# Effect of an Amine Fluoride Dentifrice on Dental Caries Used in a Community-based Oral Health Education Program

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#### Abstract

**Objectives:** The purpose of this study was to investigate the caries-reducing effect of an amine fluoride toothpaste when used under real-life conditions in a community preventive program. **Methods:** Approximately 12,500 children 3–12 years of age were provided with toothpaste (four tubes or 360 grams annually during three years) to be used in kindergartens or schools and once a day at home. The teachers supervised daily toothbrushing sessions. Random samples of children in each of the ages 3, 6, 9, and 12 years were selected from the intervention and the reference communities at both the start of the study and after three years, and examined for dental caries experience. **Results:** Amine fluoride dentifrice seemed to provide a reduction in dental caries prevalence compatible to the most commonly used fluoride dentifrice compounds. **Conclusions:** The implemented fluoride toothpaste program is a feasible and practical method of improving the oral health status of children. [J Public Health Dent 1997;57(3):181-3]

Key Words: amine fluoride, fluorides, dentifrice, caries prevention, dental caries, community project.

The worldwide literature accumulated since the 1980s shows convincing evidence of a decrease in the prevalence of dental caries among children and adolescents. The main reason for this decrease, according to most authors, is the regular use of fluoride preparations, fluoridated toothpaste being one of the most frequently used methods. More than one-half billion people around the world have regular access to fluoridated toothpaste, yet a number of obstacles such as cost and peoples' motivation levels prevent more wide-scale use (1).

Investigations on the effectiveness of adding fluoride to toothpaste have been carried out since 1945. Results of over 100 trials using sodium fluoride (NaF), sodium monofluorophosphate (NaMFP), and amine fluoride (AmF) show that brushing with fluoride toothpaste will reduce the incidence of dental caries (1). The first investigations of the caries-preventive properties of AmF were carried out in the late 1950s (2). The first clinical study with nonsupervised use of AmF toothpaste over seven years was published in 1968 and demonstrated a 35 percent caries reduction (3). Despite the facts that more than 400 papers on AmF are published in the fields of periodontal diseases, toxicology, and pharmacology, and that its efficacy and safety are proven, the number of clinical studies testing the caries-reducing effects of AmF are considerably fewer than for NaF and NaMFP.

The purpose of the present study was to investigate the caries-reducing effects of an amine fluoride toothpaste used in a community oral disease preventive program where the population previously had no exposure to fluoridated toothpaste. The present project was not designed as a controlled, longitudinal, clinical trial, but rather as an attempt to determine the level of caries reduction that can be expected when fluoridated toothpaste is distributed on a community basis, for individual free consumption, among groups of preschool children and schoolchildren.

#### Methods

Pazardjik, a small town situated in the southern part of Bulgaria with approximately 12,500 children 3-12 years of age attending kindergartens and schools, was selected as the project site. During the three years of the study an annual batch of toothpaste was delivered to the chief dental officer in Pazardjik and distributed through the oral health service to all child educational institutions. Each child was provided with AmF toothpaste in neutral 90 gram tubes, free of charge, for daily use in kindergartens, schools, and at home. "Fluoridated toothpaste for children" was written in Bulgarian on each tube of toothpaste. Approximately 360 grams of toothpaste and four Elmex junior toothbrushes were used annually by each child.

Dentists who were providing oral health care to the children conducted training courses on oral disease prevention for the teachers at the kindergartens and schools. The teachers supervised daily fluoride toothpaste brushing sessions in the kindergartens and schools. The two- to three-minute toothbrushing exercise normally took place immediately after the lunch break. Oral health education materials were developed and distributed among the children and parents prior to the main project activities. During the three years of the project, the local mass media provided relevant information about the project activities to the public in Pazardjik.

Random samples of children in each of the ages 3, 6, 9, and 12 years and

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Age of Children	Pazardjik					Panaguriche				
	n	_1989 (x±SD)	n	<u>1</u> 992 (x±SD)	P-value (T-test)	n	1989 (x±SD)	n	_1992 (x±SD)	P-value (T-test)
3	500	1.8 (2.7)	251	1.4 (2.6)	NS	99	1.7 (2.5)	0		
6	476	4.6 (3.5)	354	2.9 (3.1)*	<.001	100	5.6 (3.5)	100	5.2 (3.0)†	NS
9	503	3.9 (2.6)	367	2.7 (2.4)**	<.001	100	4.2 (3.1)	100	3.6 (2.6)‡	NS

TABLE 1 Mean dmft Scores at Baseline (1989) and at Three Years (1992), by Age and Study Area

• vs † and \*\* vs ‡ - P<.001.

