



Caries Preventive Effect of Sodium Fluoride Varnish on Deciduous Dentition: A Clinical Trial

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ABSTRACT

Aim: The aim of the study is to evaluate the efficacy of intensive application of sodium fluoride varnish in reducing caries incidence among children aged 6 to 7 years.

Materials and methods: The study was a randomized controlled trial conducted among 6- to 7-year-old children of Sangamner, Maharashtra, India. Nearly 200 randomly selected children were randomized into two groups: Control group and intervention (varnish) group. Dental examination to record the caries experiences was conducted at baseline and at 1-year follow-up. The fluoride varnish was applied for three times in a week for a period of 1 year. Mean decayed, missed, and filled teeth (DMFT) were compared between and within groups using t-test.

Results: Out of 200 participants, there were 3 dropouts for control group and 4 for intervention group. Nearly 55% study participants were males and remaining were females. There was a statistically significant difference between the baseline and follow-up caries levels in varnish group for deciduous dentition. Mean caries reduction in this study was 26%.

Conclusion: After 1 year of study, we found significant caries reversal in deciduous dentition among the 6- to 7-year-olds after intensive fluoride application. Such a regimen can be advocated to encourage the practitioners and the caregivers alike for early caries prevention.

Clinical significance: Intensive fluoride application (three times a week) once a year was found to be effective in reducing the incidence of detectable carious lesions and can be advocated

to the dental professionals to be incorporated in their routine preventive clinical practice.

Keywords: Caries prevention, Deciduous dentition, Dental caries, Sodium fluoride varnish.

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INTRODUCTION

Fluorides have been the cornerstone of preventive dentistry for a long time. Fluoride in various forms either as systemic or topical fluorides has been used to successfully reduce the incidence of dental caries. Fluoride varnish are nonaqueous-based products made from natural or synthetic base in which fluoride salts are dissolved in a solvent, such as ethanol.^{1,2} In 1964, the use of 2% sodium fluoride varnish for longer retention time was reported, and this was designed to prolong the contact time with the tooth.² The empirical advantages of fluoride varnish include its ease of use, handling, application, less prone to protocol modification,^{3,4} less prone to ingestion among children, and vulnerable populations.^{5,6}

Vanish[®] is a 5% sodium fluoride varnish which with tricalcium phosphate has an advantage of being unit-dosed, especially designed for pediatric use, and minimizes toxicity chances. It has better coverage across the dentition and also delivers targeted and sustained fluoride and calcium release. Various clinical trials have been reported using various fluoride varnishes, such as Duraphat, Fluor Protector, and Duraflor. Clinical study by Weintraub et al⁷ reported caries reduction effect of fluoride varnish. Various reviews have reported the positive effect of varnish in caries reduction.⁸⁻¹⁰ The majority of trial have reported caries inhibitory effect of fluoride

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varnish on permanent dentition, and there are few studies on primary dentition.¹¹ There is a need for clinical trials focusing on the primary dentition so as to assess their caries inhibitory effect.^{4,10}

Intensive fluoride application at the rate of three times a week for a period of 1 year has been found to show promising results among schoolchildren. It has been effective in reducing the incidence of detectable carious lesions and in healing superficial enamel lesions.⁴ Hence, the study was conducted with the aim to evaluate the efficacy of intensive application of sodium fluoride varnish in reducing caries incidence among children aged 6 to 7 years.

MATERIALS AND METHODS

The study was a randomized controlled trial conducted among 6- to 7-year-old children of Sangamner, Maharashtra, India. The study included 200 randomly selected children. Before the start of the study due approval was obtained from Institutional Ethics Committee. Written informed consent was obtained from the parents of the children. The parents and study participants were given a choice to decline the participation in the study.

The children of age group 6 to 7 years as on last birthday, those who were free of systemic illness, and those willing to participate in the study were included in the study. The selected children were randomly divided into two groups so that each group included 100 children.

- *Group I:* Intervention group—children were applied fluoride varnish
- *Group II:* Control group—children were not applied fluoride varnish.

At the baseline, participants of both groups received oral hygiene instructions and oral prophylaxis. Intervention group received varnish application (5% sodium fluoride, 3M ESPE) three times in 1 week. After oral prophylaxis and drying of teeth, fluoride varnish was applied to teeth quadrant-wise, using applicator tip after thorough missing of the contents. Varnish was allowed to dry for few seconds as per manufacturer's instruction. The children in intervention group were asked to avoid brushing and flossing for a day after fluoride application. They were instructed to avoid hard foods and hot drinks for 24 hours.

