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An open-label, parallel-group, randomized clinical trial of different silver diamine fluoride application intervals to arrest dental caries

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Abstract

Background Silver diamine fluoride (SDF) is an antimicrobial agent and alternative treatment option that can be used to arrest dental decay. While there is optimism with SDF with regard to caries management, there is no true consensus on the number and frequency of applications for children. The purpose of this study was to examine the effectiveness of 38% SDF to arrest early childhood caries (ECC) at three different application regimen intervals.

Methods Children with teeth that met International Caries Detection and Assessment System codes 5 or 6 criteria were recruited from community dental clinics into an open-label, parallel-group, randomized clinical trial from October 2019 to June 2021. Participants were randomized to one of three groups using sealed envelopes that were prepared with one of three regimens inside: visits one month, four months, or six months apart. Participants received applications of 38% SDF, along with 5% sodium fluoride varnish (NaFV), at the first two visits to treat cavitated carious lesions. Lesions were followed and arrest rates were calculated. Lesions were considered arrested if they were hard on probing and black in colour. Statistics included descriptive and bivariate analyses (Kruskal one-way analysis of variance and Pearson's Chi-squared test). A p-value of ≤ 0.05 was considered significant.

Results Eighty-four children participated in the study (49 males and 35 females, mean age: 44.4 ± 14.2 months). Treatment groups were well matched with 28 participants per group. A total of 374 teeth and 505 lesions were followed. Posterior lesions represented only 40.6% of affected surfaces. Almost all SDF treated lesions were arrested for the one-month (192/196, 98%) and four-month (159/166, 95.8%) interval groups at the final visit. The six-month group experienced the lowest arrest rates; only 72% (103/143) of lesions were arrested ($p < 0.001$). The duration of application intervals was inversely associated with improvements in arrest rates for all lesions.

Conclusions Two applications of 38% SDF and 5% NaFV in one-month and four-month intervals were comparable and very effective in arresting ECC. Applications six months apart were less effective and could be considered inferior treatment.

Trial registration ClinicalTrials.gov NCT04054635 (first registered 13/08/2019).

Keywords Randomized clinical trial, Silver diamine fluoride, Early childhood caries, Primary teeth, Antimicrobial, Arrest rates, Non-restorative treatment

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Introduction

Early childhood caries (ECC), defined as the presence of dental caries in the primary dentition of children under six years of age, is a significant issue. Recent prevalence estimates in Canada range from 28 to 98% [1–3]. The American Academy of Pediatric Dentistry (AAPD) recognizes the widespread and virulent nature of ECC, and supports the implementation of non-surgical interventions whenever possible [4]. Non-surgical interventions delay or decrease the need for dental surgery to treat severe cases of ECC. Conscious sedation or general anesthesia in operating rooms are frequently used to facilitate restorative treatment of young children with ECC. However, they come with increased costs for treatment and greater risks for the child. Restorative treatment is still the predominant method of managing ECC. It is important to note that restorative treatment alone does not address the underlying cause of ECC. Consequently, there is a high risk of recurrence and many children form new carious lesions [5, 6].

Unfortunately, many children experience limited access to dental care and go through life with untreated caries, which can pose a serious health risk [7]. The consequences of ECC are comprehensive. They include greater risk of carious lesion in the primary and permanent dentition, increased hospitalization and emergency visits, higher treatment costs, and reduced oral health-related quality of life [5, 8, 9]. Furthermore, ECC can affect a child's nutritional status and disrupt school attendance and performance [10–14]. The multifactorial nature of ECC creates challenges in identifying effective primary prevention strategies [15]. There were no effective non-surgical products available for secondary prevention until recently.

