SCIENTIFIC ARTICLE

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Caries inhibitory effect of fluoridated sugar in a trial in Indonesia

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Abstract

Background: In some regional areas of Indonesia, caries prevalence is increasing rapidly. As water, salt or milk fluoridation were not considered suitable for use throughout Indonesia, and fluoridated tooth paste is mostly too expensive, a fluoride co-crystallised sugar containing 10ppm fluoride was prepared. Its efficacy in inhibiting caries development was tested in a field trial.

Methods: The field trial was established in Medan, Sumatera. All dietary background data necessary to ensure the safety of a trial were collected. Subjects chosen were 176 children who were residents of two orphanages and a boarding school for children of poor rural families. The trial used a double-blind format. Close monitoring of fluoride consumption was maintained, and fluoride excretion rates were assessed six monthly by urinary fluoride analysis.

Results: Records of total tooth surface caries present initially and after 18 months of sugar supply showed that the children using fluoridated sugar had significantly fewer carious lesions than those who used normal sugar.

Conclusion: This result indicates that sugar might be considered as a further vehicle for supplementary dietary fluoride in communities where there is a high caries prevalence or high caries risk and little exposure to fluoride.

Key words: Fluoridated sugar, trial, co-crystallization, sugar processing.

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INTRODUCTION

Caries rates are increasing rapidly in many developing countries, due to the increased availability and resultant frequency of ingestion of refined carbohydrates.[1] This is particularly so in some regions of Indonesia. For example, caries prevalence scores for children under five years in West Java were reported to have reached a decayed, missing or filled teeth (dmft) of 7.98 in 1990.[2] This is happening at the same time as caries prevalence in children has significantly reduced in Australia and most other industrialized countries, despite the maintenance of consumption of high amounts of sugar. The major cause of this reduction has been shown to be the introduction of systemic and topical fluorides, systemic being through use of water, milk or salt as vehicles, and topical mainly through the use of fluoridated toothpaste. Research has shown that both the systemic and topical forms overlap in their mechanism of action, the predominant means of caries control being post-eruptive through the inhibition of demineralization of tooth mineral and the enhancement of remineralization at the site of acidic challenge.[3]

Many of the vehicles used to provide fluoride in developed countries, e.g., toothpaste, water and milk are not readily available or safely applicable in developing tropical countries. Salt is used effectively in more temperate climates for this purpose though its utilization rate varied markedly throughout Indonesia, limiting its usefulness. For this reason, it was decided to investigate the potential for sugar to be used as a fluoride vehicle in a community setting in Medan, Indonesia.

The use of sugar as a fluoride vehicle was first achieved successfully *in vivo* by Luoma[4] in Finland, where fluoride at a concentration of 10mg/kg was added to sugar used to prepare deserts and confections for children who were confined to an institution for the mentally handicapped. Total amounts consumed by the children were closely monitored to ensure that the intake of fluoride remained well within safe levels. A mean caries reduction of 42 per cent resulted in the test group compared with the control group over three years. A number of researchers have added fluoride to sugar in rat caries experiments, a concentration between 5-10ppm proving to be highly protective.[5-7]

The objective of this investigation was to determine whether sugar could be used as a safe, effective fluoride vehicle to inhibit caries in groups of children in Indonesia.

MATERIALS AND METHODS

Selection criteria for trial site and subjects

As the study aimed to test the effectiveness of sugar with fluoride added to control caries in a group of children, the following requirements were used in the

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choice of groups of potential subjects: a constant population for the duration of the experiment; sufficient numbers to provide statistically verifiable results; relatively equal mix of age and gender; relatively similar food intake patterns and amounts, and the ability to be strictly aware of sugar consumption rates; equivalent, high dmft/DMFT scores; similar sources of drinking water with minimal fluoride ion present; no fluoridated toothpaste used; and ability to strictly control use of foods from external sources.

Age of subjects

Selection of the age of the children to be involved was of concern. In very young children, any effects would be a combination of both systemic and topical action, involving a changing mixed dentition. Any systemic effect would not be detectable until sufficient permanent teeth had erupted. As funding and time were limited, it was decided to look for groups of older children who would satisfy the requirements listed above. Even though the predominant action of fluoride would be topical, a successful result would suggest that it would be even more likely to be effective at younger age levels with added systemic effects.

