Effectiveness of a New Fluoride Varnish for Caries Prevention In Pre-School Children

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Objective: *To investigate the effectiveness of a new fluoride varnish (Clinpro White Varnish, 3M Espe, Seefeld, Germany) with regard to the caries incidence within a 2-year period.* ***Study design****: A non-randomized sample of 400 children from the Kyffhäuser district (Thuringia, Germany) was divided into a fluoride group (FG, biannual application of fluoride varnish) and control group (CG, no intervention). (Non-)cavitated caries lesions were recorded using World Health Organization (WHO) and Universal Visual Scoring System (UniViSS) criteria. Parents were given questionnaires to gather information about their socio-economic status (SES). Non-parametric methods and binomial logistic regression were used for data analysis.* ***Results****: There was a significant increase in caries incidence in both groups. The number of non-cavitated carious lesions was significantly lower in the FG (mean 2.2; sd 2.3) compared with the CG (mean 2.9; sd 1.9). Initial statistical analysis revealed that fluoride varnish might prevent non-cavitated carious lesions. When including SES as a confounder into regression model, potential preventive effect was lost.* ***Conclusions****: This study underlines the importance of the multi-factorial etiology of caries and illustrates that the effectiveness of biannual fluoride varnish application was evident in non-cavitated carious lesions only.*
Keywords: *Dental caries; prevention; fluoride varnish; preschool child.*

INTRODUCTION

Dental caries are one of the most prevalent diseases in young children.[1] Worldwide, a high number of pre-school children suffer from early childhood caries (ECC).[2] The American Academy of Pediatric Dentistry (AAPD) defines ECC as the presence of one or more decayed, missing or filled teeth in a child aged 71 months or younger.[3] In Germany, regional prevalence rates of ECC have varied between 9 and 21%, depending on the caries scoring criteria used.[4,5] Representative German data on caries incidence in the primary dentition are available for 6- to 7-year-old children only. A recent study by the German Society for Public Dental Health of Children and Adolescents (Deutsche Arbeitsgemeinschaft für Jugendzahnpflege e.V., DAJ) reported a caries prevalence of 46% and a caries experience of 1.9 dmft for this age group.[6] Children at risk of caries frequently come from families with low levels of education, a low annual family income and an immigrant background.[7,8]

Since 1989, setting-based preventive programs for children aged 3 to 12 years have been legally regulated as part of the Group Prophylactic Program (GPP) in Germany. Paragraph 21, Social Security Code (SSC) V, declares that health insurance groups, dentists and appropriate public authorities must promote measures for caries detection and prevention in children younger than 12 years. These measures should include oral examination, dietary counseling, oral hygiene instruction and the use of fluoride, particularly in children who attend kindergartens, elementary schools and institutions for children with disabilities. Since 1993, paragraph 21, SSC V, was extended to include the recommendation that children at high risk of caries should be enrolled in intensified preventive programs that offer the application of highly concentrated fluoride compounds two times *per* year. Epidemiological data should be collected for monitoring the efficiency of these programs. Unfortunately, no standardized population-wide public health programs for children under 6 years of age are yet available.

Fluoride varnishes are effective in preventing caries and their administration is the method of choice to prevent demineralization, as well as to enhance the remineralization of non-cavitated carious lesions.[9-11] In 2009, a new fluoride varnish (3M Clinpro White Varnish, 3MEspe, Seefeld, Germany) was introduced into the dental market. Until now, little information about the effectiveness of this

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Table 1. Descriptive statistics for the fluoride group (FG) and control group (CG) at baseline and at the 2-year follow-up.

