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**Is Silver Diamine Fluoride Effective in Arresting Enamel Caries? A
Randomized Clinical Trial**

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SUMMARY OF THE ARTICLE

Araya Phonghanyudh, Duangporn Duangthip, Sirinan Mabangkhu, et al. conducted a randomized clinical trial to compare the effectiveness of 38% SDF and 5% NaF varnish in arresting enamel caries in young children. The study was conducted in Chiang Mai, Thailand. Children aged 1-3 with at least one active cavitated dentin caries were recruited as subjects of this study from 19 public child development centers. The article was published in the International Journal of Environmental Research and Public Health in July 2022 (<https://www.mdpi.com/1660-4601/19/15/8992>)

Subjects were allocated into Group 1 (38% SDF) and Group 2 (5% NaF). A single examiner conducted baseline examinations to assess for caries activity. A visual-tactile examination was used to assess the extent of carious lesions. The intervention was performed by trained dental nurses, following the same protocol for both groups and was repeated every six months. Enamel caries not progressing to dentin were classified as having caries arrest. Intention-to-treat analysis was performed.

The authors concluded that 38% SDF and 5% NaF varnish had similar effectiveness in arresting the progression of enamel caries. However, additional factors, like cost, patient preference, and useability, should be considered when selecting agents.

ARTICLE INFORMATION

The article I chose to review and analyze is titled “ Is Silver Diamine Fluoride Effective in Arresting Enamel Caries? A Randomized Clinical Trial”. It was authored by: Araya Phonghanyudh, Duangporn Duangthip, Sirinan Mabangkhu et al. The article was published on 24 July 2022 in the International Journal of Environmental Research and Public Health. The journal’s homepage is located online at: <https://www.mdpi.com/journal/ijerph>. The article is located online at: <https://www.mdpi.com/1660-4601/19/15/8992>. The article's abstract in the PubMed database is located at: <https://pubmed.ncbi.nlm.nih.gov/35897363/>, and its DOI is 10.3390/ijerph19158992.

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STUDY ANALYSIS

TYPE OF STUDY

The study was a Randomized Clinical Trial conducted in the Chiang Mai province of Thailand. It was conducted in 2021 and lasted 18 months, consisting of evaluation and data collection at set intervals: Initial Baseline data, recall visits, and data collection at the 6, 12, and 18-month mark.

STUDY PURPOSE

Early childhood caries (ECC) is one of the biggest public health problems young children face. It can have a number of harmful effects on quality of life. Due to children's limited cooperative abilities, surgical treatment for ECC is extremely distressing for them, their families, and dentists. Additionally, it calls for highly skilled dental teams and sophisticated equipment. To lower the high prevalence of ECC in young children, alternative strategies that are cost-effective and simple to implement are required.

Studies have shown that mineralization and good oral hygiene habits can slow the progression of ECC. Speedily diagnosing and treating the underlying lesion is key. Fluoride is the mineralizing agent most commonly used to treat and prevent dental caries. It works by preventing demineralization and promoting remineralization. For this purpose, various forms of fluoride are available - a fluoride varnish is a popular option. It generally contains 5% Sodium Fluoride (NaF) and has been viewed as clinically successful in halting the progression of caries. An alternative formulation known as Silver Diamine Fluoride, or SDF, has demonstrated remarkable efficacy in treating dentine caries lesions.

This study aimed to compare and contrast the clinical efficacy of semiannual applications of 38% SDF varnish with 5% NaF varnish in halting the progression of enamel caries in young children aged 1 to 3 years.

EXPERIMENTAL DESIGN

The study was conducted in Chiang Mai Province, Thailand. Participants were recruited from 19 public child development centers. Children aged 1-3 with at least one active cavitated dentin caries met the inclusion criteria. Children with a known allergy to fluoride, silver, or colophony agents, long-term medication, or a history of major systemic diseases were excluded.

The findings of meta-analysis studies and calculations served as the basis for estimating the sample size. As a result, Sample Power 2.0 (SPSS, Inc.) determined that each arm required at least 343 dentin carious tooth surfaces. Using the equation for estimating sample size in a multilevel study, it would be necessary to have 960 active carious tooth surfaces in each group of 137 children. At baseline, approximately 150 children per group needed to be recruited due to an estimated 10% dropout rate.

Using the stratified block randomization technique, the participants were randomly placed in one of the following groups: Group 1 received 38% SDF (Topamine, DentaLife, Australia), while Group 2 received 5% NaF varnish (Duraphat, Colgate Palmolive, USA). This study was conducted over 18 months, with recall examinations conducted at 6, 12, and 18 months.

The oral examinations were conducted at the child development centers using World Health Organization CPI periodontal probes (405/WHO probe) with disposable dental mirrors attached to an LED intra-oral light source in a knee-to-knee position. The examiner was trained for caries and plaque assessment by specialists in dental public health and pediatric dentistry. Carious status was measured using the ICADS criteria and WHO dmft index (decayed, missing, and filled) for teeth. To assess oral hygiene, the Visible Plaque Index (VPI) was applied to the buccal and lingual surfaces of six index teeth (55, 51, 63, 71, 75, and 83).

