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Early childhood caries management using fluoride varnish and neutral fluoride gel: a randomized clinical trial

Geovanna Peres de SOUSA[a]
Cacilda Castelo Branco LIMA[a]
Mariana Minatel BRAGA[b]
Lúcia de Fátima Almeida de Deus MOURA[a]
Marina de Deus Moura de LIMA[a]
Marcoeli Silva de MOURA[a]

[a]Universidade Federal do Piauí – UFPI, Department of Pathology and Dental Clinics, Teresina, PI, Brazil.

[b]Universidade de São Paulo – USP, School of Dentistry, Department of Pediatric Dentistry, São Paulo, SP, Brazil.

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Corresponding Author:
Marcoeli Silva de Moura
E-mail: marcoeli-moura@uol.com.br

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Abstract: The aim of this study was to evaluate the clinical efficacy of varnish and neutral fluoride gel in the management of early childhood caries (ECC). A randomized clinical trial was conducted to compare two strategies for ECC management: topical application of neutral fluoride gel (NFG group) and varnish (FV group) every four months for a period of one year. The sample consisted of children between the ages of three and four years, enrolled in public daycare centers. The incidence of ECC between the groups was compared by assessing values (new dmfs) at two levels: d^2 when enamel/dentin were affected and d^3 when dentin affected. Pearson's Chi-square, Fisher's Exact, Kolmogorov-Smirnov and Mann-Whitney tests were used to compare the incidence and increment of caries between the NFG and FV groups ($p<0.05$). A total of 240 children were included in this study and 213 children (88.7%) were followed up for 12 months. The incidence of ECC was 24.1% in the GF and 21.0% in the FV groups ($p=0.586$). The increment of caries in d^2mfs was 1.36 (95% CI = 0.83 – 1.89) in the NFG and 1.33 (95% CI = 0.75 – 1.89) in FV ($p=0.756$) groups. Increment of caries in d^3mfs was 1.60 (95% CI = 0.95 – 2.25) in NFG and 1.40 (95% CI = 0.75 – 2.04) in FV ($p=0.468$). Neutral fluoride gel and fluoride varnish exhibited similar efficacy in the management of ECC after 12 months of follow-up.

Keywords: Fluorides; Tooth, Deciduous; Health Education.

Introduction

Early childhood caries (ECC) is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled surfaces in any primary tooth of a child under the age of six.[1,2] The prevalence of ECC ranges from 0% to 98%[3] and has increased in some countries, representing a public health problem.[1,3] The etiology of the disease is associated with frequent consumption of sugary drinks or foods, prolonged breastfeeding, and poor oral hygiene, and it often manifests in children living in socially vulnerable conditions.[3,4] Children with ECC are at greater risk of pain or discomfort, abscesses, delayed growth/development, and impaired oral health-related quality of life.[1,3,5] In addition, ECC is an important predictor for the development of dental caries in permanent dentition.[6] Management involves professional application of fluorides, restorations, pulp therapy and/or extraction.[2,5]

Alternatives for professional use of fluorides include fluoride varnishes and acidulated and neutral gels.[1,7,8] Fluoride varnish is the product most frequently used in children because of its safety, easy application, and high acceptability,[9,10] but the material is relatively expensive, even considering different realities.[11] Acidulated fluoride gel is a low-cost material that has been used in supervised toothbrushing in school programs.[8] A neutral gel was developed to prevent superficial degradation of esthetic restorations,[12] and an in vitro study has shown that it was effective in controlling caries compared to acidulated gel.[13]

Fluoride varnish is the most frequently used product in clinical trials in children.[7,9,10,14] and has been shown to be similar or even superior to acidulate gel in the *in vitro* formation of calcium fluoride on the enamel surface.[15] To the best of our knowledge, no randomized clinical trial has yet compared varnish and neutral fluoride gel. Thus, the aim of this trial was to compare the clinical efficacy of varnish and neutral fluoride gel in the management of dental caries in early childhood.

Methodology

Study design and sampling procedure

This randomized, prospective, blinded clinical trial lasted 12 months, from October 2018 to October 2019. Children and their legal guardians signed a written informed consent form (Ethics Committee Approval 2527894 and Brazilian Clinical Trials Registry RBR-59dvws).