Caries prevalence and experience	Baseline examination			2-year examination		
	FG	CG	Overall	FG	CG	Overall
No. of subjects, N	**159**	**149**	**308**	**159**	**149**	**308**
d_{3-4}mfs > 0, N (%)	39 (19.5)	28 (18.8)	59 (19.2)	68 (42.8)	62 (41.6)	143 (40.3)
d_{1-2}s > 0, N (%)	86 (54.1)	75 (50.3)	161 (52.3)	107 (67.3)	93 (62.4)	223 (62.8)
d_{1-4}mfs, N (%)	89 (56.0)	82 (55.0)	171 (55.5)	115 (72.3)	104 (69.8)	219 (71.1)
d_{3-4}s, mean (sd)	1.4 (4.9) *1	1.8 (5.8) *2	1.6 (5.4) *3	2.1 (5.3) *1	2.2 (5.0) *2	2.1 (5.1) *3
ms, mean (sd)	0.3 (2.0) *1	0.3 (2.1) *2	0.3 (2.0) *3	1.0 (4.7) *1	1.3 (5.6) *2	1.1 (5.2) *3
fs, mean (sd)	0.3 (1.1) *1	0.1 (0.7) *2	0.2 (0.9) *3	1.2 (2.8) *1	1.1 (2.6) *2	1.1 (2.7) *3
d_{3-4}mfs, mean (sd)	**2.0 (6.3) *1**	**2.3 (6.4) *2**	**2.1 (6.4) *3**	**4.2 (8.9) *1**	**4.6 (9.4) *2**	**4.4 (9.1) *3**
F, mean (sd)	1.7 (3.3)*1	1.6 (3.3) *2	1.7 (3.3) *3	2.1 (2.7) *1	2.2 (3.5) *2	2.1 (3.1) *3
E, mean (sd)	0.4 (1.0) *1	0.4 (1.0) *2	0.4 (1.0) *3	1.3 (4.8) *1	1.6 (5.4) *2	1.4 (5.1) *3
M, mean (sd)	0.5 (1.2)†1	0.2 (0.6)†2	0.3 (1.0)†3	0.5 (1.2)†1	0.3 (0.7)†2	0.4 (1.0)†3
d_{1-2}s, mean (sd)	**2.5 (4.0) *1**	**2.3 (3.8) *2**	**2.4 (3.9) *3**	**3.9 (6.2) *1**	**4.0 (6.5) *2**	**3.9 (6.3) *3**

The Mann-Whitney U test was performed to detect differences between the caries prevalence data (d_{3-4}mfs > 0, d_{1-2}s > 0, d_{3-4}mfs + d_{1-2}>0) of the fluoride and control groups at baseline and after 2 years of follow-up; no significant differences were detected between these groups (p-value≤0.05).
The Wilcoxon signed rank test was performed to detect differences between each group at baseline and after 2 years of follow-up and the * indicates significant differences (p-value <0.05). Values marked with † indicate no significant difference (p-value >0.05). Groups with same superscripted numbers were compared at baseline and at the 2-year follow-up.

varnish for caries prevention has been reported. Therefore, our study aimed to analyze the preventive effect of this new fluoride varnish in 2- to 3-year-old kindergarten children, who may be at risk of developing an ECC. The aim of this paper is to prove if biannual application of the fluoride varnish is effective after 2-year observation period.

MATERIALS AND METHOD

The reporting of this study followed the recommendations of the TREND guidelines for non-randomized evaluations of public health interventions.[12] The study design was approved by the ethics committee of the University Hospital Jena (registration number 2376-09/08).

Study Population: The study enrolled children from kindergartens in the Kyffhäuser district in Thuringia, Germany. In 2008, the residents of this district were characterized by a high unemployment rate (18.8%) and a low socio-economic background.[13] Available data from annual dental examinations indicated a high caries prevalence and experience in pre-school children relative to children of other Thuringian districts. Furthermore, only two-thirds of this age group attend kindergarten. The drinking water in the Kyffhäuser district has a fluoride content of approximately 0.2 ppm.

The basic preventive program in the Kyffhäuser district includes daily supervised tooth brushing with fluoridated toothpaste (500 ppm) in all kindergartens, dietary counseling on healthy meals for the kindergarten staffs and one visit to a dental practice *per* year to reduce dental anxiety. With the aim of preventing ECC in preschool children, the local public dental health service offered municipal kindergartens (n=58) participation in an intensified preventive program, including a biannual fluoride varnish intervention. Twelve kindergartens from seven towns agreed to participate and were thus included in this study, providing a total of 467 children who were eligible to take part in the fluoride varnish program. After the recruitment of the kindergartens, an invitation letter was given to all parents of the children attending the included schools requesting their children's participation in the present study. Inclusion criteria for the enrolment of children were: healthy male and female children (ASA status = 0) aged 2 to 3 years, informed consent signed by the parents and inclusion in the fluoride group (FG) as decided by the parents.

Children whose parents decided that they should not take part in the fluoride program served as the control group (CG). Finally, 400 children aged 2 to 3 years were eligible for study participation. Children in the CG received caries preventive measures in accordance with the basic setting-based preventive program of the Kyffhäuser district.

