

Effectiveness of Silver Diamine Fluoride and Sodium Fluoride Varnish in Preventing New Carious Lesion in Preschoolers: A Randomized Clinical Trial

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ABSTRACT

Introduction: Dental caries is a site-specific, multifactorial chronic disease affected globally. The prevalence of dental caries is strongly associated with social and economic disadvantage, and also the susceptibility of children to dental caries. Dental caries prevention can be achieved with topical fluoride agents. Topical fluoride promotes the remineralization of early carious lesions and reduces the demineralization of healthy enamel.

Aim: The aim of this randomized clinical trial was to compare the effectiveness of silver diamine fluoride (SDF) and sodium fluoride varnish (FV) in preventing new carious lesions in preschoolers.

Materials and methods: This randomized clinical trial was conducted on 285 children aged 3–6 years. Children were randomly allocated into three groups namely, group I—deionized distilled water (DIW), group II—sodium FV, and group III—SDF. The biannual application was performed at an interval of 6 months. New carious lesions were recorded using defs and International Caries Detection and Assessment System (ICDAS II) under LED magnifying loupes. Descriptive and inferential statistics were applied and tabulated using Statistical Package for the Social Sciences (SPSS) 23.0 software.

Result: There was a significant difference seen in the mean values of group III (SDF) when compared with group II (FV) and also between group III (SDF) and group I (DIW) when defs index was used. The mean score of ICDAS II after 12 months in group I (DIW) was -1.171 , group II (FV) was -0.690 , and group III (SDF) was -0.374 .

Conclusion: silver diamine fluoride (SDF) was found to be most effective in preventing dental caries and also it appears to be the most cost-saving fluoride therapy.

Keywords: Fluoride therapy, Fluoride varnish, Preschoolers, Randomized clinical trial, Silver diamine fluoride, Topical.

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INTRODUCTION

Nearly 3.5 billion people suffer from dental caries, of which 530 million children suffer from caries in primary teeth.¹ Development of caries is associated with three primary factors (tooth, flora, and substrate); host factor is regarded as one of the important criteria for preventing caries. The tooth structure and morphology determine its inherent qualities for its susceptibility to dental caries. As deciduous teeth have lower mineral content and higher organic content compared to permanent teeth resulting in an increased propensity to caries.² Therefore, it becomes important to provide preventive therapies to young children so as to intervene growth and progression of carious lesions in the primary dentition.³ The use of topical fluoride agents and a home care regimen to prevent dental caries is well-established in the literature. But still, early childhood caries (ECC) prevalence ranges from 37 to 52%, which wants to search for more effective options for prevention.⁴

Sodium FV was developed at the end of the 1960s and is considered one of the best alternatives to topical fluoride used by practitioners.⁵ The effectiveness of topical fluoride as a cariostatic agent has been well documented, and topical fluoride formulations are commonly used to prevent active caries from developing.⁶ A systematic analysis shows that FVs decrease the occurrence of caries in primary teeth by 37%.⁷ It acts as an important tool for dentists and healthcare planners for the prevention of ECC.

Silver diamine fluoride (SDF) is a colorless solution containing silver and fluoride ions.⁸ Silver ions interact with protein groups of

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sulfhydryl's and deoxyribonucleic acid, altering bonding and inhibiting hydrogen. It facilitates the remineralization of hydroxyapatite, which is under constant acid challenge.⁹ SDF is effective in arresting and preventing the progression of enamel and dentinal caries and also prevents dentine demineralization. It is used at various concentrations but the concentration of 38% is commonly used.^{10,11}

Visual caries detection is the first-choice tool for the assessment of caries in patients. Traditionally, caries was measured by the defs index. It is one of the simplest and most commonly used in epidemiological surveys.¹² There are currently various caries detection and classification systems; of these, ICDAS is one of the most reliable and reproducible visual caries detection systems.^{13,14} It is a clinical scoring system and can be used for caries detection and reflects almost the exact relation of clinical hard tissues with histology of lesion. It has been widely utilized and submitted to comprehensive studies over the last decade.¹⁵

The purpose of this randomized clinical study was to compare the effectiveness of sodium FV and SDF in preventing new carious lesions in preschoolers.

