

A Comparative Study to Evaluate the Effectiveness of Silver Diamine Fluoride at Different Time Durations of Application in Treating Carious Primary Teeth: A Randomized Trial

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ABSTRACT

Background and objectives: Ideally every child must have access to preventive and restorative care of greater quality. However, in rural areas, resources and dental care services are limited. Silver diamine fluoride (SDF) has been identified as an efficient topical cariostatic and preventive medicament for managing ECC in children who cannot be treated conventionally. Since SDF is an emerging alternative for caries prevention and arrest, AAPD recommends more practice-based research to evaluate its efficacy. The aim of this study was to evaluate the effectiveness of silver diamine fluoride at different time durations of application in treatment of carious primary teeth in children with least access to dental care.

Methodology: This was a prospective, randomized, field trial that included patients with primary tooth. Primary tooth presenting carious lesion in ICDAS 3–6 category were randomly assigned to one of the three groups.

Results: At 3-week mean rank of lesions arrested in Group 1 and Group 2 were 73.3 and 72.29, whereas it was 86.9 in case of Group 3. At 6 months it was 79.15, 77.29, and 75.96 in Group 1, 2, and 3, respectively ($p > 0.05$).

Conclusion: SDF is effective in controlling caries progression in both cavitated and non-cavitated lesion with minimal time duration of application (30 seconds). This approach may be of great utility as an alternative to other expensive preventive and therapeutic methods in communities with limited resources. Nonetheless obtaining caregiver consent is mandatory.

Keywords: Deciduous molars caries, Duration of application, ICDAS, Primary tooth, Seconds, Silver diamine fluoride.

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INTRODUCTION

Regardless of sociodemographic factors, conventional dental restorative treatment may not always be affordable or available to entire community. In addition, successful outcome of early childhood caries (ECC) management relies on the cooperation of the child. Until every child get access to high quality dental treatment, there is still a necessity for substitute technique that are easier and more satisfactory to dentist, children and their parents.

Contemporary caries management philosophy has changed from the traditional surgical approach to an adjunct of medical model, which often includes the use of fluoride, chlorhexidine, and sealants.^{1,2} Among them silver diamine fluoride (SDF) has been identified as potential cost-effective, simple, safe, topical cariostatic, and preventive medicament.³ It has been recommended by AAPD in case of, difficult-to-treat lesions and patients with high caries risk, including those with medical or behavioral complications, those who require multiple treatment visits, or those without access to dental care.² It was also used as a caries-preventing agent, as well as a cavity sterilizing agent and dentin desensitizer.⁴

Although studies have demonstrated that SDF is effective in treating dental caries, the mechanism of action is unclear. It is the combined effects of silver and fluorides that have been hypothesised to have the ability to halt caries progression and prevent the development of new caries simultaneously.^{5,7} The possible mode of action of SDF for arresting caries may be attributed to its promotion of mineral remineralization, inhibition of mineral demineralization, and protection of the collagen matrix from degradation.⁵ Studies suggest that one drop of SDF orally would result in less fluoride ion exposure than 0.25 mL topical

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treatment of fluoride varnish, which is the recommended topical fluoride therapy for young children. The main drawback of SDF is its esthetic result, it will permanently blackens enamel and dentinal caries lesions and creates a temporary henna-like tattoo if comes in contact with skin.⁶

Since SDF is an emerging alternative for caries prevention and arrest, treatment guidelines are still to develop based on evidence based research. Very few studies assessing the effect of SDF as a caries control agent using ICDAS (International Caries Detection and Assessment System)⁸ criteria have been reported in literature.⁹

According to AAPD guidelines, one of the indication for SDF application is, children without access to or with difficulty in accessing dental care. Therefore, socially deprived communities were selected to conduct the study with permission from The

Director of Department of Child And Women Welfare, Himachal Pradesh (H.P.), India.

This study aimed to evaluate the effectiveness of SDF at different time durations of application in treatment of carious primary teeth which are categorized according to ICDAS criteria.

METHODOLOGY

Initial screening for dental caries was done among children attended the oral health care camps conducted at three different locations. A total of 35 children from a rural community at Rohru (H.P.) and 14 from two orphanages in Shimla were included in the baseline screening.

Inclusion Criteria

- Deciduous molar with carious lesion as defined by the ICDAS criteria; restoration/sealant code (first digit-0) and which are limited to dentin.
- Deciduous molar with active untreated non-cavitated carious lesion belonging to ICDAS caries code (second digit 3 and 4) and cavitated carious lesion belonging to ICDAS caries code (second digit 5 and 6).
- Teeth which are not near to its exfoliation age or free from pathologic mobility.

