

Effectiveness of Professionally-Applied Silver Diamine Fluoride in Arresting Dental Caries

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The purpose of Linking Research to Clinical Practice is to present evidence based information to clinical dental hygienists so that they can make informed decisions regarding patient treatment and recommendations. Each issue will feature a different topic area of importance to clinical dental hygienists with A BOTTOM LINE to translate the research findings into clinical application.

The Bottom Line:

Silver diamine fluoride has been shown to be effective in preventing and arresting dental caries. It provides an economical, noninvasive mechanism for dental hygienists to manage caries in community-based programs. The first product was cleared for marketing by the Federal Drug Administration (FDA) in 2014 as a cavity varnish for treatment of hypersensitivity in adults over 21 years of age; therefore, its use as a caries preventive or arresting agent is off label. This FDA clearance parallels that of sodium fluoride varnish. Systematic reviews of clinical trials in children and elderly adults provide evidence for the effectiveness of silver diamine fluoride in arresting dentin caries when applied every 6 months for a period of 2 to 3 years. Without excavation of soft dentin, silver diamine fluoride reacts with protein in the dentinal tissue and deposits a layer of silver protein that resists acids produced by bacteria and promotes the formation of hydroxyapatite and fluorapatite. The silver is antibacterial, and the decayed tooth surface hardens, and the lesion becomes smaller.¹

Based on the findings of these 2 studies, the ensuing conclusions regarding silver diamine fluoride can be drawn:

- Silver diamine fluoride presents a noninvasive option for caries arrest and treatment when applied directly to dentin caries lesions
- Use of silver diamine fluoride should be combined in a preventive oral health program with use of sodium fluoride varnish for remineralization of early caries lesions and application of sealants for prevention of caries when resources are available
- Clinicians need to know the indications and contraindications, follow manufacturer directions for use, and obtain informed consent before using silver diamine fluoride
- From a public health point of view, silver di-

amine fluoride might provide an option for treating patients with barriers to care¹

Gao SS, Zhang S, Mei ML, Lo EC, and Chu CH. Caries remineralisation and arresting effect in children by professionally applied fluoride treatment – a systematic review. BMC Oral Health. 2016 Feb 1;16(1):12. doi: 10.1186/s12903-016-0171-6.

Abstract

Background: As a low-cost and easily operated treatment, the use of professionally applied topical fluoride was approved for preventing dental caries and remineralising early enamel caries or white spot lesions. It is also used to arrest dentine caries. The aim of this study is to investigate the clinical efficacy of professional fluoride therapy in remineralising and arresting caries in children.

Method: A systematic search of publications from 1948 to 2014 was conducted using four databases: PubMed, Cochrane Library, ISI Web of Science and Embase. The key words used were (fluoride) AND (remineralization OR remineralization OR arresting) AND (children caries OR early childhood caries). The title and abstract of initially identified publications were screened. Clinical trials about home-use fluorides, laboratory studies, case reports, reviews, non-English articles and irrelevant studies were excluded. The full texts of the remaining papers were retrieved. Manual screening was conducted on the bibliographies of the remaining papers to identify relevant articles.

Results: A total of 2,177 papers were found, and 17 randomised clinical trials were included in this review. Ten studies investigated the remineralising effect on early enamel caries using silicon tetrafluoride, fluoride gel, silver diamine fluoride or sodium fluoride. Seven studies reported an arresting effect on dentine caries using silver diamine fluoride or nano-silver fluoride.

Meta-analysis was performed on four papers using 5% sodium fluoride varnish to remineralise early enamel caries, and the overall percentage of remineralised enamel caries was 63.6% (95 % CI: 36.0% - 91.2%; $p < 0.001$). Meta-analysis was also performed on five papers using 38% silver diamine fluoride to arrest dentine caries and the overall proportion of arrested dentine caries was 65.9% (95% CI: 41.2% - 90.7%; $p < 0.001$).

Conclusion: Professionally applied 5% sodium fluoride varnish can remineralise early enamel caries and 38% silver diamine fluoride is effective in arresting dentine caries.

