Original Research Paper

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Clinical Success of Art Approach In 38% SDF Treated Vs Untreated Dentine Caries Lesions in Primary Molars: A Split Mouth Randomized Clinical Trial

Abstract:

Objective: The aim of the study was to assess, compare and evaluate the success rates of restoring untreated and SDF-treated dentine caries lesions in primary molar teeth with atraumatic restorative treatment (ART) approach.

Methodology: 46 participants, within the age group of 4-8 years who fulfilled the inclusion criteria were selected for the trial. They were randomly assigned to 2 groups. Group A received GIC restoration on SDF-treated dentine caries with ART approach on one of the primary molars and Group B received GIC restoration on SDF untreated dentine caries with ART approach on contralateral primary molar. ART evaluation criteria was used for clinical evaluation of the restorations at baseline, 6 months and 12 months.

Results: Chi square test did not report any statistically significant difference between the groups ($p>0.05$). Chi square test and Wilcoxon signed rank test did not report any statistically significant difference between the success rates at 6 month and 12 month follow up for both the groups.

Interpretation and Conclusion: The clinical success of restoring SDF-treated and SDF-untreated dentine caries lesions in primary molar teeth with ART approach was 84.7% and 87% respectively, at 12 month follow up,there is no intergroup and intragroup statistical significant difference. Hence, using SDF with ART offers an efficient and economical way for management of caries in young highly anxious children and in community programmes. Even in cases of ART restoration failure, the treatment may still be deemed successful, as SDF effectively arrests caries progression and supports remineralization of the affected tooth structure.

Keywords: Silver Diamine Fluoride, Minimal Invasive Dentistry, Atraumatic Restorative Treatment, Glass ionomer cement.

Introduction:

Dental caries is a bacterial driven, chronic, site-specific, multifactorial, dynamic disease process that results from imbalance in the physiologic equilibrium between tooth mineral and plaque fluid.[1] The impact of dental caries is not limited to oral symptoms, but detrimentally influences on the quality of life too.[2] Hence poor nutritional health,[3] poor child growth and low weight gain[4,5] compared to caries-free controls.

Children's cooperation during dental treatment is typically very challenging, requiring extensive skills in addition to the high cost of general anesthesia or sedation for management. According to available data, deep carious lesions may not require removal of all infected dentin as long as a well-sealed restoration is placed.[6] The modern approaches, aim to preserve the natural tooth structure lead to establishment of minimal-invasive treatment (MIT) strategies which adopts a concept that utilizes prevention, remineralization and minimal intervention for the purpose of placement and replacement of restorations.[7] Among the various MIT strategies, silver diamine fluoride and atraumatic restorative treatment are commonly used in children.

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Silver diamine fluoride (SDF) acts by releasing fluoride and silver ions following application to the caries-affected tissue forming fluorohydroxyapatite.[8] The American Academy of Paediatric Dentistry (AAPD) advocates for the application of 38% silver diamine fluoride (SDF) twice a year[9], citing success rate of 84.8% in arresting caries and cavitated lesions in primary teeth.[10] This treatment is cost-effective[11] and can be administered without the need for infected soft dentin removal.[12] Additionally, SDF serves as a viable alternative for patients with severe dental anxiety, uncooperative and medically compromised individuals who may otherwise require general anesthesia for dental treatment.[13]

Clinically, the application of SDF results in a persistent black staining of the dentin and carious enamel, which is frequently seen as the biggest obstacle to parental acceptance.[14] Furthermore, application of SDF can only arrest the progress of dental caries.

Atraumatic restorative treatment (ART), one of the most known MIT involves caries removal through the use of hand instruments, followed by restoration with highly viscous glass ionomer cement (GIC), which provides chemical adhesion to tooth surface, fluoride release and biocompatibility.[15] Despite using this approach, sometimes it is still difficult to obtain good cooperation from young children.

Using SDF for young children with caries is practical, allowing later restoration for aesthetics and morphology. Due to limited in vivo studies, it is important to assess whether prior SDF affects ART restoration success before adopting this two-step approach.

Materials and Methodology:

This split mouth clinical trial was conducted in Department of Pediatric Dentistry, Government Dental College and Research Institute Bengaluru. Ethical approval was obtained by the institutional ethical committee via **GDCRI/IEC-ACM(2)/12/2022-23.** The study was adhered to Consolidated Standards of Reporting Trials (CONSORT) guidelines (registration number: CTRI/2023/03/050781). The trial was conducted from September 2022 to February 2024 over a duration of 18 months. Informed consent was taken from parents or guardians.