Ethical approval for the project was provided by the Committee on the Ethics of Human Experimentation of the University of Adelaide, and Health Authority in Medan, Indonesia.

Final selection process

The subjects were chosen from 176 children aged between seven and 19 living in two orphanages and a boarding facility for rural children from poor families. The institutions were approached to ask for their willingness to participate, the full implications being explained as a prerequisite for Ethics Committee approval for the project to proceed. All were promised provision of free sugar for the duration of the trial, on strict condition of adherence to the requirements of the trial. Written consent for involvement of the institutions and the children was given by the guardians of the children in the orphanages and the principal of the boarding school.

Subject group characteristics

The children were separated into two groups so as to provide a relatively equal mix of age and gender (seven to 19 years) with other characteristics as described previously as similar as possible. All subjects had at least 10 permanent teeth present. Age range, gender and caries prevalence scores for each group are provided in Table 1. Even though the numbers varied, it was expected that the drop out from Group I (with a greater proportion of orphanage children) would be considerably higher than for Group II. At the final count 25 children in the high and low age range from Group I were not present for the final assessment. One hundred and fifty children of ages ranging from 11-17 remained when the final clinical assessment was made.

Table 1. Age range, gender, caries prevalence scores for Groups I and II

Group	n	Age	Sex	D	M	F	DMFS
Group I	47	8-17	F	3.21	1.70	0.06	4.97
	72	7-16	M	1.60	0.62	0.10	2.32
Group II	30	11-19	F	2.93	1.0	0.27	4.20
	27	12-19	M	1.40	1.67	0.15	3.22

Analysis of subjects' diets and alternative sources of fluoride

Almost all food consumed by the children was prepared by staff of the institutions. Mean daily sugar consumption for the children in the orphanages was determined at 60 grams per child per day. This was calculated from the monthly consumption of sugar at each place. The sugar was incorporated in tea, breakfast porridge and afternoon tea, all materials being prepared in the kitchens. The children were served all food, ensuring little variation in consumption rate between children. This consumption rate was slightly increased during the fasting month of Ramadhan. In this month the children would not eat anything in daylight hours, and would break the fast when the sun set with various sweet cakes or porridge and tea before they had dinner. Detailed analysis of fluoride background levels in food supplied to the children were made, using the Taves method of fluoride separation[8] followed by use of a combination fluoride electrode. These concentrations were found to be similar for both test and control groups. It was calculated that the amount of fluoride ion consumed from rice, tempe, green bean porridge, Sumateran tea infusion, vegetables, salted fish, and tahu totalled 0.78mg/day (see Table 2 for sample fluoride content of foods consumed). The water consumed by all subjects came from the local reticulated water supply. The fluoride content was found to vary from 0 to 0.2ppm at different times of the year, which is consistent with the findings by Soeparto *et al.* for fluoride concentration of water in the Medan region.[9]

It was noted that where any toothpaste was available, only the cheaper non-fluoridated toothpastes were purchased for use by the subjects. It was also confirmed that strict control would need to be exercised to prevent outside sources of sucrose being used by children, although as all the children involved were poor, there was little opportunity to purchase such goods.

Determining the concentration of fluoride to be added to sugar

The concentration of fluoride ion which would inhibit caries development was first investigated using

Table 2. Fluoride content of foods consumed (mg/kg or ppm)

Ingredients	F content/ppm	Ingredients	F content/ppm
Rice	0.18	Green bean	0.23
Casava leaf	0.11	Sumatera tea	2.12
Salted fish	4.08	Rose tea	2.98
Salted bait	3.73	Coconut milk	0.88
Tempe	0.26	Tahu	0.30

Table 3. Effect of varying concentrations of fluoride ion in demineralizing solutions on lesion depth in enamel *in vitro* after 7, 14 and 28 days (mean lesion depth in μm)

