

A Clinical Trail of Silver Diamine Fluoride application on children's primary teeth to arrested carious lesion among preschool children, Vientiane: A pilot study

Abstract

Introduction: Recent studies indicate a double increase of the prevalence and severity of Early Child Dental Caries (ECC) in Vientiane.

Aim: This study is to deliver Silver diamine fluoride (SDF) to prevent dental caries progression among children who attending Pre-school in Vientiane Capital.

Method: This is a community demonstration study. Parents were asked via a questionnaire sent with the consent form about sociodemographic characteristics. Children washaving an oral examination for dental caries using the Caries Assessment Spectrum and Treatment (CAST) index. Only the children with caries lesions in enamel and dentine was receive SDF. An evaluation of SDF was occurred after three months fellow-up between intervention and control group. A 24-hr phone call/whatapp was be implemented to address any concerns or clinical events after SDF application and before the follow-up time. Chi-square or student T-test was used to compare caries status against sociodemographic characteristics, parents' acceptance, and caries status.

Results: A total of 400 children, mean age was 4.3 [0.8] year. In baseline, 77.8 % reported dental caries in intervention group and 74.4% in control group, there were increasing of prevalence dental caries in control group 84.3% and 74.2% in intervention group after 3 month follow up ($p=0.045$). Furthermore, after 3 months follow up, there is little change in the control group on mean number of decayed enamel or decayed dentin. However, the mean number of deep lesions increased from 0.74 to 1.13 pulp lesions from 0.64 to 0.82, and soft-tissue lesions. In the intervention group, the mean number of decayed enamel decreased from 1.80 to 1.11, decayed dentin decreased from 2.37 to 1.07. That because of the carious lesion arrested to enamel and dentin. There was statistically significant $p=0.001$. The postoperative sign and symptoms and satisfied from parental after apply Silver Diamine Fluoride is good report for initial to use SDF controlling of dental caries progression.

Conclusion: The study provide information of SDF treatment can be prevent and controlling caries progress in children due to ECC high prevalence, the effectiveness of SDF treatment to prevent dental caries, long term follow up is needed and necessary for evidence of effectiveness with low cost.

Keyword: ECC, SDF, Caries arrested, CAST

Introduction

Recent studies indicate doubling or tripling the prevalence and severity of Early Child Dental Caries (ECC) in Vientiane in the last ten years. The studies have reported over six decayed, missing, and filled teeth (dmft) on average. [1]. Most of these teeth had untreated caries lesions. These high levels maybe associated with parents' and children's lifestyles and inadequate access to preventive and

curative care. ECC causes pain and infection affecting the quality of life of children and their families. In addition, ECC affects the child's physical and psychological development and leads to school absenteeism[2]. The burden of untreated dental caries is a public health problem in Vientiane, and it is expected to spread to other Lao provinces as lifestyles and commercialization of sugary products continue throughout the country.

Treating these lesions requires dental professionals, resources, and time, which are inadequate in Laos. One treatment choice is the professional application of silver-diamine fluoride (SDF) to caries lesions to arrest its progression. SDF exerts its preventive effect against dental caries through its fluoride and silver components. The fluoride promotes remineralization. The silver component topically disinfects the exposed dentine [3], coagulates the dentinal collagen and promotes a barrier to avoid the infiltration of cariogenic bacteria in the dentinal tubules. The collagen coagulation produces a black coloration of the dentinal surface. In large dentinal lesions, especially in anterior teeth, the color change could elicit aesthetic concerns. SDF is widely considered to be safe, even in young children. A UK report by Frank shows black staining as the only SDF side effect [4]. SDF can also stain other surfaces that it comes into contact such as mucosa, or clothing [5]. Delivering SDF requires minimal training [6] making it ideal for application in school settings [7]. This is the first study on the efficacy and acceptability of SDF for the treatment of dental caries in Laos, PDR.

The objective of this pilot study was to evaluate SDF arrested to carious lesion after three months and. Also, we described parents' reports of side effects, postoperative signs and symptoms, and acceptability.