Sample Size Calculation:

The sample size for the research study was calculated based on previous literature incorporating Type I error (5%), Type II error (10%), and expected clinical success rates in two groups. The calculations determined that 41.5 restoration per group were needed, which was increased by 10% to account for potential dropouts, resulting in 46 restorations per group. Therefore, the total sample size for the study was set at 92 (46 participants) to ensure adequate power and compensate for any potential response errors.

Selection Criteria:

The selection of the patients was done according to the inclusion and exclusion criteria. The subjects who fulfilled the following criteria were enrolled in the study

Inclusion Criteria:

Children aged 4–8 years with cooperative behaviour (Frankel score 3 or 4) presenting with asymptomatic bilateral carious primary molars and no significant medical history were included. Parents were informed about the procedure's risks and benefits, and written consent was obtained. No child was excluded based on gender, race, social, or economic status.

Exclusion Criteria:

Children who suffered from serious systemic disease/conditions, tooth with pulpal involvement/pathology as evident by clinical and radiographic examination, caries lesions which were too small for hand instruments to prepare the cavity for a restoration and primary molars near exfoliation were excluded from the study.

Randomization and Allocation:

A split-mouth design was used in which all patients received 38% SDF followed by ART (Group A, experimental) on one primary molar and ART alone (Group B, control) on the contralateral molar, with sides randomly assigned using a random number table.

Group A - In the first appointment, 38% SDF was applied by the operator trained to perform the procedure.

- The tooth was washed and dried. Rubber dam was placed prior to SDF application to isolate the tooth, to prevent saliva contamination and to protect gingivae from contacting excessive solution.
- The Operator dipped a micro-applicator brush in 38% SDF solution (Kids-e-dental, India) and the solution was applied according to the manufacturer's instruction. Using the micro applicator brush, the carious tooth structure was coated with the solution. The solution was allowed to dry for 3 minutes. The excess solution was cleaned using a cotton swab.
- The children were instructed not to eat or drink for half an hour.(Figure 1)

Group B – Carious cavity was restored with the use of ART approach using high-strength chemical-cured hand-mixed GIC in the first visit itself. The restorative procedures followed the guidelines of the ART approach, which are briefly described below:

- The operation site was isolated by cotton rolls.
- Adequate access to the cavity was created, if necessary an enamel hatchet was used to enlarge the opening of a small cavity.
- Excavators of different sizes were used to remove soft carious tissues and to prepare the cavity for restoration.
- The cavity was cleaned by water and then dried by cotton pellets.
- The cavity surface was conditioned with dentin conditioner (Shofu FX Ultra, Japan) for 10 s, then washed with water and dried by cotton pellets.
- The GIC (Shofu FX Ultra, Japan) was mixed according to the manufacturer's instructions.
- The restorative material was placed and pressed into the cavity by the 'finger technique', matrix was used when placing GIC into a cavity in proximal tooth surface;
- The excess GIC material was removed and the contour and shape of the restoration was modified as necessary.
- The occlusion was checked and the finished restoration was covered by a layer of petroleum jelly.
- The children were instructed not to eat or drink for half an hour.(Figure 2)

The patients were recalled after 2 weeks. In Group A, SDF treated cavity were restored with the use of ART approach using GIC (Shofu FX Ultra, Japan).

The restorative procedures followed the guidelines of the ART approach, as described for Group B. ART evaluation criteria[16] was used for clinical evaluation of the restorations at baseline, 6 months and 12 months. Clinically the restorations were evaluated based on following criteria using Community Periodontal Index (CPI) Probe(Figure-3). The study intended to improve the reporting of parallelgroup randomized controlled trials by following the consolidated standards of reporting trials (CONSORT) guidelines (Figure-4).

Statistical Analysis:

Data was analysed using the statistical package SPSS 26.0 (SPSS Inc., Chicago, IL) and level of significance was set at $p<0.05$. Descriptive statistics was performed to assess the mean and standard deviation of the respective groups. Chi square test was used for checking the association. Wilcoxon signed rank test was performed to evaluate the success rates of 38% SDF with ART group and ART group.

Result:

Data was analysed using the statistical package SPSS 26.0 (SPSS Inc., Chicago, IL) and level of significance was set at $p <0.05$ using Chi square test and Wilcoxon signed rank test.

