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A comparison of the anticaries effectiveness of daily and weekly rinsing with sodium fluoride solutions: findings after two years

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Abstract

In 1976, a three-year study was started in Biddeford, Maine, a non-F city, to compare the cariostatic effect of weekly use of a 0.2% NaF rinse with daily use of a 0.05% NaF rinse in a public health program. Participants in grades 5-7 (ages 10-12) in public and parochial schools were randomly assigned to the weekly F rinse, daily F rinse or control group that rinsed weekly with a placebo solution (0.1% NaCl). Findings reported after two years showed anti-caries effects for both F rinse regimens, but no statistically significant difference between them. Year one to year two increments showed that subjects in the weekly and daily F rinse groups had 1.61 and 1.18 mean DMFS compared with 2.01 DMFS for children in the control group or 19.9% and 41.3% fewer new carious surfaces, respectively. Although the difference between the daily and weekly rinses was not statistically significant, the possibility of a type II error (to falsely conclude no difference between the treatments) in this experiment is large. It should be noted that findings of this study pertain to the use of fluoride mouthrinses in a public health program and should not be generalized to private practice.

Introduction

In the United States, during the past ten years, fluoride mouthrinsing has become widely used in school-based programs for the prevention of dental caries. Two mouthrinsing regimens have demonstrated their efficacy: frequent (daily, on school days) use of a dilute sodium fluoride (NaF) solution (0.02%F), and infrequent use (once a week or fortnightly) of a more concentrated NaF solution (0.09%F).[1,2] Some clinical evidence suggests that the level of caries protection may be more a function of frequency of application than fluoride concentration,[3,4] but more investigations are needed to compare directly the anti-caries effectiveness of the two mouthrinsing procedures. This report presents results after two years of a three-year study designed to help provide the information.

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Methods and Materials

A report of the first year's findings contained details of this study's design and methods.[5] In brief, 912 school children residing in Biddeford, Maine, a non-fluoridated community, were recruited for study. At the start (October 1976), subjects were in grades 5, 6, 7 (ages 10 to 12) and attended one of seven public or parochial schools. Within each school, subjects were randomly assigned to a rinsing regimen: once a week with a placebo solution (0.1%NaCl); once a week with a 0.2% NaF solution (0.09%F); or daily with a 0.05% NaF solution (0.023%F). All subjects rinsed in school under the direct supervision of the classroom teacher with 10 ml. of solution for 60 seconds.

Shortly after rinsing began, two public health service examiners made visual-tactile dental examinations of 824 children. As the children appeared by classroom, they were arbitrarily assigned in about equal numbers to each examiner. Examiners 1 and 2 used the same classification system for diagnosing dental caries and standardized their interpretation of the examination criteria; examiner 1 had limited experience in longitudinal dental field trials. Each child was re-examined after one and two years by the same examiner that had conducted the initial examination.

The classroom teacher kept a record of each child's participation. During two years, participants in the weekly groups could have rinsed as many as 65 times and those in the daily group as many as 296 times. Only a few children examined after two years (in 1978) missed more than 20 percent of the maximum number of assigned treatments, and therefore, no attempt was made to exclude inadequately exposed participants from the analysis.

Results

Of the 608 subjects examined in 1978, findings are presented for 593 who were present at baseline and for both follow-up examinations. Table 1 shows their baseline caries prevalence by examiner and treatment group. The overall difference between the mean DMFS score for all children examined by examiner 1 (6.88) and the corresponding score of examiner 2 (5.97) was not statistically significant at the 0.05 level of probability ($P=0.07$). The differences among the groups in baseline DMFS scores could easily have occurred by chance ($P=0.58$).

Table 1. Baseline DMFS for continuous participants by examiner and group.

Group	No. Subjects	Mean No. DMFS
	Examiner 1	
C (control)	87	7.06 (0.73)*
W (weekly)	99	6.30 (0.57)
D (daily)	92	7.33 (0.71)
All	278	6.88 (0.38)
	Examiner 2	
C (control)	117	6.51 (0.53)
W (weekly)	94	6.20 (0.51)
D (daily)	104	5.14 (0.48)
All	315	5.97 (0.30)

*Figures in parenthesis are standard errors of the means.