MATERIAL AND METHODS

Study Design

The present research was a triple-blinded randomized clinical trial and was ethically approved by Sumandeep Vidyapeeth Institutional Ethic Committee (SVIE/ON/DENT/BNPG18/D19035 dated—07/05/19). The Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed to design the present research as shown in [Flowchart 1](#). Once the trial was registered for Clinical Trials Registry-India (CTRI/2019/06/019557) the enrolment of participants was initiated based on the determined sample size. Written informed consent was obtained after the purpose and nature of the research were explained to the participants and

their parents with an emphasis on metallic taste and tattooing due to SDF.

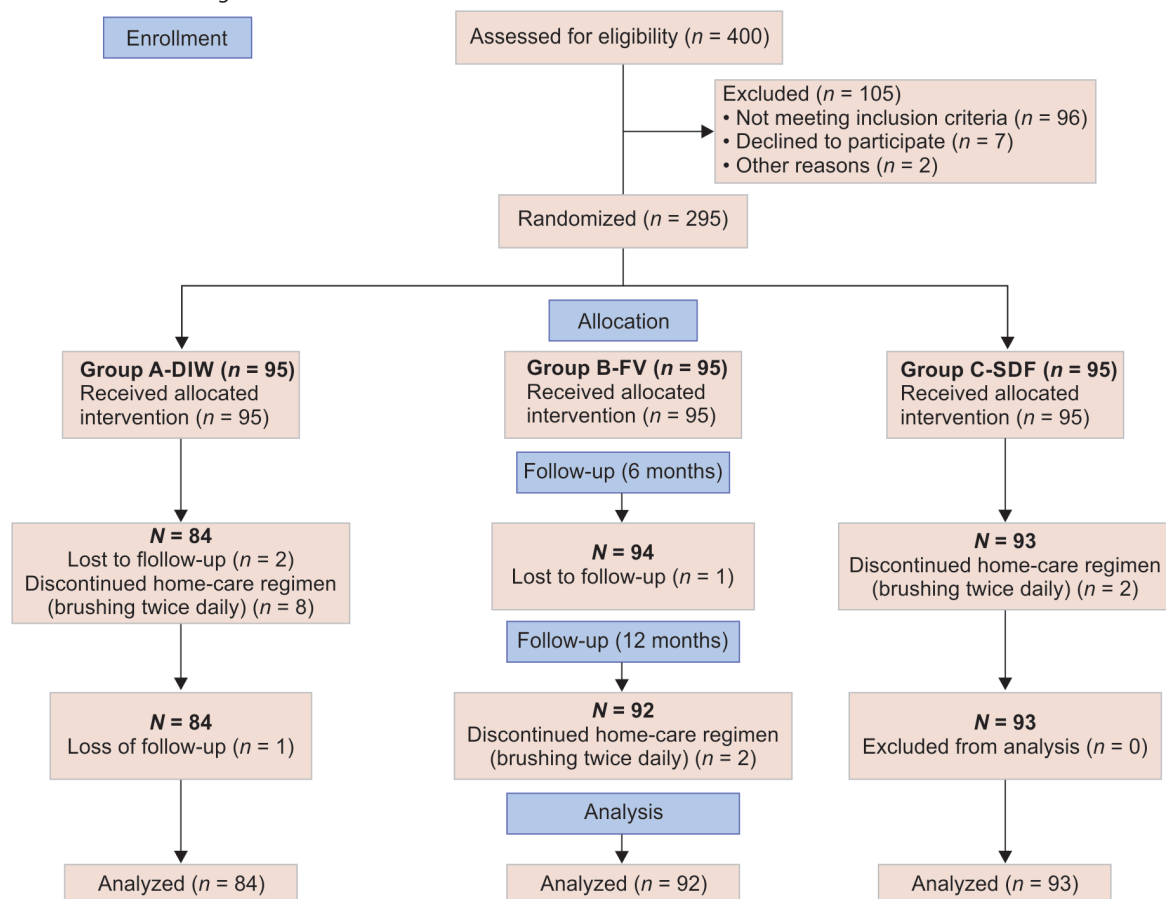
Sample Selection

The sample selection was carried out amongst preschoolers aged between 3 and 6 years on the basis of following inclusion criteria—children with noncavitated healthy dentition (defs and ICDAS II score was 0) and population receiving central water supply by the municipal corporation. The criteria for exclusion were children undergoing any other home care regimen (e.g. mouthwash), children with traumatized, hypoplastic, carious or attrited teeth, and children who were allergic to silver.