The program OpenEpi version 3.01 was used to calculate the sample size. The parameters used were: incidence of dental caries in children of preschool age who used a fluoride product (35.5%) or placebo (57.1%),[9] exposed-to-unexposed ratio of 1, 80% power and 95% significance level. This resulted in a sample of 92 children per group. The sample was increased by 30% to compensate for possible losses during the study, resulting in a final sample of 240 children, divided into two groups (120 per group). The children were randomly allocated to the two groups according to the intervention: neutral fluoride gel (Group NFG), or fluoride varnish (Group FV).

Low-income children attending public daycare centers in a municipality with fluoridated water supply, participated in this research. The inclusion criteria for participation were children aged three and four years old who lived in the same city for at least one year, had a permanent address and telhphone number, and regularly enrolled in daycare centers. Children who had received a topical application of professional fluoride in the six months prior to the RCT or had teeth with pulpal involvement (fistula, abscess, or exposed pulp chamber) or systemic diseases, were not included.

Training and calibration

A specialist in pediatric dentistry conducted the examinations. To calculate the intra-examiner agreement, 20 children with caries lesions of different degrees of severity were examined on two occasions, 15 days apart. Dental caries was measured using the dmfs index,[16] and the International Caries Assessment and Detection System (ICDAS)[17] was used to determine the severity of other lesions. The "dmfs" index indicates the number of "decayed", "missing" due to caries, and "filled" dental surfaces in primary teeth. At the end of this period, the agreement on dmfs (kappa 0.91) and ICDAS (kappa 0.87) was calculated.

Study groups, randomization, and blinding

The children received four applications of the allocated treatment: one at the beginning of the study (October 2018), and one every four months afterwards (February, June and October 2019), to align with the school calendar. Four public daycare centers in the same neighborhood attended by low-income children were selected. Simple random sampling was used, and randomization was performed using the Random Allocation Software 1.0 program (Isfahan, Iran) according to the fluoride product to be used. Each child was given a five-digit identification code generated by the program and allocated to one of the two groups: NFG and FV.

The identification codes were kept in a sealed envelope until the end of the follow-up period to ensure concealment of randomization. The children were assessed at follow-up by an examiner who did not know to which group each child belonged.

Clinical exams and interventions

Parents/guardians answered a questionnaire about socioeconomic-demographic data (sex and age of the child, family income, parent's education) and behavioral habits (number of daily toothbrushings with fluoridated toothpaste, who brushes the child's teeth, frequency of ingestion of sweets [candy, lollipop, cookie and sweet cake], reason and time of the last visit to the dentist). At the beginning of the study, parents/guardians were trained to brush the child's teeth at the daycare center. They were also instructed on the importance of reducing the consumption of sugary foods. Every four months, all children received a new brush and fluoride toothpaste (1.450 ppm F – MFP). Parents also received a letter reinforcing the oral hygiene guidelines. One week after varnish application, the parents / guardians were asked about possible adverse effects on the child and complaints regarding the color of the teeth.

Children were examined at the daycare center to collect data on the prevalence and severity of ECC. First, the presence of dental biofilm was assessed using the Visible Plaque Index (VPI) and then oral hygiene was performed with a toothbrush and fluoride toothpaste. Gingival bleeding (GB) was expressed as the number of surfaces with bleeding after brushing.[16] Dental caries was measured using the dmfs index and the ICDAS. The examination was performed in a room with artificial ceiling lighting aided by a dental operatory light (Pelican® model – Startec with 127V, São Paulo, Brazil), with the child sitting on a chair. The child's head was supported on the examiner's legs, and the examination was performed using a flat mouth mirror (Golgran®, São Paulo, Brazil) and a spherical tip probe recommended by WHO (Golgran®, São Paulo, Brazil).

Children in the NFG group were treated with neutral fluoride gel (2% sodium fluoride – DFL, Rio de Janeiro, Brazil). A pea-sized amount of gel was placed on the toothbrush, and the researcher brushed the child's teeth for one minute.[17] The excess was removed with gauze. In the FV group, children were treated with fluoride varnish (sodium fluoride 5% Duraphat, Colgate®, Eschwege, Germany). A pea-sized drop of varnish was dispensed into a disposable cup. The teeth were isolated with cotton and dried with gauze pads, and the varnish was applied using a disposable microbrush (KG Sorensen, São Paulo, Brazil). Parents/guardians were instructed not to brush their children's teeth on the day of application.

After 12 months, the children were examined again at the daycare center by the same examiner who performed this procedure the beginning of the study and did not know to which group the child belonged. The examination was performed using the same methodology as at baseline.

