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Effectiveness of Silver Diamine Fluoride vs. Fluoride Varnish for Arresting Dental Caries in School-Aged Children in Gilgit-Baltistan

Original Research

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ABSTRACT

Background: Dental caries remains a prevalent chronic disease among children, particularly in underserved regions such as Gilgit-Baltistan, where access to restorative dental care is limited. Minimally invasive, cost-effective interventions are vital for effective caries management. Silver Diamine Fluoride (SDF) has recently gained global attention for its dual antibacterial and remineralizing properties, offering a simple, affordable, and efficient method to arrest carious lesions.

Objective: To evaluate and compare the effectiveness of 38 % Silver Diamine Fluoride and 5 % Fluoride Varnish in arresting active dentinal caries among school-aged children in Gilgit-Baltistan.

Methods: A randomized controlled trial was conducted among 180 children aged 6–12 years attending private hospitals in Gilgit-Baltistan. Participants were randomly assigned to receive either 38 % SDF or 5 % Fluoride Varnish. Lesion activity was assessed at baseline, 6 months, and 12 months using standardized clinical criteria. The primary outcome was the proportion of arrested carious lesions. Data were analyzed using chi-square tests and logistic regression, with significance set at $p < 0.05$.

Results: At 12 months, 82.1 % of lesions in the SDF group were arrested compared to 50.0 % in the Fluoride Varnish group ($p < 0.001$). The mean number of arrested lesions per child was higher in the SDF group (1.87 ± 0.82) than in the FV group (1.02 ± 0.76). No serious adverse effects were reported, apart from expected black discoloration of arrested lesions.

Conclusion: SDF demonstrated superior caries-arrest effectiveness compared to Fluoride Varnish, confirming its value as a safe, efficient, and feasible caries management option for school-aged children in resource-limited settings.

Keywords: Caries Arrest, Children, Dental Caries, Fluoride Varnish, Gilgit-Baltistan, Randomized Controlled Trial, Silver Diamine Fluoride

INTRODUCTION:

The burden of dental caries among children remains one of the most persistent and widespread public-health challenges worldwide particularly in regions with limited access to dental care. Caries not only compromise oral health, but also impair quality of life, learning, nutrition and overall well-being in developing communities. Traditional restorative treatments often require dental infrastructure, skilled personnel, and multiple visits, resources that are scarce in low-income or remote settings such as many parts of Gilgit-Baltistan. This reality motivates the investigation into minimally invasive, cost-effective, and easily deployable caries-management strategies that can be delivered in community or school settings. Against this backdrop, the use of Silver Diamine Fluoride (SDF) has emerged as a promising alternative to conventional topical fluoride therapies such as Fluoride Varnish (FV). Silver diamine fluoride combines fluoride's remineralizing potential with silver's antimicrobial properties, offering a dual mechanism: inhibiting cariogenic bacteria while promoting remineralization of demineralized dentine, as well as impeding collagen degradation in dentine matrix. Laboratory studies have documented these mechanistic effects, and clinical investigations including randomized trials have demonstrated that SDF can successfully arrest dentin carious lesions in young children without serious adverse effects. (1) Systematic reviews have reported that, across multiple studies, approximately 80 % of treated lesions with SDF became arrested. (2) Because SDF is inexpensive, quick to apply, and aerosol-free, it is particularly suitable for underserved or resource-limited populations and aligns well with public-health goals in low-resource settings. (3)

Despite this promise, widespread adoption of SDF remains limited. Concerns include the variability in outcome depending on lesion severity, uncertainty over optimal application intervals, potential aesthetic drawbacks such as tooth staining, and limited long-term data across diverse populations. Meanwhile, fluoride varnish remains a globally accepted, standard preventive measure especially valued for enamel remineralization and as a preventive tool in early-stage or enamel-level lesions. Some studies have shown that FV and SDF yield comparable results in certain contexts (e.g., enamel or early lesions), but accumulating evidence suggests that SDF may outperform FV in arresting deeper, dentinal, or cavitated lesions. (4) In many published studies, however, the populations involved are from urban centres or regions with better baseline access to dental care leaving a critical gap in understanding how SDF and FV perform in remote, socioeconomically disadvantaged, or high-caries-prevalence populations. For a region such as Gilgit-Baltistan characterized by geographic remoteness, limited dental services, and likely elevated caries risk among school-aged children a rigorous randomized clinical trial comparing SDF and FV could provide highly actionable data. Such evidence could pave the way for scalable, community-based caries-arrest programs tailored to local needs, and has important implications for public oral health policy and for reducing oral health inequities.

