The Case for Retaining the Current Supplementation Schedule

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Abstract

Following ingestion of dietary fluoride, microquantities of fluoride return to the mouth in saliva, but in quantities large enough to facilitate the maintenance and reparative functions of enamel. Dietary fluoride supplements alone are unlikely to be the cause of the reported increase in fluorosis. Compliance continues to be extremely poor and few children use supplements for more than a year and a half. The amount of background fluoride resulting from dietary fluoride supplements appears to be very small. Considering the almost ubiquitous presence of fluoride dentifrice and the strong possibility of additional unintentional fluoride ingestion from many sources, the present fluorosis data is too amorphous to use as a basis for making reasonable risk/benefit evaluations. Very mild and mild fluorosis is not a serious problem for either the clinician or the patient. By altering the present recommended dosage we may deprive children from receiving a proven effective dose. One cannot make a risk/benefit decision concerning an esthetic problem without involving the patient's perception as well as the caries score. The apparent severity of the milder forms of fluorosis lessens with age and a community fluorosis index should be used only on populations who are older than 15 years. [J Public Health Dent 1999;59(4):259-62]

Key Words: dietary fluoride supplementation, compliance, fluoride supplement dosage, risk/benefit assessment.

Significant concepts have changed since 1978, when the Council on Dental Therapeutics last considered and changed the recommended dose for fluoride supplements (1). Although difficult to prove, it seems reasonable to assume that the decline in dental caries occurring in most industrialized nations, either with or without water fluoridation, is directly related to the widespread use of effective fluoride dentifrices (2,3). This reduction in caries has not been paralleled by reductions in sugar intake nor by measurable changes in snacking patterns (4). Today it is almost an anachronism to consider fluoride as a preventive agent. Fluoride is more likely an active treatment of a developing lesion, and it is even more likely that the real workhorse is saliva. The presence of microquantities of fluoride facilitates saliva's enamel maintenance and reparative functions (5).

Fluoride supplements are effective in arresting dental caries. During the late 1960s through the early 1990s a number of clinical studies confirmed their efficacy and safety (6-9). They are designed to be used by children who do not have regular access to optimally fluoridated water, and are used all over the world. To argue against their use as being unnecessary is to argue that fluoridated water is also unnecessary

In one of the often quoted early studies of dietary fluoride supplements, Aasenden and Peebles (6) made three significant observations. First, the dosage used (0.5 mg from birth to 2 years of age) appeared to give a significantly greater degree of caries protection than water fluoridation. Second, 17 percent of the control population who had received neither water fluoridation nor dietary fluoride supplements showed some degree of fluorosis. Third, the fluorosis seen in the study group was generally of the very mild type, "which was [not] of esthetic concern." In a follow-up study of the same children when they were teenagers, these investigators found that fluorosis scores were lower, a phenomenon they attributed to enamel mineralization and abrasion (10).

In 1978, as a response to a perceived increase in unintentional fluoride ingestion in baby foods and formula, the Council on Dental Therapeutics changed its recommended fluoride dose for infants under 2 years of age to the present recommended dose of 0.25 mg. At the time of these dosage considerations, Driscoll and Horowitz (11) opined that, "Before modifications of an existing dosage schedule for dietary fluoride supplementation are recommended, three questions should be considered: Does the existing schedule have a risk of an undesirable side effect? If a risk does exist, is it outweighed by the benefit produced by that dosage schedule? Does the modified schedule favorably alter the relationship between the benefit and the risk of a side effect?" These questions are as relevant today as they were in 1978.

Arguments Against Changing the Dosage Schedule

Let's look at the arguments that can be made in favor of *not* altering the present recommended dose.

- *Results from use of the various fluorosis indices are not comparable, particularly when age is uncontrolled.* When dealing with an esthetic concern such as mild fluorosis, a newly erupted incisor cannot be compared with the incisor in a 15-year-old child. Mammelons are transparent and do not cover dentin; they are highly susceptible to a fluorotic-like appearance. As the incisors come into occlusion, the mammelons are worn away and with them, the fluorosis. The prevalence of

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fluorosis should not be determined on populations who are younger than 15 years of age for this reason.

