Efficacy of Silver Diamine Fluoride for Arresting Caries Treatment

INTRODUCTION

Untreated dental caries is a global pandemic (Edelstein, 2006). Due to limited financial resources, poor access to basic oral care, and the high cost of restorative treatment, children of low-income nations have their general health, social well-being, and education opportunities affected by untreated dental caries (Baelum et al., 2007). Arresting Caries Treatment (ACT) has been proposed to manage untreated dental caries in children of disadvantaged communities (Bedi and Sardo-Infirri, 1999). Silver diamine fluoride (SDF), Ag(NH$_3$)$_2$F, has been used to arrest caries since 1969 (Nishino et al., 1969; Nishino and Yoshido, 1969; Yamaga and Yokomizo, 1969). Yearly applications of 38% SDF (44,800 ppm F) to decayed primary anterior teeth of Chinese preschool children have been shown to be significantly more effective in arresting caries and preventing new caries than three-monthly applications of sodium fluoride varnish (22,600 ppm F) (Lo et al., 2001; Chu et al., 2002). In a Cuban study, 38% SDF applied every 6 mos demonstrated clinical effectiveness in arresting caries and preventing new caries in the dentition of 6- to 15-year-old schoolchildren over a three-year period (Llodra et al., 2005).

Currently, the optimal frequency of application of SDF is unknown, but in resource-limited situations, repeated applications of SDF are unlikely to be either practical or affordable to local communities, even when applied by trained primary-health-care workers.

Therefore, this current study compares the effectiveness of a single spot application of two concentrations of SDF, 38% or 12%, in arresting caries, with or without the use of tannic acid from tea as a reducing agent. The a priori null hypothesis is that the different treatments have no effect in arresting active cavitated caries.

MATERIALS & METHODS

This prospective randomized clinical trial on a cohort of 976 kindergarten and primary schoolchildren, 545 males (56%) and 431 females (44%), with ages ranging from 3-9 yrs and a mean age of 5.2 (SD = 1.2) yrs at time of enrollment, was conducted in Kathmandu, Nepal, a city with low-fluoride-content drinking water (0.03 ppm). Fluoridated toothpaste is available from retailers, but the children received neither professionally applied fluorides nor fluoride supplements. Treatment was provided between May and August, 2005, and the children were re-examined after 6 mos, 1 yr, and 2 yrs. The study was approved by the Ethics Committee of the Nepal Health Research Council. Written information explaining the study was sent to the parents. As well as obtaining a written consent from the parents, verbal consent was obtained from the children prior to commencement of the study. The children were at liberty to withdraw from the study at any time during the study, and the same
was classified according to the criteria given in Table 1. For the
determine examiner reproducibility. Each surface of the tooth
and fissures were not probed, to prevent the risk of fissure dam-
the cavity to detect and confirm visual evidence of caries. Pits
was used, with the tip gently passed over the entire surface of
Dry the teeth and wipe away gross debris. A sharp sickle probe
on a bench or table and examined by the dental examiners using
baseline examinations prior to treatment, while follow-up exam-
habited tooth Abscessed/pulpally involved teeth with abnormal
Initial caries Localized enamel breakdown (microncavity) in
Arrested cavitated caries As d2, but the wall and floor of the cavity were
Filled surface with no decay A permanent restoration is present, and there is no
caries anywhere on the surface.
Non-vital tooth Abscessed/pulpally involved teeth with abnormal
caries surfaces. Surfaces with new caries were defined as sound or ‘initial caries’ surfaces
at baseline that changed into surfaces with active or arrested
cavitated caries or restored surfaces.
follow-up evaluation, surfaces with arrested caries were defined
as surfaces with active cavitated caries (d2) at baseline that
changed into surfaces with arrested cavitated caries. Surfaces

\[ \begin{array}{|c|c|}
\hline
\text{Caries Criteria} & \text{Description} \\
\hline
\text{Sound} & \text{Surfaces not soft to the touch with a sharp sickle probe, but they may be discolored.} \\
\text{Initial caries} & \text{Localized enamel breakdown (microncavity) in opaque or discolored enamel.} \\
\text{ Arrested cavitated caries} & \text{As d2, but the wall and floor of the cavity were hard and could not be penetrated by the sharp sickle probe.} \\
\text{Filled surface with no decay} & \text{A permanent restoration is present, and there is no caries anywhere on the surface.} \\
\text{Non-vital tooth} & \text{Abscessed/pulpally involved teeth with abnormal coloring.} \\
\text{Missing due to caries} & \text{Teeth extracted due to caries. Included in this category were teeth having more than two-thirds \((2/3)\) of the crown destroyed by caries and the root remaining.} \\
\hline
\end{array} \]

