Association between dental conditions, sliver diamine fluoride application, parental satisfaction and oral health-related quality of life of preschool children

Short title: Dental conditions, SDF application, parental satisfaction and OHRQoL

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Abstract

Objectives: To investigate the associations between dental conditions, sliver diamine fluoride (SDF) application, parental satisfaction and oral health-related quality of life (OHRQoL) of preschool children.

Materials and methods: In a clinical trial conducted in Hong Kong, preschool children who had carious lesions into dentine were randomly assigned to receive application of SDF solution or placebo on their caries lesions ten weeks before they received restorations. Additionally, a random sample of caries free children was also recruited. Parents of the study children rated their satisfaction with their child's teeth using a 5-point scale (5=very satisfied, 1=very dissatisfied) ten weeks after SDF or placebo application. Besides, the Chinese version of the Early Childhood Oral Health Impact Scale (C-ECOHIS) was used to assess the children's OHRQoL.

Results: There were 127, 133 and 154 children in the SDF, placebo and caries free groups, respectively. The parents whose child had 4 or more decayed teeth reported lower satisfaction scores (mean=2.0±0.7) with their child's dental health status compared with those of parents whose child had fewer (mean=2.6±0.9) or no (mean=3.7±0.7) decayed teeth (p<0.001). These parents also reported higher C-ECOHIS scores. However, there was no significant difference in parental satisfaction and children's OHRQoL between the SDF and placebo groups (p>0.05).

Conclusions: In this study population, parental satisfaction and children's OHRQoL were associated with children's dental caries status but not with SDF application.

Clinical Relevance: This study provides valuable information about the factors, including SDF application, that can influence parental satisfaction and OHRQoL of preschool children.

Introduction

Oral health is multifaceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow, and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex [1]. This new definition of oral health was developed by the FDI World Dental Federation. The current view of oral health is not only about oral conditions and diseases, e.g. tooth decay, but is also a fundamental component of physical and mental well‐being. The physiological, social, and psychological attributes of oral health are essential to a person's quality of life [1]. Oral health-related quality of life (OHRQoL) is a multidimensional concept which includes a subjective evaluation of the individual's oral health, functional well-being, emotional well-being, expectations and sense of self [2]. Different assessment tools have been developed to evaluate impacts of dental experience on OHRQoL.

The Early Childhood Oral Health Impact Scale (ECOHIS) is an assessment tool to measure OHRQoL of preschool children (younger than 5 years old) [3]. It is generally believed that preschool children are too young to be capable of abstract thinking which underlies perceptions of disease and impact. Due to their difficulties in fully comprehending and communicating their perceptions, proxy reporting has been adopted as a standard way to assess quality of life of preschool children [4]. Hence, the ECOHIS was developed for parents, as they are responsible and making decisions for their child's oral health, to assess impacts of their child's oral health on the child and the whole family. The ECOHIS demonstrates good reliability, responsiveness and interpretability [5]. Besides, the ECOHIS is the only tool that has been translated and validated in 14 languages, including a Chinese version [6].

Untreated caries in the primary teeth is the tenth most prevalent health condition in the world, affecting 621 million children [7]. In Hong Kong, the prevalence of dental caries among 5-year-old children is around 50% and most of their decayed teeth remain untreated [8]. Severe dental caries will not only cause clinical symptoms, such as pain and infection, but also have adverse influences on children's family, including social-psychological and economic consequences [9]. Restorative approach is the conventional way to treat decayed teeth. However, restorative approach alone is not sufficient for managing dental caries in young children, especially in deprived communities [10]. Therefore, non-invasive treatment has gained growing attention. Clinical evidence has shown that topical application of silver diamine

fluoride (SDF) solution is effective in arresting dental caries in young children [11-15]. However, a common outcome of SDF application is the black stain on the arrested caries lesions. The black stain, on one hand, is a clinical sign that the progression of dental caries has been stopped successfully [16]. On the other hand, a black unrestored cavity may cause parental concerns [17]. However, study of effects of child's oral health on parent-based subjective outcomes is limited.

Parent-based subjective outcomes, together with clinical indicators, should jointly provide a more comprehensive assessment of children's oral conditions and their impacts on OHRQoL. This study aimed to find out the associations between dental conditions, SDF application, parental satisfaction with their child's teeth and the OHRQoL of preschool children. Two null hypotheses were tested: 1) there is no association between the child's dental conditions, and parental satisfaction of their child's teeth and the child's OHRQoL; and 2) SDF application has no effect on parental satisfaction and the child's OHRQoL.

