

Caries – preventive effect of topical APF gel with three different frequencies of application in 9 – 11 years old school children in Ninevah

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ABSTRACT

This is the first study carried out in Iraq that aimed at evaluating the effect on dental caries of Acidulated Phosphate Fluoride (APF) gel applied topically with different frequencies (once per year vs. twice per year vs. four times a year).

A sample of (235) school children [116 (49.36%) males and 119 (50.64%) females] initially in the fourth grade (aged 9 - 11 years) were collected from (4) primary schools in Mosul city centre. The children were allocated randomly to (3) experimental groups and one control group. The first group received (0.4%) APF gel four times a year for (4) minutes. The second group received (0.4%) APF gel once per year for (4) minutes; whereas the third group received (0.4%) APF gel twice per year for (4) minutes.

Two examinations were done using DMFT and DMFS indices: one before fluoride application and the other after one year.

The results showed a reduction in dental caries (with respect to DMFT index, and in comparison with the control group) of (112.8%) for the first group, (35.9%) for the second group, and (80.4%) regarding the third group. With respect to DMFS index, and in comparison with the control group, the reduction in dental caries was (97.3%), (32.8%), and (72.6%), respectively.

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The best benefit from using topically applied APF gel was, therefore, achieved from applying (0.4%) gel four times a year for (4) minutes.

Key Words: Acidulated phosphate fluoride, dental caries, frequency of topical application, DMFT, DMFS .

الخلاصة

تعتبر هذه الدراسة الأولى من نوعها في العراق؛ وتهدف إلى تقييم تأثير هلام فوسفات الفلورايد المُحمّض على تسوس الأسنان بعد تطبيقه موضعياً بتكرارات مختلفة (مرة في السنة مقابل مرتان في السنة مقابل أربع مرات في السنة).

تم اختيار عينة (٢٣٥) تُميِّد من أربع مدارس ابتدائية في مركز مدينة الموصل [١١٦ (٤٩,٣٦%) ذكور و ١١٩ (٥٠,٦٤%) إناث] في المرحلة الرابعة والذين تتراوح أعمارهم عند بدء البحث بين ٩ - ١١ سنة. وزعت هذه العينة عشوائياً على ثلاثة مجاميع تجريبية ومجموعة واحدة ضابطة. تم إعطاء المجموعة الأولى (٠,٤%) من هلام الفلورايد أربع مرات في السنة ولمدة أربع دقائق، وأعطيت المجموعة الثانية (٠,٤%) من هلام الفلورايد مرة واحدة في السنة ولمدة أربع دقائق، أما المجموعة الثالثة فقد تم إعطاؤها (٠,٤%) من الهلام مرتان في السنة ولمدة أربع دقائق.

أجريت الفحوصات مرتان على أسنان الأطفال باستخدام المؤشرات (DMFT) و (DMFS): مرة قبل وضع الفلورايد والأخرى بعد مرور عام واحد. أظهرت النتائج انخفاضاً ملحوظاً في معدلات تسوس الأسنان من خلال استخدام المؤشر (DMFT) وبالمقارنة مع المجموعة الضابطة بنسبة (١١٢,٨%) للمجموعة الأولى، (٣٥,٩%) للمجموعة الثانية، (٨٠,٤%) للمجموعة الثالثة. بينما كانت معدلات الانخفاض في تسوس الأسنان من خلال استخدام المؤشر (DMFS) وبالمقارنة مع المجموعة الضابطة بنسب (٩٧,٣%) و (٣٢,٨%) و (٧٢,٦%) للمجموع التجريبية الثلاثة على التوالي.

تبين من خلال هذه الدراسة أن أفضل النتائج قد تحققت عند استخدام هلام فوسفات الفلورايد المُحمّض بتركيز (٠,٤%) لأربع مرات في السنة ولمدة أربع دقائق.

