

EFFICACY OF FLUORIDE VARNISH TO MINIMIZE ACTIVE CARIES AMONG CHILDREN

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Abstract

The efficacy of fluoride varnish (5 percent NaF, Duraphat®, Colgate) coupled with caregiver counselling to prevent early children caries was investigated in a two-year randomised, dental examiner-masked clinical trial. Initially, 400 low-income children without caries were recruited (mean age, standard deviation, 1.8 0.6 years). Everyone was assigned to one of three groups: no fluoride varnish, fluoride varnish once a year, or fluoride varnish twice a year. Some children received less active fluoride varnish than was advised due to an unforeseen event. Fluoride varnish had a protective impact on caries incidence in intent-to-treat trials, with a p value of 0.01. A dose-response effect was identified with a p value of 0.01 when the number of real, active fluoride varnish treatments received was investigated. The 'counselling only' group had a higher rate of caries than the 'counselling + fluoride varnish assigned once/year' (OR = 2.20, 95 percent CI 1.19-4.08) and 'twice/year' (OR = 3.77, 95 percent CI 1.88-7.58) groups. There were no side effects reported. Fluoride varnish has been shown to be effective in lowering the incidence of early childhood caries when used in conjunction with caregiver counselling.

Keywords: randomized controlled trial, dental caries, preventive, fluorides, preschool child.

Introduction

Early childhood caries is a public health problem that can affect children as soon as their teeth appear. In extreme cases, paediatric dental treatment may need anaesthesia in the operating room, which is not always available, especially in low-income and underprivileged regions. The prevalence of early childhood caries (one decayed, removed, or filled primary maxillary incisor) was reported to be 14% in all preschool children, but greater in children from Head Start households.

Fluoride varnish is a fluoride varnish with a resin or synthetic base that is applied to the teeth. The bulk of studies focused on the efficacy of fluoride varnish on permanent teeth in school-aged children. Fluoride varnish was applied to permanent and primary teeth in different ways. "The data for fluoride varnish's benefit on permanent teeth is mostly favourable," they said. On the other hand, there are limited and conflicting evidence supporting the effectiveness of fluoride varnish applied to primary teeth."

The purpose of this two-year randomized controlled trial was to investigate how effective different fluoride varnish treatment frequencies combined with parental/caregiver oral health Counselling were at preventing early childhood caries in young, initially caries-free children compared to Counselling alone.

Material and Method

Age 6-44 months; born in Jharkhand or a fluoridated community and planning to stay in for at least two years (eliminating water fluoridation as a potential confounder and demonstrating geographic stability); and a parent providing informed consent in excluded from the study for a

variety of reasons, including medical diseases or medicines that might affect oral health, cleft lip/palate, developmental delays, transient residence, or another family member participating.

Between October 2002 and August 2004, families were mostly recruited through Well Child Clinics, Women, Infants, and Children Supplemental Nutrition Programs, and dental clinics. The follow-up was completed in August of 2006.

Children were randomly assigned to one of three arms with parental consent: parental Counselling plus fluoride varnish twice a year (baseline, 6, 12, and 18 months) with four intended applications (4FV); parental Counselling plus fluoride varnish once a year (baseline and 12 months) with two intended applications (2FV); or Counselling only with no fluoride varnish (2FV) (0FV). The study's biostatisticians created a computer-generated random assignment of participants stratified by center using permuted blocks of varying sizes that were not disclosed to the clinicians. The assignment was kept hidden in opaque, sealed envelopes that were not opened until the doctor arrived for treatment.

Dental Examination

Dental exams without radiographs were performed three times: before the intervention, one year after the intervention, and two years after the intervention. Tests for older children were done in a dentist office, whereas examinations for very young children were done knee to knee (Ramos-Gomez et al., 2002). Infection control methods were followed universally. Saliva samples from children were taken during dental exams prior to the administration of fluoride varnish to measure salivary mutans streptococci (MS), lactobacilli (LB), and fluoride concentrations. The findings of the salivary assay will be given separately.

Fluorid Varnishing Application

Fluoride varnish was utilised in the amount of 0.1 mL (1 drop) each arch. To reduce total fluoride exposure on the day of varnish treatment, parents/caregivers were requested to refrain from cleaning their children's teeth with a fluoride dentifrice. Gauze was used to dry the teeth before varnish was applied to the proximal and occlusal surfaces of the maxillary and mandibular anterior teeth, as well as the proximal and occlusal surfaces of the posteriors. At both locations, a single dentist (BJ) who spoke English, Spanish, and Cantonese performed clinical treatments. It was tried to mask accompanying caretakers to the control group assignment. The tray set-up in the control group was identical. Fluoride varnish was applied on gauze, which was subsequently folded for the youngsters in this group. The child's teeth were wiped with the dry region, and no fluoride varnish was administered.