Materials and methods

This study was part of a randomized controlled trial (RCT) conducted in kindergartens in Hong Kong [18]. Ethical approval was obtained from the Institutional Review Board of the University of Hong Kong (IRB reference number: UW17-180) and the trial was registered (clinicaltrials.gov #NCT03657862). The study activities are shown in Figure 1.

The main aim of the non-inferior RCT was to compare the 2-year success rates of restorations placed after application of SDF or placebo. The calculated sample size of the RCT based on this primary outcome was a minimal of 76 children in each group which was sufficient for detecting an absolute difference of 10% in the success rates of restorations using one-tailed test with statistical significance set at 2.5% and a power of 80%.

In the present study, the associations between children's dental conditions, SDF application, parental satisfaction and OHRQoL of children were investigated. A difference of least 0.5 between the mean parental satisfaction or ECOHIS scores of the two groups was regarded as clinically significant. Using a statistical significance level of 5% and a power of 80%, the minimum sample size required was 63 in each group.

Preschool children attending grade 1 or 2 (aged 3 to 4 years) of nine public funded large (enrollment >100) kindergartens located in different districts in Hong Kong were invited to participate in a randomized controlled clinical trial. An invitation letter with information on the purpose and procedures of the trial was sent to the parents asking them to give written consent to allow their child to receive free dental examinations and restorations with/without prior SDF application for treatment of the decayed primary teeth. Parental consent was obtained before inclusion of a child into the study.

The clinical screening was carried out in the kindergartens by two trained dentists. After that, generally healthy children who had at least one primary tooth with decay into dentine were included. They were randomly allocated into two study groups, i.e. SDF and placebo groups, by stratified block randomization using computer generated random numbers. There were two strata based on the number of decayed teeth of the study children. The children having fewer than 4 carious teeth were grouped into one stratum while the children having 4 or more carious teeth were put in another stratum. Throughout this study, the children, their parents and clinical examiners were uninformed regarding the child's group allocation. The decayed primary teeth of the children in the SDF and placebo groups were applied with either 38% SDF solution (Saforide, Toyo Seiyaku Kasei Co., Osaka, Japan) or tonic water (placebo). During the procedure, the children were lying on a table in the kindergarten without the presence of their parents. Children who had serious systemic health conditions or were uncooperative during treatment were excluded. The children were instructed not to eat or drink for at least half an hour after the application. In addition, for comparison purpose, a random sample was chosen from the children who did not have dental caries. The sample was chosen by using a computer generated random name list of caries-free children which was 30% more in number compared to the number of children in the SDF group in order to allow for a possible lower response rate to the questionnaire survey as these children did not receive any intervention.

About 10 weeks after the SDF or placebo application, the study children were clinically examined in the kindergartens. A ball-ended probe and disposable dental mirror attached to a handle with an intra-oral LED light were used by two trained examiners to conduct clinical examinations. All primary teeth were examined and the following information was recorded:
(1) presence of dental caries according to the WHO criteria [19];
(2) presence of stain on the anterior teeth (yes/no);

(3) alignment of anterior teeth (normal; crowding, i.e. overlapping of teeth; spacing, i.e. half a tooth unit or more distance between teeth).

Calibration of the examiners with an experienced epidemiologist was carried out before the implementation of the study. Duplicate examinations on 10% of the study children were carried out to assess inter-examiner agreement regarding caries status and stain on the anterior teeth. The kappa value of the duplicate examination result was 0.96. After this examination, the decayed teeth of the children were restored.

About one week before conducting the above-mentioned clinical examination, a structured questionnaire was distributed through the kindergartens to the parents of the study children (the children in the SDF and placebo groups, and the random sample of caries free children). The completed questionnaires were collected by the kindergartens before the clinical examination. The parents were not informed of their child's oral health status, including those who were caries free, before the questionnaire survey.