Study Procedures: Randomization and Sample Power Calculation

The sample size was calculated based on the proportion of caries-free children using SPSS Statistics 21 statistical software (SPSS Inc., Chicago, Illinois, United States of America). Around 285 sample size was determined using a standard normal distribution (z) of 1.96 for a confidence level of 95%, sample proportion (p) of 0.5, and margin error (e) of 0.05%. An additional 20% were comprised in the research so as to compensate for potential refusals, absenteeism, and dropouts (d). The sample size of 285 was further randomly divided into three groups having 95 preschoolers in each group. Randomization and blinding are carried out to avoid the deviation of inferences from the truth. In the present study, randomization and blinding were carried out to avoid selection bias, observer bias, and compliance bias. Sample allocation was done by

Flowchart 1: CONSORT flow diagram



lottery method and preschoolers were randomly asked to pick the chit from the bowl to make a group of 95. It was a triple-blinded study, where the principal investigator did the index and proforma recordings on follow-ups and the coinvestigator performed an application where dispensing containers of the agent were sealed. Along with this, the statistician was given the coded data to preserve the blinding. In the present study, a placebo was included because it can provide a comparison point for fluoride therapies. It can also have positive reinforcement on children to promote oral hygiene.

Study Procedures: Operative Procedures

A comprehensive clinical examination was performed under natural light with autoclaved diagnostic instruments and a World Health Organization (WHO) probe. Following a clinical examination, 285 caries-free preschoolers were given a biannual application of each fluoride therapy. Teeth were dried before application in all three groups, and isolation was well-maintained by cotton rolls. In group I (placebo) deionized distilled water was applied to all the tooth surfaces. In group II (5% NaF varnish group) a thin layer application of 5% sodium FV (VOCO ProFluoride Varnish, VOCO, Cuxhaven, Germany) using a suitable single-use applicator tip was carried out for 4 minutes. In group III (SDF group) as a preparatory step Vaseline was applied on gums and lips so as to prevent SDF tattooing followed by SDF application (FAgamin, Tedequim, Córdoba, Argentina) with applicator tip and preschoolers of all three groups were instructed not to rinse mouth or eat for next 45 minutes and not to brush their teeth for 24 hours.

Study procedures: Calibration

The decayed, exfoliated, filled surfaces (defs) and ICDAS II indices were recorded by the principal investigator using WHO periodontal probe under magnifying loupes 2x. The occurrence of new carious lesions was assessed at 6 and 12 months of intervals.

Cost-effectiveness

The costs of providing the preventive intervention and the costs of all treatment for newly formed carious lesions in relation to caries experience was assessed. The costs of preventing caries were estimated using the number of participants, the number of product bottles/tubes used, and also the cost of the product.

Cost per child = number of bottle \times Cost of bottles/tube/number of participants

Cost-effectiveness will be calculated for each group using this formula:

Cost-effectiveness = total number of new carious lesions/number of participants

Data Analysis

Data was analyzed using SPSS 23.0 software for statistical analysis. Tabulation was carried out by various tests and inferential analysis by applying Mauchly's test of sphericity, repeated measures analysis of variance (ANOVA), and oneway test with least significant difference (LSD) *post hoc*. Differences in mean values within each group at different time intervals were assessed by repeated measures of ANOVA. Oneway test with LSD *post hoc* was applied for pairwise comparison between the three groups with respect to defs and ICDAS II at different time intervals. The number needed to treat (NNT) was also calculated by the following formula, $NNT = 1/\text{absolute risk reduction amongst all the preschoolers with caries}$

between the groups to understand the relative benefit of fluoride therapies over a control.