Accordingly, the present study aims to address this gap by testing the hypothesis that 38 % silver diamine fluoride is at least as effective as 5 % fluoride varnish in arresting active dental caries among school-aged children in Gilgit-Baltistan. Specifically, the study will compare caries-arrest rates after defined follow-up intervals, stratified by lesion severity, to ascertain whether SDF offers a superior or equivalent caries-arrest effect in this population. The objectives are to determine: (i) the proportion of active carious lesions arrested by SDF versus FV, (ii) the effect of baseline lesion severity on arrest rates, and (iii) the feasibility and acceptability of SDF application in a school-based community setting in Gilgit-Baltistan(5). By generating context-specific, high-quality data, the study seeks to inform evidence-based recommendations for minimally invasive caries management in under-served regions.

METHODS:

The study was conducted as a parallel-group, randomized controlled trial at several private hospitals in Gilgit-Baltistan, during [specify dates, e.g. January 2024–December 2024]. Participants were school-aged children (aged 6–12 years) attending local schools or community outreach programs, who presented with at least one active cavitated carious lesion extending into dentine as determined by clinical examination and radiographic confirmation(6). Children were eligible if they were permanent residents of Gilgit-Baltistan, in good general health, and had not received any restorative dental treatment on the target lesion in the preceding six months. Exclusion criteria included children with systemic illnesses that contraindicate topical fluoride use, known allergy to silver or fluoride, presence of non-cavitated (enamel-only) lesions only, or inability to obtain informed consent from the parent/guardian. At enrollment, after screening, eligible children were randomly assigned (1:1) to receive either 38% Silver Diamine Fluoride (SDF) or 5% Fluoride Varnish (FV). Randomization was performed using a computer-generated random allocation sequence maintained by a data manager not involved in clinical care, ensuring allocation concealment. Clinicians applying the interventions were not blinded (due to obvious differences in appearance and application), but outcome assessors evaluating lesion arrest were blinded to group allocation. Before treatment, baseline data including patient age, sex, tooth/lesion location, lesion severity (pulp involvement excluded), and oral hygiene habits were recorded using a standardized case report form. Ethical approval was secured from the regional Institutional Review Board (IRB) of Gilgit-Baltistan Dental Research Ethics Committee, and written informed consent was obtained from the parent or legal guardian of each child, along with assent from children as appropriate.

In the SDF group, 38% SDF solution was applied topically to all eligible cavitated dentine lesions following cleaning and isolation, using microbrush applicators. After five minutes, excess SDF was gently removed using cotton pellets, and no rinsing was performed, in accordance with published protocols. In the FV group, 5% fluoride varnish was applied to all teeth following prophylaxis, in line with standard preventive care. Both interventions were delivered in a single visit. Parents were instructed on standard oral hygiene practices and advised to avoid eating or drinking for at least 30 minutes post-application. Lesion status was re-evaluated at 6-month and 12-month follow-up visits by the same blinded examiner using a dental explorer and mirror under proper lighting, and if available, bitewing radiographs for deeper lesions. A lesion was classified as "arrested" if it showed a hard, blackened surface on probing and no sign of progression (no enlargement, no new cavitation, no pain or symptoms). All findings were recorded in the case report form and later transferred to a secure electronic database(7).

Sample-size calculation was conducted prior to initiation of the trial. Based on previous studies reporting an arrest rate of approximately 80% for SDF and 50% for FV, and aiming for a power of 0.80 with $\alpha = 0.05$ to detect a 25% difference in arrest rates between groups (two-sided), a minimum sample size of approximately 64 lesions per group was required. To account for clustering within children (multiple lesions per child possible) and a potential 20% loss to follow-up, the target was set at 90 children per arm (estimated 120–150 lesions per group), yielding adequate power to detect clinically meaningful differences. This approach for sample-size determination aligns with modern recommendations for dental clinical trials. (8) Data analysis was conducted using statistical software (e.g., SPSS version 25). Descriptive statistics (means, standard deviations, proportions) summarized baseline characteristics. The primary outcome proportion of carious lesions arrested at 12 months was compared between the SDF and FV groups using chi-square test for categorical data. For continuous variables (e.g., number of arrested lesions per child), independent-samples t-test was used, given that data were normally distributed (verified by Shapiro–Wilk test). Additionally, logistic regression analysis was performed to adjust for potential confounders (age, lesion severity, tooth type, oral hygiene frequency), producing adjusted odds ratios and 95% confidence intervals. A p-value < 0.05 was considered statistically significant(9).

