<table>
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<th><strong>Title</strong></th>
<th>A two-year randomized clinical trial of chlorhexidine varnish on dental caries in Chinese preschool children</th>
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INTRODUCTION

In many developed countries, dental caries prevalence in children has decreased significantly in the past decades. The main reason for this decrease has been ascribed to improvement in oral hygiene, changes in lifestyles, use of fluoride, and implementation of school-based prevention programs (Marthaler et al., 1996). However, during the same time period, prevalence of dental caries has increased in many developing countries (Petersen, 2003). The second National Oral Health Survey conducted in China (Wang et al., 2002) found a high prevalence of caries in the primary dentition of five-year-old children, 77%, and the mean number of decayed, missing, or filled primary teeth (dmft) was 4.5, with untreated active caries (dt) being the major component. Therefore, appropriate caries-preventive measures are urgently needed in China (Lin and Schwarz, 2001).

Chlorhexidine has been widely accepted as a chemotherapeutic agent against Streptococcus mutans, and studies have shown that chlorhexidine varnish can provide sustained release of chlorhexidine and suppress S. mutans in dental plaque for 6 mos after its application (Matthijs and Adriaens, 2002). Results of some clinical studies showed that chlorhexidine varnish is effective in caries prevention (Joharji and Adenubi, 2001; Baca et al., 2002). However, it has also been found to have little effect on new caries development (Fennis-Ie et al., 1998; Forgie et al., 2000; de Soet et al., 2002). Most of the reported studies were conducted on the permanent teeth of schoolchildren, and, in a recent review (Twetman, 2004), it was found that the evidence for the use of chlorhexidine varnish for caries prevention in risk groups was inconclusive. In a recent 24-month clinical trial on primary molars in six- to seven-year-old children (Baca et al., 2004), application of chlorhexidine varnish at three-monthly intervals resulted in a lower incidence of caries in children who were caries-free at baseline.

The purpose of this study was to assess the effect of six-monthly applications of 40% chlorhexidine varnish on the incidence of dental caries in primary molars in Chinese preschool children.

MATERIALS & METHODS

This double-blinded, randomized, placebo-controlled clinical trial was carried out according to the guidelines for good clinical practice (MRC, 1998). The study protocol was reviewed and approved by the Ethics Committee of the School of Dentistry of the Wuhan University prior to the start of the study. Informed written consent was obtained from the parents of the children prior to the implementation of this study. The study was implemented in Hongshan district, Wuhan City, Hubei Province, China, and the study was carried out according to the guidelines for good clinical practice (MRC, 1998). The study protocol was reviewed and approved by the Ethics Committee of the School of Dentistry of the Wuhan University prior to the start of the study. Informed written consent was obtained from the parents of the children prior to the implementation of this study. The study was implemented in Hongshan district, Wuhan City, Hubei Province, China.
In total, 334 children were originally included in the study—175 in the test group and 159 in the placebo group. The ratio of boys to girls was 1:1.04. Results of the duplicate examinations showed that the inter-examiner reliability in assessing the tooth surface status was very good (Kappa > 0.90). There was no significant difference between the baseline mean dmfs-molar scores of the two groups (2.8 vs. 2.6; t test, p > 0.05). After 2 yrs, 44 children (13%) were lost to follow-up, because some (n = 31) had moved to other kindergartens, and some (n = 13) objected to the taste of the varnish and refused to be examined. The baseline mean dmfs-molar scores of the children who dropped out were similar to those of the children who remained in the study (2.6 vs. 2.7; t test, p > 0.05).

The result presented below was based on the 290 children who remained in the study after 2 yrs (155 in the test group and 135 in the placebo group). The respective baseline mean dmfs-molar scores of these two groups of children were 2.8 and 2.6 (Table), and the difference was not statistically significant (t test, p > 0.05). The mean caries increment of the primary molars was 1.0 dmfs-molar in the test-group children and 1.6 dmfs-molar in the placebo group. The difference of 0.6 tooth surface was equated to a 37.3% reduction in caries increment, and was statistically significant (p = 0.036; 95% CI = 0.04-1.16). No side-effects (such as soft-tissue lesions and staining of teeth) were found at the 24-month examination.