Results of examiner 1's findings after one year showed unduly small mean caries increments and large rates of reversals, about four times that of examiner 2. Similar findings appeared in examiner 1's incremental data after two years of study. However, as discussed in the one-year report,[5] data with large reversal rates can still be used validly to detect significant differences between study groups provided that the shift in diagnostic criteria was uniformly applied across study groups. No evidence to the contrary could be found in an internal examination of examiner 1's data.

Table 2 summarizes the statistically significant effects detected for 24 month mean DMFS increments. Statistically significant differences in caries increments were shown among the study groups for surfaces present initially, erupting surfaces, each type of surface, and also between examiners. For both surfaces present intitially and those erupting during the study, specific treatment comparisons showed that the weekly and daily fluoride rinsing procedures were effective when compared with the controls. However, the difference in effectiveness between the two fluoride rinse regimens was not statistically significant.

Lack of examiner consistency precluded a further analysis of 24-month findings in terms of the traditional assessment of percentage reduction. Examiner 1's probable downward shift in diagnostic criteria (from more critical to less critical) between baseline and 1977 and 1978 follow-up examinations, however,

Table 2. Significant treatment effects for 24 month DMFS increments.

	P Values				
	Surfaces Present Initially	Erupting Surfaces	Occlusal Surfaces	Proximal Surfaces	Buccal-Lingual Surfaces
Comparison					
Group	<.001	<.01	<.05	<.01	<.01
Examiner	<.001	<.001	<.001	N.S.*	<.01
Specific Contrast					
Control vs. Weekly	<.01	<.001	<.001	<.01	N.S.
Control vs. Daily	<.001	<.01	<.001	<.05	<.01
Weekly vs. Daily	N.S.	N.S.	N.S.	N.S.	N.S.

*N.S. $P \geq 0.05$

does not rule out the possible consistent application of diagnostic criteria between the two follow-up examinations. Accordingly, the decision was made to examine the findings only during the second 12 months of study.

Table 3 shows mean DMFS increments for the second 12 months of study by examiner and by study group. Examiner 1's data no longer contain the unusual increments observed after 12 and 24 months of study. For 11 to 13-year-old children residing in a nonfluoridated area, the yearly increment of almost two DMFS in the control group is within the expected range. Compared with examiner 2's data, no striking differences in incremental values are apparent. More importantly, there is good agreement between the examiners in the direction of treatment differences among the study groups. A two-way analysis of variance of the incremental findings showed a significant effect due to treatments but no significant difference due to either examiners (P=0.30) or to the way the examiners detected difference in treatments, i.e., no examiner X treatment interaction (P=0.63).

Table 3. DMFS increment from year 1 to year 2 by examiner and group.

Group	No. Subjects	Mean DMFS
Examiner 1		
C	87	1.98 (0.36)*
W	99	1.78 (0.27)
D	92	1.41 (0.37)
Examiner 2		
C	117	2.04 (0.23)
W	94	1.44 (0.24)
D	104	0.98 (0.20)

*Figures in parenthesis are standard errors of the means.

Table 4 contains each examiner's reversal rates from year one to two by study group. The proportions of DMF surfaces at the one-year examination subsequently diagnosed as sound at the two-year examination for examiner 1 showed only small differences compared with those of examiner 2. Also, the sizes of these reversal rates are consistent with those reported in past NIDR trials.[6,7]

The foregoing analyses support the reliability of examiner 1's year 1 to year 2 incremental data, and permit an evaluation of both treatment effect and its size in terms of percentage reduction during that period. Table 5 presents the net mean DMFS increment from year one to year two for each group and for both examiners' data combined. Participants who rinsed weekly with the 0.2% NaF solution developed 19.9 percent fewer new DMF surfaces than did controls; the absolute difference in mean scores was 0.40 DMF surfaces. Compared with controls, children in the daily rinsing group who used a 0.05% NaF solution showed a 41.3 percent caries inhibition, or an average 0.83 fewer DMF surfaces. A comparison of the daily with the weekly rinsing group (D vs. W) showed a difference of 0.43 surfaces in mean incremental scores. Statistical comparisons of the differences between specific pairs of study groups showed that only the difference in scores between the daily rinsing group and the controls was significant (P=0.005).

