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ORIGINAL ARTICLE

Extended caries prevention programme with biannual application of fluoride varnish for toddlers: prevalence of dental fluorosis at ages 7–9 years and associated factors

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ABSTRACT

Objective: To investigate the prevalence of and factors associated with dental fluorosis in children living in areas of high caries risk in Stockholm and who had participated in a prospective, parallel, cluster-randomized, controlled caries prevention trial between ages 1 and 3 years.

Materials and Methods: The study group comprised a random sample of the children who had completed the 2-year prevention trial ($n = 2536$) in 2011–2014. All children were instructed to use fluoride toothpaste; the test group received fluoride varnish applications twice a year. Dental fluorosis prevalences in the reference ($n = 220$) and the test ($n = 234$) groups were compared. Presence of fluorosis was determined using the Thylsturp & Fejerskov (TF) index on photos of the permanent maxillary incisors.

Results: No significant difference in dental fluorosis was observed between the two groups. Nearly one-third (29.7%) of the children in the study cohort exhibited dental fluorosis (TF index $\geq$ 1). Associations with use of fluoride toothpaste at age 1 year and with socioeconomic status factors were found.

Conclusions: Biannual applications of fluoride varnish in toddlers was not associated with dental fluorosis, which when found was rarely of aesthetic concern. Parental education in tooth-brushing routines is recommended.

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Introduction

Pre-school children worldwide are affected by dental caries, and it is considered one of the most common chronic diseases in the world [1]. Fluoride supplements are one tool in disease prevention [2]. Early fluoride exposure, however, even before their eruption, increases the risk of dental fluorosis in permanent teeth [3]. For example, Evans and Darvell [4] observed that dietary ingestion in the first 15–30 months of life increases the risk of fluorosis in the permanent maxillary central incisors.

To minimize the negative side effects of fluorides while maximizing their caries preventive effects, the level of fluoride intake needs to be balanced [5]. The McDonagh et al.'s [6] review of 88 studies on dental fluorosis estimated a 48% prevalence of dental fluorosis and 12.5% prevalence for fluorosis comprising an aesthetic concern at fluoride water concentration of 1 ppm. Conway et al. estimated that 49% of the children in a non-fluoridated area in Sweden had dental fluorosis in 2005. Only 4% was considered to be of aesthetic concern. The majority of parents in the study (63%) had been brushing the teeth of their children since age 6–12 months, and nearly all parents (92%) reported doing so with a fluoride toothpaste ($\geq$1000 ppm) [7]. Tavener et al. [8] found that early introduction of fluoride into low-income communities with a high caries risk was shown to have a low risk of inducing dental fluorosis of aesthetic concern.

Stockholm is mapped into four regions according to the need for dental care, or four Health Need Areas (HNA 1–4); these also reflect socioeconomic differences in the region. HNA 3 and 4 represent disadvantaged areas with a high caries risk [9,10].

In 2011, all children born in 2010 in HNAs 3 and 4 were invited to participate in a 2-year prevention programme between ages 1 and 3 years. The programme goals were to prevent the initiation of caries through early interventions, to improve the oral health of the children in the areas, and to reduce existing inequalities in oral health between the two areas. At the first visit when the child was 1 year old, the parents were advised to brush the teeth of their children with a fluoride toothpaste (1000–1450 ppm) twice a day. The parallel design of the programme meant that half of the study group also had their teeth treated with fluoride varnish twice a year. No significant differences in caries development were observed between the two groups. Daily use of fluoride

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toothpaste increased from about 50% at 1 year to about 90% at age 3 years [11].

The present trial assessed the prevalence of dental fluorosis in 7–9-year-old children who had participated in the intervention programme at ages 1–3 years. Our first hypothesis was that the two groups (with and without fluoride varnish as toddlers) had similar prevalences of dental fluorosis. Our second hypothesis was that dental fluorosis prevalences had no associations with background factors in HNAs 3 and 4, the areas in which the intervention programme was conducted.

Materials and methods

Study design

This is a cohort study based on a sample of children who had participated in a parallel prospective longitudinal cluster randomized caries prevention trial in areas at high risk for dental caries during the years 2011 (March) to 2014 (March). The trial was registered at www.controlled-trials.com [ISRCTN35086887] and the Regional Ethics Committee in Stockholm (daybook no. [Dnr] 2010/1956, daybook no. [Dnr] 2016/1240-32) approved the trial. All parents of participating children signed informed-consent forms allowing a photographic evaluation of their children for the present study.

