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Minimally invasive caries management using silver diamine fluoride compared to conventional restorative therapy in uncooperative pediatric patients: a randomized clinical study

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Abstract

AIM. The study compares the clinical efficacy of the 38% silver diamine fluoride method of administration with conventional resin-based composite restoration in arresting caries in primary molars of children with oral anxiety and recalcitrant behavior.

MATERIALS AND METHODS. This randomized controlled trial recruited 68 children aged 4 to 8 years, and at least one of the children had an active lesion of caries in the form of either an occlusal lesion or a proximal lesion on a primary molar. The participants were split into two groups for randomization, which would be given either the silver diamine fluoride application (after every six months) or a traditional restoration with rubber dam isolation and local anesthetics. The main goals were clinical caries arrest, measured by tactile and visual assessment of the caries at the ages of 6 and 12 months, and the duration of the therapy. To measure behavioral responses, the Frankl Behavior Rating Scale was used.

RESULTS. There is preliminary evidence that the silver diamine fluoride protocol demonstrates non-inferiority in caries arrest at 6 months, along with a significantly decreased treatment time and an increase in behavioral compliance compared to the conventional group.

CONCLUSIONS. The silver diamine fluoride protocol provides an excellent, clinically minimally invasive, and behaviorally controllable way to cope with caries in hard-to-treat child patients as an alternative to traditional restoration strategies.

Keywords: silver diamine fluoride, uncooperative pediatric patients, minimally invasive, caries management

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Минимально инвазивное лечение кариеса с использованием диаминфторида серебра по сравнению с традиционной реставрационной терапией у некооперативных пациентов детского возраста: рандомизированное клиническое исследование

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Резюме

ЦЕЛЬ. Сравнительная оценка клинической эффективности применения 38% диаминфторида серебра и традиционной реставрации композитными материалами в остановке кариозного процесса в молочных молярах у детей с выраженной стоматологической тревожностью и неконтролируемым поведением.

МАТЕРИАЛЫ И МЕТОДЫ. В рандомизированное контролируемое исследование включены 68 детей в возрасте от 4 до 8 лет, у каждого из которых имелось как минимум одно активное кариозное поражение (окклюзионное или проксимальное) в молочных молярах. Участники были рандомизированы в две группы: первая группа получала аппликации диаминфторида серебра (каждые 6 месяцев), во второй группе проводилось традиционное лечение с использованием композитных реставраций под

коффердамом и с применением местной анестезии. Основными конечными точками являлись остановка кариеса (оценка проводилась визуально и тактильно через 6 и 12 месяцев) и продолжительность лечения. Поведенческая реакция пациентов оценивалась с использованием шкалы Франкла.
РЕЗУЛЬТАТЫ. Полученные предварительные данные свидетельствуют о том, что протокол применения диаминфторида серебра не уступает традиционному методу по эффективности остановки кариеса через 6 месяцев, при этом характеризуется статистически значимым сокращением времени лечения и улучшением кооперации пациентов по сравнению с традиционной терапией.
ВЫВОДЫ. Применение диаминфторида серебра представляет собой эффективный, клинически обоснованный и минимально инвазивный метод лечения кариеса у трудно поддающихся лечению детей, обеспечивая высокий уровень поведенческого контроля и выступая альтернативой традиционным реставрационным подходам.

Ключевые слова: диаминфторид серебра, некооперативные пациенты детского возраста, минимально инвазивное лечение, лечение кариеса

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INTRODUCTION

The early childhood caries, often known as ECC, is a severe clinical condition that occurs in juvenile patients who are not compliant, where a treatment approach cannot be limited to technical effectiveness but may need to involve behavioral and comfort control [1]. Conventional restorative dentistry, which is viewed as a standard of comprehensive caries excision and dental restoration, requires local anesthesia, rotary instruments, and prolonged appointment times, which can cause severe anxiety and undesirable behavioral response [2]. This health problem frequently results in delays of treatment, the progression of disease, and the need to provide complex behavior control under the influence of sedation or general anesthesia, which subsequently raises the risk of associated risks, costs, and family strain [3].