Reports have identified silver diamine fluoride (SDF) as an antimicrobial agent that can successfully arrest dental decay [16]. It can potentially address untreated caries in young children, which would reduce the need for rehabilitative dental surgery under general anesthesia [17–22]. SDF is a good alternative for children with ECC who may not be cooperative with traditional treatment approaches [23, 24]. One systematic review with meta-analysis found that SDF was safe and effective in arresting dental caries in primary teeth. In eight studies that used 38% SDF to treat active caries, 81% of lesions were arrested [25]. The American Dental Association (ADA) practice guidelines for non-restorative treatments of dental caries recommends the prioritization of 38% SDF over other products to manage cavitated carious lesions [26]. Despite this information, true consensus on the frequency of SDF applications for children with ECC is lacking. The current AAPD clinical practice guidelines for SDF urge researchers to conduct well-designed randomized clinical trials to compare the use and outcomes of SDF treatment on both primary and permanent teeth [27].

While Advantage Arrest™ (38% SDF) received approval for clinical use in Canada by Health Canada in 2017, there has been little guidance on the frequency and duration of its application. Proposed protocols may not translate well into some clinical and dental public health settings. Recommendations for frequent re-application may not be practical or realistic in remote communities where access to dental care is limited and where frequent follow-up visits are not possible in a short amount of time [20, 25, 28].

The purpose of this study was to examine the effectiveness of SDF to arrest cavitated carious lesions in primary teeth at three different application regimen intervals (one month, four months, and six months apart). To our knowledge, this is the first randomized clinical trial of SDF conducted in Canada for young children. This study aimed to provide new information that may aid clinicians in the decision-making process for SDF application for the greater benefit of patients.

Methods

This open-label, parallel-group, randomized clinical trial was registered at ClincialTrials.gov (registration number: NCT04054635, first registered 13/08/2019). Participants were recruited between October 2019 and June 2021 from community dental clinics in Winnipeg, Canada (Access Downtown, Mount Carmel Clinic, and SMILE plus). Study visits also took place at the Children's Hospital Research Institute of Manitoba. Children under 72 months of age were included if they had teeth that met International Caries Detection and Assessment System (ICDAS) codes 5 or 6 criteria, with softer caries extending into dentin without signs of pulpal involvement [29]. Children were excluded if they had a silver allergy, developmental enamel defects, severe medical issues, dental conditions requiring immediate rehabilitation under general anesthesia, or if they had teeth that met any PUFA (Pulpal involvement, Ulceration, Fistula, and Abscess) index criteria. Analyses of radiographs were not conducted, as not every child had them done. Parents/caregivers provided written informed consent.

A total of 84 participants were recruited for the study. Sample size was determined based on a pilot study and in consultation with a biostatistician. In the pilot study, 40 children had 239 lesions (approximately six lesions per child) that could estimate an arrest rate with a 95% confidence interval (CI) to be accurate within ± 6.5%. With at least 400 lesions in a proposed sample, the 95% CI would be ± 5%. Anticipating an average of six lesions per child, three regimen groups with 23 children each would produce approximately 414 lesions to be studied.

To deal with potential drop-outs/loss to follow-up, we over-recruited by 27.3% and sought 28 children for each group.

Participants came for a total of three study visits: one baseline visit and two follow-up visits (Fig. 1). Children underwent dental examinations at each visit. Teeth meeting ICDAS codes 5 or 6 criteria were identified at baseline, and the location, size, hardness (soft, medium, or hard), colour (yellow, brown, or black), and activity of lesions were recorded. The dmft (decayed, missing, and filled primary teeth) index scores were calculated using available clinical information (odontograms). Lesions were treated with 38% SDF (Advantage Arrest, Oral Science, Brossard, Québec, Canada) at the first

