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ORIGINAL RESEARCH

Caries Prevention Effect of Intensive Application of Sodium Fluoride Varnish in Molars in Children between Age 6 and 7 Years

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ABSTRACT

Background: The aim of this study was to evaluate the efficacy of intensive application of sodium fluoride varnish in prevention of caries in molars in children between 6 and 7 years and to evaluate the caries status in molars before and after application of fluoride varnish (Cavity Shield).

Materials and methods: Two hundred fifty children (6-7 years) randomized into varnish and control groups. Children in varnish group received fluoride varnish (Cavity Shield) three times during one week (once every 2 days). Clinical and radiographical examinations of all children were performed prior to the first application of varnish and 1 year later. For evaluation and comparison, all the collected data were subjected to statistical analysis.

Results: At the end of 1 year period, varnish group had 27.7% caries reversal in deciduous dentition which was statistically significant. Though there was a decrease in the caries increment in the permanent dentition, it was not statistically significant.

Conclusion: Application of fluoride varnish Cavity Shield three times once a week, once a year either in permanent or in deciduous dentition, is associated with substantial reduction in caries increment.

Clinical significance: Fluoride varnish can prove to be an effective tool in prevention of dental caries in both primary and permanent dentitions.

Keywords: Fluoride varnish, Intensive treatment, Caries reduction, Cavity Shield.

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INTRODUCTION

The prevention of dental caries in children and adolescents is generally regarded as a priority for dental services and is considered more cost-effective than its treatment. Fluoride therapy has been the centerpiece of caries preventive strategies since the introduction of water-fluoridation schemes over 5 decades ago. The use of topically applied fluoride products in particular, which are much more concentrated than the fluoride in drinking water, has increased over the recent decades.[1]

A fluoride dental varnish can be defined as a lacquer or liquid, made from a natural or synthetic base in which fluoride salts are dissolved in a solvent, such as ethanol.[2]

The development of fluoride varnish began in 1960s following the observations of Mellberg, who found that considerable amount of fluoride was released from enamel within the first 24 hours after the topical application of acidulated phosphate fluoride preparations. The practical and positive characteristics of fluoride varnishes include ease of use with respect to handling and application, acceptability to patients and an adequate safety level. The major clinical advantage of fluoride varnishes is their specific ability to adhere to tooth surfaces, thereby prolonging fluoride exposure and uptake.

Cavity Shield is a newer product with the advantage of being a unit-dosed varnish, thereby reducing wastage and any remote possibility of fluoride toxicity.

Numerous clinical trials evaluating the caries preventive effect of fluoride varnish in both the permanent and deciduous dentitions have been reported. Most of these studies have been done on Duraphat, Duraflor, Fluor and Protector; however, no extensive study is available on newer fluoride varnish like Cavity Shield.

Although a majority of clinical trials are associated with caries inhibition in the permanent dentition, there are some studies related to primary dentition.[3] The average caries reduction in primary dentition, where fluoride varnishes were topically applied twice per year, appears to be less than the caries reduction, seen in the permanent dentition. However, more clinical trials are necessary particularly focusing on very young children.

Recently, promising results have been reported for intensive fluoride treatment (three times a week) once a year in school children. The effect was more pronounced for keeping the tooth free from radiographically detectable caries and for healing the enamel from the most superficial lesions. Hence, the aim of the present study was to evaluate the efficacy of intensive application of sodium fluoride varnish in prevention of caries in molars in children between 6 and 7 years and to evaluate the caries status in molars before and after application of fluoride varnish (Cavity Shield).

MATERIALS AND METHODS

The present study is a randomized controlled trial conducted among two hundred and fifty children between the age group of 6 and 7 years who were randomly selected. Cluster random sampling design was used. Children with systemic diseases, physical handicap and recent history of antibiotic use were excluded from the study. Informed consent was obtained from the parents after explaining the nature and the purpose of the study. Ethical clearance was obtained from the institutional review board.