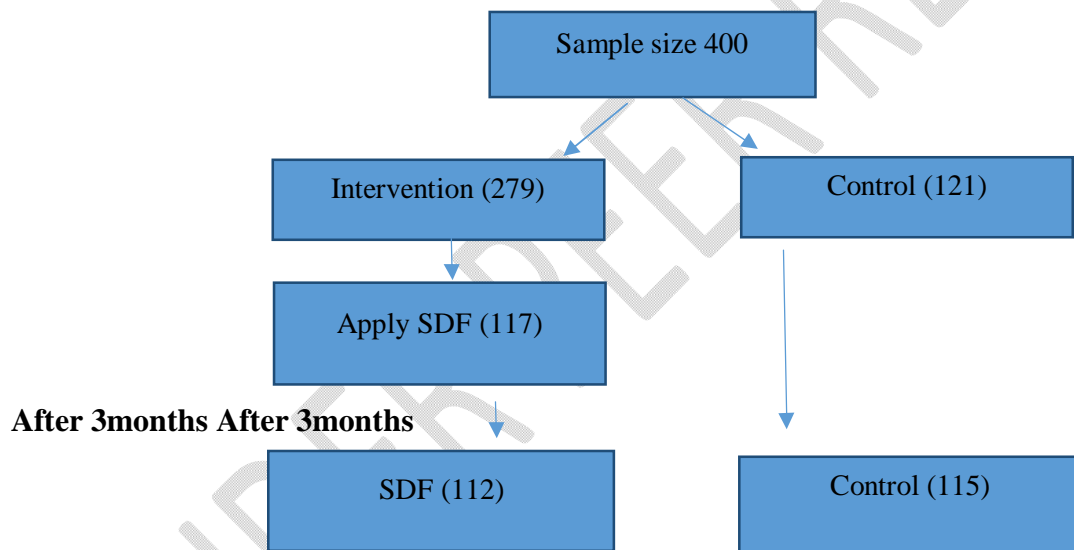
Methods

The Ethics Committee of the University of Health Sciences approved the study (approval number: 492/REC). The parents provided signed written consent. This study was a pilot randomized clinical, the active intervention was Silver Fluoride Diamine application to primary teeth of children aged 3-5 years in Nonghai preschool, Hadxayfong district, Vientiane. The school was selected by convenience because it has been included in previous caries studies [1]. The parents were asked to attend an informational session where they were asked to allow their children to participate. Only children with signed consent forms were included in the study.

Examinations took place in the preschools. All children were asked to brush their mouths to remove food debris before they were evaluated by two examiners using the modified CAST index [8]. The modification was limited to reordering the detection categories. After examination, a group of

randomly selected children received SDF and the group of children who were not received SDF was given a toothbrush and toothpaste for daily tooth brushing. We excluded children with clinical signs of pulpal inflammation, reports of unsolicited/spontaneous pain before the examination, or reporting allergies or any systemic disease.

The sample size was calculate based on a previous study reporting 72% prevalence [1]. The calculated sample size was 400 children. Due to the number of student were moving during school summer so it was effect to our sample size that we couldn't have an equal number of student between intervention and control group. from which one intervention group (N=279) and a control group (N=121) were allocated by convenient selection. Only 117 children in the intervention group had caries lesion in enamel and dentine and received SDF. Children with no caries or with pulpal infections did not received SDF. The following diagram describes the original and final sample sizes. After three months, 112 of 117 children in the intervention group and 115 children in the control group were reexamined using the same criteria than in the baseline examination.



Application procedure is as follows:

Food debris was remove from the surface of the teeth using cotton roll and dried the tooth surface. Carious tissues were not remove from the lesions before SDF application. Petroleum jelly was applied on the lips and gingiva to protect soft tissues from staining. 38% SDF solution [9,10]. SDF Solution was place in a plastic dish, the solution was slowly rub into the cavities lesion using microbrush, for up to 30-60 second with air dried, children were asked to not rinse, drink, eat for 30 minutes after application.

Re-check SDF application follow up during 3 months for arrested

The efficacy of SDF application was examined by the lesion visual-tactile, black stain. The cavities were detected by using dental probe gently to examine the softness and hardness of dentin. If the dentine surface was hard to probing it was classified as arrested caries [11]. The outcome of application was performed by comparing the intervention group with SDF and control group to define the arrested and caries progression.