In the questionnaire, information on the respondent's relationship with the child (mother, father, grandparents or others) and education level of both parents was collected. Parental satisfaction regarding four aspects of their child's teeth, (1) dental health status (tooth decay); (2) colour of anterior teeth (including stain); (3) alignment of anterior teeth; and 4) overall tooth appearance, was rated by the parents using a 5-point scale (5=very satisfied, 1=very dissatisfied). A higher score indicated higher parental satisfaction. In addition, the Chinese version of Early Childhood Oral Health Impact Scale (C-ECOHIS) was adopted to assess the OHRQoL of the study children. The parents were asked to assess the negative impacts of their child's oral health on the child as well as the whole family. The C-ECOHIS contains 13 items grouped into two sections, child impact section (CIS) and family impact section (FIS). Four domains are included in CIS: child's symptom, function, psychology and self-image/social interaction. In the FIS there are two domains, namely parent distress and family function. Response categories of the C-ECOHIS record how often an event had occurred: 0 = never; 1 = hardly ever; 2 = occasionally; 3 = often; 4 = very often; 5 = don't know. The total C-ECOHIS scores were derived by adding up responses of all 13 items (except 'don't know'). A higher C-ECOHIS score indicates greater negative impacts of oral health on OHRQoL.

Statistical analysis

Data input was performed using the software EpiData Manager 4.0 (EpiData Association, Denmark) with double check. All statistical analyses were conducted using the software SPSS (IBM SPSS statistics version 25, USA) at a statistical significance level of 5%. For parental satisfaction rating questions, missing responses were excluded from statistical analysis. As for OHRQoL, all the 'don't know' responses were recoded as missing. For those with up to 2 missing responses in the CIS or 1 missing response in the FIS, the mean response value of the remaining items for that section was imputed as a score for the missing item. Questionnaires with more than 2 items in the CIS or more than 1 item in the FIS missing were excluded from the statistical analysis [3]. The total C-ECOHIS score was calculated as the sum of the response codes of items in both CIS and FIS. The total C-ECOHIS score can range from 0 to 52, with CIS and FIS ranging from 0 to 36 and 0 to16, respectively.

The Shapiro-Wilk test was conducted to test the normality of parental satisfaction and C-ECOHIS scores. The participants' socio-demographic features were compared using the chi-square test. Since normality of the parental satisfaction and C-ECOHIS scores could not be assumed, non-parametric tests, Kruskal-Wallis test or Mann-Whitney test, were adopted to investigate the distribution of the parental satisfaction and C-ECOHIS scores among groups. Multiple comparisons were conducted using Bonferroni method. Ordinal regression was carried out to investigate the associations between different clinical factors and parental satisfaction with their child's overall tooth appearance.

Results

A total of 414 children were included in this study, with 192 girls and 222 boys (Table 1). Among them, 260 children with decayed teeth were in the SDF (n=127) and placebo (n=133) groups, while 154 children were in the caries free group. A total of 411 (99.3%) questionnaires were collected. Six questionnaires were excluded from the analysis of C-ECOHIS because more than 2 CIS items and/or more than 1 FIS item were unanswered. The majority (84.8%) of the questionnaires were answered by the child's mother. More than 65% of the mothers had relatively low education level (up to secondary school), while only less than 10% of the mothers had a university degree. Proportionally more mothers in the SDF group had low education level compared to those in the caries free group (78.8% vs 66.2%, p=0.021). Except for the education

level of mother, there was no significant difference in the participants' socio-demographic features among the three study groups (p>0.05).

The mean (SD) decayed, missing and filled tooth (dmft) score of the study children was 2.6 (3.3). There were 113 (27.3%) children with 4 or more decayed teeth, 147 (35.5%) children with less than 4 decayed teeth and 154 (37.2%) children being caries free. The mean (SD) dmft score of the children with decayed teeth was 4.1 (3.3), with no significant difference between the SDF and placebo groups (p>0.05). Regarding the location of caries lesions, 111 (42.7%) children had caries lesions in both anterior and posterior teeth, while 102 (39.2%) children had caries only in the anterior teeth and 47 (18.1%) children only had posterior teeth caries. There was no significant difference in the distribution of the location of caries lesions between the SDF and placebo groups (p>0.05). As for stain, less than a quarter of the children had stain on their anterior teeth. Proportionally more (43.3%) children in the SDF group had stain compared to that in the placebo group (12.8%) and the caries free group (13.6%) (p<0.001). Regarding the alignment of anterior teeth, about 80% of children had normal alignment, while only around 9% and 7% of children had crowding and spacing problems, respectively. There was no statistically significant difference in tooth alignment among the SDF, placebo and caries free groups (p>0.05).

