ORIGINAL RESEARCH

Arresting Active Carious Lesions Using Minimal Intervention Dentistry among a Group of Preschool Children: A Randomized Controlled Clinical Trial

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Abstract

Objectives: This clinical trial investigated the effectiveness of three minimal intervention dentistry protocols in arresting dentin caries in primary molars of preschool children. Treatment time, anxiety in children, adverse events, and parents' esthetic perception were all assessed.

Materials and methods: One hundred thirty-five 3–5-year-old children with active dentin caries lesions on the occlusal surface of primary molars were randomly allocated to the control group receiving atraumatic restorative treatment (ART) and two test groups receiving 38% silver diamine fluoride (SDF) or ultraconservative treatment (UCT). The existence and activity of caries were assessed using the International Caries Detection and Assessment System II (ICDAS II) criteria. Children were followed up at 3, 6, and 12 months. The time required to perform the treatments was recorded, and a facial image scale (FIS) was applied to assess anxiety. Questions posed to caregivers were used to investigate adverse events and esthetic assessment.

Results: After a year, the overall success rates of UCT, SDF, and ART were 61.6, 87.2, and 84.6%, respectively, with a statistically significant difference ($p < 0.05$). The time required to treat with SDF was significantly lower than that needed for ART and UCT ($p < 0.01$). Anxiety levels were significantly lower in the SDF group ($p = 0.003$). There was no difference in the percentage of adverse events and parental esthetic perception ($p = 0.604$).

Conclusion: After 3 months, the arrest rates of ART, SDF, and UCT were similar. However, after 1 year, the arrest rate of UCT was significantly lower.

Clinical significance: Silver diamine fluoride takes significantly less chair time and has success rates comparable to ART. Ultraconservative treatment has a short-term successful application. It was confirmed that there were no variations in adverse events between SDF, ART, and UCT.

Clinical trial registration number: NCT05314660.

Keywords: Dental caries, Early childhood caries, Minimal intervention dentistry, Silver diamine fluoride.

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Introduction

The American Academy of Pediatric Dentistry has defined early childhood caries (ECC) as "the presence of one or more decayed, missing due to caries, or filled tooth surfaces in any primary teeth in children under 6 years of age." In children younger than 3 years of age, any sign of smooth-surface caries is indicative of severe early childhood caries (S-ECC).[1]

Even while preschool dental caries is becoming less common in Western countries, it continues to be a significant issue in both industrialized and developing nations. According to a survey of the literature, the prevalence of ECC is between 1 and 12% in most developed nations.[2] It has been reported that the incidence can reach 70% in less developed nations.[3] The prevalence of ECC was determined to be 61.4%[4] in Egypt, confirming the disease's extensive prevalence across the globe.

Cariogenic bacteria, improper feeding practices that expose people to fermentable carbohydrates, and a variety of social factors all interact to cause the multifactorial disease known as ECC.[5] Proper mastication, esthetics, phonetics, space maintenance, and the avoidance of abnormal habits all depend on the primary dentition. ECC may hinder children's capacity to study, impair their physical development, and result in missed school days, all of which can lower their oral health-related quality of life (OHRQoL).[6]

Restorations, dietary advice, teaching parents about decay, encouraging proper feeding habits, and practicing good dental hygiene can all help stop the progression of ECC,[7] with the application of preventive measures such as topical fluorides.[8] In the case that initial preventive measures are unsuccessful, care is required to stop the disease and lessen the damaging effects of caries.[9] The treatment of ECC is costly and frequently involves substantial restorative work and early tooth extractions. Sometimes deep sedation or general anesthesia is necessary since young children are not able to handle the lengthy therapy processes.[10]

One low-cost option to increase these kids' access to restorative care is atraumatic restorative treatment (ART),[9] since it is well-liked by them, can be employed in locations without running water or

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electricity,[11,12] and has demonstrated efficiency in caries control.[13,14] ART use has been steadily rising and is still quite high, especially in underprivileged areas.[15] It entails manually excavating cavities and then restoring them with glass ionomer cement (GIC) of high viscosity.[16]

