Effectiveness of Chlorhexidine–Thymol Varnish in Preventing Caries Lesions in Primary Molars

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ABSTRACT

Purpose: The objective of this study was to evaluate the effect of chlorhexidine-thymol varnish on the prevention of caries lesions in primary molars among schoolchildren ages 6 to 7 in relation to their previous experience with caries.
Methods: Two groups of schoolchildren of lower-middle socioeconomic level were followed up in a clinical trial: one group of 86 children, treated with a chlorhexidine-thymol varnish (Cervitec) and another group of 95 children who served as controls. The varnish was reapplied every 3 months, and the caries lesion increments were compared at 24 months.
Results: There was no statistically significant difference between these 2 groups in the increment in decayed and filled primary molars. The children in the varnish group with no decayed or filled primary teeth at baseline showed a significantly lower ($P<.05$) incidence of caries lesions in primary molars (at 24 months) compared with the control group.
Conclusions: Chlorhexidine-thymol varnish can be said to reduce caries lesions in the primary molars of schoolchildren ages 6 to 7 with no previous caries lesion experience. (*J Dent Child*. 2004;71:61-65)

KEYWORDS: CARIES PREVENTION, CHLORHEXIDINE-THYMOL VARNISH, SCHOOLCHILDREN, PRIMARY MOLARS

The present follow-up study is part of a field trial started in Granada (Andalusia, Spain) in 1996. Over a period of 24 months, 6- to 7-year-old schoolchildren from a lower-middle socioeconomic background were studied to determine the effectiveness of Cervitec chlorhexidine-thymol varnish in the prevention of dental caries. One of the objectives was to evaluate the effects on primary molars due to the frequency with which they present caries lesions.[1]

In general, the prevalence of caries lesions in Spanish children can be classified as low. In 1994, 62% of children in Spain ages 5 to 6 years were caries free, and the mean number of decayed and filled primary teeth (dft) in this age group was 1.02.[2] In 1995, 7-year-old children in Andalusia presented a mean dft of 2 and mean of 0.38 decayed, missing and filled permanent teeth (DMFT),[3] and 47% were free of caries lesions in primary teeth. The lower-middle social background of the Andalusian schoolchildren in the present study represents an important risk factor for caries.[4] These children may benefit from specific programs such as the application of chlorhexidine.[5] Given the low rate of restorations in these children and the fact that the regional public health service does not include the systematic treatment of caries lesions in children, the authors believed it important to determine the effectiveness of the varnish with respect to the children's previous caries lesion experience.

The effectiveness of chlorhexidine in the prevention of caries lesions has been demonstrated,[6,7] but it is not yet clear whether the selection of high-risk individuals for treatment can improve the levels of effectiveness. A review article by Emilson[6] concluded that the best clinical effect of chlorhexidine (ie, the

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considerable reduction in caries), has been obtained in individuals highly colonized with *mutans streptococci*. However, a later meta-analysis—which reported an overall caries-inhibiting effect of 46% (95% CI=35%–57%) from the use of chlorhexidine-containing gels, mouthrinses, and toothpastes—concluded that the "caries risk" variable may exert no influence on caries lesion reduction.[7]

The incorporation of chlorhexidine in varnishes is quite recent. One of these products, Cervitec,[8] reduces the development of fissure caries lesions in permanent molars[9-11] and is useful in the control of approximal caries.[12] The authors' Cervitec treatment program achieved a 49% preventive fraction of the decayed and filled surfaces (DFS) index in first permanent molars.[13] Nonetheless, the authors found no study evaluating the effectiveness of Cervitec or any other chlorhexidine varnish in primary molars.

The aim of this study was to assess the effect of previous caries lesion experience in primary teeth (dft) on the prevention of caries lesions in the primary molars of children ages 6 to 7 years from a lower-middle socioeconomic background, within the framework of a school program of 1 chlorhexidine-thymol varnish application every 3 months.

METHODS

SELECTION OF THE SAMPLE AND STUDY DESIGN

In 1996, a field trial was launched with a planned duration of 24 months. Five elementary schools were randomly selected from all 21 elementary schools in the northern section of the city (with a very homogenous population of approximately 35,000 and a lower-middle socioeconomic level). Each school had 2 classes for the first grade, with 20 to 25 pupils in each class; the classes were randomly designated as control group or varnish group. The schoolchildren received no preventive treatment before or during the study period. The concentration of fluoride in the drinking water was 0.07 ppm.