INTRODUCTION

One of the most effective measures for prevention and control of dental caries at the present time involves the use of fluoride in a variety of manners. Multiple sources - including water fluoridation, professionally applied topical fluorides, prescription fluorides, fluoridated toothpastes, as well as fluoride in processed foods and drinks - have contributed to the reduction of caries. A declining trend in the prevalence and severity of dental caries in children over the past two decades in USA and many European countries, as shown by several epidemiological studies⁽¹⁻⁶⁾, has been well documented. From the preventive programmes which were conducted in these countries, the school-based fluoride programme appeared to be the most important and effective one.

The term *topical fluoride therapy* refers to the use of systems containing relatively large concentrations of fluoride that are applied locally, or topically, to erupted tooth surfaces to prevent the formation of dental caries. This term encompasses the use of fluoride rinses, dentifrices, pastes, varnishes, gels and solutions that are applied in various manners⁽⁷⁾.

The use of concentrated fluoride solutions applied topically to the dentition for the prevention of dental caries has been studied extensively during the past 50 years, although few studies have been conducted since the 1970s^(7,8). The procedure resulted in a significant increase in the resistance of the exposed tooth surfaces to the development of dental caries and, as a result, has become a standard procedure in most dental offices⁽⁷⁾.

The use of topical fluoride solutions has largely been superseded by topical fluoride gels^(8,9). Fluoride gels have the advantage of being used in trays, enabling the entire mouth to be treated simultaneously in a single application⁽⁸⁻¹⁰⁾. Moreover, tray application appears to be readily accepted by children⁽¹¹⁾, and the flavouring in gels further enhances patients' acceptance⁽¹²⁾.

Considerable confusion has arisen regarding the preferred frequency for administering topical fluoride treatments. Much of this confusion is due to the absence of controlled, clinical evaluations of this variable, particularly with the most commonly used agent, APF. Clinical data appear to indicate that the caries-preventive benefits from professional fluoride treatments are directly related to the number of applications, although the optimal number of applications or treatment frequency has never been established^(4,7).

Consequently, the aim of the present study was to compare the efficacy of traditional professionally applied topical APF gel when applied annually, bi-annually, or four times a year.

MATERIALS AND METHODS

The study was conducted during the period between March 2000 to March 2001 in four primary schools from different areas in Mosul city centre/ Ninevah province, after getting permissions from the concerned authorities - Education Sector of Mosul and the school authorities.

A sample of (277) school children initially in the fourth grade (initial age ranges from 9-11 years) were collected from four primary schools. The selection of the schools was based mainly on the co-operation of the school authorities. Each school contained one fourth grade class. Therefore, a total of (4) classes out of (4) primary schools were included in the study.

The parents of each child were sent detailed explanatory letters concerning the aims and benefits of the study and including their approval about the research.

Instruments and supplies that had been used include:- 1) plane mouth mirrors; 2) sharp sickle-shaped caries explorers; 3) tweezers; 4) kidney dishes; 5) fluoride trays (stock trays) with different sizes; 6) drum for placing the sterilised instruments; 7) pan for sterilising the instruments with concentrated sterilising solution (4% Septicin) for 15 minutes then washed with water; 8) cotton for removing debris from around the teeth; and 9) fluoride gels [0.4% APF thixotropic gel (Dentaclean: UK made)].

All the students were clinically examined 2 times during the study: (1) at the beginning of the study (before application of fluoride gel) in March 2000, and (2) after one year of APF treatment in March 2001. The two examinations were carried out by the same examiner in good natural daylight, using plane mirrors and probes with the student sitting in a chair in front of the examiner. After drying the teeth with cotton, they were examined carefully.

Clinical criteria for the diagnosis of dental caries followed the WHO guidelines ⁽¹³⁾ using DMFT and DMFS indices for permanent teeth with the exception that a score for the initial caries (white or chalky spots) was included in the scoring of decayed teeth ⁽¹⁴⁾. Radiographs were not taken because of practical limitations which make radiography for each child very difficult.

The (4) classes from the (4) primary schools were allocated randomly to (3) different groups of treatment and (1) control group.