Selected children were randomly divided into two groups so that each group contained 125 children. The groups were as follows:

Group 1 (control): Children for whom fluoride varnish was not applied.

Group 2 (varnish): Children for whom fluoride varnish was applied.

At the baseline examination, children from both the groups received oral prophylaxis followed by appropriate oral hygiene instructions.

Children from the varnish group were subjected to intensive application of sodium fluoride varnish (Cavity Shield, Omni Products, West Palm Beach, Florida) three times during 1 week (once every 2 days).

After oral prophylaxis, the teeth were dried with air-syringe and fluoride varnish was applied on all the teeth using a disposable brush, care being taken not to apply it on the soft tissue. Varnish was then allowed to set for a few seconds according to manufacturer's instruction.

The children who received fluoride varnish applications were asked to abstain from brushing or flossing for the entire day. They were also instructed to avoid chewing on hard foods, not to have hot drinks and products containing alcohol. Children from the control group were not given varnish application.

All the children in the control and varnish groups were examined clinically at the beginning and at the end of the experimental year. Each child was subjected to ADA. Type III oral examination using mouth mirror and probe.

Caries status in primary teeth [DEFT (decayed, extracted, filled teeth) and DEFS (decayed, extracted, filled surfaces)] were recorded according to the WHO criteria (1999).[5]

As there was a possibility of physiologic exfoliation of primary anterior teeth due to the age group included in the study, to control the bias caused by exfoliated carious incisors, caries status of posterior teeth was recorded separately. Caries status for primary posterior teeth (canine, first and second primary molars) was recorded as DEFTP (decayed, extracted, filled posterior teeth) and DEFSP (decayed, extracted, filled posterior surfaces) according to the WHO criteria.

Caries status in permanent teeth [DMFT (decayed, missing, filled teeth) and DMFS (decayed, missing, filled surfaces)] were recorded according to the WHO criteria.[5]

Two bitewing radiographs were obtained for each child at the beginning and at the end of the study. A No. 2 X-ray film was placed in the mouth with the help of an intraoral bitewing X-ray film holder to record interproximal surface of posterior teeth.

Magnifier was used to aid in diagnosis of incipient proximal lesions from the obtained bitewing radiographs. Radiographically identified proximal carious lesions which were not seen clinically, were recorded as RDT (radiographic decayed primary teeth), RDS (radiographic decayed primary surfaces), RDT (radiographic decayed posterior permanent teeth) and RDS (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.

Oral hygiene status of each child was recorded before oral prophylaxis in the beginning and at the 1 year follow-up visits as OHI-S (oral hygiene index-simplified) index according to the WHO criteria.[5] This was done in order to control the bias exerted by oral hygiene status on increment of caries.

All the children included in the study were examined and their data were recorded respectively by same examiner.

STATISTICAL ANALYSIS

Since the data was normally distributed, parametric tests were used. Mean and standard deviation of the index scores were calculated. Paired and unpaired t-test was used for

intra and intergroup comparisons repectively. p-value < 0.05 was considered statistically significant.

RESULTS

Table 1 shows the genderwise distribution of the study subjects. The Table 2 shows the comparison of control and varnish groups, with respect to different variables at baseline and it can be seen that both the groups were comparable at the baseline with no significant difference, with respect to any of the variables under consideration. Table 3 shows the comparison of control and varnish groups with respect to different variables after intervention. Table 4 shows the intragroup comparison of before and after application in control group with respect to different variables. Table 5 shows the comparison of before and after application in varnish group with respect to different variables.