Statistical Analysis

Estimation of the sample size was based on the expected number of arrested caries surfaces. Power of the study was fixed at \(80\% (\beta = 0.20)\), with \(\alpha = 0.05\) as the significance level. On the basis of a difference of 1 in mean number of arrested caries surfaces between groups, and a standard deviation of 3.5 (Llodra et al., 2005), the sample size was estimated to be around 160. When the expected dropout rate over a 2-year period was taken into account, the sample size was increased to 240 per group.

The data were entered into a computer and analyzed with SAS 9.1 software. Chi-square tests were applied to determine differences in the distribution of children’s ethnic background, parents’ education and occupation, report of oral pain, brushing habits, and use of fluoridated toothpaste among the four groups. Chi-square tests were also used to determine differences in number of dropouts among the four groups. Differences found in the data of the four groups regarding mean age, dmft, ds, d2s, mean number of non-vital teeth, and mean number of surfaces with arrested caries were tested with analysis of variance (ANOVA). In case of a significant ANOVA test, differences between groups were tested with Student’s \(t\) test. Inter-examiner reproducibility at the tooth-surface level at baseline and intra-examiner reproducibility at follow-up examinations were measured by the Kappa statistic.

RESULTS

Since inter-examiner consistency in scoring ‘initial caries’ at baseline was only 47%, the ‘initial caries’ scores were collapsed
into the 'sound' score category prior to the analysis of the data. After this adjustment, the unweighted inter-examiner Kappa at baseline examination was 0.81, and intra-examiner Kappas were 0.80 (RY) and 0.81 (DL), while intra-examiner unweighted Kappas at six-month, one-year, and two-year follow-up examinations were 0.85, 0.86, and 0.93, respectively.

Although the children were randomized over the four groups, the mean age of the children treated with 38% SDF only was significantly lower than the mean age of children in the other groups (Table 2). At baseline, 66% of the children reported brushing once a day with fluoride toothpaste. The children's ethnic background, parents' education and occupation, report of oral pain, brushing habits, and use of fluoridated toothpaste were similarly distributed in the 4 groups (X² test, p > 0.05). The caries data and the mean number of non-vital teeth among the four groups at baseline (ANOVA p > 0.05). The caries data and the mean number of non-vital teeth of the four groups at baseline are shown in Table 2. Since the numbers of missing teeth due to caries and filled teeth were very low, the dmft was almost exclusively formed by the 'd' component. No statistically significant differences were found in the caries data among the four groups at baseline (ANOVA p > 0.05).

The numbers of children who were examined at 6, 12, and 24 mos were 908, 768, and 634, respectively, resulting in dropout rates of 7%, 21%, and 35%. The dropout rates in the four groups did not differ statistically significantly (X² test, p > 0.05). The parents' educational level, ethnicity, brushing habits, and use of fluoride toothpaste did not differ for the dropouts and for the children remaining in the study at 24 mos (X² test, p > 0.05). There were also no differences in baseline caries parameters between children lost to the follow-up and those remaining in the study at 24 mos (ANOVA p > 0.05).

At 6, 12, and 24 mos, the mean number of arrested carious surfaces was significantly higher in the two groups treated with 38% SDF than in the 12% SDF and control groups (Table 3). The difference observed at 6 mos decreased over 24 mos, but remained statistically significant. There was no significant difference in the mean number of arrested carious surfaces between the 38% SDF and the 38% SDF + tannic acid groups, or between the 12% SDF and the control groups throughout the 24-month study period. There was also no significant difference between the groups in the mean number of non-vital teeth and the mean number of exfoliated surfaces at any time.