The parents in the caries free group reported higher parental satisfaction scores regarding all four aspects compared to those in the SDF and placebo groups (p<0.001) (Table 2). However, no significant difference in parental satisfaction scores was found between the SDF and placebo groups (p>0.05).

The lowest mean satisfaction score (2.0±0.7) with children's dental health status was reported by parents whose child had 4 or more decayed teeth (Table 3). Besides, the satisfaction with dental health status scores were lower in parents whose child had both anterior and posterior teeth with caries compared to those whose child had caries in either anterior or posterior teeth (p<0.001). Results of the Mann-Whitney test indicated that parents in the low education level group reported lower satisfaction scores with their child's dental health status compared to those in the high education level group (mother, p=0.004; father, p=0.012).

The parents whose child had stain on the anterior teeth gave a significantly lower mean satisfaction score regarding the colour of their child's anterior teeth (2.4±0.9) compared to

those whose child had no stain on the anterior teeth (3.2±1.0) (p<0.001). Furthermore, a significantly lower mean parental satisfaction score with tooth alignment was observed among parents whose child had spacing problems in anterior teeth (2.7±1.1) compared to normal alignment (3.4±0.9) or crowding alignment (3.3±0.9) (p<0.001). However, the associations between parents' education level and their satisfaction with child's anterior teeth color and alignment were not statistically significant (p>0.05).

In the ordinal regression model on parental satisfaction with their child's overall tooth appearance, parents who gave a satisfaction score 1 or 2 were considered as dissatisfied while those who gave a score 4 or 5 were satisfied. A satisfaction score of 3 indicated that the parents held a neutral opinion. Child's gender, parent's education level, group allocation, number of decayed teeth, location of caries, presence of stain and tooth alignment, were used as the independent variables. The final model with the statistically significant remaining independent variables is presented in Table 4. The thresholds of dissatisfied, neutral and satisfied responses in the ordinal regression model were statistically significant (p<0.01). Compared to parents whose child had 4 or more decayed teeth, parents whose child had fewer decayed teeth or did not have caries were likely to be more satisfied with their child's overall tooth appearance (p<0.01). Besides, the parents whose child had no decayed anterior teeth were more likely to be satisfied compared to those whose child had caries in the anterior teeth (p=0.008). Additionally, children's tooth alignment and presence of stain on the anterior teeth were also associated with their parents' satisfaction with overall tooth appearance.

Regarding the C-ECOHIS responses, over 90% of the parents in the caries free group never or hardly ever reported adverse impacts of their child's oral health on either the child or the family. Among the children who had decayed teeth, more than 70% of their parents reported that their child never or hardly ever had pain in the teeth, mouth or jaws. Only 2.4% and 3.9% of parents in the SDF and placebo groups, respectively, reported their child 'often or very often' had oral pain. For the other CIS domains ('function', 'psychology' and 'self-image/social interaction'), 'never' or 'hardly ever' was reported by the majority (>85%) of parents in the SDF and placebo groups. Regarding the FIS, there were about 30% and 25% of parents in the SDF and placebo groups reporting items 'been upset' and 'felt guilty', while less than 10% of them reported items in the domain of 'family function'.

The mean total C-ECOHIS score of the study children was 4.8±6.2, with 3.0±4.2 and 1.8±2.6 in the CIS and FIS, respectively (Table 5). Parents of children without caries reported lower total and sectional C-ECOHIS scores compared with those in the SDF and placebo groups (p<0.001). However, there was no statistically significant difference in the distribution of the total and sectional C-ECOHIS scores between the SDF and placebo groups (p>0.05). In addition, among the three groups of parents, parents whose child had 4 or more decayed teeth reported the highest total C-ECOHIS, CIS and FIS scores (p<0.001). Higher C-ECOHIS scores were reported by the parents whose child had stain in the anterior teeth (p<0.05). As for tooth alignment, parents whose child had spacing problems reported higher CIS and total C-ECOHIS scores compared to the parents of children with normal alignment (p<0.05).

There were no statistically significant (p>0.05) associations between the C-ECOHIS scores and the socio-demographic background of the children, including gender and parents' education level.

