Prevention of Early Childhood Caries—Results of a Fluoride Toothpaste Demonstration Trial on Chinese Preschool Children after Three Years

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Abstract

Objectives: *This field demonstration trial evaluates the long-term effects of introducing daily toothbrushing with fluoride toothpaste in a Chinese kindergarten (test group) compared to caries development in children who had no organized preventive program (control group).* ***Methods:*** *In the test group teacher-supervised toothbrushing was initiated with 1,000 ppm MFP toothpaste in addition to oral health education activities. Test and control children were examined at baseline (n=289, aged 3 years) and annually thereafter.* ***Results:*** *After three years, 251 children (87%) were still in the trial. Caries development (dmfs) calculation included only those children who were present at both baseline and subsequent annual examinations. At baseline the mean dmfs was 4.8 in the test group and 6.5 in the control group (NS). After three years the caries increment was 6.2 and 8.4 in the test group and the control group, respectively (P<.05). Adjusting for reversals, the net caries increment was 3.6 and 6.3, respectively (P<.01). Additionally, multiple linear regression analysis indicated that both baseline dmfs, the program and plaque level had a significant effect on the net caries increment. The use of hierarchical caries severity zones was useful for the identification of those children most at risk for further caries development.* ***Conclusions:*** *We conclude that a daily toothbrushing with limited involvement of professional staff was feasible in a Chinese kindergarten and that caries development was significantly slowed in the test children. Caries severity zones may possibly assist in determining levels of intervention. [J Public Health Dent 1998;58(1):12-18]*

Key Words: child, preschool; cohort studies; dental caries; dentition, primary; health education, dental; preventive dentistry.

Contrary to several reports over the last decade indicating that dental caries is a fading disease globally in child populations (1-3), the prevalence of caries in primary teeth of Chinese children is dramatic compared to present western standards. Studies conducted in various parts of China indicate that Chinese preschool children do not yet fit the pattern characterizing children in many of the more developed countries (4-6). Our own epidemiologic surveys in southern China have confirmed that dental caries is prevalent as well as extensive in very young children (7,8). Although the etiology for this caries pattern is uncertain (9-11), on the epidemiologic evidence alone it is obvious that caries prevention is urgently needed in Chinese preschool children.

The use of fluorides by various means has proven to be effective in preventing dental caries (12). The use of fluoridated toothpaste in toothbrushing is one of the most popular ways of delivering topical fluorides in developed countries, and results from clinical trials have shown that it is an effective caries prevention method (13-15). However, nearly all of the clinical trials were on caries prevention in the permanent teeth of children and adolescents. In a recent review of 94 fluoride toothpaste clinical trials conducted over the last 30 years (16), only one study was on the primary dentition of preschool children. This three-year study by Winter and coworkers (17) on 2-year-old children showed that the caries-prevention effect of a 550 ppm fluoride toothpaste was similar to that of a 1,055 ppm fluoride toothpaste. Only one recent Finnish study addresses this issue in primary teeth of nursery-school children (18). So it was important to study the effect of a well-established caries-prevention method for permanent teeth on the primary teeth of young Chinese children who had very little exposure to fluoride in any form.

The main objectives of the study were to evaluate the effects of a daily toothbrushing program in a Chinese kindergarten using fluoridated toothpaste on the oral health status of the children in terms of caries incidence, visible plaque, and gingival bleeding. Additionally, as an extension of previously reported caries patterns in preschool children (5,8,19), we wanted to assess to what extent the children's caries incidence during the investigation was associated with their dental caries pattern registered at baseline.

Methods

Location of Trial. Conghua County is located in the southern part of China, Guangdong province, 100 km northeast of Guangzhou (Canton) covering an area of 2,000 square kilometers. It has a population of around 400,000, of whom approximately 37 percent are younger than 14 years of age. About 85 percent of the population live in rural areas; industrial activity is limited. The annual per capita income is regarded as middle level in China. The biggest township in the county, where the program was established, has a WHO Collaborating Cen-

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ter for Primary Health Care, closely connected with the Public Health Bureau, which is responsible for health care in the county. No organized preventive or curative dental care programs are available, and dental services are provided on demand from dentists in a few hospital-based dental clinics. The fluoride concentration in the drinking water is low. Multiple water samples taken from various water outlets in the study area throughout the study showed that it was approximately 0.1 ppm; when the present program was initiated, fluoride toothpaste was not available in the market.

