

Fluoride varnish or fluoride mouth rinse? A comparative study of two school-based programs

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Objective: In many Danish communities, school-based fluoride programs are offered to children with high caries risk in adjunct to tooth brushing. The purpose of this field trial was to compare the caries-preventive effectiveness of two different fluoride programs in 6-12 year olds. **Basic research design:** Clinical controlled trial. **Clinical setting:** The 2-year study was conducted in Public Dental Clinics in a multicultural low-socioeconomic suburban area of Odense, Denmark with an elevated prevalence of caries compared to the city average. **Participants:** 1,018 children (aged 6-12 years) from 9 different schools were enrolled after informed consent and their class unit was randomly allocated to one of two fluoride programs. **Interventions:** One group received a semi-annual fluoride varnish applications (FV) and the other group continued with an existing program with fluoride mouth rinses once per week (FMR). All children received oral hygiene instructions and comprehensive dental care at the local Public Dental Clinics throughout the study period. **Main outcome measures:** Increment of caries lesions in permanent teeth at both cavitated and initial caries levels. **Results:** The groups were balanced at baseline. After two years, 961 children (94.4%) were reexamined. The FV group showed a mean DMFS increment of 0.36 compared to 0.41 in the FMR group. The corresponding values for initial caries lesions were 0.83 and 0.91 respectively. **Conclusion:** There were no statistically significant differences in caries development over two years among children participating in a school-based fluoride varnish or mouth rinse program.

Key words: *fluorides, topicals, mouthwashes, cariostatic agents, Denmark*

Introduction

Dental caries forms through a complex interaction over time between acid-producing bacteria, fermentable carbohydrate, and host factors such as saliva and teeth (Selwitz *et al.*, 2007). It is one of the most prevalent chronic diseases in childhood (Kassebaum *et al.*, 2015), but with a marked social gradient. Numerous epidemiological studies worldwide have revealed that the prevalence and severity of caries is significantly higher among vulnerable populations in low-income, socially deprived and immigrant areas with a low level of education (Schwendicke *et al.* 2015) and Denmark is no exception (Christensen *et al.* 2010). Vollsmose is a low-socioeconomic multicultural district in the city of Odense and data from the Public Dental Service in the region have displayed 4-5 times higher caries burden among schoolchildren from this area compared to the city average. Based on systematic reviews (Marinho, *et al.*, 2004; Marinho, 2009; Petersson *et al.*, 2004; Twetman *et al.*, 2004), community oral health actions have been taken in the last five years to bridge this gap focusing on tooth brushing and weekly fluoride mouth rinses. According to the local epidemiology, the efforts have been reasonable successful with a caries reduction of around 20%. Still, a pertinent question was could the effectiveness be further improved and achieved at a lower cost? A recent update from the Cochrane collaboration based on 22 clinical trials has yielded evidence of moderate quality for fluoride varnish applications with a prevented fraction of 43% in the young permanent dentition (Marinho *et al.*, 2013). Little is

however known on the cost-effectiveness but a model study has indicated that a varnish program may have a better outcome for proximal caries development than rinses and at half the cost (Sköld *et al.*, 2008). It was therefore thought of interest to test and implement a similar fluoride varnish program in the Vollsmose district and evaluate the time spent on the preventive measures. The primary aim of the study was therefore to evaluate the effectiveness of school-based semi-annual fluoride varnish applications in children living in a low-socioeconomic immigrant area and to compare the caries increment with weekly fluoride mouth rinses. The null hypothesis was that there would be no difference in caries-preventive effect between the two fluoride programs.

Material and methods

The project employed a two-year prospective class unit-randomized single-blind design with two parallel arms. The study was approved by the regional ethical committee and Danish Data Protection Agency (J.nr. 2009-54-0803). The setting was the Vollsmose district, a deprived multicultural suburban area of the city of Odense, Denmark. All the children registered in the academic years 0-4 (aged 6-12 years) from seven schools were invited to participate and those providing informed consent recruited. School classes were randomly allocated to one of two fluoride programs by flipping a coin. The flow chart of the study is presented in Figure 1.

