The Use of Chlorhexidine in the Management of Gingivitis in Children

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TWO DOUBLE-BLIND STUDIES WERE CONDUCTED in 191 children in Mexico. Following a dental prophylaxis, either a 0.12% chlorhexidine gluconate mouthrinse or a placebo was used under supervised conditions in comparable groups twice per day. The chlorhexidine treatments resulted in a significant decrease of gingivitis when compared to the placebo rinse. Although superficial mucosal desquamations were seen in some chlorhexidine users, they were transient and without discomfort. The increase of cosmetic side effects, e.g., dental stain and supragingival calculus, was without consequence to the gingival health of the subjects.

The use of a chlorhexidine rinse twice per day and as adjunct to regular oral hygiene procedures achieved a considerable benefit against gingivitis in children in two studies extending over ten and 12 weeks.

The uses of chlorhexidine mouthrinses in the control of dental plaque and gingivitis are well known in the international dental community. Most chlorhexidine rinses were used at a 0.2% concentration. However, Segreto et al.1 reported that the same clinical benefits were observed by using a lower concentration at 0.12% in a compatible mouthrinse vehicle (Peride®). Moreover, effects of lower concentrations were also reported by Flötta et al.,2 and Lang et al.3 in children.

The purpose of this study was to investigate whether or not a clinical benefit could be demonstrated against gingivitis in children when 0.12% chlorhexidine gluconate was used twice per day under supervision, following a dental prophylaxis. In addition, it was important to establish whether or not this treatment was well tolerated by the oral soft tissues.

MATERIALS AND METHODS

As subjects, 191 boys in an age range of eight to 18 years were selected from a boarding school in Monterrey, Mexico. For acceptance into the study, they had to have some degree of plaque-induced gingivitis. Those with gross oral neglect or pathoses that needed prompt care were not accepted. Treatments were supervised at the institution.

Following a baseline examination to establish suitability for study participation, all subjects received a dental prophylaxis to remove any dental accretions. In the design of the double-blind studies, subjects were separated by age intervals (<12 and ≥12 years) and stratified by seven intervals of gingivitis scores ranging from <0.25 to >1.50. Within these strata, the subjects were distributed into the chlorhexidine or the placebo groups at random.

Two individual studies, separated by a one-year interval, were conducted to confirm the objective.

In each study, the assessment of gingivitis was made by a different dentist according to the Papillary-Marginal-Gingivitis Index (PMGI) as published by de la Rosa and Sturzenberger.4 For the assessment of soft-tissue tolerance to the rinses, the oral mucosae were examined for pathoses that could be an indication of tissue irritation. All examinations were made at the school with adequate lighting, compressed air and the necessary dental instruments. The treatments of the subjects consisted of two supervised 30-second mouthrinses per day, one in the morning and one in the evening. Fifteen milliliters of the assigned rinse were used, either the 0.12% chlorhexidine (CH) or the placebo rinse. The evening rinsing was preceded by a one-minute toothbrushing with a sodium fluoride dentifrice,
Table 1
Study I. Gingivitis Scores (6 and 12 Weeks)

<table>
<thead>
<tr>
<th>Rinse</th>
<th>N</th>
<th>Occurrence*</th>
<th></th>
<th></th>
<th></th>
<th>Severity†</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline X</td>
<td>X</td>
<td>% Reduction</td>
<td>Baseline X</td>
<td>X</td>
<td>% Reduction</td>
<td></td>
</tr>
<tr>
<td>6 Weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>52</td>
<td>0.6530</td>
<td>0.5580</td>
<td>49.6%‡</td>
<td>0.6513</td>
<td>0.5583</td>
<td>49.5%‡</td>
<td></td>
</tr>
<tr>
<td>0.12% CH</td>
<td>50</td>
<td>0.6893</td>
<td>0.2814</td>
<td></td>
<td>0.6933</td>
<td>0.2819</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>46</td>
<td>0.6054</td>
<td>0.2896</td>
<td>51.3%‡</td>
<td>0.6215</td>
<td>0.2902</td>
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<td></td>
</tr>
<tr>
<td>0.12% CH</td>
<td>46</td>
<td>0.6763</td>
<td>0.1410</td>
<td></td>
<td>0.6807</td>
<td>0.1413</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Gingivitis occurrence is the proportion of sites graded with a PMGI score ≥1.
† The gingivitis severity score is the mean score of all sites graded.
‡ Significantly different (P ≤ 0.05) from the placebo group.