Setting and participants

The study group comprised a cohort of 7–9-year-old children at 23 dental clinics in two areas of Stockholm, Sweden, with a medium or low socioeconomic status (SES); the clinics had participated in the previous intervention trial when the children were 1–3 years old. When the trial ended in 2014, only 2536 of the initial 3404 participants remained in the programme [11]. Between 2017 (January) and 2019 (December), a random sample ($n = 774$) of the children who had completed the 2-year intervention programme were invited for a photographic assessment.

Selection of participants

This intervention trial had a parallel design, and the clinics, as well as the children, were assigned to either a test group or a reference group. The first step was a power analysis on a selection of children from the original trial, to study between-group differences in prevalence of dental fluorosis. Based on findings from other epidemiological studies in Sweden, we anticipated a similar prevalence of dental fluorosis: around 30% [15]. Setting α to 0.05 and β to 0.2, we calculated that a sample of 309 children from each intervention group would be sufficient to detect any significant differences between the groups (www. powerandsamplesize.com). In the next step, we selected random samples of children from the two groups in the original trial that had completed the extended caries prevention programme with biannual application of fluoride varnish (test group: children = 1231; clinics = 10; reference group: children = 1305, clinics = 13) using IBM SPSS software (version 21.0, Chicago, IL USA). An attrition rate of 25% was assumed.

Fluoride supplement

Between ages 1 and 3 years, starting as soon as the first tooth erupted, all participants were advised to use fluoride toothpaste (1000–1450 ppm F, an amount corresponding to the size of the child's little fingernail) morning and evening. These recommendations were given once a year to the reference group and twice a year to the test group. At each intervention visit, all parents also received a free tube of toothpaste (1000–1450 ppm F). Additionally, the test group received fluoride varnish treatments (Duraphat®, 22.6 mg F per ml, Colgate-Palmolive) at all intervention sessions. The amount of fluoride varied with the number of erupted teeth but never exceeded 0.25 ml. For more details, see Anderson et al. [11]. Between 3 and 9years of age, the children were enrolled in the same caries prevention programme. All dental caregivers for the participants where obligated to follow the caries prevention programme that the Public Dental Service introduced in Stockholm in 2004 [12].

In Sweden, fluoride supplements are the main source of fluoride ingestion; levels of naturally occurring fluoride in drinking water in Stockholm are low. During the 3 years of the study, fluoride levels in tap water were <0.2 mg/ml, according to yearly assessments [13].

Questionnaire

In the questionnaire interview in the original trial when the children were 1 year old, parents were queried on background factors and tooth-brushing habits [14]. For the present cohort study, parents were interviewed again to collect more data on factors related to mineralization disturbances. At this interview, the children were photographed for later analysis of dental fluorosis.

Assessment of dental fluorosis

Documentation

Dental fluorosis documentation for later assessment was gathered in conjunction with the annual check-up at one of the 23 dental clinics that had participated in the intervention trial. Before the check-up of the children in the study, one clinician in each participating clinic received a half day of information and training about the present study, including practical exercises in dental photography. Photographs were taken with a digital camera and, when available, a ring flash. Normal ambient lighting was recommended as background lighting. Before the pictures were taken, the upper front teeth and lower front teeth were polished with a polishing paste (RDA 250), rinsed with water, and then dried with compressed air for 5 s. Photos of the labial surfaces of the upper and lower incisors were taken with the aid of a pair of sterilized lip retractors. Before assessment, a quality check of the pictures was done. If the quality was inadequate for assessing fluorosis, the researchers informed the clinic to retake the image at the next scheduled visit for the child. Thirteen children were excluded from the study due to not fulfilling the photographic criterion.

The photos were transferred to a computer (Macbook Pro, 13.3″diagonal retina display, resolution 2560×1600) for assessment. Only children in whom at least one-third of the permanent maxillary central incisors had erupted were included. In the majority of the included children, two-thirds of the permanent maxillary central incisors had erupted (91%). Five children did not fulfil this criterion and were excluded.

Classification and calibration

Fluorosis was judged and classified according to the Thylstrup & Fejerskov index (TF index) as modified by Fejerskov et al. [15]. The highest score of a tooth was used to determine the presence and level of fluorosis. Two final year dental students (TFK, ZF) assessed the photographs after an initial training and calibration session where they evaluated 50 cases together with a senior consultant in paediatric dentistry (MA). The students then assessed the same photographs separately at 2-week intervals until intra- and inter-examiner reliability was reached ($\kappa = 1.0$; TF index ≥ 1 or TF index $= 0$).