DISCUSSION

In India, dental caries seems to be on the increase over the last few decades. Tewari and Chawla (1977) reported the prevalence of 81.60%, Nagrajreo (1980) 90.1%, Damle and Tewari (1981) 91.59%, Tandon and Paul (1992) 90.66%, Singh et al (1997) 78 to 83% whereas Gopinath et al (1999) reported 59%. Around 70 to 80% in the present scenario are suffering from this disease in our country. The average number of decayed, missing and filled teeth from the age of 15 to 16 years, is about four in rural and five in urban areas.[6]

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

Sex	Control	%	Varnish	%	Total	Dropouts		%
						Control	Varnish	
Male	58	49.15	60	50.85	118	11	12	7.81
Female	47	50.54	46	49.46	93	7	9	6.06
Total	105	49.76	106	50.24	211	18	21	7.05

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

Variables	Group	N	Mean	SD	p-value
DEFTP	Control	105	4.3810	2.9068	0.7724
	Varnish	106	4.2642	2.9514	
DEFSP	Control	105	5.3524	4.0572	0.8509
	Varnish	106	5.4717	5.0863	
DEFT	Control	105	4.4000	2.9567	0.9745
	Varnish	106	4.3868	3.0475	
DEFS	Control	105	5.6286	4.0270	0.9500
	Varnish	106	5.6698	5.4032	
DMFT	Control	105	0.4190	0.8410	0.2484
	Varnish	106	0.6038	0.8846	
DMFS	Control	105	0.4381	0.9191	0.4552
	Varnish	106	0.6792	0.8305	
OHI-S	Control	105	1.7429	0.4392	0.2397
	Varnish	106	1.8774	1.0841	

Table 3: Comparison of control and varnish groups with respect to different variables after treatment

Variables	Group	N	Mean	SD	p-value
DEFTP	Control	105	4.1429	2.7296	0.0150
	Varnish	106	3.2170	2.7534	
DEFSP	Control	105	6.1524	6.5791	0.0452
	Varnish	106	4.5566	4.7950	
DEFT	Control	105	4.3333	3.1276	0.0138
	Varnish	106	3.3113	2.8464	
DEFS	Control	105	6.5238	7.3119	0.0329
	Varnish	106	4.6792	4.9503	
DMFT	Control	105	0.5619	0.9896	0.7604
	Varnish	106	0.5566	1.0017	
DMFS	Control	105	0.6095	1.1807	0.6809
	Varnish	106	0.5283	1.2765	
OHI-S	Control	105	1.5810	0.5332	0.8339
	Varnish	106	1.5660	0.4980	

Table 4: Comparison of before and after treatment in control group with respect to different variables

Variables	Treatment	Mean	SD	p-value
DEFTP	Before	4.3810	2.9068	0.5409
	After	4.1429	2.7296	
DEFSP	Before	5.3524	4.0572	0.2537
	After	6.1524	6.5791	
DEFT	Before	4.4000	2.9567	0.8796
	After	4.3333	3.1276	
DEFS	Before	5.6286	4.0270	0.2426
	After	6.5238	7.3119	
DMFT	Before	0.4190	0.8410	0.2389
	After	0.5619	0.9896	
DMFS	Before	0.4381	0.9191	0.2046
	After	0.6095	1.1807	
OHI-S	Before	1.7429	0.4392	0.0144
	After	1.5810	0.5332	

Table 5: Comparison of before and after treatment in varnish group with respect to different variables

Variables	Treatment	Mean	SD	p-value
DEFTP	Before	4.2642	2.9514	0.0000
	After	3.2170	2.9534	
DEFSP	Before	5.4717	5.0863	0.0493
	After	4.5566	4.7950	
DEFT	Before	4.3868	3.0475	0.0000
	After	3.3113	2.8464	
DEFS	Before	5.6698	5.4032	0.0357
	After	4.6792	4.9503	
DMFT	Before	0.6038	0.8846	0.6594
	After	0.5566	1.0017	
DMFS	Before	0.6792	0.8305	0.2425
	After	0.5283	1.2765	
OHI-S	Before	1.8774	1.0841	0.0052
	After	1.5660	0.4980	

Systemic water fluoridation is no doubt ideal, but in India 70% of population particularly in the rural areas does not get piped water supply. It is therefore, imperative to find out some fluorides which can be used in school children.[7]

Cavity Shield fluoride varnish was used in our study for intensive application once a year (three times a week) in varnish group children. This mode of application was used so as to provide a sufficient high fluoride deposit on enamel surface and in superficial cavities.