Time	F concentration in solution (in ppm)						
	0	0.5	1	5	10	20	40
7 days	186.6	96	96	32	14	8	0
14 days	362	210	118	74	27	15	6
28 days	517	395	230	106.6	80	67	33

pilot *in vitro* trials, where varying concentrations of sodium flouride (NaF) were added to sugar, which was incorporated into an artificial caries system. The artificial caries system was that used successfully by Featherstone *et al.*[10] in various enamel caries experiments. The results, as seen in Table 3, indicated that with this system, between 5 to 40ppm fluoride ion (or mg of fluoride per kilogram of sugar) resulted in acceptable levels of caries inhibition. Considering that the daily sugar intake per child was 60g, it was realized that consumption of 10ppm fluoride added to the sugar would result in the ingestion of 0.6mg fluoride ion per day from that source. It was preferable not to exceed this amount, considering that fluoride intake from other foods was already 0.79mg per day. While this is well below toxic dose levels, the risk of later mild fluorosis in the younger children was to be avoided. A further factor leading to the decision to use 10ppm fluoride was that this concentration had been used successfully previously by Luoma *et al.*[4] and in rat caries inhibition studies.[5-7]

Preparation of fluoridated sucrose

It was noted that when NaF powder was added to bulk sucrose, it quickly ended up in high concentrations on the bottom of the container. Clearly this would result in variable dose levels, and of greater concern, in periods of high dose levels of fluoride ion. The possibility of bonding fluoride to sucrose had to be considered. It was noted that chemical bonding to form 1' fluorosucrose resulted in a form where the fluoride could only be released in an ionized form under conditions which could not be achieved intra-orally.[11] Hence the method of co-crystallization used by Bowen and Pearson[7] in their animal studies was followed. After numerous investigations into the way fluoride could most suitably be co-crystallized with sucrose, it was found that the most effective method for bulk sugar treatment involved spraying the sugar with a fine mist of NaF solution when it was spread in a thin layer on a flat surface. Close observation of the sugar refining process in a sugar mill near Medan showed that NaF solution could be sprayed onto moist sugar as it emerged from the centrifugal chamber onto the drying tube (see Fig 1 to indicate site for spraying). A sugar mill near Medan gave approval for batch production of the fluoridated sugar to take place after the day's normal processing had taken place.

A variety of concentrations of fluoride ion in solution were tested initially in the laboratory and then in the sugar mill, to ensure that a homogeneous concentration of fluoride ion was present in the end product crystallized sugar. Finally, a concentration of 5200ppm fluoride ion (mg/L) in solution as NaF was sprayed onto the moist sugar using an adjustable nozzle, and driven by an electric pump. The spray was adjusted to provide the width of coverage required, delivering 25mL of fluoride solution per second (3L in 120 seconds). The sugar was found to pass at the rate of 300kg in 120 seconds. This resulted in the finally dried sugar having a concentration of close to 10ppm on batch analysis using the Taves method of fluoride separation[8] as described previously (range of five samples per pack from 10 separate packs was nine to 10.5ppm, with a mean of 9.6ppm.) The dried sugar was stored in 50kg moisture proof packs and kept in a moisture and vermin proof locked environment at the sugar mill. It was clearly identified with symbols to identify the sugar for test use, though being not identifiable to the subjects using it.

Organization of the field trial to test the caries inhibitory effectiveness of the fluoridated sugar

General organization

The trial was run on a double-blind basis with test and control groups in which neither the examiners nor

Table 4. Grading system used for scoring carious lesions

Code	Category	Criteria
0	Sound enamel	There is no sign of enamel defect
1	Initial caries lesion	On smooth surface; white spot as evidence of subsurface demineralization On pit and fissure; loss or normal translucency of the enamel adjacent; shadowing at the base of the fissure
2	Enamel caries (cavitated)	Cavitation in enamel only
3	Arrested caries	Cavitation into enamel or dentine with hard base, with or without staining
4	Active dentine caries	Cavitation into dentine with soft dentine base
5	Pulpal involvement	Any signs or symptoms of pulpal involvement, e.g., pulpitis
Md	Missing due to caries	Any missing tooth that had been caused by extraction due to caries, or root fragment without any crown
Mo/Mt	Missing due to orthodontic treatment/trauma	Any missing tooth due to orthodontic treatment or trauma
P	Persistent tooth	Persistence of primary tooth
U	Unerupted tooth	Tooth unerupted at the due time
O	Restoration	Any restoration
H	Hypoplastic enamel	Enamel defect caused by hypoplasia

