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Efficacy of 30% silver diamine fluoride compared to atraumatic restorative treatment on dentine caries arrestment in primary molars of preschool children: A 12-months parallel randomized controlled clinical trial

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ABSTRACT

Objectives: This clinical trial investigated the efficacy of silver diamine fluoride (SDF) in arresting dentine caries in primary molars of preschoolers. Time required for treatment, adverse effects, parental aesthetic perception, anxiety and oral health related to quality of life (OHRQoL) was evaluated.

Materials and methods: Children, 2–5 years old, with active dentine caries lesions on the occlusal surface of primary molars were randomly allocated to test group (SDF) or control group (atraumatic restorative treatment/ART). The dmf-t/DMF-T and ICDAS indexes determined the presence of caries and activity. The main outcome after 3, 6 and 12-month follow-up was assessed by a blind examiner. The time required to perform the treatments was recorded and a facial image scale was applied to assess anxiety before and after treatment. Adverse events and aesthetic perception were assessed through questions addressed to caregivers; and the OHRQoL through the B-ECOHIS questionnaire.

Results: In 68 patients that were randomized, the mean number of treated teeth per child was 2.42(1.04) and 2.09(1.18) in the SDF and ART groups ($p = 0.074$), respectively. The mean difference of arrested lesions between the groups after 12 months was -0,07(0.05; - 0.17-0.30). The time required to treat with SDF was lower than the ART ($p < 0.001$). There was no difference in the percentage of adverse events + aesthetic perception ($p = 0.709$), and the change in anxiety ($p = 0.155$). There was a less impact in OHRQoL after ART treatment, but only when the parents' distress subscale was considered ($p = 0.012$).

Conclusion: SDF requires much less chair-time and have similar results as ART in arresting caries lesion, anxiety, adverse effects, aesthetic perception and quality of life.

1. Introduction

Early childhood caries (ECC) is a worldwide public health problem that, although prevalent in both developed and developing countries, shows a greater severity in communities with low socioeconomic status, where caries lesions most often remain untreated, causing a greater impact on overall health and quality of life of infants and young children [1]. Usually, untreated dental caries lesions lead to discomfort and pain [2] and can induce to a lack of physical development and a reduction in children's learning capacity, as well as increasing treatment costs in the future [1].

ECC restorative treatment requires sophisticated equipment and trained dentists, especially when it affects small and apprehensive children [3]. In some of these cases, costs are especially higher when there is a need for general anesthesia, besides treatment [1]. Thus, it is essential to carry out the prevention of ECC, through the correct management of risk factors [1]. If initial prevention strategies fail, there is a need for management to arrest the disease and reduce the negative

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impact of cavity caries lesion [1].

Atraumatic restorative treatment (ART) [1] is a low-cost alternative to increase the accessibility of restorative treatment in these children. It is well accepted by them, can be used in places without electricity and running water [4,5], and has shown effectiveness in caries control [4,6,7]. However, much more must be done to make oral health better and more accessible [4].

Due to its safety, efficiency, feasibility and effectiveness in arresting dentine caries, silver diamine fluoride (SDF) has been suggested as an option for controlling tooth decay, especially in preschool children with dentine caries lesions [1,8,9]. SDF may transform pediatric and community dentistry positively and may be a low-cost innovative dental agent of this century. Although SDF cause teeth black staining, the benefits of having no toothache and dental infection can overcome this unwanted factor, particularly in places where the access to dental care is a challenge [8].

Considering the above facts, taking into account that the highest concentration of commercially available SDF in Brazil is 30% and, knowing that there is no randomized controlled clinical study in preschool children comparing the efficacy of 30% SDF with ART in cavity dentine caries lesions involving only the occlusal surface of primary molars, this parallel, randomized, controlled clinical trial was performed to compare the percentage of arrested caries lesions treated with SDF and ART. Besides that, time required for treatment, children's anxiety before and after treatment, possible adverse events, aesthetic perception and impact on quality of life of treatments were evaluated. Our null hypothesis was that there would be no difference in the mean number of carious lesions arrested following SDF and those treated with ART.

2. Methods

2.1. Ethics

The Research Ethics Committee of the Clementino Fraga Filho Hospital of the Federal University of Rio de Janeiro (UFRJ) gave the approval of the present study (protocol 1.604.702/CAAE: 56374216.2.0000.5257). It is duly registered in the Brazilian Registry of Clinical Trials (ReBEC) and ClinicalTrials.gov, under UTN: U1111-1193-9649 and NCT03063307, respectively.

2.2. Study design

This randomized 2-arm parallel-group active controlled trial, with a 1:1 allocation ratio followed the CONSORT recommendations [10]. Between June 2016 and August 2017 at the Pediatric Dental Clinic of UFRJ, one trained examiner recruited 68 preschoolers with primary molars (n = 118) with occlusal active caries lesions. Children were randomized into 2 groups: the test group (treatment with SDF), and the control group (ART); to investigate the following outcomes: (1) arrestment of caries lesion; (2) time required to treat; (3) adverse events (4) parental aesthetic perception; (5) children's anxiety and (6) quality of life related to the oral health (OHRQoL) of children and their families.

2.3. Sample size calculation and interim analyses

The sample size was calculated using the Biostat 5.3 program [11], based on the difference of proportion of the clinical success observed in a previous similar study [12]. Thus, assuming a difference of 28% between groups, test and control; the use of a two-side test; a power of 80% and standard error of 0.05%; 49 patients are required to be allocated into each treatment group. Estimating a sample loss of 20%, 59 patients would contemplate the sample from each group.