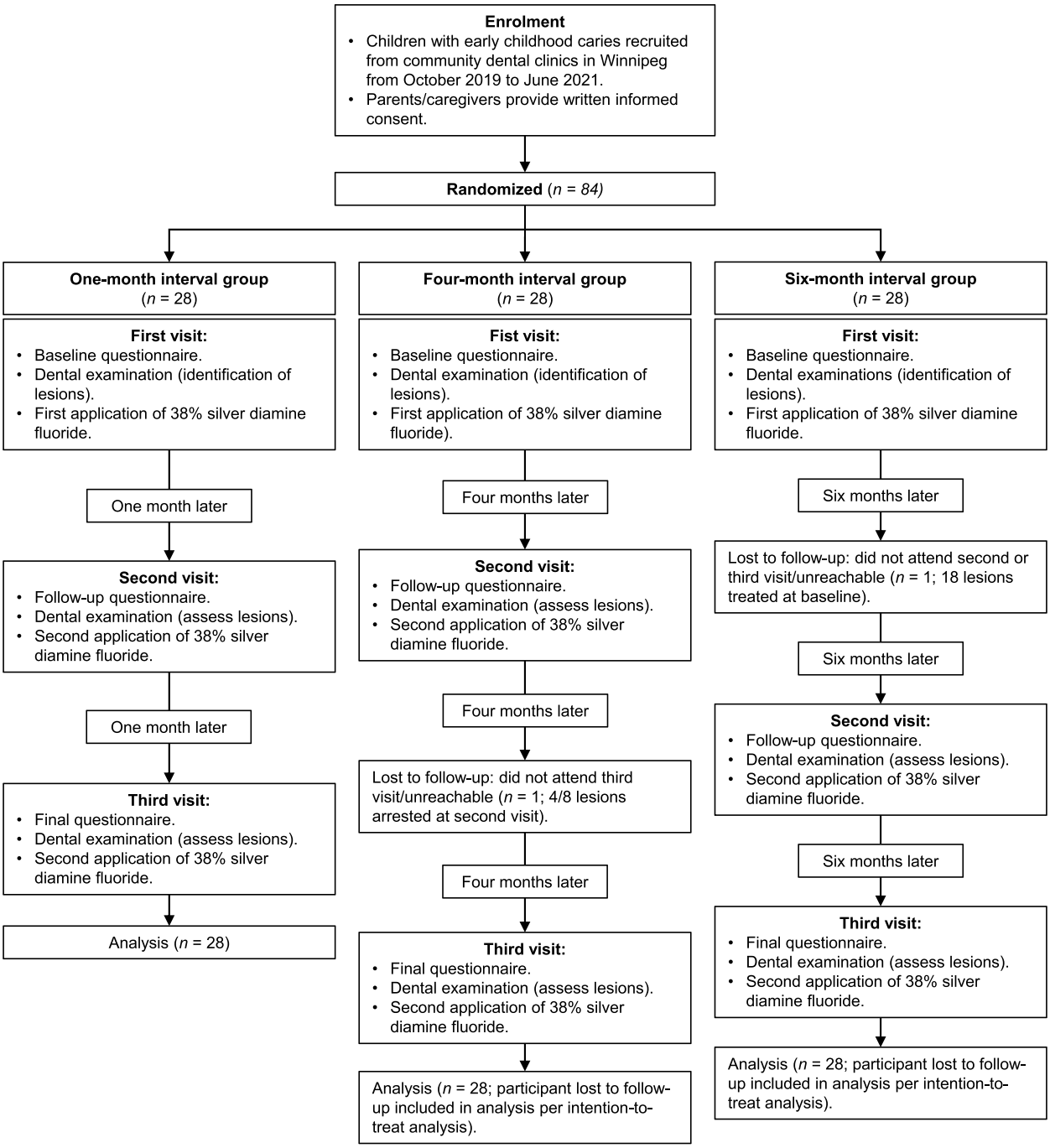

Fig. 1 Flow diagram of study process (recruitment, randomization, visits and activities, duration, and analysis)

and second visits and were followed for the duration of the study. The liquid product was applied with a microbrush for one minute, and surfaces were wiped with wet gauze and rinsed with water. Participants received applications of 5% sodium fluoride varnish (NaFV) following SDF application. One attending dentist carried out all clinical activities, while other research staff conducted all non-clinical activities. Parents/caregivers were also administered questionnaires at each visit. The questionnaires asked for information on sociodemographic characteristics, oral hygiene, pain, oral health-related quality of life, and the appearance of teeth.

