Study title: Comparative study on the outcomes of restoring untreated and SDF-treated dentine caries lesions in primary teeth of preschool children

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Study title
Comparative study on the outcomes of restoring untreated and SDF-treated dentine caries lesions in primary teeth of preschool children

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Summary

Untreated dental caries is common among preschool children in Hong Kong. When the caries extends into dentine of the tooth and a carious cavity is formed, removal of the decayed dental tissues followed by placement of a dental restoration (filling) is the conventional treatment. Atraumatic restorative treatment (ART) is an established practice to place a dental restoration using hand instruments only and adhesive filling material. It can be used in outreach dental service in a field setting and is appropriate for young children as no injection of local anesthesia is needed. Recently, topical application of silver diamine fluoride (SDF) solution is used to halt or arrest the progression of dentine caries and to promote remineralization of the caries lesion. A disadvantage of this treatment is that the arrested caries lesion will be stained black in colour.

The primary objective of this proposed clinical study is to compare the success rates of ART restorations placed in untreated and SDF-treated dentine caries lesions in primary teeth. The secondary objective is to describe the change in parents' satisfaction with the aesthetics of their child's teeth and the change in oral health-related quality of life of preschool children before and after placement of ART restorations.

The study population is preschool children attending kindergartens in different districts in Hong Kong. It is planned to recruit around 10 kindergartens. All children attending grade 1 in these kindergarten will be invited to receive a free dental examination and have their decayed primary teeth restored, if possible, in the kindergarten by dentists. Parental informed consent will be obtained before the dental examination and treatment. The planned sample size is 152 children with 396 decayed primary teeth needing restorations. Around half of these teeth, assigned randomly will received SDF treatment around 10 weeks before receiving the restoration. The restored teeth will be re-examined every 6 months for 24 months to assess the treatment outcome. Parents of the study children will be asked to complete a questionnaire at baseline, 6 months and 24 months so as to obtain data on their satisfaction with the aesthetics of their child's teeth and the oral health-related quality of life of the study children.

Background

Dental caries of young children is common in both developing and industrialized countries (Petersen et al., 2016). In Hong Kong, the prevalence of dental caries among 5-year-old children is around 50% (Department of Health, 2013). The adverse effects of dental caries can impact on both children and their families, including significant health, social and economic consequences (Colak et al., 2013).

Previous studies have shown that topical application silver diamine fluoride (SDF) solution is effective in arresting dental caries in young children (Chu et al., 2002; Yee et al., 2009; Zhi et al., 2012; Duangthip et al., 2016). A considerable drawback of SDF application is the black stain on the arrested caries lesions, which may cause dissatisfaction of both children and their parents with aesthetics of the treated teeth (Gao et al., 2016). It was suggested that by applying a saturated solution of potassium iodide (KI) immediately after the application of SDF, would minimize the black stain on the dentin caries lesions (Knight et al., 2006). However, a long term clinical study on elders has shown that the application of KI cannot reduce the blackening of arrested dentine caries lesions from SDF treatment (Li et al., 2016).

Atraumatic restorative treatment (ART), which was first developed in the 1980s, embodies the minimal intervention philosophy of dental caries management. The ART procedures involve removal of soft carious dental tissues using hand instruments and placement of a restoration using adhesive dental material, normally high viscosity glass ionomer cement (GIC) (Holmgren et al., 2013). Clinical evidence shows that ART is a patient-friendly and cost-effective treatment, especially for young children (Tedesco et al., 2016).

Although ART is considered as a satisfactory option for treatment of decayed primary teeth, it may still be difficult to obtain good cooperation from young children during operative procedures. Using SDF application to arrest active dentine caries in the primary teeth of young children may be a more practical management method. When children grow older and become more cooperative, the SDF-arrested caries lesion can then be restored with ART, so as to improve esthetics of the decayed teeth. Furthermore, it is expected that placement of a restoration on an arrested caries lesion is easier and quicker than that on an active caries lesion. The amount of demineralized dental tissues which needs to be removed will also be less, and the bond strengthen between glass ionomer and remineralized dentine may be higher. Thus, it is hypothesized that the success/retention rate of ART restorations placed in decayed teeth which has been treated with topical application of SDF is higher than that of restorations placed in untreated decayed teeth.

