

A Randomised Controlled Trial and Microbiological Investigation of Caries-Related Microorganisms and Dental Cavities in Preschoolers

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Abstract

The efficiency and safety of 38% silver diamine fluoride in stopping caries lesions were examined in the Stopping Cavities Trial. The investigation used two parallel groups in a double-blind, randomised, placebo-controlled superiority trial. The locations were preschools in Oregon. A total of 66 preschoolers with less than one lesion were enrolled. Applying topically to the lesion either silver diamine fluoride (38%) or a placebo (blue-tinted water). Caries arrest (lesion inactivity, according to Nyvad criteria) occurred 14–21 days after intervention as the main endpoint. All children's dental plaque was collected, and RNA sequencing was used to determine the microbial composition of two lesions and one unaffected surface before treatment and at follow-up for three kids from each group. In the silver diamine fluoride group, the average proportion of arrested caries lesions was greater (0.72; 95% CI: 0.55, 0.84) than in the (0.05; 95% CI: 0.00, 0.16; placebo group). The probability of arrested caries was considerably higher in the treatment group, according to confirmatory analysis using generalised estimating equation log-linear regression, based on the number of arrested lesions and accounting for the number of treated surfaces and length of follow-up. No damage was seen. No consistent changes in the relative number of caries-associated bacteria or the establishment of antibiotic or metal resistance gene expression were seen after RNA sequencing analysis. In preschoolers, topical 38% silver diamine fluoride is efficient and safe for preventing cavities. Clinical Importance: The procedure can be used in primary care settings and could lessen the burden of untreated dental decay in the general population.

Keywords: Cariostatic Agents; Dentin/Pathology; Treatment outcome; Anti-Infective Agents

Introduction

Early therapies to prevent tooth decay in young children involve more and more dental and medical care providers. Fluoride varnish is the major preventive service, and it should be applied topically every three to six months. The theory is that fluoride treatments combined with proactive advice may stop tooth decay before it starts when the risk is highest. This is crucial because dental decay lowers quality of life, especially for poor children who have limited access to dentists [1]. Despite the increased focus on young children, not all of them receive preventive care, and many still have tooth decay. Little else has been available to primary care clinicians besides invasive, expensive, and time-consuming specialist hospitalizations under general anaesthesia. There is interest in simple solutions in this area treatment to stop the progression of cavities (caries lesions) following the start of tooth decay. The active lesion surface is painted with a clear liquid called topical silver diamine fluoride. Lesion in milligramme quantities and stops it. Twelve clinical trials conducted outside of the United States have shown caries arrest [2]. This medication was approved by the Food and Drug Administration in 2014 as a treatment for sensitive teeth and has been used off-label for the treatment of cavities in the United States since 2015. Additionally, benefits of prevention also apply to unaffected teeth. Following topical treatment, serum fluoride and silver concentrations showed no signs of potential harm [3]. Silver ions are thought to be principally in charge of silver diamine fluoride's antimicrobial effects. All oral bacteria studied were inhibited by silver ions, which also denatured the enzymes responsible for breaking down collagenous dentin. On teeth treated *ex vivo*, *Streptococcus mutans*, the primary pathogen in dental caries, is less likely to establish a biofilm. Fluoride fosters adsorption of fluoroapatite, which resists acidic deterioration better than natural tooth structure. This randomised controlled trial's goal was to find out whether topically applying 38% silver diamine fluoride to primary teeth will stop caries lesions in the near term and be safe to do so [4].

Method

A double-blind, randomised, placebo-controlled superiority trial with two parallel groups made up the study's design. Three Head Start preschools in the state of Oregon in the United States served as the study's location. According to the Nyvad criterion, the participants were kids between the ages of 24 and 72 months who had at least one untreated cavitated active caries lesion with exposed dentin. According to their medical history, the kids were healthy [5]. Weight 15 kg, known sensitivity to silver or other heavy metal ions, presence of any perioral or gingival ulcers or stomatitis, or presence of a tooth abscess were the exclusion criteria. In order to maintain the applied dose within the range of the minimum risk dose for chronic exposure to silver established by the U.S. Centers for Disease Control and Prevention, weight exclusion was used.