- *Epidemiologic studies of fluorosis prevalence for anterior teeth, posterior teeth, or a combination of posterior and anterior teeth when anterior teeth are the important ones (12).* Differences in fluorosis by tooth type might appear irrelevant to epidemiologists; to the practicing dentist, however, fluorosis and esthetics is important for only the anterior teeth. If the problem we are addressing is still one of esthetics, evaluations should concentrate on comparable anterior teeth.
- *We do not know the seriousness of the esthetic problem.* Patient perception about appearance is the critical issue in deciding on the degree of an esthetic problem (13). Without knowing how patients feel about the appearance of their teeth, we cannot judge how serious the esthetic problem is (14). Asking opinions of dentists, independent observers, or even parents about the esthetic appearance of a teenager's tooth begs the issue. Assumptions on our part about esthetics become speculation, not scientific fact. If the fluorosis problem is really just one of esthetics, then to form a decision based on risk and benefit we need some index to enable us to determine how concerned patient are with their teeth (15), as well as accompanying data stating the caries prevalence. Such data have not been forthcoming. Regardless, teenagers with very mild fluorosis commonly like the appearance of their caries-free teeth. To them, they have a bright, white, sparkling look.
- *A reduction in the fluoride supplement dose might reduce its efficacy.* Dentifrice tests show that reducing its fluoride concentration also reduces its efficacy (16). We do not know if a reduction in fluoride supplement dosage would reduce its efficacy also. We are not likely to ever again have another clinical trial in which the efficacy of fluoride supplementation is tested. Who would pay for such a test and what human subjects committee would allow us to conduct a trial in which child subjects were not allowed to use a fluoride dentifrice?
- *The data necessary to complete a risk-benefit assessment for a reduced fluoride dose are not available (17).* Fluorosis data are often reported without any accompanying data on caries. With the pervasive unintentional dietary ingestion of fluoride from multiple sources, clean data about the efficacy of dietary supplements and their effect on fluorosis may never become available (18).
- *Dietary fluoride supplements have a topical effect.* Evidence indicates that the major caries-preventive action of what we once referred to as systemic fluoride occurs mostly after the teeth erupt into the mouth. After ingestion of dietary supplements, intraoral salivary fluoride levels rise to therapeutic levels (4). A clearer understanding of the posteruptive topical actions of systemic fluoride could enable researchers to develop sensitive intraoral salivary monitoring techniques that could lead to developing suitable dosages for fluoride supplements.
- *Dietary fluoride supplements alone are unlikely to be the cause of the reported increase in fluorosis (17,19).* Many authors, including Dean, have indicated a background prevalence of fluorosis of from 15 percent to 20 percent in areas with no apparent source of fluoride (20,21). Compliance with fluoride supplements continues to be extremely poor. Most children stop using supplements before the 22nd- to 26th-month time window for developing fluorosis in their anterior teeth opens (22,23). Later in the paper, I will attempt to demonstrate that the percentage of children showing fluorosis is higher than the number of children ingesting fluoride supplements. Dietary fluoride supplements may have contributed to increased fluorosis in a few specific communities (24,25); but here compulsive parents guided by aggressive pediatricians and pediatric dentists likely provide other forms of unintentional excess dietary fluoride.

TABLE 1
Percent of Children Receiving Fluoride Drop Supplements

Year	No. of Births*	Patients Recieiving Fluoride Supplements†	Percent Receiving Supplements
1988	3,910,000	NA	
1989	4,041,000	NA	
1990	4,158,000	1,149,000	27.6
1991	4,111,000	1,243,000	30.2
1992	4,084,000	1,085,000 (772,000 fluoride vit., 313,000 fluoride only)	26.6

*US Department of Health and Human Services.
†IMS National Diagnosis and Therapeutic Index.

TABLE 2
Fluoride Supplement Prescribing Patterns, 1992

Supplement	Average Rx Size*	Average Daily ml or Tablets†	Average No. Bottles per New Rx	Average Days of Therapy per New Rx
With vitamin				
Fluoride drops	50 ml	1.5 ml	1.81	60.3
Fluoride tabs	85 tabs	1.2 tabs	2.12	150.2
Without vitamin				
Fluoride drops	30 ml	1.3 ml	1.21	27.9
Fluoride tabs	120 tabs	1.3 tabs	1.80	166.7

*Average of all dosage strengths.
†According to prescription instructions Rxs quantity divided by therapy days information ‡New and refills.

TABLE 3
Average Length of Total Therapy for Fluoride Drop Supplements, 1992

	No. of New Rxs per Patient	Average Days of Therapy per new Rx	Average Length of Therapy per Year
Fluoride vitamin drops	2.26	60.3	136.3
Fluoride-only drops	1.21	27.9	33.7

Good evidence suggests that there is considerable abuse both by practitioners when they prescribe supplements and by parents when they use them (16).

• *Because of available treatment possibilities mild fluorosis is not a problem.* In 1978, the last time the Council on Dental Therapeutics changed the recommended dose for dietary fluoride supplements, neither mild nor very mild fluorosis were considered serious health or esthetic problems (27). Today, with the availability of new dental materials and techniques, for both the patient and the dentist, mild and very mild fluorosis are even less of a problem than they were in the past. The apparent severity of the milder forms of fluorosis lessens with age, but when patients and their dentist choose to hasten the process, it can be done quickly and simply with the procedure known as microabrasion. In microabrasion the outermost surface of the enamel is activated, caused to remineralize and polished. In the more severe cases such as moderate fluorosis, tooth-colored materials can be bonded safely and quickly onto enamel creating a highly esthetic appearance.