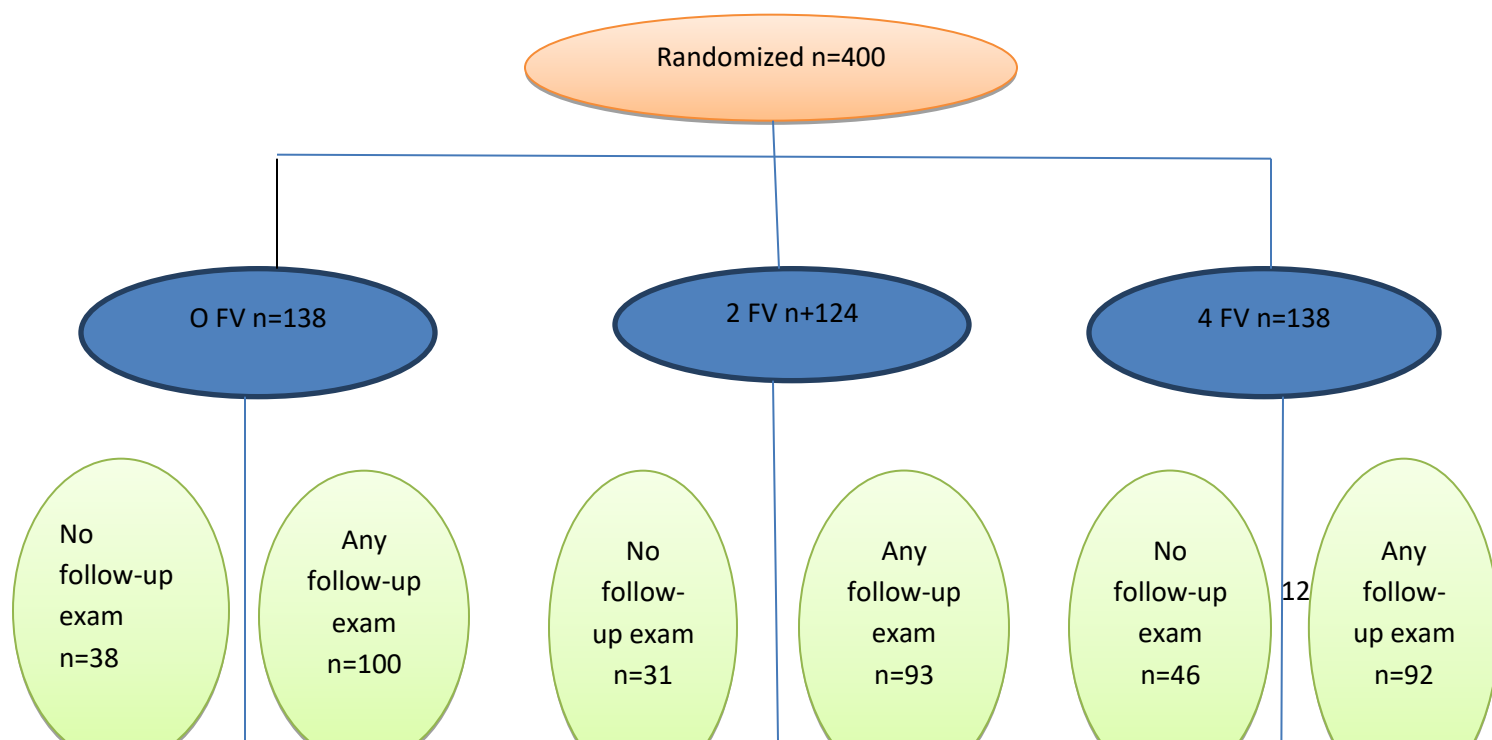
Figure:Fluorid Varnishing Application

Data Analysis

For primary analysis, we used the intention-to-treat (ITT) technique (Fisher et al., 1990). Protocol-compliant trials used a large number of genuine active fluoride varnish treatments. The analysis used data from all children who had a follow-up dental visit. The primary analysis looked at two-year caries incidence across treatment groups using a two-degree-of-freedom (d.f.) non-parametric extended Mantel-Haenszel (EMH) test stratified by centre (Koch and Edwards, 1988). Each varnish group was compared to the control using a priori step-down comparisons (Koch and Gansky, 1996), each at p 0.05: (1) 4FV vs. 0FV and (2) 2FV vs. 0FV; step (2) was undertaken only if step (1) was relevant. In a 1 d.f. EMH test stratified by centre, trends were analysed across the predicted and actual number of applications. Logistic regression was used to investigate variations in incidence between treatment groups after covariates and treatment x centre homogeneity were taken into consideration. Supplementary studies used linear regression to compare $\log(d2+fs +1)$ and $\log(d1+fs +1)$ between groups, with variables accounted for (since $dn+fs$ is skewed). Variables that modified the model treatment coefficients by more than 20% were identified as confounders. The centre, assigned group, number of actual fluoride varnish applications, factors related to loss-to-follow-up (mother's age, dental pain barrier, dental fear barrier, and fluoride toothpaste use), and salivary measures were used to impute $\log(d2+fs +1)$ scores using multiple imputation (Schafer, 1997) using the Markov Chain Monte Carlo estimation (20 imputations) ($\log_{10}MS$ and $\log_{10}LB$).

Result

400 children, with a mean (standard deviation) age of 1.8 (0.6), were enrolled and randomly assigned to two groups: 200 at SFGH and 200 at CPHC. Overall, 53% of those who took part were female, 47% were Hispanic, 46% were Asian, and 7% were of another race or ethnicity. There were no obvious randomization inequalities. Dental caries was found in around 60% of those who were screened and found to be ineligible. At the 12-month follow-up evaluation, 70 percent of enrolled children (n = 261) were visited; 51 of them were dismissed from the experiment because to caries and were referred for treatment (Fig. 1). At 24 months, twenty-seven children who were caries-free at 12 months had vanished. 78 children had their last follow-up examination at the age of 12 months. At the final 24-month follow-up, 202 children were seen (67 percent retention, including the 51 children with caries at 12 months). A total of 280 youngsters were included (74 percent).



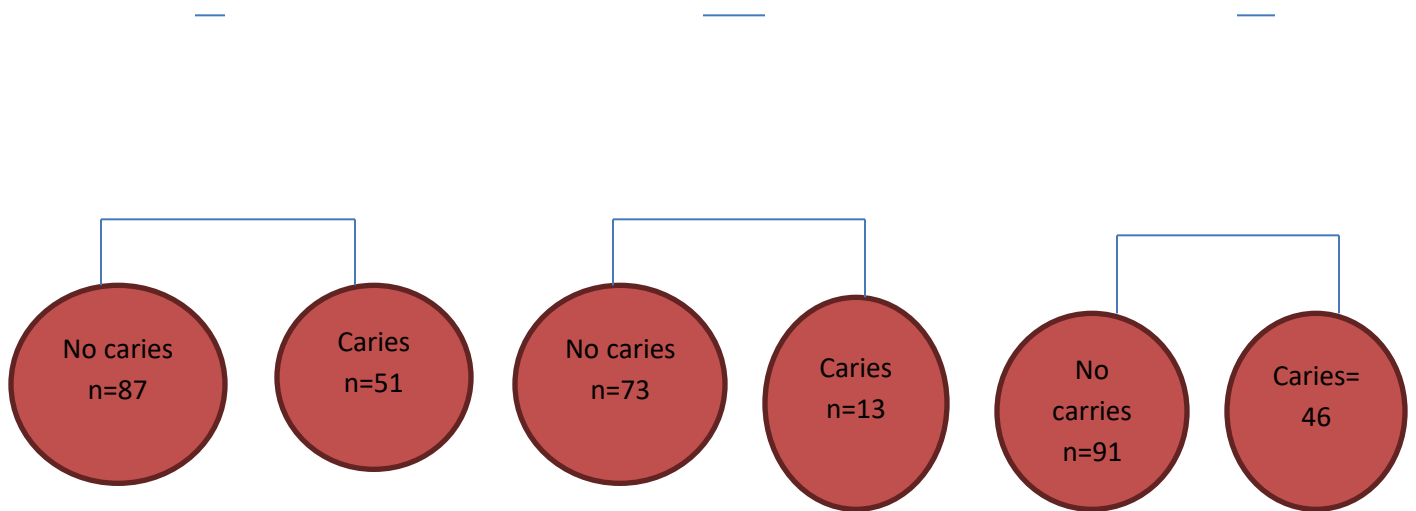


Figure:Participants in the study flow. Children with and without dental cavities by planned (randomised) fluoride varnish (FV) treatment group at each checkup.

