

**A community-based dental caries control programme for preschool children
in Southern China: 18-month result**

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Abstract

The success rate in restoring anterior primary teeth with atraumatic restorative treatment is not as good as that in posterior teeth. Fluoride agents may be used to control caries progression in carious anterior primary teeth. The purpose of the study is to investigate the effects of 3.8% silver diamine fluoride and 5% sodium fluoride in arresting caries in anterior primary teeth. 375 kindergarten children aged 3 to 5 with carious upper anterior teeth were given an oral hygiene instruction. They were randomly divided into five groups. Group 1 children had caries removed with hand instruments and annual paint of silver diamine fluoride solution (Saforide). No anaesthetics was given. Group 2 children had annual paint of Saforide solution. Group 3 children had caries removed and then sodium fluoride varnish (Duraphat) was applied every 3 months. Group 4 children had Duraphat applied every 3 months. Group 5 children received water paint as a control. 353 children (94%) attended the 12-month examination. Results after 12 months showed that the groups receiving silver diamine fluoride had their upper anterior carious teeth stained coal black. However, they were more effective in hardening and arresting caries than those receiving sodium fluoride. Sodium fluoride at 0.05% (Duraphat) has no significant caries arresting effect unless caries was remove before fluoride application. Caries removal before application of silver diamine fluoride has no significant effect on hardening and arresting caries. The study concluded silver diamine fluoride therapy is effective in hardening and arresting carious lesions in primary anterior teeth. Excavating bulk of caries before silver fluoride treatment has no significant effect in hardening and arresting caries.

Introduction

Although there is a worldwide decline in caries prevalence among children, the caries rate in young children in China is still high.¹ A recent survey among pre-school children in Southern China found that most children had decayed teeth that were left untreated.² In many rural areas of China, the present available methods for preventing and treating dental caries are neither available nor affordable. Facing with such a high rate of caries in young children, Lo and Holmgren had conducted a prospective study on secondary prevention using atraumatic restorative treatment (ART) in Chinese children and the results is promising.³ However, the success rate in restoring anterior primary teeth is not as good as that in posterior teeth. Only 30% of the Class III and IV restorations were satisfactory after 18 months.

Since professional fluoride therapy has been shown to be effective in dental caries prevention,⁴ it may be a good attempt to extend the use of fluoride to treat clinical carious lesions. In a community based preventive programme of brushing with fluoride toothpaste, Lo *et al* found 45% of proximal and 23% of buccopalatal carious lesions were arrested.⁵ Apart from fluoride toothpaste, the most common forms of fluoride agents are solutions, gels and varnishes. Fluoride solutions and gels are not practical and safe for young children due to the risk of fluoride over-ingestion. Varnish has the theoretical advantage of prolonged contact time. It also seems to be the quickest and easiest of all topical fluorides to apply.⁶ Last but not the least, it eliminates the risk of fluoride over-ingestion.⁷

Duraphat is a commercial available fluoride varnish that is the most commonly used fluoride varnish in European countries for more than 20 years. There is quite number of studies to demonstrate its success in the prevention of caries development, but its use in caries treatment is unknown.⁸⁻¹¹ Both Seppa *et al* in their 3 year clinical study¹⁰ and Koch *et al* in their 2 year clinical study^{11a} on children reported a 30% reduction in caries increment in children receiving biannual Duraphat treatment. Although acidulated phosphate fluoride (APF) gels have been used more commonly in the United States than fluoride varnishes, the latter became popular in recent years. In 1990s, the American Dental Association has granted its seal of approval to Duraphat. It contains 5% of sodium fluoride or 22,600 ppm of fluoride ion.

The School Dental Service in Western Australia has used a 40% aqueous solution of silver fluoride as the standard treatment for deep carious lesion in primary teeth since 1984 with good success rate.¹² In Japan, Moritani *et al* applied silver diamine fluoride to carious deciduous in 2 to 6-year old children and found that most of the fluoride treated caries was arrested.¹³ In Beijing Hospital of Stomatology in China, Li *et al* had found the effectiveness of silver diamine fluoride in arresting caries and inactivating bacterial activities.¹⁴ They also advocated the use of silver diamine fluoride in arresting progressive carious lesions in children. Saforide (Toyo Seiyaku Kasei Co Ltd, 15 Doshomachi 3 chome, Higashi-ku Osaka, Japan) is a commercial product of silver diamine fluoride made in Japan that has been approved by the Central Pharmaceutical Council of the Ministry of Health and Welfare as a therapeutic agent.(Figure 2) It is used by dentists in Japan especially those specialised in Paediatric Dentistry to arrest caries in primary teeth. Saforide contains 380mg water soluble silver diamine fluoride in 1ml colourless solution, or about 42,700 ppm of fluoride ion.