The study design was approved by the ethics committee of the School of Dentistry, University of Granada. Although the total number of children selected was 250, informed written consent was obtained from the parents of only 229 (92%). Since 48 of these dropped out at a later date, the results only refer to the 181 children who were followed up for 24 months—86 belonging to the varnish group and 95 to the control group.

APPLICATION OF THE CHLORHEXIDINE–THYMOL VARNISH

At the onset of the study, varnish was applied twice with an interval of 1 week between the applications, after which the varnish was applied once every 3 months. The applications were carried out in the schools by 2 dentists using portable equipment. Cervitec (1% chlorhexidine+1% thymol; Vivadent, Schaan, Liechtenstein) varnish was applied according to the manufacturer's instructions. The teeth were cleaned with a toothbrush for 2 to 3 minutes, isolated with cotton rolls, and dried. A thin coat of varnish was applied to all the teeth and surfaces, including both complete and partial eruptions and decayed, filled, and sound teeth, and they were again dried for 30 seconds.

This procedure was repeated in each quadrant. Approximately a quarter of a 1.5 ml bottle was used per application. The children were informed that they should not drink or eat for 3 hours (for this reason, application took place after their recess), brush their teeth until the following day, or use dental floss for 1 week. The control group received no treatment other than clinical examination.

EXAMINATION OF SCHOOLCHILDREN AND STATISTICAL ANALYSIS

The examination system and its periodicity were similar for the varnish and control group. The examinations were performed in classrooms with good light. Caries lesions were diagnosed and recorded using WHO criteria[14] with an explorer and flat mirror. The oral examinations were performed at the onset of the study period and every 6 months thereafter, with the final one taking place at 24 months. Data on sex, age, birth date, and socioeconomic family status were noted.[15] After the initial examination, a report was sent to the parents of all participants to inform them of the need for restorative treatment (when necessary). All examinations, which were not performed in a blinded fashion, were carried out by the same dentist.

For the initial examination and those at 12 and 24 months, the intraobserver and interobserver diagnostic agreement was tested. One week after these examinations, the examiner and a second dentist, who was blinded to the status of the children, repeated the examination of at least 10% of the participants. The reliability was analyzed using the kappa test[16] based on all the dentition.

Caries lesions were scored using the dft, decayed and filled primary surfaces (dfs), and DMFT indexes. Caries lesions in primary molars were expressed as the total number of decayed and filled molars (dftm) and decayed and filled surfaces (dfsm). Any missing primary molars were not excluded from these indexes, but rather assigned the value that they had when they fell out or were extracted.

The data on caries lesions were analyzed using the nonparametric Wilcoxon test for paired samples and the Mann-Whitney U test for independent samples, by means of the Statgraphic statistic program.

RESULTS

Out of the 229 schoolchildren with written consent to participate in the study, 48 (21%) were lost to the follow-up, usually because they changed to a different school or their parents decided to interrupt the program. A total of 181 children participated for the full 24 months: 86 in the chlorhexidine varnish group and 95 in the control group. There were no significant differences at baseline in gender, age, socioeconomic level, number of teeth present, or caries lesion index between those completing the study and the lost cases (results not shown).

The kappa coefficient for intraobserver and interobserver reliability was >0.63, which is considered satisfactory on the scale of Landis and Koch.[17]

Table 1. Initial Comparison of Children Followed Up for 24 Months

Variable	Control	Chlorhexidine varnish	Comparison *P* value
No. of children	95	86	
Mean age (±SD)	6.49 (0.28)	6.46 (0.29)	NS§, .534
Present teeth			
Permanent	4.67 (3.18)	4.61 (3.04)	NS§, .902
Primary	17.36 (2.03)	17.47 (2.31)	NS§, .738
Caries lesion indexes			
dft*	1.86 (2.73)	2.31 (3.05)	NS§, .296
Decayed	1.55 (2.33)	2.18 (2.81)	NS§, .102
Filled	0.30 (1.23)	0.12 (0.79)	NS§, .256
dfs†	3.48 (6.42)	4.40 (7.80)	NS§, .385
DMFT‡	0.17 (0.54)	0.25 (0.67)	NS§, .397

*dft=decayed and filled primary teeth.
†dfs=decayed and filled primary surfaces.
‡DMFT=decayed and missing and filled permanent teeth.
§NS=not significant.

