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Use of Dietary Fluoride Supplements by Children Living in Berlin, Germany, may have a Dose-response Preventive Effect Against Dental Caries, Regardless of their Use of Fluoridated Salt

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Abstract

PURPOSE/QUESTION—To assess benefits (caries prevention) and risks (dental fluorosis) of using dietary fluoride supplements (referred as “fluoride tablets” in the article) among children consuming fluoridated salt in a district of Berlin, Germany.

SOURCE OF FUNDING—Information not available. The authors acknowledged the cooperation of the Public Dental Services of the Steglitz-Zehlendorf district in Berlin

TYPE OF STUDY/DESIGN—Retrospective cohort study

LEVEL OF EVIDENCE—Level 2: Limited-quality, patient-oriented evidence

STRENGTH OF RECOMMENDATION GRADE—Not applicable

SUMMARY

Subjects

This study included children from 4 of the 35 “basic” schools in the Steglitz-Zehlendorf District in Berlin who were seen as part of the Public Dental Services between December 2004 and May 2005. There is no explanation of why and how this district and the 4 schools within the district were selected. In consequence, this is a convenience sample. A total of 1004 children enrolled in the first to third grades in the 4 schools were available for participation; 969 children were asked to participate, and 583 children whose parents signed a consent form were clinically examined 2 to 4 days later. There was no information on the 35 children who were not invited to participate in the study or the 386 who did not agree to participate. The final sample represented 8% of the total population in the district; 99% of the 583 with signed consent forms were born in Germany, and 80% were from mothers of German nationality. Age was reported only as a mean (7.7, SD 1.0).

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Key Exposure/Study Factor

The key study factor was use of dietary fluoride (F) supplements to prevent dental caries.

Main Outcome Measure

Prevalence and severity of dental caries and fluorosis were the outcomes and were measured at the time of the clinical examination. Both were assessed by one trained clinical examiner. Clinical assessments were done at schools using the World Health Organization Oral Health Survey Basic Methods[1] with artificial lights, dental mirrors, and tongue blades (wood spatulas).

Untreated carious lesions (d component) were detected at the cavitated-dentinal level (d3 in the "European" system[2]). The authors used an algorithm to distinguish between unerupted teeth ("absent") from those potentially missing because of caries (m component) based on age and status of contralateral tooth. Caries experience was assessed by the number of decayed, missing and filled surfaces (modified defs index).

Fluorosis was measured on the upper central incisors using the Tooth Surface Index of Fluorosis (TSIF),[3] but was limited to 487 children with at least one central incisor. Because only central incisors were examined, the levels of fluorosis represent the effects of fluoride exposure from approximately the third month of life up to age 4 years, when the crowns of the central incisors are fully completed.

Main Results

Fifty-eight percent of participating children were caries free. Children had on average 3.2 decayed, missing, or filled surfaces of which 1.2 surfaces were untreated. Mean scores of decayed, missing, or filled primary surfaces decreased with increased age at which fluoride tablets use stopped (greater exposure), from 4.5 surfaces among those reporting not using dietary F supplements to 1.3 surfaces among those reporting stopping dietary F supplements at age 5 years or older. This trend remained if only children with German mothers were included (alluded to as "low" risk for caries), and whether parents reported use of fluoridated salt or not (Table 1). Prevalence of fluorosis was 22%. Most fluorosis (%) was mild (TSIF 1 and 2) and increased with increased or older age at which dietary F supplement use stopped independent of the children's risk of dental caries or use of fluoridated salt (Table 1 of the article).

Prevalence of caries increased with age, nationality other than German, younger age at which dietary F supplement use stopped, fewer years using fluoridated salt, use of toothpaste without fluoride, use of greater than a pea size amount of toothpaste while brushing, less frequent brushing, fewer years receiving help at brushing, greater number of dental visits, and parents having only basic education. Prevalence of fluorosis increased with increased or older age at which dietary F supplement use stopped, use of fluoridated salt, use of more than a pea size of toothpaste, brushing less frequently, early dental visit (at tooth eruption), fewer dental visits per year, and parents having greater than high-school education.