The study was conducted for a duration of 12 months (1 year). A baseline examination was conducted to assess the dental caries levels among the children of both groups using American Dental Association Type III examinations. Caries levels were assessed using decayed, extracted, filled teeth (DEFT) and decayed, extracted, filled teeth, and surfaces criteria (DEFS).

Caries status for primary posterior teeth (canine, first, and second primary molars) was recorded as decayed, extracted, filled posterior teeth (DEFTP) and decayed, extracted, filled posterior surfaces (DEFSP) according to the World Health Organization criteria to avoid possibility of physiologic exfoliation of primary anterior teeth.⁴

Two bitewing radiographs were obtained for each child at the beginning and at the end of the study to assess interproximal surface. Radiographically identified proximal carious lesions which were not seen clinically were recorded as radiographic decayed primary teeth, radiographic decayed primary surfaces, radiographic decayed posterior permanent teeth, and radiographic decayed posterior permanent surfaces. Using the data recorded on caries in the beginning and at the end of the experimental year, increment in caries was calculated.⁴

Statistical analysis was conducted using Statistical Package for the Social Sciences, version 21.0. Data were normally distributed, hence, parametric paired t-test and independent t-test were used to compare the means for intergroup and intragroup comparisons. The p-value <0.05 was considered significant.

RESULTS

Table 1 shows the distribution of participants according to gender and also enumerates the number of dropouts. Table 2 shows the baseline comparison of control and intervention group. There was no statistically significant

Table 1: Distribution of study participants by gender and treatment groups

Sex	Control	Intervention	Total	Dropouts	
				Control	Intervention
Male	57	59	116	2	1
Female	43	41	84	1	3
Total	100	100	200	3	4

Table 2: Comparison of control and varnish groups with respect to different variables at baseline

Variables	Group	n	Mean ± SD	p-value
DEFTP	Intervention	96	4.278 ± 1.07	0.97
	Control	97	4.390 ± 1.57	
DEFSP	Intervention	96	5.24 ± 2.34	0.765
	Control	97	5.44 ± 2.07	
DEFT	Intervention	96	4.09 ± 2.31	0.534
	Control	97	4.29 ± 1.97	
DEFS	Intervention	96	5.28 ± 1.47	0.598
	Control	97	5.39 ± 2.04	
DMFT	Intervention	96	0.35 ± 0.04	0.67
	Control	97	0.26 ± 0.07	
DMFS	Intervention	96	0.68 ± 0.05	0.69
	Control	96	0.44 ± 0.09	

p < 0.05 is considered statistically significant; SD: Standard deviation

Table 3: Comparison of control groups at baseline and at 1-year follow-up

Variables	Group	n	Mean ± SD	p-value
DEFTP	Baseline	100	4.390 ± 1.57	0.24
	Follow-up	97	4.56 ± 1.47	
DEFSP	Baseline	100	5.44 ± 2.07	0.32
	Follow-up	97	5.65 ± 1.85	
DEFT	Baseline	100	4.29 ± 1.97	0.38
	Follow-up	97	4.36 ± 1.69	
DEFS	Baseline	100	5.39 ± 2.04	0.296
	Follow-up	97	5.50 ± 1.94	
DMFT	Baseline	100	0.26 ± 0.07	0.176
	Follow-up	97	0.31 ± 0.05	
DMFS	Baseline	100	0.44 ± 0.09	0.264
	Follow-up	97	0.50 ± 0.07	

p < 0.05 is considered statistically significant; SD: Standard deviation

difference between the control and intervention group at baseline examination for DEFTP, DEFSP, DEFT, DEFS, DMFT, and decayed, missed, and filled surface (DMFS) status.

Table 3 shows the comparison of control group at baseline and 1-year follow-up. There was no statistically significant difference seen among the scores at baseline and follow-up. There was a slight rise in the number of cariously affected teeth among the participants. Table 4 shows the comparison of intervention group at baseline and 1-year follow-up. There was statistically significant difference seen among the scores at baseline and follow-up. There was a decrease in the number of cariously affected teeth among the participants. Exception was the DMFT values and DMFS values, which remained statistically nonsignificant.

Table 5 shows the comparison of means values between intervention and control group at 1-year follow-up. There was a statistically significant difference between the scores for both groups except the DMFT and DMFS values.