The time between SDF treatments and study visits depended on the child's regimen. Prior to recruitment, the research coordinator prepared sealed envelopes labelled with each participant number. The contents of the envelopes were selected randomly and contained details for one of three regimens: treatment/visits one month apart (proposed in the AAPD's clinical practice guideline), four months apart (protocol frequency adopted by the Winnipeg Regional Health Authority), or six months apart (recommended by ADA) [30–32]. When a child was recruited into the study, research staff selected the envelope with the appropriate participant number, thus assigning the child to one of the three groups. Participants were followed for a total of two months, eight months, or 12 months. The first participant was enrolled 19 October 2019, and the last participant was seen 12 February 2022. Examiners and research staff were not blinded to the regimen or the status of lesions.

The primary outcome measure was arrest rates among individual treatment groups. Lesions that were hard upon tactile probing and black in colour were considered arrested. Overall arrest rates and specific arrest rates for anterior (primary incisors and canines) and posterior (primary molars) lesions at the second and third visits were calculated. Intention-to-treat analysis was used, where participants lost to follow-up were still included in the study, and we acted as though there were no changes to lesions for these individuals at subsequent (missed) visits. This approach was chosen since it preserved randomization and was the best neutral response for the unknown status of lesions—to assume no effect either way [33]. Data were entered into REDCap (Research Electronic Data Capture), a secure web application for online databases, and were analyzed using Number Cruncher Statistical Software Version 9.0 (NCSS; Kaysville, Utah). Descriptive statistics were also calculated for relevant questionnaire information. Kruskal–Wallis one-way analysis of variance (ANOVA) and Pearson's Chi-squared test were performed when appropriate. A p-value of ≤ 0.05 was considered statistically significant.

The ADA maintains that 5% NaFV is largely unproductive as a treatment for cavitated lesions [26]. We did not consider a control group receiving only 5% NaFV, as this would be considered unethical substandard care. NaFV was applied following the application of SDF as recommended by the AAPD's SDF chairside guide. It ensures that SDF stays in contact with the treated lesion and prevents caries on surfaces not treated with SDF by strengthening structure and increasing resistance to demineralization [30, 31, 34].

Results

Participant characteristics are summarized in Table 1. Forty-nine male participants and 35 female participants were randomized into three groups of 28 children. Overall, participants had a mean dmft of 6.8 ± 4.5. The mean age of children recruited into the study was 44.4 ± 14.2 months. The sample was diverse, with participants having different African (38.1%), Asian (28.6%), European (9.5%), or Canadian Indigenous (23.8%) ancestry. Few children (16.7%) were newcomers to Canada. There were no significant differences between the three groups in terms of age, sex, and ethnicity. A majority of participants brushed their teeth twice a day (61.9%) and used toothpaste containing fluoride (82.1%). Most participants (69.1%) also had some form of dental insurance that covered all or part of their dental care expenses. These results were consistent across all three groups in the study. Only five children experienced any tooth pain at their first study visit.

Two participants were lost to follow-up. A child in the four-month interval group did not attend their third visit (4/8 lesions arrested at second visit; 2/2 anterior lesions and 2/6 posterior lesions), and a child in the six-month group did not attend either of their follow-up visits (18 lesions treated at baseline; 12 anterior lesions and six posterior lesions). Because of intention-to-treat analysis, we assumed no changes in lesion status for these children since their last visit (i.e., 4/8 lesions were recorded as arrested at the third visit for the child in the four-month group, and no lesions were recorded as arrested at subsequent visits for the child in the six-month group).