Treatment for each group included:-

- Group 1:** Received four times a year application of (0.4%) thixotropic APF gel (Dentaclean) for (4) minutes .
- Group 2:** Received annual application of (0.4%) thixotropic APF gel (Dentaclean) for (4) minutes .
- Group 3:** Received bi-annual application of (0.4%) thixotropic APF gel (Dentaclean) for (4) minutes .
- Group 4:** Served as a control group (did not receive any application of fluoride).

Treatment was carried out at 6-month intervals (one at the beginning of the study and the other after 6 months) with respect to group (3); and once at the beginning of the study with respect to group (2). Regarding group (1), a modification in the intervals between the four treatments was done in such away that three-month intervals between the first and second applications as well as the third and fourth applications, whereas four-month intervals between the second and third applications were carried out. This modification was planned due to summer vacation at schools.

All the experimental groups received no prior prophylaxis. Five children at a time were treated according to the following procedure: each child was asked to rinse thoroughly with water in order to dislodge loose debris, then the children were seated in upright position and a suitable tray for each child was carefully selected. The teeth of each child were then wiped with cotton to remove any remaining debris and dry the teeth. The selected trays, each containing a ribbon of APF gel, were inserted over the maxillary arch for each child. Individual timer was used for each child to ensure that all children had the appropriate time contact with the fluoride gel (4 minutes). After that, the trays were removed and the children were allowed to expectorate thoroughly. Then, the same procedure was repeated for the mandibular arch and the children were asked to expectorate thoroughly once again to remove any excess fluoride, but instructed not to eat, drink, or rinse for at least 30 minutes following the treatment.

The percentage of dental caries reduction compared to the control group was calculated according to the following equation:

$$\frac{\left(\text{Mean of caries increment of the control group} \right) - \left(\text{Mean of caries increment of the experimental group} \right)}{\text{Mean of caries increment of the control group}} \times 100$$

The percentage of caries increment of each group was calculated with the following equation:

$$\frac{\left(\begin{array}{c} \text{Mean of caries at the} \\ \text{second examination} \end{array} \right) - \left(\begin{array}{c} \text{Mean of caries at the} \\ \text{first examination} \end{array} \right)}{\text{Mean of caries at the first examination}} \times 100$$

The statistical analysis of the data, which was conducted using SPSS (for Windows version 9.0), include the followings:

1. Classification of data and calculation of frequencies.
2. Calculation of statistical parameters: the mean and standard deviation.
3. One-way analysis of variance (ANOVA), followed by Duncan's Multiple Range Test, was used to determine the significant difference among the groups in the first and second examinations, both for DMFT & DMFS indices; and F-test was used for determining the differences, within each group, between the two examinations.

RESULTS

Among (277) school children involved initially at outset, (235) completed the study, representing a (15.2%) loss. Most subjects failed mainly in moving from one school to another or being absent from the school on the day of fluoride application or the second examination. The distribution of the sample by sex in different treatment groups was given in table (1). The sample consisted of 116 (49.36%) males, and 119 (50.64%) females. It was distributed to the four groups in such away that the first group contained 45 (19.15%) children, the second group contained 58 (24.68%) children, the third group consisted of 59 (25.11%) children; whereas the fourth (control) group consisted of 73 (31.06%) children.

Table (2) revealed the mean \pm SD of DMF teeth for each group in the first examination as well as the second examination. There was no statistical significance between the two examinations regarding groups (1) and (3), while the second and fourth (control) groups showed highly and very highly significant differences, respectively, between the two examinations.

Table (1): Distribution of the sample according to sex and different groups

Sex		Group 1		Group 2		Group 3		Group 4		Total
		No.	%	No.	%	No.	%	No.	%	
Males	No.	24	20.69	25	21.55	28	24.14	39	33.62	116
	%	53.33		43.10		47.46		53.42		49.36
Females	No.	21	17.65	33	27.73	31	26.05	34	28.57	119
	%	46.67		56.90		52.54		46.58		50.64
Total		45	19.15	58	24.68	59	25.11	73	31.06	235

Table (2): A comparison of DMFT index between the two examinations, with percentage of caries increment for each group

Group	Examination	Mean \pm SD	F-Test	Percentage Caries Increment
1	First	3.644 \pm 1.654	N.S	-5.48*
	Second	3.444 \pm 1.603		
2	First	3.483 \pm 2.045	H.S	28.71
	Second	4.483 \pm 2.529		
3	First	3.915 \pm 1.985	N.S	7.79
	Second	4.220 \pm 2.035		
4	First	3.877 \pm 1.224	V.H.S	40.26
	Second	5.438 \pm 2.315		

* Minus score indicates caries reduction.