Commentary: Evidence indicates the application of fluoride gel results in a large reduction in dental caries.² Sodium fluoride varnish also has been shown to have a substantial effect in preventing caries in children and adolescents.³ Nonetheless, the CDC indicates 23% of children age 2 to 5 years had caries in primary teeth and 15% of adolescents aged 12 to 19 years had untreated tooth decay in 2011 to 2012.⁴ The prevalence of dental caries is significantly higher in low income children and children without access to conventional dental care. Alternative treatments are needed to address needs of these vulnerable populations. In this article, Gao et al. reported the results of a systematic review of the literature designed to evaluate the effectiveness of professionally-applied topical fluoride in remineralizing and arresting dental caries in children. The results of 2 meta-analyses to assess the remineralizing effects of 5% sodium fluoride varnish and the use of 38% silver diamine fluoride in arresting dentin caries also were reported in this article. A meta-analysis is a research approach which statistically combines results of several individual studies to increase the power of the results and strengthen the conclusions. These authors included clinical studies of the remineralizing and arresting effect of topical fluoride application in children and divided them into 2 groups: those that measured early enamel caries and dentin caries. The random effects model was used for the meta-analyses to allow for the weighted effect of each study based on sample size. Studies evaluating effectiveness of fluoride on prevention of caries or development of new carious lesions were omitted.

The number of high quality clinical trials evaluating the effectiveness of professionally-applied topical fluoride in arresting dental caries was small, and those studies included several different agents, methods, and outcome measures. Only

studies published in the English language were included in this systematic review. As a result, the number of studies included in the meta-analysis was minimal. Four studies of the clinical efficacy of sodium fluoride varnish were included in the meta-analysis because all of them measured the overall percentage of remineralization using the 5% sodium fluoride varnish. As indicated in the abstract, the combined data indicated a 63.6% remineralization of early enamel caries in children. The length of the studies ranged from 1 to 9 months; therefore, longer term trials are indicated. Apart from sodium fluoride varnish, little evidence was found to support other topical fluoride applications in the remineralization of early enamel caries in children.

Five studies measured the clinical efficacy of 38% silver diamine fluoride alone on arresting dental caries in children. Other concentrations or combinations of silver diamine fluoride were less common and were excluded from the meta-analysis. Three of these studies used a once a year application and indicated a rate of arrested dentin caries between 65.2% and 79.2%; one study demonstrated applications every 6 months increased the mean proportion of arrested caries to 84.8%; and, one study evaluated a single application arrested dentin caries at an average proportion of 31.2%. These differences suggest a need for future studies to evaluate the optimal time interval for application of silver diamine fluoride. The length of the studies included ranged from 18 to 30 months. One finding of particular relevance to dental hygienists practicing in alternative settings outside of the conventional dental practice or clinic was that studies indicated 38% SDF treatment is superior to sodium fluoride varnish in arresting dentin caries, and there is no need to remove the soft decay before silver diamine fluoride application. Two studies included in the review found silver diamine fluoride to be more effective than glass ionomer restorations in arresting dental caries.

Silver diamine fluoride application results in black staining of caries lesions, a disadvantage that may cause dissatisfaction for children and parents, and certainly an indication for informed consent. One study used an innovative product with nano-silver fluoride and found it effective in reducing caries without dark staining. None of the studies included in this systematic review reported other significant adverse effects, although additional study of the safety of all topical fluoride products is warranted.^{2,3}

Horst JA, Ellenikiotis H, Milgrom PL. UCSF Protocol for caries arrest using silver diamine fluoride: rationale, indications and consent. J Calif Dent Assoc. 2016 Jan;44(1):16-28.

Abstract

The Food and Drug Administration recently cleared silver diamine fluoride for reducing tooth sensitivity. Clinical trials document arrest and prevention of dental caries by silver diamine fluoride. This off-label use is now permissible and appropriate under U.S. law. A CDT code was approved for caries arresting medicaments for 2016 to facilitate documentation and billing. We present a systematic review, clinical indications, clinical protocol and consent procedure to guide application for caries arrest treatment.

Commentary: This article presents a clinical protocol for application of silver diamine fluoride for caries arrest treatment developed by researchers at the University of California at San Francisco (UCSF). Horst et al conducted a systematic review prior to creating this protocol and present the results of 9 randomized clinical trials conducted for at least 1 year as background information related to the protocol. These studies in this review met accepted criteria for a well-designed trial. In all of the studies, silver diamine fluoride was applied while the teeth were isolated with cotton, and caries was detected clinically with a mirror and explorer only. These studies involved both children aged 3 to 9 years and adults aged 60 to 89.

