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Evaluation of the comparative effectiveness of fluoride mouthrinsing, fluoride tablets, and both procedures in combination: interim findings after two years

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Abstract

Children in kindergarten and first grade (mostly 5 and 6 year olds) in a nonfluoridated city were assigned randomly in each of 20 schools to: rinse weekly with a 0.2% NaF solution, ingest daily a 2.2 mg NaF tablet, or carry out both procedures, for 8 years. At baseline (1981), 1640 participants were examined clinically by 3 National Institute of Dental Research (NIDR) investigators who used the dmfs (for primary molars only) and DMFS indexes. After 2 years (1983), 1154 subjects were available for reexamination. For primary teeth, subjects in the combination treatment group had a mean increment of 1.67 dmfs, 18.9% lower than the mean scores of 2.06 dmfs for children in the tablet group and 33.2% lower than the 2.50 dmfs for those in the rinse group. Results in primary teeth by type of surface also showed consistently lower scores in the combination group than in the other treatment groups. The differences in overall caries increments among the 3 groups approached statistical significance (P = 0.06). For permanent teeth, mean increments (essentially in pits and fissure surfaces of first molars) for each group were small (< 1 DMFS/child) and similar. The findings of this study suggest that primary molars may receive enhanced anticaries benefits from a combined fluoride program in school when exposure begins in kindergarten and first grade. Also, the findings in primary molars portend more substantial results in permanent teeth as the evaluation continues.

Increasing evidence indicates that various combinations of fluoride agents produce additive anticariogenic effects (Horowitz 1980; Federation Dentaire International 1984). Self-administered fluoride procedures that may exert their cariostatic effects by different mechanisms of action are likely to achieve maximum caries-preventive benefits most efficiently. The National Institute of Dental Research (NIDR) has published a series of reports of a long-term dental health program in which a combination of fluoride procedures is used.[1] In that program, school children in Nelson County, Virginia, an area with negligible concentrations of fluoride in its drinking water, ingest a dietary fluoride supplement daily and rinse with a fluoride solution weekly. In addition, fluoride dentifrice is provided for ad libitum use at home. This combination of self-administered methods was selected to provide permanent teeth with systemic exposure to fluoride before eruption (from dietary F supplements) and topical exposure to teeth after eruption (from rinse, dentifrice, and dietary supplement). Final results after 11 years showed that the prevalence of dental caries among participants was reduced by about 65% compared with caries scores of school children before the program began (Horowitz et al. 1986). Striking results were obtained in approximal surfaces of teeth—a 90% lower prevalence of dental caries (Horowitz et al. 1986).

The anticaries effects of the combined fluoride regimen observed in Nelson County are greater than those usually reported for any of the individual components, suggesting an additive effect.[2] However, because all participating children received the entire regimen, claims of additive effects cannot be made; not all the preventive regimens used may have been necessary to produce the observed benefit. The present study was undertaken by NIDR to determine whether the combined use of school-based programs of fluoride rinsing and fluoride tablets produce additive effects. Because almost 95% of all dentifrice now sold in the United States contains fluoride (Heifetz and Horowitz 1986), the present study likely represents an evaluation of the combined fluoride therapies superimposed upon a background of home use

[1] Horowitz et al. 1977, 1979; Horowitz 1980, 1984.

[2] Driscoll 1974; ADA Council on Dental Therapeutics 1975; Heifetz and Horowitz 1986.

of fluoride dentifrice, a situation akin to the Nelson County study.

Methods

A total of 1640 children residing in Springfield, Ohio, a nonfluoridated community, began in the study. At the start (September, 1981), subjects were in kindergarten and first grade (mostly 5 and 6 year olds) and attended 1 of 20 public or parochial schools in the city. Within school, subjects were assigned randomly to rinse weekly with a 0.2% NaF solution (909 ppm F), ingest every school day a 2.2 mg NaF (1.0 mg F) tablet, or carry out both procedures. Classroom teachers supervised all treatments. Details of both rinse and tablet procedures have been described in the reports of the Nelson County study.[3] In brief, children in the rinsing group used 10 ml of solution for 60 sec (5 ml for kindergartners) and those in the supplement group chewed the tablet for 20 sec, rinsed their teeth with the resultant salivary solution for 30 sec, and then swallowed it (the solution formed when a 1 mg F tablet is chewed and diluted with 5 ml of saliva contains a fluoride ion concentration of 200 ppm). To maximize the benefits of systemic fluoride therapy, treatments are scheduled to continue through eighth grade (~ age 14).

