

ARTICLE ANALYSIS & EVALUATION

School children with a high caries experience benefit from supervised tooth brushing equally with 500 ppm and 1450 ppm sodium fluoride toothpastes after a 9-month study period

Original Article

Biesbrock AR, Bartizek RD, Gerlach RW, Jacobs SA, Archila L. Effect of three concentrations of sodium fluoride dentifrices on clinical caries. *Am J Dent* 2003;16(2):99–104.

Level of Evidence

Ib

Purpose

To determine a toothpaste dose response (500 ppm F- vs 1450 ppm F-) with supervised tooth brushing (twice daily on school days) on dental caries outcomes

Source of Funding

The Procter & Gamble Company

Type of Study/Design

Randomized, double-blind, placebo-controlled trial for a 9-month period

Summary

SUBJECTS

School children 9 to 12 years of age of an urban Guatemala setting with less than optimal fluoride in the water supplies were examined at 9-month and 21-month periods after baseline. These school children exhibited, on average, a high caries experience (Table 1). The initial study sample included 607 participants (332 females, 275 males; mean age, 10.3 years) that were randomly allocated to 3 study groups as follows: 1) placebo toothpaste (n = 210); 2) 500 ppm F- toothpaste (n = 198); 3) 1450 ppm F- toothpaste (n = 199). Of the participants, 94% and 88% of participants completed the 9-month and 21-month examinations, respectively.

THERAPY

Supervised tooth brushing twice daily during school days and ad libitum at home (evenings and weekends) for the 9-month period (placebo, 500 ppm F- and 1450 ppm F- groups).

MAIN OUTCOME MEASURE

Dental caries increments (DMFS) given by visual-tactile and radiographic exams.

MAIN RESULTS

The average caries increments at the 9-month exam were 1.28 surfaces, 0.34 surfaces, and 0.35 surfaces for the placebo, 500 ppm F-, and 1450 ppm F- groups, respectively. The differences in caries increments between the fluoride groups and placebo-based groups were statistically significant at the 9-month exam. Evidence for a dose response for the 500 ppm F- and for the 1450 ppm F- toothpastes was not apparent at 9 months.

Commentary

TABLE 1. Initial baseline balance for subjects who completed 9 months.

Treatment	N	Gender		Age Mean	DMFS (Integrated)		DMFS (Visual-Tactile)	
		Female	Male		Mean	SD	Mean	SD
Placebo	210	114	96	10.3	9.95	6.08	7.49	4.67
500 ppm F-	198	107	91	10.3	9.56	6.34	7.01	4.89
1450 ppm F-	199	111	88	10.3	10.27	6.89	7.54	5.10

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CONCLUSIONS

Two fluoride dentifrices (500 ppm F- and 1450 ppm F-) provided similar effects in reducing dental caries increments when compared with a placebo dentifrice after a 9-month period with a defined supervised tooth brushing regimen (twice daily) during school days.

ANALYSIS

There is substantial evidence that fluoride toothpaste is effective at reducing caries risk in children and adults (<http://www.cochrane.org/cochrane/revabstr/AB002278.htm>). Evidence on more than 42,000 children has been summarized in which the effect of fluoride toothpaste increased with higher baseline levels of D(M)FS, higher fluoride concentration, higher frequency of use, and supervised brushing, but was not influenced by exposure to water fluoridation. Given this evidence, it is surprising from an ethical perspective that placebo-controlled trials are still conducted. The main goal of this trial appeared to be to evaluate whether 1450 ppm F- was more effective at controlling caries than 500 ppm F-.

The results showed that dental caries increments were not affected by the concentration of fluoride in

the dentifrice (500 ppm F- vs 1450 ppm F-) in a supervised tooth brushing program. Both regimens, however, were superior to a placebo dentifrice on dental caries outcomes after 9 months. This is a well-designed randomized, double-blind, placebo-controlled trial that has shown that caries increments had no evidence of a dose response between 500 ppm F- and 1450 ppm F- dentifrices after a 9-month study period. This study is the first to demonstrate that 500 ppm F- is as effective as 1450 ppm F- in providing an anti-caries effect after a 9-month period in a population with high caries experience. Because this study was not designed to show the equivalence of 500 ppm F- and 1450 ppm F-, one cannot conclude that both toothpastes are equivalent with respect to caries control. One can conclude that the differences between 500 ppm F- and 1450 ppm F- are either moderate or nonexistent.

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