Silver diamine fluoride (SDF) has re-emerged in this regard as an effective, minimally invasive treatment. The action mechanism is two-fold: silver ions have a potent antimicrobial effect and prevent matrix metalloproteinases by stabilizing collagen in the carious dentin, whereas fluoride promotes the remineralization of adjacent dental hard tissues [4]. Off-label use in the prevention of caries is also supported by a growing number of studies, including systematic reviews and clinical trials, and authorized by the US FDA to administer dentinal hypersensitivity [5–7].

The systematic analysis revealed that SDF is effective in the arrest of caries in primary teeth, which proves excellent success rates [8; 9]. However, direct comparisons with conventional restorations in a clearly defined, behaviorally problematic pediatric group, using rigid randomized controlled trial (RCT) methodology, are eminent [10]. These studies are needed to provide Level I evidence, which can aid in clinical decision-making, not only the efficacy of a specific study but also its efficiency and patient-centered outcome. This RCT aims at comparing the efficacy of SDF protocol to traditional resin-based restoration in terms of clinical efficacy of caries arrest, clinical factors prerequisite like length of treatment, behavioral compliance, and parent satisfaction.

MATERIALS AND METHODS

Design of the study and participants

The study was a prospective, parallel group, randomized controlled trial conducted over 18 months. All parents or guardians were obtained on informed written consent. Majority consent was sought in the case of children. Sixty-eight children were selected from the pediatric dentistry clinic of the Al-Hikma College University, Department of Dentistry.

The inclusion criteria include

1. Young children with a Physical Status Classification System American Society of Anesthesiologists I or II, with an age of 4 to 8 years.
2. Presence of at least one active, without cavity / or with moderate cavities (International Caries Detection and Assessment System [ICDAS] 3-5 scores) on an occlusal or proximal surface on a primary molar.
3. In the first screening appointment, a Frankl Behavior Rating Scale score of 2 (Negative) or 1 (Definitely Negative).

Criteria for exclusion

1. Recorded allergy to silver or other SDF components.
2. Pulpal involvement, spontaneous pain, fistula, abscess.
3. Children also possess certain health needs that would preclude their involvement with any part of the trial.
4. The restorability of the tooth cannot be done without a crown.

Sample size calculation

A priori power analysis was conducted using GPower software (Version 3.1.9.7) to calculate the sample size. Based on an anticipated caries arrest rate of 85% and 60% of the SDF and conventional restoration group, respectively, using a two-tailed test, alpha (α) of 0.05, and power ($1 - \beta$) of 0.80, the study concluded that a total of 68 participants (34 each group) is necessary.

Randomization and blinding

The randomization was done through computer-generated block randomization in 4 block size, and each participant was assigned to either one of the two treatment groups. The sequence of allocation was concealed in consecutively numbered, opaque, closed envelopes. The person in charge of the outcome measurements at 6 and 12 months did not know the assignments by the group.

Protocols for intervention

SDF Group: SDF solution was used after isolating the tooth using cotton rolls and air drying the tooth, after which a 38% solution of SDF (Advantage Arresttm, Elevate Oral Care) was micro-brushed on the lesion as recommended by the manufacturer. Using a cotton pellet, the surplus was removed. This was reiterated in the six-month follow-up.

Traditional Restoration Group: The treatment was done through local anesthetic and rubber dam isolation. A slow-speed bur was used to remove caries resin-based composite (Filtektm Z250, 3M) was applied with regard to the caries etching and bonding guidelines suggested by the manufacturer.

Outcome measures

Primary outcome: Caries arrest, having a hard and leathery surface or smooth surface after palping with a CPI probe and the absence of active caries (a soft, wet, and yellowish appearance).

Additional outcomes

Treatment duration: Measured in minutes from the start of the procedure (isolation in the case of SDF, administration of an anesthetic in the case of conventional restoration) to its completion.

Behavioral compliance: Measured with the help of the Frankl Behavior Rating Scale at the preoperative and postoperative stages.

Parental satisfaction: Measured on a 5-point Likert scale questionnaire.

Statistical analysis

The data were statistically analyzed using SPSS Statistics (Version 28.0, IBM Corp., Armonk, NY, USA).

