefore, half of the amount of a 0.2% mouthrinse might be as effective as a 0.1% mouthrinse. From this author’s point of view, rinsing with 15.0 mL of mouthrinse might be clinically easier for patients than rinsing with 7.5 mL.

References