Table 2. Caries Lesion Prevalence at Baseline and Incidence in Primary Molars (dftm and dfsm) by Study Group

Caries lesion indexes primary molars	Control N=95 mean (SD)	Varnish N=86 mean (SD)	Comparison *P* value
Baseline			
dftm*	1.52 (2.32)	1.83 (2.37)	NS§, .15
dfsm†	3.07 (6.03)	3.75 (6.75)	NS§, .10
Incidence			
dftm*	0.94‡ (1.5)	0.97‡ (1.45)	NS§, .53
dfsm†	2.54‡ (3.4)	2.21‡ (2.96)	NS§, .36

*dftm=decayed and filled primary molar.
†dfsm=decayed and filled primary molar surfaces.
‡Statistically significant incidence (P<.05).
§NS=not significant.

A low percentage of the children, 43%, were free of caries lesions in primary and permanent teeth (dft+DMFT=0) at the onset of the study (47% in the control group and 38% in the varnish group). After 24 months, the caries-free percentage had dropped further to 27%. At baseline, there were no significant differences between these 2 groups in age, number of teeth present, or caries lesion index (Table 1). The number of filled primary teeth represented a very low percentage of the dft index: 6% in the varnish group and 16% in the control group. The percentage of fillings remained low throughout the study period: 26% and 14% in the varnish and control groups, respectively, after 24 months.

At baseline, the mean number of missing primary molars per child was 0.06 in the varnish group and 0.02 in the control group. At the end of the study period, both groups presented the same number of missing primary molars (0.6 molars/child). Out of these, 71% in the varnish group (N=36 molars) and 59% (N=34) in the control group were extracted due to caries lesions or had fallen out. The remaining primary molars that were lost were healthy.

At baseline, there were no significant differences between the groups in the caries lesion indexes for primary molars (dftm and dfsm), although they tended to be higher in the varnish group. Likewise, the incidence of caries lesions at 24 months showed no significant differences between the 2 groups (Table 2). Among the children who were caries free at the onset of the study, those in the varnish group showed a significantly lower incidence of caries lesions in teeth ($P<.05$) and on surfaces ($P<.05$) of primary molars at 24 months compared with those in the control group. The reduction percentage in carious primary molars was 44% (Table 3). On the other hand, among the children with dft>0 at baseline, there were no statistically significant differences between the varnish and control groups.

Table 3. Followed Up for 24 Months: Increase in Caries Lesion Indexes in Primary Molars in Schoolchildren With dft=0 or >0 at Baseline

Variable	Control group n Mean (SD)	Varnish group n Mean (SD)	Comparison *P* value	Reduction varnish versus control (%)
dft*=0 at baseline				
dftm†	49 1.10 (1.68)	34 0.61 (1.23)	.049	44
dfsm‡	49 1.73 (2.68)	34 0.94 (2.10)	.041	46
dft >0 at baseline				
dftm	46 0.76 (1.26)	52 1.21 (1.55)	.919 NS§	–
dfsm	46 3.4 (3.88)	52 3.04 (3.15)	.531 NS§	–

*dft=decayed and filled primary teeth.
†dftm=decayed and filled primary molar.
‡dfsm=decayed and filled primary molar surfaces.
§NS=not significant.

DISCUSSION

The present field trial was designed to determine whether a program of varnishing with chlorhexidine could effectively reduce caries lesions among schoolchildren with a potentially increased risk of the disease because of their socioeconomic background and lack of any previous preventive program. Indeed, the percentage of caries-free schoolchildren in this study population was lower than the mean percentage in the region and country as a whole.

The authors chose to apply the varnish every 3 months because of findings by Petersson et al,[8] that Cervitec was effective in reducing salivary *mutans streptococci* when applied at this frequency. The control group received no treatment, andthe authors' conclusions, therefore, refer to Cervitec varnish applied according to the manufacturer's instructions.

The examining clinician was not blinded to the group that the participants belonged to, which may be a study limitation. However, the authors obtained a satisfactory interobserver agreement with a second dentist who was blinded to the status of the children. Furthermore, the authors used WHO caries lesion criteria, which may have reduced the possible bias because the lesions are diagnosed in cavity phase.