In the first examination there was no statistical significance among the four groups. At the second examination, those differences between the second and third groups were not significant. However, the differences between the first group and the other experimental groups on the one hand, and those between the control group and each of the foregoing groups on the other hand, were reported to be significant (table 3).

Table (3): A comparison of DMFT index in the first and second examinations among the groups

Examination	One Way ANOVA			Group	Duncan's Test		
	No.	F-value	PR < F		No.	Mean	Letter of Subgroups
First	235	1.32	N.S	1	45	3.644	A
				2	58	3.483	A
				3	59	3.915	A
				4	73	3.877	A
Second	235	8.02	0.001	1	45	3.444	A
				2	58	4.483	B
				3	59	4.220	B
				4	73	5.438	C

* Subgroups with the same letter were not significantly different.

The percentage of caries increment for each of the four groups, as shown in table (2), was (-5.48%), (28.71%), (7.79%), and (40.26%), respectively. The negative score for the first group indicated that there was a decline in the incidence of dental caries. Regarding the percentage of caries reduction of each of the experimental groups compared with the control group, table (4) clearly showed that the percentage was (112.81%), (35.93%), and (80.46%), respectively. There was no doubt that the best results were achieved with respect to the first group, followed (in descending order) by the third, and lastly the second group.

Table (4): The percentage of caries reduction for each experimental group compared with the control group regarding DMFT and DMFS indices

Index	Group 1	Group 2	Group 3
DMFT	112.812	35.939	80.461
DMFS	97.293	32.877	72.688

Regarding the DMFS index, and as shown in table (5), the mean \pm SD for each group was given for the two examinations. The difference between them was non-significant with respect to the first and third groups; and very highly significant for the second and fourth groups.

Table (5): A comparison of DMFS index between the two examinations, with percentage of caries increment for each group

Group	Examination	Mean \pm SD	F-Test	Percentage Caries Increment
1	First	5.089 \pm 2.720	N.S	1.75
	Second	5.178 \pm 2.614		
2	First	5.190 \pm 3.148	V.H.S	42.52
	Second	7.397 \pm 4.619		
3	First	6.136 \pm 3.989	N.S	14.63
	Second	7.034 \pm 4.464		
4	First	5.849 \pm 2.509	V.H.S	56.21
	Second	9.137 \pm 4.094		

The statistical differences among the four groups in the first examination were not significant (table 6). This figure was changed in the second examination in such away that only the difference between the second and third groups was statistically not significant, whereas those among the remaining groups (including those between the control and each of the experimental groups) were statistically significant.

Table (6): A comparison of DMFS index in the first and second examinations among the groups

Examination	One Way ANOVA			Group	Duncan's Test		
	No.	F-value	PR < F		No.	Mean	Letter of Subgroups
First	235	1.68	N.S	1	45	5.089	A
				2	58	5.190	A
				3	59	6.136	A
				4	73	5.849	A
Second	235	7.96	0.001	1	45	5.178	A
				2	58	7.397	B
				3	59	7.034	B
				4	73	9.137	C

* Subgroups with the same letter were not significantly different.

The percentage of caries increment for this index was increased by about (1.75%), (42.52%), (14.63%), and (56.21%) regarding the four groups, respectively (table 5). Table (4) showed the highest and lowest percentage of caries reduction of each of the three experimental groups in comparison with the control group. The former belonged to the first group (97.29%) and the latter attributed to the second group (32.87%). The percentage of caries reduction of the remaining third group was (72.68%). The results obtained from this index were similar to those obtained from the DMFT index.