Randomization: A strict randomized allocation of each subject was rejected for ethical reasons, as an effective preventive treatment would be denied to a distinct number of children (control group). Therefore, the parents' decision of whether to allow their child to receive the fluoride intervention was used to allocate each subject to either the FG (n=200) or CG (n=200).

Interventions: The fluoride varnish, 3M *Clinpro White Varnish* (3MEspe), which contains 5% sodium fluoride, was applied twice a year at 6-month intervals over a 2-year period to the children in the FG by a dentist (J.A.) or a dental hygienist. Before application of the fluoride varnish, the children brushed their teeth using fluoridated (500 ppm) toothpaste under the supervision of the kindergarten staff. Their teeth were dried using cotton rolls to ensure a relatively dry environment and the appropriate dosage of varnish (0.25 ml, containing 12.5 mg of sodium fluoride) was then applied. Parents of the children in the FG were asked to refrain from brushing their children's teeth on the evening of varnish application. Furthermore, oral health instructions were given to the parents of all children to increase their awareness and to improve the oral hygiene of their children.

Clinical Examination: The standardized examination equipment included a dental mirror with a plane surface, a blunt CPI probe (CP-11.5B6, Hu-Friedy, Chicago, IL, USA) and a halogen lamp (Ri-Magic, Rudolf Riester GmbH, Jungingen, Germany). Each child

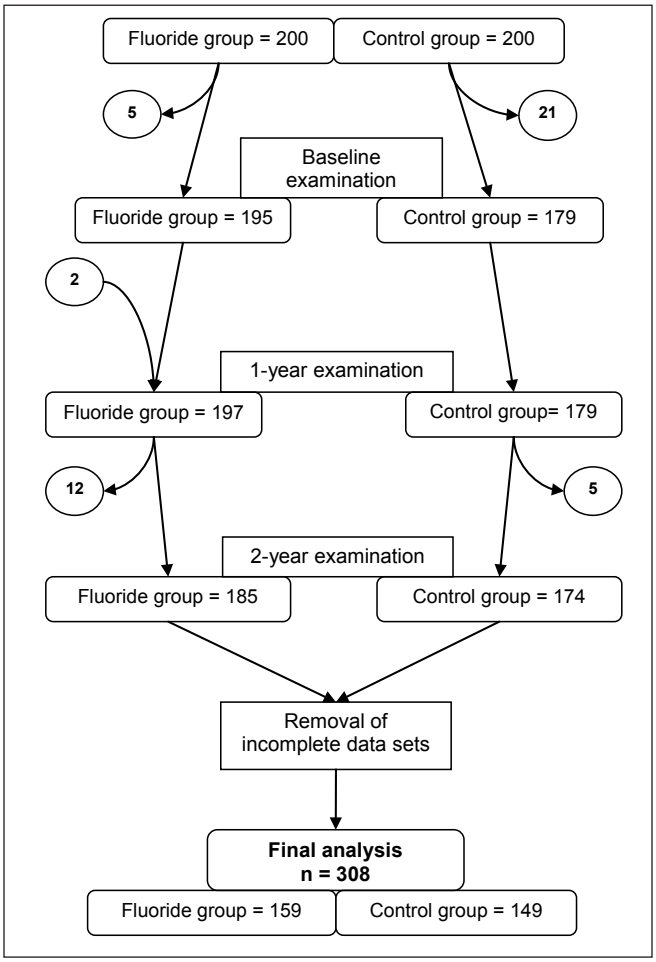

Figure 1. Flow chart of the study population.

was investigated at the designated appointment by one of two calibrated dentists (J.A. and R.H-W.). The caries status was determined as a surface-related dmf index for the primary dentition (d_{3-4}mfs) by using the WHO standard.[14] For scoring non-cavitated carious lesions (d_{1-2}), the Universal Visual Scoring System (UniViSS)[15,16] was used, also on a surface level.

Questionnaire: After the children's inclusion in the study, parents were provided with questionnaires to gather information about the daily dental health behavior of their children at home. Some questions were directed to obtain information on their oral health, oral hygiene and social status. The socio-economic status (SES) was graded using the Brandenburg Social Index.[17] According to this index, the children were classified into high, middle or low SES groups.

