

Effectiveness of 38% of Silver Diamine Fluoride in Arresting Caries in Primary Teeth: A randomized controlled trial

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Abstract

Aims: The aim of the study was to evaluate and compare the effectiveness of 38% of silver diamine fluoride (SDF) and placebo in arresting caries lesions in primary school children of Hyderabad city.

Materials and Methods: A randomized and controlled trial was carried out among 61 Primary school children in Hyderabad city. The caries status of the children was assessed using Nyvad criteria (1999). The active group received topical application of 38% of SDF and the control group received topical application of sterile water as (placebo). Examination of caries lesions was assessed at Baseline and after 21st day. On 21st day, the number of lesions that were arrested was evaluated based on the score 6 of Nyvad criteria.

Results: After 21 days, majority of subjects in active group (88%) showed significantly higher percentage of change of lesion activity from active state (i.e., score-3, nyvad criteria) to arrested state (i.e., score-6, nyvad criteria) compared to control group (8%) (P = 0.001). Logistic analysis revealed that subjects who received SDF application significantly had higher odds of changing lesion activity (OR = 12.0).

Conclusion: About 38% of SDF treatment was effective in arresting caries. The topical application was simple, inexpensive, and non-invasive in managing caries in children.

Keywords: Arresting caries, Clinical trial, Silver diamine fluoride

INTRODUCTION

Irrespective of age groups, the overall caries prevalence was found to be high and varies from 49% to 83% across different countries, according to global oral health data bank.^[1] Dental caries in primary dentition has received more attention because of its higher prevalence affecting around 560 million children worldwide.^[2] Despite dental caries being preventable, many children experience caries,

and this untreated decay can lead to further consequences of developing caries in permanent teeth, pain and infection, interference in daily activities, and school attendance affecting academic performance, with an overall negative impact on the oral health-related quality of life.^[2,3]

Although advancements in both dental techniques and scientific understanding of oral diseases being magnificent, huge differences exist in both the prevalence of dental diseases and access to dental care among children. Gambhir *et al.*,^[4] reported that various factors like less priority to dental problems, lack of time, and self-medication contribute to the non-utilization of dental services.

Among the many preventive treatments available, methods such as water fluoridation,^[5] fluoride varnishes,^[6] fluoridated tooth pastes,^[7] sealants,^[8] and or interim restorations^[8] can

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be opted, where in each of which shown to have varying levels of efficacy in clinical trials. Silver diamine fluoride (SDF) has been usually recommended as an efficient treatment for caries arrest in high risk children. Systematic review by Contreras *et al.*^[9] and various clinical studies^[10,11] have demonstrated SDF effectiveness in arresting caries at various concentrations of 30–38%.

The use of silver compounds has been reported in both medicine and dentistry because of their antimicrobial activity. Fluoride is used in various forms to prevent and arrest caries. Hence, the combined effects of silver and fluorides have been hypothesized to have the ability to halt caries progression.^[12] SDF (38% of SDF) is composed of 24.4–28.8% (w/v) silver and 5–5.9% fluoride at a pH of 10. Silver interferes with sulfhydryl groups of cariogenic proteins by changing the hydrogen bonding and inhibiting respiratory processes, cell wall synthesis, and restrict the growth of bacteria. Fluoride promotes the remineralization process.^[13] Not a single adverse effect has been reported in clinical trials^[11,14,15] in which SDF was applied to multiple teeth to arrest dental caries.

At present, the optimal frequency of application of SDF is unknown, yearly application of 38% of SDF to decayed teeth of school children has been shown to be significantly more effective in preventing caries than every half yearly application of sodium fluoride varnish.^[14] There are limited studies^[15] evaluating the short-term effectiveness of single application of SDF in arresting caries in young children. Therefore, the present study aimed to evaluate the short term effectiveness of topical application of 38% of SDF and placebo in arresting caries among primary school children of Hyderabad city.

MATERIALS AND METHODS

A randomized, double-blinded, parallel, and clinical trial was designed and before the commencement, the study protocol was submitted for approval and ethical clearance was obtained from the Institution Review Board (PMVIDS and RC/IEC/PHD/PR/0330–19). Permission to carry out the study in the primary school children was obtained from the respective Principal of schools. Participants and their parents were informed about the study and written informed consent was taken, and the anonymity and confidentiality were maintained. The study complied with the consort guidelines. The study was conducted in accordance with the Helsinki declaration 2013. The trial has been registered in clinical trial registry, India. The registration number for this trial is CTRI/2020/11/029210.