Table 5: Comparison of intervention and control group with respect to different variables at 1-year follow-up

Variables	Group	n	Mean ± SD	p-value
DEFTP	Intervention	96	3.86 ± 1.26	0.016*
	Control	97	4.56 ± 1.47	
DEFSP	Intervention	96	4.85 ± 1.97	0.027*
	Control	97	5.65 ± 1.85	
DEFT	Intervention	96	3.89 ± 2.43	0.004*
	Control	97	4.36 ± 1.69	
DEFS	Intervention	96	5.06 ± 1.23	0.003*
	Control	97	5.50 ± 1.94	
DMFT	Intervention	96	0.32 ± 0.06	0.43
	Control	97	0.31 ± 0.05	
DMFS	Intervention	96	0.59 ± 0.05	0.24
	Control	97	0.50 ± 0.07	

*p < 0.05 is considered statistically significant; SD: Standard deviation

Table 4: Comparison of intervention group at baseline and at 1-year follow-up

Variables	Group	n	Mean ± SD	p-value
DEFTP	Baseline	100	4.278 ± 1.07	0.00*
	Follow-up	96	3.86 ± 1.26	
DEFSP	Baseline	100	5.24 ± 2.34	0.038*
	Follow-up	96	4.85 ± 1.97	
DEFT	Baseline	100	4.09 ± 2.31	0.003*
	Follow-up	96	3.89 ± 2.43	
DEFS	Baseline	100	5.28 ± 1.47	0.024*
	Follow-up	96	5.06 ± 1.23	
DMFT	Baseline	100	0.35 ± 0.04	0.45
	Follow-up	96	0.32 ± 0.06	
DMFS	Baseline	100	0.68 ± 0.05	0.67
	Follow-up	96	0.59 ± 0.05	

*p < 0.05 is considered statistically significant; SD: Standard deviation

DISCUSSION

The dental caries prevalence has been reported to be consistently high in the range of as high as 91.59 to 59%.⁴ A study in Raigad, Maharashtra, India, by Shingare et al¹² reported caries prevalence of 75.8% among the 3 to 6-year-olds. The average DMFT for older children is around 4 in rural and urban areas.¹³ High caries levels have led to increased burden on existing health systems and compromise the quality of life of the children alike.

The fluoride varnish used in our study is Vanish[®], a unit-dosed pediatric usage, with 5% sodium fluoride. This varnish forms calcium fluoride layer and provides free fluoride ions to teeth, it is saliva activated, and can be applied to dry and wet teeth alike, and contains xylitol as sweetener.

In our study, we used intensive fluoride application regimen as it has shown promising results in studies by Sköld et al¹⁴ which used Duraphat three times a year. Sköld et al¹⁴ stated that three applications gave sufficiently high amount of fluoride on enamel surface and in superficial microscopic cavities to end caries process. Similar results were obtained in a study by Gugwad et al,⁴ where cavity shield used for intensive regimen has shown promising results.

Radiographic analysis was conducted to overcome drawback of missing out on proximal surface caries. As advocated by Gugwad et al,⁴ posterior teeth were recorded separately to minimize bias by physiological exfoliation of anterior teeth in the study age group.

One-year follow-up was chosen as appropriate for the study based on findings by Janna T and Frank C, who reported the fast progression of caries in deciduous dentition.¹⁵ Mean caries reduction in this study was 26%, which was comparable to those seen by Gugwad et al⁴ who noticed a mean caries reduction of 27.7%. Similarly, varnish use leads to 46% caries reduction against a caries

reduction of 26% as witnessed for gels.¹⁰ Higher effect size can also be due to well-informed caregivers.

Caries increment in control group in our study was positive as compared with intervention group. There was reduction in caries increment for intervention group, similar to those reported by Gugwad et al⁴ and Koch and Petersson.¹⁶ Koch and Petersson¹⁶ reported decrease in initial caries due to fluoride application, indicating a caries reversal.

There is a need for quality trials substantiating the use of fluoride varnish in deciduous dentition. Such trials would encourage the practitioners to use fluoride varnish for early caries prevention among the children.

CONCLUSION

After 1 year of study, we found significant caries reversal of 26% in deciduous dentition among the 6–7 year-olds after intensive fluoride application. Such a regimen can be advocated to encourage the practitioners and the caregivers alike for early caries prevention.

LIMITATIONS

First, the sample size used in this study is small and hence, studies with larger sample size need to be conducted before incorporation of this protocol in routine practice.

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