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Effectiveness of different concentrations and frequencies of sodium fluoride mouthrinse

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Abstract

The effect of different concentrations and frequencies of use of a sodium fluoride mouthrinse was tested within the same study population of 2,014 students in Polk County, FL. Five study groups were assigned as follows: a daily .05% mouthrinse, a daily .2% mouthrinse, a weekly .05% mouthrinse, a weekly .2% mouthrinse, or a weekly placebo mouthrinse. After two years, there was a significant difference in mean incremental DMFS between the daily .05% group and the control. There was also a significant difference in mean incremental proximal surfaces between both the weekly .2% and daily .05% with the control. When the study groups were combined by similar frequency or concentration, there were significant differences for all groups from the control. No differences were found between different concentrations at the same frequency or between different frequencies at the same concentration.

School based caries preventive programs involving the use of a weekly 0.2% neutral sodium fluoride mouthrinse have been rapidly gaining acceptance with public health and school officials. The use of a self-administered mouthrinse vehicle offers a convenient approach to the provision of topical fluoride to large groups of students in areas where the water supply lacks adequate fluoride. The two mouthrinse procedures most used have been the 0.2% NaF (0.09%F) weekly regimen and the 0.05% NaF (0.02%F) daily regimen.[1,2]

There have been at least two studies which have shown caries reductions of 27-36% resulting from daily school use of a mouthrinse containing 0.02-0.0225% of fluoride ion.[3,4] Four or more studies have shown 16-44% caries reductions from the weekly school use of a mouthrinse containing 0.09-0.3% fluoride ion.[5-8] Other trials have shown beneficial results from the biweekly use of 0.045-0.225% concentrations of fluoride ion.[9,10] Thus, it becomes apparent that studies testing different frequencies and concentrations within the same study population are necessary to establish the most effective procedure.

There is some evidence that a more frequent rinse may be more effective. Moreira and Tumang compared three times weekly, weekly, and biweekly frequency use of a 0.045% fluoride ion rinse and found a greater reduction in DMFS with the three times weekly rinse than with either the weekly or biweekly frequencies. There was a 22-24% greater reduction in DMFS with the more frequent rinse.[9] Two other studies also have been reported which indicate that frequency of rinsing may be of more importance than concentration.[11,12]

The purpose of this study was to compare the relative effectiveness of daily and weekly rinses at concentrations of 0.02% and 0.09% fluoride ion. This report presents interim findings after 18 months.

Methods and Materials

The study was conducted in eight Polk County, FL, junior high schools located in the neighboring towns of Winter Haven, Lakeland, Haines City, Bartow, and Lake Wales where water fluoride level was less than 0.3 ppm. Baseline examinations were conducted by two examiners on 2,014 seventh graders who averaged 12.5 years of age. The participants (who had signed parental permission) were then allocated to study groups by random permutations of five after stratification by sex and race within each school as follows: Group D.05 rinsed daily with a 0.05% NaF solution (0.02%F), Group D.2 rinsed daily with a 0.2% NaF solution (0.09%F), Group W.05 rinsed weekly with a 0.05% NaF solution, Group W.2 rinsed weekly with a 0.2% NaF solution, and Group C rinsed weekly with a placebo solution containing 0.1% NaCl. The rinses were dispensed in 10 ml aliquots, and delivered to the classrooms by aides. The one-minute rinsing procedure was then supervised by the teachers. The study coordinator or her assistants monitored the rinsing procedure in the classrooms on a regular rotating basis. Participation records were maintained by the classroom teachers. Most of the students who remained in the study after 18 months missed less than 15% of the maximum number of rinses possible.

The follow-up examinations to determine caries increments were conducted by the same two examiners on the same students examined by each at the baseline. The examiners were not aware of group assignments and did not consult baseline findings during the incremental exam.