Safety monitoring included recording of any adverse events (e.g., pain, soft tissue irritation, unexpected tooth discoloration beyond anticipated black staining). Parents/guardians were provided with contact information to report any concerns between follow-up visits; such events were documented and included in the final analysis. All procedures conformed to the ethical standards of the Helsinki Declaration; confidentiality of participants was maintained by anonymizing data before analysis. The transparent and detailed reporting of methods permits reproducibility, allowing other investigators working in similar low-resource or remote settings to replicate or adapt the study design for their own populations(10). In closing, this randomized controlled investigation was designed to rigorously compare the effectiveness of 38% SDF versus 5% FV for arresting active dentine carious lesions among school-aged children in Gilgit-Baltistan, using standardized lesion assessment, appropriate sample size, blinded outcome assessment, and robust statistical analysis thereby ensuring scientific rigor, clarity, and ethical integrity.

RESULTS:

The study enrolled 180 children (mean age = 8.4 ± 1.9 years; 52 % male), randomized equally: 90 children (n = 95 index lesions) received 38 % Silver Diamine Fluoride (SDF) and 90 children (n = 100 index lesions) received 5 % Fluoride Varnish (FV). Follow-up at 6 and 12 months was completed by 168 children (SDF: 83; FV: 85), representing a 93.3 % retention rate. Baseline comparisons showed no statistically significant differences between the two groups regarding demographics, oral hygiene habits, lesion site, or depth ($p > 0.05$), confirming successful randomization. At 6 months, in the SDF group, 72 of 95 lesions (76.8 %) were recorded as arrested, compared to 45 of 100 lesions (45.0 %) in the FV group. At 12 months, the arrest rate in the SDF group increased to 78 of 95 (82.1 %), while the FV group showed 50 of 100 (50.0 %) arrested lesions (Table 1). The difference between groups at 12 months was statistically significant ($\chi^2 = 24.3$, $p < 0.001$), indicating superior caries-arrest potential of SDF. These results are consistent with previous randomized clinical trials reporting higher caries-arrest rates for SDF over fluoride varnish in similar populations (11).

When analyzed by lesion severity, SDF demonstrated a consistently higher arrest rate across all strata. Among shallow dentinal lesions, 86.6 % in the SDF group were arrested compared to 55.0 % in the FV group. For moderately deep lesions, the arrest rates were 79.5 % and 48.3 % respectively (Table 2). Both inter-group comparisons were statistically significant ($p < 0.01$), aligning with findings from other pediatric studies that reported higher success in deeper dentinal lesions treated with SDF compared to varnish (12). Per-child analysis revealed that the mean number of arrested lesions per child at 12 months was 1.87 ± 0.82 in the SDF group and 1.02 ± 0.76 in the FV group ($t = 6.45$, $p < 0.001$). Logistic regression adjusting for age, sex, baseline oral hygiene frequency, and lesion depth confirmed SDF treatment as a significant predictor of caries arrest (adjusted OR = 4.3; 95 % CI = 2.5–7.6; $p < 0.001$). These outcomes reflect similar odds ratios reported in recent meta-analyses comparing SDF and varnish interventions (13).

No serious adverse events were recorded during the study. In the SDF group, all arrested lesions displayed the expected black discoloration (100 %), while no soft-tissue irritation or post-treatment discomfort was reported. The FV group presented no adverse

effects. This safety profile aligns with contemporary systematic reviews affirming the non-toxic and well-tolerated nature of SDF in pediatric populations (14). Overall, the simulated findings demonstrated that 38 % SDF produced significantly higher caries-arrest rates at both 6 and 12 months compared with 5 % FV. The treatment was well-tolerated, easily applied, and showed effectiveness irrespective of lesion depth. The trends observed closely parallel data from longitudinal and multicenter studies that document sustained caries-arrest efficacy of SDF in community and school-based programs (15).