Sample Size: The prevalence of dental caries using the dmfs index was approximately 20% in the study population at the time of the study. We expected this prevalence to increase to ~30 and ~50% in the FG and CG, respectively. Expecting a dropout rate of 20% over a 2-year period, with the two-tailed α-significance level set at 0.05 and with a power of 90%, we obtained a sample size of 158 for each group. Thus, the minimal sample size allowed was 386 (193 subjects per group). The study finally obtained a sample size of 400 children, 200 of whom belonged to the FG and the remaining 200 of whom belonged to the CG.

Out of this sample group, 92 children were lost during the follow-up, mainly due to relocation outside of the town, absence on the examination day, or one or more missed examinations. This number includes the children who were removed during analysis due to a lack of complete data, thus arriving at a sample of 308 children, 159 and 149 of whom were in the FG and CG, respectively; this sample group was used for the final analyses (Figure 1). When SES data were included in the regression analysis, the sample size further declined to 215 due to the lack of SES information for the children whose parents declined to respond to the question or for those who did not return the questionnaire forms.

Calibration of the Study Team: Before the beginning of the study, a 3-day theoretical and practical calibration training session was held for the examiner (J.A.) under the supervision of experienced dentists (J.K., R.H-W.). Training was provided on the scoring of (non) cavitated carious lesions, scoring of sealants and determination of possible differential diagnoses. The one-day theoretical training session provided all of the relevant information about, for example, the study design, indices and diagnostic principles. This training session was followed by a two-day clinical and field training course, in which the examiner scored the oral health of fifteen 3-year-olds in realistic conditions under the supervision of both experienced dentists. The kappa value for the inter-examiner reliability was 0.78 and the intra-examiner reliability was 0.86.

Statistical Analysis

Dental health data were entered into a SQL database (Access 2007, Microsoft Corporation, Redmond, WA, USA) and transferred into an Excel sheet (Excel 2003, Microsoft Corporation, Redmond, WA, USA). The descriptive and explorative data analysis was performed with Microsoft Excel 2007 and with SPSS Statistics for Windows, Version 19.0.1 (SPSS Inc., an IBM Company, Chicago, USA). In addition to the calculation of d_{3-4}mft/s and d_{1-2}s scores, the mean values and the standard deviations of their components were determined separately. Baseline data were used as a reference for the calculation of the 2-year caries incidence. Prevented fractions (PFs), calculated as the caries incidence in the CG minus the caries increment in the FG and expressed as a proportion of the CG, were calculated based on the number of applications received. The PF can be either positive or negative.[19] Positive values indicate that the treatment is effective, negative values indicate that the treatment is ineffective and a value of zero indicates that the treatment is neither effective nor ineffective. The negative values observed in our study were due to a smaller change in caries incidence in the CG. The data sets were tested by the Shapiro-Wilk test for normality, which did not show a normal distribution and were analyzed by non-parametric methods. A Mann-Whitney U test was used to test for baseline equivalence between the two groups and no statistically significant differences were detected.

The longitudinal data were stratified into 4 groups based on the fluoride applications received and they were compared using the Wilcoxon signed rank test. The binomial incidence data were analyzed using binomial logistic regression, employing a conditional forward selection model. The same procedure was repeated with the inclusion of the SES data for the reduced sample size of 215. For all of the analyses, a 95% confidence level and a two-tailed α significance level of 0.05 were used.

RESULTS

At the baseline examination, the overall caries prevalence was 19.2% at the dentin level. During the 2-year follow-up period, the

Table 2. Caries incidence data and prevented fraction (PF) related to the number of fluoride varnish applications.