A total of 374 teeth and 505 lesions were treated with 38% SDF and 5% NaFV. The number of teeth differed significantly by group classification ($p=0.03$), with 143 teeth treated in the one-month interval group, 121 teeth treated in the four-month interval group, and 110 teeth treated in the six-month interval group. The number of lesions also differed significantly by group classification ($p=0.002$); the one-month interval group had 196 lesions treated, the four-month interval group had 166 lesions treated, and the six-month interval group had 143 lesions treated. More anterior teeth (260) and lesions (300) were

Table 1 Participant characteristics at baseline

Variable	All participants (*n* = 84)	One-month interval group (*n* = 28)	Four-month interval group (*n* = 28)	Six-month interval group (*n* = 28)	*p*-value
Mean age (months) ± SD:	44.4 ± 14.2	43.9 ± 15.0	40.5 ± 12.6	48.9 ± 14.2	0.11[a]
Sex:					
Male	49 (58.3%)	19 (67.9%)	13 (46.4%)	17 (60.7%)	0.25[b]
Female	35 (41.7%)	9 (32.1%)	15 (53.6%)	11 (39.3%)	
Ethnic Background:					
African	32 (38.1%)	15 (53.6%)	11 (39.3%)	6 (21.4%)	0.24[b]
Asian	24 (28.6%)	5 (17.9%)	7 (25.0%)	12 (42.9%)	
European	8 (9.5%)	3 (10.7%)	2 (7.1%)	3 (10.7%)	
Indigenous	20 (23.8%)	5 (17.9%)	8 (28.6%)	7 (25.0%)	
Newcomer to Canada:	14 (16.7%)	5 (17.9%)	4 (14.3%)	5 (17.9%)	0.92[b]
Frequency of tooth brushing:					
Twice daily	52 (61.9%)	18 (64.3%)	17 (60.7%)	17 (60.7%)	0.59[b]
Once daily	24 (28.6%)	6 (21.4%)	8 (28.6%)	10 (35.7%)	
Less than once a day	8 (9.5%)	4 (14.3%)	3 (10.7%)	1 (3.6%)	
Use of fluoridated toothpaste:					
Yes	69 (82.1%)	23 (82.1%)	24 (85.7%)	22 (78.6%)	0.78[b]
No	6 (7.1%)	3 (10.7%)	1 (3.6%)	2 (7.1%)	
Do not know	9 (10.7%)	2 (7.1%)	3 (10.7%)	4 (14.3%)	
Has dental insurance:	58 (69.1%)	19 (67.9%)	20 (71.4%)	19 (67.9%)	0.95[b]
Has tooth pain:	5 (6.0%)	2 (7.1%)	1 (3.6%)	2 (7.1%)	0.81[b]
Total number of teeth treated:	374	143 (38.2%)	121 (32.4%)	110 (29.4%)	0.03[b]
Anterior teeth treated	260 (69.5%)	99 (38.1%)	88 (33.8%)	73 (28.1%)	0.57[b]
Posterior teeth treated	114 (30.5%)	44 (38.6%)	33 (28.9%)	37 (32.5%)	
Total number of lesions treated:	505	196 (38.8%)	166 (32.9%)	143 (28.3%)	0.002[b]
Anterior lesions	300	133 (44.3%)	94 (31.3%)	73 (24.3%)	0.005[b]
Posterior lesions	205	63 (30.7%)	72 (35.1%)	70 (34.1%)	
Mean dmft ± SD:	6.8 ± 4.5	7.0 ± 4.7	6.2 ± 4.7	7.3 ± 4.1	0.41[a]

SD Standard deviation, *dmft* Decayed, missing, and filled primary teeth

[a] Kruskal-Wallis ANOVA

[b] Pearson's Chi-square test

treated than posterior teeth (114) and lesions (205). The number of anterior and posterior teeth and lesions differed significantly between groups. Kruskal–Wallis one-way ANOVA found no significant difference between groups in mean dmft.

Lesion arrest rates are summarized in Table 2 and Fig. 2. The one-month interval group and the four-month interval group had high arrest rates at the first follow-up after the initial application of SDF and NaFV, with 78.1% and 81.3% of lesions arrested, respectively. The six-month interval group had just 61.5% of lesions arrested at that time. At the second follow-up visit (i.e., the third and final visit), almost all lesions were arrested for the one-month (98%) and four-month (95.8%) interval groups. The six-month interval group only had 72% of lesions arrested at that time. Pearson's Chi-squared test revealed significant associations between group classification and arrest rates ($p < 0.001$). The duration of the application regimen interval was inversely associated with improvements in arrest rates from the second to third study visit. The one-month interval group showed the greatest improvement in their condition with a 19.9% increase in arrested lesions, the four-month interval group was second with a 14.5% increase, and the six-month interval group showed the least improvement with a 10.5% increase.