Blinded to intervention group (i.e. test group or reference group), the examiners (TFK, ZF) then evaluated the photos separately. In cases of disagreement, a third examiner (MA) joined the discussion until a consensus was reached. The diagnosis of fluorosis was done in two steps. The first step was to evaluate whether the teeth exhibited dental fluorosis (TF index $\geq$ 1) or not (TF index $=$ 0). The second step was to re-evaluate the group exhibiting dental fluorosis (TF index $\geq$ 1) and assign severity (TF index 1–9).

Statistical analyses

Odds ratios were estimated with uni- and multivariable logistic regressions using a generalized estimating equation (GEE) model to account for the non-independence of observations within each clinic. In the GEE model, the covariance structure was set to exchangeable. Analysis was done in Stata Statistical Software (release 15 [2017]; StataCorp LLC, College Station, TX). Cohen's kappa estimated reliability. We considered a p value $< .05$ as statistically significant.

Results

Participants

Overall, we evaluated 454 children to determine the prevalence of dental fluorosis. Figure 1 presents the reasons for dropping out.

Background characteristics and prevalence of dental fluorosis

Table 1 presents background characteristics. The mean age of the children at the time of photography was 7.4 years. In the study cohort, dental fluorosis (TF index $\geq$ 1) was observed in 29.7%: 26.5% had a TF index $=$ 1; 2.4%, a TF index $=$ 2; and 0.7%, a TF index $\geq$ 3. A larger proportion of children in the reference group (34.1%) than in the test group (25.6%) had dental fluorosis. Most children did not use medical products ($n = 407$), but of those who did ($n = 47$) the most common reason for this was asthma/allergies ($n = 28$) and autism spectrum disorders ($n = 13$).

Table 2 presents the univariate logistic regression analysis done to control the influence of background characteristics. No significant associations were found between dental fluorosis and either intervention group (TF index $\geq$ 1). We then did a multivariate analysis that included the significant variables found in the univariate analyses (Table 3). The multivariate analysis found significant independent associations of dental fluorosis with non-immigrant background, and with the use of fluoride toothpaste once a day or more at 1 year of age.

Discussion

The present study found that children in middle to low SES areas who had participated in the 2-year caries intervention trial from age 1 year and received fluoride varnish applications every 6 months did not develop dental fluorosis more often than those who had not had fluoride varnish treatment. At 7–9 years of age, several children had developed dental fluorosis, but the fluorosis seemed to be more associated with SES variables and use of fluoride toothpaste at age 1 year than with frequency of fluoride varnish applications. The instances of dental fluorosis, however, were almost exclusively very mild and of non-aesthetic concern (TF index $<$ 3).

Further, the prevalence of dental fluorosis was higher in the reference group than in the test group. This could partly be explained by the fact that the test and reference groups were unbalanced regarding the background characteristic-non-immigrant background (Table 1) which also was shown to be associated with dental fluorosis (Tables 2 and 3).

Fluoride varnish applications (2.26% F) are considered safe [16] for 12–15-month-old children who drink non-fluoridated water and use non-fluoridated toothpaste. Lockner et al. measured urinary excretion levels of fluoride in 3–4-year-old children after fluoride varnish applications. One group used fluoridated toothpaste (1000 ppm F) and one, non-fluoridated toothpaste. Independent of toothpaste, high levels of fluoride that sometimes exceeded WHO recommendations were found. Thus, the risk of developing dental fluorosis after topical applications of fluoride varnish biannually or quarterly was considered to be very low [17]. The present study seems to confirm this, as the children who had been introduced to fluoride toothpaste early and received topical applications of fluoride varnish twice a year (2.26% F) did not develop dental fluorosis more frequently than those who had not received fluoride varnish.