Outcomes

The primary outcome was the incidence of caries measured by the proportion of children who developed new lesions during the study. Dental caries was recorded by d^2mfs or d^3mfs. Enamel or dentin caries lesions (dental surfaces that received ICDAS codes 3, 4, 5, or 6) were computed in d^2 and dentin caries lesions were computed in d^3 (surfaces with ICDAS codes 4, 5 or 6).[9] The number of decayed, missing due to caries, and filled dental surfaces at the beginning of the study (initial d^3mfs) was subtracted from the number of decayed, missing due to caries and filled dental surfaces after 12 months (final d^3mfs). A child was considered to have an incident case of dental caries if final d^2mfs/d^3mfs – initial $d^2mfs/d^3mfs > 0$. A secondary outcome was the 12-month caries increase, as measured by the change from baseline in the dmfs index at d^2 and d^3 caries detection thresholds[9]. Other secondary outcomes were changes in the VPI and GB indexes, after providing parents/guardians with guidance on oral health and toothbrushing.

Statistical analysis

The data were analyzed using SPSS® software version 20.0 (Statistical Package for the Social Science for Windows, Armonk, USA: IBM Corp., 2011). The analysis was performed by protocol, considering the children who remained in the study for 12 months. Descriptive analyses of sociodemographic data, health-related habits, and clinical indexes were performed. Pearson's Chi-square and Fisher's Exact tests were used to compare groups regarding

sociodemographic characteristics and behavioral habits. These tests were also used to compare children with and without caries at baseline and 12 months thereafter, the incidence of caries, and children who dropped out and those who remained in the study, between the NFG and FV groups. The Kolmogorov-Smirnov normality test was used to analyze the distribution and increment in the d^2mfs, d^3mfs, and VPI and GB indexes, and showed that there was a non-normal distribution of the data ($p < 0.05$). The Mann-Whitney test was performed to assess differences between groups at baseline and 12 months and the increment in caries between NFG and FV groups. The level of significance in all tests was set at 5% ($p < 0.05$).

Results

In total, 240 children were included in this study. The study flowchart is presented in Figure. After 12 months, 213 children (88.7%) were followed up (Figure). Table 1 describes the characteristics of the participants. There were no differences between groups regarding sociodemographic characteristics or behavioral habits at baseline ($p > 0.05$) (Table 1).

Table 2 shows the baseline comparison of outcomes in NFG and FV groups. The frequency of children with carious lesions was 38.9% in NFG and 30.5% in FV ($p = 0.197$). Children in the NFG group had a higher mean (2.01 ± 2.29) of gingival bleeding than those in Group FV (1.26 ± 1.68) ($p = 0.029$) (Table 2).