When more than one tooth per child fulfilled the inclusion criteria, all of them received the same treatment that guaranteed the parallel design of the study.

Changes after trial commencement: since it was not possible to reach the number of children who met the eligibility criteria within the planned recruitment interval, we chose to analyze all the eligible teeth of each child. Thus, in order to correct the internal correlation of more than one tooth per child, Bootstrap was performed to construct the Bias Corrected Accelerated (BCa) confidence interval with 10,000 resampling. Moreover, the observed difference in the proportion of success in arresting caries lesion was lower (5% between groups after 12-month follow-up) than used in the sample size determination, which is in accordance with our hypothesis that SDF is similar to ART in arresting dentine caries lesion.

2.4. Participants, eligibility criteria, and settings

Children, who sought the first dental care at the Pediatric Dental Clinic of UFRJ were recruited by a trained and calibrated examiner (ALV) from June 2016 to August 2017. The following selection criteria were applied: healthy children aged between 2 to 5 years old who had at least one untreated cavitated active caries lesion involving only the occlusal surface of a primary molar. Children were excluded if parents were unwilling to be assigned to any of the approaches; had any abnormal medical condition or silver allergy; whose families intended to move from Rio de Janeiro during the period of the study; and those molars with clinical or radiographic signals of pulp involvement.

Parents or guardians signed an informed consent before their children's recruitment.

Baseline information such as eating habits, oral hygiene, previous dental experience, socio-demographic and socioeconomic data were collected by an assistant (RVRT). In addition, oral health related to quality of life (OHRQoL) was investigated through interviews with the main caregivers, using the Brazilian version of the Early Childhood Oral Health Impact Scale (B-ECOHIS) questionnaire [13,14].

Clinical examination was performed by one operator (ALV), with the child on a dental chair, under artificial light, with a dental probe (if necessary) and flat mouth mirror nº 5. Operator was trained by an expert dentist (FBF), who was calibrated for the caries assessment according to ICDAS and dmft/DMFT indexes (Kappa inter examiner = 0.930). All teeth were classified by dmft/DMFT and exposed dentine surfaces should be diagnosed as active or inactive and received scores 5 or 6 of the ICDAS criteria.

2.5. Randomization

The selected children were allocated into the groups by block randomization of four, through the generation of a random numbers table in the Excel program, by a researcher (FBF) different from the operator. Allocation concealment was achieved with sequentially numbered, opaque, sealed envelopes containing the treatment allocation cards, which were prepared before the trial.

The operator (ALV) was responsible for taking the next envelope in sequence and giving to another person to open it, implementing the randomization process.

2.6. Interventions

The interventions were performed by the operator (ALV), who is specialist in pediatric dentistry. Oral hygiene and diet recommendations were given to caregivers and their children. They were instructed to brush the children's teeth with fluoridated toothpaste at least twice a day.

Lesions of the SDF group were treated according to the following protocol: (A) cleaning the occlusal surface to be treated with toothbrush; (B) protection of the face's skin and gums with petroleum jelly (Vaseline) to avoid staining; (C) isolation of the tooth with cotton wool rolls and saliva ejector; (D) drying the surface with triple syringe; (E) 30% SDF (Cariostop, Biodinâmica, Paraná, Brazil) was directly applied

with a micro sponge (Cavibrush-FGM, Joinville, Brazil) onto affected tooth surface for 3 min, according to manufacturers' instructions [15]; (F) the excess was removed with cotton pellets; (G) the teeth was rinsed with water simultaneously with saliva ejector suction [16].

The lesions of the control group (ART) were treated according to the following protocol: (A) cleaning of the occlusal surface with toothbrush; (B) isolation of the tooth with cotton wools rolls and saliva ejector; (C) selective removal of caries using either the small or the medium-sized excavator, depending on the size of the cavity; (D) cleaning of the occlusal surface and the cavity using a wet cotton wool pellet with water; (E) conditioning of the cavity and occlusal surface using a drop of the glass ionomer cement liquid (Ketac Molar Easy Mix 3 M ESPE) on a micro sponge (Cavibrush-FGM, Joinville, Brasil) rubbing both the cavity and the occlusal surfaces for 10 s; (F) washing the conditioned surface with wet cotton wool pellets; (G) drying the surface with dry pellets; (H) mixing glass ionomer according to manufacturers' instructions; (I) insertion of the mixed glass ionomer into the cavity and overfill slightly; using the flat end of the applier, and plugged into corners of the cavity; (J) pressing the ionomer with the gloved finger with Vaseline on the top of the entire occlusal surface and apply slight pressure for 30 s; (K) checking the bite and removing the excess of the material with manual instrument, if necessary; (L) covering the filling with Vaseline; (M) instructing the patient not to eat for at least one hour [17].

2.7. Outcomes and follow up

Recall examinations of the treatments were performed at 3, 6 and 12-month intervals. The main outcome was the caries arrestment. A blinded trained and calibrated examiner (LRC) (Kappa for ICDAS = 0.703 and for dmf-t/DMF-T = 0.889) performed the clinical examinations (performed as the baseline exam) after the patients had their teeth brushed. Information about dental exam and complaints about pain were registered in a specific form. Thus, comparing the data from the initial examination to those from the review, the teeth could be classified as success or failure according to the treatment group. The success was achieved when caries was classified as inactive (ICDAS); and failure when caries was classified as active (ICDAS) and/or when there is spontaneous pain or signs of pulpal involvement.