This split mouth study included 46 children between the age group of 4-8 years in the study with mean age of 6.21 ± 1.02 years of which 16 were male participants (34.8%) and 30 were female participants (65.2%).

From the above results it was found that the clinical success of restoring SDF-treated dentine caries lesions in primary molar teeth with ART approach at 6 month and 12 month follow up was 91.3% and 84.7% respectively with no intragroup statistical significance ($p>0.05$). (Table- 1,2)

It was also found that the clinical success of restoring SDF untreated dentine caries lesions in primary molar teeth with ART approach at 6 month and 12 month follow up was 93.5% and 87% respectively with no intragroup statistical significance ($p>0.05$).

It can also be inferred that there is no statistical significant difference ($p>0.05$) between the success rates of restoring untreated and SDF-treated dentine caries lesions in primary molar teeth with ART at 6 month and 12 month follow up.(Table-3),(figure-5)

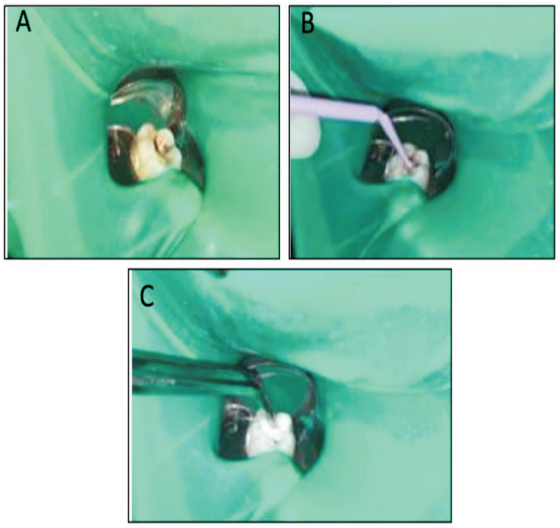

Figure-1 A- Rubber dam isolation, B- Application of 38% SDF, C- Removal of excess SDF

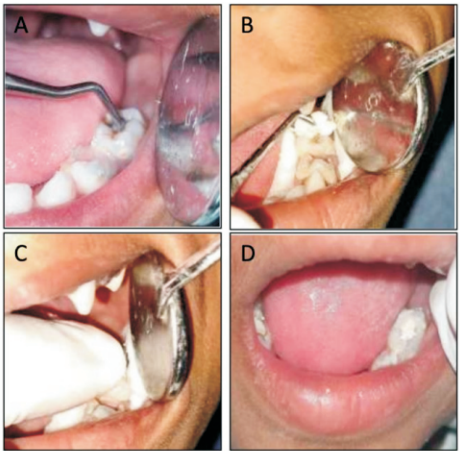

Figure 2- Procedure for ART (Group A and Group B) 2A- Caries removal using spoon excavator, B- Placement of restoration(GIC), C- Finger technique for adaptation of GIC, Dfinal restoration.

CODE	CRITERIA	DEFINITION
0	Present ,satisfactory.	Successful
1	Present ,slight defect in the cavity margin of less than 0.5 mm, no repair is needed	Successful
2	Present, marginal defect deeper than 0.5mm	Failed
3	Partially present , restoration and/or tooth breakdown.	Failed
4	Not present; restoration missing	Failed
5	Not present, other restorative treatment has been performed	Failed
6	Not present, tooth has been extracted	Failed
7	Pulpal involvement	Failed
C	Caries present	Failed

Figure 3 - Evaluation criteria used.