Since silver diamine fluoride (SDF) is safe, effective, feasible, and efficient at stopping dentin caries, it has been recommended as a treatment option for tooth decay, particularly in preschool-aged children.[9,17,18] Even though SDF discolors the teeth black, the advantages of not experiencing pain or oral infection can outweigh this undesirable aspect, particularly in places where it is challenging to receive dental care.[17]

Scientific study has been done on the theory that cavities can be prevented from growing biofilm by cleaning the teeth. A procedure known as ultraconservative treatment (UCT) was created. To facilitate biofilm removal with a toothbrush and fluoride toothpaste, medium- and large-sized cavities are excavated and widened as part of this technique.[19]

This parallel, randomized, controlled clinical trial investigated the proportion of caries lesions that were arrested when treated with ART, SDF, and UCT. This was done because it was known that no preschoolers in Egypt had had research done comparing the effectiveness of 38% SDF and UCT with ART in arresting dentin caries lesions only on the occlusal surface of deciduous molars. The study set intended to investigate the following outcomes: caries lesion arrest, treatment time, children's anxiety, adverse events, and parents' perception of esthetics.

Materials and Methods

This was a randomized parallel active controlled trial, with a 1:1 allocation ratio following the Consolidated Standards of Reporting Trials (CONSORT) recommendations[20] according to an available study protocol with the clinical trial registry number NCT05314660 on clinicaltrials.gov.

Study Sample

Between January 2020 and May 2021, at the Pediatric Dental Clinic of Mansoura University, one examiner recruited 250 preschoolers to be assessed for eligibility. The eligibility criteria were children in good health, between the ages of 3 and 5, possessing one active caries lesion forming a cavity, and the lesion was limited to the primary molar's occlusal surface. Children whose parents declined to allow them to participate, those with unusual medical issues or a silver allergy, those whose families planned to leave Mansoura during the trial, and those whose molars showed radiographic or clinical evidence of pulpitis were all excluded. The included carious lesions were classified as active and obtained ICDAS II values of 5 or 6.[21]

The code A22080120 was obtained with the consent of the Mansoura University Faculty of Dentistry's ethical committee. Before their children were examined and treated, the parents signed written informed consent forms. The confidentiality of all information provided was guaranteed to parents and caregivers.

Intraexaminer Calibration

Prior to the start of the study, 20 children underwent two examinations and diagnoses in accordance with ICDAS II criteria, separated by 1 week, to guarantee intraexaminer consistency and reliability. A Kappa score greater than 0.85, indicating very good agreement, was found when the results of the two exams were compared.

Sample Size Calculation

The G*Power 3.1.9.7 tool was used to determine the sample size, which was based on the variation between two independent means seen in a related earlier study.[22] Therefore, 41 patients were to be assigned to each therapy group, assuming an effect size difference of 0.56 across groups, power of 80%, and α error of 0.05 using a 1:1 allocation ratio. To account for possible dropouts, the initial predicted sample size of 123 was raised to 135 in total.

Study Procedures

Three groups of children were randomly assigned: the test group (treatment with SDF and UCT) and the control group (ART). A researcher distinct from the operator divided the chosen kids into groups using block randomization of nine in the Excel program. Sequentially numbered opaque sealed envelopes, which were sealed before the trial, were used to achieve allocation concealment for the treatment allocation cards. To carry out the randomization procedure, the operator had to take the next envelope in order and hand it to someone else to open.

Baseline data were gathered, including eating patterns, dental history, oral hygiene, and sociodemographic and socioeconomic information. The operator or an assistant showed the kids a facial image scale (FIS)[23] in the waiting area just before treatment to gauge their level of anxiety. Every kid was asked to choose which face most captured how they were feeling at that very moment (very happy, happy, neutral, unhappy, and very unhappy). The kids were asked to retake the test immediately following their treatment.