All the data were analyzed using the software SPSS 20.0 for Windows (SPSS Inc., Chicago, USA). The level of statistical significance was set at $p < 0.05$. An intention-to-treat analysis was conducted. The chi-square test was used to compare the differences between Group 1 and Group 2 regarding their baseline demographic background, oral health-related behaviors, caries arrest rate, and parents' satisfaction. The comparability of age, VPI scores, dmft, and dmfs scores between both groups was assessed using an independent samples t-test or Mann-Whitney U test, depending on their normality of distribution.

A single examiner was trained for caries and plaque assessment by dental public health and pediatric dentistry specialists until the weighted kappa values of inter-and intra-reliability were 0.8 each. The same examiner performed the examinations conducted at baseline and recall visits. Duplicate examinations of carious lesion activity were randomly conducted on 10% of the participants at baseline and follow-up examinations after 2 weeks of their first examinations to assess the intraexaminer reliability using kappa statistics.

Two experienced dental nurses applied the varnish. Pediatric dentists trained them to apply SDF and NaF varnish on all carious surfaces in a community setting. A protocol was established and constantly followed for this process. The interventions in both groups were repeated every six months.

RESULTS

Initially, there were significant differences in caries arrest rates between the groups at the 6 and 12-month recall visits. However, after 18 months, the groups had no significant statistical difference. Caries arrest rates of non-cavitated enamel caries were significantly higher than those of cavitated enamel caries at all follow-up examinations, regardless of the intervention group.

The study's data were analyzed, and 38% SDF and 5% NaF varnish were equally effective in arresting the progression of enamel caries.

Regarding the potential side effects and esthetic concerns of using 38% SDF, parental satisfaction with their children's dental appearance remained unchanged over the 18-month course of study. No major adverse effects, including vomiting or nausea, were reported either.

CONCLUSIONS

The efficiency of SDF in regard to halting dentine caries is well documented. However, there is a lack of information regarding its effectiveness in halting enamel caries. This study helps provide some information to fill this gap. The data showed that both formulations provided similar results. By preventing demineralization and encouraging remineralization, 38% SDF and 5% NaF can both be used to control the carious process.

The study's arrest rate for enamel caries was approximately 60%, consistent with the systematic review of studies. The study also confirmed the significance of early intervention for

successfully preventing enamel caries, as the rate of caries arrest was significantly higher regarding non-cavitated enamel caries than cavitated caries.

It also showed that other variables, including tooth- and child-related factors, influence enamel caries' progression. This finding highlights the significance of encouraging parents and other caregivers to brush their children's teeth with fluoride toothpaste and topical fluorides applied by professionals. Because of the multifactorial nature of ECC, fluoride therapy is not the only intervention. It should be used with great oral cleanliness, restricting kids' sugar consumption, and enhancing follow-up visits with caries risk appraisals.

Throughout the study, 38% SDF was found to be safe, with no systemic adverse effects observed. A common known side effect of SDF treatment is the blackening or staining of carious lesions, which may affect how happy parents and children are. Surprisingly, over the course of 18 months, parents' satisfaction with their children's dental appearance did not change. This could result from the parents receiving helpful information and communication during recruitment. Dentists should inform parents about the benefits and drawbacks of using SDF to treat caries.

The study did have a few limitations. First, it did not have a negative control group because of ethical concerns. Second, the enamel carious status was assessed by visual inspection only, without radiographs. It's possible that the study did not include some enamel carious lesions in the proximal areas that were not clinically detected. The staining of treated caries lesions by SDF may have caused bias in evaluating follow-up data, even though only one examiner was blinded to the intervention groups.

Based on the study's results, there was no statistically significant difference between the use of 5% NaF and 38% SDF for arresting enamel caries of primary teeth. SDF usage did not present with any adverse effects, nor did it adversely affect parental satisfaction with the appearance of their children. However, additional factors, such as treatment cost, patient preference, and useability, should be considered when selecting topical fluoride agents.

MY IMPRESSIONS

This study was both important and interesting. I liked the idea of comparing the effects of SDF with a known effective agent such as NaF. By limiting the data to only arrest rates of

enamel caries, this study tried to introduce another option in our efforts to control enamel caries through early intervention.

The study clearly showed that early intervention is required for the best results. The arrest rates of earlier detected non-cavitated lesions were significantly higher than the cavitated lesions that had progressed further on. This was true regardless of the agent used for intervention. It also showed that other factors played a significant role in the progression of enamel caries, including the use of fluoride toothpaste.

The use of SDF did not raise any concerns with respect to its known side effects, such as nausea or vomiting. The known side effect of dark staining of carious lesions by SDF did not cause any parental discontent with the dental appearance of their children.

Initially, the SDF seemed more effective in arresting the lesions, as seen by the data after the 6 and 12-month recalls. However, after 18 months, there was no significant difference between the groups. I found this data point very interesting and intriguing. Is this related to Fluoride ppm levels or to the initial cariogenic action of SDF silver ions, which stabilized over a longer period? Further research in this direction is warranted and will help design future protocols for early intervention.