In relation to the control group, it was considered as success of caries lesion arrestment if the restoration was present, without apparent dentin [18], or if the dentine was exposed but inactive/arrested. When the filling material was partial or totally lost and the exposed dentine was classified as active lesion (ICDAS) and/or when there is spontaneous pain or signs of pulpal involvement it was considered a failure. The lost restorations of health (arrested caries lesion) teeth were replaced immediately by the operator (ALV) and it was registered.

The secondary outcomes were the time required for treatment, the anxiety, adverse events, parental aesthetic perception and the OHRQoL. The treatment time, between the groups, was assessed by a digital timer which was triggered as soon as the tooth brushing started, which was the first step of the two treatment protocols. As the number of teeth treated per child was different, the treatment time was recorded for only one tooth (decided by lottery) per child.

A facial image scale [19] to measure the children' anxiety was shown to the children age 3 and older immediately before treatment, in the waiting room, by the operator (ALV) or an assistant (RVRT). Each child was asked to point to the face that best expressed his/her feeling at that moment (very happy; happy; neutral; unhappy; and very unhappy). Right after their treatment, the children were asked to answer the same test again.

Occurrence of possible adverse events of SDF and ART were investigated. The operator, immediately after the treatment, registered any case of complaint about pain / sensitivity on the teeth and/or unpleasant taste. Also, possible irritations, lesions, spots, tattoos on mucosa, gingiva and skin were investigated. In addition, principal caregiver for all included children was interviewed by the operator (ALV) up to two days after the child received the treatment. The following adverse events were investigated: burning in the mouth, allergy, nausea, vomiting, altered taste of food, irritation of the gums or mucosa, staining or bruising of the skin or into the mouth, and pain or tenderness in the teeth. If the caregiver reported any other information, it was recorded as the same form. They were also questioned whether, due to treatment received, the child avoided smiling or if the parents were annoyed by the appearance of their children's teeth, which represented the questions about the parental aesthetic perceptions.

Information about quality of life was obtained through interviews with main caregiver of all participants before and 15-day after treatment. The B-ECOHIS [13,14] questionnaire was applied by two trained assistants (RVRT and GSM), at both times. The same caregiver should answer the questions in the two moments. In order to minimize the possibility of memory playing (i.e., recalling only the first or last response options presented by the interviewer), the interviewer showed cards to the respondents with the response options and read the response options aloud. The total B-ECOHIS scores and the scores for individual subscales were calculated as a simple sum of the response codes. Higher scores indicated a more negative impact on the oral health-related quality of life, and vice-versa.

2.8. Blindness

Blinding of either patient or operator (ALV) during the treatment was not possible due to the difference between the materials. However, in the follow-up assessments, the examiner (LRC) was blind.

There were no outcome changes after trial commencement.

2.9. Data analyses

Data were stored and analyzed using the IBM SPSS Statistics version 24.0 software (SPSS Inc., Chicago, USA) and the significance level adopted for all tests was 5%. An intention-to-treat analysis was undertaken.

The chi-square or Fisher's exact tests were used to compare groups in relation to the following categorical variables: gender, presence of caries lesions in the siblings, parental level of education (number of years that they completed the study), socioeconomic level (low, moderate or high), amount of fluoride in the dentifrice ($\geq$ 1000 PPM), nocturnal nutritional suction, characteristics of the primary molars (upper or lower, first or second molar, ICDAS 5 or 6 on occlusal surface) and percentage of dropouts and patients/teeth followed up. The abnormality of the data was verified by the Shapiro Wilk test. Thus, when comparing the mean ages, the dmft/DMFT indexes of the children, as well as the time of treatment by the groups, Mann Whitney test was used. To identify the difference between mean rates of adverse events (including aesthetic perception), considering the SDF and ART groups, the chi-square test was used.

In addition to the frequency of arrested lesions per group, a difference in the proportion of arrested lesions between them was calculated by applying Student *t*-test

In relation to the anxiety evaluation of children treated with SDF and ART, the Indicator of Positive Change (IpC) [20] was calculated to measure the proportion of possible categories of change (in the direction of improvement) obtained by each group, considering the time before and after treatment. In addition, the percentage of children who had positive change, negative or no change was obtained by dividing the number of children located in the blue, red or gray sector (graph constructed to analyze IpC), respectively, by the total number of children in each group.

Quality of life was assessed using the B-ECOHIS instrument, in which the total, children impact section (CIS) and family impact section (FIS) scores and their domains or subscales (child's symptoms, child's function, child's psychological, self-image / social interaction, family

distress and family function) were calculated. The magnitude of change in OHRQoL was determined after each type of treatment, subtracting the total B-ECOHIS scores after 15 days of treatment of those obtained before the treatment. The same calculation was used for CIS and FIS as well as for all its subscales. The Mann Whitney test served as a comparison between the groups regarding the difference of these scores, between the two moments of evaluation. The magnitude of the effector effect size (ES) was also calculated according to Cohen [21]. Therefore, the mean change was divided by the standard deviation of the total B-ECOHIS means or sections / subscales means observed in the baseline evaluation. Thus, depending on the value, ES indicates a small ($\leq$0.2), moderate (0.21-0.79) or large ($\geq$0.8) effect [21,22].