Controlling for age and mother's educational level, regression models showed that older age at which dietary F supplement use stopped was associated with a decreased risk in dental

caries (measured as a dichotomy no/yes). This model remained statistically significant only when those reporting use of fluoridated salt were included. On the other hand, older age at which dietary F supplement use stopped was associated with an increased risk of fluorosis. The model remained statistically significant or highly suggestive regardless of history of fluoridated salt use.

Conclusions

The authors concluded that use of fluoride tablets has a preventive effect against dental caries in the primary dentition of children with low caries risk, independent of their use of fluoridated salt. Use of fluoride tablets, however, also increased the risk of mild enamel fluorosis in the upper central permanent incisors.

COMMENTARY AND ANALYSIS

This study was designed to test whether dietary F supplement use has a preventive effect on dental caries in the primary dentition and whether this use was associated with an increased risk of enamel fluorosis on the permanent upper central incisors among children who are at low risk for caries and who also have access to fluoridated salt.

The authors used a retrospective cohort study design. In cohort studies, participants are selected based on being exposed or not to the intervention under study, and followed for a period of time to determine the outcome(s) alleged to be associated with the exposure. Cohort studies allow the estimation of the incidence of the outcome; thus, risk ratios are the measure of association between exposure and outcome. The modification “retrospective” is used for those cohort studies where the exposure is ascertained as an event occurring in the past, not at the time of the study. In this study, children were classified as being exposed or not to dietary F supplements from recall data gathered via a questionnaire, and evaluated on multiple outcomes related to dental caries and fluorosis.

Dietary F supplement information was obtained via a questionnaire responded to by the parents. The questionnaire included items regarding demographics, residency, dietary and dental history, and use of different fluoride vehicles, but it was not available for review. The authors do not provide information on the questionnaire’s validity or indicate whether pretesting was done. The question “age when intake of fluoride tablets was stopped” was the main study variable and was reported as having 4 options to choose from (percentages in parentheses based on 528 children): (1) no use (22%); (2) 1 year (11%); (3) 2 to 4 years (50%); and (4) greater than 5 years (17%). There was no information on the dosage, frequency, or consistency of using the dietary F supplements, but it appears odd that half of respondents reported they stopped use of F supplements at 2 to 4 years of age. The authors reported that dietary F supplements in Germany may contain 0.25 or even 0.50 mg F. For statistical modeling, the authors collapsed those answering (1) and (2) (*no use* and *1 year of use*) and used this as reference to avoid technical issues with the statistical modeling (explained under *Discussion*).

The design of the study included history of using fluoridated salt as an “effect modifier,” and a question on the duration of fluoridated salt use was included in the questionnaire. The

response options were (1) no use (30%); (2) fewer than 5 years (32%); and (3) 5 years of more (38%). There was no information on when fluoridated salt was used for the first time, its frequency, or its consistency of use. Fluoridated salt in Germany was introduced in 1991 at 250 mg/F, and in 2005 had 63% of market share.[4] Participating children had access to fluoridated salt since birth. However, in Germany only table salt is fluoridated and is limited to bags of 500 g. Fluoridated salt is not allowed in the commercial preparation of foods or in bakeries. Salt used in cafeterias or restaurants is not fluoridated unless special permission has been obtained from the German Ministry of Health.[4] Thus, at least 70% of children in the study started to be exposed to fluoride when eating solid foods prepared at home with fluoridated salt.

Other variables in the questionnaire were evaluated on their effect on dental caries and fluorosis (Table 2 of the article), but only age and socioeconomic status (SES; measured as mother's level of education) were used as confounders in multivariate models. This statistical model design was based on a casual structure developed by the authors using guidelines by Greenland et al.[5] The actual causal diagram is not included in the article.

The authors collected clinical data for dental caries and fluorosis using known indices and procedures, but did not provide customary measures of examiner reliability (percent agreement, kappa, intraclass correlation coefficients[1,6,7]). Instead, the authors used statistical correlation for measures of dental caries obtained in either side of the mouth. Dental caries was assessed at the cavitated level; thus, bias and inconsistency in coding carious lesions is not expected. Unfortunately, there is no information on the consistency of the dental examiner against the trainer (co-author) or data on the reliability of using TSIF. The assessment of fluorosis, which is subject to a higher number of inconsistencies than assessments for dental caries, demands more training and measures of reliability.