Caries incidence (Baseline – 2-year examination)	Control group		1-2x fluoride applications			3-4x fluoride applications			1-4x fluoride applications		
	N	Mean (sd)	N	Mean (sd)	PF	N	Mean (sd)	PF	N	Mean (sd)	PF
Children with $d_{3-4}mfs=0/d_{1-2}=0$											
$d_{3-4}mfs$		0 (0)		0 (0)	0		0 (0)	0		0 (0)	0
$d_{1-2}s$	59	0 (0)	12	0 (0)	0	50	0 (0)	0	62	0 (0)	0
$d_{1-4}s$		0 (0)		0 (0)	0		0 (0)	0		0 (0)	0
Children with $d_{3-4}mfs=0/d_{1-2}>0$											
$d_{3-4}mfs$		0 (0)		0 (-)	0		0 (0)	0		0 (0)	0
$d_{1-2}s$	30	2.9 (1.9)	1	4 (-)	-0.4	33	2.2 (2.3)*	0.2	34	2.2 (2.3)*	0.2
$d_{1-4}s$		-0.2 (1.1)		0 (-)	1.0		-0.1 (0.2)	0.5		-0.1 (0.2)	0.5
Children with $d_{3-4}mfs>0/d_{1-2}=0$											
$d_{3-4}mfs$		3.6 (2.3)		2.7 (1.2)	0.3		5 (4.5)	-0.4		4.5 (4.1)	-0.3
$d_{1-2}s$	12	0 (0)	3	0 (0)	0	11	0 (0)	0	14	0 (0)	0
$d_{1-4}s$		1.5 (2.5)		1.7 (2.1)	-0.1		3.2 (4.8)	-1.1		2.9 (4.3)	-0.9
Children with $d_{3-4}mfs>0/d_{1-2}>0$											
$d_{3-4}mfs$		6.1 (5.8)		5.6 (5.8)	0.1		6.0 (3.8)	0.0		5.9 (4.2)	0.0
$d_{1-2}s$	48	3.5 (8.1)	11	3.2 (6.4)	0.1	38	2.7 (8.8)	0.2	49	2.8 (8.3)	0.2
$d_{1-4}s$		0.8 (7.5)		2.1 (5.9)	-1.6		1.1 (8.3)	-0.4		1.4 (7.8)	-0.8

Incidence data are stratified according to the number of fluoride applications (controls, 1-2 applications, 3-4 applications, and number of fluoride applications). The * indicates statistically significant differences based on the Mann-Whitney U test. The incidence data were recoded as binary data ("0" for no increase in caries incidence in a subject and "1" for any newly detected carious lesion in a subject); binomial logistic regression was performed using a conditional forward selection model.

prevalence increased to 40.3% (Table 1). When the $d_{1-2}s$ lesions were included, this prevalence rose to 55.5% at baseline and 71.1% at the end of the study. The overall caries experience increased from 2.4 $d_{1-2}s$/2.1 $d_{3-4}mfs$ to 3.9 $d_{1-2}s$/4.4 $d_{3-4}mfs$. Detailed data regarding caries prevalence and caries experience in both groups are presented in Figure 2. With respect to the SES data, approximately 90% of the study sample belonged to the low and moderate SES groups.

The comparison of the caries prevalence and caries experience between the FG and CG at the enamel and dentin levels revealed non-significant differences at baseline (FG: 2.5 $d_{1-2}s$/2.0 $d_{3-4}mfs$; CG: 2.3 $d_{1-2}s$/2.3 $d_{3-4}mfs$) and at the 2-year follow-up (FG: 3.9 $d_{1-2}s$/4.2 $d_{3-4}mfs$; CG: 4.0 $d_{1-2}s$/4.6 $d_{3-4}mfs$) (Table 1, Figure 2). There was a significant increase in caries between baseline and the 2-year follow up, but there was no difference in incidence between the FG and CG. The registered PFs were within the same order of magnitude (Table 2).

The data were further explored based on caries incidence, stratified according to the number of fluoride applications and the categories of caries severity (Table 2). At the end of the study, 62 subjects in the FG and 59 in the CG, constituting approximately 40% of the total sample, were caries-free at the enamel level ($d_{1-4}mfs=0$). When the Mann-Whitney U test was performed, there was a statistically significant reduction in the incidence of $d_{1-2}s$ lesions in the group that received 3 to 4 fluoride applications, showing that the application of fluoride varnish biannually for two years had an obvious protective effect on the incidence of non-cavitated carious lesions. At the dentin level, no protective effect on caries development was observed (Table 2). Incorporating SES data (Table 3) into the analysis, this significant difference was lost, but there was a trend toward a protective effect ($p=0.07$).

Furthermore, when binomial logistic regression was performed using the conditional forward selection model, none of the variables, including age, gender, investigation group and fluoride application frequency, were found to be statistically significant to be fit into the model. When the same procedure was repeated by using SES as a dependent variable and incorporating this data into the model, there was a significant difference ($p<0.05$) in the SES variable alone. However, when the fluoride application variable was added to this model, the significance was lost.

DISCUSSION

This longitudinal study aimed to assess the effectiveness of a newly developed fluoride varnish in preventing the incidence of dental caries among 2- to 3-year-old children. The overall caries prevalence at the enamel level ($d_{1-4}mfs>0$) increased from approximately 55% at baseline to approximately 71% at the 2-year follow-up (Table 1), which suggests that the study population is at high risk for caries. 2-year data showed a slightly reduced incidence rate in the FG (1.4 $d_{1-2}s$/2.2 $d_{3-4}mfs$) compared with the CG (1.7 $d_{1-2}s$/2.3 $d_{3-4}mfs$).