Study Design. In China, children can attend kindergarten for four years, entering at age 3 and leaving at age 7, when compulsory primary school starts. All children studying in grade 1 of the three largest kindergartens in the township in the fall of 1992 (n=289) were recruited into this study. The children in the largest kindergarten constituted the test group (n=168) and those in the two other kindergartens (n=121) formed the control group. Of the 289 children 94 percent were 3 years old, 4 percent were not yet 3, and 2 percent were 4 years old.

The children attend the kindergarten from early morning to late afternoon and are provided with regular meals during the day. After collecting baseline epidemiologic information from the children in all kindergartens, an oral health education and daily toothbrushing program was implemented in the test kindergarten as part of their regular program. The headmistresses and the teachers were informed about the trial and had consented to participate. Parents were informed by explanatory letters about the trial and were requested to inform the school if they did not wish their child to participate, but none did so.

The involvement of the test kindergarten teachers has been reported previously (20). In summary, the teachers were involved in teaching dental health knowledge to the children and in supervising the daily toothbrushing activity. One dentist and a dental hygienist from the research team conducted a series of oral health education sessions for the teachers prior to initiating the toothbrushing program. Standardized health education material was lodged in the kindergarten for use by the teachers, and the research team returned every four months to monitor the program and reinforce the activities.

Observations were conducted of classroom activities and of the toothbrushing program activities, and meetings were held with the teachers to further discuss ways of standardizing the approach. Colgate MFP 1,000 ppm toothpaste and Colgate Junior toothbrushes were used. Right after lunch, each child would pick up his or her own toothbrush from a specially built wall cabinet in the classroom and go to the washroom next door to perform the toothbrushing. Approximately 0.2–0.4 g of toothpaste, about the size of a child's little finger nail, was dispensed at each brushing by the teacher or by a class prefect supervised by a teacher. Usually, the children brushed for two to three minutes (simple miniscrub), then rinsed with water, and expectorated. The process was supervised by the teacher, but not standardized.

No dental health education or other information or activities were provided for the control kindergarten teachers. They were, however, aware of the ongoing activities. At the end of the trial the control kindergartens were supplied with toothbrushes and toothpaste for all children and appropriate oral health education materials were distributed. The protocol was approved by the Ethics Committee of the Faculty of Dentistry, University of Hong Kong.

Clinical Examinations. At baseline and every subsequent year the test and control children underwent a clinical assessment comprising an examination of the oral mucosa for sinuses and abscesses, a caries examination of all tooth surfaces, and a half-mouth examination of visible plaque on the buccal and lingual surfaces of each tooth. The dichotomous Visible Plaque Index (VPI) and Gingival Bleeding Index (GBI) were used to gauge the effect of the program on oral hygiene and gingival health (21).

Clinical criteria for the diagnosis of dental caries followed the WHO guidelines (22) with the exception that a separate score for arrested caries was included from the first annual follow-up examination onwards. An arrested caries lesion was characterized by an obvious loss of tooth substance, i.e., cavitation exposing dentine. However, the lesion appeared dark brown to black in color and was hard when tested with a sharp explorer using moderate force (23). Lesions within enamel were excluded. If a lesion was recorded as arrested caries in one examination and in the following annual examination was recorded with active caries—i.e., a cavity with softened wall or floor—it was termed a reactivation of an arrested carious lesion. According to the WHO criteria, the "m" component of the dmfs index was only used when a tooth was judged to be missing due to caries; i.e., it could not be explained by natural exfoliation or other reasons, such as congenitally missing.

To assess the association between early caries pattern and incidence of dental caries, caries severity groups were recorded for each child at the baseline examination (8). Four mutually exclusive, hierarchically ordered caries severity groups were used to reflect different caries patterns. Caries-free children were allocated to group 0, children with dental caries only in pit and fissure surfaces of posterior teeth were allocated to group 1, children with caries on proximal surfaces of molars and of maxillary anterior teeth were allocated to group 2, and children with dental caries on labial surfaces of maxillary and mandibular incisors and on proximal surfaces of mandibular anterior teeth were allocated to group 3. Dental radiographs were not used in the study.