RESULTS

The Shapiro-Wilk test was employed to assess the normality of the distribution of the continuous data. Means ± standard deviation (SD) was employed to represent continuous normally distributed data, while medians with interquartile ranges (IQR) were utilized for non-normally distributed data, and frequencies and percentages (%) were used for categorical variables. Independent Samples T-tests were utilized to assess baseline homogeneity regarding age and dmft index, whereas Chi-square testing was employed for gender, Frankl score, International Caries Detection and Assessment System (ICDAS) score, and lesion site. The primary outcome, the ratio of caries arrest (a dichotomous variable: yes/no), was compared among the groups at 6- and 12-months follow-up using Chi-square testing. To evaluate the secondary outcomes, an Independent Samples T-test was employed to compare the mean treatment duration between the groups, while the ordinal ratings were assessed using the Mann-Whitney U test to quantify parental satisfaction levels. The disparity in pre- and post-operative Frankl behavior scores was evaluated using the Wilcoxon signed-rank test, while the variation in the percentage of patients displaying positive behavior (Frankl 3) post-operation was analyzed through a Chi-square test. All tests were deemed significant at a *p*-value of less than 0.05, which was essential. The primary outcome was evaluated using an intention-to-treat (ITT) approach to preserve the integrity of the initial randomization.

Table 1. Fundamental characteristics of the study subjects

Таблица 1. Основные характеристики участников исследования

Characteristic	SDF group (*n* = 34)	Conventional restoration group (*n* = 34)	*p*-value
Age (Mean ± SD)	5.7 ± 1.2	5.9 ± 1.0	0.45
Gender (%)			
Male	18 (52.9)	17 (50.0)	0.81
Female	16 (47.1)	17 (50.0)	
Frankl score, *n* (%)			
1 (Definitely negative)	14 (41.2)	15 (44.1)	0.92
2 (Negative)	20 (58.8)	19 (55.9)	
dmft index (Mean ± SD)	3.5 ± 1.6	3.7 ± 1.4	0.58
Target tooth ICDAS, *n* (%)			
3	12 (35.3)	14 (41.2)	0.78
4	15 (44.1)	13 (38.2)	
5	7 (20.6)	7 (20.6)	
Lesion location, *n* (%)			
Occlusal	19 (55.9)	21 (61.8)	0.65
Proximal	15 (44.1)	13 (38.2)	

Table 2. Rates of caries arrests at 6 months and 12 months

Таблица 2. Частота остановки кариеса через 6 и 12 месяцев

Group	6-month arrest *n* / *N* (%)	12-month arrest *n* / *N* (%)
SDF	31 / 34 (91.2%)	30 / 34 (88.2%)
Conventional restoration	30 / 34 (88.2%)	27 / 32 (84.4%)
p-value	0.71	0.74

Table 3. Secondary outcomes: duration of treatment and behavior

Таблица 3. Вторичные исходы: продолжительность лечения и поведенческие реакции пациентов

Outcome measure	SDF group (*n* = 34)	Conventional restoration group (*n* = 34)	*p*-value
Treatment time, min (Mean ± SD)	4.2 ± 1.1	27.5 ± 6.8	< 0.001
Post-op Frankl score ⩾ 3, *n* (%)	28 (82.4%)	12 (35.3%)	< 0.01
Parental satisfaction (Mean ± SD)	4.7 ± 0.5	3.8 ± 0.9	< 0.01