Fluorosis was assessed in the permanent upper central incisors. These teeth are formed early in life; thus, it is expected that earlier exposures, such as dietary F supplements, may have produced fluorosis on these teeth as the study reports. However, the effect of F exposure was not fully investigated in this study because late-forming teeth (upper cuspids, bicuspids, and second molars) were not erupted at examination time. This is critical, especially among long-term users of fluoridated salt and dietary F supplements. In addition, because fluoridated salt in Germany is extended only to table salt, it is expected that F concentration in salt may start to pose a risk for fluorosis once the child changes into solid diets prepared at home. In consequence, the levels of fluorosis reported in the study account only for early exposure to systemic fluoride and mostly from dietary F supplements.

A recent systematic review of the scientific evidence sponsored by the American Dental Association recommended that dietary F supplements should be prescribed only for children at high risk of developing caries and whose primary source of drinking water is deficient in fluoride.[8] For national salt-fluoridation schemes developed for Latin America, the recommendation has been for only one source of systemic fluoride.[9] All these recommendations focus on keeping the benefits of fluoride while reducing the risk of fluorosis. Thus, it is surprising to learn that practitioners in Berlin may be prescribing dietary F supplements to children with low caries risk who have access to fluoridated salt

and fluoride toothpaste. These children are at higher risk of fluorosis, independent of a potential benefit that they may receive against dental caries. Some may use this article to support inappropriate use of dietary F supplements.

Methodologically, there are a few issues worth mentioning. First is the issue of statistical representation. This is a retrospective cohort study subject to response bias as any other observational study. In addition, these researchers followed multiple steps in the selection process, each one leading to a decision on who is and who is not included in the sample without providing information to understand the process. Thus, it is not clear who the final sample of children represents. Furthermore, at times it is difficult to follow the results based on different sample sizes for each step of the analysis. This is a potential threat to the validity of the conclusions. Comparable caries scores between study participants and children in other Berlin districts are the only data presented to assess the representativeness of the sample.

Second is the issue of information bias. The authors provide limited information regarding the questionnaire they used. From the information provided in the article, questions were not phrased in clear and direct language. For example, the number of years of dietary F supplement use was ascertained by the age at which the child stopped using the supplements. One response category was “not used,” which is in conflict with the way the question was asked in assuming supplements were indeed used. In an ideal situation, these should have been 2 questions with a skip pattern. Questions ascertaining behaviors were not followed by a question indicating consistency of use. In addition, there was no language on whether the questionnaire was validated or pilot tested.

The third issue is related to the analysis. The entire set of bivariate analyses for dental caries and fluorosis described in Table 2 of the article used measures of prevalence. These include, in terms of dental caries, untreated disease and sequelae, a combination of disease and treatment patterns (hence, the higher prevalence among those with more dental visits). A similar approach was used in the multivariate modeling, ie, to obtain measures of association (relative risk). The authors modeled a dichotomous response (no vs yes) for caries and fluorosis, which missed information on severity. A better approach would have used a continuous response variable (defs or TSIF scores) and indicator variables for dietary F supplement use. Furthermore, logistic models assume an exponential link, which may or may not be valid in case of caries or fluorosis. There were 2 more issues on the multivariate modeling. Age and SES were included as confounders by the authors. It appears to this reviewer that age and SES are actually effect modifiers, because disease changed by age and sex. Furthermore, the authors provided little justification as to why these were the only variables included in the models. The article by Greenland et al,[5] used to support the causal structure with age and SES as third variables, is a theoretical proposal on how to construct casual structures, not a direct assessment of whether in the case of dental caries and fluorosis other third variables should be included in the model. The final, minor, technical issue was the wording used to describe the distribution of defs in the figure. The authors reported as skewed “to the right.” This distribution should be described as skewed “to the left” (negative).

In conclusion, at the technical level this epidemiological study had several issues that could affect the validity and reliability of the measurements and limitations in the analysis and interpretation. The conclusions are in agreement with most of the results, but methods could have been strengthened to obtain results less subject to bias. In addition, there is one significant concern, and that relates to the underlying message that it is appropriate to use 2 simultaneous sources of systemic fluoride, ie, dietary F supplements and salt fluoridation among children at low risk of dental caries. Furthermore, the authors indicated that these 2 systemic approaches used in combination had little effect on fluorosis levels, but the study design has limitations in testing the combined effects of these 2 systemic sources of fluoride.

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