Findings

Table 1 presents mean baseline DMF surface scores for all 2,014 examined initially and for those 1,238 remaining after two years. The difference of 0.7 mean DMFS between Group W.2 and the control approaches statistical significance ($P < .06$) in the data for all baseline examinations. The other study groups are not significantly different from the control in terms of mean DMFS scores or in numbers of students assigned. The attrition rate over the first two years of the study was 38.5%, or 19.3% per year. The baseline data for those remaining in the study after two years indicates a significant ($\Delta = .82$, $P < .025$) difference between mean DMFS scores between Group W.2 and the control. The other groups remain statistically balanced with the control concerning numbers of subjects and mean DMFS.

Table 2 contains mean net DMFS incremental data for the study groups after two years. Those participants in Group D.05 were recorded as having an average of 0.94 or 28.1% fewer incremental DMF surfaces than the control group. This difference was statistically significant at $P < .05$ applying Dunnett's "t" test. This test was specifically designed to compare multiple treatment groups with a single control.[13] The critical value for one-sided comparisons at a joint confidence coefficient of $P = 95\%$ for four treatment means and a control is 2.16.[14] The difference of 22.8% or 0.76 mean net incremental surfaces between Group D.2 and the control ($P < .06$) is not significant at the .05 level. The weekly rinse groups showed differences of 0.68 (20.4%) mean net incremental surfaces between Group W.2 and the control and differences of 0.55 (16.5%) mean net incremental surfaces between Group W.05 and the control. These differences were not statistically significant and there were no significant differences among treatment groups.

The mean net increments on mesial and distal surfaces only are presented in Table 3. Both Group D.05 and Group W.2 show significant differences from the control with mesial and distal surface increments. The difference between Group D.2 and the control with these surfaces is very small.

Table 4 presents the data by grouping according to frequency or concentration. The two study groups utilizing the daily rinsing regimen (D.05 and D.2) showed a combined 0.85 or 25.4% difference from the control in mean net incremental surfaces. This difference was significant at $P < .01$. The difference of 0.62 surfaces or 18.6% between the combined groups (W.05 and W.2) using the weekly rinsing regimen was also significant ($P < .05$). The critical Dunnett's "t" value for the comparison of two treatment means and a control is 1.92.[14] The difference between daily and weekly rinsing groups was not significant. When the study groups were combined by concentration, both the 0.05% NaF and the 0.2% NaF groups showed a difference from the control of approximately 22%. That difference was significant at $P < .05$.

Discussion

There was a significant difference between Group W.2 and the control at the baseline which may have biased the results reported for this group. The variation in mean baseline data could have had an effect on the mean increments found. A covariance analysis utilizing base-

Table 1. Mean DMFS scores by study group for all baseline examinations.

Study Group	Number Subjects	After Two Years	Mean DMFS	After Two Years
	Baseline		*Baseline*	
D.05	421	235	5.09 (.28)*	4.71
D.2	415	257	5.50 (.33)	5.17
W.05	397	244	4.75 (.27)	4.75
W.2	397	253	4.46 (.28)	4.11
C	384	249	5.16 (.34)	4.93
	2,014	1,238		

* Figures in parentheses are standard errors of the means.

Table 2. Mean net incremental DMFS scores after two years by study group.

Study Group	Number Subjects	Mean net DMFS increment	Percent Difference From Control	Dunnett's "t" Value
D.05	235	2.40 (.23)	28.1	2.55*
D.2	257	2.58 (.24)	22.8	2.11
W.05	244	2.79 (.28)	16.5	1.51
W.2	253	2.66 (.25)	20.4	1.88
C	249	3.34 (.28)		

* Significant at $P < .05$.

Table 3. Mean net DFS increments on proximal surfaces after two years by study group.

Study Group	Number Subjects	Mean Net DFS Increment	Percent Difference From Control	Dunnett's "t" Value
D.05	235	.42 (.07)	46.2%	2.76*
D.2	257	.67 (.09)	14.1%	0.89
W.05	244	.52 (.10)	33.3%	2.05
W.2	253	.47 (.08)	39.7%	2.47*
C	249	.78 (.10)		

* Significant at $P < .05$.

Table 4. DMFS increment over two years by frequency of rinsing.