DISCUSSION

The prevalence of dental caries in our country is increased due mainly to the increase in sugar consumption in addition to the lack of such preventive programmes conducted at schools⁽¹⁵⁻¹⁷⁾. So, we need to establish an effective programme to be used in Iraqi school to prevent and control dental caries focused on prevention, where the preventive approach is an essential and inescapable recommendation. This can be achieved by first: setting dental health education programmes that inform the people generally and students especially about the harmful effects of sugar on the general and dental health. Second: by the use of fluoride supplements (fluoridated toothpastes, fluoride tablets, fluoride mouthrinses, or fluoride gels) as a school-based programme.

This is the first study with regard to the evaluation of the effect of fluoride (at different frequencies of application) on dental caries conducted in Iraq.

The topical application of fluoride is routinely preceded by a rubber cup prophylaxis of the teeth. The rationale for performing the prophylaxis is to remove plaque and materia alba to enable the fluoride to contact the enamel surface of the tooth more efficiently⁽¹⁸⁾. A recent change has been the elimination of the need for routine prophylaxis before a topical fluoride application. The findings of many studies have demonstrated that removal of plaque may not be necessary because it does not reduce fluoride uptake by enamel but may favour it⁽¹⁹⁻²¹⁾. Consequently, the improvement in cost regarding the elimination of this step as well as the decrease in chair-side time for each treatment is making the single step procedure for application of fluoride more suitable for public health programmes as well as those programmes conducted at schools⁽⁹⁾.

The results of the present study revealed a significant difference between the group which received four times a year fluoride application on the one hand and both groups which received annual and bi-annual applications on the other hand. Although the percentages of caries reduction (for both the DMFT and DMFS indices) of the bi-annual group were more than twice as great as those of the annual group, they were statistically not significant. These results are in agreement with other studies which compared the effectiveness of annual versus bi-annual applications of APF solution⁽²²⁾ and APF gel⁽²¹⁾. They showed, after three years, that there is no difference in mean caries increment between the two frequencies. Also, the findings of the present study are comparable with other study which reported a reduction in DMF surfaces of 28% after one year among children 8 to 12 year old who had received a single application of APF gel applied in foam-rubber trays, compared with controls⁽²³⁾.

The difference between the bi-annual and four times a year application frequencies, which is statistically significant, can be explained as that with the more frequent application of fluoride, there is a chance for teeth to expose to fluoride in such away that permits a greater degree of remineralisation and/or arrestment of initial carious lesions than the less frequent (once or twice a year) application. This is in agreement with the results of other studies⁽²⁴⁻²⁶⁾. Furthermore, the more frequent application coincides with those teeth that erupted during the study better than the less frequent application. These results are in agreement with a study which found that increased frequency of application of a low-fluoride topical solution twice than the high-fluoride topical solution may provide caries protection to pre-school children with a relatively high caries activity⁽²⁷⁾. In contrast, the results of our study disagree with the findings of the study that reported no statistical difference between fluoride varnish applied (2) and (4) times a year⁽²⁸⁾. However, their trial was conducted on children with a relatively low caries activity.

In Ninevah, many studies found that the concentration of fluoride in drinking water to be less than 0.2 ppm⁽²⁹⁻³¹⁾. The use of intensive repeated topical fluoride therapy as a substitute to water fluoridation seems to be highly efficacious.

CONCLUSION

The results of the present study after one year of topical APF gel application with different frequencies revealed a significant differences between the group receiving the fluoride treatment four times a year and both groups which received the treatment once or twice a year in favour of the four times a year frequency, indicating that the effect of fluoride in reducing dental caries increased with increasing the frequency of application. However, although there is a difference between the once and twice a year application, but this difference is not statistically significant.

In view of the foregoing background, it seems that the frequency of topical applications should be dictated by the conditions and needs presented by each patient and not by the convenience of the dental office. This conclusion is supported by the data cited earlier that a series of applications is required to impart maximal caries resistance to the tooth surface^(1,7).

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