Data collection:

The questionnaire had 30 items and was used at baseline and follow-up. Parents reported general information about their age, sex, occupation, education level and income, and history of child's dental visit, and oral hygiene behaviors. The interviewing dentist used clear colored picture of primary teeth diagnosed with caries before and after treatment using SDF in posterior and anterior teeth and show to the parents to ask for cooperation. After 24 hours of SDF application, the parents were asked to report symptoms and rate of satisfaction with the clinical outcome. Oral examinations were done by two dentists using Cast Index after the children have brushed their teeth. During the oral examination, the child was lay-down on a portable dental chair in a supine position, as recommended by WHO, Oral Health Basic Methods, 5th edition [12]. Following the examination and the SDF application, where applied, the child was dismissed with the findings of the examination and post-application recommendations. After 3 months' children were reexamined for evaluation of the SDF applications using the same criteria. The outcome of application was performed by comparing the SDF and control groups. Data were entered to MS Excel, and transferred to SPSS program. Chi-square analysis was used to describe percentage of dental caries and sociodemographic characteristics, stratified by parents' acceptance. And student T-test were used to compare the mean number of carious lesion arrested and also mean number of severity of dental caries between intervention and control group.

Results:

The original selection of 400 children included 205 girls (51.2%) and 195 boys (48.8%). The age ranged from 2 to 5 with mean age 4.2(0.8) years, 48% were over 5 years of age. Thirty-two percent of children had pain and 29.3% had problems for eating 117. Parent reported that only 25.3% of their children had a previous dental visit and the main reason among those having a visit was pain or infection (9.8%), filling teeth (4.5%), and tooth extraction (3.0%). However, 5% of parents reported

that the last visit was a routine check-up visit. Over half of parents reported “other” as the reason for not having a dental visit. Seven percent reported having no time, 5% reported child’s fear to the dentist, and in 4% is the child that does not want to go for treatment.

Thirty-seven percent of parents knew about fluoride toothpaste. Thirty-three percent would allow their children to receive SDF with a very small difference regarding whether it was a front or a back tooth. Around 45% reported need for more information to decide.

Characteristic	Intervention (279) n (%)	Control (121) n (%)	Total n (%)
Age (year)			
3	49 (17.6)	41 (33.9)	90 (22.6)
4	74 (26.5)	45 (37.3)	119 (29.8)
5	156 (55.9)	35 (28.9)	191 (47.8)
Gender			
Female	149 (53.4)	56 (46.3)	205(51.2)
Male	130 (46.6)	65 (53.7)	195 (48.8)
Relationship with child			
Parent	276 (98.9)	118 (97.5)	394 (98.5)
Other	3 (1.1)	3 (2.5)	6 (1.6)
Parental income			
≤5.000.000 kip (200\$)	50 (17.9)	18 (14.9)	68 (17.0)
>5.000.000 kip (200\$)	229 (82.1)	103 (85.1)	332 (83.0)
Parent education			
High school and higher	82 (29.4)	42 (34.7)	124 (31.0)
Primary and secondary school	148 (53.0)	47 (38.9)	195 (48.8)
No attend school	41 (14.7)	28 (23.1)	69 (15.3)
Apply anterior and posterior teethSDF			
Cooperate	90 (32.3)	41 (33.9)	131 (32.8)
Incorporate	83 (29.7)	19 (15.7)	102 (25.5)
Need more information	106 (38.0)	61 (50.4)	167 (44.8)

In baseline, 77.8 % reported dental caries in intervention group and 74.4% in control group, there were increasing of prevalence dental caries in control group 84.3% and 74.2% in intervention group after 3 month follow up. There were statistically significant difference between intervention group and control group within SDF arrested in the carious lesion $p=0.045$. Only 6% had filled or missing teeth. One quarter of children (29%) had deep cavities with potential pulp infection. Almost 21% had soft-tissue sequelae (fistula and abscess).

Characteristic	Full sample,N (%)			3 months Follow-up after, N (%)		
	All(400*)	Intervention group (279)	Control group (121)	All (383) **	Intervention group (268)	Control group (115)
Girls	205 (51.2)	149 (53.4)	56 (46.3)	197 (51.6)	144 (73.1)	53 (26.9)
Boys	195 (48.8)	130 (46.6)	65 (53.7)	185 (48.4)	125 (67.6)	60 (32.4)
Untreated dental caries	307 (76.8)	217 (77.8)	90 (74.4)	296 (77.1)	199 (74.2)	97 (84.3)