Study Group	Number Subjects	Mean Net DMFS Increment	Percent Difference From Control	Dunnett's "t" Value
W	497	2.72 (.26)	18.6%	1.97*
D	492	2.49 (.23)	25.4%	2.70**
C	249	3.34 (.28)		

** Significant at $P < .01$.
* Significant at $P < .05$.

DMFS increment over two years by concentration of rinse

Study Group	Number Subjects	Mean Net DMFS Increment	Percent Difference From Control	Dunnett's "t" Value
.05	479	2.60 (.25)	22.2%	2.34*
.2	510	2.62 (.24)	21.6%	2.30*
C	249	3.34 (.28)		

* Significant at $P < .05$.

line means as the covariant, however, failed to change the results of the tests reported. There was also a relatively high attrition rate of 19.3% per year. This may have resulted from the migratory nature of the communities—which had a high percentage of citrus workers—or because some of the study population was changing schools entering the eighth grade.

The daily rinses tended to be somewhat more effective over all surfaces but the difference is not a significant one. The small difference between Group D.2 and the control on mesial and distal surfaces only appears to be an artifact and is not consistent with the rest of the data. The overall larger percentage differences on proximal surfaces only is consistent with the reported literature for surface-specific effects of topical fluorides in nonfluoridated areas.

Recent studies similarly have tested a daily and a weekly rinse within the same study population. Three-year results from a nonfluoridated community in Maine showed no significant differences between the effect of daily and weekly rinses.[15] Another study in a fluoridated city was also in agreement, showing no significant differences by frequency.[16] The small differences found between frequency of use is not sufficient to recommend daily rather than weekly rinses. The cost of daily rinses has been estimated to be about three to four times more than the cost of the weekly procedure, exclusive of personnel costs.[17] Thus the cost-effectiveness of a weekly rinse is better. The weekly procedure also has the practical advantage of requiring less school time and is a more acceptable regimen to school officials, teachers, and participating students.

A small difference in increments between the study groups aggregated according to concentration would lead one to speculate that a concentration lower than 0.2% NaF may be appropriate for the weekly procedure. Studies of concentrations between 0.05% NaF or 0.2% NaF used at a weekly frequency could provide more information concerning the dose-response relationship. Although the safety of the 0.2% NaF rinse is not in question, the possibility of a weekly rinse at a lower fluoride concentration providing the same benefits is worthy of consideration. There was no difference between the two concentrations used at either the daily or weekly frequency.

In summary, findings after two years indicated a significant caries preventive benefit on all surfaces for those using a daily .05 rinse and a significant difference on proximal surfaces for both the daily .05 and the weekly .2 groups. When the study groups were combined by similar frequency or concentration, there were significant differences found between all groups and the control. No differences between different concentrations at the same frequency or between different frequencies at the same concentration were found.

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Quotable Quote

Of the 300,000 children with epilepsy in the United States, a large number take anticonvulsant drugs indefinitely because their physicians assume that the risk of recurrent seizures outweighs the risk of adverse effects from the drugs. Now good news for many of these youngsters is reported in the May 7 *New England Journal of Medicine* by Ronald Emerson and colleagues at Johns Hopkins University School of Medicine in Baltimore. A study conducted by Emerson and his team of epilepsy researchers suggests that these young people safely can discontinue their anticonvulsant medication if they have been free of seizures for four years while taking the medication.

Thus, an epileptic youngster who has been without seizures for four years while taking anticonvulsants, has normal EEG's while on the drugs, had few seizures before going on the drugs, and is of normal intelligence probably should be taken off anticonvulsants, Emerson and his team conclude. "Giving a child a target of four seizure-free years," they said, "implies that he or she will become 'well' at some point and will no longer carry the stigma of epilepsy." Also, they added, if epileptic youngsters are taken off anticonvulsants it can spare them drug costs, doctor visits and costs, and possibly detrimental learning and behavior effects from the drugs.

In fact, even as far as high-risk children who have been free of seizures for four years while on anticonvulsants are concerned, one can question whether the risk of seizure recurrence would necessitate lifelong continuation of anticonvulsants. If such youngsters relapse, they would do so soon after stopping their drugs and could begin drug therapy again.

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