RESULTS

Sample Characteristics

The study was initiated with 285 participants in all three groups constituting 95 participants each. Whereas there was a drop out of 16 participants on follow-up visits; out of which 11 were from group I (DIW), three were from group II (FV), and two were from group III (SDF). Hence the statistical analysis was carried out for a total sample of 269. Before employing inferential statistics, it is essential to verify for errors, which was undertaken in this study using Mauchly's test of sphericity, which revealed a significant difference between the groups. As a result, after determining a significant difference in Mauchly's test of sphericity, the intercept and errors were determined by using corrected tests of between-subjects effects to adjust the degrees of freedom for the averaged tests of significance. Since the *p*-values in both analyses were significant, the *post hoc* test was applied to compare the three groups at baseline, 6 and 12 months intervals for the defs index and ICDAS index.

Intragroup Comparison

New carious lesion status was recorded using defs index and the marginal means were estimated, whereas in group I (DIW) it showed that there was a significant difference seen at different intervals. From baseline to 6 months the *p*-value was 0.04, from 6 to 12 months the *p*-value was 0.004, and from baseline to 12 months the *p*-value was 0.006. Because all the *p*-values were >0.05 , suggestive of a significant difference. In group II (FV) at all, it is observed that there was a highly significant difference at different intervals. From baseline to 6 months, 6 to 12 months, and from baseline to 12 months the *p*-value was 0.000. In group III (SDF) it is discovered that there was a highly significant difference seen in group III (SDF) only when compared from baseline to 6 months where the *p*-value was 0.00. Whereas, from 6 to 12 months and baseline to 12 months the *p*-value was 0.475. This states that *p*-values were <0.05 , suggestive of no significant difference (Fig. 1).

The new carious lesion status was also recorded using ICDAS II and the marginal means were estimated. The results of group I

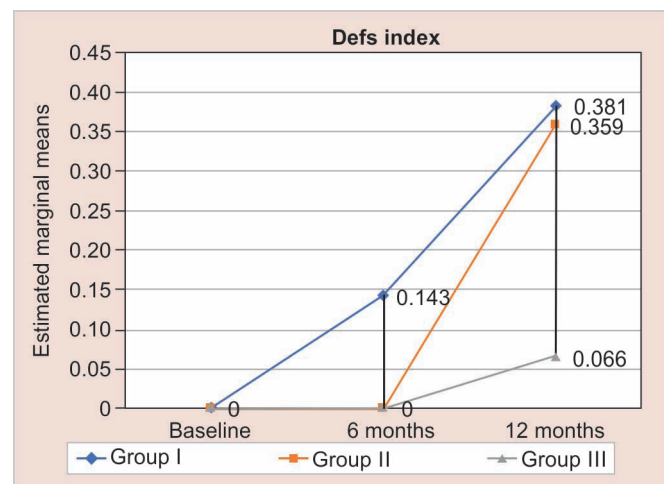


Fig. 1: Graphical Representation of mean difference in new carious lesions recorded by defs index in Group I (DIW), Group II (FV) and Group III (SDF).

(DIW) revealed that there was no significant difference seen from 6 to 12 months as the *p*-value was 1.000 which was >0.05. In group II (FV) it is observed that there was a highly significant difference at different intervals. From baseline to 6 months, 6 to 12 months, and from baseline to 12 months the *p*-value was 0.000. In group III (SDF) it revealed that there was a highly significant difference seen when compared from 6 to 12 months and baseline to 12 months, the *p*-value was 0.00. There was no significant difference seen from baseline to 6 months as the *p*-value was 0.74, which was >0.05 (Fig. 2).

Intergroup Comparison

In the following tabulations, new carious lesions status was compared between three groups at three different intervals of baseline, 6 months, and 12 months. It was compared on the basis of defs and ICDAS II indices (Table 1).

Number Needed to Treat (NNT) and Cost-effectiveness

The NNT was calculated between the groups with 95% confidence interval (CI) and the values are as follows—group I (DIW)—group II (FV) is 10.5; group I (DIW)—group III (SDF) is 3.9; group II