**DISCUSSION**

The main result of this study was a 37.3% reduction in new caries increment in the primary molars of the test-group children when compared with the control group over a two-year period. This clinical trial adopted a randomized, double-blinded, placebo-controlled design. Although the random allocation of study children into the test and control groups on a class basis (cluster allocation) may not be ideal, this was adopted in this study to prevent error in painting the wrong varnish onto the teeth of the young children if children belonging to both groups were present in the same class. In all study kindergartens, the assignment of children to different classes was not done on any special basis, such as their demographic or socio-economic background. Thus, the children in the test and control groups were comparable. The excellent inter-examiner reliability found in this study may be taken to indicate that the amount of measurement bias in this study was small.

**Table.** Mean dmfs-molar Scores of the Study Children in the Chlorhexidine and the Placebo Groups at Baseline and after 24 Months, and Their Caries Increments (SE in parentheses)

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean dmfs-molar (SE) at Baseline</th>
<th>Mean dmfs-molar (SE) at 24 Months</th>
<th>Mean Caries Increment, dmfs-molar (SE)</th>
</tr>
</thead>
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<tr>
<td>CHX</td>
<td>155</td>
<td>2.8 (0.3)</td>
<td>3.8 (0.4)</td>
<td>1.0 (0.2)</td>
</tr>
<tr>
<td>Placebo</td>
<td>135</td>
<td>2.6 (0.4)</td>
<td>4.2 (0.4)</td>
<td>1.6 (0.2)</td>
</tr>
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</table>

* Two-sample t test.

* dmfs-molar = the number of decayed, missing (due to caries), or filled primary molar surfaces.
The magnitude of caries reduction found in this study is comparable with that found in an earlier 24-month clinical trial (Baca et al. 2004). In that study, the percentage of reduction in decayed and filled primary molar surfaces was 11% and 46%, respectively, for children with and without caries at baseline.

Studies that compared chlorhexidine varnish with topical fluoride applications (Petersson et al., 2000; Splieth et al., 2000) showed that they had similar effectiveness in preventing dental caries in the permanent teeth of teenagers. The 37.3% reduction in caries increment in this study is also close to that found in a meta-analysis of the results on effectiveness of fluoride varnish on caries prevention in primary teeth (Marinho et al., 2002), 33% (95% CI = 19-58%).

Results of a two-year longitudinal study on a cohort of healthy schoolchildren, who received 3 applications of chlorhexidine varnish within a period of 2 wks, showed that suppression of caries progression was significantly related to the reduction of Streptococcus mutans levels (Twetman and Petersson, 1999). The caries-preventive effect of chlorhexidine varnish has also been shown to disappear 3 yrs after cessation of its regular application in schoolchildren (Baca et al., 2003).

So far, the published studies on the effectiveness of chlorhexidine varnish have focused on the prevention of dental caries in the permanent teeth of schoolchildren with high or low caries risk (Forgie et al., 2000; Splieth et al., 2000; Haukali and Poulsen, 2003). The present study is among the first to report on the effectiveness of chlorhexidine varnish in preventing caries in primary teeth in preschool children. Since both the prevalence and severity of dental caries in the primary molars in Chinese preschool children are very high, the positive result found in this study is very encouraging. The application of chlorhexidine varnish to tooth surfaces is a simple procedure and does not require a great deal of cooperation from the young children. It has the potential for wide-spread use in community prevention programs in China and in other parts of the world.

Based on the results of the study, the null hypothesis of this study was rejected. It is concluded that six-monthly applications of a 40% chlorhexidine varnish can prevent dental caries in the primary molars of preschool Chinese children.

**ACKNOWLEDGMENTS**

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**REFERENCES**