The procedure and its possible discomforts and benefits were explained to the parent/care taker of the children and consent was obtained prior to the treatment. The patients enrolled for the present study were randomly allotted to one of the three groups by the envelope draw method. When multiple teeth falling in inclusion criteria are present in a single patient, the next tooth was allotted to the successive group. Included patients and tooth were designated numbers so as to allow future comparison and study purpose. Moreover, all individuals was provided orientation about dietary and oral hygiene habits.

The teeth were randomly allocated into three groups based on time duration of SDF application:

- In group 1, applied silver diamine fluoride was allowed to absorb for 30 seconds.
- In group 2, applied silver diamine fluoride was allowed to absorb for 60 seconds.
- In group 3, applied silver diamine fluoride was allowed to absorb for 120 seconds.

Each group is further categorized into subgroups according to ICDAS criteria as:

- Subgroup 1-ICDAS 5 and 6 (Cavitated lesion).
- Subgroup 2-ICDAS 3 and 4 (Non-cavitated lesions).

Clinical Procedure of SDF Application

One drop of the 38 % SDF (FAGamin) solution was placed in a small plastic dappen dish. An applicator tip was dipped and dampened on the side of the dappen dish to remove excess liquid. Specifically identified tooth was dried and a noninvasive probe (CPITN) was used to detect and confirm visual evidence of caries. Site was isolated with gauze and cotton rolls and carious lesion is gently brushed with the applicator tip dipped in SDF. AAPD guidelines and manufacturer's directions was followed while application of SDF. Material was allowed to absorb as per predetermined time interval (Group 1-30 seconds, Group 2-60 seconds, and Group 3-120 seconds). During this period lesion is kept isolated and

dried with a gentle flow of air using a chip blower. Excess material was removed with cotton pellet to minimize systemic absorption.

As per previous clinical trials on SDF following clinical criteria were evaluated at 3 week, 3 months, and 6 months:¹⁰

- Dentin color
- Lesion texture

The presence or absence of pain and infection was noted at baseline and at each recall visit using examination and parent interview.

Positive Outcomes: Dark, hard, and black lesions with no pain or infection (inactive or arrested) were considered positive outcomes.

Treatment Failure: Progression of the lesion, a yellow, brown, soft lesion with or without pain or infection (active lesion) indicated treatment failure.

Statistical Analysis

The collected data were tabulated and statistically analyzed using Windows IBM SPSS 20.0.

Chi-square test, Kruskal Wallis test followed by Man-Whitney Test as a *Post Hoc* Test was used to interpret the results.

The null hypothesis was set as there is no significant difference between the results of three groups, that is, $\eta_1 = \eta_2 = \eta_3$. Whereas alternative hypothesis was there is a significant difference between the results of three groups, that is, $\eta_1 \neq \eta_2 \neq \eta_3$. The decision criteria was to reject the null hypothesis if the *p*-value is less than 0.05.

RESULTS

A total of 176 deciduous molars in 49 children were included to participate in the study. Out of which twenty two teeth were excluded from study due to drop out. Finally, a total of 154 deciduous molar were available with complete 6 months follow-up. Among them the percentage of lesions got arrested at 3 week, 3 months, and 6 months were 70.13% ($n = 108$), 83.77% ($n = 129$), 97.4% ($n = 150$), respectively. In Group 1, Group 2, and Group 3, at the end of 6 months, the percentage of caries arrest were 33.12% ($n = 51$), 31.81% ($n = 49$), 32.47% ($n = 50$), respectively. Among them 51.9 % lesions belongs to subgroup 1 (ICDAS 5 and 6) criteria whereas 45.5 % belongs to subgroup 2 (ICDAS 3 and 4).

Table 1 summarizes lesions arrested according to duration of SDF application at each visit.

Although the caries arrest was higher in Group 3 compared to Group 1 and Group 2, this difference was not statistically significant ($p > 0.05$) (Table 1). Further evaluation was done on lesions arrested in each ICDAS criteria according to duration of application of SDF (Table 2). However no significant difference in the lesions arrested was found ($p > 0.05$).

DISCUSSION

This randomized clinical study compared the efficacy of different time duration of SDF application in arresting active caries lesions in the primary tooth. Among 42 children included in the present study 76.2% were males whereas 23.8% were females. The reason for this statistically significant disproportionality in male and female ratio is due to participation of orphanages incorporated male children only. The mean age of children participated in the study was 7.55 ± 2.34 years. Although AAPD recommends 1 minute application of SDF, literature reported studies with time duration ranges from 10 seconds to 3 minutes (Table 3). On literature review we found only very few studies regarding the caries arrest rate of SDF evaluated under ICDAS criteria. In

addition only one study was reported in the literature comparing the caries arresting efficacy of SDF at different time duration of application, in which, although the targeted SDF exposure time was 120 seconds, the reduced cooperation levels of the children ensued in an exposure of 30, 45, 60, 75, 90, and 120 seconds in different candidates.¹⁰