Arrested Lesions					112 (37.4)	
Filled Primary	25 (6.3)	18 (6.5)	7 (5.8)	28 (7.4)	26 (9.7)	2 (1.8)
Cavity in enamel	238 (59.6)	161 (57.7)	77 (63.6)	200 (52.5)	117 (43.7)	83 (73.5)
Cavity in dentine	236 (59.1)	178 (64.1)	58 (47.9)	138 (36.2)	85 (31.7)	53 (46.9)
Deep cavity and pulp involve	104 (26.2)	76 (27.5)	28 (23.1)	115 (30.2)	79 (29.5)	36 (31.9)
Pulp	118 (29.6)	95 (34.2)	23 (19.0)	125 (32.8)	97 (36.2)	28 (24.8)
Soft Tissue Sequelae (Abscess/fistula)	86 (21.6)	69 (24.9)	17 (14.2)	99 (26.0)	80 (29.9)	19 (16.8)
Missing	22 (5.5)	18 (6.5)	4 (3.3)	38 (10.0)	30 (11.2)	8 (7.1)
dmft>0	330 (82.7)	234 (84.2)	96 (79.3)	296 (77.7)	199 (74.3)	97 (88.8)

*One participant originally in the intervention group had no examination data in baseline.

**Thirteen in the intervention and 8 in the control were lost at follow-up.

On average, there were 6.7 ± 5.2 decayed, missing, and filled teeth, which range from 0 to 20 teeth. Decayed teeth (enamel or dentine) accounted for 4.8 ± 3.9 teeth with SDF arrested and 2.1 ± 2.5 were dentinal lesions. Less than one tooth had deep dentinal lesions with potential pulp infection (0.72 ± 1.7) or pulp (0.9 ± 1.9).

Furthermore, after 3 months follow up, there is little change in the control group on mean number of decayed enamel or decayed dentin. However, the mean number of deep lesions increased from 0.74 to 1.13 pulp lesions from 0.64 to 0.82, and soft-tissue lesions from 0.55 to 0.72. Interestingly, the mean number of missing teeth increased from 0.07 to 0.21 and the mean number of filled teeth decreased from 0.14 to 0.05.

In the intervention group, the mean number of decayed enamel decreased from 1.80 to 1.11, (gain of 0.7) decayed dentin decreased from 2.37 to 1.07 (gain 1.30). That because of the carious lesion arrested to enamel and dentin. There were little changes in deep cavities, pulp, or sequelae with who not receiving SDF according to protocol). There were minor increases in missing teeth and filled teeth. The statistically significant shown high association with the mean number of intervention and control group after 3 months follow up ($p=0.001$).

Characteristic (mean number)	Baseline			3 months Follow-up		
	N (400)	Intervention group (279)	Control group (121)	N (383)	Intervention group (268)	Control group (115)
Sound teeth	13.27 \pm 5.28	13.88 \pm 5.51	13.05 \pm 5.12	12.47 \pm 5.42	12.35 \pm 5.29	12.76 \pm 5.71
Arrested teeth					4.80 \pm 3.02	
Filled Teeth	0.11 \pm 0.51	0.10 \pm 0.41	0.14 \pm 0.70	0.11 \pm 0.44	0.13 \pm 0.45	0.05 \pm 0.42
Decayed enamel	1.97 \pm 2.39	1.80 \pm 2.29	2.37 \pm 2.57	1.58 \pm 2.18	1.11 \pm 1.76	2.69 \pm 2.65
Decayed dentine	2.14 \pm 2.58	2.37 \pm 2.61	1.61 \pm 2.20	1.23 \pm 2.11	1.07 \pm 2.07	1.61 \pm 2.16
Deep cavity and pulp involve	0.70 \pm 1.65	0.68 \pm 1.60	0.74 \pm 1.78	0.85 \pm 1.75	0.73 \pm 1.57	1.13 \pm 2.09
Pulp	0.92 \pm 1.94	1.04 \pm 2.05	0.64 \pm 1.62	0.99 \pm 1.99	1.06 \pm 1.98	0.82 \pm 2.00
Soft Tissue Sequelae (Abscess/fistula)	0.72 \pm 1.94	0.80 \pm 2.00	0.55 \pm 1.81	0.83 \pm 1.91	0.88 \pm 1.84	0.72 \pm 2.09
Missing Teeth	0.12 \pm 0.62	0.15 \pm 0.69	0.07 \pm 0.42	0.28 \pm 1.02	0.31 \pm 1.08	0.21 \pm 0.85
dmft	6.69 \pm 5.26	6.93 \pm 5.13	6.12 \pm 5.51	5.88 \pm 2.57	5.30 \pm 4.98	7.23 \pm 5.71

Parent was reported in 24 hours that 9 children has pain their tooth. Two children have red gum, had bad mouth and nausea or vomiting. Half of parent accept to have their child receiving additional treatment and satisfied with the treatment given 82.5%. In overall the postoperative sign and symptoms

after apply Silver Diamine Fluoride is good report for initial to use SDF prevent the progress of dental caries due to high prevalence dental caries and it was effect to children pain, eat which relevant to physical growth and child's quality of life.