This study did not include primary incisors due to the high frequency of their exfoliation at these ages. At the beginning of the study, the number of absent primary molars was so low (0.06 and 0.02 molars/child in varnish and control groups, respectively) that it was not taken into account. However, by the end of the study and largely due to caries, 0.6 molars/child had fallen out or been extracted, which could have introduced a bias in the results. The study design had addressed this potential weakness by establishing 6 monthly examinations of the state of oral health of the schoolchildren. These data allowed the inclusion of lost molars in the results analysis according to the degree of health they presented before their loss or extraction. In this way, the authors were able to calculate the caries lesion experience score for the primary molars.

The incidence of caries lesions in primary molars (dftm and dfsm scores) did not significantly differ between the varnish group and the controls. This lack of overall effectiveness of the varnish could be for any number of reasons. One would be a greater level of basal disease in the test group. However, although the authors observed this tendency (dft index of 2.31 for the varnish group vs 1.86 for the control group), the difference with the control group did not reach statistical significance. The percentage of caries-free schoolchildren also tended to be lower in the varnish group (39% of the varnish group vs 47% of controls). These tendencies may have influenced the results. It could be argued that this study should have evaluated the effectiveness in the primary molars of younger children, because many molars already have caries lesions by the time the child is 6 years old. On the other hand, the control group showed an increase of 2.54 in its dfsm index over the 24 months of this study, demonstrating that caries lesions in many primary molars can be prevented in children ages 6 to 7 years.

Analysis of the study population according to the baseline dft showed a significant reduction of 44% (varnish-treated vs controls) in primary molar caries among the children, with an initial dft of 0. This percentage may not be clinically relevant in these low-risk schoolchildren, so that it is of interest to determine the clinical impact of the absolute difference in caries lesion increment between the 2 groups. Thus, in the present study, 0.49 (=1.1-0.61, Table 3) teeth were saved per treated child. The varnish treatment had no significant effect in preventing caries lesions in children with a baseline dft above 0 (Table 3). The influence of previous caries lesions on the success of preventive programs is not an unusual finding.[19,20]

A study of the application of a 40% chlorhexidine varnish to permanent molars found no significant results when the children were stratified according to their basal caries lesions, but reported significant reductions when only the children with high basal counts of *mutans streptococci* were considered.[21] However, in contrast to this study population, the children in the former study presented an overall low prevalence of caries lesions and received regular preventive and operative care. In situations where caries lesions are nearly always treated, it may be more useful to select the children with high *mutans streptococci* levels for a specific preventive varnish treatment.

The schoolchildren in this study can be classified overall as at mid-to-high risk, given that they received no preventive treatment of any kind and only rarely underwent restorative treatment. The percentage of filled teeth was very low (5% and 16% of dft index in varnish and control groups, respectively) and this trend hardly altered over the study period, with a large number of teeth with caries lesions going untreated. Moreover, these lesions were cavitated according to WHO criteria. The lack of restoration of previous caries lesions may limit the efficacy of preventive measures to control infection.

Although the restoration of caries lesions does not seem to reduce the levels of cariogenic bacteria over the long term,[22,23] the treatment of the caries lesions may lead to a drop in *mutans streptococci* levels, thereby reducing the risk of infection of other teeth.[24] In children under 5 years of age, full dental treatment significantly suppressed *mutans streptococci* in plaque, whereas a single application of 40% chlorhexidine varnish achieved no significant additional suppression.[25]

The complex microbiota of cavitated lesions[26] may possibly serve as a reservoir from which the microorganisms can readily recolonize oral ecosystems after treatment with chlorhexidine varnish. On the other hand, nightly treatment with chlorhexidine varnish mouthguards for 1 week was recently shown to reduce the salivary levels of *mutans streptococci* for 3 months in children with active lesions in mixed and primary dentition,[27] although long-term effects were not reported. It may even be that chlorhexidine varnish, despite effectively reducing salivary levels of *mutans streptococci*, is not effective in preventing caries lesions in high-risk adolescents.[28]

CONCLUSIONS

The 3-month application of a chlorhexidine-thymol varnish (Cervitec) for 24 months in schoolchildren ages 6 to 7 from a lower-middle socioeconomic background resulted in a reduced incidence of caries lesions in primary molars in the children

with no previous caries lesion experience. Further research is needed to assess the efficacy of chlorhexidine varnishes in the reduction of caries lesions in general, and in primary teeth in particular, to establish clearer associations in terms of distinct protocols and different age and risk groups.

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