Treatment Conditions

Silver diamine fluoride (Advantage Arrest™, Elevate Oral Care LLC., West Palm Beach, FL) was the medication under test. The medication is a clear, blue-tinted solution with 5.5 w/v% fluorine and 38 w/v% silver (Ag) (F). Blue-tinted sterile water that wasn't fluoridated served as the placebo. We used cotton gauze to gently clean and dry the afflicted tooth surface [6]. Pet-rorum jelly was used to shield the tooth's

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gingival tissue. 3–4 mg of the drug were applied to the lesion using an applicator that had been dipped in it (1 drop treats 3 to 5 teeth). No special after-application instructions or rinses were supplied.

Plaque Sample Collection

Plaque samples were taken from up to two caries lesions and one unaffected tooth surface before treatment and at the start of the follow-up examination. These samples were collected sequentially from a list of dental identifiers that was randomised for each patient. After that, the applicator was submerged in 250 litres of tryptic soy broth containing 15% glycerol and 2% sucrose, twice inverted, and maintained at 20 °C for up to two months before being transferred to 80 °C to wait processing [7].

Allocation

Using a computer-generated randomization schedule with stratification by Head Start programme and randomly permuted blocks of sizes 2 and 4, participants were divided into groups with a 1:1 allocation [8].

Blinding

Participants, examiners, and the dental professionals who administered the treatments were all blinded. By distributing the test and comparative liquids from identical bottles, blinding was maintained. Codes A, B, C, or D were assigned to the test and placebo bottles, with two codes for each. Four similar bottles were utilised to reinforce the blinding of the therapy [9]. The biostatistician was blinded to which labels were the test or control conditions and only knew which two labels were identical.

Results

Sixty-six kids were randomly assigned. Thirty-six subjects received a placebo treatment administered with liquid A or D, and 30 received a silver diamine fluoride treatment administered with liquid B or C. 64 (97%) people had their follow-ups finished. Each group had one kid who skipped the follow-up appointment. Additionally, only 11 of 20 teeth, including all four treated teeth, were inspected in the placebo group because one kid was not cooperative during the follow-up examination [10]. Characteristics of the participant the mean (SD) number of treated teeth among the 64 children who underwent follow-up was 2.63 (1.09 in the placebo group and 2.83 (1.26) in the silver dime fluoride group, respectively. In the placebo group, the mean (SD) number of treated surfaces was 3.97 (2.56), while it was 4.31 (2.74) Groups of silver diamine fluoride, respectively. In the placebo group, the mean (SD) follow-up duration was 17.2 (6.5) days, while in the silver diamine fluoride group, it was 16.4 (5.5) days. In the placebo group, the mean (SD) number of arrested caries lesions was 0.17 (0.71), but in the silver diamine fluoride group, it was 3.17 (2.77). Individuals who took part in the Silver Diamine Fluoride (SDF) for Stopping Cavities experiment to stop dental caries. The National Institutes of Health classifies Hispanic

or Latino people as an ethnicity, not a race, but a subgroup of White children [11].

Discussion

38% silver diamine fluoride was significantly more clinically beneficial than placebo in stopping lesions in children aged 3 to 5 and was also safe. This study provides evidence of immediate effectiveness. If such treatments are offered from primary care providers, they may reduce treatment requirements for patients awaiting expert care in hospitals and prevent morbidity associated with untreated Early Childhood Caries, or they may be a crucial part of non-surgical management. Nine published paediatric clinical trials ranging in duration from 18 to 36 months have helped to optimise the clinical protocol and regimen in numerous ways. A dosage response is reached by a larger concentration (38% versus 12%), and longer-term effectiveness is accomplished by mechanical excavation of lesions using hand instruments or a dental drill.

Conclusion

According to the research, topical 38% silver diamine fluoride stops tooth decay and is effective for treating dental caries in young children for a short period of time. The outcome is quick and secure. Microbiological resistance seems to be unlikely.

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