Similar study done by Skold L et al reported promising results for intensive Duraphat application once a year (three times a week) in school children[4] whereas Seppa and Tolonen (1990) suggested that fluoride varnish application performed more frequently than twice a year which may not provide additional caries protection.[8] We, therefore, think that it may be useful to start-up this intensive treatment model.

Relatively a few clinical studies have been performed on the effectiveness of fluoride varnishes for preventing caries in mixed dentition and the results are somewhat inconclusive.[2]

Anna T and Frank C reported that caries progression in primary dentition is rapid and within 12 months, enamel caries may progress into the dentin.[9] Therefore 1 year should be a sufficient period to study the progression rate of enamel carious lesions.

In the study done by S Zimmer et al (2001) no radiographs were taken, therefore the results obtained gave limited information about proximal surfaces.[10] At the start of our study the total baseline caries prevalence in control and varnish groups were statistically nonsignificant, thus avoiding any bias.

Caries status of posterior teeth and radiographic caries lesions were recorded separately, so as to control the bias caused by physiologic exfoliation of primary anterior teeth due to the age group (6-7 years) included in the study.

In our study, the caries prophylactic effect of intensive application of Cavity Shield (sodium fluoride varnish) in molars after treatment in varnish group was statistically significant for primary teeth and was not significant in permanent teeth.

The reason for statistical significant reversal of caries in primary dentition for molars in our study may be due to three applications performed a week. Skold et al stated that three applications within a week gave a sufficiently high fluoride deposit on the enamel surface and in superficial microscopic cavities to end all carious processes.[4]

Whereas, a study done by Grodzka et al to evaluate the caries increment in primary teeth after application of Duraphat twice yearly found a very small reduction in caries increment (of less than 15%) which was not significant. According to the author, the reason attributed for this result, may be due to the samples selected, were from different schools with varying caries activity.[11]

In vitro studies done on Cavity Shield have reported an improved caries resistance of primary teeth enamel against a continuous cariogenic challenges. As enamel bounded fluoride from Cavity Shield varnish is responsible for marked caries prevention in these laboratory studies and the current investigation.[12,13]

Tewari et al reported that fluoride varnish is very effective on newly erupted tooth surface.[14] They observed that dental caries reduction was higher in all of the study group on teeth erupted during the study as compared to the teeth present at the baseline. However, in our study permanent molars in varnish group though showed reduction in the caries increment, but were found to be nonsignificant. This finding may be attributed to the fact that children included in this study belong to 6 to 7 years age group, out of which 34 children in varnish and 37 in control group had no molars erupted. Most of the 59 children (82%) in whom molars were erupted, had no caries and the remaining 13 (18%) children had caries limited to occlusal surfaces only.

The mean caries reduction seen in our study was 27.7%. Whereas in a study conducted by Holm et al who applied Duraphat semiannually for two years found caries reduction of 44%, which was higher when compared to our results. The author quoted that one of the reason for their high percentage of caries reduction was the prevalence of low caries activity in their sample and probably because the parents were well-informed about caries prophylaxis.

Tewari A et al conducted a study to evaluate the effect of topical application of NaF, APF and Duraphat. At the end of their study, APF group had caries reduction of 32 to 37% and Duraphat had caries reduction of 72 to 75%, which are higher as compared to our study. The author attributed this difference to the variations observed in population inherent and the variable techniques of application.[7]

In our study, caries increment in control group showed an increase at the end of 1 year study period, though it was statistically insignificant. This might be due to the oral hygiene motivation provided to the control group children during the course of study; this finding was further supported by the decreased value of OHI-S in control group.