3. Results

Sixty-eight patients with the mean age of 3.62 (1.07) years old were allocated into the SDF group (n = 34) or the control group - ART (n = 34). One child in ART group was excluded because distal marginal ridge fractured during excavation. Therefore, sixty-seven children with 117 eligible teeth received treatment and completed 3-month follow-up (100.0%), while at 12-month follow-up, 56 children and 107 teeth were evaluated. The mean (SD) length of 12-month follow-up was of 11.92 (4.65) in the SDF group and 12.65 (2.35) in the ART group. Participant flow and recruitment are represented in clinical trial flow chart (Fig. 1). Table 1 shows a comparison between dropouts or excluded due to failure and patients who were followed up in both groups. Table 2 shows the participant characteristics.

From 67 children with follow-up, they did not present difference between their age (p = 0.77) and, also, no difference was observed among dmft (p = 0.58). The mean (SD) number of treated teeth per child was 2.42 (1.04) in SDF group and 2.09 (1.18) in ART group (p = 0.07) (Table 3). Likewise, there was no difference between the type of molar (p = 0.77), location of them in the arch (p = 0.84) and ICDAS index (p = 1.00) (Table 2).

The mean (SD; 95%CI) proportion of treated teeth with arrested lesions in each group (number of teeth with arrested lesion / number of teeth treated) at 3-month follow-up was of 1.00 (100%) in SDF group (65/65) and 0.96 (0.19; 0.90–1.00) in ART group (50/52). At 6-months follow-up, the values were 0.89 (0.31; 0.83-0.95) (57/64) in SDF group and 0.92 (0.69; 0.85-0.98) (44/48) in ART group. And, at 12-months follow-up it was found 0.89 (0.30; 0.82-0.95) (55/62) for SDF group and 0.96 (0.25; 0.91–1,00) (43/45) for ART. When the groups are compared, the observed mean (SD; 95%CI) difference of arrested lesions between the groups was 0.04 (0.02; 0.02-0.10); -0.03 (0.06; -0.14-0.09) and -0,07 (0.05; - 0.17-0.30) at 3, 6 and 12-months follow-up.

The mean treatment time for SDF (n = 34/34) was 6.97(1.31) minutes with the median of 7.00 (5.0–10.0). For ART (n = 33/33), the mean time was 13.88 (4.25) minutes with the median of 14.0 (8.0–26.0). Thus, there was a significant difference between the groups (p < 0.001).

Two days after treatment, the operator (ALV) successfully contacted all 67 (100%) main caregiver by telephone. The caregivers reported that eight children presented 11 adverse events), including complaints about appearance. Based on all contacted caregivers, the adverse event rate per child was 14.7% (n = 5) in the SDF group and 9.1% (n = 3) in ART group (p = 0.709). During the treatment appointment, the operator registered 24 events, 12 from each group; thus 29.4% of children from SDF and 33.3% from ART present these effects (p = 0.796). Table 4 shows the type of adverse event according to the groups.

Considering the anxiety, children for both group (28/34 of SDF; 26/33 of ART) were evaluated without difference between them (p = 0.155). The children (n = 13) under 3 years old were excluded from the analyses. There was a positive change or no change of 71.4% and 80.8% of children from SDF and ART group, respectively. The IpC was 48.1% for SDF and 50% for ART group, respectively (Fig. 2).

Comparing the difference between the groups, there was a less impact in the QOLRoH at ART than SDF group, considering FIS (p = 0.011) and parents' distress subscale (p = 0.012). Before treatment, the B-ECOHIS questionnaires were answered by 34 and 33 main caregivers of SDF and ART group, respectively. One child from ART group was excluded from analyses because more than two “don’t know” answers were obtained in CIS section and more than one of this answer

