FLUORIDE LEVEL IN DENTIFRICES

R Abdul-Kadir, L Abdol-Latif. Flouride Level in Dentifrices, Annals Dent Univ Malaya 1998; 5: 2-5

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ABSTRACT

To date, fluorides has remained to be the best means of controlling dental caries. Fluoride is given either systematically via fluoridated water or topically through other supplements including toothpastes. In recent years increasing prevalence of enamel defects or fluorosis is observed in both populations receiving or not receiving water fluoridation. It is suspected that excessive ingestion of a "standard" 1000 to 1500 ppm fluoride from toothpastes might be a contributing factor to the presence of such defects. In Malaysia, reports of enamel defects occurring amongst 12 to 16 year-old schoolchildren ranged between 67 to 88 percent. Where water fluoridation is available, the amount of fluorides received from the home is between 0.3 to 0.5 ppm F. However, almost all toothpastes sold locally contains fluoride, the content of which is unknown to the consumers. This study reports on the analysis of fluoride levels carried out on 20 toothpaste samples sold locally. Results showed that fluoride levels in all 20 samples ranged between 20 to 1970 ppm F. Only two of the 20 samples analyzed, however, indicated having a level anywhere near the "standard" level. In addition, only two types of children's toothpaste with a fluoride concentration of 20 and 450 ppm F were commonly available as compared to adult toothpastes in all the samples studied.

Keywords: fluorides, dentifrice

INTRODUCTION

Fluoride has universally been accepted as a major contributor to the decline in dental caries (1). It is available naturally in foods and also artificially added to drinking water and other supplementary forms such as dentifrices. Ingestion of fluorides during tooth formation increases the resistance of the enamel to initial acid attack and also promotes remineralization of existing lesions(2,3). However, ingestion of excessive amounts of fluoride during the period of tooth formation can lead to mottling of the enamel, or fluorosis(4).

In the last ten years, increased prevalence of enamel fluorosis were reported with widespread availability of fluorides and increased modes of fluoride delivery(5,6). These reports were not limited to areas with optimal fluoride water but include fluoride deficient communities as well(7,8). While the fluoride regiments used may differ, what is common in all these areas is the use of dentifrices containing between 1000 to 1500 ppm of fluoride(9,10). In view of this, researchers had in turn expressed concern in that fluoride from fluoridated toothpastes might be a contributing factor to fluorosis when excessively ingested by young children(3,10-13).

In Malaysia, available cross-sectional studies in Penang, Selangor and Johore recorded the prevalence of enamel defects amongst 6 to 16 year-old children to be ranging from 67 to 88 percent(14,16). Fluoride concentration in the water supplies received at the homes has been shown to be between 0.3 to 0.5 ppm F(17). Toothpastes has been introduced since the early 1970's and, to date almost all toothpastes produced locally is observed to contain fluorides. It is also observed that an influx of dentifrices of all kinds and brand, both locally manufactured and imported, had steadily entered into the Malaysian market in more recent times. In addition, there is a general lacking in the monitoring of product formulation, level of fluorides used and, cost of the dentifrices sold on the counter. Studies in other countries indicated that the fluoride content of adult size dentifrices commonly used ranged between 1000 to 1500 ppm F(9-11). However, no report of the fluoride content in the dentifrices sold locally is available. In addition, the concentration of active fluoride used on locally sold toothpaste is also not available. The purpose of this study is to report on the fluoride level in dentifrices sold locally.

MATERIALS AND METHODS

Twenty different types of imported or locally manufactured fluoridated toothpastes tested in this project were bought off the shelf from 5 different large and most frequented supermarkets in the Klang Valley. It was assumed that the replacement rate of the stocks in such supermarkets was high due to sufficiently good sales.

Preparation of Total Ionic Strength Adjustment Buffer (TISAB) solution.

58 g of sodium chloride and 0.3 g of sodium citrate were dissolved in 500 ml of distilled water, followed by the addition of 57.0 cm^3 of glacial acetic acid. The reaction mixture was heated to ensure that all the salts had dissolved. On cooling the reaction mixture, a concentrated sodium hydroxide solution was added to reach a pH of 5.0 - 5.5. The solution was then diluted to 1.0 liter mark.