In summary, the high cost of conventional dental care and the inadequate training of dental health care workers make it impractical in China to control the high caries prevalence of preschool children in the usual manner. Programme to promote brushing with fluoride toothpaste has been demonstrated with success.¹⁵ However, it may not be able to deal with the high prevalence of active caries of preschool children in China. The ART programme has promising results in caries control with simple technique and instruments. However, the success rate in anterior teeth is not satisfactory.³ Since fluoride has been proven to be effective in caries prevention,⁸⁻¹¹ it is tempting to extend its use for caries treatment in a community measure. The main purpose of the present study is to investigate longitudinally the effects of a commercial available 3.8% silver diamine fluoride solution (Saforide) and a 5% sodium fluoride varnish (Duraphat) in treating carious lesions in anterior primary teeth of preschool children in China. The effect of caries removal prior to the fluoride therapy will also be studied. The objectives are firstly, to describe the effect of annual topical application of Saforide in treating dental caries in primary anterior teeth in preschool children. Secondly, to describe the effect of using Duraphat every 3 months in treating dental caries in primary anterior teeth in preschool children. Thirdly, to find out the effect of caries removal prior to fluoride therapy and; fourthly, to compare the results of the different treatment regimes listed above. The present paper reported the findings after 12 months.

Materials and Methods

1,116 2 to 5-year-old children from 8 kindergartens were screened in Guangzhou, southern part of China in December 1998. 375 children (209 boys and 166 girls) with caries on upper anterior teeth participated in the study. They were given an oral hygiene instruction and a baseline examination to record the caries status on their upper front teeth. One tenth of the examined children were re-examined to assess the intra-examiner reproducibility. The clinical examination was conducted in the kindergartens using dental front surface mirror under fiber-optic light. Caries was diagnosed at cavitation level and explored with a sharp sickle-shaped probe in the centre of the cavity. It was classified as caries if the dentine could be penetrated with the probe using light force of less than 30 grams. If the dentine could not be penetrated, it would be classified as arrested caries, either black or not black in colour.

The status of each upper anterior tooth was firstly recorded by four surfaces which are the buccal, mesial, palatal and distal surfaces and secondly the pulp status. A tooth with caries destroying more than two third of the clinical crown was treated as retained root. The surface A proximal caries lesion extending to buccal or palatal surface would only be recorded as a single surface if the extended lesion was less than one third in the width of the extended surface. A palatal lesion was recorded if the lesion involved only the incisal edge. The pulp status was examined and recorded as vital or non-vital tooth. Pulpal exposure, buccal abscess, sinus tract, obvious discolouration, premature hypermobility were signs of non-vital tooth. Tooth would be regarded as vital if doubt existed.

The children were randomly divided into five groups for treatment. The bulk of the caries lesions in upper anterior primary teeth (incisors and canines) of children in Group 1 were carefully removed by a hand instrument (excavator) without giving local anaesthesia. Effort was made to remove caries along the dentino-enamel junction (DEJ). To render the cavity self cleansing, attempt was made to break the unsupported enamel. The cavities were then painted with 3.8% silver diamine fluoride solution (Saforide). The fluoride application was repeated every 12 months. Children in Group 2 had Saforide applied onto the caries lesions without removal of caries. The Saforide application was repeated every 12 months. For children in Group 3, the soft dentine in the caries lesions in upper anterior primary teeth was carefully removed. A commercially available 2.26% sodium fluoride varnish (Duraphat) was then applied onto the caries lesion. This fluoride application was repeated every 3 months. Children

in Group 4 had Duraphat vanish applied onto the caries lesions without removal of the caries. The Duraphat application was repeated every 3 months. Children in Group 5 act as a control receiving water placebo paint to their teeth. All children were instructed not to eat for at least one hour after treatment.

The 12-month follow-up examination was conducted in December 1999. As the proposed study is a 24-month longitudinal cohort study, another follow-up examination will be carried out in December 2000.

The data collected were entered into a computer and analysed with the software SPSS. One-way analysis of variance (ANIOVA) was performed to compare the five treatment groups on the age of children, number of decay surface of upper anterior primary teeth and the number of non-vital teeth at the baseline examination. The differences among the five treatment groups on the increment of surface of new caries, the number of carious surface became arrested, and the increment of non-vital teeth at the 12-month examination were also compared. The level of statistical significant was set at 0.05. Bonferroni multiple comparison procedure was used to study the significant differences found among the five treatment groups.