In the present study though the caries arrest rate was higher with 120 seconds duration of SDF application as compared to 30 seconds and 90 seconds, this difference was not statistically significant ($p > 0.05$). This result is in accordance with the study conducted by Clemens et al. They reported 100% caries arrest with 30 and 90 seconds application duration and 97.3% with 120 seconds. However efficiency of caries arrest does not varied significantly in different time duration of application.¹⁰

Cooperation level in young children varies significantly, which further determine the duration of time the carious tooth can be isolated for SDF absorption without saliva contamination. Our result suggest that a minimally cooperative patient should not be a contraindication to SDF use, especially if isolation of the tooth for at least 30 seconds is possible. However Horst recommends longest possible absorption time as it have an additional advantage of decreasing concerns about systemic absorption and need of removing SDF with a posttreatment rinse.³ Removing any excess material with the same cotton used to isolate also minimize systemic absorption.

As per present study a statistically significant higher arrest rate was seen with 30 and 60 seconds application at 6th month and the least at 3rd week ($p < 0.05$). 120 second applied group also showed higher arrested lesions at 6th month but this difference was not statistically significant ($p > 0.05$). As per a previous study when biofilm was exposed to 1,000 ppm fluoride solution, exposure of up to 120 seconds increased plaque surface fluoride concentrations only, while 30-minute exposure allowed penetration of fluoride to 900 micrometer into the plaque.¹⁸ This explains the possible variation in arrest rate with different time duration, if at all significant. However, clinical relevance or practicality of a 30-minute exposure is disputed, apart from placement of high concentration. Even though Clemens et al. followed a similar methodology, no data is available regarding recall visits except for the final result (6 months). Nonetheless our result is in accordance with a current review which states that application time in clinical studies does not correlate to outcome.³

Present study groups are categorized with ICDAS criteria based on lesion extension and the effectiveness (caries arrest) of different time duration of application of SDF is compared within the subgroups. Results indicated that time duration of application does not have significant difference in caries arrest rate within cavitated (ICDAS 5 and 6) and non-cavitated lesion (ICDAS 3 and 4) at none of the recall visit ($p > 0.05$). These results were in accordance with that reported by Clemens et al. In an another study although the investigators reported, results for proximal, occlusal, and

Table 1: Lesions arrested according to duration of SDF application at each visit

	Duration	N	No. of lesions arrested	Mean rank	χ^2	p value
3rd week	Group 1	54	33	73.33	5.659	0.059
	Group 2	49	32	72.29		
	Group 3	51	43	86.92		
3rd month	Group 1	54	41	74.31	2.379	0.304
	Group 2	49	41	75.86		
	Group 3	51	47	82.45		
6th month	Group 1	54	51	79.15	0.821	0.663
	Group 2	49	49	77.29		
	Group 3	51	50	75.96		

Table 2: Lesions arrested in each ICDAS criteria according to duration of application of SDF

		6th month		Total	χ^2	p value
		Not arrested	Arrested			
Subgroup 1	Group 1	1 (50.0 %)	27 (33.7%)	28 (34.1%)	0.439	0.803 (NS)
	Group 2	1 (50.0 %)	27 (34.7%)	28 (34.1%)		
	Group 3	0 (00.0%)	26 (32.5 %)	26 (31.7%)		
	Total	2	80	82		
Subgroup 2	Group 1	0 (0%)	26 (37.1%)	26 (36.1%)	1.187	0.552 (NS)
	Group 2	1 (50%)	20 (28.6%)	21 (29.2%)		
	Group 3	1 (50%)	24 (34.3%)	25 (34.7%)		
	Total	6	66	72		

Table 3: Studies reported in literature with different time durations application of SDF

Study, country, year	Age of participants	Tooth	Concentration and time period of application of SDF
Bijella, Brazil, 1991 ¹¹	3–4	Deciduous dentition	12% SDF applications for 2 min
Llodra, ¹² Cuba 2005	6.29 ± 0.48)	Primary canines and molars and first permanent molars	38% SDF applications for 3 min
Braga, USA, 2009 ¹³	–	Permanent first molars	10% SDF applied for 3 min, and wash for 30
Yee et al., Nepal, 2009 ¹⁴	6–15	Primary anterior teeth	38% SDF for 2 min and 12% SDF for 2 min,
Dos Santos et al., Brazil, 2012 ¹⁵	5–6	–	30% SDF applications for 3 min
Monse et al., Philippines, 2012 ¹⁶	6.7 ± 0.8	First permanent molars	SDF 38% for 1 minute
Duangthip et al., Hong Kong, 2016 ¹⁷	4 ± 0.8	Primary tooth with active caries	SDF 30% for 10 sec

smooth surfaces combined, they remains uncertain about the effect of SDF on ICDAS 3 and 4 lesions on each of these surfaces separately.¹⁹ Moreover AAPD (2017) advocates need of more studies to confirm an ideal protocol regarding time duration of application of SDF and our study is one of that kind.