Preparation of the sodium fluoride (NaF) standard solution (~ 100 mg F per 100 ml)

0.22 g of NaF was dissolved in distilled water to the 1.0 liter mark in a volumetric flask.

Preparation of the NaF calibration solution (~10 mg F per 100 ml)

10 ml of the 100 mg F per 100 ml stock solution was diluted to the mark in a 100 ml volumetric flask.

Fluoride ion measurement

Fluoride ion content was determined by using the fluoride ion

selective electrode, which consists of a fluoride ion-sensitive membrane sealed over the end of an inert and usually opaque plastic tube which contains an internal electrode and filling solution10. For each product, a weighed sample of toothpaste of approximately 200 mg was placed in a 250 ml beaker containing 50 ml of Total Ionic Strength Adjustment Buffer (TISAB). The TISAB solution was introduced for the purpose of adjusting the condition of fluoride analysis so that fluoride ion concentration could be deduced from measurement of fluoride ion activity. The sample-TISAB mixture was then boiled for 2 minutes. After cooling, the solution was quantitatively transferred to a 100 ml volumetric flask and diluted to the mark with distilled water. A 10 ml of this freshly prepared solution and 10 ml of the NaF calibration solution, prepared from the standard solution, were then pipetted into a 25 ml beaker and stirred with a magnetic bar. Electrodes were rinsed with distilled water and dried with a tissue before and after each measurement. Readings were taken after 3 minutes. The whole procedure was repeated three times for each study sample. The same procedure was repeated for the other nineteen formulations.

The formula used to calculate percentage of fluoride in the samples was:

Percentage fluoride (%F) = M/S x 100

where,

M: concentration of fluoride in mg/100 ml

S: weight of the sample.

RESULTS

Table 1 presents analyses of the fluoride levels in all seventeen toothpaste formulations, cosmetic or therapeutic toothpastes, for adults. The fluoride composition in all the toothpastes ranged from 20 to 1970 ppm. The fluoride content of all but two of the adult toothpastes, were found to be below the commonlly used level of 1000 to 1500 ppm F. The two imported toothpastes, Colgate Total and Oral-B formulations were found to contain 1020 and 1970 ppm F, respectively.

Only two brands of children size toothpastes most commonly found on the shelves of the supermarkets were included in the study (Table 2). Another toothpaste brand (Colgate) with no specified indication for which consumer group but is also given as part of the tooth drill programme in schools was also included. The concentration of fluoride was found to range between 40 ppm and 390 ppm F for the two imported toothpastes (Switzal) and Kodomo Lion, respectively to 750 ppm F for the locally manufactured Colgate toothpaste.

DISCUSSION

Since its introduction in the mid 1950's, numerous dosage formulations of fluoridated toothpastes had been concocted to emulate the effects of drinking 1000 ml of water fluoridated at 1 mg per litre(18). Studies had shown that caries prevention efficacy of fluoride toothpaste was achieved when the concentration of fluorides in toothpaste ranged between 500 to 2800 ppm F(9,11,12,19) Most toothpastes sold in the industrialized countries today, however, contain between 1000 to 1500 ppm F(9,11). In this study, eighteen formulations comprising of 6 locally manufactured and 12 imported

Table 1. Fluoride content of a selection of standard fluoride toothpastes sold locally.

Brarnd	Mean Sample weight (mg)	Fluoride ingredient added	Total F %	ppm F
Colgate (Extra Mint)	235.9	NaF +MFP	0.023	230
Colgate (Max cavityProtection)	210.9	NaF +MFP	0.030	300
Colgate (Total)*	211.9	NaF	0.102	1020
Periogard*	213.4	nl	0.087	870
Sparkle*	222.4	NaMFP	0.010	100
Fresh & White	225.4	2 F1 system	0.020	200
Darlie*	239.3	NaMFP	0.032	320
Oral-B*	203.6	NaF	0.197	1970
Metadent P*	205.1	MFP	0.030	300
Sendodyne-F*	200.4	MFP	0.024	240
Fluocaril bi-fluore*	208.9	NaMFP + NaF	0.029	290
Pyodontyl*	207.2	nl	0.002	20
ABCDent*	212.0	nl	0.02	200
Signal	220.2	MFP + NaF	0.048	480
Topol Plus*	212.9	NaMFP	0.016	160
Pepsodent*	217.4	NaF	0.012	120
Promise	243.4	nl	0.025	250

** Imported* *nl- not labelled*

Table 2: Fluoride content of children's toothpastes sold locally

Brand	Fluoride ingredient added	Average F (/)	ppm F
Kodomo Lion*	nl	0.039	390
Zwitsal (Strawberry)*	NaF + MFP	0.004	40
Colgate (School Prog)	NaF + MFP	0.075	750

** imported* *nl - not labelled*

toothpastes were found to be below 1000 ppm F thus raising concern as to its efficacy.