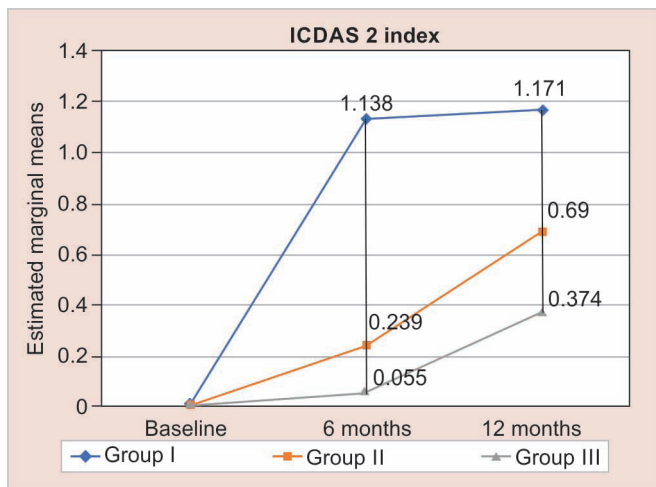


Fig. 2: Graphical representation of new carious lesions recorded by defs index in group I (DIW), group II (FV), and group III (SDF)

(FV)—group III (SDF) is 5.6. The costs of preventing caries were estimated using the number of participants, the number of product bottles/tubes used, and also the cost of the product. Cost per child and cost-effectiveness were calculated and are depicted in (Table 2).

DISCUSSION

The rationale of this randomized controlled trial was to evaluate the effectiveness of placebo, FV, and SDF among preschoolers aged between 3 and 6 years in preventing a healthy tooth from a new carious lesion. These new carious lesions were recorded by defs and ICDAS II indices at baseline, 6 and 12 months.

Burden of dental caries

Dental caries is the most common and globally seen chronic disease in children that interferes with regular intake of diet, speech, self-esteem, and everyday routine activities. A study conducted in Australia showed caries prevalence as 44.4% and a similar prevalence was reported in Brazil by Abanto et al.^{16,17} whereas, 26.2% was reported in Germany by Grund et al.¹⁸ In Asia, Adiatman et al.,¹⁹ Lin et al.,²⁰ and Chen et al.²¹ reported caries prevalence of 90.0, 81.0, and 55% in Indonesia, Taiwan, and Hong Kong, respectively. In India, dental caries was the tenth most prevalent disease in primary dentition, affecting 62.1 crore children.²² Caries prevalence in the 3–6 years group was 47.29% in Ghaziabad City,²³ 94.3% in Mangalore city aged 5–7 years,²⁴ and 32% in 3–5 years of Western Maharashtra.²⁵ As, from the above literature it can be associated that the prevalence of dental caries is high in children of all age groups but children below 5 years are adversely affected by ECC. Children usually are unaware of the appropriate brushing technique. Hence, it is difficult for children below 5 years to preserve good oral health. Ngatemi²⁶ observed that preschoolers do not

Table 2: Group wise calculation of cost of fluoride therapies per child and cost-effectiveness based on number of new carious lesion and number of total participants

Serial Number	Groups	Cost per child	Cost-effectiveness
1	Group I (DIW)	–	0.6
2	Group II (FV)	Rs. 145	0.5
3	Group III (SDF)	Rs. 59.2	0.3

Table 1: Intergroup comparison of new carious lesions status at 6 and 12 months using defs and ICDAS II index

Indices at each interval	(I) Group	(J) Group	Mean difference (I–J)	Significance ^b	95% CI for difference ^b	
					Lower bound	Upper bound
Defs (6 months)	Group I (DIW)	Group II (FV)	0.14286*	0.001**	0.0573	0.2284
	Group I (DIW)	Group III (SDF)	0.14286*	0.001**	0.0566	0.2291
	Group II (FV)	Group III (SDF)	0.00000	1.000	–0.0838	0.0838
Defs (12 months)	Group I (DIW)	Group II (FV)	0.02226	0.859	–0.2249	0.2694
	Group I (DIW)	Group III (SDF)	0.31502*	0.013*	0.0673	0.5628
	Group II (FV)	Group III (SDF)	0.29276*	0.02*	0.0507	0.5349
ICDAS II (6 months)	Group I (DIW)	Group II (FV)	0.88278*	0.000**	0.6498	1.1157
	Group I (DIW)	Group III (SDF)	1.08315*	0.000**	0.8484	1.3179
	Group II (FV)	Group III (SDF)	0.20037	0.085	–0.0278	0.4285
ICDAS II (12 months)	Group I (DIW)	Group II (FV)	0.48121*	0.001*	0.2034	0.7590
	Group I (DIW)	Group III (SDF)	0.79780*	0.000**	0.5193	1.0763
	Group II (FV)	Group III (SDF)	0.31659*	0.023*	0.0444	0.5887

