

Effectiveness of Various Fluoride Varnishes in Arresting Cavitated Dentinal Lesion in Preschool Children: A Randomized Clinical Trial

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ABSTRACT

Aim: The aim of this randomized clinical trial was to compare the effectiveness of various fluoride varnishes in arresting cavitated dentinal lesions among preschool children.

Materials and methods: Children aged 3–5 years old with at least one active cavitated dentinal carious lesion were recruited and randomly assigned into two groups as follows. Children in group I received 38% silver diamine fluoride (SDF) (FAGamin, Tedequim SRL, Argentina) application and children in group II received bifluorid 10 varnish (VOCO Bifluorid 10) application on carious lesion respectively. Lesion activity was assessed by visual-tactile examination using the World Health Organization (WHO) consumer price index (CPI) probe. Baseline and follow-up examinations were done by different examiners to collect the data.

Result: Baseline and 1-week follow-up data was collected and subjected to statistical analysis using the Chi-squared test. The caries arrest rate in group I (100%) was highly significant.

Conclusion: Silver diamine fluoride (SDF) was effective in arresting caries in preschool children and facilitating the early restoration of the cavitated lesion and was also helpful in instilling positive behavior in preschool children toward dental treatment.

Clinical significance: Caries control methods used here are simple, noninvasive, highly efficient, cost-effective, well accepted, and can be used in all children. The results were satisfactory as cavitated lesions were restored in a short time in achieving good oral health.

Keywords: Caries arrest, Cavitated dentinal lesion, Early childhood caries, Fluoride varnish, Preschool children, Silver diamine fluoride.

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INTRODUCTION

Early childhood caries (ECC) is one of the major global health problems. Infants and preschool children are at high caries risk of developing ECC. Initial caries can progress into cavitated lesions rapidly involving pulp and cause pain and infection.¹ In a recent review, it was found that the prevalence of ECC in Southeast Asian countries varied from 70 to 90%, and most decayed teeth remained untreated which affects children's oral health, and compromises general growth and development, and quality of life.^{2,3} Developing cognitive and psychological behavior in young children limits cooperation during restorative treatment. Thus, the traditional approaches are replaced by minimally invasive approaches to arrest the progression of caries. A variety of fluoride-based chemotherapeutic agents are used for arresting and preventing dental caries.⁴ Restorations are needed for cavitated lesions for esthetics and function, and also act as a self-cleansing surface.

Silver diamine fluoride (SDF) 38% (44,800 ppm) has been drawing increased attention contemporarily, due to its efficacy in arresting the progression of dental caries.^{4–6} SDF possess caries arrest through remineralization and rehardening. Though antimicrobial, SDF stains the caries lesion black and due to its high fluidity, the contact time with the carious lesion is limited.⁷

Bifluorid varnish is a unique combination of 5% sodium fluoride (22,600 ppmF) and 5% calcium fluoride, when applied adheres well to enamel and dentin and dries quickly, and does not affect esthetics. It helps in the prevention and arrest of dental caries through remineralization.^{6,7}

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As there are no clinical studies conducted to precisely understand the duration of success between the application of the above agents and caries arrest followed by placement of final restoration in preschool children. The aim of *in vivo* study was to investigate and compare the effectiveness of various fluoride varnishes (38% SDF and bifluorid 10 varnish) in arresting cavitated dentinal lesions and to evaluate fluoride-treated surface for placement of restoration after a 1-week follow-up.

MATERIALS AND METHODS

Study Design

This is a randomized clinical trial, a double-blinded study conducted at the Department of Pedodontics and Preventive Dentistry,

Bengaluru. The participants were allocated in a 1:1 ratio following the Consolidated Standards of Reporting Trials recommendation as shown in [Flowchart 1](#). The participants and their parents/guardians, as well as the examiners, were not aware of patient allocation.

Ethical Consideration and Registration

The parents or the guardian were explained the procedure, purpose, risks, and benefits of the study before they signed an informed consent for recruiting the children. This study has received approval from the ethical committee of the institution and the study was registered in the (Clinical Trials Registry India/2021/10/037395).

Sample Size Calculation

The sample size has been estimated using the G*Power software version 3.1.9.4 (Franz Faul, Universität Kiel, Kiel, Germany). Considering the effect size measured (d) at 80% for the two-tailed hypothesis, the power of the study at 80%, and the margin of error at 10%, the total sample size needed is 40. Hence each study group will comprise 20 samples.