Fluoridated toothpastes had strongly been suggested to be a major contributor to the caries decline reported in many industrialized countries, particularly those without water fluoridation, since the 1970's(9,10). Given the high dentist to population ratio of approximately 1:1 3,000(20) and, the fact that only 66% of Malaysia received the benefits of water fluoridation(20), fluoridated toothpaste is therefore an important additional vehicle in the country's effort to combat dental caries. In light of the above findings, monitoring of effective fluoride level in both locally manufactured and imported toothpastes sold in the country should seriously be undertaken by appropriate agencies.

On the other hand, in a tropical country like Malaysia, a low level of fluoride containing toothpastes need not necessarily be interpreted as being insufficient. Ingestion of fluorides can come from different sources. Apart from its water being fluoridated, Malaysia also had an abundance of foodstuffs and beverages that contain fluorides(21). In addition, the so- called "optimal' fluoride intake that is aufficient to confer caries protection and beyond which dental fluorosis may occur is not known accurately(3,13). An appropriate dosage should therefore be interpreted as a compromise between one that provides caries preventive action yet does not introduce avoidable risks. A reduced or lower fluoride concentration in toothpaste than the 'standard' could contribute significantly to reducing the prevalence of visible fluorosis(22).

Findings from this study also showed that locally sold children's toothpaste contained between 20 to 450 ppm F while the toothpaste used in school tooth drill programme contained 750 ppm F. More recent studies(6,23) had reported that when children 2 years or younger regularly used 1000 ppm F toothpaste, the risk of developing fluorosis in the permanent dentition was measurably elevated. Rock(12) claimed that a 'standard' 1000 ppm F paste contains twice as much, and a higher fluoride paste three times as much, fluoride as on formulation especially for children. For this reason, a toddler dentifrice containing 250 ppm F was introduced in 14 European countries since early 1990's(24). On the other hand, other studies(25,26) showed that low fluoride toothpastes compromise caries prevention efficacy. Nevertheless, recent reviews had recommended that for children considered to be at low risk of caries and living in fluoridated areas, a low fluoride formulation containing no more than 600 ppm of fluoride should be used. But for those at higher risk of developing caries, a standard toothpaste containing 1000 ppm F should be recommended(11,19). In light of these reports, the current dosage in children's toothpaste should perhaps be reviewed.

It is also important to note that current knowledge is of the opinion that it is abuse through ingestion rather than use of fluoride toothpastes which constitutes the main risk to enamel opacities or fluorosis(11-13). In this context, Beltran and Szpunar(13) are of the opinion that young children may be receiving amounts of fluoride large enough to be considered a risk for developing fluorosis specifically through accidental swallowing of fluoridated toothpaste . In light of such concerns, fluoridated dentifrices on sale within the United Kingdom now carry the advice that only a 'pea-sized' amount of toothpaste once per day need to be used for children under 6 years old(11). In USA, the North Carolina Workshop on "Changing Patterns of Fluoride Intake" recommended that toothpastes with a concentration of >1100 ppm F should be clearly labelled 'Not for use by children under 6 years old(19). In addition, the Workshop also recommended that the use of flavors which may increase ingestion of fluoride dentifrice by young children should be strongly discouraged. Furthermore, to enable informed choice, toothpaste packaging should also include clear labelling to indicate the amount of fluoride present, expressed in ppm F(11). Rock(12) is also of the opinion that junior dentifrices in gel form produced by manufacturers with claims of longer brushing time than when using coventional pastes may in fact further increase the chance of ingestion. In view of these reports and given the relatively high prevalence of enamel opacities amongst 12 and 16 year-old Malaysians, all the above views should be given due attention by the dental fraternity.

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