In the cohort sample in our study, we assessed that 29.7% had developed dental fluorosis, which is a lower number than Macpherson et al. [18] reported in their Swedish

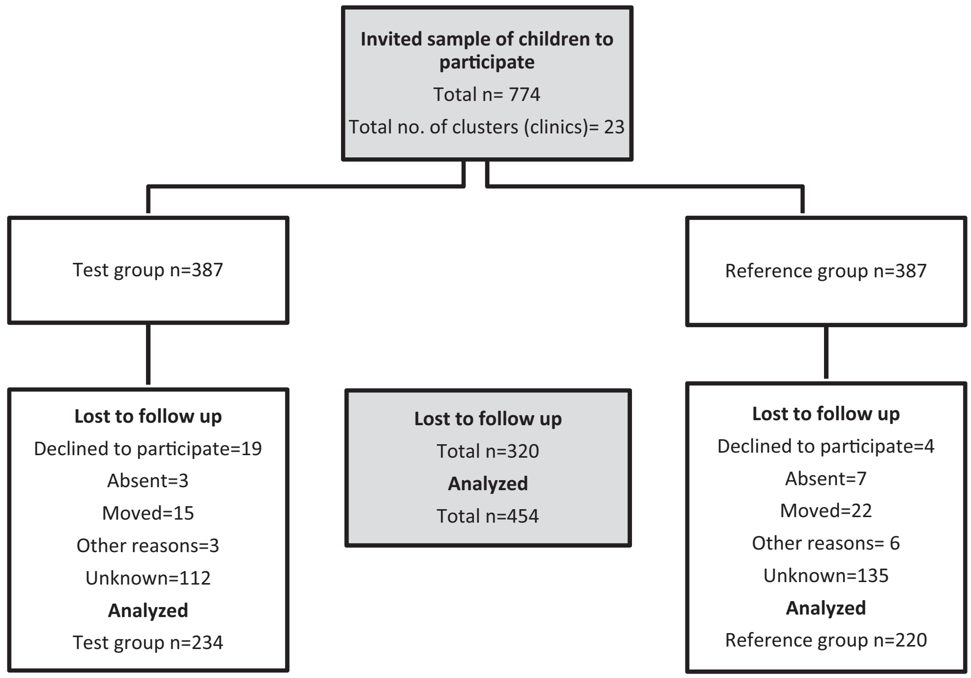

Figure 1. Flowchart of children and reasons for dropping out.

Table 1. Background characteristics of the test group of children who had received applications of fluoride varnish biannually for 2 years and the reference group, who had not received fluoride varnish.

Data baseline at 1 year	Test group ($n = 234$) (%)	Reference group ($n = 220$) (%)
Gender: boy/girl	49/51	45/55
Family income > EUR 2000/month[a]	58	63
Maternal education > 9 years[b]	76	78
Non-immigrant background[c]	17	26*
Fluoride toothpaste ≥ 1/day	59	56
Fluoride toothpaste ≥ 2/day	36	37
Data follow-up		
Family history of tooth development disorder	8	9
Use of medical products	9	11

*$p < .05$.
[a]Above threshold for low-income level.
[b]Above comprehensive school level.
[c]Only Swedish spoken at home.

Table 2. Univariate logistic regression analysis with dental fluorosis (TF index ≥ 1) as the dependent variable.

Variable	OR	95% CI of OR
Test group	0.71	0.41–1.08
Gender: female	0.78	0.54–1.12
Family income > EUR 2000/month[a]	1.51**	1.16–1.96
Maternal education > 9 years[b]	1.52**	1.13–2.08
Non-immigrant background[c]	1.68**	1.24–2.28
Fluoride toothpaste ≥ 1/day	1.53**	1.20–1.97
Family history of tooth development disorder[d]	1.19	0.79–1.80
Use of medical products[d]	1.48	0.78–1.68

TF index: Thylsturp & Fejerskov index; OR: odds ratio; CI: confidence interval; test group: applications of fluoride varnish biannually for 2 years.
**$p < .01$.
[a]Above threshold for low-income level.
[b]above comprehensive school level.
[c]Only Swedish spoken at home.
[d]Data from follow-up evaluation.

Table 3. Multivariate logistic regression analysis with dental fluorosis (TF index ≥ 1) as the dependent variable for the study cohort overall ($n = 454$).

Variable	OR	95% CI of OR
Family income > EUR 2000/month[a]	1.19	0.89–1.60
Maternal education > 9 years[b]	1.25	0.89–1.74
Non-immigrant background	1.42*	1.02–1.97
Fluoride toothpaste ≥ 1/day[c]	1.31*	1.00–1.71

TF index: Thylsturp & Fejerskov index; OR: odds ratio; CI: confidence intervals.
*$p < .05$.
[a]Above threshold for low-income level.
[b]Above comprehensive school level.
[c]Only Swedish spoken at home.

intervention study, also conducted in a non-fluoridated, high caries-risk area. In their study, the children in the test group began receiving fluoride tablets (one 0.25 mg NaF tablet/day) at the age of 2 along with tooth-brushing instructions. Dental fluorosis was found in 43% of the children. However, 38% of the reference group, which had not received fluoride tablets, was also considered to have developed dental fluorosis.