Table 4. Reversals in diagnosis from year 1 to year 2 by examiner and group.

Group	D→S*	D→D	Reversal** Rate
Examiner 1			
C	54	597	0.08
W	33	583	0.05
D	44	658	0.06
Examiner 2			
C	34	976	0.03
W	38	669	0.05
D	44	614	0.07

*D = Decayed; S = Sound

**Reversal Rate = $\frac{D \rightarrow S}{D \rightarrow S + D \rightarrow D}$

Table 5. DMFS increment from year 1 to year 2 by group.

Group	No. Subjects	Mean DMFS	Diff. in Mean DMFS	% Diff.	P Value
C	204	2.01 (0.20)*	—	—	—
W	193	1.61 (0.18)	0.40	19.9	0.16
D	196	1.18 (0.20)	0.83	41.3	0.005
D vs W			0.43	—	0.15

*Figures in parenthesis are standard errors of the means.

Discussion and Conclusions

A recent review of clinical trials of fluoride mouthrinses concluded that " . . . daily rinses do

not seem markedly better than weekly or fortnightly rinses with neutral fluoride solutions."[8] The conclusion, however, was based essentially on a comparison of caries protection measured in different clinical trials. The weaknesses of interpreting data that are collected in this manner are well known.[9] In the present clinical trial, both the daily and weekly rinsing procedures were evaluated by the same methods under the same study conditions.

Results after the first 12 months of study showed that each fluoride rinse was effective in controlling decay but no difference in caries inhibition between the two fluoride rinses could be detected. Presently, reported findings after 24 months continued to show the same results. However, numerical findings of percentage reductions, permitted by the analysis of year one to year two data, suggest that the daily rinse may confer greater caries inhibition than the weekly rinse. During the second treatment year the caries protection in the daily fluoride rinsing group (41.3%) was twice as great as that observed in the weekly fluoride rinsing group (19.9%), although again no significant difference could be shown. Part of the problem is the lack of sensitivity of the experiment in detecting other than relatively large differences between the treatment groups. Large coefficients of variation (variability of measurements as percent of its average) of caries increments were observed in the study and the group sizes used for a comparison of one effective treatment with another were relatively small. Both factors contributed to the possibility of a large type II error (to falsely conclude no difference between the treatments). For example, for the year one to year two data, there is a 40% chance of falsely concluding no difference between the effectiveness of the two fluoride rinses when, in fact, a difference as great as 20% really exists.

In private practice, the clinical effectiveness of fluoride mouthrinsing assumes paramount importance. However, the value of fluoride mouthrinsing as a public health measure depends not only on its effectiveness, but also on its costs of implementation. Cost-effectiveness determination should be made for each rinsing regimen under consideration, and that procedure which is the most cost-effective, i.e., results in the largest total number of surfaces protected on a population basis for every dollar spent, should be adopted.

Weekly fluoride mouthrinsing has been shown to be a cost-effective procedure.[10] Since there is a considerable difference in the cost and amount of school time and effort needed to implement a daily rinse procedure compared with that required for the weekly procedure, the difference in expected additional benefit would have to be substantial before one could recommend daily rinsing as the more cost-effective public health measure. Interim results of the present study do not suggest that the daily rinse regimen possesses any such decisive advantage in effectiveness. Currently, about nine million school children in the United States are participating in programs of weekly fluoride rinsing. Because of this regimen's many advantages, it is likely to remain the method of preference for fluoride mouthrinsing in public health programs.

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