Children in the control group received ART,[24] wherein the carious molar's occlusal surface was cleaned using a toothbrush, the tooth was isolated using cotton rollers, the caries was excavated manually, and glass ionomer was mixed in accordance with the manufacturer's instructions before being placed into the cavity. The test groups received 38% SDF[25] varnish and UCT.[26] Silver diamine fluoride was applied twice a year. The occlusal surfaces of teeth to receive SDF were cleaned with a toothbrush and dried. Vaseline was used to cover the skin and gingiva to prevent discoloration, and a micro-sponge was used to directly apply 38% SDF in accordance with the manufacturer's recommendations. For children receiving UCT, carious cavities were widened with a hatchet to make removal of biofilm easier, along with the use of fluoridated toothpaste (1450 ppm) twice daily.

Outcomes and Follow-up

To evaluate caries arrestment, follow-up exams were conducted after 3, 6, and 12 months. The same examiner performed the baseline clinical assessments after the patients had cleaned their teeth. Data from the initial examination were compared with information on dental examinations and pain complaints that were recorded. Thus, teeth could be categorized as successful or unsuccessful. According to ICDAS[21] criteria, caries was considered successful when it was diagnosed as inactive and unsuccessful when it was classified as active and/or when there was spontaneous pain or pulpitis symptoms.

As for ART, the treatment was considered successful if the restoration was present, without apparent dentin, or if the dentin was exposed but inactive/arrested. A procedure was deemed unsuccessful if the filling material was lost completely or partially, the exposed dentin met ICDAS[21] criteria for an active lesion, if there was spontaneous pain, or there were indications of pulpal involvement.

Statistical Analysis and Data Interpretation

The computer was fed data, and IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 22.0 (New York/Armonk: IBM Corp., 2013) was used for analysis. Numbers and percentages were used to describe the qualitative data. After the Shapiro–Wilk test was used to confirm that the data were normal, the quantitative data were described using the median (lowest and maximum) and mean, standard deviation for parametric data. The acquired results were deemed significant at the 0.05 level.

Data Statistical Analysis

For the qualitative data, the Chi-squared test for comparison of two or more groups was used. For the quantitative data, the parametric test one-way analysis of variance (ANOVA) was used to compare three independent groups, and for the nonparametric data, the Kruskal–Wallis test was used to compare three independent groups, while the Wilcoxon signed-rank test was used to compare between two studied periods.

Results

The average age of the 135 preschoolers in this study was 3.94 ± 0.76 years old (standard deviation). They were recruited between January 2020 and May 2021, and after starting treatment, they were followed up for a full year. May 2022 was the end of the follow-up period. They were assigned into three treatment groups: ART (n = 45), SDF (n = 45), and UCT (n = 45). No losses occurred in the first 3 months of the study. At 6 and 12 months, a total of four and three subjects were excluded due to dropout, respectively.

Figure 1 shows a CONSORT flowchart that depicts the recruiting and participant flow. Information about each participant's sociodemographic and behavioral characteristics is displayed in Table 1. Regarding any of the factors, there was no statistically significant difference between the three groups.

With respect to the rates of caries arrestment in the study and control groups, Table 2 indicates that, at the 3-month follow-up, every tooth exhibited 100% success. At 6 months, three teeth failed in the ART group and 4 teeth failed in both SDF and UCT groups, producing arrest rates equal to 93% for ART and 90.9% for SDF and UCT. There was no significant difference between the success rates within the three groups at 3- and 6-month follow-up. However, at 12 months, the success rates were 87.2% for ART, 84.6% for SDF, and 61.6% for UCT. There was a statistically significant difference in caries arrestment between ART, SDF, and UCT ($p < 0.05$). The total arrest rate was significantly higher for ART, followed by SDF and then UCT.

The mean treatment time for ART was 7.9 ± 3.45 minutes. For SDF, the mean time was 3.37 ± 0.457 minutes, and for UCT, the mean treatment time was 4.1 ± 1.35 minutes. The length of time each group needed for treatment varied significantly from one another ($p < 0.01$) (Table 2).

