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CLINICAL EFFECTIVENESS OF SDF COMPARED TO RESTORATIVE APPROACH FOR THE TREATMENT OF EARLY CHILDHOOD CARIES: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: This study aimed to assess the impact of the caries arrest technique using silver diamine fluoride or the conventional drill and fill technique with composite filling in children suffering from early childhood caries on clinical failure rates, postoperative pain, and duration of treatment.

Methods: The study included 40 children aged three to six with early childhood caries. They were divided randomly into two groups: one receiving treatment using the silver diamine fluoride caries arrest technique and the other receiving conventional drill and fill treatment. Clinical failure was categorized as no, minor, or major failure at three and six months. The Wong-Baker Faces rating scale was utilized to assess postoperative pain at three and six months, and a stopwatch was employed to measure the duration of the treatment. Data were analyzed using the chi-square test for categorical data and the independent t-test for continuous data.

Results: In both groups, all participants reported no failure three and six months after treatment. All the participants reported no pain at three and six months. The mean and standard deviation for the procedure duration in minutes was 4.66 (0.84) for the silver diamine fluoride group and 12.7 (0.11) for the composite group. A statistically significant difference was found between the two groups, with a p-value of 0.0001.

Conclusion: both the treatment modalities showed similar clinical effectiveness with no failures or pain reported, while the silver diamine fluoride application was faster.

KEYWORDS: silver diamine fluoride, early childhood caries, clinical effectiveness, failure, postoperative pain.

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INTRODUCTION

Dental caries is the most common childhood disease globally, affecting individuals of all ages, especially in low-income countries [1]. The global burden of this disease is estimated that 532 million children's primary teeth have untreated caries [2]. Restorative management of early childhood caries (ECC) in young children is time-consuming due to their lack of cooperation and lengthy procedures. One alternative method is to use silver diamine fluoride (SDF), which is effective in arresting the progression of carious lesions, both cavitated and non-cavitated. SDF is easy to apply, even outside dental offices, and represents a relatively inexpensive treatment modality, especially when compared to restorative interventions [3,4].

SDF is a clear liquid that contains ammonia, fluoride, and silver. It combines the remineralizing properties of fluoride with the antimicrobial properties of silver, aiding in caries arrest [5]. Based on available data quality, the American Academy of Pediatric Dentistry (AAPD) recommends using 38% SDF to treat cavities in primary teeth [6]. SDF is favored for its quick application, cost-effectiveness, and non-invasive approach to treating ECC in children[7]. While no toxicity or adverse events have been observed, the benefits of SDF generally outweigh its drawbacks, such as the dark staining of treated teeth [3].

A new proposed method addresses tooth discoloration caused by SDF by applying a layer of potassium iodide (KI) over the initial layer of SDF. When combined with the free silver ions in SDF, KI prevents the formation of silver phosphate and the subsequent tooth discoloration. Research has demonstrated that using KI after SDF treatment leads to the forming of a yellow silver iodide precipitate, which stops discoloration from worsening[8–10]. Detsomboonrat and colleagues observed a significant and immediate reduction in discoloration after applying KI in a dose-dependent manner [11]. The conventional drill-and-fill technique is considered one of the most common restorative approaches to treating ECC in primary teeth in pediatric dental clinics. However, an overview of systematic reviews found that there is low evidence of the effectiveness of non-operative approaches compared to restorative approaches [12]. Therefore, this study aims to assess the clinical effectiveness of SDF compared to the conventional drill and fill technique in treating early childhood caries in children.

MATERIAL AND METHODS

Sample size

The sample size was determined using a prior study as a guide [13]. This study found that each subject group's response was generally distributed with a standard deviation of 6. To reject the null hypothesis, which states that there is a 0.8 probability of equality between the population means of the experimental and control groups, the study required a minimum of 16 subjects in each group if the genuine difference between the means of the experimental and control groups is 6.2. For this test of the null hypothesis, the Type I error probability is 0.05. To account for 20% dropout, the total sample size was increased to 20 patients in each group.

Randomization and blinding

Allocation sequence generation was accomplished using simple randomization with computer-generated random numbers from the Random.org website. Allocation concealment was achieved through sequentially numbered opaque sealed envelopes containing a folded piece of paper indicating the type of intervention the patient would receive. Due to the nature of the intervention, the parents and the operator were not blinded; only the statistician was blinded.