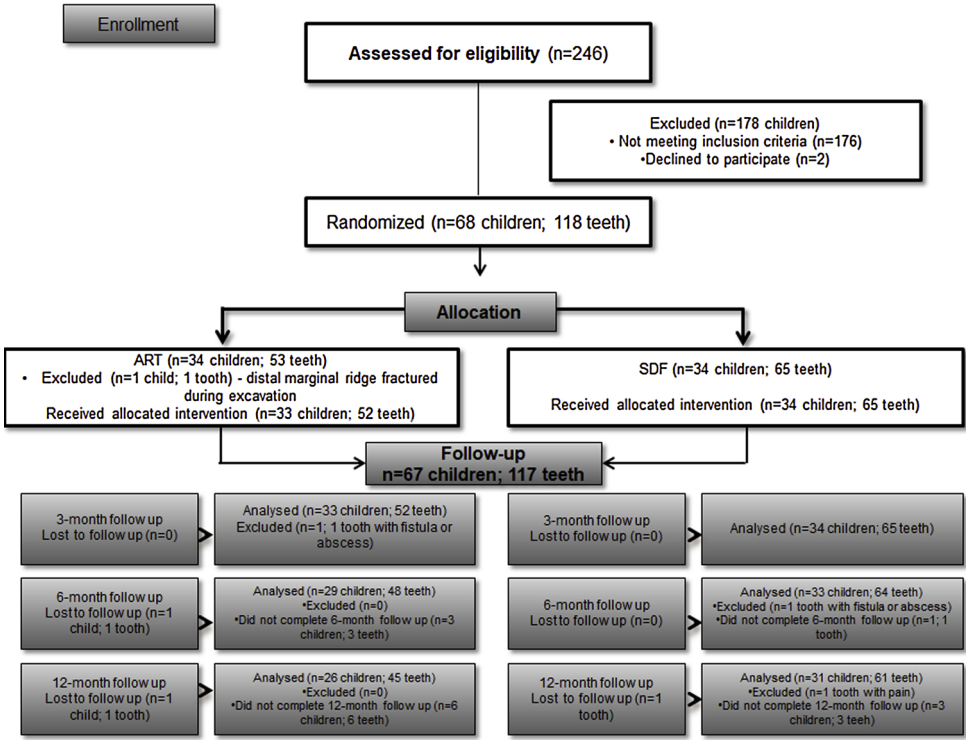

Fig. 1. Consort flow diagram of the trial.

Table 1
Number of dropouts or excluded due to failure and patients/teeth followed up.

	Groups	3 months	6 months	12 months	Total
Dropouts and excluded	SDF	0	1 (2.94%) patient 1 (1.54%) tooth	3 (8.82%) patients 4 (6.15%) teeth	4 (11.76%) patients 5 (7.69%) teeth
	ART	0	4 (12.12%) patients 4 (7.69%) teeth	7 (21.21%) patients 7 (13.46%) teeth	11 (33.33%) patients 11 (21.15%) teeth
Followed up	SDF	34 (100%) patients 65 (100%) teeth	33 (97.06%) patients 64 (98.46%) teeth	31 (91.18%) patients 61 (93.85%) teeth	31 (91.18%) patients 61 (93.85%) teeth
	ART	33 (100%) patients 52 (100%) teeth	29 (87.88%) patients 48 (92.31%) teeth	26 (78.79%) patients 45 (86.54%) teeth	26 (78.78%) patients 45 (86.54%) teeth

Note: No difference between SDF and ART groups was observed considering dropouts/excluded due to failure and teeth followed up at 3, 6 (p = 0.121) and 12 months (p = 0.152). Also, no difference between dropouts/excluded due to failure and patients at 3, 6 (p = 0.169) and 12 months (p = 0.140) was verified.

Table 2
Baseline demographic and clinical characteristics in all patients by the groups.

	All Participants		ART		SDF		*p-value**
	n	(%)	n	(%)	N	(%)	
Patients	***67***	***100***	***33***	***50***	***34***	***50***	
Gender							
Female	26	38.8	13	39.4	13	38.2	0.922
Male	41	61.2	20	60.6	21	61.8	
S.economic class							
Middle income	11	16.4	7	21.2	4	11.8	0.340
Low income	56	83.6	26	78.8	30	88.2	
Race							
White	29	43.3	13	39.4	16	47.1	0.693
Brown	25	37.3	14	42.4	11	32.4	
Black	13	19.4	6	18.2	7	20.6	
Caries in siblings							
No	20	29.9	9	27.3	11	32.4	0.776
Yes	31	46.3	16	48.5	15	44.1	
Without siblings	16	23.9	8	24.2	8	23.5	
Night brushing daily							
No	19	28.4	9	27.3	10	29.4	1.000
Yes	48	71.6	24	72.7	24	70.6	
Fluoride paste (≥1000 ppm F)							
Yes	56	83.6	29	87.9	27	79.4	0.340
< 1000 ppm	3	4.5	1	3.0	2	5.9	
Without fluoride	8	11.9	3	9.1	5	14.7	
Nourishing suction at night							
No	52	77.6	26	78.8	26	76.5	1.000
Yes	15	22.4	7	21.2	8	23.5	
Mothers' educational level							
0-7 years	9	13.4	6	18.2	3	8.8	0.676
8-11 years	13	19.4	6	18.2	7	20.6	
12-14 years	38	56.7	17	51.5	21	61.8	
≥15 years	7	10.4	4	12.1	3	8.8	
Fathers' educational level							
0-7 years	11	16.4	4	12.1	7	20.6	0.281
8-11 years	19	28.4	12	36.4	7	20.6	
12-14 years	30	44.8	13	39.4	17	50.0	
≥15 years	1	1.5	1	3.0	0	0.0	
No response	6	9.0	3	9.1	3	8.8	
Teeth	***117***		***52***	***49.1***	***65***	***55.1***	
Arch							
Maxillary	49	41.9	22	42.3	27	41.5	0.933
Mandibullary	68	58.1	30	57.7	38	58.5	
Molar							
First	65	55.6	30	57.7	35	53.8	0.677
Second	52	44.4	22	42.3	30	46.2	
ICDAS							
5	102	87.7	45	86.5	57	87.7	1,000
6	15	12.8	7	13.5	8	12.3	

Note: *The significance level was considered as p ≤ 0.05. Chi square test was used of all binary's variables. Fischer exact test was the choice for mothers' and father's educational level analyses.

was noticed in the FIS section [14]. No difference (p = 0.19) of the initial B-ECOHIS scores between the groups was observed. After 15 days of treatment, the number of responses were 32/34 and 30/32 in SDF and ART group, respectively. Thus, four patients were excluded from the analyses, because they did not have their 15-day questionnaire filled in by their caregivers. The B-ECOHIS total, CIS and FIS scores and their subscales before and after 15 days of treatment, well as the effect size for each group are demonstrated in Table 5.