Results

353 out of the 375 children attended the 12-month follow-up examination. Thus the dropout rate after one year was 5.9%. There were 194 boys and 155 girls with a mean age of 4.0.(Table 1) The intra-examiner reproducibility as measured by Kappa is 0.98 for the baseline examination and 0.95 for the 12-month examination. The mean number of decay surface in their upper anterior teeth was 4.0. The mean number of non-vital teeth was 0.3. There were no statistically significant differences among the five groups of children in age, number of decay surface and number of non-vital teeth in their upper anterior teeth. The mean increment of new caries detected after 12 months of the five treatment groups ranged from 0.41 to 1.00 tooth surface.(Table 2) Children in Group 5 had the highest caries increment whereas those in Group 1 had the lowest caries increment. The difference is statistically significant. Children in Group 1 had a significant less new caries increment than those in other four groups. Children in Group 1 also had the more hardening and arrested caries surfaces among the five groups following treatment. The difference is again statistically significant. Statistical analysis

showed that Group 1 was more effective in arresting caries than Group 3 to 5, Group 2 is better than Group 4 and 5, and there is no significant difference among Group 3, 4 and 5. When we measured the increment of non-vital teeth, there is no statistically significant difference among the five groups.

Children receiving Saforide had their arrested caries lesions staining coal black.(Figure 3) On the other hand, children in Group 3 had more arrested caries lesions not staining black. This observation is statistically significant. (Table 3)

Discussion

The 12-month results supported the effectiveness of 3.8% silver diamine fluoride solution (Saforide) to harden or arrest caries lesions in primary anterior teeth. Sodium fluoride at 0.05% (Duraphat) has no significant caries arresting effect unless caries was removed before fluoride application. The results showed annual application of silver diamine fluoride is more effective than sodium fluoride application at 3-month interval. However, only silver diamine fluoride is effective in preventing new caries development. The findings agreed with Grodzka *et al* who noticed the cariostatic effect of Duraphat application twice yearly in primary teeth of young children was slight.¹⁶ The findings of the present community trial agreed with the studies in China, Japan and the unpublished observations in Western Australia.^{12-14,17} Since restorations on primary anterior teeth have a high failure rate, use of silver diamine fluoride may be an alternative strategy. Children that are too young and apprehensive to dental treatment can have their active caries arrested with silver diamine fluoride; and definitive restorative treatment can be carried out when they become co-operative and old enough. This non-invasive treatment that requires no injection is conceivably welcome by the dentists in Japan.

The simple armamentarium of the low cost silver diamine fluoride therapy makes it a useful tool in caries control community programmes in population with high caries prevalence. Bedi and Infirri reported that the benefits of silver diamine fluoride has been investigated for 25 years in several countries.¹⁸ There are many advantages of silver diamine fluoride therapy when used in community programmes in developing countries. Firstly, silver diamine fluoride is effective to arrest caries progression which cause pain and infection. Secondly, cost of silver diamine fluoride is low and is estimated to be USD 0.2 per child.¹⁸ Thirdly, silver diamine

fluoride therapy involves minimal training. This allows non-dental professionals like health care assistants or trained community members to apply silver diamine fluoride to children. Fourthly, silver diamine fluoride therapy does not require expensive equipment or support infrastructure, such as pipe water and electricity. Fifthly, the simple armamentarium allows trained community members to deliver treatment to children that live in remote areas. Finally, silver diamine fluoride therapy is non-invasive and therefore there is very low risk of spread of infection.

It is assumed that caries removal before fluoride treatment is advantageous as the bacteria load in the carious lesion is reduced. Caries removal before sodium fluoride treatment lessens black staining effect of the arrested caries and is essential in arresting caries. However, the findings of the study indicated no significant beneficial effect in excavating bulk of caries before treatment of silver diamine fluoride. This finding is important when silver diamine fluoride is considered as a therapeutic agent to control caries of children in community based programme. Firstly, the treatment procedure is simpler when caries excavation is not necessary. Hand instrument is not essential. Secondly, non-professional people with simple training can carry out the treatment. Thirdly, the non-invasive nature of the therapy enables good compliance even for young children. Some children were not cooperative during caries removal. The authors found no management problem in delivering silver diamine fluoride paint even to timid children. Last but not the least, it is cost-effective. To validate the long-term success of this treatment method, it is essential to evaluate the treatment outcome after at least 24 months.