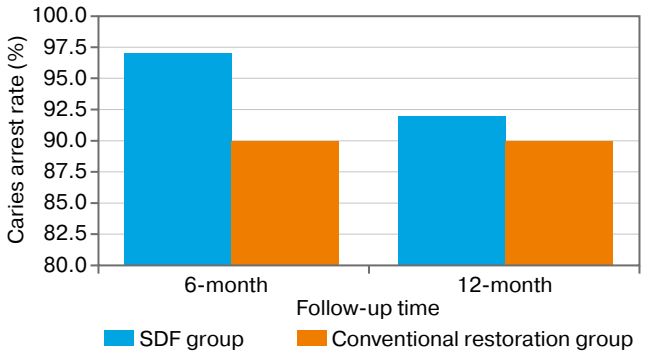

Fig. 1. Caries arrest rates over time

Рис. 1. Динамика частоты остановки кариеса во времени

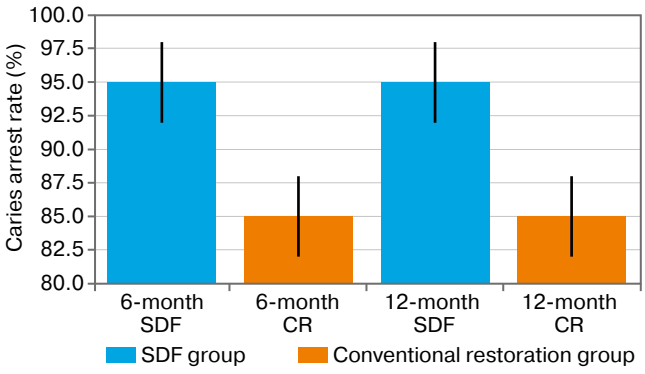

Fig. 2. Caries arrest rates at 6 and 12 months

Рис. 2. Частота остановки кариеса через 6 и 12 месяцев

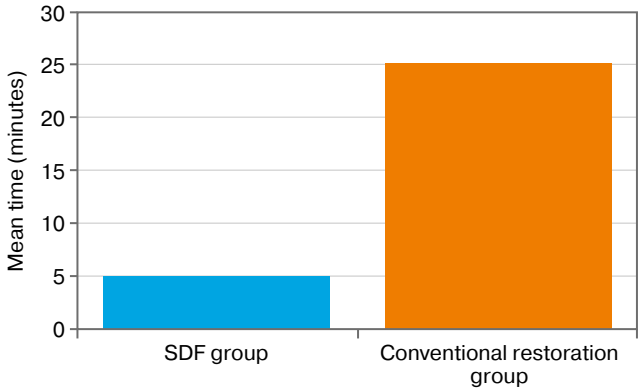

Fig. 3. Mean treatment time per procedure ($p < 0.001$)

Рис. 3. Средняя продолжительность лечения на одну процедуру ($p < 0.001$)

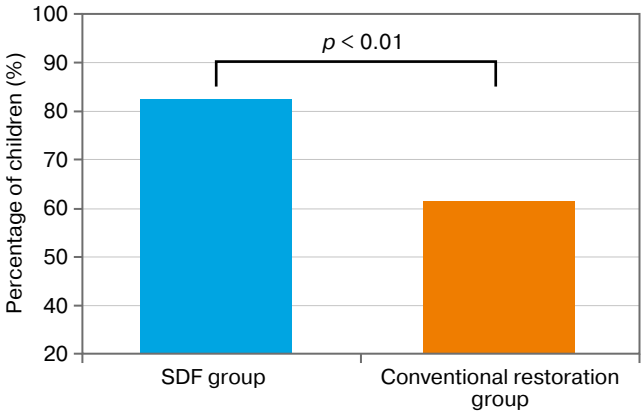

Fig. 4. Post-operative behavioral compliance (Frankl score ⩾ 3)

Рис. 4. Послеоперационная кооперация пациентов (оценка по шкале Франкла ⩾ 3)

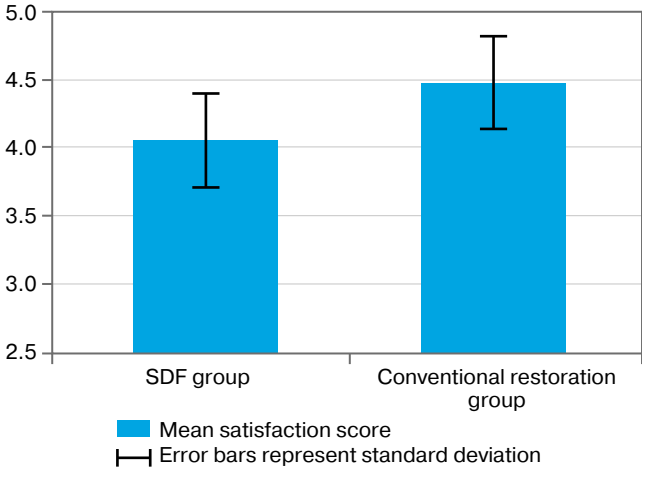

Fig. 5. Parental satisfaction scores (5-point likert scale)

Рис. 5. Уровень удовлетворенности родителей (по 5-балльной шкале Лайкерта)

DISCUSSION

The randomized controlled experiment demonstrates that a semi-annual 38% SDF regimen is not inferior in clinical outcomes to conventional resin composite repar in halting the cavitated caries in the primary molars of hard-to-treat children over a time span of 12 months. Caries' arrest rates of 91.2 at 6 months and 88.2 at 12 months documented using SDF are in line with those of earlier systematic reviews and meta-analyses. A comprehensive meta-analysis by Chibinski et al. [8] reported a caries arrest of 89% in primary teeth with SDF used in a pooled analysis. Another trial indicated that the percentage of arrested lesions increased as the duration of SDF treatment increased [11].