Trial design

The study follows a parallel-arm, randomized clinical trial design based on a superiority framework with a 1:1 allocation ratio. This protocol is registered at clinicaltrials.gov under the trial identifier NCT05337449. The Research Ethics Committee at the Faculty of Dentistry, Cairo University, approved the trial protocol on September 27, 2022, with approval number #22/9/22.

Participants

The study was conducted in the Pediatric Dentistry and Dental Public Health Department outpatient clinic at the Faculty of Dentistry, Cairo University, Egypt. The eligible participants were children aged three to six years with ECC and at least one primary molar with a simple occlusal carious lesion class I identified by the International Caries Detection and Assessment System (ICDAS) as code 3 or 4 [14]. The participants were healthy, free from chronic diseases, and cooperative, showing normal radiographic findings. Children with deep carious lesions nearing the pulp with ICDAS codes of 5 or 6 who were unable to attend follow-up visits or whose parents refused to participate were excluded from the trial. All eligible participants had their guardians sign a written informed consent, and verbal consent was obtained from the child before the trial began.

Interventions

After enrollment and before starting the trial, all children underwent a comprehensive clinical and radiographic examination, and baseline information, including personal details, medical history, and dental history, was recorded in a dental chart. The clinical examination confirmed the participants' eligibility. Forty pediatric patients with 40 carious primary molars were deemed eligible and enrolled in the study. The patients were randomly assigned to two groups of 20 for either SDF for the caries arrest technique or the conventional drill and fill technique using composite resin restoration.

For the SDF group, the affected tooth was isolated with cotton rolls after petroleum jelly was applied to the lips to avoid irritation or pigmentation. The occlusal surface of the tooth was gently dried by air, and then the 38% SDF (RIVA STAR AQUA step 1, SDI) was applied using a bond brush directly over the affected surface. Cotton pellets were used to remove any excess, and the SDF was let to settle for a minute. Potassium iodide (RIVA STAR AQUA step 2, SDI) was applied repeatedly after SDF until no white perception was seen.

For the conventional drill and fill technique, the mucosa of the affected tooth was dried using a cotton pellet, followed by two minutes of application of topical anesthesia gel (Dr. Numb 16%). Mepivacaine Local anesthesia with Levonordefrin 1:20,000 (Septodont, Scandonest 2%) was administered using an infiltration technique on the affected side. After rubber dam isolation, standard cavity preparation was achieved with a sterile round diamond bur in a highspeed handpiece with copious coolant. After selective enamel etching with 37% phosphoric acid (Meta Etchant, Meta Biomed), a universal adhesive (Nova Compo B plus, IMICRYL) was applied in the cavity and light cured for 20 seconds. A nano-filled composite (3M Filtek Z350 XT) using the incremental placement technique was used to restore the cavity following the manufacturer's instructions. After finishing and polishing the restoration, the rubber dam was removed and occlusion checked.

The patients and their parents were given oral hygiene measures and instructed that any gingival discomfort would generally resolve within 24 hours. All patients were followed up for 36 months.

Outcomes

Primary outcome measures assessed at each follow-up visit were clinical failure rates: minor and major failure according to the definition by Santamaria and colleagues shown in Table 1 [15]. Clinical failure rates were assessed at three and six months.

TABLE (1) Definitions of clinical major and minor failures.

	SDF	Restorative approach
No failure	• Caries arrested: dentin feels hard to explorer • No clinical signs or symptoms of pulpal pathology • Tooth exfoliated without major or minor failure	• Restoration appears satisfactory • No clinical signs or symptoms of pulpal pathology • Tooth exfoliated without major or minor failure
Minor failure	• Caries progression: soft dentin, increase in lesion size clinically or radiographically • Reversible pulpitis to be treated without pulpotomy or extraction	• Secondary caries • Restoration of fracture or wear requiring repair • Loss of restoration • Reversible pulpitis to be treated without pulpotomy or extraction
Major failure	• Pulpitis requiring pulpotomy or extraction • Abscess formation • Caries progress to the extent that tooth is unrestorable	• Pulpitis requiring pulpotomy or extraction • Abscess formation • Restoration loss leaving tooth unrestorable.

Secondary outcomes included the time of the procedure, measured in minutes by a stopwatch, and postoperative pain, measured by the Wong-Baker Faces pain scale. The child selected which face represented the pain they felt. The pain scale ranged from 0 (no hurt) to 10 (hurts worst) [16]. Postoperative pain was assessed at three and six months.