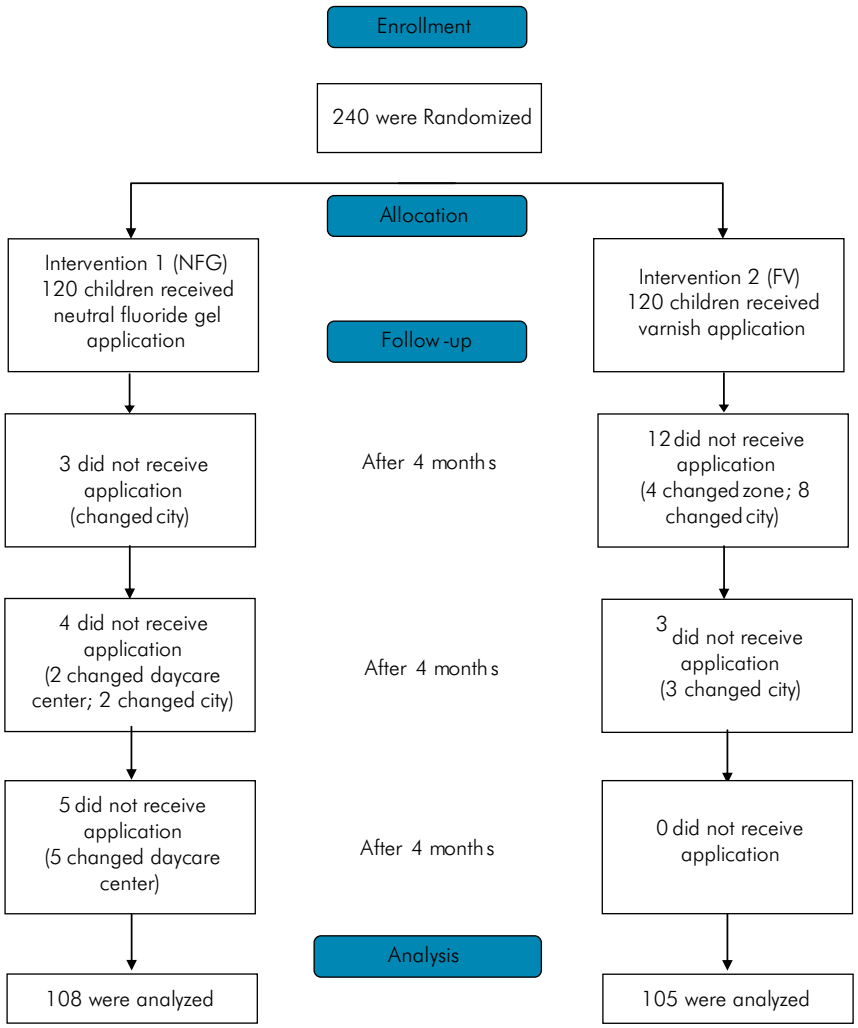

Figure. Study flowchart.

Table 1. Socioeconomic/demographic characteristics and oral health habits of the participants in the NFG and FV groups.

Variables	Total	NFG	FV	p**
	n (%)	n (%)	n (%)	
Sex				
Male	108 (50.7)	55 (50.9)	53 (49.1)	1.000
Female	105 (49.3)	53 (50.5)	52 (49.5)	
Age (years)				
3	23 (10.8)	10 (43.5)	13 (56.5)	0.513
4	190 (89.2)	98 (51.6)	92 (48.4)	
Family Income (minimum wages)				
< 1	92 (43.2)	44 (47.8)	48 (52.2)	0.491
≥ 1	121 (56.8)	64 (52.9)	57 (47.1)	
Maternal schooling (years of formal study) *				
≤ 8	70 (33.0)	38 (54.3)	32 (45.7)	0.560
> 8	142 (67.0)	70 (49.3)	72 (50.7)	
Number of daily toothbrushing				
1	28 (13.1)	15 (53.6)	13 (46.4)	
2	98 (46.0)	57 (58.2)	41 (41.8)	0.070
≥ 3	87 (40.8)	36 (41.4)	51 (58.6)	
Who performs the child's toothbrushing				
Parent	119 (55.9)	61 (51.3)	58 (48.7)	
Child	36 (16.9)	17 (47.2)	19 (52.8)	0.929
Child and Parent	58 (27.2)	30 (51.7)	28 (48.3)	
Frequency of sweets ingestion				
Daily	46 (21.6)	23 (50.0)	23 (50.0)	
3 to 5 times a week	48 (22.5)	26 (54.2)	22 (45.8)	0.960
1 to 2 times a week	60 (28.2)	30 (50.0)	30 (50.0)	
Rarely / Does not ingest	59 (27.7)	29 (49.2)	30 (50.8)	
Last visit to the dentist (months)				
Never	111 (52.1)	59 (53.2)	52 (46.8)	
< 6	28 (13.1)	12 (42.9)	16 (57.1)	0.805
6 – 12	45 (21.1)	22 (48.9)	23 (51.1)	
> 12	29 (13.6)	15 (51.7)	14 (48.3)	
Reason for the last visit to the dentist				
Never visited	111 (52.1)	59 (53.2)	52 (46.8)	
Prevention	77 (36.2)	34 (44.2)	43 (55.8)	0.135
Restoration	12 (5.6)	5 (41.7)	7 (58.3)	
Extraction / Other	13 (6.1)	10 (76.9)	3 (23.1)	
Reason for not visiting the dentist				
Child has visited the dentist	102 (47.9)	49 (48.0)	53 (52.0)	
No need	49 (23.0)	26 (53.1)	23 (46.9)	
Difficulty on making an appointment	20 (9.4)	9 (45.0)	11 (55.0)	0.649
Lack of time	17 (8.0)	8 (47.1)	9 (52.9)	
Other	25 (11.7)	16 (64.0)	9 (36.0)	
Total	213 (100.0)	108 (50.7)	105 (49.3)	

Minimum wage = $171.24 *Variable with missing information. **Pearson's Chi-square test.

Table 2. Baseline comparison of NFG and FV groups.