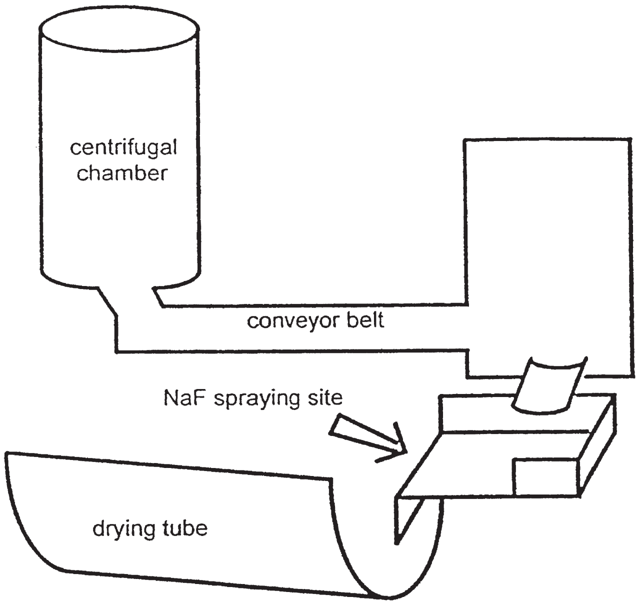

Fig 1. Diagram of parts of the sugar mill. Arrow indicates spraying site of NaF solution.

the subjects were aware which group had the fluoridated sugar or that without fluoride. To facilitate this, and to assist with the complexity of general organization of the project, a co-ordinator was employed to determine which would be experimental and control groups, and keep this information hidden until the end of the project. The co-ordinator also organized distribution of the appropriate sugar to both groups, ensuring batch analyses of fluoride concentrations of the fluoridated sugar were made on each lot prior to distribution. Organization of the clinical assessments, urine analyses, and maintainance of records was also the responsibility of the project co-ordinator. The first sugar was provided in early August 1993.

Initial and continuing clinical assessment

The following were carried out for each child prior to, and at the conclusion of the study: clinical assessment of general dental health and calculation of decayed, missing or filled surfaces (DMFS) scores; clinical assessment of incipient caries lesions present on occlusal and smooth surfaces; and standardized radiographic bitewing diagnosis of proximal and occlusal surface caries.

Clinical examinations were preceded by a prophylaxis using pumice paste (no fluoride). A strong light source was used, and the teeth dried thoroughly before examination. Incipient enamel lesions were examined separately using a 'dry-wet-dry' examination procedure, i.e., where the visible tooth surfaces were examined initially following thorough drying, then after salivary coverage, followed by drying again to confirm the presence of the 'white spot' lesions. Both examiners had had much experience detecting such lesions during involvement in another clinical study in Adelaide. The lesions visible clinically were recorded as per the criteria presented in Table 4.

Table 5. Changes in DMFS scores for both Groups over 18 months

Variable	Group I (n: 51)			Group II (n: 77)		
	Mean	SD	SE	Mean	SD	SE
DMFS (BL)	4.96*	3.92	0.55	5.74	4.23	0.59
DMFS (F)	6.43*	4.23	0.59	6.04	4.62	0.53
DMFS increment	1.47†	1.69	0.24	0.30†	0.63	0.07

* †Significant difference at $p<0.05$ (Anova).
(BL=baseline; F=final).

A second examination was carried out on randomly selected subjects by the main examiner and a second clinician to determine examiner reliability and inter-examiner agreement. A high level of inter-examiner reliability was recorded (R values ranging from 0.91 to 0.97).

Radiography was carried out by a trained radiographer using a standardized method, involving tube locating devices and film holders. Radiographs were viewed using a darkened viewing box in a dark room, windows to fit radiographs only being left undarkened. Fixed distance magnification was used, and lesions classified according to the method of Pitts.[12] Radiographs from 30 children were read twice within a week, and results compared to estimate examiner reliability. The reliability scores were high, with R values of 0.94 and 0.90.