All children were assessed prior to therapy, without distinction, in light of their dental anxiety (p = 0.155). After treatment, ART children showed statistically significantly higher scores than SDF

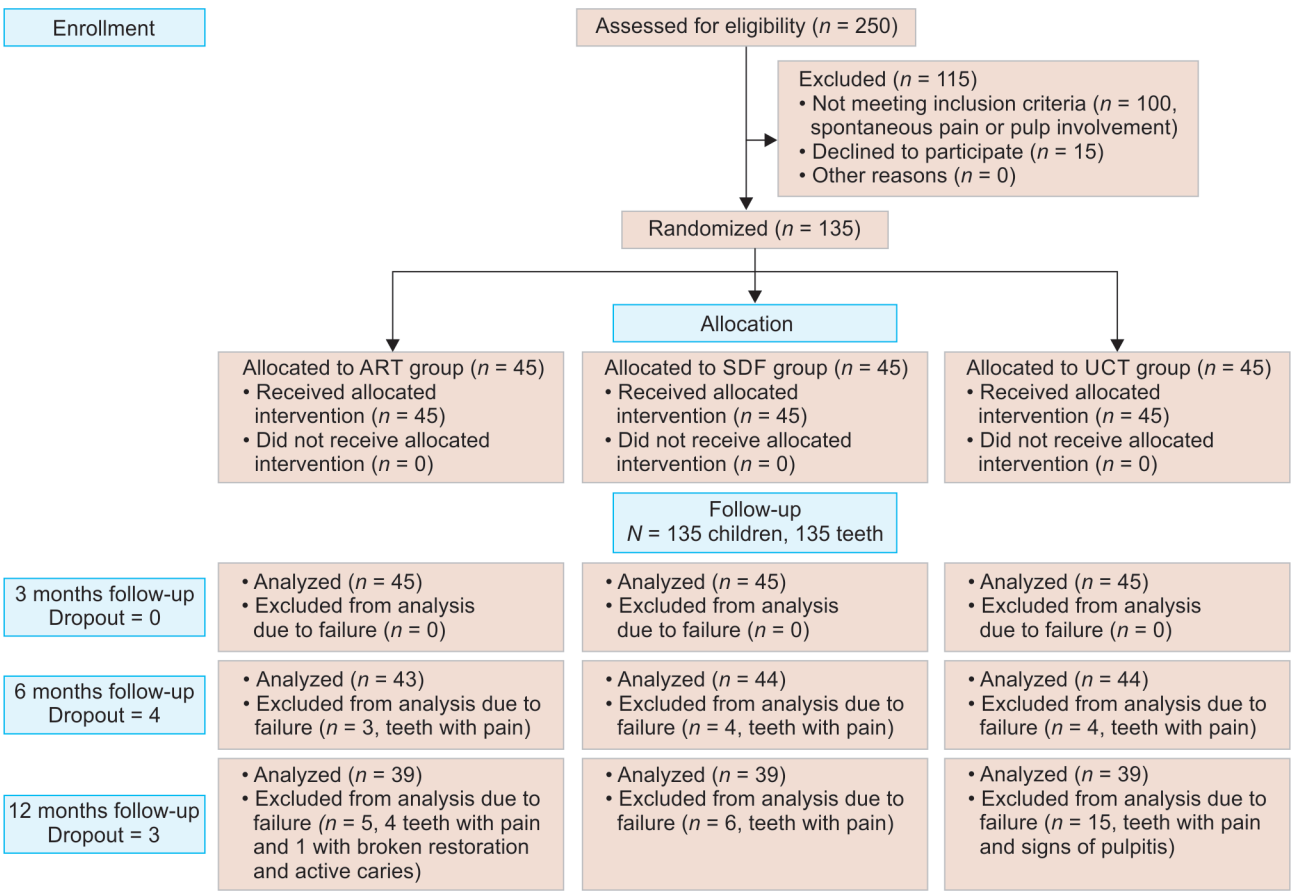

Fig. 1: Consolidated Standards of Reporting Trials flow diagram of the trial

Table 1: Baseline sociodemographic and behavioral characteristics of all study participants