4. Discussion

This 12-month analysis of a 12-month randomized clinical trial is very relevant because it brings information about the short and long-term efficacy of 30% SDF in arresting caries lesions in primary teeth of preschoolers. It is known that SDF treatment can be useful in specific situations for short periods of time as in cases of patients awaiting specialist care in the hospital or even in outpatient service; and may

Table 3
Baseline of the children's age, number of teeth and dmft mean, according to the groups.

Variables	All Participants					ART					SDF					*p-value*
	Mean	SD	Min	Median	Max	Mean	SD	Min	Median	Max	Mean	SD	Min	Median	Max	
Child Age (years)	3.58	1.03	2.00	4.00	5.00	3.61	1.09	2.00	4.00	5.00	3.56	0.99	2.00	4.00	5.00	0.814
N of teeth per child	2.28	1.11	1.00	2.00	4.00	2.12	1.18	1.00	2.00	4.00	2.42	1.04	1.00	2.00	4.00	0.096
dmft	6.72	3.73	1.00	7.00	16.00	7.00	3.74	1.00	7.00	16.00	6.44	3.74	1.00	7.00	16.00	0.545

Table 4
Number of adverse events related to the patients from SDF and ART groups, when the operator exam and caregiver report (2 days after treatment) were considered.

Adverse event	ART		SDF	
	Operator	Caregiver	Operator	Caregiver
Burning	–	–	1	1
Allergy	–	–	–	–
Nausea	–	1	–	–
Vomit	–	–	–	–
Bad taste	1	1	–	1
Pain or sensitivity in teeth	11*	2	1	2
Mouth injure	–	–	1	–
Spot or pigmentation of the skin or mouth	–	–	9Ω	3
Avoid smiling	–	–	–	–
Annoyed with teeth appearance	–	–	–	1
TOTAL	12	4	12	8

Note.
* The sensitivity was reported by patients during excavation (selective caries removal); Ω 1 black staining and 8 white staining (suggesting a superficial asymptomatic chemical burn).

also prevent morbidity associated with untreated ECC and reduces more complex treatment needs [23]. At the same time, SDF may be the only treatment option for certain populations where resources are scarce. Thus, the knowledge of SDF efficacy at various time intervals is very important and has a great deal of clinical applicability. The treatments were conducted by a specialist; however, it is important to emphasize that SDF is simpler than ART to be applied, so that there would be no difficulty for the general dentist to use SDF, since less technique or practice is needed.

Most of trials with SDF focus only in longer periods of follow-up, but nowadays it has been changing and shorter periods of follow up results are available [23,24]. Although the number of children of our sample is shorter than planned, we analyzed 117 teeth, as initially calculated considering the tooth as the unit of analyses. Thus, Bootstrap analysis was used to correct the internal correlation by the fact that we considered more than one tooth per child, different from planned for the analysis of the complete sample. This strategy was used in a previous study [23] to also observe the efficacy of SDF; where the authors reported the results of 33% of the original sample size calculated, in a short final analyze of 21-days follow-up. We are reporting our results with similar number of children and teeth per child as Milgrom et al. [23], but different from them, because 60% of our original calculated sample size (children) was analyzed. Besides that, we only treated a single lesion surface (occlusal) of primary molars, while they analyzed anterior and posterior teeth, mixing single and multiple surfaces in the analyses, which may have increased the risk of bias. We need to emphasize the complexity of doing such a study; the sample is small, not because we were not careful enough about the sample size; but because we were careful to select children in the low age group (who usually present a greater need for treatments with lower chair time) and specific teeth and type of lesions (only primary molars and occlusal lesions involving dentine), instead of comparing all the types of teeth and injuries.

The average caries arrest rate in short-term analysis in the present study was higher than previous one; only two studies performed short-term follow up and reported 72% [23] and 98% [24] of arrested caries in 21-days and 3-month follow-up respectively, using 38% SDF. Comparing with 6 and 12-months studies, we found higher rates of caries arrestment than previous one [12,25], which reported 84.7% [12] and 43.3% [25] in 6-months and 66.9% [12] in 12-months follow-up. The higher rates detected were in studies which isolated and dried the teeth before application of SDF [12,24], like performed in the present study. Clemens et al. [24] stated that good isolation and drying the tooth lesion were essential components of the protocol to maximize the ability of SDF to arrest the lesion. Moreover, the first reported trial [24] did not allocated children by randomization and the second one [12] used school as the unit of the randomization process. It placed our study in a better position of confidence.

Biannually interval application of SDF was adopted since it shows higher rates of arrestment [25,26]. Although this may seem a disadvantage for requiring the patient to return every six months, it seems better than the disadvantage of those ART cases subject to fractures, which require repair. In the present study, one restoration had to be repaired at 3-month, 5 at both 6 and 12-months.