Anterior-specific analyses showed higher arrest rates for primary incisors and canines with the one-month (85%), four-month (83%), and six-month (75.3%) interval groups at the first follow-up. Pearson's Chi-squared test results were non-significant for these findings ($p = 0.22$). At the second follow-up visit, almost all lesions were arrested for the one-month (99.2%, + 14.2% improvement) and four-month (97.9%, + 14.9 improvement) interval groups. The six-month interval group, however,

Table 2 Arrest rates after SDF and 5% NaFV application(s)

Overall lesions arrest rates			
Participants	**At second visit (first follow-up)**	**At third visit (second follow-up)**	**Second to third visit differential**
All participants	74.5% (376/505)	89.9% (454/505)	+15.4%
One-month interval group	78.1% (153/196)	98.0% (192/196)	+19.9%
Four-month interval group	81.3% (135/166)	95.8% (159/166)	+14.5%
Six-month interval group	61.5% (88/143)	72.0% (103/143)	+10.5%
[a]*p* value	< 0.001	< 0.001	
Anterior lesions arrest rates			
Participants	At second visit (first follow-up)	At third visit (second follow-up)	Second to third visit differential
All participants	82.0% (246/300)	92.7% (278/300)	+10.7%
One-month interval group	85.0% (113/133)	99.2% (132/133)	+14.2%
Four-month interval group	83.0% (78/94)	97.9% (92/94)	+14.9%
Six-month interval group	75.3% (55/73)	74.0% (54/73)	-1.3%
[a]*p* value	0.22	< 0.001	
Posterior lesions arrest rates			
Participants	At second visit (first follow-up)	At third visit (second follow-up)	Second to third visit differential
All participants	63.9% (131/205)	85.9% (176/205)	+22.0%
One-month interval group	63.5% (40/63)	95.2% (60/63)	+31.7%
Four-month interval group	79.2% (57/72)	93.1% (67/72)	+13.9%
Six-month interval group	48.6% (34/70)	70.0% (49/70)	+21.4%
[a]*p* value	< 0.001	< 0.001	

[a] Pearson's Chi-square test

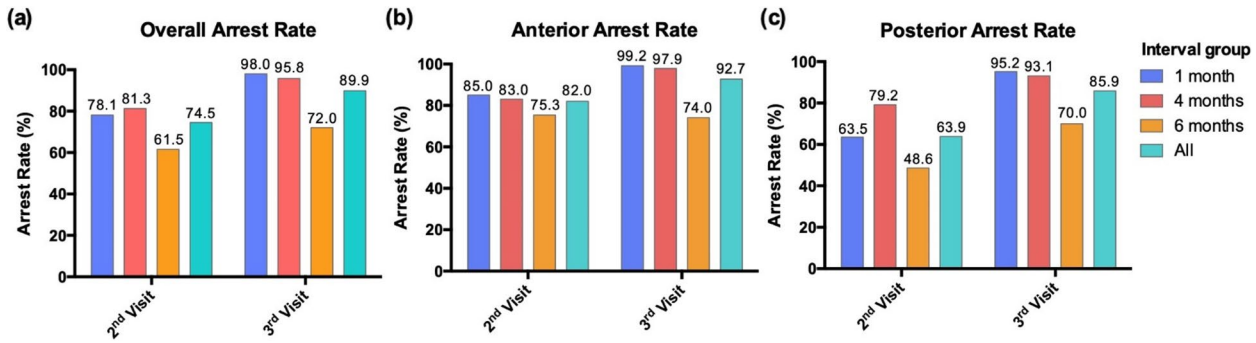

Fig. 2 Early childhood caries arrest rates after SDF treatment for different application regimen intervals: (**a**) overall lesions, (**b**) anterior lesions), and (**c**) posterior lesions

experienced less success and only had 74% of lesions arrested at that last visit (- 1.3% improvement). These findings were significant ($p < 0.001$).

