A Clinical Trail of Silver Diamine Fluoride application on children's primary teeth to prevent dental caries progression among preschool children, Vientiane: A pilot study

Abstract

Introduction: Recent studies indicate a doubling or tripling of the prevalence and severity of Early Child Dental Caries (ECC) in Vientiane in the last ten years.

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 was having 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. the prevalence of dental caries was 98% and the mean dmft was 6.93 in the intervention group. 7949% and mean dmft was 6.12 in the control group at the baseline. Child was reported pain 126 (31.5%) and problem eating 117 (29.3%). After 3 months' follow-up by applied SDF data shown that prevalence dental caries in enamel and dentine was (44% and 32%) intervention group and mean dmft was decrease from 6.93 to 5.30, while in dental caries in enamel and dentine was control group was (74% and 47%) with mean dmft 7.23. This number show an increase the progress of dental caries in control group compare to intervention group, there was statistically significant p=0.001. The difference mean number of SDF application on enamel was 0.38 (intervention) and 2.69 (control) with 95% CI (-2.83 to -1.79), and dentine was 0.04 (intervention) and 1.58 (control) with 95% CI (-1.94 to -1.14) shown highly statistically significance p=.0001. The postoperative sign and symptoms and satisfied from parental after apply Silver Diamine Fluoride is good report for initial to use SDF prevent the progress of dental caries

Conclusion: The study provide information of SDF treatment can be prevent or control caries progress in children due to ECC high prevalence, the effectives 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 a doubling or tripling of the prevalence and severity of Early Child Dental Caries (ECC) in Vientiane in the last ten years. For example, two studies have reported an average of eight out of 20 teeth affected by dental caries (ranging from 3.2 to 9.0) [1]. This outbreak of dental caries is associated with changes in the lifestyle of parents and children and denotes a lack of preventive interventions. 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. The burden untreated dental caries is a public health problem in Vientiane, and

it is expected to spread to other Lao provinces as lifestyles and comercialization of sugary products continues throughout the country. Furthermore, restorating these lesions requires resources, time, dental materials and dental professionals, which is already inadequate in the country. One alternative currently used in other countries is the application of silver-diamine fluoride over caries lesions to arrest the progression of the lesion. Silver-diamine fluorides have two dental caries preventive components, fluoride and silver. Professionally applied fluorides for the prevention of dental caries promotes the remineralization of incipient caries lesions and stops the progression of the lesion toward the dentine. Delivering professionally applied fluorides require minimal training [2]. The silver component acts over the exposed dentine [3], and produces a topical disinfection of the lesion, and the coagulation of the collagen in the dentine, producing a barrier to avoid the continue infiltration of the dentine tubule. The coagulation produces a black coloration of the dentinal surface. In large dentinal lesions, especially in anterior teeth, the change in color could elicit aesthetic concerns. Few harmful or negative side effects have been found with use of SDF. SDF is widely considered to be safe, even on young children. A report by Frank in the U.K., shown that the only common side effect of SDF is black staining. SDF can also stain other surfaces that it comes into contact such as: mucosa, or clothing [4]. The objective of this study to evaluate children's satisfaction, after applying SDF. The parents were report safety of drug use with side effect, postoperative signs and symptoms, acceptability as described in a questionnaire. The investigators were also follow-up the initial efficacy of SDF in preventive of caries progression at three months after treatment.

Methods

Ethics committee of University of Health Sciences approved the study (approval number: 492/REC). The patient's parents provided written informed consent. This study was a randomized clinical trial of Silver Fluoride Diamine (SDF) applied to children aged 3-5 years in Nonghai preschool, Hadxayfong district, Vientiane. The parents were asked to attend an informational session where they were asked to allow their children to participate and sign a consent form. All participating children were asked to brush their mouth to remove food debris before they were evaluated by two examiners using the CAST index [5] within the school premises. After examination, a group of randomly selected children received SDF. Inclusion criteria: Children whose parents willing agree for their children to participant and provide a signed consent form. Exclusion Criteria: Children with clinical signs of pulpal inflammation or report of unsolicited/spontaneous pain before the first examination were exclude along those who report allergies, and any systemic disease.

The sample size was calculate based on a previous study reporting 72% prevalence [1]. The calculated sample size was 400 children from which one intervention group (N=279) and a control group (N=121) were randomly allocated. Only 114 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.

Sample size 400

Sample size 400

Control (121)

Control (121)

Intervention (279)

Intervention (279)

Apply SDF (117)

Apply SDF (117)

Control (115)

Control (115)

SDF (112)
SDF (112)

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, edition [6]. 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 efficacy of the SDF application was evaluated using a dental probe gently to assess the softness/hardness of the lesion. If the dentinal surface was hard to probing it was classified as an arrested caries. 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 or student T-test were used to compare caries status against sociodemographic characteristics, stratified by parents' acceptance.

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.

Table 1. Characteristics of study participants at baseline examination

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 teeth SDF			
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, almost 98% of the participants had ECC and 59% have untreated caries lesions in the enamel or dentine. 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).