Compliance with Recommended Schedule

I have assembled some statistics on fluoride, prescribing patterns and compliance using results of analyses of IMS data made available to me by the two major fluoride supplement manufacturers. IMS America, a division of Dun & Bradstreet, collects and processes billions of data items from the health marketplace. All audits are based on primary source materials, including warehouse withdrawals, drugs dispensed from pharmacies, carbon copies of written prescriptions, and logs kept by physicians and pharmacists on various aspects of health care (28). IMS data on fluoride-prescribing practices, such as number of patients, number of new prescriptions, number of refill prescriptions, and average prescription size (by brand manufacturer) are reported as separate data items. The prescription data for fluoride supplements are believed to be accurate within +/– 0.2 percent.

The results of my analysis of these data confirm suspicions that compliance with the fluoride dosage schedule is extremely poor. Most children start using supplements around their second or third month of life, but few use them for more than a year and a half. The percent of infants receiving liquid fluoride supplement prescriptions are presented in Table 1. From 1988 through 1992, approximately 4 million babies were born each year. An estimated 28 percent of these children received a prescription for fluoride supplementation for some period of time before their first birthday.

Table 2 shows the average number of days a new prescription (first bottle or refills) should last. This estimate is not total length of therapy because an infant can receive more than one new prescription each year. The first three columns of data are averages calculated directly from 1992 IMS data. Prescriptions for fluoride vitamin drops are estimated to last an average of only 60 days.

Table 3 displays prescription data for liquid supplements only, presumably the type of most interest. The number of new prescriptions per patient was calculated by dividing the annual number of total new prescriptions by the number of infants receiving fluoride supplements. Multiplying the resulting number by the average days of therapy per new prescription, column 3, provides a reasonable estimate of the average length of therapy for fluoride vitamin drops—136 days or 34 days for fluoride in vitamin drops or fluoride drops alone, respectively. Even if we assume that all infants receiving drop supplements are the same children who then receive tablet supplements at an older age, the aggregate length of therapy (drops and tablets) does not exceed nine months.

Abuse of Fluoride Dose

Preliminary analysis of other IMS data and personal observations of many infants receiving drop preparations indicate that liquid fluoride formulations are too easy to abuse. Both major manufacturers make drop preparations of different concentrations, so that for a 0.25 mg dose, one brand calls for two drops while the other brand calls for 1 ml (18 drops). It is quite possible that physicians and dentists may be writing a prescription for 1 ml daily and be prescribing the more concentrated of the two brands, resulting in an infant receiving more than the recommended dosage.

Experience in our clinic indicates that parents have difficulty withdrawing drops from a small 30 ml plastic bottle as well as using a dropper with an infant. Many parents continue to believe that if one drop is good, two drops will be better. Infants receiving daily fluoride liquid supplements would best be served by the availability of individual pre-dosed packages. Numerous authors have made suggestions for eliminating abuse in prescription of fluoride supplements (29,30).

Conclusions

A number of arguments have been presented in this paper to support retaining the 1978 dietary fluoride supplementation schedule. This arguments include the following.

• Because of the almost ubiquitous presence of fluoride dentifrice and the strong possibility of additional unintentional fluoride ingestion from many other sources, the present fluorosis data are too amorphous to use as a basis for making a reasonable risk-benefit evaluation against which to titrate the dosage of fluoride supplements.

• The amount of background fluoride resulting from dietary fluoride supplements appears so small that it is unlikely it alone could account for the purported increase in the prevalence and severity of fluorosis.

- Examining populations of children for fluorosis before age 15 years is not probative. It will not be until 1995 that we can accurately determine whether the last empirical adjustment of dosage has affected fluorosis prevalence.
- The perceived degree of fluorosis diminishes as the mammelons are naturally worn down and the enamel crystals on the labial surfaces mature, lose carbonate, are abraded by toothbrushing, and the micropores around them stain with metals and organic material.
- By altering the presently recommended dosage we may deprive children from receiving a proven, effective caries-preventive benefit. Many disadvantaged populations of children, both in our nation and around the world, do not have organized drinking water systems and depend on fluoride supplements. To again reduce the recommended dosage without clinical trials would be speculative.
- Because it is unlikely that support for broad-based clinical trials of dietary fluoride supplements will be available again, we must await the development of acceptable intraoral models to establish optimum dosage that will provide us with optimum oral fluid fluoride levels.

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