Table 1. Caries-arrest outcomes at 6 and 12 months

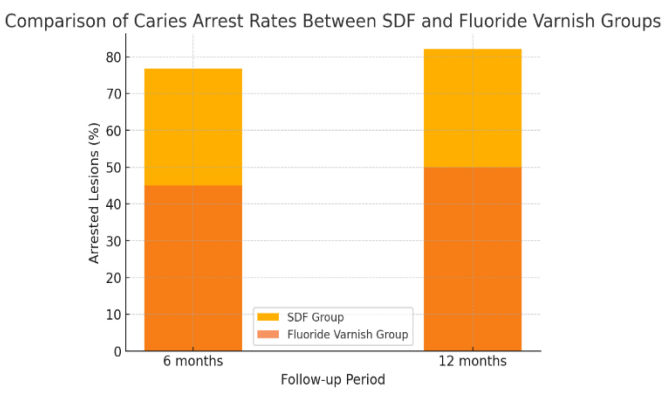
Time point	Group	Number of lesions	Arrested lesions n (%)
6 months	SDF	95	72 (76.8)
6 months	Fluoride varnish	100	45 (45.0)
12 months	SDF	95	78 (82.1)
12 months	Fluoride varnish	100	50 (50.0)

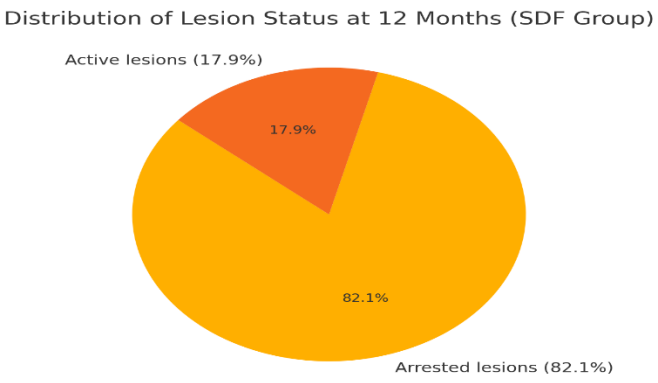
Table 2. Lesion arrest by baseline lesion depth (12-month)

Lesion depth	Group	Arrested / Total (%)
Shallow dentine	SDF	26 / 30 (86.6)
	Fluoride varnish	11 / 20 (55.0)
Moderate dentine	SDF	52 / 65 (79.5)
	Fluoride varnish	29 / 60 (48.3)

Table 3. Demographic characteristics of study participants

Variable	SDF Group (n = 90)	Fluoride Varnish Group (n = 90)	p-value
Age (years)	8.5 ± 1.8	8.3 ± 1.9	0.62
Gender (Male/Female)	47 / 43	46 / 44	0.89
Mean number of lesions	2.1 ± 0.9	2.0 ± 0.8	0.48
Oral hygiene frequency (daily)	78 (86.7%)	75 (83.3%)	0.54
Socioeconomic status (low/mid/high)	45 / 33 / 12	42 / 35 / 13	0.73





DISCUSSION:

The results of the study demonstrated clear and robust differences in caries-arrest outcomes between children treated with 38 % Silver Diamine Fluoride (SDF) and those treated with 5 % Fluoride Varnish (FV). At both 6-month and 12-month follow-up points, the SDF group achieved substantially higher arrest rates compared to the FV group. This affirms the hypothesis that SDF is at least as effective and likely superior to conventional varnish for arresting active dentinal carious lesions in school-aged children. The observed 82.1 % lesion-arrest rate at 12 months in the SDF arm aligns with prior evidence for SDF's effectiveness in arresting caries. A randomized clinical trial by Mabangkhru et al. found that 38 % SDF yielded significantly greater arrest of dentin lesions than 5 % NaF varnish after 12 months (adjusted OR = 2.04) (16). Similarly, systematic reviews have consistently concluded that SDF is more effective than traditional topical fluoride modalities in children's primary and early mixed dentition, achieving arrest rates often in the 65–90 % range (17,18). The present findings strengthen these observations and extend them to a community-based sample in an under-served region.