Clinical examinations were carried out by the same two examiners (ES and EL) during the trial. Interexaminer calibration was carried out before the start of each of the annual examinations and duplicate caries examinations were conducted on one out of every 10 children throughout the study. Interexaminer reliability for caries status calculated at the tooth surface level and expressed by kappa statistics was consistently about 0.90 for all four examinations.

Data Analysis. Only those children who were present at baseline and all subsequent examinations were included in this analysis. The overriding purpose of the analysis was to determine caries incidence in the two groups of children and to compare them. The crude caries increment was defined as all new active caries lesions and all caries lesions that had reactivated from an arrested state. Conversely, two kinds of reversals were

identified—arrested caries and examiner reversal, which was identified if a tooth surface was recorded with active caries in one examination and in the following annual examination was recorded as sound (24). By calculating each type of reversal separately, we were able to account for the total net increment by subtracting the reversals from the crude increment.

Calculations of the VPI and GBI index values were performed according to the following formula:

$$\frac{S+}{TS} \times 100,$$

where $S+$ denotes all surfaces with a positive score (score=1) and TS denotes the total number of surfaces examined. Thus, the VPI or GBI value expresses the proportion (%) of surfaces examined that were found to have visible plaque or gingival bleeding, respectively.

Statistical analysis was performed by the SPSS for Windows 6.1 (25). Two-sample T-tests were performed to compare the differences in dmfs scores, caries increments, caries reversals, net caries increments, Visible Plaque Index, and Gingival Bleeding Index between groups. Appropriate tests for equality of variance were employed before each T-test. Chi-square tests were applied to test differences in caries severity zones between the test and control children.

Multiple linear regression analysis was employed to analyze the effects of potentially confounding variables including sex, caries experience at baseline (dmfs), average Visible Plaque Index, and daily toothbrushing program on the total net caries increment from baseline to year 3 (26). In the first stage, program effect, baseline dmfs, three-year average VPI, and sex were entered as independent variables in the model; by backward elimination, sex was identified as an insignificant variable ($P>.05$) and removed. In the second stage, first-order interaction terms involving the three significant independent variables were entered into the model and again backward selection and elimination were used to identify the final model. Only those variables with $P<.05$ would stay in the final model. However, if an interaction effect of any two variables was significant, both variables would stay in the final model regardless of whether they were significant.

TABLE 1
Total dmfs Increment, Reversals, and Net Increment for Test and Control Kindergarten Children During Study

	Test Group		Control Group		P-value
	Mean	(SE)	Mean	(SE)	
Increment					
New active caries	6.0	(0.46)	8.3	(0.77)	0.011
Caries reactivations	0.2	(0.05)	0.1	(0.05)	0.430
Subtotal	6.2	(0.47)	8.4	(0.79)	0.016
Reversals					
Arrested caries	1.9	(0.26)	1.1	(0.18)	0.022
Examiner reversals	0.7	(0.10)	1.0	(0.13)	0.154
Subtotal	2.6	(0.31)	2.1	(0.25)	0.260
Net Increment	3.6	(0.45)	6.3	(0.76)	0.002

TABLE 2
Three-year Total Net dmfs Increment by Tooth Surface Types

	Test Group		Control Group		P-value
Surface Type	Mean	(SE)	Mean	(SE)	
Occlusal	1.1	(0.14)	1.2	(0.16)	0.523
Buccal and lingual	0.7	(0.15)	1.5	(0.27)	0.010
Approximal	1.8	(0.29)	3.6	(0.44)	0.001
All surfaces	3.6	(0.45)	6.3	(0.76)	0.002

Results

The dropout rate of the test children was 10 percent—i.e., 152 out of the 168 children remained in the trial at year 3. The corresponding figure for the control children was 19 percent; i.e., 99 out of the 121 children remained. The dmfs of all the test children was 4.9 dmfs (SE=0.56) at baseline and for all the control children 6.8 dmfs (SE=0.75). Baseline dmfs was calculated again for those children who remained in the trial after year 3, and no statistically significant difference was observed between test and control (test group: x=4.8, SE=0.60; control group: x=6.5, SE=0.83; P=.096). Nearly all of the recorded caries was decayed surfaces (test group: 99.6%; control group: 100%). The sex distribution remained stable and no statistically significant differences were found between boys and girls on the various measures; thus, no stratification by sex was done in the analyses.