In order to find out and compare the outcomes of restoring active dentine caries lesions and those of restoring SDF-treated dentine caries in primary teeth, a well-designed clinical trial is needed. Results of the trial will provide high quality evidence to guide dental clinicians in treating dentine caries in primary teeth of young children.

Objectives

1. To describe the success rate of restorations placed using the atraumatic restorative technique (ART) in untreated dentine caries lesions in primary teeth

2. To describe the success rate of ART restorations placed in dentine caries lesions in primary teeth previously treated by topical application of silver diamine fluoride (SDF) solution

3. To compare the success rate of ART restorations placed in untreated and SDF-treated dentine caries lesions in primary teeth

4. To describe parents' satisfaction with the aesthetics of their child's teeth before and after placement of ART restorations

5. To describe the change in oral health-related quality of life of preschool children before and after placement of ART restorations

Materials and Methods

Study design

This study is a clinical interventional study with two parallel groups. The ICH-GCP principles will be followed.

Study subjects and recruitment

The study population of this proposed study is Hong Kong preschool children attending grade 1 of kindergarten (aged 3-4 years). Around 10 kindergartens in different districts of Hong Kong will be selected. All children attending grade 1 in the selected kindergartens will be invited to join this study. An invitation letter with information on the purpose and procedures of the study will be sent to the parents of the children through the kindergarten. The parents will be asked to give written consent for allowing their child to receive a free oral examination and ART restorations, if indicated for treating the decayed primary teeth in their child's mouth, provided by dentists in the kindergarten. Parental consent will be obtained before inclusion of a child in this study.

Inclusion criteria

Generally healthy children who have at least one decayed primary tooth with a cavity into dentine.

Exclusion criteria

Children with serious systemic diseases/conditions or who are uncooperative during treatment will be excluded. Teeth with signs of pulpal pathology, such as having an abscess or discoloured, will be excluded. Caries lesions which do not have adequate access for hand instruments to prepare the cavity for a filling and those that were treated with SDF solution but with most parts still being active, i.e. easily penetrated by a blunt probe with light force, will also be excluded.

Sample size

Sample size calculation is based on the primary outcome of this study which is the success of ART restorations, defined as restoration present without major defects nor associated active caries. According to a recent systematic review, the two-year survival rate of ART restoration placed in primary teeth is around 70% (Tedesco et al. 2016). It is anticipated that the survival rate of ART restorations placed on arrested caries is slightly higher at 75%. An absolute difference of 10% in the success rate of restorations is regarded as clinically significant. In this non-inferior clinical trial, using one-tailed test with a statistical significance set at 2.5% and a power of 80%, the calculated minimal number of restorations needed in each group is 139 (http://powerandsamplesize.com/).

Since more than one caries lesion can be found in a child's mouth, the clustering effect on sample size needs to be considered. Results of the latest oral health survey of Hong Kong 5-year-old children showed that the mean number of untreated decayed primary teeth for children who had dental caries was 4.7 (Department of Health, 2013). In this sample size calculation, it is anticipated that the number of decayed teeth included per study child is 2.5. A design effect of 1.15 is calculated, using an assumed intra-class correlation roh of 0.1. Thus, the necessary sample size would need to be multiplied by 1.15 and become 160. Furthermore, to compensate for a possible drop-out rate of 15%, the initial sample size is increased to 188 restorations per group. Therefore, 76 children in each group children will be recruited at baseline and the total number of study children will be 152.

Placement of ART restorations

Cavitated caries lesions in the primary teeth of the study children will be restored following the ART procedures (Holmgren et al., 2013). The instruments used are LED illuminated dental mirror, sickle probe, tweezers, hatchet, excavators and flat plastic. The dental restorative material used is a high-strength chemical-cured glass ionomer (Ketac-molar, 3M ESPE, Germany).