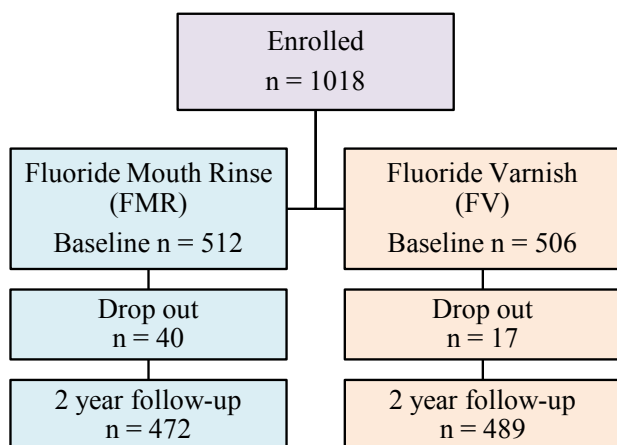


Figure 1. Flow chart showing the number of participants at the enrollment and after two years.

The children of 38 class units received a fluoride varnish program (FV) with six-monthly applications of a 5% sodium fluoride varnish (Profluoride varnish, Voco, Germany) for two years professionally applied in the schools by specially trained dental assistants. After self-performed tooth brushing with a disposable toothbrush, the teeth were dried by cotton rolls. The varnish (0.4 ml) was applied to all accessible tooth surfaces in the permanent and primary dentition with aid of a micro-brush. The children were asked to avoid eating and drinking for two hours after the application. The fluoride mouth rinse group (FMR, 40 class units) had supervised fluoride mouth rinses with 10ml of 0.1% sodium fluoride for two minutes once a week. All children went through individual tooth brushing training once yearly and they were encouraged to use fluoride toothpaste (1,450 ppm) twice daily. A toothbrush and a dentifrice was supplied free of charge each academic year. All children received free comprehensive dental care at the public dental clinics throughout the study period. The dental teams that collected the caries data were informed of the objective of the study but unaware of the group assignment. The outcome measures were the DMFS increment and the incidence of initial lesions in permanent teeth.

The children were clinically examined at their local public dental clinic by one of four dentists not involved in the study. At baseline and then once yearly, examinations using a dental mirror and a blunt probe were performed after professional tooth cleaning and drying. Carious lesions were scored on cavity level according to WHO criteria (1997) in

permanent teeth and expressed as DMFS. The presence of initial lesions (visible white chalky area with no cavitation) in permanent teeth was also registered on surface level. Missing teeth were recorded only if there was information that they were extracted due to caries. Bitewing radiographs were exposed only on individual indications (approximately 40% of the study groups) and taken into account when available. The dental examiners received a revision course in caries detection and were calibrated against the principal investigator before the baseline registrations and again after one year. Twenty children were scored independently by each examiner and the results were later discussed in consensus.

No power calculation was carried out prior to the study since the number of eligible subjects was fixed and thought to provide sufficient power. It was assumed that around 130 children in each group would be needed to detect a difference of 0.5 DMFS between the groups at follow-up with α set at 0.05 and β to 0.2. The data were processed using IBM-SPSS software v.22.0. The caries increment was computed for each individual by counting the number of surfaces that changed from sound to decayed, filled or missed over the study period. Due to the clustered design, the caries outcome was analyzed with age as a covariate in a multilevel logistic regression. The intracluster correlation coefficient, which reflects the homogeneity of the sample, was calculated with one-way ANOVA and accounted for throughout the analysis. Cohen's kappa value was calculated for the inter-examiner reliability. The level of significance was set at 5% ($p < 0.05$).

Results

Overall 1,018 children were recruited. The groups were balanced concerning gender, age and caries prevalence at baseline. The mean age (SD) was 8.2 (1.7) in the FV group and 8.3 (1.7) in the FMR group. After two years, 961 children (94.4%) were reexamined. The attrition rate was slightly higher in the FMR group. For both groups, the drop out was mainly due to closure and restructuring of some of the schools after one year of the study. Baseline information on the participants who completed the study and those that dropped-out is presented in Table 1. The mean value of initial lesions was slightly lower in the FV group than in the FMR group ($p < 0.05$) but did not differ significantly from the dropouts.

Table 1. Baseline, follow-up and increment caries data among those that completed the study and the dropouts.