Sign & symptoms	yes	no	Not sure,
child has pain in their teeth after treatment	9 (7.9)	78 (68.4)	13 (11.4)
child having gums that are more red than usual	2 (1.8)	77 (67.5)	21 (18.4)
child having gums that are whiter than usual	0	55 (48.2)	45 (39.5)
child had bad mouth odor after treatment	1 (0.9)	61 (53.5)	38 (33.1)
child had nausea or vomiting after treatment	2 (1.8)	76 (66.7)	22 (19.3)
Stratified			
Do you accept to have your child receiving additional treatment after six months to prevent and treat dental caries?	53 (46.5)	20 (17.5)	27 (23.7)
satisfied with the treatment given to your child	94 (82.5)	2 (1.8)	4 (3.5)
How would you rate	Unsatisfied	Somewhat	satisfied
How satisfied are you with the change of color in the teeth receiving treatment	2 (1.8)	7 (6.1)	81 (79.8)

Discussion:

SDF has been used for decades since the late 1960s in Japan and Argentina, at concentrations ranging from 10% to 38% [13,14]. The efficacy of Silver Diamine Fluoride treatment is a simple, beneficial, and cost effective for caries prevention and control in children. As The US Food and Drug Administration (FDA)[15], the AAPD, and the WHO have regarded it as an essential strategy for oral health management to address the burden of dental caries [16]. SDF treatment has been well known and widely use in community-based around the world and safe application. In our study shown the efficacy of 38% Silver Diamine Fluoride arrested to the caries lesion on enamel and dentine during follow up time. This study has an achieved the objective on preliminary result of arresting and controlling accessible dental caries in primary teeth among early child dental caries in preschool. Present study shown an increase prevalence dental caries in control group from baseline and 3 months follow up, with children who received SDF shown an arrested with hard tissue in intervention group. However, the efficacy of 38% SDF should be long term follow-up.

Despite the strong variability observed in the application protocols adopted, the meta-analysis shows that SDF is more effective compared to fluoride varnish or ART technique, although less effective than other silver-based compounds [17]. Applications should be repeated (at least every six months) are more effective in caries arrest, calling for the need of an evidence-based application protocol [18, 19]. Study from Aparna 2022 the clinical efficacy of biannual application of 38% solution followed by 5% NaF Varnish in arresting active. Results shown that SDF was 92.3% effective in arresting the carious lesion at 12 months follow up [20]. the effectiveness of one-time SDF application in arresting carious lesion ranges from 47%-90% depend on the lesion size and the location of teeth [21]. The systematic review shows that when SDF is used to arrest caries lesions in primary teeth it also provides an anticaries benefit for the entire dentition; that is, 38% SDF applications decrease by 77%

the development of new caries in treated children in comparison to non-treated children (2 studies, 558 participants) [21]. Further study requires a larger sample size and longer follow-up period to verify the clinical effectiveness of SDF in young children with high caries risk and combine with ART or Sealant will be retreat tooth functional with deep and large cavitate.

From Dauangthip studies in 2017 shown the based report from parental SDF does not cause any sign symptom same as studied from other studied not illness Tooth or gum pain, gum swelling, only 2 child felt nausea because of SDF smell. The postoperative sign and symptoms are slight and temporary [22]. The reported by Gordon in 2018, parental acceptance of the utilization of SDF on their children was higher among parents of uncooperative children or children who require more advanced behavior management [23]. No matter on tooth coloration parent are stratified on caries prevention The discoloration of the teeth was generally well accepted by both children and parents of all groups [24]. However, the parental acceptance to the utilization of SDF and need to filled cavity [25,26].

The limitation our study was conducted in school summer so we couldn't get the equal number between intervention and control group. Parents were worried and concern that investigator was asked parent to answer sign symptoms. Our study provides only baseline study during 3 months (parent acceptance, side effect after apply fluoride, stain arrested cavity) to know the benefit of SDF need to follow-up 6 and 12 months. Strength of study was sufficient number of attended and small number of lost follow up, school principal, teacher was very active and follow the instruction of SDF treatment. The result from our study will be good evidence for community based of applying fluoride and continue follow-up as long term to fine out the effective of SDF treatment can be able to prevent and reduce dental caries.

Conclusion

This clinical trial was providing evidence on whether SDF treatment can be arrested and controlling dental caries progression in primary teeth's children and beneficial to use in the community with low cost.

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