The present study works more in an exploratory than statistical perspective, which could be view as a limitation. Comparison of treatments should involve, besides the investigation of clinical efficacy, other important factors, since the treatment must aim at the individual as a whole. In pediatric dentistry, this is particularly essential. An effective treatment must obviously have clinical efficacy, but also should assemble other features no less important than the first one. Thus, by associating the results of the main outcome, which were very similar about the success percentage, with the secondary outcomes and the operational and cost characteristics [27], we can really suggest that the SDF treatment is a superior clinical option to the ART in arresting caries lesions. In this sense, we can highlight some factors in favor of the SDF, such as the shorter chair time, the cost [27] and be less dependent on the operator's ability. In contrast, as an advantage, ART provides an occlusal area for mastication and avoidance of food trapping. Moreover, a tooth-colored restoration is probably more esthetic than a black

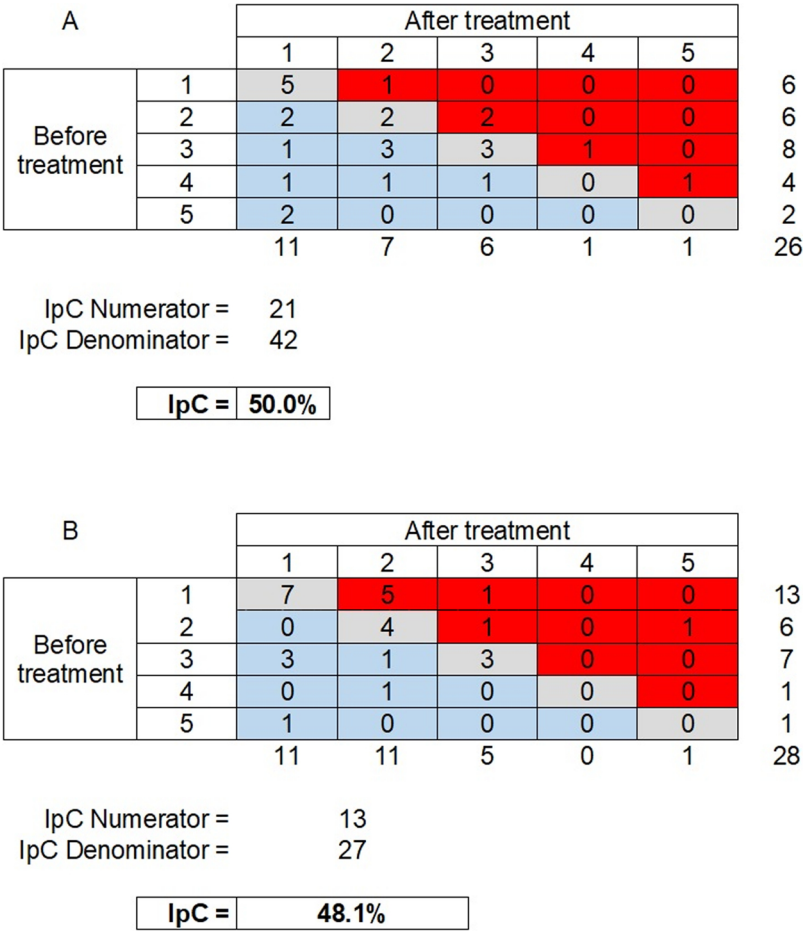

Fig. 2. Anxiety assessment of 26 children from ART group (A) and 28 from SDF group (B), before and immediately after the treatment, considering five categories: (1) very happy; (2) happy; (3) neutral; (4) unhappy; (5) very unhappy. IpC means positive change index; the denominator represents how many steps the total number of children could have improved; and the numerator represents the number of steps that really improved.

Table 5
Total mean values of B-ECOHIS, their sections and subscales, and the change in the scores at the baseline and 15 days after ART and SDF treatments.

B-ECOHIS (No. of items)	Baseline		Period of 15 days after treatment		Change in the scores (SD)*	p-value	Effect size
	Mean (SD)	Range	Mean (SD)	Range			
ART GROUP							
Total (13)	11.0 (8.7)	0-36	4.5 (7.5)	0-34	6.5 (6.7)	< 0.000	**0.75**
CIS (9)	6.1 (6.0)	0-26	2.6 (5.3)	0-25	3.5 (4.4)	< 0.000	0.58
Child Symptoms (1)	1.4 (1.4)	0-4	0.6 (1.3)	0-5	0.7 (1.5)	0.015	0.50
Child Function (4)	2.2 (2.4)	0-9	1.1 (2.4)	0-11	1.1 (2.1)	0.009	0.46
Child Psychological (2)	1.9 (2.5)	0-7	0.8 (1.7)	0-7	1.2 (2.1)	0.003	0.48
Child Self-image/social interaction (2)	0.6 (1.3)	0-6	0.1 (0.7)	0-4	0.4 (0.9)	0.020	0.31
FIS (4)	4.9 (3.6)	0-11	1.9 (2.7)	0-10	3.1 (3.2)	< 0.000	**0.86**
Parent distress (2)	3.9 (3.0)	0-8	1.4 (2.4)	0-8	2.5 (2.7)	< 0.000	**0.83**
Family function (2)	1.0 (1.2)	0-4	0.4 (0.7)	0-2	0.6 (1.1)	0.011	0.50
SDF GROUP							
Total (13)	9.1 (8.9)	0-34	3.9 (5.1)	0-20	5.2 (7.8)	< 0.000	0.58
CIS (9)	5.7 (6.5)	0-23	1.8 (2.8)	0-12	3.9 (5.7)	< 0.000	0.60
Child Symptoms (1)	1.2 (1.4)	0-4	0.4 (1.0)	0-4	0.8 (1.2)	0.002	0.57
Child Function (4)	2.0 (2.6)	0-9	0.8 (1.3)	0-4	1.2 (2.4)	0.008	0.46
Child Psychological (2)	1.6 (2.1)	0-6	0.4 (1.1)	0-4	1.1 (2.0)	0.004	0.52
Child Self-image/social interaction (2)	1.0 (1.9)	0-7	0.1 (0.5)	0-2	0.9 (1.9)	0.017	0.47
FIS (4)	3.3 (3.2)	0-11	2.1 (2.8)	0-10	2.3 (3.1)	0.027	**0.72**
Parent distress (2)	2.7 (2.7)	0-8	1.8 (2.5)	0-8	0.9 (2.4)	0.042	0.33
Family function (2)	0.6 (1.3)	0-6	0.3 (0.8)	0-4	0.3 (1.3)	0.136	0.23

Note: An effect of 0.2 indicated a small, but a clinical change; the effect size of 0.2 – 0.7 demonstrated a moderate change, and the effects with values of over 0.7, represented a large change, which are in bold format.

