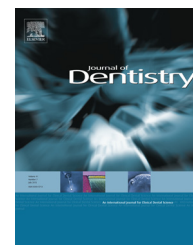


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Caries-preventive effectiveness of fluoride varnish as adjunct to oral health promotion and supervised tooth brushing in preschool children: A double-blind randomized controlled trial

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ABSTRACT

Objectives: To evaluate the effect of biannual fluoride varnish applications in preschool children as an adjunct to school-based oral health promotion and supervised tooth brushing with 1000 ppm fluoride toothpaste.

Methods: 424 preschool children, 2–5 year of age, from 10 different pre schools in Athens were invited to this double-blind randomized controlled trial and 328 children completed the 2-year programme. All children received oral health education with hygiene instructions twice yearly and attended supervised tooth brushing once daily. The test group was treated with fluoride varnish (0.9% difluorosilane) biannually while the control group had placebo applications. The primary endpoints were caries prevalence and increment; secondary outcomes were gingival health, mutans streptococci growth and salivary buffer capacity. **Results:** The groups were balanced at baseline and no significant differences in caries prevalence or increment were displayed between the groups after 1 and 2 years, respectively. There was a reduced number of new pre-cavitated enamel lesions during the second year of the study ($p = 0.05$) but the decrease was not statistically significant. The secondary endpoints were unaffected by the varnish treatments.

Conclusions: Under the present conditions, biannual fluoride varnish applications in preschool children did not show significant caries-preventive benefits when provided as an adjunct to school-based supervised tooth brushing with 1000 ppm fluoride toothpaste.

Clinical significance: In community based, caries prevention programmes, for high caries risk preschool children, a fluoride varnish may add little to caries prevention, when 1000 ppm fluoride toothpaste is used daily.

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1. Introduction

Caries in the primary dentition is a common public health problem that may affect the quality of life of children as well as their families.^{1,2} The condition affects a large number of children, and a clear socioeconomic gradient is evident,^{3,4} underlining the need for targeted oral health programmes directed to vulnerable populations or groups of children.^{5,6} Daily plaque removal together with topical fluoride application is the basis of any preventive programme for dental caries. Recent systematic reviews have established strong evidence for daily use of fluoride toothpaste as the most cost-effective self-applied method of preventing caries in preschool children.⁷⁻⁹ In addition, an increased prevented fraction is evident when the tooth brushing is supervised by an adult.¹⁰ For preschool children with increased caries risk, regular fluoride varnish applications are often advocated as an effective, safe and practical way to increase fluoride exposure in the oral biofilm.¹¹⁻¹³ Fluoride varnish, in conjunction to caregiver oral health counselling has been shown to prevent dental caries in this age group, both in public health centers¹⁴ and large community based preventive programmes.¹⁵ To our knowledge, few studies have combined supervised use of 1000 ppm fluoride toothpaste with fluoride varnish applications for early childhood caries prevention. The purpose of this study was, therefore, to evaluate the effect of biannual fluoride varnish applications in preschool children as an added measure to a preventive programme consisting of school-based oral health education and supervised tooth brushing with 1000 ppm fluoride toothpaste. The null hypothesis was that the caries incidence over a 2-year period would not differ from a group treated with placebo varnish.

2. Materials and methods

2.1. Study group

Children from 10 public preschools, located in medium and low socioeconomic areas of Athens, Greece, were invited to participate. In Greece, there is no free of charge dental treatment even for young children. Furthermore there are not any organized preventive programmes for preschool children and regular dental care is provided only in private settings. Emergencies can be treated in the children's hospital free of charge, but no further treatment will be provided. The schools for this study were selected based on previously established caries risk profiles¹⁶ and the schools with the highest risk were considered for enrollment. The total number of the preschools in Athens was 90 and they were located in areas of all socioeconomic levels. A cluster sampling technique was used to draw a sample representative of the preschool age population in this area.¹⁶ For the present study, the sample size was calculated and then ten schools were chosen that had the appropriate number of children and were of high risk. The high risk children were chosen because it was anticipated that they would benefit more than low risk individuals from the preventive interventions. Children can attend preschools until they have completed their sixth year of age so they can enrol in

the first grade of primary school. The parents received an invitation letter explaining the purpose of the study and for signing their informed consent. The inclusion criteria were: (i) being between 2 and 5 years of age and attending one of the preselected public preschools, (ii) born in Greece, and (iii) residing in the greater area of Athens. Children born outside of Greece and children taking antibiotics within the last 2 weeks prior to the clinical examination were excluded. In total, 424 children were eligible, 409 were enrolled and randomized, and 328 completed the programme. A flow-chart with main reasons for the attrition is presented in Fig. 1.

2.2. Study design

The project employed a double-blind randomized controlled trial with two parallel arms conducted between 2009 and 2011. The duration was two years. The protocol was approved by the Ethics Committee of the Dental School at the University of Athens, Greece.

2.3. Randomization

The children were stratified with respect to caries risk before the randomization with the objective to have similar number of high and low risk caries children in each group. A child was considered at high risk if there was at least one carious lesion (pre-cavitated or cavitated) and/or presence of mutans streptococci in the microbiological test. Random permuted blocks of size 8 were used and the randomization lists were produced with computer software (<http://mahmoodsaghaei-tripod.com/Softwares/randalloc.html>). The random lists were generated by the principal investigator and a secretary allocated the names of the children for every school. An assistant, not participating in the field study, prepared the bottles with the varnish according to the allocation lists, placing a tag for each subject. The allocation of the subjects was unknown to the examiner, parents and their children and not unveiled until after the statistical calculations. Allocation to treatment groups was made approximately one week after the baseline examination, in order to calculate the caries risk based on examination data.

2.4. Questionnaire

All parents that agreed to participate completed a questionnaire on demographic data and general health. In case the parents were of foreign origin, the teachers assisted them with the questionnaire.

2.5. Oral health education and daily tooth brushing

The teachers and headmasters of the participating schools were informed about the study protocol and were requested to actively support the oral health promotion programme. All children and their teachers received comprehensive oral health education in the class room by dental professionals, including oral hygiene instructions and dietary advice, twice a year, over the two-year period. The information was adapted to match the age of the children. Furthermore, all children received a toothbrush to use at school. A pea-size amount of

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