Discussion

A main finding of this study is that the children's dental conditions, e.g. dental caries, presence of stain on the anterior teeth and tooth alignment, and parental satisfaction were significantly related. With regard to the parental satisfaction with their child's dental health status, parents of the children with caries lesions were generally dissatisfied, while parents of children without decayed teeth were more likely satisfied. Additionally, it was found that parents were less satisfied when there were more decayed teeth in their child's mouth. Despite being lay persons, the parents were probably able to recognize their child's dental problems regarding tooth status and appearance. Parents can have an active role in maintaining and improving children's oral health.

In this study, parents' education level was related to parental satisfaction with their child's dental health status. The finding that higher dmft scores were found among the study children whose parents had lower education level is consistent with the results of previous studies [9, 20, 21]. Thus, parents in lower education level were less satisfied with their child's dental health status probably because their child had more decayed teeth.

Parental satisfaction with their child's tooth appearance is a complex thought process because parents probably take various factors into account. In this study, it was found that parents were less satisfied with the colour of their child's front teeth if stain was present. Besides, parents whose child had spacing problems in anterior teeth were more likely to be dissatisfied with their child's tooth alignment. Furthermore, parental satisfaction with overall dental appearance was also associated with other clinical dental features such as the number and location of decayed teeth in their child's mouth. Parents' individual perception of aesthetics may also contribute to the parental satisfaction with overall tooth appearance.

Clinical evidence shows that topical application of SDF solution is effective in arresting dentine caries in young children [11-15]. However, the black stain on the arrested caries lesions caused by SDF was thought to be the major side effect of SDF treatment [22]. It was reported that parental acceptance of esthetics following SDF treatment was the most frequently reported barrier for dentists in the United States to use SDF [17]. In this study, there was no statistically significant difference in parental satisfaction with their child's dental health, as well as their child's tooth appearance, between the SDF and placebo groups. These findings may be explained in several ways. Firstly, SDF solution application may not be considered by parents as a 'real' dental caries treatment. Different from placement of restoration in decayed tooth, which is commonly accepted by the public as the way to treat dental caries, SDF application, as a non-invasive treatment, may not be fully understood by the parents. Even though application of SDF solution can halt the disease process, a cavity is still present in the tooth. Probably, most parents would like to see that the cavity in the tooth is filled with dental material [23], which is the 'real treatment' in their minds. Hence, in this study, compared to the placebo treatment, SDF treatment did not have a significant influence on parental satisfaction with their child's dental health status. Secondly, stains on children's teeth can come from multiple sources. Even without receiving SDF application, some children in the placebo and caries-free groups had extrinsic stain on their anterior teeth. These black stains probably came from the deposition of dietary chromogens and other substances on the tooth surface [24]. Since parents cannot distinguish the stain caused by SDF application or other substances, it is not surprising to find out no significant difference in parental satisfaction with the colour of their child's anterior teeth between the SDF and placebo groups. Thirdly, the results of ordinal regression of this study showed that the presence of stain on the anterior teeth only presented a relatively small effect on the parental satisfaction with their child's overall dental appearance. Therefore, even

though SDF application causes black stain on the arrested caries lesions, it may not have a significant adverse effect on parental satisfaction.

Regarding OHRQoL, in this study, the C-ECOHIS score was associated with the number of decayed teeth, which is consistent with the results reported in previous studies [25-29]. Parents of children with four or more decayed teeth reported higher sectional (CIS, FIS) and total C-ECOHIS scores compared with parents whose child had fewer or no decayed teeth. This indicates that more decayed teeth present greater adverse impacts on OHRQoL. Interestingly, in this study, there was no statistically significant difference between the CIS scores of the children without caries and those of the children with fewer than four decayed teeth, while a significant difference was found between their FIS scores. This may be because having a few caries lesions would only had slight impacts on most of the study children and these might not be perceived by their parents. However, the fact that their child had dental caries would adversely influence the parents, mainly in the domain of parental distress (being upset or feeling guilty).

Although the adverse impact on OHRQoL can be detected among children with decayed teeth, the total C-ECOHIS score in the present study is lower than those reported in studies conducted in other countries [3, 30-33], but similar to those in Hong Kong [34, 35]. One explanation is that the participants of the studies conducted in other countries were recruited from dental clinics or hospitals while the children in this study were recruited from kindergartens. Children seeking dental treatment most probably have poorer oral health and worse OHRQoL, compared with the general child population. Thus, higher C-ECOHIS scores were reported in those studies. Cultural differences might be another reason that Chinese parents may perceive less impact from their child's dental problems compared to parents in other countries.