Urinary fluoride measurements

It was decided as part of the overall plan of the trial to keep a record of the fluoride concentrations in urine in a randomly sampled group of subjects representing both control and test group before the trial began, and at six monthly intervals until completion. This would act as both a monitoring and a safety device, to ensure no unexpected factors were being introduced affecting fluoride intake levels. Urinary fluoride samples were collected three hours after breakfast for three days in a row. These samples were collected by the children with staff supervision, and the samples brought to the co-ordinator for assessment. Total ionic strength adjustment buffer (TISAB II) was added to urine samples and to fluoride standards (1:1; vol/vol), and the fluoride concentrations measured directly from a combination fluoride selective electrode. As the fluoride samples were collected at fixed regular times, urinary creatinine levels were not determined.

Duration of the study

Ideally the study should have been conducted over three years. However, as it was supported by a limited budget through the Dental School, the University of Adelaide, it was necessary to stop after 18 months. Attempts to obtain further funding from a number of sources were unsuccessful.

Clinical assessment

Paired *t* test and analysis of variance (ANOVA) were used to test the differences between the control group

Table 6. Changes in individual DS, MS and FS scores for both Groups

D component scores of Group I and Group II (age group 11-17 years) at baseline (BL) and final (F) examinations and their increments

Variable	Group I (n: 51)			Group II (n: 77)		
	Mean	SD	SE	Mean	SD	SE
D comp (BL)	3.86*	3.04	0.42	3.50	2.56	0.43
D comp (F)	5.00*	3.50	0.47	3.70	2.53	0.29
D comp increment	1.14†	1.79	0.25	0.21†	0.86	0.10

* †Significant difference at p<0.05 (Anova).

M component scores

Variable	Group I (n: 51)			Group II (n: 77)		
	Mean	SD	SE	Mean	SD	SE
M comp (BL)	1.06	2.60	0.37	1.91	3.11	0.36
M comp (F)	1.39	3.12	0.36	2.10	3.12	0.36
M comp increment	0.33	0.86	0.12	0.20	0.65	0.07

F component scores

Variable	Group I (n: 51)			Group II (n: 77)		
	Mean	SD	SE	Mean	SD	SE
F comp (BL)	0.06	0.31	0.04	0.34	0.60	0.07
F comp (F)	0.04	0.20	0.03	0.24	0.54	0.06
F comp increment	-0.02	0.14	0.02	-0.10	0.35	0.04

(Group I with ordinary sugar) and the test group (Group II with fluoridated sugar) after 18 months of continuous utilization of each.

RESULTS

Changes in caries increment scores

The incremental increase in DMFS scores was 1.47 in the control group, compared with 0.3 in the group consuming fluoridated sugar (Table 5). This was statistically significant at p<0.05 (ANOVA). The baseline scores for both groups were relatively similar. When viewed as individual D, M and F scores (Table 6), the greatest component of the difference was in the D increment. Further, when both incipient and proximal cavity scores were considered separately (Fig 2), it is clear that the incipient lesions comprised the greatest incremental component to increase in the control group.