	Total n = 213	NFG n = 108	FV n = 105	p
Primary Outcome				
Children without carious lesion, n (%)	139 (65.3)	66 (61.1)	73 (69.5)	0.197*
Children with carious lesion, n (%)	74 (34.7)	42 (38.9)	32 (30.5)	
Secondary Outcome				
Mean $d^2mfs \pm SD$ (median; max-min)	2.21 ± 4.46 (0.0; 0-24)	2.63 ± 4.87 (0.0; 0-24)	1.77 ± 3.98 (0.0; 0-24)	0.108**
Mean $d^3mfs \pm SD$ (median; max-min)	1.76 ± 3.92 (0.0; 0-24)	2.11 ± 4.22 (0.0; 0-23)	1.40 ± 3.57 (0.0; 0-24)	0.093**
Mean VPI ± SD (median; max-min)	4.92 ± 4.12 (4.0; 0-20)	5.26 ± 4.50 (4.0; 0-20)	4.56 ± 3.65 (4.0; 0-20)	0.447**
Mean GB ± SD (median; max-min)	1.64 ± 2.05 (1.0; 0-10)	2.01 ± 2.29 (1.0; 0-10)	1.26 ± 1.68 (0.0; 0-7)	0.029**

d^2mfs = number of decayed surfaces (enamel + dentin), missing due to caries and filled; d^3mfs = number of decayed surfaces (dentin), missing due to caries and filled; SD = standard deviation; VPI = visible plaque index; GB = gingival bleeding; max = maximum; min = minimum; *Pearson's Chi-square test; **Mann-Whitney test.

Comparison of NFG and FV groups at the 12-month follow-up is presented in Table 3. The frequency of children with caries was 39.8% in NFG and 35.2% in FV (p = 0.490). After 12 months, there was no difference between groups in any parameter of oral health (p > 0.05) (Table 3).

The incidence and caries increment, VPI, and GB in NFG and FV groups at the 12-month follow-up are shown in Table 4. Caries incidence was 24.1% in NFG and 21.0% in FV (p = 0.586). The increment in caries in d^2mfs was 1.36 (95% CI: 0.83–1.89) in NFG and 1.33 (95%CI: 0.75–1.89) in FV (p = 0.756). The increment in caries in d^3mfs was 1.60 (95%CI: 0.95–2.25) in NFG and 1.40 (95%CI: 0.75–2.04) in FV (p = 0.468). There was a difference in the increment of gingival bleeding between the groups (p = 0.017) (Table 4).

There were no differences between children who abandoned the study and those who remained (12 in the NFG and 15 in the FV) (p > 0.05). No complaints or adverse effects were reported.

Discussion

This was the first study to evaluate the professional use of neutral fluoride gel for the management of ECC. In this 12-month randomized clinical trial, the efficacy of neutral fluoride gel was shown to be similar to that of the varnish. Studies have reported that the use of varnish applied two to four times a year can reduce the incidence of ECC,[14,18] and this reduction could could be as high as 25% when compared with a placebo.[18] However, some clinical trials have shown no benefits in using fluoride varnish to reduce the incidence of caries in preschool children regardless of whether they were exposed[9,10,19] to fluoridated water and/or fluoridated toothpaste, or not.[20]

Table 3. Comparison of NFG and FV groups at the 12-month follow-up.

	Total n = 213	NFG n = 108	FV n = 105	p
Primary Outcome				
Children without carious lesion, n (%)	133 (62.4)	65 (60.2)	68 (64.8)	0.490*
Children with carious lesion, n (%)	80 (37.6)	43 (39.8)	37 (35.2)	
Secondary Outcome				
Mean $d^2mfs \pm SD$ (median; max-min)	3.55 ± 6.63 (0.0; 0-36)	3.99 ± 7.07 (0.0; 0-36)	3.10 ± 6.16 (0.0; 0-30)	0.264**
Mean $d^3mfs \pm SD$ (median; max-min)	3.26 ±6.43 (0.0; 0-36)	3.71 ± 6.84 (0.0; 0-36)	2.80 ± 5.97 (0.0; 0-28)	0.202**
Mean VPI ± SD (median; max-min)	1.31 ± 2.89 (0.0; 0-20)	1.30 ± 2.94 (0.0; 0-20)	1.32 ± 2.86 (0.0; 0-15)	0.987**
Mean GB ± SD (median; max-min)	0.77 ± 1.70 (0.0; 0-10)	0.76 ± 1.68 (0.0; 0-8)	0.79 ± 1.73 (0.0; 0-10)	0.984**

d^2mfs = number of decayed surfaces (enamel + dentin), missing due to caries and filled; d^3mfs = number of decayed surfaces (dentin), missing due to caries and filled; SD = standard deviation; VPI = visible plaque index; GB = gingival bleeding; max = maximum; min = minimum; *Pearson's Chi-square test; **Mann-Whitney test.