The inherent disadvantage is the silver diamine fluoride solution stains the caries lesions coal black. Silver diamine fluoride stops caries by forming a hard, black, impermeable layer on the tooth which is resistant to decay. Yamaga *et al* observed that when with carious dentine was treated with silver diamine fluoride, silver phosphate was formed and it is hardly soluble.¹⁷ It is yellow when it is first formed, but is readily turning black under sunlight or by reducing agents. Some children and their parents may not be pleased with the aesthetics of the treatment outcome. Hence, it is essential to study their acceptance of treatment. The satisfaction of this treatment has been studied but will not be discussed in this paper. The silver diamine fluoride solution also has a metallic taste, however; the amount applied appeared acceptable by all children in the present study. Sodium fluoride was well accepted by the

children. However, the effect of arresting caries needs caries removal and even so it is not as good as that of silver diamine fluoride even with a more frequent application.

Conclusion

3.8% silver diamine fluoride is more effective in hardening and arresting caries than 5% sodium fluoride. Sodium fluoride at 0.05% (Duraphat) has no significant caries arresting effect unless caries was removed before fluoride application. Caries removal before application of silver diamine fluoride has no significant effect on hardening and arresting caries. The drawback of silver diamine fluoride is that it stains the carious teeth coal black. The success of silver diamine fluoride treatment in the present study also supports its use in community measure in developing countries.

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Legends

Figure 1 Duraphat sodium fluoride varnish

Figure 2 Saforide silver diamine fluoride solution

Figure 3 Coal black appearance of arrested caries lesions after silver diamine fluoride treatment

Table 1 Age of the preschool children, their number of decay surface and number of non-vital upper anterior teeth at baseline examination

Table 2 Fluoride treatment result on primary anterior teeth after 1 year

Table 3 Number of arrested caries surface with fluoride treatment after 1 year

Table 1 Age of the preschool children, their number of decay surface and number of non-vital upper anterior teeth at baseline examination

Treatment group	No. of children (boy/girl)	Age	No. of decay (surface)	No. of non-vital teeth
1.AgF & CE	71(38/33)	3.9±0.8	4.1±2.3	0.30±0.80
2.AgF	70(38/32)	4.2±0.8	4.4±2.8	0.27±0.90
3.NaF & CE	71(37/34)	4.0±0.8	3.9±2.7	0.27±0.85
4.NaF	70(43/27)	4.1±0.7	3.7±2.4	0.41±1.34
5.Control	71(39/32)	4.0±0.7	3.8±2.5	0.27±0.79
All groups	349(194/155)	4.0±0.8	4.0±2.6	0.30±0.95
Significance		N S	N S	N S

AgF - Silver diamine fluoride; NaF - Sodium fluoride; CE - Caries excavation;

N S - No significant difference.

Table 2 Fluoride treatment result on primary anterior teeth after 1 year

Treatment group	New caries (surface)	Arrested carie (surface)	Non-vital teeth increment
1.AgF & CE	0.41±0.79	2.55±2.03	0.15±0.73
2.AgF	0.57±1.02	2.10±2.43	0.26±1.24
3.NaF & CE	0.68±1.41	1.34±1.60	0.27±0.91
4.NaF	0.67±0.85	1.09±1.82	0.30±1.32
5.Control	1.00±1.29	0.51±0.97	0.03±0.38
All groups	0.67±1.11	1.52±1.96	0.20±0.98
Significance	p<0.05	p<0.001	N S
Bonferroni Comparison	Gp2-5>Gp1	Gp1,2>Gp3-5 Gp2,3>Gp4,5	

AgF - Silver diamine fluoride; NaF - Sodium fluoride; CE - Caries excavation;

N S - No significant difference.

Table 3 Number of arrested caries surface with fluoride treatment after 1 year

Treatment group	Arrested caries, black	Arrested caries, not black	Arrested caries, all
1.AgF & CE	2.48±2.01	0.01±0.31	2.55±2.03
2.AgF	2.04±2.45	0.01±0.33	2.10±2.43
3.NaF & CE	0.25±0.73	1.08±1.40	1.34±1.60
4.NaF	0.70±1.60	0.41±0.96	1.09±1.82
5.Control	0.17±0.59	0.34±0.83	0.51±0.97
All groups	1.13±1.90	0.39±0.94	1.52±1.96
Significance	p<0.001	p<0.001	p<0.001
Bonferroni Comparison	Gp1,2>Gp3-5	Gp3>Gp1,2,4,5	Gp1,2>Gp3-5 Gp2,3>Gp4,5

AgF - Silver diamine fluoride; NaF - Sodium fluoride; CE - Caries excavation;

N S - No significant difference.