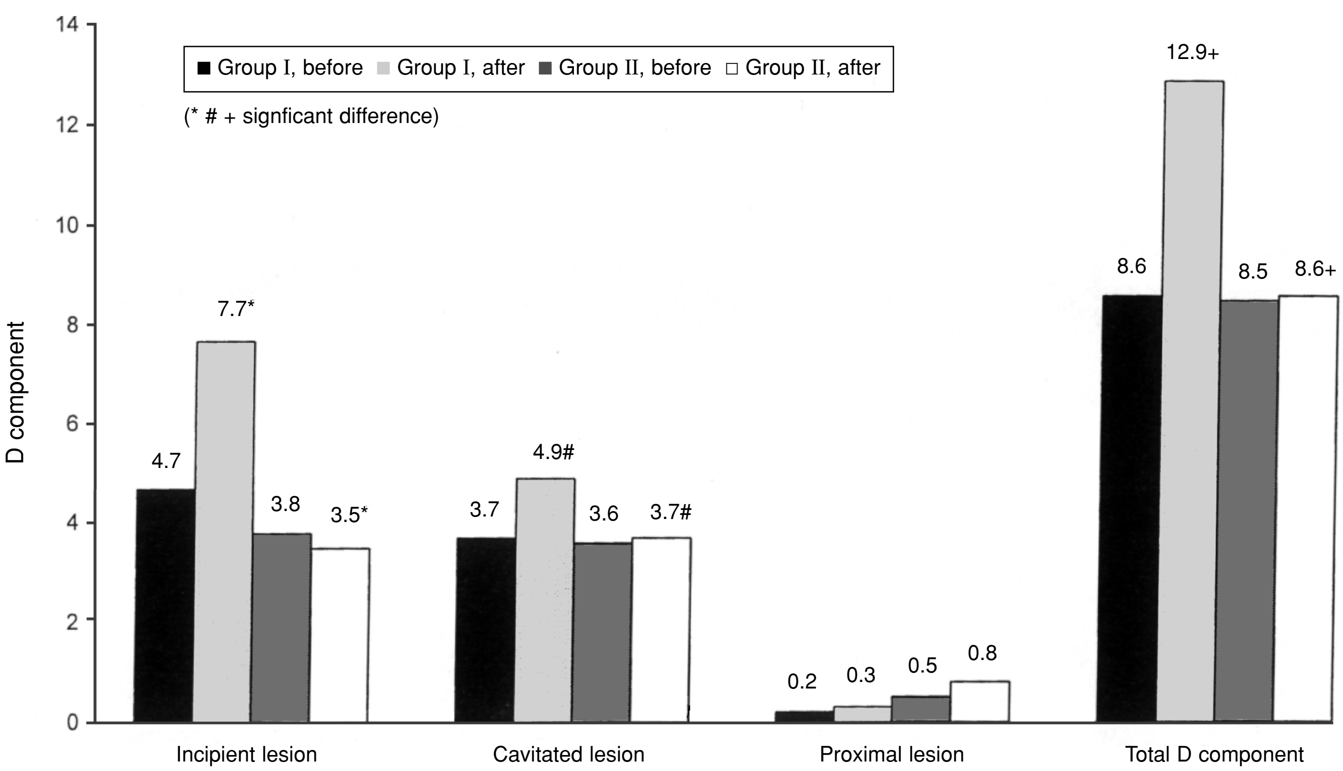

Fig 2. Changes in DS scores – total decayed component (incipient, cavitated and proximal lesions) for both groups.

Table 7. Mean urinary fluoride levels from the initial and for three six monthly samples during the 18 month period

Test	Group I (n: 30)			Group II (n: 30)		
	Mean	SD	SE	Mean	SD	SE
Baseline	0.21	0.10	0.02	0.13	0.05	0.01
Follow up 1	0.19	0.13	0.02	0.17	0.07	0.01
Follow up 2	0.13*	0.04	0.01	0.34*	0.14	0.03
Follow up 3	0.17†	0.07	0.01	0.29†	0.14	0.03

* †Significant difference at $p<0.05$ (Anova).

Urinary fluoride changes

Mean urinary fluoride levels are recorded in Table 7 for the initial (baseline) and for three, six monthly samples covering the 18 month period. These remained relatively similar in the control group, and doubled in the test group. There was no evidence of any unscheduled rise in background fluoride intake levels during the course of the trial.

DISCUSSION

Even though dental caries may be regarded as a multifactorial disease, sucrose is demonstrably the most cariogenic factor in initiating the caries process.[13]

Many studies have also shown that the oral physiological condition is directly affected by the intake of sugars. Plaque pH drops immediately by around two pH units following a rinse of glucose or sucrose solution, and returns to the initial state within approximately two hours.[14] This pH drop can be inhibited by fluoride and other ions if these ions are incorporated in sugar solution, either in experimental animals[15] or in humans[16] in which fluoride inhibits lactate production. Hata *et al.*[17] found that flouride inhibited acid production even more strongly under anaerobic condition found in thick plaque.

The successful role of fluoride in inhibiting caries in the more industrialized countries over the last two decades, despite the maintenance in most of a continuing high level of sugar consumption, makes it the most practical means of assisting the developing countries to control the effects of the inevitable increase in refined carbohydrate consumption which increasing prosperity brings. However, as stated previously, the vehicles used for both systemic and topical delivery used in the former countries are not generally applicable in the developing countries. This applies to Indonesia, where dental health care is not widely available and water fluoridation cannot be applied due to geographical location and limited access (only 5-20 per cent of the population in the cities use reticulated water). The fluoride content of well water used in some areas in South Sumatra and Kalimantan is about 0.3ppm except in an area in west Java (0.75ppm) and in east Java (2.10ppm). In the latter area the caries prevalence was found to be very low (5 per cent of children experiencing caries) while in other areas caries prevalence was high. The percentage of pre-school children experiencing caries in separate 1988 and 1992 surveys were 75 per cent and 95.5 per cent respectively with dmft scores of 7.02-7.98.[18] As suggested by Koloway and Kailis[2] the management of high caries experience would consume a very large part of the national health budget. A caries preventive method that can be easily applied nation wide at low cost and have a high level of effectiveness and safety is strongly needed.