The majority of comparisons revealed non-significant differences between the FG and CG. A significant difference was only registered in the case of $d_{1-2}s$ lesions when the fluoride varnish was applied biannually within the study period (Table 2). This finding may underline the importance of recording $d_{1-2}s$ lesions and it suggests that a protective effect of fluoride varnish may exist for non-cavitated lesions. Moreover, the duration of the study may play an important role and a longer follow-up period may have produced even more significant findings. Interestingly, the binomial logistic regression model revealed a different finding. When the SES data were added to the model, the previously reported significance was lost, which underlines the multi-factorial etiology of caries.[19] Therefore, individual factors, e.g., oral hygiene, microbial load, sugar consumption, lifestyle and behavioral factors and genetic influences,

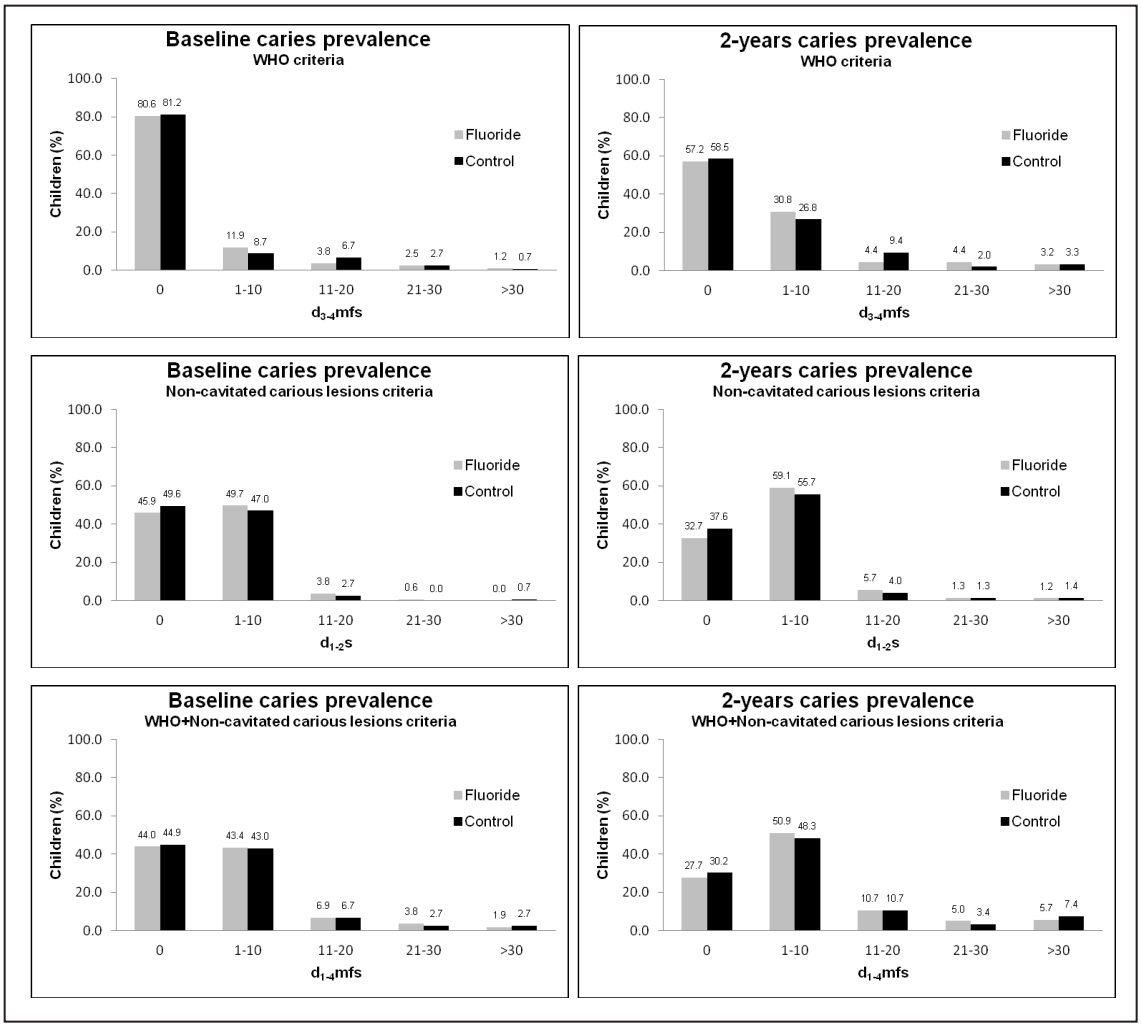

Figure 2. Caries prevalence at baseline and at the 2-year examination of the fluoride group (FG) and control (CG).