Statistical methods

All study variables were collected, coded, and analyzed using the Statistical Package for the Social Sciences (SPSS Version 23, Inc., Chicago, IL). Categorical data were summarized using proportions and percentages, and continuous data were summarized using means and standard deviations. The level of statistical significance was set at 5%. The chi-square test was applied to compare proportions among groups, while the independent t-test was used to compare mean values between groups.

RESULTS

Forty children with 40 primary molars were enrolled in the study and randomly divided into two equal groups of 20 each. Table 2 shows the participants' age, gender, and tooth distribution. Figure 1 shows the flow of the participants through the study. All the patients completed the follow-up period with no dropouts. The distribution of participating teeth differs between the groups, but no single tooth type shows a statistically non-significant difference (p=0.29 overall). The most common tooth in the SDF group is the lower right E at 35%, while in the composite group, the lower left E is most frequent at 25%

Regarding clinical failure rates, no patients reported failures during the follow-up periods at three and six months, and no patients indicated experiencing pain at those time points. The mean and standard deviation for the procedure duration in minutes were 4.66 (0.84) for the SDF group and 12.7 (0.11) for the composite group. A statistically significant difference was found between the two groups, with a p-value of 0.0001.

TABLE (2) Demographics of the participants.

Variables		Composite	SDF	P value
Age (Mean and SD)		4.70 ± 0.66	4.95 ± 0.69	0.24 ns
Gender		Male 6 (30%)	Male 4 (20%)	0.46 ns
		Female 14 (70%)	Female 16 (80%)	
Tooth location	Upper right D	3	2	0.29 ns
	Upper left D	1	0	
	Upper left E	2	6	
	Lower left D	3	1	
	Lower left E	5	3	
	Lower right D	3	1	
	Lower right E	3	7	

Ns: non-significant difference, SD: standard deviation.

DISCUSSION

Preventive measures for ECC include daily brushing with age-appropriate fluoridated toothpaste, professional topical fluoride varnish, and dietary modifications. While these strategies are the foundation of ECC prevention, non-invasive interventions offer additional benefits for high-risk children. One promising tool is SDF, which has antibacterial properties that stop the progression of cavities and can aid in diagnosis by staining softened dentin. Unlike traditional fillings, SDF is minimally invasive and helps to halt cavity progression through its antibacterial properties and promote the remineralization of tooth enamel. These characteristics make SDF a valuable option for managing ECC in young children [17,18].

Few studies directly compare ECC treatments with SDF and composite restorations. This knowledge gap makes identifying the best intervention for each situation challenging. Therefore, the current study aims to assess the clinical effectiveness of SDF compared to the drill-and-fill technique for treating ECC in children.

Clinical effectiveness of SDF (as arresting caries technique) and Composite (as drill and fill technique) could be measured using well-defined minor and major failure criteria as in previous trials [15,19]. This distinction allows researchers to distinguish between cases requiring additional SDF application or composite restoration (minor failures) and those progressing to pulp involvement and requiring advanced treatment (major failures). Implementing these criteria strengthens the evaluation's objectivity and interpretability, ultimately providing more precise insights into intervention efficacy for cavity management and informing future clinical recommendations.

Regarding pain and sensitivity after treatment, VAS is a valuable tool for measuring those parameters directly from children. Unlike multiple-choice scales, VAS offers a continuous line where children mark their discomfort level, providing a more precise assessment. Its simplicity and ease of use make it ideal for young children and those with limited communication skills, encouraging researchers to select it [20,21].

Regarding the clinical effectiveness related to minor and major failures in both groups over various time intervals, our study results indicated no clinical failures among all participants. This can be explained by our sample comprising individuals with ICDAS scores of 3 and 4 during the six-month

follow-up period. A study by Mabangkhru and colleagues [22] evaluated the longevity and clinical efficacy of 38% SDF and 5% NaF. After a 12-month follow-up, they concluded that the SDF group showed no clinical complications and demonstrated its effectiveness in arresting caries in young children. These findings support our results. Another study by Gao and colleagues [23] compared the effectiveness of SDF and silver nitrate application. The children received semiannual applications of both materials, with assessment occurring every 6 to 30 months. The study reported greater clinical effectiveness of SDF over the other material and recommended it as a non-invasive and cost-effective strategy for halting caries. These findings are consistent with our results.