**p* < 0.05 (significant difference), ** *p* < 0.01 (highly significant difference)

^badjustment for multiple comparisons: least significant difference (equivalent to no adjustments)



have the ability to brush their teeth properly proving the average value of children's tooth brushing skills of 5.67 which was recorded as poor. The second infectivity window is seen at the age of 6 years and the first permanent molars emerge in the oral cavity at the age of 6 years. As pediatric dentists, preserving permanent molars from caries becomes our essential task. Thus, 3–6 years of children have been included in the current research as they are more prone to ECC.

New Carious Lesion and its Association with Home Care Instructions

The established etiological factors of dental caries are host, intake of dietary sugars, time of exposure, and biofilm formation leading to lowering of pH, plaque accumulation, and demineralization.²⁷ So, to avoid plaque accumulation brushing at least twice a day is recommended. This demineralization of tooth or caries progression can be prevented by the dual effect of a home care regimen and in-office application of topical fluoride agents. In the present study, to maintain the standardized protocol all children were taught the Fones brushing technique, and the same dentifrice (Colgate Strong teeth Toothpaste) was distributed among children. Children who were not able to follow home care instructions were counted as dropouts so as to avoid compliance bias. Ashkenazi et al.²⁸ stated that there was a significant difference seen between brushing and new carious lesions in 651 children. Holmes²⁹ observed individuals who have brushed their teeth infrequently were at greater risk of new carious lesions occurring than those who brush more regularly. Hence, along with topical fluoride application, a home care regimen is equally crucial to maintain fluoride recharge. All the new carious lesions were recorded using defs and ICDAS II indices.

World Health Organization (WHO) and defs is a traditional and predominant index used in various epidemiological surveys. Though this index is widely accepted but is not reliable to evaluate initial caries as it fails to justify the progression of caries. Hence, along with defs, ICDAS II was also used in evaluating new carious lesions. ICDAS II assesses the severity and incidence of caries in its spectrum. As the index aims to understand the mechanism of initiation of dental caries and its progression. In accordance with our study, Honkala et al.¹³ ICDAS gives much more relevant information on caries progress than defs and WHO. Alves et al.³⁰ stated that the prevalence and extent of caries were mainly recorded by ICDAS and showed more precise results than any other caries detection criteria or index.

Intragroup Comparison

Group I (DIW) showed a decrease in the number of caries-free preschoolers respectively at 6 and 12 months follow-up, wherein 90.38 and 86.9% were caries-free based on defs index and 47.1 and 46.4% caries-free preschoolers using ICDAS II, respectively. Two aspects of these findings can be implicated, firstly; oral health counseling had an impact on child's psychology as they became aware of the possibility of preventing caries by brushing and application of certain agents. Secondly, appropriate oral home care by means of brushing with fluoridated dentifrice could be effective in caries prevention. This is suggestive of the partial success of the home care regime for caries prevention.

In group II (FV), at 6 months and 12 months, 96.8 and 79.3% were caries-free when recorded using defs in group II (FV). Whereas, when recorded using ICDAS II, 74.5 and 52.2% were caries-free at 6 and 12 months, respectively. The results of our study were in accordance with research conducted by Borutta et al.³¹ suggested that out of both the fluoride therapy groups, there was a substantial

increase in the initial caries lesions in the control group. Arruda et al.³² indicated that 5% sodium fluoride (NaF) varnish applications showed a significant difference in increments of defs score after 12 months of follow-up than control group. Contrary to our results, Oliveira³³ stated that there was no significant difference observed in the decrease of caries incidence after twice yearly professional FV application and control group. Muñoz-Millán³⁴ concluded that biannual FV application is not effective in preschoolers from rural non-fluoridated communities. Jiang³⁵ confirmed that adding 5% NaF in water, and hands-on instruction, had no additional impact on reducing the prevalence of ECC in young children with low-risk groups.