TABLE 2Mean DMFT Scores at Baseline (1989) and at Three Years (1992), by Age and Study Site

	Pazardjik					Panaguriche				
Age of Children	n	<u>1</u> 989 (x±SD)	n	<u>1992</u> (x±SD)	P-value (T-test)	n	<u>1</u> 989 (x±SD)	n	<u>1</u> 992 (x±SD)	P-value (T-test)
6	476	0.7 (1.3)	354	0.1 (0.4)*	<.001	100	0.6 (1.0)	100	0.7 (0.7)†	NS
9	503	1.8 (1.6)	367	1.7 (1.4)**	NS	100	1.4 (2.0)	100	2.0 (1.7)†	NS
12	500	3.2 (2.7)	372	2.4 (1.9)***	<.001	101	3.5 (2.4)	100	3.2 (2.0)‡	NS

\* vs t, \*\* vs  $\ddagger$ , and \*\*\* vs  $\ddagger - P < .001$ .

equally distributed by sex were selected and examined at both the start of the study (1989) and at the end of the study (1992). A nearby town, Panaguriche, was selected as the reference area where random samples of approximately 100 children of the same ages were selected and examined at the start and end of the study.

The clinical examination team was calibrated according to the WHO standard methodology (4) immediately prior to the baseline examinations (1989) and the final examinations (1992). The team consisted of four dentists-three from the Dental School in Sofia and one from the World Health Organization who acted as the calibrator. These dentists only visited the project sites in connection with the clinical examinations and were not involved in the intervention itself. At the end of each calibration exercise, interexaminer agreement was 90 percent for total dmft or DMFT scores and 95 percent for mean dmft or DMFT scores per child. Radiographic examinations were not performed.

The natural fluoride content in the drinking water was less than 0.2 ppm  $F^-$  and systemic or topical fluorides other than the amine fluoride tooth-

paste were not available to children in the reference or test areas. Mean caries scores at baseline and at follow-up were compared within and between study groups using student's *T*-test.

## Results

Table 1 shows the results obtained in the primary dentition after three years of the intervention in the test area of Pazardjik. As expected, there was no significant difference in the dmft scores for 3-year-old children in 1992 and 1989, since these children had not previously been exposed to the community intervention. For the 6and 9-year-old children, statistically significant reductions in dmft scores of 37 percent (P<.001) and 31 percent (*P*<.001) were noted, respectively. Data in this table also indicate that no significant changes in the dmft scores took place in children from the reference area during the study period. A comparison between the test and reference areas at the end of the study indicate reductions in the dmft scores for 6- and 9-year-old children of 44 percent (P<.001) and 23 percent (*P*<.001), respectively.

Table 2 shows the results obtained in the permanent dentition after three

years. For the 6- and 12-year-old children in Pazardjik a statistically significant reduction was noted in mean DMFT scores corresponding to 86 percent (P<.001) and 25 percent (P<.001), respectively. In the 9-year-old children, the reduction of 6 percent was not statistically significant. Differences in mean DMFT scores for 6-, 9and 12-year-old children in Pazardjik and Panaguriche were 86 percent (P<.001), 15 percent (P<.001), and 25 percent (P<.001), respectively. These reductions are consistent with those found in children from Pazardjik before and at the end of the project.

## Discussion

The results obtained in this study on the caries-reducing effects of use of an amine fluoride dentifrice seem to confirm those of previous studies (3,5-7). Differences in these studies such as their design, length of study periods, and varying age groups make direct comparisons difficult. All studies seem to indicate, however, that the caries-inhibiting effect of amine fluorides is compatible with the most commonly used fluoride compounds.

The reductions obtained in this study might be explained by the fact

that no exposure to any fluoride-containing oral disease preventive measures had been available prior to the start of the study. The introduction of the program also could have been instrumental in improving awareness and knowledge among children, their parents, and teachers.

The reason for the surprisingly large reduction in the permanent dentition of 6-year-old children might be due to the fact that caries risk in this age group is limited mostly to the first permanent molars because these are practically the only permanent teeth erupted at this age. The nonsignificant caries reductions found in the permanent dentition of 9-year-old children might be explained by the fact that we are dealing with the mixed dentition, where it is difficult to ensure that the number of erupted permanent teeth at risk in 1989 is similar to the number in 1992.

This study was not intended to be a longitudinal clinical trial, but rather an attempt to determine the level of caries reduction that can be expected when fluoridated toothpaste is distributed on a community basis, for individual consumption, among groups of preschool children and schoolchildren. The study started before profound political changes took place in Bulgaria. The local authorities in Pazardjik gave permission at that time to launch the project and the teaching staff and oral health personnel were instructed on how to carry out the planned activities. An intensive oral health education program for teachers, children, and parents conducted by the responsible dentists ensured the successful continuation of the project even after the collapse of the old political system. Ironically, the socioeconomic changes that were positively accepted by most Bulgarians also undermined the smooth implementation of the project, as many teachers refused to provide their assistance without compensation. Only the enthusiasm of the oral health personnel and the provision of free toothpaste for the children enabled the project to continue until its scheduled completion date.

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