Table 4. Comparison of caries increment of NFG and FV groups at the 12-month follow-up.

	Increment after 12 months		p
	NFG n=108	FV n= 105	
Primary Outcome			
Children who developed new lesions, n^1 (%)	26 (24.1)	22 (21.0)	0.586*
Children without caries who developed lesions, n^2 (%)	03 (4.5)	06 (8.2)	0.498**
Children with caries who developed new lesions, n^3 (%)	23 (54.8)	16 (50.0)	0.684*
Secondary Outcome			
d^2mfs (95% CI)	1.36 (0.83 – 1.89)	1.33 (0.75 – 1.89)	0.756***
d^3mfs (95% CI)	1.60 (0.95 – 2.25)	1.40 (0.75 – 2.04)	0.468***
VPI (95% CI)	-3.96 (-4.91 – -3.02)	-3.24 (-4.09 – -2.38)	0.558***
GB (95% CI)	-1.25 (-1.77 – -0.73)	-0.47 (-0.85 – -0.08)	0.017***

d^2mfs = number of decayed surfaces (enamel + dentin), missing due to caries and filled; d^3mfs = number of decayed surfaces (dentin), missing due to caries and filled; CI = confidence interval; VPI = visible plaque index; GB = gingival bleeding; max = maximum; min = minimum; n^1 = 108 children for the gel and 105 children for the varnish; n^2 = 139 children without caries at baseline; n^3 = 74 children with caries at baseline; *Pearson's Chi-square test; **Fisher's exact test;; ***Mann-Whitney test.

The World Health Organization (WHO) recommends two to four fluoride applications a year in children at high risk for caries,[1] but this frequency may not be effective in controlling ECC.[21] The contradictory results in the literature[9,10,14,18,20] can be explained by the methodological differences between studies, such as the heterogeneity of patients in presence or absence of caries at baseline and the interval between varnish applications. In the present study, the incidence of caries was higher in children with ECC at baseline than in children without caries, corroborating the findings of another study[9] and consistent with previous experience that caries is an important predictor of the occurrence of new lesions[6]. This observation was indipendent of the fluoride product used.

Clinical trials have shown that the acidulated fluoride gel reduces caries incidence in primary dentition compared with a placebo;[8] however, to date, there has been no clinical study that compared acidic or neutral gels with varnishes. In the Brazilian public health system, fluoride gel is available in different centers and is routinely used in schoolchildren.[22] The cost of fluoride gel is 60 times lower than that of varnish and both showed the same efficacy in this study, which suggests that the use of neutral fluoride gel in children may be a favorable alternative to be implemented in health system. Furthermore, professional application of the gel with a brush for one minute is sufficient to promote a reaction with enamel and the formation of calcium fluoride deposits.[17] However, further cost-effectiveness analyses are needed to provide definitive answers for implementation and adoption in health systems or inclusion in health policies.

Professionally applied fluoride products contain a high concentration of fluoride to compensate for patient non-use and enrich the dental surface with calcium fluoride deposits.[23] These periodic applications can assist in ECC management[1], favoring dental remineralization after cariogenic challenges[23] and delaying the progression of existing lesions[1]. The etiology of ECC is related to the accumulation of biofilm on dental surfaces frequently exposed to dietary sugars.[3] The onset and progression of the disease are modulated by biological, behavioral, and social aspects.[2]

In this study, most children consumed sugar very frequency on a daily basis and neglected oral hygiene, as shown increased rates of biofilm and gingival bleeding. All children in this study were from low-income families and lived in socially vulnerable conditions and therefore they were at high risk of developing dental caries. In addition, sugar consumption in the Brazilian population exceeds international recommendations.[24] High sugar consumption produces excessive amounts of acids, which could overide the capacity of fluoride to replenish minerals to the teeth.[2] Thus, the professional application of fluorides as a collective procedure is important for prevention, acting while behavioral changes are not assimilated.

The observed reduction in plaque and gingival bleeding rates is associated with caries control, since dental biofilm accumulation is necessary for occurrence of the disease.[19,23] One explanation for this reduction in mean values would be the Hawthorne effect, in which behavior of individulas changes when they know they are being evaluated by an observer,[25] as occurred in this study. Although there is evidence that parent education does not seem to have an effect on oral health or caries,[19] the adoption of healthy habits in childhood begins at the family level.[3] Therefore, we could not discard the possibility that oral health education for parents and fluoride topical application four times a year were an important factor in reducing caries progression in this study. Because oral health education was standardized for both groups, it probably did not interfere with differences (or absence of difference) between groups.