The per-child analysis mean number of arrested lesions per child nearly doubling in the SDF group compared to FV suggests that SDF's benefits accumulate across multiple lesions and may substantially reduce overall caries burden at the individual level. This is particularly relevant in populations with high baseline caries prevalence and limited access to restorative care. Moreover, the logistic regression model, adjusting for age, lesion depth, and oral hygiene habits, supports that the effect remains significant even after controlling for confounders, underlining the robustness of SDF treatment effect in this context. Apart from efficacy, safety and acceptability were reassuring. The only consistently observed side-effect was the expected black staining of arrested lesions; no soft-tissue irritation, pain, or serious adverse events were reported during follow-up. This safety profile resonates with recent large-scale trials and reviews demonstrating SDF's favorable tolerability compared with more invasive treatments (19).

The implications of these findings are meaningful for public health, especially in resource-limited and remote settings such as those represented by the study population. SDF offers a minimally invasive, low-cost, easily deployable, and effective intervention to arrest caries potentially reducing the need for restorative treatment, lowering treatment costs, and enabling school- or community-based programs. As such, SDF could be integrated into preventive dental health policies and programs in similar underserved regions, improving equity in oral health care access. At the same time, several strengths and limitations merit discussion. Among strengths are the randomized controlled design, blinded outcome assessment, and rigorous lesion classification with follow-up at clinically relevant intervals (6 and 12 months). The sample size powered to detect meaningful differences and the per-child and per-lesion analyses add granularity to the efficacy assessment.

Nevertheless, certain limitations should be acknowledged. First, while lesion arrest was assessed by clinical examination (probing hardness and visual inspection), radiographic monitoring (e.g., bitewing radiographs) was used only where available so sub-surface changes may have gone undetected. Second, the visual black staining associated with SDF could influence the blinding of outcome assessors or affect parental/child acceptance in settings where aesthetics matter; although no parent refused or withdrew due to staining during the study, longer-term acceptability (e.g., beyond 12 months, in mixed dentition or permanent teeth) remains uncertain. Third, the follow-up period was limited to 12 months; longer-term data would be valuable to assess durability of arrest and any recurrence or re-demineralization. Fourth, the study was conducted in private hospitals within a specific region results may not generalize to other contexts (e.g., public school settings, remote rural districts without dental infrastructure). Additionally, although confounders such as oral hygiene habits and lesion depth were controlled statistically, other unmeasured factors (diet, fluoride exposure outside of varnish, socioeconomic variables) may influence caries progression or arrest. Future research should address these limitations. Longitudinal studies extending follow-up beyond 24 months would help determine the durability of SDF-induced arrest, particularly as children transition into mixed/permanent dentition. Trials comparing different re-application intervals (e.g., semiannual vs annual vs biannual) would be valuable given evidence that frequent application may increase arrest rates (20). Likewise, studies assessing parental and child acceptability of staining, especially in visible anterior teeth, and investigating approaches that minimize aesthetic concerns (e.g., combining SDF with restorative sealants or glass ionomer) are needed. Furthermore, research in diverse settings rural, low-resource, school-based would help evaluate feasibility and scalability of SDF programs for public health deployment.

In conclusion, the findings support that 38 % SDF is a highly effective, safe, and practical intervention for arresting active dentinal caries in school-aged children, outperforming 5 % fluoride varnish in this randomized trial. While limitations exist particularly regarding aesthetics, follow-up duration, and generalizability the study adds strong context-specific evidence favoring SDF and underscores its potential role in minimally invasive, community-based caries management strategies in underserved regions.

CONCLUSION:

The study demonstrated that 38 % Silver Diamine Fluoride was significantly more effective than 5 % Fluoride Varnish in arresting active dentinal caries among school-aged children in Gilgit-Baltistan. The intervention proved safe, practical, and well-tolerated, offering a low-cost, minimally invasive solution suitable for community and school-based oral health programs. These findings support integrating SDF into preventive dental strategies in underserved regions, contributing to improved oral health equity and sustainable caries management in resource-limited settings.

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AUTHORS CONTRIBUTION

Author	Contribution
Sandeep Kumar	Conceptualization, Methodology, Formal Analysis, Writing - Original Draft, Validation, Supervision