Table 2. Mean Age, Mean dmft, Mean Number of Decayed, Missing and Filled Teeth, Mean Number of Cavitated Active and Arrested Caries Surfaces, Mean Number of Cavitated Active Caries (d2) Surfaces, and Mean Number of Non-vital Teeth of Children at Baseline According to the Different Groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Mean Age (yrs, SD)</th>
<th>dmft (SD)</th>
<th>ds* (SD)</th>
<th>d2s (SD)</th>
<th>Non-vital Teeth (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>38% SDF</td>
<td>243</td>
<td>5.0 (1.2)a</td>
<td>4.5 (3.1)</td>
<td>7.9 (7.6)</td>
<td>6.6 (6.4)</td>
<td>0.3 (1.5)</td>
</tr>
<tr>
<td>38% SDF + tea</td>
<td>249</td>
<td>5.3 (1.2)b</td>
<td>4.7 (4.7)</td>
<td>8.3 (8.5)</td>
<td>7.2 (7.6)</td>
<td>0.3 (1.6)</td>
</tr>
<tr>
<td>12% SDF</td>
<td>243</td>
<td>5.3 (1.2)a</td>
<td>4.5 (4.6)</td>
<td>8.0 (7.9)</td>
<td>6.8 (7.0)</td>
<td>0.3 (1.5)</td>
</tr>
<tr>
<td>Control</td>
<td>241</td>
<td>5.3 (1.2)b</td>
<td>4.6 (4.7)</td>
<td>8.0 (8.5)</td>
<td>6.6 (7.3)</td>
<td>0.3 (1.6)</td>
</tr>
<tr>
<td>All groups</td>
<td>976</td>
<td>5.2 (1.2)b</td>
<td>4.6 (4.3)</td>
<td>8.0 (8.1)</td>
<td>6.8 (7.1)</td>
<td>0.3 (1.6)</td>
</tr>
</tbody>
</table>

a>b P < 0.01.

DISCUSSION

This is the first clinical trial to evaluate the effectiveness of a one-time application of SDF with 2 different concentrations of SDF and the effect of a reducing agent. The use of a reducing agent such as 10% stannous fluoride (Craig et al., 1981) has been advocated to accelerate the deposition of silver phosphate, which results in the instantaneous black discoloration of the area. This indicates that a successful reaction has occurred and minimizes the risk of SDF being washed away or contaminated by saliva. However, stannous fluoride is difficult to obtain in low-income countries, and tannic acid from boiled tea has been suggested as an inexpensive substitute.

The large proportion of dropouts from the study (35%) at 24 mos was due to a school closing and to the mobility of the parents. This did not have any effect on the results, since the 4 groups, as well as the dropouts and those remaining in the study, were similar in all other respects.

The results of this study support the null hypothesis for the application of 12% SDF, in that this agent had no significant effect on arresting caries. For a single application of 38% SDF, the hypothesis was rejected. A single application of 38% SDF, with or without the use of tea as a reducing agent, was significantly more effective in arresting dental caries in both the anterior and posterior primary dentitions of young children than 12% SDF or no application (control). The arresting caries effect of 38% SDF decreases slowly over time. A single application of 38% SDF was sufficient to prevent only 50% of the arrested surfaces at 6 mos from reverting to active lesions again over 24 mos. The tannic acid from boiled tea does not appear to have any significant additional effect on arresting caries compared with 38% SDF alone.

The advantages and disadvantages of this ACT approach have been elucidated in previous studies (Chu et al., 2002; Llo德拉 et al., 2005). The black discoloration of the carious dentin after SDF treatment is probably the most notable undesirable side-effect. This staining may be eliminated by the application of potassium iodide (KI) after the SDF application (Knight et al., 2005); however, the clinical effectiveness of SDF/KI remains to be evaluated. Some concerns have also been raised over dental fluorosis and accidental toxic overdose from the routine use of 40% silver fluoride, which has the same mode of action as SDF (Gotjamanos and Afonso, 1997; Gotjamanos, 1997). Although these concerns have been refuted (Neesham, 1997), the less-frequent application of lower concentrations of SDF might help to alleviate such concerns. In this current study, there were no adverse effects observed or complaints from either parents or the children concerning the SDF treatment.

The outcomes of this 24-month SDF study on both anterior and posterior primary teeth show that: a single spot application of 38% SDF is effective in arresting caries lesions, but the effectiveness decreases over time; tannic acid from tea confers no additional benefit; and 12% SDF is not effective.
Arresting Caries Treatment (ACT) with a single spot application of 38% SDF provides an alternative where restorative treatment for primary teeth is not an option.

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REFERENCES