A large number of children in this study had never visited a dentist or had only sought dental care when they were in pain, which suggests that parents did not consider dental care a priority.[26] However, it may also have been because parents had difficulty accessing public oral health services.[1] On average, the children with caries had more than one carious/restored surface. If the caries were not treated at this point, we could expect a negative impact of ECC on the quality of life of preschool children.[5]

Uncertainty about whether the parents followed the instructions for brushing the teeh of children only the day after the varnish was applied can be considered one of the limitations of the study. Since the reaction of the varnish with the enamel depends on the duration of exposure to the fluoride and dissolution of the insoluble fluoride in the intraoral environment, removal of the varnish should be avoided to improve the anti-caries effect.[27] Further clinical studies comparing neutral fluoride gel with placebo in preschool children are needed to assess the efficacy of this product, as the scarcity of studies makes it difficult to make comparisons, considering that the gel may be part of public policy planning for ECC prevention and control in this age group. The results of this RCT can be applied to a population of children under six years of age and low-income, but they cannot be extrapolated to the reference population in the same age group. Because no difference was found between the fluoride products tested in this study, patient and dentist could choose which product to use or receive. The public service would benefit by having a more accessible product available.

Despite the short follow-up period, there was a significant increase in caries, probably because the study population was in the low-income bracket at high risk of disease. This clinical trial was interrupted due to the new coronavirus pandemic that started on March 11, 2020. The incidence and increase of new carious lesions might have been higher if the proposed three-year follow-up had been completed. However, since we included ICDAS score 3 in our outcomes, we believe that the comparability between groups would have been maintained.

Conclusion

At one-year follow-up, the efficacy of neutral fluoride gel was similar to that of fluoride varnish in early childhood caries management.

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References

1. World Health Organization. Ending childhood dental caries: WHO implementation manual. Geneva: World Health Organization; 2020.
2. Early childhood caries: IAPD Bangkok Declaration. Int J Paediatr Dent. 2019 May;29(3):384-6. https://doi.org/10.1111/ipd.12490
3. Phantumvanit P, Makino Y, Ogawa H, Rugg-Gunn A, Moynihan P, Petersen PE, et al. WHO Global Consultation on Public Health Intervention against Early Childhood Caries. Community Dent Oral Epidemiol. 2018 Jun;46(3):280-7. https://doi.org/10.1111/cdoe.12362