Study Group

A total of 40 preschool children who sought dental care at the institution were recruited by trained and calibrated pediatric dentists according to following inclusion and exclusion criteria as follows.

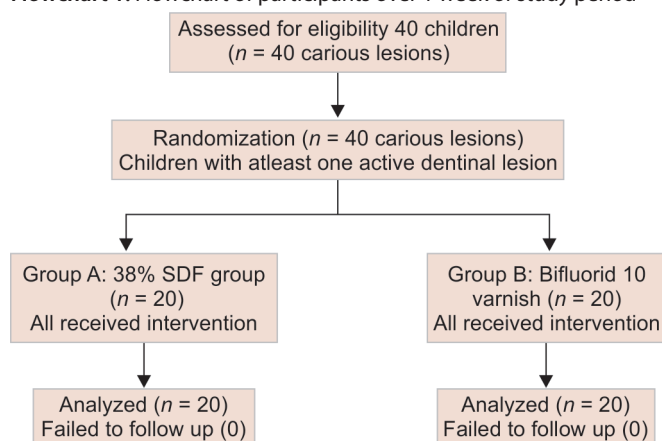
Inclusion Criteria

- Children aged between 3 and 5 years from either gender.
- Parents giving consent for the study.
- At least one carious lesion as defined by the International Caries Detection and Assessment System (ICDAS). Using ICDAS, lesions were categorized as active (soft) cavitated carious lesions in the primary dentition, extending into the dentin (ICDAS 5 or 6).⁸
- Using ICDAS radiographic scoring RB4 radiolucency reaching the middle one-third of dentine.

Exclusion Criteria

Children who received fluoride topical application during the last 48 hours, children with special health care needs, a tooth with an abscess, symptoms of irreversible pulpitis or a mobile tooth, children who were on antibiotic therapy within the past 3 months, and those with known sensitivity to silver or other heavy metal ions.

Flowchart 1: Flowchart of participants over 1 week of study period



Randomization

The selected children were randomly allocated into two groups ($n = 20$) based on computer-generated numbers. Children in group I treated with 38% SDF and group II with bifluorid 10 varnish.

Method

A baseline clinical examination was performed by a pediatric dentist with a child on a dental chair, under artificial light using a mouth mirror and WHO CPI periodontal probe (405/WHO probe) using the visual-tactile method, and radiographs were taken to assess the extent of the carious lesion. A carious lesion was recorded as active if the tooth surface is soft on gently drawing the probe. No effort was made to remove caries/unsupported enamel for caries treatment in both groups.

The intervention was performed by the same operator who did the baseline clinical examination. In group I, teeth with carious dentin was treated with 38% SDF.

Procedure

Initial cleaning of the cavity was performed by using a small cotton pellet under good isolation and the tooth surface is dried, 38% SDF solution was dispensed into a mixing well and then applied directly onto the primary teeth dentin using a disposable micro applicator tip and was allowed to absorb for up to 1 minute. In group II teeth with carious dentin was treated with bifluorid 10 varnish, the same above procedure was carried out as in group I, but here bifluorid 10 varnish was allowed to absorb for up to 2 minutes. Then the oral hygiene instructions were given and parents are instructed that the child should not take any liquid or solid substitutes for at least 45 minutes after the application in both groups. All children were scheduled for follow-up in 1 week.

Recall examination of the treatment was performed by two examiners who were blinded to assess the carious lesion activity. Thus, the data from the initial examination were compared to those from the review, based on which the teeth could be classified as success or failure according to the treatment group. Success was achieved when the carious lesion was inactive, and failure when the caries was active or had any signs and symptoms of pain and discomfort. If the carious lesions were arrested, we further proceeded with glass ionomer cement (GIC) restorations on the same day and if the lesions were active caries excavation was done followed by GIC restoration and an appointment for the same was scheduled during the 2nd week. The duration of the study was 6 months.

STATISTICAL ANALYSIS

Statistical Package for Social Sciences for Windows version 22.0 released in 2013, Armonk, New York, International Business Machines Corporation, was used to perform the analysis.

Descriptive Statistics

The descriptive analysis includes the expression of the status of caries arrest in terms of frequency and proportions in each study group.