Posterior-specific arrest rates at the first follow-up for the one-month (63.5%), four-month (79.2%), and six-month (48.6%) interval groups were lower than overall and anterior-specific arrest rates at that time ($p < 0.001$). Almost all molar lesions were arrested for the one-month (95.2%) and four-month (93.1%) interval groups at the second follow-up visit. The six-month interval group only had 70% of lesions arrested at that time. All posterior-specific findings were significant ($p < 0.001$). Despite the low arrest rate at the first follow-up visit, the one-month interval group showed good improvement in their condition and had a 31.7% increase in arrested lesions. The six-month group also recovered and had a 21.4% increase in arrested lesions. The four-month group experienced a + 13.9% differential. No statistically significant difference was found with respect to interproximal lesions (i.e., on distal and mesial surfaces) compared to all other surfaces:

81.3% (39/48) interproximal lesions were arrested at the final visit and 87.3% of other posterior surface lesions were arrested at the final visit ($p=0.30$).

Discussion

The purpose of this study was to examine the effectiveness of 38% SDF, along with 5% NaFV, to arrest cavitated carious lesions in primary teeth at three different application intervals. Overall, two applications of SDF and NaFV either one month or four months apart were very successful in arresting lesions in primary teeth and resulted in similar arrest rates. Applications six months apart were less successful and more lesions were not arrested. Shorter intervals between treatments (i.e., one month and four months) appeared to be more effective than longer intervals (i.e., six months). Greater improvements in conditions following primary applications of SDF and NaFV were seen for individuals with more immediate follow-up visits.

Research on the use of SDF is mixed and there is no consensus on the number or frequency of applications to arrest dental caries in children. Some studies have also shown underwhelming results with semi-annual applications of SDF. Mabangkhru et al. examined the results of 38% SDF applications in children at six-month intervals, and found low arrest rates at first (20.5%, 228/1111 lesions) and second (35.7%, 397/1111 lesions) follow-up visits. These results were greater than those seen in a 5% NaFV control group at first (12.3%, 140/1138 lesions) and second (20.9%, 238/1138 lesions) follow-up visits ($p<0.001$) [35]. Fung et al. repeated applications of SDF every six months for young children with ECC in Hong Kong, and found a comparable arrest rate of 75.7% (685/905 lesions) at a 30-month follow-up [23]. Despite an increase in the amount of applications over a prolonged time frame, there was no outstanding difference in the outcome.

Conversely, additional time made a difference in a study conducted by Zhi et al., where semi-annual applications of 38% SDF became more effective over a two-year period. They found that arrest rates increased for each follow-up visit at six months (43.3%), 12 months (53%), 18 months (82.9%), and 24 months (90.7%) [36]. In this case, treatments at six-month intervals worked with greater use of SDF and a longer wait. Our methods were more confined in this present study. Meta-analysis of data from eight clinical studies of SDF pooled results from six-month follow-ups and found that 86% of caries had arrested at that time [25]. This is more optimistic than what we found.

Several studies have reported good success (arrest rates) with SDF [22, 31, 36]. In some cases, SDF has worked quickly in treated lesions in primary teeth. Despite equivocal evidence, SDF is a valuable treatment option for dental caries in clinical and community settings [37]. The adoption of an SDF intervention protocol has been shown to significantly reduce preventable dental hospitalizations, arrest caries in children that are unable to tolerate other restorative treatments, and improve oral health-related quality of life [38]. Our study supports two applications of 38% SDF in one-month or four-month intervals to treat dental caries in children under 72 months of age. Two applications of SDF six months apart may be inferior treatment. Since the one-month and four-month groups were similar, our findings will undoubtedly be welcome news for busy dental public health programs and clinics in rural and remote regions where it may be next to impossible to have children return for re-application of SDF within a month of the initial application. The success of the four-month interval offers some flexibility in dental public health settings and supports additional time between treatments for proper assessment and better outcomes.