The use of sugar as a fluoride vehicle makes much sense, in that the agent largely contributing to the caries increase carries the protective agent, and the greater the level of consumption, the greater the protection potentially provided. Even so, this method of fluoride distribution must be closely controlled. Hence, in this study, every precaution considered possible was applied to ensure that the level of fluoride ion intake remained as low as possible to achieve the desired result.

The use of sugar with 10ppm fluoride added, given a sugar consumption of even 100gm/day would result in approximately 1mg of fluoride ion per day from this source. Despite the consumption of fish and tea and some fluoride in drinking water, total intake of fluoride ion was around 1.4mg per day in this study. This is well below the probable toxic dose concentrations.[19] Enamel fluorosis can occur following either an acute or chronic exposure to fluoride during tooth formation. DenBesten and Thariani[20] concluded that the transitional early maturation stage of enamel formation is most susceptible to the effects of chronic fluoride ingestion at above optimal levels of fluoride in drinking water. It is unlikely that the consumption of 1.4mg fluoride ion per day would result in significant fluoritic effects visible later on tooth eruption. Even if mild fluorosis resulted in such circumstances, the alternative of inevitable tooth loss is comparatively unacceptable.

The clinical results show a very significant inhibition in caries development in test subjects over 18 months, irrespective of the method of statistical group comparisons used. While every attempt was made to ensure the parameters relating to test and control group matched as closely as possible, it is impossible to guarantee an absolute match. Hence, it would have been useful to run a reverse trial to ensure the validity of the results. This might have been difficult to support ethically, even though dental care is unavailable to either group in the long term.

It is acknowledged that the control of caries has been mainly in the incipient lesion component, and that accurate diagnosis of this lesion is most difficult. Every attempt was made to ensure any bias was removed by strict adherence to the double-blind format in all aspects of the investigation. Again, a reverse trial of longer duration would have been valuable to confirm the results. The effectiveness of fluoridation of sugar as a preventive measure should also be evaluated with a pilot trial at a general community level,[21] such as at village level involving all age groups, over a five year period.

The advantages of using sugar as a fluoride vehicle are self evident, though the potentially wide variation in sugar consumption on the wider population basis make its uncontrolled availability a risk of resulting in excessive uptake in some young children, with resultant fluorosis. This applies to all forms of systemic and topical fluoride also in both developed and developing countries. For this reason, prior estimation of all sources of fluoride ion already available to a trial community would be essential.

The use of fluoridated sugar would appear to have significant benefits in rural and urban areas of developing countries in particular, where refined carbohydrate is being introduced rapidly in large quantities and other sources of fluoride are not readily available, or not being widely used in the community. It could be marketed along side normal sugar as a choice option, with health education being provided as to its safe use.

Some concern as to the use of sugar as a fluoride vehicle has been expressed,[22] one argument being that making sugar safer to eat in terms of oral health will increase its utilization rate. This argument may apply to a well educated middle class, though it is unlikely to apply to the majority of the community for whom caries is a major problem. It is well known that despite four decades of crusading by the health authorities against frequent consumption of sugar in western countries, the level of consumption has hardly declined in most. It seems just as unlikely that health authorities in developing countries will have any power to counteract increasing sugar consumption as a result of the persuasive advertising by large corporations and the natural liking by most people of sweet foods. Perhaps it is time for the dental profession to accept the inevitable, that sugar consumption rates will become high in these countries. The profession, while continuing to educate communities as to the effects of excessive consumption of sugar, should also help them to counteract its cariogenicity in the same way as has happened in the more industrialized countries, i.e., by the controlled supplementation of fluoride ion in a way where it can have both a systemically and topically protective action.

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