In group III (SDF), at 6 months and 12 months 97.8 and 92.5% were caries-free when recorded using defs in group III (SDF). Whereas, when recorded using ICDAS II, 92.5 and 72% were caries-free at 6 months and 12 months, respectively. According to American Academy of Pediatric Dentistry (AAPD),¹¹ caries arrest is a proven function of SDF but it can also be used to prevent the development of new carious lesions as shown in the present study. Chibinski et al.³⁶ stated that SDF when compared with placebos showed 89% more effectiveness in arresting caries. Gao et al.³⁷ reported that in primary teeth SDF was effective in arresting dentinal caries. Fung et al.³⁸ stated in primary teeth a concentration of 12% SDF is less effective than the concentration of 38%. Chu et al.³⁹ showed that SDF has antimicrobial activity against *Streptococcus mutans* cariogenic and *Actinomyces naeslundii*. On dentine surfaces, SDF slowed down demineralization. This may be considered as an explanation behind the clinical success of SDF.

Intergroup Comparison

At a 6-month interval, there was a highly significant difference seen between group I (DIW)—group II (FV) and group I (DIW) and group III (SDF) using both indices. At 12 months of interval group I (DIW)—group III (SDF) and group II (FV)—group III (SDF) showed significant differences after the evaluation was done using defs. In the present study, group III (SDF) > group II (FV) > group I (DIW). Hence, from the present study, it can be stated that SDF can be used for not only arresting but preventing caries. SDF contains 44,800 ppm of fluoride, which is higher than sodium FV (22,600 pp), thus this may be the reason for the effectiveness of SDF over sodium FV and DIW. According to AAPD,¹¹ various studies have consistently concluded that SDF is indeed more effective than FVs in arresting caries. SDF is also stated to have retained fluoride for around 2–3 times more than any other form of fluoride. Results of our studies were in accordance in terms of the effectiveness of SDF with Chu et al.⁴⁰ found that in preschool children, SDF was more effective than sodium FV in arresting dentine caries of primary anterior teeth. Chu et al.⁴¹ stated that 38% SDF solution and adjunctive application of 25% AgNO₃ solution with 5% NaF varnish can effectively arrest ECC. Trieu et al.⁴² observed that NaF was less effective than SDF in arresting caries. Yu⁴³ reported that the application of SDF with or without NaF decreased the demineralization of dentine caries, but SDF inhibited biofilm growth more strongly than NaF. Zhang⁴⁴ concluded that an annually applied 38% SDF solution combined with oral health education is most likely to be the most effective in the prevention of dental root caries among the professionally applied topical fluoride therapies. Duangthip et al.⁴⁵ the annual or three consecutive weekly SDF solution application is more successful than three consecutive weekly NaF varnish applications to arrest dentinal caries in primary teeth. On

contrary, Mohammadi⁴⁶ reported that SDF and FV showed no significant difference. Rather, they showed comparable efficacy in preventing deciduous anterior teeth from demineralizing.

Cost-effectiveness

Fluoride therapy is also a cost-effective treatment since it inhibits the growth of new carious lesions or halts the worsening of existing ones. The value of an efficient and economical fluoride treatment lies in how well it addresses the public health needs of a community. In the present study, researchers evaluated the impact of sodium FV and SDF by longitudinally investigating the relationship between its costs and utilization for pediatric patients.⁴⁷ The analysis identified that SDF was potentially more cost-saving than sodium FV. Since dental caries is ranked as the tenth most prevalent disease, the promotion of preventive measures for parents and their children must be enforced.

Limitations

- Further studies are needed with a large sample size and long-term follow-up.
- Dental treatment of caries wasn't performed in the present study due to the unavailability of an ambulatory operatory.

CONCLUSION

The present study was conducted with the aim to assess the effectiveness of fluoride therapies in preschoolers to prevent new carious lesions. The results of the present study compared and evaluated the effect of SDF and sodium FV.

The following conclusions can be drawn:

- Biannual topical fluoride therapies in preschoolers can be used as effective caries prevention measures. Group III (SDF) showed a highly significant difference in preventing the development of new carious lesions than group II (sodium FV).
- Home-care regimens have great importance for caries prevention and brushing twice a day along with fluoride therapies have given significant outcomes.
- The use of SDF to prevent dental caries appears to be the most cost-saving fluoride therapy.