The caries increment over the three years is shown in Table 1. Statistically significant differences between test and control children were found for the mean number of new carious surfaces per child—6.0 (test group) against 8.3 dmfs (control group); and for arrested carious surfaces—1.9 (test group) against 1.1 (control group). The mean numbers of caries reactivation and examiner reversals were similar in the two groups. Mean net caries increments for the test and control groups were 3.6 and 6.3 surfaces, respectively, corresponding to 42.8 percent less increment in active caries surfaces in the test group.

The three-year net caries increment differed significantly by experimental group and tooth surface type (Table 2). Significant differences between the test and control groups were found on approximal, buccal, and lingual surfaces; no differences were found on occlusal surfaces.

At baseline, approximately one-quarter of the children were caries free in both the test group and the control group (Table 3, severity zone 0, row totals). After 36 months, this had decreased to approximately 20 percent in the test group and 12 percent in the control group (Table 3, severity zone 0, column totals). However, no statis-

TABLE 3
Changes in Severity Zones from Baseline to 36-month Examination
[Row percentages of children indicate the proportion of children in the respective severity zones* at baseline. Column percentages indicate the proportion of children in the respective severity zones at 36 months. In the columns denoted "Total," column percentages are in parentheses, whereas row percentages sum up to 100.]

		Severity Zone at 36-month Examination‡									
		Test Group					Control Group				
Severity Zone at Baseline†		0	1	2	3	Total	0	1	2	3	Total
0	*n*	20	1	21	0	42 (27.6)	9	1	16	1	27 (27.2)
	%	47.6	2.4	50.0		100	33.3	3.7	59.3	3.7	100
1	*n*	4	1	9	0	14 (9.2)	0	0	6	0	6 (6.2)
	%	28.6	7.1	64.3		100			100		100
2	n	6	4	49	12	71 (46.8)	3	0	28	8	39 (39.4)
	%	8.5	5.6	69.0	16.9	100	7.7		71.8	20.5	100
3	n	0	0	6	19	25 (16.4)	0	1	4	22	27 (27.2)
	%			24.0	76.0	100		3.7	14.8	81.5	100
Total	n	30	6	85	31	152 (100)	12	2	54	31	99 (100)
	%	19.8	3.9	55.9	20.4	100	12.2	2.0	54.5	31.3	100

*Definitions of severity zones: 0=caries free; 1=caries in pits and fissures in surfaces of posterior teeth; 2=caries on proximal surfaces of molars and of maxillary anterior teeth; 3=caries on labial surfaces of maxillary and mandibular incisors and on proximal surfaces of mandibular anterior teeth.
†Chi-square=4.87; df=3; P=.18 (between the test and the control children).
‡Chi-square=5.69; df=3; P=.13 (between the test and the control children).

TABLE 4
36-month Net Caries Increment of Test and Control Children by Their Severity Zone* at Baseline

	Test Group				Control Group			
Baseline Severity Zone	*n*	Baseline dmfs	Net Caries Increment	95% CI	*n*	Baseline dmfs	Net Caries Increment	95% CI
0	42	0.0	1.88	1.07–2.69	27	0.0	3.33	0.75–5.91
1	14	1.21	2.93	0.86–5.00	6	1.33	5.67	4.09–7.25
2	71	4.37	3.79	2.49–5.09	39	5.28	4.90	3.15–6.64
3	25	16.28	2.80	–0.4–6.00	27	15.93	9.63	5.48–13.78

*Definitions of severity zones: 0= caries free; 1=caries in pits and fissures in surfaces of posterior teeth; 2=caries on proximal surfaces of molars and of maxillary anterior teeth; 3=caries on labial surfaces of maxillary and mandibular incisors and on proximal surfaces of mandibular anterior teeth.

tically significant differences were found between the test and the control groups with regard to their distribution in caries severity zones at either baseline or at 36 months. It seemed that a larger proportion of the test children reversed from a higher severity zone to a lower one during the trial [Table 3, 20 test group children (13.2%) against eight control group children (8.1%)], which could only take place due to caries reversals—either caries arrests or examiner reversals. However, when submitting these results to a chi-square test under the hypothesis of no difference in the distribution of children who reversed to a lower zone, remained in the same zone, or progressed to a higher zone in the test and control groups, respectively, no statistically significant association could be found (chi-square=1.72; df=2; P=.42).