Inferential Statistics

Chi-squared test was used to compare the status of caries arrests like the presence of black stain and hard base at the cavity between the two groups.

McNemar's test was used to compare the color of the cavity and the base of the cavity between baseline and 1 week follow-up period in each study group.

The level of significance (p -value) will be set at $p < 0.05$.

And any other relevant test, if found appropriate during the time of data analysis was dealt with accordingly.

RESULTS

A total of 40 active carious dentine lesion meeting the inclusion criteria were included and were randomly allocated into two treatment groups. The mean age of children involved in this study was 3–5 years with male predominance. Most of the children brushed once daily with toothpaste. At baseline there were no statistically significant differences between study subjects in terms of demographic background, except family income (Table 1), half of the involved teeth were upper anterior and the most commonly involved surfaces were mesial, occlusal, distal surfaces in both the groups with a p -value of 0.84 (Table 2).

At 1 week, all carious lesions were examined for the outcome. Intraexaminer reproducibility was very good with Cohen K statistic values greater than 0.9 in the baseline and follow-up examination. The caries arrest rates of the SDF were 100% and bifluorid 10 varnish was 0% and the results were statistically significant ($p < 0.001$) (Table 3).

DISCUSSION

Traditionally dental caries is treated through a surgical restorative approach which requires sophisticated dental equipment and well-trained clinicians and is relatively quite expensive.^{9,10} In children remineralization of caries through minimal invasive approach has been gaining increased attention and acceptance.⁴ In cavitated lesions food impaction affects the natural cleansing and remineralization action of saliva, thus restoration of the lesion followed by oral health education and establishment of routine oral hygiene is important for the success of caries control in preschool children.¹⁰

This study is a randomized double-blinded clinical trial, focused on preschool children with cavitated dentinal lesions with a short-term follow-up of 1 week. Our study focused on providing causal inferences, evidence of a treatment's efficacy, and minimizing bias. The strengths of this study include a high patient retention rate (i.e., patients were retained till the end of the study), good intraexamination reliability, and parent and patient satisfaction was achieved. We adopted several strategies for reducing possible bias, including randomization, and double-blinding.

Although it has been documented that SDF reduces caries progression significantly compared to other modalities, most of the randomized clinical trials were performed in children 3 years old or

Table 1: Comparison of age and gender distribution between two study groups using Chi-squared test

Variable	Category	SDF 38% group		Bifluorid 10 group		χ^2 value	p -value
		<i>n</i>	%	<i>n</i>	%		
Age	3 years	6	30%	6	30%	0.583	0.75
	4 years	5	25%	7	35%		
	5 years	9	45%	7	35%		
Gender	Males	11	55%	11	55%	0.000	1.00
	Females	9	45%	9	45%		

Table 2: Comparison of distribution of teeth treated in different quadrants between two study groups using Chi-squared test

Variable	Category	SDF 38% group		Bifluorid 10 group		χ^2 value	p -value
		<i>n</i>	%	<i>n</i>	%		
Teeth treated	Upper RT anteriors	5	25%	4	20%	3.421	0.84
	Upper LT anteriors	3	15%	4	20%		
	Upper RT posteriors	2	10%	2	10%		
	Upper LT posteriors	2	10%	1	5%		
	Lower LT anteriors	0	0%	2	10%		
	Lower RT anteriors	2	10%	2	10%		
	Lower LT posteriors	1	5%	2	10%		
	Lower RT posteriors	5	25%	3	15%		

RT, right; LT, left

Table 3: Comparison of caries status between two study groups using Chi-squared test

Variable	Category	SDF 38% group		Bifluorid 10 group		χ^2 value	p -value
		<i>n</i>	%	<i>n</i>	%		
Caries status	Arrested	20	100%	0	0%	40.000	<0.001*
	Not arrested	0	0%	20	100%		

*Statistically significant

above and were focused on longer follow-up periods, but nowadays the changing trend is to complete the restoration at a shorter period of time as SDF has proven to arrest caries successfully.^{11,12} In our study clinical assessment was relayed on the characteristics such as color and consistency. On SDF application the lesion had turned black in color and was smooth and hard on probing suggestive of caries arrest, whereas the teeth treated with bifluorid 10 varnish showed yellow color and tooth surface remained soft on probing suggestive of active caries after 1 week. However, in both the groups the final restoration with GIC was carried out to avoid further progression of caries, to reduce loss of tooth structure, and to provide a good cleansing area.