All participants *N (%)*		*ART group* *n (%)*	*SDF group* *n (%)*	*UCT group* *n (%)*	*Test of significance*
Participants	135 (100%)	45 (33.3%)	45 (33.3%)	45 (33.3%)	
Age/years mean ± SD	3.94 ± 0.76	3.93 ± 0.72	3.98 ± 0.77	3.92 ± 0.797	$F = 0.066$ $p = 0.936$
Gender *n* (%)					
Boys	62 (45.9)	25 (48.9)	19 (44.4)	23 (55.5)	$X^2 = 2.19$ $p = 0.334$
Girls	73 (54.1)	20 (51.1)	26 (55.6)	22 (44.5)	
SES *n* (%)					
Middle	91 (67.4)	34 (75.6)	30 (66.7)	27 (60)	$X^2 = 2.49$ $p = 0.287$
Low	44 (32.6)	11 (24.4)	15 (33.3)	18 (40)	
Educational level *n* (%)					
College education	109 (80.7)	38 (84.4)	36 (80)	35 (77.7)	$X^2 = 3.09$ $p = 0.117$
Less than college	26 (19.3)	7 (15.6)	9 (20)	10 (22.3)	
Caries in sibling					
Yes	69 (51.1)	17 (37.8)	24 (53.3)	28 (62.2)	$X^2 = 7.43$ $p = 0.115$
No	39 (28.9)	15 (33.3)	15 (33.3)	9 (20)	
Only child	27 (20)	13 (28.9)	6 (13.3)	8 (17.8)	
Tooth brushing					
Yes	89 (65.9)	28 (62.2)	30 (66.7)	31 (68.9)	$X^2 = 0.462$ $p = 0.794$
No	46 (34.1)	17 (37.8)	15 (33.3)	14 (31.1)	
Fluoride toothpaste					
>1000 ppm	51 (37.8)	14 (31.1)	19 (42.2)	18 (40)	$X^2 = 1.38$ $p = 0.848$
<1000 ppm—no brushing	38 (28.9)	14 (31.1)	12 (26.7)	13 (28.9)	
>1000 ppm	46 (33.3)	17 (37.8)	14 (31.1)	14 (31.1)	
Frequent visits to dentist					
Yes	42 (31.1)	13 (28.9)	12 (26.7)	17 (37.8)	$X^2 = 1.45$ $p = 0.484$
No	93 (68.9)	32 (71.1)	33 (73.3)	28 (62.2)	

%, percentage; ART, atraumatic restorative technique; *F*, one-way ANOVA test; *n*, number of children in each category; *N*, total number of children in each group; SD, standard deviation; SDF, silver diamine fluoride; SES, socioeconomic status; UCT, ultraconservative technique; X^2 = Chi-squared test

Table 2: Comparison of caries arrestment rates, time required for treatment, and child anxiety between SDF and ART groups

Variables			*ART* *n (%)*	*SDF* *n (%)*	*UCT* *n (%)*	*Test of significance*
Caries arrestment	3 months	Success	45 (100)	45 (100)	45 (100)	
		Failure		0	0	
	6 months	Success	40 (93)	(90) 27	40 (90.9)	$p = 0.919$
		Failure	3 (7)	3 (10)	4 (9.1)	
	12 months	Success	34 (87.2)[a]	33 (84.6)[b]	24 (61.6)[ab]	$p = 0.001$*
		Failure	5 (12.8)	(15.46)	15 (38.4)	
Total		Success	34 (75.6)[a]	33 (73.4)[b]	24 (53.4)[ab]	$p = 0.004$
		Failure (dropouts and failure)	11 (24.4)	12 (26.6)	21 (46.6)	
Time required (mean)			7.93 ± 2.91[bc]	3.37 ± 0.45[ab]	4.14 ± 1.35[ca]	$p < 0.001$*
FIS	Pretreatment median (min-max)		2 (1–5)	1 (1–5)	1 (1–5)	$p = 0.155$
	Posttreatment median (min-max)		2 (1–5)[ab]	1 (1–5)[a]	1 (1–3)[b]	$p < 0.001$*
	Wilcoxon signed-rank test		0.535	<0.001*	<0.001*	