This study provides useful information on SDF treatment regarding parental satisfaction with their child's oral health and OHRQoL. In this study, it was found that SDF application had no significant influence on children's OHRQoL, which is consistence with the result of a clinical trial on SDF [35]. A possible reason is that SDF application, as a non-invasive caries management method, does not have a significant influence on the OHRQoL of the study children. A recent study found that the responsiveness of the ECOHIS was associated with the complexity of dental treatment received by preschool children [36]. In that study,

children who received more complicated dental treatment (endodontic treatment and/or tooth extraction) had greater changes in their ECOHIS scores than those who received non-operative treatment only. Although SDF application can arrest active dentine caries, this outcome may not lead to an improvement in parental satisfaction. Thus, extra efforts such as educating parents to accept the non-invasive caries treatment method and covering the black stain using tooth-colour material to improve dental esthetics are required after SDF application if a significant change in parental satisfaction is to be achieved.

There are some limitations in the study. Since this study was conducted in kindergartens in Hong Kong, one needs to be cautious when generalizing the results to other ethnic populations due to cultural differences and different caries severity levels. Moreover, in the present study, the parental satisfaction and OHRQoL of children were investigated 10 weeks after SDF application which, from the experience of our previous clinical studies on SDF, is sufficient for the black stain to appear on the treated caries lesion surface [14]. Since this study only reported on the short-term impacts of SDF application, further studies are needed to investigate the long-term influence of SDF treatment on parental satisfaction and OHRQoL. Within the study limitations, it is concluded that in this study population parental satisfaction and children's OHRQoL are associated with children's dental caries status but not with SDF application.

Conflict of Interest

The authors declare that they have no conflict of interest.

Funding

Ethical approval

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee (Institutional Review Board of the University of Hong Kong, IRB reference Number: UW17-180) with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The trial was registered (clinicaltrials.gov #NCT03657862).

Informed consent

Written parental consent was obtained for all the participant children in this study

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                    ┌─────────────────────────────┐
                    │  Preschool children with parental │
                    │  consent were clinically screened │
                    │            (n=883)               │
                    └─────────────────────────────┘
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Preschool children with parental consent were clinically screened (n=883)

Children with dentine caries lesions were randomly allocated into two groups (n=260)

Children without dentine caries lesions (n=623)

SDF group
SDF solution applied on caries lesions (n=127)

Placebo group
Tonic water applied on caries lesions (n=133)

A random sample of caries free children (n=154)