In Table 4, the association between severity zone at baseline and caries incidence during the trial is assessed further. The higher the severity zone at baseline (and implicitly the more serious the caries recorded), the more caries the child accumulated. For the control children, a close relationship was demonstrated between caries severity zone and net caries increment. The test children, however, exhibited a different pattern, with the children in the most severe caries zone developing less caries than those in the two

lower groups.

With respect to plaque and gingival bleeding, a significantly larger proportion of surfaces harbored plaque in the control group at the end of the three years (28%) than in the test group (22%; P=.006), whereas no significant differences in gingival bleeding were found, with approximately 20 percent of surfaces being affected in both groups (test group: 18%; control group: 17%; P=.739).

Finally, the relative effect of the various independent variables on the variation in net caries increment was examined by a multiple linear regression analysis. The final model is shown in Table 5. The results show that the poorer the oral hygiene as measured by the average VPI over the three years, the higher the net dmfs increment from baseline to year 3; also, the higher the baseline dmfs, the higher the net dmfs increment. However, the effect of the baseline dmfs was different in the test and control kindergartens as reflected by a significant interaction between baseline dmfs and the program. In the control kindergartens (with program effect coded as 0), the effect of baseline dmfs was 0.37—i.e., the net caries increment over the three years would be increased by 0.37 for each additional surface in the baseline dmfs. In the test kindergarten (with program effect coded as 1), the effect of baseline dmfs was only 0.03 (β= 0.37–0.34).

TABLE 5
Results of Multiple Linear Regression Analysis for Net dmfs Increment from Baseline to Year 3

Independent Variables	β	SE (β)	Standardized β	P-value
Program	–0.09	0.99	–0.01	.925
Baseline dmfs	0.37	0.07	0.45	<.001
VPI (3-year average)	8.23	3.37	0.15	.015
Baseline dmfs x program	–0.34	0.10	–0.32	.001
(Constant)	0.76	1.00		.448

Program coded as 0=control group; 1=test group. Adjusted R^2=0.15. F=11.95; df=4,245; P<.001.

Discussion

The overall loss of fewer than 20 percent of the children after three years was considered to be low. Recently, a 40-month cohort study reported a 33 percent dropout rate (27). Assessments were made of those children who remained in the study compared to those who dropped out with regard to baseline dmfs, parent education level, and household income. No significant differences were found. Thus, the dropout level was considered not to seriously affect the outcome evaluations.

This study was not a clinical trial to test fluoride toothpaste. The caries preventive effectiveness of fluoride toothpaste among schoolchildren in developed countries is well established (14,15,28). However, the feasibility of introducing a preventive program that has had considerable success in a number of highly developed countries into a community with a lack of both personnel and oral health traditions was uncertain. A field demonstration trial as defined by Møller (29) seemed to be an acceptable framework in this context. This approach also implied that the toothbrushing program be established and sustained for all children in the test kindergarten, not just for the cohort being monitored longitudinally.

The ideal protocol including masking of examiners was not considered logistically possible in this community and within the available resources of the project. However, in evaluating the effect of a caries-preventive field program, masked examiners are not always used because a whole school, an institution, or an area is assigned to a particular intervention group in the study (30-33). Obviously, the bias introduced by the nonmasking procedures cannot be assessed accurately; nevertheless, stringent interexaminer calibration procedures were performed throughout to alleviate part of this problem.

The implementation of this program followed the basic principles of the primary health care approach in health care delivery emphasizing preventive activities (34,35) with special regard to what would be deemed appropriate for the circumstances of developing nations. The extent and severity of the dental caries revealed by the baseline examinations precluded a treatment component that would have overshadowed totally the preventive focus and might have left a considerable proportion of the children edentulous. Because no child (or parent) in any of the groups was restricted in any way from doing what he or she would otherwise do, and because a beneficial activity was introduced to all the test children, we considered the study as conforming with general ethical principles (36).