%, percentage; *statistically significant; ART, atraumatic restorative technique; FIS, facial image scale; Monte Carlo test; *N*, total number of children in each group; *p* is significant at level ≥0.05; SDF, silver diamine fluoride; similar superscripted letters in same row denote significant difference between groups; UCT, ultraconservative technique; χ^2 = Chi-squared test

and UCT ($p < 0.001$). Within-group changes showed a positive change for SDF ($p < 0.001$) and UCT ($p < 0.001$) groups (Table 2).

Immediately after treatment, the operator registered 23 adverse events, including discoloration of the gingiva, pain/sensitivity in the teeth, and bitter/metallic taste. The adverse event rates were 11.1% in the ART group ($n = 5$), 11.1% in the SDF group ($n = 5$), and 15.5% in the UCT group ($n = 7$). All 135 parents were interviewed over the phone by the operator after 48 hours. Eleven children in the ART and SDF groups reported unpleasant events, according to the parents. The reported side effects were similar to those that existed

Table 3: Number of adverse events related to the patients of ART, SDF, and UCT groups as reported immediately and 2 days later

	ART n = 45		*SDF n = 45*		*UCT n = 45*	
Adverse event	*Immediate*	*After 2 days*	*Immediate*	*After 2 days*	*Immediate*	*After 2 days*
Burning	–	–	–	–	–	–
Allergy	–	–	–	–	–	–
Nausea	–	–	–	–	–	–
Vomit	–	–	–	–	–	–
Bad/metallic taste	–	–	3	2	–	–
Pain/sensitivity in teeth	5	5	–	–	7	–
Mouth injury	–	–	–	–	–	–
Spot or pigmentation of skin or gingiva	–	–	2	4	–	–
Avoided smiling	0	0	0	0	0	0
Total	5	5	5	6	7	

ART, atraumatic restorative technique; *n*, number of adverse events in each group; SDF, silver diamine fluoride; UCT, ultraconservative treatment

before therapy. The adverse event rate per child in the ART group was 11.1% (*n* = 5), while in the SDF group it was 13.3% (*n* = 6), as per the interviews. No adverse events in the UCT group were reported after 48 hours. Regarding parental esthetic perception, only one parent was concerned about the child's appearance immediately after treatment (Table 3).

Discussion

In comparison to traditional ART, this analysis of a 12-month randomized clinical trial provides insights into the short- and long-term effectiveness of 38% SDF and UCT in stopping dentin carious lesions in primary molars of preschoolers. In this study, the hypothesis that the caries arrestment rates of the SDF, UCT, and ART procedures would not alter over a 12-month period was tested. The groups showed no significant differences between their sociodemographic and behavioral characteristics at baseline.

In this study, both the short- and long-term arrest rates of ART were higher than those reported in previous studies by Vollú et al.[22] and Zhi et al.[27] In the first study, 11 ART restorations were broken by 12 months compared to only one broken restoration in this study. In the study performed by Zhi et al.,[27] after 24 months, only 3.5% of the treated lesions showed complete preservation of the applied glass ionomer material. This may be due to the lack of cavity retentive form.

On the contrary, the success rate of ART after 1 year in this study was lower than that found by Faustino-Silva and Figueiredo.[28] This could be a result of kids managing their dental caries processes through educational and preventive initiatives conducted during the research period.

