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A randomized clinical trial on arresting dentine caries in preschool children by topical fluorides—18 month results

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ABSTRACT

Objectives: This study aimed to compare the effectiveness of three topical fluoride application protocols in arresting dentine caries in primary teeth of preschool children in a fluoridated area.

Methods: Children aged 3–4 years who had at least one active dentine caries lesion were randomly allocated into three intervention groups: Group 1—application of 30% silver diamine fluoride (SDF) solution every 12 months; Group 2—three applications of 30% SDF solution at weekly interval at baseline; and Group 3—three applications of 5% sodium fluoride (NaF) varnish at weekly interval at baseline. A masked examiner carried out follow-up examinations every 6 months to assess whether the treated lesions had become arrested. **Results:** A total of 304 children with 1670 tooth surfaces with dentine caries received treatment at baseline. After 18 months, 275 children (91%) remained in the study. The caries arrest rates at tooth surface level were 40%, 35% and 27% for Groups 1, 2 and 3, respectively ($p < 0.001$). Result of the multi-level survival analysis showed that the two SDF application protocols could shorten the time to arrest of dentine caries compared with the NaF application protocol. Presence of plaque on lesion surface, tooth type and tooth surface all had significant effects on caries arrest rates.

Conclusions: Annual or three consecutive weekly applications of SDF solution is more effective in arresting dentine caries in primary teeth than three consecutive weekly applications of NaF varnish.

Clinical significance: In a water fluoridated area, application of SDF solution, either three weekly applications at baseline or annually, can arrest active dentine caries lesions in primary teeth faster than three weekly applications of NaF varnish at baseline.

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1. Introduction

Early childhood caries (ECC) is a global health problem that causes many children to suffer from pain and infection.^{1,2}

Studies have shown that ECC is more prevalent among children in lower socio-economic groups and carious cavitated lesions in preschool children are mostly left untreated.³ Traditionally, a restorative approach which requires powered dental equipment and well trained dental personnel is

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adopted to treat the decayed teeth. The dental profession is currently faced with an enormous task of how to manage the heavy burden of untreated dental caries amongst the young child population.⁴

A number of clinical studies have shown that progression of dental caries in young children can be arrested by the use of silver diammine fluoride (SDF) solution.⁵⁻⁷ The commonly adopted frequency of application for caries arrest is once a year or every 6 months.^{5,8} The proportion of arrested caries increases with repeated application with SDF over time. To speed up the process of caries arrest, it would be logical to reduce the time interval between SDF applications. An intensive regimen of three applications of 10% SDF in three consecutive weeks was found to be effective in arresting enamel caries in permanent first molars.⁹ However, the sample size in that study is small, only 22 children aged 5-7 years were involved. The use of three consecutive weekly applications of NaF varnish was suggested for prevention of dental caries in young children.¹⁰ Using this approach with multiple applications in a short period, the treatment may be particularly beneficial for high caries risk populations as well as for migratory populations who are unable to follow a lengthy preventive program that requires regular visits.

So far, there is no published study which specifically investigates the efficacy of intensive applications of NaF varnish and SDF solution in arresting dentine caries in preschool children. Thus, the aim of this study was to compare the effectiveness of three topical fluoride application protocols in arresting dentine caries in primary teeth of high caries risk preschool children living in a fluoridated area. The null hypothesis to be tested was that the caries arrest rates of the lesions treated according to the three protocols were the same.

2. Materials and methods

This study was conducted in 16 kindergartens in Hong Kong, where the drinking water has been fluoridated at a fluoride concentration of 0.5 ppm. Most of the toothpaste on sale in Hong Kong contain fluorides and those for children are fluoridated at 500-1000 ppm fluoride. Ethical approval was obtained from the Institutional Review Board of the University of Hong Kong and the trial was registered in the Clinical-Trials.gov registration system (no. NCT02426619). An invitation letter was sent to the parents explaining the purpose and procedures of this study. Written parental consent was received from the parents of all children. After screening, healthy children who had at least one tooth with untreated active dentine caries not involving pulp were invited to participate in the study. Clinical examination of the children was performed in the kindergarten by one dentist using disposable dental mirrors, light-emitting diode intra-oral illumination (MirrorLite) and ball-end probes (405/WHO CPI probe). The visible plaque index (VPI) and the dmfs index were used for recording the oral hygiene and dental caries status, respectively. At tooth surface level, status (inactive/active) of the dentine caries (ICDAS codes 5-6)¹¹ and presence of plaque was assessed. Lesion activity was assessed by visual inspection and tactile detection. Light force was used and great care

was taken to avoid damaging the tooth during probing. If the cavity wall or floor was easily penetrated by the ball-end probe using light force, it was diagnosed as active caries. Cavities with smooth and hard surfaces were classified as arrested caries.^{5,8,12} Tooth with a caries lesion extending into pulp or having signs that suggested it was non-vital, such as tooth discoloration, hypermobility and abscess, was not included in this study. Five surfaces (buccal, lingual, mesial, distal and occlusal) in each posterior tooth and four surfaces in each anterior teeth were assessed.

This clinical trial used a parallel group design. For ethical reasons, all active dental caries lesions were treated if possible and there was no negative control group. Participant children were put into two strata according to the number of carious tooth surfaces they had, one to four surfaces and >4 surfaces. They were then allocated by a stratified randomization method using a personal computer to one of the following three intervention groups:

Group 1: applications of a 30% SDF solution (Cariestop, Biodinamica, Brazil) at baseline and every 12 months.

Group 2: 3 applications of a 30% SDF solution at weekly interval at baseline.

Group 3: 3 applications of a 5% NaF varnish (Duraphat, Colgate Palmolive, USA) at weekly interval at baseline.

A dentist who was not involved in the examination of the children applied the fluoride agents according to the child's group allocation. No effort was made to remove the carious tissues before fluoride application. Fluoride agent was placed in a plastic dappen dish. A disposable microbrush was used to apply the agent onto each carious lesion and rub for 10 s. After application, the child was asked not to drink or eat for at least 30 min. All examinations and treatments were carried out in the kindergartens without the presence of the children's parents.

At the 12-month follow-up, water was used as placebo in Groups 2 and 3. Follow-up examinations were conducted at 6, 12 and 18 months after baseline by the same masked examiner using the same equipment, procedure and diagnostic criteria. The examiner did not know the subjects' group allocation. In all examinations, a 10% random sample of the children was re-examined for monitoring intra-examiner reproducibility.

Information about the children's demographic and socioeconomic background, and oral health related behaviors, and parent's satisfaction with the child's dental appearance was collected by a questionnaire completed by their parents at baseline. Sample size calculation was based on the results of previous studies which showed that around 70% of the active dental caries in preschool children became arrested after 24 months.⁵ An absolute difference of 10% in the rate of caries arrest (proportion of active caries) that has become hardened at a certain time point) between treatment groups was considered to be clinically significant. Based on a 5% statistical significant level and an 80% power, 360 decayed tooth surfaces would be required. A recent survey in Hong Kong found that on average a child with ECC has approximately four caries lesions.¹³ Thus, 90 children were needed in each group. Anticipating a 10% drop-out rate, a total of 304 children were recruited at baseline.

Collected data were entered into computer and analyzed using the software SPSS 20.0 for Windows (SPSS Inc., Chicago,

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