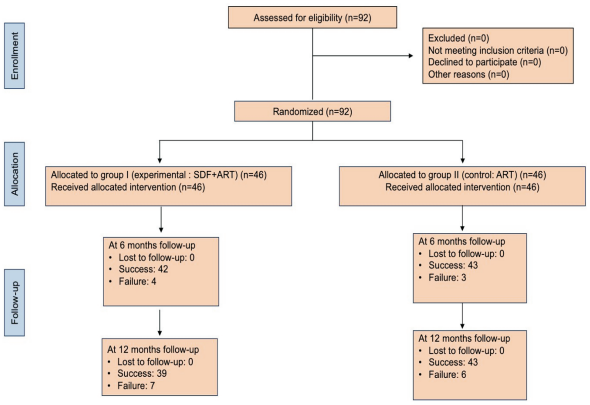

Figure 4 – CONSORT flow chart Figure

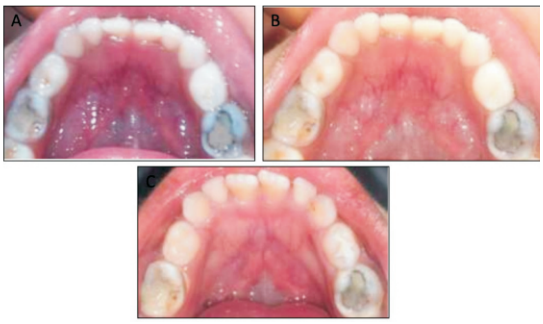

Figure 5 Follow Up And Evaluation A- Baseline, B- 6 month follow up, C- 12 month follow up

ART Scoring Criteria	Number of restorations in their respective category at 6 month follow up.		p value
	Group A (SDF+ART)	Group B (ART)	
Present ,satisfactory.	30	35	
Present ,slight defect in the cavity margin of less than 0.5 mm, no repair is needed	12	8	
Partially present , restoration and/or tooth breakdown.	3	1	0.527
Not present; restoration missing	0	1	
Caries present	1	1	
Total	46	46	

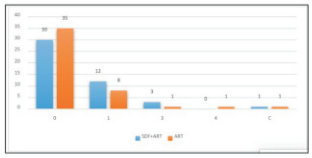

Table 1- Illustrates comparison between the ART scoring criteria for group A (SDF + ART) and group B (ART) at 6 months.

ART Scoring Criteria	Number of restorations in their respective category at 12 month follow up.		p value
	Group A (SDF+ART)	Group B (ART)	
Present, satisfactory. Score	14	19	
Present ,slight defect in the cavity margin of less than 0.5 mm, no repair is needed	25	21	0.934
Present, marginal defect deeper than 0.5mm	1	1	
Partially present , restoration and/or tooth breakdown.	1	1	
Not present; other restorative treatment has been performed	3	2	
Caries present	2	2	
Total	46	46	

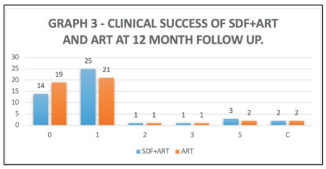

Table 2- Illustrates comparison between the ART scoring criteria for group A (SDF +ART) and group B (ART) at 12 month follow up.

GROUP	RESULT		Number of restorations	p-value
	6 month follow up	12 month follow up		
Group A (SDF+ART)	Success	Success	39	0.08
	Success	Failure	3	
	Failure	Success	0	
	Failure	Failure	4	
	Total		46	
Group B (ART)	Success	Success	40	0.08
	Success	Failure	3	
	Failure	Success	0	
	Failure	Failure	3	
	Total		46	

Table 3- Illustrates comparison between success rate of Group A (SDF+ART) and Group B (ART) at 6 month and 12 month follow up and its corresponding p value.

Discussion:

In developing and underdeveloped countries, untreated carious lesions and limited access to oral healthcare services remain significant public health concerns. Children often experience fear associated with anesthetic procedures, prolonged treatment durations, and the use of multiple dental instruments. As a result, minimally invasive treatments that are less technique-sensitive, such as the ART, are preferred over conventional caries management approaches. Another notable minimally invasive technique isSDF, an alkaline, colorless solution containing silver and fluoride, stabilized by ammonia to form a mixed heavy-metal halide coordination complex.[17] Ammonia plays a crucial role in maintaining the solution at a stable concentration over time.[18]

Silver has antibacterial qualities.[19] Fluoride is used to prevent and arrest caries.[17] Therefore, it has been hypothesized that the cumulative effects of fluorides and silver may be able to both stop the progression of existing caries and decrease the process of developing new ones

SDF's antibacterial qualities against cariogenic bacteria, its ability to remineralize the tooth's inorganic content, and its ability to prevent the organic matrix from degrading could all be contributing factors to its potential mechanism of action.[19] Studies have shown SDF has inhibited the attachment and growth of S. mutans to tooth surfaces.[20,21] The minimum inhibitory concentration is 33.3 μg /ml, while minimum bactericidal concentration of SDF is 50.0 μg /ml for S. mutans.[22]