Regarding SDF, in the present study, the average short-term (3 months) caries arrest rate was 100%, which is higher than a previous study showing 98%.[29] On the other hand, it is equal to another study[22] using 38% SDF. The 6- and 12-month arrest rates were 90.9 and 84.6%, respectively. The results of this study showed greater rates of caries arrest compared to studies conducted at 6 and 12 months. These studies revealed 84.7%[27] at 6 months and 66.9%[22] at 12 months, while one study showed 43.3%[30] at 12 months.

However, the long-term caries arrest rates of this study were lower than those found in the study conducted by Vollú et al.[22] This difference may be explained by the fact that, although every child in the previously mentioned study had multiple eligible teeth, in this study each child had only one eligible tooth. The previously mentioned study employed the single tooth as the unit of analysis. In this study, the teeth were dried and isolated before the application of SDF, as stated by Clemens et al.[31] This was similar to other studies, which also showed higher arrest rates.[22,29]

There was no significant difference between the success rates of SDF and ART in this study, both in the short and long terms. This is similar to the findings of Vollú et al.,[22] Zhi et al.,[27] and Abdellatif et al.[30] However, according to a systematic evaluation, using SDF is 89% more effective than other therapies or placebos for controlling or preventing caries.[32]

Regarding UCT, the short-term caries arrest rate was the same as in the SDF and ART groups. However, the long-term arrest rate was significantly lower. This contrasts with the results of Mijan et al.,[33] who showed that treating primary molar dentin carious cavities with UCT is just as successful at retaining primary molars as their repair.

Also, the low arrest rate of UCT in the current study contrasts with the results of a study by Peretz and Gluck,[34] which relied on a preventive treatment mode including biofilm removal and fluoride, and achieved caries arrest over a 12-month period.

In the present study, levels of anxiety were significantly lower in the SDF group. This could be explained by the instrument-free approach of SDF application, which improved the kids' impression of the treatment. This contrasts with the findings of Vollú et al.,[22] who reported no difference between the two groups but considered this a favorable feature since ART is already seen as a child-friendly technique. To the best of our knowledge, this is the first study to investigate anxiety levels associated with UCT, and the results showed a significant reduction in the FIS scores after UCT treatment. The somewhat shorter treatment duration could provide an explanation for this. The chair times for SDF and ART in this trial were significantly less than those in previous SDF-using experiments.[22,35]

The frequencies of adverse events reported in the three groups did not differ in this investigation. To the best of our knowledge, only two prior investigations[22,36] looked into the possibility of adverse events by interviewing caregivers following therapy. The current percentage of adverse events reported by caregivers was similar to those reported by Vollú et al.[22] and Milgrom et al.[36]

The findings of this study regarding parental esthetics were similar to those of previous studies.[22,27,37] It is thought that SDF's advantageous qualities in stopping caries progression outweigh any drawbacks, such as dark staining.

Clinical efficacy is a necessary component of every successful treatment in pediatric dentistry. However, other factors must also be considered. Since ART and SDF treatments did not significantly differ in their short- and long-term success rates in this study, it may be concluded that SDF treatment is a better clinical alternative for stopping caries lesions. The relationship between the primary and secondary outcome results, and the operational and financial aspects of the available treatment alternatives, lends more credence to this conclusion. Furthermore, because UCT's short-term arrest rates were equivalent to those of SDF and ART, it is a great choice for young, uncooperative children or when the tooth is about to shed.

Limitations

One of the treatment protocols used, UCT, relied largely on parent cooperation, which may have affected the results.

Conclusion

After 3 months, the arrest rates of SDF, ART, and UCT were similar. However, after 1 year, the arrest rate of UCT was significantly lower than that of SDF and ART. Silver diamine fluoride requires much less chair time than ART and UCT and does not require the use of a dental instrument. The anxiety of children receiving SDF and UCT was significantly reduced compared to those receiving ART.

Clinical Significance

Compared to ART, SDF is less expensive, less operator-dependent, and takes almost half the treatment time. For these reasons, it should be chosen as the treatment option, especially in situations where access to therapy is somewhat difficult. When short-term success is needed, particularly in situations near the exfoliation time, UCT might be a possibility.

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