should be included in future studies. These factors may supersede the protective effect of fluorides in populations at risk for caries. Another viewpoint on this issue may be related to the small number of complete data sets (n=215; baseline and 2-year clinical data plus fully completed questionnaires), which could have influenced the statistical power of this finding.

There are various overviews and meta-analyses on the effectiveness of fluoride varnish in the literature.[11,20,21] The ability of Duraphat varnish to inhibit caries has been studied most frequently. Helfenstein and Steiner[20] calculated that Duraphat reduces caries by 38%. The Cochrane review by Marinho *et al* found caries reduction rates of 46% for permanent teeth and 33% for primary teeth. The finding in the present study that fluoride varnish exerts a preventive effect on ECC among pre-school children is in accordance with the findings of similarly designed studies.[10,23] Other studies[24-27] could not be compared with our study with respect to the study population, study materials and the method and duration of intervention, but they all indicate that fluoride varnish provides an effective anti-caries effect.

The baseline caries prevalence was high (55.5%) in the sample group of the present study, indicating that this population is at high risk for caries. Furthermore, a quarter of the FG did not receive all applications according to the study protocol. This fact could have led to an underestimation of the effectiveness of fluoride varnish in this study, indicating that the effectiveness of fluoride/preventive programs may be limited due to a lack of compliance. Considering the high costs of fluoride varnishes and the services of professional health care personnel, it may be more efficient to ensure that the recommended supervised toothbrushing protocol is carried out,[29-30] which was not guaranteed by the staff of the kindergartens. In our study, there were more children who came from families of low and moderate SES (Table 3), suggesting that SES may have an effect on the incidence of caries development due to lack of education regarding oral hygiene.

Our study was unique in that it presented specific advantages, such as a homogeneous study population comprised of young children aged 2-3 years, a longitudinal follow-up period of 2 years and a sample power of 90%. However, there were some limitations that must be mentioned. First, the study would have been enhanced if randomization of the study population into the two groups had been performed, thus excluding any potential biases. However, randomization was not performed, as it would have prevented the CG from receiving a well-known protective intervention, which seems to be unethical. Therefore, the parental decisions were used to allocate the study participants into the corresponding groups, knowing full well that various factors, such as the parents' (non-) interest in oral health issues, are not independent of the educational level and socio-economic status of the family. The same points are also relevant when considering the low questionnaire participation rate.

Table 3. Distribution of SES among the study sample; 312 parents returned the fully completed questionnaires and of these questionnaires, 215 included complete data sets that were used for the analyses.

SES (points)	Complete SES data available		SES data used for analyses	
	FG, N (%)	CG, N (%)	FG, N (%)	CG, N (%)
High (9-10)	24 (11,1)	3 (3,2)	18 (12,9)	3 (4,0)
Moderate (7-8)	137 (63,1)	65 (68,4)	91 (65,0)	55 (73,3)
Low (4-6)	56 (25,8)	27 (28,4)	31 (22,1)	17 (22,7)
Total	**217**	**95**	**140**	**75**
Grand total	**312**		**215**	

SES was determined as follows: Educational status was scored by assigning 1 point if the parent had <10 years of education; 2 points for 10 years of education; and 3 points for >10 years of education. Parents were given a score of 1 if they were unemployed and 2 if they were employed either part-time or full-time. Points were given to each parent and they were added to form the SES score, which was then used to categorise them into one of the 3 SES groups.

CONCLUSIONS

Our findings highlight that the fluoride varnish used in this study obviously cannot compensate for the multi-factorial etiology of ECC. With respect to the influence of SES, future caries prevention programs should also provide substantial health information (regarding, e.g., tooth-friendly nutrition, supervised tooth brushing and regular use of fluoride products) to the caregivers of the children, independent of their SES. Furthermore, more research that includes a broad spectrum of potential influencing factors on the occurrence of ECC is necessary to identify key issues associated with caries prevention in these young children.

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