Variable	FMR group, n=472	FV group, n=489	Drop-outs (n=57)	p
Gender boys : girls, n (%)	227 : 245 (48 : 52) mean (SD)	249 : 240 (51 : 49) mean (SD)	30 : 27 (52 : 48) mean (SD)	NS
Age, year	8.2 (1.7)	8.3 (1.7)	8.4 (1.69)	NS
DMFS (baseline)	0.54 (1.64)	0.56 (1.75)	0.61 (1.73)	NS
DMFS (follow-up)	0.95 (2.16)	0.91 (2.28)		NS
DMFS increment	0.41 (1.13)	0.35 (1.18)		NS
Initial caries in permanent teeth	1.25 (1.99)*	0.92 (2.28)*	1.14 (2.20)	<0.05
Initial caries (follow up)	2.16 (3.54)	1.76 (3.53)		NS
Initial caries increment	0.91 (3.11)	0.84 (2.83)		NS

NS, no significant difference; * statistically significant; FMR, fluoride mouth rinse; FV, fluoride varnish

The mean caries increment in the two groups is presented in Table 1. The two-year DMFS increment was fairly low and there was no statistically significant difference between the FV and the FMR groups. The incidence of initial lesions was approximately doubled, but again, no significant difference between the groups was displayed. The increment was also analyzed for different age subgroups which showed a tendency to a higher incidence in older children but this was not statistically significant (data not shown).

At baseline, the inter-examiner, the adjusted Kappa values ranged from 0.53 to 0.64 (mean 0.60) which was considered moderate to good agreement. Prior to the one-year follow-up, the Kappa values were slightly improved (0.56 to 0.67).

Discussion

It is well established that regular fluoride mouth rinses (FMR) and semi-annual fluoride varnish (FV) applications exhibit a caries-preventive potential and are among the recommended procedures for children with increased caries risk (Weyant *et al.*, 2013). In this field study, both school programs performed equally and the null hypothesis could therefore not be rejected. Previous head-to-head comparisons between FV and FMR have been summarized by Marinho (2009) and based on four studies, it was estimated that FV applications had a 10% higher preventive fraction. It is however possible that this potential difference was obscured by the regular and supervised use of fluoride toothpaste in the present sample. This question will however remain open as the use of fluoride toothpaste nowadays never can be withdrawn from any community oral health program for ethical reasons. A notable finding of our project was the low caries increment in both groups, approximately 0.2 DMFS per year, in spite of the high caries risk nature of the subjects. This was comforting and may indicate that the oral health inequality gap may be bridged in late adolescence. Other important and positive points were that the compliance with both programs was considered as good and that no subjectively perceived side-effects were reported to the clinicians.

The findings must be looked upon with caution due to some obvious shortcomings that need to be noted. The cluster randomization and the single blinded design may introduce bias that may affect the outcome. Although blinded for the group allocation, the relatively large number of examiners and the inconsistent use of bitewing radiographs may also have influenced the caries scores. A visual-tactile examination often underscores the true presence of caries, even in the combination with bitewings (Mialhe *et al.*, 2009; Pereira *et al.*, 2009; Twetman *et al.*, 2013), and it is therefore very likely that the actual caries rates in this study were somewhat underestimated. The present findings were also limited to the permanent dentition. Unfortunately, we were unable to collect reliable data from the mixed dentition due to natural exfoliation and unclear history of missing primary teeth.

The clinical and administrative costs associated with fluoride-based preventive programs are of course highly important for any community health provider, society and third party stakeholders. Unfortunately, health-economics

evaluations of school-based regimens are fairly rare. As stated above, Sköld and coworkers (2008) found that a fluoride varnish program was less costly than a fluoride mouth rinse program provided that the programs were outsourced to school facilities. On the other hand, school-based mouth rinses were found to be less expensive than supervised tooth brushing according to Chen *et al.* (2010), who estimated that one minute was spent for each participating child in the FMR group, a procedure that was repeated 44 weeks each academic year. In the FV group, six minutes were spent for each application of the varnish and this was repeated twice a year. Taken together over the 2-year study period, the time used for each subject was 90 minutes in the FMR group compared to 24 minutes in the FV group. Other major direct and indirect costs are the costs of the material and disposals for application, travel time to schools as well as administration of the program and cooperation with school authorities, translators and parents.

The final decision on which preventive fluoride program that should be implemented, topical or not, must therefore be taken locally after careful evaluation of the abovementioned aspects. From an evidence point of view, the fluoride varnish concept relies on moderate quality of evidence which together with the reduced time required for the intervention may imply a certain advantage over the mouth rinses. On the other hand, the frequent contacts with a dental health professional in the mouth rinsing program may add other intangible values.

Conclusion

Within the limitations of the present study, we found no statistical significant differences in the caries preventive effectiveness of the two school-based fluoride programs directed to 6-12 year-old children living in a low-socioeconomic multicultural area in Denmark.

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