The step-by-step ART procedures are briefly described below:

1. isolate the operation site by cotton rolls
2. gain adequate access to the cavity, if necessary a hatchet is used to enlarge the opening of a small cavity
3. excavators of different sizes are used in removing soft carious tissues and preparing the cavity for a filling
4. the cavity is cleaned by water and then dried
5. condition the cavity surface with a weak organic acid, then wash and dry the cavity
6. the glass ionomer material is mixed according to manufacturer's instructions
7. the filling material is placed and pressed into the cavity
8. excess filling material is removed
9. contour and shape of the restoration is modified as necessary and occlusion checked
10. the finished restoration is covered by a layer of varnish or petroleum jelly

Baseline and follow-up data collection

At the baseline, all children with parental consent will be clinically examined in the kindergarten. Disposable dental mirror attached to a handle with an intra-oral LED light and a

ball-ended probe will be used. The status of each tooth will be recorded. Children who have at least one decayed primary tooth with a cavity into dentine will be included into the study. All decayed teeth in the children will be restored, except those with inadequate access and those with signs of pulpal pathology. Around half of these decayed teeth will receive topical application of a SDF solution (Saforide, Toyo Chemical, Japan), through simple random allocation on a child basis using random numbers, around 10 weeks before receiving the restoration. The time used for placement of each restoration will be recorded to the nearest minute.

The children will be examined at 6, 12, 18 and 24 months after placement of ART restorations by calibrated examiners who are not involved in the placement of the restorations. The same instruments used in the baseline examination will be used in the follow-up examinations. The status of the restorations and restored teeth will be assessed and recorded using codes and criteria commonly adopted in previous clinical studies of ART restorations (Lo et al., 2007):

0 = restoration present, no caries, no marginal defects or wear
1 = restoration present, no active caries, slight defects or wear not greater than 0.5 mm
2 = restoration present, marginal defects greater than 0.5 mm
3 = restoration present, wear greater than 0.5 mm
4 = restoration present, active caries found associated with the filling
5 = restoration missing, no active caries, surface hard to gentle probing
6 = restoration missing, active caries found, surface soft to probing allowing penetration of the tip of a blunt probe
7 = tooth with signs of pulpal pathology
8 = tooth missing, extracted due to caries
9 = tooth naturally exfoliated

At baseline, information on the children's oral hygiene practice, snacking habit, oral health related quality of life, and parental satisfaction with the appearance of their child's teeth will be collected by a self-completed questionnaire. A validated tool for measuring oral health related quality of life of preschool children in Hong Kong, Chinese version of Early Childhood Oral Health Impact Scale (ECOHIS), will be used (Lee et al., 2009). The same measurement tool will be used at the 6-month and 24-month follow-up.

Primary outcome measure

The primary outcome measure in this clinical study is the success of the ART restorations placed. A restoration is classified as success when it is retained on the tooth without major defects or wear and has no associated active caries (codes 0 and 1). Under this condition, no further treatment is necessary. A restoration is classified as failed when it has major defects (codes 2 and 3), associated active caries (code 4), is missing (codes 5 and 6) or the tooth has signs of pulpal pathology (code 7) or extracted due to caries (code 8). Under these conditions, further treatment may be necessary.

Secondary outcome measures

The secondary outcome measures in this clinical study are the parental satisfaction with aesthetics of their child's teeth and the oral health related quality of life of the child as measured by the ECOHIS before and after placement of ART restorations.

Data analysis

The clinical examination record form and parental questionnaires will first be checked for completeness and obvious errors. Questionnaires with more than 40% of the questions unanswered will be discarded. The collected data will be entered into computer. Data entry and logical errors will be corrected before data analysis.

Basic data analysis will be carried out by using the statistical software SPSS for Windows. Chi-square test and t-test will be performed to assess the comparability between the children in the two study groups regarding their demographic background, oral health related behaviours and baseline dental caries experience. McNemar's test and paired t-test will be used to assess the change in parental satisfaction with aesthetics of their child's teeth and the change in ECOHIS score before and after placement of ART restorations.

Clinical outcome of an ART restoration at each follow-up examination will be classified as either success or failed according to the criteria mentioned above. A two-level survival analysis for interval-censored data will be adopted. The first level is the caries lesion while the second level is the child. This analysis will account for the correlation (clustering) between observations of multiple restorations placed in the same child (Wong et al., 2006). This analyses will be carried out with the statistical software SAS for Windows (SAS Institute Inc., Cary, N.C., USA). The level of statistical significance for all tests will be set at 0.05.

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