CONCLUSION

As per our research, SDF:

- Can be used effectively in minimally cooperative child, as caries arrest does not vary significantly in different time durations of application.
- Can be used with in both cavitated as well as non-cavitated lesions alike, as caries arrest rate does not vary significantly in ICDAS 3–6 lesions with different time durations of application.

REFERENCES

1. Mei ML, Lo ECM, Chu CH. Arresting dentine caries with silver diamine fluoride: what's behind it? *J Dent Res* 2018;97(7):751–758. DOI: 10.1177/0022034518774783
2. Contreras V, Toro MJ, Elías-Boneta AR, et al. Effectiveness of silver diamine fluoride in caries prevention and arrest: a systematic literature review. *Gen Dent* 2017;65(3):22–29.
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;44(1):16–28.
4. Mei ML, Li QL, Chu CH, et al. Antibacterial effects of silver diamine fluoride on multi-species cariogenic biofilm on caries. *Ann Clin Microbiol Antimicrob* 2013;12:4. DOI: 10.1186/1476-0711-12-4
5. Zhao IS, Gao SS, Hiraishi N et al. Mechanisms of silver diamine fluoride on arresting caries: a literature review. *Int Dent J* 2018;68(2):67–76. DOI: 10.1111/idj.12320
6. Crystal YO, Marghalani AA, Ureles SD, Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needset al. *Pediatr Dent* 2017;39(5):135–145.
7. Wakshlak RB, Pedahzur R, Vanier D. Antibacterial activity of silver-killed bacteria: the “zombies” effect. *Sci Rep* 2015;5:9555. DOI: 10.1038/srep09555
8. Dikmen B. Icdas II criteria (international caries detection and assessment system.) *J Istanbul Univ Fac Dent* 2015;49(3):63–72. DOI: 10.17096/jiufd.38691
9. Frencken J. Atraumatic restorative treatment and minimal intervention dentistry. *Br Dent J* 2017;223(3):183–189. DOI: 10.1038/sj.bdj.2017.664
10. Clemens J, Gold J, Chaffin J. Effect and acceptance of silver diamine fluoride treatment on dental caries in primary teeth. *J Public Health Dent* 2018;78(1):63–68. DOI: 10.1111/jphd.12241
11. Bijella MFTB, Bijella VT, Silva MSMB, et al. Avaliação clínica da aplicação de diamino-fluoreto de prata a 12% (Bioride) na dentição decídua e seu efeito na incidência de cárie em primeiros molares permanentes. *Rev Paul Odontol* 1991; 13: 28–35.
12. Llodra JC, Rodriguez A, Ferrer B, et al. Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial. *J Dent Res* 2005;84(8):721–724. DOI: 10.1177/154405910508400807
13. Braga MM, Mendes FM, De Benedetto MS, et al. Effect of silver diamine fluoride on incipient caries lesions in erupting permanent first molars: a pilot study. *J Dent Child (Chic)* 2009;76(1):28–33.
14. Yee R, Holmgren C, Mulder J, et al. Efficacy of silver diamine fluoride for arresting caries treatment. *J Dent Res* 2009;88(7):644–647. DOI: 10.1177/0022034509338671
15. Dos Santos VE, de Vasconcelos FM, Ribeiro AG, et al. Paradigm shift in the effective treatment of caries in schoolchildren at risk. *Int Dent J* 2012;62(1):47–51. DOI: 10.1111/j.1875-595X.2011.00088.x
16. Monse B, Heinrich-Weltzien R, Mulder J, et al. Caries preventive efficacy of silver diamine fluoride (SDF) and ART sealants in a school-based daily fluoride toothbrushing program in the Philippines. *BMC Oral Health* 2012;12:52. DOI: 10.1186/1472-6831-12-52
17. Duangthip D, Chu CH, Lo ECM. A randomized clinical trial on arresting dentine caries in preschool children by topical fluorides—18 month results. *J Dent* 2016;44:57–63. DOI: 10.1016/j.jdent.2015.05.006
18. Watson PS, Pontefract HA, Devine DA et al. Penetration of fluoride into natural plaque biofilms. *J Dent Res* 2005;84(5): 451–455. DOI: 10.1177/154405910508400510
19. Slayton RL, Urquhart O, Araujo MWB, et al. Evidence-based clinical practice guideline on no restorative treatments for carious lesions. *J Am Dent Assoc* 2018;149(10):837–849. DOI: 10.1016/j.adaj.2018.07.002