Soon after treatments began, 3 NIDR investigators made visual-tactile dental examinations of the participants, using the dmf and DMF surface indexes. The criteria for diagnosing dental caries were those presented at the ADA's conference on the clinical testing of cariostatic agents in 1968 (ADA Council on Dental Research and Council on Dental Therapeutics 1972). The examiners were familiar with the classification system for diagnosing dental caries and standardized their interpretation of the examination criteria. To avoid confusing the natural exfoliation of primary teeth with their extraction, the examiners scored dental caries in the primary dentition only in molars of children younger than age 9. When missing, molars can accurately be considered to have been extracted because of caries (Miller et al. 1965; Ripa et al. 1982).

Two-year, follow-up examinations were conducted in October, 1983. Each child was reexamined by the same investigator who made the initial examination. The examiners were not aware of the group assignments of the children. A total of 1154 subjects were available for reexamination. Of the nearly 30% attrition rate after 2 years, the predominant reason for loss of subjects was movement of the family from the Springfield area.

At the start of the program, a dental hygienist from NIDR trained about 50 dental hygiene students from Ohio State University in the methods of administering the treatments. Two students then visited each participating classroom to demonstrate the procedures to the teacher and students. Three dental hygienists were employed part-time to oversee local operations and to provide supplies to the classrooms. Regular attendance records were used to determine the number of treatments each child received.

During the 2-year period of treatments, a total of 64 rinse, 304 tablet, and 368 rinse/tablet sessions were conducted. The average numbers of treatments received by children in the rinse, tablet, and rinse/tablet groups were 59, 278, and 338, respectively. The average number of each of the treatments in the combined group closely matched that of the corresponding individual treatment group. Therefore, actual exposure patterns among the groups truly permitted an evaluation of additive effectiveness. Results for all children present at the baseline and follow-up examinations were included in the analysis, irrespective of the number of treatments received.

The method of analysis used for all statistical tests in this paper was that of an analysis of variance (ANOVA) with a one-way classification.

Results

Table 1 contains 2 sets of mean baseline scores of dental caries prevalence. The top set of data shows baseline findings for the permanent teeth of the 1154 children, ages 6–9, who remained in the study after 2 years. Of these, 1045 subjects were ages 6–8 in 1983, the ages considered appropriate for the analysis of primary teeth. Their initial mean dmfs scores are shown in the bottom set of data. Despite the sizable loss of subjects, differences in baseline caries scores among the groups, whether measured by DMF or dmf surfaces, were not statistically significant, $P = 0.13$ and 0.39, respectively. The differences in baseline DMFS scores among the groups were necessarily small because permanent teeth in kindergarten and first-grade children (mostly 5 and 6 year olds) had either been in the mouth for only a short length of time or still were unerupted.

Table 2 shows net mean incremental DMFS scores by group for children examined at the 2-year, follow-up examination. Mean caries increments experienced by study participants were relatively small; all of the treatment groups averaged fewer than half of a new DMFS per year. Mean increments were similar among the study groups, $P = 0.54$. Differences in incremental DMFS scores found by the 3 examiners were not statistically significant, $P = 0.14$.

Table 3 shows mean incremental dmfs scores by study group for children ages 6–8 after 2 years of study. Subjects who used the combination of treatments demonstrated the smallest mean increment,

[3] Horowitz et al. 1977, 1979; Horowitz et al. 1980, 1984, 1986.

Table 1. Baseline Caries Experience for Remaining Children After 2 Years by Study Group

Study Group	No. of Children	Mean No. Surfaces
		DMFS for children 6–9 years old
F Rinse	380	0.22 (0.75)*
F Tablet	372	0.30 (0.85)
F Tablet + rinse	402	0.19 (0.64)
		dmfs for children 6–8 years old
F Rinse	345	5.18 (7.86)
F Tablet	331	4.42 (7.36)
F Tablet + rinse	369	4.61 (7.47)

* Standard deviation.