The present study on SDF 38% has shown a highly significant result in arresting caries compared to previous studies. Only two studies performed the short-term follow-up and reported caries arrest rates of 72%¹³ and 98%¹⁴ in 21 days and 3 months follow-up, respectively using 38% SDF, which was higher compared to long-term follow-up studies where it was reported that 43.3%¹⁵ caries arrest was seen in 6 months and 66.9%¹⁶ with 12 months follow-up. Caries arresting rate was higher in studies, that isolated and dried the teeth before the application of SDF, like performed in the present study. Clemens et al. stated that good isolation and drying of tooth lesions were essential components of the protocol.

Though in our study single application of SDF has shown high caries arrest rate, the lasting effect of arrested caries surface is questionable with respect to oral environmental changes, hence restorations are desirable to maintain the teeth in the oral cavity.

Silver diamine fluoride (SDF) when applied onto the tooth surface, it interacts with hydroxyapatite to form silver phosphate and calcium fluoride which act as a reservoir of fluoride and phosphate ions aiding in remineralization, the silver ions have antibacterial activity against cariogenic bacteria, inhibition of biofilm formation, reduce depletion of the collagen matrix.¹⁷ SDF also helps in reducing dentin hypersensitivity. The fluoride component in SDF reacts with calcium phosphate and hydroxyapatite, which results in the formation of fluorapatite and calcium fluoride, this improves the acid resistance of the dental hard tissue. The synergistic effect of silver and fluoride may be the main advantage of SDF in controlling caries when compared to other active noninvasive methods such as fluoride varnish.¹⁷

Bifluorid 10 varnish contains easily soluble sodium fluoride, which provides quick release of fluoride ions, which gets converted to calcium fluoride on the tooth surface to support effective remineralization. The anti-soluble calcium fluoride contained in the varnish provides lasting retention on the tooth surface which ensures long-term fluoridation. Few long-term studies on 5% NaF varnish have shown a caries arrest rate of 34% after 3 applications at the weekly interval with 30 month follow-up¹⁸ and with 18 month follow-up caries arrest rates were 27%¹⁶ and no restorative measures were carried. This is the first study, which used bifluorid 10 varnish to arrest dentin caries and it showed no significant caries arrest at 1 week follow-up.

Though SDF has given 100% results in arresting caries when compared to bifluorid 10 varnish they have some disadvantages such as metallic taste and permanent black staining of the tooth, which might affect esthetics and parental satisfaction.^{6,19}

Few studies used different restorative materials such as GIC, composite, resin-modified GIC, and also potassium iodide applied after SDF application and all had a satisfactory masking effect on the color change associated with the application of SDF, but only one material was successful in masking the color change produced by SDF after aging, that is, composite.²⁰ One of the studies reported 53.3% of parents considered SDF treatment for

their children acceptable due to discoloration problems.¹⁵ But in our study though complete masking of SDF staining was not possible with the restorative approach parental acceptance was seen. Although no severe adverse effect was found in the present study during 1-week follow-up. Toxicity in children due to silver ingestion might occur with increased frequency of application considering its fluidity.

Given our result, we believe that our study is a valuable contribution to the existing SDF and NaF research. In particular, we have assessed preschool children with a cavitated dentinal lesion which is quite a common issue in children and this can benefit uncooperative children. Further children of this age group may benefit from delayed operator dental procedures and achieve overall caries arrest at the same time, thus reducing potential pain and infection, expensive future emergency room visits, and the need for GA or traumatic dental experiences on uncooperative children.

Limitation of the present study was the small sample size.

CONCLUSION

In the current study, 38% SDF is more effective than that of bifluorid 10 varnish in arresting cavitated dentinal lesions in preschool children with high caries activity in a short interval of time so that restorations can be carried out to replace the lost tooth structure and function. Thus, SDF has proven to be an easy, cost-effective, highly efficient, and well-accepted minimally invasive technique to instill positive behavior in younger children toward future dental procedures.

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MANUFACTURERS NAME

- Silver diamine fluoride (SDF) 38% (FAGamin, Tedequim SRL, Argentina).
- Bifluorid 10 varnish (VOCO GmbH, Cuxhaven, Germany).

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