After 10 weeks
• Parents of the study children were asked to answer a questionnaire
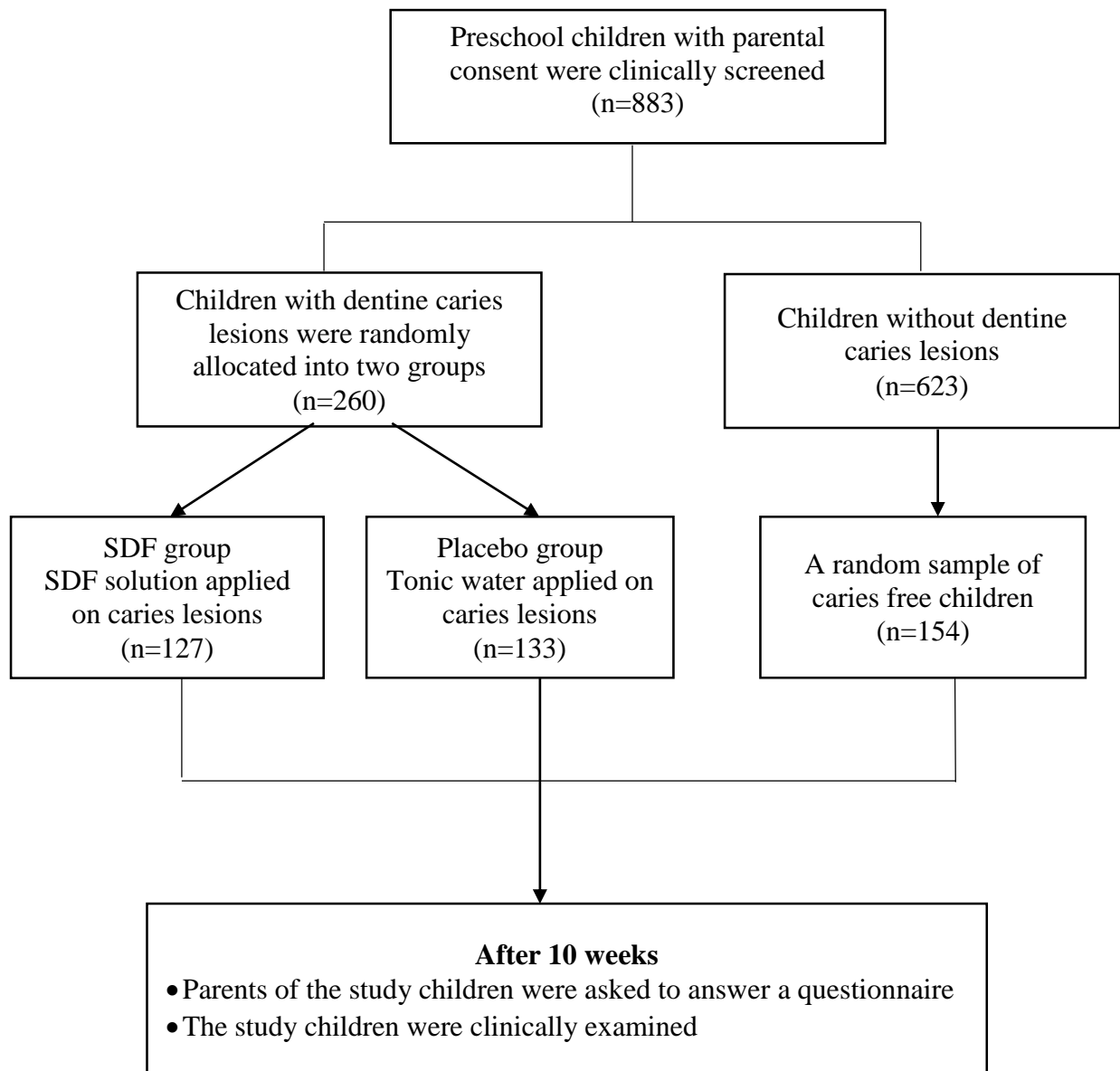• The study children were clinically examined

Figure 1 Flow chart of study activities

Table 1 Characteristics of study participants

	SDF group n=127		Placebo group n=133		Caries free group n=154		All participants n=414	
	n	%	n	%	n	%	n	%
Gender of child								
girl	53	41.7	57	43.2	82	52.9	192	46.4
boy	74	58.3	75	56.8	73	47.1	222	53.6
Relationship with child								
mother	107	84.3	112	84.8	132	85.2	351	84.8
father	16	12.6	17	12.9	19	12.3	52	12.6
grandparents/others	4	3.1	3	2.3	4	2.5	11	2.6
Education level of mother								
low education level*	100	78.8[a]	99	74.4[a,b]	102	66.2[b]	301	72.7
not completed secondary school	22	17.3	21	15.8	29	18.7	72	17.4
completed secondary school	78	61.4	78	58.6	74	47.7	229	55.3
high education level*	24	18.9[a]	32	24.1[a,b]	52	33.8[b]	108	26.1
tertiary, non-degree course	13	10.2	20	15.0	38	24.5	71	17.2
university degree program	11	8.7	12	9.0	14	9.0	37	8.9
information missing	3	2.4	2	1.5	0	0	5	1.2
Education level of father								
low education level	87	68.5	91	68.4	98	63.6	276	66.7
not completed secondary school	17	13.4	13	9.8	22	14.2	52	12.6
completed secondary school	70	55.1	78	58.6	77	49.7	224	54.1
high education level	37	29.1	39	29.3	54	35.1	130	31.4
tertiary, non-degree course	22	17.3	21	15.8	27	17.4	70	16.9
university degree program	15	11.8	18	13.5	27	17.4	60	14.5
information missing	3	2.4	3	2.3	2	1.3	8	1.9

*$p=0.021$, p-value was derived from chi-square test, multiple comparison among the three groups was tested by Bonferroni method, different subscript letters denote group proportions differ significantly at 0.05 level