Sample Size Estimation

A pilot study was conducted among 35 children attending the outpatient department of the pedodontics, with a mean

difference between Ist and IInd sample of 0.3398, at power of 95%, alpha = 5, Effect size = 1.2135, the estimated sample size was 20 in each group. To overcome the dropout rate, a sample of 30 children in each group was selected. Children in middle childhood (ages 6–11 years) having cavitated caries lesion based on Nyvad criteria. (Code: 3 Enamel/dentin cavity easily visible with the naked eye; surface of cavity feels soft or leathery on gentle probing) and parents who gave written informed consent were included in the study. Children with any gingival or perioral ulceration or stomatitis or presence of a tooth abscess were excluded from the study.

All 61 subjects were randomly allocated into two groups with 30 subjects in each group [Figure 1] using lottery method by separate investigator, who was blinded and did not had a role in the treatment of participants. The solutions were transferred into identical bottles and were code and participants in Group I received topical application of 38% SDF (FAgamine; 38% of SDF) and Group II received topical application of water. Participants were asked not to refrain from their routine tooth brushing.

The clinical examination of study subjects were carried out by a single investigator (post graduate) who was trained and calibrated in the department of Public Health Dentistry, Panineeya Maha Vidyalaya Institute of Dental Sciences. The intra examiner reliability was high with a kappa score of 0.85. The subjects were examined for their caries activity using Nyvads criteria^[16] at baseline and at 21 days.

At baseline, untreated cavitated active occlusal caries was assessed by gently passing the probe over the entire surface of the cavity to detect and confirm visual presence of caries according to Nyvad criteria level 3 (enamel/dentin

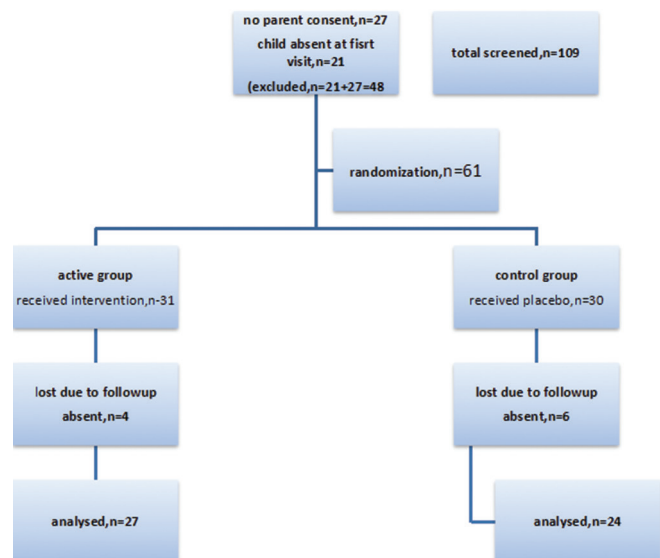


Figure 1: Flow chart of randomized controlled trial

cavity easily visible with the naked eye where the surface of cavity feels soft or leathery on gentle probing). The carious primary teeth were isolated and kept dry with cotton rolls, and any debris was removed with cotton pellets. Petroleum jelly was applied to the soft tissues to prevent any accidental staining. One drop of both solutions was placed in a plastic dappen dish, and a Vivabrush #533664 type (Ivoclar Vivadent, Schaan, Liechtenstein) was used to apply the Solution. One group received SDF solution and other received sterile water application for 1 min. The excess was removed by gentle blotting with another cotton pellet.

The subjects were re-examined after 21 days for the caries activity using Nyvad criteria. The probe is gently passed on the surface of cavity to detect for the presence of arrested caries according to code-6 of Nyvad criteria (Enamel/dentin cavity easily visible with the naked eye; surface of cavity may be shiny and feels hard on probing with gentle pressure).

Statistical Analysis

Statistical analysis was done using Statistical Package of the Social Sciences (Version 20.0) Chi-square tests and multiple logistic regression analysis were applied to determine differences in the distribution of children's age, gender, and proportion of arrested lesions and association among variables.

RESULTS

Out of 61 subjects, 51 subjects were examined at baseline and at 21 days, giving a response rate of 84% and attrition rate of 0.19% [Figure 1]. Majority of the subjects were 8 years old (39.2%) and were females (57%).

Out of 51 subjects, 26 subjects showed change of lesion activity from active to arrested state. Comparison based on groups revealed that significantly higher percentage of subjects in active group (88%) showed change in lesion activity in comparison to control group (8%) ($P = 0.001$) [Table 1].

Logistic analysis revealed that children in the age group of 7 years (odds ratio [OR] = 1.8), and subjects who received SDF application (OR = 10.0) significantly had higher odds of changing lesion activity. Gender did not show any significant association with change of lesion activity.

Adjusted logistic regression analysis revealed that only subjects who received SDF application, significantly had higher odds of changing lesion activity (OR = 12.0, respectively) [Table 2].