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SUPPLEMENTARY TABLES

Table S1: Mauchly's Test of sphericity within groups for defs index

Group	Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^b		
						Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Group I (DIW)	defs	.164	148.251	2	0.000**	.545	.546	.500
Group II (FV)	defs	.000	.	2	.	.500	.500	.500
Group III (SDF)	defs	.000	.	2	.	.500	.500	.500

**P < 0.01 (Highly Significant difference)

Table S2: Assessment of Intercepts and errors by Tests of between subjects' effects for defs index

Group	Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Group I (DIW)	Intercept	7.683	1	7.683	9.155	0.003
	Error	69.651	83	.839		
Group II (FV)	Intercept	3.946	1	3.946	16.530	0.000
	Error	21.721	91	.239		
Group III (SDF)	Intercept	.132	1	.132	2.022	0.158
	Error	5.868	90	.065		

Table S3: Intragroup comparison of Group A (DIW), Group B (FV), and Group C (SDF) on caries status at baseline, 6-months and 12-months using defs (Decayed Exfoliated Filled Surfaces) index

Group	Follow-up of Intervals		Mean Difference (I-J)	Sig. ^b	95% Confidence Interval for Difference ^b	
	(I) defs	(J) defs			Lower Bound	Upper Bound
Group I (DIW)	Baseline	6 months	-0.143*	0.040	-0.281	-0.005
	6 months	12 Months	-0.238*	0.004*	-0.412	-0.064
	Baseline	12 Months	-0.381*	0.006	-0.673	-0.089
Group II (FV)	Baseline	6 months	0.000	0.000**	0.000	0.000
	6 months	12 Months	-0.359*	0.000**	-0.574	-0.144
	Baseline	12 Months	-0.359*	0.000**	-0.574	-0.144
Group III (SDF)	Baseline	6 months	0.000	0.000**	0.000	0.000
	6 months	12 Months	-0.066	0.475	-0.179	0.047
	Baseline	12 Months	-0.066	0.475	-0.179	0.047

P* < 0.05 (Significant Difference)Table S4:** Mauchly's Test of sphericity within groups for ICDAS 2 index

Group	Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^b		
						Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Group I (DIW)	ICDAS	.195	133.893	2	0.000**	.554	.556	.500
Group II (FV)	ICDAS	.638	40.443	2	0.000**	.734	.743	.500
Group III (SDF)	ICDAS	.258	120.607	2	0.000**	.574	.577	.500

***P* < 0.01 (Highly Significant difference)**Table S5:** Assessment of Intercepts and errors by Tests of between Subjects effects for ICDAS 2 index

Group	Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Group I (DIW)	Intercept	149.349	1	149.349	70.781	0.000
	Error	175.131	83	2.110		
Group II (FV)	Intercept	26.486	1	26.486	77.691	0.000
	Error	31.024	91	.341		
Group III (SDF)	Intercept	5.571	1	5.571	24.903	0.000
	Error	20.135	90	.224		

Table S6: Intragroup comparison of Group A (DIW), Group B (FV), and Group C (SDF) on caries status at baseline, 6-months and 12-months using ICDAS 2 (International Caries Detection and Assessment System) index

Group	Follow-up of Intervals		Mean Difference (I-J)	Sig. ^b	95% Confidence Interval for Difference ^b	
	(I) defs	(J) defs			Lower Bound	Upper Bound
Group I (DIW)	Baseline	6 months	-1.138*	0.000**	-1.487	-0.789
	6 months	12 Months	-0.033	1.000	-0.127	0.060
	Baseline	12 Months	-1.171*	0.000**	-1.499	-0.844
Group II (FV)	Baseline	6 months	-0.239*	0.000**	-0.348	-0.130
	6 months	12 Months	-0.451*	0.000**	-0.644	-0.258
	Baseline	12 Months	-0.690*	0.000**	-0.890	-0.491
Group III (SDF)	Baseline	6 months	-0.055	0.074	-0.114	0.004
	6 months	12 Months	-0.319*	0.000**	-0.505	-0.132
	Baseline	12 Months	-0.374*	0.000**	-0.563	-0.184

***P* < 0.01 (Highly Significant difference)^bBaseline to 12-months the *p*-value were 0.000.