There was a statistically significant reduction in the proportion of children with any caries incidence (any decaying or filled surfaces at the last follow-up examination) when children in groups with any planned fluoride (2 or 4 treatments) were compared to the control group (2 d.f. EMH $p < 0.001$; 1 d.f. step-down 4FV vs. 0FV both $p < 0.003$; multiple imputation 2 d.f. step-down 4FV (both $p < 0.001$).

Additional exams revealed that the youngster who had four applications of fluoride varnish at the prior session had no caries, but had developed a pre-cavitated lesion. The degree of caries experience at the final examination was measured in two ways, by planned treatment group and number of active fluoride varnish treatments, with and without pre-cavitated lesions (d1+fs and d2+fs). In both cases, the data demonstrated robust inverse dose-response effects. Linear regression of $\log(d2+fs + 1)$ and $\log(d1+fs + 1)$, corrected for center, revealed statistically significant decreases in caries experience as the number of predicted or actual active fluoride varnish treatments increased (both $p < 0.001$; both multiple imputation $p < 0.002$). Restorations were seen in just 12 of the 79 children with d2+fs. Additional exams revealed that the youngster who had four applications of fluoride varnish at the prior session had no caries, but had developed a pre-cavitated lesion. The degree of caries experience at the final examination was measured in two ways, by planned treatment group and number of active fluoride varnish treatments, with and without pre-cavitated lesions (d1+fs and d2+fs). In both cases, the data demonstrated robust inverse dose-response effects. Linear regression of $\log(d2+fs + 1)$ and $\log(d1+fs + 1)$, corrected for centre, revealed statistically significant decreases in caries experience as the number of predicted or actual active fluoride varnish treatments increased (both $p < 0.001$; both multiple imputation $p < 0.002$). Restorations were seen in just 12 of the 79 children with d2+fs.

Discussion

The findings support the use of fluoride varnish to prevent early childhood caries and reduce the progression of caries in children under the age of six. A dental examination is suggested before a

child's first birthday or first tooth eruption. Because fluoride varnish administered at this initial visit can help prevent future sickness, the efficacy of fluoride varnish in this age range contributes to the argument for an early dental consultation, especially for high-caries-risk children. Several of the youngsters were under the age of one year at the time of the initial visit. The fluoride varnish was rather easy to get the little newborns to cooperate with. Collecting saliva was more challenging, but it was possible with parental support. It may be difficult for public facilities to visit children at six-month intervals. As a result, it was necessary to assess the effectiveness of only one varnish application every year. Despite this, although applying varnish more regularly was preferable, one application was preferable than none.

Based on three treatment studies, the Cochrane Collaboration meta-analysis found a pooled d(e/m) fs averted fraction of 33 percent (95 percent CI, 19-48 percent). It varied from 52 to 92 percent in our research, depending on the therapy group. The comprehensive evaluation of fluoride varnish research found conflicting results on primary teeth. Some of them weren't randomized clinical studies, and none of them had youngsters as young as the ones in our research.

Adverse events or safety issues have been reported in the fluoride varnish investigations. Families were questioned about adverse events at each visit; just one was observed for a kid in the four-fluoride-varnish group, with "ulcer on the cheek" appearing 2 months after the final fluoride varnish treatment, which was "fluoride-free," at the 18-month checkup. At the 24-month checkup, the ulcer had vanished. There has been some concerns raised regarding using fluoride varnish on asthmatic youngsters. According to parental reports, none of the 21 children with asthma who received fluoride varnish experienced any side effects. The incidence of adverse events in asthmatic children had a 95 percent upper bound of 0.14.

Many children who had caries at the time of the screening were ruled ineligible. The goal of this study was to see if it was possible to prevent caries from occurring in the first place, rather than to see if it was possible to prevent caries from increasing. It didn't look at how effective fluoride varnish is for children with caries.

The presence and quantity of the product's active component should always be tested before to and throughout study implementation, and quality control procedures should be implemented as quickly as feasible to identify and remedy protocol violations. The majority of non-compliance/non-adherence in studies is caused by the participants. Only the entrance time was linked to the number of active treatments in this study, making the findings more generalizable. Future caries-prevention clinical research at community health centers targeting vulnerable and minority groups will be supported by this project. Because the study took place at these locations, the findings are more generalizable across settings that serve a large number of high-risk adolescents than findings from other possible locations. The findings' generalizability is increased by similar results from two clinical locations with distinct demographics. Caries prevention programmers aimed at newborns and toddlers should include fluoride varnish and family Counselling.

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