It is known that early introduction of fluoride supplements may increase the risk of developing dental fluorosis [19]. In our study, children who had been introduced to fluoride toothpaste at the age of 1 developed dental fluorosis to a higher degree than those who had not. This finding correlates with the findings of a systematic review of 25 studies regarding use of fluoride toothpaste during the first year of life. The studies, however, had differing designs. The review concluded that the introduction of fluoride toothpaste before the age of 1 year is associated with an increased risk of fluorosis [19]. To minimize the risk of fluorosis and at the same time maximize the caries preventive benefit of fluorides, it was important to take account of the age of the child when considering the fluoride content of the toothpaste and the amount of fluoride toothpaste dispensed on the child's toothbrush [20].

Further it is important to help parents become aware of their responsibility to supervise tooth brushing until their children are 10 years old [5]. Another fluorosis preventive measure in young children is to recommend tooth brushing after meals (i.e. after breakfast) as studies have shown a 50% lower risk of developing dental fluorosis if tooth brushing is done after food has been consumed [21].

In a non-fluoridated area in England, Tavener et al. [8] compared prevalence and severity of fluorosis in children in deprived and less deprived communities that had received fluoride toothpaste from the age of 12 months. They found that the risk of developing aesthetically objectionable fluorosis (TF index $\geq$ 3) in disadvantaged, high caries-risk communities was low, independent of whether high or low fluoride toothpastes were used. They also found a higher risk of developing dental fluorosis of aesthetic concern in children using highly fluoridated (1450 ppm F) toothpaste in less deprived areas. Our study was conducted in areas considered mainly high-risk and disadvantaged. It is interesting that the present study found an association with the development of dental fluorosis (TF index $\geq$ 1) and SES factors such as family income $>$ EUR 2000/month, maternal education $>$9 years, and non-immigrant background. These findings are something to consider in the introduction of fluoride supplements on both the individual and the community level.

The conduct of this study has ethical concerns regarding the early introduction of fluoride in children in the original study. We were pleased to find that the children who had participated in the caries prevention trial and had received fluoride varnish exhibited no increase in the development of dental fluorosis relative to what could be expected. The present study has some limitations. The attrition rate was higher than what we expected: the power analysis indicated that two groups of 309 children each, would be needed to prove a significance difference; only 74% of these participated, which may have biased the results. Over the course of the present study, two dental clinics closed, and it is well known that children in these areas undergo frequent resettlement [22].

We did, though, find factors besides fluoride varnish that were associated with dental fluorosis and could strengthen the trustworthiness of our finding, that fluoride varnish treatment of toddlers did not seem to cause fluorosis at later ages in these demographic areas. Another limitation of our study was the photographic assessment. Some photos were excluded due to low resolution or movement during image capture, resulting in blurred and imprecise images that made tooth assessment difficult. In other cases, the lighting was poor, with bright or dark shadows projecting on the tooth surface, and sometimes, eruption of the permanent maxillary teeth was insufficient for assessment. The examiners were calibrated, but as Tavener et al. [8] showed, rescoring the same photographs after a time interval can produce different results. Further, to have an even more accurate diagnosis, we should have examined the children after all the permanent teeth had erupted. But our main goal here was an intermediate follow-up of the effects of the two interventions.

We are all aware that it is unethical to conduct RCTs that study how differing levels of fluoride supplementation influence the development of dental fluorosis, due to the risk of causing unsightly fluorosis in permanent teeth. The findings of the present observational study are thus important as they add to our knowledge of the effects of early exposure to fluoride supplementation and help fill the knowledge gap on what levels of fluoride supplementation in young children prevent dental caries without causing severe dental fluorosis [19,20]. In our study the level of dental fluorosis was the same in children receiving fluoride toothpaste, independent of whether they received biannual applications of fluoride varnish or not. In both groups, however, the dental fluorosis was generally mild.

In conclusion, considering the continuing need to prevent dental caries, if we can accept some degree of dental fluorosis, the fluoride supplementation programme described in the present study should be considered acceptable concerning the risk of dental fluorosis. All parents in this study were trained in techniques for brushing the teeth of children with fluoride toothpaste. Parental education in tooth-brushing routines is important when introducing fluorides as a way of preventing dental caries in children.

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Disclosure statement

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Data availability statement

The datasets analysed in the current study are available from the corresponding author on reasonable request.

Geolocation information

Sweden.

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