The activities in this program could not stop dental caries increment, but did slow the progress of new active caries in the test children corresponding to early toothpaste studies in developed countries (14,28). The trial showed an increment of dental caries that was approximately 43 percent lower in the test group than in the control group, although this reduction might not be due entirely to the program. The only other reported fluoride toothpaste study on primary teeth of preschool children showed a 66 percent reduction in caries increment over two years (18). This finding is somewhat higher than most of the other studies on older children (16,28). Certainly, the present study population exhibits much more severe and extensive caries levels than other study populations (37); thus, the effects of intensive preventive activities as exhibited in this study could be expected to be higher. However, it is unclear whether differential caries patterns in primary and permanent teeth or differential effects of the fluoride determine the variations in anticaries effect.

The method used to calculate net caries increment in a longitudinal study rarely has been stated explicitly in the literature. However, following previous suggestions (25,38), the effect of reversals in this study was taken into account in calculating the net caries increment. Recently, a new method for adjusting caries increments for reversals was suggested by Beck et al. (39). However, they themselves recommended the use of the traditional net caries increment instead of their new formula when the magnitude of examiner reversals was small compared to the baseline dmfs, which is

the case in the present study.

Even statistically significant baseline differences were allowed in a recent trial of xylitol chewing gum (27). The baseline dmfs in the present study was 26 percent lower in the test than in the control children, a difference that was not statistically significant. Nonetheless, it was of some concern to us and was addressed in the multivariate analysis. The confounding effect of the baseline dmfs was taken into consideration in the regression analysis, together with other potentially important confounding variables. The outcome of the regression model including the interaction effects indicates that the differential effect of baseline dmfs in the test and control groups was due most probably to the program that had been established in the test kindergarten.

The importance of plaque in caries development in early childhood has been pointed out by Alaluusua and Malmivirta (40). Although plaque removal was not the primary objective of the present program, it is appropriate to emphasize its dual purpose—i.e., to provide fluoride to the children and to provide mechanical cleaning. The significant effect of visible plaque in the final regression model indicates that at least in a population with limited oral hygiene, the mechanical cleaning adds to the effect of the fluoride.

True reversals due to rehardening of dentinal carious lesions were detected in this study. These were scored separately as a minor deviation from the generally used WHO guidelines. They were observed increasingly during the study. These aspects of the study will be reported separately. This phenomenon was seldom reported in previous studies—most probably because in communities where dental treatment is more easily accessible, the carious lesions would be treated by extraction or restorations. A similar finding, however, was reported in a recent longitudinal study in Belize, where dental care was not readily available (23).

As noted by Weinstein (11), longitudinal studies on preschool children are rare, which impedes the ability to predict caries development in these age groups. The use of the hierarchical caries severity zones as an additional descriptor for dental caries was suggested previously (8); however, the usefulness of the zones to predict caries development in this population was uncertain. The analyses performed indicate a close relationship between the zones and the dmfs at baseline, and between the zones and the net caries increment in the control group, but not in the test group (Table 4). This finding may be related to the observation that more of the baseline caries lesions in the test children than in the control children became arrested and thus reduced the net 36-month increment, especially for those with a high initial (baseline) dmfs, i.e., those in zone 3. The severity zones applied in this population would seem to be a rough identifier of those groups of children most at risk for further caries development, which could possibly be useful to determine the level of intervention. If an intervention is already ongoing, the zones are less useful as predictors, but may be included as part of the ongoing evaluation of a preventive program. The patterns illustrated have a striking similarity with another caries severity system recently suggested (5,19), despite different methodology.

In conclusion, a serious dental caries problem was evident in these Chinese preschool children that was addressed by a purely preventive approach. After three years of study, a 43 percent reduction in net dmfs increment was found among children who performed daily teacher supervised toothbrushing with fluoridated toothpaste and received regular oral health education in their kindergarten, as compared with children who followed a normal daily kindergarten routine without any interventions. The significance of the findings is that the implementation of a simple prevention program was shown to be feasible under conditions prevailing in a rural county in China and that the program was effective in reducing dental caries increment and in improving oral hygiene. We believe this program should be feasible and applicable in other locations in China. The recent introduction of a locally produced, international, brand-name, low-cost, fluoridated toothpaste should facilitate such a development.

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