Table 2
Study II. Gingivitis Scores (10 Weeks)

<table>
<thead>
<tr>
<th>Rinse</th>
<th>N</th>
<th>Occurrence*</th>
<th></th>
<th></th>
<th></th>
<th>Severity†</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline X</td>
<td>X</td>
<td>% Reduction</td>
<td>Baseline X</td>
<td>X</td>
<td>% Reduction</td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>50</td>
<td>0.3270</td>
<td>0.3584</td>
<td>33.8%‡</td>
<td>0.4263</td>
<td>0.4526</td>
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</tr>
<tr>
<td>0.12% CH</td>
<td>49</td>
<td>0.3488</td>
<td>0.2374</td>
<td></td>
<td>0.4544</td>
<td>0.2892</td>
<td>36.1%‡</td>
<td></td>
</tr>
</tbody>
</table>

* Gingivitis occurrence is the proportion of sites graded with a PMGI score ≥1.
† The gingivitis severity score is the mean score of all sites graded.
‡ Significantly different (P ≤ 0.05) from the placebo group.

Crest®.† At the beginning of the studies, the subjects received soft toothbrushes and brushing instructions. The toothpaste and mouthrinses were dispensed by the supervisory personnel who also timed the toothbrushing and mouthrinsing.

Clinical re-examinations were made after six and 12 weeks of treatment in Study I and after ten weeks in Study II. The gingivitis scores were recorded on an individual form for each subject. Previous records were not available at subsequent examinations nor did the examiners have any knowledge as to which treatment group a given subject belonged.

RESULTS AND DISCUSSION

A statistical analysis of the data was made by covariance analysis as reported by Lehnhoff and Grainger® and corroborated by the Mann Whitney U test.® These data are summarized in Tables 1 and 2. With the exception of the baseline scores that demonstrate comparability of the test and control groups, both studies show that there were lower gingivitis scores for the chlorhexidine users in comparison to the placebo groups.

In the 12-week study (Table 1) the effect of the chlorhexidine rinse on the occurrence and severity of gingivitis amounted to a 51% reduction of the disease compared to the placebo rinse. This confirms the gingivitis reductions of 50% that were observed at the six-week examinations. In the shorter study after ten weeks (Table 2), the gingivitis reductions were 34% and 36% for occurrence and severity, respectively. In each study the differences were statistically significant.

It is recognized that these study periods were relatively short to extrapolate an important clinical advantage for the chlorhexidine treatment. However, a similar advantage is expected in extended use as seen in the work of Lang et al.® who tested similar rinses over six months.

An ancillary assessment of dental plaque was made according to the index by Turesky et al.® The reductions of dental plaque were not statistically significant in either study. On the other hand, considerable anti-gingivitis effects were seen. It is conceivable that the main effect of chlorhexidine may actually lie in its ability to reduce the pathogenic nature of the plaque rather than merely the quantity.

Some mild superficial epithelial desquamations were observed in some chlorhexidine subjects. These occurrences have also been described by Flötta et al.® There was no discomfort reported in association with these transient incidences in our study. Neither was there a consequence on oral health.

There was an increase in extrinsic tooth stain and supragingival calculus in the chlorhexidine groups as also reported by Lang et al.® in children. However, the accretions were removable by professional toothcleaning and did not influence the benefit on gingivitis.

CONCLUSIONS

The 0.12% chlorhexidine gluconate rinse provided a substantial benefit in the control of gingivitis over ten-
and 12-week periods. There was no lasting side effect on the oral soft tissue or the health of the users.

ACKNOWLEDGMENTS

We appreciate the cooperation of Drs. T. D. Dickinson, Houston, TX; O. A. Ferretti, University of Kentucky, Lexington, KY; A. H. Meeke, Bright, IN; and A. L. Terraz, Saltillo, Mexico, who served as clinic examiners. We are grateful for the statistical assistance of Mr. B. W. Bollmer, Procter & Gamble Company, Cincinnati, OH.

REFERENCES


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Announcement

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