Table 2. Prevalence of Selected Characteristics at Baseline and Follow-up for Intervention and Control Groups

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 cavities	393 (98.3)	276 (98.9)	117(96.7)	376 (98.4)	267 (99.3)	109 (96.5)
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±5.23 decayed, missing, and filled teeth, which range from 0 to 20 teeth. Decayed teeth (enamel or dentine) accounted for 4.8±3.9 teeth 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 (0.92±1.9). The intervention group was 279 children (67.2%) and the control group was 115 (32.8%). There were slightly more girls in the intervention group (51.6%).

In general, disease and sequelae prevalence and severity were higher in the intervention group. For example, the prevalence of dental caries was 98% and the mean dmft was 6.93 in the intervention group, compared with 79% and mean 6.12 in the control group, respectively. Furthermore, the mean number of teeth with untreated disease (no missing or filled) was 5.9 in the control group and 6.7 in the intervention group. After 3 months' follow-up by applied SDF data shown that prevalence dental caries in enamel and dentine was (44% and 32%) intervention group and mean dmft was decrease from 6.93 to 5.30, while in dental caries in enamel and dentine was control group was (74% and 47%) with mean dmft 7.23. This number show an increase the progress of dental caries in control group compare to intervention group, there was statistically significant p=0.001.

Table 3. Mean Number of Teeth for Dental Caries or Sequelae at Baseline and Follow-up for Intervention and Control Groups.

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

Table 4. Percentage of postoperative sign & symptoms at 24 hours after fluoride treatment

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)

SDF treatment arrest 112 (94%), mean applied was 4.80 teeth per child, the mean cavities in enamel of intervention group was 0.38, and cavities in dentine was 0.04 compare to control with untreated caries shown the mean cavities in enamel was 2.69, in dentine was 1.58, 95% CI (-2.83 to -1.79) in enamel and 95% CI (-1.94 to -1.14) in dentine the difference shown the statistically significance p=.0001 in both cavities in enamel and dentine.

Table 5. outcome result for caries arrest follow-up 3 months

Outcome	Intervention group		Control group		Difference		95%CI	
	N o (mean)	SD	N o (mean)	SD	N o (mean)	SD error	lower	upper
Caries arrest	122 (4.80)	3.02						
Caries Enamel	112 (0.38)	0.87	115(2.69)	2.65	227 (-2.31)	0.26	-2.83	-1.79
Caries Dentine	112 (0.03)	0.03	115(1.58)	2.14	227 (-1.54)	0.20	-1.94	-1.14

***Caries enamel p-value <0.0001*
***Caries dentine p-value <0.0001*

Discussion:

Dental caries in preschool children in Laos is tend to be high prevalence, which been report from various studied in Laos, prevalence of dental caries young children age 3 to 5-year-old was 82% to 98% from 2010 to 2023 with limited number of treatment and prevention in children and few number of dental visited due to limited number of specialist, child fear and economic income. In our study shown the prevalence of untreated dental caries 98% and mean number 6.7 teeth/child and its was higher if compare to prevalence (42%) and mean dft 4.3 teeth/child from National Institute of Dental and Craniofacial research 2011-1016 [7], dental caries in national wide in Saudi Arabia was 72% mean dmft 3.9 [8].

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)[9], the AAPD, and the WHO have regarded it as an essential strategy for oral health management to

address the burden of dental caries [10]. SDF treatment has been well known and widely use in community-based around the world and safe application. In our study also asked parents to reported postoperative sign symptom 24 hours shown that only 9 (8%) children have pain their tooth due to baseline diagnosis. Few of children have red gum, had bad mouth and nausea or vomiting that because of smell of application. 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 [11]. Half of parent expect that their child is receiving additional treatment because of deep cavities and satisfied with the SDF treatment given 82.5% same as 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 [12]. 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 [13]. However, the parental acceptance to the utilization of SDF was questioned, almost halt of parents reported that it is strongly not acceptable 46 (43.4%) due to the staining caused by its application. On the other hand, 16 (15.1%) of them were neutral and only 2 (1.9%) found the staining acceptable [14].

Early child dental caries shown high prevalence with untreated dental caries child was suffer by deep cavities and pulp involve, tooth necrosis and infected by fistula, ulceration and abscess which negative effect to early child quality of life and school absent, SDF has been considered a therapeutic agent for treating cavitated dental caries lesion in young children and those with special needs [15].

The limitation of study was started in rainy season many children absent school and there was topical disease in children such as cold fever, eye infection and diarrhea this should be carefully for SDF treatment parental will be confuse about side effect from treatment, SDF treatment should be avoided to contact mouth mucosa it was occur white lesion so it requires dentist to be careful applying and need suction child saliva. Some parental misunderstand questionnaire and not awareness clinical, due to parent have limit time (need to explain more for the SDF to parent). 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 prevalence of dental caries 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.

The present study was carried out to evaluate the clinical efficacy of application of 38% SDF solution only our study show the SDF was arrested 94% follow-up 3-months. 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 [16]. 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 [15]. 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) [17]. 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.

Conclusion

This clinical trial was providing evidence on whether SDF treatment can be prevented or control dental caries progression in primary teeth's children due to Early child dental caries is high prevalence, the effectives of SDF treatment to prevent dental caries not well-know the Randomize Clinical trial long term follow-up is needed and necessary for evidence of effectiveness.

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