The recorded procedure times for both groups showed a significant difference in favor of SDF. In the composite group, the time was 12.70 ± 0.11 minutes, while in SDF, it was 4.66 ± 0.84 minutes. This difference can be attributed to the SDF procedure requiring no anesthesia, rubber dam for isolation, curing time, or even incremental application. Therefore, it is a simple, easy, rapid, and pain-free technique that children highly accept. Similar to our study, several studies reported that the average range of application is from 1 to 3 minutes [19,24,25]. This range may expand based on the child's degree of cooperation, the clinician's capacity for working under pressure, and the isolation technique used, whether a rubber dam or cotton roll. All the previous factors affect the time of SDF application.

The child directly assessed post-operative pain; however, no patient in either group reported these issues. A visual analog scale was used, an easy and reliable tool for children with limited communication ability to express their feelings. This may be due to the composite material's sealing ability to the tooth defect and the SDF's obliteration of the dentinal tubules, an effective treatment for hypersensitivity [26]. Similarly to our results, Abdulfattah and colleagues [27] evaluated post-operative pain after SDF treatment, with follow-ups at 3 and 6 months. Patients were assessed using the VAS scale and through radiographic evaluation. Like in our study, the group treated with SDF reported no post-treatment pain or complications.

A study conducted by Alhosaini and colleagues [28] evaluated the post-operative pain resulting from SDF treatment compared to the Hall technique. Pain was assessed using a visual analog scale, and the Face Pain Scale-Revised (FPS-R) was utilized. They evaluated pain after 1 day, 2 days, one week, two weeks, one month, and eventually at a 6-month follow-up. They concluded that about 75% of participants experienced no post-operative pain. In comparison, 25% reported intermittent pain, which stemmed from the extensive caries present in the children who participated rather than from straightforward cases. These results contradict our findings.

CONCLUSIONS

Both treatment modalities demonstrated similar clinical effectiveness with no reported failures after six months. Silver diamine application is faster and easier than composite restorative treatment, which could be a promising alternative in cases where time is a factor.

REFERENCES

1. Bernabé E, Marcenes W. Can minimal intervention dentistry help in tackling the global burden of untreated dental caries? Br Dent J. 2020 Oct 1;229(7):487–91.
2. Qin XF, Zi H, Zeng XJ. Changes in the global burden of untreated dental caries from 1990 to 2019: A systematic analysis for the Global Burden of Disease study. Heliyon. 2022 Sep 1;8(9).
3. BaniHani A, Duggal M, Toumba J, Deery C. Outcomes of the conventional and biological treatment approaches for the management of caries in the primary dentition. Int J Paediatr Dent. 2018 Jan 1;28(1):12–22.
4. Sabbagh H, Othman M, Khogeer L, Al-Harbi H, Al Harthi A, Abdulgader Yaseen Abdulgader A. Parental acceptance of silver Diamine fluoride application on primary dentition: a systematic review and meta-analysis. BMC Oral Health. 2020 Aug 20;20(1).
5. Mei ML, Lo ECM, Chu CH. Arresting Dentine Caries with Silver Diamine Fluoride: What's Behind It? J Dent Res. 2018 Jul 1;97(7):751–8.