1.67 dmfs per child, whereas those who used the rinse alone averaged the largest increment, a mean of 2.50 dmfs. Occupying an intermediate position was the score for children in the tablet group who had a mean increment of 2.06 dmfs.

Compared with the rinse group, children in the combination group developed 33.2% fewer new dmfs. When findings for children in the tablet group were considered as the comparative standard, children in the combination group showed a smaller benefit, about a 19% reduction in new decay. In addition to determining whether the combined procedure was superior to either of the treatments when used alone, an assessment of the effects of the single procedures is of interest. Children in the tablet group experienced a caries increment that was 17.6% lower than that of their cohorts in the rinse group. Statistical analysis of the incremental scores among the 3 treatment groups showed that the differences almost reached statistical significance, $P = 0.06$. There was no significant difference among the examiners in their level of detection of dmfs increments, $P = 0.91$.

Table 4 presents dmfs increments and percentage differences according to type of surface—occlusal, buccolingual, and mesiodistal. Surface-specific increments parallel the direction of effectiveness shown for overall dmfs findings. Caries in buccolingual surfaces (essentially limited to pit and fissure areas) rather than in occlusal surfaces, accounted for the largest observed increments. The often-found greater differential effect of fluoride in mesiodistal (smooth) surfaces than in the other types of surfaces is not apparent in these data (Heifetz et al. 1979). For the comparison showing the largest relative treatment effect, that is, the combined procedure vs. fluoride rinse, all types of surfaces appeared to benefit equally.

Discussion

Because of exfoliation, participants at the next scheduled follow-up examination in 1986 were too old (mostly 10 and 11 years of age) for the valid assessment of caries increment in primary teeth. Therefore, the 2-year results afforded the only opportunity in this study to evaluate the effectiveness of the treatments in the primary dentition. Although the clinical results fall just short of statistically demonstrating the additive effectiveness of fluoride tablets and fluoride rinsing, they are nevertheless encouraging.

A factor that contributed to a conservative estimate of treatment effects was the extensive placement of stainless steel crowns to restore carious primary teeth by dentists in the community. The 1983 examinations show that almost 23% of the dmfs prevalence score was derived from fillings in molars with 5 surface restorations, ostensibly stainless steel crowns. Incremental findings based on filled surfaces of crowned teeth showed the same relation among the groups as overall dmfs increments. However, the relatively high level of restorative care found in Springfield (f/dmfs = 58%) can potentially confound the findings of a clinical trial by artificially elevating the dmf (or DMF) score and diluting the estimate of treatment effectiveness (Jackson 1966). Also, the more noncarious surfaces restored due to full coverage, need for mechanical retention, and prophylactic odontotomy, the less susceptible surfaces remain to demonstrate differences in protection among the treatment groups.

Few studies have evaluated the effects of fluoride tablet and/or fluoride rinse programs in primary teeth when exposure begins as late as kindergarten and first grade. The dearth of data is understandable because primary teeth at ages 5 and 6 are long past the stage when they can derive systemic benefits from fluoride tablets and the topical exposure from fluoride

Table 2. Mean Increment of DMF Surfaces After 2 Years by Study Group

Study Group	No. of Children (6–9 years old)	Mean DMFS Increment
F Rinse	380	0.90 (1.59)*
F Tablet	372	0.80 (1.53)
F Tablet + rinse	402	0.79 (1.55)

* Standard deviation.

Table 3. Mean Increment of dmf Surfaces After 2 Years by Study Group

Study Group	No. of Children (6–8 years old)	Mean dmfs Increment	% Difference	
F Rinse	345	2.50 (4.90)*	—	
F Tablet	331	2.06 (4.79)	17.6	—
Both	369	1.67 (4.26)	33.2	18.9

* Standard deviation.