Table 1: Comparison of study subjects based on change in lesion activity according to groups

Change of lesion	Control (n%)	Active (n%)	Total (n%)	P-value
From 3 to 3	22 (92)	3 (12)	25 (49)	0.001*
From 3 to 6	2 (8)	24 (88)	26 (51)	0.0001*
Total	24	27	51 (100)	

* $P < 0.05$

Table 2: Step-wise multiple logistic regression analysis of caries activity based on variables

Variables	Model 1		Model 2	
	OR	P-value	OR	P-value
Age in years				
7	1.86	0.05*	1.83	0.01
8	0.13		0.10	
9	1.00		1.00	
10	ref		Ref	
Gender				
Male	0.83	0.6	-	
Female	ref			
Group				
Active	10.0	0.001*	12.0	0.001*
Control	ref		Ref	

OR: Odd's ratio. Model 1: Unadjusted logistic regression analysis for age, gender, and change of lesion. Model 2: Adjusted for age and change of lesion

DISCUSSION

A review by Mehta^[17] reported that more than half of Indian children have been affected by dental caries and there is an increase in caries burden in deciduous dentition. In addition, several *in vitro* studies^[18,19] have demonstrated the higher remineralization potential of primary teeth to fluorides. Hence, the present study investigated the effectiveness of 38% of silver diamine fluoride in arresting caries lesions with a placebo in primary school children in Hyderabad city.

In the present study, Nyvad criteria was used for the clinical assessment of the caries activity as it reflects the entire continuum of caries from non-cavitated to cavitated, and also assess the severity of the caries activity by differences in surface tomography and lesion texture. In accordance with the study by Ekstrand,^[20] the nyvad criteria are superior to other caries lesion descriptors for the detection of changes in the lesion activity status over time because of its predictive validity.

Among the multiple preventive interventions, SDF gained its popularity in arresting carious lesions and is commercially available at different concentrations of 10%, 12%, 30%, and 38%. Furthermore, SDF is safe (without adverse events) and is effective in reducing caries progression and subsequent caries by 80% on treated teeth.^[21] SDF application is an inexpensive, non-invasive,

quick procedure, and flexible enough to implement the procedure in a community settings, pre-schools, or health centers. Literature studies^[10-13] showed that caries of primary teeth in children treated with 38% of SDF had higher chances of becoming arrested than those treated with 12% of SDF. Thus, in the present study, 38% of SDF is used to assess its effectiveness in arresting caries.

In relation to the desirability of removal of decayed dentin before the application of SDF, Chu *et al.*,^[14] found no difference between SDF groups with or without prior excavation. Thus, in the present study, SDF was applied without prior excavation of demineralized dentin. Furthermore, Clemens *et al.*^[22] re-evaluated the SDF (38%) treated lesions at 3 weeks and 3 months and observed no significant differences in preventive fraction of arrested lesions. Further *in vitro* studies by Li *et al.*^[23] demonstrated efficacy of SDF to arrest caries within 21 days. In line with these studies, the present study evaluated the short-term effectiveness of 38% of SDF.

In the present study, with respect to the therapeutic effect of 38% of SDF (arrest of caries), around 88% of treated active caries at baseline changed to inactive at the end of follow-up. SDF on application reacts with calcium and phosphate ions of hydroxyapatite crystals and forms calcium fluoride and silver phosphate and thereby promotes remineralization and increase hardness. These findings are in accordance with the studies done by Chu *et al.*^[14] and Llodra *et al.*,^[24] wherein SDF arrested lesions showed preventive fraction of 70–84% and 79%, respectively, in primary teeth.

Adjusted logistic regression analysis revealed that only subjects who received SDF application significantly had higher odds of changing lesion activity (OR = 12.0, respectively). Thus, the present study confirms the effectiveness of 38% of SDF in arresting caries. In our study, SDF-treated lesions turned coal black in color, and such discoloration is a good indication of caries arrest, which might be aesthetically less pleasing in appearance but this out rates the anti-caries efficacy of 38% of SDF. The carious lesions in the present study also has similar characteristics to those reported in the previous studies.^[12-15]

Our study showed that a onetime intensive SDF application can lead a higher proportion of arrested lesions in the duration of 3 weeks. In contrast to studies by Chu *et al.*^[14] and Llodra *et al.*,^[24] the preventive fraction of arrested lesions was less in duration of 6 months. Reports of adverse events with the use of SDF were uncommon. In the present study, no adverse effects were observed concerning the SDF treatment and are in accordance with the studies by Fung *et al.*^[10] However, Milgrom *et al.*^[15]

reported development of reversible, small, and white lesion at the corner of the mouth which resolved after 2 weeks.

However, the present study acknowledged certain limitations. First smaller sample size, the arrested lesions turned black in color which can cause esthetical concern, the follow-up could have been longer which would have been beneficial in assessing the long-term efficacy of SDF.

CONCLUSION

Significantly, a higher percentage of children (88%) who received SDF application showed change in lesion activity (active to arrest) and thus effective in arresting caries in primary teeth in children.

SUBJECT CONSENT

Obtained.

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