To our knowledge, this is the first randomized clinical trial of SDF conducted in Canada for young children. This study provides new information that may aid clinicians in the decision-making process for SDF application for the greater benefit of patients. Our sample of children recruited from community dental clinics in Winnipeg are representative of the target population with dental decay that requires SDF treatment. Hence, our results should be relevant to other similar settings. These findings may have broader applications to other populations as well. The specificity of the inclusion criteria actually helps mitigate sampling bias, and similarities between treatment groups justify their comparability and allow us to interpret the relationship between intervention and outcome.

Our results are contingent on the use of intention-to-treat analysis, which attempts to be realistic in its assessment of an intervention [39]. This approach preserves randomization and usually allows users to draw unbiased conclusions regarding the effectiveness of treatments [33]. That said, it is important to note that 18 lesions were deemed not arrested for the one child in the six-month interval group that did not attend either of their follow-up visits. This number of lesions entails some ambiguity. An extremely optimistic view of SDF treatment could have involved a 12.6% increase in the overall arrest rate for the six-month regimen. However, even if all 18 of those lesions had been arrested, the percentage of successful treatments would still be lower than the one-month and four-month groups.

Another limitation of this study is the significant difference in the number of total teeth and lesions treated between the three groups. The number of teeth and lesions treated were in decreasing order from the

one-month group, to the four-month group, and to the six-month group. Since arrest rates were analyzed using a pooled sample, the six-month interval group, along with the four-month interval group, may have been disadvantaged from the lack of additional teeth and lesions to be examined. Furthermore, anterior teeth have been shown to have higher arrest rates than posterior teeth when treated with SDF [24, 36, 40]. Despite the comparability of the location of affected teeth between our groups, the disparity in anterior and posterior lesions may misrepresent the average effect of treatment. A greater number of posterior lesions could have been beneficial. Our main objective of looking at arrest rates at regimen-based time-points may have compromised the long-term comparability of results because of the duration of follow-up. Three months of follow-up for the one-month group may have been too short to fully evaluate the success of treatment in comparison to the other groups that had longer follow-up times (eight months and 12 months). An additional check-up at a later time could have helped us better compare the progression of SDF-treated lesions.

Conclusions

Two applications of 38% SDF, along with 5% NaFV, in one-month and four-month intervals were more effective in arresting ECC than two applications in six-month intervals. Findings from this study will help inform the refinement of existing clinical treatment protocols for SDF for use in dental public health settings. More clinical trials are needed to confirm the number and frequency of SDF applications to arrest caries lesions in young children.

Abbreviations

AAPD	American Academy of Pediatric Dentistry
ADA	American Dental Association
ANOVA	Analysis of variance
CI	Confidence interval
dmft	Decayed, missing, and filled primary teeth
ECC	Early childhood caries
ICDAS	International Caries Detection and Assessment System
NaFV	Sodium fluoride
NCSS	Number Cruncher Statistical Software),
PUFA	Pulpal involvement, Ulceration, Fistula, and Abscess
REDCap	Research Electronic Data Capture
SD	Standard deviation
SDF	Silver diamine fluoride

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Authors' contributions

RJS contributed to conception and design, data acquisition, analysis, and interpretation, drafting the manuscript, and critically revising the manuscript. SB contributed to design, data analysis, and interpretation, drafting the manuscript, and critically revising the manuscript. VHKL contributed to data acquisition, analysis, and interpretation, drafting the manuscript, and critically revising the manuscript. BAM contributed to data acquisition and analysis, and critically revising the manuscript. SS contributed to data acquisition and critically revising the manuscript. VCJ contributed to data acquisition, analysis, and interpretation and critically revising the manuscript. MB contributed to data interpretation and critically revising the manuscript. PC contributed to conception and design, data analysis and interpretation, and critically revising the manuscript.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the University of Manitoba's Biomedical Research Ethics Board (HS22998/B2019:068). Parents/caregivers of child participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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