Findings of the systematic review indicated that caries arrest increased with re-application of silver diamine fluoride after 1 year of treatment, to 18 months, and again to 2 or 3 years, and results were not sustained after 1 year without reapplication. Silver diamine fluoride was more effective in arresting caries than sodium fluoride varnish. Applications at 6-month intervals were more effective than once a year. In 1 study, the combination of annual application of silver with oral hygiene instruction every 6 months resulted in arrested root caries in a group of community-dwelling elderly adults. The authors of the review identified darkening of the entire lesion as an indication of the success of the treatment in arresting caries at follow up, and a break in the black color was indicative of active caries or sensitivity at 6 months. This characteristic may facilitate diagnosis by dental hygienists working in school, community or long-term care settings.

The findings of the review also indicated that silver diamine fluoride was effective in caries prevention in children and the elderly. Two studies indicated that silver diamine fluoride applied to

active carious lesions for arrest also prevented caries in other tooth surfaces. Similar to use for caries arrest, however, silver diamine fluoride requires continued application because prevention is effective less than 1 year without repeat application. Sealants were more effective than silver diamine fluoride; however, application was reported 20 times more costly.

Based on the findings of the systematic review, Horst et al. provided a detailed clinical protocol and informed consent form in the article. They recommended application of silver diamine fluoride twice a year to carious lesions only, without excavation, for the first 2 years. Any patient with active caries should receive silver diamine fluoride rather than sodium fluoride varnish. Silver diamine fluoride does not stain sound enamel; therefore, localized application to arrest dentin caries would not result in generalized tooth darkening. Should caries progress, minimally invasive restorative techniques would be indicated.

The authors discuss 4 indications. In cases of extreme caries risk, traditional preventive care and restorative treatment fails to arrest caries. These patients include children with severe early childhood caries and patients with salivary dysfunction resulting from cancer therapy, Sjogren's syndrome, polypharmacy, or methamphetamine abuse. Patients with physical or mental conditions that preclude standard treatment including the elderly living in nursing homes or patients on hospice without access also are indicated. Numerous lesions that can not be treated in one visit or lesions that are difficult to treat conventionally may also be treated with silver diamine fluoride.

Additional studies are needed to determine long-term effectiveness after 2 to 3 years when regular application is discontinued. Following manufacturer's dosage guidelines based on body weight is critical to safe application of silver diamine fluoride. The authors set their recommended limit at 1 drop per 10 kilograms of body weight per treatment visit. This meets the Environmental Protection Agency's short- and long-term limits. The most frequent application studied was weekly for 3 weeks annually, and twice a year was shown to be effective. More frequent application of silver diamine fluoride requires additional studies of safety and efficacy. Argyria, a condition caused by exposure to chemical forms of silver, causes the skin to become blue or grayish as a result of accumulation of silver in the body over time. This condition has not been reported with the use of silver diamine fluoride. In fact, adverse reactions are rare and limited to a transient white mucosal lesion or gingival redness in only a few subjects of thousands studied. The soft tissue and gin-

gingiva should be avoided during application; thus, the authors have recommended use of petroleum jelly for protection of adjacent gingiva, using the smallest available microsp sponge, and dabbing the dampen dish to remove any excess solution before application. Silver allergy is a contraindication. Desquamative gingivitis or mucositis is a relative contraindication.

Summary: Dental hygienists are preventive professionals responsible for providing oral health care to patients in traditional dental settings, community settings, and primary care or medical settings. Among other preventive and therapeutic services, silver diamine offers an opportunity to address dental caries with an effective, economical, and noninvasive approach. The authors of these 2 articles concluded that evidence presented supports silver diamine fluoride application as a caries preventive and arresting modality. Clinicians should be aware that this use is off label; know the indications, contraindications, and recommended procedures before use; and, obtain informed consent prior to application. Repeated application at 6-month intervals is needed for sustained effectiveness. More research is needed to determine the optimal length of time for repeated application to sustain long-term effectiveness, reasons for subsequent caries progression, and when excavation may or may not be needed.

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