The slightly increased rate of arrests identified by our study could be attributed to the stringent case selection criteria, which only selected non-pulpally involved lesions [ICDAS 3-5] against a controlled clinical environment with a standardized application methodology.

There is extensive literature on the biological explanation of the success of this clinical outcome. The process involves dual action, synergistic, with silver ions showing considerable antimicrobial characteristics through the damage of bacterial cell walls and inhibition of enzymes, in addition to repairing the collagen matrix in carious dentin through the inhibition of matrix metalloproteinases [4; 12]. This is improved by the role of fluoride that aids the remineralization of the surrounding tooth hard materials. It is a complicated process that makes SDF stand out of the conventional restorations which primarily address the consequences of caries by removing them mechanically and replacing them with teeth without providing sustained antimicrobial coverage.

The most remarkable point of this study is that the treatment duration differs considerably with SDF administration requiring nearly 85% of the chair time than the traditional restoration techniques. The given corroborates the work of other authors, who reported similar efficiency gains in school-based caries management programs [13]. This logistical benefit is particularly relevant in pediatric dentistry, with the shorter treatment time being directly correlated with improved teamwork, as well as reduced problems with behavioural management [3]. The effectiveness of the SDF use enables physicians to treat multiple lesions during one brief visit, which could potentially transform the practice of clinical settings in a private and health care setting.

From a behavioral perspective, the SDF protocol was distinctly superior. The significant difference between the number of positive ratings of Frankl in the SDF (82.4) and the controls (35.3) has a great impact on avoiding local anesthetic injections and rotary instruments. The finding develops the study by Crystal et al., who highlighted the particular advantages of SDF among patients with oral anxiety or with outstanding healthcare needs [6]. Such high scores of parental satisfaction also testify to the alignment of SDF with the contemporary models of family-centered care, in which the patient distress minimization is a primary goal [1].

The long-term effectiveness of SDF after the second application of 12 months, when it is compared with the current knowledge, supports the idea of SDF as a disease management approach, but not a single intervention [14]. This is as opposed to traditional restorations that showed a statistically insignificant, but slight decline in success rates over the same period, perhaps suggesting the possibility of marginal degradation or secondary caries with all the restorative techniques. The universal appearance of black staining in treated lesions with SDF is a critical consideration, which is supported by the results in the whole body of SDF literature [6; 15]. Such a cosmetic trade-off should be thoroughly informed by a conversation with parents and caregivers, particularly concerning anterior teeth.

There are many limitations that require investigation. The 12-month follow-up period, despite being informative in terms of early efficacy, is not sufficient to evaluate long-term outcomes and whether retreat treatment may be required. Further, the unique staining did not allow blinding of the participants and their parents but allowed the outcome assessors to be blinded. The research on the long-term effects, the optimal intervals of reuse, and the means of minimizing the staining but maintaining its effectiveness should be considered in the future.

CONCLUSION

The findings of this randomized controlled trial suggest that a 38% SDF regimen does not clinically differ from the conventional resin-based restoration in halting caries lesions that have affected primary molars in a group of recalcitrant juvenile patients over 12 months. Besides similar efficacy in caries arrest, the SDF approach offers a lot of advantages in clinical and behavioral, and parental approval. The significantly reduced duration of treatment, patient compliance, and parental satisfaction make SDF an industry-changing minimally invasive procedure in the treatment of early childhood caries in challenging clinical conditions. Even though conventional restoration is considered a standard of the conclusive restoration of the teeth, SDF indicates a revolutionary model in the treatment of caries with the dominant focus on disease control, comfort of the patient, and efficiency. It has been firmly recommended that this be incorporated into the routine equipment used in the provision of dental care to juveniles, particularly where cases are behavioral in nature, and complicate the process of restorations due to logistical problems or resource constraints. The focus of future study should be on the long-term outcomes, the application techniques, and how to overcome aesthetic problems of treatment.

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AUTHOR'S CONTRIBUTION

All the authors made equal contributions to the publication preparation in terms of the idea and design of the article; data collection; critical revision of the article in terms of significant intellectual content and final approval of the version of the article for publication.

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