Table 2 Mean (SD) parental satisfaction scores according to groups

	(a) SDF group (n=125)		(b) Placebo group (n=132)		(c) Caries free group (n=154)		multiple comparison	p-value
Dental health status	2.3	(0.8)	2.4	(0.9)	3.7	(0.7)	a, b<c	<0.001
Color	2.6	(1.0)	2.8	(1.0)	3.5	(0.8)	a, b<c	<0.001
Alignment	3.2	(1.0)	3.2	(1.0)	3.7	(0.8)	a, b<c	<0.001
Overall appearance	3.0	(1.0)	3.2	(1.0)	3.7	(0.8)	a, b<c	<0.001

p-value was derived from the Kruskal-Wallis test; multiple comparison was conducted among the three groups with the Bonferroni method at the level at 0.05

Table 3 Mean (SD) parental satisfaction scores with child's dental health status

	n	mean	SD	multiple comparison	p-value
Caries rate					
(a) dmft≥4	110	2.0	(0.7)		
(b) 0<dmft<4	147	2.6	(0.9)	a<b<c	<0.001
(c) dmft=0	154	3.7	(0.7)		
Caries location					
(a) anterior + posterior	108	2.0	(0.7)		
(b) anterior only	102	2.5	(0.9)	a<b, c	<0.001
(c) posterior only	47	2.6	(0.9)		
Education level of mother					
low	301	2.8	(1.0)		0.004
high	108	3.1	(1.1)		
Education level of father					
low	276	2.8	(1.0)		0.012
high	130	3.0	(1.0)		

p-value was derived from the Kruskal-Wallis test (among the three groups comparison) and the Mann-Whitney test (between the two groups comparison); multiple comparison was conducted among the three groups with the Bonferroni method at the level at 0.05

Table 4 Final model of the ordinal regression of parental satisfaction with their child's overall tooth appearance

	Odds ratio	95% CI Lower	95% CI Upper	p-value
Caries				
dmft=0	2.94	1.33	6.50	0.008
0<dmft<4	2.34	1.43	3.84	0.001
dmft≥4 (ref.)				
Caries location (in anterior teeth)				
no	2.49	1.26	4.88	0.008
yes (ref.)				
Alignment				
Normal	3.35	1.52	7.36	0.003
Crowding	2.70	0.99	7.38	0.053
Spacing (ref.)				
Stain				
no	1.88	1.17	3.05	0.010
yes (ref.)				

Pseudo R-square, Cox and Snell 0.205, Nagelkerke 0.237
Test of Parallel Lines was conduct and the p-value was 0.156, the null hypothesis that the ordered logit coefficients are equal across the levels of the outcome could not be rejected

Table 5 Mean (SD) C-ECOHIS scores of the study children

	n	CIS	(SD)		FIS	(SD)		ECOHIS	(SD)	
Group										
(a) SDF group	123	3.6	(4.3)		2.5	(2.6)		6.1	(6.2)	
(b) Placebo group	130	3.9	(5.0)	a, b>c	2.4	(3.0)	a, b>c	6.3	(7.5)	a, b>c
(c) Caries free group	152	1.8	(2.8)	p<0.001	0.6	(1.5)	p<0.001	2.5	(3.8)	p<0.001
Caries rate										
(a) dmft≥4	107	5.4	(5.5)	a>b, c	3.4	(3.2)	a>b>c	8.8	(7.9)	a>b>c
(b) 0<dmft<4	146	2.5	(3.5)	p<0.001	1.7	(2.3)	p<0.001	4.3	(5.3)	p<0.001
(c) dmft=0	152	1.8	(2.8)		0.6	(1.5)		2.5	(3.8)	
Stain										
yes	87	3.8	(4.5)	p=0.029	2.5	(2.8)	p=0.001	6.4	(6.8)	p=0.004
no	318	2.8	(4.1)		1.6	(2.5)		4.4	(6.0)	
Alignment										
(a) normal	341	2.8	(4.0)	a<c	1.7	(2.5)		4.5	(6.0)	a<c
(b) crowding	35	3.5	(4.1)	p=0.010	1.7	(2.2)	p=0.094	5.3	(5.6)	p=0.012
(c) spacing	29	5.0	(5.4)		2.8	(3.3)		7.8	(8.2)	
All participants	405	3.0	(4.2)		1.8	(2.6)		4.8	(6.2)	

CIS, children impact section; FIS, family impact section;
p-value was derived from the Kruskal-Wallis test (among the three groups comparison)
and the Mann-Whitney test (between the two groups comparison); multiple comparison
was conducted among the three groups with the Bonferroni method at the level at 0.05