The mean gain score for varnish group in our study after treatment was 4.04, which is statistically significant showing the reversed of a total of 4.04 caries increment, whereas the gain score value for control group after study showed an increase of 2.21 caries increment at the end of study.

Similar to our study, Koch and Peterson in their study reported a reduction in caries increment of 2.8 and 1.2

respectively, in test and control group, by using Duraphat semiannual application for one year. According to them the decrease in the number of initial carious lesion during the experimental year indicated a reversal. The number of new carious lesions might be the same in two groups but it balanced out in test group due to a higher frequency of reversal.[15]

Whereas, another study by Sylvia D and Stefan Z reported the mean DMFT of the 12-year-old decreased continuously from 2.77 to 1.64 and using Duraphat semi-annual application for one year saw a decrease of the mean DMFT of the 9-year-old from 1.09 to 0.63. The slightly better result of 9-year-old was explained by the fact that most of these children received varnish applications from the beginning of their permanent dentition, while 12-year-old began receiving the application when they were already 8-year-old.[16]

In some case of F varnish, only three trials reported on efficacy in the primary teeth, of which two found an effect (Borutta et al, Weintraub et al) while one was not able to demonstrate an effect (Hardiman et al).[18-20.] In the light of the popularity of F varnishes among clinicians, the need for more high quality clinical trials on the efficacy of these methods in preventing caries in the primary dentition is obvious. Whereas, in a study done to access the antierosive effect on primary and permanent teeth, it was found out that in permanent teeth both CPP-ACPF paste and APF gel showed effective protective effect against dental erosion as in primary teeth results showed that APF gel provided the highest protective effect against erosive enamel loss compared to fluoride varnish.[21]

The present study prevention of caries in varnish group can be further substantiated by Chiayl S and JaanaAutio Gold who reported in their *in vitro* study that all Cavity Shield packages exhibited definitely sedimentation of NaF particles in the mixing wells, according to manufacturer's instruction, one might even conclude that Cavity Shield retained most of their fluoride during the first 31 hours in artificial saliva and they can provide greater source of fluoride for calcium fluoride formation.[17]

Oral hygiene status of all the children was evaluated using OHI-S according to the WHO criteria, 5 years before and after one year period in both the groups. OHI-S was used since caries is a disease of multidimension in which improper oral hygiene can be a precipitating factor for the progression of caries and even hold good and *vice versa*. At the start of our study, the OHI-S mean score for control and varnish groups were 1.7429 and 1.8774 respectively, which were statistically insignificant. In control group the OHI-S score after a period of one year changed from 1.7429 to 1.5810 and in varnish group 1.8774 to 1.5660. The improvement seen in the oral hygiene status of both the groups was found to be statistically significant.The reason for this change may be due to the proper oral hygiene motivation provided to the school children as they were part of school dental health program associated to our college during the course of study.

After the experimental year, caries increments in control group were not statistically significant. Though there was a decrease in TDEFTP and TDEFT values, also a slight increase was seen in TDEFSP, TDEFS, TDMFT and TDMFS values, but were not statistically significant. Whereas, Koch and Petersson contradictory to our findings, reported caries increment (4.0) in control group.[15] These variations, seen in our study, may be due to good oral hygiene and preventive motivation given to the children. Jana AG and Frank C also reported in their study that a mean caries increment in control group remained constant.[9]

CONCLUSION

From the result of this 1 year study, it can be concluded that the application of fluoride varnish Cavity Shield three times a year, either in the permanent or deciduous dentition, is associated with a substantial reduction in caries increment.Varnish group showed 27.7% caries reversal, which was statistically significant.

CLINICAL SIGNIFICANCE

Fluoride varnishes are safe, easy to apply and well-accepted by patients. This study shows that fluoride varnish can offer an efficient nonsurgical alternative for the treatment of decay in children.

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