The employment of SDF hasdemonstrated to decrease the lesion depth of demineralized tooth surfaces and effectively slow the progression of dental lesions.[23] Significantly greater surface microhardness was seen in carious lesions treated with SDF, penetrated to a depth of about 150 μm.[24] Other studies identified the development of calcium fluoride and silver phosphate when enamel or dentine powder was mixed with SDF. Silver phosphate precipitates help reduce the loss of calcium and phosphorus from demineralized enamel and dentine by forming an insoluble protective coating.[25]

About 90% of dentine's organic content is type I collagen, which may limit calcium and phosphate diffusion and act as a scaffold for mineral crystal deposition during remineralization.[26] Research indicates that Matrix Metallo Proteinases (MMPs), which are found in saliva and dentine matrix, have ability to breakdown collagen.[27] Therefore, the inhibition of MMP and cysteine cathepsin activities may prevent collagen degradation and contribute to the arrest of the caries process. SDF was found to inhibit proteolytic activities of MMP-2, MMP-8, and MMP-9.[28]

Given these benefits, SDF should be considered alongside ART. However, it is essential to assess whether prior SDF application influences the success of ART restorations before recommending this two-stage approach. Therefore, a split-mouth clinical trial evaluated the outcomes of ART in untreated and 38% SDF-treated dentine caries in primary molars.

A split-mouth design was used to minimize variability and inter-subject differences, improving accuracy and statistical power while allowing a smaller sample size through withinpatient comparisons.[29]

In Group A, SDF was applied to the primary molar, followed by restoration using the ART approach with high-strength, chemically cured, hand-mixed GIC after a two-week interval. Delaying the restoration for 14 days is associated with reduced microleakage compared to immediate placement after SDF application.[30] In Group B, the carious cavity was restored using the ART approach with GIC during the initial visit itself.

In this study it was found that at the end of 12 months the clinical success rate for Group A (SDF+ART) was 84.7% and group B (ART group) was 87%.No significant difference was observed in the clinical success of both the groups ($p > 0.05$), hence the success rate was comparable for both the groups which is similar to result obtained by Jiang M[31] and Aly AA[32]. Jiang et al restored the cavity using ART approach 10 weeks after application of 38% SDF solution and observed that there were no statistically significant differences in the ART restoration success rates between the two study groups at any of the follow-ups.[31] In the present study, the restoration were placed in 2 weeks after application of 38% SDF and similar results were obtained indicating that, a longer duration is unnecessary and restoration can be placed earlier to re-establish the occlusion and function of the tooth. Both studies also observed that the lesions had become hard upon probing before the placement of ART restorations. As a result, minimal dental tissue removal was necessary, leading to a reduced treatment duration for restoring cavities treated with SDF.[31, 32]

Despite the fact that there was no significant statistical difference observed in the clinical success of the restoration, in both the follow up visits, the number of restorations with marginal defect of less than 0.5mm was higher in group A when compared to group B. While laboratory studies indicate

that SDF application does not compromise the bond strength between dentin and GIC,[33] .In group B, 2 restorations (4.3%) were categorized as carious. In group A, restoration was dislodged in the 38% SDF treated cavity. The surface was hard on probing indicating arrested caries activity hence it was replaced with a new restoration with minimal preparation, Similar results were observed by Meng Jiang[31]. This signifies the caries arresting and remineralizing effect of SDF can be a useful tool in community preventive programs.

In 2005, Knight et al. introduced applying saturated potassium iodide (KI) after SDF to address related concerns.[34] However, its effect on the bond strength of glass ionomer cement (GIC) is controversial. Some studies report reduced bond strength, which may cause restoration failure or secondary caries.[35] Therefore, further research is needed, and KI was not used in this study.

Traditional drill-and-fill caries treatment in children often requires general anaesthesia due to procedural complexity and pain, leaving many lesions untreated and reducing quality of life. Silver diamine fluoride (SDF) combined with atraumatic restorative treatment (ART) offers a cost-effective, efficient alternative for managing caries in young children. The use of 38% SDF with ART shows strong potential, though further long-term clinical trials are needed to confirm outcomes.

Conclusion:

Within the limitation of our study, it was found that the clinical success of restoring SDF-treated dentine caries lesions in primary molar teeth with ART approach and restoring SDF untreated dentine caries lesions at 12 month follow 84.7% and 87% respectively with no intergroup statistical significance ($p>0.05$) but prior SDF application to dental caries may aid in remineralization of caries which may prove to be effective procedure in community preventive programmes.

Limitations:

1. Although no significant difference was found between the groups, long term follow up of the restorations will provide more authentic results.

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