TABLE 4. Mean Increment of dmfs After 2 Years by Type of Surface and Percentage Differences According to Study Group

	Type of Surface Mean dmfs Increments		
Study Group	*Occlusal*	*Buccolingual*	*Mesiodistal*
F Rinse	0.74	1.06	0.70
F Tablet	0.54	0.88	0.63
F Tablet + rinse	0.49	0.68	0.50
Group Comparisons		*Percentage Difference*	
Both vs. rinse	33.8	35.8	28.6
Both vs. tablet	9.3	22.7	20.6
Tablet vs. rinse	27.0	17.0	10.0

rinse (or tablet) may be too late to provide much benefit.

Using cross-sectional data in a retrospectively designed study, Ripa et al. (1984) evaluated the effect of mouthrinsing with a 0.2% NaF solution on the primary dentition of first- to third-grade school children, essentially ages 6–8. After 1–3 years of continuous participating in the rinse program from kindergarten, the children showed a 32.6% decline in caries prevalence (dfs/child) compared with baseline findings.

Following the same study design, Leverett et al. (1985) reported a reduction in caries prevalence (dfs/100s) of 27.6% for children in grades 1–3 after 3 years of the rinse program. Because kindergarteners who had not previously rinsed also showed a marked decrease in caries experience, the investigators were reluctant to attribute the observed effect solely to the rinse program.

In the Nelson County study, only minimal differences and an inconsistent pattern of protection in primary teeth were found among children 6–8 years of age after 2 years of exposure to the combined fluoride program (Horowitz et al. 1977). The Nelson County study also used a retrospective control group, but rinsing did not begin until the first grade.

Results of the present study cannot be compared with the contrasting findings of the studies just cited because their designs differed. A nontreatment control group was not included in the Springfield study because ethical considerations precluded the use of a concurrent, placebo control group in a study with fluoride agents of proven efficacy. Also, the reported decline in caries prevalence during the past decade argued against the use of a retrospective control group (Glass, ed. 1982). Thus, there are no absolute effects in this study that can be compared with those of other studies.

Measurement of the relative effectiveness of the 3 test procedures indicates that caries in primary molars of school-age children still can be affected by belated fluoride exposure. That the combined fluoride measure produced a 33% lower increment in dmfs compared with 1 positive control (fluoride rinse) group which already may itself have had an effect in lowering dental caries, not only suggests additive effectiveness but increases the estimate of benefits for the combined fluoride procedure. The randomized clinical trial design of the Springfield study with differences in caries experience measured from incremental rather than cross-sectional data lend weight to these encouraging results.

The P value of 0.06 derived from the ANOVA most likely reflects the specific group comparison with the most striking difference, i.e., the combined procedure vs. the fluoride rinse. For the other specific group comparisons in this experiment, not only would their associated P values probably exceed 0.06, but the observed differences were only of marginal clinical significance.

Reductions in caries from topically applied fluorides to permanent teeth generally have been greater than those reported in primary teeth.[4] However, children 5 or 6 years old, the beginning ages of nearly all the subjects in the present study, do not develop much dental decay in their permanent teeth in a 2-year period. Moreover, caries that they do develop is essentially limited to pit and fissure sites in first molars. Studies have shown that these highly caries-prone sites receive the least protection from fluorides (Bennett and Going 1974; Driscoll et al. 1978). Therefore, it is not inconsistent that the findings of anticaries effectiveness in primary teeth in this study were not paralleled in permanent teeth.

A clinical trial that attempts to evaluate the effects of fluoride applications in permanent teeth of children initially ages 5 and 6 after only 2 years suffers from using an unfavorable age-group for study. Following similar age children for the same or slightly longer periods, a few clinical trials have shown only marginal benefits in permanent teeth from various fluoride therapies.[5] For the young cohorts included in these studies, the evaluation essentially is of effects in pits and fissures of first molars and cannot provide a complete assessment of preventive effects in the permanent dentition.

As participants in the Springfield study grow older and DMFS increments become larger and involve other types of teeth (particularly those with systemic fluoride exposure) and surfaces (particularly those prone to proximal decay), the study should have greater sensitivity to detect any additive effectiveness conferred by the combined fluoride treatments.

[4] Stookey 1966; Birkeland et al. 1977; Ripa and Leske 1980.
[5] Clark et al. 1985; Horowitz et al. 1971; Klein et al. 1985.

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