6. American Academy of Pediatric Dentistry. Policy on the Use of Silver Diamine Fluoride for Pediatric Dental Patients. In: American Academy of Pediatric Dentistry, editor. The Reference Manual of Pediatric Dentistry. III. Chicago; 2023. p. 103–5.
7. Crystal YO, Niederman R. Evidence-Based Dentistry Update on Silver Diamine Fluoride. Dent Clin North Am. 2019 Jan 1;63(1):45–68.
8. Nguyen V, Neill C, Felsenfeld J, Primus C. Potassium Iodide. The Solution to Silver Diamine Fluoride Discoloration? Advances in Dentistry & Oral Health. 2017 Jun 15;5(1).
9. Zhao IS, Mei ML, Burrow MF, Lo ECM, Chu CH. Effect of Silver Diamine Fluoride and Potassium Iodide Treatment on Secondary Caries Prevention and Tooth Discolouration in Cervical Glass Ionomer Cement Restoration. Int J Mol Sci. 2017 Feb 6;18(2).
10. Knight GM, McIntyre JM, Mulyani. The effect of silver fluoride and potassium iodide on the bond strength of auto cure glass ionomer cement to dentine. Aust Dent J. 2006;51(1):42–5.
11. Detsomboonrat P, Thongmak P, Lertpayab P, Aiemsri W, Sooampon S. Optimal concentration of potassium iodide to reduce the black staining of silver diamine fluoride. J Dent Sci. 2022 Jan 1;17(1):300–7.
12. Schmoeckel J, Gorseta K, Splieth CH, Juric H. How to Intervene in the Caries Process: Early Childhood Caries - A Systematic Review. Caries Res. 2020 Aug 1;54(2):102–12.
13. Duangthip D, Gao SS, Chen KJ, Lo ECM, Chu CH. Oral health-related quality of life of preschool children receiving silver diamine fluoride therapy: A prospective 6-month study. J Dent. 2019 Feb 1;81:27–32.
14. Gugnani N, Pandit I, Srivastava N, Gupta M, Sharma M. International Caries Detection and Assessment System (ICDAS): A New Concept. Int J Clin Pediatr Dent. 2011 Aug;4(2):93.
15. Santamaría RM, Innes NPT, Machiulskiene V, Schmoeckel J, Alkilzy M, Splieth CH. Alternative Caries Management Options for Primary Molars: 2.5-Year Outcomes of a Randomised Clinical Trial. Caries Res. 2018 Jan 4;51(6):605–14.
16. Garra G, Singer AJ, Taira BR, Chohan J, Cardoz H, Chisena E, et al. Validation of the Wong-Baker FACES Pain Rating Scale in pediatric emergency department patients. Acad Emerg Med. 2010 Jan;17(1):50–4.
17. Corrêa-Faria P, Daher A, Freire M do CM, de Abreu MHNG, Bönecker M, Costa LR. Impact of untreated dental caries severity on the quality of life of preschool children and their families: a cross-sectional study. Qual Life Res. 2018 Dec 1;27(12):3191–8.
18. 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 1;29(3):238–48.
19. Cleary J, Al-Hadidi R, Scully A, Yahn W, Zaid Z, Boynton JR, et al. A 12-Month Randomized Clinical Trial of 38% SDF vs. Restorative Treatment. JDR Clin Trans Res. 2022 Apr 1;7(2):135–44.
20. Dourado GB, Volpato GH, de Almeida-Pedrin RR, Pedron Oltramari PV, Freire Fernandes TM, de Castro Ferreira Conti AC. Likert scale vs visual analog scale for assessing facial pleasantness. Am J Orthod Dentofacial Orthop. 2021 Dec 1;160(6):844–52.
21. Yang J, Jia P, Qiu L, Lu C, Jiang T. [Feasibility analysis of visual analogue scale in esthetic evaluation of anterior implant-supported single crown in maxilla]. Zhonghua Kou Qiang Yi Xue Za Zhi. 2021 Apr 1;56(4):324–8.
22. Mabangkhru S, Duangthip D, Chu CH, Phonghanyudh A, Jirarattanasopha V. A randomized clinical trial to arrest dentin caries in young children using silver diamine fluoride. J Dent. 2020 Aug 1;99.
23. Gao SS, Chen KJ, Duangthip D, Wong MCM, Lo ECM, Chu CH. Preventing early childhood caries with silver diamine fluoride: study protocol for a randomised clinical trial. Trials. 2020 Feb 4;21(1).
24. Young DA, Quock RL, Horst J, Kaur R, MacLean JK, Frachella JC, et al. Clinical Instructions for Using Silver Diamine Fluoride (SDF) in Dental Caries Management. Compend Contin Educ Dent. 2021 Jun;42(6):e5–9.
25. Yan IG, Zheng FM, Gao SS, Duangthip D, Lo ECM, Chu CH. A Review of the Protocol of SDF Therapy for Arresting Caries. Int Dent J. 2022 Oct 1;72(5):579–88.
26. Peng JJY, Botelho MG, Matinlinna JP. Silver compounds used in dentistry for caries management: a review. J Dent. 2012 Jul;40(7):531–41.
27. Abdulfattah MM, Mahmoud SA, Abdel S, Moniem A. Post-operative pain after 38% silver diamine fluoride application in primary molars with deep caries versus interim restorative therapy: A randomized pilot study. International Journal of Applied Dental Sciences. 2021 Jan 1;7(1):358–62.
28. Alhosaini NM, Bahgat S, ElKhadem A. Postoperative Pain After Treatment With Hall Technique Versus Silver Diamine Fluoride in the Management of Carious Primary Molars: A Randomized Clinical Trial. NeuroQuantology. 2023;21(6).