* The change of the scores was the 15-day treatment mean score subtracted from the baseline one.

cavity. The chair time is a very important factor to be considered when defining the treatment plan for children, especially preschool children. In addition, it is known that a shorter treatment time means reducing costs and increasing the number of children benefited, especially in the area of public health. We registered a significant shorter time for SDF group, and it is an important positive benefit, as it is known that long treatments can trigger negative behaviors in children. Our time chair was quite shorter than the one registered in another study using SDF

[28], but that study are not comparable with the present one, as the author used rubber dam which probably increased the time of treatment.

Dental anxiety in children has been recognized as a problem in patient management for many years. Furthermore, the effects of this anxiety have been shown to persist into adulthood, which can often lead to dental avoidance and the subsequent deterioration of oral health [19]. It is known that positive dental experiences offered to children who needs dental care can convert them into preventively minded asymptomatic adult dental attenders [29]. Our results showed that there was no difference in anxiety between the groups. Through the IpC index, it was possible to measure the proportion of possible category changes (in the "improvement" direction), which showed no differences between the groups. Although the authors expected that children of the SDF group would present a higher IpC index than of those from the ART one, this result can be considered a positive feature, since ART is already a consolidate technique seen as a child-friendly technique, thus SDF treatment represents a good option in preschool children too.

We observed that some adverse events occurred after the treatments; both reported by the parents/caregivers or by the operator, without difference between the groups. However, we observed that the operator recorded a greater number of adverse events than the parents did. Actually, the difference was in the report of whitish spot on the gingiva after SDF treatment, a fact that seems to have gone unnoticed by the respondent. Specifically, to SDF adverse events, most of studies report no other than discoloration or damage to the gingival tissues [30], black staining on the arrested lesions [25,31,32] and metallic/bitter taste [16]. For the best of our knowledge, only one study [23], besides the present one, investigated the occurrence of adverse events through an interview with caregivers after treatment. The present authors could observe that the percentage of adverse events reported by caregivers were similar compared to those reported by Milgrom et al. [23]. However, they [23] did not considered discoloration as an adverse event. While the cited authors reported that the majority of the adverse events was either diarrhea or stomachache, in the present study staining or mildly painful white lesion in tongue or marginal gum were the adverse events more prevalent; which usually solved within 2 days after treatment. The authors believe that even using petroleum jelly to coat the entire gingiva and micro-sponge with the lowest caliber, the non-cooperative behavior of the children during treatment appointments may have influenced the accidental touch of SDF in other tissues.

In pediatric dentistry it is important that parents are engaged in treatment, thus, it is important that they are confident and satisfied about that. Similarly, to other studies which investigated the parent's appearance satisfaction [25,30], our findings appointed to the same direction, since no respondents reported that their child had avoided smiling after treatment and only one caregiver was bothered by the appearance. The authors believe that the undesirable effects of SDF due to dark discoloration of dentine lesions are outweighed by its desirable properties in most cases as already has been stated by Crystal et al. [33].

It is well known the impact of oral problems and consequent treatments on the quality of life of preschoolers and their families. Therefore, the OHRQoL can be used to assess the outcome of dental treatment [22]. Improvements in children's oral health after treatment are reflected in the differences between the mean pre- and post-treatment total B-ECOHIS scores. We registered a decline in all sections and subscales in both groups, which showed the positive impact of both treatments. Only family function in SDF group did not show statistical difference before and after its application. We believe that it happened because there were more reports in the question about "a family member miss works due to problems with child's teeth or dental treatments" and one family reported financial impact due to child's dental treatments. Besides that, comparing the ES between groups, SDF showed higher values in CIS section and subscales, indicating a better improvement in the OHRQoL; including the subscale child self-image/social interaction which contemplates questions that could show a possible negative effect of tooth darkening. On the other hand, considering the FIS results, we observed a better improvement in ART group related with parents' distress subscale. The authors suggest that although parents in SDF group were not annoyed about the appearance, maybe still feel guilty by the fact the treatment did not restore the teeth anatomy.

5. Conclusions

It was observed a similar rate of dentine caries arrestment in both SDF and ART groups. No differences regarding anxiety, adverse events and OHRQoL between SDF and ART were verified. Considering that SDF is cheaper, less dependent about the operator skill and consume almost half of time-treatment when compared to ART, we can suggest that SDF should be chosen as the treatment option, at least in situations where the access to treat is quite difficult.

Clinical relevance

It is of fundamental importance to make available scientific evidence about SDF because its low cost, less dependence on specific dental equipment and operator training, in addition to ease of application, puts this product in a position advantage over the ART, which has been used extensively in public health.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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