4. Folayan MO, El Tantawi M, Aly NM, Al-Batayneh O, Schroth RJ, Castilo JL, et al. Association between early childhood caries and poverty in low and middle income countries. BMC Oral Health. 2020; 6;20(1):8. https://doi.org/10.1186/s12903-019-0997-9
5. Tinanoff N, Baez RJ, Diaz Guillory C, Donly KJ, Feldens CA, McGrath C, et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: global perspective. Int J Paediatr Dent. 2019 May;29(3):238-48. https://doi.org/10.1111/ipd.12484
6. Mejàre I, Axelsson S, Dahlén G, Espelid I, Norlund A, Tranæus S, et al. Caries risk assessment: a systematic review. Acta Odontol Scand. 2014 Feb;72(2):81-91. https://doi.org/10.3109/00016357.2013.822548
7. Marinho VC, Worthington HV, Walsh T, Clarkson JE. Fluoride varnishes for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2013
8. Marinho VC, Worthington HV, Walsh T, Chong LY. Fluoride gels for preventing dental caries in children and adolescents. Cochrane Database Syst Rev. 2015 Jun;15(6):CD002280.
9. Oliveira BH, Salazar M, Carvalho DM, Falcão A, Campos K, Nadanovsky P. Biannual fluoride varnish applications and caries incidence in preschoolers: a 24-month follow-up randomized placebo-controlled clinical trial. Caries Res. 2014;48(3):228-36. https://doi.org/10.1159/000356863
10. Muñoz-Millán P, Zaror C, Espinoza-Espinoza G, Vergara-Gonzalez C, Muñoz S, Atala-Acevedo C, et al. Effectiveness of fluoride varnish in preventing early childhood caries in rural areas without access to fluoridated drinking water: a randomized control trial. Community Dent Oral Epidemiol. 2018 Feb;46(1):63-9. https://doi.org/10.1111/cdoe.12330
11. Schwendicke F, Splieth CH, Thomson WM, Reda S, Stolpe M, Foster Page L. Cost-effectiveness of caries-preventive fluoride varnish applications in clinic settings among patients of low, moderate and high risk. Community Dent Oral Epidemiol. 2018 Feb;46(1):8-16. https://doi.org/10.1111/cdoe.12320
12. Ccahuana VZ, Ozcan M, Mesquita AM, Nishioka RS, Kimpara ET, Bottino MA. Surface degradation of glass ceramics after exposure to acidulated phosphate fluoride. J Appl Oral Sci. 2010 Mar-Apr;18(2):155-65. https://doi.org/10.1590/S1678-77572010000200010
13. Delbem AC, Brighenti FL, Vieira AE, Cury JA. In vitro comparison of the cariostatic effect between topical application of fluoride gels and fluoride toothpaste. J Appl Oral Sci. 2004 Jun;12(2):121-6. https://doi.org/10.1590/S1678-77572004000200008
14. Turska-Szybka A, Gozdowski D, Twetman S, Olczak-Kowalczyk D. Clinical effect of two fluoride varnishes in caries-active preschool children: a randomized controlled trial. Caries Res. 2021;55(2):137-43. https://doi.org/10.1159/000514168
15. Santos LM, Reis JI, Medeiros MP, Ramos SM, Araújo JM. In vitro evaluation of fluoride products in the development of carious lesions in deciduous teeth. Braz Oral Res. 2009 Jul-Sep;23(3):296-301. https://doi.org/10.1590/S1806-83242009000300012
16. Mariath AA, Haas AN, Fischer CM, de Araujo FB, Rösing CK. Professional toothbrushing as a method for diagnosing gingivitis in 3- to 6-year-old preschool children. Oral Health Prev Dent. 2009;7(4):315-21.
17. Villena RS, Tenuta LM, Cury JA. Effect of APF gel application time on enamel demineralization and fluoride uptake in situ. Braz Dent J. 2009;20(1):37-41. https://doi.org/10.1590/S0103-64402009000100006
18. Divaris K, Preisser JS, Slade GD. Surface-specific efficacy of fluoride varnish in caries prevention in the primary dentition: results of a community randomized clinical trial. Caries Res. 2013;47(1):78-87. https://doi.org/10.1159/000344015
19. Jiang EM, Lo EC, Chu CH, Wong MC. Prevention of early childhood caries (ECC) through parental toothbrushing training and fluoride varnish application: a 24-month randomized controlled trial. J Dent. 2014 Dec;42(12):1543-50. https://doi.org/10.1016/j.jdent.2014.10.002
20. Yu L, Yu X, Li Y, Yang F, Hong J, Qin D, et al. The additional benefit of professional fluoride application for children as an adjunct to regular fluoride toothpaste: a systematic review and meta-analysis. Clin Oral Investig. 2021 Jun;25(6):3409-19. https://doi.org/10.1007/s00784-021-03909-5
21. Paek AE, Li Y, Wang Z, So P, Janal MN, Herman NG, et al. Caries outcome following an intensive fluoride varnish treatment regimen for children at high risk for early childhood caries. Int J Paediatr Dent. 2018 May;28(3):291-9. https://doi.org/10.1111/ipd.12353
22. Ministério da Saúde (BR). Secretaria de Atenção à Saúde. Departamento de Atenção Básica. A saúde bucal no Sistema Único de Saúde. Brasília, DF: Ministério da Saúde; 2018.
23. Tenuta LM, Cury JA. Fluoride: its role in dentistry. Braz Oral Res. 2010;24 Suppl 1:9-17. https://doi.org/10.1590/S1806-83242010000500003
24. Levy RB, Claro RM, Bandoni DH, Mondini L, Monteiro CA. Availability of added sugars in Brazil: distribution, food sources and time trends. Rev Bras Epidemiol. 2012 Mar;15(1):3-12. https://doi.org/10.1590/S1415-790X2012000100001
25. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. J Clin Epidemiol. 2014 Mar;67(3):267-77. https://doi.org/10.1016/j.jclinepi.2013.08.015
26. Curi DS, Figueiredo AC, Jamelli SR. Factors associated with the utilization of dental health services by the pediatric population: an integrative review. Cien Saúde Colet. 2018 May;23(5):1561-76. https://doi.org/10.1590/1413-81232018235.20422016
27. Fernández CE, Tenuta LM, Zárate P, Cury JA. Insoluble NaF in Duraphat® may prolong fluoride reactivity of varnish retained on dental surfaces. Braz Dent J. 2014;25(2):160-4. https://doi.org/10.1590/0103-6440201302405